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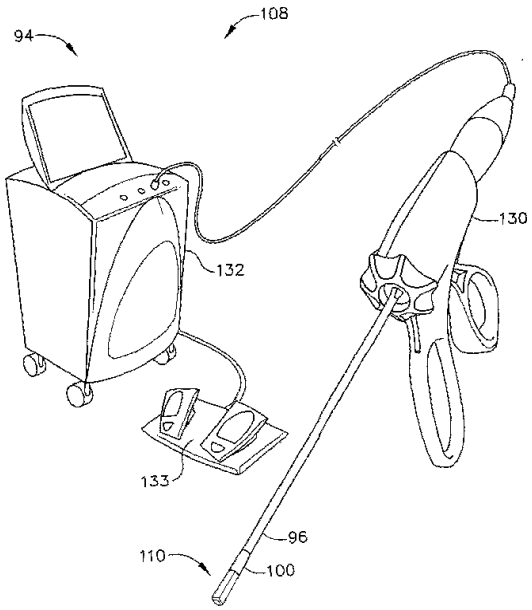
(54)【発明の名称】治療のための超音波を用いた閉塞方法

(57)【要約】
患者を超音波治療するための方法。超音波治療トランスデューサ組立体（２０）を有するエンドエフェクタ（１２）を用意する。病変に血液を供給する血管を実質的に閉塞させてその病変への血液の供給を実質的に止めるべく、その血管をトランスデューサ組立体（２０）からの超音波で治療する。一例では、超音波治療トランスデューサ組立体（２０）は、超音波イメージング／治療トランスデューサ組立体（２０）である。一変形形態では、エンドエフェクタ（１２）は患者の体内に挿入される。別の変形形態では、エンドエフェクタは患者の体外に残される。



【特許請求の範囲】
【請求項１】
患者を超音波治療するための方法であって、
（ａ）超音波治療トランスデューサ組立体を有するエンドエフェクタを用意するステップと、
（ｂ）前記患者の体内に前記エンドエフェクタを挿入するステップと、
（ｃ）前記患者の体内のエンドエフェクタを、病変を含む患者組織の領域に案内するステップと、
（ｄ）前記病変に血液を供給する前記領域の血管を特定するステップと、
（ｅ）前記血管を実質的に閉塞させて前記血管から前記病変への血液の供給を実質的に止めるべく、前記血管を前記トランスデューサ組立体からの超音波で治療するステップとを含むことを特徴とする方法。
【請求項２】
更に、前記病変を実質的にアブレーションするべく、前記トランスデューサ組立体からの超音波で治療するステップを含むことを特徴とする請求項１に記載の方法。
【請求項３】
前記エンドエフェクタが開放手術エンドエフェクタであることを特徴とする請求項１に記載の方法。
【請求項４】
前記エンドエフェクタが内視鏡エンドエフェクタであることを特徴とする請求項１に記載の方法。
【請求項５】
前記エンドエフェクタが腹腔鏡エンドエフェクタであることを特徴とする請求項１に記載の方法。
【請求項６】
前記エンドエフェクタがカテーテルエンドエフェクタであることを特徴とする請求項１に記載の方法。
【請求項７】
前記エンドエフェクタが針エンドエフェクタであることを特徴とする請求項１に記載の方法。
【請求項８】
患者を超音波治療するための方法であって、
（ａ）超音波イメージング／治療トランスデューサ組立体を有するエンドエフェクタを用意するステップと、
（ｂ）前記患者の体内に前記エンドエフェクタを挿入するステップと、
（ｃ）前記患者の体内のエンドエフェクタを、病変を含む患者組織の領域に案内するステップと、
（ｄ）少なくとも部分的に前記トランスデューサ組立体を用いた超音波イメージングから、前記病変を特定するステップと、
（ｅ）前記トランスデューサ組立体を用いた超音波イメージングから、前記病変に血液を供給する前記領域の血管を特定するステップと、
（ｆ）前記血管を実質的に閉塞させて前記血管から前記病変への血液の供給を実質的に止めるべく、前記血管を前記トランスデューサ組立体からの超音波で治療するステップと、
（ｇ）前記病変を実質的にアブレーションするべく、前記トランスデューサ組立体からの超音波で前記病変を治療するステップとを含むことを特徴とする方法。
【請求項９】
前記エンドエフェクタが開放手術エンドエフェクタであることを特徴とする請求項８に記載の方法。
【請求項１０】
前記エンドエフェクタが内視鏡エンドエフェクタであることを特徴とする請求項８に記載

の方法。
【請求項１１】
前記エンドエフェクタが腹腔鏡エンドエフェクタであることを特徴とする請求項８に記載の方法。
【請求項１２】
前記エンドエフェクタがカテーテルエンドエフェクタであることを特徴とする請求項８に記載の方法。
【請求項１３】
前記エンドエフェクタが組織貫通エンドエフェクタ（interstitial end effector）であることを特徴とする請求項８に記載の方法。
【請求項１４】
患者を超音波治療するための方法であって、
（ａ）超音波治療トランスデューサ組立体を有するエンドエフェクタを用意するステップと、
（ｂ）病変に血液を供給する前記患者の血管を特定するステップと、
（ｃ）前記血管を実質的に閉塞させて前記血管から前記病変への血液の供給を実質的に止めるべく、前記血管を前記トランスデューサ組立体からの超音波で治療するステップとを含むことを特徴とする方法。
【請求項１５】
前記エンドエフェクタが体外用エンドエフェクタであることを特徴とする請求項１４に記載の方法。
【請求項１６】
患者を超音波治療するための方法であって、
（ａ）超音波イメージング／治療トランスデューサ組立体を有するエンドエフェクタを用意するステップと、
（ｂ）少なくとも部分的に前記トランスデューサ組立体を用いた超音波イメージングから、前記患者の病変を特定するステップと、
（ｃ）前記トランスデューサ組立体を用いた超音波イメージングから、前記病変に血液を供給する血管を特定するステップと、
（ｄ）前記血管を実質的に閉塞させて前記血管から前記病変への血液の供給を実質的に止めるべく、前記血管を前記トランスデューサ組立体からの超音波で治療するステップと、
（ｅ）前記病変を実質的にアブレーションするべく、前記トランスデューサ組立体からの超音波で前記病変を治療するステップとを含むことを特徴とする方法。
【請求項１７】
前記エンドエフェクタが体外用エンドエフェクタであることを特徴とする請求項１６に記載の方法。
【発明の詳細な説明】
【０００１】
本願は、米国仮特許出願第６０／２９４，１３５号の優先権を主張するものであり、この特許出願を参照することを以ってそのすべての開示を本願の一部とするものである。
【０００２】
発明の分野
本発明は超音波に関連し、詳細には、超音波治療システム及び／または超音波治療方法に関連する。
【０００３】
発明の背景
既知の超音波医療システム及び方法では、患者の超音波画像を用いて治療のために患者の組織を識別し、超音波で識別された組織に熱を加えてその組織を医学的に破壊する。イメージングは低出力で行い、治療は高出力で行う。低出力の超音波イメージングでは、患者組織は医学的影響を受けない。高出力の治療用超音波が超音波源から離れた局所領域に集

束すると、その局所領域の患者の組織が実質的に医学的な影響を受ける。しかしながら、集束した治療用超音波は、局所領域以外の患者組織、例えば超音波源と局所領域の間の患者組織に実質的に医学的な影響を与えない。

【０００４】

ある既知の例では、トランスデューサ組立体は、患者の超音波画像を撮るため及び識別された患者組織を超音波でアブレーションするために、１つのトランスデューサ要素を備えた１つの超音波トランスデューサまたは一緒に動作するトランスデューサ要素のアレイを含む。超音波治療を監視するために超音波治療中の患者組織の超音波画像データを温度画像データに変換することは周知である。既知のトランスデューサ要素には、超音波エネルギーを集束する凹レンズまたは音響レンズを備えたトランスデューサ要素がある。既知のトランスデューサ要素のアレイには、超音波エネルギーを集束する平面、凹状、または凸状のトランスデューサ要素のアレイがある。既知のトランスデューサ要素のアレイには、そのアレイから放射された超音波を集束領域（大きくてもよいし、米粒ほど小さくてもよい）に配向及び集束して患者組織の３次元超音波治療をするようにトランスデューサ要素が同時に電子制御または機械制御されるアレイが含まれる。ある適用例では、トランスデューサを患者組織の表面に配置して、患者組織内のある領域の超音波イメージング及び／または超音波治療を行う。別の適用例では、トランスデューサをバルーンで覆い、そのバルーンを生理食塩水などの流体で満たして膨張させて患者の組織表面に接触させ、そのトランスデューサとその患者組織を音響的に結合する。

【０００５】

既知の超音波システム及び方法には、超音波トランスデューサを備えたエンドエフェクタを体外に配置して体内の腎石を医学的に破壊すること、及び超音波トランスデューサを備えたエンドエフェクタを内視鏡的に結腸に挿入して前立腺癌を医学的に破壊すること、及び超音波トランスデューサを備えたエンドエフェクタを腹腔鏡的に腹腔内に挿入して癌性肝腫瘍を医学的に破壊すること、及び超音波トランスデューサを備えたカテーテルエンドエフェクタを腕の静脈内に挿入して心臓に送り、病変心臓組織を医学的に破壊すること、及び超音波トランスデューサ針を備えた針エンドエフェクタを舌に組織を通して（interstitially）挿入し、組織を医学的に破壊してその舌の容量を小さくして鼾を解消することが含まれる。患者の体内でエンドエフェクタを案内する既知の方法には、Ｘ線画像、ＭＲＩ画像、及び超音波トランスデューサで得た超音波画像を用いてエンドエフェクタを案内する方法がある。既知の超音波イメージングには、血流を検出するためのドップラー超音波イメージングがあり、提案されている既知の超音波の利用には、体外で超音波トランスデューサを用いて、病院の救急室に運び込まれた患者の内出血を止める（破裂した血管を塞いで）ことが含まれる。

【０００６】

エシコン・エンドーサージェリィ社（Ethicon Endo-Surgery, Inc.（ジョンソン・アンド・ジョンソン社））が製造するMammotome（登録商標）乳房生検システムでチューブを乳房組織内に挿入する。このチューブは、生検切除器具を備えたエンドエフェクタを有する。トランスポンダの位置を算出して患者の体内でトランスポンダを案内する既知の電磁トランスポンダ／３次元システムは、バイオセンス・ウェブスター（Biosense Webster（ジョンソン・アンド・ジョンソン社））が製造するNAVI-STAR（登録商標）カテーテルと共に用いられるCARTO（商標）EPナビゲーションシステムである。更に、超音波治療などの治療による患者の組織の変化が超音波イメージング信号の振幅及び／または位相に影響を及ぼすことが知られている。

【０００７】

改良された超音波医療システム及び／または改良された超音波医療方法が求められている。本発明は、超音波医療システム及び／または超音波医療方法の欠点を解消する。

【０００８】

本発明の要約

本発明の１つの方法は患者の超音波治療についてであり、ステップ（ａ）からステップ（

ｃ）を含む。ステップ（ａ）は、超音波治療トランスデューサ組立体を有するエンドエフェクタを用意することを含む。ステップ（ｂ）は、病変に血液を供給する患者の血管を特定することを含む。ステップ（ｃ）は、病変に血液を供給する血管を実質的に閉塞させてその病変への血液の供給を実質的に止めるべく、その血管をトランスデューサ組立体からの超音波で治療することを含む。一例では、超音波治療トランスデューサ組立体は、超音波イメージング／治療トランスデューサ組立体である。一変形形態では、エンドエフェクタは患者の体内に挿入される。別の変形形態では、エンドエフェクタは患者の体外に残される。

【０００９】

本発明は、限定するものではないが、従来の内視鏡、開放手術器具、並びにロボット支援外科手術に適用できる。

【００１０】

発明の詳細な説明

本発明を詳細に説明する前に、本発明が、その適用及び使用において、添付の図面及び以降の説明に例示されている構造及び構成の細部に限定されるものではないことを理解されたい。本発明の例示されている実施形態は、他の実施形態、変形形態、変更形態で実施したりこれらに含めたりすることができ、様々な方法で実施できる。更に、特段の記載がない限り、本明細書に用いる用語及び表現は、読者が理解し易いように本発明の例示的な実施形態を説明するために選択したものであって、本発明を限定することが目的ではない。

【００１１】

１または複数の後述する実施形態、実施形態の表現、例、または方法などを、１または複数の後述する実施形態、実施形態の表現、例、または方法などと組み合わせることができることを理解されたい。例えば、限定するものではないが、任意のエンドエフェクタを任意の方法に、任意のトランスデューサ構造を任意のエンドエフェクタに用いることができ、第１７の方法と第２０の方法とを組み合わせるように任意の好適な方法を組み合わせることができる。

【００１２】

組織保持装置を用いた超音波治療

超音波治療用の組織保持システム

図面を参照すると、図１－図３に本発明の第１の実施形態が例示されている。本発明の第１の実施形態の第１の表現は、患者１４内に挿入可能なエンドエフェクタ１２を備えた超音波治療システム１０についてである。エンドエフェクタ１２は組織保持装置１６を含む。この組織保持装置１６は、少なくとも１つの超音波治療トランスデューサ２０（トランスデューサ２０とも呼ぶ）を備えた第１の組織保持部材１８と第２の組織保持部材２２を含む。第１の組織保持部材１８と第２の組織保持部材２２は機能的に連結されていて、協動してそれらの両部材間に患者組織２４を保持することができ、かつ保持した患者組織２４を放すことができる。

【００１３】

超音波治療トランスデューサが、限定するものではないが、少なくとも人などの患者の超音波治療ができるように適合された超音波トランスデューサであることを留意されたい。超音波トランスデューサは、当業者に周知の、１つの超音波治療トランスデューサ要素または超音波治療トランスデューサ要素のアレイのいずれかを含む。超音波治療トランスデューサは、患者の超音波イメージングを行うことができるように適合されていても、適合されていなくてもよい。同様に、超音波イメージングトランスデューサは、少なくとも患者の超音波イメージングができるように適合された超音波トランスデューサであり、患者の超音波治療ができるように適合されていても、適合されていなくてもよい。

【００１４】

組織保持部材の一方による超音波治療中に２つの組織保持部材の間に患者組織を保持する利点には、１つの器具で患者の組織を超音波的に治療すると共に、治療中にずれないように患者組織を固定できることが含まれる。またある適用例では、組織保持装置は組織を維

持及び保持するクランプであり、別の適用例では、組織保持装置はクランプではなく、組織を保持しないが組織が動かないように維持する装置であることに留意されたい。

【００１５】

図示されていない一変形形態では、第２の組織保持部材２２は、超音波イメージングトランスデューサ及び／または治療トランスデューサを有する。図示されていない同じまたは別の変形形態では、組織保持装置１６は、少なくとも１つの追加の組織保持部材を有する。２またはそれ以上の部材を遠隔操作で互いに近づけたり遠ざけたりするための機構（不図示）は当業者の一般的な知識の範囲内であって、限定するものではないが、回動部材アタッチメントの使用及びケーブルやモーターの使用が含まれる。同じまたは別の変形形態では、患者組織２４は、超音波治療トランスデューサ２０と第２の組織保持部材２２との間に保持される。同じまたは別の変形形態では、超音波治療トランスデューサ２０は超音波エネルギーを集束するが、このような収束は当業者に周知である。図示されていない同じまたは別の変形形態では、第２の組織保持部材２２は実質的に超音波を反射しない。

【００１６】

本発明の第１の実施形態の第２の表現は、患者１４内に挿入可能なエンドエフェクタ１２を含む超音波治療システム１０についてである。エンドエフェクタ１２は組織保持装置１６を含む。この組織保持装置１６は、少なくとも１つの超音波イメージング／治療トランスデューサ２６（トランスデューサ２６とも呼ぶ）を有する第１の組織保持部材１８と第２の組織保持部材２２とを含む。第１の組織保持部材１８及び第２の組織保持部材２２は機能的に連結されていて、協動してこれらの間に患者組織２４を保持することができ、かつそのように保持した患者組織２４を放すことができる。

【００１７】

超音波イメージング／治療トランスデューサは、少なくとも患者の超音波イメージング及び超音波治療の両方ができるように適合された超音波トランスデューサである。超音波イメージング／治療トランスデューサは、１つの超音波イメージング／治療トランスデューサ要素、または超音波トランスデューサ要素のアレイ（イメージングのための少なくとも１つの個別の要素と治療のための少なくとも１つの個別の要素を有するアレイ、またはそれぞれがイメージングと治療の両方ができるように適合された少なくとも２つの要素を有するアレイを含む）のいずれかを含むが、これは当業者に周知である。一変形形態では、保持された患者組織２４は、イメージング／治療トランスデューサ２６と第２の組織保持部材２２との間に保持される。同じまたは別の変形形態では、超音波イメージング／治療トランスデューサ２６は超音波エネルギーを集束する。図示されていない同じまたは別の変形形態では、第２の組織保持部材２２は実質的に超音波を反射しない。

【００１８】

図１－図３に示されている第１の実施形態の第３の表現は、患者１４内に挿入可能なエンドエフェクタ１２を含む超音波治療システム１０についてである。エンドエフェクタ１２は組織保持装置１６を含む。組織保持装置１６は、少なくとも１つの超音波治療トランスデューサ２０を有する第１の組織保持部材１８と、少なくとも１つの超音波反射器２８を有する第２の組織保持部材２２とを含む。第１の組織保持部材１８及び第２の組織保持部材２２は機能的に連結されていて、協動してそれらの両部材間に患者組織２４を保持することができ、かつそのように保持した患者組織２４を放すことができる。

【００１９】

第１の組織保持部材の超音波治療トランスデューサ及び第２の組織保持部材の超音波反射器によって超音波治療中に、２つの組織保持部材間に患者組織を保持する利点には、１つの器具で、直接の超音波によって超音波治療でき、反射された超音波によって超音波治療を促進し、更に治療中にずれないように患者組織を固定できることが含まれる。

【００２０】

超音波反射器２８は、その超音波反射器で反射される直接の超音波によって治療されている間に、少なくとも実質的に医学的な影響を患者組織に与える程度に超音波を反射する物質であることに留意されたい。超音波反射材料として、限定するものではないが、ステン

レス鋼（約１００％の反射率）及びアルミニウム（約８０％の反射率）などの音響的に硬い材料、コーポリン（corporene）（約９０％の反射率）などの音響的に柔らかい材料をあげることができる。超音波反射材料は、限定するものではないが、ゴムやプラスチック等の超音波吸収材料等と対照的である。一変形形態では、保持された患者組織２４は、超音波治療トランスデューサ２０と超音波反射器２８との間に保持される。同じまたは別の変形形態では、超音波治療トランスデューサ２０及び超音波反射器２８はそれぞれ、超音波エネルギーを集束する。このような超音波反射器のエネルギーの集束は、反射器表面の形状または成形することによって達成することができるが、これは当業者の知識の範囲内である。

【００２１】

図１－図３に示されている第１の実施形態の第４の表現は、患者１４内に挿入可能なエンドエフェクタ１２を含む超音波治療システム１０についてである。エンドエフェクタ１２は組織保持装置１６を含む。組織保持装置１６は、少なくとも１つの超音波イメージング／治療トランスデューサ２６を有する第１の組織保持部材１８と、少なくとも１つの超音波反射器２８を有する第２の組織保持部材２２とを含む。第１の組織保持部材１８及び第２の組織保持部材２２は機能的に連結されていて、協動してこれらの両部材間に患者組織２４を保持することができ、かつそのように保持した患者組織２４を放すことができる。一変形形態では、保持される患者組織２４は、超音波イメージング／治療トランスデューサ２６と超音波反射器２８との間に保持される。同じまたは別の変形形態では、超音波イメージング／治療トランスデューサ２６及び超音波反射器２８のそれぞれは超音波エネルギーを集束する。

【００２２】

第１の実施形態の前記した第３及び第４の表現の一例では、超音波反射器２８は、トランスデューサ２０及び２６からの超音波エネルギーを受けて、組織保持装置１６によって保持されている患者組織２４に超音波エネルギーを反射する向きに配置されている。同じまたは別の例では、超音波反射器２８は、患者組織１４が組織保持装置１６によって保持されているときに到達した超音波エネルギーをトランスデューサ２０及び２６から離れる方向に反射するように配置されている。この構成の利点は、反射した超音波によるトランスデューサの損傷を回避できるということである。同じまたは別の例では、第１の組織保持部材１８及び第２の組織保持部材２２の一方を、限定するものではないが図２に示されている両矢印に沿って向きを変えることができるようにして、第１の組織保持部材１８及び第２の組織保持部材２２の他方に対して制御可能に向きを合わせることができる。一変更形態では、第２の組織保持部材２２を、到達した超音波エネルギーを様々な方向に沿って反射するように第１の組織保持部材１８に対して制御可能に向きを合わせることができる。第１の代替エンドエフェクタ３０が図４に示されており、第２の組織保持部材３２を、図４の両矢印によって示されているように第１の組織保持部材３４に対して制御可能に向きを合わせることができる。一方の部材を他方の部材に対して制御可能に遠隔的に向きを合わせる機構（不図示）は当業者の知識の範囲内であり、限定するものではないが、回動部材アタッチメントの使用及びケーブルやモーターの使用が含まれる。一適用例では、トランスデューサ２０及びトランスデューサ２６は、広い範囲に集束する超音波（図３の第１の組織保持部材１８から出た矢印によって示されている）を生成し、超音波反射器２８が、狭く集束する超音波（図３の第２の組織保持部材２２から出た矢印によって示されている）を生成する。

【００２３】

第１の実施形態の前記した第１の表現から第４の表現の一例では、エンドエフェクタ１２は、当業者なら理解できる開放手術（open-surgery）エンドエフェクタ、内視鏡エンドエフェクタ、腹腔鏡エンドエフェクタ（図１に示されているような）、カテーテルエンドエフェクタ（限定するものではないが、血管内カテーテルエンドエフェクタ等）、または針エンドエフェクタである。一適用例では、エンドエフェクタ１２を用いて血管を保持し、次にその血管を超音波治療して血管を塞ぎ、保持した血管内の血液の流れを止める。別の

適用例では、エンドエフェクタ１２を用いて患者組織を保持し、次に保持した患者組織の少なくとも一部を超音波アブレーションする。

【００２４】

第１の実施形態の上記した第１の表現から第４の表現のあるデザインでは、エンドエフェクタ１２は長手方向の軸３５を有しており、第１の組織保持部材１８及び第２の組織保持部材２２の一方が、長手方向の軸３５に対して実質的に直交する方向に常に向いている。その一方の組織保持部材が平面であったら、その長手方向の軸がその一方の組織保持部材の平面に対して実質的に平行であることになる。可能な一形態では、その一方の組織保持部材は第１の組織保持部材１８である。第２の代替エンドエフェクタ３６は、図５の両矢印によって示されているように互いに対して動くように蝶番式に取り付けられた第１の組織保持部材３８及び第２の組織保持部材４０を有しており、図５に部分的に開いた状態が示されている。第２の代替エンドエフェクタ３６は、長手方向の軸４２を有しており、第１の組織保持部材３８及び第２の組織保持部材４０の一方が、その長手方向の軸４２に対して実質的に平行な方向に常に向いている。その一方の組織保持部材が平面であったら、その長手方向の軸は、その一方の組織保持部材の平面に対して実質的に直交することになる。可能な一形態では、その一方の組織保持部材は第１の組織保持部材３８である。図６に示されているように、第３の代替エンドエフェクタ３７は、第１の組織保持部材３９及び第２の組織保持部材４１を備えており、その一方の部材が他方の部材に対して長手方向に移動可能（両矢印によって示されているように）である。第３の代替エンドエフェクタ３７は長手方向の軸４３を有しており、第１の組織保持部材３９及び第２の組織保持部材４１の一方が、長手方向の軸４３に対して実質的に平行な方向に常に向いている。可能な一形態では、その一方の組織保持部材は第１の組織保持部材３９である。

【００２５】

図１に示されているように、可能な一形態では、超音波治療システム１０は、当業者なら理解できる、フットペダル電源スイッチ４７に機能的に接続された超音波制御器４６及びエンドエフェクタ１２に機能的に接続されたハンドピース４４を含む。

【００２６】

本発明の第１の方法は、前記した変形形態などを含むまたは含まない第１の実施形態の第１、第２、第３、または第４の表現で説明したような超音波治療システムのを用いる患者の超音波治療についてである。第１の方法は、ステップ（ａ）からステップ（ｅ）を含む。ステップ（ａ）は、患者の耳、鼻、または喉の中にエンドエフェクタを内視鏡的に挿入することを含む。ステップ（ｂ）は、患者の体内で内視鏡を案内することを含む。ステップ（ｃ）は、任意選択で少なくとも部分的にトランスデューサを用いた超音波イメージングから治療のために患者組織を識別することを含む。治療のために患者組織を識別する他の方法には、限定するものではないが、当業者に周知のＸ線画像及び／またはＭＲＩ画像が含まれる。ステップ（ｄ）は、組織保持装置を用いて識別した患者組織を保持することを含む。ステップ（ｅ）は、トランスデューサを用いてまたはトランスデューサと超音波反射器を用いて超音波で、保持している患者組織を治療することを含む。一実施態様では、一方の組織保持部材は、エンドエフェクタの長手方向の軸に対して実質的に平行な方向に常に向いている（図５及び図６を参照）。

【００２７】

本発明の第２の方法は、上記した変形形態などを含むまたは含まない第１の実施形態の第１、第２、第３、または第４の表現で説明したような超音波治療システムを用いる患者の超音波治療についてである。この第２の方法はステップ（ａ）からステップ（ｃ）を含む。ステップ（ａ）は、患者の体内にエンドエフェクタ１２を挿入することを含む。ステップ（ｂ）は、組織保持装置で患者の組織を含む椎間板４８（図３を参照）を保持することを含む。ステップ（ｃ）は、トランスデューサを用いてまたはトランスデューサと超音波反射器を用いて組織を収縮させるために超音波で、保持している椎間板４８を治療することを含む。一実施態様では、一方の組織保持部材は、エンドエフェクタの長手方向の軸に対して実質的に直交する方向に常に向いている（図２及び図４を参照）。本発明の第２の

方法の一適用例では、椎間板４８は結合組織及び神経組織を含む。

【００２８】

本発明の第３の方法は、上記した変形形態等を含むまたは含まない第１の実施形態の第１、第２、第３、または第４の表現で説明したような超音波治療システムを用いる患者の超音波治療についてである。この第３の方法は、ステップ（ａ）からステップ（ｃ）を含む。ステップ（ａ）は、患者の体内にエンドエフェクタを挿入することを含む。ステップ（ｂ）は、組織保持装置で患者の組織を含む関節を保持することを含む。ステップ（ｃ）は、トランスデューサを用いてまたはトランスデューサと超音波反射器を用いて組織を収縮させるために超音波で、保持している関節を治療することを含む。一実施態様では、一方の組織保持部材は、エンドエフェクタの長手方向の軸に対して実質的に直交する方向に常に向いている（図２及び図４を参照）。本発明の第３の方法の一適用例では、関節は結合組織及び神経組織を含む。

【００２９】

上記したように、第１の実施形態の上記した第１の表現から第４の表現の超音波治療システム１０の一適用例では、組織保持装置を用い血管を保持し、トランスデューサを用いてまたはトランスデューサと超音波反射器を用いてその血管内の血液の流れを実質的に止める。

【００３０】

再び図面を参照すると、図７及び図８に本発明の第２の実施形態が例示されている。この第２の実施形態は、患者の体内に挿入可能なエンドエフェクタ５２を含む超音波治療システム５０である。エンドエフェクタ５２は組織保持装置５４を含む。組織保持装置５４は、超音波イメージング／治療トランスデューサ５８を有する第１の組織保持部材５６と、超音波反射器６２を有する第２の組織保持部材６０とを含む。第１の組織保持部材５６及び第２の組織保持部材６０は機能的に連結されていて、協動してこれらの両部材間に患者組織を保持することができ、かつそのように保持した患者組織を放すことができる。第１の組織保持部材５６及び第２の組織保持部材６０は、常に実質的に平行な配置に維持される。

【００３１】

組織保持部材間を実質的に平行な配置にする利点には、一例では、トランスデューサと超音波反射器を実質的に平行な配置に維持して、組織保持部材に保持したあらゆる厚みの患者組織に対して、反射された超音波による治療が改善できることが含まれる。

【００３２】

第２の実施形態の一例では、第１の組織保持部材５６は第１のチューブ６６の先端部分６４である。超音波治療システム５０はまた、第２のチューブ６８、第１の連結部材７０、第２の連結部材７２、及びケーブル７４を含む。第２のチューブ６８は、第１のチューブ６６と実質的に平行に向いている。第１の連結部材７０及び第２の連結部材７２は、回動点７６、７８、８０、及び８２で第２の組織保持部材６０及び第２のチューブ６８に回動可能に取り付けられており、第２の組織保持部材６０の基端部分８４、第２のチューブ６８の先端部分８６、第１の連結部材７０、及び第２の連結部材７２によって蝶番式平行四辺形が画定されている。超音波反射器６２が、トランスデューサ５８に面するように第２の組織保持部材６０の先端部分８８に配置されている。ケーブル７４が、第２の組織保持部材６０を第１の組織保持部材５６に対して近づけたり放したりできるように蝶番式平行四辺形に機能的に連結されている。

【００３３】

一変形形態では、超音波治療システム５０は外側チューブ９０も含む。外側チューブ９０の中には、ケーブル７４、第１のチューブ６６、及び第２のチューブ６８が配置されている。一変更形態では、超音波治療システム５０はハンドピース９２も含む。ハンドピース９２には、ケーブル７４、第１のチューブ６６、第２のチューブ６８、及び外側チューブ９０が機能的に連結されている。あるデザインでは、第１のチューブ６６の長手方向の軸に対する第１のチューブ６６の向きを、ハンドピース９２内に配置されたステップモータ

（不図示）をそのハンドピース９２で操作して制御できる。同じまたは別のデザインでは、第１のチューブ６６は、トランスデューサの配線（不図示）が可能となるように中空のチューブであり、第２のチューブ６８は硬質チューブ（不図示）である。用途によって、チューブ６６、６８、及び９０を硬質にすることも柔軟にすることもでき、これが、あらゆるエンドエフェクタのあらゆるチューブ構造（具体的に硬質または柔軟性と開示した、または具体的には開示していない）に当てはまり、また本発明の前記した実施形態または後述する実施形態のあらゆるエンドエフェクタ自体に当てはまる。

【００３４】

特定のトランスデューサ構造を用いた超音波治療
配置可能な超音波治療トランスデューサ

図面を参照すると、図９－図１１に本発明の第３の実施形態が例示されている。本発明の第３の実施形態の第１の表現は、チューブ９６と弾力的に可撓性を有する複数のフィンガー９８を含む超音波医療システム９４についてである。チューブ９６は、患者の体内に挿入可能な先端部１００と、先端開口１０４を備えた内腔１０２とを有する。フィンガー９８は、内腔１０２の先端開口１０４から突き出た展開状態（図１０を参照）をとることができ、また内腔１０２の先端開口１０４内に少なくとも部分的に格納された収納状態（図１１を参照）をとることができる。それぞれのフィンガー９８は超音波トランスデューサ１０６を含む。近接するフィンガー９８の各超音波トランスデューサ１０６間の距離は、収納状態よりも展開状態で大きい。超音波医療システムは、少なくとも患者の超音波イメージングまたは超音波治療を提供する医療システムである。

【００３５】

チューブと伸長可能／格納可能な可撓性フィンガーのアレイ構造の利点には、トランスデューサが展開された状態で共通の集束ゾーンを有する超音波治療トランスデューサである場合、トランスデューサ超音波放射表面積をより大きくすることができ、これにより治療時間を短縮できることが含まれる。この超音波放射表面積は、患者の体内において超音波治療を行う患者組織の部位に対して送る及び戻す際にコンパクトな形状に簡単に収納することができる。

【００３６】

一変形形態では、フィンガー９８は、収納された状態でその一部のみが内腔１０２の先端開口１０４内に格納される（図１１を参照）。図示されていない別の変形形態では、フィンガー９８は、収納された状態で完全に内腔１０２の先端開口１０４内に格納される。フィンガー９８が内腔１０２の先端開口１０４から伸長可能である展開状態をとることができ、内腔１０２の先端開口１０４内に少なくとも部分的に格納可能であるため収納状態をとることができる。すなわち、フィンガー９８は収納された状態（仮にあったとして）よりも伸長した状態で内腔１０２の先端開口１０４からより突き出ている。チューブのフィンガーを遠隔操作で伸長させたり格納したりする機構（不図示）には、限定するものではないが、ハンドピースを圧迫すると前進し、その圧迫を緩めると後退するようにばね付勢された、フィンガーの基端部に取り付けられてチューブの内腔内に配置される普通のシャフトが含まれるが、これは当業者の知識の範囲内である。一変更形態では、内腔１０２の先端開口１０４はチューブ９６の先端部１００と一致する。図示されていない別の変更形態では、内腔の先端開口はチューブの先端部から離間している。一実施態様では、内腔１０２の先端開口１０４はチューブ９６の先端部１００と同じ方向を向いている。例えば、限定するものではないが内腔の先端開口がチューブの先端部に直交するように向いている別の実施態様も当業者には明らかであろう。一例では、少なくとも１つのトランスデューサ１０６が超音波イメージングトランスデューサである。同じまたは別の例では、少なくとも１つのトランスデューサ１０６が超音波治療トランスデューサである。同じまたは別の例では、少なくとも１つのトランスデューサ１０６が超音波イメージング／治療トランスデューサである。

【００３７】

第３の実施形態の第２の表現は、チューブ９６と、複数のフィンガー９８を有するエンド

エフェクタ１１０を含む超音波治療システム１０８についてである。チューブ９６は、患者の体内に挿入可能な先端部１００と、先端開口１０４を備えた内腔１０２とを有する。フィンガー９８は、内腔１０２の先端開口１０４から伸長した展開状態をとり（図１０を参照）、少なくとも部分的に内腔１０２の先端開口１０４内に格納された収納状態をとる（図１１を参照）。それぞれのフィンガー９８は超音波治療トランスデューサ１１２を含む。近接するフィンガー９８の各治療トランスデューサ１１２間の距離は、収納状態よりも展開状態で広い。

【００３８】

第３の実施形態の第３の表現は、チューブ９６と、複数のフィンガー９８を有するエンドエフェクタ１１０とを含む超音波治療システム１０８についてである。チューブ９６は、患者の体内に挿入可能な先端部１００と、先端開口１０４を備えた内腔１０２とを有する。フィンガー９８は、内腔１０２の先端開口１０４から伸長した展開状態をとり（図１０を参照）、少なくとも部分的に内腔１０２の先端開口１０４内に格納された収納状態をとる（図１１を参照）。それぞれのフィンガー９８は、超音波イメージング／治療トランスデューサ１１４を含む。近接するフィンガー９８の各超音波イメージング／治療トランスデューサ１１４間の距離は、収納状態よりも展開状態で広い。

【００３９】

第３の実施形態の第１の表現について説明した変形形態、変更形態、及び実施態様などは、第３の実施形態の第２の表現及び第３の表現に等しく適用できることを理解されたい。

【００４０】

第３の実施形態の第１、第２、及び第３の表現の一例では、トランスデューサ１０６、１１２、及び１１４はそれぞれ、超音波放射凹面１１６を有する。図示されていない別の例では、トランスデューサは平坦な超音波放射面を有する。ある構造では、それぞれの凹面１１６は、対応するフィンガー９８に沿って凹状である（図１０に最もよく示されている）。図示されていない別の構造では、それぞれの凹面は、対応するフィンガーを横断するような凹状、または対応するフィンガーを横断しかつ沿っているような凹状である（例えば、半球状の凹面など）。あるデザインでは、各凹面１１６は、フィンガー９８が展開された状態のときに実質的に共通の集束ゾーンを有する。図１０のエンドエフェクタ１１０では、フィンガー９８はそれぞれ、患者組織１１９に面している。図示されていない別のデザインでは、集束ゾーンは共通ではない。ある構造では、フィンガー９８は、展開した状態でオープンハンド・フィンガーアレイ１１８を画定する。代替エンドエフェクタ１２０の形である代替可撓性フィンガー構成が図１２に示されており、フィンガー１２２が展開した状態でクローハンド（clawed hand）・フィンガーアレイ１２４を画定している。図１２の代替エンドエフェクタ１２０では、そのフィンガー１２２は、超音波トランスデューサ１２８でイメージング及び／または治療をするべく患者組織１２６を覆っている。図示されていない別のトランスデューサの構造では、１または複数、または全ての超音波トランスデューサは内側ではなく外側を向いている。

【００４１】

第３の実施形態の第１、第２、及び第３の表現の同じまたは別の例では、フィンガー９８の個数は少なくとも４個である。第３の実施形態の第２及び第３の表現の同じまたは別の例では、エンドエフェクタ１１０（及び代替エンドエフェクタ１２０）は、当業者なら理解できる開放手術エンドエフェクタ、内視鏡エンドエフェクタ、腹腔鏡エンドエフェクタ（図９を参照）、カテーテルエンドエフェクタ（限定するものではないが、血管内脈カテーテルエンドエフェクタなど）、または針エンドエフェクタである。

【００４２】

図９に示されているような可能な一形態では、超音波治療システム１０８は、当業者なら理解できるフットペダル電源スイッチ１３３に機能的に接続された超音波制御器１３２及びエンドエフェクタ１１０に機能的に接続されたハンドピース１３０も含む。

【００４３】

多面型超音波治療トランスデューサ組立体

本発明の第４の実施形態が図１３－図１５に示されている。本発明の第４の実施形態の第１の表現は、患者の体内に挿入可能な超音波トランスデューサ組立体１３６を含む超音波利用システム１３４についてである。超音波トランスデューサ組立体１３６は長手方向の軸１３８を有する。超音波トランスデューサ組立体１３６は、Ｐ個の超音波トランスデューサ１４０を含む。それぞれのトランスデューサ１４０は、超音波放射面を有する。超音波放射面は、長手方向の軸１３８に直交するように切り取ったトランスデューサ組立体１３６の断面図（図１５を参照）を見ると、近接するトランスデューサ１４０の超音波放射面１４２から実質的に３６０／Ｐ度の角度ずれて配置されている。

【００４４】

このようなトランスデューサ構造の利点には、一例では、円筒状超音波トランスデューサでは不可能な配向即ち集束された治療超音波を提供できることが含まれるが、これは当業者なら理解できるであろう。

【００４５】

患者の体内に挿入可能な超音波トランスデューサ組立体１３６が、超音波イメージングトランスデューサ組立体、超音波治療トランスデューサ組立体、または超音波イメージング／治療トランスデューサ組立体であることを留意されたい。超音波イメージングトランスデューサ組立体は少なくとも１つの超音波イメージングトランスデューサを有しており、超音波治療トランスデューサ組立体は少なくとも１つの超音波治療トランスデューサを有する。超音波イメージング／治療トランスデューサ組立体は、少なくとも１つの超音波イメージングトランスデューサと少なくとも１つの超音波治療トランスデューサを含むか、または少なくとも１つの超音波イメージング／治療トランスデューサを含む。

【００４６】

本発明の第４の実施形態の第２の表現は、患者の体内に挿入可能なエンドエフェクタ１４６を含む超音波治療システム１４４についてである。エンドエフェクタ１４６は、超音波治療トランスデューサ組立体１４８を含む。超音波治療トランスデューサ組立体１４８は長手方向の軸１３８を有する。超音波治療トランスデューサ組立体１４８は、Ｐ個の超音波治療トランスデューサ１５０を有する。それぞれのトランスデューサ１５０は、長手方向の軸１３８から離れる方に向いた超音波放射面１４２を有する。この超音波放射面１４２は、長手方向の軸に対して直交するように切り取ったトランスデューサ組立体１４８の断面図（図１５を参照）を見ると、近接するトランスデューサ１５０の超音波放射面１４２から実質的に３６０／Ｐ度の角度ずれて配置されている。一例では、少なくとも１つの超音波治療トランスデューサ１５０が、超音波イメージングができるようにも適合されている。

【００４７】

本発明の第４の方法は、第４の実施形態の第２の表現で説明したような超音波治療システム１４４を用いる患者の超音波治療についてである。第４の方法はステップ（ａ）及びステップ（ｂ）を含む。ステップ（ａ）は、患者の肝臓内にエンドエフェクタ１４６を挿入することを含む。ステップ（ｂ）は、超音波治療トランスデューサ組立体１４８からの超音波で肝臓内の病変を治療することを含む。一例では、ステップ（ａ）で、エンドエフェクタ１４６を病変内に組織を通して（interstitially）挿入する。別の例では、ステップ（ａ）で、エンドエフェクタ１４６を肝臓胆管系を介して肝臓内に内視鏡的に挿入する。

【００４８】

本発明の第４の実施形態の第３の表現は、患者の体内に挿入可能なエンドエフェクタ１４６を含む超音波治療システム１４４についてである。エンドエフェクタ１４６は、超音波イメージング／治療トランスデューサ組立体１５２を含む。超音波イメージング／治療トランスデューサ組立体１５２は長手方向の軸１３８を有する。超音波イメージング／治療トランスデューサ組立体１５２は、Ｐ個の超音波イメージング／治療トランスデューサ１５４を含む。それぞれのトランスデューサ１５４は超音波放射面１４２を有する。超音波放射面１４２は、長手方向の軸１３８に対して直交するように切り取ったトランスデューサ組立体１５２の断面図（図１５を参照）を見ると、近接するトランスデューサ１５４の

超音波放射面１４２から実質的に３６０／Ｐ度ずれて配置されている。

【００４９】

本発明の第５の方法は、第４の実施形態の第３の表現で説明したような超音波治療システム１４４を用いる患者の超音波治療についてである。第４の方法はステップ（ａ）からステップ（ｃ）を含む。ステップ（ａ）は、患者の肝臓内にエンドエフェクタ１４６を挿入することを含む。ステップ（ｂ）は、少なくとも部分的に超音波イメージング／治療トランスデューサ組立体１５２を用いて超音波イメージングから、治療のために肝臓の病変を特定することを含む。ステップ（ｃ）は、超音波イメージング／治療トランスデューサ組立体１５２からの超音波で病変を治療することを含む。一例では、ステップ（ａ）で、エンドエフェクタ１４６を組織を通して病変内に挿入する。別の例では、ステップ（ａ）で、エンドエフェクタ１４６を肝胆導管を介して肝臓内に内視鏡的に挿入する。

【００５０】

第４の実施形態の前記した第１、第２、及び第３の表現の一例では、トランスデューサ組立体１３６、１４８、及び１５２が先端部１５６及び先端トランスデューサ１５８を有する。あるデザインでは、先端トランスデューサは前方を向いた先端トランスデューサである。別のデザインでは、先端トランスデューサは側面を向いた先端トランスデューサである。一変形形態では、先端トランスデューサは超音波イメージング先端トランスデューサである。別の変形形態では、先端トランスデューサは超音波治療先端トランスデューサである。更なる変形形態では、先端トランスデューサは超音波イメージング／治療先端トランスデューサである。更なる変形形態では、先端トランスデューサは、電磁波または機械波（mechanical waves）、またはそれら両方を放出するトランスポンダである。

【００５１】

第３の実施形態の前記した第１、第２、及び第３の表現の同じまたは別の例では、それぞれの超音波放射面１４２は、図１５に示されているその断面図を見ると実質的に直線状である。図１４に示されている一変形形態では、それぞれの超音波放射面１４２は、長手方向の軸１３０に平行な方向に超音波放射面１４２に沿って実質的に凹状であり、それぞれが集束ゾーンを有する。図１６に示されている第１の代替トランスデューサ構造では、それぞれの超音波放射面１６２は実質的に平坦な形状である。図１７に示されている第２の代替トランスデューサ構造では、それぞれの超音波放射面１６４は断面図で見たときに実質的に凹状であり、それぞれの超音波放射面１６４が集束ゾーンを有する。一変更形態では、それぞれの超音波放射面１６４は、長手方向の軸に平行な方向に超音波放射面１６４に沿って実質的に凹状である（例えば、半球状で凹状の超音波放射面１６４など）。このような超音波放射面の形状は、本発明の他のすべての実施形態で説明した全ての超音波トランスデューサに等しく適用することができる。

【００５２】

第３の実施形態の前記した第１、第２、及び第３の表現の同じまたは別の例では、Ｐは４以下である。一変形形態では、Ｐは図１５及び図１７に示されているように３である。別の変形形態では、Ｐは図１６に示されているように２である。

【００５３】

第３の実施形態の前記した第２の及び第３の表現の同じまたは別の例では、エンドエフェクタ１４６は、当業者なら理解できる開放手術エンドエフェクタ、内視鏡エンドエフェクタ、腹腔鏡エンドエフェクタ（図１３に示されている）、カテーテルエンドエフェクタ（限定するものではないが、血管内カテーテルエンドエフェクタなど）、または針エンドエフェクタである。図１３に示されている可能な一形態では、超音波治療システム１４４は、当業者なら理解できるフットペダル電源スイッチ１６９に機能的に接続された超音波制御器１６８及びエンドエフェクタ１４６に機能的に接続されたハンドピース１６６も含む。

【００５４】

超音波治療の適用

切除／超音波治療システム

本発明の第５の実施形態が図１８－図２０に示されている。本発明の第５の実施形態の第１の表現では、超音波治療システム１７０は、チューブ１７２、第１のエンドエフェクタ１７４、及び第２のエンドエフェクタ１７６を含む。チューブ１７２は、患者の体内に挿入可能な先端部１７８及び内腔１８２を有する。第１のエンドエフェクタ１７４は、切除器具１８０を有しており、患者１８０の外部から挿入されたチューブ１７２の内腔１８２の中に導入することができ、挿入されたチューブ１７２の内腔１８２を介して患者１８０の体内に送ることができる。第２のエンドエフェクタ１７６は、超音波治療トランスデューサ組立体１８６を有しており、患者１８０の外部から挿入されたチューブ１７２の内腔１８２の中に導入することができ、挿入されたチューブ１７２の内腔１８２を介して患者１８０の体内に送ることができる。一変形形態では、第１のエンドエフェクタ及び第２のエンドエフェクタは、内腔の別々の開口からその内腔内に導入される、または内腔に続いた別々のブランチチャネルから導入される。別の変形形態では、第１のエンドエフェクタ及び第２のエンドエフェクタは、内腔の同じ開口からその内腔内に導入される。一変更形態では、内腔の開口がチューブの端部に設けられている。別の変更形態では、内腔の開口は、チューブの端部から離間して設けられている。

【００５５】

本発明の第５の実施形態の第２の表現は、チューブ１７２、第１のエンドエフェクタ１７４、及び第２のエンドエフェクタ１７６を含む超音波治療システム１７０についてである。チューブ１７２は、患者１８０の体内に挿入可能な先端部１７８と、先端開口１８８及び基端開口１９０を備えた内腔１８２とを有する。第１のエンドエフェクタ１７４は、切除器具１８４を有しており、基端開口１９０内に導入することができ、内腔１８２を介して先端開口１８８に送ることができる。第２のエンドエフェクタ１７６は、超音波治療トランスデューサ組立体１８６を有しており、基端開口１９０内に導入することができ、内腔１８２を介して先端開口１８８に送ることができる。

【００５６】

本発明の第５の実施形態の第１及び第２の表現の一例では、内腔１８２の大きさは、第１のエンドエフェクタ１７４及び第２のエンドエフェクタ１７６を一度に一方しか導入できない大きさである。同じまたは別の例では、チューブ１７２の先端部１７８は、組織を通して患者１８０の患者組織１９２内に挿入することができる。同じまたは別の例では、切除器具１８４は、生検切除器具１９４または他の切除器具である。

【００５７】

本発明の第５の実施形態の第３の表現は、チューブ１７２、第１のエンドエフェクタ１７４、及び第２のエンドエフェクタ１７６を含む超音波治療システム１７０についてである。チューブ１７２は、患者１８０の乳房組織１９６内に組織を通して挿入できる先端部１７８と、先端開口１８８及び基端開口１９０を備えた内腔１８２とを有する。第１のエンドエフェクタ１７４は、生検切除器具１９４（または他の切除器具）を有しており、基端開口１９０内に導入することができ、内腔１８２を介して先端開口１８８に送ることができる。第２のエンドエフェクタ１７６は、超音波治療トランスデューサ組立体１８６を有しており、基端開口１９０内に導入することができ、内腔１８２を介して先端開口１８８に送ることができる。内腔１８２の大きさは、第１のエンドエフェクタ１７４及び第２のエンドエフェクタ１７６を一度に一方しか導入できない大きさである。あるデザインでは、第１のエンドエフェクタは、生検切除器具１９４で生検する患者組織を吸引する吸引機構も含む。ある適用例では、チューブ１７２及び第１のエンドエフェクタ１７４（吸入機構を含む生検切除器具１９４を備えた）は、エシコン・エンドーサージェリィ社（Ethicon Endo-Surgery, Inc.(ジョンソン・アンド・ジョンソン社)）が製造するMammotome（登録商標）乳房生検システムの構成要素をベースにしている。

【００５８】

本発明の第６の方法は、本発明の第５の実施形態の第３の表現で説明したような超音波治療システム１７０を用いる患者１８０の超音波治療についてである。この第６の方法はステップ（ａ）からステップ（ｈ）を含む。ステップ（ａ）は、癌の可能性がある患者の乳

房組織１９６を識別することを含む。ステップ（ｂ）は、先端開口１８８が乳房組織１９６に近接し、基端開口１９０が患者の外部に位置するように、患者１８０の体内にチューブ１７２の先端部１７８を組織を通して挿入することを含む。ステップ（ｃ）は、基端開口１９０内に第１のエンドエフェクタ１７４を導入して、その第１のエンドエフェクタ１７４を内腔１８２を介して先端開口１８８に送ることを含む。ステップ（ｄ）は、生検切除器具１９４で乳房組織１９６の生検試料を採取することを含む。ステップ（ｅ）は、内腔１８２から第１のエンドエフェクタ１７４を取り出すことを含む。ステップ（ｆ）は、第２のエンドエフェクタ１７６を基端開口１９０内に導入して、その第２のエンドエフェクタ１７６を内腔１８２を介して先端開口１８８に送ることを含む。ステップ（ｇ）は、生検試料を採取した乳房組織の出血している領域を特定することを含む。ステップ（ｈ）は、トランスデューサ組立体１８６を用いて超音波で特定した領域を治療し、出血を実質的に止めることを含む。ある適用例では、本発明の第６の方法は、生検試料を癌について検査するステップ、並びに乳房組織に残っている全ての癌をトランスデューサ組立体１８６を用いて超音波で実質的にアブレーションするステップも含む。このような超音波治療システム及び方法の利点には、最小侵襲性で乳房生検を容易に行うことができ、かつその生検によって生じた出血を容易に抑制できることが含まれる。

【００５９】

本発明の第５の実施形態の第４の表現では、超音波治療システム１７０は、チューブ１７２、第１のエンドエフェクタ１７４、及び第２のエンドエフェクタ１７６を含む。チューブ１７２は、患者１８０の体内に挿入可能な先端部１７８及び内腔１８２を有する。第１のエンドエフェクタ１７４は切除器具１８４を有しており、患者１８０の外部から挿入されたチューブ１７２の内腔１８２内に導入することができ、導入されたチューブ１７２の内腔１８２を介して患者１８０の体内に送ることができる。第２のエンドエフェクタ１７６は、超音波イメージング／治療トランスデューサ組立体１９８を有しており、患者１８０の外部から挿入されたチューブ１７２の内腔１８２内に導入することができ、挿入されたチューブ１７２の内腔１８２を介して患者１８０の体内に送ることができる。一変形形態では、第１のエンドエフェクタ及び第２のエンドエフェクタは、内腔の別々の孔からその内腔内に導入される、または別のブランチチャネルから内腔内に導入される。別の変形形態では、第１のエンドエフェクタ及び第２のエンドエフェクタは、内腔の同じ開口を介してその内腔内に導入される。一変更形態では、内腔の開口はチューブの端部に設けられている。別の変更形態では、内腔の開口はチューブの端部から離間している。

【００６０】

本発明の第５の実施形態の第５の表現は、チューブ１７２、第１のエンドエフェクタ１７４、及び第２のエンドエフェクタ１７６を含む超音波治療システム１７０についてである。チューブ１７２は、患者１８０の体内に挿入可能な先端部１７８と、先端開口１８８及び基端開口１９０を備えた内腔１８２とを有する。第１のエンドエフェクタ１７４は、切除器具１８４を有しており、基端開口１９０内に導入することができ、内腔１８２を介して先端開口１８８に送ることができる。第２のエンドエフェクタ１７６は、超音波イメージング／治療トランスデューサ組立体１９８を有しており、基端開口１９０内に導入することができ、内腔１８２を介して先端開口１８８に送ることができる。

【００６１】

本発明の第５の実施形態の第４及び第５の表現の一例では、内腔１８２の大きさは、第１のエンドエフェクタ１７４及び第２のエンドエフェクタ１７６を一度に一方しか導入できない大きさである。同じまたは別の例では、チューブ１７２の先端部１７８は、患者１８０の患者組織１９２内に組織を通して挿入することができる。同じまたは別の例では、切除器具１８４は、生検切除器具１９４または他の切除器具である。

【００６２】

本発明の第５の実施形態の第６の表現は、チューブ１７２、第１のエンドエフェクタ１７４、及び第２のエンドエフェクタ１７６を含む超音波治療システム１７０についてである。チューブ１７２は、患者１８０の乳房組織１９６内に組織を通して挿入することができ

る先端部１７８と、先端開口１８８及び基端開口１９０を備えた内腔１８２とを有する。第１のエンドエフェクタ１７４は、生検切除器具１９４（または他の切除器具）を有しており、基端開口１９０内に導入することができ、内腔１８２を介して先端開口１８８に送ることができる。第２のエンドエフェクタ１７６は、超音波イメージング／治療トランスデューサ組立体１９６を有しており、基端開口１９０内に導入することができ、内腔１８２を介して先端開口１８８に送ることができる。内腔１８２の大きさは、第１のエンドエフェクタ１７４及び第２のエンドエフェクタ１７６を一度に一方しか導入できない大きさである。一適用例では、チューブ１７２及び第１のエンドエフェクタ１７４（吸入機構を含む生検切除器具１９４を備えた）は、エシコン・エンドーサージェリィ社（Ethicon Endo‐Surgery, Inc.(ジョンソン・アンド・ジョンソン社)）が製造するMammotome（登録商標）乳房生検システムの構成要素をベースにしている。

【００６３】

本発明の第７の方法は、本発明の第５の実施形態の第６の表現で説明したような超音波治療システム１７０を用いる患者１８０の超音波治療についてである。第７の方法はステップ（ａ）からステップ（ｈ）を含む。ステップ（ａ）は、癌の可能性がある患者の乳房組織１９６を識別することを含む。ステップ（ｂ）は、先端開口１８８が乳房組織１９６に近接し、基端開口１９０が患者の外部に位置するように、患者１８０の体内にチューブ１７２の先端部１７８を組織を通して挿入することを含む。ステップ（ｃ）は、第１のエンドエフェクタを基端開口１９０内に導入して、その第１のエンドエフェクタ１７４を内腔１８２を介して先端開口１８８に送ることを含む。ステップ（ｄ）は、乳房組織１９６の生検試料を生検切除器具１９４で採取することを含む。ステップ（ｅ）は、内腔１８２から第１のエンドエフェクタ１７４を取り出すことを含む。ステップ（ｆ）は、基端開口１９０内に第２のエンドエフェクタ１７６を導入して、その第２のエンドエフェクタ１７６を内腔１８２を介して先端開口１８８に送ることを含む。ステップ（ｇ）は、トランスデューサ組立体１９８を用いて超音波イメージングから、生検試料を採取した乳房組織の出血している領域を特定することを含む。ステップ（ｈ）は、トランスデューサ組立体１９８を用いて超音波で特定した領域を治療し、出血を実質的に止めることを含む。一適用例では、本発明の第７の方法は、生検試料を癌について検査するステップ、並びに乳房組織に残っている全ての癌をトランスデューサ組立体１９８を用いて超音波で実質的にアブレーションするステップも含む。このような超音波治療システム及び方法の利点には、最小侵襲性で乳房生検を容易に行うことができ、かつその生検によって生じた出血を容易に抑制できることが含まれる。

【００６４】

図１８に示されている可能な一形態は、超音波治療システム１７０は、第１のエンドエフェクタ１７４を備えたチューブ１７２に取り付けられたハンドピース１９９も含む。このハンドピース１９９は、第１のケーブル２０３を介して超音波制御器２０１に機能的に接続されている。また、このハンドピース１９９により、切除器具１８０を内腔１８２内で伸長したり、引き戻すことができる。この可能な一形態では、第２のエンドエフェクタ１７６は、第２のケーブル２０５を介して超音波制御器２０１に機能的に接続されており、図１８に示されているようにハンドピース１９９の外部から内腔１８２内に挿入することができる。

【００６５】

超音波を用いた治療の実施

本発明の第８の方法は患者の治療についてであり、図２１にそのブロック図が示されている。この第８の方法はステップ（ａ）からステップ（ｆ）を含む。ステップ（ａ）は、図２１のブロック２００に「トランスデューサ組立体を用意する」と示されてある。ステップ（ａ）は、超音波イメージングトランスデューサ組立体を用意することを含む。ステップ（ｂ）は、図２１のブロック２０２に「組立体を胃腸領域内に挿入する」と示されている。ステップ（ｂ）は、トランスデューサ組立体を患者の胃腸領域内に挿入することを含む。ステップ（ｃ）図２１のブロック２０４の「組立体を案内する」と示されている。ス

テップ（ｃ）は、トランスデューサ組立体を胃腸領域内に案内することを含む。ステップ（ｄ）は、図２１のブロック２０６に「治療のために患者組織を識別する」と示されている。ステップ（ｄ）は、治療のために胃腸領域の患者組織を識別することを含む。ステップ（ｅ）は、図２１のブロック２０８に「超音波イメージングから治療を実施する」と示されている。ステップ（ｅ）は、トランスデューサ組立体を用いて超音波イメージングから治療を実施することを含む。ステップ（ｆ）は、図２１のブロック２１０に「患者を治療する」と示されている。ステップ（ｆ）は、ステップ（ｅ）の治療の実施に応じて患者組織を治療することを含む。第８の方法において、治療は、治療の実施のために用いたトランスデューサ組立体を用いた超音波治療を含まなくてもよく、かつ／または他の任意の超音波トランスデューサ組立体を用いた超音波治療を含まなくてもよいことに留意されたい。病理学的な大きさ及び部位に左右されるある方法では、ステップ（ｅ）で、第１のトランスデューサ組立体を内視鏡的に用いて治療を実施し、ステップ（ｆ）で第２のトランスデューサ組立体を腹腔鏡的に用いて超音波による患者組織の治療を行う。一変形形態では、ステップ（ｅ）で、第１のトランスデューサ組立体を腹腔鏡的に用いて治療を実施し、ステップ（ｆ）で、第２のトランスデューサ組立体を内視鏡的に用いて超音波による患者組織の治療を行う。別の方法では、ステップ（ｆ）の治療が、高周波、レーザー、マイクロ波、または化学アブレーション治療である。別の種類の治療処置も当業者には明らかである。

【００６６】

人の患者の胃腸（ＧＩ）領域には、限定するものではないが、上部ＧＩ領域の食道及び胃、並びに下部ＧＩ領域の直腸及び結腸が含まれる。更にこの方法では、ＧＩ領域に肝臓も含まれることを留意されたい。

【００６７】

「超音波イメージングから治療の実施」は、少なくとも超音波イメージを用いて治療する患者組織の３次元的大きさ及び形状を決定することを指す。例えば、限定するものではないが、上部ＧＩ及び下部ＧＩの腫瘍は、内視鏡的にＧＩ管内に導入される円筒型、側面放射型、または半凸型の超音波アレイ型、または単一要素トランスデューサを用いて高周波（６ＭＨｚ～３０ＭＨｚ）超音波イメージングで視覚化することができる。食道、胃、十二指腸、及び結腸のすべての層を含むＧＩ管のすべての層は、視覚化することができる。ある方法では、ＧＩ構造の三次元表示が、超音波トランスデューサの軸方向の前進により生成された一連の二次元スキャンを合わせて生成される。この三次元表示から、あらゆる腫瘍成長、その形態学的特徴、及び腫瘍の大きさや形状を容易に決定することができる。

【００６８】

このような超音波イメージングからの治療の実施の利点には、一例では、より解像度が高く、更にＸ線画像やＭＲＩ画像などの従来の体外治療実施方法または従来の内視鏡光学方法と比べてより実用的な非侵襲性の治療実施方法を提供できることが含まれる。

【００６９】

本発明の第９の方法は患者の超音波治療についてであり、ステップ（ａ）からステップ（ｆ）を含む。この第９の方法は、第８の方法と同じ図２１のブロック図を用いるが、ブロック２００の「トランスデューサ組立体」が「エンドエフェクタ」に代わり、ブロック２０２及びブロック２０４の「組立体」が「エンドエフェクタ」に代わっている。ステップ（ａ）は、超音波イメージング／治療トランスデューサ組立体を有するエンドエフェクタを用意することを含む。ステップ（ｂ）は、患者の胃腸領域内にエンドエフェクタを挿入することを含む。ステップ（ｃ）は、トランスデューサ組立体を胃腸領域内において案内することを含む。ステップ（ｄ）は、治療のために胃腸領域の患者組織を識別することを含む。ステップ（ｅ）は、トランスデューサ組立体を用いて超音波イメージングから治療を実施することを含む。ステップ（ｆ）は、ステップ（ｅ）の治療の実施に応じてトランスデューサ組立体を用いて超音波で患者組織を治療することを含む。

【００７０】

本発明の第１０の方法は患者の超音波治療についてであり、ステップ（ａ）からステップ

（ｆ）を含む。この第１０の方法は、第８の方法と同様に図２１のブロック図を用いるが、ブロック２００の「トランスデューサ組立体」が「エンドエフェクタ」に代わり、ブロック２０２及びブロック２０４の「組立体」が「エンドエフェクタ」に代わっている。ステップ（ａ）は、超音波イメージング／治療トランスデューサ組立体を有するエンドエフェクタを用意することを含む。ステップ（ｂ）は、患者の胃腸領域内にエンドエフェクタを挿入することを含む。ステップ（ｃ）は、胃腸領域内においてトランスデューサ組立を案内することを含む。ステップ（ｄ）は、少なくとも部分的にトランスデューサ組立体を用いた超音波イメージから、治療のために胃腸領域の患者組織を識別することを含む。ステップ（ｅ）は、トランスデューサ組立体を用いて超音波イメージングから治療を実施することを含む。ステップ（ｆ）は、ステップ（ｅ）の治療の実施に応じてトランスデューサ組立体を用いて超音波で患者組織を治療することを含む。ある方法では、腹腔鏡によりＧＩ領域にアクセスして、超音波イメージング／治療トランスデューサ組立体を有するエンドエフェクタを用いて大きなＧＩ腫瘍を特定し、治療を実施し、治療を行う。

【００７１】

本発明の第９および第１０の方法の一例では、患者組織は病変を含む胃腸組織であり、ステップ（ｆ）で、超音波でその病変を実質的にアブレーションする。一変更形態では、胃腸組織は、その病変に血液を供給する血管を含み、ステップ（ｆ）で、その血管から病変への血液の供給を実質的に止めるべくその血管を超音波で治療する。

【００７２】

本発明の第９及び第１０の方法の別の例では、患者組織は病変及びその病変に血液を供給する血管を含む肝組織であり、ステップ（ｆ）で、その血管から病変への血液の供給を実質的に止めるべくその血管を超音波で治療する。

【００７３】

本発明の第９及び第１０の方法の別の例では患者組織は病変を含む肝臓組織であり、ステップ（ｆ）で、その病変を超音波で実質的にアブレーションする。一変更形態では、肝臓組織が病変に血液を供給する血管を含み、ステップ（ｆ）ではまた、その病変に血管からの血液の供給を実質的に止めるべくその血管を超音波で治療もする。ある方法では、超音波イメージング／治療トランスデューサ組立体を有するエンドエフェクタをＧＩ管の中に腹腔鏡的に導入し、総胆管の上のファーテル膨大部を介して逆方向に前進させ、更に胆管系に進め、そこで、治療が必要な肝実質（例えば胆管癌等）をエンドエフェクタを用いて特定し、治療を実施し、治療を行う。

【００７４】

超音波を用いた肺病変の治療

本発明の第１１の方法は患者の超音波治療についてであり、図２２のブロック図に示されている。この第１１の方法はステップ（ａ）からステップ（ｆ）を含む。ステップ（ａ）は、図２２のブロック２１２に「エンドエフェクタを用意する」と示されている。ステップ（ａ）は、超音波治療トランスデューサ組立体を有するエンドエフェクタを用意することを含む。ステップ（ｂ）は、図２２のブロック２１４に「エンドエフェクタを挿入する」と示されている。ステップ（ｂ）は、患者の体内にエンドエフェクタを挿入することを含む。ステップ（ｃ）は、図２２のブロック２１６に「エンドエフェクタを肺に案内する」と示されている。ステップ（ｃ）は、患者の体内のエンドエフェクタを患者の肺に案内することを含む。ステップ（ｄ）は、図２２のブロック２１８に「病変を特定する」と示されている。ステップ（ｄ）は、治療のために肺上の病変または肺内部の病変を特定することを含む。ステップ（ｅ）は、図２２のブロック２２０に「トランスデューサ組立体を配置する」と示されている。ステップ（ｅ）は、病変上または病変内にトランスデューサ組立体を配置することを含む。ステップ（ｆ）は、図２２のブロック２２２に「病変を治療する」と示されている。ステップ（ｆ）は、トランスデューサ組立体を用いて超音波で病変を治療することを含む。

【００７５】

本発明の第１２の方法は患者の超音波治療についてであり、ステップ（ａ）からステップ

（ｆ）を含む。この第１２の方法は、第１１の方法と同様に図２２のブロック図を用いる。ステップ（ａ）は、超音波イメージング／治療トランスデューサ組立体を有するエンドエフェクタを用意することを含む。ステップ（ｂ）は、患者の体内にそのエンドエフェクタを挿入することを含む。ステップ（ｃ）は、患者の体内のエンドエフェクタを患者の肺に案内することを含む。ステップ（ｄ）は、少なくとも部分的にトランスデューサ組立体を用いた超音波イメージングから、治療のために肺上または肺内部に病変を特定することを含む。ステップ（ｅ）は、病変上または病変内部にトランスデューサ組立体を配置することを含む。ステップ（ｆ）は、トランスデューサ組立体を用いて超音波でその病変を治療することを含む。

【００７６】

第１１及び第１２の方法の一例では、ステップ（ｆ）で超音波で病変を実質的にアブレーションする。一適用例では、エンドエフェクタは内視鏡エンドエフェクタであり、ステップ（ｂ）で患者の体内にエンドエフェクタを経気管支内視鏡的に挿入する。別の適用例では、エンドエフェクタは針エンドエフェクタであり、ステップ（ｂ）で患者の体内にエンドエフェクタを組織を通して挿入する。一実施態様では、ステップ（ｅ）で病変上にトランスデューサ組立体を配置する。別の実施態様では、ステップ（ｅ）で病変内にトランスデューサ組立体を配置する。第１１及び第２の方法の一実施例では、ステップ（ｃ）で、気管支鏡を用いてエンドエフェクタを患者の肺に案内する。

【００７７】

肺の超音波治療は従来から避けられてきた。なぜなら、超音波の殆どを反射して超音波が肺から病変に到達するのを阻止する空気を含む肺の気泡によって、超音波が肺の中の病変に到達できないためである。肺を通過して病変に到達させるために高出力の超音波を用いると、呼吸に必要な気泡を傷つけたり破壊したりすることがある。出願者は、超音波トランスデューサを肺の病変上または病変内に配置することにより気泡を傷つけることなく病変の超音波治療（例えば、腫瘍や梗塞等）が可能になるという理論を立てた。この出願者の方法が病変の表面及び非表面に適用できることに留意されたい。出願者の超音波治療の第１１及び第１２の方法の利点には、一例では、他の方法で手術や治療ができない肺の癌病変を破壊できることが含まれる。

【００７８】

超音波を用いた治療のための計測法

本発明の第１３の方法は患者の超音波治療についてであり、図２３のブロック図に示されている。この第１３の方法はステップ（ａ）からステップ（ｅ）を含む。ステップ（ａ）は、図２３のブロック２２４に「エンドエフェクタを用意する」と示されている。ステップ（ａ）は、超音波治療トランスデューサ組立体を有するエンドエフェクタを用意することを含む。ステップ（ｂ）は、図２３のブロック２２６に「エンドエフェクタを挿入する」と示されている。ステップ（ｂ）は、患者の体内にエンドエフェクタを挿入することを含む。ステップ（ｃ）は、図２３のブロック２２８に「エンドエフェクタを案内する」と示されている。ステップ（ｃ）は、患者の体内のエンドエフェクタを病変を含む患者組織の領域に案内することを含む。ステップ（ｄ）は、図２３のブロック２３０に「病変に血液を供給する血管を特定する」と示されている。ステップ（ｄ）は、病変に血液を供給する領域の血管を特定することを含む。ステップ（ｅ）は、図２３のブロック２３２に「超音波を用いて血液の供給を止める」と示されている。ステップ（ｅ）は、トランスデューサ組立体からの超音波で血管を治療してその血管を実質的に閉塞し、その血管から病変への血液の供給を止める。本発明の第１３の方法のある実施態様は、病変を実質的にアブレーションするためにトランスデューサ組立体からの超音波でその病変を治療するステップも含む。

【００７９】

本発明の第１４の方法は患者の超音波治療についてであり、ステップ（ａ）からステップ（ｇ）を含む。この第１４の方法は第１３の方法に類似している。ステップ（ａ）は、超音波イメージング／治療トランスデューサ組立体を有するエンドエフェクタを用意するこ

とを含む。ステップ（ｂ）は、患者の体内にエンドエフェクタを挿入することを含む。ステップ（ｃ）は、患者の体内のエンドエフェクタを病変を含む患者組織の領域に案内することを含む。ステップ（ｄ）は、少なくとも部分的にトランスデューサ組立体を用いた超音波イメージングから病変を特定することを含む。ステップ（ｅ）は、トランスデューサ組立体を用いて超音波イメージングから、病変に血液を供給する領域の血管を特定することを含む。ステップ（ｆ）は、血管を実質的に閉塞させてその血管からの病変への血液の供給を実質的に止めるべく、トランスデューサ組立体からの超音波で血管を治療する。ステップ（ｇ）は、病変を実質的にアブレーションするためにトランスデューサ組立体からの超音波で病変を治療することを含む。ドップラー超音波イメージング、グレイスケール超音波イメージング、及びこれらの組み合わせが、血管内の血流をイメージングするための既知の超音波技術であることに留意されたい。

【００８０】

第１３及び第１４の方法の一適用例では、エンドエフェクタは開放手術エンドエフェクタである。別の適用例では、エンドエフェクタは内視鏡エンドエフェクタである。更なる適用例では、エンドエフェクタは腹腔鏡エンドエフェクタである。更に別の適用例では、エンドエフェクタはカテーテルエンドエフェクタ（限定するものではないが、血管内カテーテルエンドエフェクタなど）である。別の適用例では、エンドエフェクタは針エンドエフェクタである。

【００８１】

本発明の広い意味の第１３の方法は、上記した第１３の方法の挿入するステップ及び案内するステップを含まず、ステップ（ａ）からステップ（ｃ）を含む。ステップ（ａ）は、超音波治療トランスデューサ組立体を有するエンドエフェクタを用意することを含む。ステップ（ｂ）は、病変に血液を供給する患者の血管を特定することを含む。ステップ（ｃ）は、血管を実質的に閉塞させてその血管から病変への血液の供給を実質的に止めるべく、トランスデューサ組立体からの超音波で血管を治療することを含む。

【００８２】

本発明の広い意味の第１４の方法は、上記した第１４の方法の挿入するステップ及び案内するステップを含まず、ステップ（ａ）からステップ（ｅ）を含む。ステップ（ａ）は、超音波イメージング／治療トランスデューサ組立体を有するエンドエフェクタを用意することを含む。ステップ（ｂ）は、少なくとも部分的にトランスデューサ組立体を用いた超音波イメージングから、患者の病変を特定することを含む。ステップ（ｃ）は、トランスデューサ組立体を用いて超音波イメージングから、病変に血液を供給する血管を特定することを含む。ステップ（ｄ）は、血管を実質的に閉塞させてその血管から病変への血液の供給を実質的に止めるべく、トランスデューサからの超音波で血管を治療することを含む。ステップ（ｅ）は、病変を実質的にアブレーションするためにトランスデューサ組立体からの超音波で病変を治療することを含む。

【００８３】

広い意味の第１３及び第１４の方法の一例では、エンドエフェクタは体外エンドエフェクタである。別の例では、エンドエフェクタは体内エンドエフェクタである。更なる例では、エンドエフェクタは体外モード及び体内モードの両方で用いることができる。

【００８４】

超音波治療のための出願者の第１３の方法及び広い意味の第１３の方法の利点には、一例では、癌病変の位置のために他の方法では手術または治療ができない場合に、癌病変に血液を供給する血管を超音波で止血して、直接的に癌を破壊できることが含まれる。超音波治療のための出願者の第１４の方法及び広い意味の第１４の方法の利点には、一例では、超音波アブレーションによる癌病変の直接的な破壊、並びに超音波アブレーションステップで破壊できなかった癌病変をそこに血液を供給する血管を超音波で止血して間接的にその癌病変を破壊ができることが含まれる。

【００８５】

超音波エンドエフェクタの案内及びターゲッティング

治療のための超音波エンドエフェクタの案内
本発明の第６の実施形態が図２４に示されている。本発明の第６の実施形態の第１の表現では、超音波治療システム２３４（一部のみが図２４に示されている）は、エンドエフェクタ２３６及び少なくとも３つのレシーバ２３８を含む。エンドエフェクタ２３６は、トランスデューサ２４２を含むトランスデューサ組立体２４０を有する。このトランスデューサ２４２は、治療超音波及び機械波を放出するように適合された少なくとも１つのトランスデューサ要素２４４を有する。用語「機械波」は、超音波及び非超音波である圧縮（音響）波、並びに超音波及び非超音波である剪断波を含み、これらの波は波パルスを含む。レシーバ２３８は、トランスデューサ組立体２４０から離間している。レシーバ２３８はまた、トランスデューサ組立体２４０の位置を求めるために放射された機械波を受け取るように適合されている。放出する波が３つのレシーバによって受け取られるトランスポンダの位置を求めるための従来の方法（三角法を含む）は周知である。第６の実施形態の第２の表現は、少なくとも１つのトランスデューサ要素２４４がイメージング超音波を放出するようにも適合されている点を除けば、第６の実施形態の第１の表現と同一である。第６の実施形態の第１及び第２の表現の一変形形態では、エンドエフェクタ及びレシーバを患者の外部（一変更形態では患者の上）に配置可能である。別の変形形態では、エンドエフェクタを患者の体内に挿入可能であり、レシーバを患者の外部（一変更形態では患者の上）に配置可能である。

【００８６】
本発明の第７の実施形態が図２５に示されている。本発明の第７の実施形態の第１の表現では、超音波治療システム２４６（一部のみが図２５に示されている）はエンドエフェクタ２４８及び少なくとも３つのレシーバ２５０を含む。エンドエフェクタ２４８は、超音波治療トランスデューサ組立体２５２及びトランスポンダ２５４を有する。トランスポンダ２５４は、波を放出するように適合されており、その波には電磁波、機械波、またはその両方が含まれる。レシーバ２５０はトランスデューサ組立体２５２から離間している。レシーバ２５０はまた、トランスポンダ２５４の位置を求めるために、放出された波を受け取るように適合されている。第７の実施形態の第２の表現では、超音波治療トランスデューサ組立体２５２は、超音波イメージング／治療トランスデューサ組立体２５６である。

【００８７】
第７の実施形態の第１及び第２の表現の一適用例では、エンドエフェクタ２４８は患者の体内に挿入可能であり、トランスポンダ２５４は電磁波を放出するように適合されており、レシーバ２５０は患者の外部に配置可能である。一変形形態では、レシーバ２５０は患者上に配置可能である。別の適用例では、エンドエフェクタは患者の外部（一変更形態では患者の上）に配置可能であり、レシーバは、患者の外部（一変更形態では患者の上）に配置可能である。

【００８８】
第７の実施形態の第１及び第２の表現の一例では、エンドエフェクタ２４８は内視鏡エンドエフェクタ、腹腔鏡エンドエフェクタ、カテーテルエンドエフェクタ（限定するものではないが、血管内カテーテルエンドエフェクタなど）、または針エンドエフェクタである。第７の実施形態の第１及び第２の表現のあるデザインではエンドエフェクタ２４８は先端部２６０を有しており、その先端部２６０にはトランスポンダ２５４が配置されている。一変形形態では、トランスデューサ組立体２５２及び２５６はトランスポンダ２５４に近接して配置される。

【００８９】
本発明の第１５の方法は、第７の実施形態の第１の表現の超音波治療システムを用い、ステップ（ａ）からステップ（ｈ）を含む。ステップ（ａ）は、患者の体内にエンドエフェクタ２４８を挿入することを含む。ステップ（ｂ）は、患者の外部にレシーバ２５０を配置することを含む。ステップ（ｃ）は、トランスポンダ２５４から電磁波を放出することを含む。ステップ（ｄ）は、その電磁波を配置されたレシーバ２５０で受け取ることを含

む。ステップ（ｅ）は、その受け取った電磁波からトランスポンダ２５４の位置を算出することを含む。ステップ（ｆ）は、トランスポンダ２５４の算出した位置から、患者の体内のエンドエフェクタを所望の位置に案内することを含む。ステップ（ｇ）は、ステップ（ｆ）の後に、治療のために患者組織を識別することを含む。ステップ（ｈ）は、トランスデューサ組立体２５２を用いて超音波で識別された患者組織を治療することを含む。

【００９０】

本発明の第１６の方法は、第７の実施形態の第２の表現の超音波治療システムを用い、ステップ（ａ）からステップ（ｈ）を含む。ステップ（ａ）は、患者の体内にエンドエフェクタ２４８を挿入することを含む。ステップ（ｂ）は、患者の外部にレシーバ２５０を配置することを含む。ステップ（ｃ）は、トランスポンダ２５４から電磁波を放出することを含む。ステップ（ｄ）は、配置されたレシーバ２５０でその電磁波を受け取ることを含む。ステップ（ｅ）は、受け取った電磁波からトランスポンダ２５４の位置を算出することを含む。ステップ（ｆ）は、トランスポンダ２５４の算出した位置から所望の位置に、患者の体内のエンドエフェクタを案内することを含む。ステップ（ｇ）は、ステップ（ｆ）の後に、少なくともトランスデューサ組立体２５６を用いて超音波イメージングから、治療のために患者組織を識別することを含む。ステップ（ｈ）は、トランスデューサ組立体２５６を用いて超音波で識別された患者組織を治療することを含む。

【００９１】

トランスポンダの位置を算出するため及び患者の体内のトランスポンダ（心臓を監視するための心臓カテーテルに取り付けられている）を案内するための既知の電磁トランスポンダ／３レシーバ・システムは、バイオセンス・ウェブスター（Biosense Webster（ジョンソン・アンド・ジョンソン社））が製造するNAVI-STAR（登録商標）カテーテルと共に用いられるCARTO（商標）EPナビゲーションシステムである。

【００９２】

超音波治療及び位置を求めることができるエンドエフェクタの利点には、一例では、患者組織の超音波治療のために患者の体内のエンドエフェクタを患者組織により正確に案内できることが含まれる。

【００９３】

治療のために超音波の照準を合わせるための方法

本発明の第１７の方法は患者の超音波治療についてであり、図２６のブロック図に示されている。この第１７の方法は、ステップ（ａ）からステップ（ｆ）を含む。ステップ（ａ）は、図２６のブロック２６２に「エンドエフェクタを用意する」と示されている。ステップ（ａ）は、超音波治療トランスデューサ組立体を有するエンドエフェクタを用意することを含む。ステップ（ｂ）は、図２６のブロック２６４に「トランスデューサ組立体の照準を合わせる」と示されている。ステップ（ｂ）は、患者組織の所望の集束ゾーンに超音波エネルギーを集束するためにトランスデューサ組立体の照準を合わせることを含む。一例では、トランスデューサ組立体の照準を合わせることは、トランスデューサ組立体から特定の方向に沿って特定の距離に超音波エネルギーを集束させることを指すことに留意されたい。ステップ（ｃ）は、図２６のブロック２６６に「トランスデューサ組立体を作動させる」と示されている。ステップ（ｃ）は、照準を合わせたトランスデューサ組立体を作動させて、実質的に患者組織に医学的影響を与えることなく、患者組織の温度上昇を達成するのに十分な超音波エネルギーを放出することを含む。ステップ（ｄ）は、図２６のブロック２６８に「実際の集束ゾーンを検出する」と示されている。ステップ（ｄ）は、ステップ（ｃ）の後に、反射された超音波エネルギーから温度が上昇した患者組織の実際の集束ゾーンを検出することを含む。ステップ（ｅ）は、図２６のブロック２６９に「あらゆる照準エラーを修正する」と示されている。ステップ（ｅ）は、所望の集束ゾーンと実際の集束ゾーンとの間のあらゆるエラーを修正することを含む。ステップ（ｆ）は、図２６のブロック２７０に「患者組織を治療する」と示されている。ステップ（ｆ）は、ステップ（ｅ）の後に、トランスデューサ組立体を用いて超音波で患者組織を治療することを含む。一適用例では、ステップ（ｄ）では、ステップ（ａ）からステップ（ｃ）及び

ステップ（ｅ）からステップ（ｆ）で用いた超音波トランスデューサ組立体とは別の１または複数の追加の超音波トランスデューサ組立体を用いて、反射された超音波エネルギーから実際の集束ゾーンを検出する。別の適用例では、同じ超音波トランスデューサ組立体をステップ（ａ）からステップ（ｆ）で用いる。第１７の方法の一例では、エンドエフェクタは体外エンドエフェクタである。別の例では、エンドエフェクタは体内エンドエフェクタである。更に別の例では、エンドエフェクタは体外モード及び体内モードの両方で用いることができる。

【００９４】

本発明の第１８の方法は患者の超音波治療についてであり、ステップ（ａ）からステップ（ｆ）を含む。この第１８の方法は、第１７の方法と同様に図２６のブロック図を用いる。ステップ（ａ）は、超音波イメージング／治療トランスデューサ組立体を有するエンドエフェクタを用意することを含む。ステップ（ｂ）は、患者の所望の集束ゾーンに超音波エネルギーを集束させるためにトランスデューサ組立体の照準を合わせることを含む。ステップ（ｃ）は、照準を合わせたトランスデューサ組立体を作動させて、実質的に患者組織に医学的影響を与えることなく、患者組織の温度上昇を達成するのに十分な超音波エネルギーを放出することを含む。ステップ（ｄ）は、ステップ（ｃ）の後にトランスデューサ組立体を用いて、反射された超音波エネルギーから温度が上昇した患者組織の実際の集束ゾーンを検出することを含む。ステップ（ｅ）は、所望の集束ゾーンと実際の集束ゾーンとの間のあらゆるエラーを修正することを含む。ステップ（ｆ）は、ステップ（ｅ）の後に、トランスデューサ組立体を用いて超音波で患者組織を治療することを含む。一例では、エンドエフェクタは体外エンドエフェクタである。別の例では、エンドエフェクタは体内エンドエフェクタである。更なる例では、エンドエフェクタは体外モード及び体内モードの両方で用いることができる。

【００９５】

本発明の第１９の方法は患者の超音波治療についてであり、ステップ（ａ）からステップ（ｉ）を含む。この第１９の方法は、第１７の方法と同様に図２６のブロック図を用いるが、第１７の方法のブロック２６２のステップ（ａ）とブロック２６４のステップ（ｂ）との間に追加ステップが追加されているという点が異なる。第１９の方法では、ステップ（ａ）は、超音波イメージング／治療トランスデューサ組立体を有するエンドエフェクタを用意することを含む。ステップ（ｂ）は、患者の体内にエンドエフェクタを挿入することを含む。ステップ（ｃ）は、患者の体内のエンドエフェクタを案内することを含む。ステップ（ｄ）は、少なくとも部分的にトランスデューサ組立体を用いた超音波イメージングから、患者組織の所望の集束ゾーンを特定することを含む。ステップ（ｅ）は、患者組織の所望の集束ゾーンに超音波エネルギーを集束するためにトランスデューサ組立体の照準を合わせることを含む。ステップ（ｆ）は、照準を合わせたトランスデューサ組立体を作動させて、実質的に患者組織に医学的影響を与えることなく、患者組織の温度上昇を達成するのに十分な超音波エネルギーを放出することを含む。ステップ（ｇ）は、ステップ（ｆ）の後に、トランスデューサ組立体を用いて、反射された超音波エネルギーから温度が上昇した患者組織の実際の集束ゾーンを検出することを含む。ステップ（ｈ）は、所望の集束ゾーンと実際の集束ゾーンとの間のあらゆるエラーを修正することを含む。ステップ（ｉ）は、ステップ（ｈ）の後に、トランスデューサ組立体を用いて超音波で患者組織を治療することを含む。

【００９６】

第１７の方法から第１９の方法の一例では、エンドエフェクタは体外エンドエフェクタである。別の例では、エンドエフェクタは、腹腔鏡エンドエフェクタである。更なる例では、エンドエフェクタは、カテーテルエンドエフェクタ（限定するものではないが血管内カテーテルエンドエフェクタなど）である。更なる例では、エンドエフェクタは針エンドエフェクタである。

【００９７】

上昇した温度は時間と共に低下するため、検出した温度上昇は達成した温度上昇と正確に

は等しくないであろう。第１７の方法から第１９の方法のある実施態様では、検出ステップで検出された温度上昇は、動作ステップで達成された温度上昇に実質的に等しい。第１７の方法から第１９の方法の一適用例では、検出された温度上昇は約５℃以下である。一変形形態では、検出された温度上昇は約２℃以下である。

【００９８】

当業者に知られているように従来の方法が超音波イメージデータを温度イメージに変換することに留意されたい。第１７の方法から第１９の方法の一変形形態では、修正するステップが、当業者なら理解できるように、照準を合わせるステップでトランスデューサ組立体の照準合わせに用いられる同じ機構に対するフィードバック制御により自動的に行われる。上記したように、超音波治療トランスデューサ組立体の照準合わせ用の機構には、当業者に周知の従来の電子技術及び／または機械技術が含まれる。

【００９９】

治療の前に所望の集束ゾーンと実際の集束ゾーンとの間のあらゆるエラーを修正する利点には、患者組織のより正確な超音波治療ができることが含まれる。一例では、よりよいターゲッティングにより病変（及びあらゆる好適な縁）のアブレーションを最大にすることができると共に、病変の外側（及びあらゆる好適な縁の外側）の患者組織の治療を最小にすることができる。

【０１００】

患者組織の超音波イメージング

治療している患者の超音波フィードバック

本発明の第２０の方法は患者組織の超音波イメージングについてであり、図２７のブロック図に示されている。第２０の方法はステップ（ａ）からステップ（ｃ）を含む。ステップ（ａ）は、図２７のブロック２７２に「第１の時間にある位置から第１の信号を得る」と示されている。ステップ（ａ）は、第１の時間に患者組織のある位置から反射された第１のイメージング超音波の第１の信号を得ることを含む。ステップ（ｂ）は、図２７のブロック２７４に「後の第２の時間にその位置から第２の信号を得る」と示されている。ステップ（ｂ）は、第２の時間までの間に患者が少なくともある治療を受けた、後の第２の時間に患者組織のその位置から反射された第２のイメージング超音波の第２の信号を得ることを含む。ステップ（ｃ）は、図２７のブロック２７６に「２つの信号を用いてその位置のイメージを生成する」と示されている。ステップ（ｃ）は、第１の信号及び第２の信号を用いてその位置のイメージを生成することを含む。用語「イメージを生成する」は、限定するものではないが、例えばモニター上で表示される視覚形態のイメージを生成すること、モニター上に視覚形態で表示されるのではなく、例えばコンピュータによって用いられる電子形態でイメージを生成することが含まれる。本発明の第２０の方法の可能な一形態では、位置のイメージはモニター上のピクセル位置に表示される。

【０１０１】

本発明の第２０の方法の一例では、ステップ（ｃ）は、少なくとも第１の信号の振幅及び第２の信号の振幅を用いて位置のイメージを生成することを含む。一変形形態では、ステップ（ｃ）は、第１の信号と第２の信号の振幅の差を算出することを含む。一変更態様では、ステップ（ｃ）で、算出した振幅の差と、第１の信号及び第２の信号の一方の信号の振幅の１つを用いる。一実施態様では、ステップ（ｃ）で、その１つの振幅と算出した振幅の差の関数（function）の合計を算出する。６の第１の信号の振幅及び７の第２の信号の振幅の一例では、ステップ（ｃ）で、振幅の差を算出し、その差を第２の信号に加えて８の処理した振幅を生成し、処理した振幅を用いてその位置のイメージを生成する。治療後のその位置のイメージの生成において、第１の信号及び第２の信号の振幅を用いてあらゆる振幅の差を強調する別のアルゴリズムは当業者には明らかである。

【０１０２】

本発明の第２０の方法の別の例では、ステップ（ｃ）は、少なくとも第１の信号の位相及び第２の信号の位相を用いて位置のイメージを生成することを含む。一変形形態では、ステップ（ｃ）で、第１の信号と第２の信号の位相差を算出する。一変更形態では、ステッ

プ（ｃ）で、算出した位相差と、第１の信号及び第２の信号の一方の信号の位相の１つを用いる。ある実施態様では、ステップ（ｃ）で、その１つの位相と算出した位相差の関数の合計を算出する。６度の第１の信号の位相及び７度の第２の信号の位相の一例では、ステップ（ｃ）で、位相差を算出して、その位相差を第２の信号の位相に加えて、８度の処理した位相を生成し、その処理した位相を用いて位置のイメージを生成する。治療後のイメージの生成において、第１の信号及び第２の信号の位相を用いてあらゆる位相差を強調する他のアルゴリズムは当業者には明らかである。

【０１０３】

本発明の第２０の方法の更なる例では、ステップ（ｃ）は、少なくとも第１の信号の振幅及び位相並びに第２の信号の振幅及び位相を用いて位置のイメージを生成することを含む。一変形形態では、ステップ（ｃ）で、前記した２つのパラグラフの説明を組み合わせるが、これは当業者の知識の範囲内である。

【０１０４】

第２０の方法の一適用例及びその例などでは、ステップ（ａ）の第１の信号は、第１の周波数（例えば、シグマを有する第１の中心周波数）を有しており、ステップ（ｂ）の第２の信号は、第１の周波数とは異なる（すなわち、例えば、中心周波数が異なる）第２の周波数（例えば、シグマを有する第２の中心周波数）を有する。同じまたは別の適用例では、治療は超音波治療である。同じまたは別の適用例では、ステップ（ａ）からステップ（ｃ）を別の位置で繰り返して、別の位置の患者組織のイメージをとる。この患者組織のイメージには、治療された位置及び治療されていない位置が含まれる。本発明の第２０の方法の可能な一形態では、患者組織のイメージをモニター上に表示する。別の可能な形態では、モニター上に表示するのではなくイメージマップとしてコンピュータにイメージが保持される。第２０の方法の一派生形態では、ステップ（ａ）とステップ（ｂ）との間で更なる信号が得られ、この信号もステップ（ｃ）の位置のイメージの生成に用いられる。

【０１０５】

出願者たちは初めに、超音波イメージング信号の振幅及び／または位相に影響を与える超音波治療などの治療による患者組織の変化を利用して、治療した患者組織と周囲の治療していない組織の超音波イメージの差を強調することができることに気づいた。出願者たちは、２つの信号に対して異なる周波数を用いることにより、治療した組織と治療していない組織の振幅及び／または位相の差を強調することができ、治療した患者組織と周囲の治療していない患者組織との超音波イメージの差を強調することができるという理論をたてた。第２０の方法及びその例などの利点には、一適用例では、治療した患者組織と治療していない患者組織の超音波イメージのよりよいコントラストにより、患者治療中によりよい監視ができることが含まれる。

【０１０６】

第２０の方法に適用できる他の治療には、限定するものではないが、高周波、レーザー、及びマイクロ波による治療などの他の熱アブレーション技術、並びにエタノールや化学療法薬（抗がん剤を含む）などの化学アブレーション技術が含まれる。第２０の方法における他の任意選択のステップには、当業者に周知の信号平滑化技術を用いることが含まれる。

【０１０７】

前記した任意の１または複数の実施形態、実施形態の表現、例、及び方法などを、前記した任意の１または複数の他の実施形態、実施形態の表現、例、及び方法などと組み合わせることができることを理解されたい。例えば、限定するものではないが、いずれの本エンドエフェクタもいずれの本方法に用いることができ、いずれの本トランスデューサの構成もいずれの本エンドエフェクタに用いることができ、いずれの好適な本方法も第１７及び第２０の方法などと組み合わせできる。

【０１０８】

本発明の方法及び実施形態の幾つかの表現の前記した説明は単に例示目的である。本発明は、非限定的すなわち前記した厳密な形態及び方法に限定されるものではなく、上記した

開示から様々な変更形態及び変形形態が明らかであることを理解されたい。例えば、当業者には明らかなように、本発明の明らかな変更形態がロボットシステムに適合することから、ここに記載した超音波システム及び方法の開示をロボット支援外科手術に等しく適用できる。本発明の範囲は添付の特許請求の範囲によって規定されるものとする。

【図面の簡単な説明】

【０１０９】

【図１】組織保持装置を含む超音波治療システムを示す本発明の第１の実施形態の斜視図である。

【図２】図１の超音波治療システムのエンドエフェクタの拡大図である。

【図３】患者の椎間板を保持する図２のエンドエフェクタの立面図である。

【図４】図１の超音波治療システムに用いることができる第１の代替エンドエフェクタの斜視図である。

【図５】図１の超音波治療システムに用いることができる第２の代替エンドエフェクタの斜視図である。

【図６】図１の超音波治療システムに用いることができる第３の代替エンドエフェクタの斜視図である。

【図７】組織保持装置を含む別の超音波治療システムを示す本発明の第２の実施形態の側面図である。

【図８】図７の超音波治療システムのエンドエフェクタの拡大部分破断図である。

【図９】それぞれが超音波トランスデューサを含む可撓性フィンガーを備えた超音波治療システムを示す本発明の第３の実施形態の斜視図である。

【図１０】展開されたファン状の可撓性フィンガーを示す図９の超音波治療システムの可撓性フィンガー及びチューブの拡大図である。

【図１１】収納された状態を示す図１０の可撓性フィンガーの斜視図である。

【図１２】患者組織を覆うように展開されてクロー状（claw-like）の状態の可撓性フィンガーを示す、図９の超音波治療システムに用いることができる代替の可撓性フィンガー構造の斜視図である。

【図１３】少なくとも２つの超音波トランスデューサを備えた超音波トランスデューサ組立体を含む超音波治療システムを示す本発明の第４の実施形態の斜視図である。

【図１４】図１３の超音波治療システムの超音波トランスデューサ組立体の拡大図である。

【図１５】図１４のトランスデューサ組立体の断面図である。

【図１６】図１５の構造の代わりに用いることができる第１の代替トランスデューサ構造の断面図である。

【図１７】図１５の構造の代わりに用いることができる第２の代替トランスデューサ構造の断面図である。

【図１８】切除器具及び超音波治療トランスデューサ組立体を含む超音波治療システムを示す本発明の第５の実施形態の斜視図である。

【図１９】チューブの内腔内に導入された切除器具を示す、図１８のチューブの拡大断面図である。

【図２０】チューブの内腔内に導入された超音波治療トランスデューサ組立体を示す、図１８のチューブの拡大断面図である。

【図２１】胃腸領域の患者組織の治療のために超音波を実施することを含む本発明の第８の方法のブロック図である。

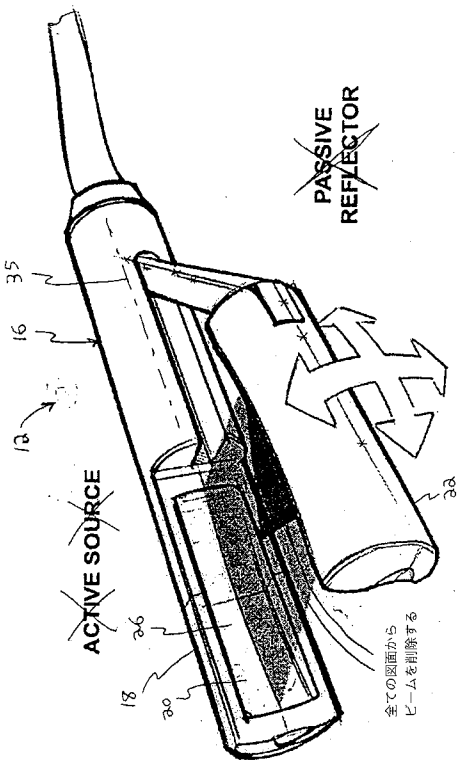
【図２２】患者の肺上または肺内部の超音波治療を含む本発明の第１１の方法のブロック図である。

【図２３】血管から病変への血液の供給を止めるために血管を超音波治療することを含む本発明の第１３の方法のブロック図である。

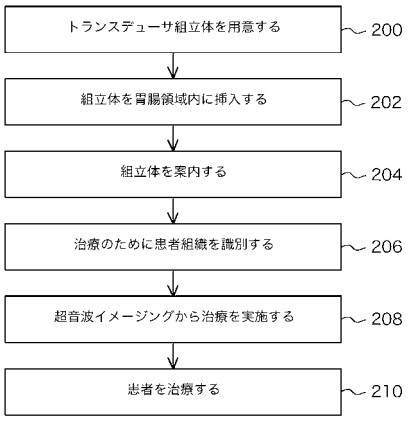
【図２４】本システムのトランスデューサ組立体の位置を求めるためのレシーバを含む超音波治療システムの一部を示す本発明の第６の実施形態の斜視図である。

【図２５】本システムのトランスポンダの位置を求めるためのレシーバを含む別の超音波治療システムの一部を示す本発明の第７の実施形態の斜視図である。
【図２６】トランスデューサ組立体の照準を合わせることを含む本発明の第１７の方法のブロック図である。
【図２７】治療前のイメージング超音波及び治療後のイメージング超音波を用いて、治療開始後のイメージを生成することを含む本発明の第２０の方法のブロック図である。

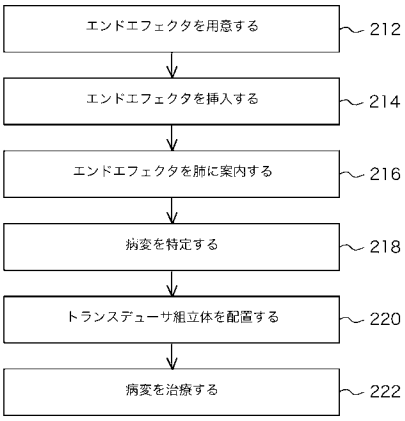
【図２】



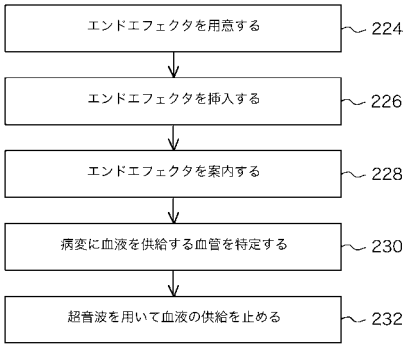
【図２１】



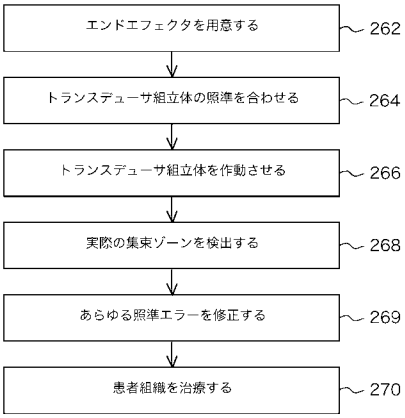
【図２２】



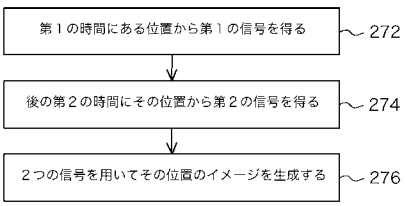
【図２３】



【図２６】



【図２７】



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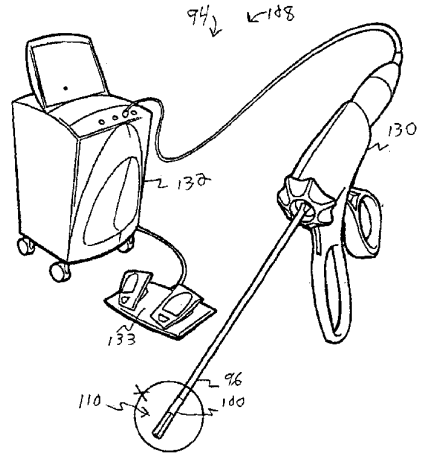
(54) Title: ULTRASOUND-BASED OCCLUSIVE PROCEDURE FOR MEDICAL TREATMENT



(57) Abstract: A method for ultrasound medical treatment of a patient. An end effector is obtained having an ultrasound medical-treatment transducer assembly. A blood vessel is identified in the patient which supplies blood to a lesion. The blood vessel is medically treated with ultrasound from the transducer assembly to substantially seal the blood vessel to substantially stop the supply of blood to the lesion from the blood vessel. In one example, the ultrasound medical-treatment transducer assembly is an ultrasound imaging and medical-treatment transducer assembly. In one variation, the end effector is inserted into the patient. In another variation, the end effector remains outside the patient.

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ULTRASOUND-BASED OCCLUSIVE PROCEDURE FOR MEDICAL TREATMENT

The present application claims priority of U.S. Provisional Application Serial No. 60/294,135 filed May 29, 2001, the entire disclosure of which is incorporated herein by reference.

Field of the Invention

The present invention relates generally to ultrasound, and more particularly to an ultrasound medical system and/or to an ultrasound medical method.

Background of the Invention

Known ultrasound medical systems and methods include using ultrasound imaging of patients to identify patient tissue for medical treatment and include using ultrasound to medically destroy identified patient tissue by heating the tissue. Imaging is done at lower power and medical treatment is done at higher power. Low power imaging ultrasound will not medically affect patient tissue. High power medical-treatment ultrasound, when focused at a focal zone a distance away from the ultrasound source, will substantially medically affect patient tissue in the focal zone. However, focused medical-treatment ultrasound will not substantially medically affect patient tissue outside the focal zone such as patient tissue located between the source and the focal zone.

In one known example, a transducer assembly includes a single ultrasound transducer having a single transducer element, or an array of transducer elements acting together, to ultrasonically image the patient and to ultrasonically ablate identified patient tissue. It is known to convert ultrasound imaging data into temperature imaging data for ultrasound-treated patient tissue to monitor the ultrasound treatment. A known transducer element includes a transducer element having a concave shape or an acoustic lens to focus ultrasound energy. A known array of transducer elements includes a planar, concave, or convex array of

transducer elements to focus ultrasound energy. A known array of transducer elements includes an array whose transducer elements are electronically or mechanically controlled together to steer and focus the ultrasound emitted by the array to a focal zone (which may be large or which may be as small as, for example, a grain of rice) to provide three-dimensional medical ultrasound treatment of patient tissue. In some applications, the transducer is placed on the surface of patient tissue for ultrasound imaging and/or ultrasound medical treatment of areas within the patient tissue. In other applications, the transducer is surrounded with a balloon which is expanded to contact the surface of patient tissue by filling with a fluid such as a saline solution to provide acoustic coupling between the transducer and the patient tissue.

Known ultrasound medical systems and methods include deploying an end effector having an ultrasound transducer outside the body to break up kidney stones inside the body, endoscopically inserting an end effector having an ultrasound transducer in the colon to medically destroy prostate cancer, laparoscopically inserting an end effector having an ultrasound transducer in the abdominal cavity to medically destroy a cancerous liver tumor, intravenously inserting a catheter end effector having an ultrasound transducer into a vein in the arm and moving the catheter to the heart to medically destroy diseased heart tissue, and interstitially inserting a needle end effector having an ultrasound transducer needle into the tongue to medically destroy tissue to reduce tongue volume to reduce snoring. Known methods for guiding an end effector within a patient include guiding the end effector from x-rays, from MRI images, and from ultrasound images obtained using the ultrasound transducer. Known ultrasound imaging includes Doppler ultrasound imaging to detect blood flow, and a proposed known use of ultrasound includes using an ultrasound transducer outside the body to stop internal bleeding (by sealing ruptured blood vessels) of a patient brought to an emergency room of a hospital.

A Mammotome® Breast Biopsy System manufactured by Ethicon Endo-Surgery, Inc. (a Johnson & Johnson Company) inserts a tube into breast tissue, wherein the tube contains an end effector having a biopsy cutting tool. A known electromagnetic transponder and three-receiver system for calculating the position of the transponder and for guiding the transponder (which is attached to a heart catheter

for monitoring the heart) inside a patient is the CARTO™ EP Navigation System used with a NAVI-STAR® catheter manufactured by Biosense Webster (a Johnson & Johnson Company). Further, it is known that changes in patient tissue because of medical treatment of patient tissue, such as ultrasound medical treatment, affect the amplitude and/or phase of ultrasound imaging signals.

What is needed is an improved ultrasound medical system and/or an improved ultrasound medical method. This invention addresses those needs lacking in an ultrasonic medical system and/or an ultrasonic medical method.

Summary of the Invention

One method of the invention is for ultrasound medical treatment of a patient and includes steps a) through c). Step a) includes obtaining an end effector having an ultrasound medical-treatment transducer assembly. Step b) includes identifying a blood vessel in the patient which supplies blood to a lesion. Step c) includes medically treating the blood vessel with ultrasound from the transducer assembly to substantially seal the blood vessel to substantially stop the supply of blood to the lesion from the blood vessel. In one example, the ultrasound medical-treatment transducer assembly is an ultrasound imaging and medical-treatment transducer assembly. In one variation, the end effector is inserted into the patient. In another variation, the end effector remains outside the patient.

The present invention has, without limitation, application in conventional endoscopic and open surgical instrumentation as well as application in robotic-assisted surgery.

Brief Description of the Drawings

Figure 1 is a perspective view of a first embodiment of the present invention showing an ultrasound medical treatment system which includes a tissue-retaining device;

Figure 2 is an enlarged view of the end effector of the ultrasound medical treatment system of Figure 1;

Figure 3 is a view of the end effector of Figure 2 retaining an intervertebral disk of a patient;

Figure 4 is a perspective view of a first alternate end effector which can be used in the ultrasound medical treatment system of Figure 1;

Figure 5 is a perspective view of a second alternate end effector which can be used in the ultrasound medical treatment system of Figure 1;

Figure 6 is a perspective view of a third alternate end effector which can be used in the ultrasound medical treatment system of Figure 1;

Figure 7 is a side elevational view of a second embodiment of the present invention showing another ultrasound medical treatment system which includes a tissue-retaining device;

Figure 8 is an enlarged, partially-cutaway view of the end effector of the ultrasound medical treatment system of Figure 7;

Figure 9 is a perspective view of a third embodiment of the present invention showing an ultrasound medical system which includes flexible fingers, wherein each finger includes an ultrasound transducer;

Figure 10 is an enlarged view of the tube and the flexible fingers of the ultrasound medical system of Figure 9 showing the flexible fingers in a deployed fan-like state;

Figure 11 is a view of the flexible fingers of Figure 10 shown in a stowed state;

Figure 12 is a perspective view of an alternate flexible finger arrangement which can be used in the ultrasound medical system of Figure 9, showing the flexible fingers in a deployed claw-like state surrounding patient tissue;

Figure 13 is a perspective view of a fourth embodiment of the present invention showing an ultrasound medical system which includes an ultrasound transducer assembly which includes at least two ultrasound transducers;

Figure 14 is an enlarged view of the ultrasound transducer assembly of the ultrasound medical system of Figure 13;

Figure 15 is a cross-sectional view of the transducer assembly of Figure 14;

Figure 16 is a cross-sectional view of a first alternate transducer arrangement which can be used in place of the arrangement of Figure 15;

Figure 17 is a cross-sectional view of a second alternate transducer arrangement which can be used in place of the arrangement of Figure 15;

Figure 18 is a perspective view of a fifth embodiment of the present invention showing an ultrasound medical treatment system which includes a cutting tool and an ultrasound medical-treatment transducer assembly;

Figure 19 is an enlarged, cross-sectional view of the tube of Figure 18 showing a cutting tool that has been introduced into the lumen of the tube;

Figure 20 is an enlarged, cross-sectional view of the tube of Figure 18 showing an ultrasound medical-treatment transducer assembly that has been introduced into the lumen of the tube;

Figure 21 is a block diagram of an eighth method of the present invention which includes ultrasound staging of medical treatment of patient tissue in the gastrointestinal area;

Figure 22 is a block diagram of an eleventh method of the present invention which includes ultrasound medical treatment of a lesion on or in the lung of a patient;

Figure 23 is a block diagram of a thirteenth method of the present invention which includes ultrasound medical treatment of a blood vessel to stop the supply of blood to a lesion from the blood vessel;

Figure 24 is a perspective view of a sixth embodiment of the present invention showing a portion of an ultrasound medical treatment system which includes receivers for locating the position of the transducer assembly of the system;

Figure 25 is a perspective view of a seventh embodiment of the present invention showing a portion of another ultrasound medical treatment system which includes receivers for locating the position of the transponder of the system;

Figure 26 is a block diagram of a seventeenth method of the present invention which includes aiming the transducer assembly; and

Figure 27 is a block diagram of a twentieth method of the present invention which includes creating an image after starting medical treatment using an imaging ultrasound wave before medical treatment and an imaging ultrasound wave after starting medical treatment.

Detailed Description of the Invention

Before explaining the present invention in detail, it should be noted that the invention is not limited in its application or use to the details of construction and arrangement of parts illustrated in the accompanying drawings and description. The illustrative embodiments of the invention may be implemented or incorporated in other embodiments, variations and modifications, and may be practiced or carried out in various ways. Furthermore, unless otherwise indicated, the terms and expressions employed herein have been chosen for the purpose of describing the illustrative embodiments of the present invention for the convenience of the reader and are not for the purpose of limiting the invention.

It is understood that any one or more of the following-described embodiments, expressions of embodiments, examples, methods, etc. can be combined with any one or more of the other following-described embodiments, expressions of embodiments, examples, methods, etc. For example, and without limitation, any of the end effectors can be used in any of the methods, any of the transducer arrangements can be used in any of the end effectors, and any appropriate methods can be combined such as combining the seventeenth and twentieth methods, etc.

Ultrasound Medical Treatment Using Tissue-Retaining Devices

Tissue-Retaining System for Ultrasound Medical Treatment

Referring now to the drawings, Figures 1-3 illustrate a first embodiment of the present invention. A first expression of the first embodiment of the present invention is for an ultrasound medical treatment system 10 including an end effector 12 insertable into a patient 14. The end effector 12 includes a tissue-retaining device 16. The tissue-retaining device 16 includes a first tissue-retaining member 18 having an (i.e., at least one) ultrasound medical-treatment transducer 20 (also called "transducer 20") and includes a second tissue-retaining member 22. The first and second tissue-retaining members 18 and 22 are operatively connected together to

retain patient tissue 24 between the first and second tissue-retaining members 18 and 22 and to release patient tissue 24 so retained.

It is noted that an ultrasound medical-treatment transducer is an ultrasound transducer adapted at least for ultrasound medical treatment of a patient such as, but not limited to, a human patient. An ultrasound medical-treatment transducer includes either a single ultrasound medical-treatment transducer element or an array of ultrasound medical-treatment transducer elements, as is known to those skilled in the art. An ultrasound medical-treatment transducer may or may not also be adapted for ultrasound imaging of a patient. Likewise, an ultrasound imaging transducer is an ultrasound transducer adapted at least for ultrasound imaging of a patient and may or may not also be adapted for ultrasound medical-treatment of a patient.

Advantages of retaining patient tissue between two tissue-retaining members during ultrasound medical treatment by one of the tissue-retaining members include having a single instrument which ultrasonically medically treats patient tissue and at the same time immobilizes patient tissue against undesired movement during the treatment. It is also noted that in one application the tissue-retaining device is a clamp which retains and holds tissue and that in another application the tissue-retaining device retains tissue against movement, but does not hold tissue, and therefore is not a clamp.

In one variation, not shown, the second tissue-retaining member 22 has an ultrasound imaging and/or medical treatment transducer. In the same or a different variation, not shown, the tissue-retaining device 16 has at least one additional tissue-retaining member. Mechanisms, not shown, for remotely moving two (or more) members toward and away from each other are within the ordinary level of skill of the artisan and include, without limitation, the use of pivotal member attachments and the use of cables or motors. In the same or a different variation, the retained patient tissue 24 is retained between the ultrasound medical-treatment transducer 20 and the second tissue-retaining member 22. In the same or a different variation, the ultrasound medical-treatment transducer 20 focuses ultrasound energy, such focusing being known to those skilled in the art. In the same or a different variation, not shown, the second tissue-retaining member 22 is substantially ultrasonically non-reflective.

A second expression of the first embodiment of the present invention is for an ultrasound medical treatment system 10 including an end effector 12 insertable into a patient 14. The end effector 12 includes a tissue-retaining device 16. The tissue-retaining device 16 includes a first tissue-retaining member 18 having an (i.e., at least one) ultrasound imaging and medical-treatment transducer 26 (also called "transducer 26") and includes a second tissue-retaining member 22. The first and second tissue-retaining members 18 and 22 are operatively connected together to retain patient tissue 24 between the first and second tissue-retaining members 18 and 22 and to release patient tissue 24 so retained.

It is noted that an ultrasound imaging and medical-treatment transducer is an ultrasound transducer adapted at least for both ultrasound imaging and ultrasound medical treatment of a patient. An ultrasound imaging and medical-treatment transducer includes either a single ultrasound imaging and medical-treatment transducer element or an array of ultrasound medical transducer elements (including an array having at least one separate element for imaging and at least one separate element for medical treatment or an array having at least two elements each adapted for both imaging and medical treatment), as is known to those skilled in the art. In one variation, the retained patient tissue 24 is retained between the imaging and medical-treatment transducer 26 and the second tissue-retaining member 22. In the same or a different variation, the ultrasound imaging and medical-treatment transducer 26 focuses ultrasound energy. In the same or a different variation, not shown, the second tissue-retaining member 22 is substantially ultrasonically non-reflective.

A third expression of the first embodiment shown in Figures 1-3 is for an ultrasound medical treatment system 10 including an end effector 12 insertable into a patient 14. The end effector 12 includes a tissue-retaining device 16. The tissue-retaining device 16 includes a first tissue-retaining member 18 having an (i.e., at least one) ultrasound medical-treatment transducer 20 and includes a second tissue-retaining member 22 having an (i.e., at least one) ultrasound reflector 28. The first and second tissue-retaining members 18 and 22 are operatively connected together to retain patient tissue 24 between the first and second tissue-retaining members 18 and 22 and to release patient tissue 24 so retained.

Advantages of retaining patient tissue between two tissue-retaining members during ultrasound medical treatment by an ultrasound medical-treatment transducer of a first tissue-retaining member and an ultrasound reflector of a second tissue-retaining member include having a single instrument which ultrasonically medically treats patient tissue by direct ultrasound, which enhances the ultrasound medical treatment by reflected ultrasound, and which at the same time immobilizes patient tissue against undesired movement during the treatment.

It is noted that an ultrasound reflector 28 is a material which reflects ultrasound at least to a degree that would substantially medically affect patient tissue over a treatment period by direct ultrasound which is being reflected back by the ultrasound reflector. Choices of ultrasound reflecting materials include, without limitation, acoustically-rigid materials such as stainless steel (which reflects about 100%) and aluminum (which reflects about 80%) and acoustically-softer materials such as corporene (which reflects about 90%). An ultrasound reflecting material is contrasted with an ultrasound absorbing material such as, without limitation, rubber or plastic. In one variation, the retained patient tissue 24 is retained between the ultrasound medical-treatment transducer 20 and the ultrasound reflector 28. In the same or a different variation, the ultrasound medical-treatment transducer 20 and the ultrasound reflector 28 each focus ultrasound energy, such ultrasound reflector focusing being accomplished by the shape of, or by shaping, the reflector surface as is within the ordinary level of skill of the artisan.

A fourth expression of the first embodiment shown in Figures 1-3 is for an ultrasound medical treatment system 10 including an end effector 12 insertable into a patient 14. The end effector 12 includes a tissue-retaining device 16. The tissue-retaining device 16 includes a first tissue-retaining member 18 having an (i.e., at least one) ultrasound imaging and medical-treatment transducer 26 and includes a second tissue-retaining member 22 having an (i.e., at least one) ultrasound reflector 28. The first and second tissue-retaining members 18 and 22 are operatively connected together to retain patient tissue 24 between the first and second tissue-retaining members 18 and 22 and to release patient tissue 24 so retained. In one variation, the retained patient tissue 24 is retained between the ultrasound imaging and medical-treatment transducer 26 and the ultrasound reflector 28. In the same or

a different variation, the ultrasound imaging and medical-treatment transducer 26 and the ultrasound reflector 28 each focus ultrasound energy.

In one example of the previously-described third and fourth expressions of the first embodiment, the ultrasound reflector 28 is disposed to receive ultrasound energy from the transducer 20 and 26 and is oriented to reflect the received ultrasound energy back into patient tissue 24 retained by the tissue-retaining device 16. In the same or a different example, the ultrasound reflector 28 is oriented to reflect the received ultrasound energy away from the transducer 20 and 26 when the patient tissue 14 is retained by the tissue-retaining device 16. An advantage of this arrangement is that it avoids damage to the transducer from the reflected ultrasound. In the same or a different example, one of the first and second tissue-retaining members 18 and 22 is controllably orientatable relative to the other of the first and second tissue-retaining members 18 and 22 such as, without limitation, by being orientatable along the double-headed arrows shown in Figure 2. In one modification, the second tissue-retaining member 22 is controllably orientatable relative to the first tissue-retaining member 18 to reflect the received ultrasound energy back along different directions. A first alternate end effector 30 is shown in Figure 4 wherein the second tissue-retaining member 32 is controllably orientatable relative to the first tissue-retaining member 34 as shown by the double-headed arrows in Figure 4. Mechanisms, not shown, for remotely controlling the orientation of one member relative to another member are within the ordinary level of skill of the artisan and include, without limitation, the use of pivotal member attachments and the use of cables or motors. In one application, the transducer 20 and 26 generates wide-focused ultrasound (shown by the two single-headed arrows coming from the first tissue-retaining member 18 in Figure 3) and the ultrasound reflector 28 generates narrow-focused ultrasound (shown by the two single-headed arrows coming from the second tissue-retaining member 22 in Figure 3).

In one example of the previously-described first through fourth expressions of the first embodiment, the end effector 12 is an open-surgery end effector, an endoscopic end effector, a laparoscopic end effector (as shown in Figure 1), a catheter end effector (such as, but not limited to, an intravascular catheter end effector), or a needle end effector, as can be appreciated by those skilled in the art.

In one application, the end effector 12 is used to retain a blood vessel and then to ultrasonically treat the blood vessel to seal the blood vessel stopping the flow of blood in the retained blood vessel. In another application, the end effector 12 is used to retain patient tissue and then to ultrasonically ablate at least a portion of the retained patient tissue.

In one design of the previously-described first through fourth expressions of the first embodiment, the end effector 12 has a longitudinal axis 35, and one of the first and second tissue-retaining members 18 and 22 at all times faces along a direction which is substantially perpendicular to the longitudinal axis 35. If the one tissue-retaining member were planar, this means that the longitudinal axis would be substantially parallel to the plane of the one tissue-retaining member. In one enablement, the one tissue-retaining member is the first tissue-retaining member 18. A second alternate end effector 36 has first and second tissue-retaining members 38 and 40 which are hinged together to relatively move as indicated by the double-headed arrow and which are shown in a partially open configuration in Figure 5. The second alternate end effector 36 has a longitudinal axis 42, and one of the first and second tissue-retaining members 38 and 40 at all times faces along a direction which is substantially parallel to the longitudinal axis 42. If the one tissue-retaining member were planar, this means that the longitudinal axis would be substantially perpendicular to the plane of the one tissue-retaining member. In one enablement, the one tissue-retaining member is the first tissue-retaining member 38. A third alternate end effector 37 having first and second tissue-retaining members 39 and 41 with one member longitudinally movable with respect to the other member (as indicated by the double-headed arrow) is shown in Figure 6. The third alternate end effector 37 has a longitudinal axis 43, and one of the first and second tissue-retaining members 39 and 41 at all times faces along a direction which is substantially parallel to the longitudinal axis 43. In one enablement, the one tissue-retaining member is the first tissue-retaining member 39.

In one enablement, as shown in Figure 1, the ultrasound medical treatment system 10 also includes a handpiece 44 operatively connected to the end effector 12 and to an ultrasound controller 46 operatively connected to a foot-pedal power switch 47, as can be appreciated by those skilled in the art.

A first method of the invention is for ultrasound medical treatment of a patient and uses the ultrasound medical treatment system as previously described in the first, second, third or fourth expression of the first embodiment with or without the previously-described variations, etc. thereof. The first method includes steps a) through e). Step a) includes endoscopically inserting the end effector into an ear, nose, or throat of the patient. Step b) includes guiding the end effector in the patient. Step c) includes identifying patient tissue for medical treatment such as optionally at least in part from ultrasound imaging using the transducer. Other ways of identifying patient tissue for medical treatment include, without limitation, using x-rays and/or MRI imaging, as are known to the artisan. Step d) includes retaining the identified patient tissue using the tissue-retaining device. Step e) includes medically treating the retained patient tissue with ultrasound using the transducer or using the transducer and the ultrasound reflector. In one implementation, one tissue-retaining member at all times faces along a direction which is substantially parallel to the longitudinal axis of the end effector (as seen in Figures 5 and 6).

A second method of the invention is for ultrasound medical treatment of a patient and uses the ultrasound medical treatment system as previously described in the first, second, third or fourth expression of the first embodiment with or without the previously-described variations, etc. thereof. The second method includes steps a) through c). Step a) includes inserting the end effector 12 into the patient. Step b) includes retaining an intervertebral disk 48 (see Figure 3) of the patient with the tissue-retaining device, wherein the intervertebral disk 48 includes tissue. Step c) includes medically treating the retained intervertebral disk 48 with ultrasound to shrink the tissue using the transducer or using the transducer and the ultrasound reflector. In one implementation, one tissue-retaining member at all times faces along a direction which is substantially perpendicular to the longitudinal axis of the end effector (as seen in Figures 2 and 4). In one application of the second method of the invention, the intervertebral disk 48 includes connective and nerve tissue.

A third method of the invention is for ultrasound medical treatment of a patient and uses the ultrasound medical treatment system as previously described in the first, second, third or fourth expression of the first embodiment with or without the previously-described variations, etc. thereof. The third method includes steps a)

through c). Step a) includes inserting the end effector into the patient. Step b) includes retaining a joint of the patient with the tissue-retaining device, wherein the joint includes tissue. Step c) includes medically treating the retained joint with ultrasound to shrink the tissue using the transducer or using the transducer and the ultrasound reflector. In one implementation, one tissue-retaining member at all times faces along a direction which is substantially perpendicular to the longitudinal axis of the end effector (as seen in Figures 2 and 4). In one application of the third method of the invention, the joint includes connective and nerve tissue.

As previously mentioned, one application of the ultrasound medical treatment system 10 of the previously-described first through fourth expressions of the first embodiment uses the tissue-retaining device to retain a blood vessel and uses the transducer, or the transducer and the ultrasound reflector, to substantially stop the flow of blood within the blood vessel.

Referring again to the drawings, Figures 7-8 illustrate a second embodiment of the present invention which is an ultrasound medical treatment system 50 including an end effector 52 insertable into a patient. The end effector 52 includes a tissue-retaining device 54. The tissue-retaining device 54 includes a first tissue-retaining member 56 having an ultrasound imaging and medical-treatment transducer 58 and includes a second tissue-retaining member 60 having an ultrasound reflector 62. The first and second tissue-retaining members 56 and 60 are operatively connected together to retain patient tissue between the first and second tissue-restraining members and to release patient tissue so retained. The first and second tissue-retaining members 56 and 60 always maintain a substantially parallel alignment.

Advantages of having a substantially parallel alignment between the tissue-retaining members include, in one example, having the transducer and the ultrasound reflector maintain a substantially parallel alignment for improved reflected ultrasound medical treatment enhancement for any thickness of patient tissue retained by the tissue-retaining members.

In one example of the second embodiment, the first tissue-retaining member 56 is a distal end portion 64 of a first tube 66. The ultrasound medical treatment system 50 also includes a second tube 68, first and second link members 70 and 72,

and a cable 74. The second tube 68 is oriented substantially parallel to the first tube 66. The first and second link members 70 and 72 are pivotally attached to the second tissue-retaining member 60 and to the second tube 68 at pivot points 76-82 creating a hinged parallelogram defined by a proximal portion 84 of the second tissue-retaining member 60, a distal portion 86 of the second tube 68, and the first and second link members 70 and 72. The ultrasound reflector 62 is disposed at a distal portion 88 of the second tissue-retaining member 60 and faces the transducer 58. The cable 74 is operatively connected to the hinged parallelogram to move the second tissue-retaining member 60 toward and away from the first tissue-retaining member 56.

In one variation, the ultrasound medical treatment system 50 also includes an outer tube 90. The cable 74 and the first and second tubes 66 and 68 are disposed in the outer tube 90. In one modification, the ultrasound medical treatment system 50 also includes a handpiece 92. The cable 74 and the first, second, and outer tubes 66, 68 and 90 are operatively connected to the handpiece 92. In one design, the orientation of the first tube 66 about the longitudinal axis of the first tube 66 is controlled by a step motor (not shown) disposed in, and actuated by, the handpiece 92. In the same or another design, the first tube 66 is a hollow tube allowing for transducer wiring (not shown), and the second tube is a solid tube (not shown). Depending on use, the tubes 66, 68, and 90 may be rigid or flexible which also is true for any tube arrangement (specifically disclosed as rigid or flexible, or not so specifically disclosed) of any end effector and for any end effector itself of any of the previous or following embodiments of the invention.

Ultrasound Medical Treatment Using Specific Transducer Arrangements

Deployable Ultrasound Medical Transducers

Referring to the drawings, Figures 9-11 illustrate a third embodiment of the present invention. A first expression of the third embodiment of the present invention is for an ultrasound medical system 94 including a tube 96 and a plurality of resiliently flexible fingers 98. The tube 96 has a distal end 100 insertable into a patient and has a lumen 102 with a distal opening 104. The fingers 98 are

extendable out of the distal opening 104 of the lumen 102 creating a deployed state (seen in Figure 10) and which are at-least-partially retractable into the distal opening 104 of the lumen 102 creating a stowed state (seen in Figure 11). Each finger 98 includes an ultrasound transducer 106. The distance between the ultrasound transducers 106 of adjacent fingers 98 is greater in the deployed state than in the stowed state. It is noted that an ultrasound medical system is a medical system which at least provides ultrasound imaging or ultrasound medical treatment of a patient.

Advantages of the tube and extendable/retractable flexible-finger array arrangement include, when the transducers are ultrasound medical-treatment transducers having a common focal zone in the deployed state, providing faster medical treatment times by allowing for more transducer ultrasound-emitting surface area which can be simply stowed into a compact shape for transport within a patient to and from the site of patient tissue receiving ultrasound medical treatment.

In one variation, the fingers 98 are only partially retracted into the distal opening 104 of the lumen 102 in the stowed state (as seen in Figure 11). In another variation, not shown, the fingers 98 are completely retracted into the distal opening 104 of the lumen 102 in the stowed state. By the fingers 98 being extendable out of the distal opening 104 of the lumen 102 creating the deployed state and being at-least-partially retractable into the distal opening 104 of the lumen 102 creating the stowed state means the fingers 98 protrude more out of the distal opening 104 of the lumen 102 in the extended state than (if at all) in the stowed state. Mechanisms, not shown, for remotely extending and retracting fingers in a tube include, without limitation, a common shaft attached to the proximal ends of the fingers, disposed in the lumen of the tube, and spring-biased to move forward upon squeezing of a handpiece and to return backward upon relaxing of the handpiece, as is within the ordinary level of skill of the artisan. In one modification, the distal opening 104 of the lumen 102 coincides with the distal end 100 of the tube 96. In another modification, not shown, the distal opening of the lumen is spaced apart from the distal end of the tube. In one implementation, the distal opening 104 of the lumen 102 faces in the same direction as the distal end 100 of the tube 96. Other implementations are left to the artisan, such as, without limitation, the distal opening

of the lumen facing perpendicular to the distal end of the tube. In one example, at least one of the transducers 106 is an ultrasound imaging transducer. In the same or a different example, at least one of the transducers 106 is an ultrasound medical-treatment transducer. In the same or a different example, at least one of the transducers 106 is an ultrasound imaging and medical-treatment transducer.

A second expression of the third embodiment is for an ultrasound medical treatment system 108 including a tube 96 and including an end effector 110 having a plurality of fingers 98. The tube 96 has a distal end 100 insertable into a patient and has a lumen 102 with a distal opening 104. The fingers 98 are extendable out of the distal opening 104 of the lumen 102 creating a deployed state (seen in Figure 10) and are at-least-partially retractable into the distal opening 104 of the lumen 102 creating a stowed state (seen in Figure 11). Each finger 98 includes an ultrasound medical-treatment transducer 112. The distance between the ultrasound medical-treatment transducers 112 of adjacent fingers 98 is greater in the deployed state than in the stowed state.

A third expression of the third embodiment is for an ultrasound medical treatment system 108 including a tube 96 and including an end effector 110 having a plurality of fingers 98. The tube 96 has a distal end 100 insertable into a patient and has a lumen 102 with a distal opening 104. The fingers 98 are extendable out of the distal opening 104 of the lumen 102 creating a deployed state (seen in Figure 10) and are at-least-partially retractable into the distal opening 104 of the lumen 102 creating a stowed state (seen in Figure 11). Each finger 98 includes an ultrasound imaging and medical-treatment transducer 114. The distance between the ultrasound imaging and medical-treatment transducers 114 of adjacent fingers 98 is greater in the deployed state than in the stowed state.

It is noted that the variations, modifications, and implementations, etc. previously discussed for the first expression of the third embodiment are equally applicable to the second and third expressions of the third embodiment.

In one example of the first, second and third expressions of the third embodiment, the transducers 106, 112 and 114 each have an ultrasound-emitting concave surface 116. In another example, not shown, the transducers have a planar ultrasound-emitting surface. In one arrangement, each concave surface 116 is

concave as one moves along the corresponding finger 98 (as best seen in Figure 10). In another arrangement, not shown, each concave surface is concave as one moves across the corresponding finger or is concave as one moves both along and across the corresponding finger (such as, for example, with a hemispherically-concave surface). In one design, the concave surfaces 116 together have a substantially common focal zone when the fingers 98 are in the deployed state. The end effector 110 is seen with its fingers 98 facing the patient tissue 119 in Figure 10. In another design, not shown, the focal zones are not common. In one configuration, the fingers 98 define an open-hand finger array 118 in the deployed state. An alternate flexible finger arrangement in the form of a substitute end effector 120 is shown in Figure 12, wherein the fingers 122 define a clawed-hand finger array 124 in the deployed state. The substitute end effector 120 is seen with its fingers 122 surrounding the patient tissue 126 for imaging and/or medical treatment by the ultrasound transducers 128 in Figure 12. In other transducer arrangements, not shown, one or more or all of the ultrasound transducers face outward rather than facing inward.

In the same or another example of the first, second and third expressions of the third embodiment, the fingers 98 are at least four in number. In the same or yet another example of the second and third expressions of the third embodiment, the end effector 110 (as well as the substitute end effector 120) is an open-surgery end effector, an endoscopic end effector, a laparoscopic end effector (as shown in Figure 9), a catheter end effector (such as, but not limited to, an intravascular catheter end effector), or a needle end effector, as can be appreciated by those skilled in the art.

In one enablement, as shown in Figure 9, the ultrasound medical treatment system 108 also includes a handpiece 130 operatively connected to the end effector 110 and to an ultrasound controller 132 operatively connected to a foot-pedal power switch 133, as can be appreciated by those skilled in the art.

Faceted Ultrasound Medical Transducer Assembly

A fourth embodiment of the present invention is shown in Figures 13-15. A first expression of the fourth embodiment of the present invention is for an ultrasound medical system 134 including an ultrasound transducer assembly 136

insertable into a patient. The ultrasound transducer assembly 136 has a longitudinal axis 138. The ultrasound transducer assembly 136 includes a plurality P of ultrasound transducers 140. Each transducer 140 has an ultrasound-emitting surface 142 oriented at an angle of substantially 360/P degrees apart from the ultrasound-emitting surface 142 of an adjacent transducer 140 when viewed in a cross section (see Figure 15) of the transducer assembly 136 taken by a cutting plane which is perpendicular to the longitudinal axis 138.

Advantages of such a transducer configuration include, in one example, providing directed or focused medical-treatment ultrasound which is not possible with a cylindrical ultrasound transducer, as can be appreciated by those skilled in the art.

It is noted that an ultrasound transducer assembly 136 insertable into a patient is an ultrasound imaging transducer assembly, an ultrasound medical-treatment transducer assembly, or an ultrasound imaging and medical-treatment transducer assembly. An ultrasound imaging transducer assembly has at least one ultrasound imaging transducer, and an ultrasound medical-treatment transducer assembly has at least one ultrasound medical-treatment transducer. An ultrasound imaging and medical-treatment transducer assembly has at least one ultrasound imaging transducer and at least one ultrasound medical-treatment transducer or has at least one ultrasound imaging and medical-treatment transducer.

A second expression of the fourth embodiment of the present invention is for an ultrasound medical-treatment system 144 including an end effector 146 insertable into a patient. The end effector 146 includes an ultrasound medical-treatment transducer assembly 148. The ultrasound medical-treatment transducer assembly 148 has a longitudinal axis 138. The ultrasound medical-treatment transducer assembly 148 includes a plurality P of ultrasound medical-treatment transducers 150. Each transducer 150 has an ultrasound-emitting surface 142 which faces away from the longitudinal axis 138 and which is oriented at an angle of substantially 360/P degrees apart from the ultrasound-emitting surface 142 of an adjacent transducer 150 when viewed in a cross section (see Figure 15) of the transducer assembly 148 taken by a cutting plane which is perpendicular to the longitudinal

axis 138. In one example, at least one of the ultrasound medical-treatment transducers 150 is also adapted for ultrasound imaging.

A fourth method of the present invention is for ultrasound medical treatment of a patient and uses the ultrasound medical treatment system 144 as previously described in the second expression of the fourth embodiment. The fourth method includes steps a) through b). Step a) includes inserting the end effector 146 into the liver of the patient. Step b) includes medically treating a lesion in the liver with ultrasound from the ultrasound medical-treatment transducer assembly 148. In one example, step a) interstially inserts the end effector 146 into the lesion. In another example, step a) endoscopically inserts the end effector 146 into the liver through the hepato-biliary duct system.

A third expression of the fourth embodiment of the present invention is for an ultrasound medical treatment system 144 including an end effector 146 insertable into a patient. The end effector 146 includes an ultrasound imaging and medical-treatment transducer assembly 152. The ultrasound imaging and medical-treatment transducer assembly 152 has a longitudinal axis 138. The ultrasound imaging and medical-treatment transducer assembly 152 includes a plurality P of ultrasound imaging and medical-treatment transducers 154. Each transducer 154 has an ultrasound-emitting surface 142 which faces away from the longitudinal axis 138 and which is oriented at an angle of substantially 360/P degrees apart from the ultrasound-emitting surface 142 of an adjacent transducer 154 when viewed in a cross section (see Figure 15) of the transducer assembly 152 taken by a cutting plane which is perpendicular to the longitudinal axis 138.

A fifth method of the present invention is for ultrasound medical treatment of a patient and uses the ultrasound medical-treatment system 144 as previously described in the third expression of the fourth embodiment. The fourth method includes steps a) through c). Step a) includes inserting the end effector 146 into the liver of the patient. Step b) includes identifying a lesion in the liver for medical treatment at least in part from ultrasound imaging using the ultrasound imaging and medical-treatment transducer assembly 152. Step c) includes medically treating the lesion with ultrasound from the ultrasound imaging and medical-treatment transducer assembly 152. In one example, step a) interstially inserts the end effector

146 into the lesion. In another example, step a) endoscopically inserts the end effector 146 into the liver through the hepato-biliary duct system.

In one example of the previously-described first, second and third expressions of the fourth embodiment, the transducer assembly 136, 148, and 152 has a distal tip 156 and has a tip transducer 158. In one design, the tip transducer is a forward facing tip transducer. In another design, the tip transducer is a sideways facing tip transducer. In one variation, the tip transducer is an ultrasound imaging tip transducer. In another variation, the tip transducer is an ultrasound medical-treatment tip transducer. In a further variation, the tip transducer is an ultrasound imaging and medical-treatment tip transducer. In an additional variation, the tip transducer is a transponder which emits electromagnetic waves or mechanical waves or both.

In the same or a different example of the previously-described first, second and third expressions of the third embodiment, each ultrasound-emitting surface 142 is substantially straight when viewed in the cross section, as seen in Figure 15. In one variation, as seen in Figure 14, each ultrasound-emitting surface 142 has a substantially concave shape as one moves along the ultrasound-emitting surface 142 in a direction parallel to the longitudinal axis 138, and each ultrasound-emitting surface 142 has a focal zone. In a first alternate transducer arrangement seen Figure 16, each ultrasound-emitting surface 162 has a substantially planar shape. In a second alternate transducer arrangement seen in Figure 17, each ultrasound-emitting surface 164 has a substantially concave shape when viewed in the cross section, and each ultrasound-emitting surface 164 has a focal zone. In one modification, each ultrasound-emitting surface 164 also has a substantially concave shape as one moves along the ultrasound-emitting surface 164 in a direction parallel to the longitudinal axis (such as, for example, by the ultrasound-emitting surface 164 having a hemispherically-concave shape). Such ultrasound-emitting surface shapes are equally applicable to any ultrasound transducer mentioned in any other embodiment of the invention.

In the same or a different example of the previously-described first, second and third expressions of the third embodiment, P is no greater than four. In one

variation, P equals three as seen in Figures 15 and 17. In another variation, P equals two as seen in Figure 16.

In the same or a different example of the previously-described second and third expressions of the third embodiment, the end effector 146 is an open-surgery end effector, an endoscopic end effector, a laparoscopic end effector (as shown in Figure 13), a catheter end effector (such as, but not limited to, an intravascular catheter end effector), or a needle end effector, as can be appreciated by those skilled in the art. In one enablement, as shown in Figure 13, the ultrasound medical treatment system 144 also includes a handpiece 166 operatively connected to the end effector 146 and to an ultrasound controller 168 operatively connected to a foot-pedal power switch 169, as can be appreciated by the artisan.

Ultrasound Medical Treatment Applications

Excisional And Ultrasound Medical treatment System

A fifth embodiment of the present invention is shown in Figures 18-20. In a first expression of the fifth embodiment of the present invention, an ultrasound medical treatment system 170 includes a tube 172, a first end effector 174, and a second end effector 176. The tube 172 has a distal end 178 insertable into a patient 180 and has a lumen 182. The first end effector 174 has a cutting tool 184, is introducible into the lumen 182 of the inserted tube 172 from outside the patient 180, and is translatable through the lumen 182 of the inserted tube 172 to inside the patient 180. The second end effector 176 has an ultrasound medical-treatment transducer assembly 186, is introducible into the lumen 182 of the inserted tube 172 from outside the patient 180, and is translatable through the lumen 182 of the inserted tube 172 to inside the patient 180. In one variation, the first and second end effectors are introduced into the lumen through separate openings in the lumen or through separate branch channels leading to the lumen. In another variation, the first and second end effectors are introduced into the lumen through the same opening in the lumen. In one modification, a lumen opening is disposed at the end of the tube. In another modification, a lumen opening is spaced apart from the end of the tube.

A second expression of the fifth embodiment of the present invention is for an ultrasound medical treatment system 170 including a tube 172, a first end effector 174, and a second end effector 176. The tube has a distal end 178 insertable into a patient 180 and has a lumen 182 with a distal opening 188 and a proximal opening 190. The first end effector 174 has a cutting tool 184, is introducible into the proximal opening 190, and is translatable through the lumen 182 to the distal opening 188. The second end effector 176 has an ultrasound medical-treatment transducer assembly 186, is introducible into the proximal opening 190, and is translatable through the lumen 182 to the distal opening 188.

In one example of the first and second expressions of the fifth embodiment of the present invention, the lumen 182 is sized to allow introduction of only one of the first and second end effectors 174 and 176 at a time. In the same or another example, the distal end 178 of the tube 172 is interstitially insertable into patient tissue 192 of the patient 180. In the same or a different example, the cutting tool 184 is a biopsy cutting tool 194 or other excisional cutting tool.

A third expression of the fifth embodiment of the present invention is for an ultrasound medical treatment system 170 including a tube 172, a first end effector 174, and a second end effector 176. The tube 172 has a distal end 178 interstitially insertable into breast tissue 196 of a patient 180 and has a lumen 182 with a distal opening 188 and a proximal opening 190. The first end effector 174 has a biopsy cutting tool 194 (or other excisional cutting tool), is introducible into the proximal opening 190, and is translatable through the lumen 182 to the distal opening 188. The second end effector 176 has an ultrasound medical-treatment transducer assembly 186, is introducible into the proximal opening 190, and is translatable through the lumen 182 to the distal opening 188. The lumen 182 is sized to allow introduction of only one of the first and second end effectors 174 and 176 at a time. In one design, the first end effector also includes a suction mechanism to draw in patient tissue to be biopsied by the biopsy cutting tool 194. In one application, the tube 172 and the first end effector 174 (with the biopsy cutting tool 194 including a suction mechanism) are based on components of a Mammotome® Breast Biopsy System manufactured by Ethicon Endo-Surgery, Inc. (a Johnson & Johnson Company).

A sixth method of the invention is for ultrasound medical treatment of a patient 180 and uses the ultrasound medical treatment system 170 as previously described in the third expression of the fifth embodiment of the present invention. The sixth method includes steps a) through h). Step a) includes identifying possibly cancerous breast tissue 196 of the patient. Step b) includes interstitially inserting the distal end 178 of the tube 172 into the patient 180 with the distal opening 188 disposed proximate the breast tissue 196 and with the proximal opening 190 disposed outside the patient. Step c) includes introducing the first end effector 174 into the proximal opening 190 and translating the first end effector 174 through the lumen 182 to the distal opening 188. Step d) includes obtaining a biopsy sample of the breast tissue 196 with the biopsy cutting tool 194. Step e) includes removing the first end effector 174 from the lumen 182, Step f) includes introducing the second end effector 176 into the proximal opening 190 and translating the second end effector 176 through the lumen 182 to the distal opening 188. Step g) includes identifying an area of hemorrhaging in the breast tissue where the biopsy sample was obtained. Step h) includes medically treating the identified area with ultrasound using the transducer assembly 186 to substantially stop the hemorrhaging. In one application, the sixth method of the invention also includes the steps of testing the biopsy sample for cancer and substantially ablating any remaining cancer in the breast tissue with ultrasound using the transducer assembly 186. Advantages of such an ultrasound medical treatment system and method include the ease of obtaining a breast biopsy and the control of hemorrhaging caused by the biopsy procedure coupled together in a minimally invasive manner.

In a fourth expression of the fifth embodiment of the present invention, an ultrasound medical treatment system 170 includes a tube 172, a first end effector 174, and a second end effector 176. The tube 172 has a distal end 178 insertable into a patient 180 and has a lumen 182. The first end effector 174 has a cutting tool 184, is introducible into the lumen 182 of the inserted tube 172 from outside the patient 180, and is translatable through the lumen 182 of the inserted tube 172 to inside the patient 180. The second end effector 176 has an ultrasound imaging and medical-treatment transducer assembly 198, is introducible into the lumen 182 of the inserted tube 172 from outside the patient 180, and is translatable through the lumen

182 of the inserted tube 172 to inside the patient 180. In one variation, the first and second end effectors are introduced into the lumen through separate openings in the lumen or through separate branch channels leading to the lumen. In another variation, the first and second end effectors are introduced into the lumen through the same opening in the lumen. In one modification, a lumen opening is disposed at the end of the tube. In another modification, a lumen opening is spaced apart from the end of the tube.

A fifth expression of the fifth embodiment of the present invention is for an ultrasound medical treatment system 170 including a tube 172, a first end effector 174, and a second end effector 176. The tube has a distal end 178 insertable into a patient 180 and has a lumen 182 with a distal opening 188 and a proximal opening 190. The first end effector 174 has a cutting tool 184, is introducible into the proximal opening 190, and is translatable through the lumen 182 to the distal opening 188. The second end effector 176 has an ultrasound imaging and medical-treatment transducer assembly 198, is introducible into proximal opening 190, and is translatable through the lumen 182 to the distal opening 188.

In one example of the fourth and fifth expressions of the fifth embodiment of the present invention, the lumen 182 is sized to allow introduction of only one of the first and second end effectors 174 and 176 at a time. In the same or another example, the distal end 178 of the tube 172 is interstitially insertable into patient tissue 192 of the patient 180. In the same or a different example, the cutting tool 184 is a biopsy cutting tool 194 or other excisional cutting tool.

A sixth expression of the fifth embodiment of the present invention is for an ultrasound medical treatment system 170 including a tube 172, a first end effector 174, and a second end effector 176. The tube 172 has a distal end 178 interstitially insertable into breast tissue 196 of a patient 180 and has a lumen 182 with a distal opening 188 and a proximal opening 190. The first end effector 174 has a biopsy cutting tool 194 (or other excisional cutting tool), is introducible into the proximal opening 190, and is translatable through the lumen 182 to the distal opening 188. The second end effector 176 has an ultrasound imaging and medical-treatment transducer assembly 196, is introducible into the proximal opening 190, and is translatable through the lumen 182 to the distal opening 188. The lumen 182 is

sized to allow introduction of only one of the first and second end effectors 174 and 176 at a time. In one application, the tube 172 and the first end effector 174 (with the biopsy cutting tool 194 including a suction mechanism) are based on components of a Mammotome® Breast Biopsy System manufactured by Ethicon Endo-Surgery, Inc. (a Johnson & Johnson Company).

A seventh method of the invention is for ultrasound medical treatment of a patient 180 and uses the ultrasound medical treatment system 170 as previously described in the sixth expression of the fifth embodiment of the present invention. The seventh method includes steps a) through h). Step a) includes identifying possibly cancerous breast tissue 196 of the patient. Step b) includes interstitially inserting the distal end 178 of the tube 172 into the patient 180 with the distal opening 188 disposed proximate the breast tissue 196 and with the proximal opening 190 disposed outside the patient. Step c) includes introducing the first end effector 174 into the proximal opening 190 and translating the first end effector 174 through the lumen 182 to the distal opening 188. Step d) includes obtaining a biopsy sample of the breast tissue 196 with the biopsy cutting tool 194. Step e) includes removing the first end effector 174 from the lumen 182, Step f) includes introducing the second end effector 176 into the proximal opening 190 and translating the second end effector 176 through the lumen 182 to the distal opening 188. Step g) includes identifying an area of hemorrhaging in the breast tissue where the biopsy sample was obtained from ultrasound imaging using the transducer assembly 198. Step h) includes medically treating the identified area with ultrasound using the transducer assembly 198 to substantially stop the hemorrhaging. In one application, the seventh method of the invention also includes the steps of testing the biopsy sample for cancer and substantially ablating any remaining cancer in the breast tissue with ultrasound using the transducer assembly 198. Advantages of such an ultrasound medical treatment system and method include the ease of obtaining a breast biopsy and the imaging and control of hemorrhaging caused by the biopsy procedure coupled together in a minimally invasive manner.

In one enablement, as shown in Figure 18, the ultrasound medical treatment system 170 also includes a handpiece 199 which is attached to the tube 172, which contains the first end effector 174 for extending the cutting tool 184 into, and

withdrawing it from, the lumen 182, and which is operatively connected to an ultrasound controller 201 via a first cable 203. The second end effector 176, in this enablement, is operatively connected to the ultrasound controller 201 via a second cable 205 and is inserted into the lumen 182 from outside the handpiece 199 as shown in Figure 18.

Staging Medical Treatment Using Ultrasound

An eighth method of the invention is shown in block diagram form in Figure 21 and is for medical treatment of a patient. The eighth method includes steps a) through f). Step a) is labeled "Obtain Transducer Assembly" in block 200 of Figure 21. Step a) includes obtaining an ultrasound imaging transducer assembly. Step b) is labeled "Insert Assembly Into Gastrointestinal Area" in block 202 of Figure 21. Step b) includes inserting the transducer assembly into a gastrointestinal area of the patient. Step c) is labeled "Guide Assembly" in block 204 of Figure 21. Step c) includes guiding the transducer assembly within the gastrointestinal area. Step d) is labeled "Identify Patient Tissue For Treatment" in block 206 of Figure 21. Step d) includes identifying patient tissue in the gastrointestinal area for medical treatment. Step e) is labeled "Stage Treatment From Ultrasound Imaging" in block 208 of Figure 21. Step e) includes staging the medical treatment from ultrasound imaging using the transducer assembly. Step f) is labeled as "Medically Treat Patient" in block 210 of Figure 21. Step f) includes medically treating the patient tissue according to the staging of step e). It is pointed out that in the eighth method the medical treatment need not include ultrasound medical treatment with the transducer assembly used for staging and/or need not include ultrasound medical treatment with any other ultrasound transducer assembly. In one procedure depending on the pathology size and site, a first transducer assembly is used endoscopically to stage the medical treatment in step e) and a second transducer assembly is used laparoscopically to medically treat the patient tissue with ultrasound in step f). In one variation, the first transducer assembly is used laparoscopically to stage the medical treatment in step e) and the second transducer assembly is used endoscopically to medically treat the patient tissue with ultrasound in step f). In another procedure, the medical treatment in step f) is radio-frequency, laser,

microwave, or chemical ablation medical treatment. Other types of medical treatment are left to the artisan.

It is noted that the gastrointestinal (GI) area of a human patient includes, without limitation, the esophagus and the stomach of the upper GI area and the rectum and the colon of the lower GI area. It further is noted that the liver is also considered to be in the GI area for purposes of this method.

By "staging the medical treatment from ultrasound imaging" is meant at least using ultrasound images to determine the three-dimensional size and shape of the patient tissue that is to receive medical treatment. For example, and without limitation, upper and lower GI tumors can be visualized with high frequency (6-30 MHz) ultrasound imaging using a cylindrical, side-firing, or half-convex ultrasound array or single-element transducer introduced endoscopically into the GI tract. All layers of the GI tract can be visualized including all layers of the esophagus, stomach, duodenum, colon, etc. In one procedure, a three-dimensional representation of the GI structures is created by collating a series of two-dimensional scans generated by axially advancing the ultrasound transducer. Any neoplastic growth, its morphological characteristics, as well as the tumor's size and shape can easily be determined from the three-dimensional representation.

Advantages of such medical-treatment staging from ultrasound imaging include, in one example, providing a non-invasive medical-treatment staging technique which has greater resolution and which is more practical compared to conventional extracorporeal medical-treatment staging techniques such as using x-rays or MRI imaging or compared to using conventional endoscopic optical techniques.

A ninth method of the invention is for ultrasound medical treatment of a patient and includes steps a) through f). The ninth method uses the same block diagram of Figure 21 as does the eighth method but with "end effector" replacing "transducer assembly" in block 200 and with "end effector" replacing "assembly" in blocks 202 and 204. Step a) includes obtaining an end effector having an ultrasound imaging and medical-treatment transducer assembly. Step b) includes inserting the end effector into a gastrointestinal area of the patient. Step c) includes guiding the transducer assembly within the gastrointestinal area. Step d) includes identifying

patient tissue in the gastrointestinal area for medical treatment. Step e) includes staging the medical treatment from ultrasound imaging using the transducer assembly. Step f) includes medically treating the patient tissue with ultrasound using the transducer assembly according to the staging of step e).

A tenth method of the invention is for ultrasound medical treatment of a patient and includes steps a) through f). The tenth method uses the same block diagram of Figure 21 as does the eighth method but with "end effector" replacing "transducer assembly" in block 200 and with "end effector" replacing "assembly" in blocks 202 and 204. Step a) includes obtaining an end effector having an ultrasound imaging and medical-treatment transducer assembly. Step b) includes inserting the end effector into a gastrointestinal area of the patient. Step c) includes guiding the transducer assembly within the gastrointestinal area. Step d) includes identifying patient tissue in the gastrointestinal area for medical treatment at least in part from ultrasound imaging using the transducer assembly. Step e) includes staging the medical treatment from ultrasound imaging using the transducer assembly. Step f) includes medically treating the patient tissue with ultrasound using the transducer assembly according to the staging of step e). In one procedure, large GI tumors are staged through a laparoscopic access to the GI area, whereby the tumors are identified, staged and treated using an end effector having an ultrasound imaging and medical-treatment transducer assembly.

In one example of the ninth and tenth methods of the invention, the patient tissue is gastroesophageal tissue containing a lesion, and step f) ultrasonically substantially ablates the lesion. In one modification, the gastroesophageal tissue contains a blood vessel supplying blood to the lesion, and step f) ultrasonically treats the blood vessel to substantially stop the supply of blood to the lesion from the blood vessel.

In another example of the ninth and tenth methods of the invention, the patient tissue is liver tissue containing a lesion and a blood vessel supplying blood to the lesion, and step f) ultrasonically treats the blood vessel to substantially stop the supply of blood to the lesion from the blood vessel.

In an additional example of the ninth and tenth methods of the invention, the patient tissue is liver tissue containing a lesion, and step f) ultrasonically

substantially ablates the lesion. In one modification, the liver tissue contains a blood vessel supplying blood to the lesion, and step f) also ultrasonically treats the blood vessel to substantially stop the supply of blood to the lesion from the blood vessel. In one procedure, an end effector having an ultrasound imaging and medical-treatment transducer assembly is introduced endoscopically into the GI tract, is advanced retrogradely through the ampulla of Vater up the common bile duct, and is advanced further into the hepatic duct system where liver parenchyma requiring medical treatment (such as cholangio-carcinomas) are identified, staged, and treated using the end effector.

Treatment Of Lung Lesions Using Ultrasound

An eleventh method of the invention is shown in block diagram form in Figure 22 and is for ultrasound medical treatment of a patient. The eleventh method includes steps a) through f). Step a) is labeled "Obtain End Effector" in block 212 of Figure 22. Step a) includes obtaining an end effector having an ultrasound medical-treatment transducer assembly. Step b) is labeled "Insert End Effector" in block 214 of Figure 22. Step b) includes inserting the end effector into the patient. Step c) is labeled "Guide End Effector To Lung" in block 216 of Figure 22. Step c) includes guiding the end effector within the patient to a lung of the patient. Step d) is labeled "Identify Lesion" in block 218 of Figure 22. Step d) includes identifying a lesion on or in the lung for medical treatment. Step e) is labeled "Position Transducer Assembly" in block 220 of Figure 22. Step e) includes positioning the transducer assembly on or in the lesion. Step f) is labeled "Medically Treat Lesion" in block 222 of Figure 22. Step f) includes medically treating the lesion with ultrasound using the transducer assembly.

A twelfth method of the invention is for ultrasound medical treatment of a patient and includes steps a) through f). The twelfth method uses the same block diagram of Figure 22 as does the eleventh method. Step a) includes obtaining an end effector having an ultrasound imaging and medical-treatment transducer assembly. Step b) includes inserting the end effector into the patient. Step c) includes guiding the end effector within the patient to a lung of the patient. Step d) includes identifying a lesion on or in the lung for medical treatment at least in part

from ultrasound imaging using the transducer assembly. Step e) includes positioning the transducer assembly on or in the lesion. Step f) includes medically treating the lesion with ultrasound using the transducer assembly.

In one example of the eleventh and twelfth methods, step f) ultrasonically substantially ablates the lesion. In one application, the end effector is an endoscopic end effector and step b) transbronchial-endoscopically inserts the end effector into the patient. In another application, the end effector is a needle end effector and step b) interstitially inserts the end effector into the patient. In one implementation, step e) positions the transducer assembly on the lesion. In another implementation, step e) positions the transducer assembly in the lesion. In one practice of the eleventh and twelfth methods, step c) a bronchoscope is used to guide the end effector to a lung of the patient.

Ultrasound medical treatment of the lung has conventionally been avoided because such ultrasound is prevented from reaching a lesion within the lung by the alveoli of the lung which contain air which reflect back most of the ultrasound preventing the ultrasound from effectively penetrating the lung to the lesion. Using higher power ultrasound for effective penetration of the lung to reach the lesion would injure or destroy the alveoli which are needed for breathing. Applicants theorized that positioning the ultrasound transducer on or in a lesion of the lung would allow ultrasound medical treatment of the lesion (such as a tumor or an infarct) without injury to the alveoli. It is noted that Applicants' method is applicable to surface lesions as well as non-surface lesions. Advantages of Applicants' eleventh and twelfth methods for ultrasound medical treatment include, in one example, the destruction of lung cancer lesions in cases which otherwise would be inoperable or incurable.

Ultrasound-Based Occlusive Procedure For Medical Treatment

A thirteenth method of the invention is shown in block diagram form in Figure 23 and is for ultrasound medical treatment of a patient. The thirteenth method includes steps a) through e). Step a) is labeled "Obtain End Effector" in block 224 of Figure 23. Step a) includes obtaining an end effector having an ultrasound medical-treatment transducer assembly. Step b) is labeled "Insert End

Effector" in block 226 of Figure 23. Step b) includes inserting the end effector into the patient. Step c) is labeled "Guide End Effector" in block 228 of Figure 23. Step c) includes guiding the end effector within the patient to a region of patient tissue containing a lesion. Step d) is labeled "Identify Blood Vessel Supplying Lesion" in block 230 of Figure 23. Step d) includes identifying a blood vessel in the region which supplies blood to the lesion. Step e) is labeled "Stop Blood Supply Using Ultrasound" in block 232 of Figure 23. Step e) includes medically treating the blood vessel with ultrasound from the transducer assembly to substantially seal the blood vessel to stop the supply of blood to the lesion from the blood vessel. One implementation of the thirteenth method of the invention also includes the step of medically treating the lesion with ultrasound from the transducer assembly to substantially ablate the lesion.

A fourteenth method of the invention is for ultrasound medical treatment of a patient and includes steps a) through g). The fourteenth method is similar to the thirteenth method. Step a) includes obtaining an end effector having an ultrasound imaging and medical-treatment transducer assembly. Step b) includes inserting the end effector into the patient. Step c) includes guiding the end effector within the patient to a region of patient tissue containing a lesion. Step d) includes identifying the lesion at least in part from ultrasound imaging using the transducer assembly. Step e) includes identifying a blood vessel in the region which supplies blood to the lesion from ultrasound imaging using the transducer assembly. Step f) includes medically treating the blood vessel with ultrasound from the transducer assembly to substantially seal the blood vessel to substantially stop the supply of blood to the lesion from the blood vessel. Step g) includes medically treating the lesion with ultrasound from the transducer assembly to substantially ablate the lesion. It is noted that Doppler ultrasound imaging alone, gray-scale ultrasound imaging alone, and a combination of Doppler and gray-scale ultrasound imaging are known ultrasound techniques to image blood flow in blood vessels.

In one application of the thirteenth and fourteenth methods, the end effector is an open-surgery end effector. In another application, the end effector is an endoscopic end effector. In a further application, the end effector is a laparoscopic end effector. In an additional application, the end effector is a catheter end effector

(such as, but not limited to, an intravascular catheter end effector). In a different application, the end effector is a needle end effector.

A broadened thirteenth method of the invention eliminates the inserting into and guiding within steps of the above-described thirteenth method and includes steps a) through c). Step a) includes obtaining an end effector having an ultrasound medical-treatment transducer assembly. Step b) includes identifying a blood vessel in the patient which supplies blood to a lesion. Step c) includes medically treating the blood vessel with ultrasound from the transducer assembly to substantially seal the blood vessel to substantially stop the supply of blood to the lesion from the blood vessel.

A broadened fourteenth method of the invention eliminates the inserting into and guiding within steps of the above-described fourteenth method and includes steps a) through e). Step a) includes obtaining an end effector having an ultrasound imaging and medical-treatment transducer assembly. Step b) includes identifying a lesion in the patient at least in part from ultrasound imaging using the transducer assembly. Step c) includes identifying a blood vessel which supplies blood to the lesion from ultrasound imaging using the transducer assembly. Step d) includes medically treating the blood vessel with ultrasound from the transducer assembly to substantially seal the blood vessel to substantially stop the supply of blood to the lesion from the blood vessel. Step e) includes medically treating the lesion with ultrasound from the transducer assembly to substantially ablate the lesion.

In one example of the broadened thirteenth and fourteenth methods, the end effector is an extracorporeal end effector. In another example, the end effector is an intracorporeal end effector. In a further example, the end effector can be used in both an extracorporeal mode and in an intracorporeal mode.

Advantages of Applicants' thirteenth and broadened thirteenth methods for ultrasound medical treatment include, in one example, the indirect destruction of cancer lesions by ultrasound hemostasis in blood vessels supplying the cancer lesions in cases which otherwise would be inoperable or incurable because the location of the cancer lesions prevents medical treatment of the lesions themselves. Advantages of Applicants' fourteenth and broadened fourteenth methods for ultrasound treatment include, in one example, direct destruction of cancer lesions by

ultrasound ablation of the cancer lesions together with the indirect destruction of any cancer lesions missed in the ultrasound ablation step by ultrasound hemostasis in blood vessels supplying blood to the missed cancer lesions.

Guiding and Targeting Ultrasound End Effectors

Guiding Ultrasound End Effector for Medical Treatment

A sixth embodiment of the present invention is shown in Figure 24. In a first expression of the sixth embodiment of the present invention, an ultrasound medical treatment system 234 (only a portion of which is shown in Figure 24) includes an end effector 236 and at least three receivers 238. The end effector 236 has a transducer assembly 240 including a transducer 242 having at least one transducer element 244 adapted for emitting medical-treatment ultrasound waves and for emitting mechanical waves. It is noted that the terminology "mechanical waves" includes ultrasound and non-ultrasound compression (acoustic) waves and ultrasound and non-ultrasound shear waves, and that waves include wave pulses. The receivers 238 are spaced apart from the transducer assembly 240, and the receivers 238 are adapted to receive the emitted mechanical waves for use in locating the position of the transducer assembly 240. Conventional methods (including triangulation methods) for locating the position of a transponder emitting waves which are received by three receivers are well known. A second expression of the sixth embodiment is identical to the first expression of the sixth embodiment except that the at-least-one transducer element 244 is also adapted for emitting imaging ultrasound waves. In one variation of the first and second expressions of the sixth embodiment, the end effector and the receivers are disposable outside (including in one modification on) the patient. In another variation, the end effector is insertable into the patient and the receivers are disposable outside (including in one modification on) the patient.

A seventh embodiment of the present invention is shown in Figure 25. In a first expression of the seventh embodiment of the present invention, an ultrasound medical treatment system 246 (only a portion of which is shown in Figure 25) includes an end effector 248 and at least three receivers 250. The end effector 248

has an ultrasound medical-treatment transducer assembly 252 and has a transponder 254 The transponder 254 is adapted to emit waves, and the waves include electromagnetic waves or mechanical waves or both. The receivers 250 are spaced apart from the transducer assembly 252, and the receivers 250 are adapted to receive the emitted waves for use in locating the position of the transponder 254. In a second expression of the seventh embodiment, the ultrasound medical-treatment transducer assembly 252 is an ultrasound imaging and medical-treatment transducer assembly 256.

In one application of the first and second expressions of the seventh embodiment, the end effector 248 is insertable into a patient, the transponder 254 is adapted to emit electromagnetic waves, and the receivers 250 are disposable outside the patient. In one variation, the receivers 250 are disposable on the patient. In another application, the end effector is disposable outside (including in one modification on) the patient and the receivers are disposable outside (including in one modification on) the patient.

In one example of the first and second expressions of the seventh embodiment, the end effector 248 is an endoscopic end effector, a laparoscopic end effector, a catheter end effector (such as, but not limited to, an intravascular catheter end effector), or a needle end effector. In one design of the first and second expressions of the seventh embodiment, the end effector 248 has a distal tip 260, and the transponder 254 is disposed at the distal tip 260 of the end effector 248. In one variation, the transducer assembly 252 and 256 is disposed proximate the transponder 254.

A fifteenth method of the invention uses the ultrasound medical treatment system of the first expression of the seventh embodiment and includes steps a) through h). Step a) includes inserting the end effector 248 into the patient. Step b) includes disposing the receivers 250 outside the patient. Step c) includes emitting electromagnetic waves from the transponder 254. Step d) includes receiving the electromagnetic waves with the disposed receivers 250. Step e) includes calculating the position of the transponder 254 from the received electromagnetic waves. Step f) includes guiding the end effector within the patient to a desired location from the calculated position of the transponder 254. Step g) includes, after step f), identifying

tissue. It is noted that, in one example, to aim a transducer assembly means to focus ultrasound energy at a particular distance from the transducer assembly and along a particular direction. Step c) is labeled "Activate Transducer Assembly" in block 266 of Figure 26. Step c) includes activating the aimed transducer assembly to emit ultrasound energy sufficient to achieve a temperature increase in the patient tissue essentially without medically affecting the patient tissue. Step d) is labeled "Detect Actual Focal Zone" in block 268 of Figure 26. Step d) includes after step c) detecting, from reflected ultrasound energy, an actual focal zone of patient tissue having a temperature increase. Step e) is labeled "Correct For Any Aiming Error" in block 269 of Figure 26. Step e) includes correcting for any error between the desired focal zone and the actual focal zone. Step f) is labeled "Medically Treat Patient Tissue" in block 270 of Figure 26. Step f) includes after step e), medically treating the patient tissue with ultrasound using the transducer assembly. In one application, step d) uses one or more additional ultrasound transducer assemblies, separate from the ultrasound transducer assembly used in steps a) through c) and e) through f), to detect, from reflected ultrasound energy, the actual focal zone. In another application, the same ultrasound transducer assembly is used for steps a) through f). In one example of the seventeenth method, the end effector is an extracorporeal end effector. In another example, the end effector is an intracorporeal end effector. In a further example, the end effector can be used in both an extracorporeal mode and in an intracorporeal mode.

An eighteenth method of the invention is for ultrasound medical treatment of a patient and includes steps a) through f). The eighteenth method uses the same block diagram of Figure 26 as does the seventeenth method. Step a) includes obtaining an end effector having an ultrasound imaging and medical-treatment transducer assembly. Step b) includes aiming the transducer assembly to focus ultrasound energy at a desired focal zone of patient tissue. Step c) includes activating the aimed transducer assembly to emit ultrasound energy sufficient to achieve a temperature increase in the patient tissue essentially without medically affecting the patient tissue. Step d) includes after step c) detecting, from reflected ultrasound energy using the transducer assembly, an actual focal zone of patient tissue having a temperature increase. Step e) includes correcting for any error

patient tissue for medical treatment. Step h) includes medically treating the identified patient tissue with ultrasound using the transducer assembly 252.

A sixteenth method of the invention uses the ultrasound medical treatment system of the second expression of the seventh embodiment and includes steps a) through h). Step a) includes inserting the end effector 248 into the patient. Step b) includes disposing the receivers 250 outside the patient. Step c) includes emitting electromagnetic waves from the transponder 254. Step d) includes receiving the electromagnetic waves with the disposed receivers 250. Step e) includes calculating the position of the transponder 254 from the received electromagnetic waves. Step f) includes guiding the end effector within the patient to a desired location from the calculated position of the transponder 254. Step g) includes, after step f), identifying patient tissue for medical treatment at least in part from ultrasound imaging using the transducer assembly 256. Step h) includes medically treating the identified patient tissue with ultrasound using the transducer assembly 256.

A known electromagnetic transponder and three-receiver system for calculating the position of the transponder and for guiding the transponder (which is attached to a heart catheter for monitoring the heart) inside a patient is the CARTO™ EP Navigation System used with a NAVI-STAR® catheter manufactured by Biosense Webster (a Johnson & Johnson Company).

Advantages of an end effector with ultrasound medical treatment and position-location capabilities include, in one example, more accurately guiding the end effector inside a patient to patient tissue for ultrasound medical treatment of the patient tissue.

Method For Aiming Ultrasound For Medical Treatment

A seventeenth method of the invention is shown in block diagram form in Figure 26 and is for ultrasound medical treatment of a patient. The seventeenth method includes steps a) through f). Step a) is labeled "Obtain End Effector" in block 262 of Figure 26. Step a) includes obtaining an end effector having an ultrasound medical-treatment transducer assembly. Step b) is labeled "Aim Transducer Assembly" in block 264 of Figure 26. Step b) includes aiming the transducer assembly to focus ultrasound energy at a desired focal zone of patient

between the desired focal zone and the actual focal zone. Step f) includes after step e), medically treating the patient tissue with ultrasound using the transducer assembly. In one example, the end effector is an extracorporeal end effector. In another example, the end effector is an intracorporeal end effector. In a further example, the end effector can be used in both an extracorporeal mode and in an intracorporeal mode.

A nineteenth method of the invention is for ultrasound medical treatment of a patient and includes steps a) through i). The nineteenth method uses the same block diagram of Figure 26 as does the seventeenth method but with three extra steps added between block 262's step a) and block 264's step b) of the seventeenth method. In the nineteenth method, step a) includes obtaining an end effector having an ultrasound imaging and medical-treatment transducer assembly. Step b) includes inserting the end effector into the patient. Step c) includes guiding the end effector inside the patient. Step d) includes identifying a desired focal zone of patient tissue at least in part from ultrasound imaging using the transducer assembly. Step e) includes aiming the transducer assembly to focus ultrasound energy at the desired focal zone of patient tissue. Step f) includes activating the aimed transducer assembly to emit ultrasound energy sufficient to achieve a temperature increase in the patient tissue essentially without medically affecting the patient tissue. Step g) includes after step f) detecting, from reflected ultrasound energy using the transducer assembly, an actual focal zone of patient tissue having a temperature increase. Step h) includes correcting for any error between the desired focal zone and the actual focal zone. Step i) includes after step h), medically treating the patient tissue with ultrasound using the transducer assembly.

In one example of the seventeenth through nineteenth methods, the end effector is an endoscopic end effector. In another example, the end effector is a laparoscopic end effector. In a further example, the end effector is a catheter end effector (such as, but not limited to, an intravascular catheter end effector). In an additional example, the end effector is a needle end effector.

It is noted that the achieved temperature increase will decrease over time so that the detected temperature increase may not exactly equal the achieved temperature increase. In one implementation of the seventeenth through nineteenth

methods, the temperature increase detected in the detecting step is equal substantially to the temperature increase achieved in the activating step. In one application of the seventeenth through nineteenth methods, the detected temperature increase is not greater than about five degrees Celsius. In one variation, the detected temperature increase is not greater than about two degrees Celsius.

It is noted that conventional methods are known to the artisan to convert ultrasound image data into temperature images. In one variation of the seventeenth through nineteenth methods, the correcting step is performed automatically by a feedback control on the same mechanism used to aim the transducer assembly in the aiming step, as can be appreciated by the artisan. As previously noted, mechanisms for aiming an ultrasound medical-treatment transducer assembly include conventional electronic and/or mechanical techniques as are known to those skilled in the art.

Advantages of correcting for any error between the desired and actual focal zones before medical treatment include more precise ultrasound medical treatment of patient tissue. In one example, better targeting maximizes the ablation of a lesion (and any appropriate margin) while minimizing medical treatment of patient tissue outside the lesion (and outside any appropriate margin).

Ultrasound Imaging Of Patient Tissue

Ultrasound Feedback In Medically-Treated Patients

A twentieth method of the invention is shown in block diagram form in Figure 27 and is for ultrasound imaging of patient tissue of a patient. The twentieth method includes steps a) through c). Step a) is labeled "Obtain A First Signal From A Location At A First Time" in block 272 of Figure 27. Step a) includes obtaining a first signal of a first imaging ultrasound wave which has been reflected back from a location in the patient tissue at a first time. Step b) is labeled "Obtain A Second Signal From The Location At A Later Second Time" in block 274 of Figure 27. Step b) includes obtaining a second signal of a second imaging ultrasound wave which has been reflected back from the location in the patient tissue at a later second time wherein the patient has received at least some medical treatment by the second

time. Step c) is labeled "Create An Image Of The Location Using The Two Signals" in block 276 of Figure 27. Step c) includes creating an image of the location using the first signal and the second signal. It is understood that the terminology "creating an image" includes, without limitation, creating an image in visual form displayed, for example, on a monitor and creating an image in electronic form which, for example, is used by a computer without being displayed in visual form on a monitor. In one enablement of the twentieth method of the invention, the image of the location is visually displayed at a pixel location on a monitor.

In one example of the twentieth method of the invention, step c) includes creating an image of the location using at least the amplitude of the first signal and the amplitude of the second signal. In one variation, step c) calculates the difference in the amplitudes between the first and second signals. In one modification, step c) uses the calculated amplitude difference and uses one of the amplitudes of one of the first and second signals. In one implementation, step c) calculates the sum of the one amplitude and a function of the calculated amplitude difference. In one illustration for a first signal amplitude of 6 and a second signal amplitude of 7, step c) calculates the amplitude difference, adds the difference to the second signal amplitude creating a processed amplitude of 8, and creates the image of the location using the processed amplitude. Other algorithms for using the amplitude of the first and second signals to enhance any amplitude difference in creating the image of the location after medical treatment are left to the artisan.

In another example of the twentieth method of the invention, step c) includes creating an image of the location using at least the phase of the first signal and the phase of the second signal. In one variation, step c) calculates the difference in the phase between the first and second signals. In one modification, step c) uses the calculated phase difference and uses one of the phases of one of the first and second signals. In one implementation, step c) calculates the sum of the one phase and a function of the calculated phase difference. In one illustration of a first signal phase of 6 degrees and a second signal phase of 7 degrees, step c) calculates the phase difference, adds the difference to the second signal phase creating a processed phase of 8 degrees, and creates the image of the location using the processed phase. Other

algorithms for using the phase of the first and second signals to enhance any phase difference in creating the image after medical treatment are left to the artisan.

In an additional example of the twentieth method of the invention, step c) includes creating an image of the location using at least the amplitude and the phase of the first signal and the amplitude and phase of the second signal. In one variation step c) combines the discussions in the previous two paragraphs, as is within the ordinary level of skill of the artisan.

In one application of the twentieth method and examples, etc. thereof, the first signal of step a) has a first frequency (e.g., a first center frequency having a sigma) and the second signal of step b) has a second frequency (e.g., a second center frequency having a sigma) which is different from the first frequency (meaning, for example, that the center frequencies are different). In the same or a different application, the medical treatment is ultrasound medical treatment. In the same or a different application, steps a) through c) are repeated for different locations to image the patient tissue, wherein the image of the patient tissue includes medically-treated locations and medically-untreated locations. In one enablement of the twentieth method of the invention, the image of the patient tissue is visually displayed on a monitor. In another enablement, the image remains as an image map in a computer without being displayed on a monitor. In one extension of the twentieth method, additional signals are obtained between steps a) and b) which are also used in creating the image of the location in step c).

Applicants were the first to realize that changes in patient tissue because of medical treatment of patient tissue, such as ultrasound medical treatment, which affect the amplitude and/or phase of ultrasound imaging signals can be used to enhance the ultrasound image differences of medically-treated patient tissue from surrounding untreated tissue. Applicants have theorized that using different frequencies for the two signals can enhance amplitude and/or phase differences for medically treated and untreated tissue and can be used to enhance the ultrasound image differences of medically-treated patient tissue from surrounding untreated tissue. Advantages of the twentieth method and examples, etc. thereof include, in one application, better ultrasound image contrast between treated and untreated patient tissue providing better monitoring during patient treatment.

Other medical treatments applicable to the twentieth method include, without limitation, other thermal ablation techniques such as radio-frequency, laser, and microwave medical treatments and chemical ablation techniques such as ethanol and chemo-therapeutics (including anti-cancer drugs). Other optional steps in the twentieth method include using signal smoothing techniques, as are known to those skilled in the art.

It is understood that any one or more of the previously-described embodiments, expressions of embodiments, examples, methods, etc. can be combined with any one or more of the other previously-described embodiments, expressions of embodiments, examples, methods, etc. For example, and without limitation, any of the end effectors can be used in any of the methods, any of the transducer arrangements can be used in any of the end effectors, and any appropriate methods can be combined such as combining the seventeenth and twentieth methods, etc.

The foregoing description of several expressions of embodiments and methods of the invention has been presented for purposes of illustration. It is not intended to be exhaustive or to limit the invention to the precise forms and procedures disclosed, and obviously many modifications and variations are possible in light of the above teaching. For example, as would be apparent to those skilled in the art, the disclosures herein of the ultrasonic systems and methods have equal application in robotic assisted surgery taking into account the obvious modifications of the invention to be compatible with such a robotic system. It is intended that the scope of the invention be defined by the claims appended hereto.

WHAT IS CLAIMED IS:

1. A method for ultrasound medical treatment of a patient comprising the steps of:

a) obtaining an end effector having an ultrasound medical-treatment transducer assembly;

b) inserting the end effector into the patient;

c) guiding the end effector within the patient to a region of patient tissue containing a lesion;

d) identifying a blood vessel in the region which supplies blood to the lesion; and

e) medically treating the blood vessel with ultrasound from the transducer assembly to substantially seal the blood vessel to substantially stop the supply of blood to the lesion from the blood vessel.

2. The method of claim 1, also including the step of medically treating the lesion with ultrasound from the transducer assembly to substantially ablate the lesion.

3. The method of claim 1, wherein the end effector is an open-surgery end effector.

4. The method of claim 1, wherein the end effector is an endoscopic end effector.

5. The method of claim 1, wherein the end effector is a laparoscopic end effector.

6. The method of claim 1, wherein the end effector is a catheter end effector.

7. The method of claim 1, wherein the end effector is a needle end effector.

8. A method for ultrasound medical treatment of a patient comprising the steps of:

a) obtaining an end effector having an ultrasound imaging and medical-treatment transducer assembly;

b) inserting the end effector into the patient;

c) guiding the end effector within the patient to a region of patient tissue containing a lesion;

d) identifying the lesion at least in part from ultrasound imaging using the transducer assembly;

e) identifying a blood vessel in the region which supplies blood to the lesion from ultrasound imaging using the transducer assembly;

f) medically treating the blood vessel with ultrasound from the transducer assembly to substantially seal the blood vessel to substantially stop the supply of blood to the lesion from the blood vessel; and

g) medically treating the lesion with ultrasound from the transducer assembly to substantially ablate the lesion.

9. The method of claim 8, wherein the end effector is an open-surgery end effector.

10. The method of claim 8, wherein the end effector is an endoscopic end effector.

11. The method of claim 8, wherein the end effector is a laparoscopic end effector.

12. The method of claim 8, wherein the end effector is a catheter end effector.

13. The method of claim 8, wherein the end effector is an interstitial end effector.

14. A method for ultrasound medical treatment of a patient comprising the steps of:

a) obtaining an end effector having an ultrasound medical-treatment transducer assembly;

b) identifying a blood vessel in the patient which supplies blood to a lesion; and

c) medically treating the blood vessel with ultrasound from the transducer assembly to substantially seal the blood vessel to substantially stop the supply of blood to the lesion from the blood vessel.

15. The method of claim 14, wherein the end effector is an extracorporeal end effector.

16. A method for ultrasound medical treatment of a patient comprising the steps of:

a) obtaining an end effector having an ultrasound imaging and medical-treatment transducer assembly;

b) identifying a lesion in the patient at least in part from ultrasound imaging using the transducer assembly;

c) identifying a blood vessel which supplies blood to the lesion from ultrasound imaging using the transducer assembly;

d) medically treating the blood vessel with ultrasound from the transducer assembly to substantially seal the blood vessel to substantially stop the supply of blood to the lesion from the blood vessel; and

e) medically treating the lesion with ultrasound from the transducer assembly to substantially ablate the lesion.

17. The method of claim 16, wherein the end effector is an extracorporeal end effector.

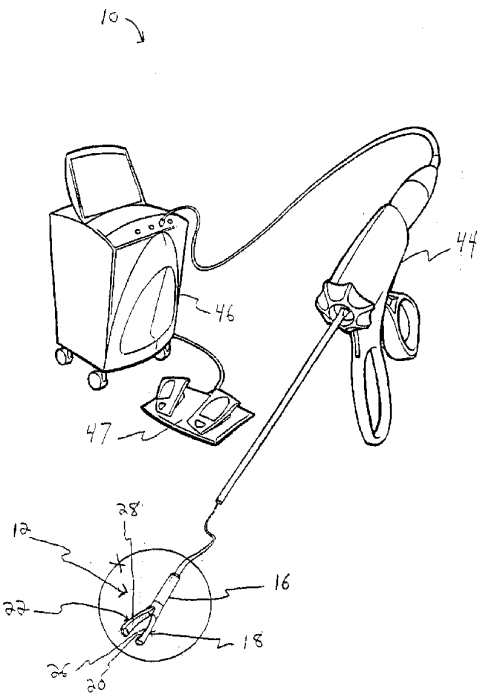


Fig. 1

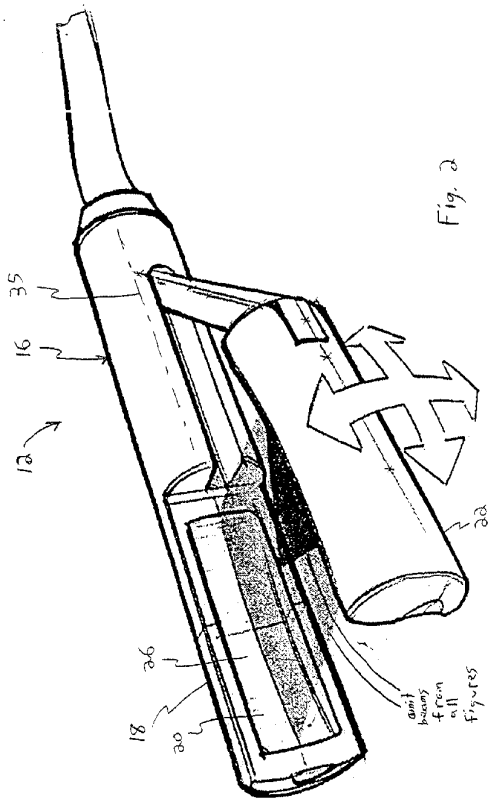


Fig. 2

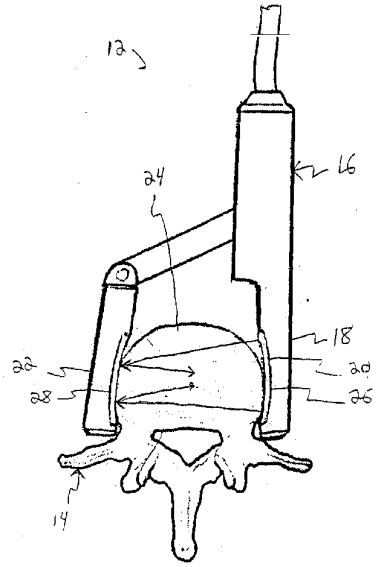


Fig. 3

Fig. 4

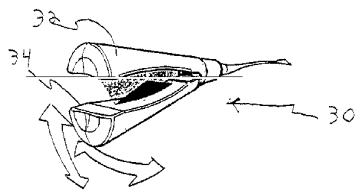


Fig. 5

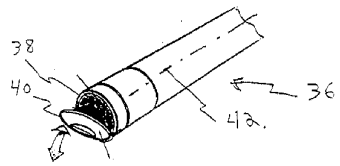
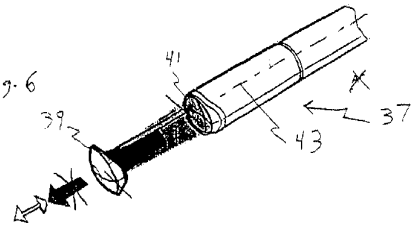


Fig. 6



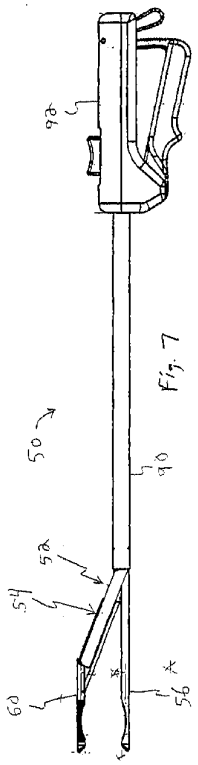

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Fig. 7

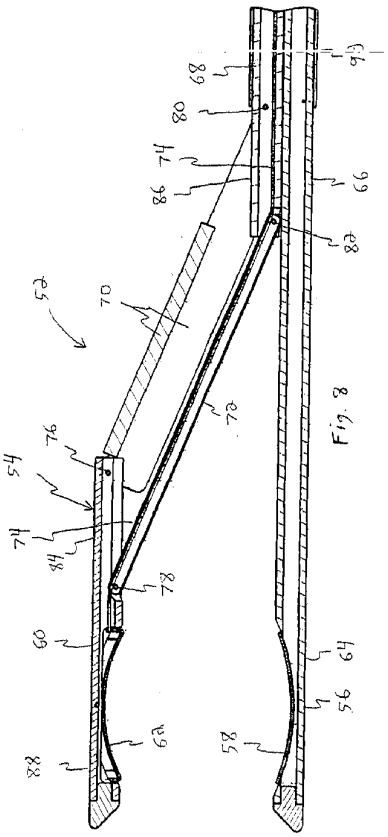
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Fig. 8

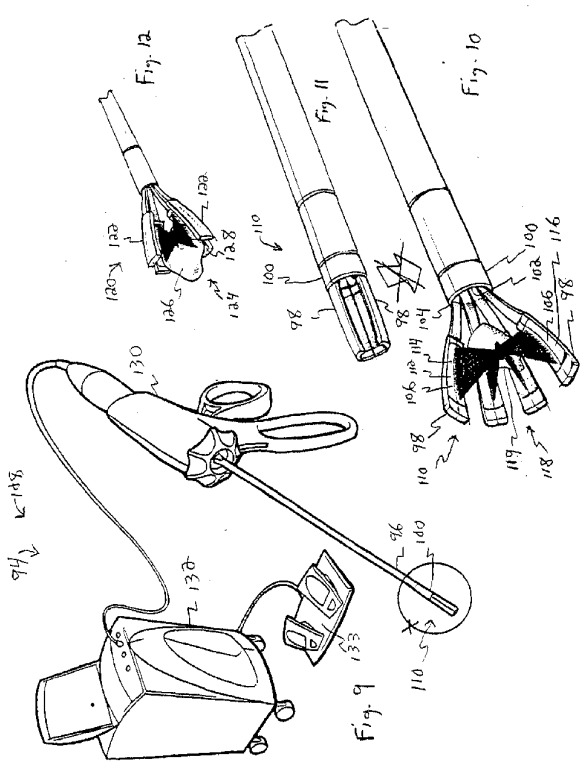
Fig. 12
Fig. 11
Fig. 10
Fig. 9
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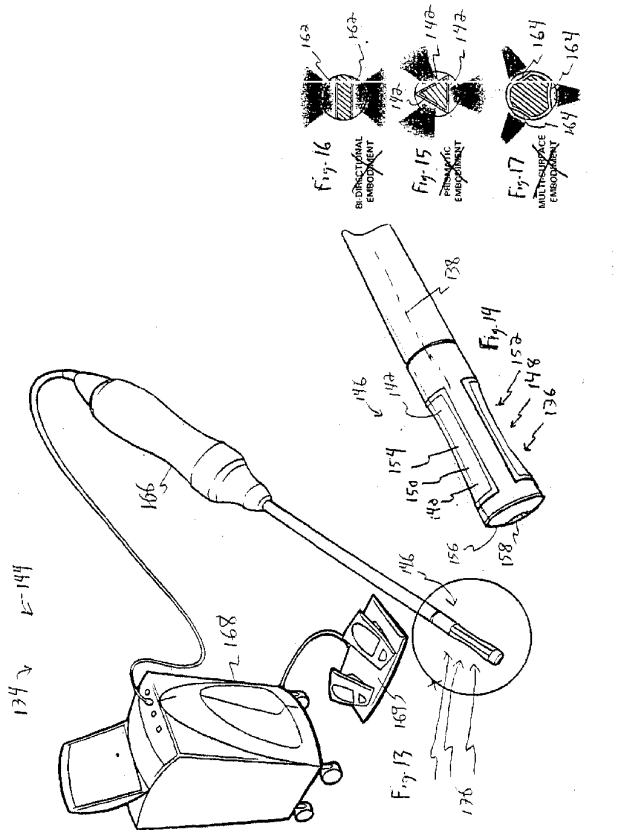
Fig. 16
BI-DIRECTIONAL EMBODIMENT
Fig. 15
PRISMATIC EMBODIMENT
Fig. 17
MULTI-SURFACE EMBODIMENT
Fig. 14
Fig. 13

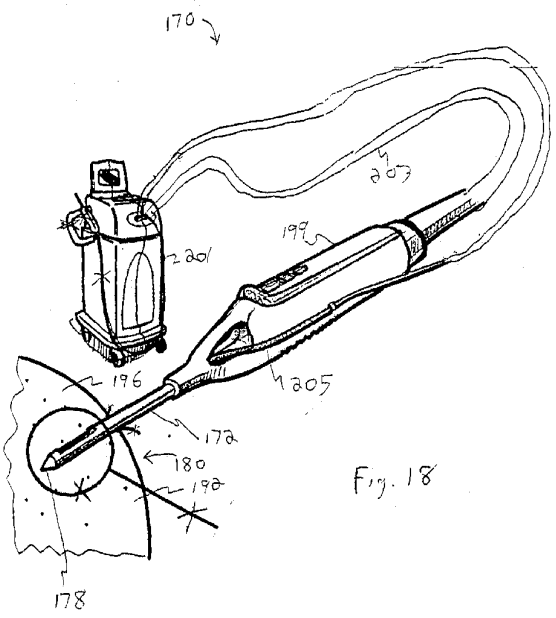

Fig. 18

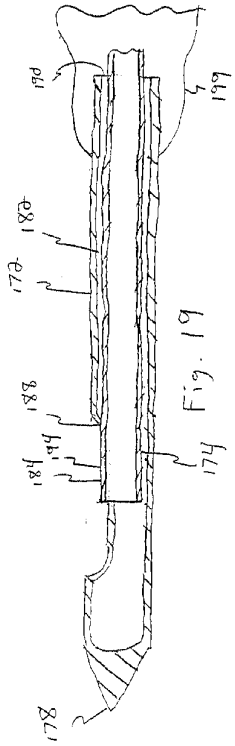
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Fig. 19

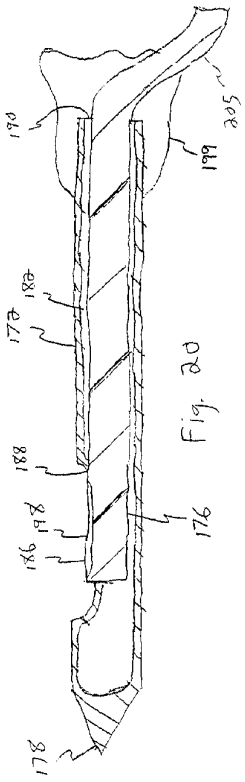
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Fig. 20

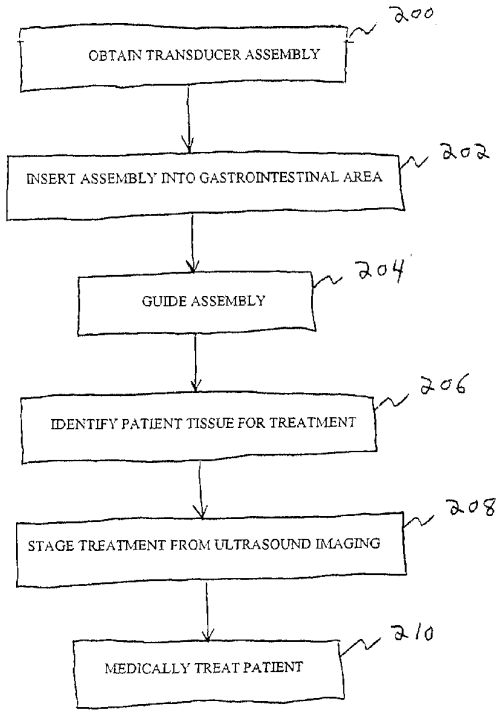
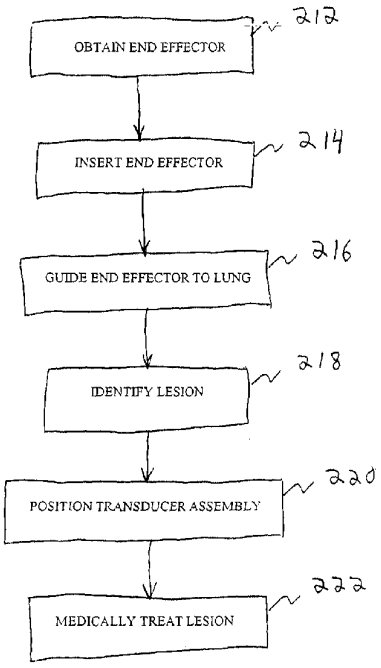

200
OBTAIN TRANSDUCER ASSEMBLY
202
INSERT ASSEMBLY INTO GASTROINTESTINAL AREA
204
GUIDE ASSEMBLY
206
IDENTIFY PATIENT TISSUE FOR TREATMENT
208
STAGE TREATMENT FROM ULTRASOUND IMAGING
210
MEDICALLY TREAT PATIENT

FIG. 21


OBTAIN END EFFECTOR
212
INSERT END EFFECTOR
214
GUIDE END EFFECTOR TO LUNG
216
IDENTIFY LESION
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POSITION TRANSDUCER ASSEMBLY
220
MEDICALLY TREAT LESION
222

FIG. 22

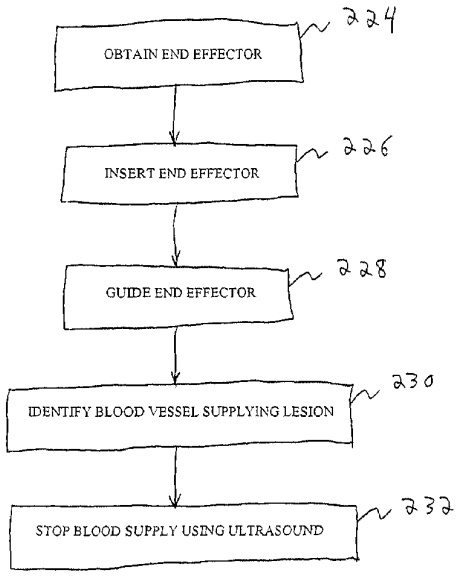
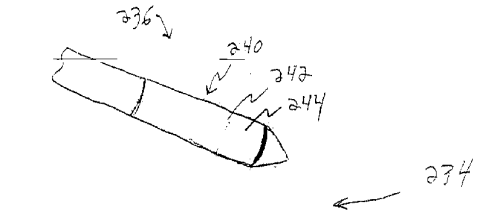

224
OBTAIN END EFFECTOR
226
INSERT END EFFECTOR
228
GUIDE END EFFECTOR
230
IDENTIFY BLOOD VESSEL SUPPLYING LESION
232
STOP BLOOD SUPPLY USING ULTRASOUND

FIG. 23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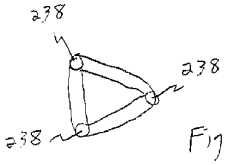
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Fig. 24

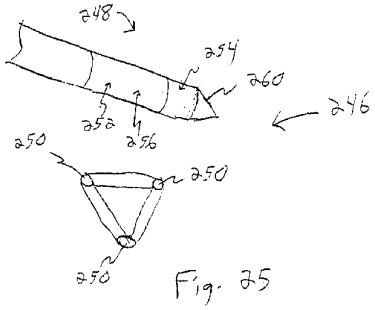
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Fig. 25

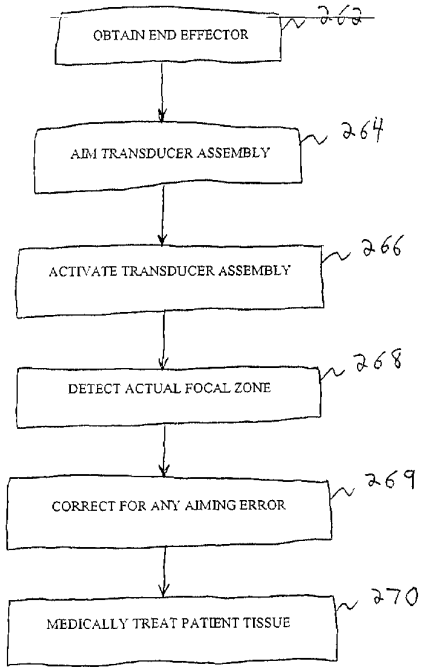
OBTAIN END EFFECTOR
262
AIM TRANSDUCER ASSEMBLY
264
ACTIVATE TRANSDUCER ASSEMBLY
266
DETECT ACTUAL FOCAL ZONE
268
CORRECT FOR ANY AIMING ERROR
269
MEDICALLY TREAT PATIENT TISSUE
270

FIG. 26

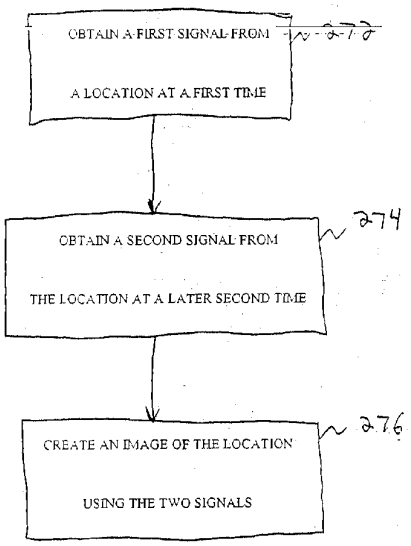
OBTAIN A FIRST SIGNAL FROM
A LOCATION AT A FIRST TIME
274
OBTAIN A SECOND SIGNAL FROM
THE LOCATION AT A LATER SECOND TIME
276
CREATE AN IMAGE OF THE LOCATION
USING THE TWO SIGNALS

FIG. 27

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(81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZM, ZW.

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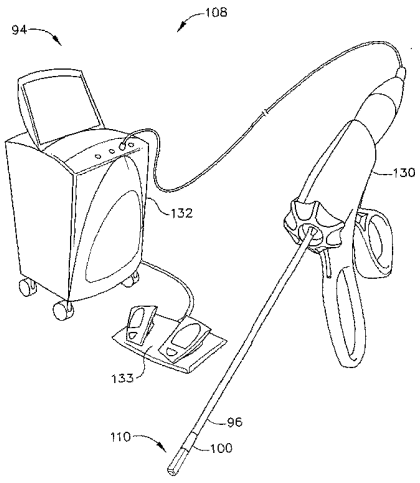
(54) Title: ULTRASOUND-BASED OCCLUSIVE PROCEDURE FOR MEDICAL TREATMENT



(57) Abstract: A method for ultrasound medical treatment of a patient. An end effector (12) is obtained having an ultrasound medical-treatment transducer assembly (20). A blood vessel is identified in the patient which supplies blood to a lesion. The blood vessel is medically treated with ultrasound from the transducer assembly (20) to substantially seal the blood vessel to substantially stop the supply of blood to the lesion from the blood vessel. In one example, the ultrasound medical-treatment transducer assembly (20) is an ultrasound imaging and medical-treatment transducer assembly (20). In one variation, the end effector (12) is inserted into the patient. In another variation, the end effector remains outside the patient.

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(74) Agents: JOHNSON, Philip, S. et al.; Johnson & Johnson, One Johnson & Johnson Plaza, New Brunswick, NJ 45242 (US).

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(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent

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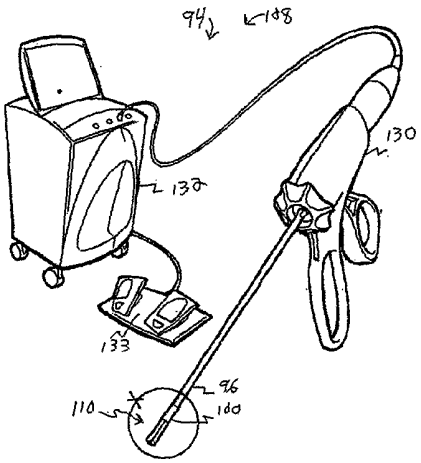

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(BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

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Published:

— *without international search report and to be republished upon receipt of that report*

ULTRASOUND-BASED OCCLUSIVE PROCEDURE FOR MEDICAL TREATMENT

The present application claims priority of U.S. Provisional Application Serial No. 60/294,135 filed May 29, 2001, the entire disclosure of which is incorporated herein by reference.

Field of the Invention

The present invention relates generally to ultrasound, and more particularly to an ultrasound medical system and/or to an ultrasound medical method.

Background of the Invention

Known ultrasound medical systems and methods include using ultrasound imaging of patients to identify patient tissue for medical treatment and include using ultrasound to medically destroy identified patient tissue by heating the tissue. Imaging is done at lower power and medical treatment is done at higher power. Low power imaging ultrasound will not medically affect patient tissue. High power medical-treatment ultrasound, when focused at a focal zone a distance away from the ultrasound source, will substantially medically affect patient tissue in the focal zone. However, focused medical-treatment ultrasound will not substantially medically affect patient tissue outside the focal zone such as patient tissue located between the source and the focal zone.

In one known example, a transducer assembly includes a single ultrasound transducer having a single transducer element, or an array of transducer elements acting together, to ultrasonically image the patient and to ultrasonically ablate identified patient tissue. It is known to convert ultrasound imaging data into temperature imaging data for ultrasound-treated patient tissue to monitor the ultrasound treatment. A known transducer element includes a transducer element having a concave shape or an acoustic lens to focus ultrasound energy. A known array of transducer elements includes a planar, concave, or convex array of

transducer elements to focus ultrasound energy. A known array of transducer elements includes an array whose transducer elements are electronically or mechanically controlled together to steer and focus the ultrasound emitted by the array to a focal zone (which may be large or which may be as small as, for example, a grain of rice) to provide three-dimensional medical ultrasound treatment of patient tissue. In some applications, the transducer is placed on the surface of patient tissue for ultrasound imaging and/or ultrasound medical treatment of areas within the patient tissue. In other applications, the transducer is surrounded with a balloon which is expanded to contact the surface of patient tissue by filling with a fluid such as a saline solution to provide acoustic coupling between the transducer and the patient tissue.

Known ultrasound medical systems and methods include deploying an end effector having an ultrasound transducer outside the body to break up kidney stones inside the body, endoscopically inserting an end effector having an ultrasound transducer in the colon to medically destroy prostate cancer, laparoscopically inserting an end effector having an ultrasound transducer in the abdominal cavity to medically destroy a cancerous liver tumor, intravenously inserting a catheter end effector having an ultrasound transducer into a vein in the arm and moving the catheter to the heart to medically destroy diseased heart tissue, and interstitially inserting a needle end effector having an ultrasound transducer needle into the tongue to medically destroy tissue to reduce tongue volume to reduce snoring. Known methods for guiding an end effector within a patient include guiding the end effector from x-rays, from MRI images, and from ultrasound images obtained using the ultrasound transducer. Known ultrasound imaging includes Doppler ultrasound imaging to detect blood flow, and a proposed known use of ultrasound includes using an ultrasound transducer outside the body to stop internal bleeding (by sealing ruptured blood vessels) of a patient brought to an emergency room of a hospital.

A Mammotome® Breast Biopsy System manufactured by Ethicon Endo-Surgery, Inc. (a Johnson & Johnson Company) inserts a tube into breast tissue, wherein the tube contains an end effector having a biopsy cutting tool. A known electromagnetic transponder and three-receiver system for calculating the position of the transponder and for guiding the transponder (which is attached to a heart catheter

for monitoring the heart) inside a patient is the CARTO™ EP Navigation System used with a NAVI-STAR® catheter manufactured by Biosense Webster (a Johnson & Johnson Company). Further, it is known that changes in patient tissue because of medical treatment of patient tissue, such as ultrasound medical treatment, affect the amplitude and/or phase of ultrasound imaging signals.

What is needed is an improved ultrasound medical system and/or an improved ultrasound medical method. This invention addresses those needs lacking in an ultrasonic medical system and/or an ultrasonic medical method.

Summary of the Invention

One method of the invention is for ultrasound medical treatment of a patient and includes steps a) through c). Step a) includes obtaining an end effector having an ultrasound medical-treatment transducer assembly. Step b) includes identifying a blood vessel in the patient which supplies blood to a lesion. Step c) includes medically treating the blood vessel with ultrasound from the transducer assembly to substantially seal the blood vessel to substantially stop the supply of blood to the lesion from the blood vessel. In one example, the ultrasound medical-treatment transducer assembly is an ultrasound imaging and medical-treatment transducer assembly. In one variation, the end effector is inserted into the patient. In another variation, the end effector remains outside the patient.

The present invention has, without limitation, application in conventional endoscopic and open surgical instrumentation as well as application in robotic-assisted surgery.

Brief Description of the Drawings

Figure 1 is a perspective view of a first embodiment of the present invention showing an ultrasound medical treatment system which includes a tissue-retaining device;

Figure 2 is an enlarged view of the end effector of the ultrasound medical treatment system of Figure 1;

Figure 3 is a view of the end effector of Figure 2 retaining an intervertebral disk of a patient;

Figure 4 is a perspective view of a first alternate end effector which can be used in the ultrasound medical treatment system of Figure 1;

Figure 5 is a perspective view of a second alternate end effector which can be used in the ultrasound medical treatment system of Figure 1;

Figure 6 is a perspective view of a third alternate end effector which can be used in the ultrasound medical treatment system of Figure 1;

Figure 7 is a side elevational view of a second embodiment of the present invention showing another ultrasound medical treatment system which includes a tissue-retaining device;

Figure 8 is an enlarged, partially-cutaway view of the end effector of the ultrasound medical treatment system of Figure 7;

Figure 9 is a perspective view of a third embodiment of the present invention showing an ultrasound medical system which includes flexible fingers, wherein each finger includes an ultrasound transducer;

Figure 10 is an enlarged view of the tube and the flexible fingers of the ultrasound medical system of Figure 9 showing the flexible fingers in a deployed fan-like state;

Figure 11 is a view of the flexible fingers of Figure 10 shown in a stowed state;

Figure 12 is a perspective view of an alternate flexible finger arrangement which can be used in the ultrasound medical system of Figure 9, showing the flexible fingers in a deployed claw-like state surrounding patient tissue;

Figure 13 is a perspective view of a fourth embodiment of the present invention showing an ultrasound medical system which includes an ultrasound transducer assembly which includes at least two ultrasound transducers;

Figure 14 is an enlarged view of the ultrasound transducer assembly of the ultrasound medical system of Figure 13;

Figure 15 is a cross-sectional view of the transducer assembly of Figure 14;

Figure 16 is a cross-sectional view of a first alternate transducer arrangement which can be used in place of the arrangement of Figure 15;

Figure 17 is a cross-sectional view of a second alternate transducer arrangement which can be used in place of the arrangement of Figure 15;

Figure 18 is a perspective view of a fifth embodiment of the present invention showing an ultrasound medical treatment system which includes a cutting tool and an ultrasound medical-treatment transducer assembly;

Figure 19 is an enlarged, cross-sectional view of the tube of Figure 18 showing a cutting tool that has been introduced into the lumen of the tube;

Figure 20 is an enlarged, cross-sectional view of the tube of Figure 18 showing an ultrasound medical-treatment transducer assembly that has been introduced into the lumen of the tube;

Figure 21 is a block diagram of an eighth method of the present invention which includes ultrasound staging of medical treatment of patient tissue in the gastrointestinal area;

Figure 22 is a block diagram of an eleventh method of the present invention which includes ultrasound medical treatment of a lesion on or in the lung of a patient;

Figure 23 is a block diagram of a thirteenth method of the present invention which includes ultrasound medical treatment of a blood vessel to stop the supply of blood to a lesion from the blood vessel;

Figure 24 is a perspective view of a sixth embodiment of the present invention showing a portion of an ultrasound medical treatment system which includes receivers for locating the position of the transducer assembly of the system;

Figure 25 is a perspective view of a seventh embodiment of the present invention showing a portion of another ultrasound medical treatment system which includes receivers for locating the position of the transponder of the system;

Figure 26 is a block diagram of a seventeenth method of the present invention which includes aiming the transducer assembly; and

Figure 27 is a block diagram of a twentieth method of the present invention which includes creating an image after starting medical treatment using an imaging ultrasound wave before medical treatment and an imaging ultrasound wave after starting medical treatment.

Detailed Description of the Invention

Before explaining the present invention in detail, it should be noted that the invention is not limited in its application or use to the details of construction and arrangement of parts illustrated in the accompanying drawings and description. The illustrative embodiments of the invention may be implemented or incorporated in other embodiments, variations and modifications, and may be practiced or carried out in various ways. Furthermore, unless otherwise indicated, the terms and expressions employed herein have been chosen for the purpose of describing the illustrative embodiments of the present invention for the convenience of the reader and are not for the purpose of limiting the invention.

It is understood that any one or more of the following-described embodiments, expressions of embodiments, examples, methods, etc. can be combined with any one or more of the other following-described embodiments, expressions of embodiments, examples, methods, etc. For example, and without limitation, any of the end effectors can be used in any of the methods, any of the transducer arrangements can be used in any of the end effectors, and any appropriate methods can be combined such as combining the seventeenth and twentieth methods, etc.

Ultrasound Medical Treatment Using Tissue-Retaining Devices

Tissue-Retaining System for Ultrasound Medical Treatment

Referring now to the drawings, Figures 1-3 illustrate a first embodiment of the present invention. A first expression of the first embodiment of the present invention is for an ultrasound medical treatment system 10 including an end effector 12 insertable into a patient 14. The end effector 12 includes a tissue-retaining device 16. The tissue-retaining device 16 includes a first tissue-retaining member 18 having an (i.e., at least one) ultrasound medical-treatment transducer 20 (also called "transducer 20") and includes a second tissue-retaining member 22. The first and second tissue-retaining members 18 and 22 are operatively connected together to

retain patient tissue 24 between the first and second tissue-retaining members 18 and 22 and to release patient tissue 24 so retained.

It is noted that an ultrasound medical-treatment transducer is an ultrasound transducer adapted at least for ultrasound medical treatment of a patient such as, but not limited to, a human patient. An ultrasound medical-treatment transducer includes either a single ultrasound medical-treatment transducer element or an array of ultrasound medical-treatment transducer elements, as is known to those skilled in the art. An ultrasound medical-treatment transducer may or may not also be adapted for ultrasound imaging of a patient. Likewise, an ultrasound imaging transducer is an ultrasound transducer adapted at least for ultrasound imaging of a patient and may or may not also be adapted for ultrasound medical-treatment of a patient.

Advantages of retaining patient tissue between two tissue-retaining members during ultrasound medical treatment by one of the tissue-retaining members include having a single instrument which ultrasonically medically treats patient tissue and at the same time immobilizes patient tissue against undesired movement during the treatment. It is also noted that in one application the tissue-retaining device is a clamp which retains and holds tissue and that in another application the tissue-retaining device retains tissue against movement, but does not hold tissue, and therefore is not a clamp.

In one variation, not shown, the second tissue-retaining member 22 has an ultrasound imaging and/or medical treatment transducer. In the same or a different variation, not shown, the tissue-retaining device 16 has at least one additional tissue-retaining member. Mechanisms, not shown, for remotely moving two (or more) members toward and away from each other are within the ordinary level of skill of the artisan and include, without limitation, the use of pivotal member attachments and the use of cables or motors. In the same or a different variation, the retained patient tissue 24 is retained between the ultrasound medical-treatment transducer 20 and the second tissue-retaining member 22. In the same or a different variation, the ultrasound medical-treatment transducer 20 focuses ultrasound energy, such focusing being known to those skilled in the art. In the same or a different variation, not shown, the second tissue-retaining member 22 is substantially ultrasonically non-reflective.

A second expression of the first embodiment of the present invention is for an ultrasound medical treatment system 10 including an end effector 12 insertable into a patient 14. The end effector 12 includes a tissue-retaining device 16. The tissue-retaining device 16 includes a first tissue-retaining member 18 having an (i.e., at least one) ultrasound imaging and medical-treatment transducer 26 (also called "transducer 26") and includes a second tissue-retaining member 22. The first and second tissue-retaining members 18 and 22 are operatively connected together to retain patient tissue 24 between the first and second tissue-retaining members 18 and 22 and to release patient tissue 24 so retained.

It is noted that an ultrasound imaging and medical-treatment transducer is an ultrasound transducer adapted at least for both ultrasound imaging and ultrasound medical treatment of a patient. An ultrasound imaging and medical-treatment transducer includes either a single ultrasound imaging and medical-treatment transducer element or an array of ultrasound medical transducer elements (including an array having at least one separate element for imaging and at least one separate element for medical treatment or an array having at least two elements each adapted for both imaging and medical treatment), as is known to those skilled in the art. In one variation, the retained patient tissue 24 is retained between the imaging and medical-treatment transducer 26 and the second tissue-retaining member 22. In the same or a different variation, the ultrasound imaging and medical-treatment transducer 26 focuses ultrasound energy. In the same or a different variation, not shown, the second tissue-retaining member 22 is substantially ultrasonically non-reflective.

A third expression of the first embodiment shown in Figures 1-3 is for an ultrasound medical treatment system 10 including an end effector 12 insertable into a patient 14. The end effector 12 includes a tissue-retaining device 16. The tissue-retaining device 16 includes a first tissue-retaining member 18 having an (i.e., at least one) ultrasound medical-treatment transducer 20 and includes a second tissue-retaining member 22 having an (i.e., at least one) ultrasound reflector 28. The first and second tissue-retaining members 18 and 22 are operatively connected together to retain patient tissue 24 between the first and second tissue-retaining members 18 and 22 and to release patient tissue 24 so retained.

Advantages of retaining patient tissue between two tissue-retaining members during ultrasound medical treatment by an ultrasound medical-treatment transducer of a first tissue-retaining member and an ultrasound reflector of a second tissue-retaining member include having a single instrument which ultrasonically medically treats patient tissue by direct ultrasound, which enhances the ultrasound medical treatment by reflected ultrasound, and which at the same time immobilizes patient tissue against undesired movement during the treatment.

It is noted that an ultrasound reflector 28 is a material which reflects ultrasound at least to a degree that would substantially medically affect patient tissue over a treatment period by direct ultrasound which is being reflected back by the ultrasound reflector. Choices of ultrasound reflecting materials include, without limitation, acoustically-rigid materials such as stainless steel (which reflects about 100%) and aluminum (which reflects about 80%) and acoustically-softer materials such as corporene (which reflects about 90%). An ultrasound reflecting material is contrasted with an ultrasound absorbing material such as, without limitation, rubber or plastic. In one variation, the retained patient tissue 24 is retained between the ultrasound medical-treatment transducer 20 and the ultrasound reflector 28. In the same or a different variation, the ultrasound medical-treatment transducer 20 and the ultrasound reflector 28 each focus ultrasound energy, such ultrasound reflector focusing being accomplished by the shape of, or by shaping, the reflector surface as is within the ordinary level of skill of the artisan.

A fourth expression of the first embodiment shown in Figures 1-3 is for an ultrasound medical treatment system 10 including an end effector 12 insertable into a patient 14. The end effector 12 includes a tissue-retaining device 16. The tissue-retaining device 16 includes a first tissue-retaining member 18 having an (i.e., at least one) ultrasound imaging and medical-treatment transducer 26 and includes a second tissue-retaining member 22 having an (i.e., at least one) ultrasound reflector 28. The first and second tissue-retaining members 18 and 22 are operatively connected together to retain patient tissue 24 between the first and second tissue-retaining members 18 and 22 and to release patient tissue 24 so retained. In one variation, the retained patient tissue 24 is retained between the ultrasound imaging and medical-treatment transducer 26 and the ultrasound reflector 28. In the same or

a different variation, the ultrasound imaging and medical-treatment transducer 26 and the ultrasound reflector 28 each focus ultrasound energy.

In one example of the previously-described third and fourth expressions of the first embodiment, the ultrasound reflector 28 is disposed to receive ultrasound energy from the transducer 20 and 26 and is oriented to reflect the received ultrasound energy back into patient tissue 24 retained by the tissue-retaining device 16. In the same or a different example, the ultrasound reflector 28 is oriented to reflect the received ultrasound energy away from the transducer 20 and 26 when the patient tissue 14 is retained by the tissue-retaining device 16. An advantage of this arrangement is that it avoids damage to the transducer from the reflected ultrasound. In the same or a different example, one of the first and second tissue-retaining members 18 and 22 is controllably orientatable relative to the other of the first and second tissue-retaining members 18 and 22 such as, without limitation, by being orientatable along the double-headed arrows shown in Figure 2. In one modification, the second tissue-retaining member 22 is controllably orientatable relative to the first tissue-retaining member 18 to reflect the received ultrasound energy back along different directions. A first alternate end effector 30 is shown in Figure 4 wherein the second tissue-retaining member 32 is controllably orientatable relative to the first tissue-retaining member 34 as shown by the double-headed arrows in Figure 4. Mechanisms, not shown, for remotely controlling the orientation of one member relative to another member are within the ordinary level of skill of the artisan and include, without limitation, the use of pivotal member attachments and the use of cables or motors. In one application, the transducer 20 and 26 generates wide-focused ultrasound (shown by the two single-headed arrows coming from the first tissue-retaining member 18 in Figure 3) and the ultrasound reflector 28 generates narrow-focused ultrasound (shown by the two single-headed arrows coming from the second tissue-retaining member 22 in Figure 3).

In one example of the previously-described first through fourth expressions of the first embodiment, the end effector 12 is an open-surgery end effector, an endoscopic end effector, a laparoscopic end effector (as shown in Figure 1), a catheter end effector (such as, but not limited to, an intravascular catheter end effector), or a needle end effector, as can be appreciated by those skilled in the art.

In one application, the end effector 12 is used to retain a blood vessel and then to ultrasonically treat the blood vessel to seal the blood vessel stopping the flow of blood in the retained blood vessel. In another application, the end effector 12 is used to retain patient tissue and then to ultrasonically ablate at least a portion of the retained patient tissue.

In one design of the previously-described first through fourth expressions of the first embodiment, the end effector 12 has a longitudinal axis 35, and one of the first and second tissue-retaining members 18 and 22 at all times faces along a direction which is substantially perpendicular to the longitudinal axis 35. If the one tissue-retaining member were planar, this means that the longitudinal axis would be substantially parallel to the plane of the one tissue-retaining member. In one enablement, the one tissue-retaining member is the first tissue-retaining member 18. A second alternate end effector 36 has first and second tissue-retaining members 38 and 40 which are hinged together to relatively move as indicated by the double-headed arrow and which are shown in a partially open configuration in Figure 5. The second alternate end effector 36 has a longitudinal axis 42, and one of the first and second tissue-retaining members 38 and 40 at all times faces along a direction which is substantially parallel to the longitudinal axis 42. If the one tissue-retaining member were planar, this means that the longitudinal axis would be substantially perpendicular to the plane of the one tissue-retaining member. In one enablement, the one tissue-retaining member is the first tissue-retaining member 38. A third alternate end effector 37 having first and second tissue-retaining members 39 and 41 with one member longitudinally movable with respect to the other member (as indicated by the double-headed arrow) is shown in Figure 6. The third alternate end effector 37 has a longitudinal axis 43, and one of the first and second tissue-retaining members 39 and 41 at all times faces along a direction which is substantially parallel to the longitudinal axis 43. In one enablement, the one tissue-retaining member is the first tissue-retaining member 39.

In one enablement, as shown in Figure 1, the ultrasound medical treatment system 10 also includes a handpiece 44 operatively connected to the end effector 12 and to an ultrasound controller 46 operatively connected to a foot-pedal power switch 47, as can be appreciated by those skilled in the art.

A first method of the invention is for ultrasound medical treatment of a patient and uses the ultrasound medical treatment system as previously described in the first, second, third or fourth expression of the first embodiment with or without the previously-described variations, etc. thereof. The first method includes steps a) through e). Step a) includes endoscopically inserting the end effector into an ear, nose, or throat of the patient. Step b) includes guiding the end effector in the patient. Step c) includes identifying patient tissue for medical treatment such as optionally at least in part from ultrasound imaging using the transducer. Other ways of identifying patient tissue for medical treatment include, without limitation, using x-rays and/or MRI imaging, as are known to the artisan. Step d) includes retaining the identified patient tissue using the tissue-retaining device. Step e) includes medically treating the retained patient tissue with ultrasound using the transducer or using the transducer and the ultrasound reflector. In one implementation, one tissue-retaining member at all times faces along a direction which is substantially parallel to the longitudinal axis of the end effector (as seen in Figures 5 and 6).

A second method of the invention is for ultrasound medical treatment of a patient and uses the ultrasound medical treatment system as previously described in the first, second, third or fourth expression of the first embodiment with or without the previously-described variations, etc. thereof. The second method includes steps a) through c). Step a) includes inserting the end effector 12 into the patient. Step b) includes retaining an intervertebral disk 48 (see Figure 3) of the patient with the tissue-retaining device, wherein the intervertebral disk 48 includes tissue. Step c) includes medically treating the retained intervertebral disk 48 with ultrasound to shrink the tissue using the transducer or using the transducer and the ultrasound reflector. In one implementation, one tissue-retaining member at all times faces along a direction which is substantially perpendicular to the longitudinal axis of the end effector (as seen in Figures 2 and 4). In one application of the second method of the invention, the intervertebral disk 48 includes connective and nerve tissue.

A third method of the invention is for ultrasound medical treatment of a patient and uses the ultrasound medical treatment system as previously described in the first, second, third or fourth expression of the first embodiment with or without the previously-described variations, etc. thereof. The third method includes steps a)

through c). Step a) includes inserting the end effector into the patient. Step b) includes retaining a joint of the patient with the tissue-retaining device, wherein the joint includes tissue. Step c) includes medically treating the retained joint with ultrasound to shrink the tissue using the transducer or using the transducer and the ultrasound reflector. In one implementation, one tissue-retaining member at all times faces along a direction which is substantially perpendicular to the longitudinal axis of the end effector (as seen in Figures 2 and 4). In one application of the third method of the invention, the joint includes connective and nerve tissue.

As previously mentioned, one application of the ultrasound medical treatment system 10 of the previously-described first through fourth expressions of the first embodiment uses the tissue-retaining device to retain a blood vessel and uses the transducer, or the transducer and the ultrasound reflector, to substantially stop the flow of blood within the blood vessel.

Referring again to the drawings, Figures 7-8 illustrate a second embodiment of the present invention which is an ultrasound medical treatment system 50 including an end effector 52 insertable into a patient. The end effector 52 includes a tissue-retaining device 54. The tissue-retaining device 54 includes a first tissue-retaining member 56 having an ultrasound imaging and medical-treatment transducer 58 and includes a second tissue-retaining member 60 having an ultrasound reflector 62. The first and second tissue-retaining members 56 and 60 are operatively connected together to retain patient tissue between the first and second tissue-restraining members and to release patient tissue so retained. The first and second tissue-retaining members 56 and 60 always maintain a substantially parallel alignment.

Advantages of having a substantially parallel alignment between the tissue-retaining members include, in one example, having the transducer and the ultrasound reflector maintain a substantially parallel alignment for improved reflected ultrasound medical treatment enhancement for any thickness of patient tissue retained by the tissue-retaining members.

In one example of the second embodiment, the first tissue-retaining member 56 is a distal end portion 64 of a first tube 66. The ultrasound medical treatment system 50 also includes a second tube 68, first and second link members 70 and 72,

and a cable 74. The second tube 68 is oriented substantially parallel to the first tube 66. The first and second link members 70 and 72 are pivotally attached to the second tissue-retaining member 60 and to the second tube 68 at pivot points 76-82 creating a hinged parallelogram defined by a proximal portion 84 of the second tissue-retaining member 60, a distal portion 86 of the second tube 68, and the first and second link members 70 and 72. The ultrasound reflector 62 is disposed at a distal portion 88 of the second tissue-retaining member 60 and faces the transducer 58. The cable 74 is operatively connected to the hinged parallelogram to move the second tissue-retaining member 60 toward and away from the first tissue-retaining member 56.

In one variation, the ultrasound medical treatment system 50 also includes an outer tube 90. The cable 74 and the first and second tubes 66 and 68 are disposed in the outer tube 90. In one modification, the ultrasound medical treatment system 50 also includes a handpiece 92. The cable 74 and the first, second, and outer tubes 66, 68 and 90 are operatively connected to the handpiece 92. In one design, the orientation of the first tube 66 about the longitudinal axis of the first tube 66 is controlled by a step motor (not shown) disposed in, and actuated by, the handpiece 92. In the same or another design, the first tube 66 is a hollow tube allowing for transducer wiring (not shown), and the second tube is a solid tube (not shown). Depending on use, the tubes 66, 68, and 90 may be rigid or flexible which also is true for any tube arrangement (specifically disclosed as rigid or flexible, or not so specifically disclosed) of any end effector and for any end effector itself of any of the previous or following embodiments of the invention.

Ultrasound Medical Treatment Using Specific Transducer Arrangements

Deployable Ultrasound Medical Transducers

Referring to the drawings, Figures 9-11 illustrate a third embodiment of the present invention. A first expression of the third embodiment of the present invention is for an ultrasound medical system 94 including a tube 96 and a plurality of resiliently flexible fingers 98. The tube 96 has a distal end 100 insertable into a patient and has a lumen 102 with a distal opening 104. The fingers 98 are

extendable out of the distal opening 104 of the lumen 102 creating a deployed state (seen in Figure 10) and which are at-least-partially retractable into the distal opening 104 of the lumen 102 creating a stowed state (seen in Figure 11). Each finger 98 includes an ultrasound transducer 106. The distance between the ultrasound transducers 106 of adjacent fingers 98 is greater in the deployed state than in the stowed state. It is noted that an ultrasound medical system is a medical system which at least provides ultrasound imaging or ultrasound medical treatment of a patient.

Advantages of the tube and extendable/retractable flexible-finger array arrangement include, when the transducers are ultrasound medical-treatment transducers having a common focal zone in the deployed state, providing faster medical treatment times by allowing for more transducer ultrasound-emitting surface area which can be simply stowed into a compact shape for transport within a patient to and from the site of patient tissue receiving ultrasound medical treatment.

In one variation, the fingers 98 are only partially retracted into the distal opening 104 of the lumen 102 in the stowed state (as seen in Figure 11). In another variation, not shown, the fingers 98 are completely retracted into the distal opening 104 of the lumen 102 in the stowed state. By the fingers 98 being extendable out of the distal opening 104 of the lumen 102 creating the deployed state and being at-least-partially retractable into the distal opening 104 of the lumen 102 creating the stowed state means the fingers 98 protrude more out of the distal opening 104 of the lumen 102 in the extended state than (if at all) in the stowed state. Mechanisms, not shown, for remotely extending and retracting fingers in a tube include, without limitation, a common shaft attached to the proximal ends of the fingers, disposed in the lumen of the tube, and spring-biased to move forward upon squeezing of a handpiece and to return backward upon relaxing of the handpiece, as is within the ordinary level of skill of the artisan. In one modification, the distal opening 104 of the lumen 102 coincides with the distal end 100 of the tube 96. In another modification, not shown, the distal opening of the lumen is spaced apart from the distal end of the tube. In one implementation, the distal opening 104 of the lumen 102 faces in the same direction as the distal end 100 of the tube 96. Other implementations are left to the artisan, such as, without limitation, the distal opening

of the lumen facing perpendicular to the distal end of the tube. In one example, at least one of the transducers 106 is an ultrasound imaging transducer. In the same or a different example, at least one of the transducers 106 is an ultrasound medical-treatment transducer. In the same or a different example, at least one of the transducers 106 is an ultrasound imaging and medical-treatment transducer.

A second expression of the third embodiment is for an ultrasound medical treatment system 108 including a tube 96 and including an end effector 110 having a plurality of fingers 98. The tube 96 has a distal end 100 insertable into a patient and has a lumen 102 with a distal opening 104. The fingers 98 are extendable out of the distal opening 104 of the lumen 102 creating a deployed state (seen in Figure 10) and are at-least-partially retractable into the distal opening 104 of the lumen 102 creating a stowed state (seen in Figure 11). Each finger 98 includes an ultrasound medical-treatment transducer 112. The distance between the ultrasound medical-treatment transducers 112 of adjacent fingers 98 is greater in the deployed state than in the stowed state.

A third expression of the third embodiment is for an ultrasound medical treatment system 108 including a tube 96 and including an end effector 110 having a plurality of fingers 98. The tube 96 has a distal end 100 insertable into a patient and has a lumen 102 with a distal opening 104. The fingers 98 are extendable out of the distal opening 104 of the lumen 102 creating a deployed state (seen in Figure 10) and are at-least-partially retractable into the distal opening 104 of the lumen 102 creating a stowed state (seen in Figure 11). Each finger 98 includes an ultrasound imaging and medical-treatment transducer 114. The distance between the ultrasound imaging and medical-treatment transducers 114 of adjacent fingers 98 is greater in the deployed state than in the stowed state.

It is noted that the variations, modifications, and implementations, etc. previously discussed for the first expression of the third embodiment are equally applicable to the second and third expressions of the third embodiment.

In one example of the first, second and third expressions of the third embodiment, the transducers 106, 112 and 114 each have an ultrasound-emitting concave surface 116. In another example, not shown, the transducers have a planar ultrasound-emitting surface. In one arrangement, each concave surface 116 is

concave as one moves along the corresponding finger 98 (as best seen in Figure 10). In another arrangement, not shown, each concave surface is concave as one moves across the corresponding finger or is concave as one moves both along and across the corresponding finger (such as, for example, with a hemispherically-concave surface). In one design, the concave surfaces 116 together have a substantially common focal zone when the fingers 98 are in the deployed state. The end effector 110 is seen with its fingers 98 facing the patient tissue 119 in Figure 10. In another design, not shown, the focal zones are not common. In one configuration, the fingers 98 define an open-hand finger array 118 in the deployed state. An alternate flexible finger arrangement in the form of a substitute end effector 120 is shown in Figure 12, wherein the fingers 122 define a clawed-hand finger array 124 in the deployed state. The substitute end effector 120 is seen with its fingers 122 surrounding the patient tissue 126 for imaging and/or medical treatment by the ultrasound transducers 128 in Figure 12. In other transducer arrangements, not shown, one or more or all of the ultrasound transducers face outward rather than facing inward.

In the same or another example of the first, second and third expressions of the third embodiment, the fingers 98 are at least four in number. In the same or yet another example of the second and third expressions of the third embodiment, the end effector 110 (as well as the substitute end effector 120) is an open-surgery end effector, an endoscopic end effector, a laparoscopic end effector (as shown in Figure 9), a catheter end effector (such as, but not limited to, an intravascular catheter end effector), or a needle end effector, as can be appreciated by those skilled in the art.

In one enablement, as shown in Figure 9, the ultrasound medical treatment system 108 also includes a handpiece 130 operatively connected to the end effector 110 and to an ultrasound controller 132 operatively connected to a foot-pedal power switch 133, as can be appreciated by those skilled in the art.

Faceted Ultrasound Medical Transducer Assembly

A fourth embodiment of the present invention is shown in Figures 13-15. A first expression of the fourth embodiment of the present invention is for an ultrasound medical system 134 including an ultrasound transducer assembly 136

insertable into a patient. The ultrasound transducer assembly 136 has a longitudinal axis 138. The ultrasound transducer assembly 136 includes a plurality P of ultrasound transducers 140. Each transducer 140 has an ultrasound-emitting surface 142 oriented at an angle of substantially 360/P degrees apart from the ultrasound-emitting surface 142 of an adjacent transducer 140 when viewed in a cross section (see Figure 15) of the transducer assembly 136 taken by a cutting plane which is perpendicular to the longitudinal axis 138.

Advantages of such a transducer configuration include, in one example, providing directed or focused medical-treatment ultrasound which is not possible with a cylindrical ultrasound transducer, as can be appreciated by those skilled in the art.

It is noted that an ultrasound transducer assembly 136 insertable into a patient is an ultrasound imaging transducer assembly, an ultrasound medical-treatment transducer assembly, or an ultrasound imaging and medical-treatment transducer assembly. An ultrasound imaging transducer assembly has at least one ultrasound imaging transducer, and an ultrasound medical-treatment transducer assembly has at least one ultrasound medical-treatment transducer. An ultrasound imaging and medical-treatment transducer assembly has at least one ultrasound imaging transducer and at least one ultrasound medical-treatment transducer or has at least one ultrasound imaging and medical-treatment transducer.

A second expression of the fourth embodiment of the present invention is for an ultrasound medical-treatment system 144 including an end effector 146 insertable into a patient. The end effector 146 includes an ultrasound medical-treatment transducer assembly 148. The ultrasound medical-treatment transducer assembly 148 has a longitudinal axis 138. The ultrasound medical-treatment transducer assembly 148 includes a plurality P of ultrasound medical-treatment transducers 150. Each transducer 150 has an ultrasound-emitting surface 142 which faces away from the longitudinal axis 138 and which is oriented at an angle of substantially 360/P degrees apart from the ultrasound-emitting surface 142 of an adjacent transducer 150 when viewed in a cross section (see Figure 15) of the transducer assembly 148 taken by a cutting plane which is perpendicular to the longitudinal

axis 138. In one example, at least one of the ultrasound medical-treatment transducers 150 is also adapted for ultrasound imaging.

A fourth method of the present invention is for ultrasound medical treatment of a patient and uses the ultrasound medical treatment system 144 as previously described in the second expression of the fourth embodiment. The fourth method includes steps a) through b). Step a) includes inserting the end effector 146 into the liver of the patient. Step b) includes medically treating a lesion in the liver with ultrasound from the ultrasound medical-treatment transducer assembly 148. In one example, step a) interstially inserts the end effector 146 into the lesion. In another example, step a) endoscopically inserts the end effector 146 into the liver through the hepato-biliary duct system.

A third expression of the fourth embodiment of the present invention is for an ultrasound medical treatment system 144 including an end effector 146 insertable into a patient. The end effector 146 includes an ultrasound imaging and medical-treatment transducer assembly 152. The ultrasound imaging and medical-treatment transducer assembly 152 has a longitudinal axis 138. The ultrasound imaging and medical-treatment transducer assembly 152 includes a plurality P of ultrasound imaging and medical-treatment transducers 154. Each transducer 154 has an ultrasound-emitting surface 142 which faces away from the longitudinal axis 138 and which is oriented at an angle of substantially 360/P degrees apart from the ultrasound-emitting surface 142 of an adjacent transducer 154 when viewed in a cross section (see Figure 15) of the transducer assembly 152 taken by a cutting plane which is perpendicular to the longitudinal axis 138.

A fifth method of the present invention is for ultrasound medical treatment of a patient and uses the ultrasound medical-treatment system 144 as previously described in the third expression of the fourth embodiment. The fourth method includes steps a) through c). Step a) includes inserting the end effector 146 into the liver of the patient. Step b) includes identifying a lesion in the liver for medical treatment at least in part from ultrasound imaging using the ultrasound imaging and medical-treatment transducer assembly 152. Step c) includes medically treating the lesion with ultrasound from the ultrasound imaging and medical-treatment transducer assembly 152. In one example, step a) interstially inserts the end effector

146 into the lesion. In another example, step a) endoscopically inserts the end effector 146 into the liver through the hepato-biliary duct system.

In one example of the previously-described first, second and third expressions of the fourth embodiment, the transducer assembly 136, 148, and 152 has a distal tip 156 and has a tip transducer 158. In one design, the tip transducer is a forward facing tip transducer. In another design, the tip transducer is a sideways facing tip transducer. In one variation, the tip transducer is an ultrasound imaging tip transducer. In another variation, the tip transducer is an ultrasound medical-treatment tip transducer. In a further variation, the tip transducer is an ultrasound imaging and medical-treatment tip transducer. In an additional variation, the tip transducer is a transponder which emits electromagnetic waves or mechanical waves or both.

In the same or a different example of the previously-described first, second and third expressions of the third embodiment, each ultrasound-emitting surface 142 is substantially straight when viewed in the cross section, as seen in Figure 15. In one variation, as seen in Figure 14, each ultrasound-emitting surface 142 has a substantially concave shape as one moves along the ultrasound-emitting surface 142 in a direction parallel to the longitudinal axis 138, and each ultrasound-emitting surface 142 has a focal zone. In a first alternate transducer arrangement seen Figure 16, each ultrasound-emitting surface 162 has a substantially planar shape. In a second alternate transducer arrangement seen in Figure 17, each ultrasound-emitting surface 164 has a substantially concave shape when viewed in the cross section, and each ultrasound-emitting surface 164 has a focal zone. In one modification, each ultrasound-emitting surface 164 also has a substantially concave shape as one moves along the ultrasound-emitting surface 164 in a direction parallel to the longitudinal axis (such as, for example, by the ultrasound-emitting surface 164 having a hemispherically-concave shape). Such ultrasound-emitting surface shapes are equally applicable to any ultrasound transducer mentioned in any other embodiment of the invention.

In the same or a different example of the previously-described first, second and third expressions of the third embodiment, P is no greater than four. In one

variation, P equals three as seen in Figures 15 and 17. In another variation, P equals two as seen in Figure 16.

In the same or a different example of the previously-described second and third expressions of the third embodiment, the end effector 146 is an open-surgery end effector, an endoscopic end effector, a laparoscopic end effector (as shown in Figure 13), a catheter end effector (such as, but not limited to, an intravascular catheter end effector), or a needle end effector, as can be appreciated by those skilled in the art. In one enablement, as shown in Figure 13, the ultrasound medical treatment system 144 also includes a handpiece 166 operatively connected to the end effector 146 and to an ultrasound controller 168 operatively connected to a foot-pedal power switch 169, as can be appreciated by the artisan.

Ultrasound Medical Treatment Applications

Excisional And Ultrasound Medical treatment System

A fifth embodiment of the present invention is shown in Figures 18-20. In a first expression of the fifth embodiment of the present invention, an ultrasound medical treatment system 170 includes a tube 172, a first end effector 174, and a second end effector 176. The tube 172 has a distal end 178 insertable into a patient 180 and has a lumen 182. The first end effector 174 has a cutting tool 184, is introducible into the lumen 182 of the inserted tube 172 from outside the patient 180, and is translatable through the lumen 182 of the inserted tube 172 to inside the patient 180. The second end effector 176 has an ultrasound medical-treatment transducer assembly 186, is introducible into the lumen 182 of the inserted tube 172 from outside the patient 180, and is translatable through the lumen 182 of the inserted tube 172 to inside the patient 180. In one variation, the first and second end effectors are introduced into the lumen through separate openings in the lumen or through separate branch channels leading to the lumen. In another variation, the first and second end effectors are introduced into the lumen through the same opening in the lumen. In one modification, a lumen opening is disposed at the end of the tube. In another modification, a lumen opening is spaced apart from the end of the tube.

A second expression of the fifth embodiment of the present invention is for an ultrasound medical treatment system 170 including a tube 172, a first end effector 174, and a second end effector 176. The tube has a distal end 178 insertable into a patient 180 and has a lumen 182 with a distal opening 188 and a proximal opening 190. The first end effector 174 has a cutting tool 184, is introducible into the proximal opening 190, and is translatable through the lumen 182 to the distal opening 188. The second end effector 176 has an ultrasound medical-treatment transducer assembly 186, is introducible into the proximal opening 190, and is translatable through the lumen 182 to the distal opening 188.

In one example of the first and second expressions of the fifth embodiment of the present invention, the lumen 182 is sized to allow introduction of only one of the first and second end effectors 174 and 176 at a time. In the same or another example, the distal end 178 of the tube 172 is interstitially insertable into patient tissue 192 of the patient 180. In the same or a different example, the cutting tool 184 is a biopsy cutting tool 194 or other excisional cutting tool.

A third expression of the fifth embodiment of the present invention is for an ultrasound medical treatment system 170 including a tube 172, a first end effector 174, and a second end effector 176. The tube 172 has a distal end 178 interstitially insertable into breast tissue 196 of a patient 180 and has a lumen 182 with a distal opening 188 and a proximal opening 190. The first end effector 174 has a biopsy cutting tool 194 (or other excisional cutting tool), is introducible into the proximal opening 190, and is translatable through the lumen 182 to the distal opening 188. The second end effector 176 has an ultrasound medical-treatment transducer assembly 186, is introducible into the proximal opening 190, and is translatable through the lumen 182 to the distal opening 188. The lumen 182 is sized to allow introduction of only one of the first and second end effectors 174 and 176 at a time. In one design, the first end effector also includes a suction mechanism to draw in patient tissue to be biopsied by the biopsy cutting tool 194. In one application, the tube 172 and the first end effector 174 (with the biopsy cutting tool 194 including a suction mechanism) are based on components of a Mammotome® Breast Biopsy System manufactured by Ethicon Endo-Surgery, Inc. (a Johnson & Johnson Company).

A sixth method of the invention is for ultrasound medical treatment of a patient 180 and uses the ultrasound medical treatment system 170 as previously described in the third expression of the fifth embodiment of the present invention. The sixth method includes steps a) through h). Step a) includes identifying possibly cancerous breast tissue 196 of the patient. Step b) includes interstitially inserting the distal end 178 of the tube 172 into the patient 180 with the distal opening 188 disposed proximate the breast tissue 196 and with the proximal opening 190 disposed outside the patient. Step c) includes introducing the first end effector 174 into the proximal opening 190 and translating the first end effector 174 through the lumen 182 to the distal opening 188. Step d) includes obtaining a biopsy sample of the breast tissue 196 with the biopsy cutting tool 194. Step e) includes removing the first end effector 174 from the lumen 182, Step f) includes introducing the second end effector 176 into the proximal opening 190 and translating the second end effector 176 through the lumen 182 to the distal opening 188. Step g) includes identifying an area of hemorrhaging in the breast tissue where the biopsy sample was obtained. Step h) includes medically treating the identified area with ultrasound using the transducer assembly 186 to substantially stop the hemorrhaging. In one application, the sixth method of the invention also includes the steps of testing the biopsy sample for cancer and substantially ablating any remaining cancer in the breast tissue with ultrasound using the transducer assembly 186. Advantages of such an ultrasound medical treatment system and method include the ease of obtaining a breast biopsy and the control of hemorrhaging caused by the biopsy procedure coupled together in a minimally invasive manner.

In a fourth expression of the fifth embodiment of the present invention, an ultrasound medical treatment system 170 includes a tube 172, a first end effector 174, and a second end effector 176. The tube 172 has a distal end 178 insertable into a patient 180 and has a lumen 182. The first end effector 174 has a cutting tool 184, is introducible into the lumen 182 of the inserted tube 172 from outside the patient 180, and is translatable through the lumen 182 of the inserted tube 172 to inside the patient 180. The second end effector 176 has an ultrasound imaging and medical-treatment transducer assembly 198, is introducible into the lumen 182 of the inserted tube 172 from outside the patient 180, and is translatable through the lumen

182 of the inserted tube 172 to inside the patient 180. In one variation, the first and second end effectors are introduced into the lumen through separate openings in the lumen or through separate branch channels leading to the lumen. In another variation, the first and second end effectors are introduced into the lumen through the same opening in the lumen. In one modification, a lumen opening is disposed at the end of the tube. In another modification, a lumen opening is spaced apart from the end of the tube.

A fifth expression of the fifth embodiment of the present invention is for an ultrasound medical treatment system 170 including a tube 172, a first end effector 174, and a second end effector 176. The tube has a distal end 178 insertable into a patient 180 and has a lumen 182 with a distal opening 188 and a proximal opening 190. The first end effector 174 has a cutting tool 184, is introducible into the proximal opening 190, and is translatable through the lumen 182 to the distal opening 188. The second end effector 176 has an ultrasound imaging and medical-treatment transducer assembly 198, is introducible into proximal opening 190, and is translatable through the lumen 182 to the distal opening 188.

In one example of the fourth and fifth expressions of the fifth embodiment of the present invention, the lumen 182 is sized to allow introduction of only one of the first and second end effectors 174 and 176 at a time. In the same or another example, the distal end 178 of the tube 172 is interstitially insertable into patient tissue 192 of the patient 180. In the same or a different example, the cutting tool 184 is a biopsy cutting tool 194 or other excisional cutting tool.

A sixth expression of the fifth embodiment of the present invention is for an ultrasound medical treatment system 170 including a tube 172, a first end effector 174, and a second end effector 176. The tube 172 has a distal end 178 interstitially insertable into breast tissue 196 of a patient 180 and has a lumen 182 with a distal opening 188 and a proximal opening 190. The first end effector 174 has a biopsy cutting tool 194 (or other excisional cutting tool), is introducible into the proximal opening 190, and is translatable through the lumen 182 to the distal opening 188. The second end effector 176 has an ultrasound imaging and medical-treatment transducer assembly 196, is introducible into the proximal opening 190, and is translatable through the lumen 182 to the distal opening 188. The lumen 182 is

sized to allow introduction of only one of the first and second end effectors 174 and 176 at a time. In one application, the tube 172 and the first end effector 174 (with the biopsy cutting tool 194 including a suction mechanism) are based on components of a Mammotome® Breast Biopsy System manufactured by Ethicon Endo-Surgery, Inc. (a Johnson & Johnson Company).

A seventh method of the invention is for ultrasound medical treatment of a patient 180 and uses the ultrasound medical treatment system 170 as previously described in the sixth expression of the fifth embodiment of the present invention. The seventh method includes steps a) through h). Step a) includes identifying possibly cancerous breast tissue 196 of the patient. Step b) includes interstitially inserting the distal end 178 of the tube 172 into the patient 180 with the distal opening 188 disposed proximate the breast tissue 196 and with the proximal opening 190 disposed outside the patient. Step c) includes introducing the first end effector 174 into the proximal opening 190 and translating the first end effector 174 through the lumen 182 to the distal opening 188. Step d) includes obtaining a biopsy sample of the breast tissue 196 with the biopsy cutting tool 194. Step e) includes removing the first end effector 174 from the lumen 182, Step f) includes introducing the second end effector 176 into the proximal opening 190 and translating the second end effector 176 through the lumen 182 to the distal opening 188. Step g) includes identifying an area of hemorrhaging in the breast tissue where the biopsy sample was obtained from ultrasound imaging using the transducer assembly 198. Step h) includes medically treating the identified area with ultrasound using the transducer assembly 198 to substantially stop the hemorrhaging. In one application, the seventh method of the invention also includes the steps of testing the biopsy sample for cancer and substantially ablating any remaining cancer in the breast tissue with ultrasound using the transducer assembly 198. Advantages of such an ultrasound medical treatment system and method include the ease of obtaining a breast biopsy and the imaging and control of hemorrhaging caused by the biopsy procedure coupled together in a minimally invasive manner.

In one enablement, as shown in Figure 18, the ultrasound medical treatment system 170 also includes a handpiece 199 which is attached to the tube 172, which contains the first end effector 174 for extending the cutting tool 184 into, and

withdrawing it from the lumen 182, and which is operatively connected to an ultrasound controller 201 via a first cable 203. The second end effector 176, in this enablement, is operatively connected to the ultrasound controller 201 via a second cable 205 and is inserted into the lumen 182 from outside the handpiece 199 as shown in Figure 18.

Staging Medical Treatment Using Ultrasound

An eighth method of the invention is shown in block diagram form in Figure 21 and is for medical treatment of a patient. The eighth method includes steps a) through f). Step a) is labeled "Obtain Transducer Assembly" in block 200 of Figure 21. Step a) includes obtaining an ultrasound imaging transducer assembly. Step b) is labeled "Insert Assembly Into Gastrointestinal Area" in block 202 of Figure 21. Step b) includes inserting the transducer assembly into a gastrointestinal area of the patient. Step c) is labeled "Guide Assembly" in block 204 of Figure 21. Step c) includes guiding the transducer assembly within the gastrointestinal area. Step d) is labeled "Identify Patient Tissue For Treatment" in block 206 of Figure 21. Step d) includes identifying patient tissue in the gastrointestinal area for medical treatment. Step e) is labeled "Stage Treatment From Ultrasound Imaging" in block 208 of Figure 21. Step e) includes staging the medical treatment from ultrasound imaging using the transducer assembly. Step f) is labeled as "Medically Treat Patient" in block 210 of Figure 21. Step f) includes medically treating the patient tissue according to the staging of step e). It is pointed out that in the eighth method the medical treatment need not include ultrasound medical treatment with the transducer assembly used for staging and/or need not include ultrasound medical treatment with any other ultrasound transducer assembly. In one procedure depending on the pathology size and site, a first transducer assembly is used endoscopically to stage the medical treatment in step e) and a second transducer assembly is used laparoscopically to medically treat the patient tissue with ultrasound in step f). In one variation, the first transducer assembly is used laparoscopically to stage the medical treatment in step e) and the second transducer assembly is used endoscopically to medically treat the patient tissue with ultrasound in step f). In another procedure, the medical treatment in step f) is radio-frequency, laser,

microwave, or chemical ablation medical treatment. Other types of medical treatment are left to the artisan.

It is noted that the gastrointestinal (GI) area of a human patient includes, without limitation, the esophagus and the stomach of the upper GI area and the rectum and the colon of the lower GI area. It further is noted that the liver is also considered to be in the GI area for purposes of this method.

By "staging the medical treatment from ultrasound imaging" is meant at least using ultrasound images to determine the three-dimensional size and shape of the patient tissue that is to receive medical treatment. For example, and without limitation, upper and lower GI tumors can be visualized with high frequency (6-30 MHz) ultrasound imaging using a cylindrical, side-firing, or half-convex ultrasound array or single-element transducer introduced endoscopically into the GI tract. All layers of the GI tract can be visualized including all layers of the esophagus, stomach, duodenum, colon, etc. In one procedure, a three-dimensional representation of the GI structures is created by collating a series of two-dimensional scans generated by axially advancing the ultrasound transducer. Any neoplastic growth, its morphological characteristics, as well as the tumor's size and shape can easily be determined from the three-dimensional representation.

Advantages of such medical-treatment staging from ultrasound imaging include, in one example, providing a non-invasive medical-treatment staging technique which has greater resolution and which is more practical compared to conventional extracorporeal medical-treatment staging techniques such as using x-rays or MRI imaging or compared to using conventional endoscopic optical techniques.

A ninth method of the invention is for ultrasound medical treatment of a patient and includes steps a) through f). The ninth method uses the same block diagram of Figure 21 as does the eighth method but with "end effector" replacing "transducer assembly" in block 200 and with "end effector" replacing "assembly" in blocks 202 and 204. Step a) includes obtaining an end effector having an ultrasound imaging and medical-treatment transducer assembly. Step b) includes inserting the end effector into a gastrointestinal area of the patient. Step c) includes guiding the transducer assembly within the gastrointestinal area. Step d) includes identifying

patient tissue in the gastrointestinal area for medical treatment. Step e) includes staging the medical treatment from ultrasound imaging using the transducer assembly. Step f) includes medically treating the patient tissue with ultrasound using the transducer assembly according to the staging of step e).

A tenth method of the invention is for ultrasound medical treatment of a patient and includes steps a) through f). The tenth method uses the same block diagram of Figure 21 as does the eighth method but with "end effector" replacing "transducer assembly" in block 200 and with "end effector" replacing "assembly" in blocks 202 and 204. Step a) includes obtaining an end effector having an ultrasound imaging and medical-treatment transducer assembly. Step b) includes inserting the end effector into a gastrointestinal area of the patient. Step c) includes guiding the transducer assembly within the gastrointestinal area. Step d) includes identifying patient tissue in the gastrointestinal area for medical treatment at least in part from ultrasound imaging using the transducer assembly. Step e) includes staging the medical treatment from ultrasound imaging using the transducer assembly. Step f) includes medically treating the patient tissue with ultrasound using the transducer assembly according to the staging of step e). In one procedure, large GI tumors are staged through a laparoscopic access to the GI area, whereby the tumors are identified, staged and treated using an end effector having an ultrasound imaging and medical-treatment transducer assembly.

In one example of the ninth and tenth methods of the invention, the patient tissue is gastroesophageal tissue containing a lesion, and step f) ultrasonically substantially ablates the lesion. In one modification, the gastroesophageal tissue contains a blood vessel supplying blood to the lesion, and step f) ultrasonically treats the blood vessel to substantially stop the supply of blood to the lesion from the blood vessel.

In another example of the ninth and tenth methods of the invention, the patient tissue is liver tissue containing a lesion and a blood vessel supplying blood to the lesion, and step f) ultrasonically treats the blood vessel to substantially stop the supply of blood to the lesion from the blood vessel.

In an additional example of the ninth and tenth methods of the invention, the patient tissue is liver tissue containing a lesion, and step f) ultrasonically

substantially ablates the lesion. In one modification, the liver tissue contains a blood vessel supplying blood to the lesion, and step f) also ultrasonically treats the blood vessel to substantially stop the supply of blood to the lesion from the blood vessel. In one procedure, an end effector having an ultrasound imaging and medical-treatment transducer assembly is introduced endoscopically into the GI tract, is advanced retrogradely through the ampulla of Vater up the common bile duct, and is advanced further into the hepatic duct system where liver parenchyma requiring medical treatment (such as cholangio-carcinomas) are identified, staged, and treated using the end effector.

Treatment Of Lung Lesions Using Ultrasound

An eleventh method of the invention is shown in block diagram form in Figure 22 and is for ultrasound medical treatment of a patient. The eleventh method includes steps a) through f). Step a) is labeled "Obtain End Effector" in block 212 of Figure 22. Step a) includes obtaining an end effector having an ultrasound medical-treatment transducer assembly. Step b) is labeled "Insert End Effector" in block 214 of Figure 22. Step b) includes inserting the end effector into the patient. Step c) is labeled "Guide End Effector To Lung" in block 216 of Figure 22. Step c) includes guiding the end effector within the patient to a lung of the patient. Step d) is labeled "Identify Lesion" in block 218 of Figure 22. Step d) includes identifying a lesion on or in the lung for medical treatment. Step e) is labeled "Position Transducer Assembly" in block 220 of Figure 22. Step e) includes positioning the transducer assembly on or in the lesion. Step f) is labeled "Medically Treat Lesion" in block 222 of Figure 22. Step f) includes medically treating the lesion with ultrasound using the transducer assembly.

A twelfth method of the invention is for ultrasound medical treatment of a patient and includes steps a) through f). The twelfth method uses the same block diagram of Figure 22 as does the eleventh method. Step a) includes obtaining an end effector having an ultrasound imaging and medical-treatment transducer assembly. Step b) includes inserting the end effector into the patient. Step c) includes guiding the end effector within the patient to a lung of the patient. Step d) includes identifying a lesion on or in the lung for medical treatment at least in part

from ultrasound imaging using the transducer assembly. Step e) includes positioning the transducer assembly on or in the lesion. Step f) includes medically treating the lesion with ultrasound using the transducer assembly.

In one example of the eleventh and twelfth methods, step f) ultrasonically substantially ablates the lesion. In one application, the end effector is an endoscopic end effector and step b) transbronchial-endoscopically inserts the end effector into the patient. In another application, the end effector is a needle end effector and step b) interstitially inserts the end effector into the patient. In one implementation, step e) positions the transducer assembly on the lesion. In another implementation, step e) positions the transducer assembly in the lesion. In one practice of the eleventh and twelfth methods, step c) a bronchoscope is used to guide the end effector to a lung of the patient.

Ultrasound medical treatment of the lung has conventionally been avoided because such ultrasound is prevented from reaching a lesion within the lung by the alveoli of the lung which contain air which reflect back most of the ultrasound preventing the ultrasound from effectively penetrating the lung to the lesion. Using higher power ultrasound for effective penetration of the lung to reach the lesion would injure or destroy the alveoli which are needed for breathing. Applicants theorized that positioning the ultrasound transducer on or in a lesion of the lung would allow ultrasound medical treatment of the lesion (such as a tumor or an infarct) without injury to the alveoli. It is noted that Applicants' method is applicable to surface lesions as well as non-surface lesions. Advantages of Applicants' eleventh and twelfth methods for ultrasound medical treatment include, in one example, the destruction of lung cancer lesions in cases which otherwise would be inoperable or incurable.

Ultrasound-Based Occlusive Procedure For Medical Treatment

A thirteenth method of the invention is shown in block diagram form in Figure 23 and is for ultrasound medical treatment of a patient. The thirteenth method includes steps a) through e). Step a) is labeled "Obtain End Effector" in block 224 of Figure 23. Step a) includes obtaining an end effector having an ultrasound medical-treatment transducer assembly. Step b) is labeled "Insert End

Effector" in block 226 of Figure 23. Step b) includes inserting the end effector into the patient. Step c) is labeled "Guide End Effector" in block 228 of Figure 23. Step c) includes guiding the end effector within the patient to a region of patient tissue containing a lesion. Step d) is labeled "Identify Blood Vessel Supplying Lesion" in block 230 of Figure 23. Step d) includes identifying a blood vessel in the region which supplies blood to the lesion. Step e) is labeled "Stop Blood Supply Using Ultrasound" in block 232 of Figure 23. Step e) includes medically treating the blood vessel with ultrasound from the transducer assembly to substantially seal the blood vessel to stop the supply of blood to the lesion from the blood vessel. One implementation of the thirteenth method of the invention also includes the step of medically treating the lesion with ultrasound from the transducer assembly to substantially ablate the lesion.

A fourteenth method of the invention is for ultrasound medical treatment of a patient and includes steps a) through g). The fourteenth method is similar to the thirteenth method. Step a) includes obtaining an end effector having an ultrasound imaging and medical-treatment transducer assembly. Step b) includes inserting the end effector into the patient. Step c) includes guiding the end effector within the patient to a region of patient tissue containing a lesion. Step d) includes identifying the lesion at least in part from ultrasound imaging using the transducer assembly. Step e) includes identifying a blood vessel in the region which supplies blood to the lesion from ultrasound imaging using the transducer assembly. Step f) includes medically treating the blood vessel with ultrasound from the transducer assembly to substantially seal the blood vessel to substantially stop the supply of blood to the lesion from the blood vessel. Step g) includes medically treating the lesion with ultrasound from the transducer assembly to substantially ablate the lesion. It is noted that Doppler ultrasound imaging alone, gray-scale ultrasound imaging alone, and a combination of Doppler and gray-scale ultrasound imaging are known ultrasound techniques to image blood flow in blood vessels.

In one application of the thirteenth and fourteenth methods, the end effector is an open-surgery end effector. In another application, the end effector is an endoscopic end effector. In a further application, the end effector is a laparoscopic end effector. In an additional application, the end effector is a catheter end effector

(such as, but not limited to, an intravascular catheter end effector). In a different application, the end effector is a needle end effector.

A broadened thirteenth method of the invention eliminates the inserting into and guiding within steps of the above-described thirteenth method and includes steps a) through c). Step a) includes obtaining an end effector having an ultrasound medical-treatment transducer assembly. Step b) includes identifying a blood vessel in the patient which supplies blood to a lesion. Step c) includes medically treating the blood vessel with ultrasound from the transducer assembly to substantially seal the blood vessel to substantially stop the supply of blood to the lesion from the blood vessel.

A broadened fourteenth method of the invention eliminates the inserting into and guiding within steps of the above-described fourteenth method and includes steps a) through e). Step a) includes obtaining an end effector having an ultrasound imaging and medical-treatment transducer assembly. Step b) includes identifying a lesion in the patient at least in part from ultrasound imaging using the transducer assembly. Step c) includes identifying a blood vessel which supplies blood to the lesion from ultrasound imaging using the transducer assembly. Step d) includes medically treating the blood vessel with ultrasound from the transducer assembly to substantially seal the blood vessel to substantially stop the supply of blood to the lesion from the blood vessel. Step e) includes medically treating the lesion with ultrasound from the transducer assembly to substantially ablate the lesion.

In one example of the broadened thirteenth and fourteenth methods, the end effector is an extracorporeal end effector. In another example, the end effector is an intracorporeal end effector. In a further example, the end effector can be used in both an extracorporeal mode and in an intracorporeal mode.

Advantages of Applicants' thirteenth and broadened thirteenth methods for ultrasound medical treatment include, in one example, the indirect destruction of cancer lesions by ultrasound hemostasis in blood vessels supplying the cancer lesions in cases which otherwise would be inoperable or incurable because the location of the cancer lesions prevents medical treatment of the lesions themselves. Advantages of Applicants' fourteenth and broadened fourteenth methods for ultrasound treatment include, in one example, direct destruction of cancer lesions by

ultrasound ablation of the cancer lesions together with the indirect destruction of any cancer lesions missed in the ultrasound ablation step by ultrasound hemostasis in blood vessels supplying blood to the missed cancer lesions.

Guiding and Targeting Ultrasound End Effectors

Guiding Ultrasound End Effector for Medical Treatment

A sixth embodiment of the present invention is shown in Figure 24. In a first expression of the sixth embodiment of the present invention, an ultrasound medical treatment system 234 (only a portion of which is shown in Figure 24) includes an end effector 236 and at least three receivers 238. The end effector 236 has a transducer assembly 240 including a transducer 242 having at least one transducer element 244 adapted for emitting medical-treatment ultrasound waves and for emitting mechanical waves. It is noted that the terminology "mechanical waves" includes ultrasound and non-ultrasound compression (acoustic) waves and ultrasound and non-ultrasound shear waves, and that waves include wave pulses. The receivers 238 are spaced apart from the transducer assembly 240, and the receivers 238 are adapted to receive the emitted mechanical waves for use in locating the position of the transducer assembly 240. Conventional methods (including triangulation methods) for locating the position of a transponder emitting waves which are received by three receivers are well known. A second expression of the sixth embodiment is identical to the first expression of the sixth embodiment except that the at-least-one transducer element 244 is also adapted for emitting imaging ultrasound waves. In one variation of the first and second expressions of the sixth embodiment, the end effector and the receivers are disposable outside (including in one modification on) the patient. In another variation, the end effector is insertable into the patient and the receivers are disposable outside (including in one modification on) the patient.

A seventh embodiment of the present invention is shown in Figure 25. In a first expression of the seventh embodiment of the present invention, an ultrasound medical treatment system 246 (only a portion of which is shown in Figure 25) includes an end effector 248 and at least three receivers 250. The end effector 248

has an ultrasound medical-treatment transducer assembly 252 and has a transponder 254 The transponder 254 is adapted to emit waves, and the waves include electromagnetic waves or mechanical waves or both. The receivers 250 are spaced apart from the transducer assembly 252, and the receivers 250 are adapted to receive the emitted waves for use in locating the position of the transponder 254. In a second expression of the seventh embodiment, the ultrasound medical-treatment transducer assembly 252 is an ultrasound imaging and medical-treatment transducer assembly 256.

In one application of the first and second expressions of the seventh embodiment, the end effector 248 is insertable into a patient, the transponder 254 is adapted to emit electromagnetic waves, and the receivers 250 are disposable outside the patient. In one variation, the receivers 250 are disposable on the patient. In another application, the end effector is disposable outside (including in one modification on) the patient and the receivers are disposable outside (including in one modification on) the patient.

In one example of the first and second expressions of the seventh embodiment, the end effector 248 is an endoscopic end effector, a laparoscopic end effector, a catheter end effector (such as, but not limited to, an intravascular catheter end effector), or a needle end effector. In one design of the first and second expressions of the seventh embodiment, the end effector 248 has a distal tip 260, and the transponder 254 is disposed at the distal tip 260 of the end effector 248. In one variation, the transducer assembly 252 and 256 is disposed proximate the transponder 254.

A fifteenth method of the invention uses the ultrasound medical treatment system of the first expression of the seventh embodiment and includes steps a) through h). Step a) includes inserting the end effector 248 into the patient. Step b) includes disposing the receivers 250 outside the patient. Step c) includes emitting electromagnetic waves from the transponder 254. Step d) includes receiving the electromagnetic waves with the disposed receivers 250. Step e) includes calculating the position of the transponder 254 from the received electromagnetic waves. Step f) includes guiding the end effector within the patient to a desired location from the calculated position of the transponder 254. Step g) includes, after step f), identifying

tissue. It is noted that, in one example, to aim a transducer assembly means to focus ultrasound energy at a particular distance from the transducer assembly and along a particular direction. Step c) is labeled "Activate Transducer Assembly" in block 266 of Figure 26. Step c) includes activating the aimed transducer assembly to emit ultrasound energy sufficient to achieve a temperature increase in the patient tissue essentially without medically affecting the patient tissue. Step d) is labeled "Detect Actual Focal Zone" in block 268 of Figure 26. Step d) includes after step c) detecting, from reflected ultrasound energy, an actual focal zone of patient tissue having a temperature increase. Step e) is labeled "Correct For Any Aiming Error" in block 269 of Figure 26. Step e) includes correcting for any error between the desired focal zone and the actual focal zone. Step f) is labeled "Medically Treat Patient Tissue" in block 270 of Figure 26. Step f) includes after step e), medically treating the patient tissue with ultrasound using the transducer assembly. In one application, step d) uses one or more additional ultrasound transducer assemblies, separate from the ultrasound transducer assembly used in steps a) through c) and e) through f), to detect, from reflected ultrasound energy, the actual focal zone. In another application, the same ultrasound transducer assembly is used for steps a) through f). In one example of the seventeenth method, the end effector is an extracorporeal end effector. In another example, the end effector is an intracorporeal end effector. In a further example, the end effector can be used in both an extracorporeal mode and in an intracorporeal mode.

An eighteenth method of the invention is for ultrasound medical treatment of a patient and includes steps a) through f). The eighteenth method uses the same block diagram of Figure 26 as does the seventeenth method. Step a) includes obtaining an end effector having an ultrasound imaging and medical-treatment transducer assembly. Step b) includes aiming the transducer assembly to focus ultrasound energy at a desired focal zone of patient tissue. Step c) includes activating the aimed transducer assembly to emit ultrasound energy sufficient to achieve a temperature increase in the patient tissue essentially without medically affecting the patient tissue. Step d) includes after step c) detecting, from reflected ultrasound energy using the transducer assembly, an actual focal zone of patient tissue having a temperature increase. Step e) includes correcting for any error

patient tissue for medical treatment. Step h) includes medically treating the identified patient tissue with ultrasound using the transducer assembly 252.

A sixteenth method of the invention uses the ultrasound medical treatment system of the second expression of the seventh embodiment and includes steps a) through h). Step a) includes inserting the end effector 248 into the patient. Step b) includes disposing the receivers 250 outside the patient. Step c) includes emitting electromagnetic waves from the transponder 254. Step d) includes receiving the electromagnetic waves with the disposed receivers 250. Step e) includes calculating the position of the transponder 254 from the received electromagnetic waves. Step f) includes guiding the end effector within the patient to a desired location from the calculated position of the transponder 254. Step g) includes, after step f), identifying patient tissue for medical treatment at least in part from ultrasound imaging using the transducer assembly 256. Step h) includes medically treating the identified patient tissue with ultrasound using the transducer assembly 256.

A known electromagnetic transponder and three-receiver system for calculating the position of the transponder and for guiding the transponder (which is attached to a heart catheter for monitoring the heart) inside a patient is the CARTO™ EP Navigation System used with a NAVI-STAR® catheter manufactured by Biosense Webster (a Johnson & Johnson Company).

Advantages of an end effector with ultrasound medical treatment and position-location capabilities include, in one example, more accurately guiding the end effector inside a patient to patient tissue for ultrasound medical treatment of the patient tissue.

Method For Aiming Ultrasound For Medical Treatment

A seventeenth method of the invention is shown in block diagram form in Figure 26 and is for ultrasound medical treatment of a patient. The seventeenth method includes steps a) through f). Step a) is labeled "Obtain End Effector" in block 262 of Figure 26. Step a) includes obtaining an end effector having an ultrasound medical-treatment transducer assembly. Step b) is labeled "Aim Transducer Assembly" in block 264 of Figure 26. Step b) includes aiming the transducer assembly to focus ultrasound energy at a desired focal zone of patient

between the desired focal zone and the actual focal zone. Step f) includes after step e), medically treating the patient tissue with ultrasound using the transducer assembly. In one example, the end effector is an extracorporeal end effector. In another example, the end effector is an intracorporeal end effector. In a further example, the end effector can be used in both an extracorporeal mode and in an intracorporeal mode.

A nineteenth method of the invention is for ultrasound medical treatment of a patient and includes steps a) through i). The nineteenth method uses the same block diagram of Figure 26 as does the seventeenth method but with three extra steps added between block 262's step a) and block 264's step b) of the seventeenth method. In the nineteenth method, step a) includes obtaining an end effector having an ultrasound imaging and medical-treatment transducer assembly. Step b) includes inserting the end effector into the patient. Step c) includes guiding the end effector inside the patient. Step d) includes identifying a desired focal zone of patient tissue at least in part from ultrasound imaging using the transducer assembly. Step e) includes aiming the transducer assembly to focus ultrasound energy at the desired focal zone of patient tissue. Step f) includes activating the aimed transducer assembly to emit ultrasound energy sufficient to achieve a temperature increase in the patient tissue essentially without medically affecting the patient tissue. Step g) includes after step f) detecting, from reflected ultrasound energy using the transducer assembly, an actual focal zone of patient tissue having a temperature increase. Step h) includes correcting for any error between the desired focal zone and the actual focal zone. Step i) includes after step h), medically treating the patient tissue with ultrasound using the transducer assembly.

In one example of the seventeenth through nineteenth methods, the end effector is an endoscopic end effector. In another example, the end effector is a laparoscopic end effector. In a further example, the end effector is a catheter end effector (such as, but not limited to, an intravascular catheter end effector). In an additional example, the end effector is a needle end effector.

It is noted that the achieved temperature increase will decrease over time so that the detected temperature increase may not exactly equal the achieved temperature increase. In one implementation of the seventeenth through nineteenth

methods, the temperature increase detected in the detecting step is equal substantially to the temperature increase achieved in the activating step. In one application of the seventeenth through nineteenth methods, the detected temperature increase is not greater than about five degrees Celsius. In one variation, the detected temperature increase is not greater than about two degrees Celsius.

It is noted that conventional methods are known to the artisan to convert ultrasound image data into temperature images. In one variation of the seventeenth through nineteenth methods, the correcting step is performed automatically by a feedback control on the same mechanism used to aim the transducer assembly in the aiming step, as can be appreciated by the artisan. As previously noted, mechanisms for aiming an ultrasound medical-treatment transducer assembly include conventional electronic and/or mechanical techniques as are known to those skilled in the art.

Advantages of correcting for any error between the desired and actual focal zones before medical treatment include more precise ultrasound medical treatment of patient tissue. In one example, better targeting maximizes the ablation of a lesion (and any appropriate margin) while minimizing medical treatment of patient tissue outside the lesion (and outside any appropriate margin).

Ultrasound Imaging Of Patient Tissue

Ultrasound Feedback In Medically-Treated Patients

A twentieth method of the invention is shown in block diagram form in Figure 27 and is for ultrasound imaging of patient tissue of a patient. The twentieth method includes steps a) through c). Step a) is labeled "Obtain A First Signal From A Location At A First Time" in block 272 of Figure 27. Step a) includes obtaining a first signal of a first imaging ultrasound wave which has been reflected back from a location in the patient tissue at a first time. Step b) is labeled "Obtain A Second Signal From The Location At A Later Second Time" in block 274 of Figure 27. Step b) includes obtaining a second signal of a second imaging ultrasound wave which has been reflected back from the location in the patient tissue at a later second time wherein the patient has received at least some medical treatment by the second

time. Step c) is labeled "Create An Image Of The Location Using The Two Signals" in block 276 of Figure 27. Step c) includes creating an image of the location using the first signal and the second signal. It is understood that the terminology "creating an image" includes, without limitation, creating an image in visual form displayed, for example, on a monitor and creating an image in electronic form which, for example, is used by a computer without being displayed in visual form on a monitor. In one enablement of the twentieth method of the invention, the image of the location is visually displayed at a pixel location on a monitor.

In one example of the twentieth method of the invention, step c) includes creating an image of the location using at least the amplitude of the first signal and the amplitude of the second signal. In one variation, step c) calculates the difference in the amplitudes between the first and second signals. In one modification, step c) uses the calculated amplitude difference and uses one of the amplitudes of one of the first and second signals. In one implementation, step c) calculates the sum of the one amplitude and a function of the calculated amplitude difference. In one illustration for a first signal amplitude of 6 and a second signal amplitude of 7, step c) calculates the amplitude difference, adds the difference to the second signal amplitude creating a processed amplitude of 8, and creates the image of the location using the processed amplitude. Other algorithms for using the amplitude of the first and second signals to enhance any amplitude difference in creating the image of the location after medical treatment are left to the artisan.

In another example of the twentieth method of the invention, step c) includes creating an image of the location using at least the phase of the first signal and the phase of the second signal. In one variation, step c) calculates the difference in the phase between the first and second signals. In one modification, step c) uses the calculated phase difference and uses one of the phases of one of the first and second signals. In one implementation, step c) calculates the sum of the one phase and a function of the calculated phase difference. In one illustration of a first signal phase of 6 degrees and a second signal phase of 7 degrees, step c) calculates the phase difference, adds the difference to the second signal phase creating a processed phase of 8 degrees, and creates the image of the location using the processed phase. Other

algorithms for using the phase of the first and second signals to enhance any phase difference in creating the image after medical treatment are left to the artisan.

In an additional example of the twentieth method of the invention, step c) includes creating an image of the location using at least the amplitude and the phase of the first signal and the amplitude and phase of the second signal. In one variation step c) combines the discussions in the previous two paragraphs, as is within the ordinary level of skill of the artisan.

In one application of the twentieth method and examples, etc. thereof, the first signal of step a) has a first frequency (e.g., a first center frequency having a sigma) and the second signal of step b) has a second frequency (e.g., a second center frequency having a sigma) which is different from the first frequency (meaning, for example, that the center frequencies are different). In the same or a different application, the medical treatment is ultrasound medical treatment. In the same or a different application, steps a) through c) are repeated for different locations to image the patient tissue, wherein the image of the patient tissue includes medically-treated locations and medically-untreated locations. In one enablement of the twentieth method of the invention, the image of the patient tissue is visually displayed on a monitor. In another enablement, the image remains as an image map in a computer without being displayed on a monitor. In one extension of the twentieth method, additional signals are obtained between steps a) and b) which are also used in creating the image of the location in step c).

Applicants were the first to realize that changes in patient tissue because of medical treatment of patient tissue, such as ultrasound medical treatment, which affect the amplitude and/or phase of ultrasound imaging signals can be used to enhance the ultrasound image differences of medically-treated patient tissue from surrounding untreated tissue. Applicants have theorized that using different frequencies for the two signals can enhance amplitude and/or phase differences for medically treated and untreated tissue and can be used to enhance the ultrasound image differences of medically-treated patient tissue from surrounding untreated tissue. Advantages of the twentieth method and examples, etc. thereof include, in one application, better ultrasound image contrast between treated and untreated patient tissue providing better monitoring during patient treatment.

Other medical treatments applicable to the twentieth method include, without limitation, other thermal ablation techniques such as radio-frequency, laser, and microwave medical treatments and chemical ablation techniques such as ethanol and chemo-therapeutics (including anti-cancer drugs). Other optional steps in the twentieth method include using signal smoothing techniques, as are known to those skilled in the art.

It is understood that any one or more of the previously-described embodiments, expressions of embodiments, examples, methods, etc. can be combined with any one or more of the other previously-described embodiments, expressions of embodiments, examples, methods, etc. For example, and without limitation, any of the end effectors can be used in any of the methods, any of the transducer arrangements can be used in any of the end effectors, and any appropriate methods can be combined such as combining the seventeenth and twentieth methods, etc.

The foregoing description of several expressions of embodiments and methods of the invention has been presented for purposes of illustration. It is not intended to be exhaustive or to limit the invention to the precise forms and procedures disclosed, and obviously many modifications and variations are possible in light of the above teaching. For example, as would be apparent to those skilled in the art, the disclosures herein of the ultrasonic systems and methods have equal application in robotic assisted surgery taking into account the obvious modifications of the invention to be compatible with such a robotic system. It is intended that the scope of the invention be defined by the claims appended hereto.

WHAT IS CLAIMED IS:

1. A method for ultrasound medical treatment of a patient comprising the steps of:

a) obtaining an end effector having an ultrasound medical-treatment transducer assembly;

b) inserting the end effector into the patient;

c) guiding the end effector within the patient to a region of patient tissue containing a lesion;

d) identifying a blood vessel in the region which supplies blood to the lesion; and

e) medically treating the blood vessel with ultrasound from the transducer assembly to substantially seal the blood vessel to substantially stop the supply of blood to the lesion from the blood vessel.

2. The method of claim 1, also including the step of medically treating the lesion with ultrasound from the transducer assembly to substantially ablate the lesion.

3. The method of claim 1, wherein the end effector is an open-surgery end effector.

4. The method of claim 1, wherein the end effector is an endoscopic end effector.

5. The method of claim 1, wherein the end effector is a laparoscopic end effector.

6. The method of claim 1, wherein the end effector is a catheter end effector.

7. The method of claim 1, wherein the end effector is a needle end effector.

8. A method for ultrasound medical treatment of a patient comprising the steps of:

a) obtaining an end effector having an ultrasound imaging and medical-treatment transducer assembly;

b) inserting the end effector into the patient;

c) guiding the end effector within the patient to a region of patient tissue containing a lesion;

d) identifying the lesion at least in part from ultrasound imaging using the transducer assembly;

e) identifying a blood vessel in the region which supplies blood to the lesion from ultrasound imaging using the transducer assembly;

f) medically treating the blood vessel with ultrasound from the transducer assembly to substantially seal the blood vessel to substantially stop the supply of blood to the lesion from the blood vessel; and

g) medically treating the lesion with ultrasound from the transducer assembly to substantially ablate the lesion.

9. The method of claim 8, wherein the end effector is an open-surgery end effector.

10. The method of claim 8, wherein the end effector is an endoscopic end effector.

11. The method of claim 8, wherein the end effector is a laparoscopic end effector.

12. The method of claim 8, wherein the end effector is a catheter end effector.

13. The method of claim 8, wherein the end effector is an interstitial end effector.

14. A method for ultrasound medical treatment of a patient comprising the steps of:

a) obtaining an end effector having an ultrasound medical-treatment transducer assembly;

b) identifying a blood vessel in the patient which supplies blood to a lesion; and

c) medically treating the blood vessel with ultrasound from the transducer assembly to substantially seal the blood vessel to substantially stop the supply of blood to the lesion from the blood vessel.

15. The method of claim 14, wherein the end effector is an extracorporeal end effector.

16. A method for ultrasound medical treatment of a patient comprising the steps of:

a) obtaining an end effector having an ultrasound imaging and medical-treatment transducer assembly;

b) identifying a lesion in the patient at least in part from ultrasound imaging using the transducer assembly;

c) identifying a blood vessel which supplies blood to the lesion from ultrasound imaging using the transducer assembly;

d) medically treating the blood vessel with ultrasound from the transducer assembly to substantially seal the blood vessel to substantially stop the supply of blood to the lesion from the blood vessel; and

e) medically treating the lesion with ultrasound from the transducer assembly to substantially ablate the lesion.

17. The method of claim 16, wherein the end effector is an extracorporeal end effector.

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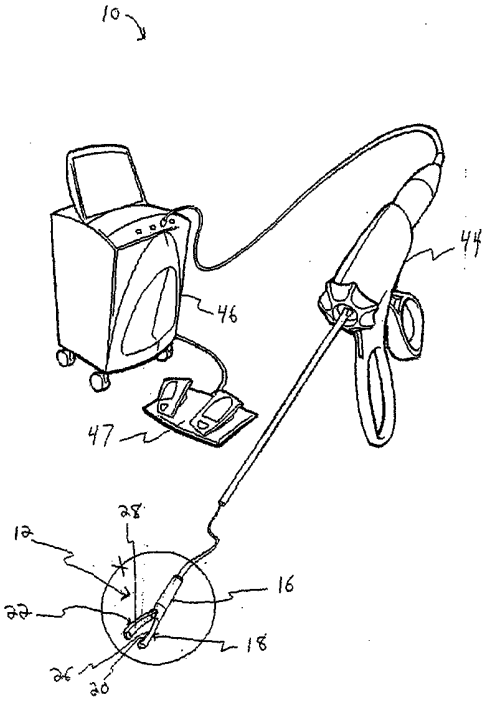

Fig. 1

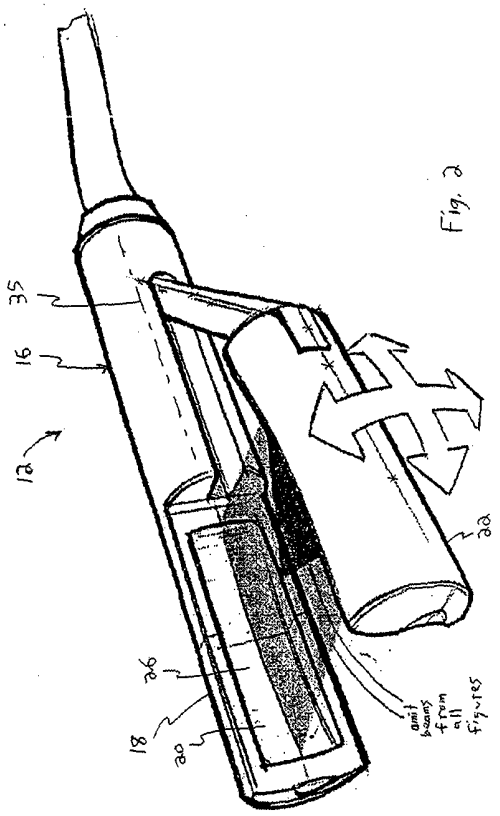
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Fig. 2
same beams from all figures

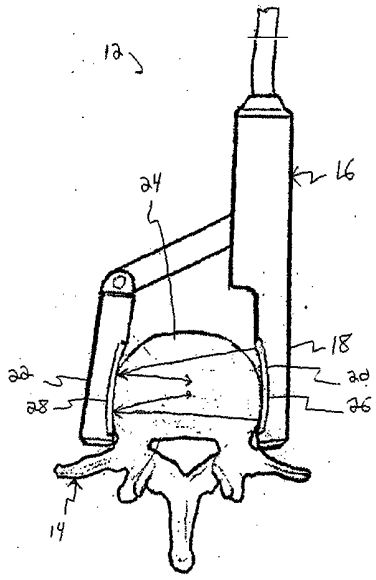

Fig. 3

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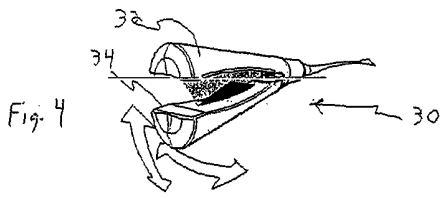

Fig. 4

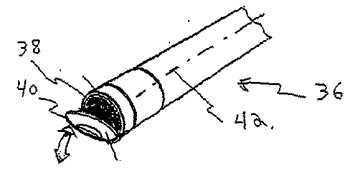

Fig. 5

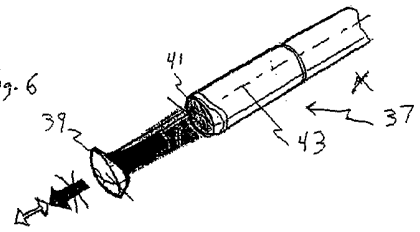

Fig. 6

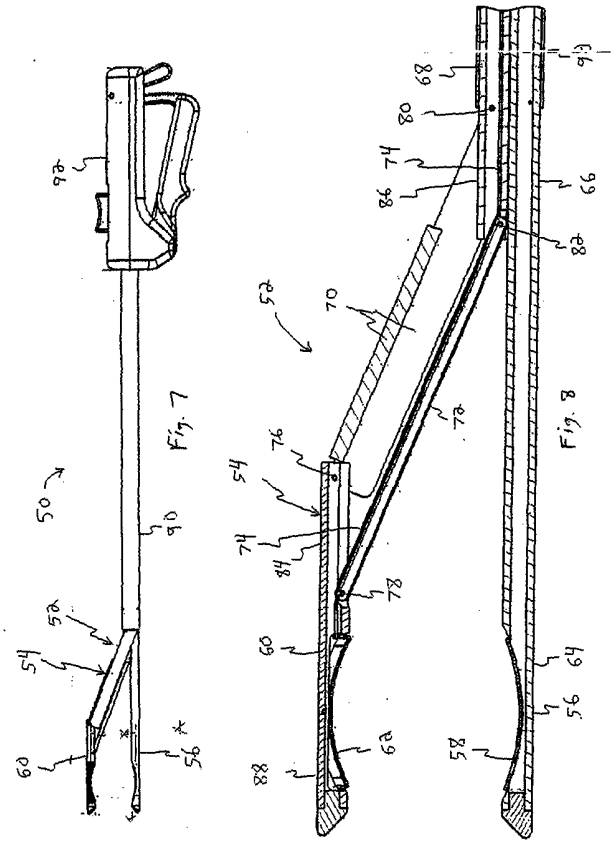
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Fig. 7
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Fig. 8

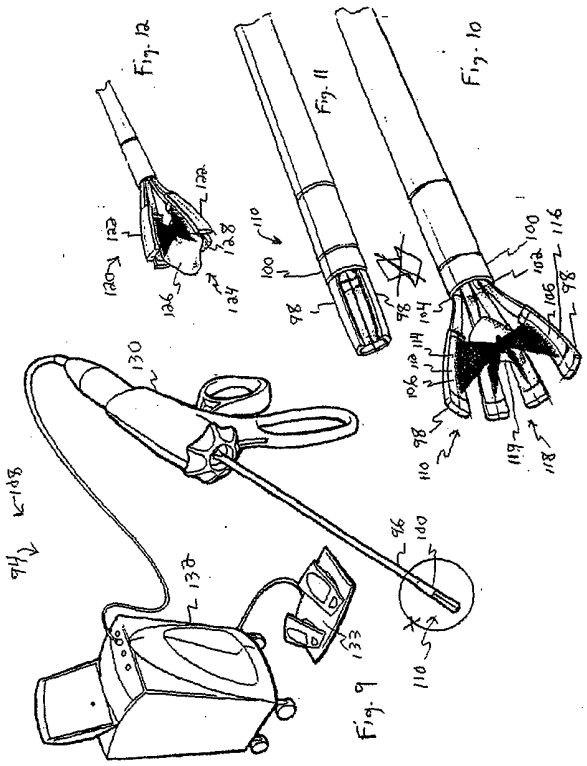
Fig. 12
Fig. 11
Fig. 10
Fig. 9
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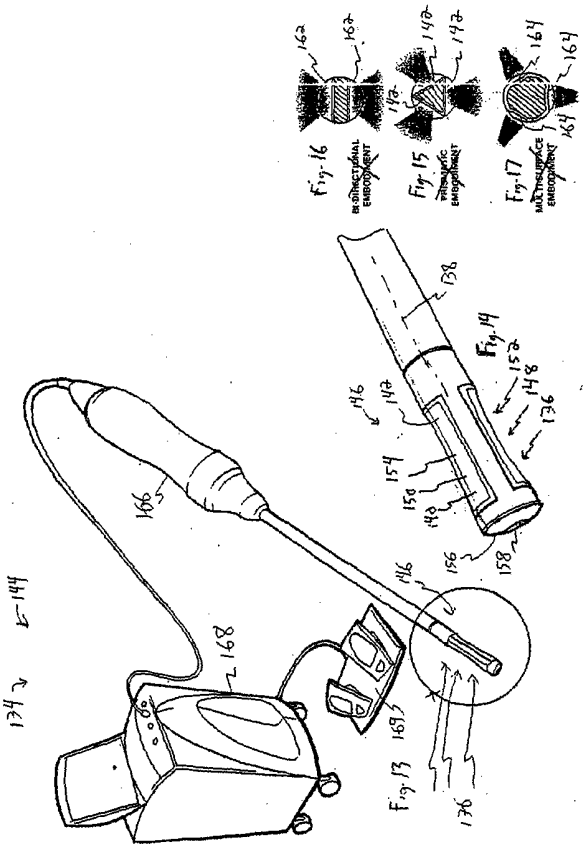


Fig. 16
BI-DIRECTIONAL EMBODIMENT
Fig. 15
UNIDIRECTIONAL EMBODIMENT
Fig. 17
MULTI-SURFACE EMBODIMENT
Fig. 14
Fig. 13

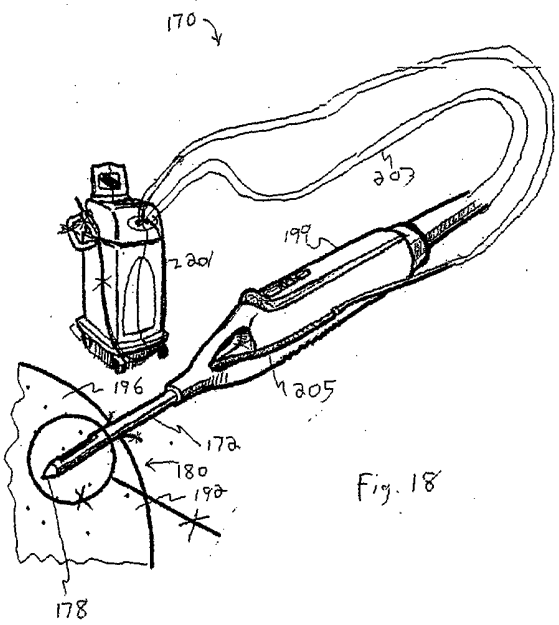


Fig. 18

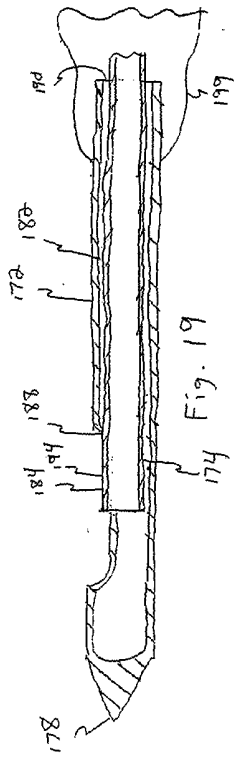


Fig. 19

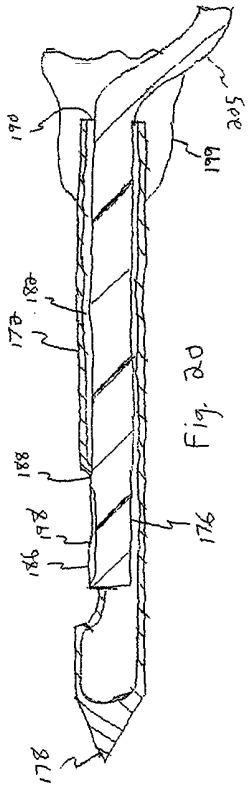
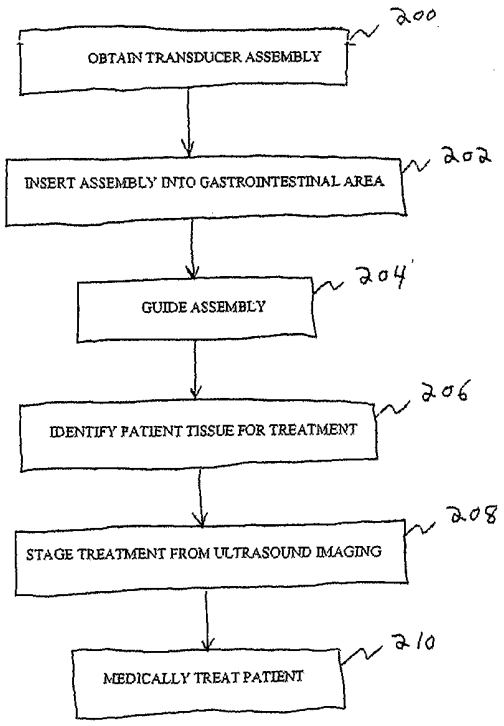


Fig. 20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GUIDE ASSEMBLY
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IDENTIFY PATIENT TISSUE FOR TREATMENT
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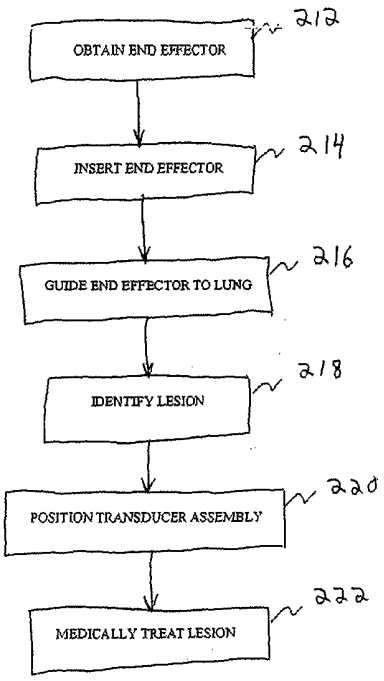
STAGE TREATMENT FROM ULTRASOUND IMAGING
208
MEDICALLY TREAT PATIENT
210

FIG. 21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GUIDE END EFFECTOR TO LUNG
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IDENTIFY LESION
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POSITION TRANSDUCER ASSEMBLY
220
MEDICALLY TREAT LESION
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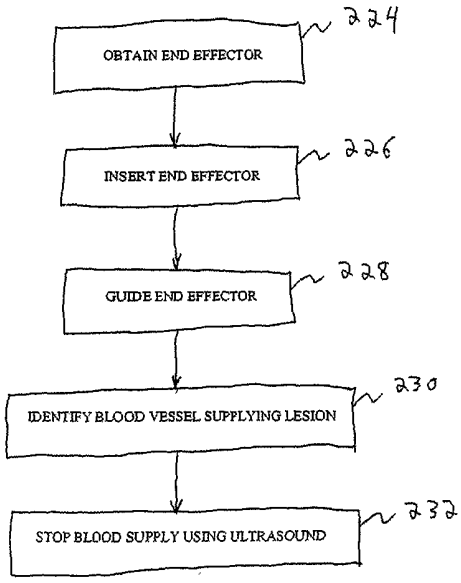
FIG. 22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INSERT END EFFECTOR
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GUIDE END EFFECTOR
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IDENTIFY BLOOD VESSEL SUPPLYING LESION
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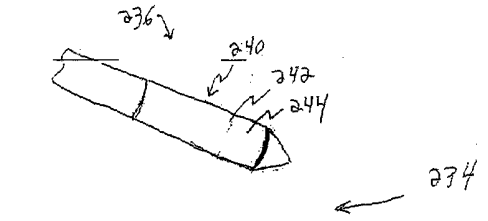
STOP BLOOD SUPPLY USING ULTRASOUND

FIG. 23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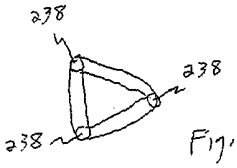
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Fig. 24

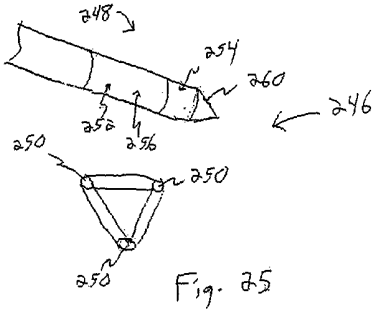
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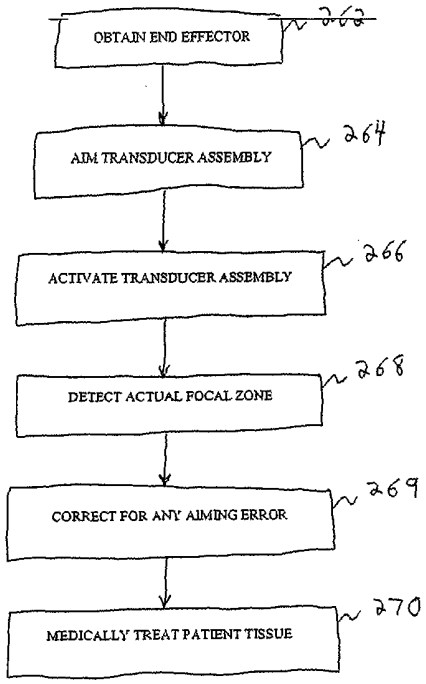
Fig. 25


OBTAIN END EFFECTOR
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AIM TRANSDUCER ASSEMBLY
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ACTIVATE TRANSDUCER ASSEMBLY
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DETECT ACTUAL FOCAL ZONE
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CORRECT FOR ANY AIMING ERROR
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MEDICALLY TREAT PATIENT TISSUE
270

FIG. 26

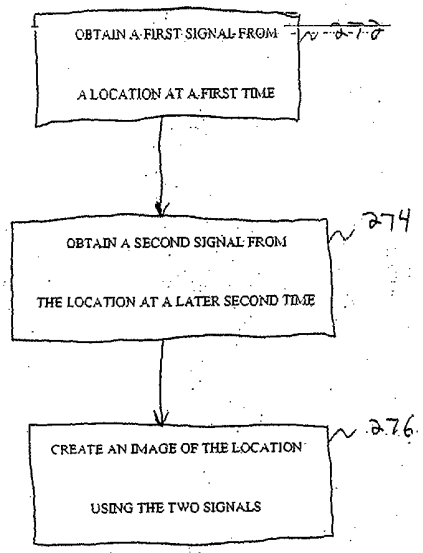
OBTAIN A FIRST SIGNAL FROM
A LOCATION AT A FIRST TIME
274
OBTAIN A SECOND SIGNAL FROM
THE LOCATION AT A LATER SECOND TIME
276
CREATE AN IMAGE OF THE LOCATION
USING THE TWO SIGNALS

FIG. 27

【国際公開パンフレット（コレクトバージョン）】

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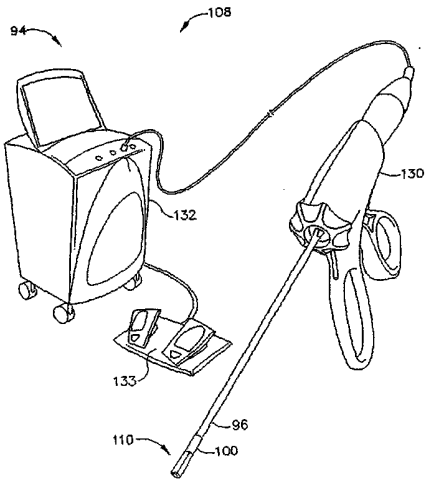
[Continued on next page]

(54) Title: ULTRASOUND-BASED OCCLUSIVE PROCEDURE FOR MEDICAL TREATMENT



(57) Abstract: A method for ultrasound medical treatment of a patient. An end effector (12) is obtained having an ultrasound medical-treatment transducer assembly (20). A blood vessel is identified in the patient which supplies blood to a lesion. The blood vessel is medically treated with ultrasound from the transducer assembly (20) to substantially seal the blood vessel to substantially stop the supply of blood to the lesion from the blood vessel. In one example, the ultrasound medical-treatment transducer assembly (20) is an ultrasound imaging and medical-treatment transducer assembly (20). In one variation, the end effector (12) is inserted into the patient. In another variation, the end effector remains outside the patient.

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A. CLASSIFICATION OF SUBJECT MATTER
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B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 606/027, 28, 29, 30, 31; 600/439; 601/2-4

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,769,790 A (WATKINS et al.) 23 June 1998, see entire document.	1-17
Y	US 5,993,389 A (DRISCOLL, Jr. et al.) 30 November 1999, see entire document.	1-17
X,P	US 6,425,867 B1 (VAEZY et al.) 30 July 2002, col. 25, line 59 - col. 26, line 29.	1-17

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

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"O" document referring to an oral disclosure, use, exhibition or other means

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"&" document member of the same patent family

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摘要(译)

超声医学治疗系统包括可插入患者体内的末端执行器。末端执行器包括组织保持装置。组织保持装置包括具有超声医疗处理换能器的第一组织保持构件，并且包括第二组织保持构件。第一和第二组织保持构件可操作地连接在一起，以将患者组织保持在第一和第二组织保持构件之间，并释放如此保留的患者组织。在一个示例中，第二组织保持构件具有超声反射器。在相同或不同的示例中，超声医学治疗换能器是超声成像和医学治疗换能器。