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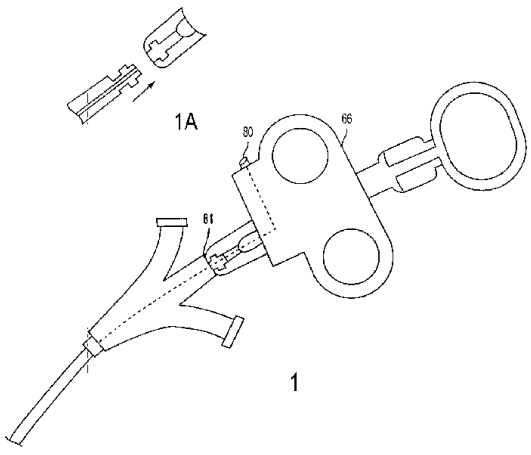
(54)【発明の名称】操舵自在な括約筋切開具およびカニューレ挿入法、乳頭切開法、ならびに、括約筋切開法

(57)【要約】
本発明は、内視鏡カニューレ挿入と、乳頭切開術と、括約筋切開術と、これらに類似する処置を実施する方法および装置に関するものである。本件技術によれば、総胆管の内視鏡カニューレ挿入と、乳頭切開術と、これらに類似する処置は、内視鏡／十二指腸内視鏡の内部へ装置を前進させ、装置の遠位先端部が、括約筋に隣接したファーテル乳頭の位置で内視鏡から外に出るようにすることにより達成される。ここで、内視鏡の機構が操作され、装置の遠位先端部を所望の位置へ配向し、胆管の適切なカニューレ挿入を行う。例えば、括約筋切開具、解剖学的部位、および、内視鏡操作の不一致のせいで、適切なカニューレ挿入のために括約筋切開具を正確かつ一貫して位置決めすることは困難である。本発明の操舵自在な括約筋切開具により、医師は内視鏡とは無関係に装置の遠位先端部の位置を制御し、装置および解剖学的部位の不一致を調整することができる。本発明によれば、切断用ワイヤを取付けているハンドルはカテーテルに対して自由に回転できる。切断ワイヤに固着されてはいるがカテーテルのシャフトに対しては回転可能であるハンド



【特許請求の範囲】
【請求項１】
患者の体内で実施される拡張処置を含む治療療法で使用する装置であって、該装置は患者体内の通路を通して方向調節されるようにしたカテーテルを備えており、前記カテーテルは近位端および遠位端と、近位端、遠位端のそれぞれに隣接した近位部、遠位部とを有しており、該装置は、第１の管腔および少なくとも第２の管腔の概ね互いに平行な管腔を更に備えており、これら管腔は近位部と遠位部の間で延びており、該装置は、第２の管腔を通って延びて近位端の位置における操作に応答して遠位部で作動するようにした、拡張処置を実施する切断用ワイヤを更に備えており、切断用ワイヤはその遠位端が第２の管腔の遠位端においてカテーテルに取付けられており、切断用ワイヤの一部はカテーテルの外側の位置では、カテーテルの遠位部の一部と同延の長さに沿って延びており、該装置は、カテーテルの近位の一点から切断用ワイヤを作動させるハンドルを更に備えており、
ハンドルをカテーテルに取付けて、ハンドルをカテーテルの近位端に対して回転させることができるようにすると同時に、切断用ワイヤの近位端と係合してこれを回転させることにより、ハンドルの回転の結果としてカテーテルの遠位部が回転するようにした、回転自在な結合部材を更に備えることを特徴とする、装置。
【請求項２】
前記カテーテルの近位端に対して前記ハンドルの更なる回転を抑止する回転ロックを更に備えていることを特徴とする、請求項１に記載の装置。
【請求項３】
前記カテーテルの近位端に対する前記ハンドルの回転量を示すように構成された回転指示器を更に備えていることを特徴とする、請求項１に記載の装置。
【請求項４】
前記回転指示器は回転量の視覚指示器であることを特徴とする、請求項３に記載の装置。
【請求項５】
前記視覚指示器は指標マーキングとこれに対応する目盛マーキングとを備えており、回転量の指示を与えるようにしたことを特徴とする、請求項４に記載の装置。
【請求項６】
前記回転指示器は、前記カテーテルの近位端に対する前記ハンドルの回転に応じて聴取可能な指示を与える装置を備えていることを特徴とする、請求項３に記載の装置。
【請求項７】
体内通路で組織を切開する方法であって、ワイヤガイドを受け入れるように構成された第１の管腔と、電子外科手術用切断ワイヤを受け入れるように構成された第２の管腔とを有するカテーテルを選択し、内視鏡を用いて肉体通路の所望の位置にカテーテルを設置し、第２の管腔で電子外科手術用切断ワイヤを作動させることを含む方法において、
カテーテルの近位端に対してハンドルを回転させることにより電子外科手術用切断ワイヤの配向を設定する工程を含んでいることを特徴とする方法。
【請求項８】
前記切断ワイヤは前記ハンドルに装着されており、ハンドルを回転させる前記工程により、切断ワイヤの近位端の回転を引き起こし、それにより、切断ワイヤが前記第２の管腔内で回転させられるようにしたことを特徴とする、請求項７に記載の方法。
【請求項９】
前記切断ワイヤの遠位端は、切断ワイヤの近位部と遠位部の中間の切断ワイヤの一部の捩れにより回転させられることを特徴とする、請求項８に記載の方法。
【請求項１０】
回転ロックに係合することにより、前記カテーテルの近位端に対して前記ハンドルの更なる回転を抑止する工程を更に含んでいることを特徴とする、請求項７に記載の方法。
【請求項１１】
回転指示器を使用することにより、前記カテーテルの近位端に対する前記ハンドルの回転量を示す工程を更に含んでいることを特徴とする、請求項７に記載の方法。

【請求項１２】
回転量を示す前記工程は回転量の視覚指示を含んでいることを特徴とする、請求項１１に記載の方法。
【請求項１３】
前記視覚指示は指標マーキングとこれに対応する目盛マーキングとを含み、回転量の指示を与えることを特徴とする、請求項１２に記載の方法。
【請求項１４】
回転量を示す前記工程は、前記カテーテルの近位端に対する前記ハンドルの回転に応じて装置により供与される聴取可能な指示器を含んでいることを特徴とする、請求項１１に記載の方法。
【請求項１５】
カテーテルハンドルであって、
カテーテルの近位端の自由な回転を許容するように構成された回転可能な結合部材と、
カテーテルに形成された管腔を通って延在している装置の近位端に係合するように構成され、ハンドルの回転により管腔内の装置の近位端を回転させるようにした締め付け部材とを備えていることを特徴とする、カテーテルハンドル。
【請求項１６】
前記装置は前記カテーテルの近位端からカテーテルの遠位端まで延在び、カテーテルの遠位端に接続されている切断ワイヤを備えていることを特徴とする、請求項１５に記載の装置。
【請求項１７】
前記カテーテルの近位端に関して前記ハンドルが回転するのを抑止するように係合可能な回転ロックを更に備えていることを特徴とする、請求項１５に記載のカテーテルハンドル。
【請求項１８】
前記カテーテルの近位端に関する前記ハンドルの回転量を示すように構成された回転指示器を更に備えていることを特徴とする、請求項１５に記載のカテーテルハンドル。
【請求項１９】
前記回転指示器は回転量の視覚指示器を備えていることを特徴とする、請求項１８に記載のカテーテルハンドル。
【請求項２０】
前記視覚指示器は指標マーキングとこれに対応する目盛マーキングとを備えており、回転量の指示を供与するようにしたことを特徴とする、請求項１９に記載のカテーテルハンドル。
【請求項２１】
前記回転指示器は前記カテーテルの近位端に対する前記ハンドルの回転に応じた聴取可能な指示を供与する装置を備えていることを特徴とする、請求項１５に記載のカテーテルハンドル。
【発明の詳細な説明】
【０００１】
【発明の属する技術分野】
本発明は一般に、樹枝状胆管系で診断や治癒療法を実施する際に有用となる装置に関するものであり、特に、胆管や樹枝状胆管系の他の部位における胆石の診断や胆石の除去を容易にするのに適した装置に関連する。
【０００２】
【従来の技術】
従来、患者個人の総胆管内へと胆石が移動する症状は、一般的な外科手術処置手順によって治療されていた。外科医は胆管を切開して胆石を除去するのを常とし、通常は、胆嚢を除去していた。近年では、切開にあまり依存しない治療療法が上述のような外科手術処置手順に取って代わり、患者の外傷を低減するとともに、長期在院や回復期間を短縮してき

た。
例えば、米国特許第４，６９６，６６８号および米国特許第４，７８１，６７７号は、その両件ともがウイルコックス（Ｗｉｌｃｏｘ）に付与されたものであるが、胆管に溶解剤を投与して胆石を本質的に溶解させる措置を含む治療療法を開示している。より詳細に述べると、カテーテルが、２個のバルーンの各々を膨張および収縮させ、胆液を排泄し、溶解剤を潅注および脱液するための複数の管腔を備えている。バルーンを膨張させると、胆管は２つの互いから間隔を設けた部位で閉塞させられ、溶解剤を受容する密封空間が設けられる。
【０００３】
残余の樹枝状胆管系からこの空間が封止されると、胆嚢底部からの胆液を除いて、溶解剤は胆嚢管を通って胆嚢および胆嚢内部の胆石に接近できる。溶解剤は胆管内胆石付近で高濃度で閉じ込められることになる。胆石が溶解した後、バルーンは収縮させられ、カテーテルを引出すことができる。この特別なアプローチでは、消化管を通る標準的な十二指腸内視鏡を利用して、カテーテルが樹枝状胆管系内へ方向調節される。このアプローチと、これに類似するアプローチは患者の外傷を最小限に抑える潜在的可能性を有しているが、かかる治療は患者体内への十二指腸内視鏡の長時間設置を必要とし、効能も明らかではなく、溶解剤に対する副作用の恐れを導く。
【０００４】
代替のアプローチでは、外科医は、少なくとも胆管の切開部を通して外科手術用の抜取り鉗子の方向調節を行い、樹枝状胆管系に挿入する。例えば、グラスマン（Ｇｌａｓｓｍａｎ）に付与された米国特許第３，１０８，５９３号では、外科医は胆管と十二指腸の両方を切開する。次いで外科医は、胆管切開部、樹枝状胆管系、オッディ括約筋、および、十二指腸を通して抜取り鉗子を方向調節し、十二指腸切開部を通して外へ出す。この抜取り鉗子は一連の長軸線方向に互いから間隔を設けたケージ部を備えており、胆管内の胆石を捕獲したり、いずれかの切開部を通して胆石を除去したりする。
ゴンザーロ（Ｇｏｎｚａｌｏ）に付与された米国特許第４，６２７，８３７号は、遠位端に１対の膨張可能なバルーンを備えたカテーテル装置を開示している。このカテーテルは胆管の切開部を通して十二指腸に向けて導かれる。遠位端のバルーンがオッディの括約筋を通過した後で、両方のバルーンが拡張してカテーテルを適所に固定する。これにより、他の管腔を通して潅注および洗浄を行って、第２のバルーンに胆石を捕獲したまま切開部を設けた胆管から外へ除去するのにカテーテルが利用できるようになる。
【０００５】
狭窄症の治療についてのまた別な療法によれば、外科医は、オッディ括約筋を拡張したり広げたりするために、胆管または十二指腸を通してカテーテル装置を挿入してもよい。例えば、キム（Ｋｉｍ）に付与された米国特許第４，７０５，０４１号は、胆管およびオッディ括約筋の切開部を通して方向調節される拡張器を開示している。拡張自在な先端部がオッディの括約筋を拡張させる。ライデル（Ｒｙｄｅｌｌ）に付与された米国特許第５，０３５，６９６号は、括約筋切開術を実施する目的で十二指腸を通して方向調節することでオッディ括約筋に向かわせられる電子外科手術機具を開示している。この装置は括約筋を切断するために加熱される切断用ワイヤを備えている。カルピエル（Ｋａｒｐｉｅｌ）に付与された米国特許第５，０２４，６１７号は、十二指腸内視鏡により方向調節することのできる同様の装置を開示している。ソーエル・ジュニア（Ｓｅｗｅｌｌ，　Ｊｒ．）に付与された米国特許第５，１５２，７７２号は、胆管の切開部を通して方向調節され、括約筋を切断するためのナイフを備えている括約筋切開術用装置を開示している。
【０００６】
ライデル特許およびカルピエル特許に例示されているような十二指腸内視鏡装置や括約筋切開装置の使用により、医師は、患者への観血介入を最小限に抑えながら、樹枝状胆管の症状を診断および治療することができるようになる。例えば、これら特許に記載されているような療法は、胆管を切開するのに必要な外科手術を排除している。その結果、これらの療法は外来または日帰り外科手術処置として実施することができる。このような処置は

患者の外傷を大いに低減し、在院期間と回復時間を短縮する。例えば、樹枝状胆管系、とりわけ、総胆管に胆石が存在していると医師が判断した場合、医師は十二指腸に十二指腸内視鏡を挿入してオッディ括約筋を目視することができる。次いで、ガイドワイヤを用いて、或いは、ガイドワイヤ用いずに、十二指腸内視鏡の作業チャネルを通して第１のカテーテルを前進させ、オッディ括約筋を通して方向調節し、樹枝状胆管系に入れる。カテーテルを通して注入された造影剤により、Ｘ線透視検査または他の画像処置手順を実施して樹枝状胆管系内に胆石が存在していることを確認することができるようになる。

【０００７】

次に医師は第１のカテーテルを第２のカテーテルと交換し、上述のライデル特許およびカルピエル特許に開示されているタイプのような括約筋切除術を実施する。続いて、第２のカテーテルに代えて、グラスマン特許に例示されているような第３のカテーテルか、何か別な同等の回収用カテーテルを用いて、拡張したオッディ括約筋を通して胆石を引出す。その後、回収用カテーテルを操作して、十二指腸内へ胆石を解放する。続いて、カテーテルと、ガイドワイヤ、および、十二指腸内視鏡を除去して、処置を完了することができる。

この処置手順は、括約筋切開術中にしか切開を行わないので、他の先行技術の処置手順に比べて患者の外傷は相当に少なくなる。しかし、現在実施されているようなこの処置手順は、３種の別個のカテーテルと２回のカテーテル交換を必要とする。このようなカテーテル交換が必要である理由として、括約筋切開術を実施し、胆石を取り除くために、第１のカテーテル、第２のカテーテル、および、第３のカテーテルが造影剤を注入するというだけの機能しかないことが挙げられる。カテーテル交換を実施するたびに必要となる時間は患者の外傷を増大させ、処置時間を長引かせ、効率を下げる恐れがある。更に、かかる処置のたびごとに、２種または３種の別個のカテーテル装置を使用することが必要となる。

【０００８】

【発明が解決するべき課題】

よって、本発明の目的は、カテーテル交換をする必要なしに、診断と治癒治療の療法を実施する装置を提供することである。

本発明のまた別な目的は、必要なカテーテルの数とカテーテル交換回数を低減する処置手順により、樹枝状胆管系から胆石を除去することができるようにした装置を提供することである。

本発明のまた別な目的は、括約筋切開術を実施し、かつ、総胆管内の胆石を除去することのできる１つのカテーテル装置を提供することである。

本発明のまた別な目的は、括約筋切開術を実施し、かつ、樹枝状胆管系に造影剤材料を注入することのできる１つのカテーテル装置を提供することである。

本発明のまた別な目的は、樹枝状胆管系に造影剤を注入して括約筋切開術を実施し、胆管内の胆石を十二指腸内に排出することのできる１つのカテーテル装置を提供することである。

【０００９】

本発明により修正することのできる現在入手可能な製品としては、ボストン・サイエンティフィック・ウルトラトーム（Ｂｏｓｔｏｎ Ｓｃｉｅｎｔｉｆｉｃ Ｕｌｔｒａｔｏｍｅ）のウルトラトームＸＩ（Ｕｌｔｒａｔｏｍｅ ＸＩ）、ストーントーム（Ｓｔｏｎｅｔｏｍｅ）、フルオロトーム（Ｆｌｏｕｒｏｔｏｍｅ）、テーパートーム（Ｔａｐｅｒｔｏｍｅ）、アールエックス・シー・チャネル・スフィンクテロトーム（ＲＸ ”Ｃ” Ｃｈａｎｎｅｌ Ｓｐｈｉｎｃｔｅｒｏｔｏｍｅ）、アールエックス・ユー・チャネル・スフィンクテロトーム（ＲＸ ”Ｕ” Ｃｈａｎｎｅｌ Ｓｐｈｉｎｃｔｅｒｏｔｏｍｅ）、および、アールエックス・テーパートーム（ＲＸ Ｔａｐｅｒｔｏｍｅ）がある。本発明により修正することのできる上記以外の製品として、ウイルソンクック・カニューレトーム（Ｗｉｌｓｏｎ Ｃｏｏｋ Ｃａｎｕｌａｔｏｍｅ）、ウイルテックス・アキュラトーム（Ｗｉｌｔｅｘ Ａｃｃｕｒａｔｏｍｅ）、バード・プロフォルマ（Ｂａｒｄ ＰｒｏＦｏｒｍａ）、および、オリンパスクレバー・クレバーカット（Ｏｌｙｍｐｕｓ Ｃｌｅｖｅｒ Ｃ

ｌｅｖｅｒｃｕｔ）がある。
【００１０】
【課題を解決する手段】
従って、本発明により、適切に設置された内視鏡によりカテーテルを通す方法が提供されるが、この方法のカテーテルは少なくとも２つの管腔を備えており、或いは、ガイドワイヤ管腔と、造影剤管腔と、切断用ワイヤ管腔の３つの管腔を備えているのが好ましく、それにより、切断用ワイヤに固着された装置のハンドルがカテーテルシャフトとは無関係に回転することができるようになり、ハンドル組立体が内視鏡位置とは無関係に遠位先端部の位置を変更するように回転させられて、総胆管のカニューレ挿入の所望の位置を達成するようにしている。回転マーキングを利用して、現在の回転量を示すことができるとともに、回転ロックを利用して、先端部の配向を維持するようにしてもよい。
本発明は括約筋切開方法も提供し、この方法により、カニューレ挿入後に、機械装置のハンドルを所望の切開位置を達成するのに必要なだけ再度回転させることができるが、切開は切断用ワイヤに電流を付与することにより実施される。回転ロックと回転マーキングを組み入れるようにしてもよい。
【００１１】
本発明によれば、２つの管腔を備えており、或いは、ガイドワイヤ管腔と、造影剤管腔と、切断ワイヤ管腔の３つの管腔を備えているのが好ましいカテーテルを有している装置も提供されるが、このカテーテルは切断用ワイヤの近位端に固定されたハンドルに回動自在に取付けられている。カテーテルの近位端は、ガイドワイヤの入口点および造影剤液の注入点を有している成形ルアーポート組立体で終端するようにしてもよい。ガイドワイヤ管腔および造影剤管腔はカテーテルの遠位端で終端する。ハンドルと、カテーテルまたは成形ルアーポート組立体は、高速かつ廉価な製造を促進するように、スナップ式に一緒に結合するような設計にされてもよい。回転ロックと回転マーキングをこの実施形態に取り入れてもよい。
本発明は、米国特許第５，５４７，４６９号、米国特許第５，８６８，６９８号、米国特許第５，６８３，３６２号、および、米国特許出願連続番号第０９／１５４，８３４号に開示された装置および方法の改良であって、これらは全てローランド（Ｒｏｗｌａｎｄ）ほかの名で出願されており、本件出願の所有者が所有しており、これらに共通する開示内容は、本件に組み入れられているとともに、これらの主題は本件後段に明示されるような発明の一部と思量される。本件の図１および図２は本件出願が最初である。従って、ローランドらの出願のオリジナルの図面１から図面９は、本件では図３から図１１になるように、図面番号を打ち直してある。
【００１２】
本発明の一観点によれば、拡張処置およびこれ以外の実施するべき処置を含む治療療法で装置を利用することができる。この装置は近位端および遠位端と近位部および遠位部を備えたカテーテルを有している。カテーテルは第１、第２、および、第３の概ね互いに平行な管腔を備えている。第１の管腔は第２の管腔および第３の管腔のいずれよりも大きな直径を有しており、これら３つの管腔は各々がカテーテルの近位部と遠位部の間で延びている。拡張処置を実施する装置は第２の管腔を通って延び、カテーテルの近位端において操作者が操作するのに応じてカテーテルの遠位末端で作動する。第１の管腔は第１の管腔に接近できるようにするための近位ポートを有しており、第３の管腔は近位ポートと、別な処置を遠隔制御できるようにするための遠位ポートとを有している。
【００１３】
本発明の別な観点によれば、樹枝状胆管系から物体を除去する装置が提供される。この装置は、十二指腸の作業チャネルおよびオッディ括約筋を通して方向調節されて樹枝状胆管系に入れられるカテーテルを備えている。カテーテルは第１の管腔、第２の管腔、および、第３の管腔を備えているが、第１の管腔は第２の管腔または第３の管腔のいずれよりも大きく、これら３つの管腔は概ね、互いに平行な軸線に沿ってカテーテルの近位部と遠位部の間に延在している。オッディ括約筋を切開する装置は切断用ワイヤを備えており、こ

のワイヤは、第２の管腔を貫いて延びているとともに、カテーテルの遠位部の一部と同延である長さに沿って遠位ポートを通るカテーテル手段から外側に延びている。ハンドルは近位部でカテーテルに取付けられているとともに、近位ワイヤ部にも取付けられており、切断用ワイヤの位置と配向とを制御するようにしている。回転ロックおよび回転マーキングを組み入れて、それぞれにより、遠位先端部の配向を固定するとともに、遠位先端部の配向を示すようにしてもよい。膨張可能なバルーンが切断用ワイヤから間隔を設けた遠位部に搭載されており、拡張されたオッディ括約筋を通して樹枝状胆管系内の胆石を除去するのに、このバルーンが第３の管腔を通して膨張させられる。

【００１４】

本発明のまた別な観点によれば、造影剤を方向調節して樹枝状胆管系内に入れ、十二指腸内視鏡の作業チャネルを通して括約筋切開術を実施する装置が提供される。この装置は、十二指腸内視鏡の作業チャネルとオッディ括約筋を通して方向調節され、樹枝状胆管系に入れられる。カテーテルは第１の管腔、第２の管腔、および、第３の管腔を備えており、第１の管腔は第２の管腔または第３の管腔のいずれよりも大きく、これら３つの管腔は概ね、互いに平行な軸線に沿ってカテーテルの近位部と遠位部の間に延びている。オッディ括約筋を切断する装置は切断用ワイヤを備えており、このワイヤは、第２の管腔を通って延びているとともに、カテーテルの遠位部の一部と同延である長さに沿って遠位ポートを通るカテーテル手段から外側で延びている。ハンドルはカテーテルに取付けられているとともに近位ワイヤ部にも取付けられており、切断用のワイヤの位置と配向を制御するようにしている。回転ロックと回転マーキングを組み入れて、それぞれにより、遠位先端部の配向を固定し、遠位先端部の配向を示すようにすることもできる。第３の管腔の近位ポートは造影剤源に接続され、第３の管腔はカテーテルの遠位端の遠位ポートを通して樹枝状胆管系に造影剤を搬入する。

【００１５】

【発明の実施の形態】

本発明の多様な目的、利点、および、新規な特性は、添付の図面に関連付けて後段の詳細な説明を読めば、より十分に明らかとなるが、図面中、同一参照番号は同一要素を示している。

図３は、造影剤を樹枝状胆管系に注入し、括約筋切開術を実施し、十二指腸に胆石を移動させることができるカテーテル装置１０を描いたものである。装置１０はカテーテル１１を有しており、このカテーテルは、明確にするために、近位端１２から遠位端１４まで延びる近位部１３を含んでおり、遠位端１４から短い距離だけ遠位部１５が延びている。典型的な応用例では、カテーテルは２００ｃｍの作業長さを有しており、遠位部１５は６ｃｍから９ｃｍの長さを有している。通常は、遠位部１５は近位端部よりも直径が小さく、その結果、遠位部１５は可撓性を増大させている。直径の低減は先端部により与えられる外傷を少なくし、先端部がより小さい通路に達することができるようにすると同時に、大きい近位端部が所要の周方向強度と剛性を備えることができるようにし、特にこの場合、近位部１３は十二指腸の作業チャネルと同延である。例えば、近位部と遠位部は、７Ｆｒカテーテル寸法と５．５ Ｆｒカテーテル寸法（すなわち、それぞれ、約２．２８６ｍｍ（０．０９インチ）と約１．７７８ｍｍ（０．０７インチ））に対応する直径を有しているようにしてもよい。

【００１６】

とりわけ図４に例示されているように、カテーテル１１は３つの管腔を備えている。第１の管腔１６は第２の管腔１７または第３の管腔２０のいずれよりも直径が大きい。或る特定の実施形態では、管腔１６は近位部１３における直径が約１．０１６ｍｍ（０．０４０インチ）であり、この寸法は遠位部１５では約０．９４ｍｍ（約０．０３７インチ）まで低減し、標準の約０．８８９ｍｍ（０．０３５インチ）のガイドワイヤを受け入れるようになっている。更に、管腔１６はカテーテル１１の中心から片寄らせた位置にある。

管腔１７および管腔２０は各々が管腔１６よりも直径が小さく、カテーテルの中心線から半径方向に片寄らせてあるとともに、互いからも片寄った位置にあり、更には、管腔１６

からも片寄らせた位置にある。或る特定の実施形態では、管腔１７および管腔２０は各々が近位部１３では約０．７１１ｍｍ（０．０２８インチ）の内径を有しており、この寸法は遠位部１５では約０．５０８ｍｍ（約０．０２０インチ）まで低減する。後述するように、この管腔２０は、括約筋切開術を実施するとともに造影剤を理に適った割合で注入できるようにする切断用ワイヤを保有する。管腔１７と管腔２０の間の角間隔は約４５度であり、第１の管腔１６と管腔１７および管腔２０の各々との間の角間隔は約１５７．５度である。この構成で上述のような寸法を利用した場合には、近位部１３は、どのような十二指腸内視鏡であれ、その作業チャネルを容易に通過する。

【００１７】

再度、図３および図４を参照すると、管腔１６、管腔１７、および、管腔２０は各々が近位部１３に入口ポートを有しているとともに、遠位部１５に出口ポートを有している。一般に、また、後段でより詳細に説明するように、第１の管腔１６は遠位端１４を通る出口ポートを有しているが、管腔１７および管腔２０の出口ポートは、特定の応用例次第で、遠位部１５のそれぞれ異なる位置に設けられてもよい。

図３では、近位端１２に隣接した位置にある近位部１３の入口ポートの１つとして入口ポート２１があるが、これは、管腔１６への接近路を設けているとともに、任意のルアーロック取付け具２２を有している。より近位に設けられた入口ポート２３は管腔１７への接近路を設けており、任意のルアーロック取付け具２４を有している。管腔２０の、より近位の入口ポート２５は、近位端１２に取付けられたハンドル２６の一部と同延で配置されている。

【００１８】

遠位部１５に注目すると、この特定の実施形態のカテーテル１１は、カテーテル１１の外部における切断用ワイヤ３１の可動域より近位で、膨張可能なバルーン３０を保持している。図５に例示されているように、管腔１７は、カテーテル１１の側面を貫く遠位出口ポート３２に出て、膨張可能なバルーン３０の内部と合流する。遠位ポート３２を越えて延びた管腔１７の延長部は公知の製造方法により封止される。その結果、ルアーロック取付け具２４に取付けられた注射器（図示せず）などにより入口ポート２３を通るように強制された流体がバルーン３０を膨張させて図５に例示されているような閉塞配向にするが、この時の膨張径は２０ｍｍまでの範囲である。

図５および図６を見れば明らかになるように、第１の管腔１６はカテーテル１１を通って延びて、遠位端１４の出口ポート３３で終端する。従って、管腔１６は入口ポート２１を通るガイドワイヤを受け入れるのに適するようになっており、このガイドワイヤがカテーテル１１を通って延びて遠位端１４から外に出て、カテーテルがガイドワイヤの上を滑動できるようにしている。

【００１９】

図６を参照すると、切断用ワイヤ３１の遠位端３４が、管腔２０の遠位端に形成されたクランプ３５に取付けられている。削り形成され、互いから間隔を設けたポート３６Ａおよび３６Ｂにより、切断用ワイヤ３１の作動部３７がカテーテル１１から削り形成された開口３６Ａを通って外に出て、カテーテル１１の外側ではカテーテルと平行に延びて、更に、ポート３６Ｂと補強スリーブ３８を通って管腔２０に戻る。次いで、切断用ワイヤ３１は管腔２０を通って図３に例示されたハンドル２６まで延びるが、図３では、切断用ワイヤは近位端部４０として現れている。

【００２０】

図３に例示されているように、ハンドル２６は親指受け（サム・リング）４２で終端している中央部材４１を備えている。中央部材４１は、互いに対向する指受け４４を備えた本体部４３を貫いて延び、この本体部に関連して滑動する。中央部材４１はカテーテル１１にも取付けられており、よって、カテーテル１１の延長部となっている。部材４３は更に内部コネクタ４５を有しており、これで切断用ワイヤ３１の近位端４０を締め付ける。従って、本体部４３が図３に例示されているように遠位位置にある場合は、カテーテルの遠位部１５は図３に例示されているような本質的に真直ぐな線を描き、この時、切断用ワイ

ヤ３１の作動部３７はカテーテル１１の真近に隣接した状態となる。本体部４３を後退させると、切断用ワイヤ３１が図３に例示されたように遠位端を上方向に屈曲させて、後段で示されるように、カテーテルの主軸に対して本質的に直角を成す位置まで来させる。
コネクタブロック４５と切断用ワイヤ３１は、ＲＦコネクタ４６によりＲＦ加熱源４７に装着された、全般的に伝導性のある部材である。このようなＲＦ加熱源４７を使用して切断用ワイヤ３１にエネルギー投与し、括約筋を切断する処理は当該技術では周知であり、本発明の装置に適合し得る１つの可能な括約筋切開処置手順を表しているが、ここではこれ以上説明しない。

【００２１】

装置の構造をこのように説明することで、特定の応用例における装置の用途を理解することができるようになる。図７は、部分切取り概略図で、オッディ括約筋５２に隣接した十二指腸５１に十二指腸内視鏡５０を設置する処理を開示している。図３のような構成にされたカテーテル１１はオッディ括約筋５２を通過して総胆管５３に入り、膵管５４を回避している。遠位端１４が胆嚢５５まで延びることはない。
遠位部１５の一連の放射線不透過性マーカー５６を利用することで、Ｘ線透視検査により適切な位置決めが行えるようになるが、この遠位端は図６のクランプ３５および補強スリーブ３８を備えていてもよい。図４、図５、および、図６に例示された管腔１６内にガイドワイヤ５７が存在していようと、存在していまいと、いずれにせよカテーテル１１の位置決めは行える。造影剤を注入するためにガイドワイヤ５７を引出して、Ｘ線透視検査のために造影剤を管腔１６を通して注入することができるようにし、１個以上の胆石５８が存在していることを確認すればよい。手術中にバルーン３０を膨張させて胆管５３を閉塞させ、十二指腸５１または膵管５４に造影剤が移動するのを阻止することも可能である。

【００２２】

図８は、十二指腸５１、オッディ括約筋５２、膵管５４の各部、および、総胆管５３を例示した拡大図である。図８では、カテーテル１１はオッディ括約筋５２の開口部を通して十二指腸内視鏡５０に対して位置決めが完了している。図３のハンドル４３は近位方向に引出され、遠位部１５が本質的に直角形状へと偏向し、切断用ワイヤ３１をオッディ括約筋５２の一部に当接させている。ここでＲＦ加熱を切開用ワイヤ３１に適用することでオッディ括約筋５２を切開し、中を貫く開口部を広げることになる。明らかに、括約筋切開術は十二指腸内視鏡によりオッディ括約筋を直接視覚化することで実施される。
更に、他の当業者によっても確認されたことであるが、ガイドワイヤ管腔と切断ワイヤ管腔を有しているカテーテルは、遠位部１５が十二指腸内視鏡から外に出ると、特定の角配向を呈する傾向にある。この配向は、カテーテルが十二指腸内視鏡に挿入された際のカテーテルの角位置とは本質的に無関係である。図４に例示されているような管腔２０の片寄せの特質により、遠位部１５がオッディ括約筋５２を通過すると、切断用ワイヤ３１の位置が改善される。特に、角度の片寄せにより、切断用ワイヤ３１は総胆管５３との整合状態がより良好となり、切断用ワイヤを膵管５４から退去させる。

【００２３】

図９は、括約筋切開術後で、かつ、カテーテル１１が使用されたとして、ガイドワイヤ５７の上を前進させられた後の、カテーテルを描いている。図９は胆管５３内の胆石５８を越えた先までバルーンが移動させられてしまった後のカテーテル１１を例示している。バルーン３０を膨張させた結果、カテーテル１１を引出すと、バルーン３０が胆石５８を移動させ、オッディ括約筋５２を通して胆石を十二指腸５１に掃き出す。
図３に例示された特定のカテーテル装置１０の説明から明らかになるように、また、図７、図８、図９に関連付けて論じたような用途からも明らかとなるように、本発明の１つのカテーテル装置で、カテーテルを交換しなくても、診断用の造影剤を注入し、括約筋切開術を実施し、総胆管または樹枝状胆管系の他の部分にある胆石を移動させることができる。更に、管腔の位置決めと寸法設定により、標準的な十二指腸内視鏡の作業チャネルで使用するのに容易に適合するようにされたカテーテル装置を用いて、上記のような諸機能を実施することができるようになる。その結果、胆管切開や、それに付随する外科手術処置

を施さなくとも、消化管を通して十二指腸内視鏡を導入することができるので、樹枝状胆管系から胆石を除去することができる。結果的に、この全処置手順が先行技術の処置手順よりもより迅速に、かつ、より少数の装置部品を用いて実施されるようになっている。正味の効果は、患者の外傷を低減し、処置手順の遂行に要する全体的時間と経費を低減することである。

【００２４】

図３では、バルーン３０は切断用ワイヤ３１の近位に置かれる。図１０は、バルーン６０が切断用ワイヤ３１の遠位に置かれた代替の実施形態を例示している。より詳細に述べると、図５および図６の管腔１７に対応している管腔１７Ａの遠位端は封止されている。削り形成された、或いは、他の様式でカテーテル１１に形成された側面出口ポート６１はバルーン６０により形成されたチャンバー６２の中に向けて開放している。バルーン６０の第１の封止部６３と第２の封止部６４は開口部６１の近位と遠位でそれぞれ接合し、チャンバー６２を密封状態にしている。

管腔１７Ａを通してバルーン膨張液を導入するとバルーン６０が膨張して、図５に例示したバルーンの配向に対応する閉塞配向になる。遠位のバルーン６０が膨張したままでカテーテル１１を後退させると、胆管から胆石を引出すことができる。この特定の実施形態は、胆石が樹枝状胆管系の高い位置にあるため、樹枝状胆管系を通して胆石を越えた先まで遠位部１５を侵入させるのが最小限で済むと判断された場合、或いは、塞栓バルーンを越えた先まで延びている遠位部１５の長さを最小限にするのが望ましいと医師が考える応用例に特に適している。

【００２５】

図１１は、オッディ括約筋を広げたり、樹枝状胆管系の狭窄部の診断および治療で利用されるように、樹枝状胆管系への造影剤の注入のような別な処置手順を実施するための、本発明の別な実施形態を開示している。この特定の実施形態では、管腔１７Ｂからの出口ポート６５は遠位部１５の遠位端１４に配置されている。ここでは、管腔１６はガイドワイヤのために使用され、管腔１７Ｂは、ガイドワイヤを適所に設置したままで、樹枝状胆管系内に造影剤を直接注入するために使用することができる。次いで、装置を設置して、処置が確かであると保証されれば、括約筋切開術を実施するのにカテーテルを交換する必要がない。

また別な代替例として、造影剤を注入するために従来のカテーテルを利用して、医師は胆石除去の必要性を判断することができる。治療の必要が既に示されている場合は、医者は図３に例示されるような装置を利用して、先に説明したように、管腔１６を通過するガイドワイヤの上で１回だけカテーテルの交換を行うことができる。

よって、本発明に従って構成された装置が本発明の複数の目的と複数の利点を達成していることが明白となる。特に、本発明に従って構成されたカテーテル装置は、カテーテルを全く交換せずに、造影剤を注入し、括約筋切開術を実施し、更に、広げたオッディ括約筋を通して総胆管から十二指腸へ胆石を移動させることができる。更に、この装置により、上述のような処置手順を十二指腸内視鏡によって行うことで、患者の外傷を最小限に抑えることができるようにする。カテーテルの交換を行わずに１つのカテーテルのみを使用することで、多数の１機能カテーテル装置を使用したのに付随する時間と経費が更に低減される。

【００２６】

先の説明から明らかなように、特に開示された実施形態に対して多くの変更を行うことができる。異なるバルーン構造を利用し、代替の位置に配置するようにしてもよい。異なる切断用ワイヤの実施形態や異なる配向を利用することもできる。従って、本発明は或る実施形態に関して開示されてきたが、本発明から逸脱しなければ、開示された装置に多数の修正を行うことができることも明らかである。特に、先の実施形態は全てが、切断用ワイヤには固定されているがカテーテルに対しては回転自在であるハンドルに関連づけて利用されてもよいものと思量される。切断用ワイヤ、および／または、回転の量を示す回転マーキングの配向を固定する回転ロックも本発明に含めてもよい。よって、本発明の真の精

神および範囲に入るような変更例や修正例を全て網羅することが、前掲の特許請求の範囲の意図である。

【００２７】

これと矛盾することなく、ローランドらの特許および出願で請求項に記載された下記の主題は、本発明に特有の主題と関連づけて請求項に特に記載されており、ローランドの主題とはすなわち、切断用ワイヤには固定されているが、カテーテルのシャフトに対しては回転自在であるハンドルであって、カテーテルとは無関係にハンドルを回転させ、かつ、内視鏡とも無関係にハンドルを回転させると、装置の遠位先端部が内視鏡とは無関係に回転し、外科手術人員らは、カニューレ挿入とその後の括約筋切開術について、装置の位置をより良好に制御できるようになる、という点である。切断用ワイヤ、および／または、回転の量を示す回転マーキングの配向を固定する回転ロックも本発明に含めてもよい。

【００２８】

括約筋切開術、解剖学的処置、内視鏡操作においては矛盾が生じるため、適切なカニューレ挿入を行うために括約筋切開具を正確かつ一貫して位置決めすることは困難である。本発明の操舵自在な括約筋切開具により、医師は内視鏡とは無関係に装置の遠位先端部の位置を制御し、また、装置と解剖学的部位についての矛盾を調整することができる。本発明によれば、切断用ワイヤを取付けているハンドルはカテーテルに対して自由に回転できる。本発明のハンドルを回転させることで取付け済みの切断用ワイヤに捩れを誘発し、これによって、取付けたカテーテルの近位端を回転させずに遠位端の配向を整えることができる。図１および図２を参照のこと。８０の位置で切断用ワイヤに固着されてはいるが、８１の位置でカテーテルのシャフトに対して回転できるハンドル６６は、ワイヤを回転させながら装置先端部を回転させる力を伝達する機構を提供している。ハンドルが近位端のシャフトとは無関係に回転すると、シャフト全体に捩れを生じることなく、遠位先端部に直接的に力を付与することができる。また、先端部の配向を維持するための回転ロック、および／または、回転の量を示すための回転マーキングが備わっていてもよい。２種および３種の管腔カテーテルのための一体型成形ルアーポート組立体を設けて回動自在ハンドルにスナップ式に嵌合させ、図１および図１ａに例示されているように、迅速かつ経済的な製造を促進するようにしてもよい。代替例として、先行技術の直列式管腔ポートを、図２に例示されているように、回動自在ハンドルにスナップ式に嵌合するように構成することもできる。

【００２９】

図１２を参照すると、本発明は、回転ロックとして公知の特性も備えている。回転ロック６８により、ユーザーは常時、先端部の配向を維持することができる。これは、ハンドルを回転させ終えた後で分岐コネクタに対してハンドル６６の位置を維持することにより実施される。回転ロック６８により、ユーザーは処置手順の最中は常時、ハンドル６６を解放することができるようになると同時に、ロックが係合したままである間はハンドル６６の配向を維持して、それ以上の回転を阻止することができる。ハンドル６６の位置を維持することで、遠位先端部の配向を所望の配向に維持する。遠位先端部の配向を維持することで、遠位先端部が動かされた場合でも、カニューレ挿入に必要な時間と労力の量を低減する。遠位先端部が思いがけず移動するのを防止することで、患者が傷を受けることも防止することができる。

【００３０】

図１３を参照すると、この回転ロックを設けるために、２対の互いに嵌合する移動止め６９とスロット７０を利用することができる。移動止め６９とスロット７０は本体７１の中央軸線に沿って、本体７１と分岐コネクタ６７の交差点に配置されている。図１３では、２対の移動止め６９とスロット７０は中央軸線に関して互いに１８０度離されている。これにより、ハンドル６６の半回転ごとにロック位置が設けられる。装置を使用している最中は、ハンドル６６が回転させられると、移動止め６９がスロット７０から切離される。移動止め６９は、切離されると、僅かだけ縮む。ハンドル６６が回転を開始した位置から１８０度の位置に達すると、移動止め６９は縮んだ状態から回復し、再度、スロット７０

と係合する。移動止め６９が或る位置から次の位置へ横断すると、互いに嵌合した部品の間に相当な量の摩擦が生じる。この摩擦は、遠位先端部の配向位置を失う恐れもなく、常時、ハンドルを解放することができる程度に十分に強い。

【００３１】

カテーテルが梱包材から取り出され、内視鏡に挿入され、内視鏡により操作されている間、回転ロック６８は遠位先端部をホームポジションにロックし続けるという二次的機能も果たす。この特性が無ければ、遠位先端部の初期配向は予想できない状態になってしまう。図１３ａは、移動止め６９とスロット７０の間の相互作用を詳細に描いた図である。図１４を参照すると、移動止め６９とスロット７０が係合状態にある場合、分岐コネクタ６７と指受け（フィンガー・リング）４４は全て同一平面上にある。これが回転マーカーとして作用する。指受け４４が分岐コネクタ６７と同一平面へと回転する時はいつでも、回転ロックが係合し、従って、直前の位置から１８０度回転したことの合図となる。このようなマーカーの利用により、ユーザーは、ハンドル６６がどれくらい回転させられたかを一層容易に追跡し続けることができる。ユーザーが遠位先端部を元の位置へ逆戻しさせたい場合には、これが役立つ。実際に、ユーザーには、例えば、ハンドル６６が元の位置から３刻みの回転を完了したことが分かる。よって、ハンドル６６を元の位置に戻すには、ハンドルを反対方向に３刻み回転させなければならない。

【００３２】

図１５ａから図１５ｄは回転ロック６８の代替の実施形態を示している。図１５ａは純正な摩擦ロックを例示している。分岐コネクタ６９のハンドル６６への接続部は、回転ロック６８が純粋に２つの部品の間の摩擦干渉の機能部分となるように設計することができる。代替の実施形態は、この摩擦を設けるために様々なタイプの組立て接合部を備えていてもよい。主たる実施形態では、２つの構成要素の組立体は、分岐コネクタの雄ポストを同一寸法および同一形状の雌ホールと嵌合させることにより達成される。代替の実施形態はこれを逆転させて、雄突出部材がハンドル６６の主要本体の一部となるようにすることができる。摩擦ロックは主要本体部と分岐コネクタの各嵌合面に備えつきられていてもよく、この場合、主要軸線に直交した状態となる。図１６ａは、図１５ａの線Ｚ－Ｚに沿った回転ロックの断面を例示している。

【００３３】

図１５ｂは本発明の楕円形ポストロックの実施例を示している。分岐コネクタ６７のハンドル６６への接続部も、楕円形に成形された雄ポスト７３と雌ホール７２を組み入れて設計することができる。この実施形態では、ハンドル６６が分岐コネクタ６７に対して回転させられると、楕円形に成形されたホール７２が変形し、楕円形ポスト７３が回転することができるようになる。ハンドル６６が１８０度回転した位置に達すると、楕円形に成形されたホール７２はその元の形状に戻ろうとし、従って、ハンドル６６を適所にロックする。図１５ｃおよび図１５ｄに例示されているように、この基本的概念を伸展させて、図１５ｂに例示されているような楕円形とは異なる形状を組み入れるようにしてもよい。当業者ならば、各ロック位置同士の間の回転角度を外表面の形状が支配することを正しく認識するだろう。例えば、ポスト７３と楕円形に成形されたホール７２の形状が互いに嵌合する正三角形から成っていた場合（図１５ｃ）ロック位置同士の間に１２０度の回転角度が存在することになる。正方形の形状を利用した場合は（図１５ｄ）、ロック位置とロック位置の間には９０度の角度が設けられる。図１６ｂは図１５ｂの線Ｙ－Ｙに沿った断面領域を例示している。図１６ｃは図１５ｃの線Ｘ－Ｘに沿った断面領域を例示しており、図１６ｄは図１５ｄの線Ｗ－Ｗ切片に沿った断面領域を例示している。

【００３４】

図１７ａから図１７ｃは本発明の代替の実施形態を例示しており、ここでは、回転マーカーが設けられ、本発明に含められてもよい。当業者ならば、これらの実施形態を伸展させることができることを理解するだろう。ハンドル６６が元の位置、および／または、直前の位置から厳密にはどのぐらい回転させられたかをユーザーが知るのを助けるために、視覚マーカーの幾つかの様式がこの設計に組み入れられてもよい。或る代替の実施形態は、

主要軸線の周囲の、主要本体と分岐コネクタ６７が出会う領域で（図１７ａ）放射方向に設置された１組の線を含んでいる。静止構成要素上の、すなわち、分岐コネクタ６７上の一本の線が本体４３上の対応する線と付合わされる。ハンドル６６が分岐コネクタ６７に対して回転させられると、本体上の一連の線が分岐コネクタ６７上の静止線を越えて回転する。線は各々が移動の増分量を示している。例えば、４本の等間隔の線が本体部にあった場合は、分岐コネクタ上のマーカーを通り越した線は各々が９０度の回転を意味している。

【００３５】

この特性は多数の方法により更に向上させることができる。線の代わりに連続する数字を利用して回転の量を示すこともできる（図１７ｂ）。交互に現れる色を利用して回転量を示すこともできる。交互に現れる線のパターンも同様に利用できる（図１７ｃ）。

また別な代替の実施形態は聴取可能な音を利用して、回転量をユーザーに知らせることができる。これを実施する方法として、１刻みが本体の回転軌跡に沿った所定の各点で明瞭に聴き取れるように、回転ロック特性を設計することができる。

【００３６】

図１８ａおよび図１８ｂを参照すると、幾つかの代替の手段が示されており、これにより、分岐コネクタを設けることができる。当業者なら、このような実施例は本願に提示された実施例から伸展させてできることを理解するだろう。

本発明は２つの管腔を備えたコネクタから構成されているが、コネクタ設計は３種以上の管腔を収容するように容易に修正することができる（図１８ａ）。これにより、将来の設計ではガイドワイヤポストコネクタ７４と注入ポートコネクタ７５の両方を１つの構成要素として組み入れることができるようになる。

このような設計の分岐コネクタのまた別な代替例として、電気コネクタ７６を収容したものがある（図１８ｂ）。電気コネクタ７６は、ここでは指受けに組み込まれているが、分岐コネクタに移転させることもできる。

【００３７】

ここで図１９ａおよび図１９ｂを参照すると、本発明の別な実施形態は、前述のものに類似しているが、弓状ロックを付加したハンドル６６を備えていてもよい。弓状ロックは、ハンドル６６を常時解放することができて、カテーテル先端部が弓状に曲った位置を維持するという点で、ユーザーの助けとなる。回転ロックがより安全でより効率のよい処置を提供しているのと同じように、弓状ロックも同様の効果を提供する。

弓状ロックは多くの方法で設計に組み入れることができる。最も簡単な様式では、弓状ロックは指受け４４と主要本体４３の間に設けられた摩擦ロック７７から構成される（図１９ａ）。この設計の代替案では、類似の摩擦ロックを設けているが、ワイヤ終端部７８と主要本体４３の間の表面を利用することになる（図１９ｂ）。図１９ｂに例示された摩擦ロックは、幾つかのロックリブ７９を組み入れることにより性能向上させられている。ロックリブ７９を利用して、特別な所定の角度でカテーテル先端部を保持することになる。実際には、ハンドル６６を第１の位置にロックすると、例えば、先端を３０度だけ偏向させることになる。次の位置は先端を６０度偏向させる。この特性により、カテーテル先端部を解剖学的部位の内部に位置決めする際にユーザーは一層の制御を行えるようになる。いずれの事例についても、指受け４４は主要本体４３に沿って作動され、カテーテル先端部８０は弓状に屈曲し、互いに嵌合する構成要素間の摩擦によりハンドルの位置を保ち、従って、弓状部の位置を保持することになる。

【図面の簡単な説明】

【図１】回動自在なハンドルが切断用ワイヤに取付けられた、本発明に従って構成された装置の一実施形態の平面図であり、図１ａは図１の装置のハンドル接続部のスナップ部材の平面図である。

【図２】本発明の回動自在ハンドルの代替の実施形態の図である。

【図３】本発明に従って構成された装置の一実施形態の平面図である。

【図４】図３の線２－２に沿って破断された断面図である。

【図５】図４の線３－３に沿って破断された断面図である。
【図６】図５の線４－４に沿って破断された断面図である。
【図７】十二指腸内視鏡を通して位置決めされて、樹枝状胆管系に造影剤を注入するための図３の装置を描いた図である。
【図８】括約筋切開術を実施するための図３の装置の配向を描いた拡大図である。
【図９】十二指腸内視鏡を通して位置決めされて、総胆管内の材料を移動させるための図３の装置を描いた図である。
【図１０】概ね図４の線３－３に沿って見た場合の、装置の代替の実施形態の断面図である。
【図１１】図４の線３－３に沿って破断された、本発明の別な実施形態の断面図である。
【図１２】回転ロックを備えている本発明の回動自在ハンドルの図である。
【図１３】図１２の回転ロックの詳細図である。
【図１３ａ】図１３の線Ａ－Ａに沿った断面図である。
【図１４】回動自在ハンドルと分岐コネクタとの間の整合状態を示し、回転自在ハンドルの回転がゼロである状態を例示した図である。
【図１５ａ】本発明の回転ロックの代替の実施例を示す図である。
【図１５ｂ】本発明の回転ロックの代替の実施例を示す図である。
【図１５ｃ】本発明の回転ロックの代替の実施例を示す図である。
【図１５ｄ】本発明の回転ロックの代替の実施例を示す図である。
【図１６ａ】図１５ａの代替の実施形態の断面領域を示す図である。
【図１６ｂ】図１５ｂの代替の実施形態の断面領域を示す図である。
【図１６ｃ】図１５ｃの代替の実施形態の断面領域を示す図である。
【図１６ｄ】図１５ｄの代替の実施形態の断面領域を示す図である。
【図１７ａ】本発明の回転マーキングの３つの代替の実施形態を示す図である。
【図１７ｂ】本発明の回転マーキングの３つの代替の実施形態を示す図である。
【図１７ｃ】本発明の回転マーキングの３つの代替の実施形態を示す図である。
【図１８ａ】分岐コネクタの代替例を例示した図である。
【図１８ｂ】分岐コネクタの代替例を例示した図である。
【図１９ａ】本発明に含まれたの弓状ロックを例示した図である。
【図１９ｂ】本発明に含まれたの弓状ロックを例示した図である。

【図３】

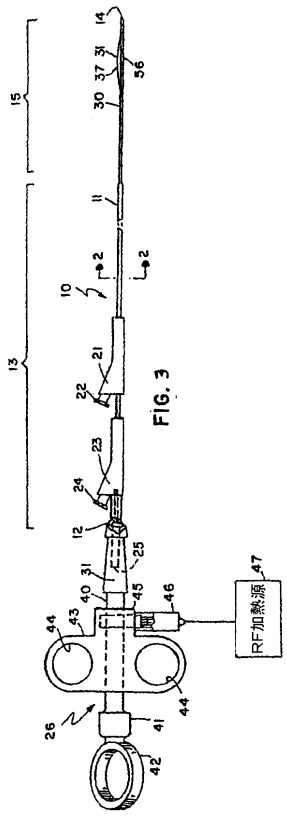
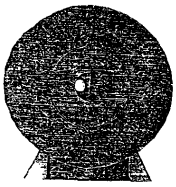


FIG. 3

【図１３ａ】



A－A破断断面

FIG 13A

【図１５ａ】

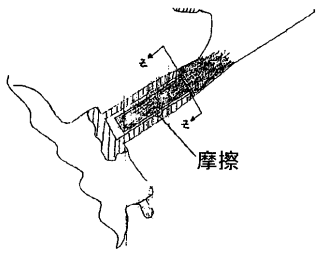


Fig. 15a

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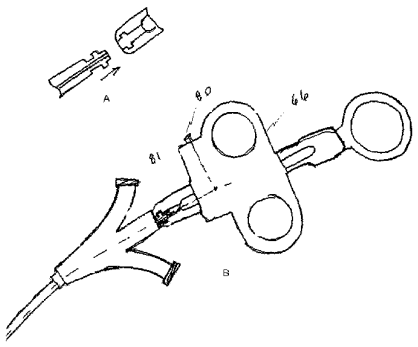
[Continued on next page]

(54) Title: STEERABLE SPHINCTEROTOME AND METHODS FOR CANNULATION, PAPILLOTOMY AND SPHINCTEROTOMY



(57) Abstract: The present invention relates to methods and devices for performing endoscopic cannulation, papillotomy and sphincterotomy and similar procedures. According to the present state of the art, endoscopic cannulation of the common bile duct and papillotomy and similar procedures are accomplished by advancing the device into an endoscope/duodenoscope so that the distal tip of the device exits the endoscope adjacent the sphincter muscles at the Papilla of Vater. The endoscope mechanisms are then manipulated to orient the distal tip of the device to the desired position for proper cannulation of the duct. Due to inconsistencies in, for example, the sphincterotome, anatomy, and endoscope manipulation, it is difficult to accurately and consistently position the sphincterotome for proper cannulation. The steerable sphincterotome of the present invention allows the physician to control the position of the distal tip of the device independently of the endoscope and adjust for inconsistencies in the device and the anatomy. According to the present invention, the handle to which the cutting wire is attached is freely rotatable relative to the catheter. The handle, secured to the cutting wire but rotatable relative to the shaft of the catheter, provides a mechanism to rotate the wire, transmitting the force to rotate the device tip. With the handle rotating independently of the shaft at the proximal end, the force can be applied directly to the distal tip without twisting the entire shaft. Also a rotation lock to maintain the orientation of the tip and/or a rotation marking, to indicate the amount of rotation may be included.

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Steerable Sphincterotome and Methods for Cannulation, Papillotomy and Sphincterotomy

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention generally relates to apparatus that is useful in performing diagnostic and therapeutic modalities in the biliary tree and more particularly to apparatus that is adapted for facilitating the diagnosis of gallstones in the bile duct and other portions of the biliary tree and the removal of such gallstones.

2. Description of Related Art

Historically the migration of gallstones into an individual's common bile duct was corrected by general surgical procedures. A surgeon would incise the bile duct and remove the gallstones and normally remove the gallbladder. In recent years less invasive treatment modalities have replaced these general surgical procedures and reduced patient trauma, long hospital stays and recovery periods.

For example, U.S. Pat. No. 4,696,668 and U.S. Pat. No. 4,781,677, both to Wilcox, disclose a treatment modality involving the administration of a dissolution agent in the bile duct to essentially dissolve any gallstones. More specifically, a catheter contains several lumens for inflating and deflating each of two balloons, venting bile, and infusing and aspirating the dissolution agent. Inflating the balloons occludes the bile duct at two spaced sites and creates a sealed spaced that receives the dissolution agent. As the space is sealed from the remaining biliary tree, the dissolution agent finds access to the gallbladder and any gallstones therein through the cystic duct with the exclusion of bile from the gallbladder fundus. The dissolution agent also will be confined in high concentration around bile duct gallstones. After the gallstones dissolve the balloons are deflated and the catheter can be withdrawn. In this particular approach, the catheter is directed into the biliary tree using a standard duodenoscope that passes through the alimentary tract. Although this and analogous approaches have the potential of minimizing patient trauma, such treatments require extended placement of the

duodenoscope in the patient, exhibit low efficacy and introduce a potential for adverse reactions to the dissolution agents.

In an alternative approach, a surgeon directs a surgical extractor into the biliary tree through at least an incision in the bile duct. For example, in U.S. Pat. No. 3,108,593 to Glassman a surgeon incises both the bile duct and duodenum. Then the surgeon directs an extractor through the bile duct incision, biliary tree, sphincter of Oddi and duodenum to exit through the duodenum incision. This extractor includes a series of longitudinally spaced cages for trapping any gallstones in the bile duct and removing them through either of the incisions.

U.S. Pat. No. 4,627,837 to Gonzalo discloses a catheter device with a pair of inflatable balloons at its distal end. This catheter is led through an incision in the bile duct toward the duodenum. After the distal balloon passes through the sphincter of Oddi, both balloons are expanded to anchor the catheter in place. This enables the catheter to be used for irrigating and flushing through other lumens in order to capture any gallstone in the second balloon for removal through the incised bile duct.

In accordance with still another modality as for the treatment of strictures, a surgeon may insert a catheter device through the bile duct or duodenum for the purpose of dilating or enlarging the sphincter of Oddi. For example, U.S. Pat. No. 4,705,041 to Kim discloses a dilator that is directed through an incision in the bile duct and the sphincter of Oddi. An expandable tip dilates the sphincter of Oddi. U.S. Pat. No. 5,035,696 to Rydell discloses an electrosurgical instrument that is directed through the duodenum and to the sphincter of Oddi for performing a sphincterotomy. This apparatus contains a cutting wire that is heated to cut the sphincter muscle. U.S. Pat. No. 5,024,617 to Karpiel, discloses a similar device that can be directed through a duodenoscope. U.S. Pat. No. 5,152,772 to Sewell, Jr. discloses a device for performing a sphincterotomy that is directed through an incision in the bile duct and includes a knife for cutting the sphincter muscle.

The use of the duodenoscope and sphincterotomy devices, such as shown in the Rydell and Karpiel patents, enables an internist to diagnose and treat problems in the biliary tree with minimal patient invasion. For example, modalities as described in these

patents eliminates the surgery needed for incising the bile duct. Consequently, these modalities can be performed as outpatient or day surgical procedures. These procedures greatly reduce patient trauma, the length of a hospital stay and recovery times. For example, if an internist determines that gallstones are present in the biliary tree, particularly the common bile duct, the internist can insert a duodenoscope into the duodenum to view the sphincter of Oddi. Then a first catheter can be advanced through the working channel of the duodenoscope with or without a guidewire and directed through the sphincter of Oddi into the biliary tree. Contrast agent injected through the catheter enables fluoroscopy or other imaging procedures to confirm the presence of gallstones within the biliary tree. Next the internist exchanges the first catheter for a second catheter for performing a sphincterotomy such as the types disclosed in the above-identified Rydell and Karpiel patents. The second catheter is then exchanged for a third catheter such as shown in the Glassman patent or some other equivalent retrieval catheter for drawings gallstones through the enlarged sphincter of Oddi. Thereafter the retrieval catheter is manipulated to release the gallstone into the duodenum. The catheter, any guidewire and the duodenoscope can then be removed to complete the procedure.

This procedure is significantly less traumatic to the patient than other prior art procedures because the only incision occurs during the sphincterotomy. However, this procedure as presently practiced requires three separate catheters and two catheter exchanges. These exchanges are required because the first, second and third catheters function solely to inject contrast agent to perform the sphincterotomy and to dislodge gallstones, respectively. The time required for performing each catheter exchange can increase patient trauma and increase the duration of the procedure and reduce efficiency. Moreover, each such procedure requires the use of two or three separate catheter devices.

SUMMARY

Therefore, an object of this invention is to provide apparatus for performing both diagnosis and additional therapeutic treatment without requiring a catheter exchange.

Yet another object of this invention is to provide apparatus that enables the removal of gallstones from the biliary tree by a procedure that reduces the number of required catheters and catheter exchanges.

Still another object of this invention is to provide a single catheter apparatus that can perform a sphincterotomy and remove gallstones in the common bile duct.

Yet another object of this invention is to provide a single catheter apparatus that can perform a sphincterotomy and inject contrast material into the biliary tree.

Still yet another object of this invention is to provide a single catheter apparatus that can inject contrast agent into the biliary tree, performing a sphincterotomy and remove gallstones in the bile duct into the duodenum.

Presently available products that may be modified according to the present invention include the Boston Scientific Ultratome, Ultratome XL, Stonetome, Flourotome, Tapertome, RX "C" Channel Sphincterotome, RX "U" Channel Sphincterotome, and RX Tapertome. Other products that may be modified according to the present invention include the Wilson Cook Canulatome, Wiltex Accuratome, Bard ProForma, and Olympus Clever Clevercut.

Accordingly, there is provided according to the present invention a method for cannulation of a common bile duct comprising threading a catheter through an appropriately placed endoscope, wherein said catheter comprises at least two and preferably three lumens, preferably a guide wire lumen, a contrast lumen, and a cutting wire lumen, whereby the handle of the device, secured to the cutting wire, may rotate independently of the catheter shaft and whereby the handle assembly is rotated to change the position of the distal tip independently of the scope position to achieve desired position for cannulation of the common bile duct. A rotation marking may be used to indicate the amount of rotation present and a rotation lock may be used to maintain the orientation of the tip.

The present invention also provides a method for sphincterotomy, whereby following cannulation, the handle of the mechanism may be rotated again, to the extent necessary to achieve the desired cutting position and cutting is effected by application of current to the cutting wire. Rotation lock and rotation markings may also be incorporated.

According to the invention, there is also provided a device comprising a catheter comprising two or preferably three lumens, preferably a guide wire lumen, a contrast fluid lumen, and a cutting wire lumen, whereby the catheter is rotatably attached to a handle fixed to the proximal end of the cutting wire. The proximal end of the catheter may terminate in a molded luer port assembly comprising entry points for the guide wire and for injection of contrast fluid. The guide wire and contrast lumens terminate at the distal end of the catheter. The handle and the catheter or molded luer port assembly may be designed to snap together to facilitate fast and inexpensive manufacture. Rotation lock and markings may also be included in this embodiment.

The present invention is an improvement of the devices and methods disclosed in U.S. Patent No. 5,547,469, U.S. Patent No. 5,868,698 and U.S. Patent No. 5,683,362 and in U.S. Patent Application serial no. 09/154,834 in the name of Rowland, et al., all owned by the owner of the present application, the common disclosure of which is incorporated herein and the subject matter of which is considered part of the present invention as set forth below. Figures 1 and 2 herein are original to the present application. Accordingly, original figures 1-9 of the Rowland, et al. applications are renumbered herein as Figures 3 through 11.

In accordance with one aspect of this invention, apparatus can be used in a treatment modality including an enlargement procedure and another procedure to be performed. This apparatus includes a catheter with proximal and distal ends and proximal and distal portions. The catheter includes first, second and third generally parallel lumens. The first lumen has a greater diameter than either of the second and third lumens and the lumens each extend between proximal and distal portions of the catheter. The apparatus for performing the enlargement procedure extends through the second lumen for operating distally of the catheter in response to manipulations of an operator at the proximal end of the catheter. The first lumen has a proximal port for enabling access to the first lumen and the third lumen has a proximal port and a distal port for enabling the remote control of some other procedure.

In accordance with another aspect of this invention, apparatus is provided for removing objects from the biliary tree. This apparatus includes a catheter that is directed

through the working channel of a duodenoscope and the sphincter of Oddi into the biliary tree. The catheter includes first, second and third lumens with the first lumen being larger than either the second or third lumens and the lumens generally extending between proximal and distal portions of the catheter along parallel axes. Apparatus for cutting the sphincter of Oddi includes a cutting wire extending through the second lumen and externally of the catheter means through a distal port along a length that is coextensive with part of the distal portion of the catheter. A handle attaches to the catheter at the proximal portion and to the proximal wire portion to control the position and orientation of the cutting wire. A rotation lock and marking may be incorporated to fix the orientation of the distal tip and to indicate the orientation of the distal tip respectively. An expansible balloon is mounted on the distal portion spaced from the cutting wire and can be inflated through the third lumen in order to move any gallstone in the biliary tree through the enlarged sphincter of Oddi.

In accordance with still another aspect of this invention, the apparatus is provided for directing contrast agent into the biliary tree and performing a sphincterotomy through the working channel of a duodenoscope. This apparatus includes a catheter that is directed through the working channel of the duodenoscope and the sphincter of Oddi into the biliary tree. The catheter includes first, second and third lumens with the first lumen being larger than either the second or third lumens and the lumens generally extending between proximal and distal portions of the catheter along parallel axes. Apparatus for cutting the sphincter of Oddi includes a cutting wire extending through the second lumen and externally of the catheter means through a distal port along a length that is coextensive with part of said distal portion of the catheter. A handle attaches to the catheter into the proximal wire portion to control the position and orientation of the cutting wire. A rotation lock and marking may be incorporated to fix the orientation of the distal tip and to indicate the orientation of the distal tip respectively. The proximal port of the third lumen connects to a contrast agent source and the third lumen delivers contrast agent into the biliary tree through a distal port in the distal end of the catheter.

BRIEF DESCRIPTION OF THE DRAWINGS

The various objects, advantages and novel features of this invention will be more fully apparent from a reading of the following detailed description in conjunction with the accompanying drawings in which like reference numerals refer to like parts, and in which:

FIG. 1 is a plan view of one embodiment of apparatus constructed in accordance with the present invention with a rotatable handle attached to a cutting wire;

FIG. 1a is a plan view of a snap in handle connection for the apparatus of FIG. 1;

FIG. 2 is a view of an alternative embodiment of the rotatable handle of the present invention;

FIG. 3 is a plan view of one embodiment of apparatus constructed in accordance with this invention;

FIG. 4 is a cross-section taken along lines 2--2 in FIG. 3;

FIG. 5 is a cross-section taken along lines 3--3 in FIG. 4;

FIG. 6 is a cross-section taken along lines 4--4 in FIG. 5;

FIG. 7 depicts the apparatus of FIG. 3 positioned through a duodenoscope for injecting contrast agent into the biliary tree.

FIG. 8 is an enlarged view that depicts the orientation of the apparatus in FIG. 3 for performing a sphincterotomy;

FIG. 9 depicts the apparatus of FIG. 3 positioned through a duodenoscope for dislodging material within the common bile duct;

FIG. 10 is a cross-section of an alternative embodiment of the apparatus as viewed generally along lines 3--3 in FIG. 4.;

FIG. 11 is a cross-section of still another embodiment of this invention taken along lines 3--3 in FIG. 4;

FIG. 12 is a view of the rotatable handle of the present invention including a rotation lock;

FIG. 13 is a detailed view of the rotation lock of FIG. 12;

FIG. 13a is a sectional view along line A-A of FIG. 13;

FIG. 14 shows an alignment between the rotatable handle and the bifurcation connector showing zero rotation of the rotatable handle;

FIGS. 15a-d show alternative embodiments of the rotation lock of the present invention;

FIGS. 16a-d show cross-sectional areas of the alternate embodiment of FIGS. 15a-d;

FIGS. 17a-c show three alternative embodiments of rotation markings for the present invention;

FIGS. 18a & b illustrate alternatives of bifurcation connectors; and

FIGS. 19a & b illustrate a bowing lock included in the present invention.

DESCRIPTION OF ILLUSTRATED EMBODIMENTS

FIG. 3 depicts a catheter apparatus 10 that has the capability of injecting a contrast agent into the biliary tree, of performing a sphincterotomy and of dislodging a gallstone into the duodenum. The apparatus 10 includes a catheter 11 which, for purposes of definition, includes a proximal end portion 13 extending from a proximal end 12 and a distal end 14 with a distal portion 15 extending a short distance from the distal end 14. In a typical application, the catheter will have a working length of 200 cm and the distal end portion 15 will have a length of 6 cm to 9 cm. Normally the distal portion 15 will have a diameter that is smaller than the diameter of the proximal portion to increase the flexibility of the distal portion 15. The reduction in diameter also makes the tip less traumatic and allows the tip portion to reach smaller passages while allowing the larger proximal portion to provide necessary hoop strength and rigidity, particularly where the proximal portion 13 is coextensive with the working channel of a duodenoscope. For example, the proximal and distal portions might have diameters corresponding to 7 Fr and 5.5 Fr catheter sizes (i.e., 0.09"and 0.07"respectively).

As shown particularly in FIG. 4, the catheter 11 has three lumens. A first lumen 16 has a diameter that is greater than either a second lumen 17 or a third lumen 20. In one particular embodiment the lumen 16 has a diameter of 0.040" in the proximal portion 13 that reduces to about 0.037" in the distal portion 15 to receive a standard 0.035" guidewire. In addition the lumen 16 is offset from the center of the catheter 11.

The lumens 17 and 20 are each smaller in diameter than the lumen 16 and are radially offset from the centerline of the catheter, from each other and from the lumen 16. In one particular embodiment the lumens 17 and 20 each have internal diameters of 0.028" in the proximal portions 13 that reduces to about 0,020" in the distal portion 15. As described later, this lumen 20 carries a cutting wire for performing a sphincterotomy and for allowing the infusion of a contrast agent at reasonable rates. The angular spacing between the lumens 17 and 20 is about 45 degrees and the angular spacing between the first lumen 16 and each of the lumens 17 and 20 each is about 157.5 degrees. In this configuration and with these dimensions the proximal portion 13 readily passes through the working channel of any duodenoscope.

Referring again to FIGS. 3 and 4, each of the lumens 16, 17 and 20 includes an entry port in the proximal portion 13 and an exit port in the distal portion 15. Generally, and as described in more detail later, the first lumen 16 has an exit port through the distal end 14 while the exit ports for the lumens 17 and 20 can be sited at different locations in the distal portion 15 depending upon a particular application.

In FIG. 3, the entry ports in proximal portion 13 adjacent the proximal end 12 include an entry port 21 that provides access to the lumen 16 and includes an optional Leur lock fitting 22. A proximally positioned entry port 23 provides access to the lumen 17 and includes an optional Leur lock fitting 24. A proximal entry port 25 for the lumen 20 is located coextensively with a portion of a handle 26 attached to the proximal end 12.

Referring to the distal end portion 15, the catheter 11 in this particular embodiment carries an expansible balloon 30 proximally of the excursion of a cutting wire 31 externally of the catheter 11. As shown in FIG. 5, the lumen 17 emerges at a distal exit port 32 through the side of the catheter 11 with the interior of the expansible balloon 30. An extension of the lumen 17 beyond the distal port 32 is sealed by known

methods of manufacture. Consequently, fluid forced through the entrance port 23, as by a syringe (not shown) attached to the Leur lock fitting 24, expands the balloon 30 into an occluding orientation as shown in FIG. 5 with an inflated diameter in the range up to 20 mm.

As will also be apparent from viewing FIGS. 5 and 6, the first lumen 16 extends through the catheter 11 and terminates with an exit port 33 in the distal end 14. Thus the lumen 16 is adapted for receiving a guidewire through the entrance port 21 that will extend through the catheter 11 and exit the distal end 14 and allow the catheter to slide over that guidewire.

Referring to FIG. 6, a distal end 34 of the cutting wire 31 attaches to a clamp 35 formed at the distal end of the lumen 20. Spaced skived ports 36A and 36B allow an active portion 37 of the cutting wire 31 to emerge from the catheter 11 through the skived aperture 36A, parallel the catheter 11 exteriorly thereof and return into the lumen 20 through the port 36B and a reinforcing sleeve 38. The cutting wire 31 then extends through the lumen 20 to the handle 26 shown in FIG. 1 where it emerges as a proximal end portion 40.

The handle 26, as shown in FIG. 3, includes a central member 41 terminating with a thumb ring 42. The central member 41 extends through and slides with respect to a body section 43 having opposed finger rings 44. The central member 41 also attaches to the catheter 11, and is therefore an extension of the catheter 11. The member 43 additionally includes an internal connector 45 for clamping the proximal end 40 of the cutting wire 31. Thus, when the body 43 is at its distal position as shown in FIG. 3, the distal portion of the catheter 15 is in essentially straight line as shown in FIG. 3 with the active portion 37 of the cutting wire 31 being closely adjacent the catheter 11. Retracting the body portion 43, causes the cutting wire 31 to bend the distal end upwardly as shown in FIG. 3 to a position that is essentially at right angles to the main axis of the catheter, as will be shown later.

The connector block 45 and the cutting wire 31 are generally conductive members that attach through an RF connector 46 to an RF heating source 47. The use of such RF heating sources 47 for energizing a cutting wire 31 thereby to cut the sphincter muscle is

well known in the art and represents one possible sphincterotomy procedure that can be adapted for the apparatus of this invention and is not described further.

With this description of the apparatus structure, it will now be possible to understand its use in a particular application. FIG. 7 discloses, in a partially broken and schematic view, the positioning of a duodenoscope 50 in the duodenum 51 adjacent the sphincter of Oddi 52. A catheter 11 such as constructed in FIG. 3 passes through the sphincter of Oddi 52 into the common bile duct 53, bypassing the pancreatic duct 54. The distal end 14 does not extend to the gallbladder 55.

Fluoroscopy allows the appropriate positioning by utilizing a series of radio-opaque markers 56 at the distal portion 15 that may include the clamp 35 and the reinforcing sleeve 38 in FIG. 6. The catheter 11 can be positioned with or without the presence of a guidewire 57 in the lumen 16 shown in FIGS. 4, 5 and 6. For purposes of injecting the contrast agent, any guidewire 57 can be withdrawn to allow the contrast agent to be injected through the lumen 16 for purposes of fluoroscopic examination to confirm the presence of one or more gallstones 58. It is also possible during the operation to expand the balloon 30 to occlude the bile duct 53 and block any migration of contrast agent into the duodenum 51 or the pancreatic duct 54.

FIG. 8 is an enlarged view showing the duodenum 51, sphincter of Oddi 52, portions of the pancreatic duct 54 and the common bile duct 53. In FIG. 8 the catheter 11 has been positioned relative to the duodenoscope 50 through the opening of the sphincter of Oddi 52. The handle 43 in FIG. 3 has been drawn proximally to deflect the distal portion 15 into essentially a right angle configuration such that the cutting wire 31 abuts a portion of the sphincter of Oddi 52. The application of RF heating to the cutting wire 31 then will cut the sphincter of Oddi 52 and enlarge the opening therethrough. As will be apparent, the sphincterotomy is performed with direct visualization of the sphincter of Oddi through the duodenoscope.

Moreover, as has been observed by others, catheters having guidewire and cutting wire lumens tend to assume a particular angular orientation when the distal portion 15 emerges from the duodenoscope. This orientation is essentially independent of the angular position of the catheter when it is inserted into the duodenoscope. The offset

nature of the lumen 20 as shown in FIG. 4, improves the location of the cutting wire 31 as the distal portion 15 passes through the sphincter of Oddi 52. Specifically the angularly offset brings the cutting wire 31 into better alignment with the common bile duct 53 and displaces the cutting wire from the pancreatic duct 54.

FIG. 9 depicts the catheter after the sphincterotomy and after the catheter 11 is advanced over the guidewire 57, if used. FIG. 9 also discloses the catheter 11 after the balloon 30 has been moved beyond a gallstone 58 in the bile duct 53. The balloon 30 is expanded so that upon withdrawal of the catheter 11 the balloon 30 will dislodge the gallstones 58 and sweep them through the sphincter of Oddi 52 into the duodenum 51.

As will now be apparent from the description of the particular catheter apparatus 10 shown in FIG. 3 and its use as discussed with respect to FIGS. 7, 8, and 9, the single catheter apparatus of this invention is capable of providing diagnostic contrast agent injection, of performing a sphincterotomy and of dislodging gallstones in the common bile duct or other portions of the biliary tree without having to exchange a catheter. Moreover, positioning and sizing of the lumens enables these functions to be performed with a catheter apparatus that is readily adapted for use in the working channels of standard duodenoscopes. Consequently the gallstones can be removed from the biliary tree without bile duct incisions and accompanying surgical procedures, as duodenoscope can be introduced through the alimentary tract. Consequently the entire procedure is adapted for being performed more rapidly than prior art procedures and with fewer components. The net effect is to reduce patient trauma and the overall time and cost of conducting the procedure.

In FIG. 3 the balloon 30 is located proximally of the cutting wire 31. FIG. 10 discloses an alternative embodiment in which a balloon 60 is located distally of the cutting wire 31. More specifically, the distal end of a lumen 17A, corresponding to the lumen 17 in FIGS. 5 and 6, is sealed. A side facing exit port 61 skived or otherwise formed in the catheter 11 opens into a chamber 62 formed by the balloon 60. A first sealing portion 63 and a sealing portion 64 of the balloon 60 connect proximally and distally of the aperture 61 respectively and seal the chamber 62.

Introduction of a balloon inflation fluid through the lumen 17A expands the balloon 60 into an occluding orientation corresponding to the orientation of the balloon 30 shown in FIG. 5. Retraction of the catheter 11 with the distal balloon 60 inflated enables withdrawal of a gallstone from the bile duct. This particular embodiment is particularly adapted when it is determined that a gallstone is located high in the biliary tree to minimize the incursion of the distal portion 15 through the biliary tree beyond the gallstone or in any application in which the internist desires to minimize the length of the distal portion 15 that extends beyond the occluding balloon.

FIG. 11 discloses another embodiment of this invention for enlarging the sphincter of Oddi and performing another procedure, such as injecting a contrast agent into the biliary tree, as might be used in the diagnosis and treatment of a stricture in the biliary tree. In this particular embodiment an exit port 65 from the lumen 17B is located in the distal end 14 of the distal portion 15. The lumen 16 then can be used for a guidewire and the lumen 17B, for injecting the contrast agent directly into the biliary tree while the guidewire remains in place. The apparatus would then be positioned to perform a sphincterotomy without having to exchange a catheter should the procedure be warranted.

As still another alternative, the internist could utilize a conventional catheter for purposes of injecting the contrast agent to determine the need for gallstone removal. If treatment were indicated, the internist could then utilize apparatus as shown in FIG. 3 with a single exchange over the guidewire that would pass through the lumen 16 as previously described.

Therefore, it will now be apparent that apparatus constructed in accordance with this invention attains the several objects and the advantages of this invention. More particularly, catheter apparatus constructed in accordance with this invention allows the injection of a contrast agent, the performance of a sphincterotomy and dislodging gallstones from the common bile duct through the enlarged sphincter of Oddi into the duodenum all without requiring any catheter exchanges. Moreover, this apparatus allows such a procedure to occur through a duodenoscope to minimize patient trauma. The use

of a single catheter with an elimination of catheter exchanges further reduces the time and costs associated with the use of multiple, single-function catheter devices.

As will be apparent from the foregoing description, many alterations can be made to the specifically disclosed embodiments. Different balloon structures can be used and located at alternative positions. Different cutting wire embodiments and orientations can be used. Thus, although this invention has been disclosed in terms of certain embodiments, it will be apparent that many modifications can be made to the disclosed apparatus without departing from the invention. In particular, it is considered that all of the foregoing embodiments may be used in conjunction with a handle fixed to the cutting wire but rotatable relative to the catheter. A rotation lock fixing the orientation of the cutting wire and/or a rotation marking, indicating the amount of rotation may be included with the current invention. Therefore, it is the intent of the appended claims to cover all such variations and modifications as come within the true spirit and scope of this invention.

Consistent therewith, the following subject matter claimed in the Rowland, et al patents and applications is specifically claimed in connection with the subject matter specific to the present application, namely, a handle fixed to the cutting wire and rotatable relative to the shaft of the catheter, whereby turning of the handle independently of the catheter and independently of the endoscope causes the distal tip of the device to rotate independently of the endoscope allowing the surgical team greater control over the position of the device for cannulation and subsequently for sphincterotomy A rotation lock fixing the orientation of the cutting wire and/or a rotation marking, indicating the amount of rotation may be included with the current invention.

Due to inconsistencies in the sphincterotome, anatomy, and endoscope manipulation, it is difficult to accurately and consistently position the sphincterotome for proper cannulation. The steerable sphincterotome of the present invention allows the physician to control the position of the distal tip of the device independently of the endoscope and adjust for inconsistencies in the device and the anatomy. According to the present invention, the handle to which the cutting wire is attached is freely rotatable relative to the catheter. Rotating the handle of the present invention induces a twisting of

the attached cutting wire which allows orientation of the distal end without rotating the proximal end of the attached catheter. See Figs. 1 and 2. Handle 66, secured to the cutting wire at 80 but rotatable relative to the shaft of the catheter at 81, provides a mechanism to rotate the wire, transmitting the force to rotate the device tip. With the handle rotating independently of the shaft at the proximal end, the force can be applied directly to the distal tip without twisting the entire shaft. Also a rotation lock to maintain the orientation of the tip and/or a rotation marking, to indicate the amount of rotation may be included. An integrated molded luer port assembly for 2 and 3 lumen catheters may be provided to snap into the rotatable handle, to facilitate fast and economical manufacturing, as shown in Figs. 1 and 1a. Alternatively, prior art serial lumen ports may be configured to snap into the rotatable handle as shown in Fig. 2.

Referring to FIG. 12, the present invention also contains a feature known as a rotation lock. Rotation lock 68 allows the user to maintain the orientation of the tip at all times. This is done by maintaining the position of handle 66 relative to bifurcation connector 67 after the handle has been rotated. Rotation lock 68 allows the user to release handle 66 at any time during the procedure, while maintaining the orientation of handle 66 and preventing further rotation while the lock is engaged. Maintaining the position of handle 66 maintains the orientation of the distal tip in the desired orientation. Maintaining the orientation of the distal tip reduces the amount of time and effort required to cannulate if the distal tip moved. Preventing undesired movement of the distal tip may also prevent patient injury.

Referring to FIG. 13, two pair of mating detents 69 and slots 70 may be used to create this rotation lock. Detents 69 and slots 70 are located along the central axis of body 71, at the intersection of body 71 and bifurcation connector 67. In FIG. 13, the two pair of detents 69 and slots 70 are located 180° apart, relative to the central axis. This creates a lock position every half rotation of handle 66. During use of the device, as handle 66 is rotated, detents 69 become disengaged from slots 70. As detents 69 become disengaged, they compress slightly. As handle 66 reaches a position 180° from where rotation began, detents 69 recover from their compressed state, and engage with slots 70 once again. As detents 69 traverse from one position to the next, there is a noticeable amount of friction between the mating components. This friction is great enough that

handle 66 can be released at any time without fear of losing the orientation position of the distal tip.

Rotation lock 68 also serves a secondary function of keeping the distal tip locked in the home position while the catheter is being removed from the package, inserted into the endoscope, and manipulated through the endoscope. Without this feature, the initial orientation position of the distal tip would become unpredictable. FIG. 13a shows a detailed diagram of the interaction between detents 69 and slots 70.

Referring to FIG. 14, when detents 69 and slots 70 are engaged, bifurcation connector 67 and finger rings 44 all lie in the same plane. This acts as the rotation marker. Whenever finder rings 44 are rotated into the same plane as bifurcation connector 67, the rotation lock is engaged, thus signaling 180° of rotation from the last position. The use of a marker such as this allows the user to more easily keep track of how much handle 66 has been rotated. This is helpful if the user desires to move the distal tip back to its original position. In effect, the user will know, for example, that handle 66 has been rotated three clicks from the original position. Therefore, to return handle 66 to the original position, it must be rotated three clicks in the opposite direction.

FIGURES 15a – 15d show alternative embodiments of rotation lock 68. FIGURE 15a shows a pure frictional lock. The connection of bifurcation connector 69 to the handle 66 could be designed such that rotation lock 68 is purely a function of frictional interference between the two components. Alternative embodiments could include different types of assembly joints to create this friction. In the primary embodiment, the assembly of the two components is accomplished by mating a male post of the bifurcation connector to a female hole of the same size and shape. Alternative embodiments could reverse this, so that the male protrusion is part of the main body of handle 66. The friction lock could also be built into the mating faces of main body and bifurcation connector, which are perpendicular to the major axis. FIGURE 16a shows a cross section of the rotation lock along Z-Z of FIGURE 15a.

FIGURE 15b shows a oval post lock embodiment of the present invention. The connection of bifurcation connector 67 to handle 66 could also be designed incorporating an ovalized male post 73 and female hole 72. In this embodiment, as handle 66 is rotated

relative to bifurcation connector 67, ovalized hole 72 would deform, allowing oval post 73 to rotate. As handle 66 reached a rotation of 180°, ovalized hole 72 would conform back to its original shape, thus locking handle 66 in place. As shown in FIGURES 15c and 15d, this basic concept may be expanded to incorporate other shapes rather than oval as shown in FIGURE 15b. One of ordinary skill in the art would appreciate that the shape of the geometry however, governs the degrees of rotation between locked positions. For example, if post 73 and ovalized hole 72 configuration were made up of mating equilateral triangles (FIGURE 15c), there would be 120° of rotation between locked positions. Using a square configuration (FIGURE 15d), would give 90° between locked positions. FIGURE 16b, illustrates the cross-sectional area across Y-Y of FIGURE 15b. FIGURE 16c illustrates the cross-sectional area of FIGURE 15c across X-X and FIGURE 16d illustrates the cross-sectional area of FIGURE 15d along cross-section W-W.

FIGURES 17a-c show alternative embodiments by which a rotation marker may be created and included in the present invention. One of ordinary skill in the art would understand these embodiments may be expanded. To aid the user in knowing exactly how much handle 66 has been rotated from its original and/or last position, several forms of visual markers can be incorporated into the design. One alternative embodiment is comprised of a set of lines placed radially, around the major axis, at the area where the main body and bifurcation connector 67 meets (FIG. 17a). A single line on the stationary component, bifurcation connector 67, would match up with a corresponding line on body 43. As handle 66 is rotated relative to bifurcation connector 67, the series of lines on the body would rotate past the stationary line on bifurcation 67. Each line would indicate an incremental amount of movement. For example, if there were four, equally spaced lines on the body, each line that passed the marker on the bifurcation connection would signify 90° of rotation.

This feature could be further enhanced by many methods. A series of numbers rather than lines could be used to signify the amount of rotation (FIG. 17b). Alternating colors could also be used to signify the amount of rotation. Alternating line patterns could be used as well (FIG. 17c).

Another alternative embodiment may use audible tones to make the user aware of the amount of rotation. One method for doing this would be able to design the rotation lock features so that a click is clearly audible at predetermined points along the rotational travel of the body.

Referring to FIGURES 18a and 18b, there are several alternative means by which a bifurcation connector can be created. One of ordinary skill would understand these embodiments may be expanded from those presented in the current application.

Although the present invention is comprised of a connector with two lumens, the connector design could easily be modified to accommodate three or more lumens (FIG. 18a). This would allow future designs to incorporate both guidewire post connector 74 and injection port connector 75 into one component.

Another alternative to the bifurcation connector of the present design would be one, which also houses the electrical connector 76 (FIG. 18b). Electrical connector 76, presently incorporated into the finger ring, could be moved to the bifurcation connector.

Referring now to FIGURES 19a and 19b, other embodiments of the present invention may consist of handle 66 similar to that previously described, but with the addition of a bowing lock. A bowing lock would aid the user in that handle 66 could be released at any time, and the catheter tip would maintain its bowed position. Just as the rotation lock provides for a safer and more efficient procedure, the bowing lock would do the same.

The bowing lock could be incorporated into the design in many ways. The bowing lock, in its simplest form, would consist of friction lock 77 created between finger rings 44 and main body 43 (FIG. 19a). An alternative to this design would create a similar friction lock, but would use the surfaces between wire termination 78 and main body 43 (FIG. 19b). The friction lock shown in figure 19b is enhanced by incorporating several lock ribs 79. Lock ribs 79 would be used to hold the catheter tip at a specific, predetermined angle. In effect, locking handle 66 into the first position would, for example, deflect the tip 30°. The next position would deflect the tip 60°. This feature would give the user even more control when positioning the catheter tip within the anatomy. In both cases, as finger rings 44 are actuated along main body 43, and catheter

tip 80 is bowed, the friction between the mating components would hold the position of the handle, and thus hold the position of the bow.

CLAIMS

1. An apparatus for use in a treatment modality including an enlargement procedure to be performed within a patient, said apparatus including a catheter for being directed through internal passageways in the patient, said catheter having proximal and distal ends, and proximal and distal portions adjacent to said proximal and distal ends respectively, and a first and at least second generally parallel lumens, said lumens extending between said proximal and distal portions, and a cutting wire for performing the enlargement procedure extending through said second lumen for operating at said distal portion in response to manipulations at said proximal end, said cutting wire having a distal end attached to said catheter at the distal end of said second lumen, a portion thereof external to said catheter along a length coextensive with a portion of said distal portion of said catheter and a handle for operating said cutting wire from a point proximal of said catheter, the improvement comprising:

a rotatable coupling attaching said handle to said catheter allowing said handle to rotate relative to said proximal end of said catheter while engaging and rotating a proximal end of said cutting wire whereby said distal portion of said catheter rotates as a result of said rotation of said handle.

2. The apparatus of claim 1 further comprising:

a rotation lock which inhibits further rotation of said handle relative to said proximal end of said catheter.

3. The apparatus of claim 1, further comprising:

a rotation indicator configured to indicate an amount of rotation of said handle relative to said proximal end of said catheter.

4. The apparatus of claim 3, wherein said rotation indicator comprises a visual indicator of said amount of rotation.

5. The apparatus of claim 4, wherein said visual indicator comprises an index marking and a corresponding scale marking providing an indication of said amount of rotation.

6. The apparatus of claim 3, wherein said rotation indicator comprises a device providing an audible indication in response to said rotation of said handle relative to said proximal end of said catheter.

7. A method of cutting tissue in a body passage comprising selecting a catheter having a first lumen configured for receiving a wire guide, a second lumen configured for receiving an electrosurgical cutting wire, positioning said catheter in said passage at a desired position using an endoscope, actuating the electrosurgical cutting wire in the second lumen, the improvement comprising:

orientating said electrosurgical cutting wire by rotating a handle relative to a proximal end of said catheter.

8. The method of claim 7 wherein said cutting wire is affixed to said handle, wherein said step of rotating said handle causes a rotation of a proximal end of said cutting wire whereby said cutting wire is caused to rotate within said second lumen.

9. The method of claim 8 wherein a distal end of said cutting wire is caused to rotate by a twisting of a portion of said cutting wire intermediate said proximal and said distal portions of said cutting wire.

10. The method of claim 7 further comprising:

inhibiting further rotation of said handle relative to said proximal end of said catheter by engaging a rotation lock.

11. The method of claim 7, further comprising:

indicating an amount of rotation of said handle relative to said proximal end of said catheter through the use of a rotation indicator.

12. The method of claim 11, wherein said step of indicating an amount of rotation includes a visual indication of said amount of rotation.

13. The method of claim 12, wherein said visual indication includes an index marking and a corresponding scale marking providing an indication of said amount of rotation.

14. The method of claim 11, wherein said step of indicating an amount of rotation includes an audible indicator provided by a device in response to said rotation of said handle relative to said proximal end of said catheter.

15. A catheter handle comprising:

a rotatable coupling configured to allow free rotation of a proximal end of a catheter; and

a clamping member configured to engage a proximal end of a device extending through a lumen formed in said catheter whereby rotation of said handle causes rotation of a proximal end of said device in said lumen.

16. The catheter handle of claim 15, wherein said device comprises a cutting wire extending from said proximal end of said catheter to and connecting to a distal end of said catheter.

17. The catheter handle of claim 15, further comprising:

a rotation lock engageable to inhibit a rotation of said handle with respect to said proximal end of said catheter.

18. The catheter handle of claim 15, further comprising:

a rotation indicator configured to indicate an amount of rotation of said handle relative to said proximal end of said catheter.

19. The catheter handle of claim 18, wherein said rotation indicator comprises a visual indicator of said amount of rotation.

20. The catheter handle of claim 19, wherein said visual indicator comprises an index marking and a corresponding scale marking providing an indication of said amount of rotation.

21. The catheter handle of claim 15, wherein said rotation indicator comprises a device providing an audible indication in response to said rotation of said handle relative to said proximal end of said catheter.

FIG 1

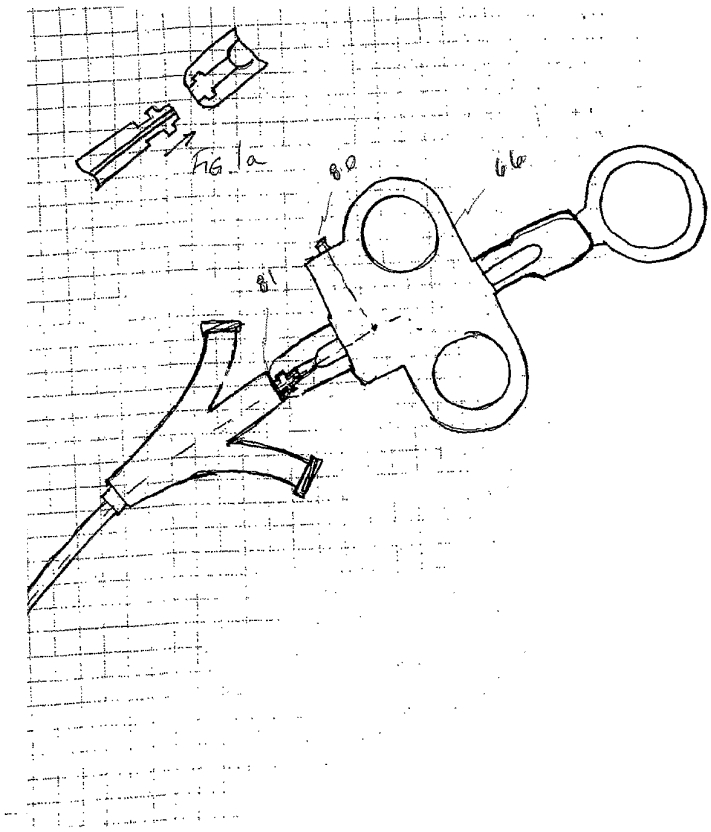
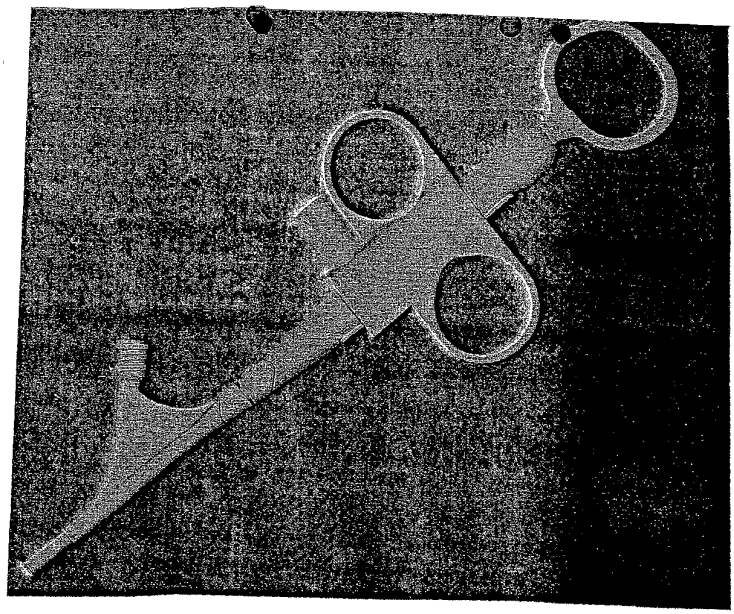


FIG 2



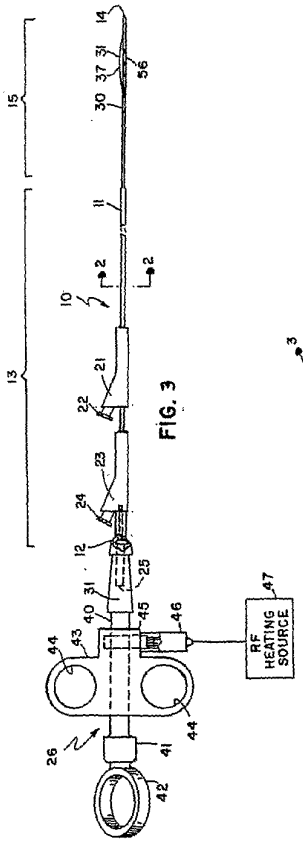


FIG. 3

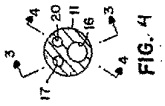


FIG. 4

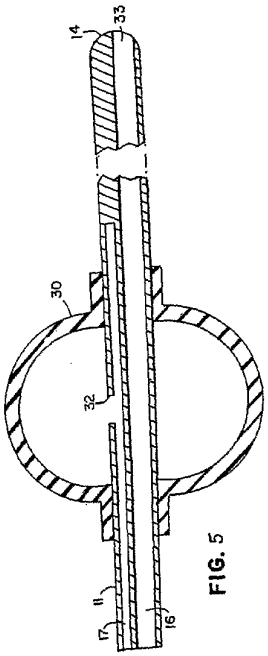


FIG. 5

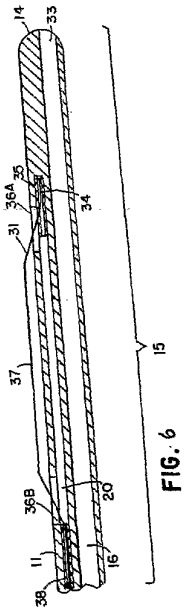
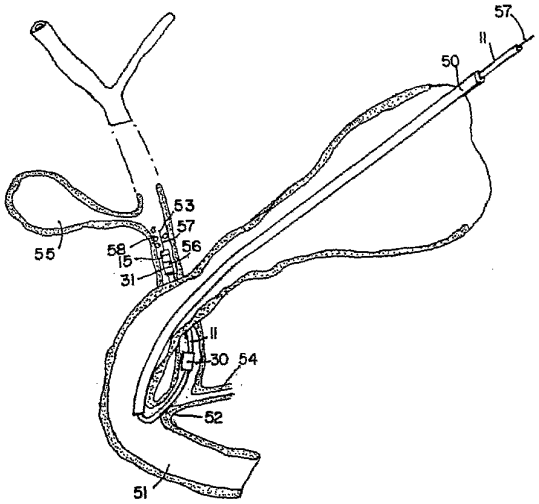


FIG. 6

FIG. 7



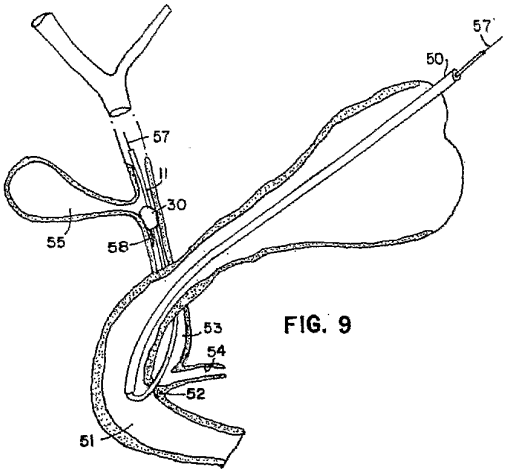


FIG. 9

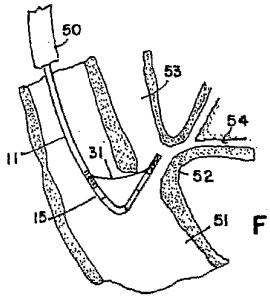


FIG. 8

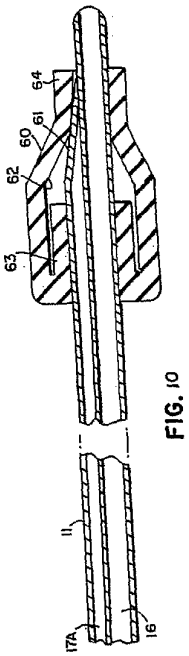


FIG. 10

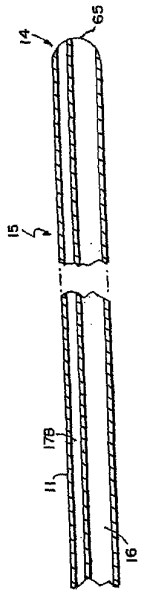


FIG. 11

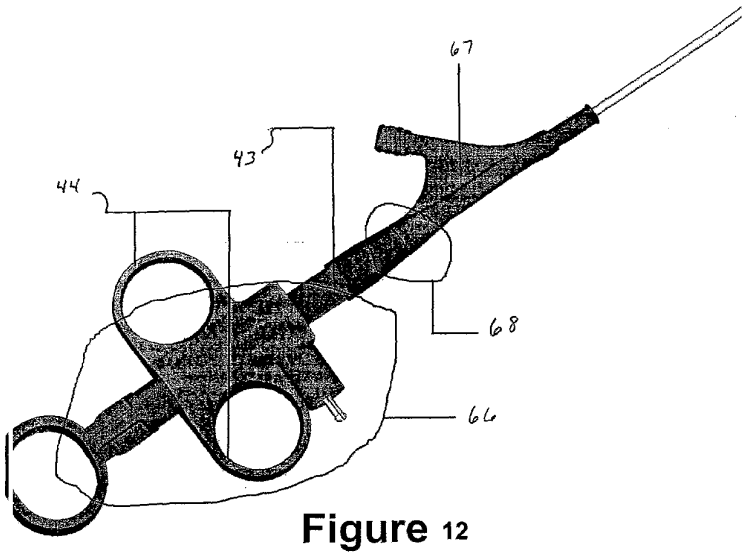


Figure 12

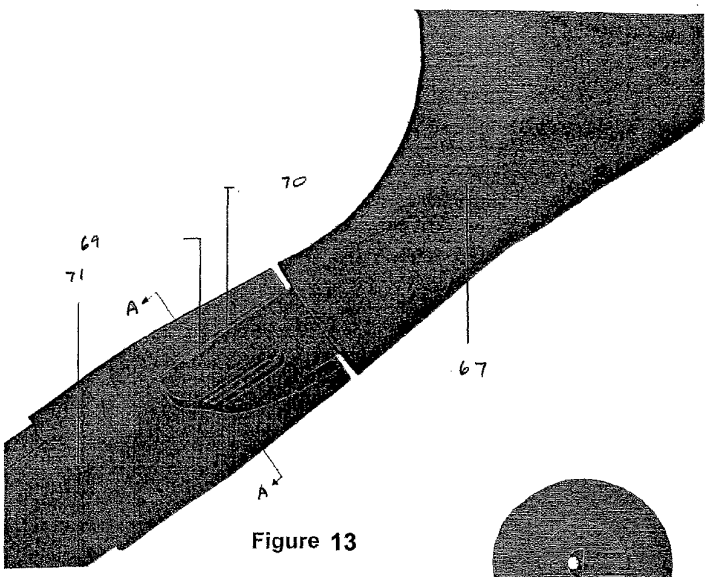


Figure 13

SECTION A-A

FIG 13A

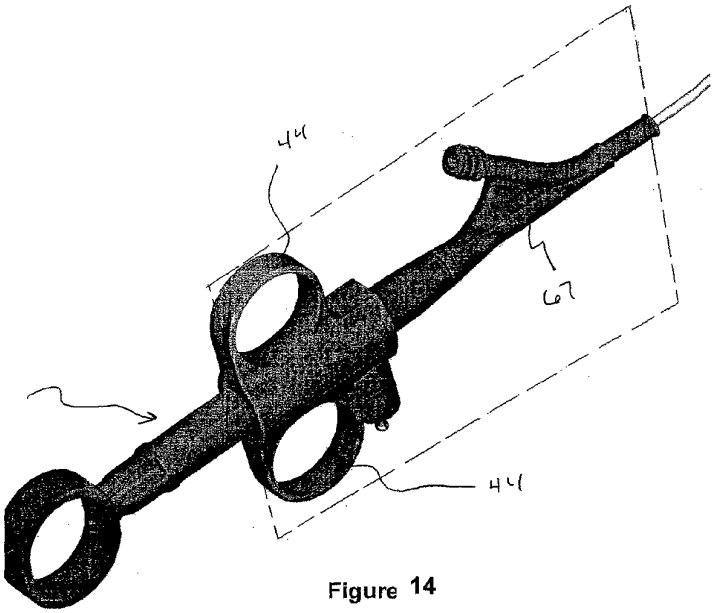


Figure 14

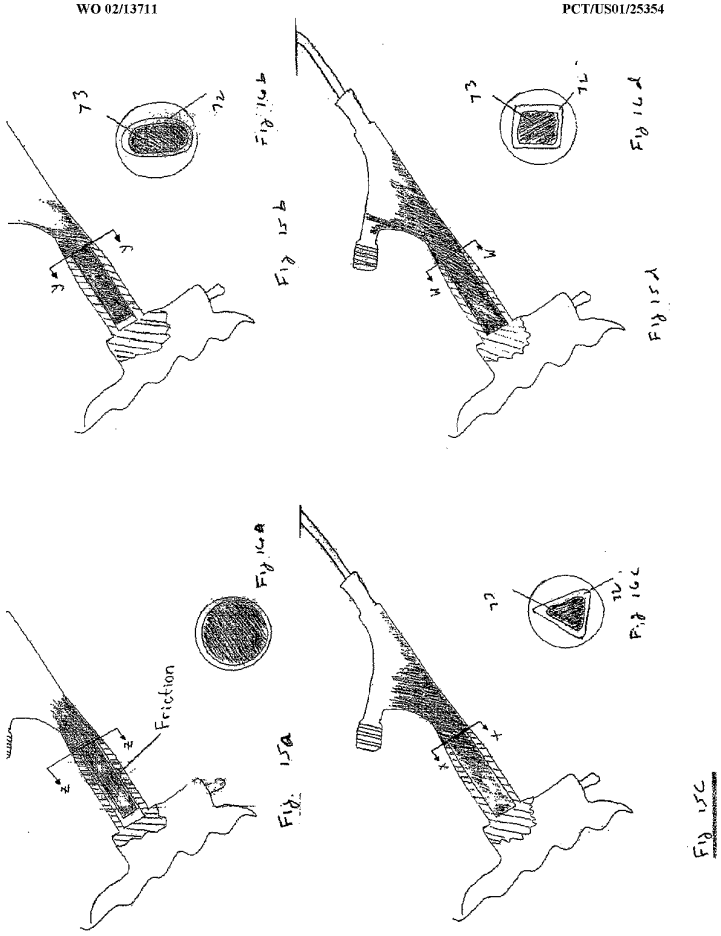


Fig. 15A Fig. 15B Fig. 15C Fig. 15D

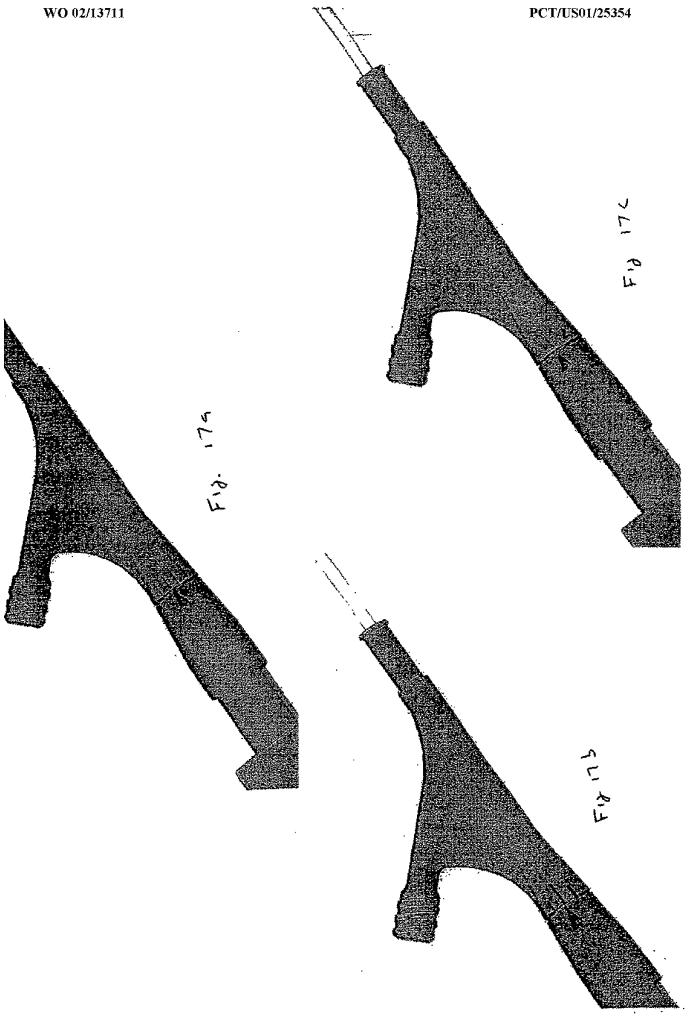


Fig. 17A

Fig. 17B

Fig. 17C

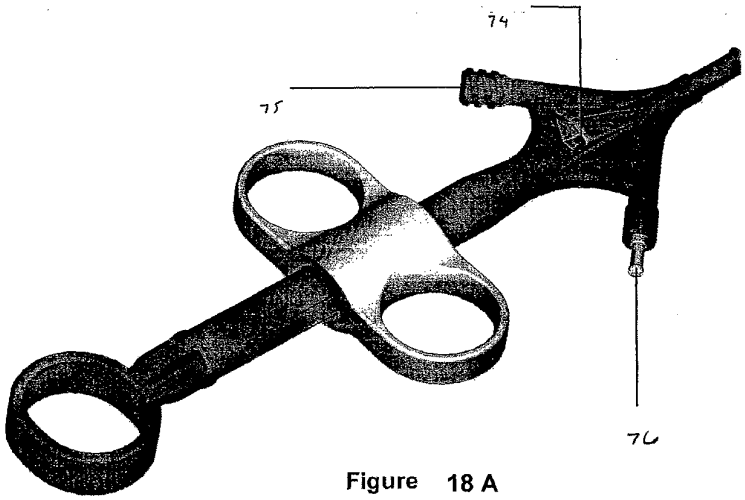


Figure 18 A

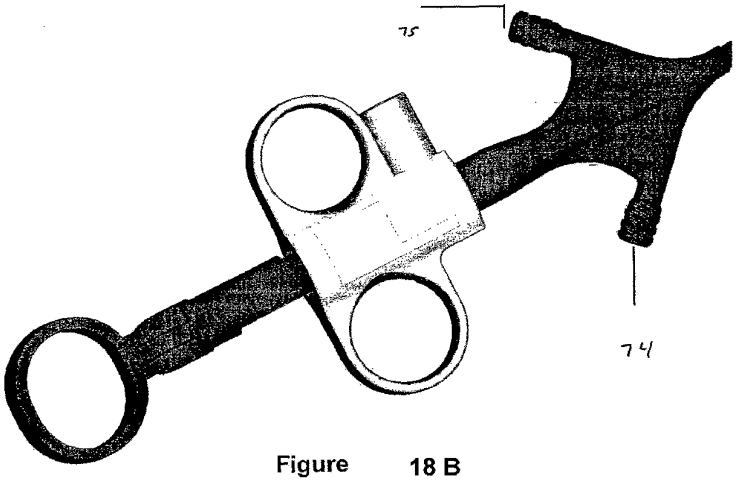


Figure 18 B

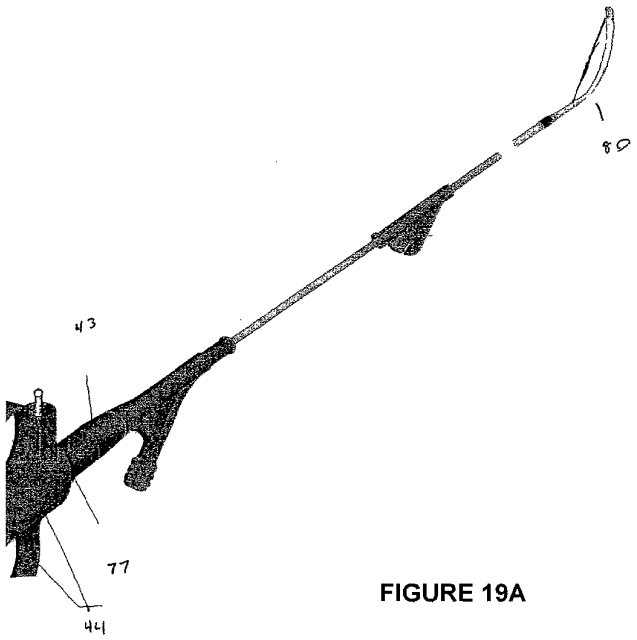


FIGURE 19A

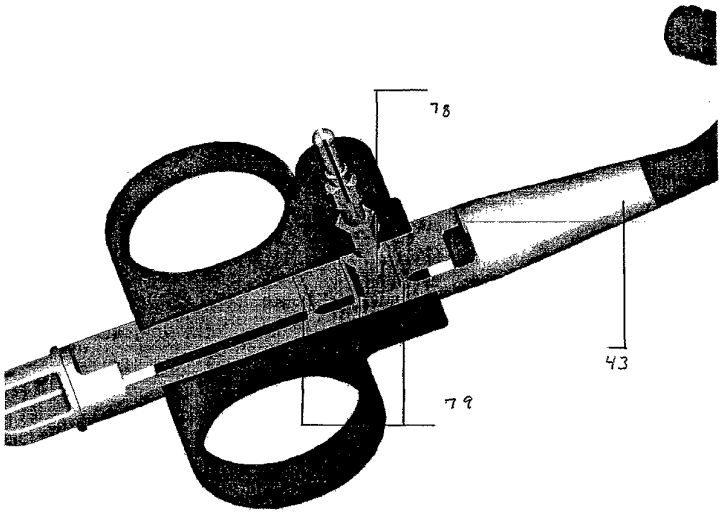


Figure 19B

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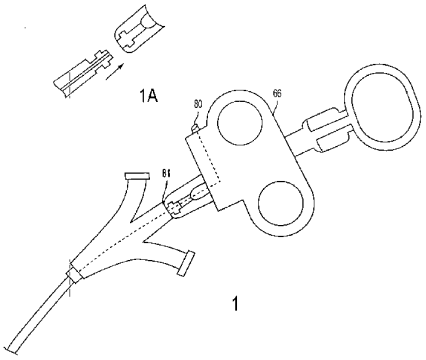
[Continued on next page]

(54) Title: STEERABLE SPHINCTEROTOME AND METHODS FOR CANNULATION, PAPILLOTOMY AND SPHINCTEROTOMY



(57) Abstract: The present invention relates to methods and devices for performing endoscopic cannulation, papillotomy and sphincterotomy and similar procedures. According to the present state of the art, endoscopic cannulation of the common bile duct and papillotomy and similar procedures are accomplished by advancing the device into an endoscope/duodenoscope so that the distal tip of the device exits the endoscope adjacent the sphincter muscles at the Papilla of Vater. The endoscope mechanisms are then manipulated to orient the distal tip of the device to the desired position for proper cannulation of the duct. Due to inconsistencies in, for example, the sphincterotome, anatomy, and endoscope manipulation, it is difficult to accurately and consistently position the sphincterotome for proper cannulation. The steerable sphincterotome of the present invention allows the physician to control the position of the distal tip of the device independently of the endoscope and adjust for inconsistencies in the device and the anatomy. According to the present invention, the handle to which the cutting wire is attached is freely rotatable relative to the catheter. The handle, secured to the cutting wire but rotatable relative to the shaft of the catheter, provides a mechanism to rotate the wire, transmitting the force to rotate the device tip. With the handle rotating independently of the shaft at the proximal end, the force can be applied directly to the distal tip without twisting the entire shaft. Also a rotation lock to maintain the orientation of the tip and/or a rotation marking, to indicate the amount of rotation may be included.

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Steerable Sphincterotome and Methods for Cannulation, Papillotomy and Sphincterotomy

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention generally relates to apparatus that is useful in performing diagnostic and therapeutic modalities in the biliary tree and more particularly to apparatus that is adapted for facilitating the diagnosis of gallstones in the bile duct and other portions of the biliary tree and the removal of such gallstones.

2. Description of Related Art

Historically the migration of gallstones into an individual's common bile duct was corrected by general surgical procedures. A surgeon would incise the bile duct and remove the gallstones and normally remove the gallbladder. In recent years less invasive treatment modalities have replaced these general surgical procedures and reduced patient trauma, long hospital stays and recovery periods.

For example, U.S. Pat. No. 4,696,668 and U.S. Pat. No. 4,781,677, both to Wilcox, disclose a treatment modality involving the administration of a dissolution agent in the bile duct to essentially dissolve any gallstones. More specifically, a catheter contains several lumens for inflating and deflating each of two balloons, venting bile, and infusing and aspirating the dissolution agent. Inflating the balloons occludes the bile duct at two spaced sites and creates a sealed spaced that receives the dissolution agent. As the space is sealed from the remaining biliary tree, the dissolution agent finds access to the gallbladder and any gallstones therein through the cystic duct with the exclusion of bile from the gallbladder fundus. The dissolution agent also will be confined in high concentration around bile duct gallstones. After the gallstones dissolve the balloons are deflated and the catheter can be withdrawn. In this particular approach, the catheter is directed into the biliary tree using a standard duodenoscope that passes through the alimentary tract. Although this and analogous approaches have the potential of minimizing patient trauma, such treatments require extended placement of the

duodenoscope in the patient, exhibit low efficacy and introduce a potential for adverse reactions to the dissolution agents.

In an alternative approach, a surgeon directs a surgical extractor into the biliary tree through at least an incision in the bile duct. For example, in U.S. Pat. No. 3,108,593 to Glassman a surgeon incises both the bile duct and duodenum. Then the surgeon directs an extractor through the bile duct incision, biliary tree, sphincter of Oddi and duodenum to exit through the duodenum incision. This extractor includes a series of longitudinally spaced cages for trapping any gallstones in the bile duct and removing them through either of the incisions.

U.S. Pat. No. 4,627,837 to Gonzalo discloses a catheter device with a pair of inflatable balloons at its distal end. This catheter is led through an incision in the bile duct toward the duodenum. After the distal balloon passes through the sphincter of Oddi, both balloons are expanded to anchor the catheter in place. This enables the catheter to be used for irrigating and flushing through other lumens in order to capture any gallstone in the second balloon for removal through the incised bile duct.

In accordance with still another modality as for the treatment of strictures, a surgeon may insert a catheter device through the bile duct or duodenum for the purpose of dilating or enlarging the sphincter of Oddi. For example, U.S. Pat. No. 4,705,041 to Kim discloses a dilator that is directed through an incision in the bile duct and the sphincter of Oddi. An expandable tip dilates the sphincter of Oddi. U.S. Pat. No. 5,035,696 to Rydell discloses an electrosurgical instrument that is directed through the duodenum and to the sphincter of Oddi for performing a sphincterotomy. This apparatus contains a cutting wire that is heated to cut the sphincter muscle. U.S. Pat. No. 5,024,617 to Karpiel, discloses a similar device that can be directed through a duodenoscope. U.S. Pat. No. 5,152,772 to Sewell, Jr. discloses a device for performing a sphincterotomy that is directed through an incision in the bile duct and includes a knife for cutting the sphincter muscle.

The use of the duodenoscope and sphincterotomy devices, such as shown in the Rydell and Karpiel patents, enables an internist to diagnose and treat problems in the biliary tree with minimal patient invasion. For example, modalities as described in these

patents eliminates the surgery needed for incising the bile duct. Consequently, these modalities can be performed as outpatient or day surgical procedures. These procedures greatly reduce patient trauma, the length of a hospital stay and recovery times. For example, if an internist determines that gallstones are present in the biliary tree, particularly the common bile duct, the internist can insert a duodenoscope into the duodenum to view the sphincter of Oddi. Then a first catheter can be advanced through the working channel of the duodenoscope with or without a guidewire and directed through the sphincter of Oddi into the biliary tree. Contrast agent injected through the catheter enables fluoroscopy or other imaging procedures to confirm the presence of gallstones within the biliary tree. Next the internist exchanges the first catheter for a second catheter for performing a sphincterotomy such as the types disclosed in the above-identified Rydell and Karpiel patents. The second catheter is then exchanged for a third catheter such as shown in the Glassman patent or some other equivalent retrieval catheter for drawings gallstones through the enlarged sphincter of Oddi. Thereafter the retrieval catheter is manipulated to release the gallstone into the duodenum. The catheter, any guidewire and the duodenoscope can then be removed to complete the procedure.

This procedure is significantly less traumatic to the patient than other prior art procedures because the only incision occurs during the sphincterotomy. However, this procedure as presently practiced requires three separate catheters and two catheter exchanges. These exchanges are required because the first, second and third catheters function solely to inject contrast agent to perform the sphincterotomy and to dislodge gallstones, respectively. The time required for performing each catheter exchange can increase patient trauma and increase the duration of the procedure and reduce efficiency. Moreover, each such procedure requires the use of two or three separate catheter devices.

SUMMARY

Therefore, an object of this invention is to provide apparatus for performing both diagnosis and additional therapeutic treatment without requiring a catheter exchange.

Yet another object of this invention is to provide apparatus that enables the removal of gallstones from the biliary tree by a procedure that reduces the number of required catheters and catheter exchanges.

Still another object of this invention is to provide a single catheter apparatus that can perform a sphincterotomy and remove gallstones in the common bile duct.

Yet another object of this invention is to provide a single catheter apparatus that can perform a sphincterotomy and inject contrast material into the biliary tree.

Still yet another object of this invention is to provide a single catheter apparatus that can inject contrast agent into the biliary tree, performing a sphincterotomy and remove gallstones in the bile duct into the duodenum.

Presently available products that may be modified according to the present invention include the Boston Scientific Ultratome, Ultratome XL, Stonetome, Flourotome, Tapertome, RX "C" Channel Sphincterotome, RX "U" Channel Sphincterotome, and RX Tapertome. Other products that may be modified according to the present invention include the Wilson Cook Canulatome, Wiltex Accuratome, Bard ProForma, and Olympus Clever Clevercut.

Accordingly, there is provided according to the present invention a method for cannulation of a common bile duct comprising threading a catheter through an appropriately placed endoscope, wherein said catheter comprises at least two and preferably three lumens, preferably a guide wire lumen, a contrast lumen, and a cutting wire lumen, whereby the handle of the device, secured to the cutting wire, may rotate independently of the catheter shaft and whereby the handle assembly is rotated to change the position of the distal tip independently of the scope position to achieve desired position for cannulation of the common bile duct. A rotation marking may be used to indicate the amount of rotation present and a rotation lock may be used to maintain the orientation of the tip.

The present invention also provides a method for sphincterotomy, whereby following cannulation, the handle of the mechanism may be rotated again, to the extent necessary to achieve the desired cutting position and cutting is effected by application of current to the cutting wire. Rotation lock and rotation markings may also be incorporated.

According to the invention, there is also provided a device comprising a catheter comprising two or preferably three lumens, preferably a guide wire lumen, a contrast fluid lumen, and a cutting wire lumen, whereby the catheter is rotatably attached to a handle fixed to the proximal end of the cutting wire. The proximal end of the catheter may terminate in a molded luer port assembly comprising entry points for the guide wire and for injection of contrast fluid. The guide wire and contrast lumens terminate at the distal end of the catheter. The handle and the catheter or molded luer port assembly may be designed to snap together to facilitate fast and inexpensive manufacture. Rotation lock and markings may also be included in this embodiment.

The present invention is an improvement of the devices and methods disclosed in U.S. Patent No. 5,547,469, U.S. Patent No. 5,868,698 and U.S. Patent No. 5,683,362 and in U.S. Patent Application serial no. 09/154,834 in the name of Rowland, et al., all owned by the owner of the present application, the common disclosure of which is incorporated herein and the subject matter of which is considered part of the present invention as set forth below. Figures 1 and 2 herein are original to the present application. Accordingly, original figures 1-9 of the Rowland, et al. applications are renumbered herein as Figures 3 through 11.

In accordance with one aspect of this invention, apparatus can be used in a treatment modality including an enlargement procedure and another procedure to be performed. This apparatus includes a catheter with proximal and distal ends and proximal and distal portions. The catheter includes first, second and third generally parallel lumens. The first lumen has a greater diameter than either of the second and third lumens and the lumens each extend between proximal and distal portions of the catheter. The apparatus for performing the enlargement procedure extends through the second lumen for operating distally of the catheter in response to manipulations of an operator at the proximal end of the catheter. The first lumen has a proximal port for enabling access to the first lumen and the third lumen has a proximal port and a distal port for enabling the remote control of some other procedure.

In accordance with another aspect of this invention, apparatus is provided for removing objects from the biliary tree. This apparatus includes a catheter that is directed

through the working channel of a duodenoscope and the sphincter of Oddi into the biliary tree. The catheter includes first, second and third lumens with the first lumen being larger than either the second or third lumens and the lumens generally extending between proximal and distal portions of the catheter along parallel axes. Apparatus for cutting the sphincter of Oddi includes a cutting wire extending through the second lumen and externally of the catheter means through a distal port along a length that is coextensive with part of the distal portion of the catheter. A handle attaches to the catheter at the proximal portion and to the proximal wire portion to control the position and orientation of the cutting wire. A rotation lock and marking may be incorporated to fix the orientation of the distal tip and to indicate the orientation of the distal tip respectively. An expansible balloon is mounted on the distal portion spaced from the cutting wire and can be inflated through the third lumen in order to move any gallstone in the biliary tree through the enlarged sphincter of Oddi.

In accordance with still another aspect of this invention, the apparatus is provided for directing contrast agent into the biliary tree and performing a sphincterotomy through the working channel of a duodenoscope. This apparatus includes a catheter that is directed through the working channel of the duodenoscope and the sphincter of Oddi into the biliary tree. The catheter includes first, second and third lumens with the first lumen being larger than either the second or third lumens and the lumens generally extending between proximal and distal portions of the catheter along parallel axes. Apparatus for cutting the sphincter of Oddi includes a cutting wire extending through the second lumen and externally of the catheter means through a distal port along a length that is coextensive with part of said distal portion of the catheter. A handle attaches to the catheter into the proximal wire portion to control the position and orientation of the cutting wire. A rotation lock and marking may be incorporated to fix the orientation of the distal tip and to indicate the orientation of the distal tip respectively. The proximal port of the third lumen connects to a contrast agent source and the third lumen delivers contrast agent into the biliary tree through a distal port in the distal end of the catheter.

BRIEF DESCRIPTION OF THE DRAWINGS

The various objects, advantages and novel features of this invention will be more fully apparent from a reading of the following detailed description in conjunction with the accompanying drawings in which like reference numerals refer to like parts, and in which:

FIG. 1 is a plan view of one embodiment of apparatus constructed in accordance with the present invention with a rotatable handle attached to a cutting wire;

FIG. 1a is a plan view of a snap in handle connection for the apparatus of FIG. 1;

FIG. 2 is a view of an alternative embodiment of the rotatable handle of the present invention;

FIG. 3 is a plan view of one embodiment of apparatus constructed in accordance with this invention;

FIG. 4 is a cross-section taken along lines 2--2 in FIG. 3;

FIG. 5 is a cross-section taken along lines 3--3 in FIG. 4;

FIG. 6 is a cross-section taken along lines 4--4 in FIG. 5;

FIG. 7 depicts the apparatus of FIG. 3 positioned through a duodenoscope for injecting contrast agent into the biliary tree.

FIG. 8 is an enlarged view that depicts the orientation of the apparatus in FIG. 3 for performing a sphincterotomy;

FIG. 9 depicts the apparatus of FIG. 3 positioned through a duodenoscope for dislodging material within the common bile duct;

FIG. 10 is a cross-section of an alternative embodiment of the apparatus as viewed generally along lines 3--3 in FIG. 4.;

FIG. 11 is a cross-section of still another embodiment of this invention taken along lines 3--3 in FIG. 4;

FIG. 12 is a view of the rotatable handle of the present invention including a rotation lock;

FIG. 13 is a detailed view of the rotation lock of FIG. 12;

FIG. 13a is a sectional view along line A-A of FIG. 13;

FIG. 14 shows an alignment between the rotatable handle and the bifurcation connector showing zero rotation of the rotatable handle;

FIGS. 15a-d show alternative embodiments of the rotation lock of the present invention;

FIGS. 16a-d show cross-sectional areas of the alternate embodiment of FIGS. 15a-d;

FIGS. 17a-c show three alternative embodiments of rotation markings for the present invention;

FIGS. 18a & b illustrate alternatives of bifurcation connectors; and

FIGS. 19a & b illustrate a bowing lock included in the present invention.

DESCRIPTION OF ILLUSTRATED EMBODIMENTS

FIG. 3 depicts a catheter apparatus 10 that has the capability of injecting a contrast agent into the biliary tree, of performing a sphincterotomy and of dislodging a gallstone into the duodenum. The apparatus 10 includes a catheter 11 which, for purposes of definition, includes a proximal end portion 13 extending from a proximal end 12 and a distal end 14 with a distal portion 15 extending a short distance from the distal end 14. In a typical application, the catheter will have a working length of 200 cm and the distal end portion 15 will have a length of 6 cm to 9 cm. Normally the distal portion 15 will have a diameter that is smaller than the diameter of the proximal portion to increase the flexibility of the distal portion 15. The reduction in diameter also makes the tip less traumatic and allows the tip portion to reach smaller passages while allowing the larger proximal portion to provide necessary hoop strength and rigidity, particularly where the proximal portion 13 is coextensive with the working channel of a duodenoscope. For example, the proximal and distal portions might have diameters corresponding to 7 Fr and 5.5 Fr catheter sizes (i.e., 0.09"and 0.07"respectively).

As shown particularly in FIG. 4, the catheter 11 has three lumens. A first lumen 16 has a diameter that is greater than either a second lumen 17 or a third lumen 20. In one particular embodiment the lumen 16 has a diameter of 0.040" in the proximal portion 13 that reduces to about 0.037" in the distal portion 15 to receive a standard 0.035" guidewire. In addition the lumen 16 is offset from the center of the catheter 11.

The lumens 17 and 20 are each smaller in diameter than the lumen 16 and are radially offset from the centerline of the catheter, from each other and from the lumen 16. In one particular embodiment the lumens 17 and 20 each have internal diameters of 0.028" in the proximal portions 13 that reduces to about 0,020" in the distal portion 15. As described later, this lumen 20 carries a cutting wire for performing a sphincterotomy and for allowing the infusion of a contrast agent at reasonable rates. The angular spacing between the lumens 17 and 20 is about 45 degrees and the angular spacing between the first lumen 16 and each of the lumens 17 and 20 each is about 157.5 degrees. In this configuration and with these dimensions the proximal portion 13 readily passes through the working channel of any duodenoscope.

Referring again to FIGS. 3 and 4, each of the lumens 16, 17 and 20 includes an entry port in the proximal portion 13 and an exit port in the distal portion 15. Generally, and as described in more detail later, the first lumen 16 has an exit port through the distal end 14 while the exit ports for the lumens 17 and 20 can be sited at different locations in the distal portion 15 depending upon a particular application.

In FIG. 3, the entry ports in proximal portion 13 adjacent the proximal end 12 include an entry port 21 that provides access to the lumen 16 and includes an optional Leur lock fitting 22. A proximally positioned entry port 23 provides access to the lumen 17 and includes an optional Leur lock fitting 24. A proximal entry port 25 for the lumen 20 is located coextensively with a portion of a handle 26 attached to the proximal end 12.

Referring to the distal end portion 15, the catheter 11 in this particular embodiment carries an expansible balloon 30 proximally of the excursion of a cutting wire 31 externally of the catheter 11. As shown in FIG. 5, the lumen 17 emerges at a distal exit port 32 through the side of the catheter 11 with the interior of the expansible balloon 30. An extension of the lumen 17 beyond the distal port 32 is sealed by known

methods of manufacture. Consequently, fluid forced through the entrance port 23, as by a syringe (not shown) attached to the Leur lock fitting 24, expands the balloon 30 into an occluding orientation as shown in FIG. 5 with an inflated diameter in the range up to 20 mm.

As will also be apparent from viewing FIGS. 5 and 6, the first lumen 16 extends through the catheter 11 and terminates with an exit port 33 in the distal end 14. Thus the lumen 16 is adapted for receiving a guidewire through the entrance port 21 that will extend through the catheter 11 and exit the distal end 14 and allow the catheter to slide over that guidewire.

Referring to FIG. 6, a distal end 34 of the cutting wire 31 attaches to a clamp 35 formed at the distal end of the lumen 20. Spaced skived ports 36A and 36B allow an active portion 37 of the cutting wire 31 to emerge from the catheter 11 through the skived aperture 36A, parallel the catheter 11 exteriorly thereof and return into the lumen 20 through the port 36B and a reinforcing sleeve 38. The cutting wire 31 then extends through the lumen 20 to the handle 26 shown in FIG. 1 where it emerges as a proximal end portion 40.

The handle 26, as shown in FIG. 3, includes a central member 41 terminating with a thumb ring 42. The central member 41 extends through and slides with respect to a body section 43 having opposed finger rings 44. The central member 41 also attaches to the catheter 11, and is therefore an extension of the catheter 11. The member 43 additionally includes an internal connector 45 for clamping the proximal end 40 of the cutting wire 31. Thus, when the body 43 is at its distal position as shown in FIG. 3, the distal portion of the catheter 15 is in essentially straight line as shown in FIG. 3 with the active portion 37 of the cutting wire 31 being closely adjacent the catheter 11. Retracting the body portion 43, causes the cutting wire 31 to bend the distal end upwardly as shown in FIG. 3 to a position that is essentially at right angles to the main axis of the catheter, as will be shown later.

The connector block 45 and the cutting wire 31 are generally conductive members that attach through an RF connector 46 to an RF heating source 47. The use of such RF heating sources 47 for energizing a cutting wire 31 thereby to cut the sphincter muscle is

well known in the art and represents one possible sphincterotomy procedure that can be adapted for the apparatus of this invention and is not described further.

With this description of the apparatus structure, it will now be possible to understand its use in a particular application. FIG. 7 discloses, in a partially broken and schematic view, the positioning of a duodenoscope 50 in the duodenum 51 adjacent the sphincter of Oddi 52. A catheter 11 such as constructed in FIG. 3 passes through the sphincter of Oddi 52 into the common bile duct 53, bypassing the pancreatic duct 54. The distal end 14 does not extend to the gallbladder 55.

Fluoroscopy allows the appropriate positioning by utilizing a series of radio-opaque markers 56 at the distal portion 15 that may include the clamp 35 and the reinforcing sleeve 38 in FIG. 6. The catheter 11 can be positioned with or without the presence of a guidewire 57 in the lumen 16 shown in FIGS. 4, 5 and 6. For purposes of injecting the contrast agent, any guidewire 57 can be withdrawn to allow the contrast agent to be injected through the lumen 16 for purposes of fluoroscopic examination to confirm the presence of one or more gallstones 58. It is also possible during the operation to expand the balloon 30 to occlude the bile duct 53 and block any migration of contrast agent into the duodenum 51 or the pancreatic duct 54.

FIG. 8 is an enlarged view showing the duodenum 51, sphincter of Oddi 52, portions of the pancreatic duct 54 and the common bile duct 53. In FIG. 8 the catheter 11 has been positioned relative to the duodenoscope 50 through the opening of the sphincter of Oddi 52. The handle 43 in FIG. 3 has been drawn proximally to deflect the distal portion 15 into essentially a right angle configuration such that the cutting wire 31 abuts a portion of the sphincter of Oddi 52. The application of RF heating to the cutting wire 31 then will cut the sphincter of Oddi 52 and enlarge the opening therethrough. As will be apparent, the sphincterotomy is performed with direct visualization of the sphincter of Oddi through the duodenoscope.

Moreover, as has been observed by others, catheters having guidewire and cutting wire lumens tend to assume a particular angular orientation when the distal portion 15 emerges from the duodenoscope. This orientation is essentially independent of the angular position of the catheter when it is inserted into the duodenoscope. The offset

nature of the lumen 20 as shown in FIG. 4, improves the location of the cutting wire 31 as the distal portion 15 passes through the sphincter of Oddi 52. Specifically the angularly offset brings the cutting wire 31 into better alignment with the common bile duct 53 and displaces the cutting wire from the pancreatic duct 54.

FIG. 9 depicts the catheter after the sphincterotomy and after the catheter 11 is advanced over the guidewire 57, if used. FIG. 9 also discloses the catheter 11 after the balloon 30 has been moved beyond a gallstone 58 in the bile duct 53. The balloon 30 is expanded so that upon withdrawal of the catheter 11 the balloon 30 will dislodge the gallstones 58 and sweep them through the sphincter of Oddi 52 into the duodenum 51.

As will now be apparent from the description of the particular catheter apparatus 10 shown in FIG. 3 and its use as discussed with respect to FIGS. 7, 8, and 9, the single catheter apparatus of this invention is capable of providing diagnostic contrast agent injection, of performing a sphincterotomy and of dislodging gallstones in the common bile duct or other portions of the biliary tree without having to exchange a catheter. Moreover, positioning and sizing of the lumens enables these functions to be performed with a catheter apparatus that is readily adapted for use in the working channels of standard duodenoscopes. Consequently the gallstones can be removed from the biliary tree without bile duct incisions and accompanying surgical procedures, as duodenoscope can be introduced through the alimentary tract. Consequently the entire procedure is adapted for being performed more rapidly than prior art procedures and with fewer components. The net effect is to reduce patient trauma and the overall time and cost of conducting the procedure.

In FIG. 3 the balloon 30 is located proximally of the cutting wire 31. FIG. 10 discloses an alternative embodiment in which a balloon 60 is located distally of the cutting wire 31. More specifically, the distal end of a lumen 17A, corresponding to the lumen 17 in FIGS. 5 and 6, is sealed. A side facing exit port 61 skived or otherwise formed in the catheter 11 opens into a chamber 62 formed by the balloon 60. A first sealing portion 63 and a sealing portion 64 of the balloon 60 connect proximally and distally of the aperture 61 respectively and seal the chamber 62.

Introduction of a balloon inflation fluid through the lumen 17A expands the balloon 60 into an occluding orientation corresponding to the orientation of the balloon 30 shown in FIG. 5. Retraction of the catheter 11 with the distal balloon 60 inflated enables withdrawal of a gallstone from the bile duct. This particular embodiment is particularly adapted when it is determined that a gallstone is located high in the biliary tree to minimize the incursion of the distal portion 15 through the biliary tree beyond the gallstone or in any application in which the internist desires to minimize the length of the distal portion 15 that extends beyond the occluding balloon.

FIG. 11 discloses another embodiment of this invention for enlarging the sphincter of Oddi and performing another procedure, such as injecting a contrast agent into the biliary tree, as might be used in the diagnosis and treatment of a stricture in the biliary tree. In this particular embodiment an exit port 65 from the lumen 17B is located in the distal end 14 of the distal portion 15. The lumen 16 then can be used for a guidewire and the lumen 17B, for injecting the contrast agent directly into the biliary tree while the guidewire remains in place. The apparatus would then be positioned to perform a sphincterotomy without having to exchange a catheter should the procedure be warranted.

As still another alternative, the internist could utilize a conventional catheter for purposes of injecting the contrast agent to determine the need for gallstone removal. If treatment were indicated, the internist could then utilize apparatus as shown in FIG. 3 with a single exchange over the guidewire that would pass through the lumen 16 as previously described.

Therefore, it will now be apparent that apparatus constructed in accordance with this invention attains the several objects and the advantages of this invention. More particularly, catheter apparatus constructed in accordance with this invention allows the injection of a contrast agent, the performance of a sphincterotomy and dislodging gallstones from the common bile duct through the enlarged sphincter of Oddi into the duodenum all without requiring any catheter exchanges. Moreover, this apparatus allows such a procedure to occur through a duodenoscope to minimize patient trauma. The use

of a single catheter with an elimination of catheter exchanges further reduces the time and costs associated with the use of multiple, single-function catheter devices.

As will be apparent from the foregoing description, many alterations can be made to the specifically disclosed embodiments. Different balloon structures can be used and located at alternative positions. Different cutting wire embodiments and orientations can be used. Thus, although this invention has been disclosed in terms of certain embodiments, it will be apparent that many modifications can be made to the disclosed apparatus without departing from the invention. In particular, it is considered that all of the foregoing embodiments may be used in conjunction with a handle fixed to the cutting wire but rotatable relative to the catheter. A rotation lock fixing the orientation of the cutting wire and/or a rotation marking, indicating the amount of rotation may be included with the current invention. Therefore, it is the intent of the appended claims to cover all such variations and modifications as come within the true spirit and scope of this invention.

Consistent therewith, the following subject matter claimed in the Rowland, et al patents and applications is specifically claimed in connection with the subject matter specific to the present application, namely, a handle fixed to the cutting wire and rotatable relative to the shaft of the catheter, whereby turning of the handle independently of the catheter and independently of the endoscope causes the distal tip of the device to rotate independently of the endoscope allowing the surgical team greater control over the position of the device for cannulation and subsequently for sphincterotomy A rotation lock fixing the orientation of the cutting wire and/or a rotation marking, indicating the amount of rotation may be included with the current invention.

Due to inconsistencies in the sphincterotome, anatomy, and endoscope manipulation, it is difficult to accurately and consistently position the sphincterotome for proper cannulation. The steerable sphincterotome of the present invention allows the physician to control the position of the distal tip of the device independently of the endoscope and adjust for inconsistencies in the device and the anatomy. According to the present invention, the handle to which the cutting wire is attached is freely rotatable relative to the catheter. Rotating the handle of the present invention induces a twisting of

the attached cutting wire which allows orientation of the distal end without rotating the proximal end of the attached catheter. See Figs. 1 and 2. Handle 66, secured to the cutting wire at 80 but rotatable relative to the shaft of the catheter at 81, provides a mechanism to rotate the wire, transmitting the force to rotate the device tip. With the handle rotating independently of the shaft at the proximal end, the force can be applied directly to the distal tip without twisting the entire shaft. Also a rotation lock to maintain the orientation of the tip and/or a rotation marking, to indicate the amount of rotation may be included. An integrated molded luer port assembly for 2 and 3 lumen catheters may be provided to snap into the rotatable handle, to facilitate fast and economical manufacturing, as shown in Figs. 1 and 1a. Alternatively, prior art serial lumen ports may be configured to snap into the rotatable handle as shown in Fig. 2.

Referring to FIG. 12, the present invention also contains a feature known as a rotation lock. Rotation lock 68 allows the user to maintain the orientation of the tip at all times. This is done by maintaining the position of handle 66 relative to bifurcation connector 67 after the handle has been rotated. Rotation lock 68 allows the user to release handle 66 at any time during the procedure, while maintaining the orientation of handle 66 and preventing further rotation while the lock is engaged. Maintaining the position of handle 66 maintains the orientation of the distal tip in the desired orientation. Maintaining the orientation of the distal tip reduces the amount of time and effort required to cannulate if the distal tip moved. Preventing undesired movement of the distal tip may also prevent patient injury.

Referring to FIG. 13, two pair of mating detents 69 and slots 70 may be used to create this rotation lock. Detents 69 and slots 70 are located along the central axis of body 71, at the intersection of body 71 and bifurcation connector 67. In FIG. 13, the two pair of detents 69 and slots 70 are located 180° apart, relative to the central axis. This creates a lock position every half rotation of handle 66. During use of the device, as handle 66 is rotated, detents 69 become disengaged from slots 70. As detents 69 become disengaged, they compress slightly. As handle 66 reaches a position 180° from where rotation began, detents 69 recover from their compressed state, and engage with slots 70 once again. As detents 69 traverse from one position to the next, there is a noticeable amount of friction between the mating components. This friction is great enough that

handle 66 can be released at any time without fear of losing the orientation position of the distal tip.

Rotation lock 68 also serves a secondary function of keeping the distal tip locked in the home position while the catheter is being removed from the package, inserted into the endoscope, and manipulated through the endoscope. Without this feature, the initial orientation position of the distal tip would become unpredictable. FIG. 13a shows a detailed diagram of the interaction between detents 69 and slots 70.

Referring to FIG. 14, when detents 69 and slots 70 are engaged, bifurcation connector 67 and finger rings 44 all lie in the same plane. This acts as the rotation marker. Whenever finder rings 44 are rotated into the same plane as bifurcation connector 67, the rotation lock is engaged, thus signaling 180° of rotation from the last position. The use of a marker such as this allows the user to more easily keep track of how much handle 66 has been rotated. This is helpful if the user desires to move the distal tip back to its original position. In effect, the user will know, for example, that handle 66 has been rotated three clicks from the original position. Therefore, to return handle 66 to the original position, it must be rotated three clicks in the opposite direction.

FIGURES 15a – 15d show alternative embodiments of rotation lock 68. FIGURE 15a shows a pure frictional lock. The connection of bifurcation connector 69 to the handle 66 could be designed such that rotation lock 68 is purely a function of frictional interference between the two components. Alternative embodiments could include different types of assembly joints to create this friction. In the primary embodiment, the assembly of the two components is accomplished by mating a male post of the bifurcation connector to a female hole of the same size and shape. Alternative embodiments could reverse this, so that the male protrusion is part of the main body of handle 66. The friction lock could also be built into the mating faces of main body and bifurcation connector, which are perpendicular to the major axis. FIGURE 16a shows a cross section of the rotation lock along Z-Z of FIGURE 15a.

FIGURE 15b shows a oval post lock embodiment of the present invention. The connection of bifurcation connector 67 to handle 66 could also be designed incorporating an ovalized male post 73 and female hole 72. In this embodiment, as handle 66 is rotated

relative to bifurcation connector 67, ovalized hole 72 would deform, allowing oval post 73 to rotate. As handle 66 reached a rotation of 180°, ovalized hole 72 would conform back to its original shape, thus locking handle 66 in place. As shown in FIGURES 15c and 15d, this basic concept may be expanded to incorporate other shapes rather than oval as shown in FIGURE 15b. One of ordinary skill in the art would appreciate that the shape of the geometry however, governs the degrees of rotation between locked positions. For example, if post 73 and ovalized hole 72 configuration were made up of mating equilateral triangles (FIGURE 15c), there would be 120° of rotation between locked positions. Using a square configuration (FIGURE 15d), would give 90° between locked positions. FIGURE 16b, illustrates the cross-sectional area across Y-Y of FIGURE 15b. FIGURE 16c illustrates the cross-sectional area of FIGURE 15c across X-X and FIGURE 16d illustrates the cross-sectional area of FIGURE 15d along cross-section W-W.

FIGURES 17a-c show alternative embodiments by which a rotation marker may be created and included in the present invention. One of ordinary skill in the art would understand these embodiments may be expanded. To aid the user in knowing exactly how much handle 66 has been rotated from its original and/or last position, several forms of visual markers can be incorporated into the design. One alternative embodiment is comprised of a set of lines placed radially, around the major axis, at the area where the main body and bifurcation connector 67 meets (FIG. 17a). A single line on the stationary component, bifurcation connector 67, would match up with a corresponding line on body 43. As handle 66 is rotated relative to bifurcation connector 67, the series of lines on the body would rotate past the stationary line on bifurcation 67. Each line would indicate an incremental amount of movement. For example, if there were four, equally spaced lines on the body, each line that passed the marker on the bifurcation connection would signify 90° of rotation.

This feature could be further enhanced by many methods. A series of numbers rather than lines could be used to signify the amount of rotation (FIG. 17b). Alternating colors could also be used to signify the amount of rotation. Alternating line patterns could be used as well (FIG. 17c).

Another alternative embodiment may use audible tones to make the user aware of the amount of rotation. One method for doing this would be able to design the rotation lock features so that a click is clearly audible at predetermined points along the rotational travel of the body.

Referring to FIGURES 18a and 18b, there are several alternative means by which a bifurcation connector can be created. One of ordinary skill would understand these embodiments may be expanded from those presented in the current application.

Although the present invention is comprised of a connector with two lumens, the connector design could easily be modified to accommodate three or more lumens (FIG. 18a). This would allow future designs to incorporate both guidewire post connector 74 and injection port connector 75 into one component.

Another alternative to the bifurcation connector of the present design would be one, which also houses the electrical connector 76 (FIG. 18b). Electrical connector 76, presently incorporated into the finger ring, could be moved to the bifurcation connector.

Referring now to FIGURES 19a and 19b, other embodiments of the present invention may consist of handle 66 similar to that previously described, but with the addition of a bowing lock. A bowing lock would aid the user in that handle 66 could be released at any time, and the catheter tip would maintain its bowed position. Just as the rotation lock provides for a safer and more efficient procedure, the bowing lock would do the same.

The bowing lock could be incorporated into the design in many ways. The bowing lock, in its simplest form, would consist of friction lock 77 created between finger rings 44 and main body 43 (FIG. 19a). An alternative to this design would create a similar friction lock, but would use the surfaces between wire termination 78 and main body 43 (FIG. 19b). The friction lock shown in figure 19b is enhanced by incorporating several lock ribs 79. Lock ribs 79 would be used to hold the catheter tip at a specific, predetermined angle. In effect, locking handle 66 into the first position would, for example, deflect the tip 30°. The next position would deflect the tip 60°. This feature would give the user even more control when positioning the catheter tip within the anatomy. In both cases, as finger rings 44 are actuated along main body 43, and catheter

tip 80 is bowed, the friction between the mating components would hold the position of the handle, and thus hold the position of the bow.

CLAIMS

1. An apparatus for use in a treatment modality including an enlargement procedure to be performed within a patient, said apparatus including a catheter for being directed through internal passageways in the patient, said catheter having proximal and distal ends, and proximal and distal portions adjacent to said proximal and distal ends respectively, and a first and at least second generally parallel lumens, said lumens extending between said proximal and distal portions, and a cutting wire for performing the enlargement procedure extending through said second lumen for operating at said distal portion in response to manipulations at said proximal end, said cutting wire having a distal end attached to said catheter at the distal end of said second lumen, a portion thereof external to said catheter along a length coextensive with a portion of said distal portion of said catheter and a handle for operating said cutting wire from a point proximal of said catheter, the improvement comprising:

a rotatable coupling attaching said handle to said catheter allowing said handle to rotate relative to said proximal end of said catheter while engaging and rotating a proximal end of said cutting wire whereby said distal portion of said catheter rotates as a result of said rotation of said handle.

2. The apparatus of claim 1 further comprising:

a rotation lock which inhibits further rotation of said handle relative to said proximal end of said catheter.

3. The apparatus of claim 1, further comprising:

a rotation indicator configured to indicate an amount of rotation of said handle relative to said proximal end of said catheter.

4. The apparatus of claim 3, wherein said rotation indicator comprises a visual indicator of said amount of rotation.

5. The apparatus of claim 4, wherein said visual indicator comprises an index marking and a corresponding scale marking providing an indication of said amount of rotation.

6. The apparatus of claim 3, wherein said rotation indicator comprises a device providing an audible indication in response to said rotation of said handle relative to said proximal end of said catheter.

7. A method of cutting tissue in a body passage comprising selecting a catheter having a first lumen configured for receiving a wire guide, a second lumen configured for receiving an electrosurgical cutting wire, positioning said catheter in said passage at a desired position using an endoscope, actuating the electrosurgical cutting wire in the second lumen, the improvement comprising:

orientating said electrosurgical cutting wire by rotating a handle relative to a proximal end of said catheter.

8. The method of claim 7 wherein said cutting wire is affixed to said handle, wherein said step of rotating said handle causes a rotation of a proximal end of said cutting wire whereby said cutting wire is caused to rotate within said second lumen.

9. The method of claim 8 wherein a distal end of said cutting wire is caused to rotate by a twisting of a portion of said cutting wire intermediate said proximal and said distal portions of said cutting wire.

10. The method of claim 7 further comprising:

inhibiting further rotation of said handle relative to said proximal end of said catheter by engaging a rotation lock.

11. The method of claim 7, further comprising:

indicating an amount of rotation of said handle relative to said proximal end of said catheter through the use of a rotation indicator.

12. The method of claim 11, wherein said step of indicating an amount of rotation includes a visual indication of said amount of rotation.

13. The method of claim 12, wherein said visual indication includes an index marking and a corresponding scale marking providing an indication of said amount of rotation.

14. The method of claim 11, wherein said step of indicating an amount of rotation includes an audible indicator provided by a device in response to said rotation of said handle relative to said proximal end of said catheter.

15. A catheter handle comprising:

a rotatable coupling configured to allow free rotation of a proximal end of a catheter; and

a clamping member configured to engage a proximal end of a device extending through a lumen formed in said catheter whereby rotation of said handle causes rotation of a proximal end of said device in said lumen.

16. The catheter handle of claim 15, wherein said device comprises a cutting wire extending from said proximal end of said catheter to and connecting to a distal end of said catheter.

17. The catheter handle of claim 15, further comprising:

a rotation lock engageable to inhibit a rotation of said handle with respect to said proximal end of said catheter.

18. The catheter handle of claim 15, further comprising:

a rotation indicator configured to indicate an amount of rotation of said handle relative to said proximal end of said catheter.

19. The catheter handle of claim 18, wherein said rotation indicator comprises a visual indicator of said amount of rotation.

20. The catheter handle of claim 19, wherein said visual indicator comprises an index marking and a corresponding scale marking providing an indication of said amount of rotation.

21. The catheter handle of claim 15, wherein said rotation indicator comprises a device providing an audible indication in response to said rotation of said handle relative to said proximal end of said catheter.

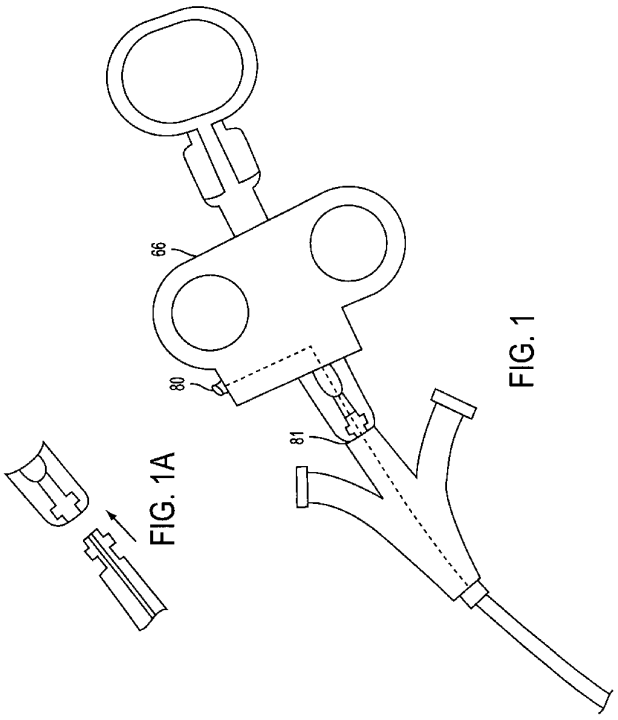

FIG. 1

FIG. 1A

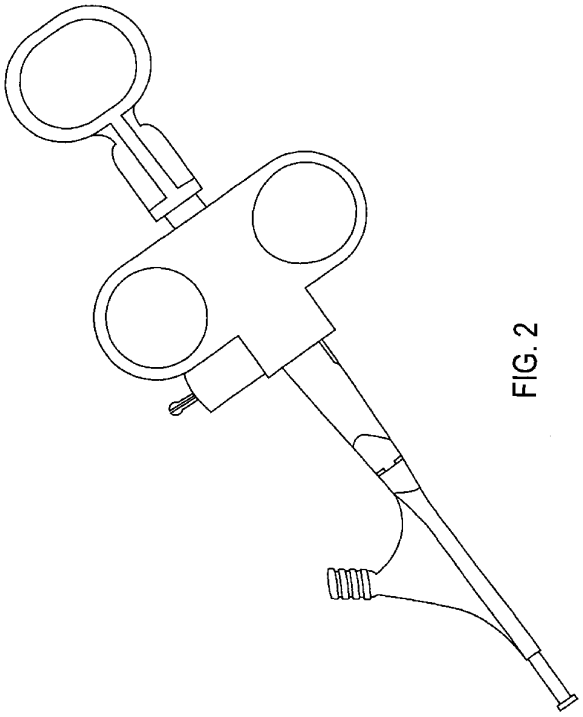

FIG. 2

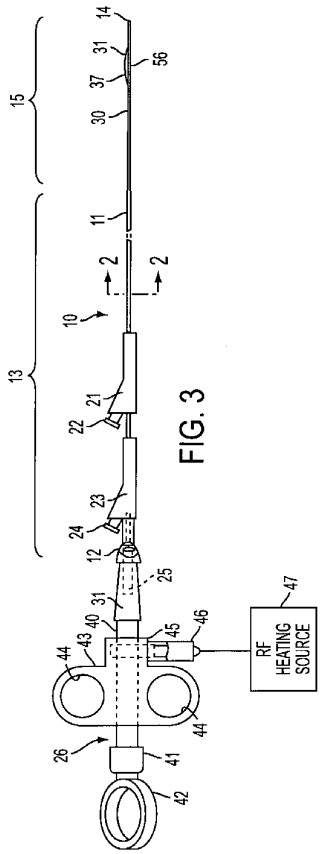
14
31
56
37
30
15
11
2
2
10
13
21
22
23
24
12
25
31
40
43
44
45
46
47
RF
HEATING
SOURCE
44
26
41
42

FIG. 3

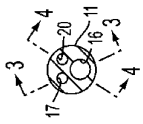
4
20
11
3
16
3
3
4
17

FIG. 4

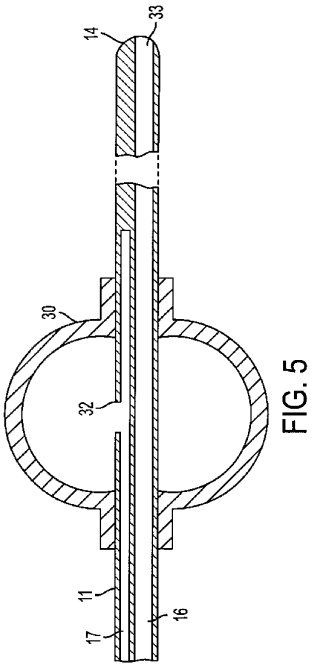

FIG. 5

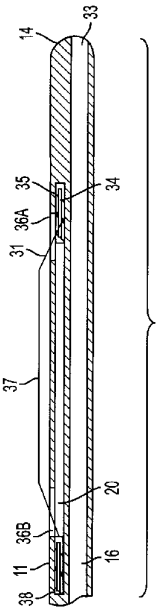

FIG. 6

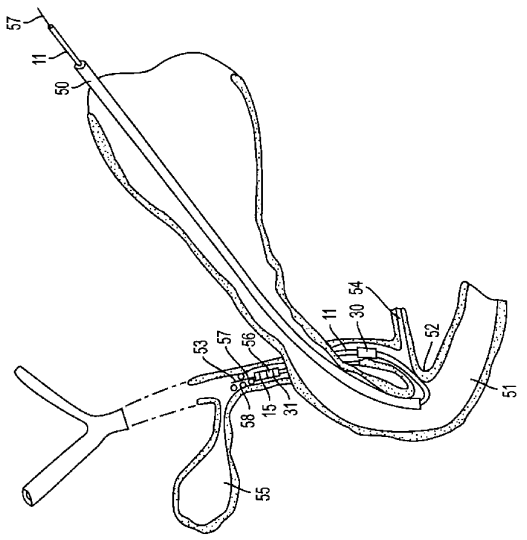

FIG. 7

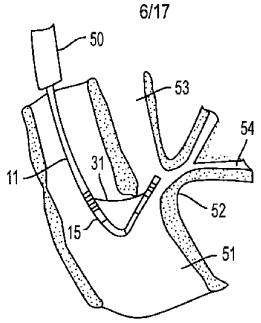

FIG. 8

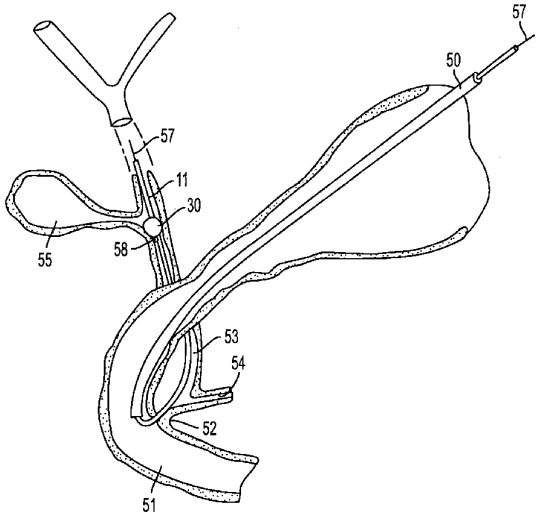

FIG. 9

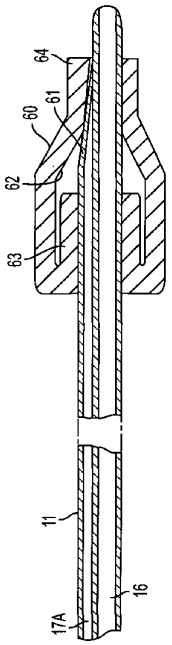

FIG. 10

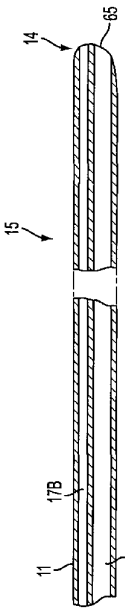

FIG. 11

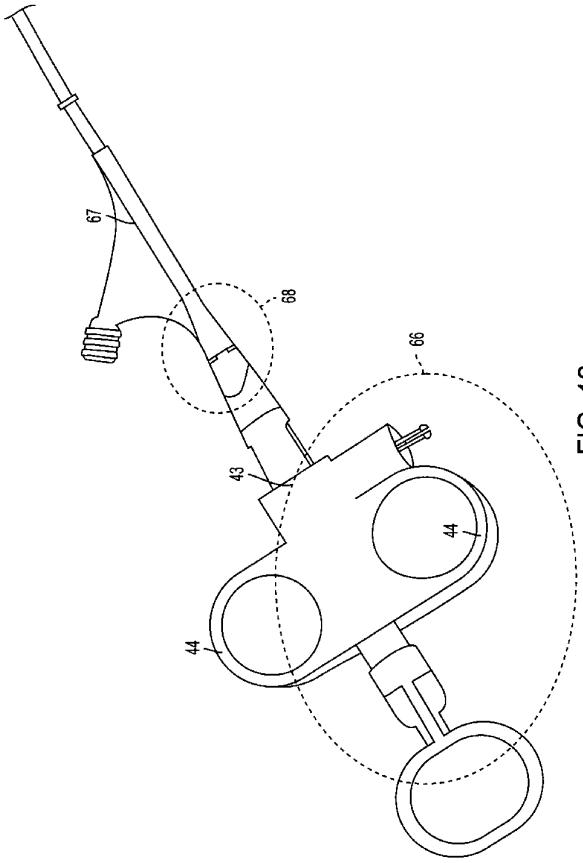

FIG. 12

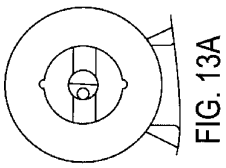

FIG. 13A

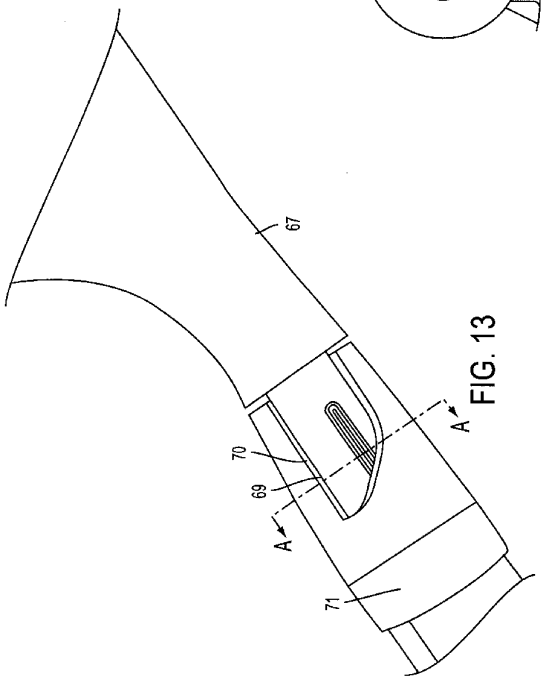

FIG. 13

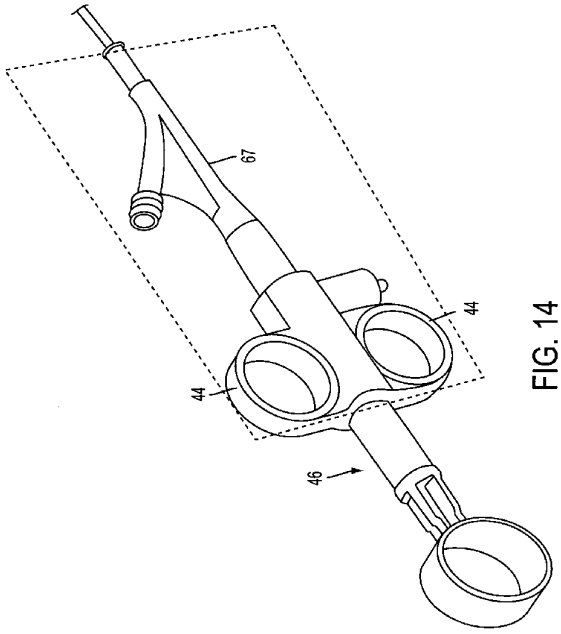

FIG. 14

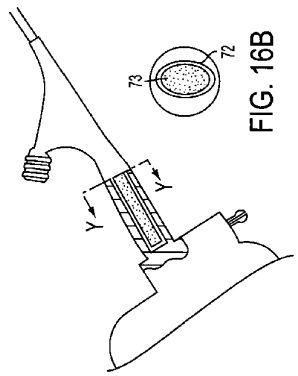

FIG. 16B

FIG. 15B

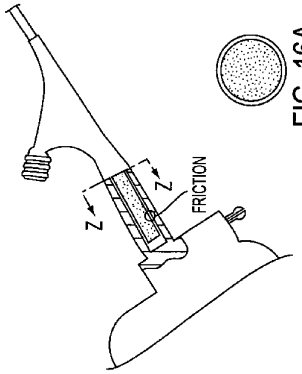

FIG. 16A

FIG. 15A

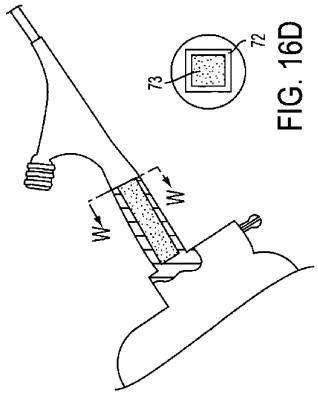

FIG. 16D

FIG. 15D

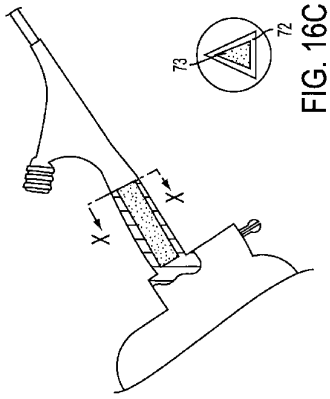

FIG. 16C

FIG. 15C

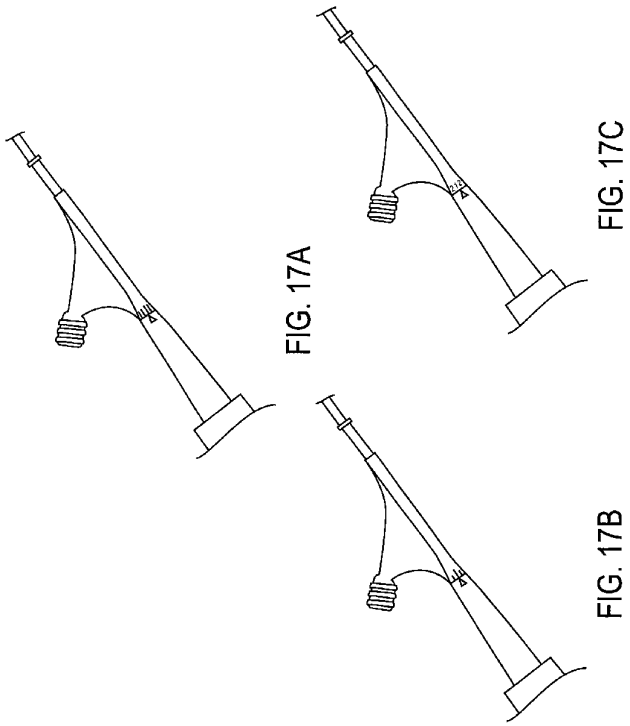

FIG. 17A

FIG. 17C

FIG. 17B

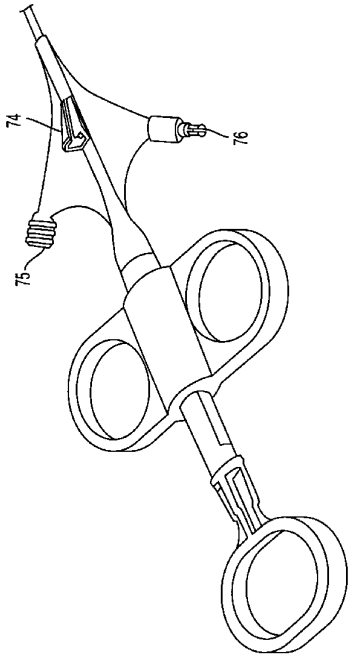

FIG. 18A

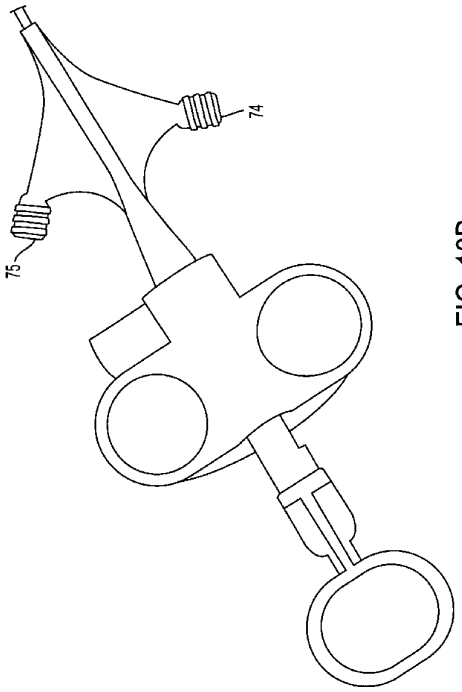

FIG. 18B

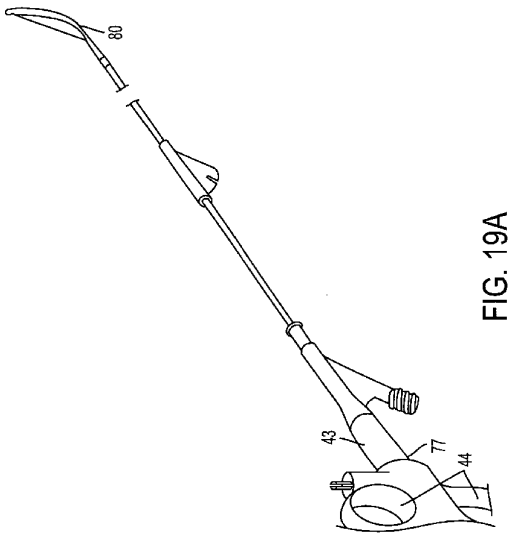

FIG. 19A

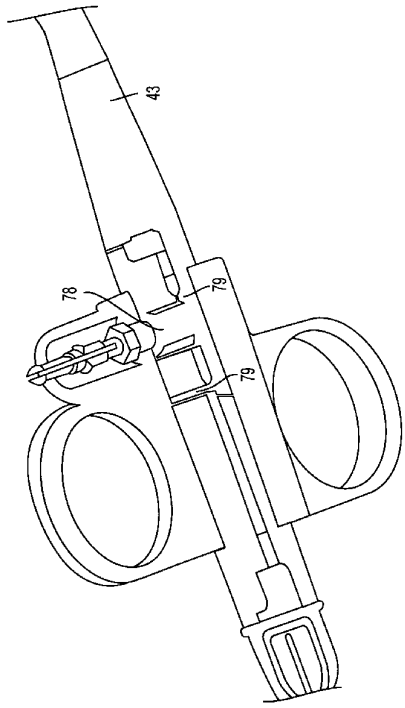

FIG. 19B

【国際調査報告】

INTERNATIONAL SEARCH REPORT

Interna tal Application No
PCT/US 01/25354

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B18/14

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

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 practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 00 42926 A (GEN SCIENCE & TECHNOLOGY CORP) 27 July 2000 (2000-07-27)	15,16
A	see summary of the invention page 10, paragraph 5 -page 11, paragraph 1; figures 1,5	1
A	US 5 066 295 A (KOZAK MARK ET AL) 19 November 1991 (1991-11-19) abstract; figure 1	1,15
A	US 6 015 381 A (OUCHI TERUO) 18 January 2000 (2000-01-18)	
P,A	US 6 235 026 B1 (SMITH KEVIN W) 22 May 2001 (2001-05-22)	

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

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

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

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

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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【要約の続き】
ルは、ワイヤを回転させて装置先端を回転させる力を伝達する機構を供与している。ハンドルが近位端シャフトとは無関係に近位端で回転すれば、シャフト全体を捩らせること無く、遠位先端部に力を直接付与することができる。また、先端部の配向を維持するための回転ロック、および／または、回転量を示す回転マーキングが備えられていてもよい。

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摘要(译)

本发明和内窥镜插管，乳头状切口，一个括约肌切开术，涉及用于执行类似于这些的处理的方法和装置。根据本技术，内窥镜插管胆总管，乳头状切口，治疗类似，推进装置到内窥镜/十二指肠内窥镜的内部，该装置的远端尖端还有就是通过内窥镜实现在邻近括约肌Fateru乳头的位置出去。这里，内窥镜的操作机构，该装置的远端尖端定位到期望的位置上，进行胆管的适当插管。例如，括约肌切开术器械，解剖部位，并且由于所述内窥镜操作的失配，也难以将括约肌切开术仪器准确一致地定位适当插管。本发明的可转向括约肌切开器械中，医师独立地控制所述内窥镜的所述装置的远端尖端的位置，能够调节差异装置和解剖部位。根据本发明，附接切割线的手柄可相对于导管自由旋转。并且它被固定在切割金属丝，但可相对于该导管手柄的轴是捐赠机构用于旋转装置尖端以旋转线传递力。如果在手柄的近端，而不管旋转是近端轴，而不会引起扭曲整个轴，你可以直接将力施加到远侧尖端。旋转锁定，以保持尖端的取向，和/或也可以设置旋转标记指示旋转的量。