

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
11 December 2003 (11.12.2003)

PCT

(10) International Publication Number
WO 03/101531 A2

(51) International Patent Classification⁷: **A61N**

(21) International Application Number: PCT/US03/17677

(22) International Filing Date: 4 June 2003 (04.06.2003)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/386,119 4 June 2002 (04.06.2002) US

(71) Applicant: **SOUND SURGICAL TECHNOLOGIES LLC** [US/US]; 1300 Plaza Court North #203, Lafayette, CO 80026 (US).

(72) Inventor: **CIMINO, William, W.**; 578 West Sagebrush Court, Louisville, CO 80027 (US).

(74) Agent: **DAIGNAULT, Ronald, A.**; Merchant & Gold P.C., P.O. Box 2903, Minneapolis, MN 55402-0903 (US).

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

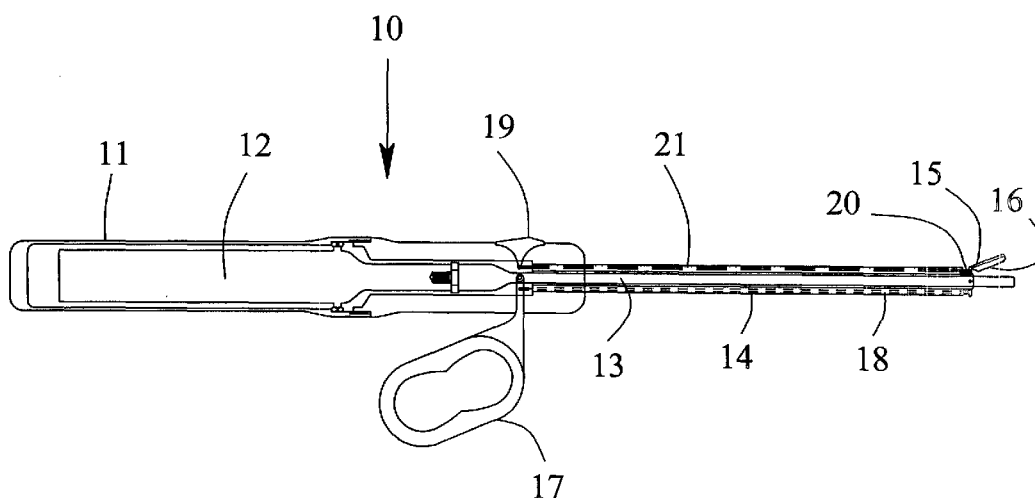
(84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

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

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: **ULTRASONIC DEVICE AND METHOD FOR TISSUE COAGULATION**



(57) **Abstract:** An ultrasonic surgical device for the coagulation of animal tissue having an ultrasonic applicator and a movable jaw with a jaw surface adjacent the distal portion of the ultrasonic applicator for movement toward the applicator to a closed position at a predefined clearance of between about 0.075 to about 1.9 millimeters from the applicator. The device may also include a mechanical cutting element that can be extended into the clearance to cut the tissue and means to vary the predefined clearance without removing the applicator from the patient. Tissue coagulating and cutting can be maximized and performed separately and can be easily monitored by the surgeon.



WO 03/101531 A2

ULTRASONIC DEVICE AND METHOD FOR TISSUE COAGULATION

SOUND SURGICAL TECHNOLOGIES LLC, a United States national and resident, is filing this application as a PCT application designating all countries
5 except US, claiming priority to US Provisional Patent Application No. 60/386,119, filed June 4, 2002.

I. FIELD OF THE INVENTION

The present invention relates generally to surgical instruments, and more
10 particularly, to an ultrasonic surgical device for use in coagulation of tissues of a patient.

II. BACKGROUND OF THE INVENTION

Hemostasis of bleeding or potentially bleeding tissues is of premium
15 importance in open or laparoscopic surgery. Several methods are currently used to coagulate tissues to achieve the desired hemostasis. Sutures are safe, reliable, and commonly used on larger vessels or structures, but are difficult to use on small vessels or structures or in situations involving diffuse bleeding. Monopolar electrosurgery works by electrically heating and burning the tissue to achieve
20 coagulation. It is effective on the smaller vessels and structures but may cause undesirable thermal trauma to adjacent tissues due to stray electrical conduction in a wet surgical environment. Bipolar electrosurgery also works by electrically heating the tissues and provides improved control of stray electrical conduction relative to monopolar electrosurgery. Bipolar instruments may suffer from tissue adherence to
25 the electrodes, causing the coagulated tissue to be re-opened and bleed again as the probes are removed. Ultrasonic instruments use frictional heat generated by rapid vibration rubbing of the tissue to create hemostasis.

Ultrasonic surgical devices for cutting and coagulation of tissue are known. All of these devices utilize longitudinal vibrations in an ultrasonic member to
30 accomplish a desired surgical effect such as cutting with simultaneous coagulation. Clamping mechanisms have been disclosed which claim to improve cutting and coagulation performance by enhancing the tissue contact between the vibrating

member and the clamp surface. U.S. Patents Number 3,862,630 and 3636,943, both to Balamuth, disclose two types of ultrasonic surgical devices: a first device for simultaneously cutting and coagulating tissue, and a second device for joining together layers of tissue. The device for joining together layers of tissue has a
5 vibrating ultrasonic member and a clamp mechanism, the working surface of the clamp mechanism being perpendicular to the direction of the longitudinal vibrations of the tool, so that tissues are compressed between the working surface of the clamp and the end surface of the vibrating ultrasonic member. This "end-on" design blocks tissue access to the clamped region between the ultrasonic member and clamp
10 mechanism from the axial direction, requiring that tissue be accessed laterally, and thereby severely limits application of the device for surgical application because tissue cannot be accessed in a scissor-like fashion.

U.S. Patent Number 5,322,055 to Davidson discloses an ultrasonic surgical device for simultaneously cutting and coagulating tissue having a vibrating
15 ultrasonic member and a clamp mechanism, the ultrasonic member having a surgical blade with an elongated edge parallel to the axis of longitudinal vibration at the distal end of the vibrating ultrasonic member. This patent alleges enhanced cutting performance due to the surgical blade with the elongated edge and also improves performance by providing tissue access to the ultrasonic member and the clamp
20 mechanism from the axial direction. The clamp mechanism is designed to close completely (i.e., touch) against the vibrating ultrasonic member to achieve the described cutting and coagulation effects. The improved cutting action in this design is allegedly caused by the vibration of the surgical blade with an elongated edge and the complete closure of the blade against the clamp mechanism.

25 U.S. Patent Number 6,193,709 to Manna discloses an ultrasonic surgical device for simultaneously cutting and coagulating tissue having a vibrating ultrasonic member and a clamp mechanism, the ultrasonic member having a blade at the distal end of the vibrating ultrasonic member, the blade forming an acute angle with respect to the axis of longitudinal vibration. The patent alleges that the angled
30 design enhances tissue contact between the clamp mechanism and the blade during operation and thereby improves performance. The clamp mechanism is designed to close completely (touch) against the vibrating ultrasonic member to achieve the described cutting and coagulation effects. Improved cutting action in this design is

due to the vibration of the blade with the acute angle with respect to the axis of longitudinal vibration and the complete closure of the blade against the clamp mechanism.

U.S. Patent Number 6,193,709 to Miyawaki discloses an ultrasonic surgical
5 device for treatments such as incision and coagulation having a vibrating ultrasonic member and a clamp having a follow-up mechanism so that the clamp can follow a deflective displacement of the distal end portion of the vibrating ultrasonic member. This patent asserts that the follow-up mechanism eliminates potential gaps between the vibrating ultrasonic member and the clamp mechanism as the clamp mechanism
10 is closed onto the vibrating ultrasonic member, thereby improving grasping and treatment performance. The clamp mechanism is designed to close completely (i.e., touch) against the vibrating ultrasonic member to achieve the described treatments such as incision and coagulation.

None of the patents discloses a device for limiting the closure of the clamp
15 mechanism relative to the vibrating ultrasonic member for the purpose of creating a predetermined clearance there between so that an improved coagulation effect is achieved. Holding the clamp against the ultrasonic member in the prior art devices will inevitably result in the cutting of the tissue. The surgeon has no way of knowing how far the process has occurred from the intended coagulation to
20 undesirable cutting. Indeed, these prior art devices are designed to achieve simultaneous cutting and coagulation as the clamp closes completely against the vibrating ultrasonic member, regardless of the shape of the jaw surface of the clamp mechanism and the shape of the vibrating ultrasonic member. It is often desirable in the course of surgery to coagulate tissue without cutting. It is impossible to reliably
25 separate these two processes in the prior art devices. Thus, there is a need to improve the coagulation performance of ultrasonic surgical devices and further to provide independent cutting and coagulation capabilities.

Deficiencies in the performance of prior art coagulation devices have been noted in the literature. (See, for example, Spivak H. et al., "The Use of Bipolar
30 Cautery, Laparoscopic Coagulating Shears, and Vascular Clips for Hemostasis of Small and Medium-sized Vessels," Surgical Endoscopy, 12(2):183-85 (Feb. 1998) and Landman, J. (Washington University), "Comparison of the Ligasure System, Bipolar Electrosurgery, Harmonic Scalpel, Titanium Clips, Endo-GIA, and Sutures for

Laparoscopic Vascular Control in a Porcine Model,” presented at the Society of American Gastrointestinal Endoscopic Surgeons, St. Louis, Missouri, (April 10-21, 2001). Both of these studies included the ultrasonic laparoscopic coagulating shears (“LCS”) manufactured and distributed by Johnson & Johnson using technology

5 believed to be covered by the Davidson ‘055 Patent referenced above. Spivak et al. tested the capability of the LCS device and others to coagulate small and medium sized blood vessels in pigs by increasing the associated blood pressure to the point of failure or a maximum load of 300 mm. Hg. While the authors personally concluded that the devices “can be considered safe,” the devices were not uniformly successful.

10 The LCS device was successful in all of the “small vessel” tests but had two complete failures in the twelve tests of medium-sized vessels and two additional instances where the medium-sized vessel commenced bleeding before the defined pressure limit was reached. This is an unacceptable failure rate of 33%. As noted by the authors, the LCS needs to be properly sized and the surgeon properly trained in

15 order to use the LCS successfully on medium-sized vessels. In addition, the authors recommended that “the surgeon have a good alternative method in case initial hemostasis fails.” Similarly, Landman compared various modalities for sealing vessels. On arteries, the LCS succeeded 5/6 times for an 83% success rate; on veins the LCS succeeded 3/6 times for a 50% success rate. Thus, there is clearly a need

20 for significant improvement in a surgical coagulation device.

A means to substantially improve the coagulation performance of ultrasonic surgical instruments has now been discovered. First, the coagulation performance can be improved by separating the coagulation and cutting functions of the instrument so that they are done sequentially rather than simultaneously. Indeed, it

25 has proven helpful to perform the coagulation prior to the cutting rather than simultaneously or in the opposite order. A sequential approach allows time for the tissue to be coagulated and cooled so that it sets before any cutting action occurs. Indeed, tissue bleeding may be totally avoided in this manner. The present invention accomplishes the sequential coagulating and cutting steps with a single grasp of the

30 instrument, meaning that the tissue grasp does not have to be released to alter the instrument for cutting purposes once coagulation is achieved. Second, the coagulation performance is substantially improved by providing a predefined clearance between a jaw surface and a vibrating ultrasonic applicator so that a tissue

flow will occur in a carefully controlled manner. The "tissue flow" (i.e., the propensity of the tissue to move plastically upon sufficient heating) in the predefined clearance creates a zone of coagulated tissue that is much less likely to re-bleed than tissue that is simultaneously cut and coagulated with previously disclosed methods.

5 It has now been discovered that if the predefined clearance is carefully controlled to be between about 0.075 to about 1.9 millimeters, and preferably between about 0.075 and about 0.75 millimeters, then the most effective coagulation performance is obtained. It has been found that if the predefined clearance is less than about 0.075 mm, simultaneous cutting action may occur. If the predefined clearance is greater
10 than about 1.9 mm, it has been found that insufficient tissue flow is achieved and complete coagulation may not occur.

III. SUMMARY OF THE INVENTION:

The present invention provides a novel, improved ultrasonic surgical device
15 for and method for coagulating tissue. The device of the present invention has a surgical handle with an ultrasonic transducer mounted therein for generating ultrasonic vibrations. An ultrasonic applicator is attached to the ultrasonic transducer for transmitting longitudinal ultrasonic vibrations and extends distally from the surgical handle. The ultrasonic applicator is generally and substantially
20 round in cross-section at the distal end and has a diameter between approximately 2 millimeters and 6 millimeters. A clamp with a jaw surface is supported on an elongated support member that is releasably attached to the surgical handle that generally surrounds the ultrasonic applicator along its length. The clamp and jaw surface are designed so that the clamp cannot be completely closed against the
25 vibrating ultrasonic applicator, but is stopped at a predefined clearance, i.e., distance between the jaw surface and the vibrating ultrasonic applicator. This predefined clearance provides a zone for controlled tissue flow as the vibrating ultrasonic member heats the tissue. The shape and thickness of the predefined clearance determine the quality and final shape of the coagulated tissue. The predefined
30 clearance may be varied between between about 0.075 to about 1.9 mm, and preferably between about 0.075 and about 0.75 mm, depending on the type and structure of the targeted tissue to be coagulated. The surgical device can include

means for adjusting the clearance within this range. Thus, the vibrating ultrasonic applicator is not a vibrating "blade" and is not used for the cutting of tissues, but only for improved coagulation. The zone of controlled tissue flow also contributes to improved coagulation by creating an improved coagulation effect and by avoiding simultaneous cutting during coagulation. The thickness and shape of the tissue flow is carefully controlled.

If a cutting capability is desired with the surgical device, a separate non-ultrasonic cutting element may be provided that can be advanced and retracted to accomplish the cutting function as a separate step. The cutting element may be advanced after the coagulation has been completed, and the jaw is still closed to the maximum permitted extent. Preferably, the cutting element may be a surgical blade with a sharpened leading edge that cuts the coagulated tissue as it is advanced. Other forms of mechanical cutting tools can be employed. The surgeon can wait to advance the cutting tool until sufficient time has elapsed for the tissue to have been coagulated and "cooled" to minimize bleeding during the cutting process.

The device of the present invention may also be employed in an improved method of coagulation comprising the application of ultrasonic surgery via an applicator having a round cross-section to tissue held by a clamp located at a fixed distance from the applicator's surface. A surgical method may also be employed using that coagulation method to coagulate or cauterize tissue prior to cutting with a mechanical cutting tool attached to, but separate from, the ultrasonic applicator.

Thus, the present invention provides an improved ultrasonic surgical instrument and method for tissue coagulation alone or with a separate cutting of tissue. To accomplish this, the present invention includes an ultrasonic surgical instrument and method with a predetermined clearance between the surfaces of a clamp holding the tissue against a vibrating ultrasonic member having a substantially circular cross-section so that controlled flow of the tissue can occur without ultrasonic cutting. In addition, the present invention includes an ultrasonic surgical instrument and method where the cutting means is contained in the same instrument but is independent of the ultrasonic vibrations. Other features or variations of the present invention for improved coagulation may be apparent to one skilled in the art from the enclosed specification, drawings and claims.

The invention may be best understood by reference to the detailed description

of some preferred embodiments and the illustrations of preferred embodiments in the accompanying figures.

IV. BRIEF DESCRIPTION OF THE DRAWINGS

5 The following drawings show specific embodiments that help appreciate the novel features of the present invention.

Figure 1a is a partial cut-away, side-view of one embodiment of the device of the present invention. The drawing depicts the device with the clamp in an open position and the mechanical cutting tool in a retracted position.

10 Figure 1b is a partial cut-away, side view of one embodiment of the device of the present invention. The drawing depicts the device with the clamp in the closed position and the mechanical cutting tool in a retracted position.

Figure 1c is a partial cut-away, side view of one embodiment of the device of the present invention. The drawing depicts the device with the clamp in the closed position and the mechanical cutting tool in an advanced position for cutting.

15 Figure 2 is detailed partial cut-away, side-view representation of the distal portion of the ultrasonic device including the electronic applicator, clamp and mechanical cutting tool.

Figure 3a is an end-on view of the ultrasonic device showing a clamp with a concave jaw surface in the closed position.

20 Figure 3b is an end-on view of the ultrasonic device showing a clamp with a convex jaw surface in the closed position.

Figure 3c is an end-on view of the ultrasonic device showing a clamp with a flat jaw surface in the closed position.

25 Figure 4 is a partial cut-away, side-view of one embodiment of the device of the present invention in which the stop for establishing the pre-defined clearance is located on the handle of the ultrasonic device.

Common reference numerals have been used on all drawings for convenience.

30

V. DETAILED DESCRIPTION

Referring to the drawings, Figure 1a is a schematic representation of one

preferred embodiment of the invention. Figure 1 illustrates a partial cut-away view of the present invention including an ultrasonic surgical instrument, generally designated **10**. The instrument has a surgical handle **11** to be held and manipulated by the surgeon. The surgical handle **11** may be fabricated from either machined or
5 molded plastic components. An ultrasonic transducer **12** is mounted within the surgical handle **11** for generating ultrasonic vibrations. The ultrasonic vibrations may be generated using any common and well-known means such as the use of PZT crystals held in compression.

An ultrasonic applicator **13** is attached to the ultrasonic transducer **12** and
10 extends distally from the ultrasonic transducer **12**. The preferred method of attachment is a threaded joint. The ultrasonic applicator may be fabricated from any suitable metallic material including, for example, titanium alloys, aluminum alloys, or stainless steel alloys. The preferred material is titanium alloy Ti6Al4V. Standard machining processes such as lathe or mill processes can be used.

15 As mentioned previously, ultrasonic applicators employed in the present invention are generally round in cross-section at the point of application of energy to the tissue. These applicators do not have edges that would focus and disseminate ultrasonic energy in a manner promoting cutting, but instead are designed to provide energy in a uniform manner consistent exclusively with the coagulation of tissue.
20 Indeed, cutting functionality, if needed, is provided in a separate mechanical component of the surgical instrument to avoid compromising the design of the ultrasonic applicator.

The combined length of the ultrasonic transducer **12** and the ultrasonic applicator **13** must be designed to have the desired resonant frequency of vibration.
25 The range of vibration frequencies is generally 20 kHz to 60 kHz. Any vibration frequency in this range can be utilized.

An elongated support member **14** is releasably attached to the surgical handle **11** and generally surrounds the ultrasonic applicator **13** along its length. The elongated support member **14** may be fabricated from metal or plastic materials.
30 The preferred material is plastic such as DelrinR (acetyl copolymer) or "ABS" (acrylonitrile-butadiene-styrene). A clamp **15** with a jaw surface **16** is supported on the distal end of the elongated support member **14**. The clamp may be fabricated from metal or plastic using either standard machining processes or standard molding

process (metal or plastic). The preferred method and material is a molded metal clamp mechanism as this provides for maximum stiffness of the part and the best clamping performance. The jaw surface 16 may have a variety of cross-sectional shapes, for example, those depicted in Figures 3a-3c. The jaw surface 16 may also
5 have a serrated or grooved surface to improve grasping performance.

The clamp 15 may be opened and closed relative to the side of the ultrasonic applicator 13. In Figure 1a, the clamp is depicted in the open position. An actuation handle 17 is connected to the surgical handle 11 and is used to actuate the clamp 15 between the open and closed positions. A clamp transmission rod 18 connects the
10 actuation handle 17 and the clamp 15.

An actuation slider 19 is connected to the surgical handle 11 and is used to advance and retract a cutting element 20 in a direction parallel or generally parallel to the ultrasonic applicator. The cutting element 20 may be a stainless steel blade or a formed cutting shape on the end of a blade connecting rod 21. The blade
15 connecting rod 21 connects the actuation slider 19 and the cutting element 20. The connecting rod 21 is preferably fabricated from stainless steel wire that can be soldered or welded to the cutting element 20.

Figure 2 shows a more detailed side-view of the distal end of the ultrasonic surgical instrument 10 as depicted in Figure 1a, with the clamp 15 and associated
20 jaw 16 in the open position relative to the ultrasonic applicator 13. Surface 32 of the clamp assembly 30 is separated from surface 31 of the support member 14. The mechanical cutting tool or blade 20 attached to blade connecting rod 21 is in the retracted position. The cutting element 20 can be advanced to cut tissues that have been coagulated between the jaw surface 16 and the ultrasonic applicator 13. (See
25 Figure 1c.) Thus, the cutting element 20 is advanced and retracted through the clearance between the jaw surface 16 and the ultrasonic applicator 13. In a further embodiment, the clamp 15 and jaw surface 16 may have a vertical slot through with the edge of the blade also passes as it is extended and retracted. This would allow the use of a wider mechanical cutting element and assist in ensuring that the blade
30 cuts all of the tissue held in the space between the jaw surface and the ultrasonic applicator. Figure 1b shows the same ultrasonic surgical instrument 10 depicted in Figure 1a, except that the actuation handle 17 has been rotated to the closed position,

thereby pulling the clamp transmission rod **18** toward the ultrasonic transducer **12** causing rotation and closing of the clamp **15** relative to the ultrasonic applicator **13**. The movement of the transmission rod **18** is limited by a stop, in this the contacting of surface **32** of the clamp housing **30** against surface **31** of the support **14**. This occurs so that the jaw face **16** of clamp **15** is "closed" at a predefined distance or clearance from the surface of ultrasonic applicator **13**. (See Figures 3a through 3c.) This distance can be pre-set and varied by controlling the length of the transmission rod **18**. It is within the skill of the art to provide means so that this length can be varied by the physician or an assistant during the course of the surgical procedure without requiring removal of the surgical instrument from the patient. For example, the effective length of the rod from the clamp support **30** to the actuator **17** can be varied by using a rotatable transmission rod threaded into a portion of the handle **11**. In Figure 1b, the cutting blade or tool **20** is in the retracted position.

Figure 1c illustrates the ultrasonic surgical device **10** of Figure 1a with the clamp in the closed position and the cutting blade **20** in the extended position. This was accomplished by the movement of actuating slider **10** in a direction toward the distal end of the ultrasonic surgical device, thereby moving the blade connecting rod **21** and the blade **20** in the same direction. As this is accomplished, the tissue held between the clamp **15** and the ultrasonic applicator **13** is cut by the blade **20**.

Figures 3a through 3c show three different configurations of the jaw surface and the predefined clearance.

Figure 3a is an end-view showing the ultrasonic applicator **13** and the elongated support member **14** and the clamp **15** in a fully "closed" position. The jaw surface **16** is concave, which provides for improved width of tissue coagulation between the jaw surface **16** and the ultrasonic applicator **13**. The predefined clearance **22** is the space between the jaw surface **16** and the ultrasonic applicator **13** when the clamp **15** is closed to its maximum extent, typically between about 0.075 to about 1.9 millimeters, and preferably between about 0.075 and about 0.75 millimeters. Optimal values for the predefined clearance will vary with intended application.

Figure 3b is an end-view showing the ultrasonic applicator **13** and the elongated support member **14** and the clamp **15** in a fully closed position. The jaw

surface 16 is convex which provides for a reduced width of tissue coagulation with improved transition at the edges to the uncoagulated tissue. The predefined clearance 22 is the space between the jaw surface 16 and the ultrasonic applicator 13 when the clamp 15 is fully closed, again typically between about 0.075 to about 1.9 millimeters, and preferably between about 0.075 and about 0.75 millimeters. Optimal values for the predefined clearance will vary with intended application.

Figure 3c is an end-view showing the ultrasonic applicator 13 and the elongated support member 14 and the clamp 15 in a fully closed position. The jaw surface 16 is flat which provides for a combination of the results obtained with shapes as shown in Figures 2a and 2b. The predefined clearance 22 is the space between the jaw surface 16 and the ultrasonic applicator 13 when the clamp 15 is fully closed, typically between about 0.075 to about 1.9 millimeters, and preferably between about 0.075 and about 0.75 millimeters. Optimal values for the predefined clearance will vary with intended application.

The pre-determined clearance between jaw 16 of clamp 15 and ultrasonic applicator 13 can be established in a number of ways. As depicted in Figures 1a through 1c and in Figure 2 this can be established by a stop of clamp housing surface 32 against surface 31 of the support. Other mechanical stops can be used. One such stop is depicted in Figure 4, which illustrates an ultrasonic surgical device as in Figure 1a. In this case, however, the stop is physical element 26 extending from the handle 11 and prohibiting closure of actuator 17 against the housing. This replaces the contacting of surfaces 31 and 31 as the stop mechanism. One skilled in the art, would know how to make the effective length of stop 26 variable, so that the predetermine separation 22 between the jaw and applicator can also be varied. For example, the stop 26 could be screwed within a limited range into a hole in the handle 11 so that it could be effectively lengthened or shortened as desired. Other techniques for establishing a predefined clearance between the jaw 16 and the ultrasonic applicator 13 would be known to one skilled in the art and could be substituted for the examples described herein.

The present invention also provides an improved method for the surgical coagulation of animal tissue including locating a portion of the animal tissue between: (a) an ultrasonic applicator having a generally round cross-section with a

diameter between approximately 2 and 6 millimeters to provide a broad surface for coagulation and to avoid cutting of the animal tissue and (b) a clamp located adjacent the ultrasonic tissue. The clamp is then moved toward the ultrasonic applicator to a predefined clearance of between about 0.075 to about 1.9 millimeters, and preferably between about 0.075 and about 0.75 millimeters, from the ultrasonic applicator to provide a zone for tissue flow and coagulation. Ultrasonic vibrations are then applied to the clamped tissue via the ultrasonic applicator sufficient to cause coagulation of the tissue. If desired the tissue can then be cut with a separate mechanical cutting tool as illustrated, for example, in the drawings and description herein.

As previously noted the device and method of the present invention are particularly useful in separating and maximizing each of the coagulation and cutting functions. It also provides a convenient way for the surgeon to know at all times the position of the clamp relative to the ultrasonic applicator and the position of the cutting element or blade. Thus, the surgeon can easily monitor and focus on these tasks.

The description and drawings contained herein disclose illustrative embodiments of the invention. Given the benefit of this disclosure, those skilled in the art will appreciate that various modifications, alternate constructions, and equivalents may also be employed to achieve the advantages of the invention. For example, given the benefit of this disclosure, those skilled in the art will be able to implement various forms of the clamp, the stop and the mechanical cutting tool within the spirit of the invention. Therefore, the invention is not to be limited to the description and illustrations contained herein, but is defined by the following claims.

CLAIMS:

1. An ultrasonic surgical apparatus for the coagulation of animal tissue having a handle for manipulation by a surgeon, an ultrasonic transducer for
5 generating ultrasonic vibration, and an ultrasonic applicator attached to the ultrasonic transducer and extending from the handle for delivery of ultrasonic vibrations to the tissues of the animal, wherein said apparatus further comprises:
a distal portion on the ultrasonic applicator having a generally round cross-section with a diameter between approximately 2 and 6 millimeters to provide a
10 broad surface for coagulation and to avoid cutting of the animal tissue;
an elongated support member releasably attached to the surgical handle and extending to the distal portion of the ultrasonic applicator; and
a movable jaw with a jaw surface attached to the elongated support member adjacent the distal portion of the ultrasonic applicator for movement toward said
15 distal portion to a closed position at a predefined clearance of between about 0.075 to about 1.9 millimeters, from said distal portion of the ultrasonic applicator.
2. The ultrasonic surgical apparatus of Claim 1 wherein the predefined clearance is between about 0.075 and about 0.75 millimeters.
20
3. The ultrasonic surgical apparatus of Claim 2 wherein the jaw surface in the closed position is generally parallel with the surface of the elongated support member.
- 25 4. The ultrasonic surgical device of Claim 2 wherein the jaw surface is concave.
5. The ultrasonic surgical device of Claim 2 wherein the jaw surface is convex.
30
6. The ultrasonic surgical device of Claim 2 wherein the jaw surface is flat.
7. The ultrasonic surgical device of Claim 2 wherein the predetermined
35 clearance is determined by a stop located on the elongated support member.

8. The ultrasonic surgical device of Claim 2 wherein the predetermined clearance is determined by a stop located on the handle of the ultrasonic surgical device.

5

9. The ultrasonic surgical device of Claim 2 wherein the predetermined clearance may be varied without requiring removal of the ultrasonic surgical device from the patient during a medical procedure.

10

10. An ultrasonic surgical apparatus for the treating of animal tissue having a handle for manipulation by a surgeon, an ultrasonic transducer for generating ultrasonic vibration, and an ultrasonic applicator attached to the ultrasonic transducer and extending from the handle for delivery of ultrasonic vibrations to the tissues of the animal, wherein said apparatus further comprises:

15

a distal portion on the ultrasonic applicator having a generally round cross-section with a diameter between approximately 2 and 6 millimeters to provide a broad surface for coagulation and to avoid cutting of the animal tissue;

an elongated support member releasably attached to the surgical handle and extending to the distal portion of the ultrasonic applicator;

20

a movable jaw with a jaw surface attached to the elongated support member adjacent the distal portion of the ultrasonic applicator for movement toward said distal portion to a closed position at a predefined clearance of between about 0.075 to about 1.9 millimeters from said distal portion of the ultrasonic applicator to provide a zone for tissue flow and coagulation as the tissue is heated by vibration of

25

the ultrasonic applicator; and

a mechanical cutting device for movement parallel to the ultrasonic applicator to cut the tissue located between the ultrasonic applicator and the clamp.

30

11. The ultrasonic surgical apparatus of Claim 10 wherein the predefined clearance is between about 0.075 and about 0.75 millimeters.

12. The ultrasonic surgical apparatus of Claim 11 wherein the jaw surface in the closed position is generally parallel with the surface of the elongated support member.

13. The ultrasonic surgical device of Claim 11 wherein the jaw surface is concave.
- 5 14. The ultrasonic surgical device of Claim 11 wherein the jaw surface is convex.
15. The ultrasonic surgical device of Claim 11 wherein the jaw surface is flat.
- 10 16. The ultrasonic surgical device of Claim 11 wherein the predetermined clearance is determined by a stop located on the elongated support member.
- 15 17. The ultrasonic surgical device of Claim 11 wherein the predetermined clearance is determined by a stop located on the handle of the ultrasonic surgical device.
18. The ultrasonic surgical device of Claim 11 wherein the predetermined clearance may be varied without requiring removal of the ultrasonic surgical device
- 20 from the patient during a medical procedure.
19. The ultrasonic surgical device of Claim 11 wherein the mechanical cutting device is a blade.
- 25 20. A method for the surgical coagulation of animal tissue comprising: locating a portion of the animal tissue between
- an ultrasonic applicator having a generally round cross-section with a diameter between approximately 2 and 6 millimeters to provide a broad surface for coagulation and to avoid cutting of the
- 30 animal tissue and
- a clamp located adjacent the ultrasonic tissue;
- moving the clamp toward the ultrasonic applicator to a predefined clearance of between about 0.075 to about 1.9 millimeters from the ultrasonic applicator to provide a zone for tissue flow and coagulation; and
- 35 applying ultrasonic vibrations to the portion of the tissue via the ultrasonic

applicator sufficient to cause coagulation of the tissue.

21. The method of Claim 20 wherein the predefined clearance is between about 0.075 and about 0.75 millimeters.

5

22. The method of Claim 21 wherein the predetermined clearance may be varied without requiring removal of the ultrasonic surgical device from the patient during a medical procedure.

10

23. A method for the surgically animal tissue with minimal bleeding comprising:

locating the animal tissue between

an ultrasonic applicator having a generally round cross-section

with a diameter between approximately 2 and 6 millimeters to

15

provide a broad surface for coagulation and to avoid cutting of the animal tissue and

a clamp located adjacent the ultrasonic tissue;

moving the clamp toward the ultrasonic applicator to a predefined clearance

of between about 0.075 to about 1.9 millimeters from the ultrasonic applicator to

20

provide a zone for tissue flow and coagulation as the tissue is heated by vibration of the ultrasonic applicator;

applying ultrasonic vibrations to the portion of the tissue via the ultrasonic applicator sufficient to cause coagulation of the tissue, and

cutting said tissue after it has been coagulated using a mechanical cutting

25

device.

24. The method of Claim 23 wherein the predefined clearance is between about 0.075 and about 0.75 millimeters.

30

25. The method of Claim 24 wherein the predetermined clearance may be varied without requiring removal of the ultrasonic surgical device from the patient during a medical procedure.

26. The method of Claim 24 wherein the mechanical cutting device is a

35

blade.

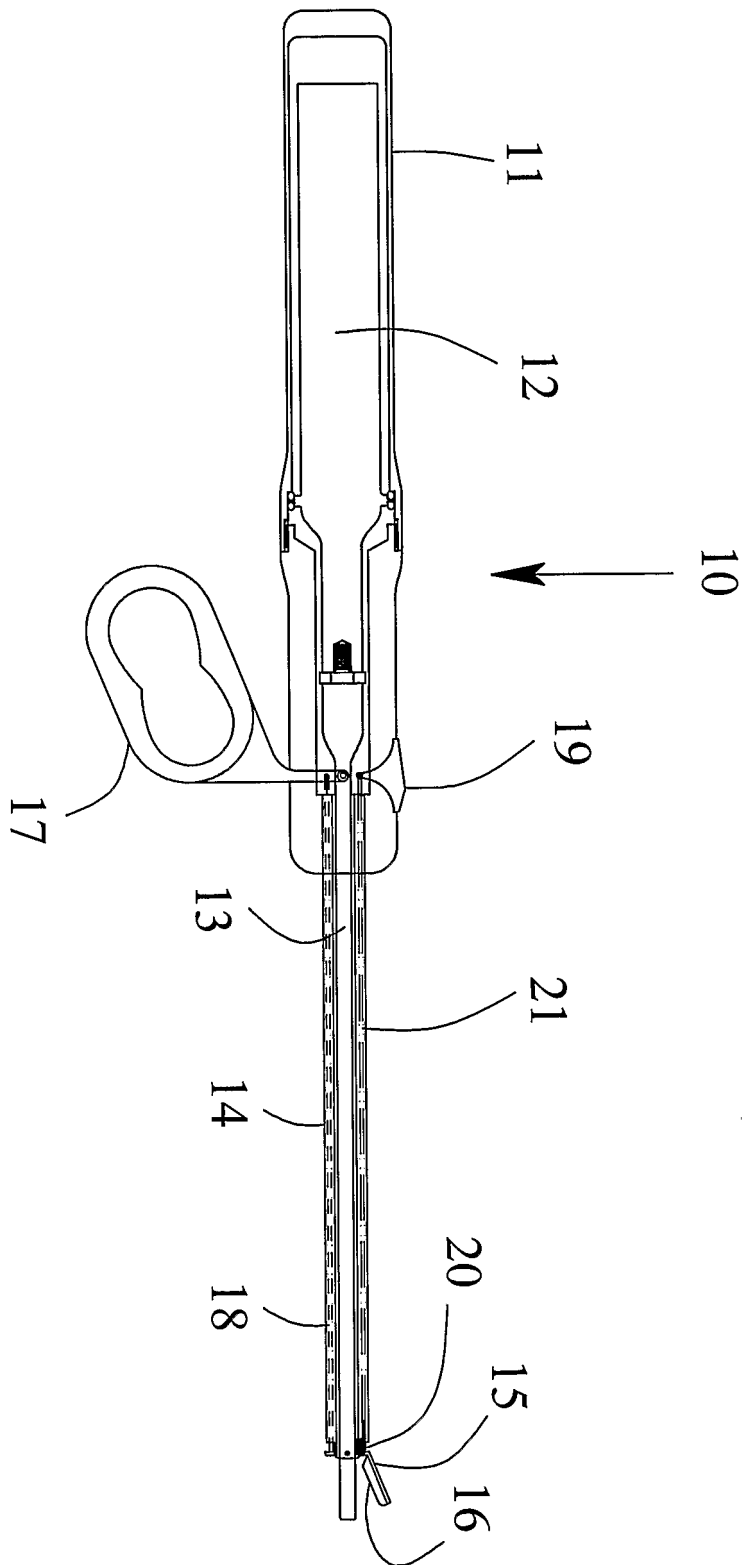


Figure 1a

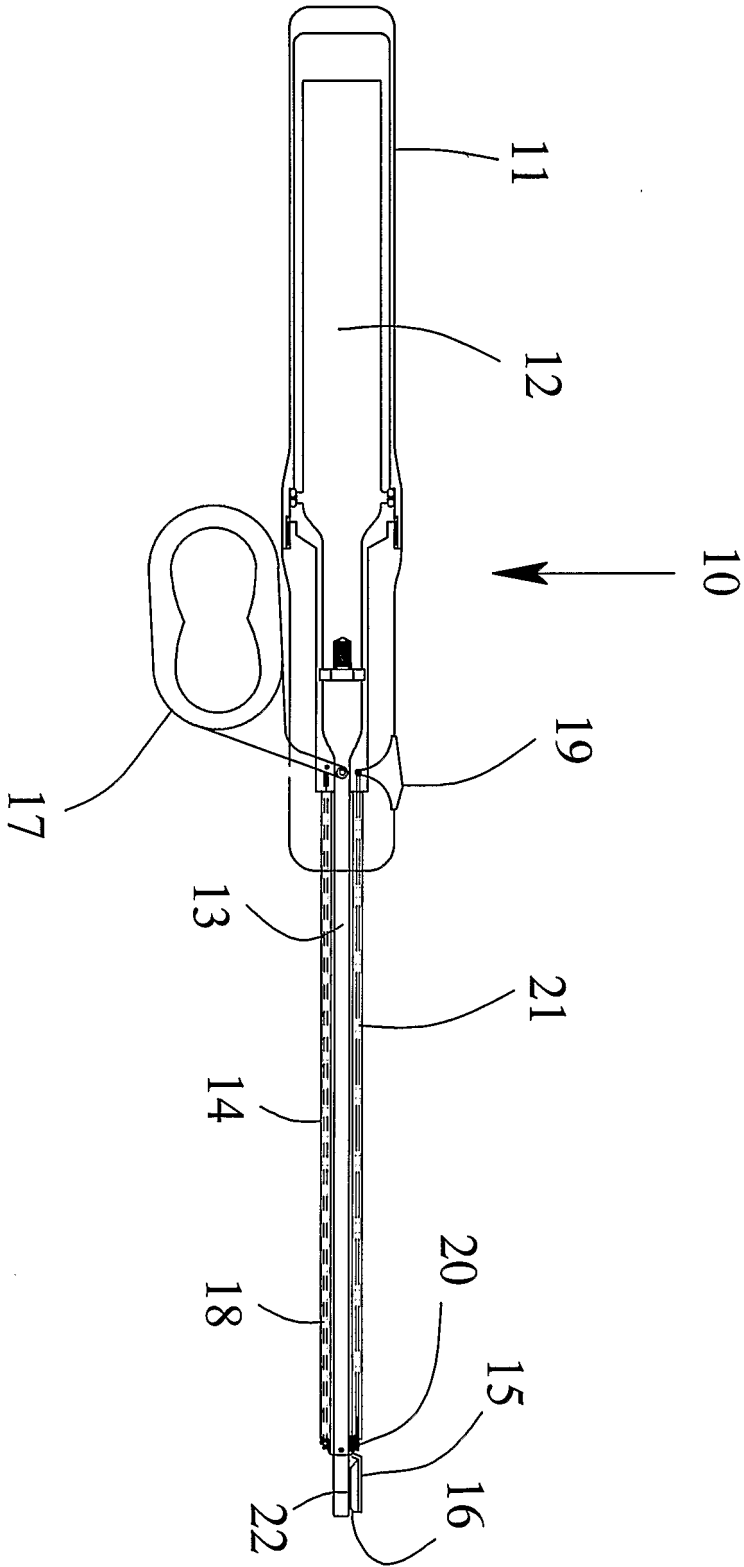


Figure 1b

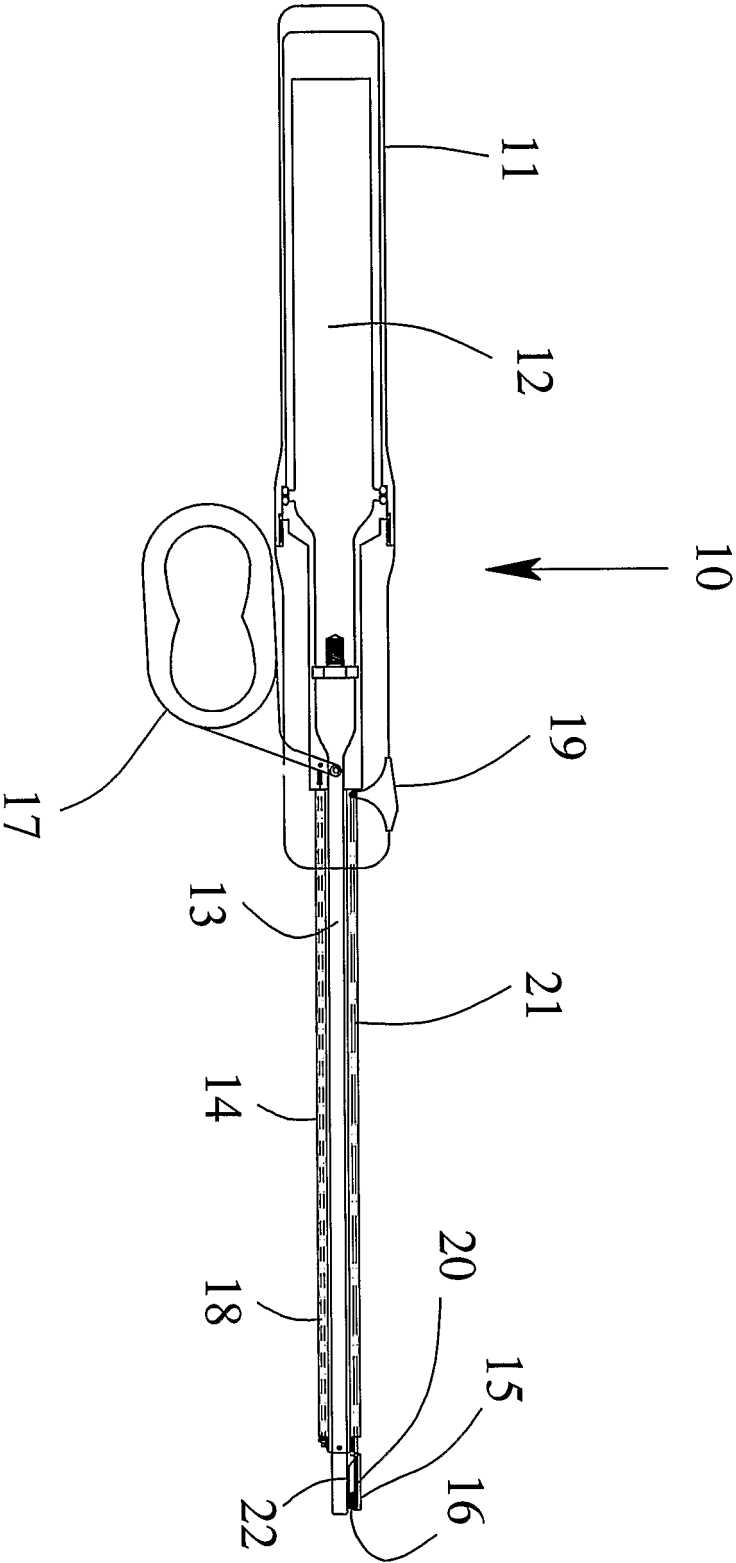


Figure 1c

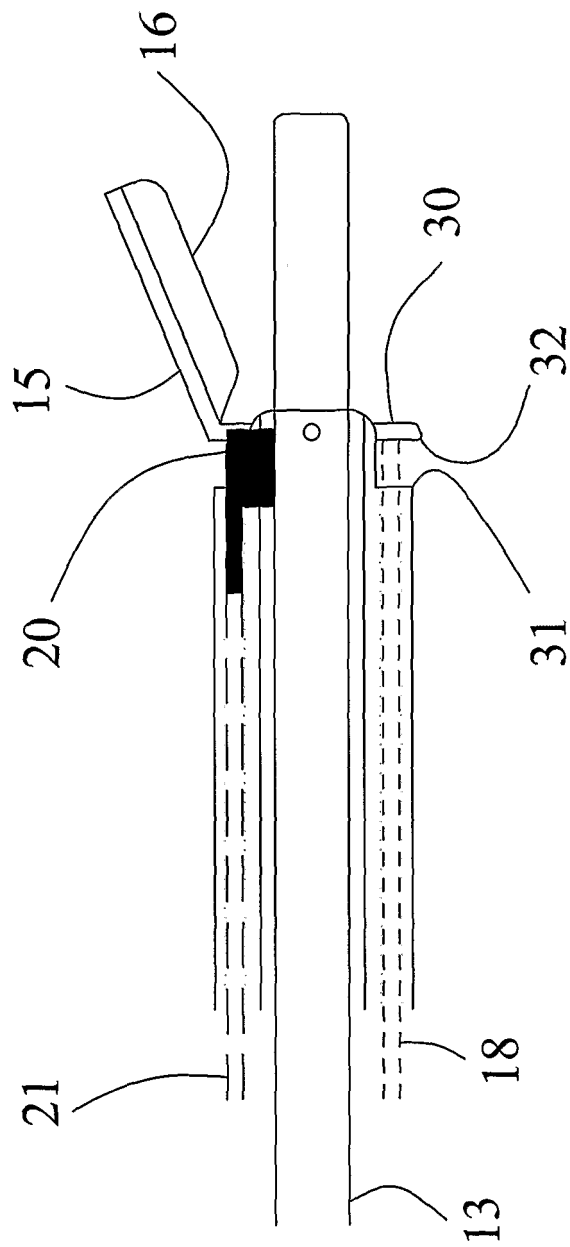


Figure 2

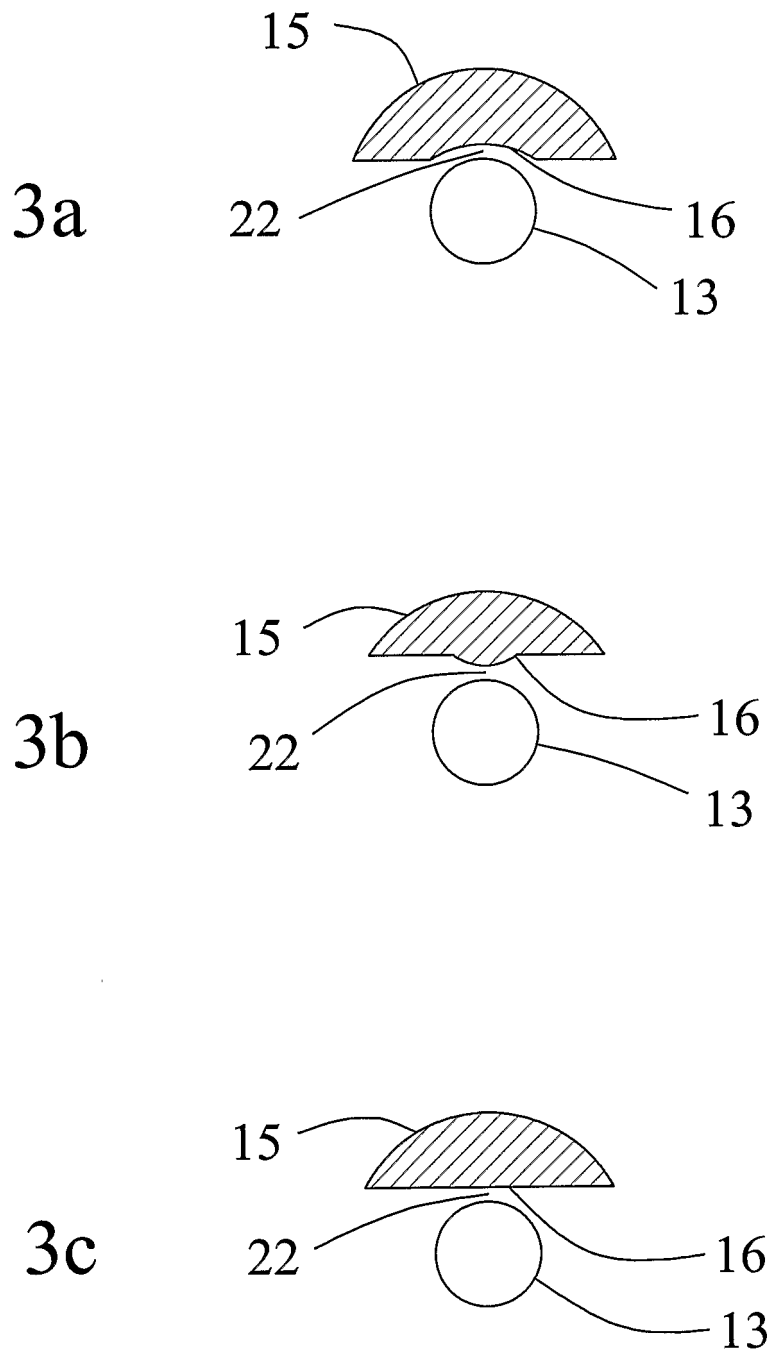


Figure 3

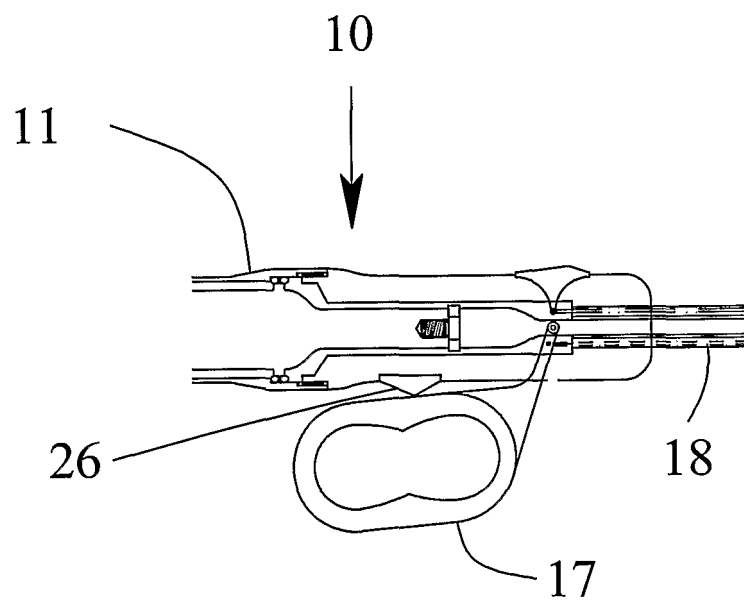


Figure 4

专利名称(译)	超声波装置和组织凝固方法		
公开(公告)号	EP1551321A2	公开(公告)日	2005-07-13
申请号	EP2003736854	申请日	2003-06-04
[标]申请(专利权)人(译)	声外科技术有限公司		
申请(专利权)人(译)	SOUND外科技术有限责任公司		
当前申请(专利权)人(译)	SOUND外科技术有限责任公司		
[标]发明人	CIMINO WILLIAM W		
发明人	CIMINO, WILLIAM, W.		
IPC分类号	A61N7/02 A61B17/00 A61B17/28 A61B17/32 A61B18/00 A61B18/18 A61N B29C65/74		
CPC分类号	A61N7/02 A61B2017/00504 A61B2017/320093 A61B2017/320094 A61B2017/320095		
优先权	60/386119 2002-06-04 US		
其他公开文献	EP1551321A4 EP1551321B1		
外部链接	Espacenet		

摘要(译)

一种用于动物组织凝固的超声外科手术装置 (10) , 具有超声波施加器 (13) 和可动钳口 (15) , 钳口表面 (16) 邻近超声波施加器 (13) 的远端部分, 用于朝向施加器移动 (13) 到距施加器 (13) 约0.075至约1.9毫米的预定间隙 (22) 处的闭合位置。装置 (10) 还可包括机械切割元件 (20) , 其可延伸到间隙中以切割组织, 并且装置可改变预定间隙 (22) 而无需从患者移除涂抹器 (13) 。组织凝固和切割可以最大化并单独进行, 并且可以由外科医生容易地监测。