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- (71) Applicant: **ETHICON ENDO-SURGERY, INC.**  
[US/US]; 4545 Creek Road, Cincinnati, OH 45242 (US).

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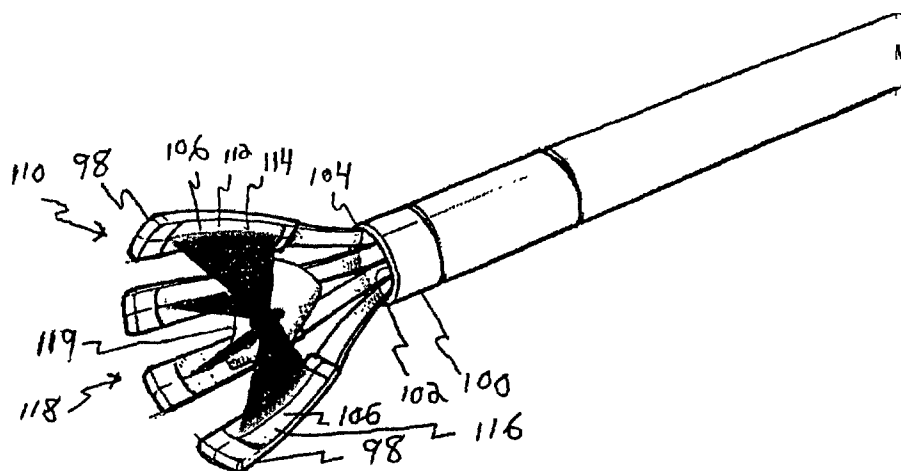
- (72) Inventors: **MAKIN, Inder, Raj., S.**; 11388 Donwiddle Drive, Loveland, OH 45140 (US). **DUNKI-JACOBS, Robert**; 4600 Wesley Court, Mason, OH 45040 (US).
- (74) Agents: **JOHNSON, Philip, S.** et al.; Johnson & Johnson, One Johnson & Johnson Plaza, New Brunswick, NJ 45242 (US).

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(54) Title: FACETED ULTRASOUND MEDICAL TRANSDUCER ASSEMBLY



(57) **Abstract:** An ultrasound medical system includes an ultrasound transducer assembly which is insertable into a patient, which has a longitudinal axis, and which has a plurality P of ultrasound transducers. Each transducer has an ultrasound-emitting surface oriented at an angle of substantially 360/P degrees apart from the ultrasound-emitting surface of an adjacent transducer when viewed in a cross section of the transducer assembly taken by a cutting plane which is perpendicular to the longitudinal axis. In one example, the ultrasound transducer assembly is an ultrasound imaging transducer assembly, an ultrasound medical-treatment transducer assembly, or an ultrasound imaging and medical-treatment transducer assembly.



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## FACETED ULTRASOUND MEDICAL TRANSDUCER ASSEMBLY

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

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### Field of the Invention

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

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### Background of the Invention

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

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

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

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

A Mammotome® Breast Biopsy System manufactured by Ethicon Endo-Surgery, Inc. (a Johnson & Johnson Company) inserts a tube into breast tissue, wherein the tube contains an end effector having a biopsy cutting tool. A known electromagnetic transponder and three-receiver system for calculating the position of the transponder and for guiding the transponder (which is attached to a heart catheter for monitoring the heart) inside a patient is the CARTO™ EP Navigation System used with a NAVI-STAR® catheter manufactured by Biosense Webster (a Johnson & Johnson Company). Further, it is known that changes in patient tissue because of medical treatment of patient tissue, such as ultrasound medical treatment, affect the amplitude and/or phase of ultrasound imaging signals.

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

#### Summary of the Invention

One expression of an embodiment of the invention is an ultrasound medical system including an ultrasound transducer assembly which is insertable into a patient, which has a longitudinal axis, and which has a plurality P of ultrasound transducers. Each transducer has an ultrasound-emitting surface oriented at an angle of substantially  $360/P$  degrees apart from the ultrasound-emitting surface of an adjacent transducer when viewed in a cross section of the transducer assembly taken by a cutting plane which is perpendicular to the longitudinal axis. In one example, the ultrasound transducer assembly is an ultrasound imaging transducer assembly, an ultrasound medical-treatment transducer assembly, or an ultrasound imaging and medical-treatment transducer assembly.

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

### Brief Description of the Drawings

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

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

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

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

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

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

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

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

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

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

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

Figure 12 is a perspective view of an alternate flexible finger arrangement which can be used in the ultrasound medical system of Figure 9,

showing the flexible fingers in a deployed claw-like state surrounding patient tissue;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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#### Detailed Description of the Invention

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

It is understood that any one or more of the following-described embodiments, expressions of embodiments, examples, methods, etc. can be combined with any one or more of the other following-described embodiments, expressions of embodiments, examples, methods, etc. For example, and

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without limitation, any of the end effectors can be used in any of the methods, any of the transducer arrangements can be used in any of the end effectors, and any appropriate methods can be combined such as combining the seventeenth and twentieth methods, etc.

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## Ultrasound Medical Treatment Using Tissue-Retaining Devices

### Tissue-Retaining System for Ultrasound Medical Treatment

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

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

Advantages of retaining patient tissue between two tissue-retaining members during ultrasound medical treatment by one of the tissue-retaining



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

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

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

It is noted that an ultrasound imaging and medical-treatment transducer is an ultrasound transducer adapted at least for both ultrasound imaging and

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

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

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

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

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

In one example of the previously-described third and fourth expressions of the first embodiment, the ultrasound reflector 28 is disposed to receive

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

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

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

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

30           In one enablement, as shown in Figure 1, the ultrasound medical treatment system 10 also includes a handpiece 44 operatively connected to the

end effector 12 and to an ultrasound controller 46 operatively connected to a foot-pedal power switch 47, as can be appreciated by those skilled in the art.

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

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

(as seen in Figures 2 and 4). In one application of the second method of the invention, the intervertebral disk 48 includes connective and nerve tissue.

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

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

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

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

In one example of the second embodiment, the first tissue-retaining member 56 is a distal end portion 64 of a first tube 66. The ultrasound medical treatment system 50 also includes a second tube 68, first and second link members 70 and 72, and a cable 74. The second tube 68 is oriented  
10 substantially parallel to the first tube 66. The first and second link members 70 and 72 are pivotally attached to the second tissue-retaining member 60 and to the second tube 68 at pivot points 76-82 creating a hinged parallelogram defined by a proximal portion 84 of the second tissue-retaining member 60, a distal portion 86 of the second tube 68, and the first and second link members 70 and  
15 72. The ultrasound reflector 62 is disposed at a distal portion 88 of the second tissue-retaining member 60 and faces the transducer 58. The cable 74 is operatively connected to the hinged parallelogram to move the second tissue-retaining member 60 toward and away from the first tissue-retaining member 56.

20 In one variation, the ultrasound medical treatment system 50 also includes an outer tube 90. The cable 74 and the first and second tubes 66 and 68 are disposed in the outer tube 90. In one modification, the ultrasound medical treatment system 50 also includes a handpiece 92. The cable 74 and the first, second, and outer tubes 66, 68 and 90 are operatively connected to the  
25 handpiece 92. In one design, the orientation of the first tube 66 about the longitudinal axis of the first tube 66 is controlled by a step motor (not shown) disposed in, and actuated by, the handpiece 92. In the same or another design, the first tube 66 is a hollow tube allowing for transducer wiring (not shown), and the second tube is a solid tube (not shown). Depending on use, the tubes  
30 66, 68, and 90 may be rigid or flexible which also is true for any tube arrangement (specifically disclosed as rigid or flexible, or not so specifically



disclosed) of any end effector and for any end effector itself of any of the previous or following embodiments of the invention.

### Ultrasound Medical Treatment Using Specific Transducer Arrangements

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#### Deployable Ultrasound Medical Transducers

Referring to the drawings, Figures 9-11 illustrate a third embodiment of the present invention. A first expression of the third embodiment of the present invention is for an ultrasound medical system 94 including a tube 96 and a plurality of resiliently flexible fingers 98. The tube 96 has a distal end 100 insertable into a patient and has a lumen 102 with a distal opening 104. The fingers 98 are extendable out of the distal opening 104 of the lumen 102 creating a deployed state (seen in Figure 10) and which are at-least-partially retractable into the distal opening 104 of the lumen 102 creating a stowed state (seen in Figure 11). Each finger 98 includes an ultrasound transducer 106. The distance between the ultrasound transducers 106 of adjacent fingers 98 is greater in the deployed state than in the stowed state. It is noted that an ultrasound medical system is a medical system which at least provides ultrasound imaging or ultrasound medical treatment of a patient.

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

In one variation, the fingers 98 are only partially retracted into the distal opening 104 of the lumen 102 in the stowed state (as seen in Figure 11). In another variation, not shown, the fingers 98 are completely retracted into the distal opening 104 of the lumen 102 in the stowed state. By the fingers 98 being extendable out of the distal opening 104 of the lumen 102 creating the

deployed state and being at-least-partially retractable into the distal opening 104 of the lumen 102 creating the stowed state means the fingers 98 protrude more out of the distal opening 104 of the lumen 102 in the extended state than (if at all) in the stowed state. Mechanisms, not shown, for remotely extending and retracting fingers in a tube include, without limitation, a common shaft attached to the proximal ends of the fingers, disposed in the lumen of the tube, and spring-biased to move forward upon squeezing of a handpiece and to return backward upon relaxing of the handpiece, as is within the ordinary level of skill of the artisan. In one modification, the distal opening 104 of the lumen 102 coincides with the distal end 100 of the tube 96. In another modification, not shown, the distal opening of the lumen is spaced apart from the distal end of the tube. In one implementation, the distal opening 104 of the lumen 102 faces in the same direction as the distal end 100 of the tube 96. Other implementations are left to the artisan, such as, without limitation, the distal opening of the lumen facing perpendicular to the distal end of the tube. In one example, at least one of the transducers 106 is an ultrasound imaging transducer. In the same or a different example, at least one of the transducers 106 is an ultrasound medical-treatment transducer. In the same or a different example, at least one of the transducers 106 is an ultrasound imaging and medical-treatment transducer.

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

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

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

In one example of the first, second and third expressions of the third embodiment, the transducers 106, 112 and 114 each have an ultrasound-emitting concave surface 116. In another example, not shown, the transducers have a planar ultrasound-emitting surface. In one arrangement, each concave surface 116 is concave as one moves along the corresponding finger 98 (as best seen in Figure 10). In another arrangement, not shown, each concave surface is concave as one moves across the corresponding finger or is concave as one moves both along and across the corresponding finger (such as, for example, with a hemispherically-concave surface). In one design, the concave surfaces 116 together have a substantially common focal zone when the fingers 98 are in the deployed state. The end effector 110 is seen with its fingers 98 facing the patient tissue 119 in Figure 10. In another design, not shown, the focal zones are not common. In one configuration, the fingers 98 define an open-hand finger array 118 in the deployed state. An alternate flexible finger arrangement in the form of a substitute end effector 120 is shown in Figure 12, wherein the fingers 122 define a clawed-hand finger array 124 in the deployed state. The substitute end effector 120 is seen with its fingers 122 surrounding the patient

tissue 126 for imaging and/or medical treatment by the ultrasound transducers 128 in Figure 12. In other transducer arrangements, not shown, one or more or all of the ultrasound transducers face outward rather than facing inward.

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

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

#### Faceted Ultrasound Medical Transducer Assembly

A fourth embodiment of the present invention is shown in Figures 13-15. A first expression of the fourth embodiment of the present invention is for an ultrasound medical system 134 including an ultrasound transducer assembly 136 insertable into a patient. The ultrasound transducer assembly 136 has a longitudinal axis 138. The ultrasound transducer assembly 136 includes a plurality P of ultrasound transducers 140. Each transducer 140 has an ultrasound-emitting surface 142 oriented at an angle of substantially  $360/P$  degrees apart from the ultrasound-emitting surface 142 of an adjacent transducer 140 when viewed in a cross section (see Figure 15) of the transducer assembly 136 taken by a cutting plane which is perpendicular to the longitudinal axis 138.

Advantages of such a transducer configuration include, in one example, providing directed or focused medical-treatment ultrasound which is not

possible with a cylindrical ultrasound transducer, as can be appreciated by those skilled in the art.

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

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

A fourth method of the present invention is for ultrasound medical treatment of a patient and uses the ultrasound medical treatment system 144 as previously described in the second expression of the fourth embodiment. The fourth method includes steps a) through b). Step a) includes inserting the end effector 146 into the liver of the patient. Step b) includes medically treating a

lesion in the liver with ultrasound from the ultrasound medical-treatment transducer assembly 148. In one example, step a) interstitially inserts the end effector 146 into the lesion. In another example, step a) endoscopically inserts the end effector 146 into the liver through the hepato-biliary duct system.

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

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

30           In one example of the previously-described first, second and third expressions of the fourth embodiment, the transducer assembly 136, 148, and

152 has a distal tip 156 and has a tip transducer 158. In one design, the tip transducer is a forward facing tip transducer. In another design, the tip transducer is a sideways facing tip transducer. In one variation, the tip transducer is an ultrasound imaging tip transducer. In another variation, the tip transducer is an ultrasound medical-treatment tip transducer. In a further variation, the tip transducer is an ultrasound imaging and medical-treatment tip transducer. In an additional variation, the tip transducer is a transponder which emits electromagnetic waves or mechanical waves or both.

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

In the same or a different example of the previously-described first, second and third expressions of the third embodiment, P is no greater than four. In one variation, P equals three as seen in Figures 15 and 17. In another variation, P equals two as seen in Figure 16.

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

### Ultrasound Medical Treatment Applications

#### Excisional And Ultrasound Medical treatment System

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



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

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

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

first end effector 174 (with the biopsy cutting tool 194 including a suction mechanism) are based on components of a Mammotome® Breast Biopsy System manufactured by Ethicon Endo-Surgery, Inc. (a Johnson & Johnson Company).

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

          In a fourth expression of the fifth embodiment of the present invention,  
30   an ultrasound medical treatment system 170 includes a tube 172, a first end effector 174, and a second end effector 176. The tube 172 has a distal end 178

|                |                                                                                                                                                                                 |         |            |
|----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|------------|
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| [标]申请(专利权)人(译) | 伊西康内外科公司                                                                                                                                                                        |         |            |
| 申请(专利权)人(译)    | 爱惜康内镜手术，INC.                                                                                                                                                                    |         |            |
| 当前申请(专利权)人(译)  | 爱惜康内镜手术，INC.                                                                                                                                                                    |         |            |
| [标]发明人         | MAKIN INDER RAJ S<br>DUNKI JACOBS ROBERT                                                                                                                                        |         |            |
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#### 摘要(译)

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