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(54) **HIGH INTENSITY ULTRASOUND APPARATUS METHODS AND SYSTEMS**

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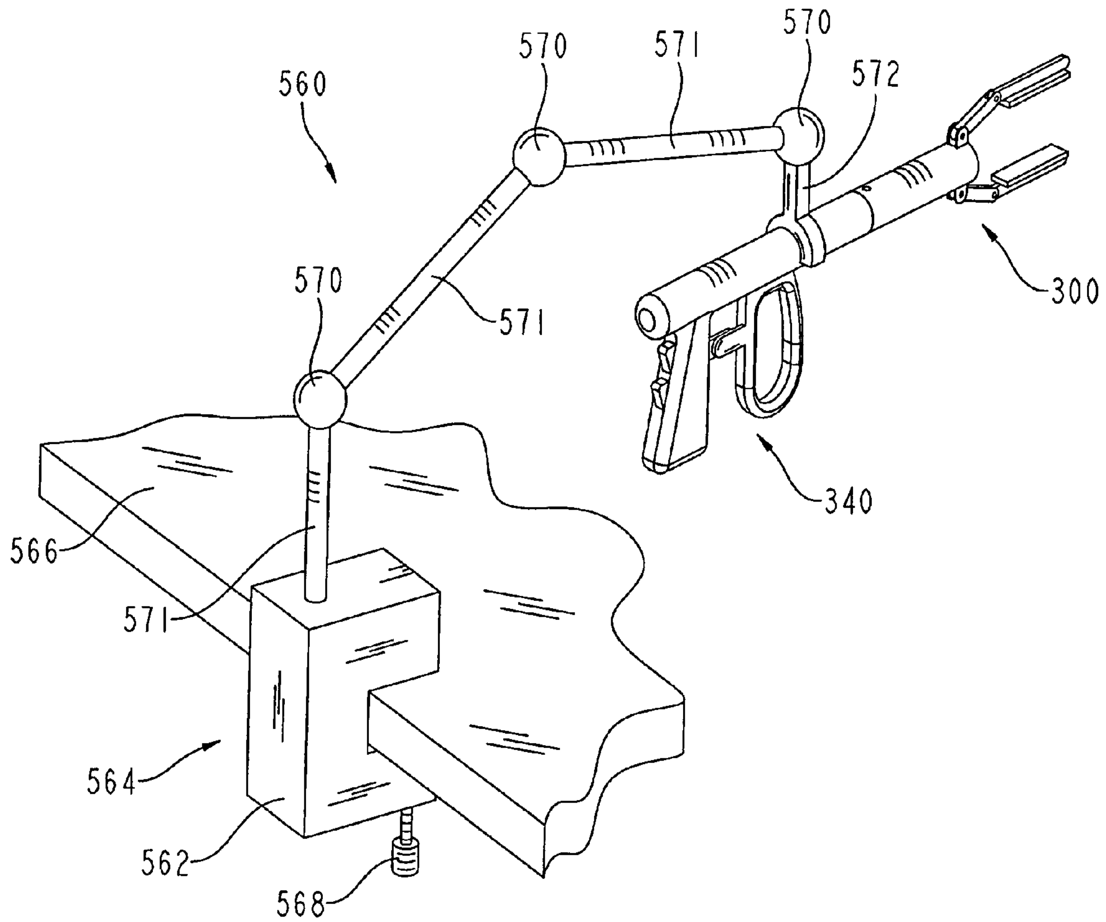
(52) **U.S. Cl.** **600/471**

(57) **ABSTRACT**

A surgical clamp including a first arm and a second arm, a source of high intensity unfocused ultrasound the source coupled to the first arm, and an ultrasound reflector coupled to the second arm is provided. At least one of the first arm and the second arm is moveable to position the reflector to reflect non-focused high intensity ultrasound emitted by the source and to clamp an organ or tissue intermediate the source and the reflector.



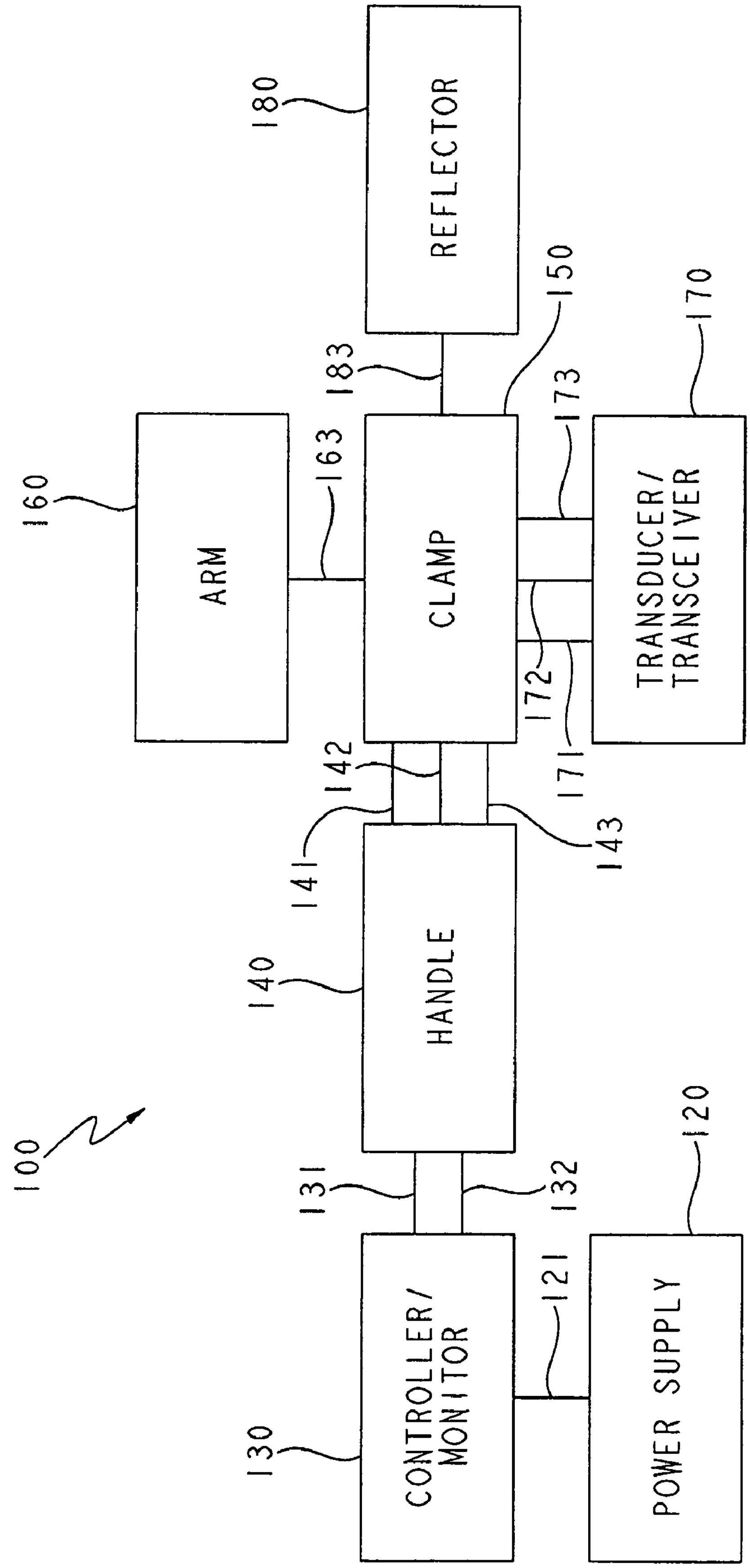

REFLECTOR
ARM
CLAMP
TRANSDUCER/ TRANSCEIVER
HANDLE
CONTROLLER/ MONITOR
POWER SUPPLY
100
120
121
130
131
132
140
141
142
143
150
160
163
170
171
172
173
180
183

FIG. 1

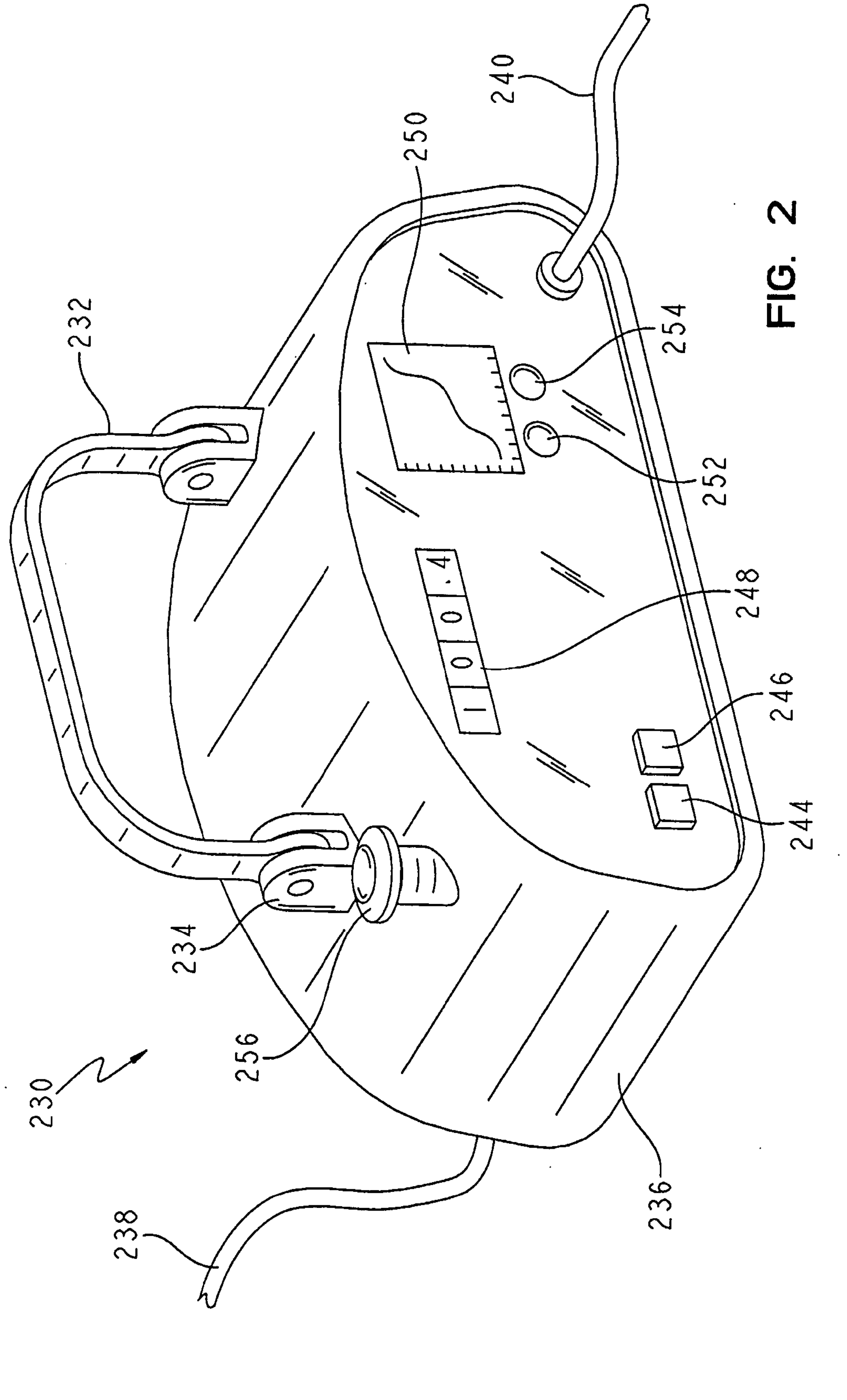


FIG. 2

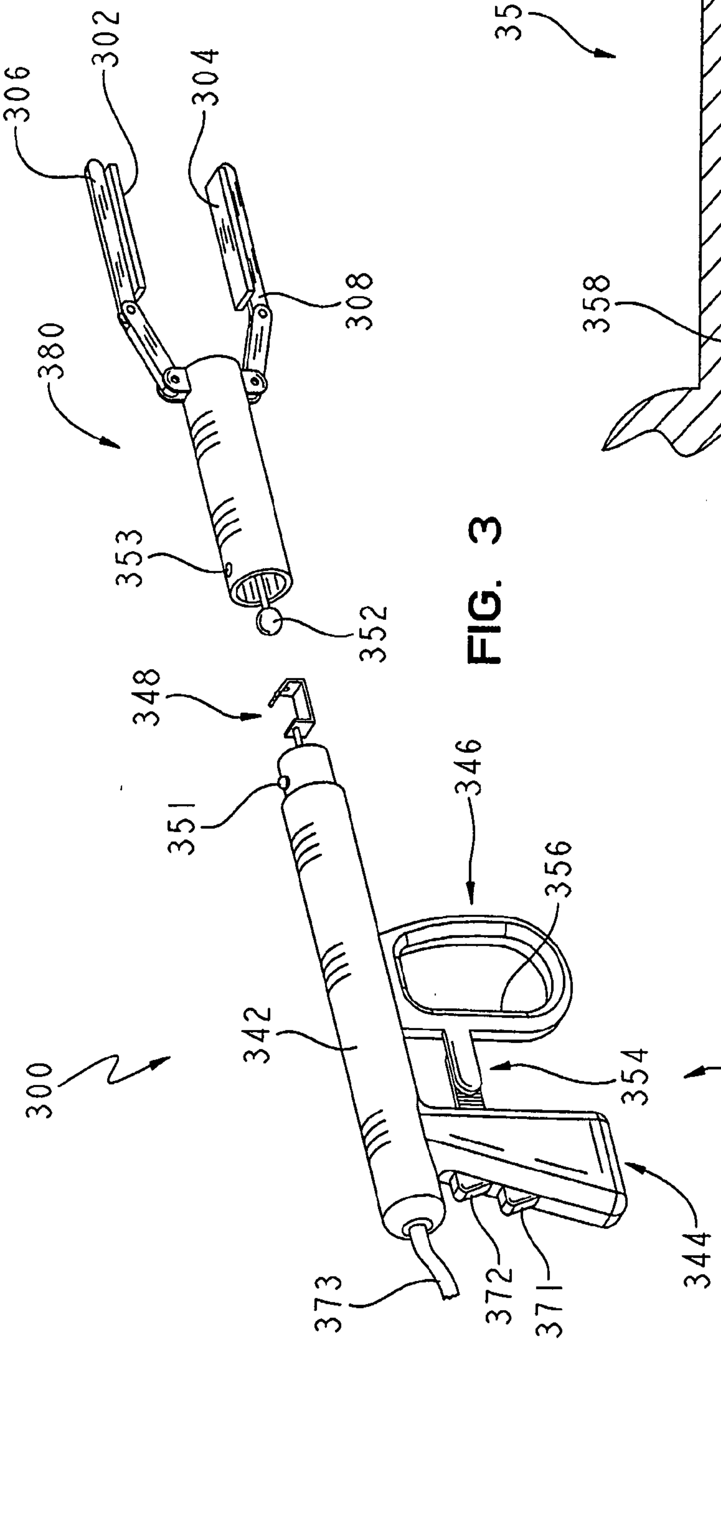

306
302
304
308
380
353
352
348
351
346
356
342
300
354
340
344
373
372
371

FIG. 3

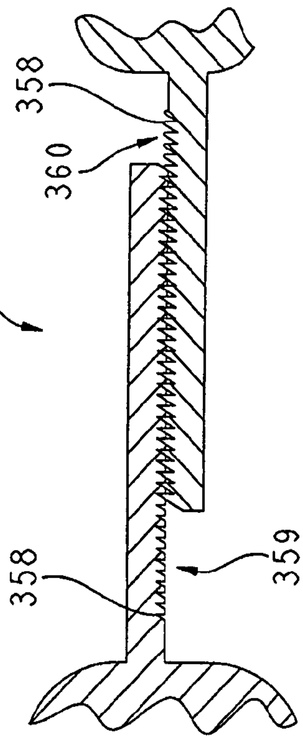

358
360
354
358
359

FIG. 4

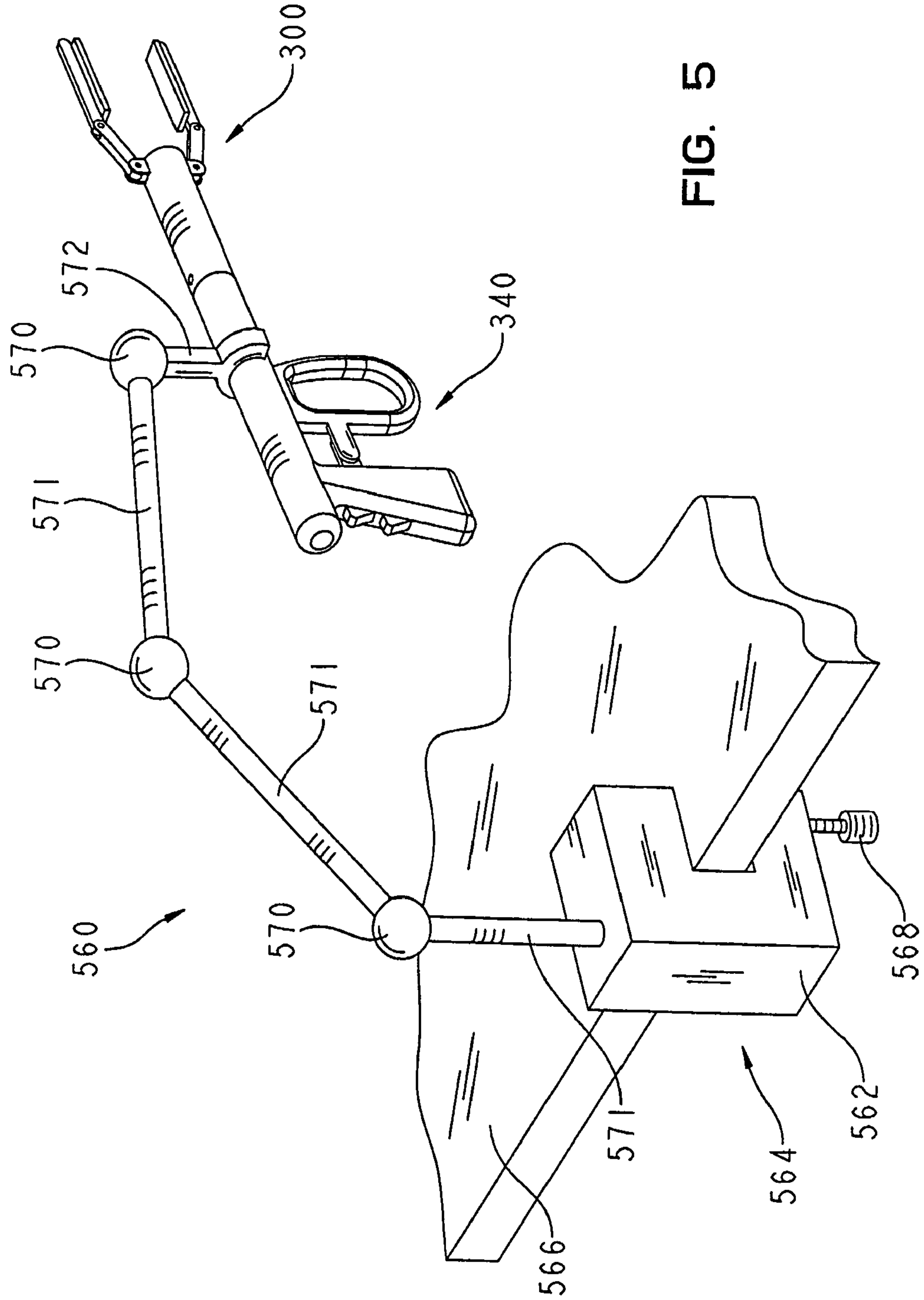


FIG. 5

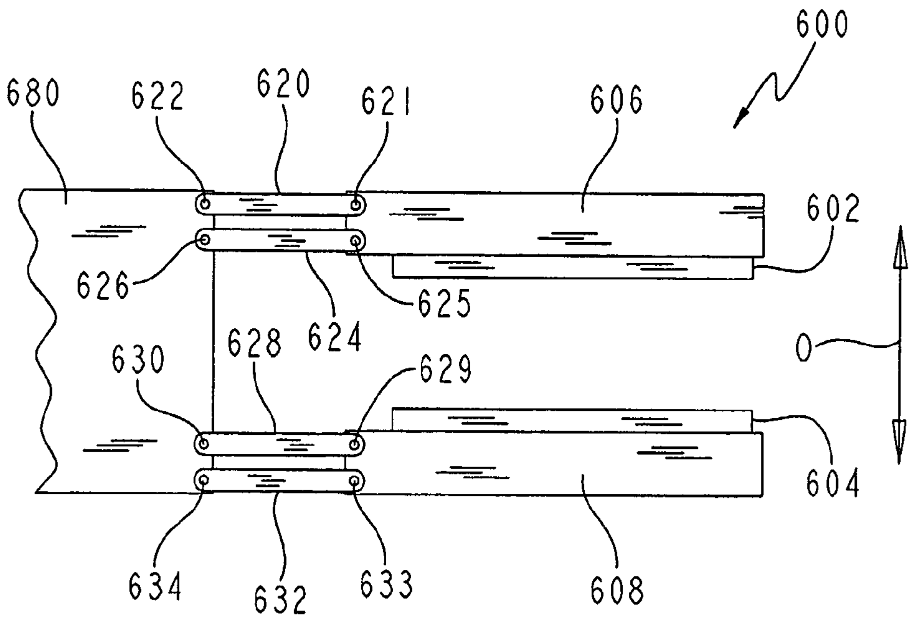

600
680
622
620
621
606
602
626
625
624
0
628
630
629
604
634
632
633
608

FIG. 6

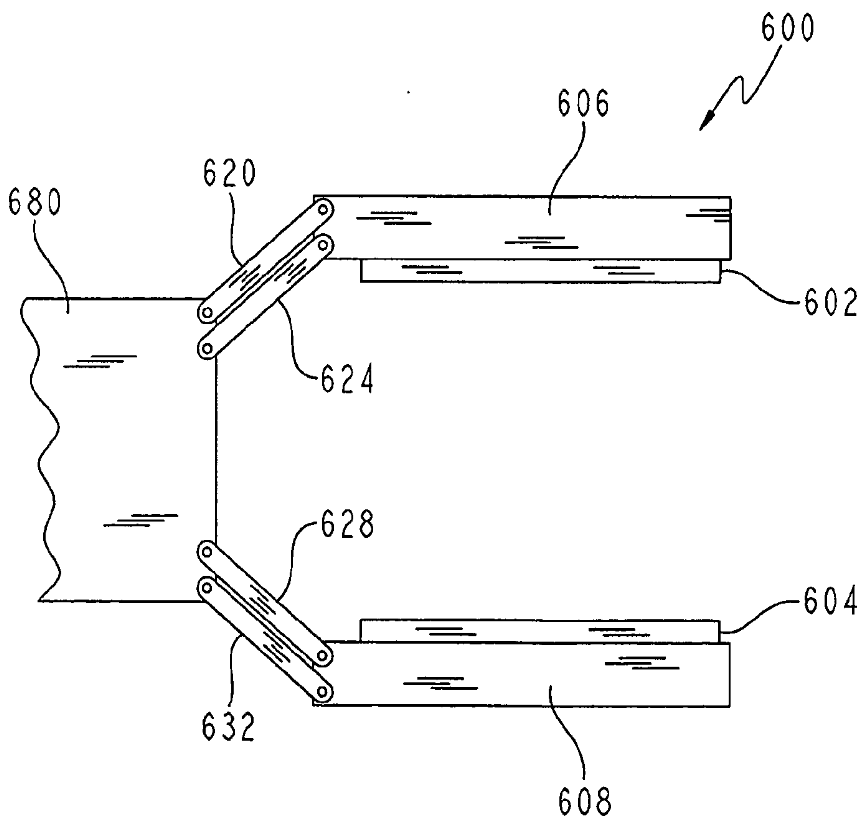

600
606
620
680
602
624
628
604
632
608

FIG. 7

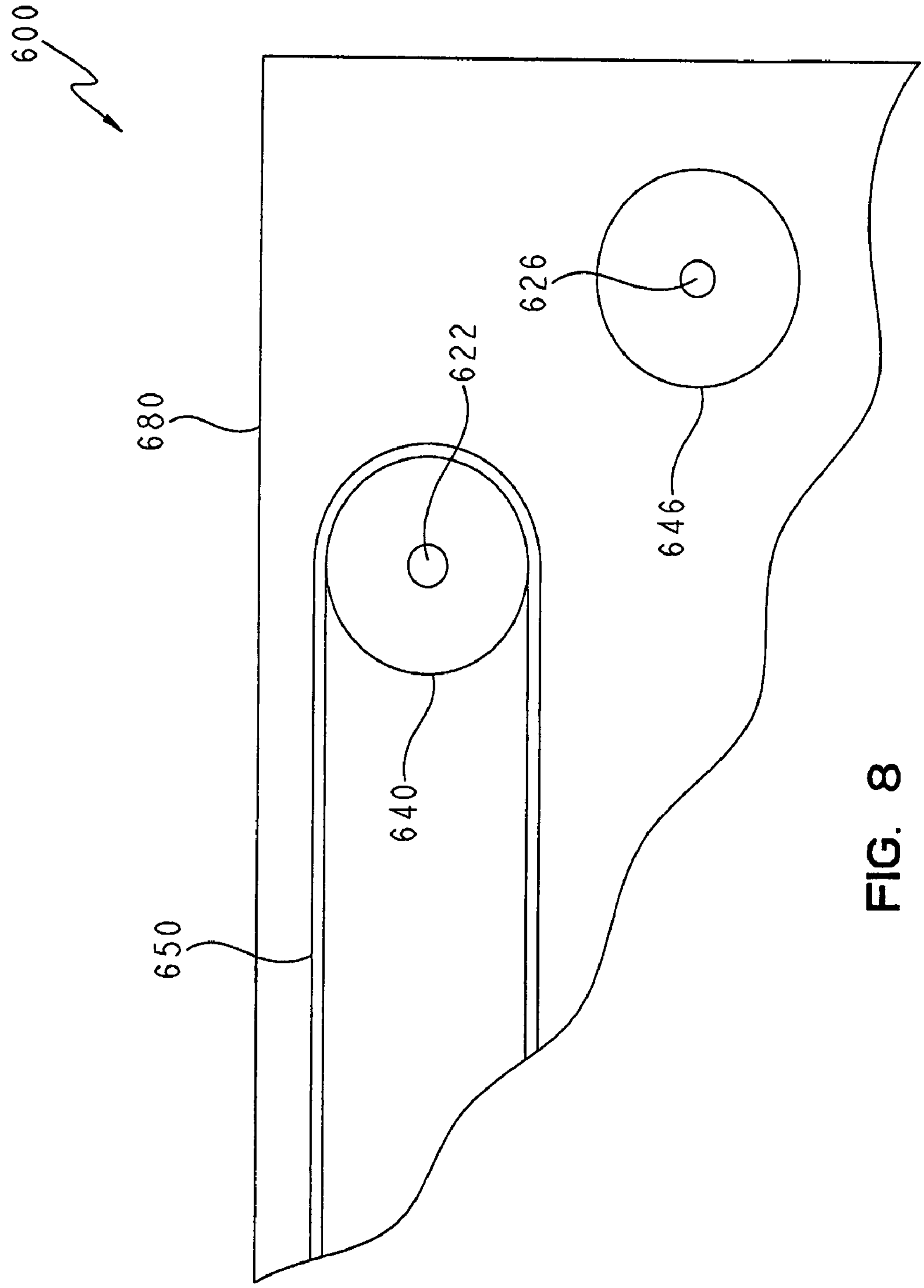
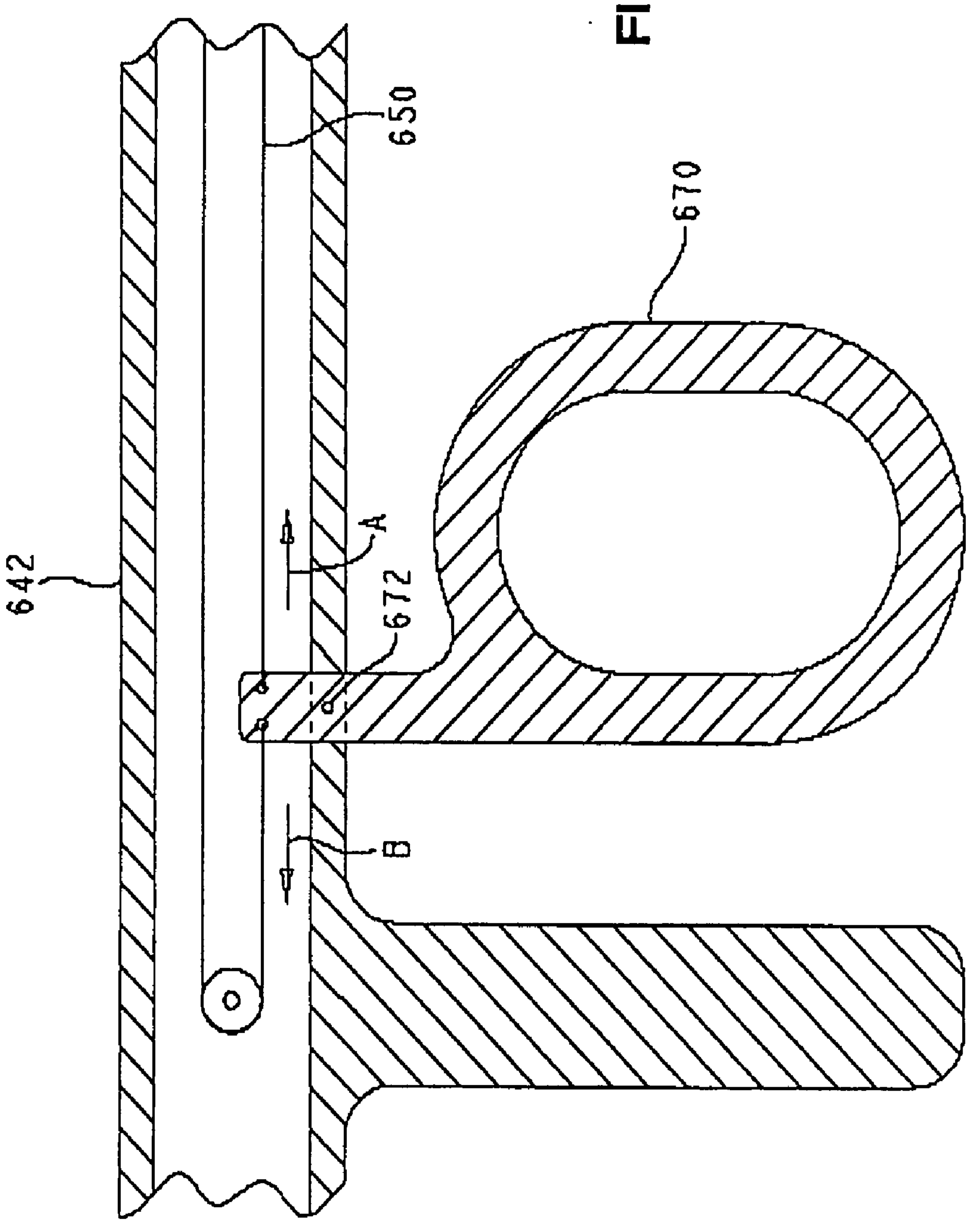


FIG. 8

FIG. 9



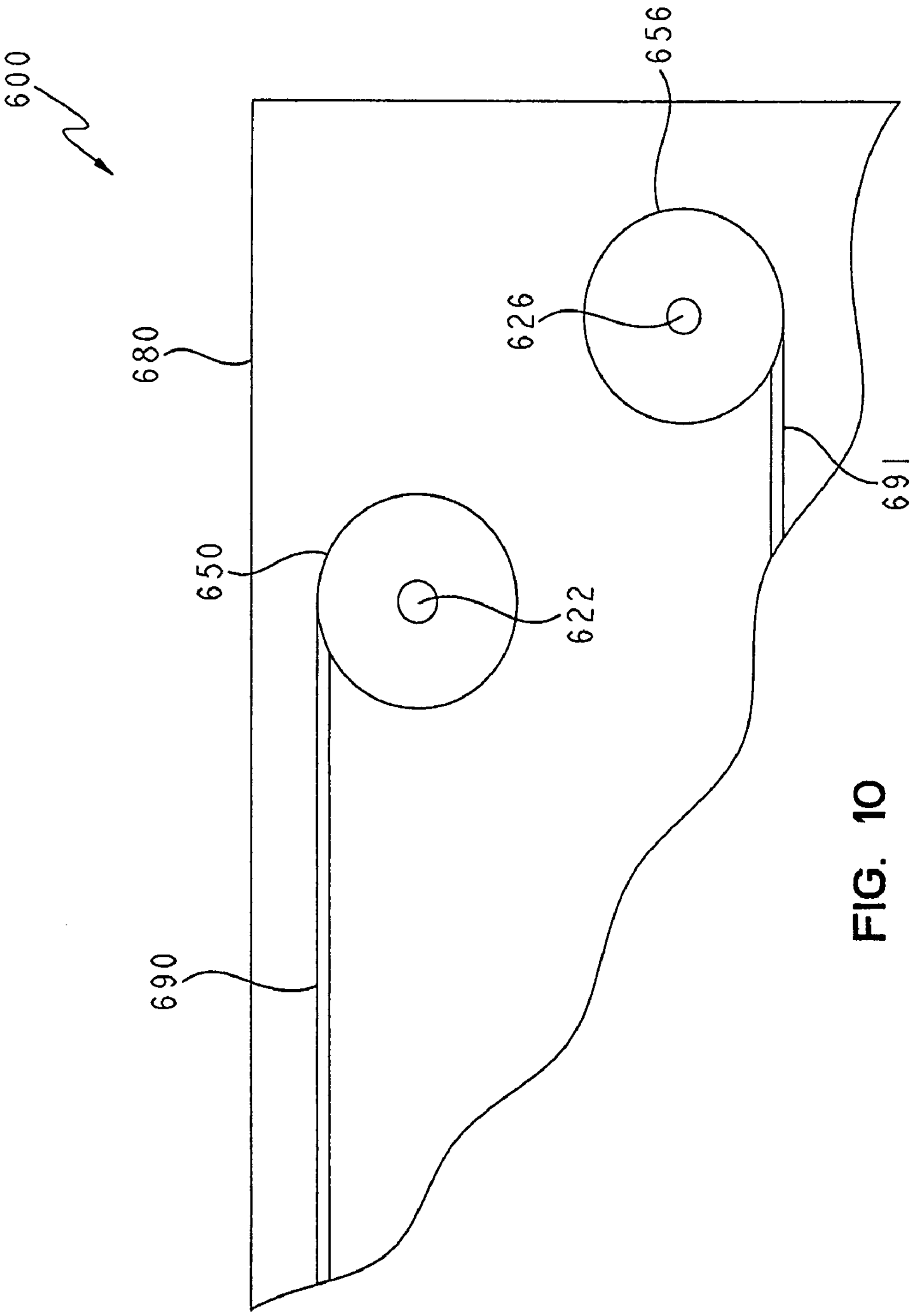


FIG. 10

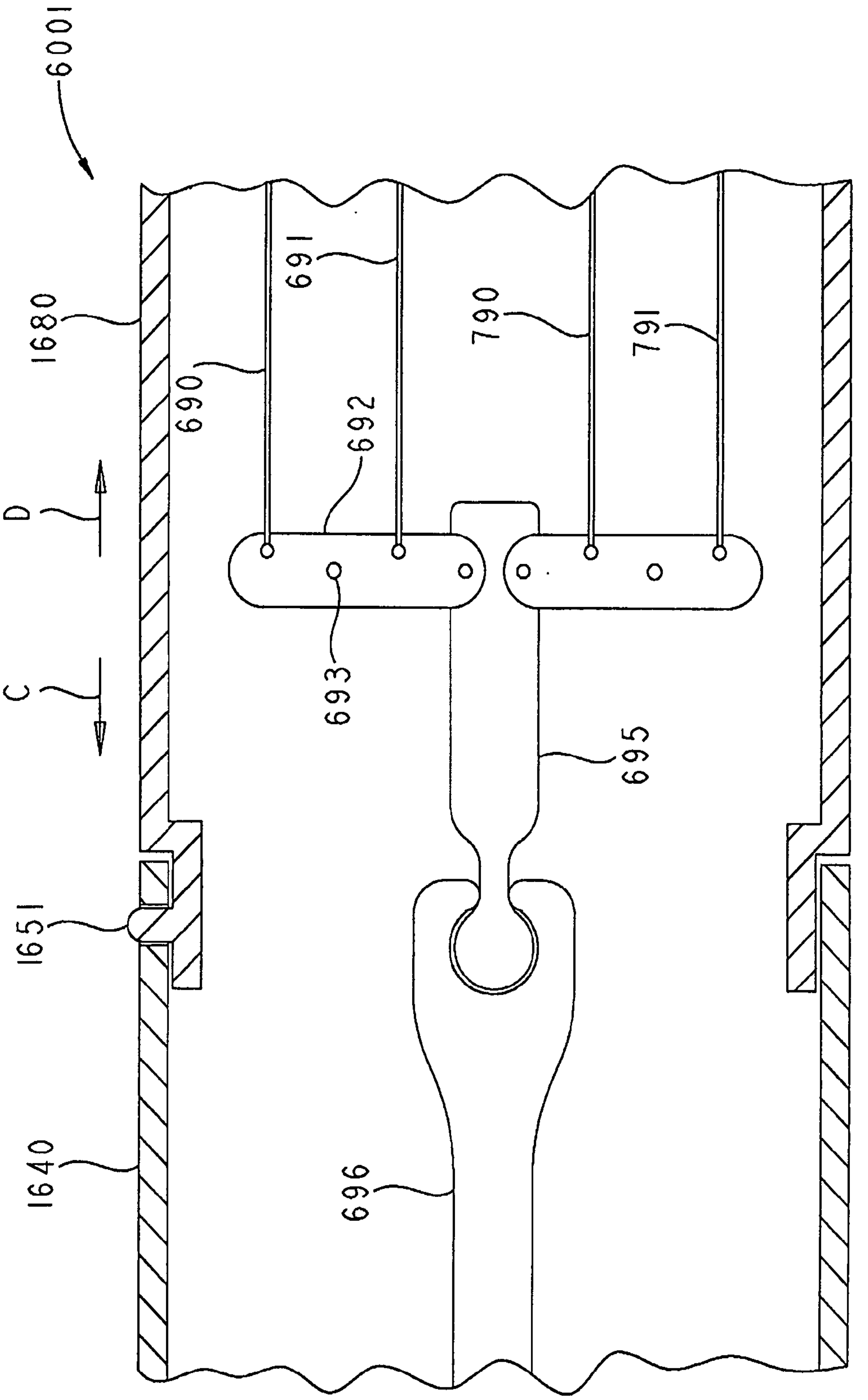


FIG. 11

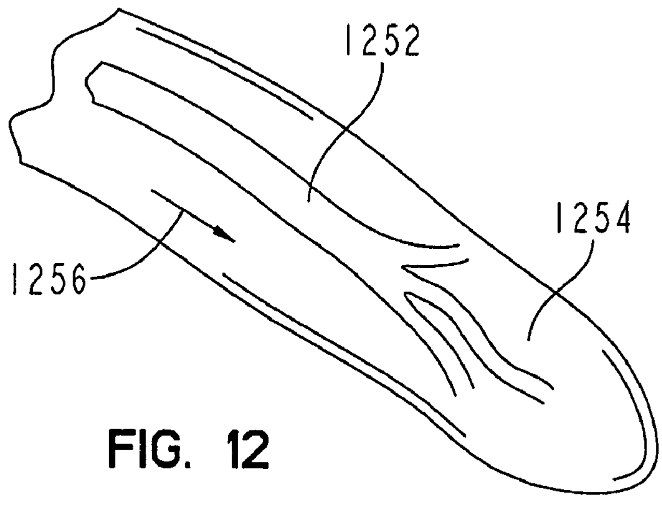


FIG. 12

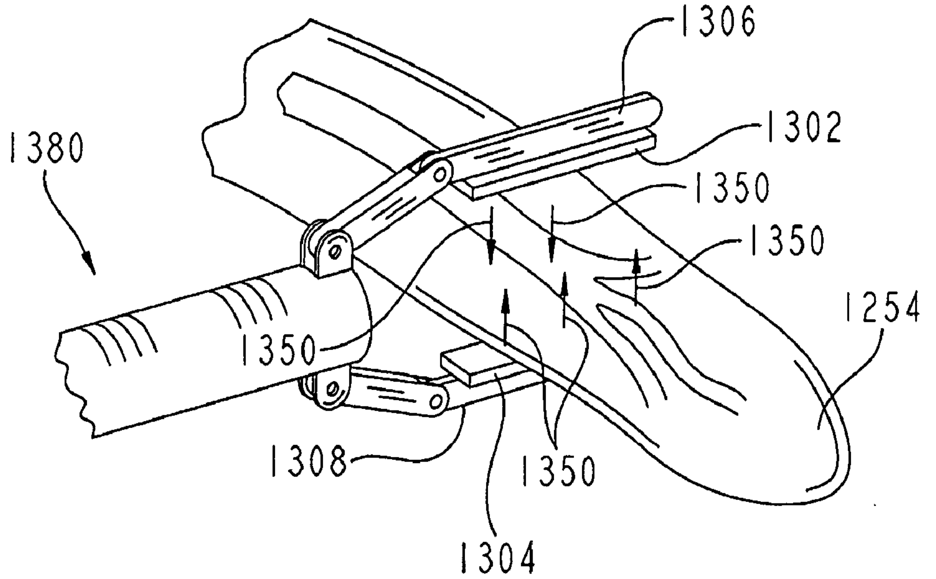


FIG. 13

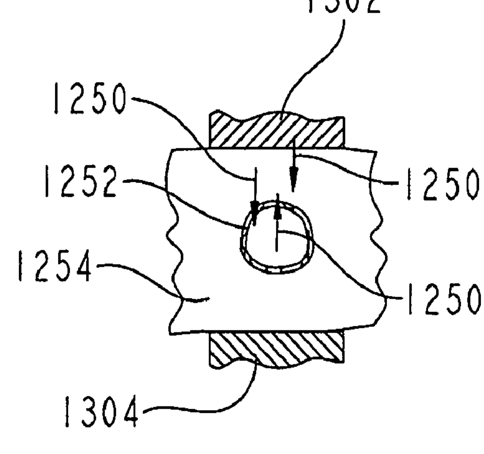


FIG. 14

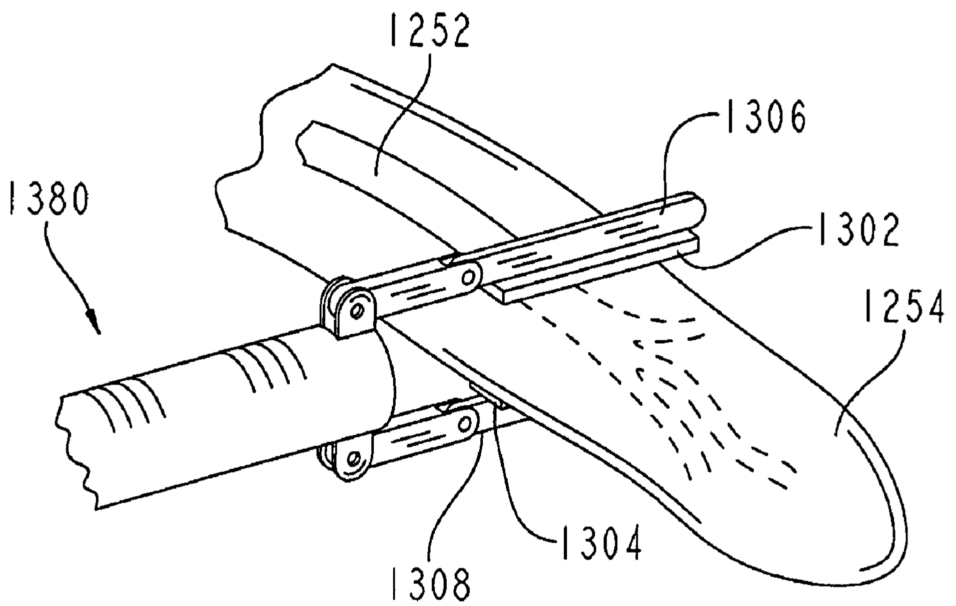

1252
1306
1380
1302
1254
1304
1308

FIG. 15

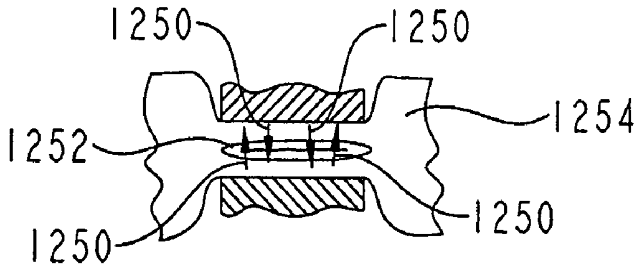

1250
1250
1254
1252
1250
1250

FIG. 16

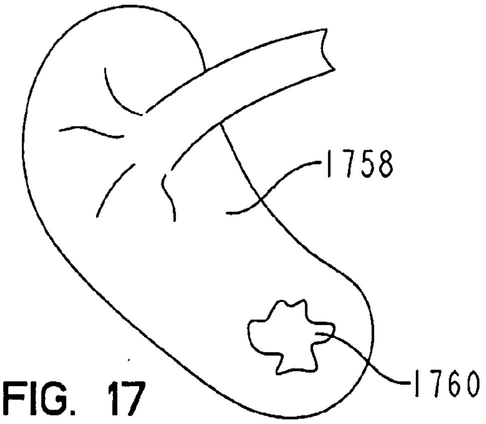


FIG. 17

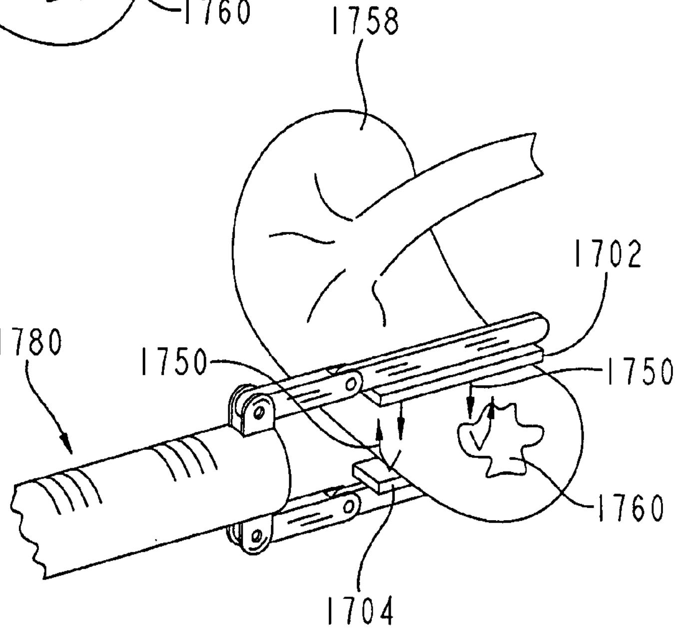


FIG. 18

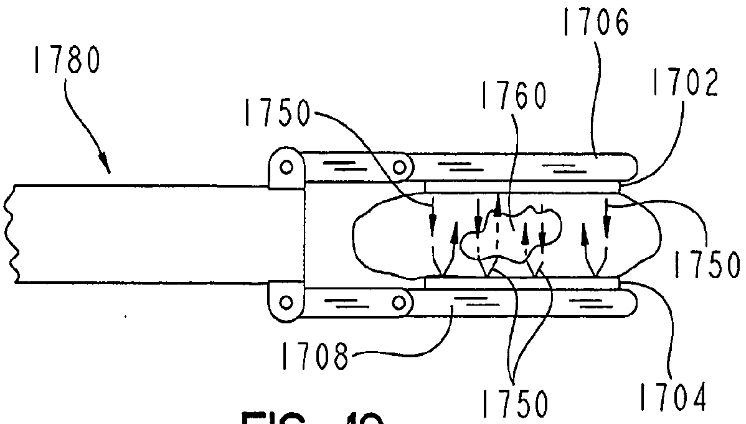


FIG. 19

HIGH INTENSITY ULTRASOUND APPARATUS METHODS AND SYSTEMS

CROSS REFERENCES

[0001] This application claims the benefit of U.S. Provisional Patent Application Ser. No. 60/707,914, entitled "High Intensity Reflected Ultrasound System," filed on Aug. 12, 2005, and the same is expressly incorporated herein by reference.

BACKGROUND

[0002] The present invention relates to surgical apparatus, systems and methods including or utilizing a surgical clamp having an ultrasound source.

[0003] Ultrasound techniques have contributed greatly to the advancement of medical treatment and diagnosis. Ultrasound has been useful in diagnosing and treating various disorders, illnesses, conditions and diseases. Presently there is a need to deliver diagnostic and therapeutic ultrasound in surgical applications in connection with or in lieu of other care. Various embodiments of the present invention address this and other needs.

SUMMARY

[0004] In general, embodiments of the present invention provide devices, systems and methods relating to high intensity ultrasound surgical clamps. One embodiment of the present invention provides a surgical clamp including a first arm and a second arm, a source of high intensity unfocused ultrasound coupled to the first arm, and an ultrasound reflector coupled to the second arm. In this embodiment at least one of the first arm and the second arm is moveable to position the reflector to reflect non-focused high intensity ultrasound emitted by the source and to clamp an organ or tissue intermediated the source and the reflector.

[0005] Another embodiment of the present invention provides a system including a surgical clamp having a multi-mode ultrasound transducer and a controller operatively coupled to the transducer to power the transducer. In this embodiment the controller is operable in a first mode to power the transducer to emit therapeutic ultrasound and is further operable in a second mode to power the transducer to emit diagnostic ultrasound, including feedback, imaging, and/or non-imaging ultrasound.

[0006] A further embodiment of the present invention provides a method including providing a medical instrument including a clamp and an ultrasound transducer coupled to the clamp, clamping tissue with the clamp, subjecting clamped tissue to high intensity ultrasound emitted by the transducer, determining a characteristic of the clamped tissue using ultrasound emitted by the transducer.

[0007] Additional aspects and advantages of the present invention will be apparent from the following description.

BRIEF DESCRIPTION OF THE DRAWING

[0008] FIG. **1** is a simplified block diagram of a surgical system according to one embodiment of the present invention;

[0009] FIG. **2** is a perspective view of a controller/monitor according to one embodiment of the present invention;

[0010] FIG. **3** is a perspective view of surgical device according to one embodiment of the present invention;

[0011] FIG. **4** is a sectional view of a portion of a surgical device according to one embodiment of the present invention;

[0012] FIG. **5** is a perspective view of an articulating arm and a surgical device according to one embodiment of the present invention;

[0013] FIG. **6** is a side view of a portion of a surgical device according to one embodiment of the present invention;

[0014] FIG. **7** is a side view of a portion of a surgical device according to one embodiment of the present invention;

[0015] FIG. **8** is an internal view of a portion of a surgical device according to one embodiment of the present invention;

[0016] FIG. **9** is a sectional view of a portion of a surgical device according to one embodiment of the present invention;

[0017] FIG. **10** is an internal view of a portion of a surgical device according to one embodiment of the present invention;

[0018] FIG. **11** is an internal view of a portion of a surgical device according to one embodiment of the present invention;

[0019] FIG. **12** is a perspective view of an organ;

[0020] FIG. **13** is a perspective view of a surgical device according to one embodiment of the present invention and an organ;

[0021] FIG. **14** is a sectional view of a surgical device according to one embodiment of the present invention and an organ;

[0022] FIG. **15** is a perspective view of a surgical device according to one embodiment of the present invention and an organ;

[0023] FIG. **16** is a sectional view of a surgical device according to one embodiment of the present invention and an organ;

[0024] FIG. **17** is a perspective view of an organ;

[0025] FIG. **18** is a perspective view of a surgical device according to one embodiment of the present invention and an organ; and

[0026] FIG. **19** is a side view of a surgical device according to one embodiment of the present invention and an organ.

DETAILED DESCRIPTION

[0027] For the purposes of promoting an understanding of the principles of the invention, reference will now be made to the embodiments illustrated in the drawings and specific language will be used to describe the same. It will nevertheless be understood that no limitation of the scope of the invention is thereby intended, such alterations and further modifications in the illustrated device, and such further applications of the principles of the invention as illustrated therein being contemplated as would normally occur to one skilled in the art to which the invention relates.

[0028] With reference to FIG. 1 there is shown a block diagram of a system **100** according to one embodiment of the present invention. System **100** includes controller/monitor **130** which is electrically coupled to and powered by power supply **120** via power coupling **121**. The controller/monitor **130** supplies power to a clamp handle **140** via power coupling **131**, which supplies power to a clamp **150** via power coupling **141**, which supplies power to ultrasound transducer or transceiver **170** via power coupling **171**. Power couplings **121**, **131**, **141**, and **171** may include, for example, one or more insulated electrically conductive wires or power cords and may also include one or more junctions, connectors, splitters, transformers, rectifiers, fuses, and/or switches for distributing and controlling the distribution of power to various elements of system **100** and allowing releasable interconnection of the various elements of system **100**.

[0029] System **100** also allows the transmission of information, such as electrical signals between various components of system **100**. Information coupling **132** couples controller/monitor **130** and handle **140**, information coupling **142** couples handle **140** and clamp **150**, and information coupling **172** couples clamp **150** and transducer or transceiver **170**. Information couplings **132**, **142** and **172** may include, for example, one or more electrically conductive transmission wires, printed circuit boards including electrically conductive pathways and/or electrical connectors and could also include fiber optics, transmitters and receivers or other couplings for transmitting information. Information couplings **132**, **142** and **172** allow transmission of information to, from and between various components of system **100**. In one embodiment, it is contemplated that information couplings **132**, **142** and **172** constitute a single transmission route that couples information between controller/monitor **130** and transducer or transceiver **170**.

[0030] System **100** further includes mechanical interconnections or couplings. Handle **140** and clamp **150** may be mechanically coupled and decoupled at mechanical coupling **143**. Similarly, information coupling **142** and power coupling **141** may be selectably coupled and decoupled to permit clamp **150** and handle **140** to be joined and separated as desired. Clamp **150** may be mechanically coupled to transceiver or transducer **170** at coupling **173**, to reflector **180** at coupling **183** and coupled and decoupled to articulating arm **160** at mechanical coupling **163**. It is contemplated that couplings **143**, **163**, **173**, and **183** could include any couplings or interconnections including those described below in further detail. Additional exemplary attributes of the components of system **100** are also described below.

[0031] With reference to FIG. 2 there is shown a monitor/controller **230** according to one embodiment of the present invention. Monitor/controller **230** is illustrated as a portable unit housed in cabinet **236** and including a handle **232** connected to cabinet **236** at hinge **234**. It is also contemplated that monitor/controller **230** could be a dedicated unit or could be housed on a cart to allow positioning or transportation. Cabinet **236** and handle **232** are made of water resistant, non-reactive materials that permit easy cleaning such as stainless steel, hospital grade plastics or other such materials.

[0032] Monitor/controller **230** is connected to and powered by a power source, such as an electrical outlet, via a detachable hospital grade power cord **238**. Monitor/controller **230** outputs electrical power suitable for driving an ultrasound transducer or transceiver via power output cord **240** and includes an emergency stop switch **256** for interrupting power output. Cord **240** may also include a separate information pathway such as one or more wires for transmitting and/or receiving information. An information pathway may also be provided through a separate cord, wire, or wire bundle or by various other information couplings, such as those previously described.

[0033] Monitor/controller **230** includes on and off switches **244** and **246**, which may optionally be a single switch, digital display **248**, monitor **250**, controls **252** and **254** and may include additional controls such as an alphanumeric keypad or a computer interface for receiving control or diagnostic input from a computer and sending information to a computer or computing device. Display **248** permits the display of digital alpha-numeric information. For example, display **248** can be used to display temperature of a remotely located ultrasound transducer, thermistor, or transceiver that is calculated by a microprocessor of monitor/controller **230** based upon an electrical signal received from a sensor located at or near the remote transducer or transceiver. Display **248** may be a LED display that is electrically coupled to and driven by a microprocessor or other driver circuitry.

[0034] Monitor **250** may be a CRT monitor, LCD display, plasma display or other display suitable for depicting graphical information. In one example, display **250** displays a graph that depicts the rate of blood flow through an organ or tissue as a function of time. The display is generated based upon information received from a remote ultrasound transducer employing a Doppler ultrasound technique. The rate of blood flow of a tissue or organ can be determined using a microprocessor or other circuitry based on information received from the pickup or receiver of an ultrasound transducer or transceiver and transmitted to monitor/controller **230** via one or more information couplings. In another example, display **250** displays graphical information of the degree of ablation or cauterization of a tissue or organ based upon information received from an ultrasound transducer using an elastography ultrasound technique. The degree of ablation or cauterization can be determined using microprocessor techniques based upon information received from the pickup or receiver of an ultrasound transceiver corresponding to the elasticity of the tissue or organ and transmitted to monitor/controller **230** via one or more information couplings. In still another example monitor **250** can display information indicating the mode of operation the monitor/controller **230**, for example whether monitor/controller **230** is outputting power and/or control signals appropriate for a remote ultrasound transducer to operate in a Doppler ultrasound mode, an elastography ultrasound mode or a high intensity ultrasound mode. Alternatively, this information can be displayed on display **248**.

[0035] Controls **252** and **254** and/or similar controls can be used to change the information displayed on monitor **250** and to adjust the operation of monitor/controller **230**, for example to cause monitor/controller **230** to output power and/or control signals appropriate for a remote ultrasound transducer to operate in a Doppler ultrasound mode, in an elastography ultrasound mode or a high intensity ultrasound mode. These or similar controls could also be used to dynamically adjust power levels of high intensity ultrasound in a therapeutic mode of operation.

[0036] With reference to FIG. 3 there is shown surgical instrumentation **300** according to one embodiment of the present invention. Instrumentation **300** includes handle **340** and clamp **380**. Handle **340** includes tubular housing **342** which is formed of stainless steel or other material which can be readily sterilized as may be required for a surgical environment. Handle **340** further includes hand grips **344** and **346** which are formed of surgical grade plastic or other material which can be readily sterilized as may be required for a surgical environment. Other materials suitable for a surgical environment can also be used to construct handle **340** and the other components of instrumentation **300**.

[0037] Handle **340** is connected to a controller/monitor, for example monitor/controller **230** illustrated in FIG. **2**, via cord **373** which provides for transmission of power suitable to drive an ultrasound transducer to instrumentation **300**. Cord **373** may also provide for transmission of information to or from instrumentation **300** to a remotely located controller/monitor via one or more transmission wires or other information couplings. Alternatively, information couplings may be independent from cord **373**, such as through a separate cord.

[0038] Handle **340** includes operator control buttons **372** and **371** which are operable by the user to control the operation of an ultrasound transducer. In one embodiment button **372** is a safety that must be released to permit operation of the transducer and button **371** is a trigger that operates the transducer when the safety is released. Handle **340** also includes grip locking mechanism **354** and finger handle **356** which can control the actuation of clamp **380**.

[0039] Clamp **380** includes clamp arms **306** and **308** which may be actuated as described below. Ultrasound transducer **302** is coupled to and moves with clamp arm **306**. Ultrasound transducer **302** may be a flat ultrasound transducer and may be ultrasonically insulated on the surface that is attached to clamp arm **306**, for example, with an air pocket or other ultrasonic insulator, and when energized emits ultrasound on its opposite face. Ultrasound transducer **302** may also be an array of two or more ultrasound transducers, such as an array of hinged ultrasound transducers arranged, for example, in a line or other configuration. Ultrasound transducer **302** is configured to transmit and receive a variety of types of ultrasound. For example, transducer **302** may transmit and receive ultrasound appropriate for Doppler ultrasound techniques, elastography ultrasound techniques, and high intensity ultrasound techniques. Transducer **302** may be configured to perform particular high intensity ultrasound techniques such as high intensity focused ultrasound or high intensity unfocused ultrasound. In combination with ultrasound reflector **304**, transducer **302** may provide high intensity reflected ultrasound. Ultrasound transducer **302** may have the capacity of operating to emit one or more of the foregoing types of ultrasound, and in the case of Doppler and elastography ultrasound to receive signals through one or more pickups, receivers or detectors.

[0040] Ultrasound transducer **302** may be encapsulated in a leak proof membrane which is transparent to ultrasound to permit transmission of ultrasound to a treatment site. Transducer **302** may also include an ultrasound coupling element, such as degassed water which is contained within the leak proof membrane and facilitates the propagation of ultrasound. The degassed water also cools the transducer and may be circulated using a pump to increase cooling efficacy. Transducer **302** may also directly contact an organ or tissue to create a water-based tissue interface or sterilized ultrasound gel may be placed on the transducer surface to create an ultrasonic interface.

[0041] The ultrasound transducer **302** is connected to a power supply via wires which are routed internally through clamp **380** and handle **340** or through other power couplings to a controller/monitor, such as monitor/controller **230** illustrated in FIG. **2**. In this manner electrical signals can be applied to one or more piezoelectric elements of transducer **302** to cause it to emit ultrasound. Ultrasound transducer **302** can be driven in a variety of manners, depending on the nature of the desired ultrasound emission. In one mode of operation, the transducer is powered by electrical signals in the range of about 1 MHz to 30 MHz to transmit high intensity ultrasound having the capacity to cauterize tissue. In another mode of operation the, transducer is powered by electrical pulse signals appropriate to produce diagnostic ultrasound where a receiver portion of the transducer receives reflected ultrasound energy which it converts to an electrical signal that is sent via information transmission wires routed internal to clamp **380** and handle **340** or through other information couplings to a controller/monitor.

[0042] Various types of diagnostic ultrasound operation are contemplated, including feedback, imaging, and/or non-imaging ultrasound. For example, Doppler ultrasound can be used to determine a rate of blood flow in a tissue and elastography ultrasound can be used to determine the elastic properties of a tissue. A temperature thermistor or other temperature sensor can also be attached to, near or within ultrasound transducer **302**. Additionally, a pressure sensor can be attached to, near or within ultrasound transducer **302**. Information from transducer **302** and any associated temperature or pressure sensor can be transmitted through one or more wires or other information transmission pathways routed internally through clamp **380** and coupled to wires or other information transmission pathways of handle **340** which are in turn coupled to a controller/monitor. Thus, in conjunction with a controller/monitor ultrasound transducer **302** may have the capacity for cauterizing tissue, determining a rate of blood flow in tissue, determining tissue elasticity, determining temperature associated with transducer **302** and/or determining pressure associated with transducer **302**.

[0043] Ultrasound reflector **304** is coupled to clamp arm **308**. Reflector **304** is polished stainless steel that reflects high intensity ultrasound energy emitted by transducer **302** when operating a high intensity ultrasound mode to cauterize tissue. Reflector **304** could also be any other material which absorbs or reflects ultrasound. During operation of transducer, reflector **304** can define a boundary beyond which ultrasound emitted by transducer **302** does not pass.

[0044] As illustrated in FIG. **3**, clamp **380** includes clamp connector **352** and handle **340** includes handle connector **348**. Handle connector **348** can receive and retain clamp connector **352** to form a mechanical interconnection between handle **340** and clamp **380** permitting the transfer of mechanical force, and can also release handle connector **352**. Additionally, connector **352** and **348** can establish electrical interconnections between handle **340** and clamp **380** through one or more pairs of electrical contacts and associated internally routed wires. An electrical interconnection can also be provided through separate internally routed wires. The electrical interconnections between clamp **380** and handle **340** can be used to drive transducer **302** and send and receive information.

[0045] Clamp **380** and handle **340** are configured to be interconnected by the end of handle **340** being inserted into the end of clamp **380**, and locking mechanism **352** releasably engaging with receptacle **353**. This interconnection is illustrated in FIGS. **5** and **11**. It is also contemplated that a variety of other interconnections could be established between clamp **380** and handle **340**, for example, a twist lock mechanism could be provided at the end of handle **380** to rotatably engage one or more studs on clamp **340**, a threaded collar of handle **340** could attach to threads on the exterior of clamp **340**, and still other interconnections could be used. Regardless of the type of interconnection used, it is contemplated that clamp **380** could be a disposable or single use device, while handle **340** could be reusable. Alternatively, clamp **380** could be a multiple use device that could also be sterilized and reused. It is also contemplated that handle **340** and clamp **380** could be a single piece instrument.

[0046] With reference to FIG. **4** there is shown a more detailed illustration of grip locking mechanism **354**. Grip locking mechanism **354** includes serrated surfaces **359** and **360** and maximum stop points **358**. Grip locking mechanism provides controlled indexed movement of hand grips **344** and **346** relative to one another. When such force is applied to finger handle **356** in the direction toward hand grip **344** the serrations of serrated surfaces **359** and **360** incrementally engage and release to accommodate movement in this direction. When such force is no longer applied, serrated surfaces **359** and **360** engage to maintain the current position. Movement in the opposite direction is similarly accommodated.

[0047] With reference to FIG. **5** there is shown an articulated instrument holder **560** which includes a number of articulating joints **570** and arm sections **571**. Instrument holder **560** includes a base **564** that is secured to surgical table **566** with knob **568** which can be tightened and loosened to permit installation, removal and positioning of instrument holder **560**. Base **564** may also include an adaptor (not shown) for attaching to other articulated arms as may be required in adjunctive therapy situations.

[0048] Instrument holder **560** further includes a coupler **572** which couples holder **560** to instrumentation **300**. As illustrated coupler **572** is a clamp that attaches to handle **340** of instrumentation **300**. It is contemplated, however, that a variety of couplings could be employed. Joints **570** are multiaxial and may be adjusted to articulate at any angle to maintain instrumentation **100** in a desired position.

[0049] With reference to FIG. **6** there is shown a portion of a surgical clamp **600** according to one embodiment of the present invention. As illustrated in FIG. **6**, clamp **600** includes clamp arms **606** and **608**, clamp body **680**, and clamp linkages **620**, **624**, **628** and **632** which interconnect clamp arms **606** and **608** and clamp body **680**. Clamp **600** further includes ultrasound transducer **602** and ultrasound reflector **604** which may be the same or similar to the ultrasound transducers and reflectors described herein. Clamp linkages **620** and **624** are rotatably connected to clamp arm **606** and clamp body **680** with axles or shafts **621**, **622**, **625**, and **626**. Clamp linkages **628** and **632** are rotatably connected to clamp arm **608** and clamp body **680** with axles or shafts **629**, **630**, **633**, and **634**.

[0050] The interconnection of clamp arms **606** and **608** and clamp body **680** permits clamp arms **606** and **608** to move generally in the direction indicated by arrow O in order to move clamp arms **606** and **608** apart and also to move in the opposite direction in order to move clamp arms **606** and **608** together. Linkages **620** and **624** form a parallelogram linkage between clamp arm **606** and clamp body **680** which maintains the angular relationship between clamp arm **606** and clamp body **680** during movement of clamp arm **606**. Similarly, linkages **628** and **632** form a parallelogram linkage between clamp arm **608** and clamp body **680** which maintains the angular relationship between clamp arm **608** and clamp body **680** during movement of clamp arm **608**. The angular relationship between clamp arm **606** and clamp arm **608** is also maintained during movement of the clamp arms **606** and **608**.

[0051] With additional reference to FIG. **7** there is shown surgical clamp **600** as was just described in connection with FIG. **6**. In FIG. **6** clamp **600** was illustrated in a configuration in which clamp arms **606** and **608** were in a relatively closed or low profile configuration. In FIG. **7** clamp **600** is illustrated in a different configuration in which arms **606** and **608** have been moved apart in the direction of arrow O illustrated in FIG. **6** to a relatively more open configuration. Clamp arms **606** and **608** can also be moved to positions intermediate those illustrated in FIG. **6** and FIG. **7**, to even more open positions, and to even more closed positions.

[0052] It is contemplated that surgical clamp **600** could vary in a number of manners to facilitate greater or lesser ranges of movement of clamp arms **606** and **608**. For example, the position of axles **622** and **626** could be offset with axle **622** being located farther to the left, and the position of axles **621** and **625** could be offset with axle **625** being located farther to the right to permit greater range of motion of clamp arm **606** and a similar offset could be provided between axles **630** and **634**, and axles **629** and **633** to permit greater range of motion of clamp arm **608**. The length of linkages **620**, **624**, **628**, and **632** could be increased to provide greater range of motion or decreased to provide lesser range of motion. The thickness of linkages **620**, **624**, **628**, and **632** could be increased to reduce range of motion or decreased to increase range of motion. The closeness or shape of linkages could also vary to increase or decrease range of motion. For example the linkages could be curved, bent, compound, jointed, tapered, or otherwise modified to accommodate or facilitate the particular range of motion desired. Furthermore, one or more stops or other structures could physically limit range of movement.

[0053] With reference to FIG. **8** there is shown a portion of a surgical clamp **600** as was just described in connection with FIGS. **6** and **7**. In FIG. **8** a portion of the interior of clamp body **680** is illustrated including drive wheel **640**, drive axle **622**, free wheel **646**, free axle **626** and drive belt **650**. As described above, surgical clamp **600** can be operated so that clamp arms **606** and **608**, illustrated in FIGS. **6** and **7**, can be moved. This movement may be controlled by a surgeon who manipulates controls on a clamp handle such as those described below in connection with FIG. **9**. Movement of the controls causes a corresponding movement of drive belt **650** which, in turn, causes drive wheel **640** to rotate in either a clockwise or counter clockwise direction. Rotation of drive wheel **640** causes rotation of drive axle **622** in the same direction. Drive axle **622** extends through clamp body **680** and is coupled to linkage **620** which was illustrated and described above in connection with FIGS. **6** and **7**. Through this connection, rotation of axle **622** causes movement of linkage **620** which, in turn causes movement of clamp arm **606** as was described above in connection with FIGS. **6** and **7**. Free wheel **646** is connected to and can rotate with and free axle **626** which extends through clamp body **680** and is coupled to linkage **624** which was illustrated and described above in connection with FIGS. **6** and **7**. Free wheel **626**, free axle **646** and linkage **624** rotate together in passive response to the movement of clamp arm **606** as was described above. Additionally, a similar drive belt, drive wheel, drive axle, free wheel, and free axle are interconnected with linkages **628** and **632** to provide for the controlled movement of clamp arm **608**.

[0054] A number of variations and modifications to the features described and illustrated above in connection with FIG. **8** are contemplated. For example, free wheel **646** and free axle **626** could be driven by a second drive belt that was actuated along with drive belt **650** or wheels **640** and **646** could be interconnected with an interconnection belt so that rotation of wheel **640** would cause rotation of wheel **646**. A similar interconnection belt could be used to interconnect and drive one or more wheels associated with linkages **628** and **632**. It is contemplated that the drive belts and interconnection belts could be flat belts, or could have a geared inner surface and that wheels of surgical clamp **600** could also have gear teeth around their circumference to engage the geared surface of the belts. It is further contemplated that the belts of surgical clamp **600** could be chains.

[0055] With reference to FIG. **9** there is shown an internal view of a portion of a clamp handle **642**. Handle **642** includes adjuster **670** which is connected to drive belt **650**. Adjuster **670** can be moved in the directions indicated by arrows A and B to cause a corresponding movement of drive belt **650**. As was described above in connection with FIGS. **7** and **8**, the movement of drive belt **650** is used to control the movement of clamp arms **606** and **608**. Adjuster **670** therefore provides user control of the movement of clamp arms **606** and **608**. As was previously described in connection with FIGS. **3** and **4** adjuster **670** may slide in the direction of arrows A and B and may include a grip locking mechanism. It is also contemplated that adjuster **670** could pivot at a point **672** shown in FIG. **9** to accomplish movement of belt **650**.

[0056] With reference to FIG. **10** there is shown an internal view of a portion of a clamp handle **642** of an alternate embodiment of surgical clamp **600**. In FIG. **10** a portion of the interior of clamp body **680** is illustrated including spool **650**, axle **622**, wire **690**, spool **656**, axle **626** and wire **691**. As described above, surgical clamp **600** can be operated so that clamp arms **606** and **608**, illustrated in FIGS. **6** and **7**, can be moved. This movement may be controlled by a surgeon who manipulates controls on a clamp handle similar to those described above in connection with FIG. **9**. Movement of the controls causes wires **690** and **691** to move in opposite directions which, due to wires **690** and **691** being wound around their respective spools in opposite directions, causes spools **650** and **656** to rotate in the same direction. As wire **690** moves in a direction away from spool **650** it unwinds from spool **650** and as it moves in a direction toward spool **650** it winds around spool **650**. Similarly, as wire **691** moves in a direction away from spool **651** it unwinds from spool **651** and as it moves in a direction toward spool **651** it winds around spool **651**. Rotation of spools **650** and **656** causes rotation of axles **622** and **626** in the same direction. As was described above axle **622** and **626** extend through clamp body **680** and are coupled to linkages **620** and **624** which were illustrated and described above in connection with FIGS. **6** and **7**. The rotation of axles **622** and **626** causes opening and closing of the clamp arms of clamp **600** as was described above in connection with FIGS. **6**, **7** and **8**.

[0057] With reference to FIG. **11** there is shown a cross section of a portion of surgical device **6001** according to the present invention. Surgical device **6001** includes clamp handle **1640** and clamp **1680** which are only partially illustrated. Clamp handle **1640** and clamp **1680** are separable pieces that fit together and are held in position by interlock **1651**. Clamp handle **1640** includes control rod **696** which is connected to and moved by user controls such as finger handle **356** and hand grip **346** described above in connection with FIG. **3**. Control rod **696** releasably interconnects with control rod **695** of clamp **1680** and is effective to transfer motion between the two control rods. Thus when control rod **696** is moved in the direction of arrow C control rod **695** is also moved in the direction of arrow C.

[0058] Control rod **695** is coupled to control lever **692** which rotates about central axle **693** which is connected to clamp **1680**. Wires **690** and **691** are connected to lever **692** on opposite sides of axle **693**. Wire **690** continues to a spool such as spool **650** which was illustrated and described above in connection with FIG. **10**. Wire **691** continues on to a spool such as spool **656** which was also which was also illustrated and described above in connection with FIG. **10**. This interconnection further translates movement of control rod **696** to wires **690** and **691**. For example, when control rod **696** moves in the direction or arrow C control rod **695** also moves in that direction. Consequently, the lever **692** rotates around axle **693** in a clockwise fashion. This, in turn causes wire **690** to move in the direction of arrow D and wire **691** to move in the direction of arrow C. This causes spools **650** and **656** to rotate in a clockwise direction and, in turn, the closing movement of clamp arm **606** is accomplished as was previously described in connection with FIGS. **6-8**. Similarly, when control rod **696** moves in the direction of arrow D the opposite movement is achieved and clamp arm **606** can open. A similar lever and axle are provided for wires **790** and **791** which are connected to similar spools to control movement of clamp arm **608**. It is also contemplated that wires **690** and **691** could be substituted for a belt or chain and interconnected with one or more drive wheels as was described in connection with FIG. **8** above. Furthermore, it is contemplated that control rods **696** and **695** could provide electrical interconnection and was described in connection with FIG. **3**.

[0059] With reference to FIG. **12** there is shown a portion of an organ **1254** which includes vasculature **1252** having bloodflow therethrough indicated by arrow **1256**. Organ **1254** is illustrated generically, but could be any organ or tissue, for example, a kidney, gall bladder pancreas, spleen, uterus, stomach, intestine, blood vessel, liver, appendix or other organs of the cardiovascular system, digestive system, endocrine system, immune system, lymphatic system, muscular system, nervous, reproductive system, respiratory system, skeletal system, urinary system, or organs or tissues of other body systems.

[0060] With reference to FIG. **13** there is shown a portion of surgical clamp **1380** which has been introduced to a surgical site and positioned around organ **1254** which was previously described. Clamp **1380** is positioned so that clamp arms **1304** and **1306** are on either side of a portion of organ **1254**. As was previously described, an ultrasound transducer **1302** is coupled to clamp arm **1306** and an ultrasound reflector **1304** is coupled to clamp arm **1308**. Thus, ultrasound transducer **1302** and ultrasound reflector **1304** are positioned to be on either side of the portion of organ **1254**. In this position clamp arms **1306** and **1308** can be moved as was previously described to a relatively closed position so as to exert force on organ **1254** in the locations and directions generally indicated by arrows **1350**. Thus, the clamp **1380** can exert force on organ **1254** in the location of ultrasound transducer **1302** and ultrasound reflector **1304** and can cause ultrasound transducer **1302** and ultrasound reflector **1304** to contact organ **1254**. Using this positioning capability a variety of diagnostic and therapeutic processes can be performed. Furthermore, stabilization, positioning, compression, and manipulation of organ **1254** can be accomplished. Additionally, the clamping capability can reduce or eliminate the need for additional vascular clamping during a procedure, for example arterial and/or venous clamping upstream from an organ or tissue targeted for therapy.

[0061] With reference to FIG. **14** there is shown a partial sectional view of ultrasound transducer **1302** organ **1254** and ultrasound reflector **1304**. As illustrated in FIG. **14** ultrasound reflector **1302** and ultrasound reflector **1304** have been positioned to contact organ **1254**. In this position ultrasound transducer can operate in a Doppler ultrasound mode to detect blood flow in organ **1254**. In Doppler ultrasound mode ultrasound transducer **1302** emits ultrasound which is reflected by red blood cells in vasculature **1252** of organ **1254** and received by transducer **1302**. This reflection of Doppler ultrasound is illustrated generally by arrows **1250**.

[0062] Doppler ultrasound techniques such as the technique illustrated in FIG. **14** can be used to determine whether there is blood flow occurring between transducer **1302** and ultrasound reflector **1304** and the rate of that bloodflow. This determination can be used as the basis for determining whether increased mechanical compression of the clamp is needed to stop or significantly reduce the blood flow prior to the administration of a primary therapy such as administration of high intensity ultrasound, high intensity reflected ultrasound, high intensity unfocused ultrasound or high intensity focused ultrasound via transducer **1302**, or administration of an independent primary therapy such as conventional surgical intervention, laser surgical intervention or other surgical intervention to remove part of organ **1254**. Doppler ultrasound techniques can also be used during or after administration of such ultrasound therapy techniques to verify the degree of tissue cauterization and to determine whether additional therapy was indicated, for example, a reading of no blood flow would indicate sufficient sealing off of all significant arterial, venous and capillary blood flow after the pressure of a surgical clamp is released. Graphical or numeric output indicating the rate of blood flow can be shown on digital display **248** or monitor **250** of monitor/controller **230** as described above in connection with FIG. **2**. Location and volume of blood flow can also be similarly shown or depicted.

[0063] With reference to FIG. **15** there is shown a portion of surgical clamp **1380** which has been introduced to a surgical site, positioned around organ **1254**, and adjusted to clamp organ **1254**. The clamping is accomplished by clap arms **1304** and **1306** on either side of a portion of organ **1254** being moved to a relatively closed position so as to exert force on organ **1254** as was previously described. In the FIG. **15** the clamping force exerted on organ **1254** is sufficient to substantially interrupt or stop blood flow in vasculature **1252** beyond the clamped portion as is indicated by the dashed portions of vasculature **1252**. Using this clamping capability a variety of diagnostic and therapeutic processes can be performed.

[0064] With reference to FIG. **16** there is shown an example of therapy and/or diagnostic techniques performed on organ **1254** with vasculature **1252** in due to clamping of organ **1254**. As represented generally by arrows **1250**, a therapeutic or diagnostic ultrasound can be delivered in this configuration. For example, therapeutic ultrasound in the form of high intensity ultrasound, high intensity reflected ultrasound, high intensity unfocused ultrasound or high intensity focused ultrasound via an ultrasound transducer and/or reflector which are illustrated in cross section above and below organ **1254**, and could have characteristics the same as or similar to ultrasound transducers and reflectors that were previously described. Diagnostic Doppler ultrasound may also be administered in this configuration to confirm the interruption of blood flow. It is also contemplated that elastography techniques could be administered in connection with the configuration illustrated in FIG. **16**.

[0065] Elastography ultrasound techniques can be used to determine the stiffness or compressibility of tissue of organ **1252** which will vary, for example, before and after organ **1252** is subjected to high intensity ultrasound. Elastography techniques involve a comparison of the response of tissue subjected to ultrasound before and after a slight compression, for example, on the order of about 1%-2% compression, or a different percent compression depending upon the tissue involved. Comparison of ultrasound data or images of a tissue subjected to ultrasound from before compression and after compression can be used to determine the degree of compression that the tissue experiences when subjected to a given force. The data collected before and after compression are compared to determine the amount of displacement each small portion of tissue undergoes in response to the compression applied by an ultrasound transducer as illustrated in FIG. **16**. The compression can be on the order of about 0.1 to 1 mm, or can vary according to the particular tissue being examined. Furthermore, the compressive force can be determined with a pressure transducer coupled or located adjacent to the ultrasound transducer, or can be determined for a particular clamp and correlated to the indexed control provided by grip locking mechanism **354** described above in connection with FIG. **4**. The rate of change of displacement of the tissue as a function of distance from the transducer causing the compression can be used to display a strain image or elastogram or can be presented numerically on monitor **250** or digital display **248** of monitor/controller **230** as described above in connection with FIG. **2**.

[0066] Elastography techniques can be employed to provide a variety of diagnostic information. For example, tissue stiffness or compressibility will vary according to the degree of tissue cauterization by high intensity ultrasound. Cauterized tissue that has lost its cellular structure has a very different compression ratio from that of normal healthy or viable tissue. Thus elastography techniques can be used to determine the degree of cauterization of a tissue subjected to high intensity ultrasound and to determine whether further application of such therapy is indicated. Similarly, cancerous tissue has a different elasticity coefficient than benign tumor tissue or healthy tissue. Thus, diagnostic elastography ultrasound techniques can be used to locate a tumor or lesion within a tissue or organ for proper positioning of an ultrasound transducer for application of high intensity ultrasound, interruption of blood flow or other therapy.

[0067] With reference to FIG. **17**, there is shown an organ **1758** with a tumor **1760**. Organ **1758** is illustrated as a kidney, but could be any organ or tissue including those described above. Tumor **1760** is illustrated generically and could be any type of tumor, lesion or injury.

[0068] With reference to FIGS. **18** and **19** there is shown a portion of a surgical clamp **1780** including ultrasound transducer **1702** and an ultrasound reflector **1704**. As illustrated in FIG. **18**, clamp **1780** can be positioned around and can clamp a portion of organ **1758** as was previously described. In this position ultrasound can be administered to organ **1758** as generally illustrated by arrows **1750**. As illustrated, arrows **1750** are high intensity unfocused ultrasound that is emitted form ultrasound transducer **1702** and reflected by ultrasound reflector **1704** to cauterize a region of tissue in organ **1758**. It is also contemplated that a variety of other diagnostic and therapeutic ultrasound techniques can be performed on organ **1758** including those described above. With specific reference to FIG. **19** there is shown a side view of the arrangement of FIG. **18**. As illustrated in FIG. **19**, high intensity ultrasound can be administered to cauterize a plane of tissue defined by the area between transducer **1702** and reflector **1704**.

[0069] There are a variety of diagnostic and surgical methods according to the present invention. It is contemplated that ultrasonic surgical clamps according to the present invention may be used to deliver adjunctive and primary therapies to a variety of organs or tissues. For example, ultrasonic surgical clamps according to the present invention can be used to grasp, immobilize stabilize, evaluate and cauterize portions of the kidney, liver, blood vessels, and other organs. Such clamps are also contemplated as being useful in performing appendectomies, hysterectomies and removal of other organs and tissues or portions thereof.

[0070] In one method according to the present invention an ultrasonic surgical clamp is introduced into a patient via a conventional surgical opening or an endoscopic surgical opening. The clamp is positioned around a tissue or organ and clamps the tissue or organ. The ultrasound transducer is operated in a Doppler diagnostic mode to determine a rate of blood flow in the organ or tissue. Information of the rate of blood flow is displayed on a screen and, if desired the clamp is tightened. These steps are repeated until the rate of blood flow is reduced to a desired level or substantially stopped. Once the desired clamping effect is achieved additional therapy can be administered to the tissue or organ. For example, an ultrasound transducer of the ultrasonic surgical clamp can emit high intensity unfocused ultrasound which is reflected by the reflector of the clamp effective to cauterize tissue intermediate the transducer and the reflector.

[0071] In another method according to the present invention an ultrasonic surgical clamp is introduced into a patient via a conventional surgical opening or an endoscopic surgical opening, the clamp is positioned to clamp an organ or tissue, the ultrasound transducer of the clamp is operated to emit high intensity unfocused ultrasound which is reflected by the reflector of the clamp and is effective to cauterize at least part of the tissue or organ intermediate the transducer and the reflector. The transducer is then operated in an elastography mode to measure the elastic properties of the tissue. Based on the result of the elastography the degree of cauterization of tissue can be determined.

[0072] While the invention has been illustrated and described in detail in the drawings and foregoing description, the same is to be considered as illustrative and not restrictive in character, it being understood that only the preferred embodiment has been shown and described and that all changes and modifications that come within the spirit of the invention are desired to be protected.

What is claimed is:

1. An apparatus comprising:

a surgical clamp including a first arm and a second arm;

a source of high intensity unfocused ultrasound, the source being coupled to the first arm; and

an ultrasound reflector coupled to the second arm;

wherein at least one of the first arm and the second arm is moveable to position the reflector to reflect non-focused high intensity ultrasound emitted by the source and to clamp an organ or tissue intermediate the source and the reflector.

2. The apparatus of claim 1 further comprising a first linkage connected to the first arm and a second linkage connected to the second arm wherein the first linkage and the second linkage maintain the emitter and the reflector in a substantially parallel relationship upon said movement of at least one of the first arm and the second arm.

3. The apparatus of claim 1 wherein the source comprises a flat ultrasound transducer or an array of hinged ultrasound transducers.

4. The apparatus of claim 1 further comprising;

a handle including operator controls, the handle releasably connectable to the clamp;

an electrical interconnection between the handle and the clamp effective to provide power to the source of high intensity unfocused ultrasound; and

a mechanical interconnection between the handle and the clamp operable to provide mechanical energy to the at least one of the first arm and the second arm which is moveable to clamp an organ or tissue.

5. The apparatus of claim 4 wherein the surgical clamp is a disposable or single use device.

6. The apparatus of claim 1 wherein both the first arm and the second arm are moveable.

7. A system comprising:

a surgical clamp including a multi-mode ultrasound transducer; and

a controller operatively coupled to the transducer to power the transducer;

wherein the controller is operable in a first mode to power the transducer to emit therapeutic ultrasound and is further operable in a second mode to power the transducer to emit diagnostic ultrasound.

8. The system of claim 7 wherein the first mode to power the transducer to emit therapeutic ultrasound powers the transducer to emit unfocused high intensity ultrasound.

9. The system of claim 7 wherein the second mode to power the transducer to emit diagnostic ultrasound powers the transducer to emit Doppler ultrasound.

10. The system of claim 7 wherein the second mode to power the transducer to emit diagnostic ultrasound powers the transducer to emit elastography ultrasound.

11. The system of claim 7 wherein the controller further includes a display device operable to display information based upon the diagnostic ultrasound.

12. The system of claim 7 wherein the controller is operable in a third mode to power the transducer to emit second diagnostic ultrasound.

13. A method comprising:

providing a medical instrument including a clamp and an ultrasound transducer coupled to the clamp;

clamping tissue with the clamp;

subjecting tissue clamped with the clamp to high intensity ultrasound emitted by the transducer; and

determining a characteristic of tissue clamped with the clamp using ultrasound emitted by the transducer.

14. The method of claim 13 wherein the ultrasound emitted by the transducer is high intensity unfocused ultrasound.

15. The method of claim 13 wherein the determining includes one of determining bloodflow using Doppler ultrasound emitted by the transducer and determining a mechanical characteristic of tissue using elastography ultrasound emitted by the transducer.

16. The method of claim 13 wherein the clamping is effective to interrupt bloodflow in the tissue.

17. The method of claim 13 wherein the determining occurs before the subjecting and the determining is effective to provide an indication of a bloodflow in the tissue.

18. The method of claim 13 wherein the subjecting occurs before the determining and the determining is effective to provide an indication of a degree of tissue cauterization.

19. The method of claim 13 further comprising second determining a second characteristic of the clamped tissue using ultrasound emitted by the transducer.

20. The method of claim 19 wherein the determining is effective to provide an indication of bloodflow and the second determining is effective to provide an indication of a degree of tissue cauterization.

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patsnap

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摘要(译)

提供了一种手术夹具，其包括第一臂和第二臂，高强度未聚焦超声源，耦合到第一臂的源，以及耦合到第二臂的超声反射器。第一臂和第二臂中的至少一个是可移动的，以定位反射器，以反射由源发射的非聚焦高强度超声，并夹住源和反射器中间的器官或组织。