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(54) **Title**: DISPOSABLE ACOUSTIC COUPLING MEDIUM CONTAINER

(57) **Abstract**: A medical imaging and therapy device is provided that may include any of a number of features. One feature of the device is that it can acoustically couple an ultrasound therapy transducer to a patient. In some embodiments, the medical imaging and therapy device is configured to conform to the anatomy of a patient's perineal area to acoustically couple an ultrasound therapy transducer to the patient for treatment of BPH. The medical imaging and therapy device can be used in therapeutic applications such as Histotripsy, Lithotripsy, and HIFU, for example. Methods associated with use of the medical imaging and therapy device are also covered.

DISPOSABLE ACOUSTIC COUPLING MEDIUM CONTAINER

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit under 35 U.S.C. 119 of U.S. Provisional Patent Application No. 61/234,559, filed August 17, 2009, titled "Disposable Acoustic Coupling Medium Container". This application is herein incorporated by reference in its entirety.

INCORPORATION BY REFERENCE

[0002] All publications, including patents and patent applications, mentioned in this specification are herein incorporated by reference in their entirety to the same extent as if each individual publication was specifically and individually indicated to be incorporated by reference.

FIELD OF THE INVENTION

[0003] The present invention generally relates to acoustically coupling ultrasound devices to a patient. More specifically, the present invention relates to acoustically coupling ultrasound therapy devices to a patient for treatment of tissue.

BACKGROUND OF THE INVENTION

[0004] Histotripsy and Lithotripsy are non-invasive tissue ablation modalities that focus pulsed ultrasound from outside the body to a target tissue inside the body. Histotripsy mechanically damages tissue through cavitation of microbubbles, and Lithotripsy is typically used to fragment urinary stones with acoustic shockwaves.

[0005] Histotripsy is the mechanical disruption via acoustic cavitation of a target tissue volume or tissue embedded inclusion as part of a surgical or other therapeutic procedure. Histotripsy works best when a whole set of acoustic and transducer scan parameters controlling the spatial extent of periodic cavitation events are within a rather narrow range. Small changes in any of the parameters can result in discontinuation of the ongoing process.

[0006] Histotripsy requires high peak intensity acoustic pulses which in turn require large surface area focused transducers. These transducers are often very similar to the transducers used for Lithotripsy and often operate in the same frequency range. The primary difference is in how the devices are driven electrically.

[0007] Histotripsy pulses consist of a (usually) small number of cycles of a sinusoidal driving voltage whereas Lithotripsy is (most usually) driven by a single high voltage pulse with the transducer responding at its natural frequencies. Even though the Lithotripsy pulse is only

one cycle, its negative pressure phase length is equal to or greater than the entire length of the Histotripsy pulse, lasting tens of microseconds. This negative pressure phase allows generation and continual growth of the bubbles, resulting in bubbles of sizes up to 1 mm. The Lithotripsy pulses use the mechanical stress produced by a shockwave and these 1 mm bubbles to cause tissue damage.

[0008] In comparison, each negative and positive cycle of a Histotripsy pulse grows and collapses the bubbles, and the next cycle repeats the same process. The maximal sizes of bubbles reach approximately tens to hundreds of microns. These micron size bubbles interact with a tissue surface to mechanically damage tissue.

[0009] In addition, Histotripsy delivers hundreds to thousands of pulses per second, i.e., 100-1kHz pulse repetition frequency. Lithotripsy only works well within a narrow range of pulse repetition frequency (usually 0.5-1Hz). Studies show that the efficacy and efficiency of lithotripsy decreases significantly when the pulse repetition frequency is increased to 10-100Hz. The reduced efficiency is likely due to the increased number of mm size bubbles blocking the shock waves and other energy from reaching the stone.

[00010] Histotripsy transducers have a focal point positioned a distance from the transducer where the cavitational bubble clouds are formed. In order to non-invasively treat tissue inside a patient, the transducers must be positioned away from the patient's skin so as to locate the cavitational focal point on the target tissue. Thus, when the transducer is positioned away from the patient's skin, the pulsed ultrasound of a Histotripsy ultrasound transducer must be carried through an aqueous coupling medium that is in intimate contact with the ultrasound transducer and the skin surface.

[00011] One prior solution to acoustic coupling for therapeutic ultrasound includes a water bath disposed in a treatment table. During therapy, the patient lies with the body immersed in the water bath. This coupling solution is both cumbersome and expensive as it requires a specialized examination table and is not versatile or portable. Additionally, it requires a large volume of an acoustic coupling medium (typically degassed water) which is expensive and can be messy.

[00012] Thus, there is a need for an inexpensive, minimal, and versatile acoustic coupling device for use in ultrasonic therapy applications such as Histotripsy and Lithotripsy.

SUMMARY OF THE INVENTION

[00013] In one embodiment, a method of treating a prostate of a patient comprises imaging the prostate with an ultrasound probe, placing an acoustic medium container over a perineum of

the patient, and applying ultrasonic therapy through the acoustic medium container to cause mechanical fractionation of a target portion of the prostate.

[00014] In one embodiment, the prostate can be imaged by inserting the ultrasound probe into the patient's rectum to image the prostate. In some embodiments, the ultrasound probe is inserted into a rectal sheath to provide a liquid seal barrier between the ultrasound probe and the patient's rectum.

[00015] In some embodiments, the method comprises at least partially filling the acoustic medium container with an acoustic coupling medium, such as degassed water. In some embodiments, the acoustic coupling medium directly contacts the patient's skin. In other embodiments, the acoustic coupling medium does not directly contact the patient's skin.

[00016] In other embodiments, the method further comprises securing the acoustic medium container to the patient with an adhesive. In other embodiments, the method comprises securing the acoustic medium container to the patient with a strap. The acoustic medium container can be secured to the patient to form a liquid seal between the container and the patient's skin.

[00017] The applying step can further comprise applying ultrasonic therapy with an ultrasonic therapy transducer coupled to the acoustic medium container. In some embodiments, the applying ultrasonic therapy step comprises applying histotripsy to treat the patient. In other embodiments, the applying ultrasonic therapy step comprises forming cavitation bubbles in the target portion of the prostate. In additional embodiments, the applying ultrasonic therapy step comprises applying acoustic pulses that operate at a frequency between approximately 50 KHz and 5MHz, having a pulse intensity with a peak negative pressure of approximately 8-25 MPa, a peak positive pressure of more than 10 MPa, a pulse length shorter than 50 cycles, a duty cycle between approximately 0.1% and 5%, and a pulse repetition frequency of less than 5 KHz.

[00018] In additional embodiments, the applying ultrasonic therapy step comprises applying lithotripsy or HIFU to treat the patient.

[00019] In some embodiments, the method further comprises expelling a volume of the acoustic coupling medium into a remote reservoir from the acoustic medium container when the acoustic medium container is compressed, and infusing a volume of the acoustic coupling medium into the acoustic medium container from the remote reservoir when the acoustic medium container is expanded.

[00020] In another embodiment, an ultrasound therapy device is provided, comprising a frame configured to conform to and provide a liquid seal against a patient's skin, a reservoir portion configured to hold an acoustic coupling medium in direct contact with the patient's skin, and an ultrasound transducer in acoustic communication with the acoustic coupling medium, wherein

movement of the ultrasound transducer relative to the frame maintains acoustic communication between the ultrasound transducer and the acoustic coupling medium.

[00021] In some embodiments, the ultrasound therapy device further comprising a rectal imaging probe configured to image the patient's prostate. In one embodiment, the reservoir portion comprises a sheath configured to receive the rectal imaging probe.

[00022] In one embodiment, the frame is sized and shaped to conform to a male patient's anatomy surrounding the perineum.

[00023] In some embodiments of the ultrasound therapy device, the reservoir portion is pliable. In other embodiments, the reservoir portion is transparent. In another embodiment, the reservoir portion is open so as to expose the acoustic coupling medium to air.

[00024] In some embodiments, the ultrasound transducer is coupled to the reservoir portion and configured to direct ultrasonic therapy through the perineum to the patient's prostate.

[00025] In one embodiment, the ultrasound therapy device further comprises a sling configured to hold the patient's scrotum away from the perineum.

[00026] In one embodiment, the ultrasound transducer is submerged in the acoustic coupling medium.

[00027] In another embodiment, the reservoir portion is sealed to contain the acoustic coupling medium against the patient's skin.

[00028] In many embodiments, the acoustic coupling medium comprises a degassed water. In other embodiments, the acoustic coupling medium comprises an acoustic gel.

[00029] In some embodiments of the ultrasound therapy device, the frame is secured to the patient with an adhesive. In other embodiments, the frame is secured to the patient with a strap. In another embodiment, the frame comprises a wearable garment. The wearable garment can provide a liquid seal against the patient's skin near the patient's waist and near the patient's legs, for example. Alternatively, the wearable garment can provide a liquid seal against the patient's skin around the patient's perineum.

[00030] In some embodiments, the ultrasound therapy device further comprises a remote reservoir configured to receive the acoustic coupling medium from the reservoir portion when the reservoir portion is compressed and to deliver the acoustic coupling medium to the reservoir portion when the reservoir portion is expanded.

[00031] In some embodiments, the ultrasonic transducer is configured to deliver a histotripsy pulse to the patient's prostate. In another embodiment, the ultrasonic transducer is configured to form cavitation bubbles in the patient's prostate. In yet another embodiment, the ultrasonic transducer is configured to deliver acoustic pulses that operate at a frequency between approximately 50 KHz and 5MHz, having a pulse intensity with a peak negative pressure of

approximately 8-25 MPa, a peak positive pressure of more than 10 MPa, a pulse length shorter than 50 cycles, a duty cycle between approximately 0.1% and 5%, and a pulse repetition frequency of less than 5 KHz.

[00032] An ultrasound coupling container is also provided, comprising a frame configured to provide a liquid seal against a patient's skin, the frame including first and second portions sized and configured to conform to each side of the patient's groin, and a reservoir portion coupled to the frame and configured to allow positioning and movement of an ultrasound transducer over the patient's perineum and prostate.

[00033] In some embodiments, the ultrasound coupling container further comprises a rectal sheath coupled to the reservoir portion.

[00034] In another embodiment, the ultrasound coupling container further comprises a receptacle coupled to the reservoir portion, the receptacle configured to receive the ultrasound transducer.

[00035] In some embodiments, the reservoir portion is pliable.

[00036] In other embodiments, the frame comprises a third portion connecting the first and second portions, the third portion being configured to conform to the patient's skin below the rectum.

[00037] In some embodiments, the ultrasound coupling container further comprises a sling configured to hold the patient's scrotum away from the perineum.

[00038] In another embodiment, the frame is coupled to a wearable garment that is configured to be worn by the patient.

BRIEF DESCRIPTION OF THE DRAWINGS

[00039] Fig. 1 illustrates one embodiment of an ultrasound coupling container.

[00040] Fig. 2 illustrates one embodiment of an ultrasound coupling container attached to a patient.

[00041] Fig. 3 illustrates another embodiment of an ultrasound coupling container.

[00042] Fig. 4 illustrates one embodiment of an ultrasound coupling container attached to a patient.

[00043] Fig. 5 illustrates one embodiment of an ultrasound coupling container in the form of a garment worn by a patient.

[00044] Fig. 6 is an exploded view of one embodiment of an ultrasound coupling container.

[00045] Figs. 7-8 are additional views of the ultrasound coupling container of Fig. 5.

[00046] Figs. 9-10 illustrate one embodiment of an ultrasound coupling container having a remote reservoir.

DETAILED DESCRIPTION OF THE INVENTION

[00047] In addition to imaging tissue, ultrasound technology is increasingly being used to treat and destroy tissue. In medical applications such as Histotripsy, where ultrasound pulses are used to form cavitational microbubbles in tissue to mechanically break down and destroy tissue, it is necessary to acoustically couple the ultrasound therapy transducer to the patient while allowing for movement of the therapy transducer in all directions. Particular challenges arise in the application of Histotripsy for the treatment of BPH and prostate cancer, where the male anatomy provides only a small acoustic window through the perineum to deliver ultrasound energy. The present invention describes several embodiments of an ultrasound coupling apparatus for acoustically coupling an ultrasound therapy transducer to a patient. In particular, the present invention provides for acoustic coupling of ultrasound therapy transducers, such as those used in Histotripsy, Lithotripsy, and HIFU, for the treatment of a variety of medical conditions including but not limited to BPH and prostate cancer.

[00048] Referring now to Fig. 1, an ultrasound coupling container 100 is shown comprising a frame 102 and a pliable reservoir portion 104. The ultrasound coupling container 100 is configured to acoustically couple an ultrasound therapy transducer to a patient to allow for movement of the ultrasound therapy transducer relative to the patient during treatment while maintaining acoustic communication between the transducer and the target tissue undergoing therapy.

[00049] Frame 102 can comprise a pliable material that is configured to conform to a patient's skin and provide a liquid seal against the patient's skin. The frame may also include, for example, foam or another conforming material 103 to improve the liquid seal between the frame to skin interface. Referring still to Fig. 1, frame 102 may comprise laterally opposed first and second frame portions 106 and 108, and longitudinally opposed third and fourth frame portions 110 and 112 to define a treatment aperture 114. Frame 102 may incorporate straps or belts (not shown) through slits 116, and/or adhesives to help secure the frame of the ultrasound coupling container to the patient's skin to form a liquid seal against the patient's skin.

[00050] As shown in Fig. 1, reservoir portion 104 can be attached to frame 102 and can extend outward from the frame and aperture 114. Reservoir portion may include transducer receptacle 118 configured to hold and position an ultrasound therapy transducer over treatment aperture 114. The reservoir portion can comprise a flexible, pliable material and is configured to allow for positioning and movement of an ultrasound therapy transducer over the treatment aperture 114 during set-up and treatment. In some embodiments, the reservoir portion 104 comprises a pliable, transparent plastic. The transparent plastic construction facilitates direct

visual access to the patient and the contents of the ultrasonic medium container, which can assist the operator with set-up and monitoring throughout the treatment procedure. In the embodiment shown in Fig. 1, the reservoir portion 104 includes an opening 121, which can be used to fill the reservoir portion with an acoustic coupling medium such as degassed water, for example. Because the frame 102 defines an open aperture 114, acoustic coupling medium is allowed to be in direct contact with the patient's skin when the reservoir portion 104 is filled.

[00051] The pliable nature of the reservoir portion 104 allows the transducer receptacle 118, and thus the ultrasound transducer inserted therein, to be moved with respect to the patient and the frame. In therapeutic applications such as Histotripsy, where the relative position of the therapy transducer with respect to the target tissue must be adjusted to align a therapy focal point with the target tissue, it is necessary to be able to move the therapy transducer while maintaining acoustic communication between the transducer and the patient. Thus, in Fig. 1 when the reservoir portion is filled with an acoustic coupling medium and the reservoir portion is compressed (e.g., during positional adjustment of the therapy transducer), then acoustic coupling medium may be allowed to spill out of the opening 121 in response to the change in volume of the reservoir portion.

[00052] The reservoir portion 104 can further include a sheath 120 for acoustically coupling a rectal ultrasonic imaging probe (not shown) to the patient. The sheath can be a pliable and liquid impermeable, similar to a condom. This "condom" like sheath 120 can provide a liquid seal barrier for coupling the rectal ultrasonic imaging probe to the ultrasound coupling container and also can act as the protective barrier for inserting the rectal ultrasonic imaging probe into the patient's rectum, as it is typically done in urological trans-rectal imaging.

[00053] Referring now to Fig. 2, an ultrasound coupling container 200 is shown positioned on a male patient. As seen in Fig. 2, frame 202 can be positioned on the patient so that first and second frame portions 206 and 208 are sized and configured to conform to each side of the patient's groin. Third frame portion 210 can be sized and configured to conform to the patient's skin below the rectum, and fourth frame portion 212 can be sized and configured to conform to the patient's skin above the penis. It can be seen that frame 202 completely surrounds the patient's penis, testicles, perineum, and rectum.

[00054] When the ultrasound coupling container 200 is positioned as shown in Fig. 2, transducer receptacle 218 can be positioned directly above the patient's perineum so as to have a direct acoustic window towards the prostate. Sheath 220 can then be aligned with the patient's rectum to allow for insertion of a rectal ultrasonic imaging probe for trans-rectal imaging of the prostate.

[00055] The pliable nature of the reservoir portion 204 allows the transducer receptacle 218, and thus the ultrasound transducer inserted therein, to be moved with respect to the patient and the frame. In the embodiment of Fig. 2, the ultrasound coupling container 200 is shown filled with an acoustic coupling medium 222 to provide acoustic communication between the transducer receptacle 218 and the patient. It can be seen that the aperture 214 defined by frame 202 allows the acoustic coupling medium 222 to directly contact the patient's skin in the region surrounding the perineum. Furthermore, in contrast to the embodiment of Fig. 1 which included an opening 121 to allow spillover of acoustic coupling medium, the embodiment of Fig. 2 can include a seal 224 to keep the acoustic coupling medium 222 fully contained within the device. When reservoir portion 204 is filled with an acoustic coupling medium the acoustic coupling medium is allowed to be in direct contact with the patient's skin. However, movement of the therapy transducer can cause the volume of the reservoir portion to change, so the ultrasound coupling container 200 of Fig. 2 can further include a remote reservoir 226 coupled to the reservoir portion. The remote reservoir can be configured to receive excess acoustic coupling medium from the reservoir portion when the reservoir portion is compressed, and can be configured to deliver additional acoustic coupling medium to the reservoir portion when the reservoir portion is expanded.

[00056] The ultrasound coupling container 200 may include ports 232 for filling, maintaining and removing the acoustic coupling medium. Filling and draining the reservoir portion may be accomplished by using a gravity feed system similar to an IV bag, as shown by remote reservoir 226. Placing the remote reservoir on an IV pole at the correct height in relationship to the ultrasound coupling container can fill the reservoir portion 204 to the desired fill level and maintain the desired fill level throughout the therapeutic procedure. When treatment is complete, lowering the remote reservoir can allow for draining the ultrasound coupling container back to the remote reservoir for disposal.

[00057] Referring still to Fig. 2, the ultrasound coupling container 200 may further include a sling 228 configured to hold and support the patient's scrotum away from the perineum. The sling can provide a larger acoustic window to the prostate through the perineum of the patient. Additionally, the sling 228 may include padding 230 around the patient's penis to increase patient comfort.

[00058] During a Histotripsy procedure, the patient can positioned in the extended lithotomy position and the ultrasound coupling container 200 can be applied to the patient's skin. With the ultrasound coupling container secured to the patient, a rectal ultrasonic imaging probe can be prepared and inserted into the sheath 220 and the patient's rectum for imaging of the prostate. Once the rectal ultrasonic imaging probe is positioned and coupled to the ultrasound coupling

container, an ultrasound therapy transducer can be coupled to the transducer receptacle 218 and be initially positioned for ultrasound therapy delivery. With the patient, rectal ultrasonic imaging probe, and ultrasound therapy transducer all coupled to the ultrasound coupling container, the container can then be filled with the acoustic coupling medium.

[00059] Fig. 3 is one embodiment of an ultrasound coupling container 300, which is a variation of the coupling containers described above. In Fig. 3, the ultrasound coupling container 300 comprises a pouch 334 that can be applied directly to the patient's perineal region, such as with an adhesive, to create an acoustic seal against the patient's skin.

[00060] The pouch 334 can further include a transducer receptacle 318 configured to couple to an ultrasound therapy transducer, thus forming a pliable reservoir pouch in the perineal region that allows for movement of the ultrasound therapy transducer during treatment and set-up. Additionally, the pouch can include a sheath 320 configured to receive a rectal ultrasonic imaging probe for imaging of the prostate.

[00061] The pouch 334 can be sealed and filled with an acoustic coupling medium, such as degassed water. The pouch 334 may optionally include ports for filling, maintaining and removing the acoustic coupling medium. In some embodiments, the pouch can comprise a transparent plastic that enables the surgeon to directly view the perineum. In contrast to the ultrasound coupling containers described above in Figs. 1-2, the pouch 334 does not allow the acoustic coupling medium to directly contact the patient's skin. Instead, the acoustic coupling medium is fully contained within the pouch to allow for shipping and transport of a fully filled pouch.

[00062] Referring still to Fig. 3, pouch 334 can be sized and shaped to cover only the perineal region of a male patient. Thus, the pouch may extend laterally between each side of the groin, and may extend longitudinally from just above the perineum to below the rectum. When placed on a patient, the sheath 320 is configured to align with the patient's rectum and the transducer receptacle 318 is configured to align with the patient's perineum.

[00063] Fig. 4 illustrates yet another embodiment of an ultrasound coupling container 400, comprising a plurality of walls 436 to form a "dam" like structure. The embodiment of Fig. 4 includes three walls 436, but any number of walls can be used to form a reservoir of acoustic coupling medium 422 against the patient's skin. The walls 436 include a pliable frame 402 configured to conform to a patient's skin and provide a liquid seal against the patient's skin. In the embodiment of Fig. 4, the frame can conform to the patient's skin along either side of the groin as well as below the rectum and perineum.

[00064] During therapy, an ultrasound therapy transducer can be immersed in the acoustic coupling medium 422, providing acoustic communication between the transducer and the

patient. The reservoir of acoustic coupling medium can be large enough to allow for movement of the ultrasound therapy transducer during treatment. In some embodiments, the reservoir level is allowed to rise and fall against the walls 436 as the transducer is inserted and pulled from the reservoir. In other embodiments, the ultrasound coupling container 400 includes ports for filling, maintaining and removing the acoustic coupling medium.

[00065] The ultrasound coupling container may incorporate straps, belts, and/or adhesives, as described above, to help secure it to the patient and form the liquid seal against the patient's skin. The ultrasound coupling container may be formed from a transparent plastic that enables the surgeon to directly view the perineum, for example.

[00066] Fig. 5 illustrates an additional embodiment of an ultrasound coupling container 500, which is implemented as a wearable "shorts" or "boxers" type garment 538. The ultrasound coupling container 500 includes many of the same features described above with respect to ultrasound coupling container 200 of Fig. 2, including reservoir portion 504, transducer receptacle 518, and sheath 520. The garment 538 may optionally include an opening, pouch, zipper, or other mechanism in the garment to gain access to the penis, such as for catheter placement/removal as well as cystoscopy as needed.

[00067] As described above, ultrasound coupling container 500 provides a liquid seal against the patient's skin and acoustically couples an ultrasound therapy transducer to the patient. The reservoir portion 504 can be filled with an acoustic coupling medium, and can be formed from a pliable material so as to allow for movement of the ultrasound therapy transducer during treatment. In the embodiment of Fig. 5, the acoustic coupling medium is allowed to be in direct contact with the patient's skin when the reservoir portion 504 is filled The reservoir portion may additional include ports for filling, maintaining and removing the acoustic coupling medium.

[00068] Referring still to Fig. 5, the ultrasound coupling container 500 can provide a liquid seal to the patient's skin in a variety of ways. In one embodiment, the garment 538 can include a frame 502a surrounding the reservoir portion to provide a liquid seal around the patient's perineal region and rectum. When the garment is worn by the patient, the reservoir portion can be configured to surround the perineal area, and the sheath 520 can be configured to align with the patient's rectum. The frame 502a may be attached to the patient's skin with an adhesive and/or straps, or may contain inflatable bladders to improve the liquid sealing mechanism against the patient's skin. When the frame 502a is sealed against the patient's skin, the reservoir portion may be filled with an acoustic coupling medium.

[00069] In another embodiment, frame 502b may be used to provide a liquid seal between the garment and the patient's skin. In this embodiment, frame 502b can attached to the patient's

skin with an adhesive and/or straps, or may contain inflatable bladders to improve the liquid sealing mechanism against the patient's skin. When the frame 502b is sealed against the patient's skin, the entire garment including the reservoir portion may be filled with an acoustic coupling medium. However, this embodiment requires more acoustic coupling medium to be used than if only frame 502a is sealed to the skin.

[00070] Figs. 6-10 illustrate several embodiments of an ultrasound coupling container. Fig. 6 is an exploded view of an ultrasound coupling container 600, comprising bellows 640 containing highly compliant inner bladder 642, which can be filled with an acoustic coupling medium. The bellows 640 can be sealed at both ends with caps 644 to contain the bladder and acoustic coupling medium during storage and shipping.

[00071] The bellows can be constructed of plastic, preferably polypropylene (PP), polyvinyl chloride (PVC), silicone (SI), or polyethylene formulations which are commonly used to make bellows and components with living hinges and flexibility. Plastic bellows can be fabricated economically by blow molding (PP, PVC, and PE), injection molding (PE and SI) or dip coating (PVC). Bellows 640 can also be formed from metals such as titanium or stainless steel; however these are relatively expensive.

[00072] The bellows can be made with an extension 646 that may include integral screw threads, snap fittings, bayonet locks or other fittings for attaching to the end caps 644. Alternatively, the caps can be attached with a separate piece that connects to the bellows with an adhesive, a weld, or other attachment methods. The caps 644 can facilitate attachment of an ultrasound therapy transducer 650 having a concave surface 652 on one end of the ultrasound coupling container and a skin adapter 648 on the other end of the ultrasound coupling container at the skin interface.

[00073] The inner bladder 642 can be fabricated from highly compliant elastic materials such as silicone, polyurethane, latex, rubber or other such material. The bladder can be filled with an acoustic coupling medium, such as degassed water or a gel (phantom gel). The bladder may include vents 656 for filling or emptying the acoustic coupling medium from the bladder.

[00074] In use, the caps 644 can be removed from each end of the ultrasound coupling container to expose the inner compliant bladder 642. The ultrasound therapy transducer 650 can be attached to the top of the ultrasound coupling container, and a skin adapter 648 may be placed on the bottom of the ultrasound coupling container to provide a better seal and improved patient comfort. The skin adapter can be a highly compliant ring fabricated from a sealed foam, an air filled bladder, or other such material. The patient's skin can then be prepped with standard ultrasonic coupling gel 654, which can also be applied to the surface of the ultrasound therapy

transducer 650. The ultrasonic coupling gel assures proper transmission of ultrasound at these surfaces.

[00075] Fig. 7 illustrates the ultrasound coupling container 700 in a relaxed, expanded configuration. Fig. 8 illustrates ultrasound coupling container 800 in a compressed configuration against the patient's skin. In Fig. 8, the compliant bladder is forced down on the patient's skin and up into the ultrasound therapy transducer 850. The bladder can then conform to the concave surface 852 of the ultrasound therapy transducer and also the curves on the patient's skin surface. Vents 856 can be provided at the top or at other locations in the ultrasound therapy transducer to facilitate conformance of the bladder to the concave surface. In some embodiments, the vents can include a one way valve that allows air to escape and not return from the space between the bladder and concave surface. In this manner, the one way valve vent can create a vacuum in the space between the bladder and the concave surface. Similarly, a vent 856 in the skin adapter at the patient skin surface 858 can be provided to facilitate conformance of the bladder to the curves on the skin surface. This vent may also include a one way valve to facilitate creation of a vacuum between the bladder and patient skin surface.

[00076] The embodiments illustrated above in Figs. 6-8 may be enhanced with a remote reservoir that enables more compression and expansion of the ultrasound coupling container during use. Referring now to Figs. 9-10, remote reservoir 960 is connected to the bellows 940 or bladder 942 with tubing 962. Referring now to Fig. 10, the remote reservoir bag can expand with the acoustic coupling medium when the bellows 1040 are compressed, and deliver acoustic coupling medium to the bellows or bladder when the bellows are expanded during Histotripsy treatment.

[00077] The remote reservoir can be a bag or other compliant or rigid container. A rigid container would require a vent. A remote reservoir can be similar to an intravenous solution bag that made from PVC or other suitable plastic film. The tubing can be made of PVC or other suitable flexible plastic material. In use, the remote reservoir can be elevated to increase the pressure within the remote reservoir to provide better contact with the bladder skin surfaces.

[00078] Methods of treating a prostate with the devices and systems described herein are also provided. In one embodiment, a method of treating a prostate of a patient comprises imaging the prostate with an ultrasound probe, placing an acoustic medium container over a perineum of the patient, and applying ultrasonic therapy through the acoustic medium container to cause mechanical fractionation of a target portion of the prostate.

[00079] The acoustic medium container can be any of the acoustic medium containers described herein and throughout Figs. 1-10.

[00080] The prostate can be imaged by inserting the ultrasound probe into the patient's rectum to image the prostate. In some embodiments, the ultrasound probe is inserted into a rectal sheath to provide a liquid seal barrier between the ultrasound probe and the patient's rectum.

[00081] In some embodiments, the method comprises at least partially filling the acoustic medium container with an acoustic coupling medium, such as degassed water. In some embodiments, the acoustic coupling medium directly contacts the patient's skin. In other embodiments, the acoustic coupling medium does not directly contact the patient's skin.

[00082] In some embodiments, the method further comprises securing the acoustic medium container to the patient with an adhesive. In other embodiments, the method comprises securing the acoustic medium container to the patient with a strap. The acoustic medium container can be secured to the patient to form a liquid seal between the container and the patient's skin.

[00083] The applying step can further comprise applying ultrasonic therapy with an ultrasonic therapy transducer coupled to the acoustic medium container. In some embodiments, the applying ultrasonic therapy step comprises applying histotripsy to treat the patient. In other embodiments, the applying ultrasonic therapy step comprises forming cavitation bubbles in the target portion of the prostate. In additional embodiments, the applying ultrasonic therapy step comprises applying acoustic pulses that operate at a frequency between approximately 50 KHz and 5MHz, having a pulse intensity with a peak negative pressure of approximately 8-25 MPa, a peak positive pressure of more than 10 MPa, a pulse length shorter than 50 cycles, a duty cycle between approximately 0.1% and 5%, and a pulse repetition frequency of less than 5 KHz. In additional embodiments, the applying ultrasonic therapy step comprises applying lithotripsy or HIFU to treat the patient.

[00084] As for additional details pertinent to the present invention, materials and manufacturing techniques may be employed as within the level of those with skill in the relevant art. The same may hold true with respect to method-based aspects of the invention in terms of additional acts commonly or logically employed. Also, it is contemplated that any optional feature of the inventive variations described may be set forth and claimed independently, or in combination with any one or more of the features described herein. Likewise, reference to a singular item, includes the possibility that there are plural of the same items present. More specifically, as used herein and in the appended claims, the singular forms "a," "and," "said," and "the" include plural referents unless the context clearly dictates otherwise. It is further noted that the claims may be drafted to exclude any optional element. As such, this statement is intended to serve as antecedent basis for use of such exclusive terminology as "solely," "only" and the like in connection with the recitation of claim elements, or use of a "negative" limitation. Unless defined otherwise herein, all technical and scientific terms used herein have the same meaning as

commonly understood by one of ordinary skill in the art to which this invention belongs. The breadth of the present invention is not to be limited by the subject specification, but rather only by the plain meaning of the claim terms employed.

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CLAIMS

WHAT IS CLAIMED IS:

1. A method of treating a prostate of a patient, comprising:

imaging the prostate with an ultrasound probe;

placing an acoustic medium container over a perineum of the patient; and

applying ultrasonic therapy through the acoustic medium container to cause mechanical fractionation of a target portion of the prostate.

2. The method of claim 1 further comprising inserting the ultrasound probe into the patient's rectum to image the prostate.

3. The method of claim 2 further comprising inserting the ultrasound probe into a rectal sheath to provide a liquid seal barrier between the ultrasound probe and the patient's rectum.

4. The method of claim 1 further comprising at least partially filling the acoustic medium container with an acoustic coupling medium.

5. The method of claim 1 further comprising securing the acoustic medium container to the patient with an adhesive.

6. The method of claim 1 further comprising securing the acoustic medium container to the patient with a strap.

7. The method of claim 1 wherein the applying step further comprises applying ultrasonic therapy with an ultrasonic therapy transducer coupled to the acoustic medium container.

8. The method of claim 7 further comprising moving the ultrasonic therapy transducer with respect to the patient during the applying ultrasonic energy step.

9. The method of claim 1 further comprising forming a liquid seal against the patient's skin with the acoustic medium container.

10. The method of claim 1 further comprising filling the acoustic medium container with an acoustic coupling medium that directly contacts the patient's skin.

11. The method of claim 1 further comprising filling the acoustic medium container with an acoustic coupling medium that does not directly contact the patient's skin.

12. The method of claim 1 wherein the placing step comprises placing a wearable garment over the perineum of the patient.

13. The method of claim 12 further comprising forming a liquid seal between the wearable garment and the patient.

14. The method of claim 13 further comprising forming a liquid seal between the wearable garment and the patient near the patient's waist and near the patient's legs.

15. The method of claim 13 further comprising forming a liquid seal between the wearable garment and the patient around the patient's perineum.

16. The method of claim 12 wherein the wearable garment comprises a pliable portion around the perineum of the patient.

17. The method of claim 1 further comprising expelling a volume of the acoustic coupling medium into a remote reservoir from the acoustic medium container when the acoustic medium container is compressed, and infusing a volume of the acoustic coupling medium into the acoustic medium container from the remote reservoir when the acoustic medium container is expanded.

18. The method of claim 1 wherein the applying ultrasonic therapy step comprises applying histotripsy.

19. The method of claim 1 wherein the applying ultrasonic therapy step comprises forming cavitation bubbles in the target portion of the prostate.

20. The method of claim 1 wherein the applying ultrasonic therapy step comprises applying acoustic pulses that operate at a frequency between approximately 50 KHz and 5MHz, having a pulse intensity with a peak negative pressure of approximately 8-25 MPa, a peak positive pressure of more than 10 MPa, a pulse length shorter than 50 cycles, a duty cycle between approximately 0.1% and 5%, and a pulse repetition frequency of less than 5 KHz.

21. An ultrasound therapy device, comprising:

a frame configured to conform to and provide a liquid seal against a patient's skin;

a reservoir portion configured to hold an acoustic coupling medium in direct contact with the patient's skin; and

an ultrasound transducer in acoustic communication with the acoustic coupling medium, wherein movement of the ultrasound transducer relative to the frame maintains acoustic communication between the ultrasound transducer and the acoustic coupling medium.

22. The ultrasound therapy device of claim 21 further comprising a rectal imaging probe configured to image the patient's prostate.

23. The ultrasound therapy device of claim 22 wherein the reservoir portion comprises a sheath configured to receive the rectal imaging probe.

24. The ultrasound therapy device of claim 21 wherein the frame is sized and shaped to conform to a male patient's anatomy surrounding the perineum.

25. The ultrasound therapy device of claim 24 wherein the reservoir portion is pliable.

26. The ultrasound therapy device of claim 25 wherein the ultrasound transducer is coupled to the reservoir portion and configured to direct ultrasonic therapy through the perineum to the patient's prostate.

27. The ultrasound therapy device of claim 24 further comprising a sling configured to hold the patient's scrotum away from the perineum.

28. The ultrasound therapy device of claim 21 wherein the reservoir portion is open so as to expose the acoustic coupling medium to air.

29. The ultrasound therapy device of claim 21 wherein the ultrasound transducer is submerged in the acoustic coupling medium.

30. The ultrasound therapy device of claim 21 wherein the reservoir portion is sealed to contain the acoustic coupling medium against the patient's skin.

31. The ultrasound therapy device of claim 21 wherein the acoustic coupling medium comprises a degassed water.

32. The ultrasound therapy device of claim 21 wherein the frame is secured to the patient with an adhesive.

33. The ultrasound therapy device of claim 21 wherein the frame is secured to the patient with a strap.

34. The ultrasound therapy device of claim 21 wherein the frame comprises a wearable garment.

35. The ultrasound therapy device of claim 34 wherein the wearable garment provides a liquid seal against the patient's skin near the patient's waist and near the patient's legs.

36. The ultrasound therapy device of claim 34 wherein the wearable garment provides a liquid seal against the patient's skin around the patient's perineum.

37. The ultrasound therapy device of claim 21 further comprising a remote reservoir configured to receive the acoustic coupling medium from the reservoir portion when the reservoir portion is compressed and to deliver the acoustic coupling medium to the reservoir portion when the reservoir portion is expanded.

38. The ultrasound therapy device of claim 21 wherein the ultrasonic transducer is configured to deliver a histotripsy pulse to the patient's prostate.

39. The ultrasound therapy device of claim 21 wherein the ultrasonic transducer is configured to form cavitation bubbles in the patient's prostate.

40. The ultrasound therapy device of claim 21 wherein the ultrasonic transducer is configured to deliver acoustic pulses that operate at a frequency between approximately 50 KHz and 5MHz, having a pulse intensity with a peak negative pressure of approximately 8-25 MPa, a peak positive pressure of more than 10 MPa, a pulse length shorter than 50 cycles, a duty cycle between approximately 0.1% and 5%, and a pulse repetition frequency of less than 5 KHz.

41. An ultrasound coupling container, comprising:

a frame configured to provide a liquid seal against a patient's skin, the frame including first and second portions sized and configured to conform to each side of the patient's groin; and

a reservoir portion coupled to the frame and configured to allow positioning and movement of an ultrasound transducer over the patient's perineum and prostate.

42. The ultrasound coupling container of claim 41 further comprising a rectal sheath coupled to the reservoir portion.

43. The ultrasound coupling container of claim 41 further comprising a receptacle coupled to the reservoir portion, the receptacle configured to receive the ultrasound transducer.

44. The ultrasound coupling container of claim 41 wherein the reservoir portion is pliable.

45. The ultrasound coupling container of claim 41 wherein the frame comprises a third portion connecting the first and second portions, the third portion configured to conform to the patient's skin below the rectum.

46. The ultrasound coupling container of claim 41 further comprising a sling configured to hold the patient's scrotum away from the perineum.

47. The ultrasound coupling container of claim 41 wherein the frame is coupled to a wearable garment that is configured to be worn by the patient.

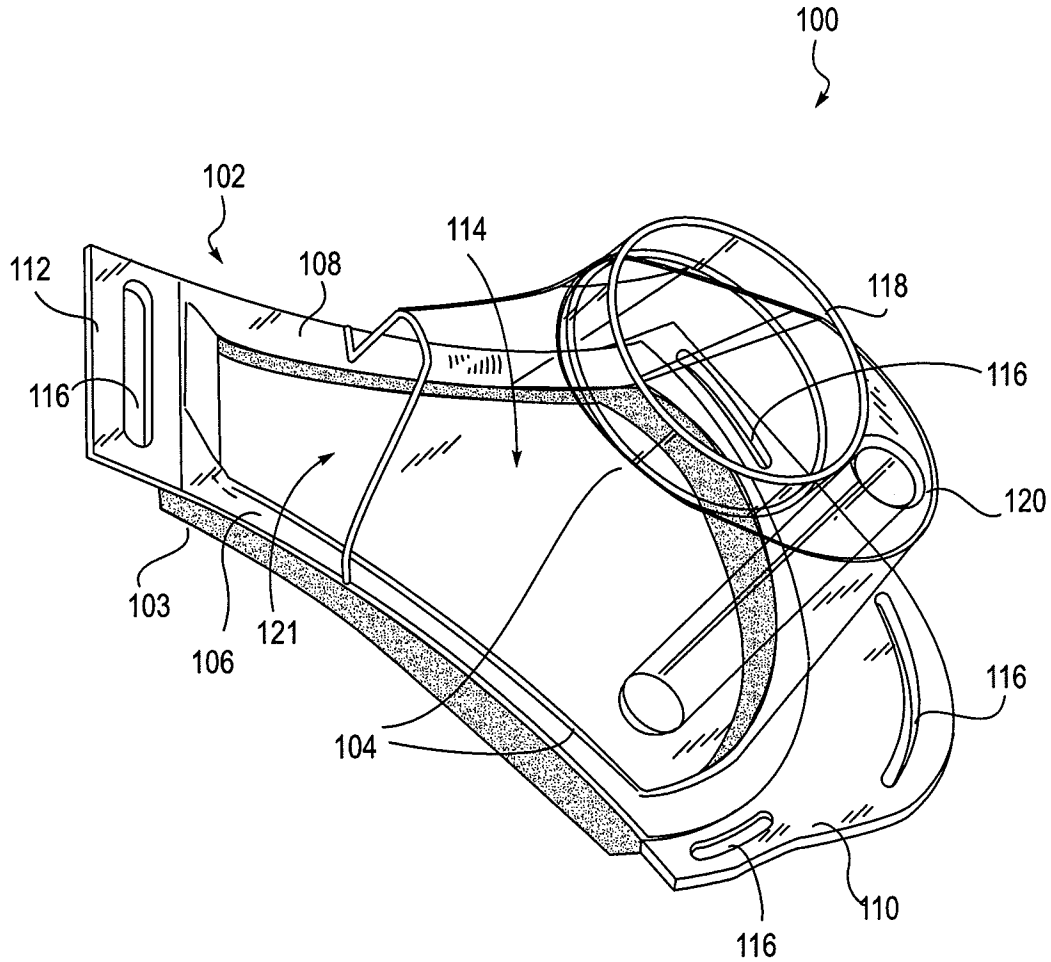

FIG. 1

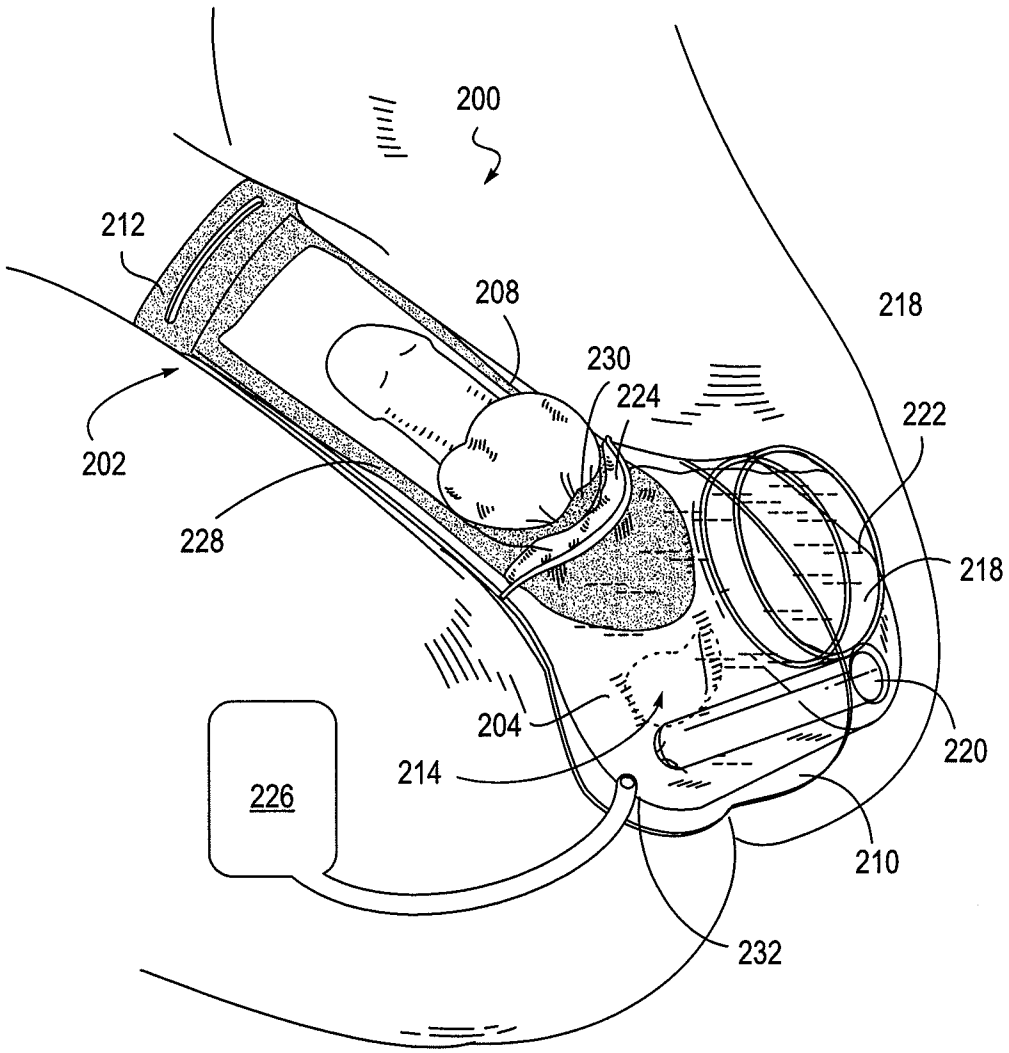

FIG. 2

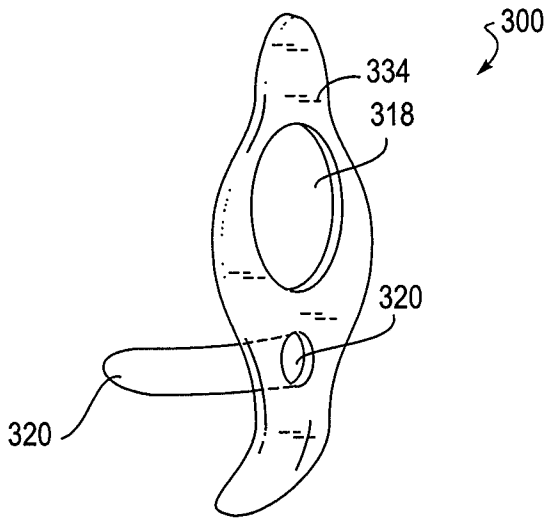

FIG. 3

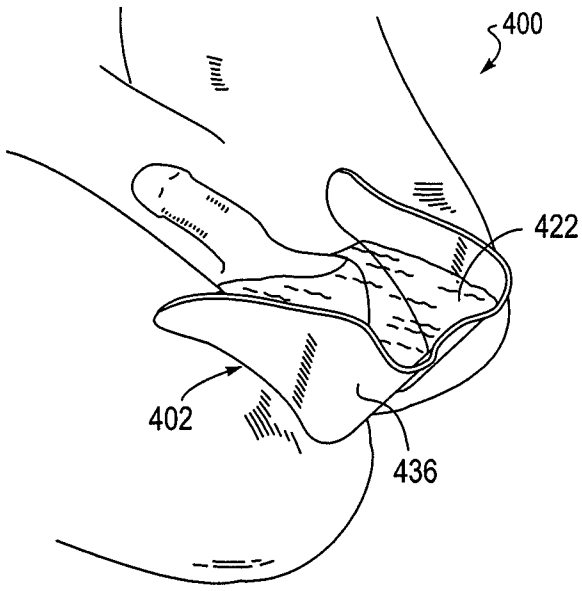

FIG. 4

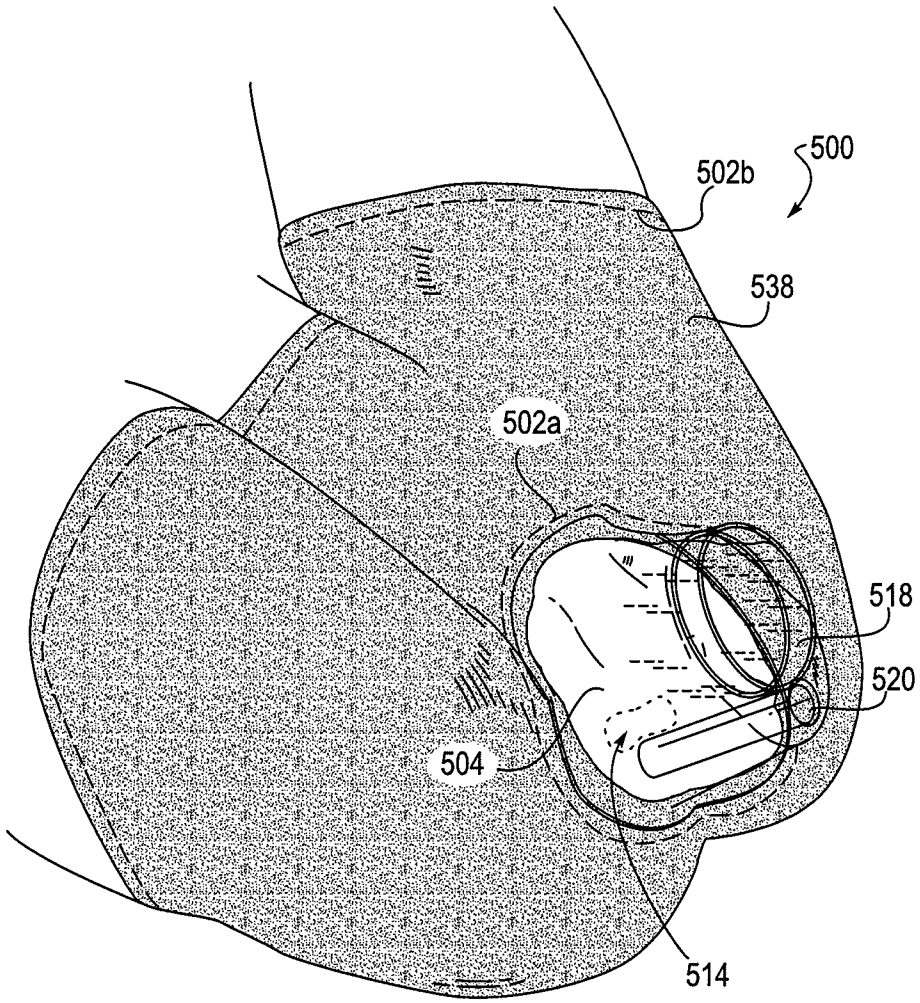

FIG. 5

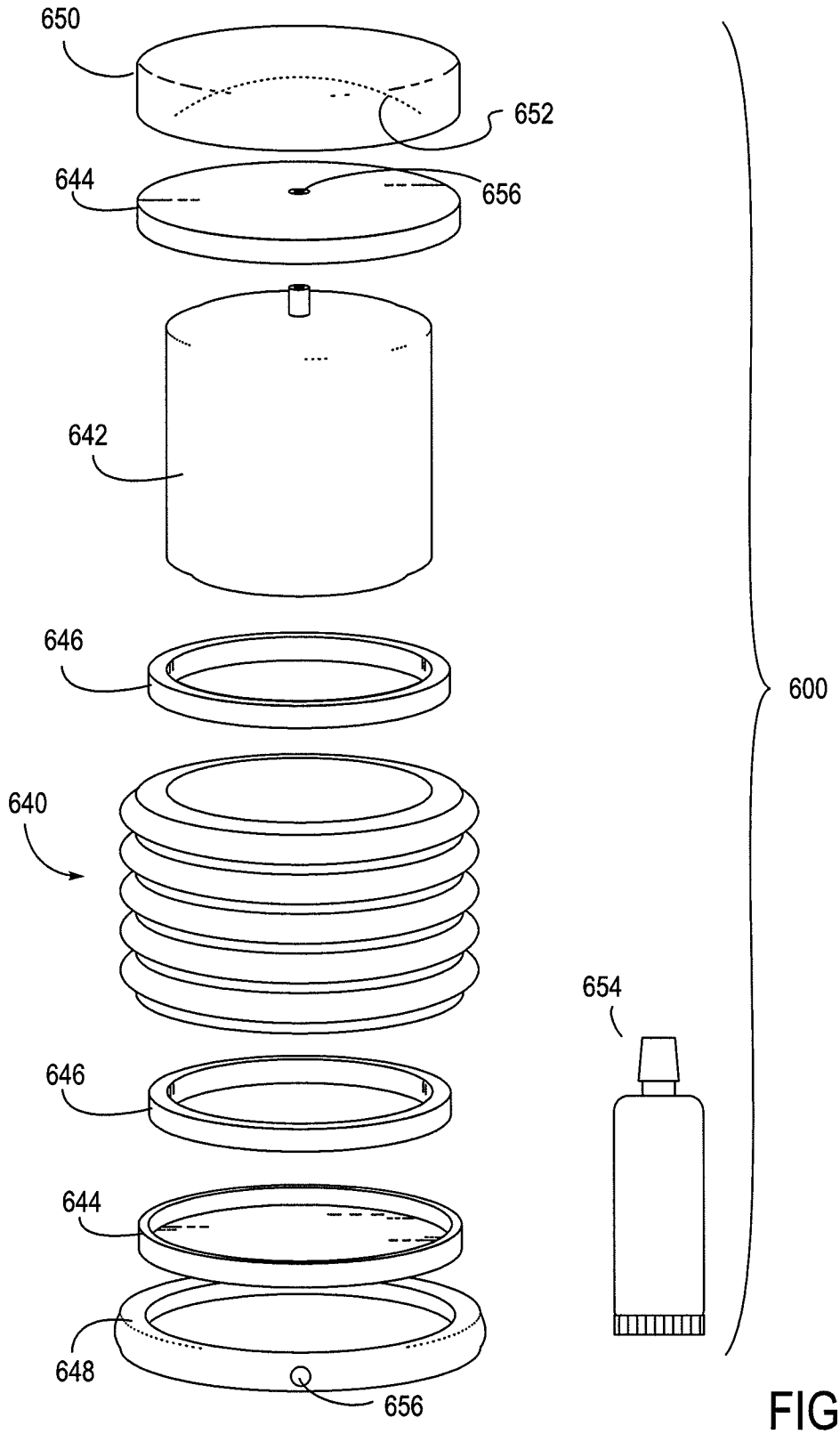

FIG. 6

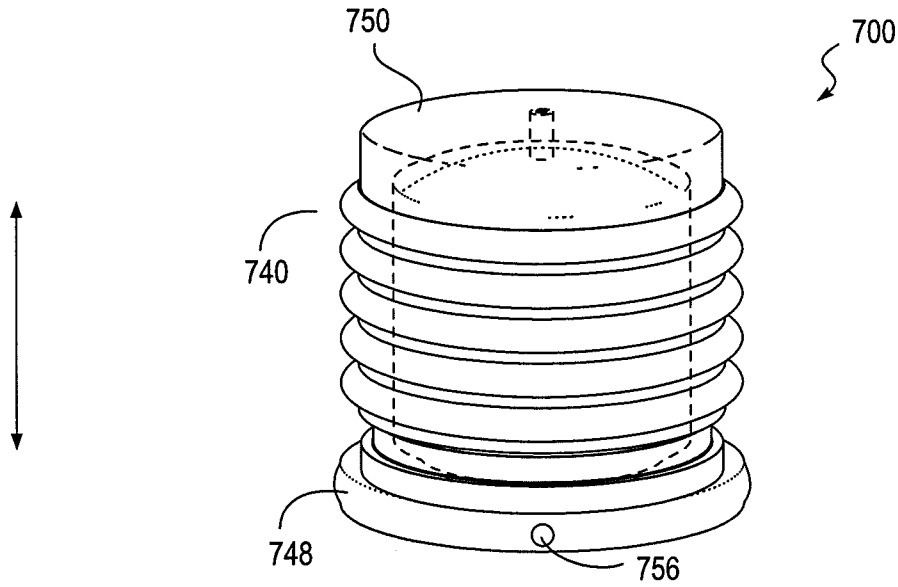

FIG. 7

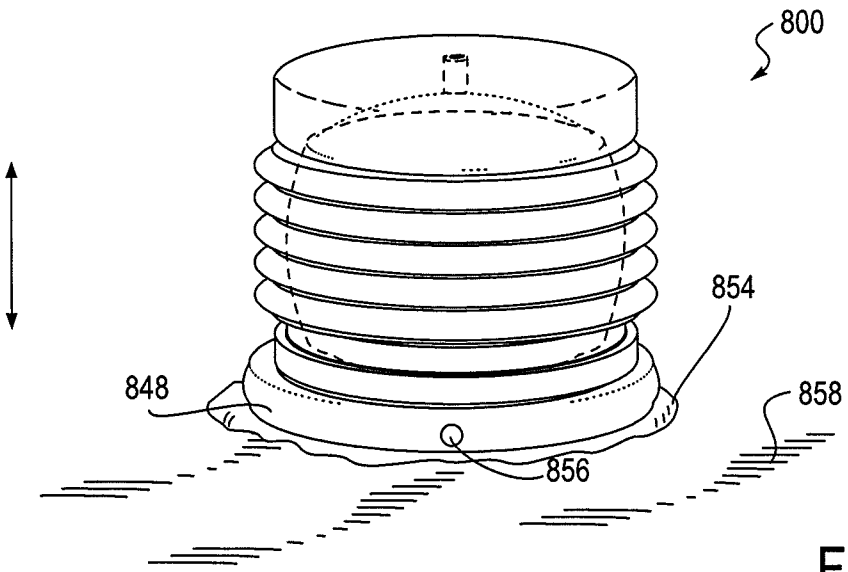

FIG. 8

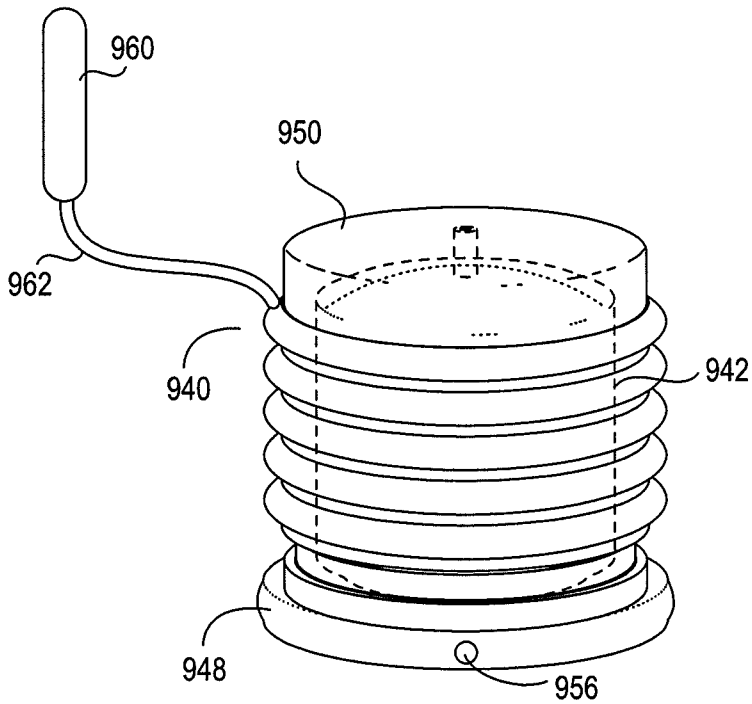

FIG. 9

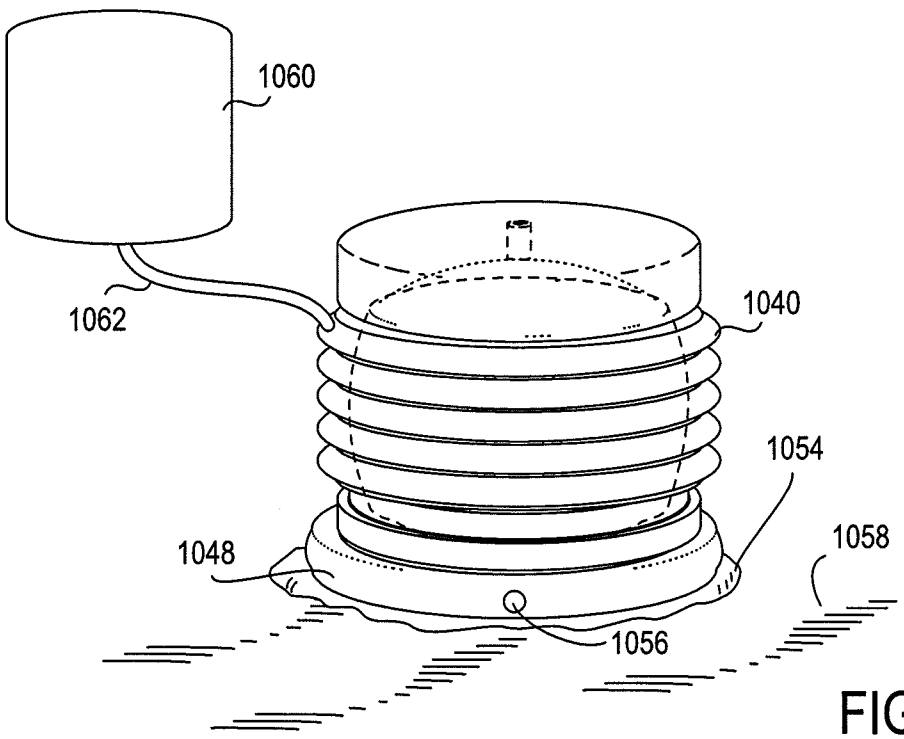

FIG. 10