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(54) **Title:** DEVICES AND METHODS FOR SHUNT EVALUATION

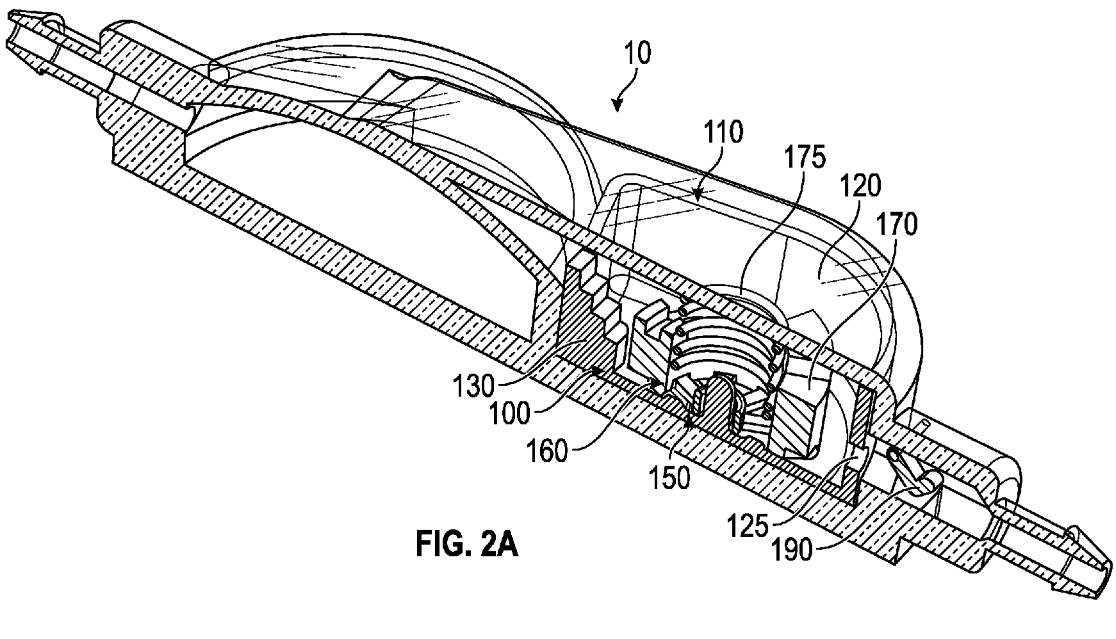

FIG. 2A

(57) **Abstract:** An implantable valve device includes a valve unit having a flow limiter in operative association with a dial for controlling a flow of material through a lumen in communication with the valve unit. The dial includes a dial indicator viewable through cross-sectional imaging for determining and/or otherwise verifying a "pressure setting" of the valve unit. The valve unit can include a housing that encapsulates the dial therein and provides one or more reference indicators that enable a practitioner to determine an orientation of the valve unit and further clarify the position of the dial indicator. The valve unit can be interrogated through conventional non-invasive cross-sectional imaging methods such as ultrasound.

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DEVICES AND METHODS FOR SHUNT EVALUATION

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This is a PCT Patent Application that claims benefit to U.S. Provisional Patent Application Serial No. 63/296,783 filed 5 January 2022, which is herein incorporated by reference in its entirety.

FIELD

[0002] The present disclosure generally relates to surgical shunts, and in particular, to devices and methods for shunt evaluation through non-invasive cross-sectional imaging.

BACKGROUND

[0003] Most modern commercial surgical shunts have adjustable pressure settings that allow physicians and other providers to noninvasively adjust the pressure settings as needed. However, the only reliable and recordable method of confirming the pressure setting on current commercial shunts are through x-ray, a form of ionizing radiation that can harm patients over repeated exposures. Not properly confirming shunt pressure settings can be devastating and life-threatening; for example, in neurosurgical applications, patients can develop hydrocephalus and/or over-shunting which can lead to subdural hematomas. Thus, patients with shunts can be exposed to countless x-rays over their lifetime, which is especially concerning in pediatric patients, where shunt placement takes up an even larger portion of neurosurgical cases.

[0004] Furthermore, patients with shunts utilize healthcare frequently due to concerns for shunt failure. The only definitive method of confirming shunt patency is to perform surgery to expose and test the shunt. Other less invasive methods are either inaccurate, expensive, and/or result in significant radiation exposure.

[0005] It is with these observations in mind, among others, that various aspects of the present disclosure were conceived and developed.

BRIEF DESCRIPTION OF THE DRAWINGS

[0006] FIG. **1A** is an illustration showing a perspective view of a valve device having a valve unit according to aspects of the present disclosure;

[0007] FIG. **1B** is an illustration showing the valve device of FIG. **1A** implanted within the body and being interrogated by an ultrasound device;

[0008] FIG. **2A** is an illustration showing a cross-sectional perspective view of the valve device of FIG. **1A** having a first embodiment of a valve unit;

[0009] FIG. **2B** is an illustration showing a top plan view of one embodiment of the valve device of FIG. **2A** with a reference marker in a first arrangement;

[0010] FIG. **2C** is an illustration showing a top plan view of one embodiment of the valve device of FIG. **2A** with a reference marker in a second arrangement;

[0011] FIG. **3A** is an illustration showing a top perspective view of a housing of the valve unit of FIG. **2A**;

[0012] FIG. **3B** is an illustration showing a bottom perspective view of the housing of FIG. **3A**;

[0013] FIG. **3C** is an illustration showing a cross-sectional perspective view of the housing of FIG. **3A** taken along line **3C**-**3C** of FIG. **3A**;

[0014] FIG. **3D** is an illustration showing a cross-sectional side view of the housing of FIG. **3A** taken along line **3D**-**3D** of FIG. **3A**;

[0015] FIG. **3E** is an illustration showing a full cross-sectional perspective view of the housing of FIG. **3A** taken along line **3D-3D** of FIG. **3A**;

[0016] FIG. **4A** is an illustration showing a top perspective view of a dial of the valve unit of FIG. **2A**;

[0017] FIG. **4B** is an illustration showing a bottom perspective view of the dial of FIG. **4A**;

[0018] FIG. **4C** is an illustration showing a bottom perspective view of the dial of FIG. **4B** coupled with a flow control unit;

[0019] FIG. **5** is an illustration showing a locking mechanism of the valve unit of FIG. **2A** including engagement of the dial with the housing;

[0020] FIG. **6A** is an illustration showing a top perspective view of the valve unit of FIG. **2A** with the housing in phantom;

[0021] FIG. **6B** is an illustration showing a cutaway side view of the valve unit of FIG. **6A** being adjusted by an external magnetic device;

[0022] FIG. **6C** is an illustration showing a cross-sectional side view of the valve unit of FIG. **6A**;

[0023] FIG. **7A** is an illustration showing a cross-sectional side view of the valve unit of FIG. **6C** with boxes indicating areas visible under cross-sectional imaging;

[0024] FIG. **7B** is an illustration showing a cross-sectional image of the valve unit of FIG. **7A** captured by an ultrasound device with boxes indicating corresponding areas with respect to FIG. **7A**;

[0025] FIG. **8A** is an illustration showing an example embodiment of a dial indicator of the dial of FIG. **2A**;

[0026] FIGS. **8B**-**8K** are a series of illustrations showing example shapes of dial indicator surfaces of the dial of FIG. **2A**;

[0027] FIG. **9** is an illustration showing a cross-sectional perspective view of the valve device of FIG. **1A** having a second embodiment of a valve unit;

[0028]

[0029] FIG. **10A** is an illustration showing a top perspective view of a housing of the valve unit of FIG. **9**;

[0030] FIG. **10B** is an illustration showing a cross-sectional perspective view of the housing taken along line **10B**-**10B** of FIG. **10A**;

[0031] FIG. **10C** is an illustration showing a cross-sectional side view of the housing taken along line **10C**-**10C** of FIG. **10A**;

[0032] FIG. **10D** is an illustration showing a cross-sectional perspective view of the housing taken along line **10D**-**10D** of FIG. **10A**;

[0033] FIG. **11A** is an illustration showing a top perspective view of a dial of the valve unit of FIG. **9**;

[0034] FIG. **11B** is an illustration showing a bottom perspective view of the dial of FIG. **11A**;

[0035] FIG. **11C** is an illustration showing a bottom perspective view of the dial of FIG. **11B** coupled with a flow control unit;

[0036] FIG. **12** is an illustration showing a locking mechanism of the valve unit of FIG. 9 including engagement of the dial with the housing;

[0037] FIG. **13A** is an illustration showing a top perspective view of the valve unit of FIG. **9** with the housing in phantom;

[0038] FIG. **13B** is an illustration showing a first cutaway side view of the valve unit of FIG. **13A** being adjusted by an external magnetic device;

[0039] FIG. **13C** is an illustration showing a second cutaway side view of the valve unit of FIG. **13A** with a top surface of the housing removed;

[0040] FIG. **13D** is an illustration showing an exploded view of the valve unit of FIG. **13A**;

[0041] FIG. **13E** is an illustration showing a cross-sectional side view of the valve unit of FIG. **13A**;

[0042] FIG. **14A** is an illustration showing a cross-sectional side view of the valve unit of FIG. **13A** with the dial in a first position and a dial indicator indicating the first position of the dial;

[0043] FIG. **14B** is an illustration showing a cross-sectional side view of the valve unit of FIG. **14A** with the dial in a second position and the dial indicator indicating the second position of the dial;

[0044] FIG. **14C** is an illustration showing a cross-sectional side view of the valve unit of FIG. **14A** with the dial in a fourth position and the dial indicator indicating the fourth position of the dial;

[0045] FIG. **14D** is an illustration showing a cross-sectional side view of the valve unit of FIG. **14A** with the dial in a sixth position and the dial indicator indicating the sixth position of the dial;

[0046] FIG. **15A** is an illustration showing an alternate arrangement of the valve unit of FIG. **13A**;

[0047] FIG. **15B** is an illustration showing a cross-sectional side view of the valve unit of FIG. **15A** with boxes indicating areas visible under cross-sectional imaging;

[0048] FIG. **15C** is an illustration showing a cross-sectional image of the valve unit of FIG. **15A** captured by an ultrasound device with boxes indicating corresponding areas with respect to FIG. **15B**;

[0049] FIG. **16A** is an illustration showing a cross-sectional perspective view of a first embodiment of a flow indicator within a flow indicator chamber of the valve device of FIG. **1A**;

[0050] FIG. **16B** is an illustration showing a perspective view of the flow indicator of the valve device of FIG. **16A**;

[0051] FIG. **16C** is an illustration showing a cross-sectional side view of the flow indicator within the flow indicator chamber of FIG. **16A** when no material is flowing through a distal lumen in communication with the flow indicator chamber;

[0052] FIG. **16D** is an illustration showing a cross-sectional side view of the flow indicator within the flow indicator chamber of FIG. **16A** when material is flowing through a distal lumen in communication with the flow indicator chamber;

[0053] FIG. **17A** is an illustration showing a cross-sectional side view of a second embodiment of a flow indicator within a flow indicator chamber of the valve device of FIG. **1A** in a non-occluding position;

[0054] FIG. **17B** is an illustration showing an example image that can be captured by an ultrasound device when the flow indicator of FIG. **17A** is in the non-occluding position;

[0055] FIG. **17C** is an illustration showing a cross-sectional side view of the flow indicator within the flow indicator chamber of FIG. **17A** when the flow indicator is actuated into a distal lumen in communication with the flow indicator chamber for interrogation;

[0056] FIG. **17D** is an illustration showing a cross-sectional side view of the flow indicator within the flow indicator chamber of FIG. **17A** when the flow indicator is fully inserted into a distal lumen in communication with the flow indicator chamber for interrogation;

[0057] FIG. **17E** is an illustration showing a cross-sectional side view of the flow indicator within the flow indicator chamber of FIG. **17A** when material is not flowing through a distal lumen in communication with the flow indicator chamber;

[0058] FIG. **17F** is an illustration showing an example image that can be captured of the flow indicator of FIG. **17E** by an ultrasound device;

[0059] FIG. **17G** is an illustration showing a cross-sectional side view of the flow indicator within the flow indicator chamber of FIG. **17A** when material not flowing through a distal lumen in communication with the flow indicator chamber;

[0060] FIG. **17H** is an illustration showing an example image that can be captured of the flow indicator of FIG. **17G** by an ultrasound device;

[0061] FIG. **17I** is an illustration showing returning the flow indicator of FIG. 17G to the non-occluding position of FIG. 17A by an external magnetic device;

[0062] FIG. **18A** is an illustration showing a testing setup for testing visibility of various dial indicator surfaces and reference indicator surfaces by an ultrasound device;

[0063] FIG. **18B** is an illustration showing a testing setup for testing visibility of various dial indicator surfaces and reference indicator surfaces by an ultrasound device underneath simulated tissue (chicken breast); and

[0064] FIG. **19** is a process flow diagram showing an example method for interrogation and adjustment of the valve device of FIG. **1A**.

[0065] Corresponding reference characters indicate corresponding elements among the view of the drawings. The headings used in the figures do not limit the scope of the claims.

DETAILED DESCRIPTION

[0066] An implantable valve device includes a valve unit having a flow limiter in operative association with a dial for controlling a flow of material through a lumen in communication with the valve unit. The dial controls the flow limiter and includes a dial indicator viewable through cross-sectional imaging for determining and/or otherwise verifying a “pressure setting” of the valve unit. The dial is moveable between a plurality of positions corresponding with respective “pressure settings” of the flow limiter which can be determined based on a position of the dial indicator as observed through cross-sectional imaging. The valve unit can include a housing that encapsulates the dial therein and provides one or more reference indicators that enable a practitioner to determine an orientation of the valve unit and further clarify the position of the dial indicator (e.g., by comparing the position of the dial indicator to the reference indicator). The valve unit can be interrogated through conventional non-invasive cross-sectional imaging methods (e.g., ultrasound), as opposed to current technologies that require x-ray imaging for interrogation.

[0067] In one aspect, a “pressure setting” of the valve unit can be adjusted by rotating or otherwise altering a position of the dial to adjust a pressure applied at the flow limiter. The valve unit can include a locking mechanism that can prevent rotation of the dial by default but can be disengaged to enable adjustment of the position of the dial. In some embodiments, the dial can include a first magnetic-responsive element that, when activated by an external magnetic device, can disengage the locking mechanism and enable a practitioner to adjust a position of the dial. The dial can further include a second magnetic-responsive element that, when activated by an external magnetic device, can enable a practitioner to rotate the dial to a new position of the plurality of positions of the dial. The dial can include a cam that interfaces with the flow limiter such that the position of the dial determines the “pressure setting” of the flow limiter.

[0068] In a further aspect, the valve unit can include a flow indicator that is positionable within a lumen distal to the dial. The flow indicator can be moveable by flow of material through the lumen and is similarly viewable through cross-sectional imaging of the flow indicator. In some embodiments, the flow indicator can be configured for temporary positioning within the lumen so as not to occlude flow of material through the lumen during normal operation.

[0069] FIG. **1A** shows a valve device **10** having a valve unit **100** that can be interrogated by non-invasive cross-sectional imaging techniques. As shown, the valve unit **100** can include a housing **110** and a flow indicator 190 positioned within a distal lumen distal to the housing **110**. FIG. **1B** shows a side view of one embodiment of the valve device **10** implanted within a body and being interrogated by an ultrasound device **50**; the valve device **10** can be positioned between a bodily structure (such as skull **2**) and an external surface (such as scalp **4**) of the body. When interrogating the valve device **10**, probing sound waves emitted by ultrasound device **50** can be directed towards the valve device **10** as shown to obtain a cross-sectional image of the valve device **10**.

[0070] FIG. **2A** shows a cross-sectional view of the valve device **10** and valve unit **100** of FIGS. **1A** and **1B**. As shown, the housing **110** includes a cavity **120** that receives a dial **160** therein for controlling a flow of material through the valve unit **100** and for indicating a “pressure setting” of the valve unit **100** when observed through non-invasive cross-sectional imaging techniques such as ultrasound. The dial **160** is moveable within the housing **110** between a plurality of positions; the position of the dial **160** corresponds with the “pressure setting” of the valve unit **100**. The dial **160** includes one or more dial indicators **170** that indicate the position of the dial **160** (and therefore the “pressure setting” of the valve unit **100**) and can be observed through cross-sectional imaging. The housing **110** includes one or more reference indicators **130** that can aid a practitioner in determining an orientation of the valve unit **100** and determining a position of the one or more dial indicators **170** to ensure correct interpretation of the “pressure setting” of the valve unit **100**. As further shown, and as will be discussed in greater detail below, the valve unit **100** can include a locking mechanism **150** having or otherwise associated with a tensioning element **175** that prevents unintentional alteration of the position of the dial **160**. FIG. **2A** further shows an outlet **125** of the valve unit **100** and the flow indicator **190** that indicates flow of material though the valve unit **100** when observed through non-invasive cross-sectional imaging techniques such as ultrasound.

[0071] FIGS. **2B** and **2C** show simplified illustrations of the valve unit **100**, where FIG. **2C** shows one example valve unit **100** having reference indicators **130** in a first arrangement within the housing **110** relative to the dial **160** and FIG. **2C**

shows another example valve unit **100** having reference indicators **130** in a second arrangement within the housing **110** relative to the dial **160**.

[0072] FIGS. **3A**-**3E** illustrate the housing **110** of the valve unit **100** including the cavity **120** that receives the dial **160** (FIG. **2A**) therein. As shown, the housing **110** can include a top surface **121**, a bottom surface **122** defined opposite from the top surface **121**, and sidewalls **123** between the top surface **121** and the bottom surface **122** that define the outlet **125**. The housing **110** further defines an inlet **124** formed generally opposite from the outlet **125**; in operation, material enters the housing **110** at the inlet **124** and exits the housing **110** at the outlet **125**. As shown in FIGS. **3B** and **3C**, the housing **110** can include one or more radiopaque elements (e.g., first radiopaque element **134** and second radiopaque element **135**) that enable aspects of the valve unit **100** to be detectable under x-ray in addition to cross-sectional imaging. FIGS. **3C**-**3E** show the housing **110** having the reference indicators **130**; in particular, the reference indicators **130** can include a plurality of reference indicator surfaces **131** that can be configured in a stepped arrangement as shown. When viewed in cross-section from the side of the housing **110**, the varying vertical positions of each reference indicator surface **131** are clearly visible and remain stationary relative to the housing **110**; this aspect enables practitioners to use the reference indicators **130** as reference to determine a position of the dial **160**, and thereby the “pressure setting” enforced by the dial **160**. The housing **110** can also include a dial stem **132** that receives the dial **160** in an arrangement that will be discussed in greater detail below. The housing **110** can further include one or more locking mechanism protrusions **151** of the locking mechanism **150** (FIG. **5**) that also receive the dial **160** in an arrangement that will be discussed in greater detail below. In the example shown, the locking mechanism protrusions **151** surround the dial stem **132**. In a further aspect, with reference to FIG. **3E**, the housing **110** can include a flow lever stem **133** positioned near the inlet **124** for receipt of a flow lever **182** (FIG. **4C**) in an arrangement that will be discussed in greater detail below.

[0073] FIGS. **4A**-**4C** show the dial **160** of the valve unit **100** that can be encapsulated within the housing **110** as discussed above and as shown in the cross-sectional image of FIG. **2A**. The dial **160** is moveable between the plurality of positions within the housing **110** and controls the flow of material through the valve unit **100**; in particular, the dial **160** can be rotated between the plurality of positions to select a “pressure setting” for the flow of material though the valve unit **100**. As shown, the dial **160** includes a top surface **161**, a bottom surface **162** defined opposite the top surface **161**, and a sidewall **163** between the top surface **161** and the bottom surface **162**. The dial **160** further includes a dial aperture **172** that receives the dial stem **132** of the housing **110** when the dial **160** is coupled with the housing. The top surface **161** can include the dial indicators **170** that indicate the position of the dial **160** when viewed through cross-sectional imaging. The dial indicators **170** include a plurality of dial indicator surfaces **171** that each define a unique vertical position and/or a unique cross-sectional shape when viewed through cross-sectional imaging. As the dial **160** rotates within the housing **110** between different positions (e.g., between different angular positions), different dial indicator surfaces **171** become visible through cross-sectional imaging. In the example shown in FIG. **4A**, the dial indicators **170** include six unique dial indicator surfaces **171**; the positions of these dial indicator surfaces **171** relative to the housing **110** (including the reference indicator surfaces **131** of the housing **110**) can inform practitioners as to the position of the dial **160** and thereby the “pressure setting” of the valve unit **100**. Note that while six unique dial indicator surfaces **171** are shown in FIGS. **4A**-**4C**, other embodiments are contemplated and shown herein that include more or fewer unique dial indicator surfaces **171** to corresponding “pressure settings”. In a further aspect, the dial **160** can also include a third radiopaque element **166** that enables a practitioner to determine a position of the dial **160** through x-ray imaging.

[0074] FIG. **4B** shows the bottom surface **162** of the dial **160**. As shown, the bottom surface **162** includes one or more locking mechanism recesses **152** of the locking mechanism **150** (FIG. **5**) that receive the one or more locking mechanism protrusions **151** (FIGS. **3C**-**3E**) positioned along the bottom surface **122** of the housing **110**. In a further aspect, the bottom surface **162** of the dial **160** includes a cam **164** having a plurality of cam surfaces **165** as shown. With additional reference to FIG. **4C**, the cam **164** of the dial **160** engages a flow control unit **180** that controls a flow of material that enters the housing 110 through the inlet 124 (FIG. **3E**). In the example shown, each cam surface **165** of the plurality of cam surfaces **165** of the dial **160** corresponds with a respective dial indicator surface **171** of the plurality of dial indicator surfaces **171**. The flow control unit **180** can include the flow lever **182** in operative association with a cam follower **188** that contacts a cam surface **165** of the plurality of cam surfaces **165** as shown. The flow lever **182** can also include a flow occluder **189** positioned opposite from the cam follower **188** that contacts the inlet **124** of the housing **110** at selective pressure settings to control the flow of material through the inlet **124**. In the embodiment shown, the cam surface **165** occupied by the cam follower **188** determines a pressure applied at the inlet **124** by the flow lever **182**; as such, the cam surface **165** occupied by the cam follower **188** corresponds directly with the position of the dial **160**. In some embodiments, the flow lever **182** can include a first lever arm **184** and a second lever arm **186** that couple at the flow lever stem **133** (FIG. **3E**) of the housing **110**.

[0075] As shown, the dial **160** can include a magnetic-responsive element **174** that, when influenced by external application of a magnetic force by an external magnetic device **90** (FIG. **6B**), enables alteration of the position of the dial **160**. In particular, when influenced by an external magnetic device **90**, the magnetic-responsive element **174** can be attracted to or repulsed by the external magnetic device **90** and can thus be used to rotate or otherwise move the dial **160** to a desired position of the plurality of positions of the dial **160**. Rotation of the dial **160** to a new position will also cause the cam follower **188** of the flow control unit **180** to occupy a new cam surface **165** of the cam **164** of the dial **160**, which changes the “pressure setting” of the valve unit **100**.

[0076] FIG. **5** shows engagement of the dial **160** with the housing **110** at a locking mechanism **150** of the valve unit **100**. As discussed, the housing **110** can include the locking mechanism protrusions **151** of the locking mechanism **150** along the bottom surface **122** of the housing **110** and surrounding the dial stem **132**. The housing **110** is shown in FIG. **5** with the top surface **121** removed. The dial **160** can include the locking mechanism recesses **152** of the locking mechanism **150** along the bottom surface **162** of the dial **160** and surrounding the dial aperture **172**. As illustrated, the dial **160** couples with the housing **110** by insertion of the dial stem **132** of the housing **110** into the dial aperture **172** of the dial **160**. The locking mechanism recesses **152** along the dial **160** engage the locking mechanism protrusions **151** along the housing **110** as shown. When the magnetic-responsive element **174** is not being activated by the external magnetic device **90** (e.g., absent external application of the magnetic force by the external magnetic device **90**), the bottom surface **162** of the dial **160** rests against the bottom surface **122** of the housing **110** and the locking mechanism protrusions **151** couple with the locking mechanism recesses **152** to prevent rotation of the dial **160** within the housing **110**. When the magnetic-responsive element **174** is being activated by the external magnetic device **90**, the bottom surface **162** of the dial **160** lifts away from the bottom surface **122** of the housing **110** to deactivate the locking mechanism **150** such that the locking mechanism protrusions **151** decouple from the locking mechanism recesses **152** to allow rotation of the dial **160** within the housing **110**. With the locking mechanism **150** deactivated, the dial **160** can be rotated to a new position by the external magnetic device **90** interacting with the magnetic-responsive element **174**.

[0077] FIGS. **6A**-**6C** show the valve unit **100** including the dial **160**, the flow control unit **180** and the housing **110**. As discussed, the dial aperture **172** of the dial **160** receives the dial stem **132** of the housing **110**. The cam follower **188** of the flow control unit **180** contacts the cam **164** of the dial **160** to selectively control a flow of material through the valve unit **100**; the “pressure setting” of the valve unit **100** depends on which cam surface **165** of the cam **164** is occupied by the cam follower **188** of the flow control unit **180**. The flow lever **182** of the flow control unit **180** couples with the flow lever stem **133** of the housing **110** as shown. In some embodiments, the flow lever **182** can include the flow occluder **189** that contacts the inlet **124** of the housing **110** at variable pressure (e.g., dependent upon which cam surface **165** of the cam **164** is occupied by the cam follower **188**) to control the flow of material through the valve unit **100**. As further shown, the dial **160** can include the tensioning element **175** positioned between the top surface **161** of the dial **160** and the top surface **121** of the housing **110**. The tensioning element **175** ensures that the bottom surface **162** of the dial **160** rests against the bottom surface **122** of the housing **110** and the locking mechanism protrusions **151** couple with the locking mechanism recesses **152** to prevent rotation of the dial **160** within the housing **110** when the magnetic-responsive element **174** is not being activated by the external magnetic device **90**. When the magnetic-responsive element **174** is being activated by the external magnetic device **90** as shown in FIG. **6B**, the tensioning element **175** can compress to enable the bottom surface **162** of the dial **160** to lift up from the bottom surface **122** of the housing **110** and deactivate the locking mechanism **150** such that the locking mechanism protrusions **151** decouple from the locking mechanism recesses **152**. To rotate the dial **160** and alter the setting of the dial **160**, a practitioner can lift the dial **160** away from the bottom surface **122** of the housing **110** by the external magnetic device **90** and rotate the external magnetic device **90** in a clockwise or counterclockwise direction such that the magnetic-responsive element **174** follows the external magnetic device **90**, thereby rotating the dial **160** in the clockwise or counterclockwise direction. This motion likewise causes the flow occluder **189** of the flow control unit **180** to adjust a pressure being applied at the inlet **124** of the housing **110**.

[0078] FIG. **6C** shows a cross-sectional side view of the valve unit **100**. The dial **160** is shown in a position of the plurality of positions of the dial **160** identifiable by positions of a first dial indicator surface **171A** and a second dial indicator surface **171B** of the dial indicator **170** as shown. In the example, the first dial indicator surface **171A** is at a first height and has a first shape (solid block across); the second dial indicator surface **171B** is at a second height and has a second shape (notched top). The respective heights and shapes of the first dial indicator surface **171A** and the second dial indicator surface **171B** are visible under cross-sectional imaging, along with the reference indicators **130** of the housing **110** which can be used to verify an orientation of the valve unit **100** and discern the position of the dial **160** (e.g., by comparison of the heights and shapes of the first dial indicator surface **171A** and the second dial indicator surface **171B** with the reference indicator surfaces **131** of the reference indicators **130**). Further, the flow indicator **190** is shown positioned distal to the outlet **125** of the housing **110**.

[0079] FIGS. **7A** and **7B** show an example cross-sectional view of the valve unit **100**, along with a corresponding cross-sectional image of the housing **110** and the dial **160** captured by ultrasound. The reference indicators **130** are indicated at Box **A** of FIG. **7A** and FIG. **7B** in both images. A first dial indicator surface **171A** and a second dial indicator surface **171B** of the dial indicator **170** are respectively visible at Box **B** and Box **C** of FIG. **7A** and FIG. **7B**. Note that the first dial indicator surface **171A** includes a notched top; this is well-distinguishable within the captured cross-sectional image of FIG. **7B** from the second dial indicator surface **171B**, which shows a solid top in FIG. **7B**. The locking mechanism **150** is also visible in both FIGS. **7A** and **7B**, indicated by Box **D** in both images. A practitioner can determine the position of the dial **160**, and thereby the “pressure setting” of the valve unit **100**

by identifying relative positions of the reference indicators **130** and the first dial indicator surface **171A** and the second dial indicator surface **171B** of the dial indicator **170** within the cross-sectional image captured by ultrasound. The practitioner can determine an orientation of the valve unit **100** by observing which side the reference indicators **130** are on, and can then determine the “pressure setting” of the valve unit **100** by comparing heights and shapes of the first dial indicator surface **171A** and the second dial indicator surface **171B** of the dial indicator **170** relative to one another and relative to the reference indicators **130**.

[0080] FIGS. **8A**-**8K** show example dial indicators of the dial **160**. FIG. **8A** shows one example dial **160** having ten settings and ten dial indicator surfaces **171**; when viewed in cross-section, a first dial indicator surface and a corresponding second dial indicator surface would be at opposite “sides” of the dial **160** (e.g., if the first dial indicator surface on the “left” is surface #5 when captured under cross-sectional image, then the second dial indicator surface on the “right” would be surface #10). As shown, each respective dial indicator surface **171** can have a unique height to distinguish itself from other dial indicator surfaces **171**; when visually compared with the reference indicators **130** a practitioner can determine which “pressure setting” the valve unit **100** is at.

[0081] FIGS. **8B**-**8K** show various shapes of dial indicator surfaces **171** that can be distinguished under cross-sectional imaging (as demonstrated in FIGS. **7A** and **7B** discussed above). FIG. **8B** shows a simple “solid block” shape, FIG. **8C** shows a narrow triangular notch shape, FIG. **8D** shows a narrow semicircular notch shape, and FIG. **8E** shows a single squared notch shape. FIG. **8F** shows a wide triangular notch shape, FIG. **8G** shoes a wide semicircular notch shape, and FIG. **8H** shows a double squared notch shape. FIG. **8I** shows an asymmetric notch shape (that may also help with distinguishing an orientation of the device as well), FIG. **8J** shows a semicircular protrusion shape, and FIG. **8K** shows a triangular protrusion shape. The dial indicator surfaces **171** and reference indicator surfaces **131** can be of any suitable shape, size, and general configuration including but not limited to the examples shown in FIGS. **2A** and **4A**-**8K**.

[0082] FIG. **9** shows a cross-sectional view of a second embodiment of a valve unit **200** of the valve device **10** of FIGS. **1A** and **1B**. As shown, a housing **210** of the valve unit **200** includes a cavity **220** that receives a dial **260** therein for controlling a flow of material through the valve unit **200** and for indicating a "pressure setting" of the valve unit **200** when observed through non-invasive cross-sectional imaging techniques such as ultrasound. The dial **260** is moveable within the housing **210** between a plurality of positions; the position of the dial **260** corresponds with the "pressure setting" of the valve unit **200**. The dial **260** includes a dial indicator **270** that indicates the position of the dial **260** (and therefore the "pressure setting" of the valve unit **200**) and can be observed through cross-sectional imaging. The housing **210** includes one or more reference indicators **230** (FIG. **10D**) that can aid a practitioner in determining an orientation of the valve unit **200** and determining a position of the dial indicator **270** to ensure correct interpretation of the "pressure setting" of the valve unit **200**. As further shown, and as will be discussed in greater detail below, the valve unit **200** can include a locking mechanism **250** (FIG. **12**) having or otherwise associated with a tensioning element **275** that prevents unintentional alteration of the position of the dial **260**. FIG. **9** further shows an outlet **225** of the valve unit **200** and a flow indicator **290** that indicates flow of material through the valve unit **200** when observed through non-invasive cross-sectional imaging techniques such as ultrasound.

[0083] FIGS. **10A**-**10D** illustrate the housing **210** of the valve unit **200** that receives the dial **260** (FIG. **9**) therein. As shown, the housing **210** can include a top surface **221**, a bottom surface **222** defined opposite from the top surface **221**, and sidewalls **223** between the top surface **221** and the bottom surface **222** that define the outlet **225**. The housing **210** further defines an inlet **224** opposite from the outlet **225**; in operation, material enters the housing **210** at the inlet **224** and exits the housing **210** at the outlet **225**. In some embodiments, the housing **210** can include one or more radiopaque elements **234** that enable aspects of the valve unit **200** to be detectable under x-ray in addition to cross-sectional imaging. FIGS. **10B**-**10D** show the housing **210** having the reference indicators **230**; in particular, the reference indicators **230** can include a plurality of reference indicator surfaces **231** that can be configured in a stepped arrangement as shown. In the embodiment shown, the reference indicators **230** can include a first reference indicator grouping **239A** and a second reference indicator grouping **239B** along opposing sides of the cavity **220** that each include reference indicator surfaces **231** at different heights to help indicate an orientation of the valve unit **200**. When viewed in cross-section from a side of the housing **210**, the varying vertical positions of each reference indicator surface **231** are clearly visible and remain stationary relative to the housing **210**; this aspect enables practitioners to use the reference indicators **230** as reference to determine a position of the dial **260**, and thereby the “pressure setting” enforced by the dial **260**. The housing **210** can also include a dial stem **232** that receives the dial **260** in an arrangement that will be discussed in greater detail below; in the example shown, the housing **210** can further include a locking mechanism protrusion **251** of the locking mechanism **250** (FIG. **12**) along the dial stem **232** that engages the dial **260** in an arrangement that will be discussed in greater detail below. In a further aspect, with reference to FIG. **10B**, the housing **210** can include a flow lever receptacle **238** positioned near the inlet **224** for coupling with a flow lever **282** (FIG. **11C**) in an arrangement that will be discussed in greater detail below. The housing **210** can further include a top surface recess **226** having a dial guide element **236** protruding therefrom for capture of the dial 260, and a disc guide element **237** that extends from the top surface **221** to engage the dial indicator **270** in an arrangement which will be described in greater detail herein.

[0084] FIGS. **11A-11C** show the dial **260** of the valve unit **200** that can be encapsulated within the housing **210** as discussed above and as shown in the cross-sectional image of FIG. **9**. The dial **260** is moveable between the plurality of positions within the housing **210** and controls the flow of material through the valve unit **200**; in particular, the dial **260** can be rotated between the plurality of positions to select a “pressure setting” for the flow of material though the valve unit **200**. As shown, the dial **260** includes a top surface **261**, a bottom surface **262** defined opposite the top surface **261**. The dial **260** further includes a dial aperture **272** that receives the dial stem **232** of the housing **210** when the dial **260** is coupled with the housing.

[0085] The dial **260** can include a lead screw **263** protruding outward from the top surface **261**; as shown, the lead screw **263** includes a lead screw groove **267** that engages a dial indicator **270** of the dial **260**. The lead screw **263** can include a lead screw aperture **268** that engages the dial guide element **236** of the housing **210** at a top of the lead screw **263**. The dial indicator **270**, in contrast to the dial indicator **170** of FIGS. **11A-11C**, can be a disc-shaped element that engages the lead screw **263** and is operable for translation in the vertical direction along the lead screw **263** when the dial **260** rotates between different positions (e.g., between different angular positions). The dial indicator **270** includes a dial indicator surface **271** that is visible under cross-sectional imaging. As such, the dial indicator **270** indicates a “pressure setting” of the valve unit **200** by its vertical position along the lead screw **263** when viewed through cross-sectional imaging. As shown, the dial indicator **270** can include a first indicator aperture **276** through a center of the dial indicator **270** having a dial follower **278** that engages the lead screw **263**. The dial indicator **270** can also include a second indicator aperture **277** adjacent to the first indicator aperture **276** that engages the disc guide element **237** of the housing **210** and ensures that the dial indicator **270** reliably moves in the vertical direction when the dial **260** rotates.

[0086] FIG. **11B** shows the bottom surface **262** of the dial **260**. As shown, the bottom surface **262** includes a plurality of locking mechanism recesses **252** of the locking mechanism **250** (FIG. **12**) that can each receive the locking mechanism protrusion **251** (FIGS. **10B** and **10C**) at the dial stem **232** of the housing **210**. In a further aspect, the bottom surface **262** of the dial **260** includes a cam **264** having a plurality of cam surfaces **265** as shown. With additional reference to FIG. **11C**, the cam **264** of the dial **260** engages a flow control unit **280** that controls a flow of material that enters the housing **210** through the inlet **224** (FIGS. **10B** and **10C**). In the example shown, each cam surface **265** of the plurality of cam surfaces **265** of the dial **260** corresponds with a respective locking mechanism recess **252** of the plurality of locking mechanism recesses **252**, which in turn correspond with an angular position of the dial **260**. The flow control unit **280** can include the flow lever **282** in operative association with a cam follower **288** that contacts a cam surface **265** of the plurality of cam surfaces **265** as shown. The flow lever **282** can also include a flow occluder **289** positioned opposite from the cam follower **288** that contacts the inlet **224** of the housing **210** at selective pressure settings to control the flow of material through the inlet **224**. In the embodiment shown, the cam surface **265** occupied by the cam follower **288** determines a pressure applied at the inlet **224** by the flow occluder **289**; as such, the cam surface **265** occupied by the cam follower **288** corresponds directly with the position of the dial **260**. In some embodiments, the flow lever **282** can include a first lever arm **284** and a second lever arm **286** that couple at a hinge **285** that inserts into the flow lever receptacle **238** (FIG. **10B**) of the housing

210. Further, as shown, the cam **264** can include a “minimum flow” cam surface **265A** and a “maximum flow” cam surface **265B**. When the cam follower **288** occupies the minimum flow cam surface **265A**, the pressure applied at the inlet **224** by the flow occluder **289** is minimized and the dial indicator **270** is at a maximum height along the lead screw **263**; conversely, when the cam follower **288** occupies the maximum flow cam surface **265B**, the pressure applied at the inlet **224** by the flow occluder **289** is maximized and the dial indicator **270** is at a minimum height along the lead screw **263**.

[0087] In the example shown in FIGS. **11A**-**11C**, the dial **260** is configured for eight unique “pressure settings”, dictated by the plurality of cam surfaces **265** and the plurality of locking mechanism recesses **252** that correspond with respective cam surfaces **265**. The vertical position of the dial indicator **270** relative to the housing **210** (including the reference indicator surfaces **231** of the housing **210**) can inform practitioners as to the position of the dial **260** and thereby the “pressure setting” of the valve unit **200**. Note that while eight unique dial indicator surfaces **271** are shown in FIGS. **11A**-**11C**, other embodiments are contemplated and shown herein that include more or fewer unique dial indicator surfaces **271** to corresponding “pressure settings”. In a further aspect, the dial **260** can also include a radiopaque element **266** that enables a practitioner to determine a position of the dial **260** through x-ray imaging if necessary.

[0088] As shown, the dial **260** can include a magnetic-responsive element (e.g., a first magnetic-responsive element **273** and a second magnetic-responsive element **274**) that, when influenced by an externally-applied magnetic force by the external magnetic device **90**, enables alteration of the position of the dial **260**. The first magnetic-responsive element **273** can be positioned adjacent to the lead screw **263** for rotating the dial **260**; the second magnetic-responsive element **274** can be positioned within the lead screw **263**, particularly within the dial aperture **272**, for disengaging the locking mechanism **250** and lifting the dial **260** away from the bottom surface **222** of the housing **210** such that the dial **260** can subsequently be rotated using the first magnetic-responsive element **273** and the external magnetic device **90** in an arrangement which will be discussed in greater detail herein. In particular, when influenced by an external magnetic device **90**, the first magnetic-responsive element **273** and the second magnetic-responsive element **274**

can be attracted to or repulsed by the external magnetic device **90** and can thus be used to rotate or otherwise move the dial **260** to a desired position of the plurality of positions of the dial **260**. Rotation of the dial **260** to a new position will also cause the cam follower **288** of the flow control unit **280** to occupy a new cam surface **265** of the cam **264** of the dial **260**, which changes the “pressure setting” of the valve unit **200**.

[0089] FIG. **12** shows the engagement of the dial **260** with the housing **210** at a locking mechanism **250** of the valve unit **200**. As discussed, the housing **210** can include the locking mechanism protrusion **251** of the locking mechanism **250** along the bottom surface **222** of the housing **210** and surrounding the dial stem **232**. The housing **210** is shown in FIG. **12** with the top surface **221** removed. The dial **260** can include the plurality of locking mechanism recesses **252** of the locking mechanism **250** along the bottom surface **262** of the dial **260** and surrounding the dial aperture **272**. As illustrated, the dial **260** couples with the housing **210** by insertion of the dial stem **232** of the housing **210** into the dial aperture **272** of the dial **260**. One locking mechanism recess **252** of the plurality of locking mechanism recesses **252** along the dial **260** engage the locking mechanism protrusion **251** along the dial stem **232** of the housing **210** as shown. When the second magnetic-responsive element **274** is not being activated by the external magnetic device **90** (e.g., absent external application of the magnetic force by the external magnetic device **90**), the bottom surface **262** of the dial **260** rests against the bottom surface **222** of the housing **210** and the locking mechanism protrusion **251** couples with the locking mechanism recess **252** to prevent rotation of the dial **260** within the housing **210**. When the second magnetic-responsive element **274** is being activated by the external magnetic device **90**, the bottom surface **262** of the dial **260** lifts up from the bottom surface **222** of the housing **210** to deactivate the locking mechanism **250** such that the locking mechanism protrusion **251** decouples from the locking mechanism recess **252** to allow rotation of the dial **260** within the housing **210**. With the locking mechanism **250** deactivated, the dial **260** can be rotated to a new position by the external magnetic device **90** interacting with the first magnetic-responsive element **273**.

[0090] FIGS. **13A**-**13E** show the valve unit **200** including the dial **260**, the flow control unit **280** and the housing **210**, with FIG. **13D** showing an exploded view of the valve unit **200**. As discussed, the dial aperture **272** of the dial **260**

receives the dial stem **232** of the housing **210** at a bottom of the dial **260**; likewise, the lead screw aperture **268** of the lead screw **263** receives the dial guide element **236** at a top of the lead screw **263** as shown. The dial indicator **270** receives the lead screw **263** of the dial **260** at the first indicator aperture **276** of the dial indicator **270** and receives the disc guide element **237** of the housing **210** at the second indicator aperture **277** as shown. The cam follower **288** of the flow control unit **280** contacts the cam **264** of the dial **260** to selectively control a flow of material through the valve unit **200**; the "pressure setting" of the valve unit **200** depends on which cam surface **265** of the cam **264** is occupied by the cam follower **288** of the flow control unit **280**. The hinge **285** of the flow lever **282** of the flow control unit **280** couples with the flow lever receptacle **238** of the housing **210** as shown. In some embodiments, the flow lever **282** can include the flow occluder **289** that contacts the inlet **224** of the housing **210** at variable pressure (e.g., dependent upon which cam surface **265** of the cam **264** is occupied by the cam follower **288**) to control the flow of material through the valve unit **200**. As further shown, the dial **260** can include the tensioning element **275** positioned between the lead screw **263** of the dial **260** and the top surface **221** of the housing **210**; in the embodiment shown, the tensioning element **275** can be positioned within the top surface recess **226** of the housing **210**, where the dial guide element **236** extends from the top surface recess **226** as shown in FIG. **13E**. The tensioning element **275** ensures that the bottom surface **262** of the dial **260** rests against the bottom surface **222** of the housing **210** and the locking mechanism protrusion **251** couples with a locking mechanism recess **252** of the plurality of locking mechanism recesses **252** to prevent rotation of the dial **260** within the housing **210** when the second magnetic-responsive element **274** is not being activated by the external magnetic device **90**. When the second magnetic-responsive element **274** is being activated by the external magnetic device **90**, the tensioning element **275** can compress to enable the bottom surface **262** of the dial **260** to lift up from the bottom surface **222** of the housing **210** and deactivate the locking mechanism **250** such that the locking mechanism protrusion **251** decouples from the locking mechanism recess **252**. To rotate the dial **260** and alter the setting of the dial **260**, a practitioner can lift the dial **260** away from the bottom surface **222** of the housing **210** by the external magnetic device **90** (which interacts with the first magnetic-responsive element **273** and the second magnetic-responsive element

274) and rotate the external magnetic device **90** in a clockwise or counterclockwise direction such that the first magnetic-responsive element **273** follows the external magnetic device 90, thereby rotating the dial **260** (including the lead screw **263**) in the clockwise or counterclockwise direction. This motion likewise causes the flow occluder **289** of the flow control unit **280** to adjust a pressure being applied at the inlet **224** of the housing **210**.

[0091] Further, the flow indicator **290** is shown positioned distal to the outlet **225** of the housing **210**. FIG. **13E** shows a cross-sectional side view of the housing **210** and the dial **260**. The dial **260** is shown in a position of the plurality of positions of the dial **260** identifiable by the position the dial indicator surface **271** of the dial indicator **270** as shown. The vertical position of the dial indicator surface **271** is visible under cross-sectional imaging.

[0092] FIGS. **14A**-**14D** show a series of cross-sectional side views of the valve unit **200**, particularly the dial indicator **270** and the reference indicators **230**. In the examples shown, the reference indicators **230** include the first reference indicator grouping **239A** and the second reference indicator grouping **239B** along opposing sides of the cavity **220** that each include reference indicator surfaces **231** at different heights to help indicate an orientation of the valve unit **200**. FIG. **14A** shows a first “pressure setting” of the valve unit **200** indicated by a first vertical position of the dial indicator **270** along the lead screw **263**, where the reference indicators **230** along the sides of the cavity **220** can provide reference to a practitioner to help discern the vertical position of the dial indicator **270**; note that the cam follower (not shown) would occupy the minimum flow cam surface **265A** along the cam **264** of the dial **260** visible in FIG. **14A**. FIG. **14B** shows a second “pressure setting” of the valve unit **200** indicated by a second vertical position of the dial indicator **270** along the lead screw **263**; note that the cam follower (not shown) would occupy another cam surface **265**. FIG. **14C** shows a fourth “pressure setting” of the valve unit **200** indicated by a fourth vertical position of the dial indicator **270** along the lead screw **263**, and FIG. **14D** shows a sixth “pressure setting” of the valve unit **200** indicated by a sixth vertical position of the dial indicator **270** along the lead screw **263**.

[0093] FIGS. **15A**-**15C** shows an alternate arrangement of the valve unit **200** of FIGS. **9**-**14D** where reference indicators **230** are grouped in a single grouping but still show the plurality of reference indicator surfaces **231** at different heights to help indicate an orientation of the valve unit **200**. The dial **260** includes the dial indicator **270** at a vertical position along the lead screw **263** as shown. FIG. **15B** shows a cross-sectional view of the housing **210** and the dial **260** of FIG. **15A**, which can be compared directly with FIG. **15C** which shows a corresponding cross-sectional image of the housing **210** and the dial **260** captured by ultrasound. The reference indicators **230** are indicated by Box **A** of FIGS. **15B** and **15C**, the dial indicator **270** is indicated by Box **B** of FIGS. **15B** and **15C**, and the dial **260** is indicated by Box **C** of FIGS. **15B** and **15C**. A practitioner can determine the position of the dial indicator **270**, and thereby the “pressure setting” of the valve unit **200** by identifying relative positions of the reference indicators **230**, the dial indicator **270** and dial **260** within the cross-sectional image captured by ultrasound. The practitioner can determine an orientation of the valve unit **200** by observing which side the reference indicators **230** are on and can then determine the “pressure setting” of the valve unit **200** by comparing the vertical position of the dial indicator **270** relative to the reference indicators **230**.

[0094] FIGS. **16A-16D** show a first embodiment of the flow indicator **390** positioned distal to an outlet **325** of a housing **310**. The flow indicator **390** can be positioned within a flow indicator chamber **394** that communicates with or otherwise forms a part of a distal lumen **395** that communicates with the outlet **325** of the housing **310**. The flow indicator **390** can similarly be viewed through cross-sectional imaging to indicate if material is flowing out of the housing **310**. The flow indicator **390** can include a flow indicator hinge **391** that couples within the flow indicator chamber **394** and enables the flow indicator **390** to rotate about the flow indicator hinge **391** when material is flowing through the distal lumen **395**. As shown, the flow indicator **390** can include a flow indicator bend **392** that aids practitioners in identifying the flow indicator **390** within cross-sectional imaging. FIG. **16C** shows one example arrangement of the flow indicator **390** positioned within the distal lumen **395** when no material is flowing through the distal lumen **395**; in this example, the flow indicator bend **392** sits “perpendicularly” within the flow indicator chamber **394** as shown. Conversely, FIG. **16D** shows the flow indicator **390** of FIG. **16C** when material is flowing through the distal lumen **395**; in this example, the flow indicator bend **392** is pushed outward by the material to an angled position within the flow indicator chamber **394** as shown.

[0095] FIGS. **17A**-**17I** show a second embodiment of the flow indicator **490** positioned distal to an outlet **425** of a housing (not shown, but analogous to housing **110** or **210** of FIGS. **1A**-**15C**). The flow indicator **490** can be positioned within a flow indicator chamber **480** that communicates with or otherwise forms a part of a distal lumen **495** that communicates with the outlet **425** of the housing. The flow indicator **490** can similarly be viewed through cross-sectional imaging to indicate if material is flowing out of the housing. The flow indicator chamber **480** can include a flow indicator seat **486** positioned above the distal lumen **495** such that when the flow indicator **490** is not being interrogated, the flow indicator **490** can rest within the flow indicator seat **486** without occluding the flow of material through the distal lumen **495**. In this arrangement, the flow indicator seat **486** can include a first magnetic element **488** that magnetically interacts with a flow indicator capture element **494** (which can be magnetic-responsive) of the flow indicator **490** to retain the flow indicator **490** within the flow indicator seat **486** as shown in FIG. **17A** when not being interrogated. FIG. **17B** shows an example diagram of how the flow indicator **490** would appear in a corresponding cross-sectional image when in the arrangement of FIG. **17A**. As shown, the flow indicator **490** can similarly include a flow indicator bend **492** that aids practitioners in identifying the flow indicator **490** within cross-sectional imaging. The flow indicator **490** can include a flow indicator hinge **491** that couples within the flow indicator chamber **480** and enables the flow indicator **490** to rotate about the flow indicator hinge **491** when material is flowing through the distal lumen 495 and/or following manual actuation for interrogation.

[0096] The flow indicator chamber **480** can further include a flow indicator actuator **484** that, when manually actuated, causes the flow indicator **490** to rotate from the “non-occluding” position shown in FIG. **17A** to an “intermediate” position shown in FIG. **17C**, and finally to an “interrogating” position shown in FIG. **17D**. Once the flow indicator **490** is in the “interrogating” position shown in FIG. **17D**, the flow indicator actuator **484** can return to a default position as shown in FIG. **17E** (this may be accomplished by a tensioning element, not shown). FIG. **17F** shows an example diagram of how the flow indicator **490** would appear in a corresponding cross-sectional image when in the arrangement of FIG. **17E**. When no material is flowing through the distal lumen **495**, the flow indicator bend **492** sits "perpendicularly" within the flow indicator chamber **480**. FIG. **17G** shows the flow indicator **490** of FIG. **17E** when material is flowing through the distal lumen **495**; in this example, the flow indicator bend **492** is pushed by the material to an angled position within the flow indicator chamber **480** as shown. FIG. **17H** shows an example diagram of how the flow indicator **490** would appear in a corresponding cross-sectional image when in the arrangement of FIG. **17G**. To return the flow indicator **490** to the "non-occluding" position shown in FIG. **17A**, an external magnetic device **90** can activate the first magnetic element **488** and/or the flow indicator capture element **494** of the flow indicator **490** to draw the flow indicator capture element **494** and thereby the flow indicator **490** away from the distal lumen **495** and into the flow indicator seat **486** as shown in FIG. **17I**.

[0097] FIGS. **18A** and **18B** show various testing arrangements that were used to determine how well the indicators appear in captured cross-sectional images, especially reference indicators **230** and dial indicator **270** of FIGS. **2A**-**8K**. FIG. **18B** in particular shows how these indicators appear underneath chicken breast (simulating scalp tissue). As shown, the stepped reference marker (corresponding with reference indicators **230** of FIGS. **2A**-**15C**), the flat setting marker, and the "alternate-profile" marker are well-distinguishable when viewed through non-invasive cross-sectional imaging.

[0098] The present disclosure provides further discussion on material properties that are contemplated for various components of the valve device 10 and associated valve units **100** or **200** outlined herein.

[0099] In one aspect, an outer covering of the valve device 10 can be of a biocompatible and flexible material with low acoustic attenuation (e.g., silicone rubber or another suitable material). The housing **110** (**210**) of the valve unit **100** (**200**) can be of a biocompatible and rigid material with low acoustic attenuation (e.g., polymers such as polyethylene or another suitable material). The reference indicators **130** (**230**) and the dial indicator(s) **170** (**270**) can be of a biocompatible and non-ferrous (or otherwise magnetically unresponsive) material with clear visibility under ultrasound imaging; for example, the reference indicators **130** (**230**) and the dial indicator(s) **170** (**270**) can be of a material with high acoustic impedance, e.g., ceramics, silicon carbide, polymers such as Delrin, HDPE, or another suitable polymer, non-ferrous metals such as titanium, gold, aluminum, or another suitable metal or metal alloy, crystals such as sapphire, ruby, or another suitable crystalline material. Radiopaque elements **134**, **135**, **166**, **234** and/or **266** can be of a biocompatible, ferrous or non-ferrous material with clear visibility under x-ray imaging, e.g., high density substances such as barium sulfate, bismuth compounds, metals or metal-alloys such as tungsten, titanium, zinc-magnesium, cobalt-chromium, or another suitable metal or metal-alloy. Alternatively, these materials can also be used as fillers within polymer materials herein. Flow indicator **190**, **290**, **390** or **490** can be of a biocompatible material having a non-ferrous (or otherwise magnetically unresponsive) body with clear visibility under ultrasound imaging (such as a material having high acoustic impedance). Flow indicator capture element **494** can include a ferrous or otherwise magnetically responsive material that can be coated in a biocompatible layer. Flow indicator actuator **484** be of a biocompatible and rigid material with low acoustic attenuation. Tensioning element **175** (**275**) can of a biocompatible and flexible material having a small spring constant, minimal ultrasound artifact with acoustic impedance that can be similar to that of soft tissue such as cerebrospinal fluid or another biofluid (e.g., ~1.5MRayls). One example material can be a polymer such as polyethylene, or can include metals such as spring steel, titanium, nitinol.

[00100] FIG. **19** shows a method **500** for controlling and interrogating a flow of material through a valve unit.

[00101] Step **502** of method **500** includes providing a valve unit (e.g., valve unit **100** or **200**), the valve unit including a dial moveable between a plurality of positions and having a dial indicator viewable through cross-sectional imaging, the dial being configured such that a position of the dial indicator is indicative of a position of the plurality of positions of the dial. Step **504** of method **500** includes capturing, at a cross-sectional imaging device, a cross-sectional image of the valve unit including the position of the dial indicator viewable within the cross-sectional image. Step **506** of method **500** includes determining, based on the position of the reference indicator, an orientation of the valve unit. Step **508** of method **500** includes determining, based on the cross-sectional image of the dial indicator, the position of the dial based on the position of the dial indicator viewable within the cross-sectional image.

[00102] To interrogate the valve unit to see if material is flowing through the lumen: Step **510** of method **500** includes positioning the flow indicator within a lumen (e.g., distal lumen **495**) distal to the dial, the flow indicator being moveable by flow of material through the lumen. Step **512** of method **500** includes determining, based on a position of the flow indicator viewable through cross-sectional imaging, if material is flowing through the lumen. Step **514** of method **500** includes returning the flow indicator to a non-occluding position by activation of the magnetic-responsive element of the flow indicator by an external magnetic device such that the flow indicator is drawn away from the distal lumen.

[00103] To configure or otherwise select a “pressure setting” for the valve unit: Step **516** of method **500** includes disengaging the locking mechanism by activating the magnetic-responsive element to partially decouple the dial from the housing. Step **518** of method **500** includes activating the magnetic-responsive element of the dial by an external magnetic device. Step **520** of method **500** includes altering the position of the dial by rotation of the dial through the external magnetic device and the magnetic-responsive element.

[00104] Further, the valve device **10** (including associated valve unit **100** or **200**) can be applied for treatment of various diseases and/or conditions including but not limited to normal pressure hydrocephalus, obstructive hydrocephalus, pseudo tumor cerebri, congenital ventriculomegaly, chronic arachnoid cyst, and/or chronic and complex cerebrospinal fluid leak. In one aspect, the valve device **10** can be implanted within the body in communication with a medical tube for controlling a flow of material through the medical tube. The valve device **10** can be implanted for treatment of hydrocephalus or another similar condition requiring a ventriculoperitoneal shunt (e.g., from a ventricle of the brain to the peritoneal cavity), and where the valve device **10** can communicate with or otherwise include a ventriculoperitoneal shunt catheter positioned between the peritoneal cavity of the body and a ventricle of the brain. With respect to other diseases and/or conditions mentioned above, the valve device **10** can communicate with or otherwise include a ventriculopleural shunt catheter positioned between a pleural cavity of the body and a ventricle of the brain. The valve device **10** can include or otherwise communicate with a ventriculoatrial shunt catheter positioned between an atrium of a heart of the body and a ventricle of the brain. The valve device **10** can include or otherwise communicate with a cisternoperitoneal shunt catheter positioned between a peritoneal cavity of the body and a subarachnoid cistern of the brain. The valve device **10** can include or otherwise communicate with a cisternopleural shunt catheter, positioned between the pleural cavity of the body and a subarachnoid cistern of the brain. The valve device **10** can include or otherwise communicate with a cisternoatrial shunt catheter positioned between an atrium of a heart of the body and a subarachnoid cistern of the brain. In another aspect, valve device **10** can be employed and installed according to various embodiments and methods described herein for diversion of fluid from a cavity of the body at a first location of the body to an external environment at a second location of the body or for communicating fluid from an external environment at the first location to a cavity of the body at the second location. The valve device **10** can be controlled and interrogated as discussed above with reference to method **500** to ensure proper function when the valve device **10** is employed during treatment of any of the above diseases and/or conditions. As readily apparent to one of skill in the art, any number of conditions and disease treatment regimens associated with shunt implantation and evaluation, as well as diagnostic or prognostic regimens associated with shunt implantation and evaluation, could be used in conjunction with the various embodiments of valve device 10,

[00105] In some embodiments, the valve device **10** can be offered as a kit that includes the valve unit **100** or **200**, the flow indicator **190**, **290**, **390** or **490**, and further including the external magnetic device **90** for adjustment of the valve unit **100** or **200** and interrogation of the flow indicator **190**, **290**, **390** or **490**. The kit may further include any medical tubes or catheters that may be used in conjunction with the valve device **10**, including but not limited to a ventriculoperitoneal shunt catheter, a ventriculopleural shunt catheter, a ventriculoatrial shunt catheter, a cisternoperitoneal shunt catheter, a cisternopleural shunt catheter, and a cisternoatrial shunt catheter.

[00106] It should be understood from the foregoing that, while particular embodiments have been illustrated and described, various modifications can be made thereto without departing from the spirit and scope of the invention as will be apparent to those skilled in the art. Such changes and modifications are within the scope and teachings of this invention as defined in the claims appended hereto.

CLAIMS

What is claimed is:

1. A valve device, including:
a dial having a dial indicator, the dial and the dial indicator being moveable between a plurality of positions, the dial being configured such that a position of the plurality of positions of the dial is viewable through cross-sectional imaging of the dial indicator.

2. The valve device of claim 1, further comprising:
a housing encapsulating the dial and including a reference indicator, the reference indicator being viewable through cross-sectional imaging of the housing;
wherein a position of the dial indicator relative to the reference indicator is indicative of the position of the plurality of positions of the dial.

3. The valve device of claim 1, further comprising:
a flow limiter in operative association with the dial, the flow limiter being operable for limiting a flow of material through a lumen based on the position of the plurality of positions of the dial.

4. The valve device of claim 1, wherein the dial indicator includes a plurality of dial indicator surfaces identifiable through cross-sectional imaging of the dial indicator, wherein a position of each dial indicator surface of the plurality of dial indicator surfaces relative to a reference indicator is indicative of the position of the plurality of positions of the dial.

5. The valve device of claim 4, wherein each dial indicator surface of the plurality of dial indicator surfaces is identifiable through cross-sectional imaging by a vertical position and/or a cross-sectional shape of the dial indicator surface relative to the reference indicator.

6. The valve device of claim 1, wherein the dial indicator includes a dial indicator surface identifiable through cross-sectional imaging of the dial indicator, wherein a vertical position of the dial indicator surface relative to a reference indicator is indicative of the position of the plurality of positions of the dial.

7. The valve device of claim 6, wherein the dial indicator surface is moveable along a lead screw in association with the dial.

8. The valve device of claim 1, wherein the dial includes a locking mechanism that, when engaged, prevents alteration of the position of the dial.

9. The valve device of claim 8, wherein the dial includes a first magnetic-responsive element that, when activated by an external magnetic device, disengages the locking mechanism to enable alteration of the position of the dial.

10. The valve device of claim 8, wherein the dial includes a second magnetic-responsive element that, when activated by an external magnetic device, enables rotation of the dial in a clockwise direction or a counterclockwise direction to alter the position of the dial.

11. The valve device of claim 1, further comprising:

a flow indicator positionable within a lumen distal to the dial, the flow indicator being moveable by flow of material through the lumen and viewable through cross-sectional imaging of the flow indicator.

12. The valve device of claim 11, further comprising:

a flow indicator actuator in operative association with the flow indicator that, when actuated, positions the flow indicator within the lumen; and a third magnetic-responsive element that, when activated by an external magnetic device, draws the flow indicator away from the lumen.

13. A valve device, comprising:

a dial having a dial indicator and a magnetic-responsive element, the dial being moveable between a plurality of positions;

a housing having a reference indicator; and

a locking mechanism defined by the dial and the housing;

wherein external application of a magnetic force in a vertical direction draws the dial away from the housing to disengage the locking mechanism;

wherein external application of the magnetic force enables rotation of the dial to a position of the plurality of positions by the magnetic-responsive element; and

wherein a position of the dial indicator relative to the reference indicator is observable through cross-sectional imaging and is dependent upon the position of the dial.

14. The valve device of claim 13, further comprising a tensioning element in association with the dial, the housing, and the locking mechanism such that the tensioning element returns the dial to the housing to engage the locking mechanism and prevent rotation of the dial absent the external application of the magnetic force.

15. A method, comprising:

providing a valve device including a dial moveable between a plurality of positions, the dial having a dial indicator viewable through cross-sectional imaging, the dial being configured such that a position of the dial indicator is indicative of a position of the plurality of positions of the dial;

capturing, at a cross-sectional imaging device, a cross-sectional image of the valve device including the position of the dial indicator viewable within the cross-sectional image; and

determining, based on the cross-sectional image of the dial indicator, the position of the dial based on the position of the dial indicator viewable within the cross-sectional image.

16. The method of claim 15, wherein the valve device includes a housing having a reference indicator viewable through cross-sectional imaging of the housing, wherein the cross-sectional image of the valve device includes a position of the reference indicator viewable within the cross-sectional image, and wherein the method further comprises:

determining, based on the position of the reference indicator, an orientation of the valve device.

17. The method of claim 15, wherein the valve device includes a flow indicator positionable within a lumen distal to the dial, the flow indicator being moveable by flow of material through the lumen and viewable through cross-sectional imaging of the flow indicator, wherein the cross-sectional image of the valve device includes a position of the flow indicator viewable within the cross-sectional image, and wherein the method further comprises:

positioning the flow indicator within a lumen distal to the dial, the flow indicator being moveable by flow of material through the lumen; and

determining, based on a position of the flow indicator viewable through cross-sectional imaging, if material is flowing through the lumen.

18. The method of claim 17, wherein the flow indicator includes a magnetic-responsive element, the method further comprising:

returning the flow indicator to a non-occluding position by activation of the magnetic-responsive element of the flow indicator by an external magnetic device such that the flow indicator is drawn away from the distal lumen.

19. The method of claim 15, wherein the valve device includes a locking mechanism, that, when engaged, prevents alteration of the position of the dial, wherein the dial includes a magnetic-responsive element, and wherein the method further comprises:

disengaging the locking mechanism by activating the magnetic-responsive element to partially decouple the dial from a housing.

20. The method of claim 15, wherein the dial includes a magnetic-responsive element, and wherein the method further comprises:

activating the magnetic-responsive element of the dial by an external magnetic device; and

altering the position of the dial by rotation of the dial through the external magnetic device and the magnetic-responsive element.

21. The method of claim 15, further comprising:

positioning the valve device within a body in communication with a medical tube for controlling a flow of material through the medical tube.

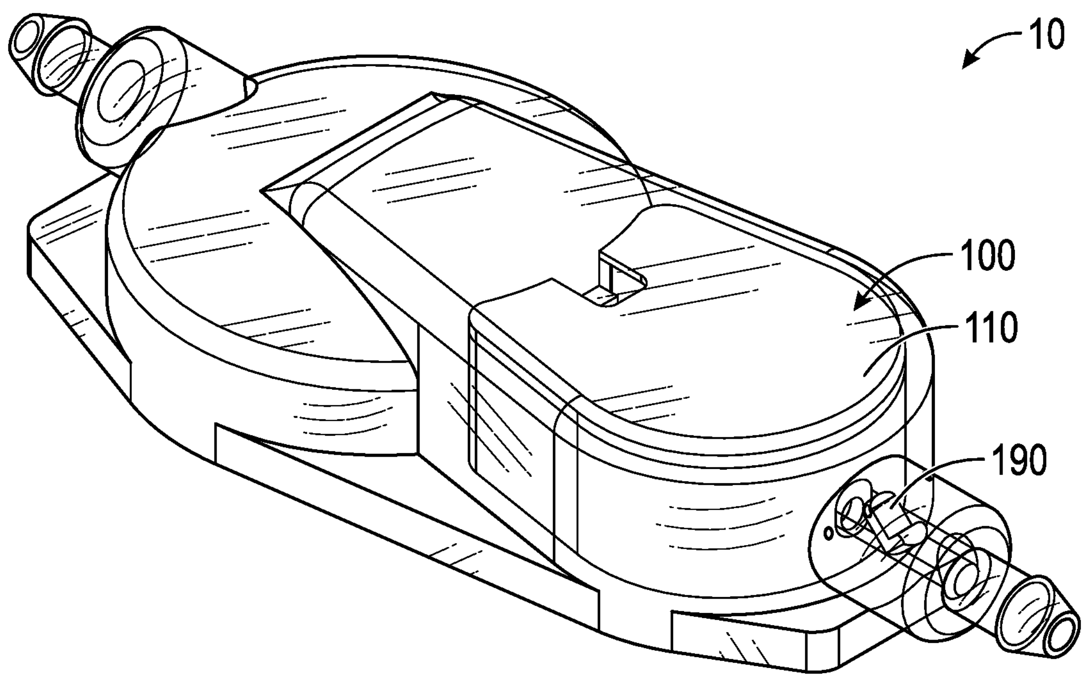

10
100
110
190

FIG. 1A

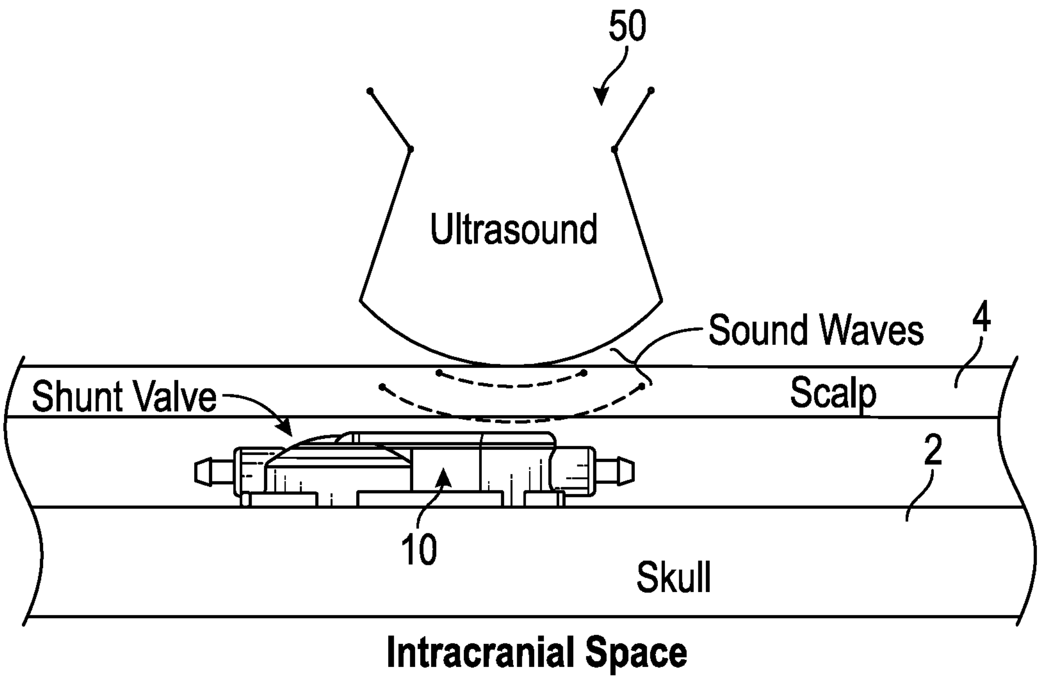

50
Ultrasound
Sound Waves
4
Scalp
Shunt Valve
2
10
Skull
Intracranial Space

FIG. 1B

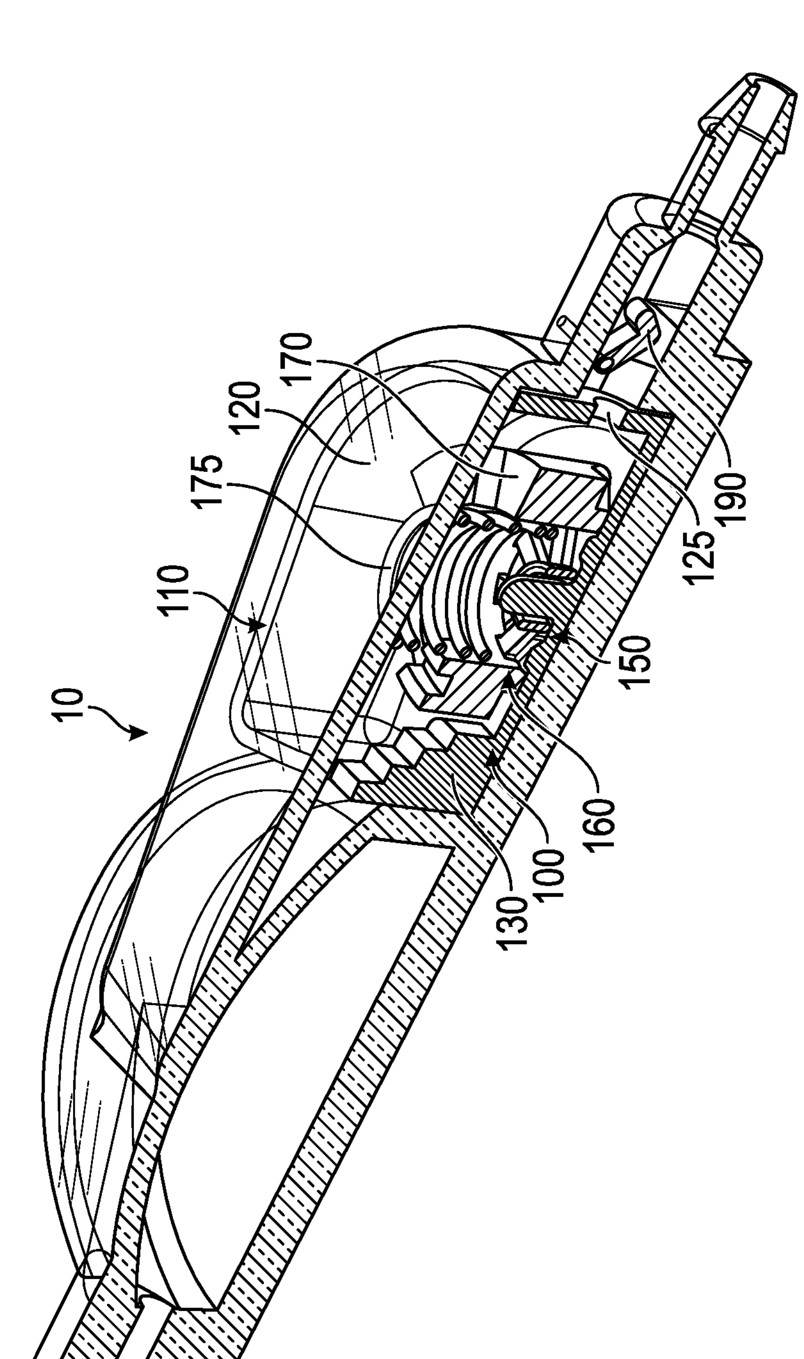


FIG. 2A

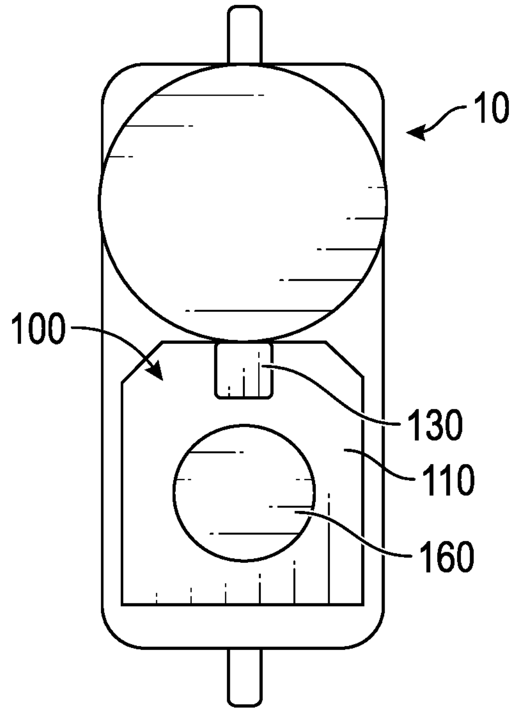


FIG. 2B

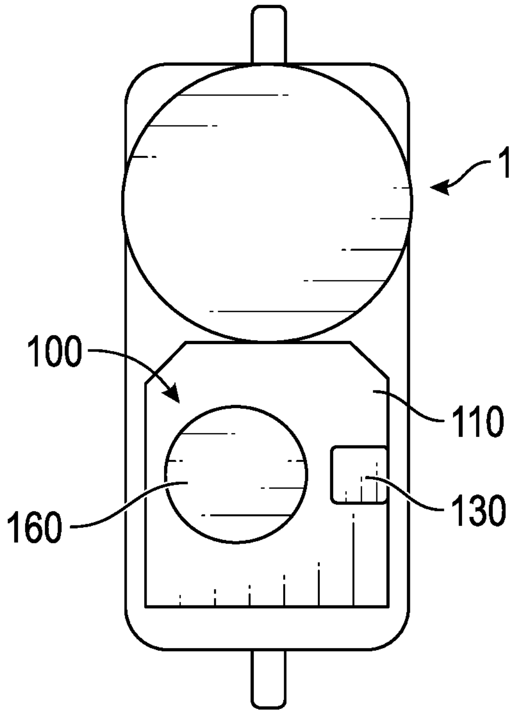


FIG. 2C

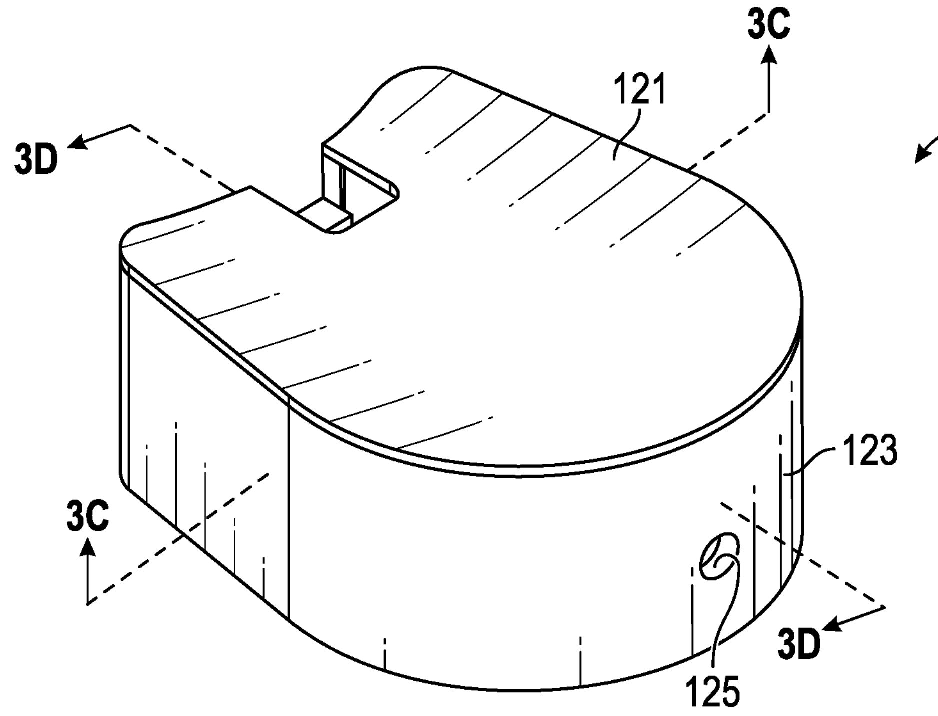


FIG. 3A

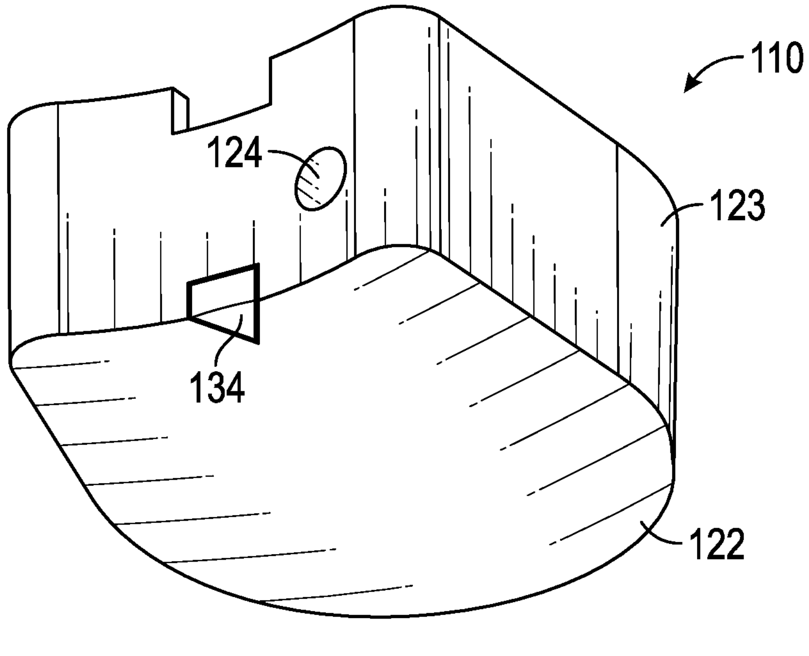


FIG. 3B

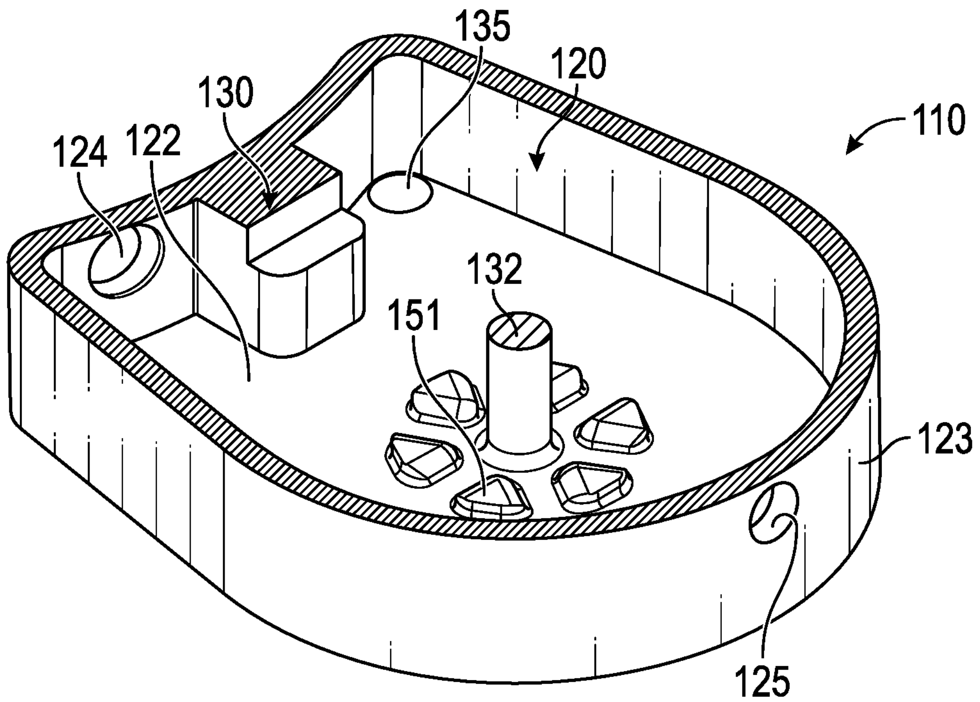

135
120
110
130
124
122
132
151
123
125

FIG. 3C

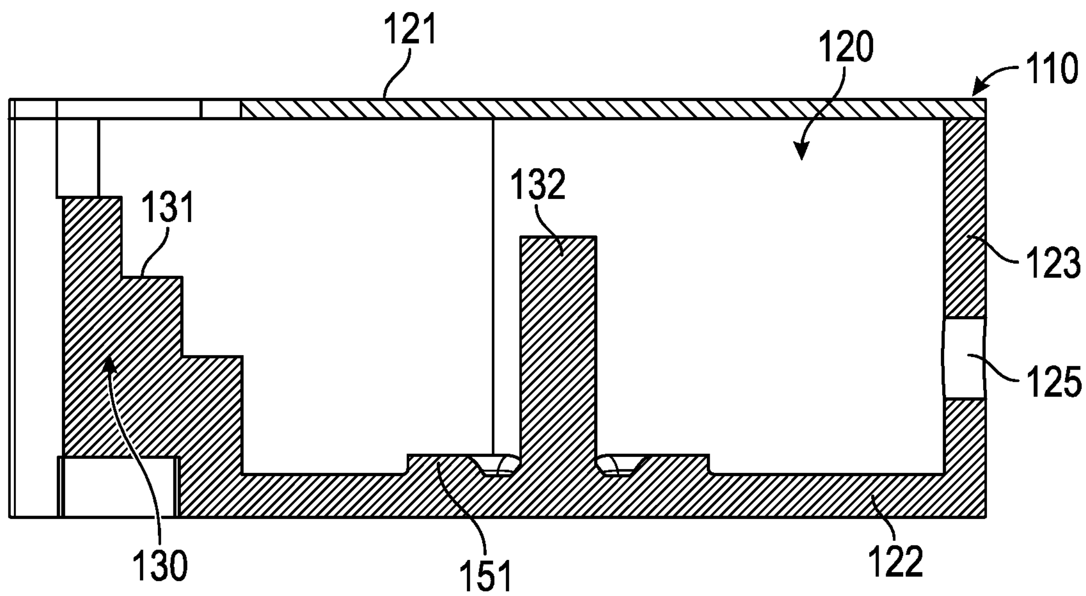

121
120
110
132
131
123
125
130
151
122

FIG. 3D

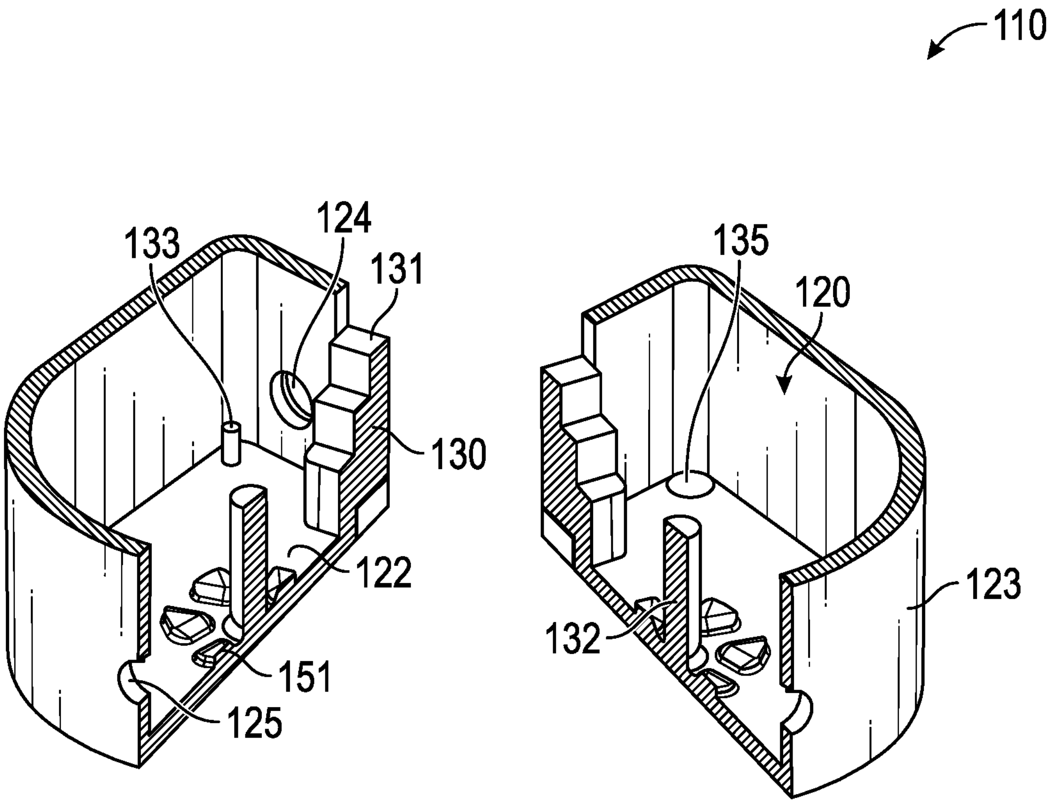


FIG. 3E

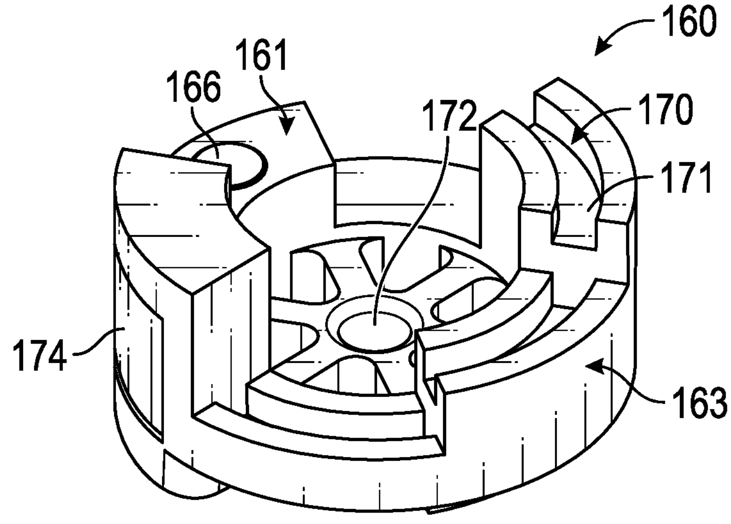
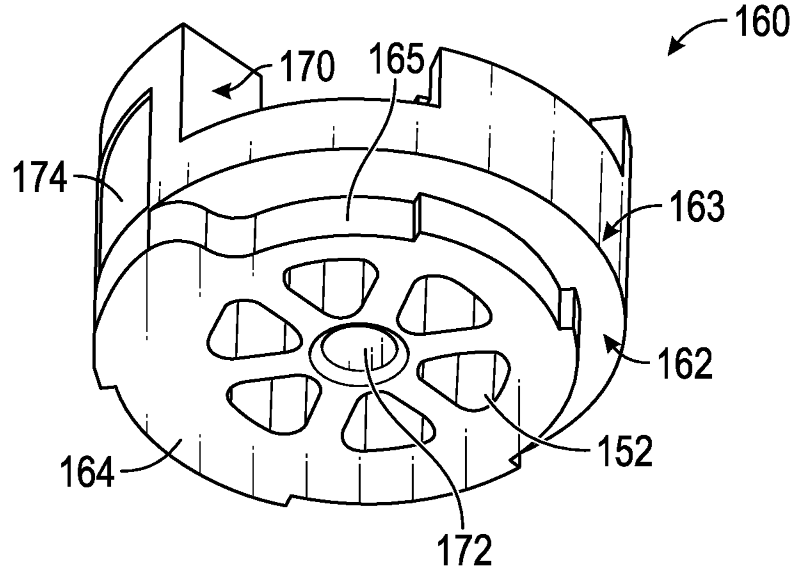

160
161
166
172
170
171
174
163

FIG. 4A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170
165
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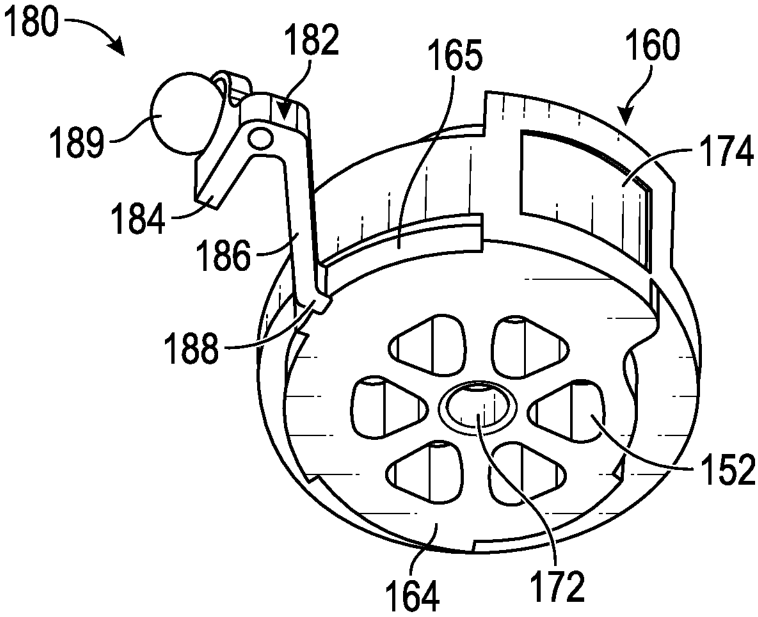
163
162
152
164
172

FIG. 4B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182
165
160
189
174
184
186
188
152
164
172

FIG. 4C

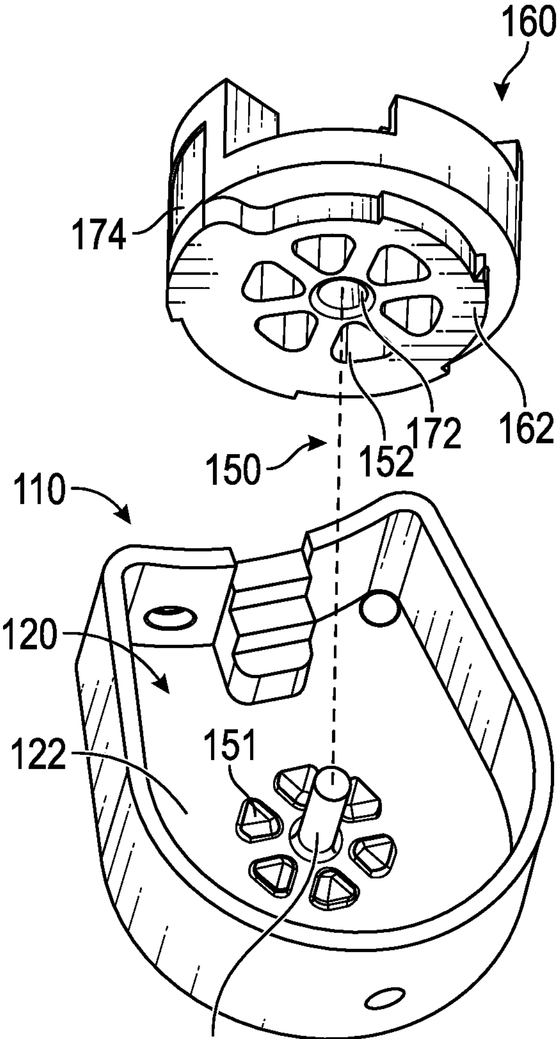

160
174
172
162
152
150
110
120
122
151
132

FIG. 5

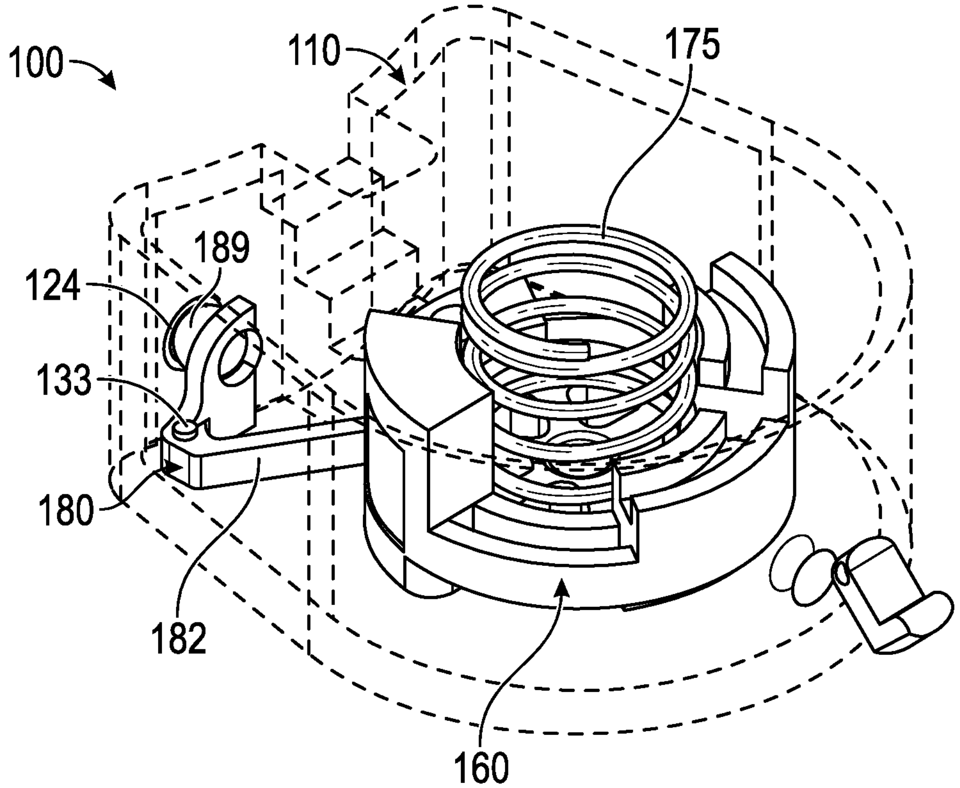
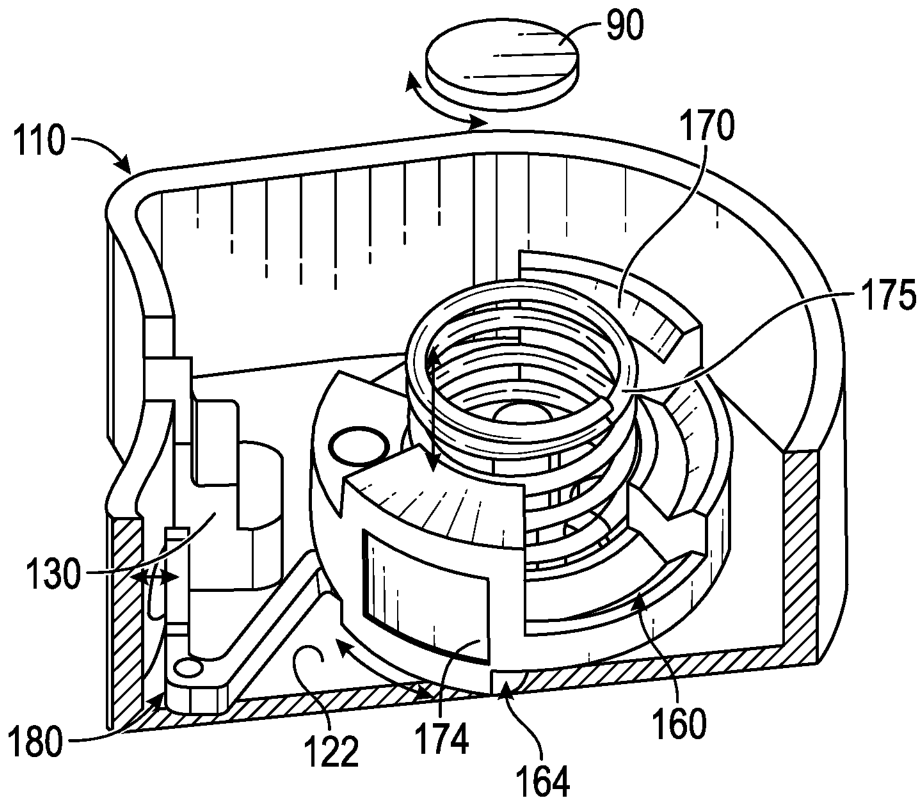

100
110
175
189
124
133
180
182
160

FIG. 6A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110
170
175
130
180
122
174
164
160

FIG. 6B

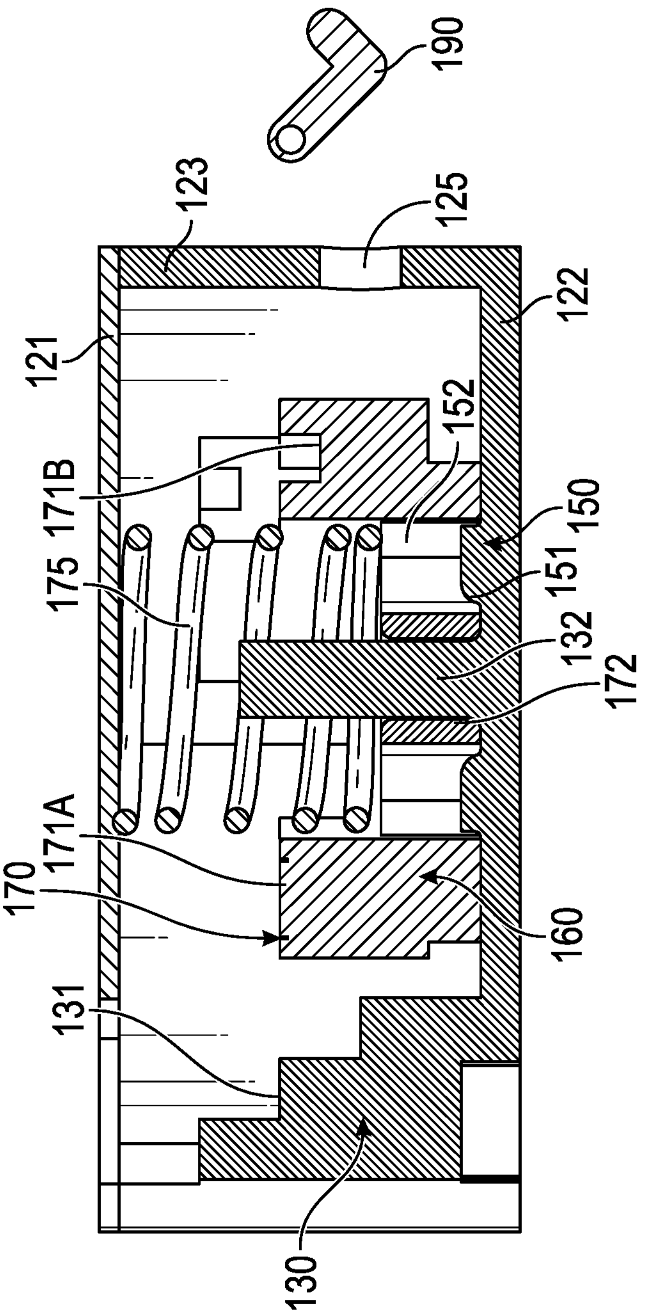
190
123
125
122
121
152
171B
150
175
151
132
172
171A
170
160
131
130

FIG. 6C

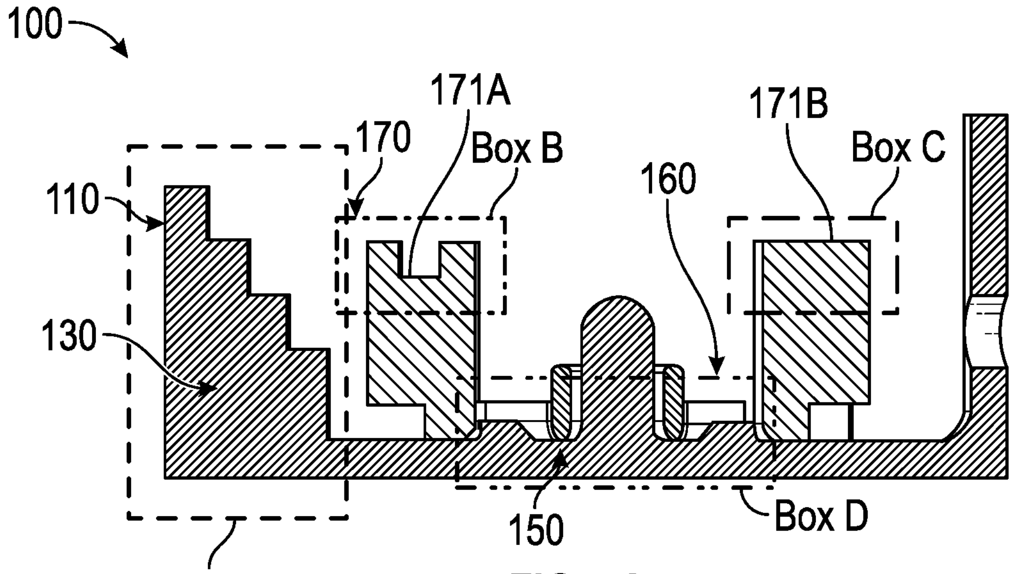
100
171A
171B
170
Box B
Box C
110
160
130
150
Box D
Box A

FIG. 7A

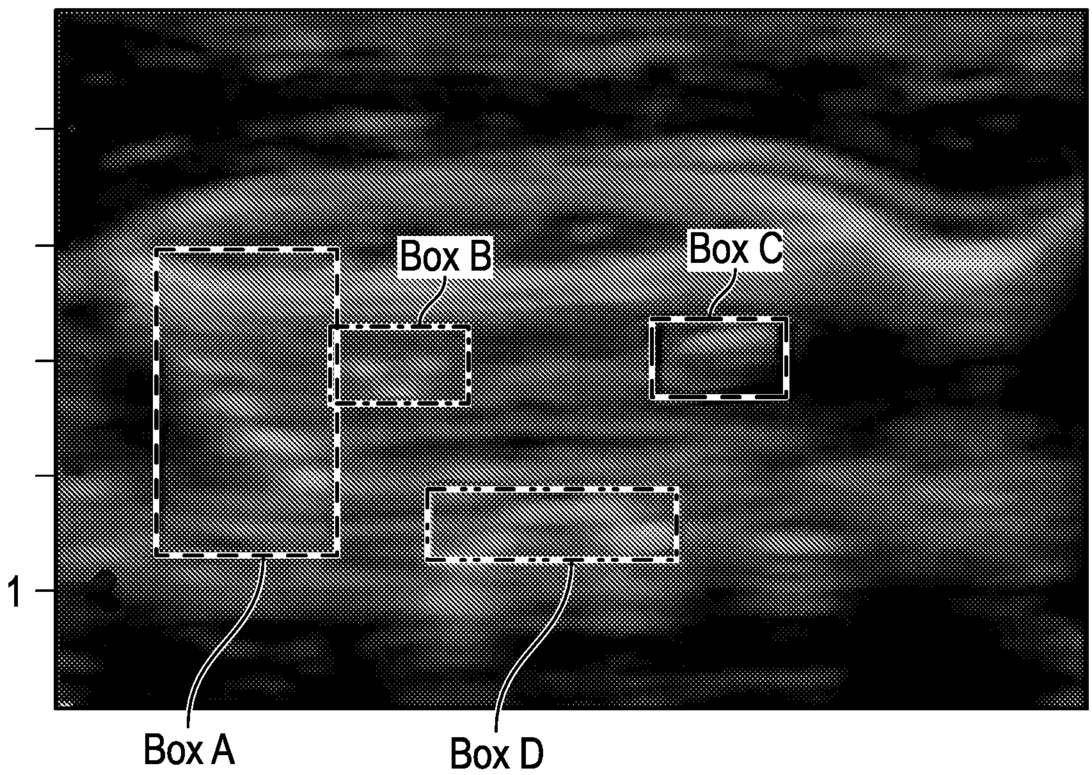
Box B
Box C
1
Box A
Box D

FIG. 7B

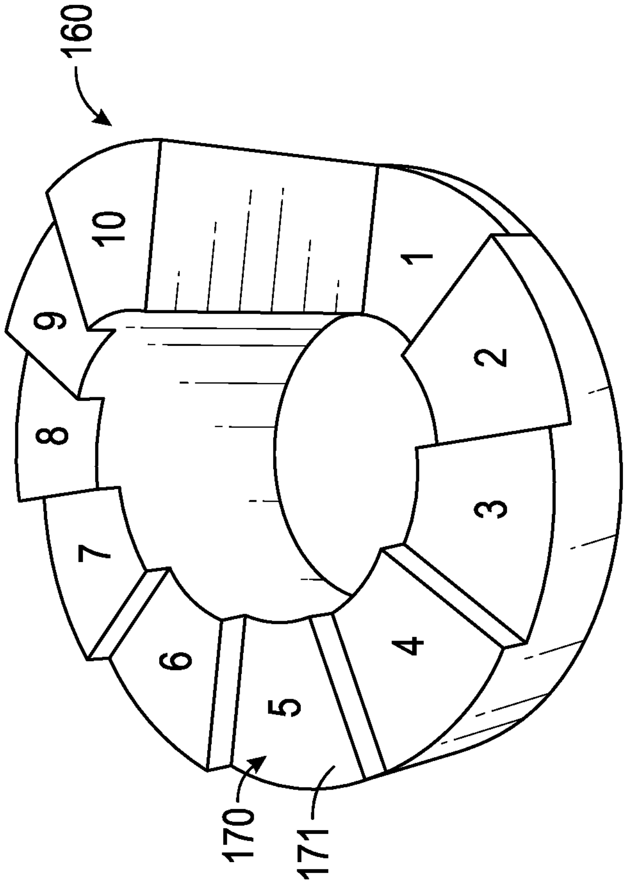

FIG. 8A

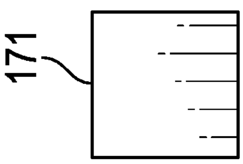

FIG. 8B

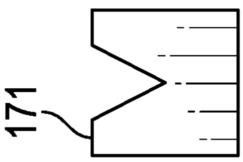

FIG. 8C

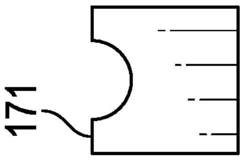

FIG. 8D

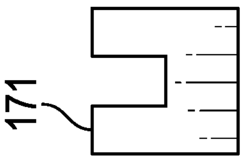

FIG. 8E

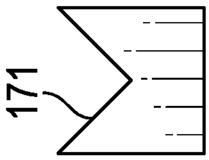

FIG. 8F

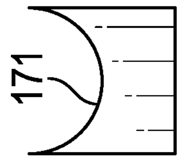

FIG. 8G

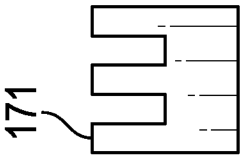

FIG. 8H

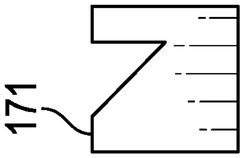

FIG. 8I

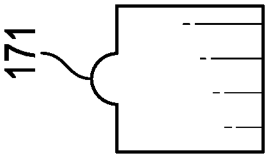

FIG. 8J

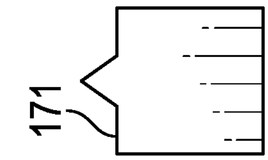

FIG. 8K

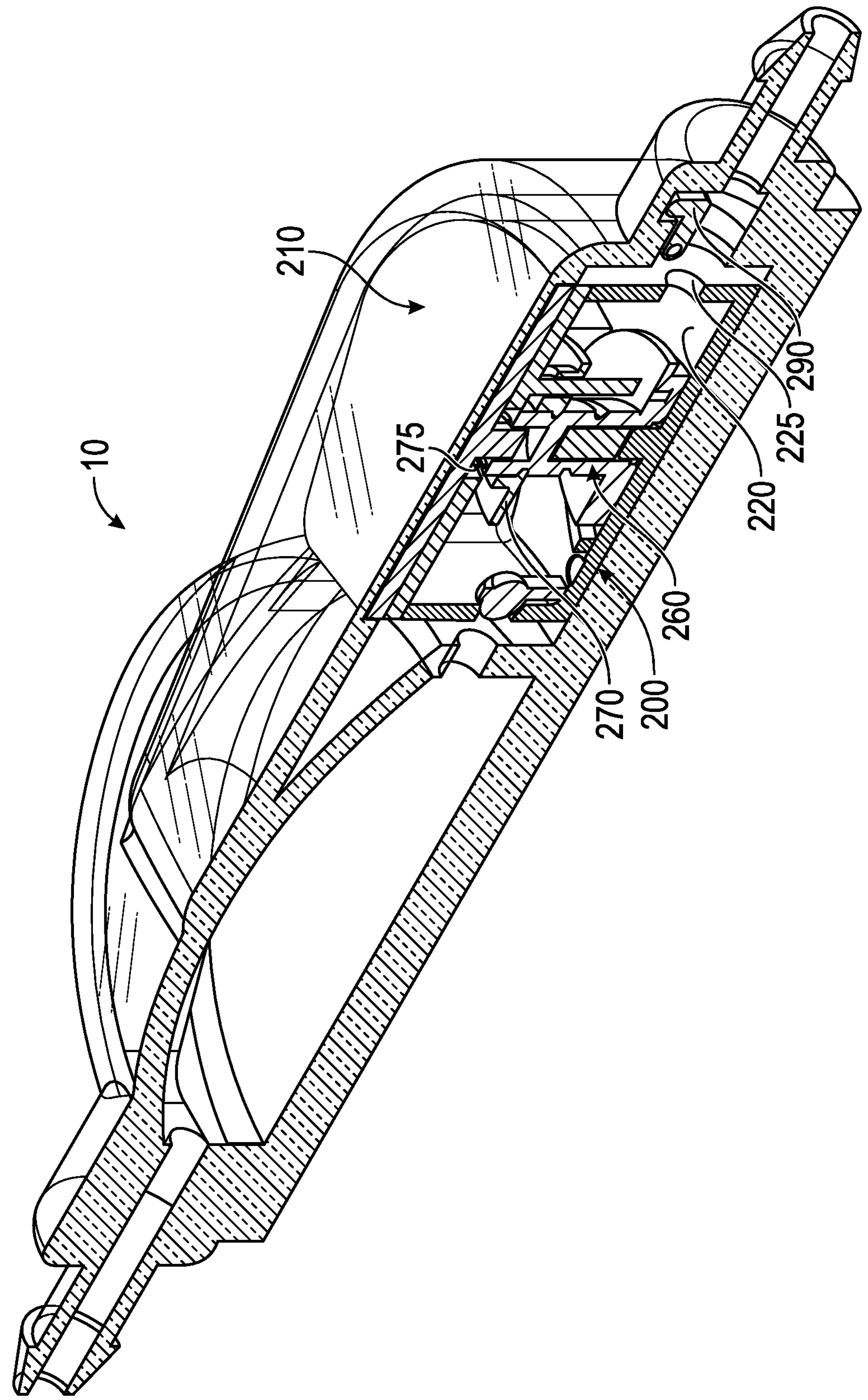

FIG. 9

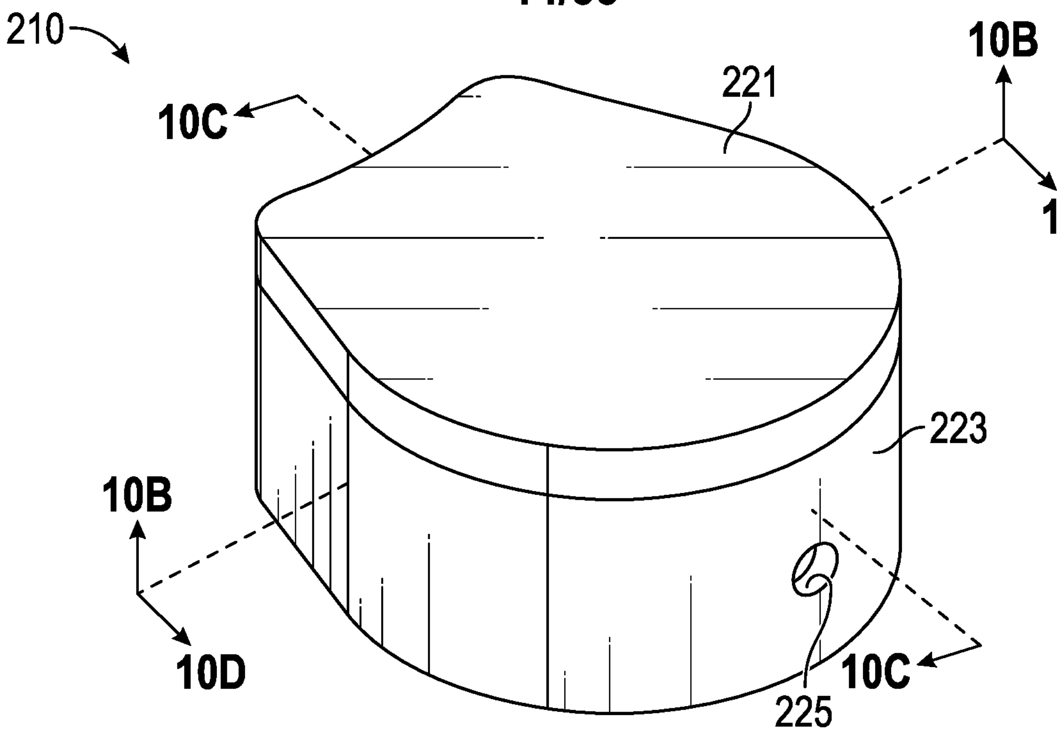

FIG. 10A

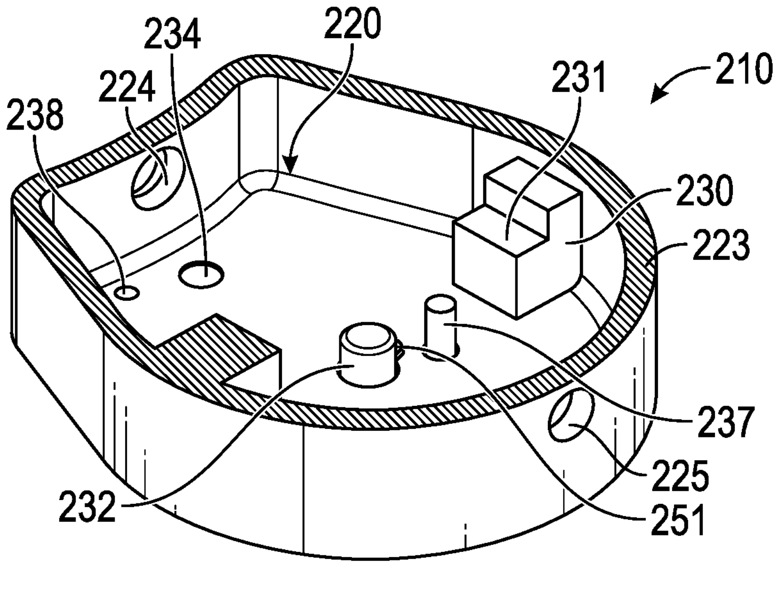

FIG. 10B

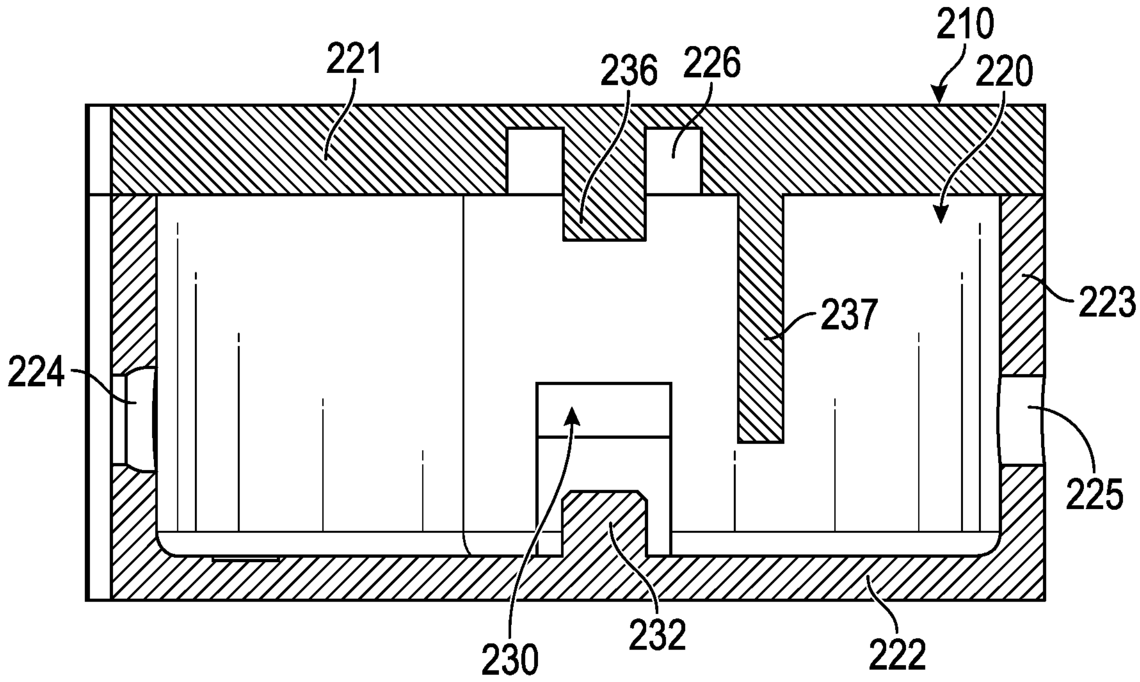

FIG. 10C

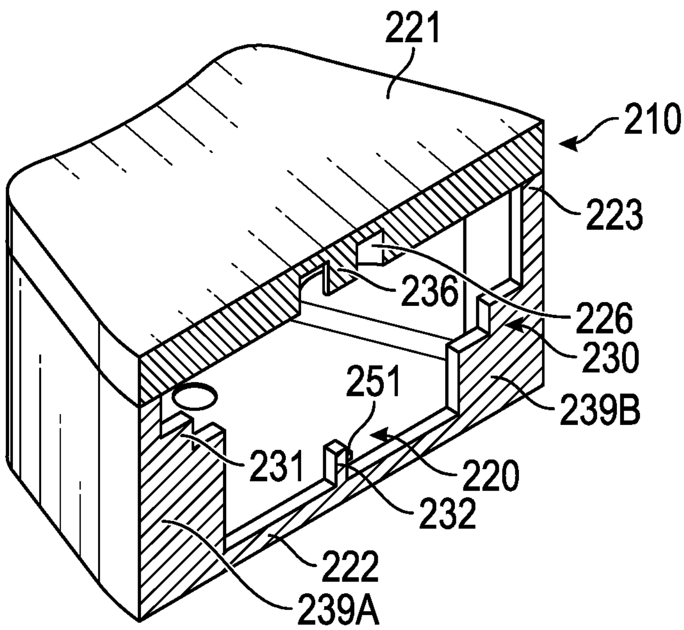

FIG. 10D

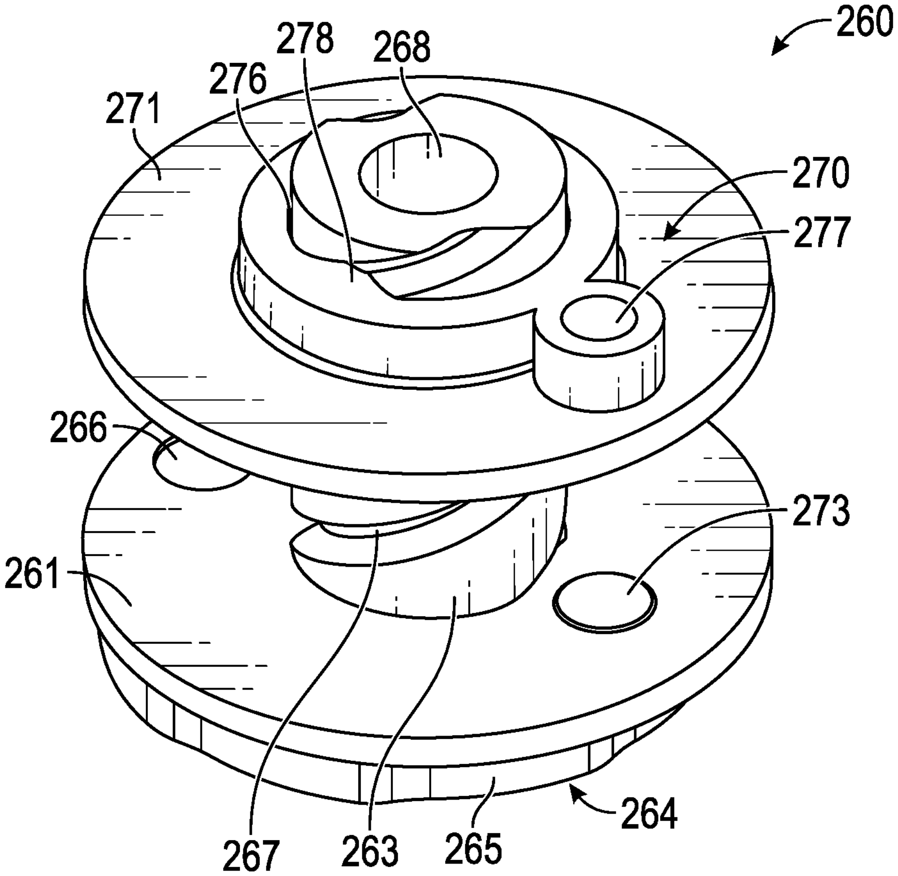

FIG. 11A

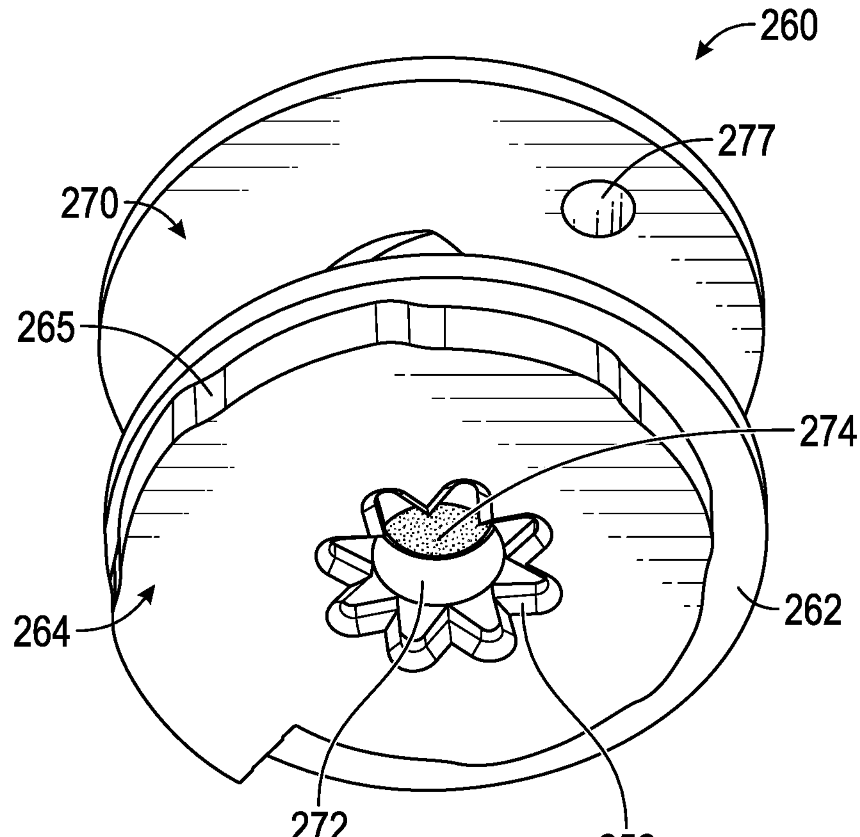

FIG. 11B

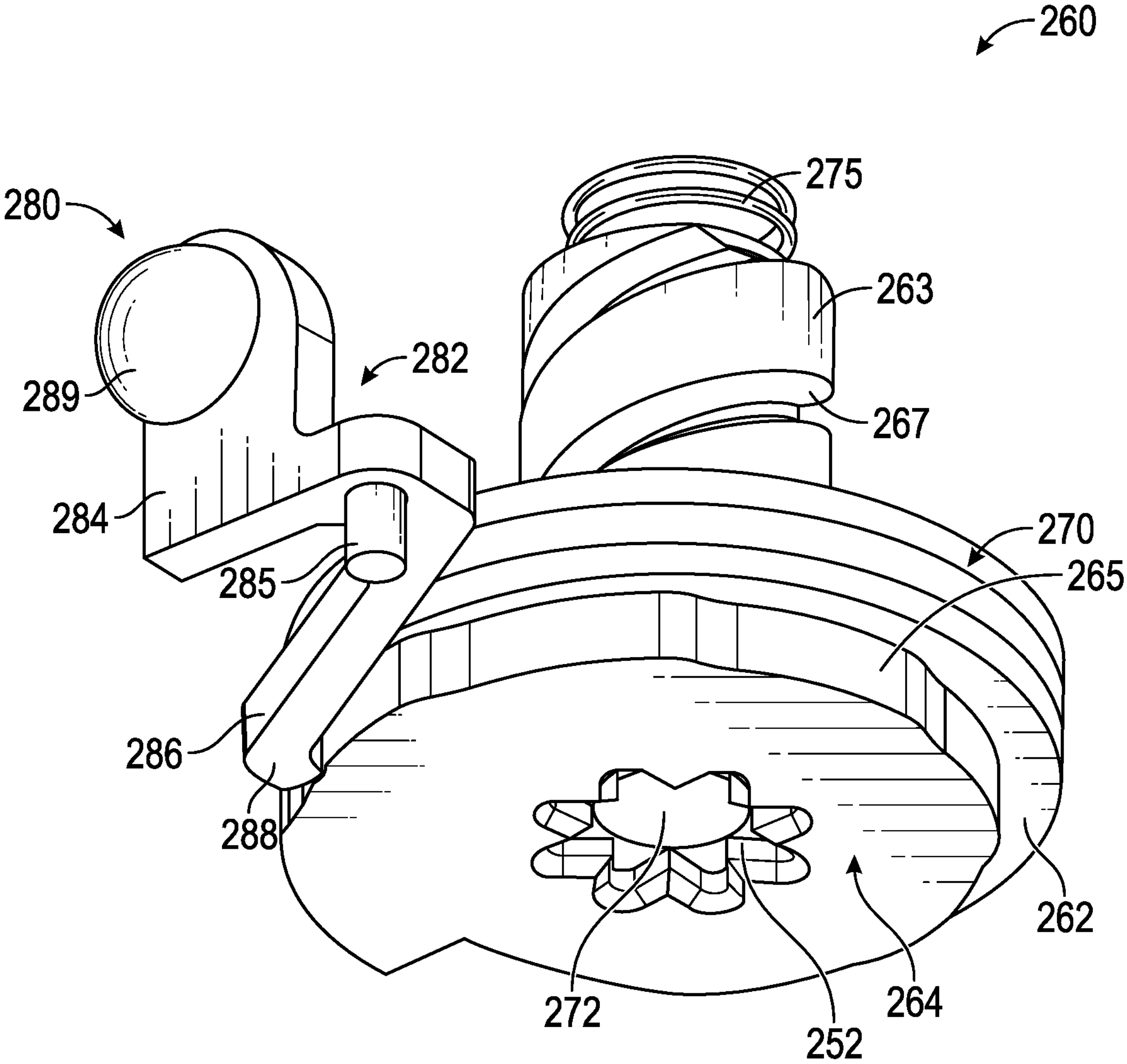
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FIG. 11C

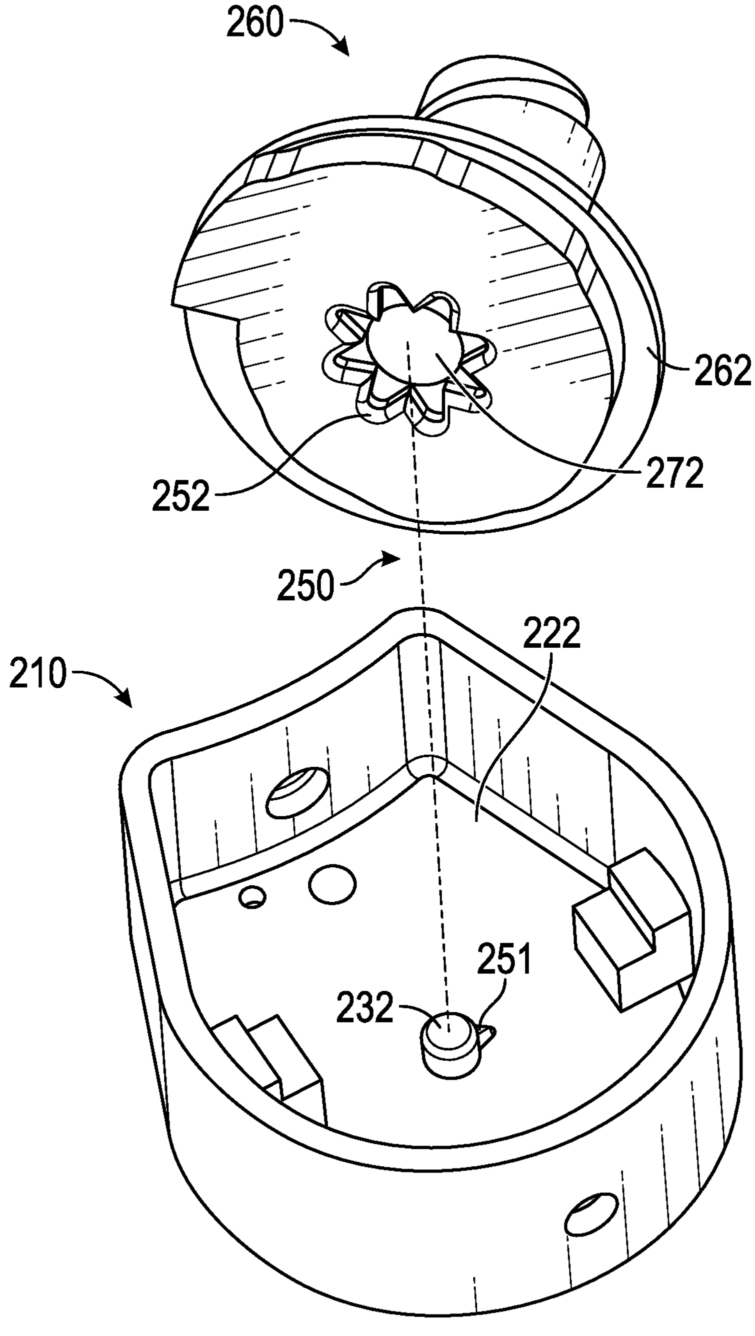

FIG. 12

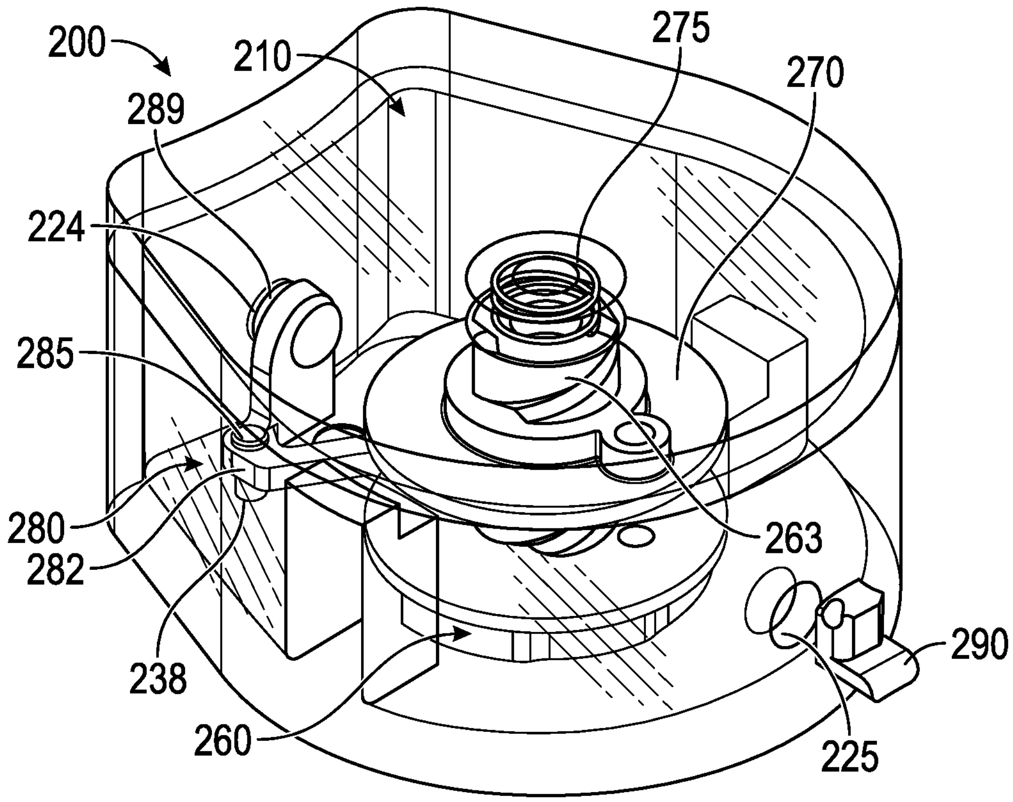

FIG. 13A

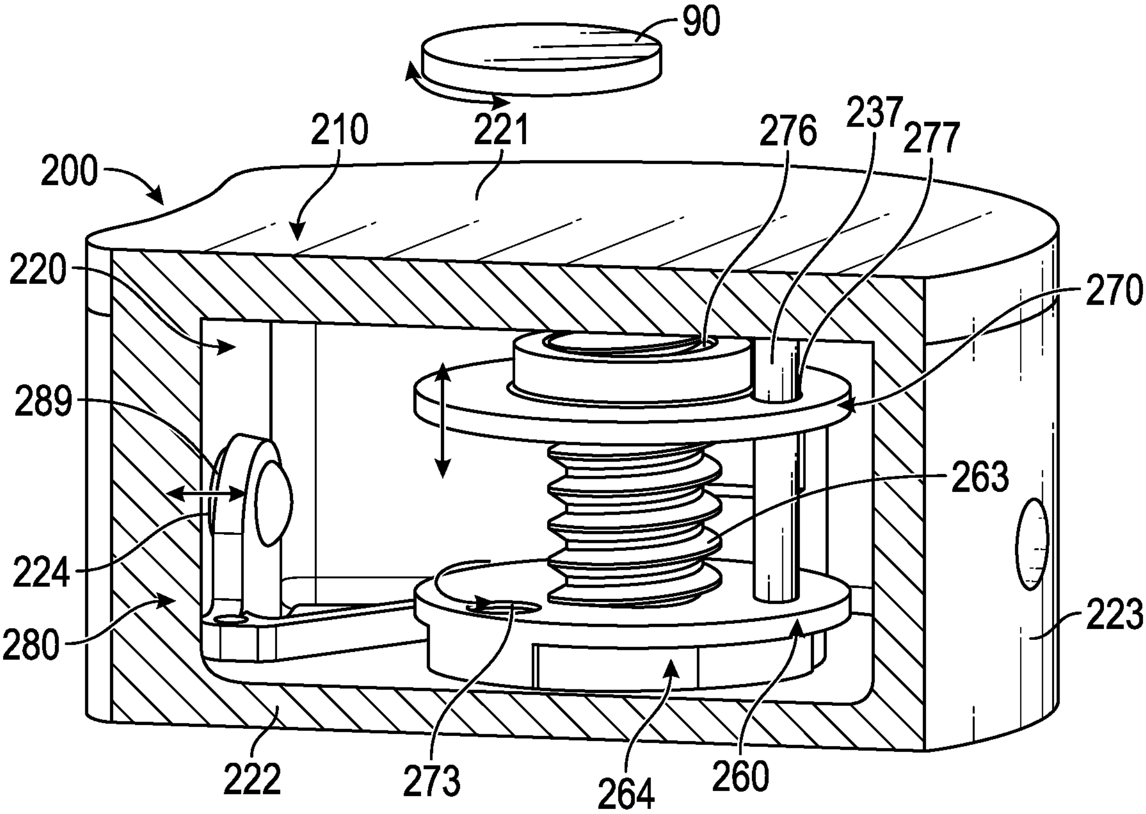

FIG. 13B

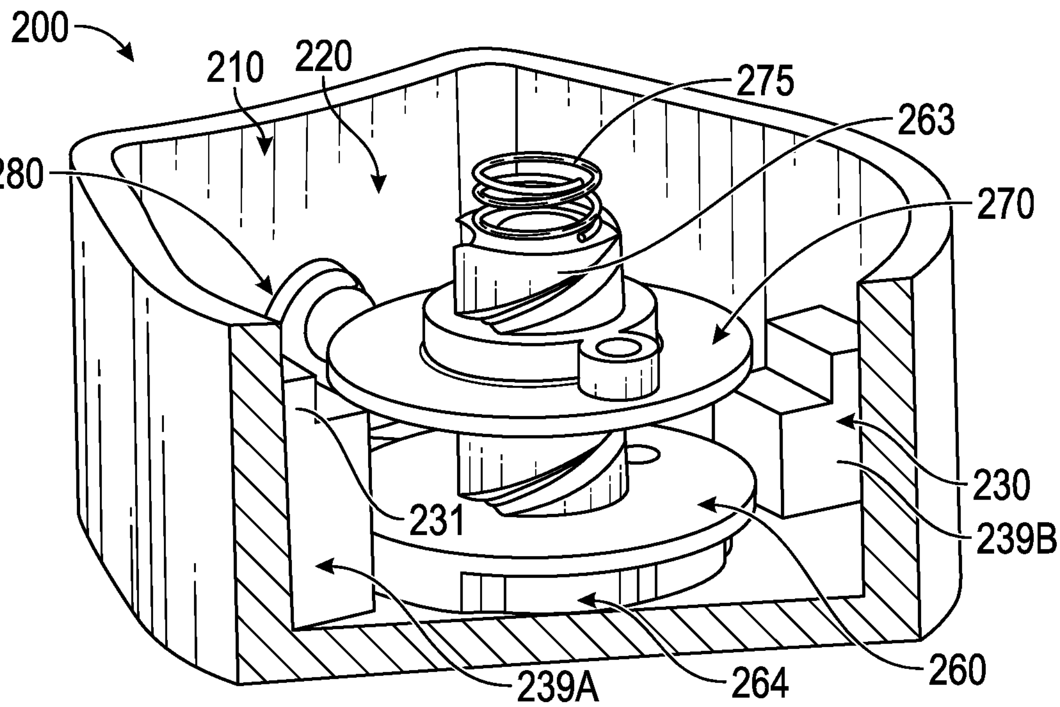

FIG. 13C

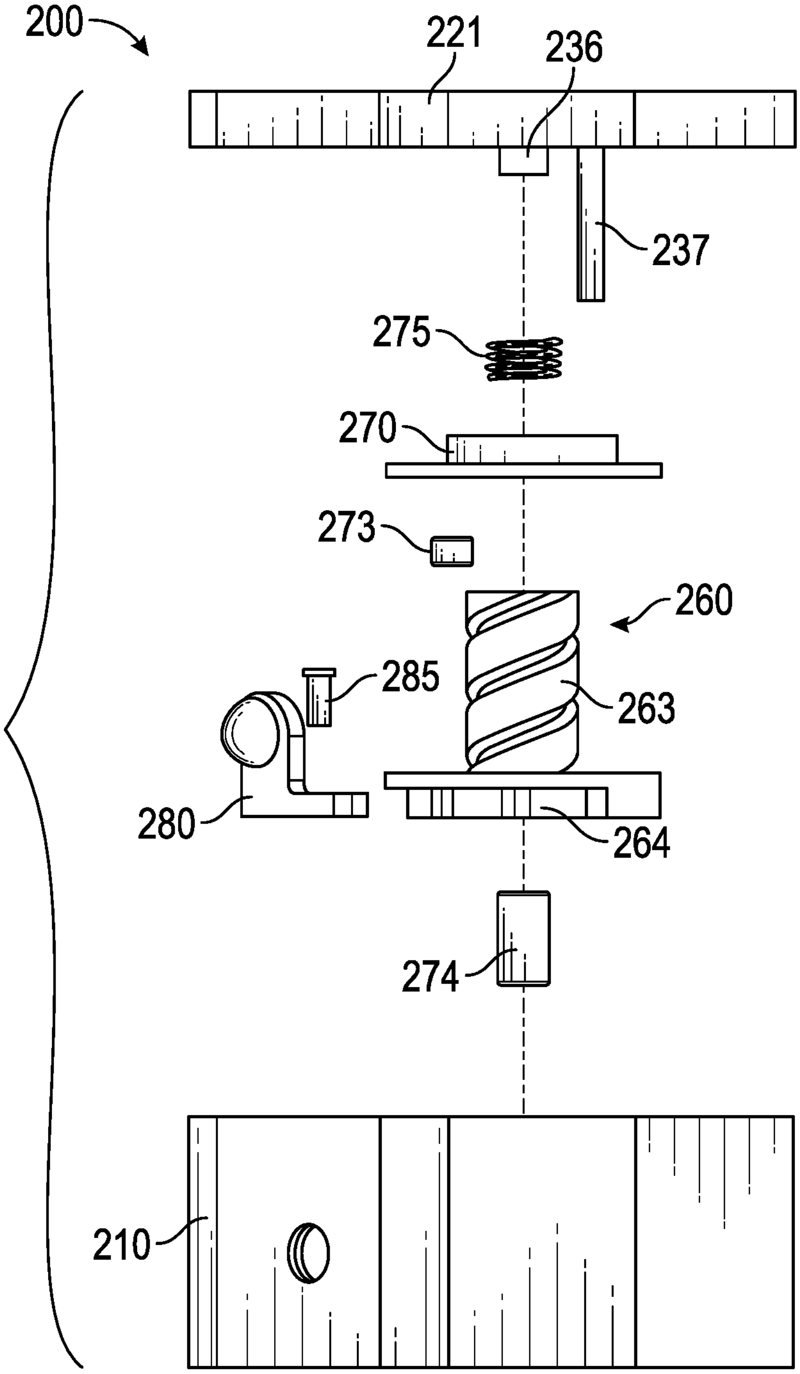

FIG. 13D

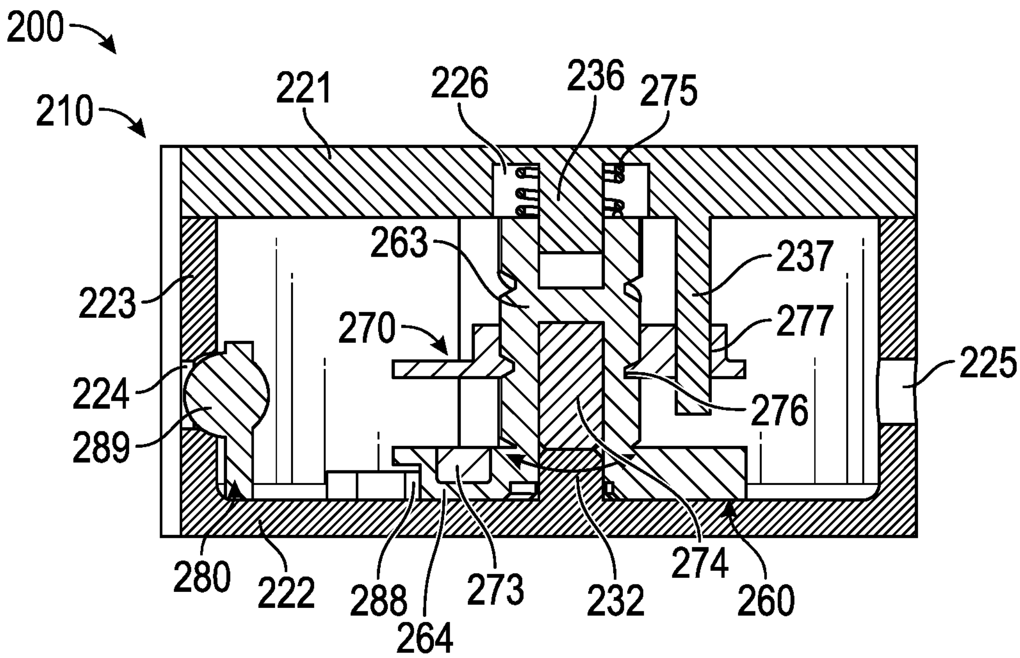
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FIG. 13E

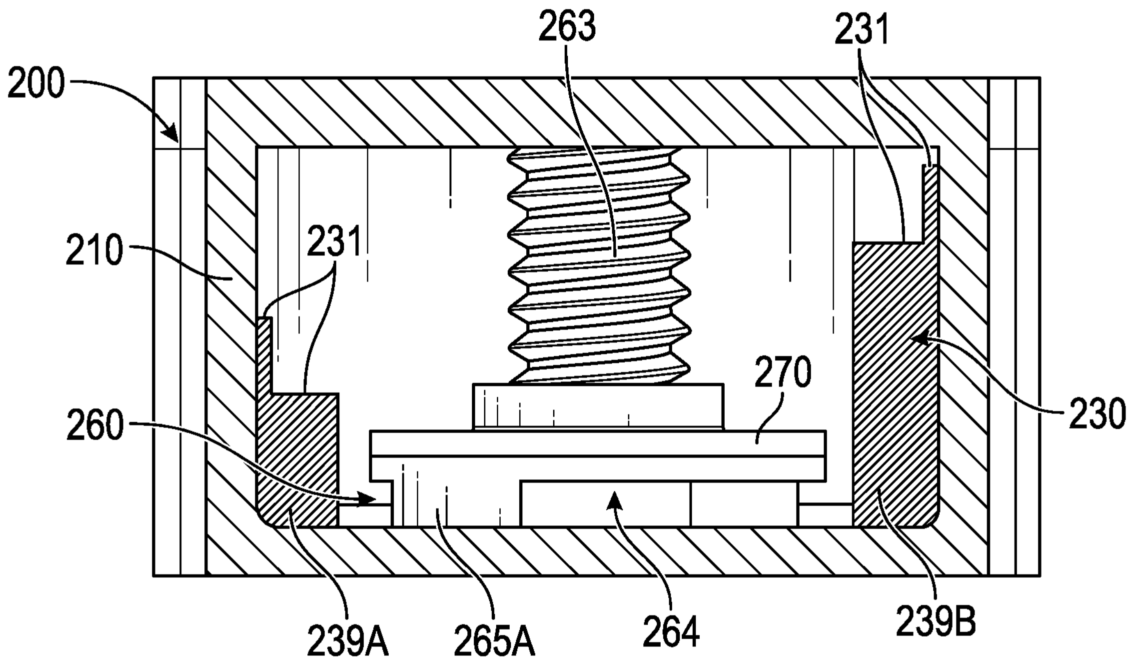


FIG. 14A

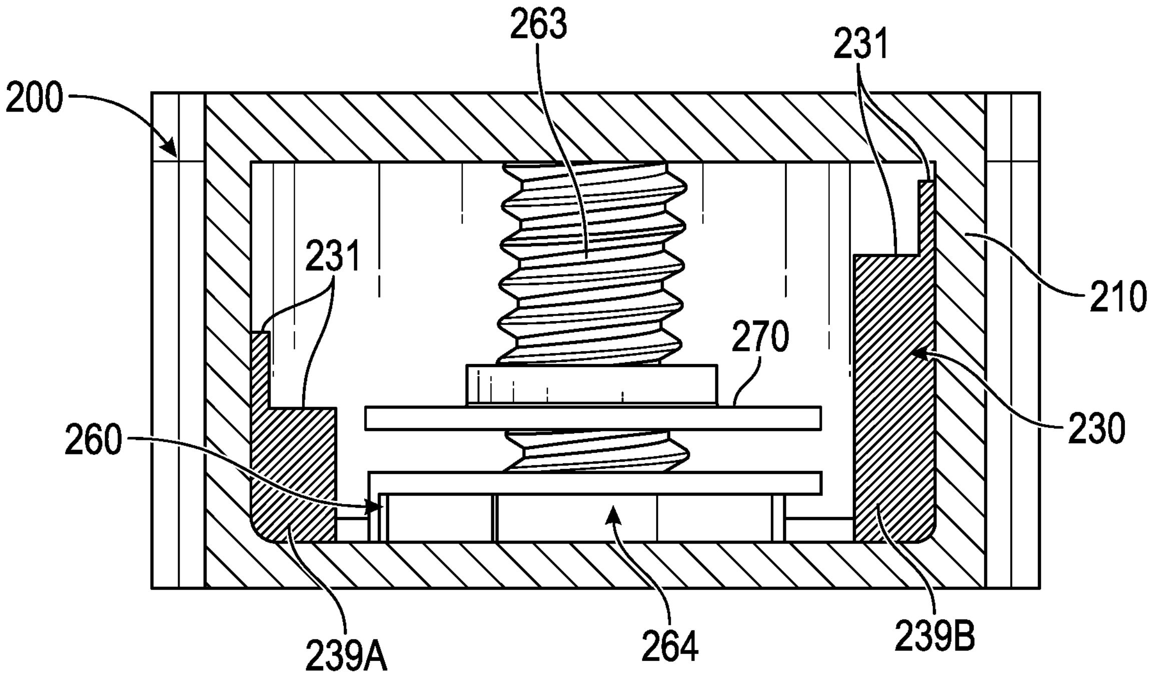


FIG. 14B

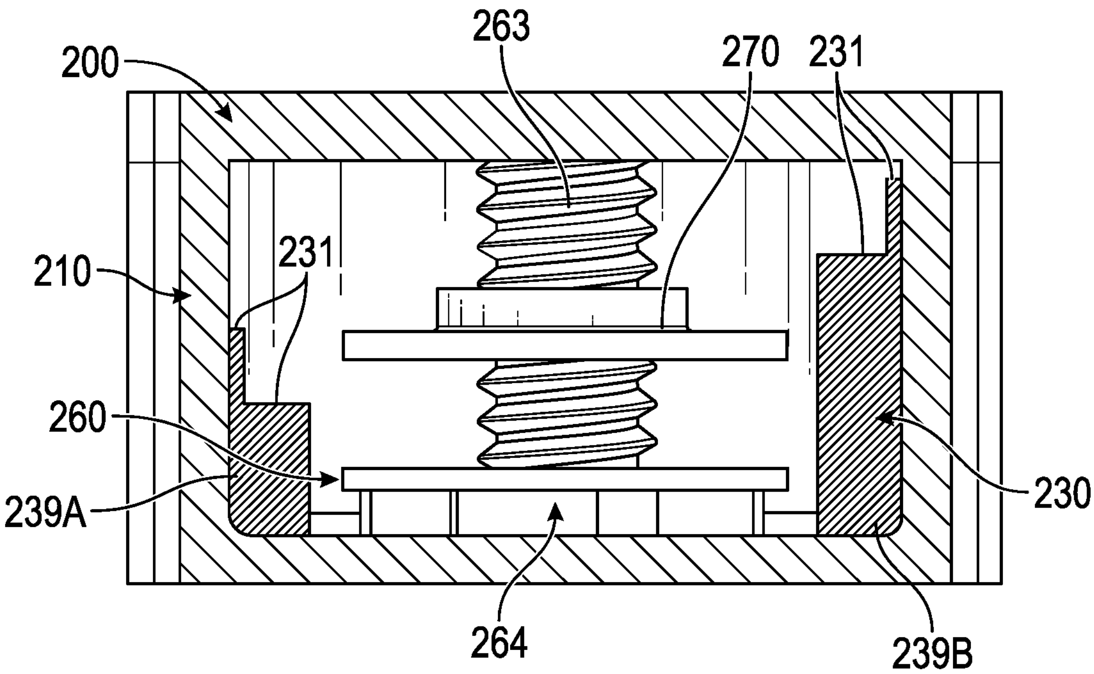


FIG. 14C

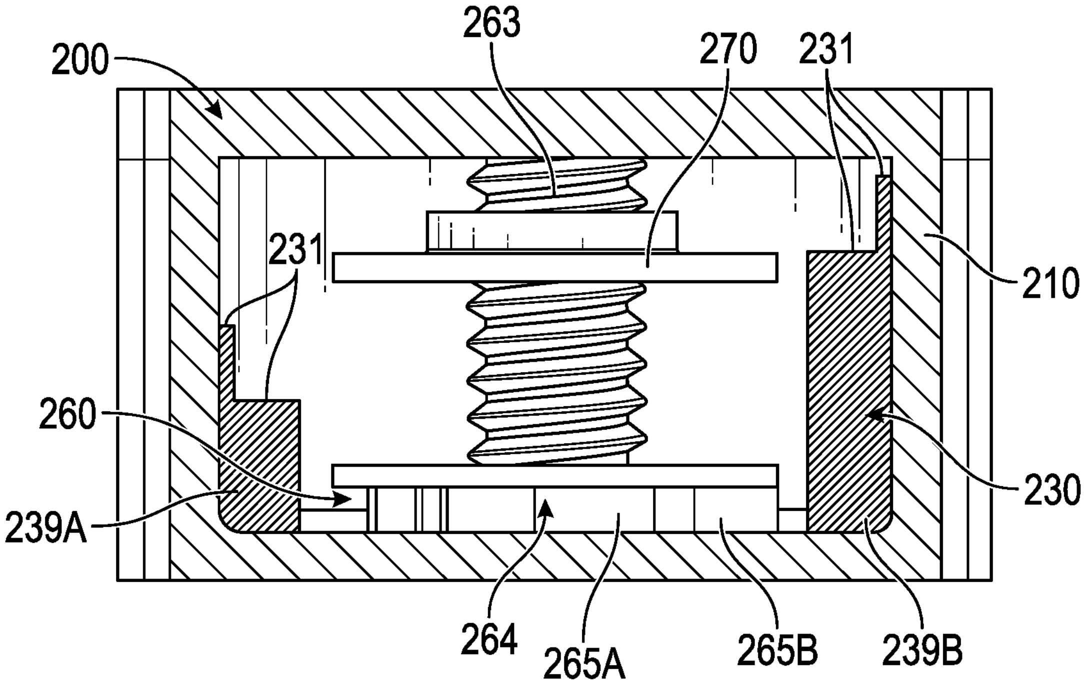


FIG. 14D

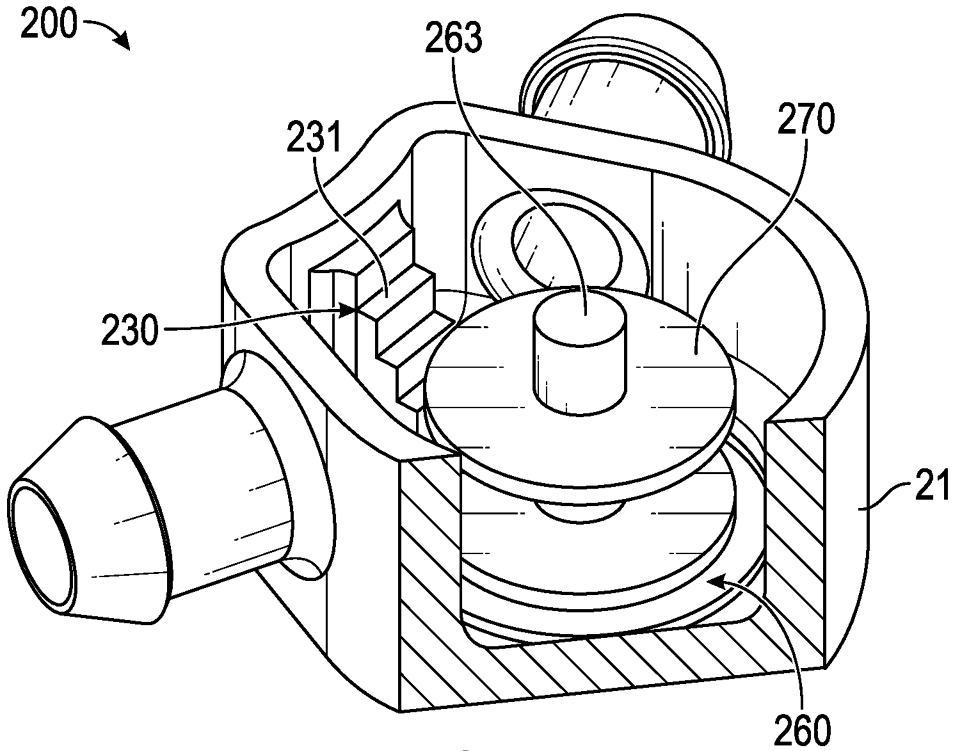


FIG. 15A

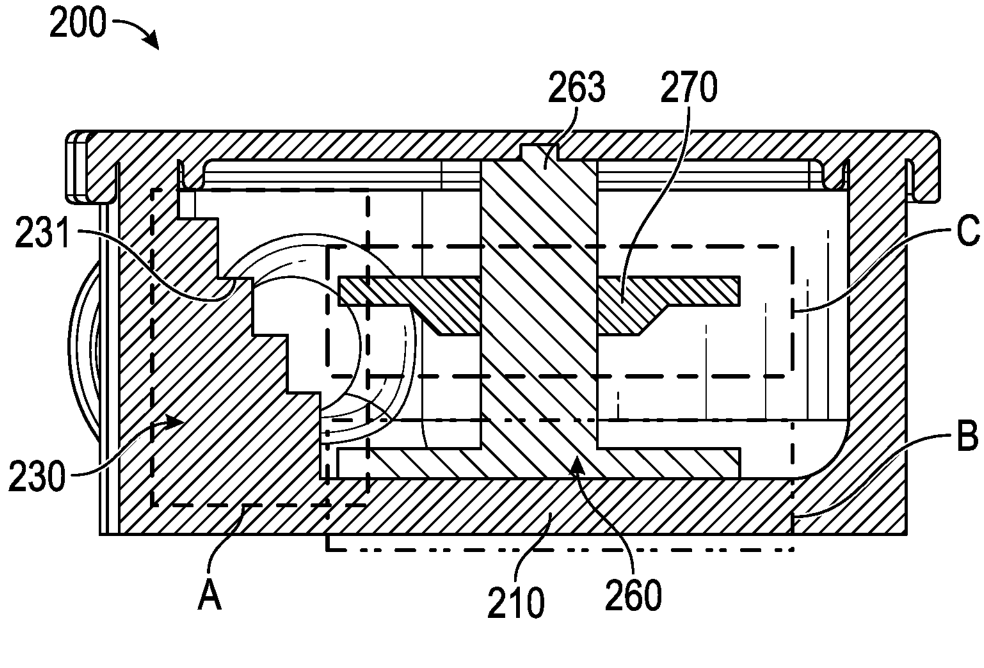


FIG. 15B

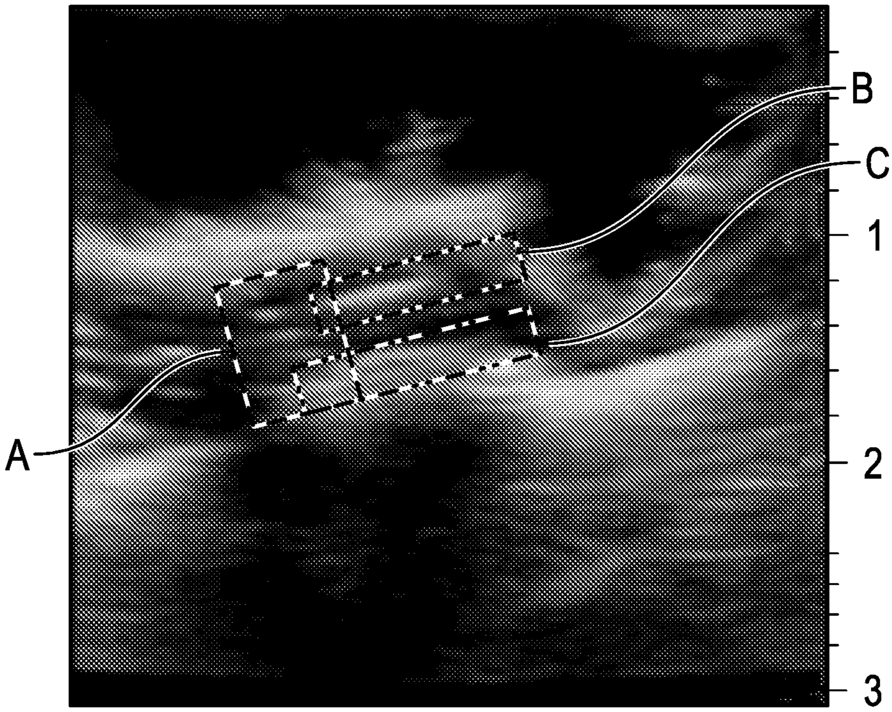


FIG. 15C

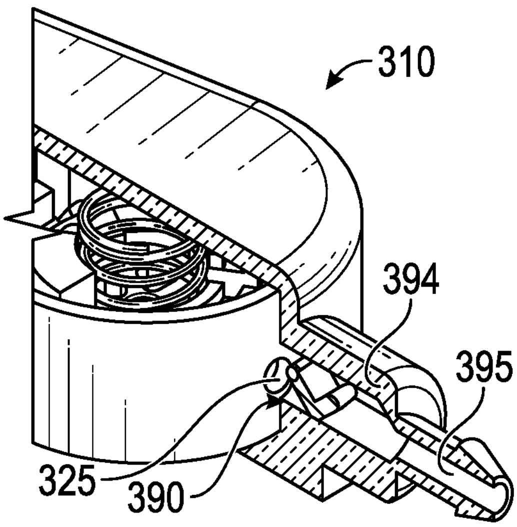


FIG. 16A

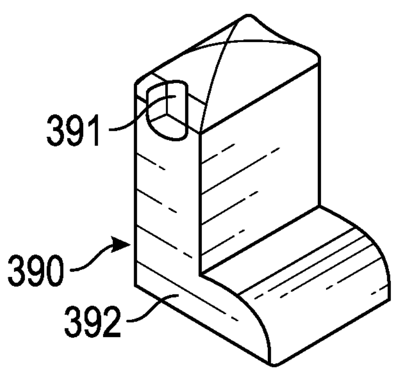


FIG. 16B

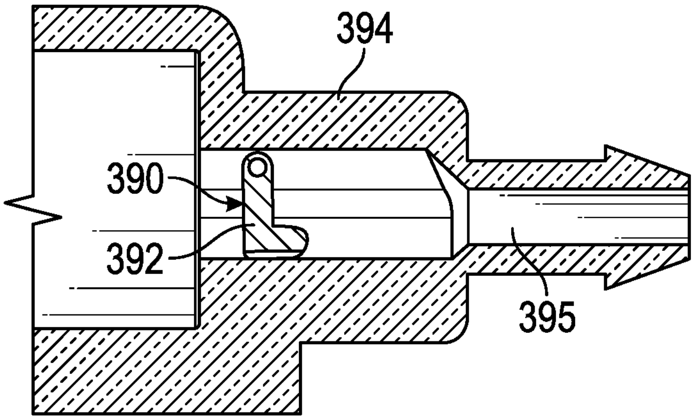


FIG. 16C

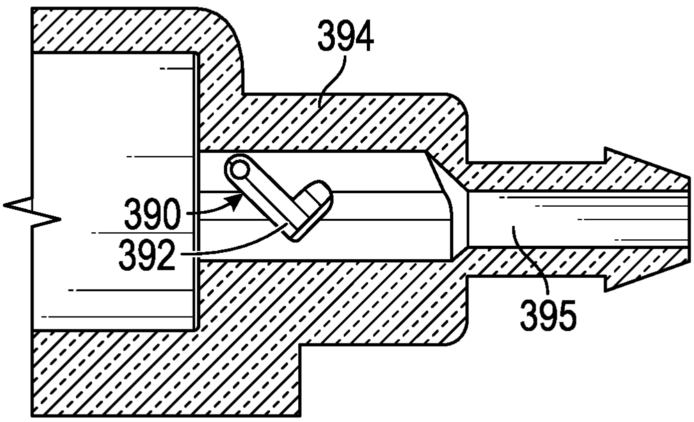


FIG. 16D

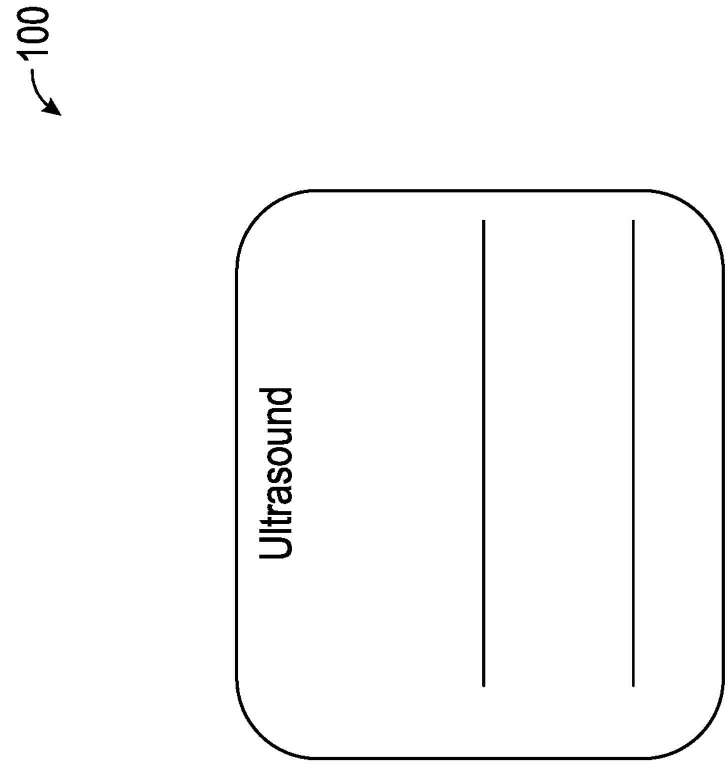


FIG. 17B

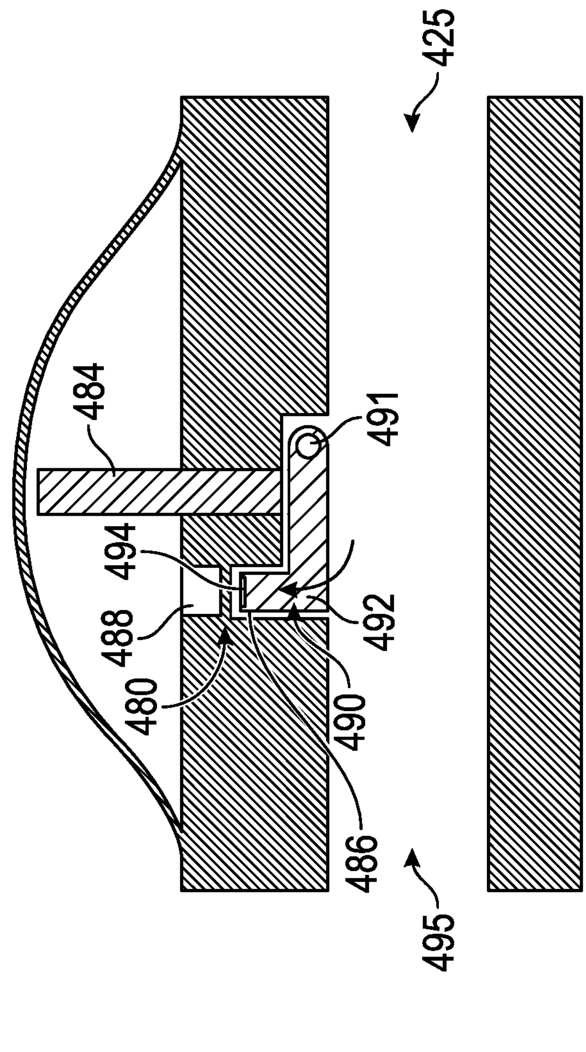


FIG. 17A

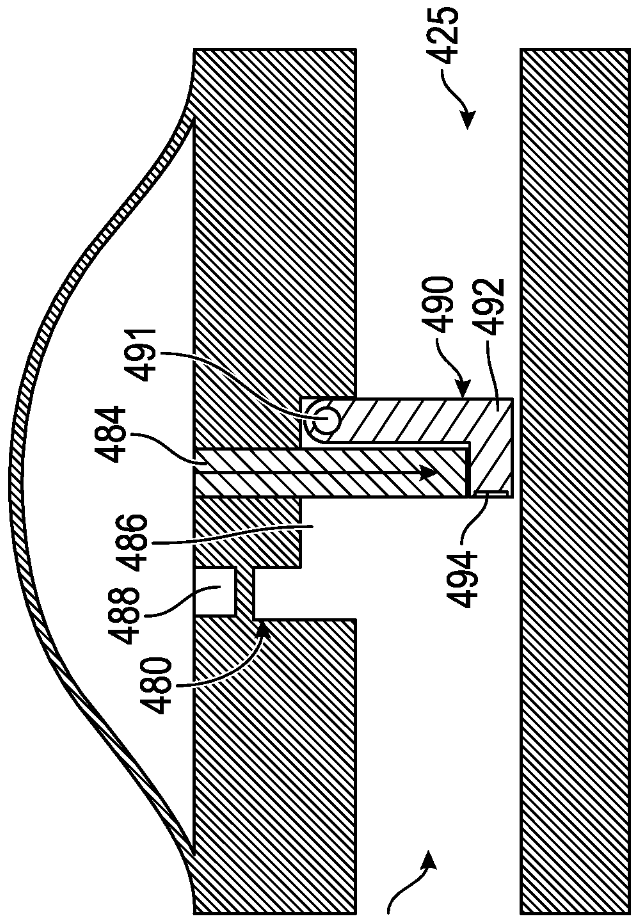


FIG. 17D

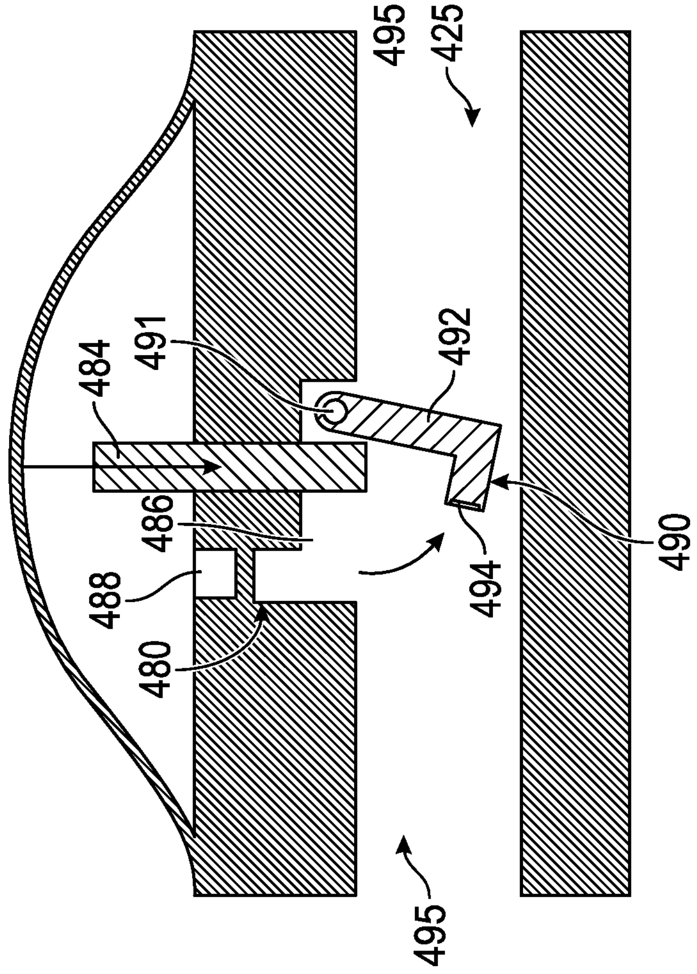


FIG. 17C

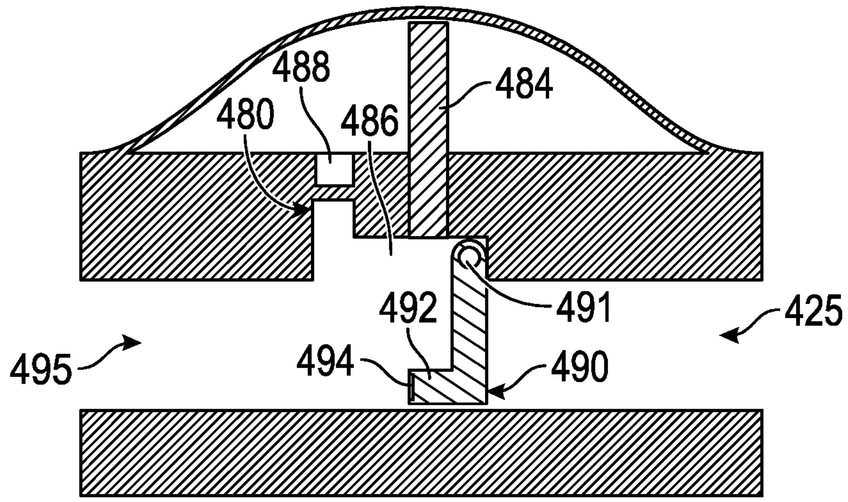


FIG. 17E

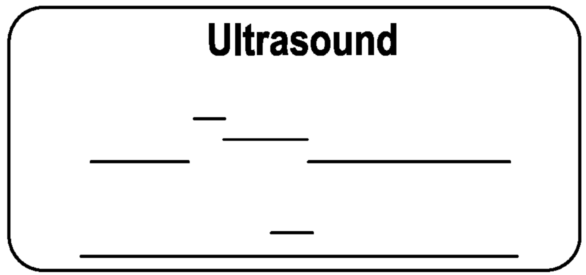


FIG. 17F

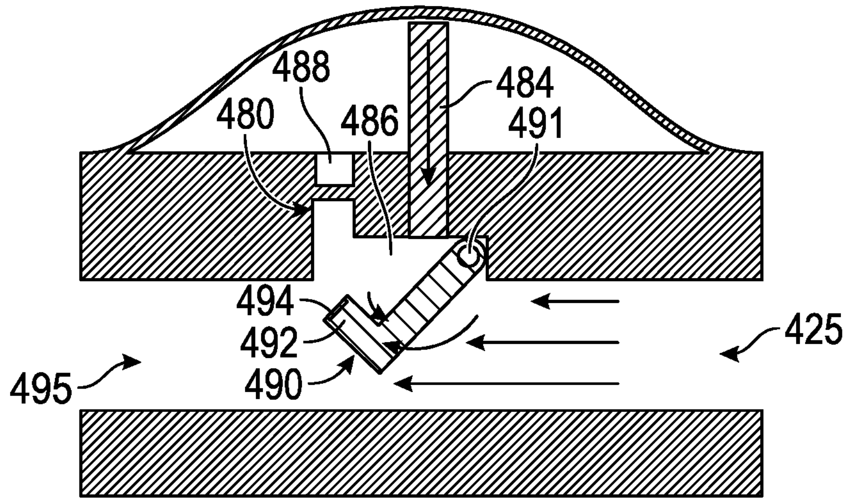


FIG. 17G

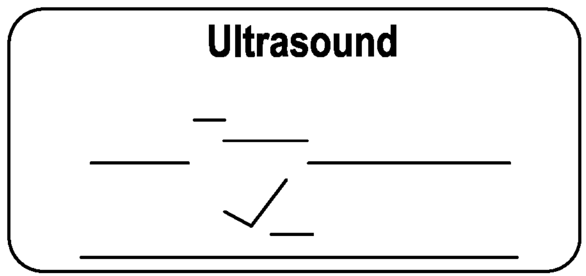


FIG. 17H

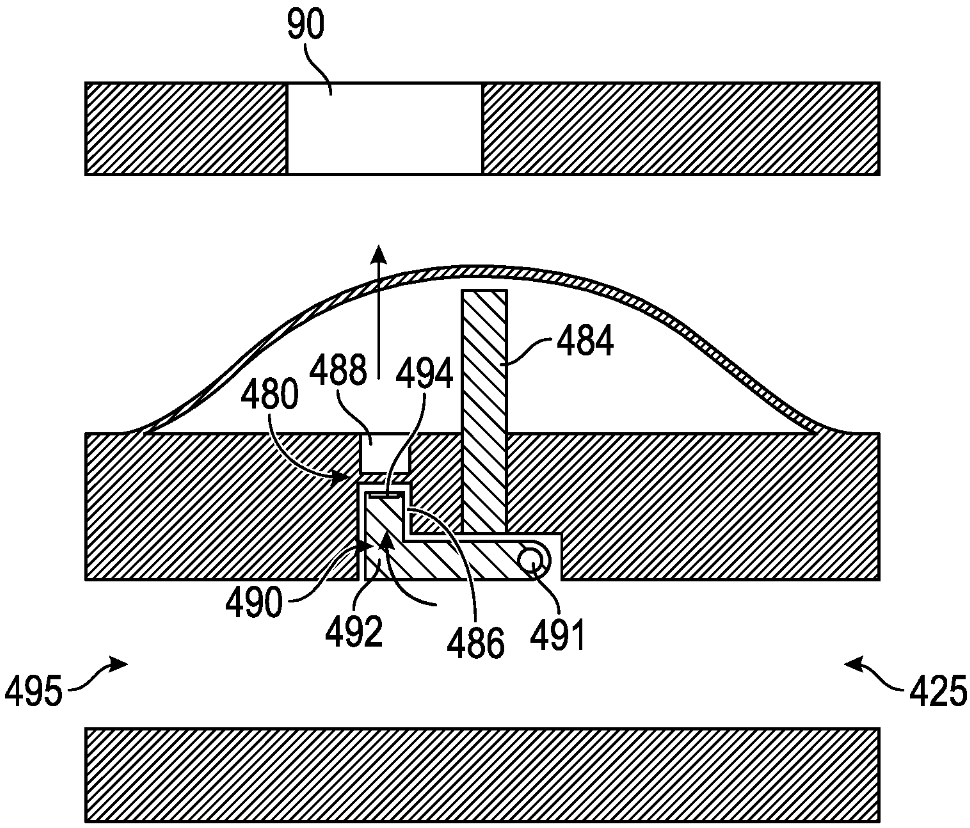


FIG. 17I

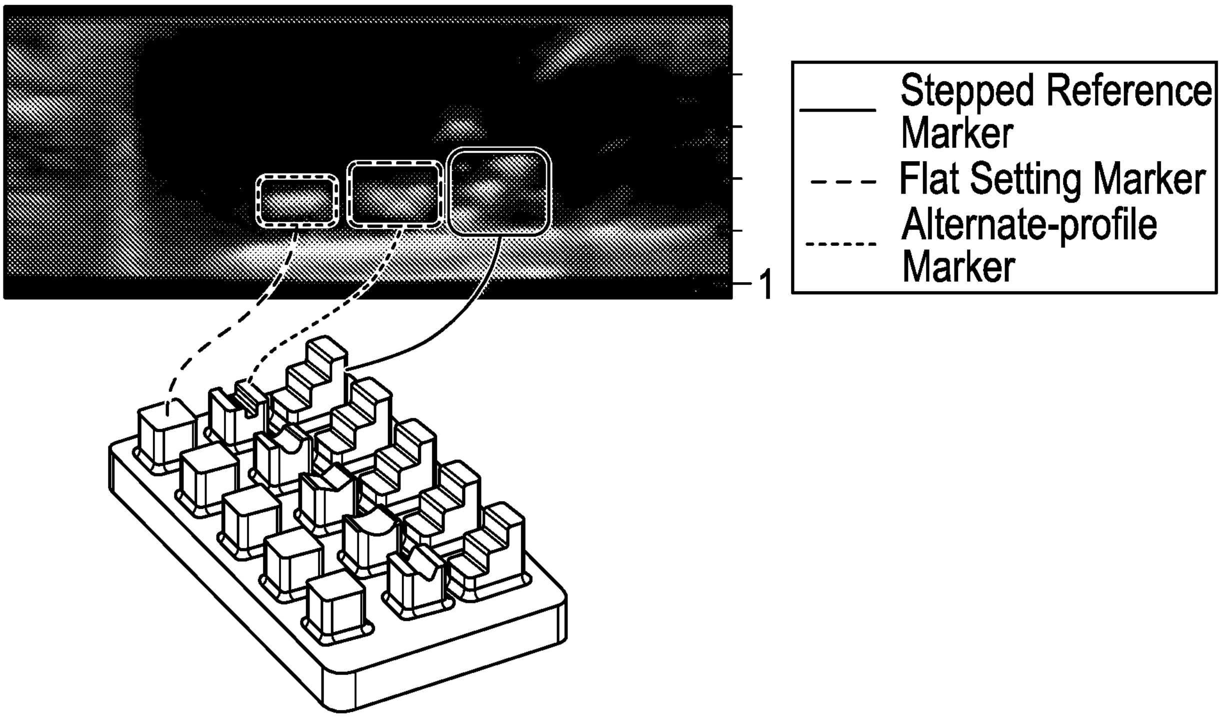


FIG. 18A

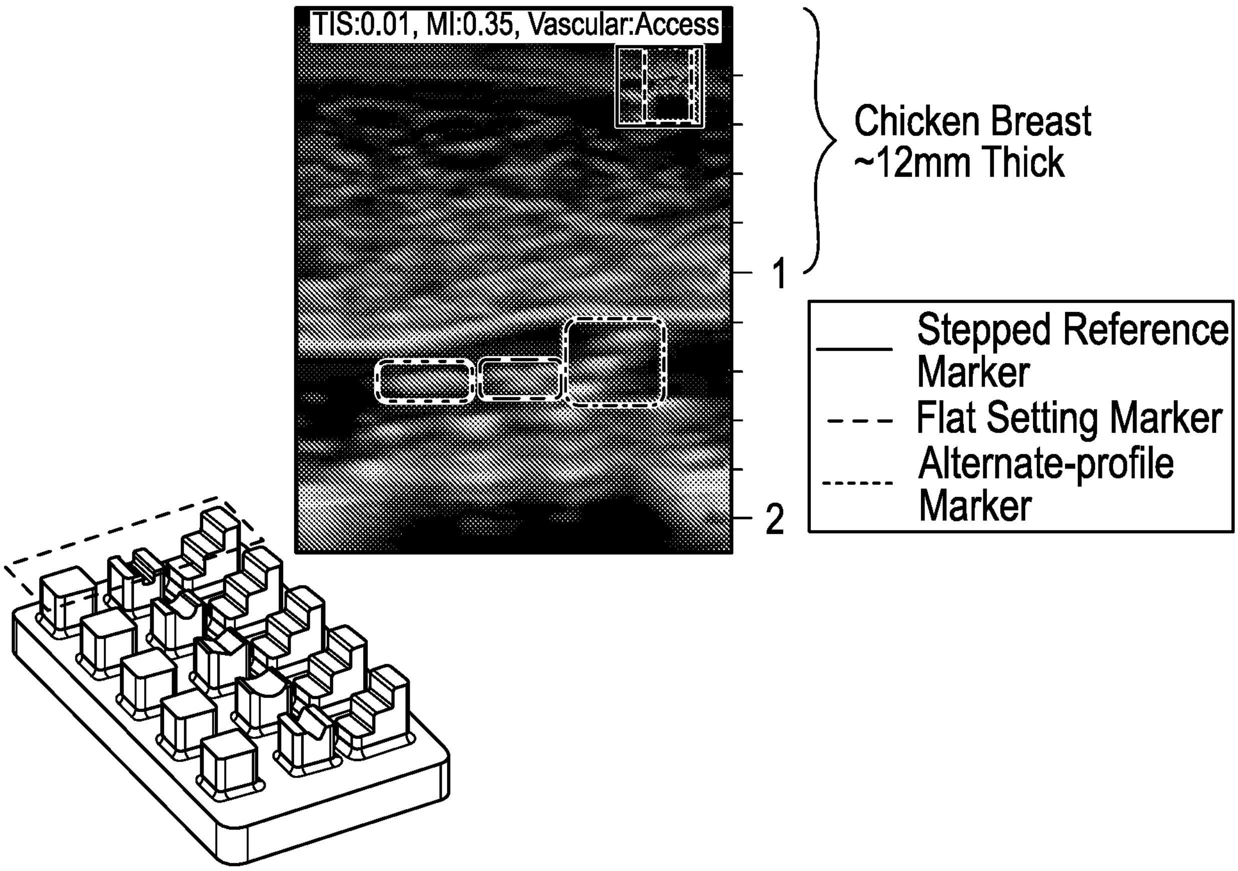
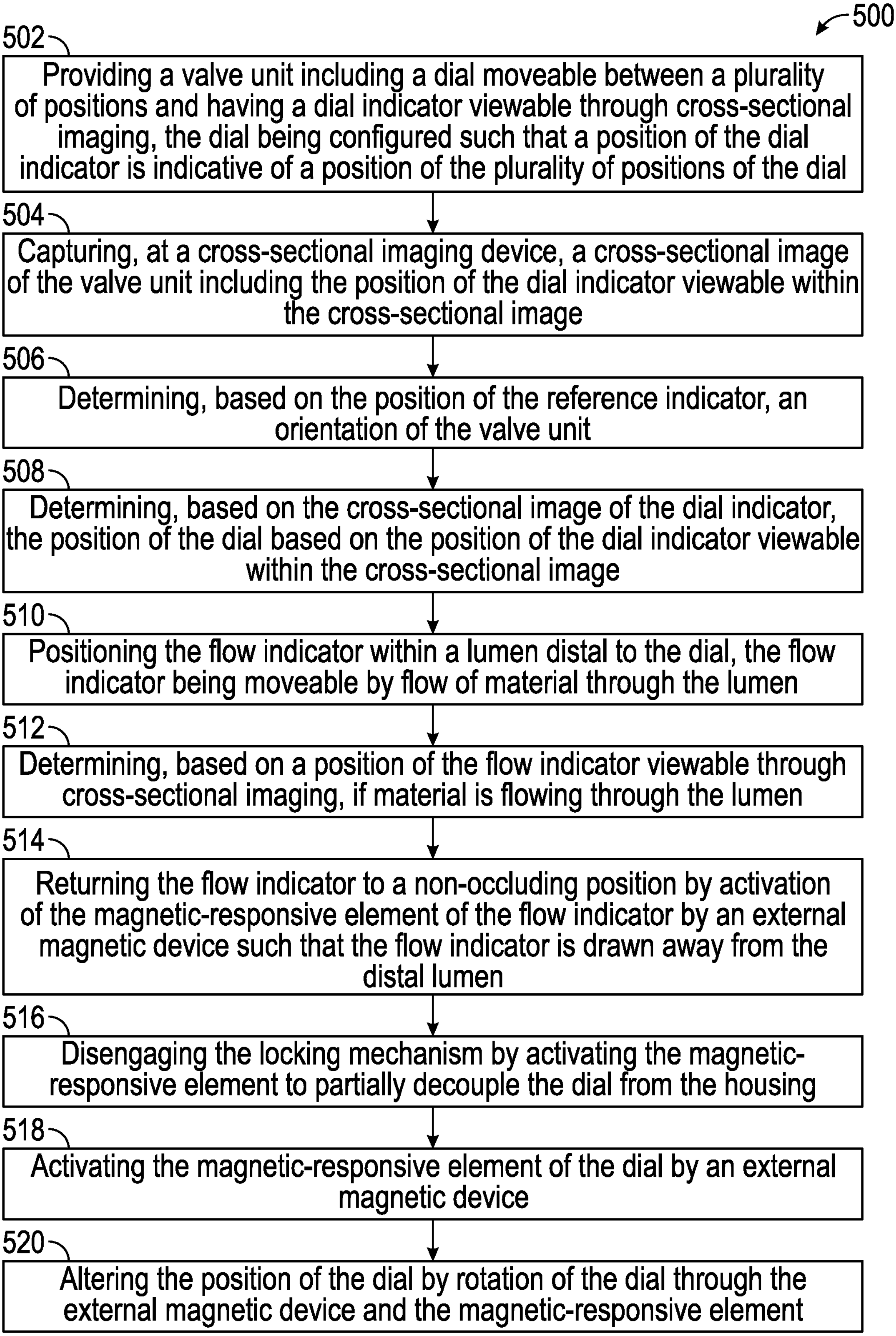


FIG. 18B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502
Providing a valve unit including a dial moveable between a plurality of positions and having a dial indicator viewable through cross-sectional imaging, the dial being configured such that a position of the dial indicator is indicative of a position of the plurality of positions of the dial
504
Capturing, at a cross-sectional imaging device, a cross-sectional image of the valve unit including the position of the dial indicator viewable within the cross-sectional image
506
Determining, based on the position of the reference indicator, an orientation of the valve unit
508
Determining, based on the cross-sectional image of the dial indicator, the position of the dial based on the position of the dial indicator viewable within the cross-sectional image
510
Positioning the flow indicator within a lumen distal to the dial, the flow indicator being moveable by flow of material through the lumen
512
Determining, based on a position of the flow indicator viewable through cross-sectional imaging, if material is flowing through the lumen
514
Returning the flow indicator to a non-occluding position by activation of the magnetic-responsive element of the flow indicator by an external magnetic device such that the flow indicator is drawn away from the distal lumen
516
Disengaging the locking mechanism by activating the magnetic-responsive element to partially decouple the dial from the housing
518
Activating the magnetic-responsive element of the dial by an external magnetic device
520
Altering the position of the dial by rotation of the dial through the external magnetic device and the magnetic-responsive element

FIG. 19