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(54) **COUPLING STRUCTURES FOR AN ULTRASOUND PROBE**

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Related U.S. Application Data

(60) Division of application No. 14/190,591, filed on Feb. 26, 2014, now abandoned, which is a continuation-in-part of application No. 13/206,396, filed on Aug. 9, 2011, which is a continuation-in-part of application No. 12/900,750, filed on Oct. 8, 2010.

(60) Provisional application No. 61/769,676, filed on Feb. 26, 2013, provisional application No. 61/372,044, filed on Aug. 9, 2010, provisional application No. 61/249,850, filed on Oct. 8, 2009.

Publication Classification

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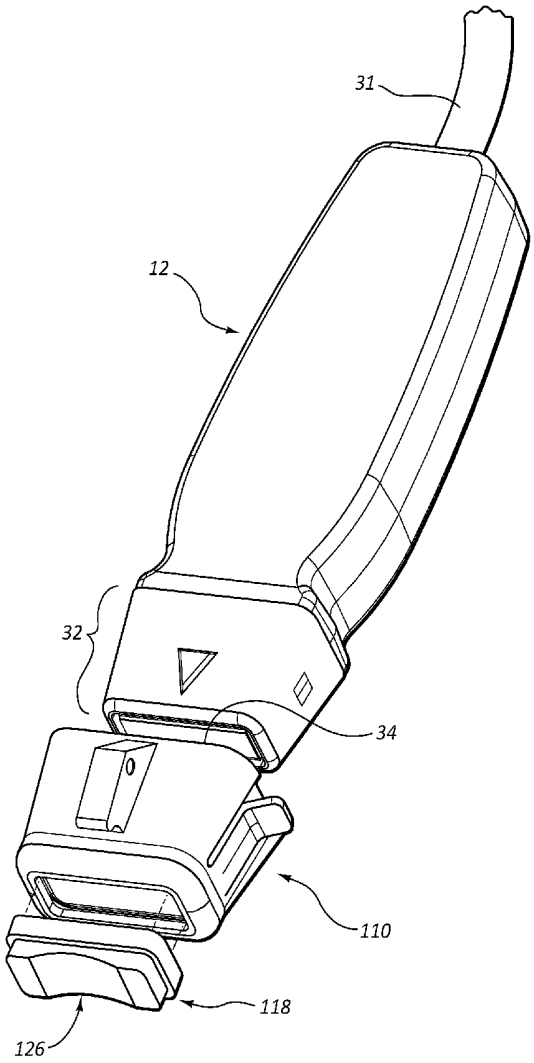
(52) **U.S. Cl.**
CPC ***A61B 8/4455*** (2013.01); *A61B 8/4472* (2013.01); ***A61B 8/4281*** (2013.01)

(57) **ABSTRACT**

A probe cap for use with an ultrasound probe including a head portion and an acoustic surface is disclosed. In one embodiment, the probe cap includes a body that defines a cavity sized for releasably receiving the head portion of the probe therein. The probe cap body further defines a hole that is proximate the acoustic surface of the head portion. A compliant spacer component is disposed in the hole. The spacer component can include a hydrogel and provides an acoustic path between the acoustic surface and a tissue surface of a patient. The spacer component includes a skin contact surface that defines a concavity and is deformable against the tissue surface. Additional embodiments disclose various probe cap and accompanying needle guide designs for use in assisting a clinician with ultrasound probe use and needle insertion into a patient.



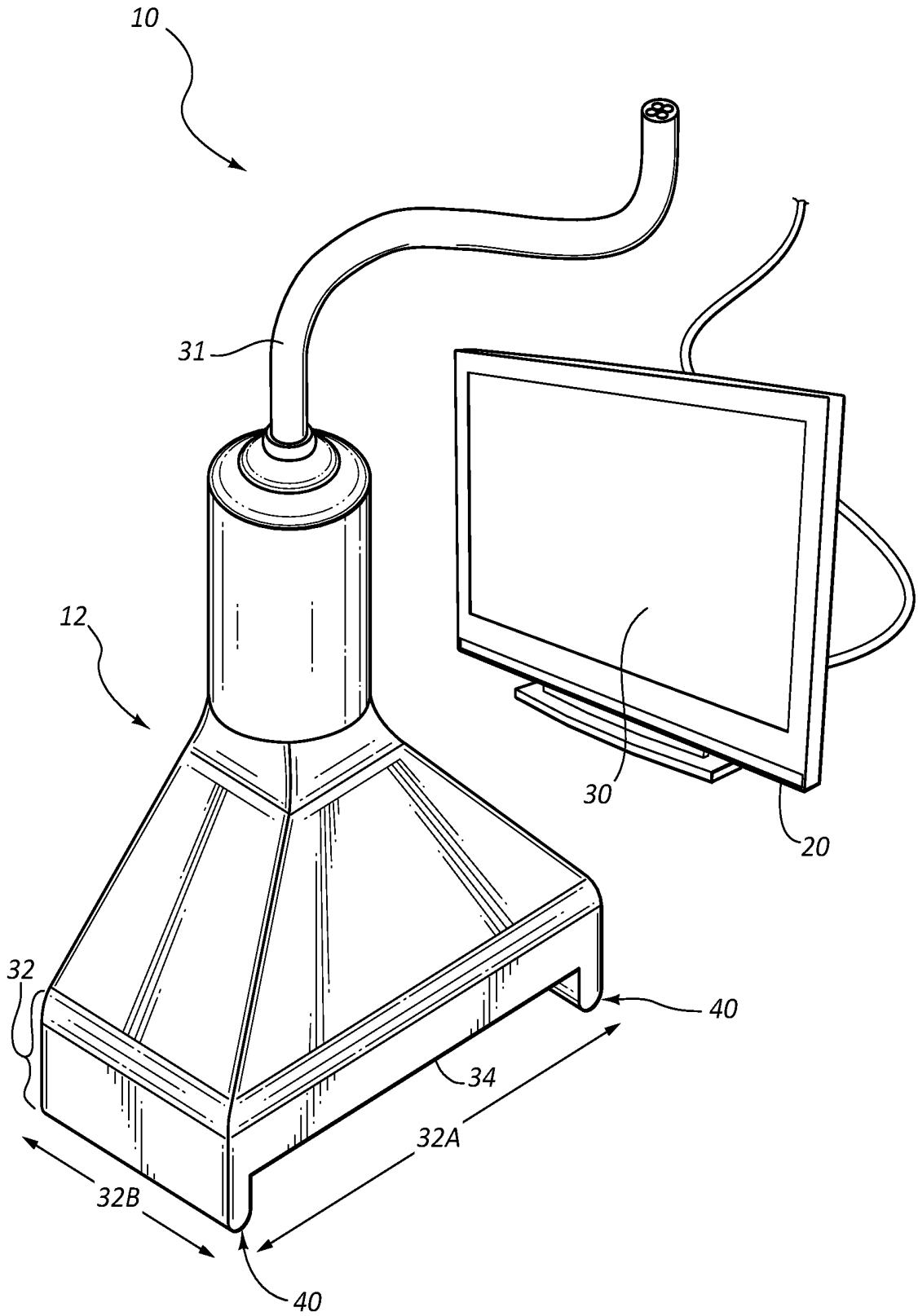


FIG. 1A

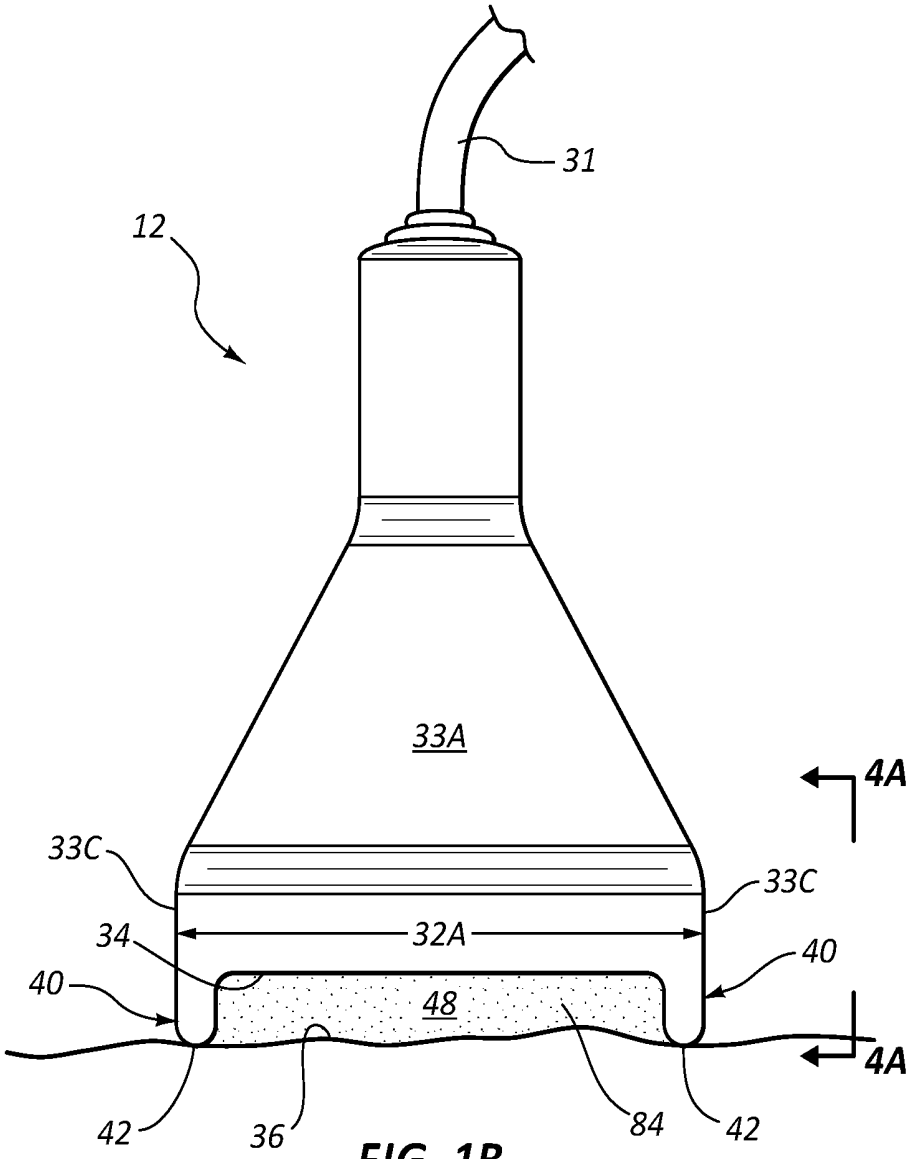

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FIG. 1B

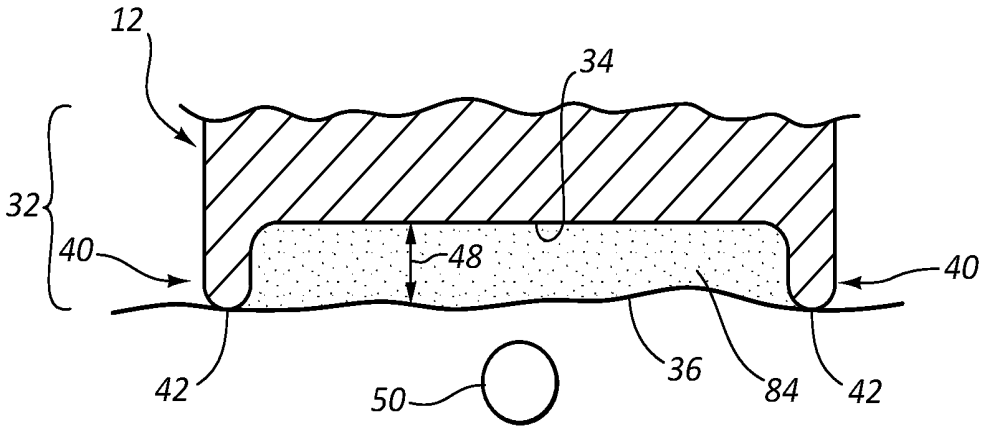
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FIG. 2

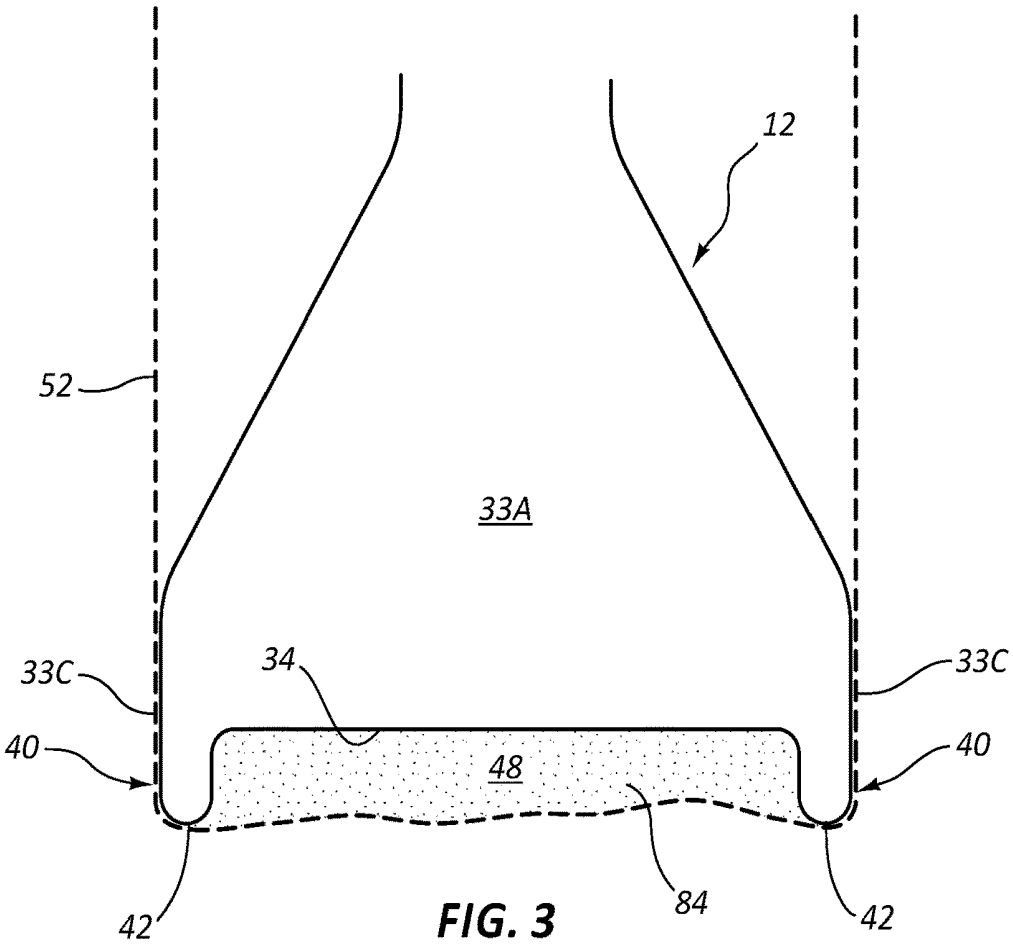


FIG. 3

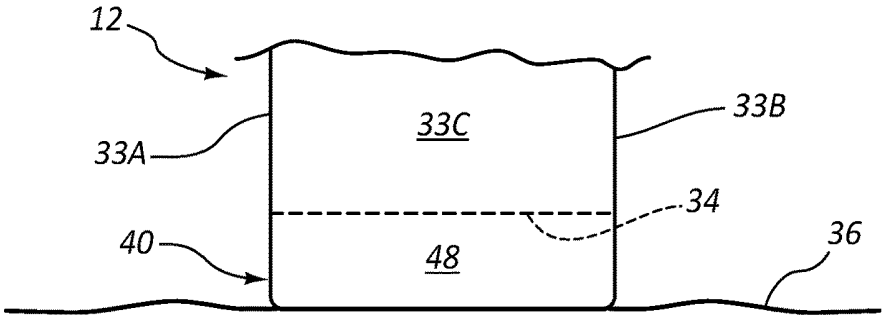


FIG. 4A

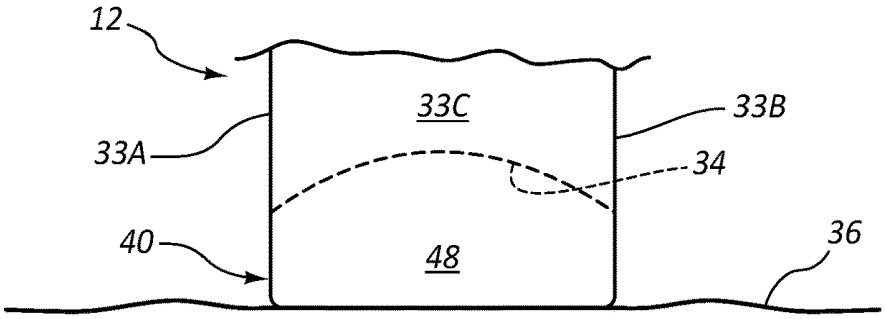


FIG. 4B

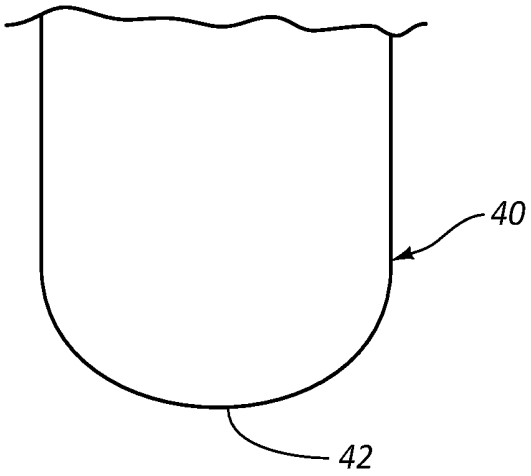


FIG. 5

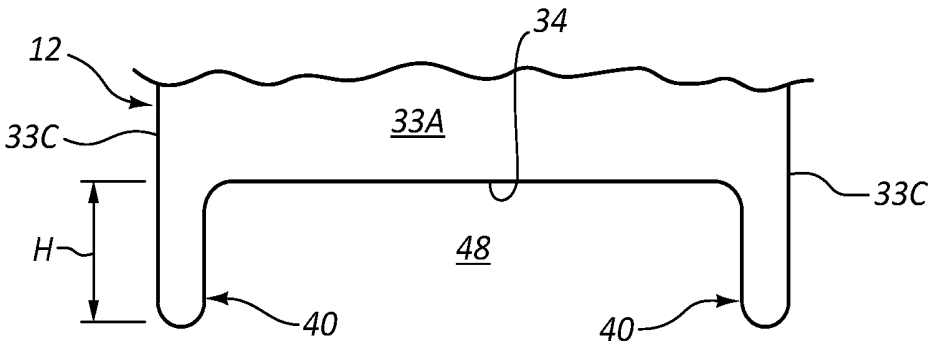
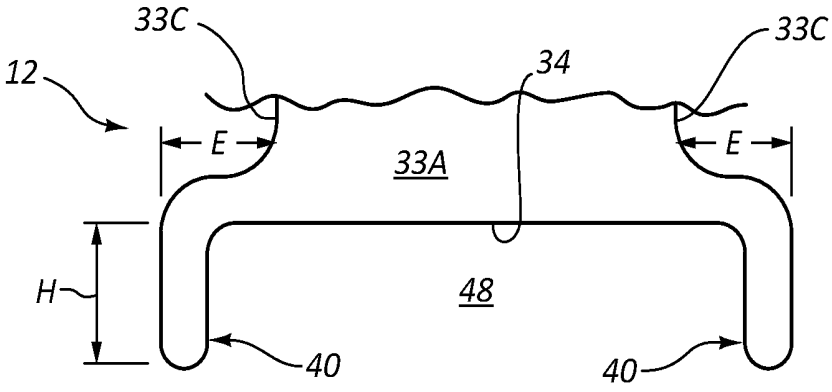


FIG. 6



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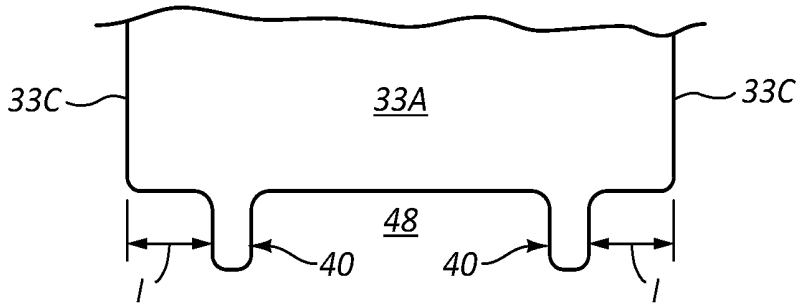

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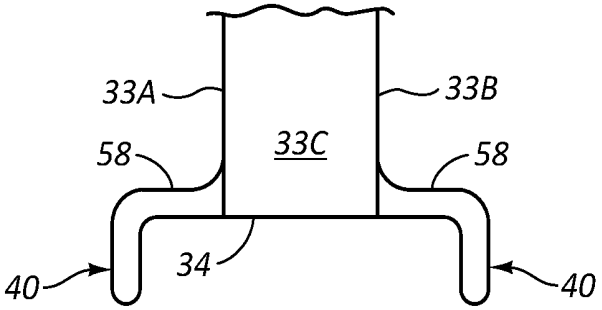


FIG. 9A

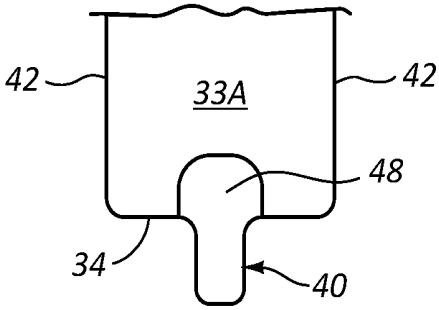
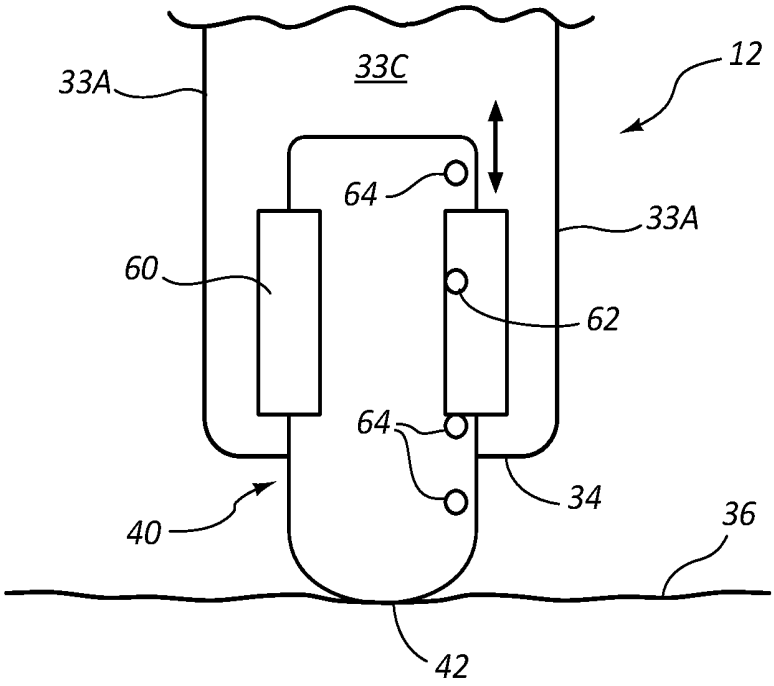


FIG. 9B



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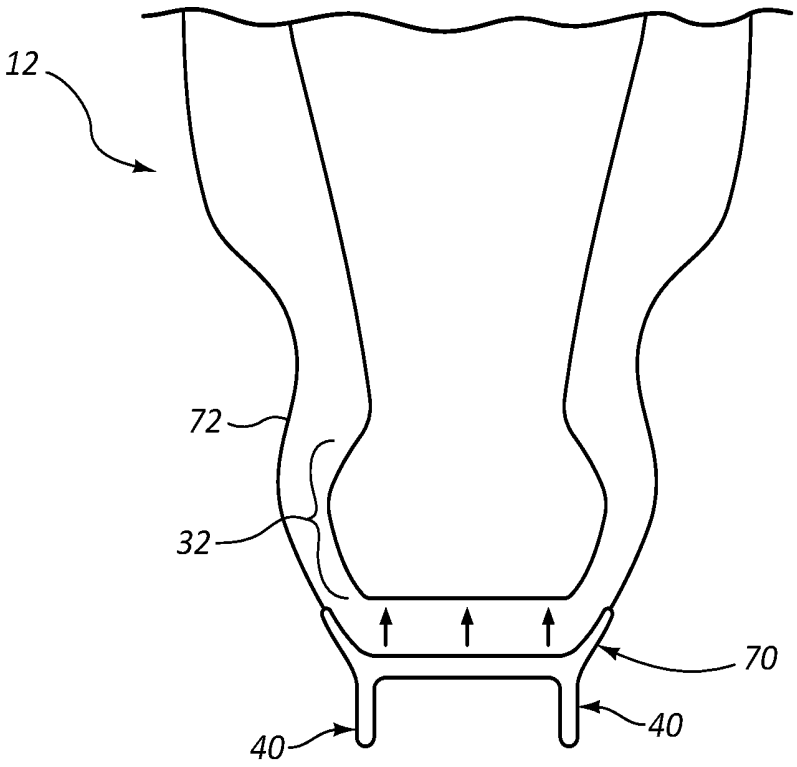

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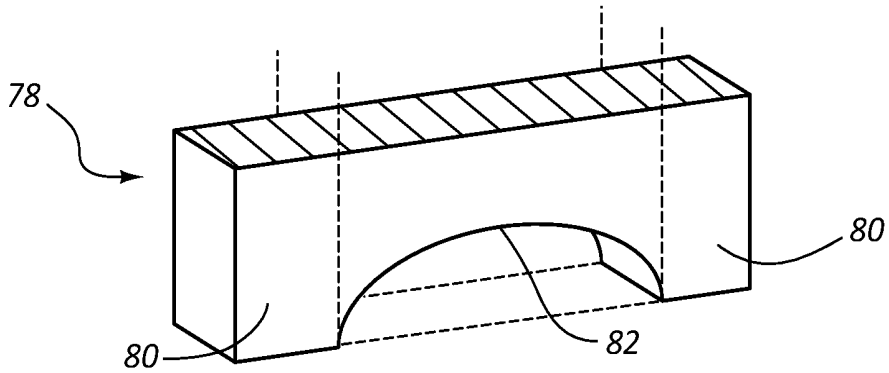


FIG. 12

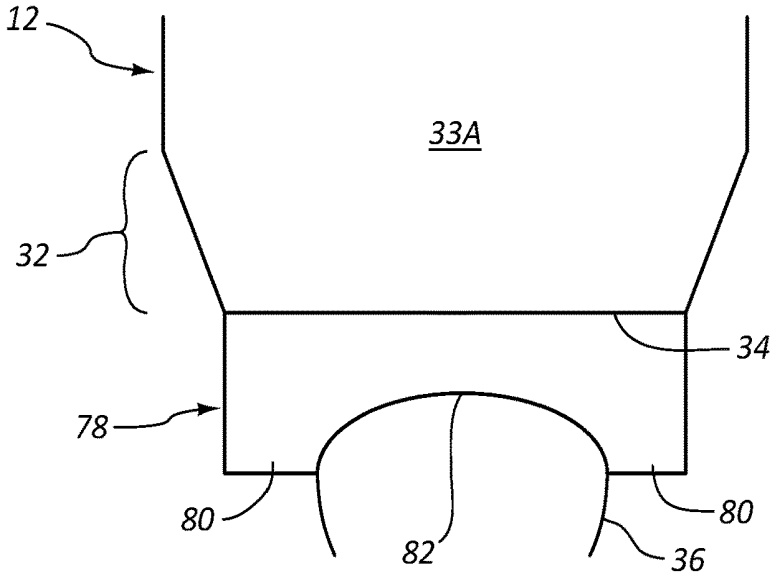


FIG. 13A

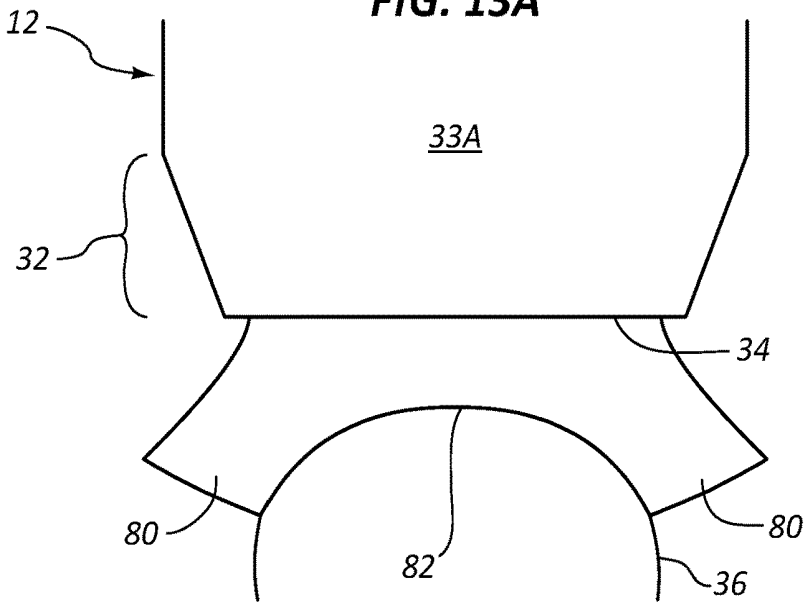


FIG. 13B

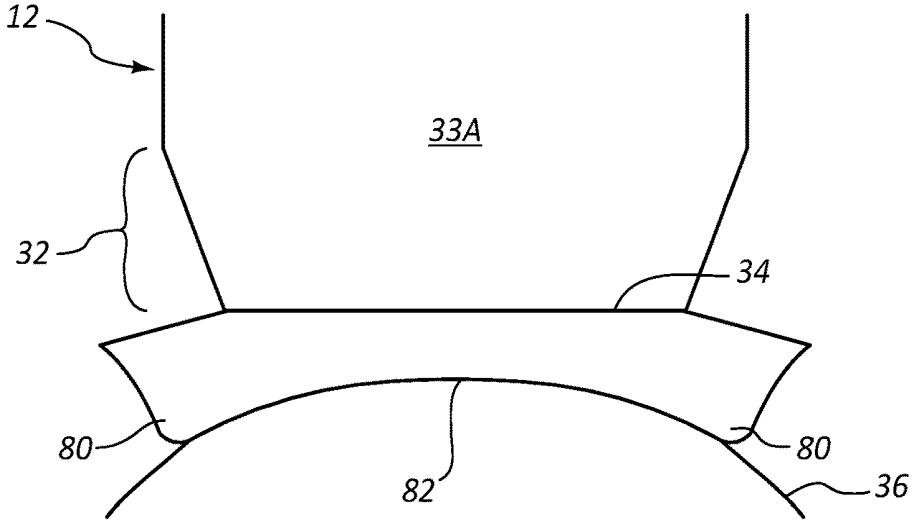
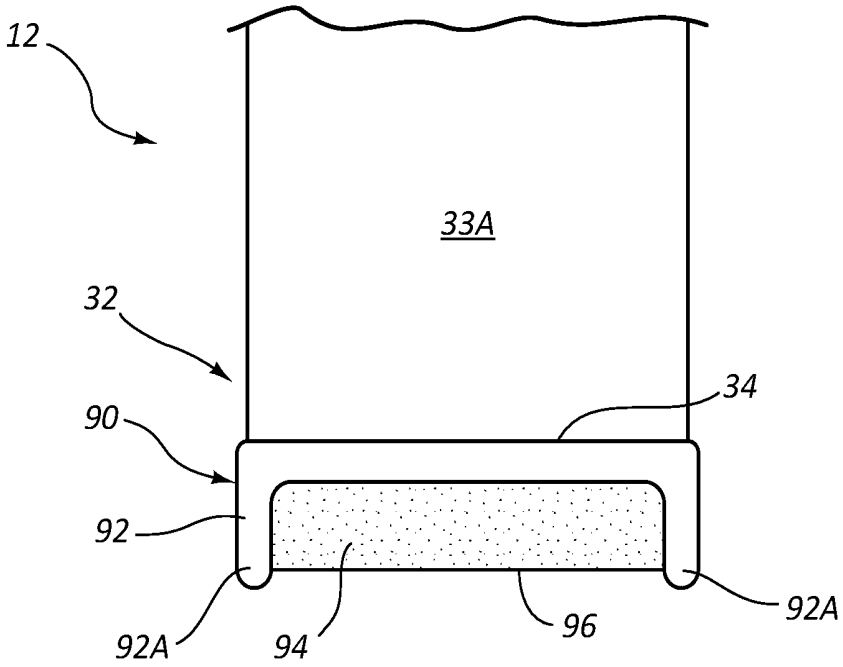


FIG. 13C



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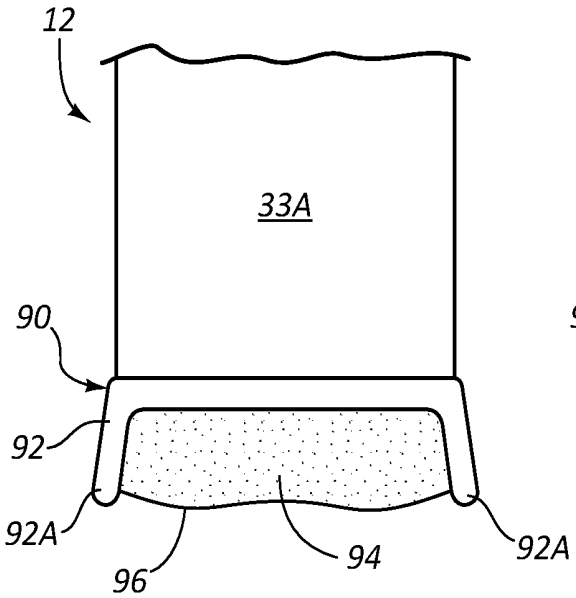

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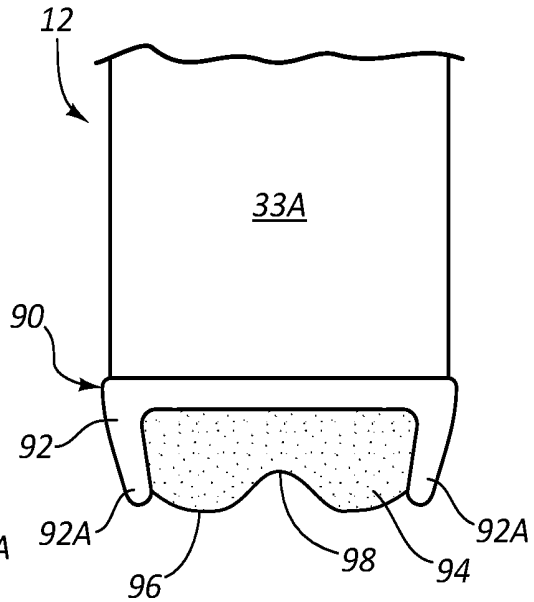

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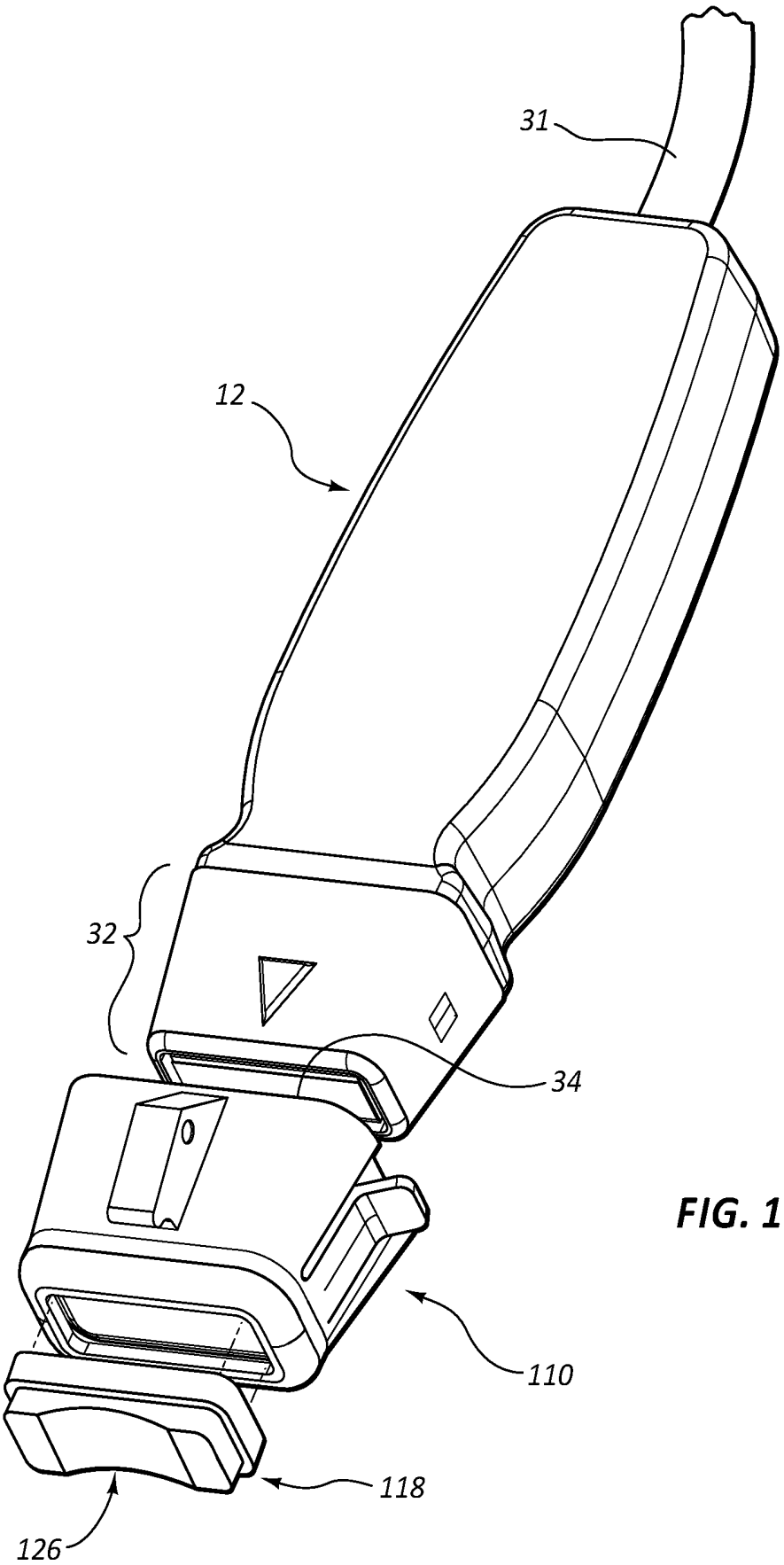

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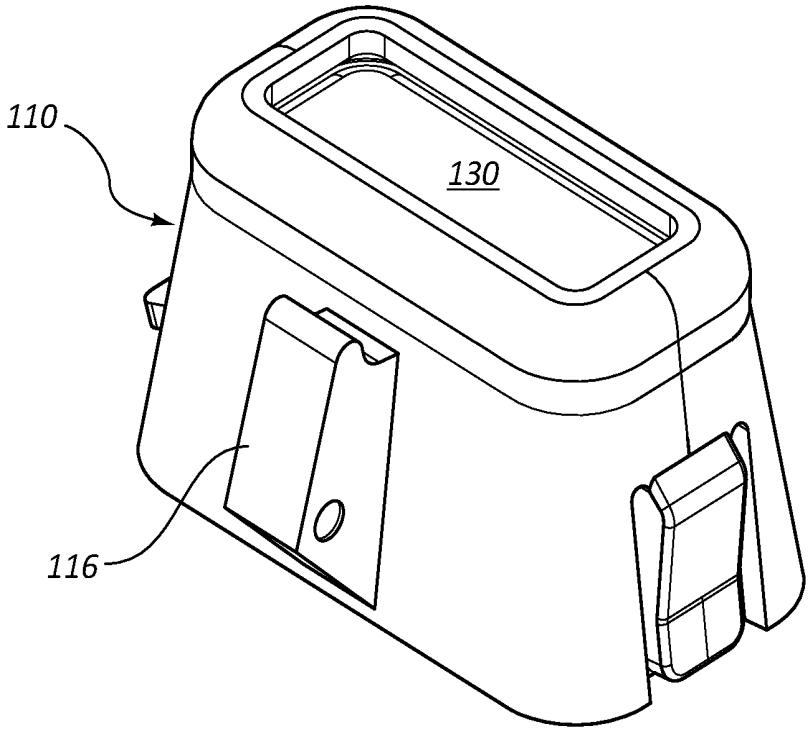

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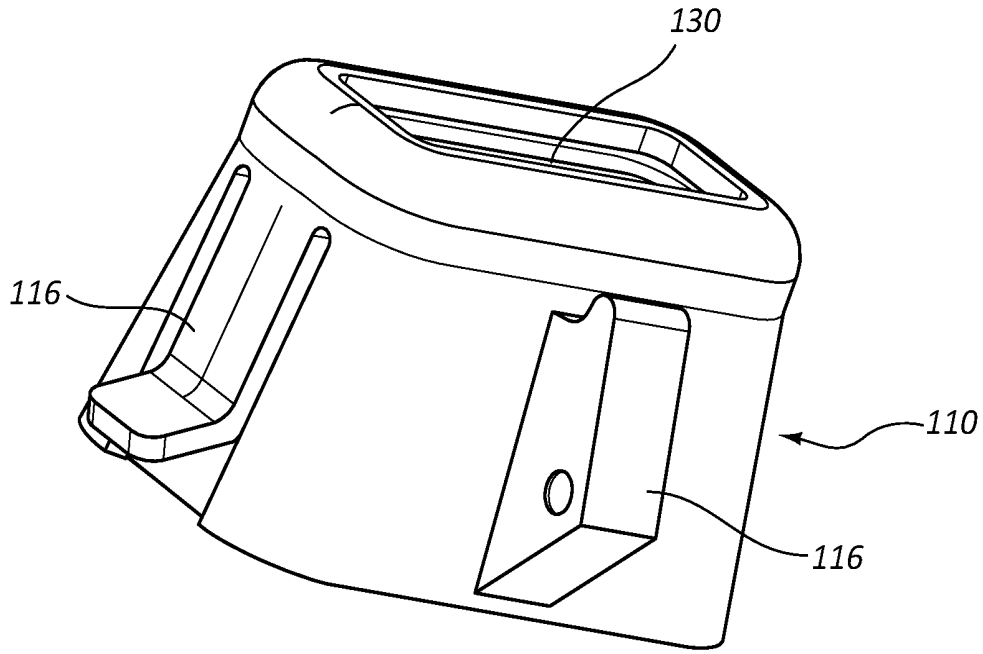

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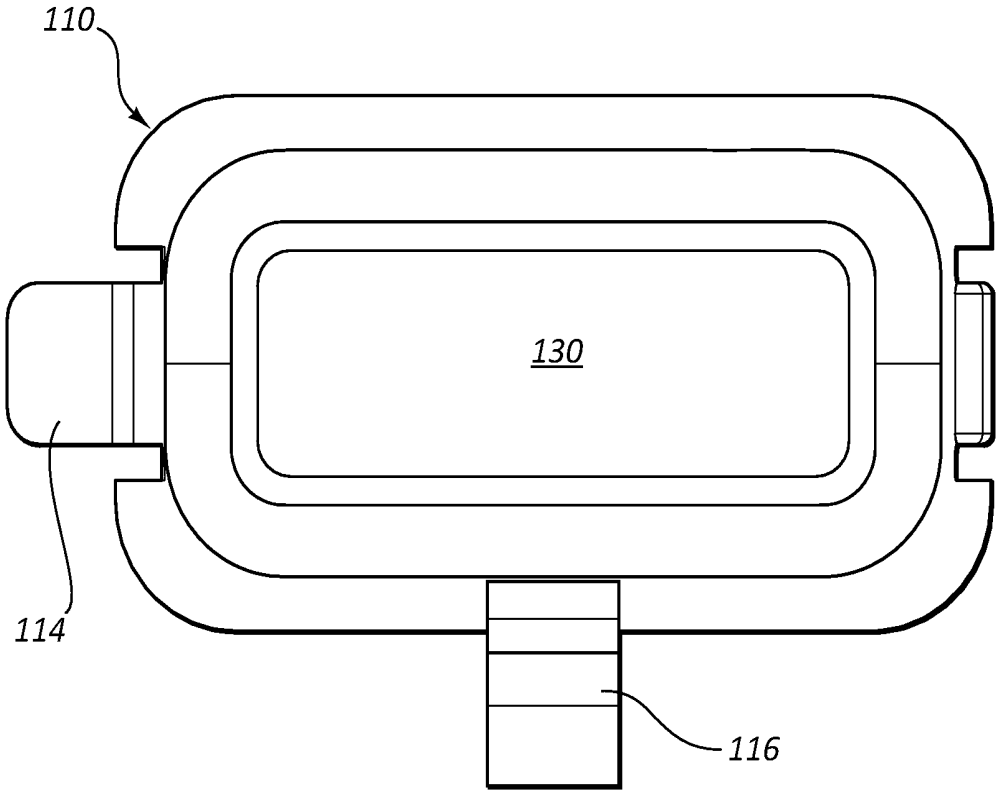

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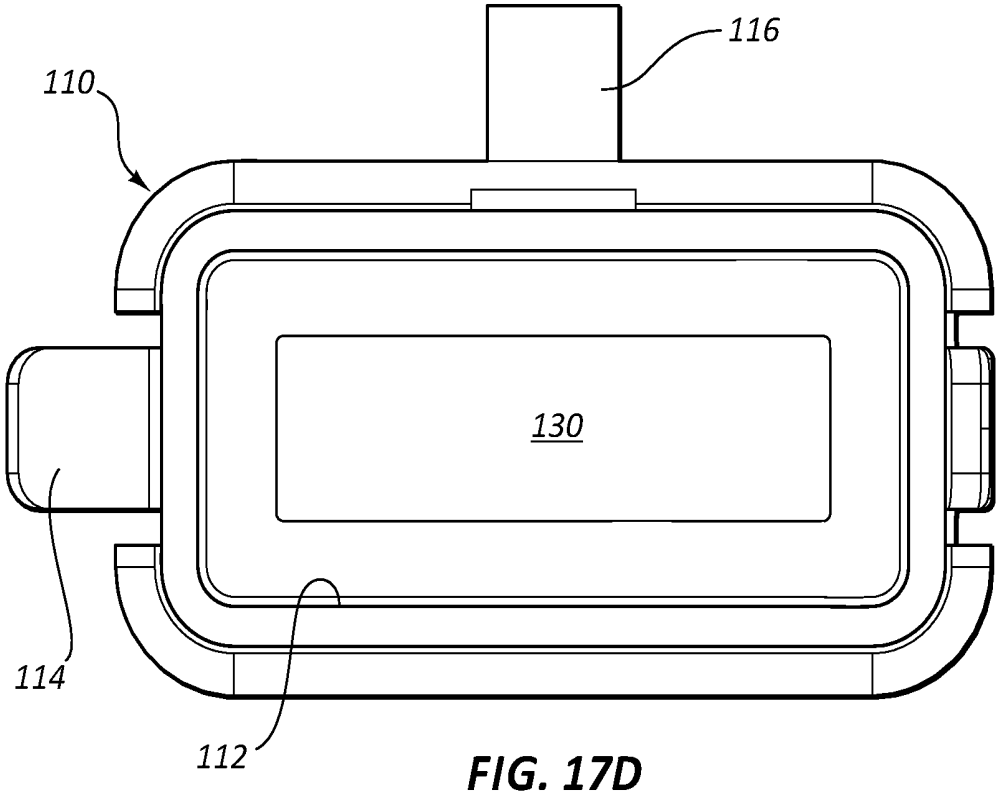

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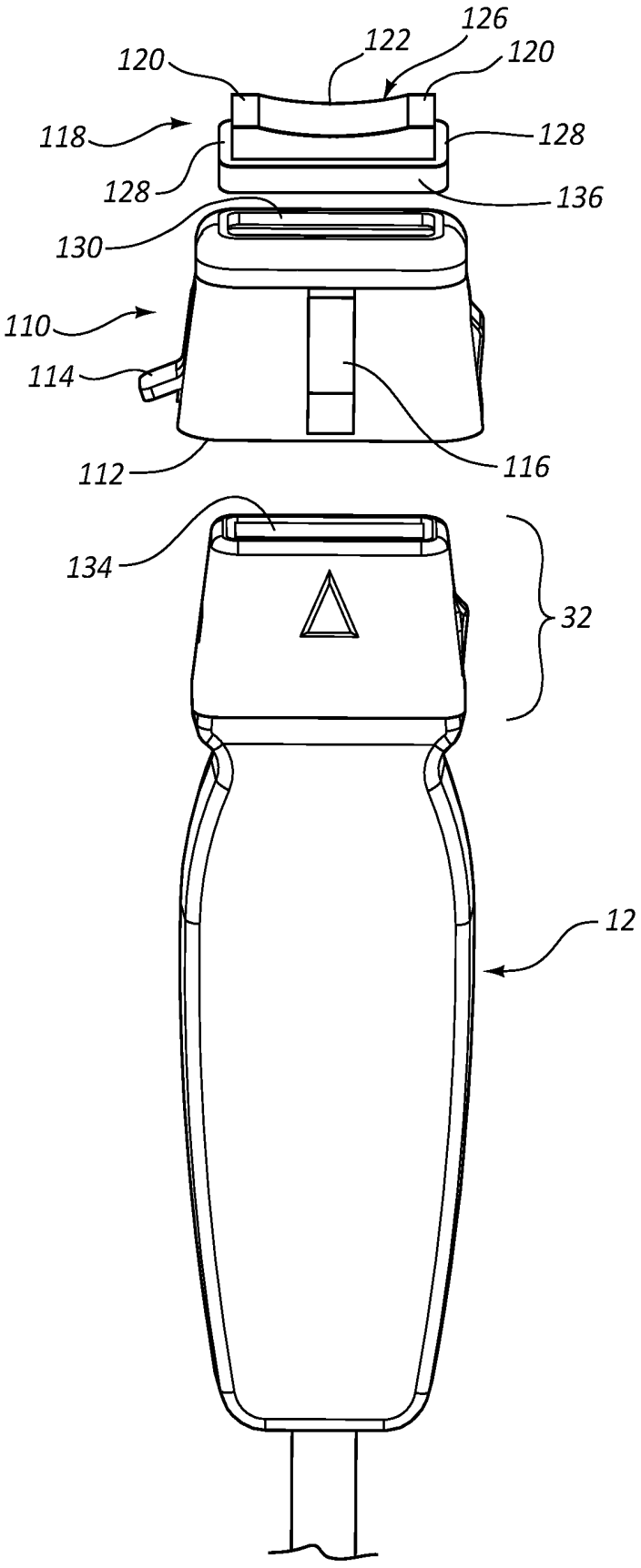

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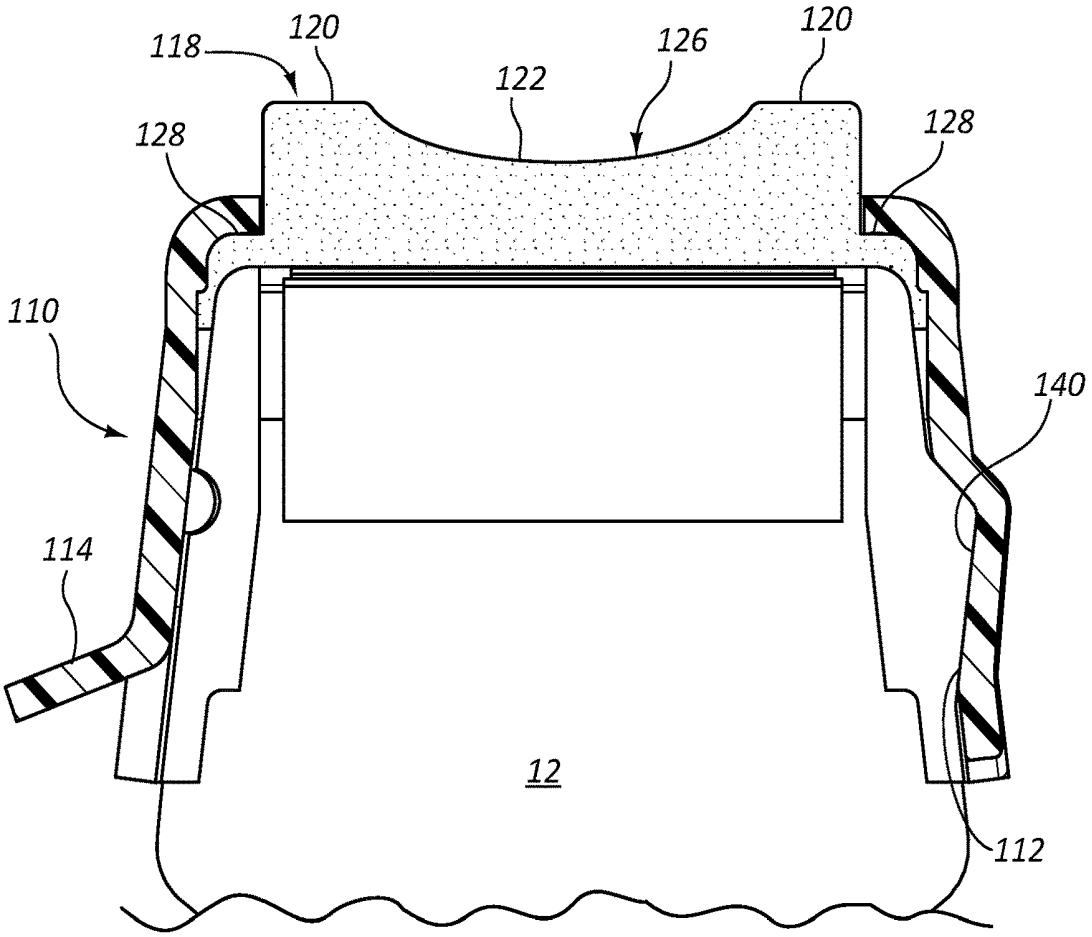

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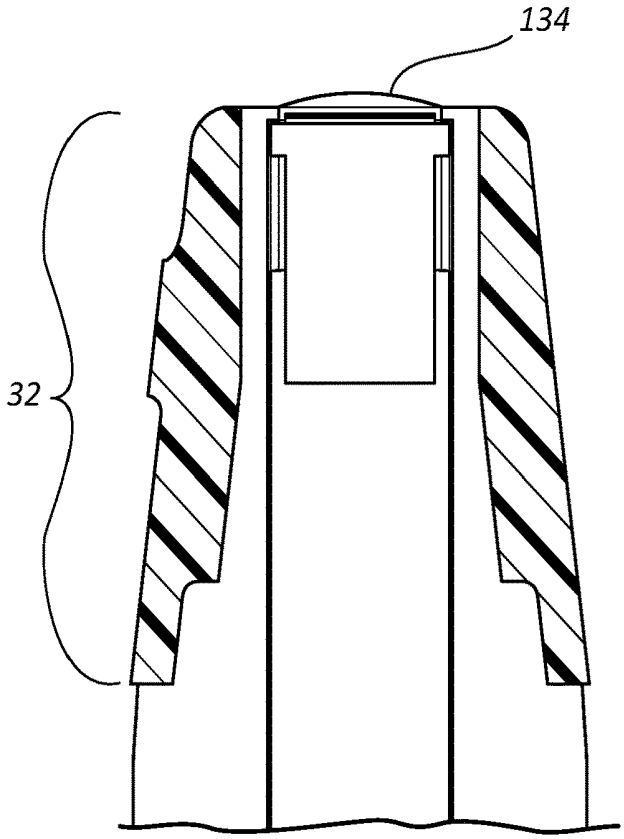

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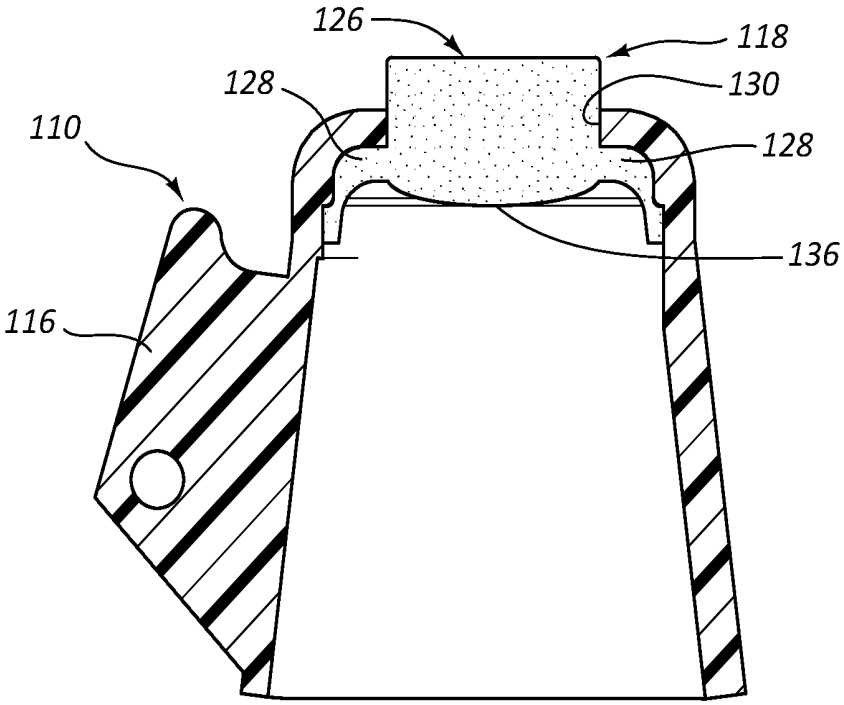
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FIG. 20

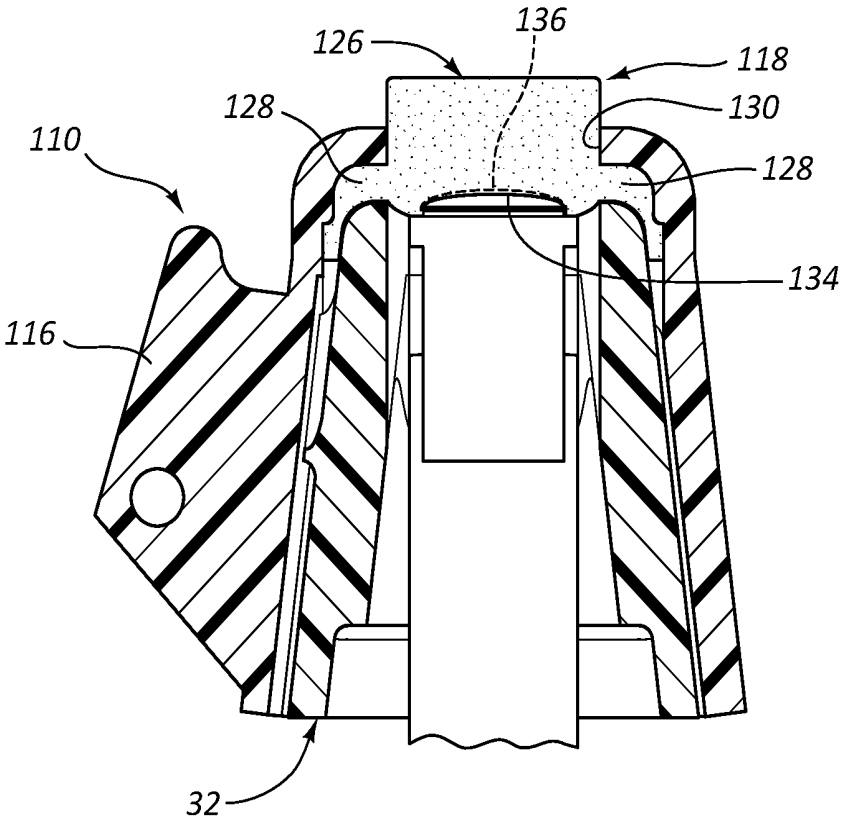
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FIG. 21

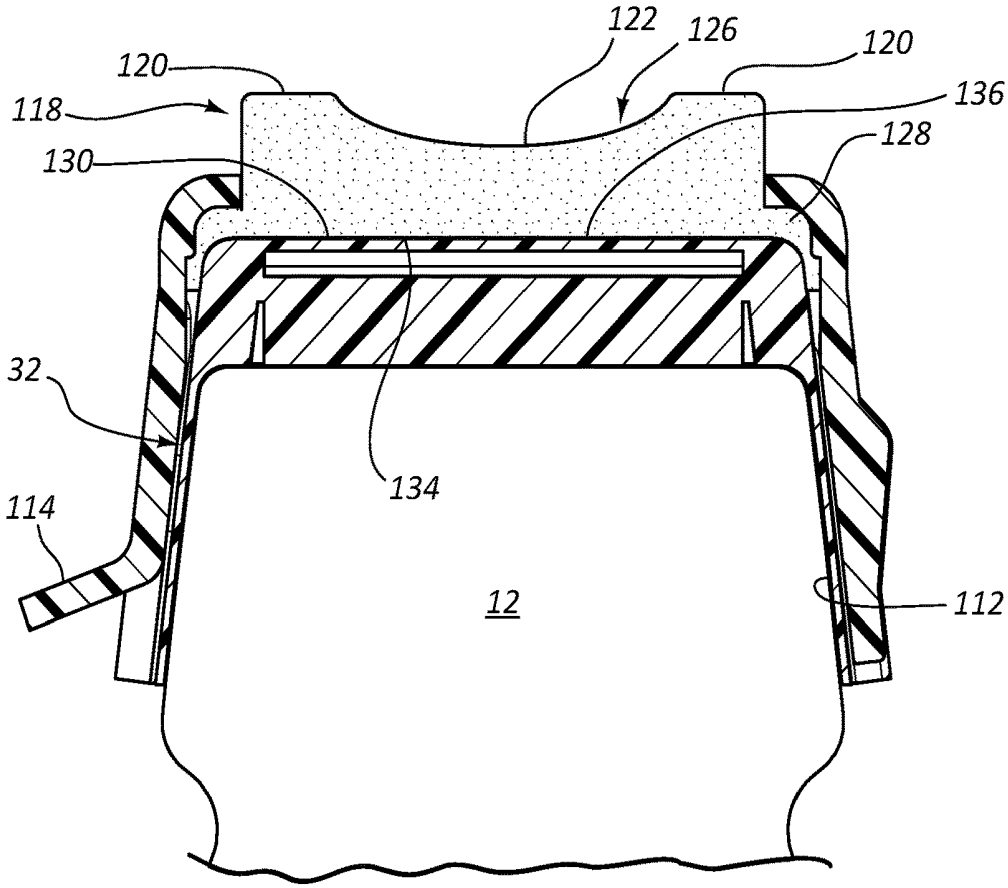
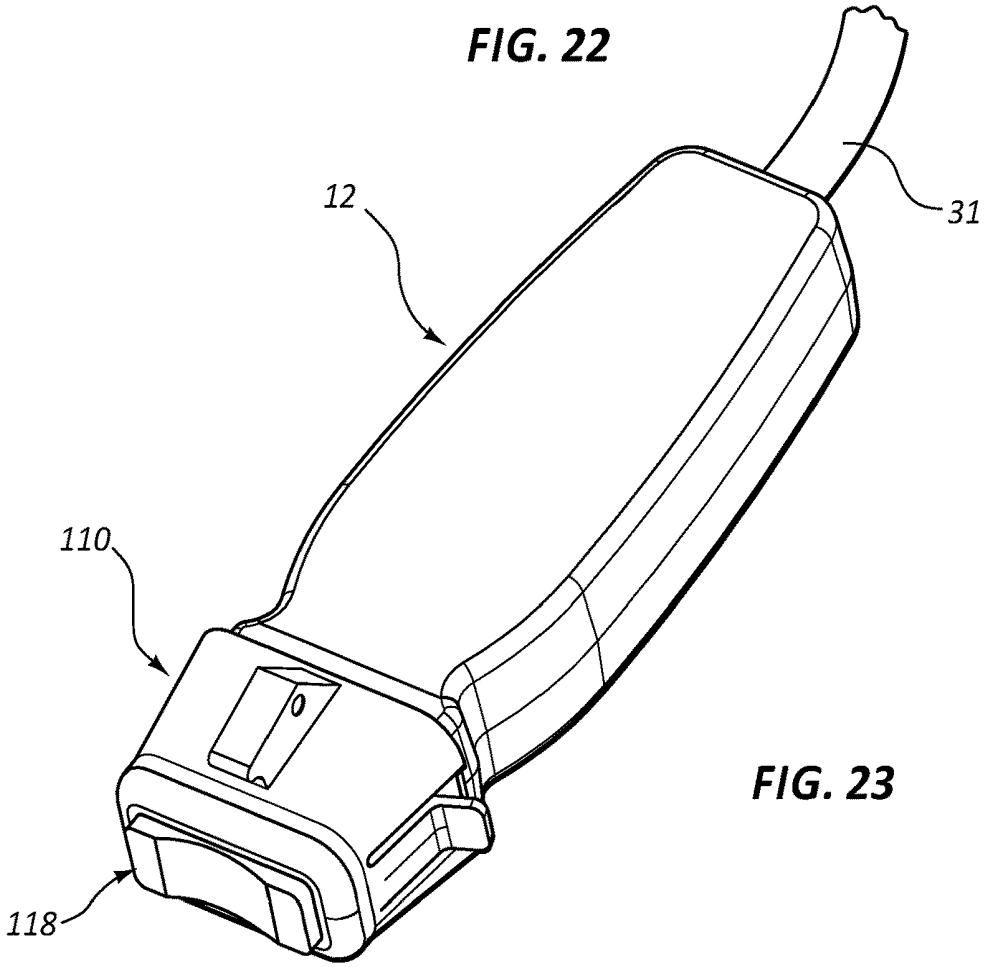


FIG. 22



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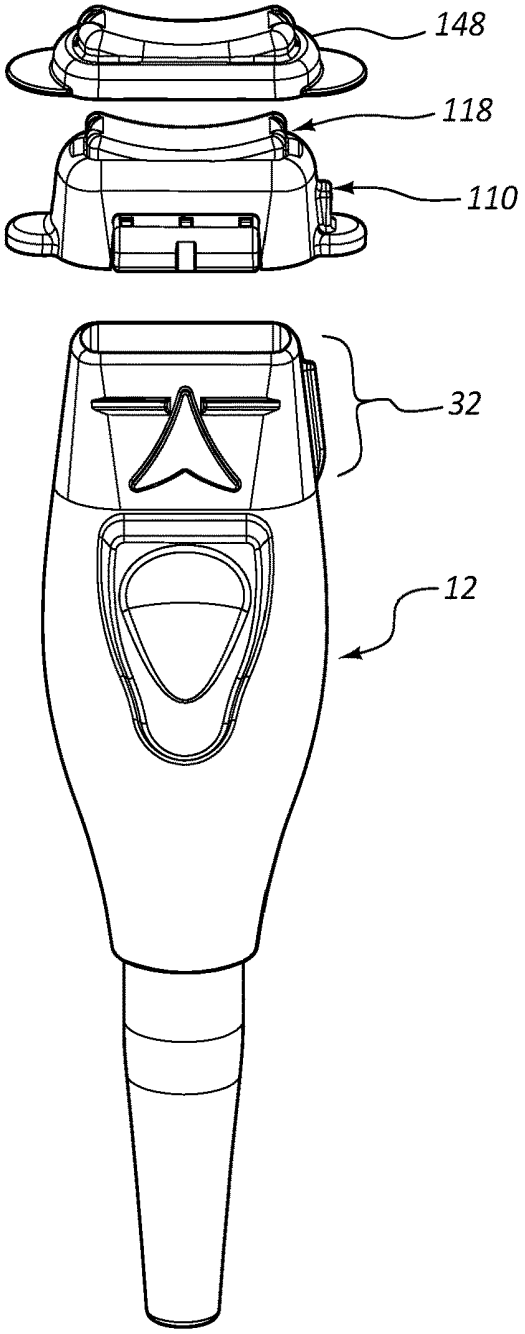

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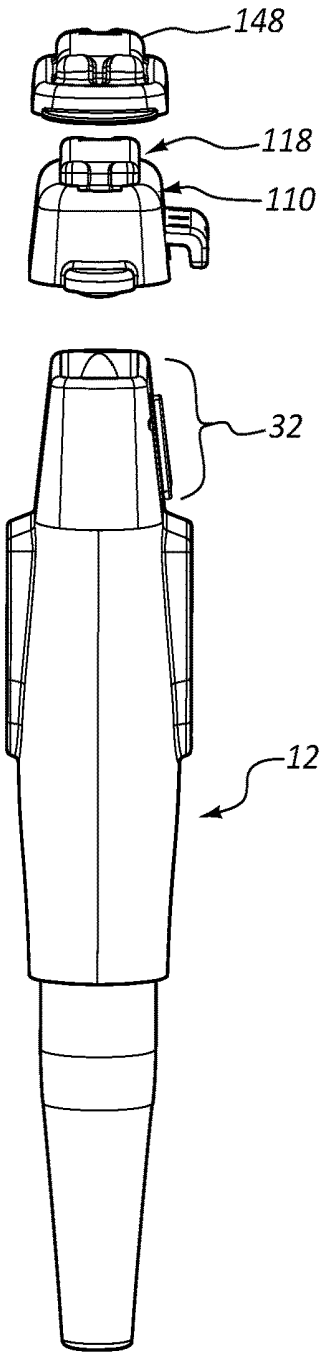
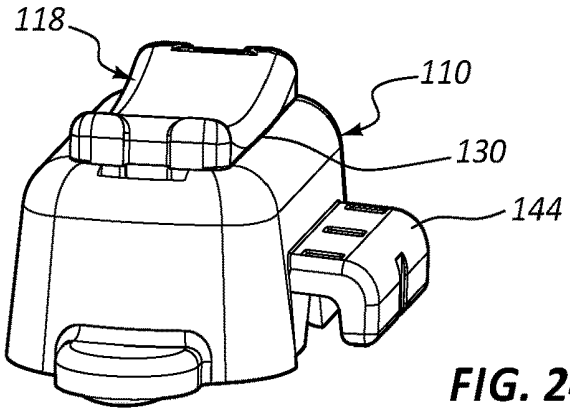


FIG. 24B



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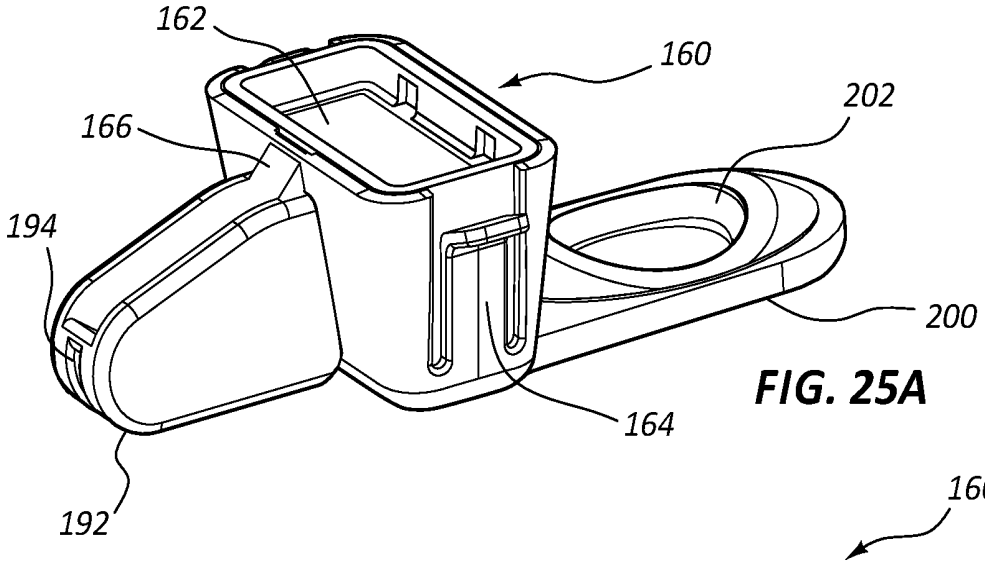


FIG. 25A

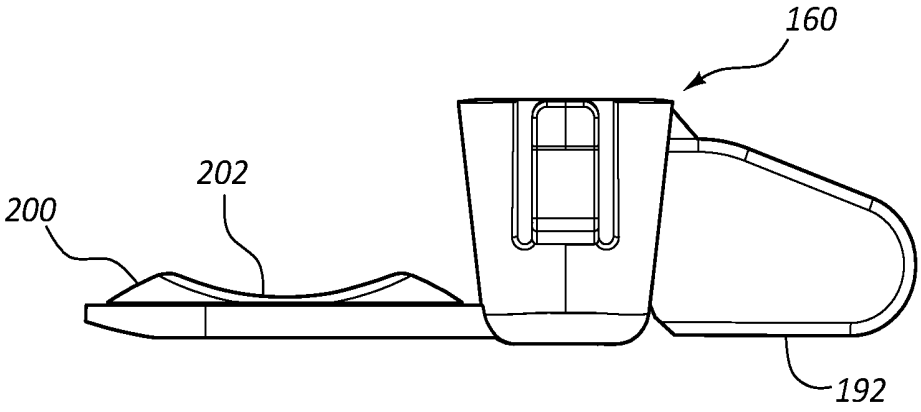


FIG. 25B

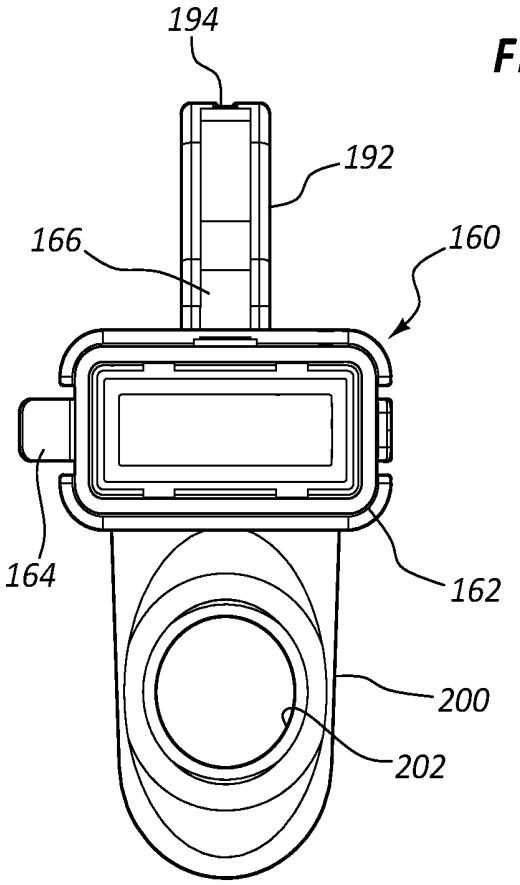


FIG. 25C

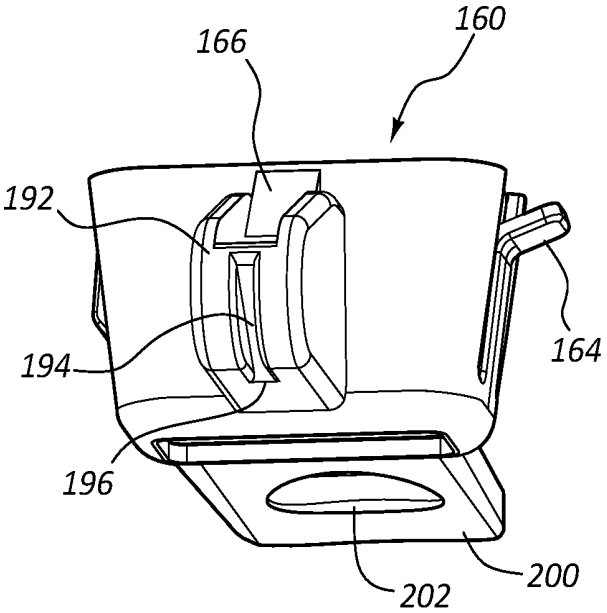


FIG. 25D

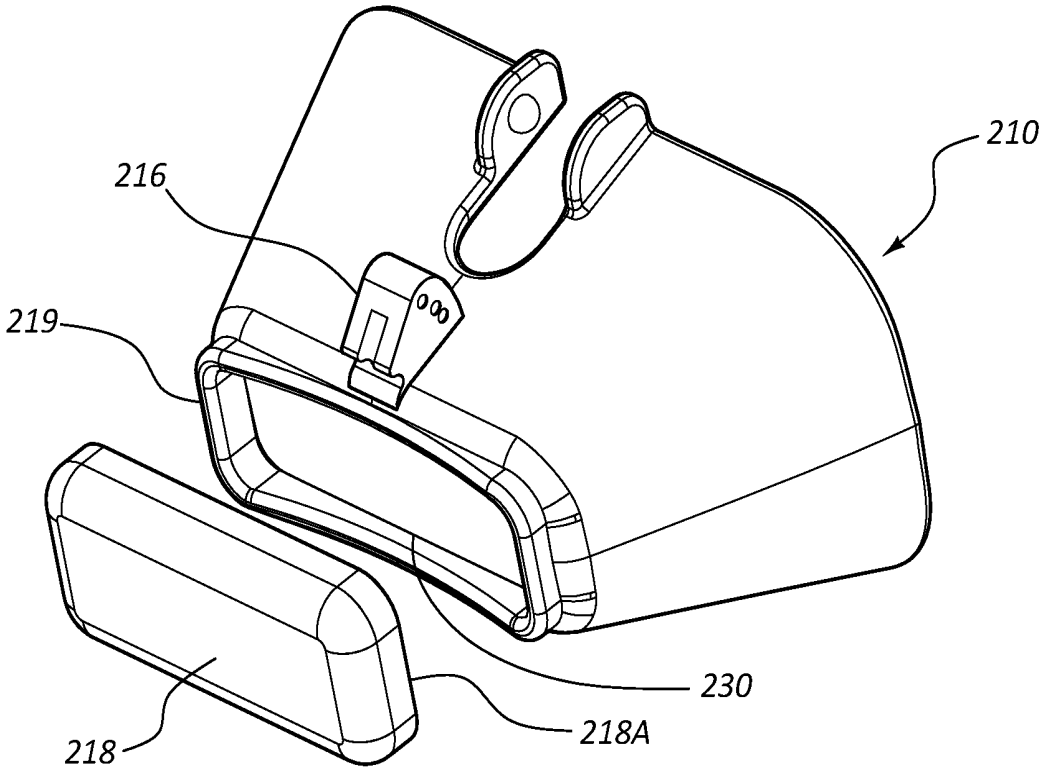
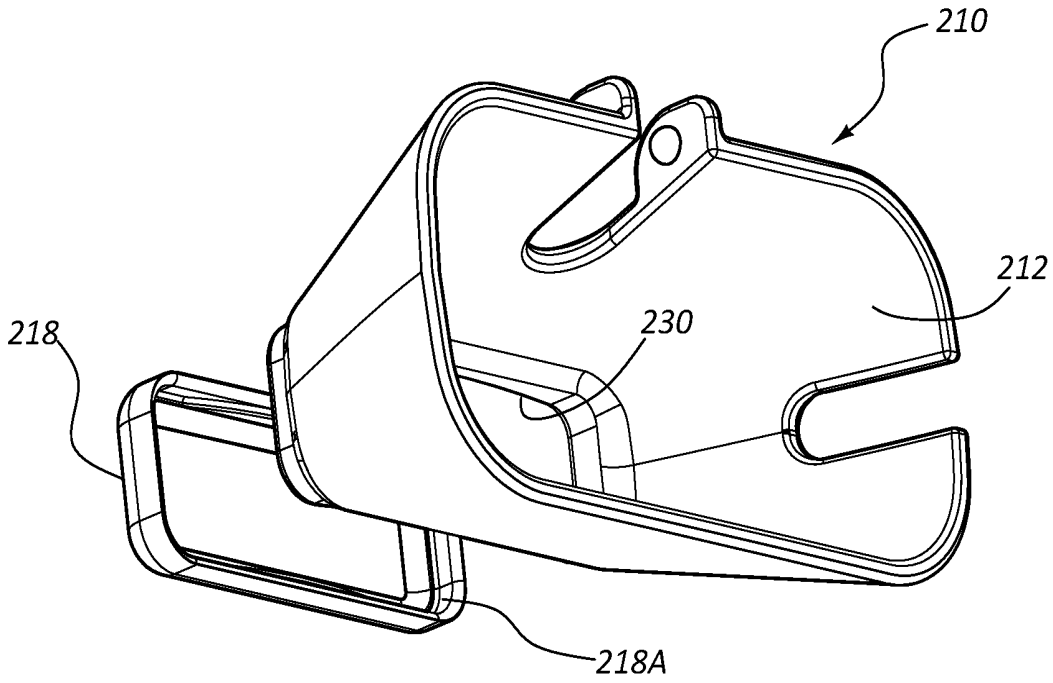


FIG. 26A



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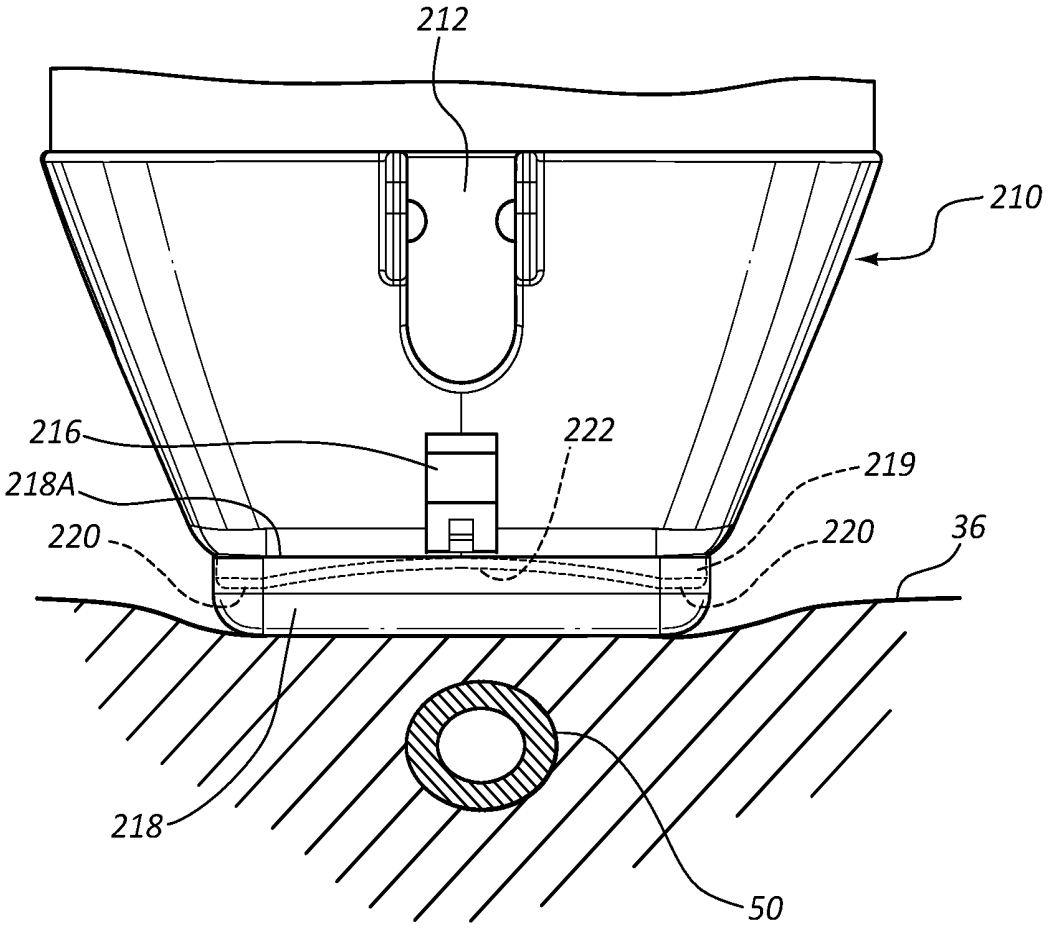

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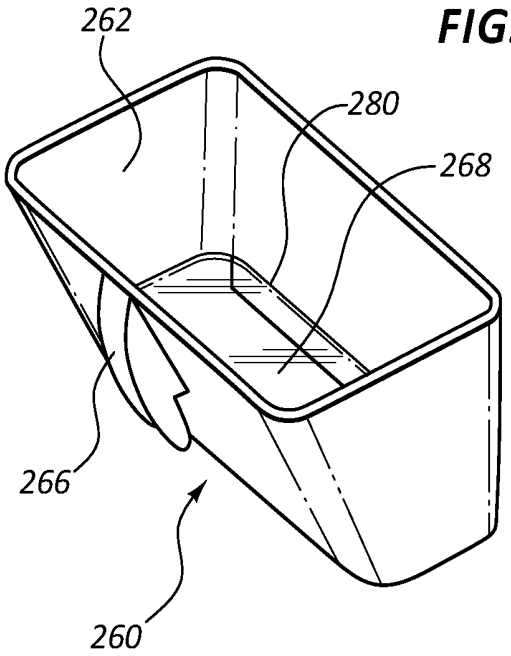
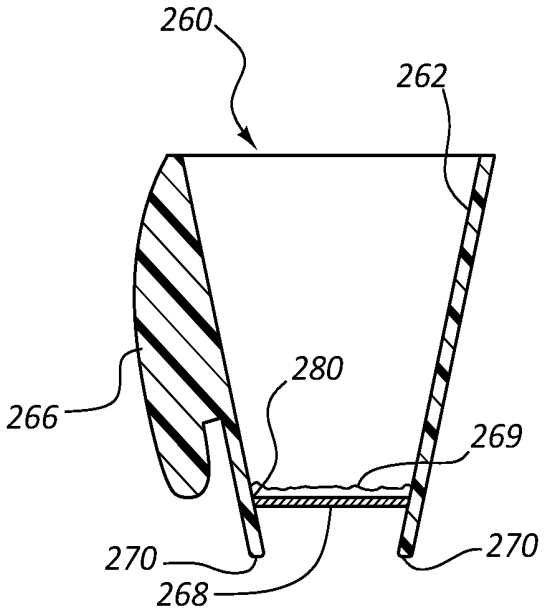


FIG. 28A



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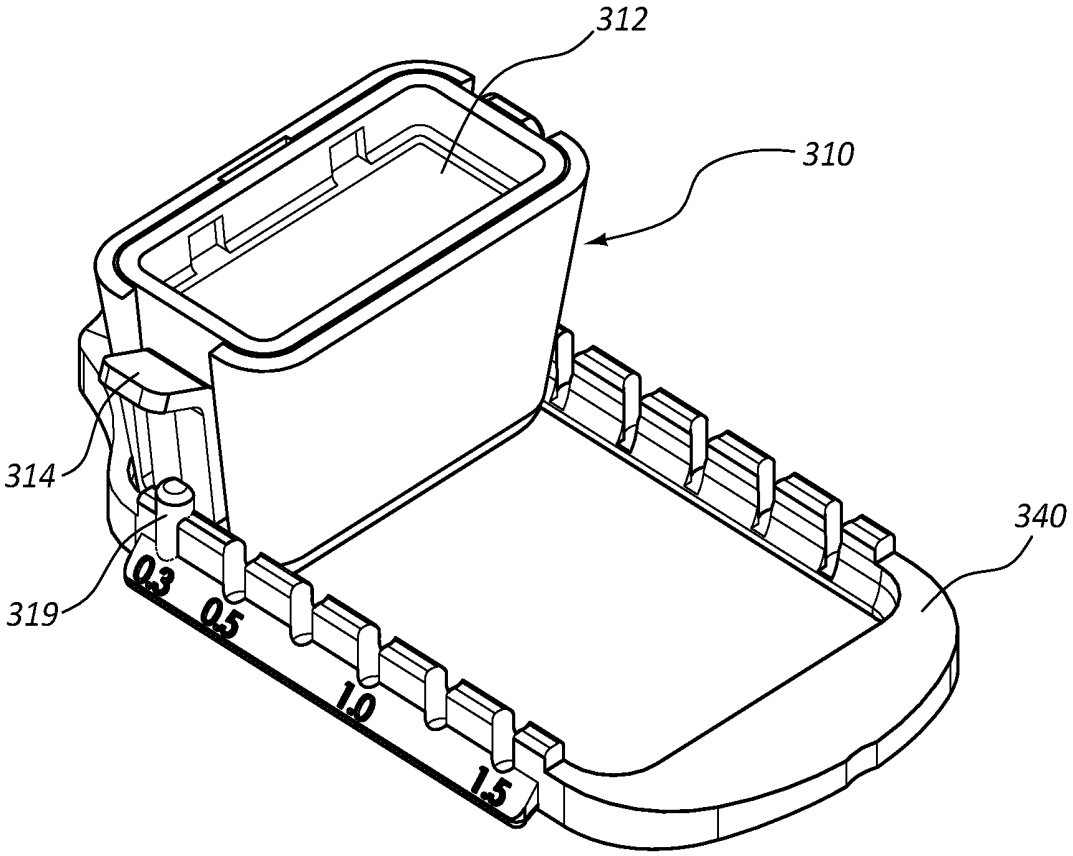

FIG. 29A

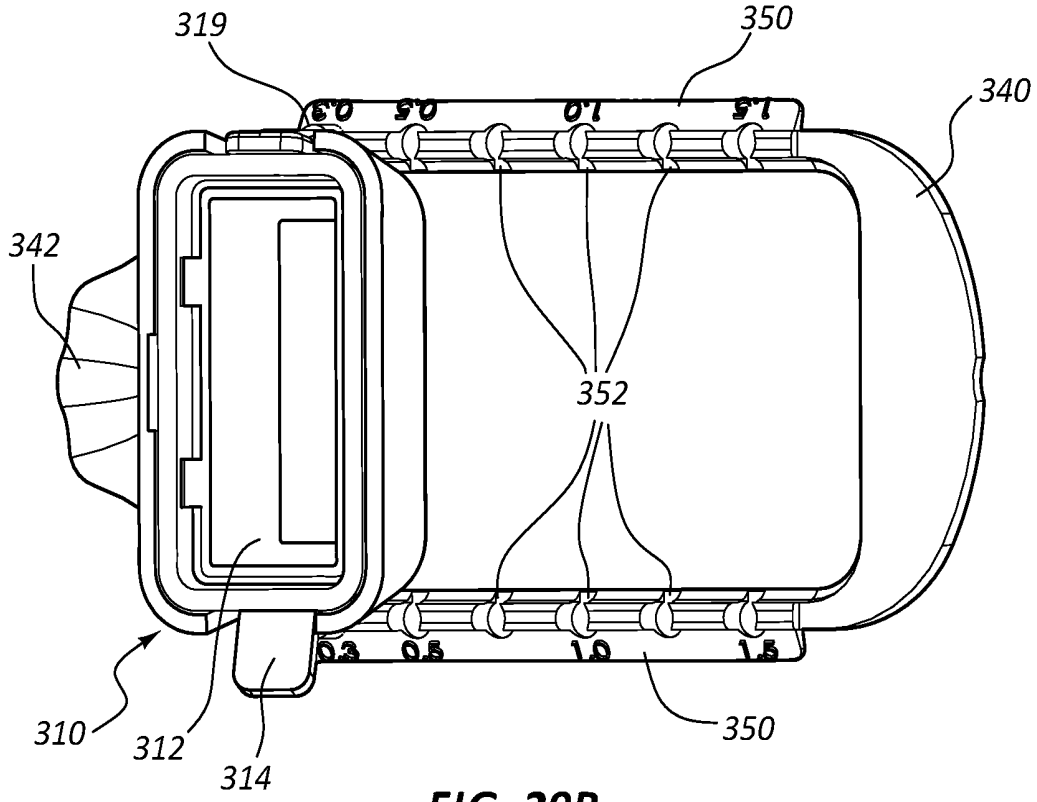

FIG. 29B

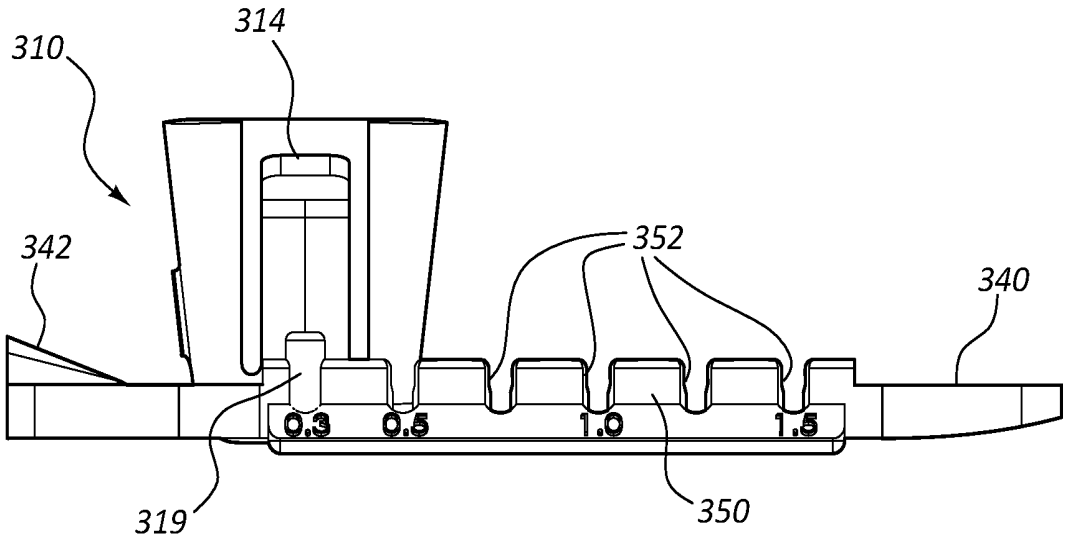

FIG. 29C

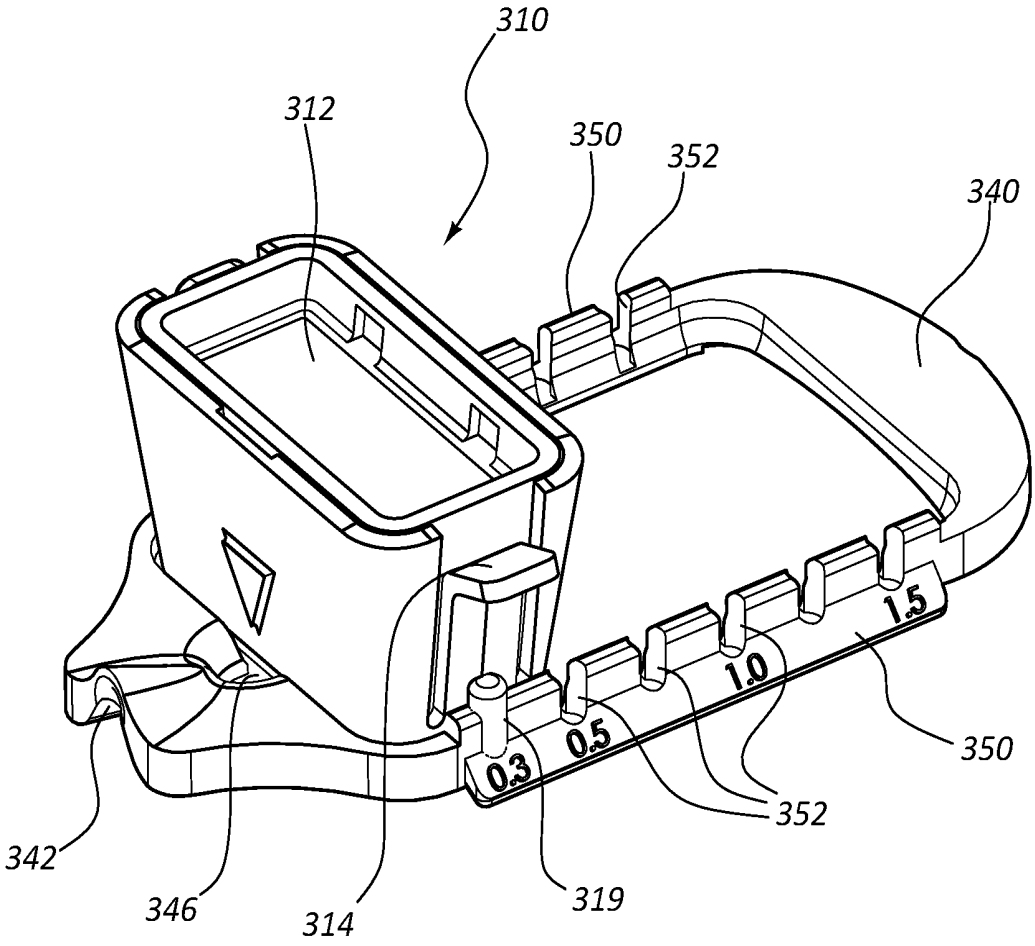

FIG. 29D

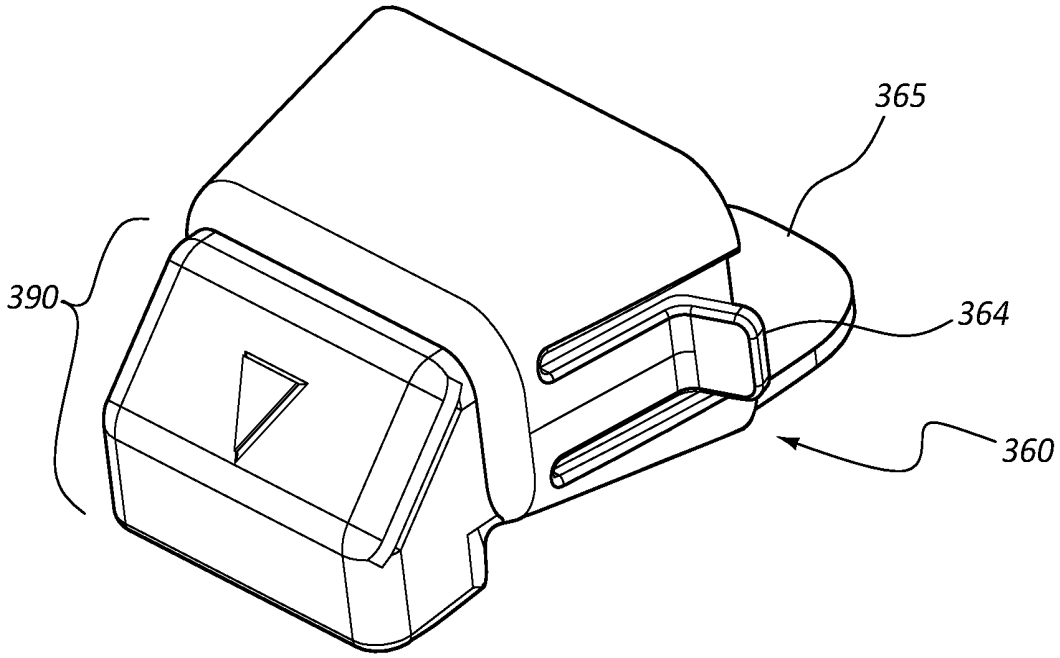

FIG. 30A

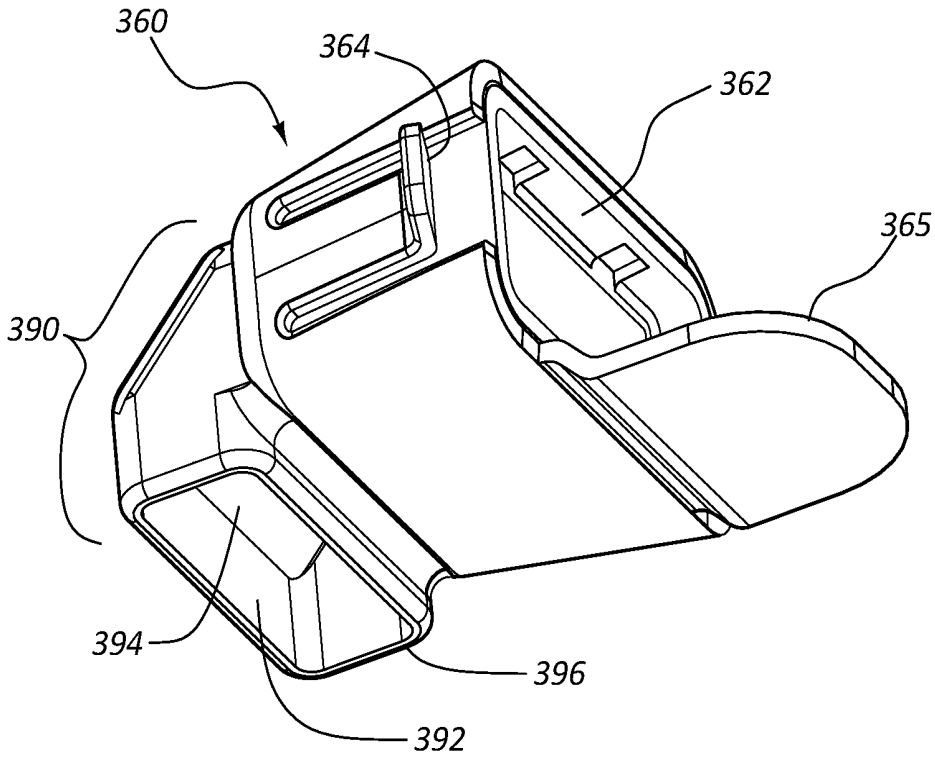

FIG. 30B

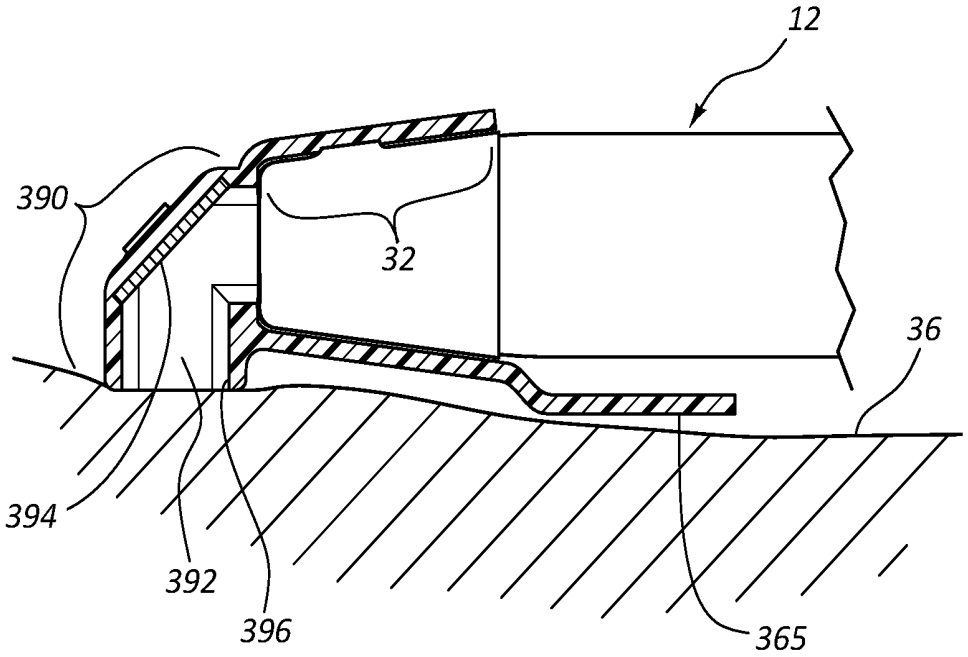
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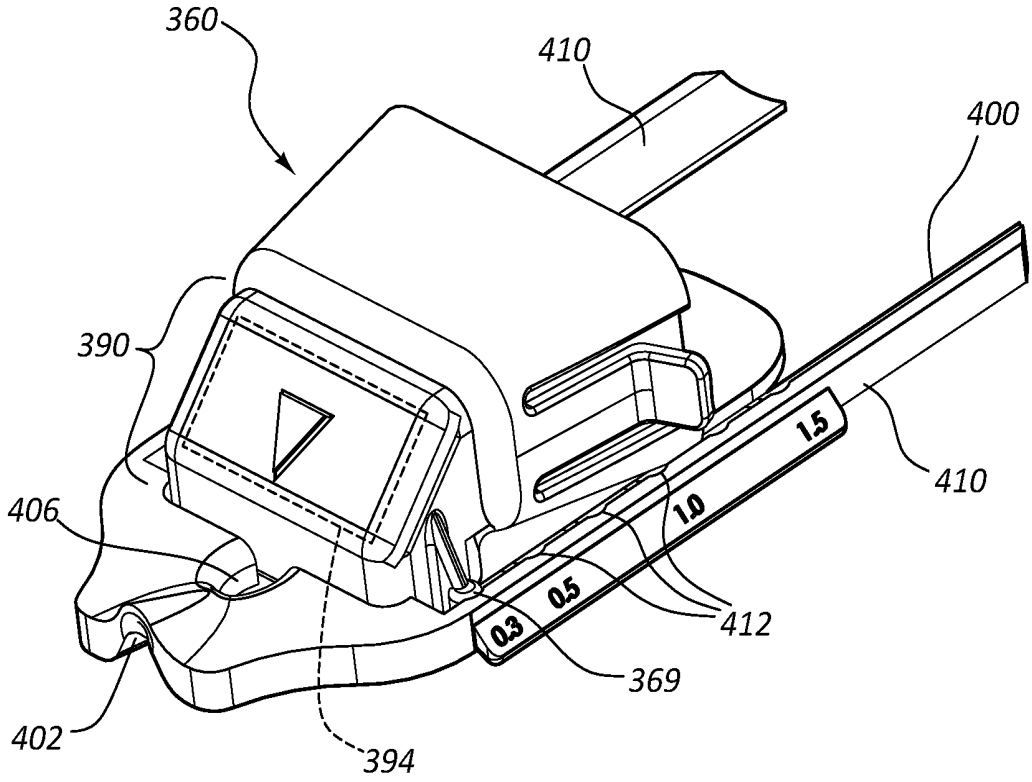
FIG. 31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390
406
1.5
1.0
0.5
0.3
410
412
369
402
394

FIG. 32

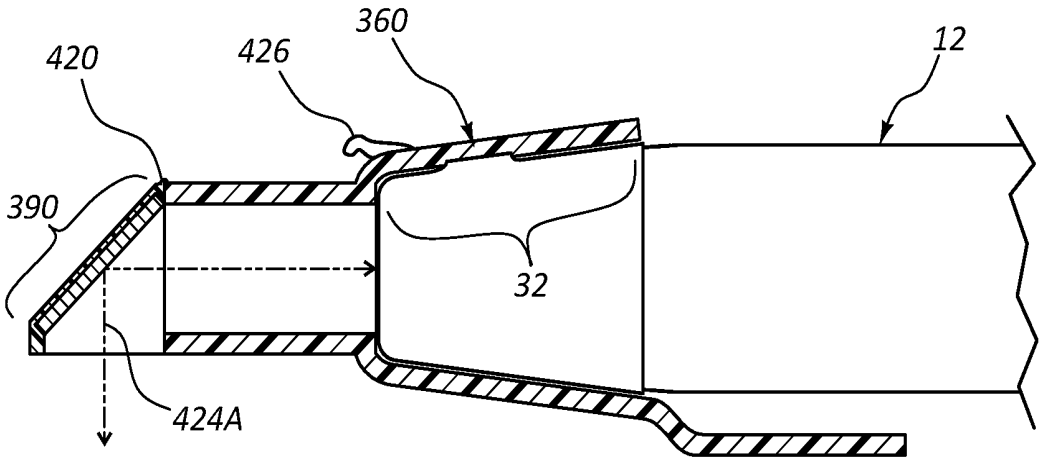

FIG. 33A

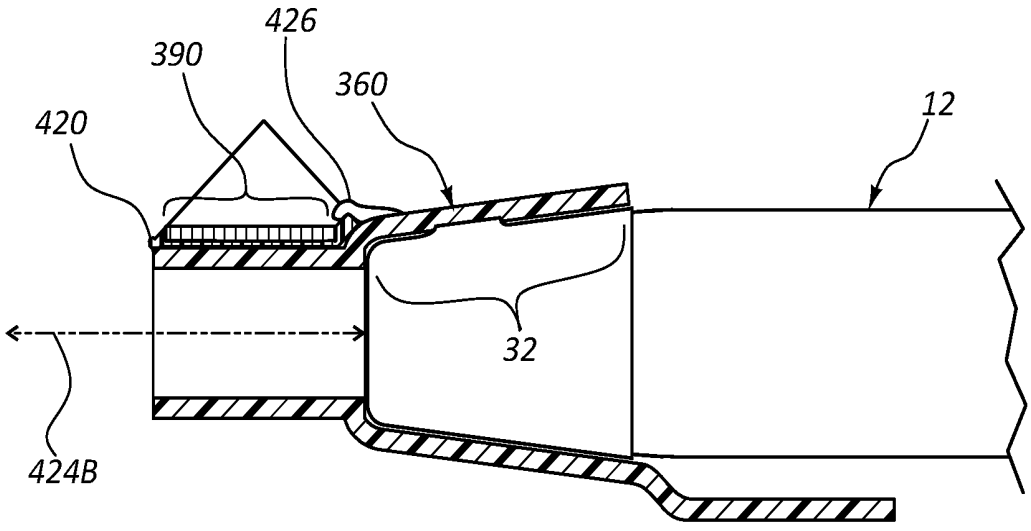

FIG. 33B

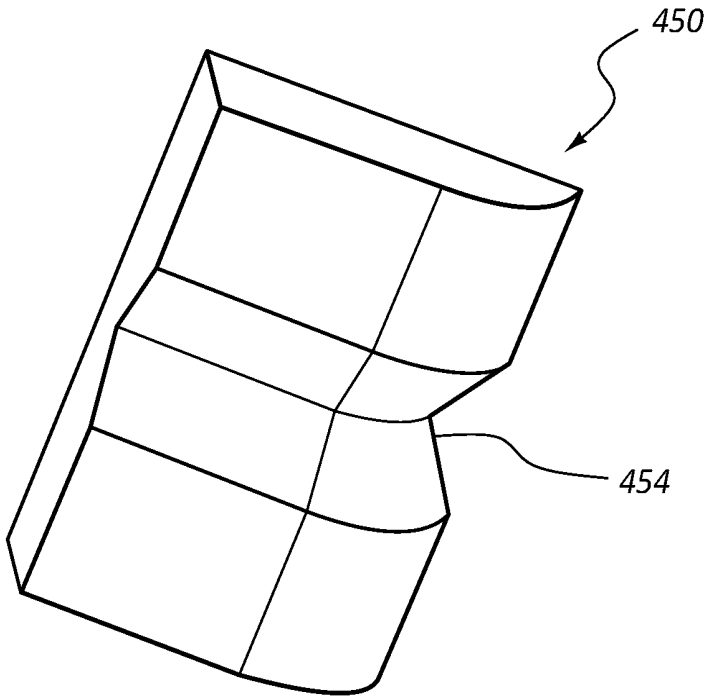

FIG. 34

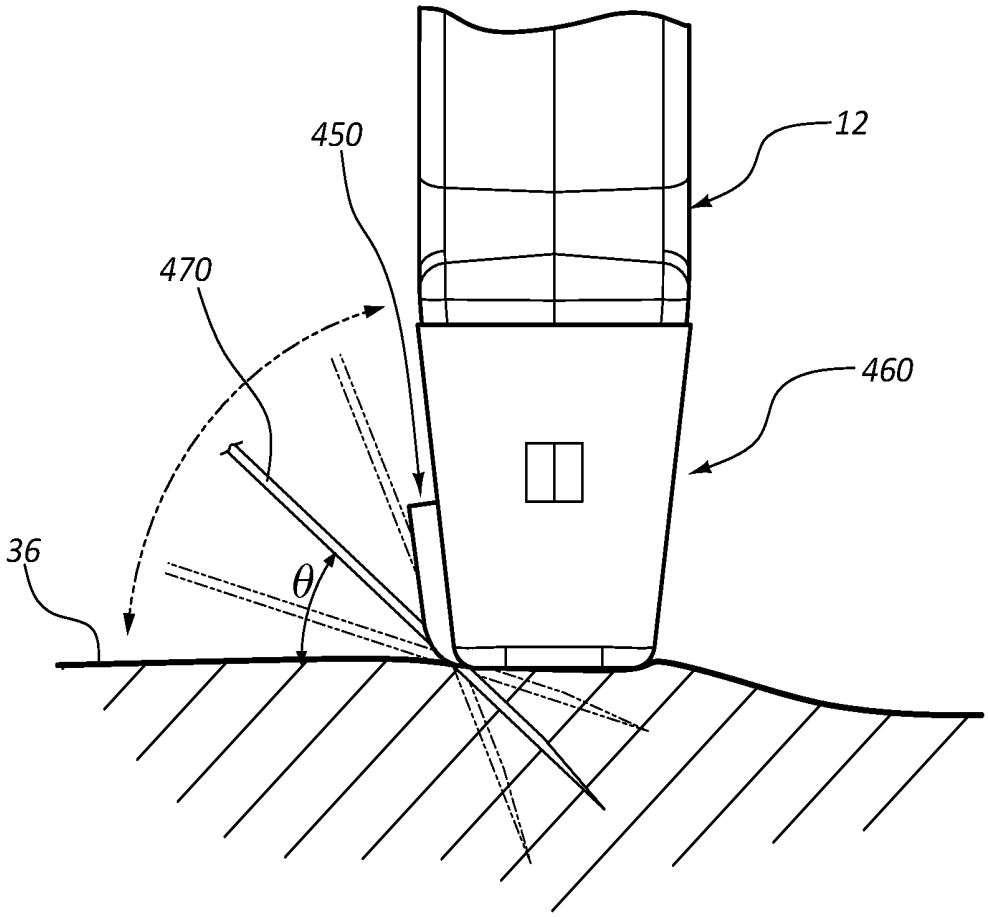

FIG. 35A

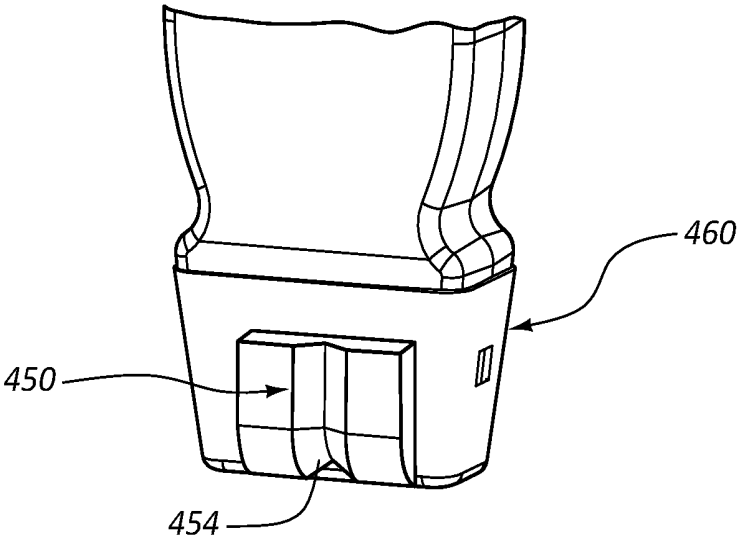

FIG. 35B

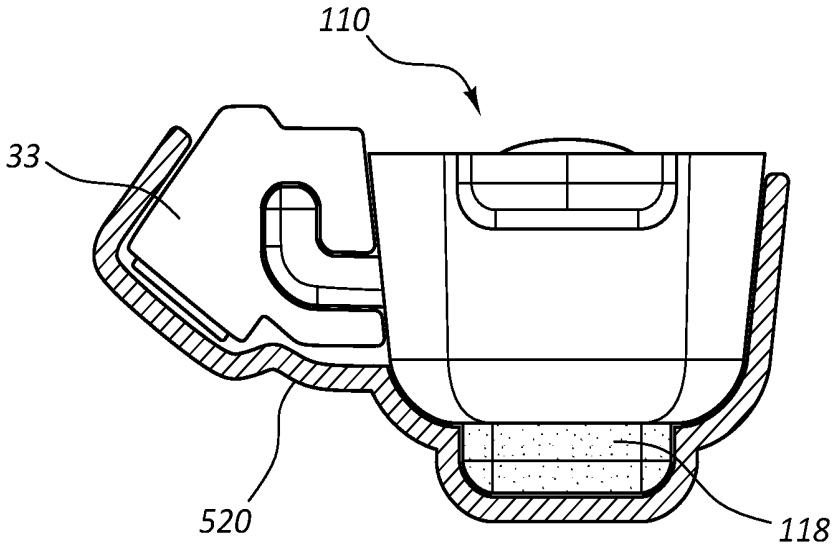

FIG. 36

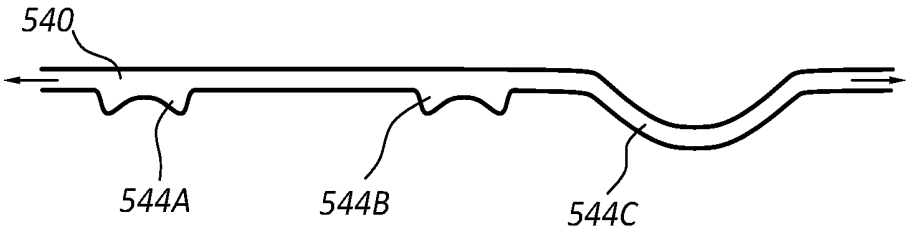

FIG. 37A

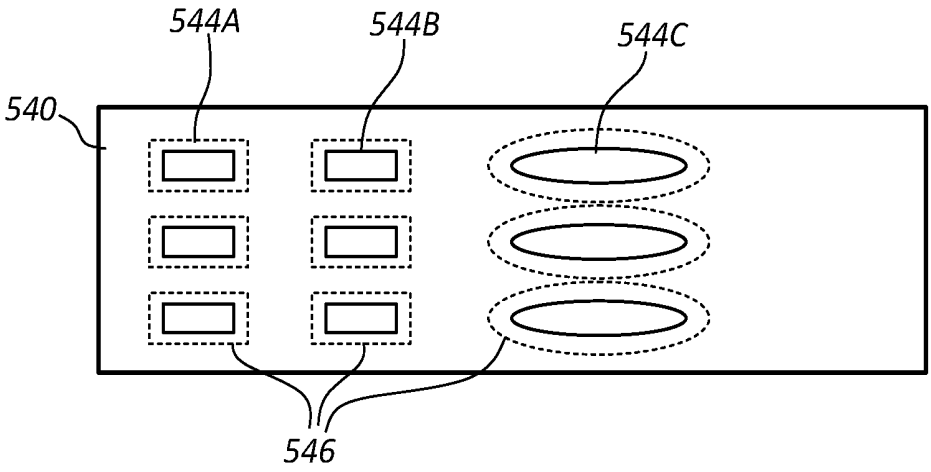

FIG. 37B

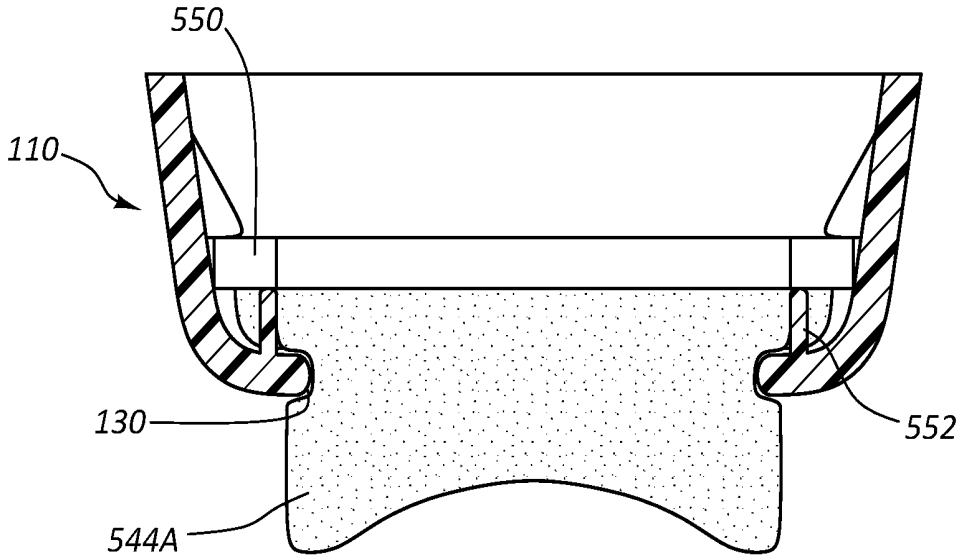

FIG. 38

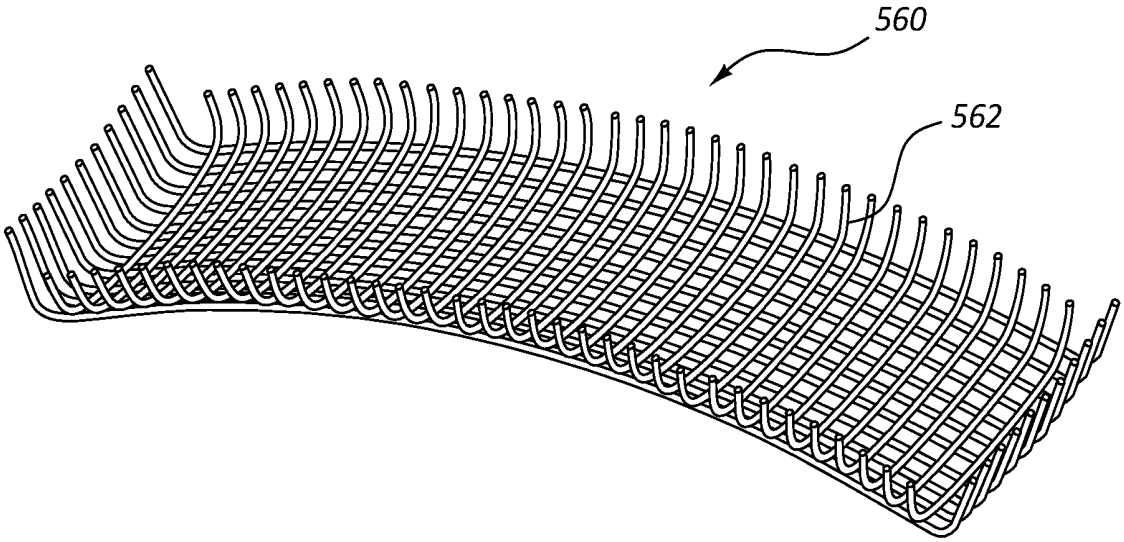

FIG. 39

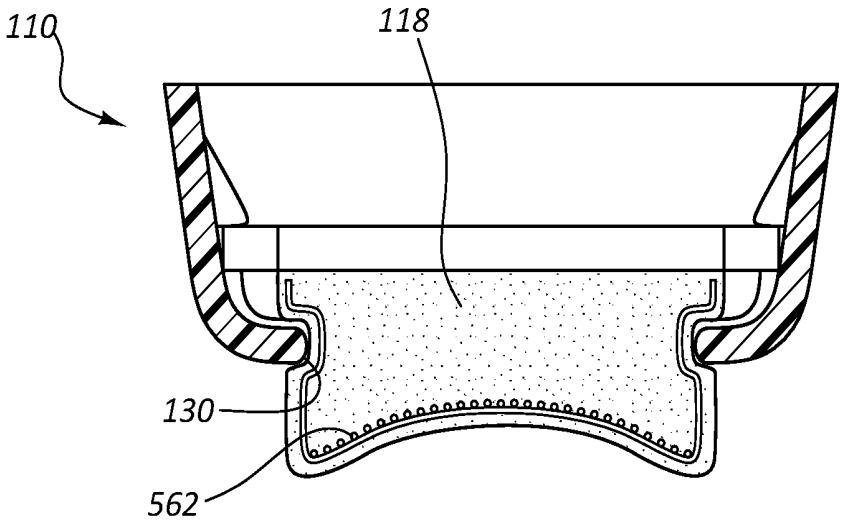

FIG. 40

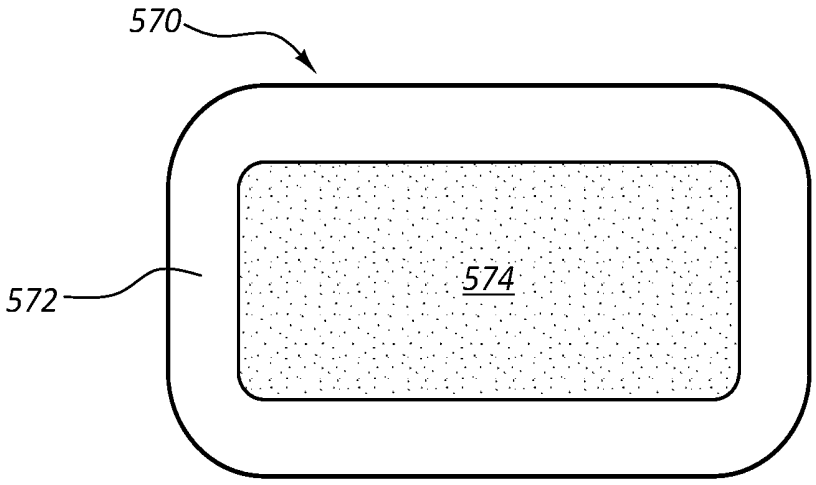

FIG. 41

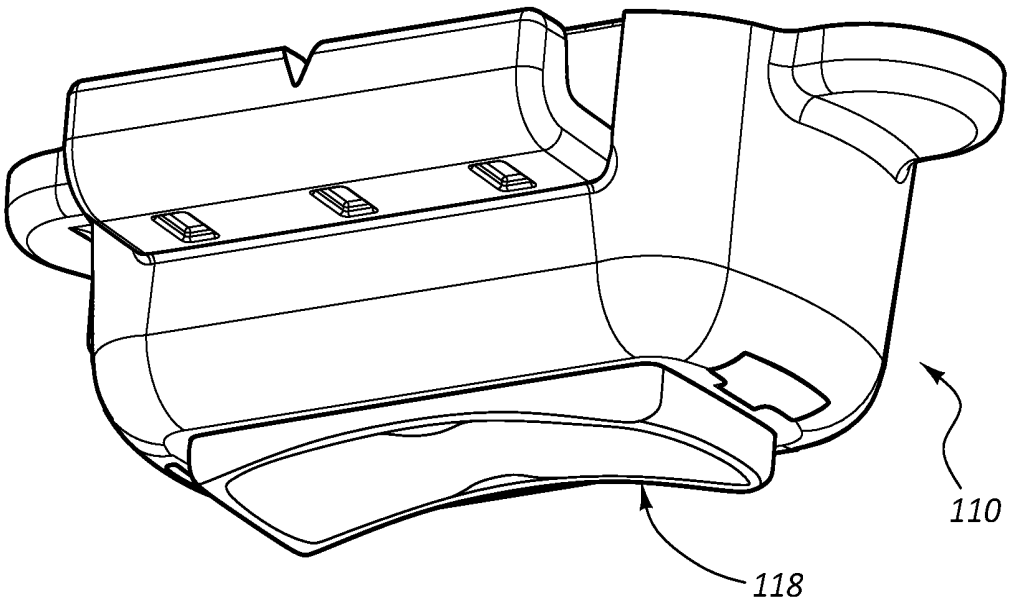

FIG. 42

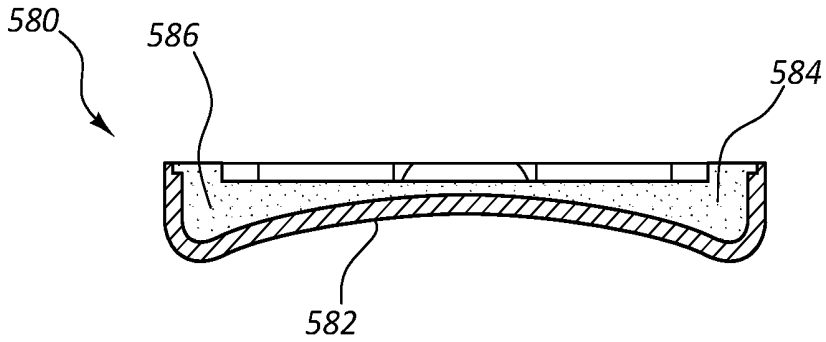

FIG. 43A

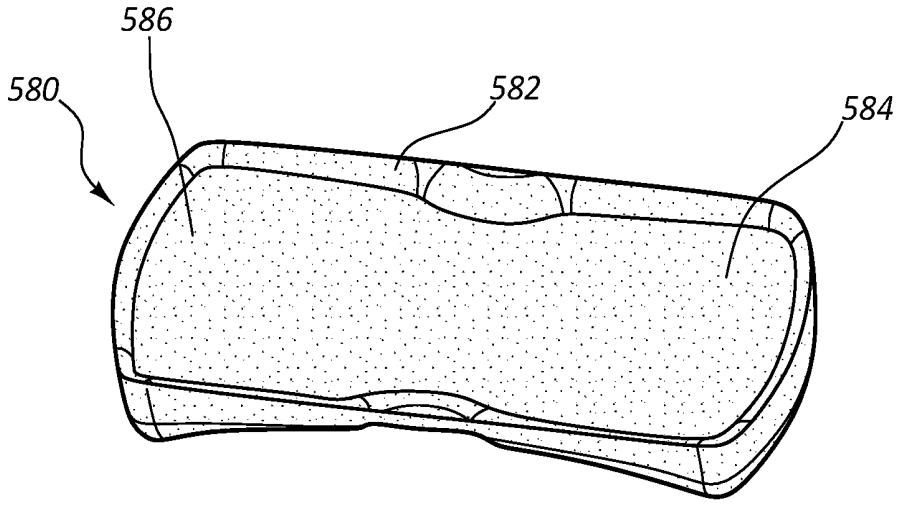

FIG. 43B

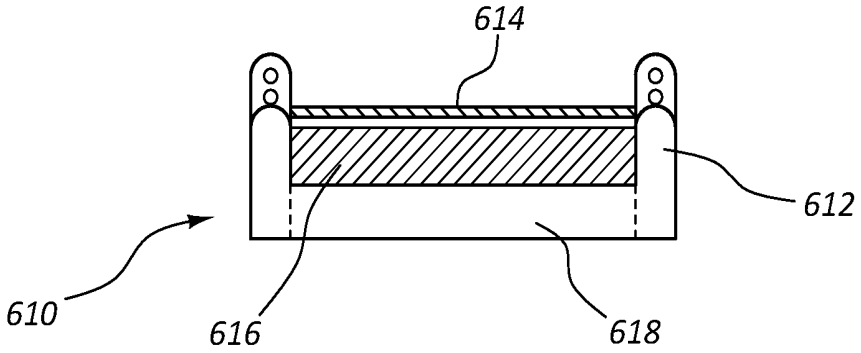

FIG. 44

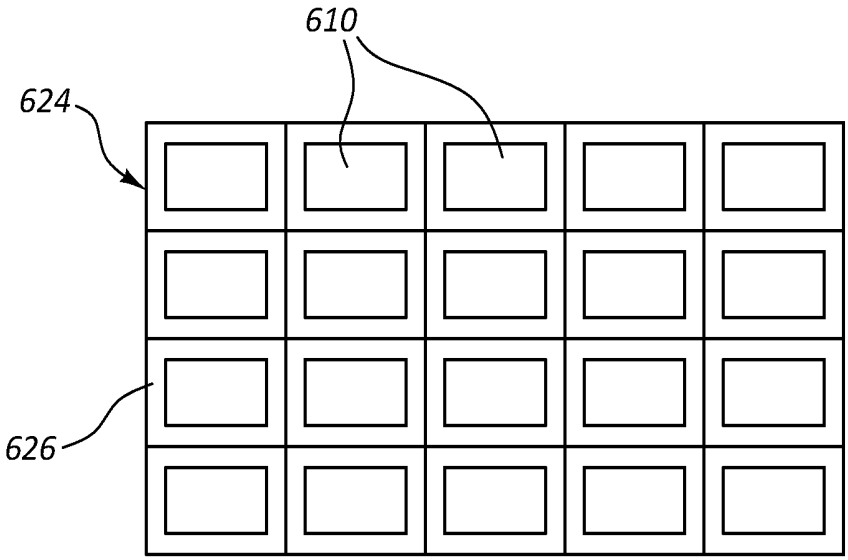

FIG. 45

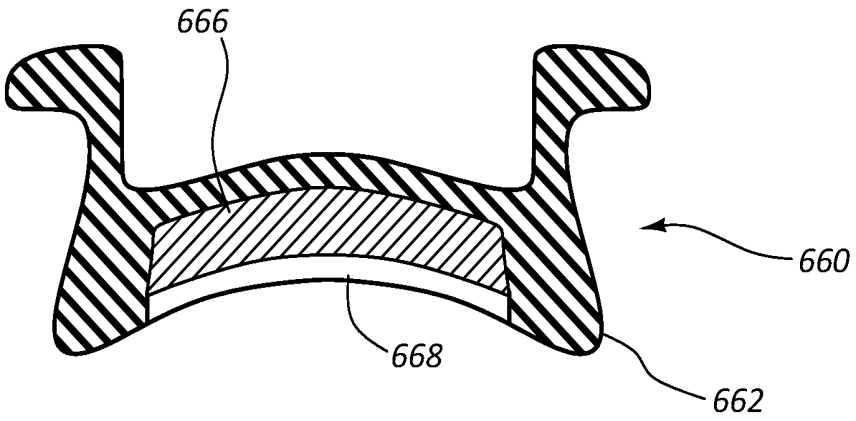

FIG. 46A

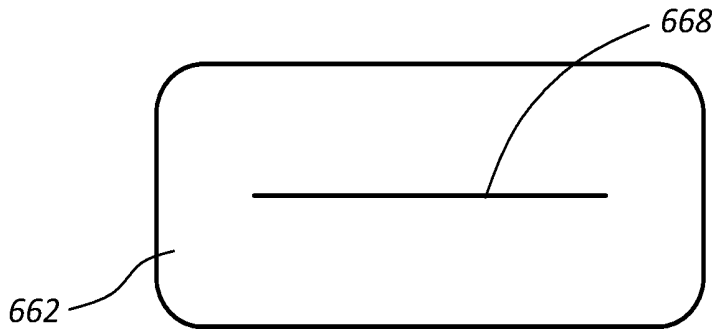

FIG. 46B

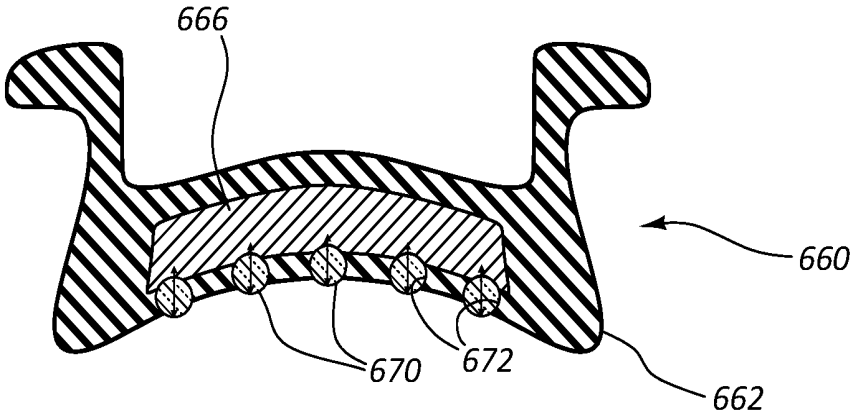

FIG. 47

COUPLING STRUCTURES FOR AN ULTRASOUND PROBE

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is a division of U.S. patent application Ser. No. 14/190,591, filed Feb. 26, 2014, which claims the benefit of U.S. Provisional Patent Application No. 61/769,676, filed Feb. 26, 2013, and which is a continuation-in-part of U.S. patent application Ser. No. 13/206,396, filed Aug. 9, 2011, which is a continuation-in-part of U.S. application Ser. No. 12/900,750, filed Oct. 8, 2010, which claims the benefit of U.S. Provisional Patent Application No. 61/372,044, filed Aug. 9, 2010, and also claims the benefit of U.S. Provisional Patent Application No. 61/249,850, filed Oct. 8, 2009, each of which applications is incorporated herein by reference in its entirety.

BRIEF SUMMARY

[0002] Briefly summarized, embodiments of the present invention are directed to a probe cap for use with an ultrasound probe including a head portion and an acoustic surface. In one embodiment, the probe cap includes a body that defines a cavity sized for releasably receiving the head portion of the probe therein. The probe cap body further defines a hole that is proximate the acoustic surface of the head portion. A compliant spacer component is disposed in the hole. The spacer component can include a hydrogel and provides an acoustic path between the acoustic surface and a tissue surface of a patient. The spacer component further includes a skin contact surface that defines a concavity and is deformable against the skin. The skin contact surface can further define one or more spacer elements adjacent the concavity for distributing the load of the probe pressing against the skin and preventing compression of subcutaneous structures of the patient.

[0003] In another embodiment, an ultrasound imaging system for imaging a subcutaneous structure of a patient is disclosed and includes a display, an ultrasound probe including an acoustic surface from which ultrasound signals are emitted, and first and second spacer elements. The spacer elements are positioned proximate opposite ends of the acoustic surface and are configured to provide a gap between the acoustic surface and a tissue surface of the patient. So configured, the spacer elements prevent compression of the subcutaneous structure of the patient.

[0004] In addition, embodiments to be further described below disclose various probe cap and accompanying needle guide designs for use in assisting a clinician with ultrasound probe use and needle insertion into a patient. In yet other embodiments, various coupling structures are described for providing an ultrasonic coupling between the ultrasound probe head and the patient's skin.

[0005] These and other features of embodiments of the present invention will become more fully apparent from the following description and appended claims, or may be learned by the practice of embodiments of the invention as set forth hereinafter.

BRIEF DESCRIPTION OF THE DRAWINGS

[0006] A more particular description of the present disclosure will be rendered by reference to specific embodiments thereof that are illustrated in the appended drawings. It is appreciated that these drawings depict only typical embodiments of the invention and are therefore not to be considered limiting of its scope. Example embodiments of the invention will be described and explained with additional specificity and detail through the use of the accompanying drawings in which:

[0007] FIGS. **1**A and **1**B are perspective and side views, respectively, of an ultrasound probe including spacer elements configured in accordance with one embodiment;

[0008] FIG. **2** is a simplified cross sectional view of the ultrasound probe of FIGS. **1**A and **1**B used to image a vessel of a patient;

[0009] FIG. **3** is a side view of the ultrasound probe of FIGS. **1**A and **1**B enclosed within a sheath in accordance with one embodiment;

[0010] FIGS. **4**A and **4**B are side views of a portion of an ultrasound probe including spacer elements and further showing examples of possible acoustic surface configurations in accordance with one embodiment;

[0011] FIG. **5** is a side view of a portion of an ultrasound probe including a spacer element in accordance with one embodiment;

[0012] FIG. **6** shows ultrasound spacer elements configured in accordance with one embodiment;

[0013] FIG. **7** shows ultrasound spacer elements configured in accordance with one embodiment;

[0014] FIG. **8** shows ultrasound spacer elements configured in accordance with one embodiment;

[0015] FIGS. **9**A and **9**B show spacer elements configured in accordance with one embodiment;

[0016] FIG. **10** is a side view of an ultrasound probe including spacer elements configured in accordance with one embodiment;

[0017] FIG. **11** is a side view of an ultrasound probe including a cap including spacer elements and a sheath in accordance with one embodiment;

[0018] FIG. **12** is a perspective view of a spacer component in accordance with one embodiment;

[0019] FIGS. **13**A-**13**C show use of the spacer component of FIG. **12** in accordance with one embodiment;

[0020] FIG. **14** is a side view of a spacer component in accordance with one embodiment;

[0021] FIGS. **15**A-**15**B show use of the spacer component of FIG. **14** in accordance with one embodiment;

[0022] FIG. **16** is an exploded perspective view of an ultrasound probe and a probe cap in accordance with one embodiment;

[0023] FIGS. **17**A-**17**D are various views of the probe cap of FIG. **16**;

[0024] FIGS. **18**A and **18**B are an exploded perspective view and cross sectional side view of an ultrasound probe/probe cap and a spacer component, respectively;

[0025] FIG. **19** is a cross sectional view of a head portion of the ultrasound probe of FIG. **16**;

[0026] FIG. **20** is a cross sectional view of the probe cap of FIG. **16**;

[0027] FIG. **21** is a cross sectional view of a head portion of the ultrasound probe of FIG. **16** received within the probe cap of FIG. **16**;

[0028] FIG. **22** is another cross sectional view showing a head portion of the ultrasound probe of FIG. **16** received within the probe cap of FIG. **16**;

[0029] FIG. **23** is a perspective view of a mated configuration of the ultrasound probe and probe cap of FIG. **16**;

[0030] FIGS. **24**A and **24**B are front and side views, respectively, of an ultrasound probe and accompanying probe cap including a compliant spacer component according to one embodiment;

[0031] FIG. **24**C is a perspective view of the probe cap of FIGS. **24**A and **24**B;

[0032] FIGS. **25**A-**25**D are various views of a probe cap according to one embodiment;

[0033] FIGS. **26**A and **26**B are various exploded views of a probe cap configured according to one embodiment;

[0034] FIG. **27** is a side view of the probe cap of FIGS. **26**A and **26**B shown in contact with a patient's skin above a subcutaneous vessel;

[0035] FIGS. **28**A and **28**B are perspective and cross sectional views, respectively, of a probe cap according to one embodiment;

[0036] FIGS. **29**A-**29**D are various views of a probe cap assembly according to one embodiment;

[0037] FIGS. **30**A and **30**B are various perspective views of a probe cap according to one embodiment;

[0038] FIG. **31** is a cross sectional side view of the probe cap of FIGS. **30**A and **30**B shown attached to an ultrasound probe;

[0039] FIG. **32** is a perspective view of a probe cap according to one embodiment;

[0040] FIGS. **33**A and **33**B are partial cross sectional side views of an ultrasound probe and probe cap in accordance with one embodiment;

[0041] FIG. **34** is a perspective view of a needle guide according to one embodiment; and

[0042] FIGS. **35**A and **35**B are side and perspective views, respectively, of the needle guide of FIG. **34** attached to a probe cap according to one embodiment.

[0043] FIG. **36** is a side view of a coupling structure for an ultrasound probe according to one embodiment;

[0044] FIGS. **37**A and **37**B show various views of coupling components for an ultrasound probe according to one embodiment;

[0045] FIG. **38** is a cross sectional view of a probe cap including one of the coupling components from the structures shown in FIGS. **37**A and **37**B;

[0046] FIG. **39** is a perspective view of a reinforcement structure for use with a coupling component according to one embodiment;

[0047] FIG. **40** is a cross sectional view of a probe cap including a coupling component and a reinforcement structure according to one embodiment;

[0048] FIG. **41** is a top view of a coupling structure for an ultrasound probe according to one embodiment;

[0049] FIG. **42** is a perspective view of a probe cap including a coupling component according to one embodiment;

[0050] FIGS. **43**A and **43**B are various views of a coupling component according to one embodiment;

[0051] FIG. **44** is a cross sectional view of a probe cap according to one example embodiment;

[0052] FIG. **45** is a top view of an array of probe caps such as those shown in FIG. **44** according to one embodiment;

[0053] FIGS. **46**A and **46**B are various views of a probe cap according to one embodiment; and

[0054] FIG. **47** is a cross sectional view of a probe cap according to one embodiment.

DETAILED DESCRIPTION OF SELECTED EMBODIMENTS

[0055] Reference will now be made to figures wherein like structures will be provided with like reference designations. It is understood that the drawings are diagrammatic and schematic representations of exemplary embodiments of the present invention, and are neither limiting nor necessarily drawn to scale.

[0056] For clarity it is to be understood that the word "proximal" refers to a direction relatively closer to a clinician using the device to be described herein, while the word "distal" refers to a direction relatively further from the clinician. For example, the end of a catheter placed within the body of a patient is considered a distal end of the catheter, while the catheter end remaining outside the body is a proximal end of the catheter. Also, the words "including," "has," and "having," as used herein, including the claims, shall have the same meaning as the word "comprising."

[0057] Embodiments of the present invention are generally directed to various components for spacing an acoustic surface of an ultrasound probe from a tissue surface of a patient during ultrasound procedures to image subcutaneous tissues of the patient. Such ultrasound procedures are employed, for instance, in connection with the placement of a catheter within a vessel of the patient. As will be described, the components for spacing the acoustic surface in one embodiment prevent undesired compression of subcutaneous vessels, especially superficial vessels, which in turn improves the imaging of such vessels by the probe. In addition, embodiments to be described further below disclose various probe cap and accompanying needle guide designs for use in assisting a clinician with ultrasound probe use and needle insertion into a patient.

[0058] Reference is first made to FIGS. **1**A and **1**B, which depict an ultrasound imaging system **10** according to one embodiment, including an ultrasound probe **12** and a console **20** including a display **30** for depicting an image produced by the probe. In the present embodiment, the probe **12** is operably connected to the console **20** via a cable **31**, though in one embodiment the probe can be wirelessly connected thereto.

[0059] The probe **12** includes a head **32** defined by a longitudinal length **32**A and a width **32**B. The body of the probe generally defines a front face **33**A, a rear face **33**B, and side faces **33**C. It should be appreciated that the preceding description of the probe is not meant to limit application of the principles described herein in any way. The probe head **32** includes an acoustic surface **34** extending along at least a portion of a longitudinal length **32**A of the probe head from which ultrasonic impulses are emitted in order to penetrate and image subcutaneous portions of the patient. Note that the size, shape and configuration of both the probe and acoustic surface can vary from what is described herein while still residing within the principles of the present disclosure. Note also that FIG. **1**A shows just one example of an ultrasound imaging system; other systems including other components can also benefit from the principles described herein.

[0060] As depicted in FIGS. **1**A and **1**B, in accordance with one embodiment the probe head **32** includes two spacer elements, generally depicted at **40**, disposed adjacent the probe acoustic surface **34** at each end of the longitudinal length **32**A. Each spacer element **40** acts as an extended

surface to provide a gap **48** between the acoustic surface **34** and the skin **36** or other tissue surface of the patient, as further described below, when the probe **12** is placed on the patient's skin for use in subcutaneous imaging.

[0061] In greater detail, each spacer element **40** in the present embodiment defines a blade-like extended surface that includes a contact surface **42** for contacting the tissue/skin **36** of the patient. The contact surface **42** can be shaped in one of several configurations, as will be discussed further below.

[0062] Reference is now made to FIG. **2**. When no spacers are present on an ultrasound probe, the acoustic surface thereof directly contacts the patient's skin during imaging, which can cause a downward pressure sufficient to undesirably compress a subcutaneous vessel disposed beneath the probe. Further, the proximity of the probe acoustic surface to the patient's skin can cause the focal point of the probe to reside below the vessel to be imaged, resulting in less than optimal image resolution of superficial vessels or other objects residing relatively close to the skin surface.

[0063] In contrast to the above, FIG. **2** shows the probe **12** including the spacer elements **40** disposed at each longitudinal end of the probe head **32** and adjacent the acoustic surface **34**. So configured, the acoustic surface **34** is spaced apart from the patient's skin **36** during probe use, and only the contact surfaces **42** of the spacer elements **40** are in contact therewith. The gap **48** is thus defined between the acoustic surface **34** and the patient's skin **36**, which can be filled with an ultrasonic gel **84** or other acoustically transparent substance to improve imaging, in one embodiment.

[0064] Because the acoustic surface **34** of the ultrasound probe head **32** is not in direct contact with the patient's skin **36** during probe use, pressure on the skin imposed by the acoustic surface is avoided, which in turn prevents a vessel **50** underneath the probe **12** from being compressed by the probe during use. Instead, any downward force provided by the probe **12** is directed through the spacer elements **40**. As such, the vessel **50** below the acoustic surface **34** remains patent and can be accurately imaged. Further, the increased distance between the acoustic surface **34** and the patient's skin **36** provided by the gap **48** moves the focal spot of the probe **12** to a location relatively close below the skin surface, which enables superficial vessels and other objects residing near the skin surface to be brought more closely to the focal point of the probe and be sharply imaged.

[0065] Note that the gap **48** shown in FIGS. **1**A-**2** is bounded during probe use by the acoustic surface **34**, the skin **36**, and the spacer elements **40**. As such, the gap **48** remains open below the front and rear faces **33**A, **33**B of the probe **12**. Note that additional spacers could be employed to further define the gap **48**, if desired.

[0066] Reference is now made to FIG. **3** in describing one embodiment, wherein a sheath **52** is placed over the probe **12** to provide a sterile field about the probe. The sheath **52** can be disposed about the probe **12** such that a relatively close fit is defined between the sheath and the side faces **33**C and front/rear faces **33**A, **33**B of the probe so that the ultrasound gel **84** can be included in and confined within the gap **48** by the sheath and the spacer elements **40**. Note that sheaths or barriers of many different styles or configurations may be used.

[0067] FIGS. **4**A and **4**B show example surface configurations for the acoustic surface **34**. In FIG. **4**A, the acoustic surface **34** is flat as to be substantially parallel with the patient's skin **36** during probe use. In FIG. **4**B, the acoustic surface **34** defines a concave shape with respect to the skin **36**. This configuration can assist in trapping a volume of ultrasound gel within the gap **48**. Of course, other acoustic surface configurations can be employed.

[0068] FIG. **5** gives one example of a possible configuration for the contact surface **42** of the spacer element **40**, wherein the contact surface defines a convex shape for engagement with the patient's skin or other tissue surface. Note this is in contrast to the relatively flat contact surface **42** shown in FIGS. **4**A and **4**B, for instance. Other spacer contact surface shapes can be employed, including straight, rounded, angled, etc.

[0069] FIG. **6** shows that a height "H" of each spacer element **40** can be defined according to a particular need or application in order to define a particular separation between the acoustic surface **34** and the patient's skin **36** during use of the probe **12**. Note that in one embodiment, the spacer elements are integrally formed with the probe housing. In another embodiment, the spacer elements are removably attached to the probe. The spacer elements can include materials similar to or different from those materials included in the probe housing.

[0070] Reference is now made to FIGS. **7** and **8**, wherein FIG. **7** shows that in one embodiment the spacer elements **40** can be configured to extend longitudinally a distance "E" past the side surfaces **33**C of the probe **12**. In FIG. **8**, each of the spacer elements **40** is inset a distance "I" from the probe side surfaces **33**C.

[0071] FIGS. **9**A and **9**B depict yet another possible spacer element configuration according to one embodiment, wherein each spacer element **40** is included at an end of an extension arm **48** that extends from a corresponding one of the front and rear faces **33**A, **33**B of the probe **12**. Such a configuration may be useful, for instance, in advancing the probe **12** along the patient skin **36** in a direction parallel to the longitudinal length of the acoustic surface **34**. These and other spacer configurations are therefore contemplated as residing with the spirit of the present disclosure.

[0072] FIG. **10** shows a height-adjustable spacer element **40** so as to allow variation in the set-off distance of the acoustic surface **34** from the skin **36**. In the illustrated embodiment, a bracket **60** that slidably receives the spacer element **40** is included on the side face **33**C of the probe **12** and includes a depression or hole **62**. Corresponding protuberances **64** are included on the spacer element **40** and are configured to be selectively received into the hole **62** so as to removably lock the spacer element in place at a specified height. The protuberances **64** are distributed along the length of the spacer element **40** such that one of multiple spacer heights may be selected. A similarly adjustable spacer element is included on the opposite side face of the probe **12**. Of course, other adjustable spacer element configurations can be included on the probe in addition to that explicitly described here.

[0073] FIG. **11** shows details of yet another embodiment, wherein the spacer elements **40** are included on a cap **70** that is removably attachable to the probe head **32**. In the present embodiment, the cap is snapped on to the probe head **32** via an interference fit, but in other embodiments other attachment schemes can be employed, including inter-engaging surfaces on the probe and cap, for example. A sheath **72** is

attached to the cap **70** so as to provide a sterile barrier for the ultrasound probe **10**. In one embodiment the cap **70** and sheath **72** are disposable.

[0074] It should be appreciated that the number, size, height, shape, etc., of the spacer elements can vary from what is explicitly described herein. For instance, one, three, or more spacers can be included. Or the relative heights of the spacers can differ one from another so as to produce an angled probe-to-skin configuration. The probe can include one of many different shapes, designs, etc. These and other modifications are thus considered part of the present disclosure.

[0075] FIG. **12** depicts details of a spacer component **78** configured for attachment to the probe head **32**, as shown in FIG. **13**A, according to one embodiment. The spacer component **78** includes a body of compliant material, such as a hydrogel, in one embodiment, which generally maintains its intended shape when deforming forces are absent. The compliant material in one embodiment can include AQUAFLEX® ultrasound gel from Parker Laboratories, Inc., Fairfield, N.J. The spacer component **78** further defines spacer elements **80** on each longitudinal end thereof, with a concavity **82** defined between the spacer elements. It is appreciated that other suitable materials can be employed for the compliant material of the spacer component, including acoustically transparent, sufficiently solid materials such as soft silicone, rubber, etc. In one embodiment, the compliant material is thermoformable, sterilizable, and shelf stable for at least one year.

[0076] As shown in FIGS. **13**A-**13**C, the spacer component **78** due to its compliant nature can deform so as to conform to the shape of the surface of the patient's skin **36** during use of the probe **12**. For example, the probe **12** including the spacer component **78** can be placed on a patient's arm. So positioned, the spacers **80** of the spacer component **78** can deform as needed as to match the cross sectional curvature of the arm surface and maintain contact with the skin **36** thereof. FIGS. **13**B and **13**C show such deformation of the spacer component **78** for relatively larger arms. Thus, the spacer component **78** provides an acoustic path between the acoustic surface and the skin surface without need of a flowable ultrasound gel. It is appreciated that the spacer component can be used in connection with imaging other portions of the patient's body and that the spacer component can define other shapes for contacting differently shaped body portions. Further, in one embodiment, an ultrasound gel can be included between the spacer component and the skin, such as in the concavity thereof.

[0077] FIG. **14** depicts a spacer component **90** according to another embodiment, including a flexible casing **92** that can operably attach to the probe head **32**, as shown. The casing **92** includes arms **92**A that contain a compliant insert **94**, such as hydrogel in one embodiment. As shown in FIGS. **15**A and **15**B, the spacer component **90** is positioned on the probe head **32** so as to provide both spacing and an acoustic path between the acoustic surface **34** and the surface of the skin **36** or other tissue surface such that flowable ultrasound gel is not needed. So configured, the insert **94** thereof defines a contact surface **96** for contacting the surface of the skin **36** during ultrasound probe use. In one embodiment, the arms **92**A of the casing **92** can be pressed inward to modify the shape of the contact surface **96**. For instance, FIG. **15**A shows that the contact surface **96** of the insert **94** defines a relatively shallow concavity **98** when the arms **92**A of the casing **92** are allowed to flex outward. When the arms **92**A are pressed inward as in FIG. **15**B, however, the insert **94** is compressed by the arms and the concavity **98** of the contact surface **96** becomes relatively more pronounced. Such a configuration of the contact surface **96** may be desirable to stabilize a position of the subcutaneous vessel while preventing its collapse. The arms **92**A can be biased to restore themselves to a given position when not being pressed by a user.

[0078] FIG. **16** shows details of a probe cap **110** for use with the probe **12** according to one embodiment. The cap **110** is configured to receive therein the head **32** of the probe **12** and to provide a spacer component **118** for providing desired spacing between the acoustic surface **34** of the probe head **32** and the skin **36**.

[0079] As shown in FIGS. **17**A-**17**D, the cap **110** defines a cavity **112** that is sized to receive therein the head **32** of the probe **12**. An engagement feature **114** is included with the cap **110** to releasably and mechanically attach the cap to the probe **12**, though it is appreciated that various designs can be employed to accomplish the same functionality. The cap **110** further includes a needle guide base **116** on which a detachable needle guide can be placed so as to assist a clinician in placing a needle through the skin **36** after a vessel has been located through use of the ultrasound system **10** (FIG. **1**A).

[0080] With continuing reference to FIGS. **17**A-**17**D, reference is made to FIGS. **18**A and **18**B, which depict various details of the spacer component **118**, which is disposed in a hole **130** defined in the cap **110**, best seen in FIGS. **17**A and **17**C. As shown, the spacer component **118** includes a skin contact surface **126** that defines two spacer elements **120** and a concavity **122** disposed therebetween. The spacer component includes **118** a compliant material, such as hydrogel in one embodiment, though it is appreciated that other suitable materials can also be employed. The spacer component **118** thus requires no use of flowable ultrasound gel to be applied to the skin **36** in order to provide an acoustic path between the acoustic surface **134** and the patient's skin. The spacer component **118** further defines a lip **128** about a perimeter thereof to assist in its retention within the hole **130** of the cap **110**, as seen in FIG. **18**B. As shown, in the present embodiment the lip **128** is shaped so as to be sandwiched between the cap **110** and probe head **32**, thus preventing its unintended removal from the cap.

[0081] FIG. **19** shows that in the present embodiment the acoustic surface **134** of the probe head **32** defines a convex shape. Correspondingly, FIG. **20** shows that a probe contact surface **136** of the compliant spacer component **118** also defines a convex surface. FIG. **21** shows that when the probe head **32** is received into the cavity **112** of the cap **110**, the convexly shaped probe contact surface **136** of the spacer component **118** deformably engages the convexly shaped acoustic surface **134** of the probe head **32** so as to ensure adequate contact therebetween and to provide a suitable acoustic path through the spacer component. Of course, other complementary shapes can be employed on the acoustic surface and probe contact surface of the spacer component.

[0082] FIG. **22** shows another view of the engagement between the probe head **32** and the cap **110**, according to the present embodiment. A recess **138** is included on the cap **110** to receive therein an orientation nub **140** on the probe head **32**, which nub provides a landmark for orienting an ultrasound image on the display **30** (FIG. **1**A) with the orienta-

tion of the probe **12** as held by the clinician. FIG. **23** shows the cap **110**, including the spacer component **118**, removably attached to the probe **12**. Note that in one embodiment the cap provides a sterile barrier for the probe head, and is disposable.

[0083] FIGS. **24**A-**24**C depict the probe cap **110** and the concavely-shaped, compliant spacer component **118** according to one embodiment, together with the ultrasound probe **12**. As shown, a suitably shaped cover **148** is also included for covering the spacer component **118** to prevent contamination thereof and to prevent the spacer component from drying out before use. When use of the probe cap is desired the cover **148**, which is fit to the probe cap **110** via a friction or other suitable fit, can be simply removed and discarded by the clinician.

[0084] As best seen in FIG. **24**C, the cap **110** includes in the present embodiment a bracket **144** to which a needle guide can be removably attached so as to enable guidance of a needle toward a desired vessel imaged by the ultrasound probe **12**. Further details regarding one non-limiting example of a needle guide that can be attached to the bracket **144** can be found, for instance, in U.S. Pat. No. 9,974,516, issued May 22, 2018, and entitled "Selectable Angle Needle Guide," which is incorporated herein by reference in its entirety. Note that the needle guide and bracket can vary from what is shown and described herein.

[0085] The discussion below discusses yet other structures for enhancing use of an ultrasonic probe in connection with placement of catheters and other medical devices in the body of a patient. Indeed, the embodiments disclosed herein facilitate ease of use when ultrasonically imaging portions of the patient body in preparation for device placement therein. Examples of such placement scenarios include the insertion by a clinician of a needle, PICC catheter, PIV catheter, mid-line catheter, etc. into the patient body via a transcutaneous insertion site.

[0086] FIGS. **25**A-**25**D show details of a probe cap **160** according to one embodiment, which defines a cavity **162** for receiving therein the head **32** of the probe **12** and an engagement feature **164** for enabling removable engagement of the cap to the probe head. A fixture **166** is included on the side of the cap **160** and is configured for removably receiving thereon a needle guide **192**. In another embodiment, this and other needle guides disclosed herein can be permanently attached to the cap. Note that, though not shown here, a spacer component similar to those shown and described in connection with FIGS. **24**A-**24**C is disposed in the aperture **130** of the cap **160** to provide an acoustic pathway from the probe head **32** to the patient's skin.

[0087] As best seen in FIG. **25**D, the needle guide **192** defines a channel **194** into which a portion of a cannula of a needle to be inserted into the patient can be temporarily received. Note that the size of the channel can accommodate needle cannulas of various sizes/diameters, as here, or can be configured to accept needles of a predetermined size. An abutment surface **196** is included at a distal end of the channel **194** about which the needle can pivot so as to continuously define differing angles of attack with respect to the patient's skin during needle insertion procedures. As such, the needle guide **192** is capable of guiding the needle at any one of a variety of angles of attack toward the patient's skin while maintaining alignment of the needle with the subcutaneous vessel being imaged by the probe **12**.

[0088] Note that the probe cap **160** and other caps discussed herein can be configured to mate with the head portion of the ultrasound probe in a variety of ways, including friction fit, clip-pocket engagement, adhesively, hook-and-loop, etc. The cap portion of the probe cap can also vary in design from what is shown and described herein.

[0089] The cap **160** further includes a stabilization arm **200** extending from a distal portion of the cap body. The stabilization arm **200** is configured to rest against the skin of the patient when the cap-equipped probe is held vertically and placed against the patient's skin during ultrasound imaging procedures, thus stabilizing the probe in the vertical position. Moreover, the stabilization arm **200** can assist in securing the cap-equipped probe to the patient's skin via the use of a cord or elastic band, for instance, that is extended about the patient's arm and over the stabilization arm, thus maintaining the ultrasound probe in the upright position without manual contact by the clinician during use and providing more freedom to the clinician during the imaging procedure. A hole **202** is also defined in the stabilization arm **200** in one embodiment to enable the clinician to press the patient's skin therethrough in order to locate/occlude a subcutaneous vessel. The area proximate the perimeter of the hole **202** is contoured in the present embodiment to assist with finger placement by the clinician. FIGS. **26**A and **26**B show various details of a probe cap **210** according to another embodiment, including a cavity **212** defined by the cap body that is configured to supportably receive the head **32** of the ultrasound probe **12** therein via snap-fit or other suitable modality. A fixture **216** for receiving thereon a needle guide is also included on the cap body.

[0090] A compliant membrane **218** defining a lip **218**A about its perimeter is included for attachment to the cap body. Specifically, the cap body defines a ridge **219** about an aperture **230** at the distal end of the body. The lip **218**A of the membrane **218** is configured to resiliently attach to the ridge **219** so as to join the membrane to the cap body and cover the ultrasound transducer of the probe head **32** when the cap **210** is attached to the probe **12**. The membrane **218** thus provides an acoustic pathway between the transducer and the patient's skin. Note that ultrasound gel on the patient's skin may, but need not, be used with the cap **210** during ultrasound imaging. Note also that the membrane **218** in one embodiment includes silicone, though other suitable, compliant materials can also be employed.

[0091] In greater detail, the ridge **219** includes a concavely shaped concavity **222**, as best seen in FIGS. **26**A and **27**, such that it defines two standoffs, or spacers **220**, on either end. The compliant nature of the membrane **218** enables it to deform to the concavity **222** of the ridge **219** when the membrane is placed against the patient's skin during ultrasound procedures. Thus, the membrane **218** can conform to the skin **36** of the patient during ultrasound imaging so as to enable imaging of subcutaneous structures, such as a superficial vessel **50** seen in FIG. **27**, without providing undesired compressive forces thereon.

[0092] FIGS. **28**A and **28**B depict a probe cap **260** according to one embodiment, wherein the body of the cap defines a cavity **262** and a fixture **266** for receiving thereon a needle guide. An ultrasonically transparent membrane **268** is included proximate an aperture **280** at a distal end of the cap body to cover the transducer of the head of an ultrasound probe inserted therein. An ultrasonically transmissive medium, such as ultrasound gel **269**, can be placed on an

interior surface of the membrane **268** to ensure acoustic coupling between the transducer and the skin of the patient. As with other cap embodiments described herein the probe cap **260** can be configured as a sterile cap to provide sterility or isolation for the ultrasound probe. Spacers **270** can also be included on either side of the membrane **268** to prevent compression by the cap **260** of superficial vessels when the cap **260** is placed against the skin. Note that ultrasound gel can also be placed between the membrane **268** and the patient's skin to improve signal transfer, if desired.

[0093] FIGS. **29**A-**29**D depict details of a probe cap assembly **310** according to another embodiment, wherein the assembly includes a cap body defining a cavity **312** for receiving therein the head **32** of the ultrasound probe **12**, as before. Also as before, an engagement feature **314** is included to secure the cap body to the probe **12**.

[0094] The cap body is movable between two parallel rails **350** of a bracket **340**. Each rail **350** includes a plurality of slots **352** that align with corresponding slots on the opposing rail **350**. Tabs **319** included on either longitudinal end of the cap body are configured to be selectively received into corresponding opposed slots **352** of the rails **350**, as shown in FIGS. **29**A-**29**D. In the illustrated embodiment, the cap body is selectively repositionable along the bracket rails **350** via manual movement by lifting the cap body so as to remove the tabs **319** from the corresponding slots **352**, repositioning the cap body as desired with respect to the bracket rail slots, then inserting the tabs into the selected slots. In other embodiments, it is appreciated that other modalities for moving the cap body relative to the bracket are possible, including sliding movement, gear-driven movement, etc.

[0095] As best seen in FIGS. **29**B-**29**D, a needle guide **342** is included in the bracket to guide a needle into the patient's body when the probe cap assembly **310** is placed on the patient's skin. An observation hole **346** is also included on the bracket **340** so as to enable a clinician inserting the needle to observe blood flashback upon the needle accessing the subcutaneous vessel.

[0096] Note that the needle guide **342** in the present embodiment is disposed at a fixed angle with respect to the bracket **340** and that the cap body is movable along the bracket with respect to the needle guide. This arrangement thus enables subcutaneous tissue to be imaged, by the ultrasound probe disposed in the cap body, at differing discrete distances from the needle guide **342**. Further, this arrangement enables a needle inserted through the needle guide **342** to access an ultrasonically imaged vessel or other target at any one of a plurality of depths below the skin without the need for adjusting the angle of attack of the needle.

[0097] In greater detail, the probe **12** while disposed in the cap body of the probe cap assembly **310** can ultrasonically image a subcutaneous vessel within the patient and determine the depth below the skin surface at which the vessel resides. One or more of the slots **352** are marked with a number, indicating the depth below the skin at which a needle inserted into the patient through the needle guide **342** will intercept the subcutaneous vessel. Thus, the bracket **340** can be adjusted until the tabs **319** thereof are disposed in the slots **352** on either rail **350** corresponding to the depth of the imaged vessel. When the needle is inserted into the patient's skin through the needle guide **342**, it can be advanced until it intercepts and accesses the imaged vessel at the determined depth, as desired. As such, it is appreciated that the probe cap assembly **310** can assist with needle access of an ultrasonically imaged vessel through a fixed-angle needle guide regardless of the depth of the vessel, thus obviating the need for an adjustable angle needle guide in the present embodiment. Note that the depth measurements of the bracket can vary from what is shown, but in one embodiment, the depths accessible via the probe cap assembly **310** vary from about 0.3 cm to about 1.5 cm.

[0098] FIGS. **30**A and **30**B depict a probe cap **360** according to another embodiment, wherein the cap body defines a cavity **362** for receiving therein the head **32** of the ultrasound probe **12** and an engagement feature **364** to secure the cap body to the probe **12**. A stabilization arm **365** extends from the cap body so as to enable the cap **360** (and the probe **12** received therein) to be secured to the patient via a band wrapped around the stabilization arm and the arm of the patient, for instance.

[0099] As shown, the probe cap **360** further includes a deflector portion **390** for deflecting an ultrasound signal both emanating from and travelling to the transducer of the ultrasound probe **12**. The deflector portion **390** is formed as part of the probe cap **360** and defines a channel **392** and an aperture **396** through which ultrasound signals can pass. The deflector portion **390** further includes a deflecting surface **394** disposed in the channel **392**. In the present embodiment the deflecting surface **394** is disposed at an angle of about 45 degrees with respect to the transducer surface of the probe head **32** so as to deflect ultrasound signals emanating therefrom through an angle of about 90 degrees, though the deflecting surface can be positioned in other embodiments at other angles so as to produce different resulting angles of signal deflection with respect to the probe transducer.

[0100] FIG. **31** shows the probe cap **360** positioned against the skin **356** of a patient such that signals emanating from the transducer of the probe head **32** travel through the channel **392**, are deflected by the deflecting surface **394**, and are directed downward into the body of the patient. Ultrasound signals reflected by an imaged target within the body and received into the channel **392** are also similarly deflected by the deflecting surface **394** toward the probe head **32** for receipt by the transducer. The deflecting surface **394** can include any suitable material having a suitable density so as to reflect the ultrasonic signals travelling through the channel **392**. In one embodiment, the deflecting surface includes a plastic material. Also, in one embodiment, the channel **392** is at least partially filled with an ultrasonically transmissive medium, such as an ultrasound gel. In another embodiment, a hydrogel-based spacer component can be disposed in the channel **392**, as in previous embodiments. In yet another embodiment, the deflector portion can be integrated into the probe head itself, without the presence of a probe cap. Use of the deflecting probe cap **360** enables the probe **12** to be positioned parallel to the skin **36** of the patient, thus eliminating the need for the clinician to hold the probe upright during use.

[0101] FIG. **32** shows that the deflecting probe cap **360** in one embodiment can be included as part of an assembly similar to that shown in FIGS. **29**A-**29**D, wherein the cap body is selectively movable between two rails **410** of a bracket **400**. The rails **410** each include corresponding slots **412** for receipt of tabs **369** included on the cap body so as to position the probe cap at one of a plurality of possible distances from a needle guide **402** included on the bracket

400. As before, an observation hole **406** is included proximate the needle guide **402**. As described further above in connection with FIGS. **29**A-**29**D, the assembly shown in FIG. **32** enables vessels at a variety of subcutaneous depths to be ultrasonically imaged and accessed by a needle disposed in the fixed-angle needle guide **402** by moving the bracket **400** with respect to the probe cap **360** such that the needle intercepts the imaged vessel at the intended depth.

[0102] FIGS. **33**A and **33**B depict the deflecting probe cap **360** according to one embodiment, wherein the deflector portion **390** is hingedly connected to the remainder portion of the cap body via a hinge component **420**, including a mechanical or living hinge for instance. So configured, the deflector portion can be selectively positioned so as to deflect ultrasound signals along a deflected signal path **424**A (FIG. **33**A), or rotated out of the ultrasound signal path (FIG. **33**B) so as to enable the ultrasound signals to travel along an undeflected signal path **424**B. A latch **426** or other suitable modality can be included to selectively secure the deflector portion **390** in place. Note that in one embodiment a deflecting probe cap can be adjustable such that deflection of the ultrasound signal can be achieved through a variety of angles.

[0103] FIG. **34** shows a needle guide **450** according to one embodiment that can be employed with one or more of the probe caps described herein, such as the probe cap **460** shown in FIG. **35**B, or can be attached directly to the ultrasound probe. As shown, the needle guide **450** includes a curved, V-shaped open channel **454** that centers a needle therein yet enables the clinician to continuously adjust the angle of attack θ for the needle at the insertion site during needle insertion, as shown in FIG. **35**A. Note that the shape of the channel can vary from what is shown and described.

[0104] FIGS. **36**-**47** depict details regarding coupling structures for ultrasonically coupling the head of an ultrasound probe with the patient's skin according to various embodiments. Such ultrasonic coupling (also referred to herein as acoustic coupling) enables the ultrasound signals produced by the head of the ultrasound probe to pass through the coupling structure and the patient's skin in order to penetrate, impinge on, and reflect from the patient's subcutaneous tissue. This in turn enables suitable ultrasound images of the subcutaneous tissue to be taken. In the embodiments to be described, the coupling structures can in many instances be adapted so as to fit handheld and other probes of varying sizes and configurations.

[0105] FIG. **36** according to one embodiment shows a cap **110** configured similarly to other caps described above and configured for removable attachment to a head portion of an ultrasound probe, such as the head portion **32** of the ultrasound probe **12** (FIGS. **24**A, **24**B). The cap **110** includes the above-described spacer component **118**, also referred to herein as an insert (such as a hydrogel insert) or a coupling component, attached therewith and extending from a bottom surface thereof. The insert spacer component **118** can include any one of a variety of acoustically transparent materials including naturally-based and synthetic hydrogels. The spacer component **118** is positioned such that it is interposed between the head of the ultrasound probe and the patient's skin to enable ultrasound signals to pass therethrough. A needle guide **33**, also described further above, is attached to the probe cap **110** to assist in guiding a needle into the patient to intercept an ultrasonically imaged vessel or other subcutaneous feature.

[0106] In accordance with the present embodiment, a second coupling component that also serves to ultrasonically couple the probe head with the patient's skin is also disclosed. As shown in FIG. **36**, the second coupling component includes a sock **520** that is disposed about the probe cap **110**, spacer component **118**, and needle guide **33**. In the present embodiment, the sock **520** includes a natural or synthetic hydrogel or other acoustically transparent material that is suitably compliant so as to fit over the aforementioned components, though in other embodiments a lesser portion of the cap and/or needle guide may be covered by the sock. In greater detail, a portion of the sock **520** covers the hydrogel spacer component **118**; being acoustically transparent, the sock nonetheless enables ultrasound signals to pass therethrough. Thus, ultrasound signals emitted and received by the head of the ultrasound probe can readily pass through both the spacer component **118** and the sock **520**. So configured, the spacer component **118** of the present embodiment serves as a first coupling component, while the sock **520** serves as a second coupling component.

[0107] The sock **520** is configured to enable the probe **12** (e.g., FIGS. **24**A, **24**B) to be employed in performing an ultrasonic pre-scan with the sock in place as shown in FIG. **36**. Once the pre-scan has been completed, the area of the patient's skin where the pre-scan took place can be washed and cleaned prior to needle insertion. The sock **520** can then be removed from the cap **110** and the remaining spacer component **118**—which is sterile due to it being previously covered by the sock—can be placed against the cleaned area of the patient's skin to perform a subsequent ultrasound scan immediately prior to inserting the needle into the skin.

[0108] Note that the sock can be sized so to fit one or more of differing probe and/or cap sizes. In one embodiment, the sock is defined from a sheet of commercially available fiber-reinforced or unreinforced hydrogel material that can be shaped before being cured via light or other radiation, temperature, etc. to define the desired sock shape. In one embodiment, the sock is defined from an initially flat sheet that is forced into the desired shaped via a heating process. Other suitable materials can be employed to define the sock, including polyethylene oxide, silicone, thermoplastic elastomers ("TPE"), etc. In another embodiment, the inner spacer component is removed and only the hydrogel sock is included with the cap assembly. In one embodiment, characteristics of the sock material include acoustic transparency with respect to the spacer component, lubricity, and durability. Glycerin, silicone oil, and other lubricants can also be employed in this and other embodiments. In another embodiment, the sock can be pre-attached to the probe cap and used as a mold for pouring and molding the hydrogel spacer component. Note that in one embodiment, the spacer component and/or the sock can include a hydrogel component such as is described in U.S. Pat. No. 9,211,107, issued Dec. 15, 2015, and entitled "Ruggedized Ultrasound Hydrogel Insert," which is incorporated herein by reference in its entirety.

[0109] FIGS. **37**A and **37**B depict various details of coupling components according to another embodiment, wherein a mold is employed into which a natural or synthetic hydrogel or other suitable solution can be poured then cured to form a sheet **540** that defines a plurality of hydrogel (in the present embodiment) coupling components, or spacer components **544**, similar to the spacer component **118** shown in FIG. **36**. In detail, FIGS. **37**A and **37**B show spacer

components of various sizes/configurations, namely, spacer components **544**A, **544**B, and **544**C, so as to fit ultrasound probes of varying sizes. In the present embodiment, the spacer components **544**A, B, and C include perforations **546** defined thereabout so as to ease their removal from the hydrogel sheet **540** after formation.

[0110] Once formed, the spacer components **544**A, B, and C can be removed from the sheet **540** using the perforations **546**, then inserted into caps, such as the probe cap **110** shown in FIG. **38**, or other coupling structure. In detail, FIG. **38** according to one embodiment shows one of the spacer components **544**A disposed in the aperture **130** of the probe cap **110** and retained in place by a retention ring **550**. Retention posts **552** and/or other retention features can also be used to secure the spacer component **544**A in place. Note that the shape and configuration of the spacer component can be specific to a particular probe head/cap, or generic so as to fit a range of probes. Indeed, in one embodiment the hydrogel spacer component discussed here can be coupled to a sheath configured to cover the ultrasound probe. The sheath can include a clasp or other suitable fixation device at/near a proximal end thereof so as to clamp on to the probe or cable of the probe and keep the spacer component in place on the head of the probe.

[0111] FIG. **39** shows a substantially rigid frame, or reinforcement structure **560** that is employed in a coupling component according to another embodiment. As shown, the reinforcement structure **560** includes a mesh-like lattice component **562** configured to generally conform to the shape of a hydrogel or other suitable insert, such as the spacer component **118** shown in FIG. **40**. In the present embodiment and as shown in FIG. **40**, the lattice component **562** is incorporated into the spacer component **118** and is shaped so as to help secure the spacer component **118** to the probe cap **110** so as to prevent displacement or removal of the spacer component from the probe cap.

[0112] In one embodiment, the lattice component **562** includes a suitable material, such as polyethylene, polyamides such as nylon, polyethylene oxide, etc. In one embodiment, the material for the lattice component **562** is chosen so as to be acoustically transparent and/or matching the acoustic transparency of the hydrogel insert, which in one embodiment, includes a density substantially near that of water. In another embodiment, though not fully acoustically transparent, the mesh size of the lattice component is small enough diameter so as to present a suitable acoustic transparency. As used herein, "acoustically transparent" includes the ability for ultrasound signals to freely pass through the subject medium without significant attenuation. The lattice component **562** is sufficiently rigid so as to prevent shredding or breakup of the hydrogel coupling component, in one embodiment, thus enabling the coupling component to be moved across the skin without significant structural compromise.

[0113] FIG. **41** shows a coupling structure according to another embodiment, wherein the coupling structure is implemented as an ultrasound imaging patch **570** including an adhesive portion **572** disposed about the patch perimeter and an imaging region **574** disposed in the central region. The patch **570** is configured to be adhered to the skin at the imaging site by the adhesive portion **572**. The imaging region **574** includes a fibrous or other suitable base material impregnated with gel or other acoustically transparent material that enables an ultrasound probe to image the patient's body therethrough when the head portion thereof is placed in contact with the imaging region. In one embodiment, the base material includes a woven natural or synthetic fiber and the gel impregnated therein includes a natural or synthetic hydrogel. Once the body portion has been imaged through the imaging region **574**, a needle or other device can penetrate through the imaging patch **570** into the patient's body without first removing the patch, in one embodiment. Also, in one embodiment, the patch **70** can include medication, pain relief or anesthetics, etc. to aid in patient care/comfort. In yet another embodiment, a hole can be defined in the patch into which a hydrogel insert can be disposed.

[0114] Yet another coupling structure is depicted in FIG. **42**, which shows the probe cap **110** including the spacer component **118** through which ultrasound signals are sent and received by the ultrasound probe when the cap is attached thereto. The spacer component **118** in the present embodiment includes an acoustically transparent, elastomeric, non-adhesive hot-melt material that can serve to enable sliding of the probe cap **82** over the skin of the patient without the use of ultrasound gel being first applied to the skin. In one embodiment, suitable lubricants and/or softeners can be added to the hot-melt material of the spacer component **118** during manufacture thereof so as to improve its compliant nature and ease its movement over the skin surface during later use. EVA copolymers, polyolefins, polyamides, polyesters, polyurethanes are non-limiting examples of materials the spacer component **118** may include, in one embodiment.

[0115] In another embodiment, the spacer component **118** of the cap **110** can include an injection-moldable, acoustically transparent material and can be molded separately before joined to the cap or molded directly to the cap in a two-shot injection molding process. The material of the spacer component **118** can include a thermoplastic elastomer ("TPE"), silicone, etc. In one embodiment, the lubricity of this or other spacer components described herein can be improved by including a suitable coating, such as a hydrophilic or parylene coating, for instance. The coating can be included on one or both of the skin-contacting portion of the spacer component and the portion that contacts the head portion of the ultrasound probe. This in turn can assist in ultrasonically coupling the spacer component **118** to the probe head portion and in enabling smooth movement of the spacer component over the skin surface. In one embodiment, the spacer component **118** and probe cap **110** can be packaged in a sterile solution, such as sterile saline. When the cap **110** is later removed from the sterile solution for use, the spacer component **118** maintains its lubrication via the residual sterile saline solution disposed thereon. In another embodiment, the saline solution can be added to surface of the spacer component **118** by the user immediately prior to use.

[0116] FIGS. **43**A and **43**B depict details of a coupling component according to another embodiment, wherein a spacer component **580** for attachment to a probe cap (such as the probe cap **110** of FIG. **42**) includes a compliant outer membrane **582** that is shaped for attachment to the probe cap about its aperture. The membrane **582** is further configured to retain therein an acoustically transparent substance, such as a hydrogel in a cavity **584** defined by the membrane. In the present embodiment, the cavity **584** of the outer membrane **582** is filled with hydrogel before or after membrane

attachment to the probe cap. Later during ultrasound probe use, the probe head portion is ultrasonically coupled to the patient's skin surface via the hydrogel-filled membrane **582** of the spacer component **580**. Isolation of the hydrogel from the patient's skin in this manner prevents degradation, flaking, or other degradation of the hydrogel during use against the patient's skin. The membrane **582** can include any suitable, compliant material, including TPEs or silicone, for instance.

[0117] FIG. **44** depicts details of a coupling structure according to another embodiment. FIG. **44** shows a probe cap **610** including a body **612** that is configured to be removably attached to a head portion of an ultrasound probe, though in another embodiment the probe cap—as with the other caps disclosed herein—can be configured for permanent attachment to the probe head. The cap body **612** includes a flexible barrier **614** that is deformed by the head portion when the cap **610** is attached to the probe. A reservoir **616** is defined by the cap body **612** and is filled with a solution that can include hydrogel, bactericide, lubricant, etc. An osmotic membrane **618** is disposed at the bottom of the cap **610** and is in fluid communication with the reservoir **616**.

[0118] During use, the cap **610** is attached to the head portion of the ultrasound probe such that the barrier **614** is deformed. Deformation of the barrier **614** causes pressure to be exerted on the fluid in the reservoir **616**. This in turn causes the fluid to penetrate through the osmotic membrane **618** and on to the patient's skin, where it can be used to lubricate cap movement over the skin, disinfect the skin, etc. The barrier **614**, reservoir fluid, and osmotic membrane **618** in the present embodiment are configured to be substantially acoustically transparent so as to permit passage of ultrasound signals therethrough.

[0119] FIG. **45** shows a plurality of probe caps **610** arranged atop a sheet **626** of osmotic membrane in an array **624** in one manufacturing configuration, according to one embodiment. Of course, varying manufacturing processes could also be employed.

[0120] FIGS. **46**A and **46**B depict various details of a coupling structure according to another embodiment. In detail, FIGS. **46**A and **46**B show a probe cap **660** including a body **662** that is configured to be removably attached to a head portion of an ultrasound probe. The cap body **612** includes a flexible barrier that is interposed between the probe head portion and a reservoir **666** of the body. The flexible barrier is deformed by the head portion when the cap **660** is attached to the probe. The reservoir **666** is filled with a solution that can include hydrogel, bactericide, lubricant, etc. A slit valve **668** is disposed at the bottom of the cap **660** and is in fluid communication with the reservoir **666**.

[0121] During use, the cap **660** is attached to the head portion of the ultrasound probe such that the barrier is deformed. Deformation of the barrier causes pressure to be exerted on the fluid in the reservoir **666**. Attachment of the cap **660** to the head portion also deforms the slit valve **668**, which in turn enables fluid to penetrate therethrough and on to the patient's skin, where it can be used to lubricate cap movement over the skin, disinfect the skin, etc. The barrier, reservoir fluid, and slit valve **668** in the present embodiment are configured to be substantially acoustically transparent so as to permit passage of ultrasound signals therethrough.

[0122] The cap **660** in the embodiment shown in FIG. **47** replaces the slit valve of FIGS. **46**A and **46**B with a plurality of spheres **670** that are each movably disposed in holes **672**, with each hole being in fluid communication with the reservoir fluid. The spheres **670** can be made from any suitable material, including plastic, metal, etc. When the cap **660** is pressed against the patient's skin, the spheres **670** are temporarily displaced upward, which enables the reservoir fluid to escape around the spheres through the holes **672** and on to the patient's skin. When skin pressure is removed, the spheres **670** return to seat within the holes **672** and prevent further fluid escape. In addition to the slit valve and spheres discussed in connection with FIGS. **46**A-**47**, other fluid escape mechanisms and configurations can be included, such as perforations, a plurality of holes, etc., as appreciated by one skilled in the art.

[0123] Embodiments of the invention may be embodied in other specific forms without departing from the spirit of the present disclosure. The described embodiments are to be considered in all respects only as illustrative, not restrictive. The scope of the embodiments is, therefore, indicated by the appended claims rather than by the foregoing description. All changes that come within the meaning and range of equivalency of the claims are to be embraced within their scope.

What is claimed is:

1. A cover for an ultrasound probe, comprising:

a cap that removably attaches to a head portion of the ultrasound probe;

a first coupling component included with the cap and capable of ultrasonically coupling the head portion to a skin surface of a patient; and

a second coupling component that removably covers the first coupling component and is capable of ultrasonically coupling the head portion to the skin surface.

2. The cover as defined in claim **1**, wherein the second coupling component covers the first coupling component so as to prevent contamination of the first coupling component before removal of the second coupling component.

3. The cover as defined in claim **1**, wherein at least one of the first and second coupling components includes a hydrogel.

4. The cover as defined in claim **1**, wherein the second coupling component includes a compliant sheet and envelops at least a portion of the cap together with the first coupling component.

5. The cover as defined in claim **4**, wherein the cap further includes a needle guide, and wherein the second coupling component covers at least a portion of the needle guide.

6. The cover as defined in claim **1**, wherein the second coupling component is pre-installed substantially over the over the entirety of the cap and is sterilized and packaged before use with the ultrasound probe.

7. A cover for an ultrasound probe, comprising:

a cap that removably attaches to a head portion of the ultrasound probe;

a compliant coupling component included with the cap and capable of ultrasonically coupling the head portion to a skin surface of a patient; and

a substantially rigid reinforcement structure disposed within the coupling component to preserve structural integrity of the coupling component when the coupling component is moved in contact with skin surface.

8. The cover as defined in claim **7**, wherein the coupling component is disposed in an aperture of the cap and wherein

the reinforcement structure cooperates with the cap to secure the coupling component within the aperture.

9. The cover as defined in claim **7**, wherein the reinforcement structure includes a lattice configuration and includes an acoustically transparent material.

10. The cover as defined in claim **9**, wherein the coupling component includes a hydrogel and wherein the reinforcement structure includes a thermoplastic elastomer.

11. A coupling patch for use with an ultrasound probe, comprising:

a base material; and

a coupling component incorporated into at least a first region of the base material, the coupling component being acoustically transparent such that the first region can ultrasonically couple the ultrasound probe to a skin surface of a patient when the coupling component is interposed between the ultrasound probe and the skin surface.

12. The coupling patch as defined in claim **11**, wherein the base material includes a sheet of fibrous material into which the coupling component can be infused.

13. The coupling patch as defined in claim **12**, wherein the base material includes a woven material and wherein the coupling component is a hydrogel.

14. The coupling patch as defined in claim **11**, wherein the perimeter of the base material includes an adhesive for adhering to the skin of the patient during use.

15. The coupling patch as defined in claim **11**, wherein the coupling component includes at least one of a medication, a pain reliever, an anesthetic, and a lubricant.

16. A cover for an ultrasound probe, comprising:

a cap that removably attaches to a head portion of the ultrasound probe; and

a coupling component included with the cap and capable of ultrasonically coupling the head portion to a skin surface of a patient, the coupling component including:

a membrane that covers an aperture in the cap, the membrane extending beyond the cap; and

an acoustically transparent coupling material disposed within a cavity defined by the membrane.

17. The cover as defined in claim **16**, wherein the membrane includes at least one of silicone and a thermoplastic elastomer.

18. The cover as defined in claim **16**, wherein the coupling material includes a hydrogel disposed within the cavity.

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摘要(译)

公开了一种用于包括头部和声学表面的超声探头的探头盖。 在一个实施例中，探针帽包括主体，该主体限定了空腔，该空腔的尺寸设计成可释放地将探针的头部容纳在其中。 探针帽主体还限定出靠近头部的声表面的孔。 顺应性的隔离部件被布置在孔中。 间隔物组件可包括水凝胶，并在患者的声学表面和组织表面之间提供声学路径。 间隔物部件包括限定凹面并且可抵靠组织表面变形的皮肤接触表面。 附加的实施例公开了各种探针帽和随附的针头引导器设计，用于协助临床医生使用超声探针并将针头插入患者体内。