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(54) Title: RADIAL AND ULNAR COMPRESSION BAND

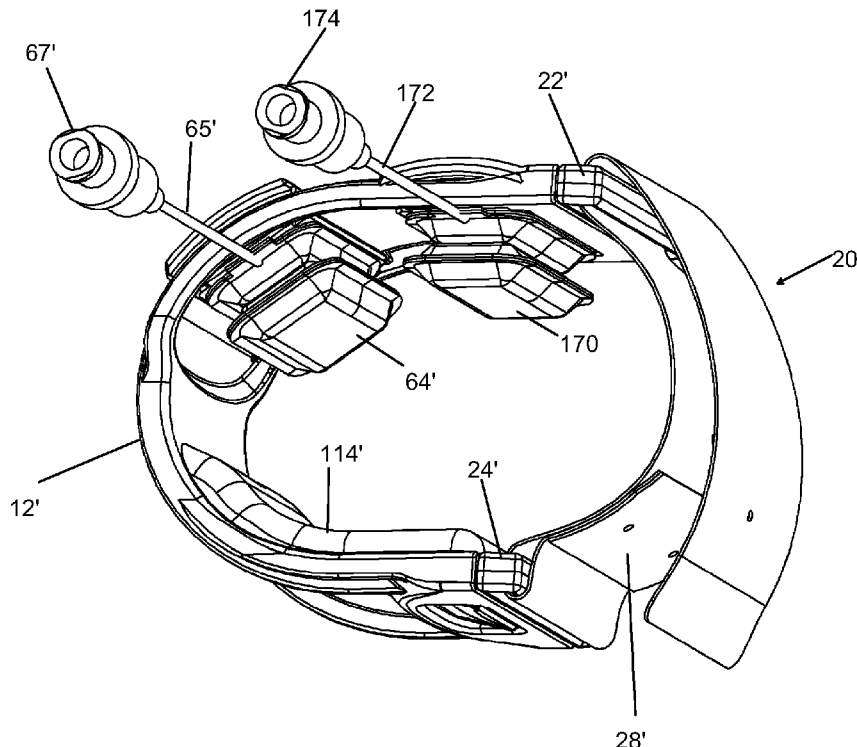


FIG. 28

(57) Abstract: A radial compression band employs a substantially rigid U-like cuff that fits over a patient's arm and then snaps onto a tightening band. A movable bubble member is positioned for movement along the band separate from the attachment to the patient and is inflatable to provide pressure to an incision or the like to accomplish hemostasis. A plural bubble member version provides multiple pressure application positions.



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RADIAL AND ULNAR COMPRESSION BAND

Cross-Reference to Related Applications

This application claims the benefit of United
5 States provisional application filed on March 25,
2016, and having application Ser. No. 62/313,591, and
is a continuation-in-part of United States Patent
Application Ser. No. 15255017 filed September 1, 2016,
the entire contents of which two applications are
10 hereby incorporated herein by reference.

Background

This disclosure relates to vascular delivery
devices and techniques, which can be advantageous by
15 allowing access to a patient's body without the
requiring general anesthetic or more invasive
procedures. With such techniques, access to a
patient's peripheral arteries is performed by use of a
sheath having a hemostatic valve. The sheath is
20 introduced into the patient via the peripheral artery
and a device such as a catheter or other apparatus can
then be received into a desired location within the
patient's vascular system via the sheath. US patent
6,355,026 entitled "Coronary catheters for use in a
25 transradial catheterization" gives an example of how
these techniques may be accomplished, via a patient's
radial arteries.

Since the radial (or ulnar) arteries of the
patient can be used for such access to the vascular
30 system, lower cost is provided than other procedures
and better/earlier mobilization of the patient can be
achieved.

When using the radial or ulnar arteries for
access, after the procedures are completed, hemostasis

can be accomplished by use of compression applied directly to the artery upon removal of the catheter or other device. However, there can be issues and difficulties in accomplishing hemostasis with a radial or ulnar artery access point. After the procedures are complete and the sheath is withdrawn, pressure application to provide compression of radial or ulnar artery at the access site is required to obtain hemostasis of the site opening that was formed into the artery wall. However, this pressure can potentially cause the artery to occlude or close, blocking blood flow beyond the occlusion point, which is detrimental to the patient. So, to lessen the likelihood of occlusion, during at least part of the time while pressure is applied, some flow of blood through the artery should be allowed to continue.

Adjustment over time of the pressure being applied to maintain hemostasis can be desirable to allow blood to flow through the artery of the access site and to get to tissue beyond the access site, by gradually reducing the pressure so that blood flow is increased as the clot at the access incision strengthens.

Existing solutions to some of the issues noted above include those described in US patents 7,498,477, 8,481,803, and 8,524,974 all directed to a HEMOSTATIC DEVICE. The devices described in those patents employ a flexible band which wraps around the patient's wrist and is then secured. A syringe is employed to inflate an air bladder which presses against the puncture site.

Summary

In accordance with the disclosure, a substantially rigid partial cuff member is provided to

receive the patient's wrist therein, with a securement member to secure the cuff to the wrist. First and second positionable inflation members are movable along portions of the cuff to allow positioning of the inflation members over the puncture site without
5 needing to move the cuff. The inflation members are then inflatable to provide pressure against the puncture site, ensure bleeding is prevented. The dual inflation members provide compression for both radial
10 and ulnar artery puncture sites.

The subject matter of the present technology is particularly pointed out and distinctly claimed in the concluding portion of this specification. However, both the organization and method of operation,
15 together with further advantages and embodiments thereof, may best be understood by reference to the following description taken in connection with accompanying drawings wherein like reference characters refer to like elements.

20

Brief Description of the Drawings

FIG. 1 is a perspective view of a radial compression band in accordance with the disclosure;

FIG. 2A is a side view of a radial compression
25 band in accordance with the disclosure, with the bubble in an inflated state;

FIG. 2B is a sectional side view of the radial compression band of FIG. 2A, taken along line 2B-2B of FIG. 1, with the bubble in an deflated state;

30 FIG. 3 is a perspective view of a partial radial band to illustrate the connection of the buckles;

FIG. 4 is a view of a buckle being inserted into the radial band brace;

FIG. 5 is a sectional view of the connection

portion the buckle taken along line 5-5 of FIG. 1;

FIG. 6 is an exploded view of the radial band bubble assembly with the bubble in an inflated configuration;

5 FIG. 7 is a partial perspective view of the radial compression band, without the bubble;

FIG. 8 is sectional view taken along line 8-8 of FIG. 7;

10 FIG. 9 is an exploded view of a partially constructed bubble assembly;

FIG. 10 is a sectional view of a fully constructed bubble assembly taken along line 10-10 of FIG. 9;

15 FIG. 11 is a sectional view taken along line 11-11 of FIG. 1;

FIG. 12 is a view of the radial band bubble assembly by itself in a partially inflated mode;

FIG. 13 is a view of the radial band bubble assembly in a fully inflated mode;

20 FIGS. 14 and 15 illustrate the radial band brace to demonstrate movement of the bubble assembly along the band brace;

25 FIG. 16 is a perspective view of the radial band brace with bubble assembly installed, illustrating an optional pad;

FIG. 17 is a perspective view of the radial band brace with bubble assembly installed, illustrating an optional positioning bubble;

30 FIG. 18 is a partial perspective sectional view taken along line 11-11 of FIG. 1, but illustrating the bubble in a fully deflated state;

FIG. 19 is a rear partial view illustrating a manner of securing the bubble assembly in position;

FIG. 20 is a view of an alternative bubble

assembly that includes a hemostatic gel or coolant;

FIGs. 21-25 illustrate exemplary variations of bubble configurations;

FIG. 26 is an exploded view that illustrates the
5 process of constructing the bubble in manufacturing;

FIGs. 27A-27D illustrate removal of the covering to activate a hemostatic gel or other substance;

FIG. 28 is a perspective view of a dual radial/ulnar compression band; and

10 FIG. 29 is a side view of the dual radial/ulnar compression band of FIG. 28.

Detailed Description

The system according to a preferred embodiment of
15 the present disclosure comprises a substantially rigid partial cuff member, approximately in a U shape, is provided to receive the patient's wrist therein, with a securement strap that is attached to one end of the cuff and adapted to loop through the other end of the
20 cuff, to secure the cuff to the wrist. One or more positionable inflation members are movable along a portion of the cuff to allow positioning of an inflation member over a puncture site. An inflation port may employ a standard leuer lock connector to
25 allow attachment of a syringe for inflation of the inflation member to provide pressure against the puncture site, for achieving non-occlusive hemostasis.

Referring to FIG. 1, a perspective view of a radial compression band in accordance with the
30 disclosure, the radial band assembly 10 comprises a radial band brace 12 that is approximately U-shaped and having a width 14, which is adapted to fit over a patient's wrist where the wrist is received in the open central portion of the radial band brace. The

band brace is slightly loaded so that the 'legs' of the U-shape are not exactly parallel to one another. In a particular embodiment, the radial band brace can be produced in different sizes, to accommodate
5 different sized patient wrists. Typically a size is chosen that is just slightly larger than the patient's wrist. The band is suitably clear such that it is easily seen through, and may comprise of clear ABS, for example. The band can be provided with a color if
10 desired. Acrylic may be used if rigidity is not an issue. The different sizes can be provided with slight color tints, each size being given a different color, to allow quick identification of which size the band is. The band is substantially rigid, with some amount
15 of flexibility such that when the strap is tightened, the U-shaped legs will move towards each other somewhat to take up slack in the fit on the patient's wrist. Examples of suitable material to use in construction of the band includes PVC, ABS, Poly
20 Urethane, or a blend thereof.

Referring to FIG. 2A, a side view of the radial compression band with the bubble in an inflated state, it may be observed that in the particular embodiment, the U-shaped configuration is a slightly varied U,
25 where one leg 16 of the U portion is shorter than the other, the shorter leg being in the lower portion of FIG. 2, while the upper leg 18 is slightly longer, extending further to the left in the view of FIG. 2.

A strap assembly 20 connects to the ends of the
30 radial band brace, suitably by means of upper and lower buckles 22 and 24, which removably connect to the radial band brace at the 'ends' of the U-shape of the band brace. A strap member 26 is received by the buckles, substantially permanently yet flexibly

attached at one of the buckles, lower buckle 24, for example, and removably looped through upper buckle 22. Hook and loop fasteners 28 are provided on the strap member to allow adjustment tightening of the tension
5 on the strap and then securing the strap with the desired tension, allowing the band to be removably secured to the patient's wrist. An optional additional hook and loop material 28a may be provided on the band to secure any excess length of the strap, if desired.

10 Upper and lower buckles 22 and 24 securely yet detachably engage with the radial band brace, to allow the band to be quickly released from a patient's wrist by disconnection of the engagement. Details of the engagement structure are illustrated in FIGs 3-5.

15 Referring to FIG. 3, a perspective view of a partial radial band, the connection of the buckles will be explained. Buckles 22 and 24 have extending tab portions 28, 30 which are sized to be received in corresponding slot portions 32, 34 in the band brace
20 (visible in FIGs. 16 and 17). Considering upper buckle 22, the tab 28 has a curved forward profile defining approximately an isosceles trapezoidal shape and has an upwardly projecting latch portion 36 defined in the center region of the trapezoid. The latch portion 36
25 is biased to extend above the general plane of the tab in absence of downward force, but is sufficiently flexible to deform if pressed, and returns to the extended position when any such force is removed. Slots 44, 46 provided in the buckles receive the strap
30 26 therethrough, buckle 22 having the strap pass through in removable fashion, while buckle 24 has the strap looped through then the end of the strap is secured to a portion of the strap to permanently mount the buckle to the strap while still allowing some

degree of movement for flexibility. The trapezoidal shape of the buckle extending tab portions provides a narrower width at the end of the tab distal from the attachment to the strap.

5 With reference to FIG. 4, a view of a buckle being inserted into the radial band brace, the curved narrower end of the trapezoidal shape allows easy insertion of the tab into the receiving slots 32, 34, allowing insertion from the side, without requiring
10 that the tab be square to the opening. The receiving slots provide for the tab portions to be inserted to the slots, which upon insertion, the interaction of the raised latch portion with the receiving slots, which have a height less than the height of the raised
15 latch portion, compresses the latch portion 36. As the tab is further guided into the slot, eventually the latch portion will align with opening 40 defined in the band (opening 42 on the other end of the band) which relieves the compressing force on the latch,
20 allowing the latch to return to its extended position and, operating to lock the buckle to the radial band brace 12. Removal of the device can be quickly accomplished by depressing the latch member 36 (38) which allows the buckle to be withdrawn from the slot,
25 freeing the device from the patient's wrist.

 The latch portion 36 has an additional forwardly extending tab portion 37 (two such tabs being provided in the illustrated embodiment) that interacts with the lower face of the upper leg 18 around the opening 40,
30 preventing the latch portion from riding up out of the opening via the top of the opening, which could prevent the removal of the latch when pulling on the strap when trying to remove buckle 22.

 Referring to FIG. 5, a sectional view of the

connection portion the buckle taken along line 5-5 of FIG. 1 (with the strap removed), the interaction of the latch 36 with the opening 40 can be observed when the tab is fully inserted into the slot 32. Latch 36
5 is fully extended upwardly, whereby the face 48 of the latch will interact with the edge of the opening 40 to prevent removal of the buckle. Upon depressing the latch in the direction of arrow 50, the face of the latch is lowered to align with the opening of the slot
10 32, allowing the buckle to be pulled out of the slot in the direction of arrow 52. The interaction of tab portion 37 with the bottom of the radial band brace at the opening 40 may also be observed in FIG. 5, where the upper face of the tab seats against the lower face
15 of the band brace adjacent of the opening 40. By this, the latch portion does not ride up over the walls of the opening 40, which could jam the latch against removal.

Referring again to FIG. 1 and FIG. 2A, the device
20 includes a radial band bubble assembly, which is slidably movable along an extent of the band, the extent of movement allowed, illustrated by arrow 66, being defined by slots 56, 58 which extend from the top to the underside portion of the band from
25 positions 60 to 62 in the illustrated embodiment. The bubble assembly may be moved to a desired position along the extent provided by the slots. On the inner side of the band, the bubble assembly comprises an inflatable bubble 64, which is in pneumatic
30 communication via tube 65 with a connector 67 that allows an inflation source to be connected to inflate or deflate the bubble. Connector 67 suitably comprises a luer lock. A valve (not shown) may be provided to allow inflation/deflation of the bubble as desired,

while maintaining the state of inflation of the bubble in absence of inflation pressure or deflation suction. In use, inflation/deflation is provided by attachment of a syringe to the connector 67 to allow a desired amount of inflation of the bubble 64. The insertion of the syringe operates the valve to allow inflation or deflation of the bubble. Removing the syringe causes the valve to close, maintaining the desired pressure. Pressure is applied by the inflated bubble in the direction of arrow 158.

Now referring to FIG. 6, an exploded view of the radial band bubble assembly 54, which comprises, in top to bottom vertical order, a top bubble brace 68, a bottom bubble brace 70 and an accordion bubble having top layer 72, middle layers 74, 76 and bottom layer 78. The middle layers have open center portions 80, 82 to allow passage of air when inflating. Top and bottom layers 72, 78 define closed top and bottom seals for the bubble. Bottom bubble brace 70 has a central opening 84 defined in its substantially rectangular profile, and has upwardly extending end members 86, 88 with outwardly extending tab members 90 defined part way up the vertical height of the end members. A central upwardly projecting tab 92 is defined in the end members. Top bubble brace 68 has corresponding slots 94 which receive tabs 92 therein and tab members 96 oriented downwardly on the lower face of the brace, whereby tabs 92 fit into slots 94 and tabs 90 and 96 snap together to secure the top and bottom bubble braces when the device is assembled. Once so assembled, it is intended that the snap together parts remain permanently secured together. The opening 84 provides a viewing window, and has on the patient facing side a slight recess 85 (visible in FIGs. 10

and 11) so that a patient's skin is not pinched when sliding the bubble assembly. The bottom portion 78 of the bubble provides a smooth contact surface with the patient's skin, without any seam lines or ridges, so
5 no irritation or marking of the skin occurs as could happen if a ridge line were present. In the view of FIG. 6, the bubble portions are in positions when the bubble is inflated

FIG. 7 is a partial perspective view of the
10 radial compression band, taken together with FIG. 8, a sectional view along line 8-8 of FIG. 7, to further illustrate the interaction and engagement of the top and bottom bubble braces 68 and 70, with the bubble removed for clarity of illustration. Tab 90 on the
15 bottom brace has an angled surface and tab 96 on the top brace has a similar angled surface, such that when the two brace parts are pushed towards each other in the direction of arrows 98, the two angled surfaces will ride on one another, tabs 96 will move outwardly
20 as a result of flexing of the top brace, allowing the upwardly oriented surface 100 of the top brace to mate with the downwardly oriented surface 102 of the bottom brace, effectively securing the two brace portions together. Upwardly extending end members 86, 88 extend
25 up through slots 56, 58 and tabs 96 extend down through the slots so that the assembled bubble brace can slide along the extent of slots 56 and 58 to allow desired positioning of the bubble when the band is in use. The configuration of the upwardly extending end
30 members 86, 88 and the slots is such that the interaction with the slots prevents binding of the bubble brace if movement pressure is applied at an angle, for example. This is accomplished by the sufficiently long rail-like configuration of the

upwardly extending end members, but can also be accomplished by having a 4 pin system with 2 spaced pins on each side interacting with slots 56 and 58.

Referring to FIG. 9, an exploded view of a
5 partially constructed bubble assembly, and FIG. 10, a sectional view of a fully constructed bubble assembly taken along line 10-10 of FIG. 9, when manufacturing the device, the bubble components 70, 72, 74, 76 and 78 are secured together, by RF welding. First middle
10 layers 74 and 76 are secured to one at joint 104 another along the extents of openings 80, 82. Tube 65 is suitably inserted between layers 72 and 74 and the peripheries of those two layers are secured at joint 106. An extra tab portion 77, 79 can be provided at
15 the edge of layers 72 and 74, to provide additional surface for securing the tube 65 at the point of entry into the bubble. The periphery of bottom layer 78 is secured to the periphery of layer 76 at joint 108, providing an assembled bubble with inflation tube. The
20 dome like upper portion of the top bubble layer 72 is moved into the opening 84 in bottom bubble brace 70 and the bubble is secured thereto at joint 110 along periphery 73. The size of opening 84 is such that the top dome portion of the bubble fits therein.

25 The process of manufacturing the bubble may be understood with reference to FIG. 26, an exploded view of the bubble in the assembly process. The bubble layers are provided in sheets of material, with the bubble shape previously thermoformed in the sheets. In
30 the preferred embodiment, each bubble section is formed to have the same concave shape. Layers 74 and 76 are stacked on each other with the bubbles aligned so as to nest together, and a polytetrafluoroethylene (PTFE) sheet 146, such as a Teflon brand sheet, having

an opening 148 is positioned between the two layers 74 and 76. Thermal welding in the shape of the bubble peripheral outline desired is then performed. Joint 104 is thus formed between layers 74 and 76 and the openings 80, 82 are then formed by die cutting the openings in the welded together layers 74, 76. Next, layer 72 is positioned on top of layer 74, by nesting the bubble shape formation of layer 74 on top of the concave bubble wall of layer 74 and the tube 65 which is connected to luer lock 67, is positioned between layers 72 and 74 so that the end of the tube will be contained within the interior of the bubble space once formed, and the periphery of layers 72 and 74 is welded in the outline of the peripheral shape of the bubble, weld 154, to form joint 106, also securing the tube to the bubble. Layer 78 is positioned below layer 76 by nesting the bubble shape of layer 78 with the bubble shape of layer 76 and joint 108 between layer 76 and 78 may be formed, weld 156, again in the peripheral shape of the ultimate bubble shape desired. The polytetrafluoroethylene (PTFE) sheet 146 is employed to properly accomplish the welding, prevents the peripheries of layers 74 and 76 from being welded together in the process, which would prevent the bubble from properly inflating in use. The PTFE sheet has a slit 150 formed from the hole to the outer edge of the PTFE sheet, so that once the bubbles are fully formed, the PTFE sheet may then be pulled out, the slit allowing the sheet to be removed from around the bubble. While a PTFE sheet is shown in the particular embodiment, other materials can be used for the sheet, such as metal, or any other material that will protect against the unintended welding of the peripheries of layers 74 and 76. While illustrated as discrete units

shaped as the final bubble in the drawings, the bubble layers are typically provided in the manufacturing process pre-formed in sheets of material, and once welded together, the periphery of the bubble is then die cut out of the stack of the 4 layers of sheets to provide a bubble of the desired dimensions. While a single bubble is shown in FIG. 26 for illustration, in production, multiple bubbles may be formed at a time, such as 4 or more bubbles formed spaced apart in a sheet of material, with a corresponding configuration of PTFE sheet having separate openings 148 corresponding to the configuration of the separate bubbles. The PTFE holes 148 where the bubbles are have corresponding slits 150 from the holes to the outer edge of the PTFE sheet. This way the bubbles are fully formed while still in the sheet form, the PTFE is then pulled away, then the multiple bubbles are die cut out of the stack of the 4 layers all at once or in some sequence of cutting operations. Once die cut to a separate bubble, the bubble may then be adhered to bottom bubble brace 70, either by welding or use of adhesive. The bubble layers are nested together so that the uninflated bubble will assume a resting shape with the layers retracted as in FIG. 18, to be substantially pulled away from a patient's skin when deflated. Suitable material to use in forming the bubble includes PVC or Poly Urethane.

Since the tube 65 inserts above the lower bubble face, when inflated, the tube is lifted above the surface of the patient's skin. Alternatively, the tube can pass through the top bubble brace 68, or through slots 56 or 58

FIG. 11 is a sectional view taken along line 11-11 of FIG. 1, illustrating the fully assembled bubble

assembly mounted to the band brace, with the bubble in a fully inflated configuration. Referring to FIG. 18, the configuration of the bubble when deflated can be observed, wherein the various layers of the bubble nest together to allow the bubble to retract within itself, so that the surface of the skin side layer 78 of the bubble is pulled away from the patient's skin and the clot. Also, this configuration assures that no sharp edges are pressing against the patient.

FIGs. 12 and 13 show the bubble (with the band removed for illustration purposes) in a partially inflated mode (FIG. 12) where bubble layer 78 has expanded, but substantially the other layers have not yet expanded outwardly, and a fully inflated mode (FIG. 13). FIG. 18 is a partial perspective sectional view illustrating the bubble in a fully deflated state, wherein the bubble is fully collapsed upward into the opening 84 defined in the bottom bubble brace 70. In this fully deflated mode, the central portion of the bubble is pulled away from the patient's body by the collapsing into the opening 84. The various layers 72, 74, 76 and 78 of the bubble sit together in a nested fashion so as to pull away to greatest extent possible from contact with the patient when deflated.

FIG. 2B, a sectional side view of the radial compression band of FIG. 2A, taken along line 2B-2B of FIG. 1, with the bubble in an deflated state, further illustrates the retraction of the bubble into the opening 84.

FIGs. 14 and 15 demonstrate movement of the bubble assembly along the band brace, where the bubble assembly has moved up along the brace in the direction of arrow 112.

FIG. 16 is a perspective view of the radial band

brace with bubble assembly installed, illustrating an optional radial band pad 114 (also visible in FIG. 2B) that may be installed at an inner portion of the radial band brace to provide added comfort to the patient and stability to the band. The pad may comprise a foam, for example, or a silicone, or more preferably a low durometer TPE, for example with a 3A shore hardness, which provides a jelly like feel and also provides gripping of the patient's arm, without pulling on hair on the arm. The pad 114 assists in providing pressure in the direction of arrow 160 against the patient's arm.

FIG. 17 is a perspective view of the radial band brace with bubble assembly installed, illustrating an optional positioning bubble 116 that may be inflated to assist with positional adjustment on a patient's wrist, which can help in accommodating different wrist sizes and shapes.

Alternative configurations can employ multiple bubbles and a valve or valves to allow selection of which bubbles to inflate, allowing a variety of pressure application choices.

The top bubble brace, bubble layers and the radial band brace (at least in the area the bubble assembly slides over) are suitably made of clear or transparent material to allow unobstructed viewing of the patient's arm through the material. The material can be clear or translucent or even opaque so long as sufficient detail of the site on the patient's arm is visible through the layers to allow accurate positioning. This enables the medical personnel operating the band to precisely position the bubble over the desired spot on the patient's arm to ensure that pressure from the inflated bubble is applied to

the proper location. In the configuration illustrated, only 4 layers of material are required to view through, the top bubble brace 68, the radial band brace 12, the top bubble layer 72 and the bottom bubble layer 78. This number could be reduced by, for example, providing a cut out viewing region in the center of the band brace 12 and/or by providing a cut out viewing region in the top bubble brace 68. The top bubble brace may have an indicator line 69 defined therein, to assist with aligning the bubble over the desired pressure point. Alternatively the indicator line may be on the bubble itself, such as on the bottom layer of the bubble. The medical personnel can use the indicator line to position the bubble over the wound site. The indicator line may be of a specific color, such as green, for example. Alternatively, the bottom bubble portion 78 may have such a line 69' (visible in FIG. 19). Since the various layers are clear or translucent, the line is clearly visible from the top surface of the band when it is positioned on the patient. The bubble layers and band in the bubble region can also be provided with a color if desired.

FIG. 19 is a rear partial view illustrating a manner of securing the bubble assembly in position. In this configuration, a band of serrations 118 is provided on an inner surface of the band 12 and corresponding projections 120 (indicated in FIG. 6) are provided on counterpart surfaces of bottom bubble brace 70, wherein on inflation of the bubble, the interaction with the bubble and the patient's arm will press the projections 120 into engagement with the serrations 118, to cause the bubble to resist against further sliding, so that the position of the bubble is maintained. An alternative way to secure the bubble

without serrations may be understood by reference to FIG. 11, wherein on inflation of the bubble, the upper bubble portion 72 expands such that the upper surface 71 of the bubble portion 72 presses against the inner surface of the central portion 13 of the band 12, and the frictional engagement of the bubble and the band will sufficiently secure the bubble assembly against unintended movement.

In another embodiment, visible in FIG. 20, a view of an alternative bubble assembly that includes a hemostatic gel or coolant, a hemostatic gel 123 may be provided in a receptacle 122 at the bottom bubble layer. A sterile sealing layer 124 may be provided over the gel receptacle, which is then removed just prior to placing the band on the patient, whereby the gel can be dispensed through openings 126 by pressure provided by the inflating bubble exerted on the rear of the receptacle 122.

In still another embodiment, receptacle 122 can contain a cooling element to provide cooling to help retract the artery. The device may then be stored in a refrigerator/freezer prior to use. A combination of cooling element and hemostatic gel may be provided.

FIG. 27A-D illustrates a manner of removing layer 124, wherein the layer 124 initially covers the gel 123, and comprises a folded over portion, and is pulled from end 121 in the direction of arrow 125 (FIG. 27A). The end of the layer 124 distal from the pulled portion rolls over and begins to peel away from the gel. As the layer is further pulled (FIGs. 27B and 27C), more of the gel is exposed until finally (FIG. 27D), the layer 124 is completely pulled away, exposing the gel fully.

Referring to FIG. 28, a perspective view of a

dual radial and ulnar compression band in accordance with the disclosure, and FIG. 29, a side view of the dual radial and ulnar compression band of FIG. 28, the radial/ulnar band assembly 10' corresponds somewhat to the construction and operation of the radial band device described above and comprises many corresponding features, including a band brace 12' that is approximately U-shaped and having a width 14', which is adapted to fit over a patient's wrist where the wrist is received in the open central portion of the radial band brace. The band brace is slightly loaded so that the 'legs' of the U-shape are not exactly parallel to one another. In a particular embodiment, the band brace can be produced in different sizes, to accommodate different sized patient wrists. As with the radial band discussed above, the band is suitably clear such that it is easily seen through, and may comprise of clear ABS, for example. The band can be provided with a color if desired. Acrylic may be used if rigidity is not an issue. The different sizes can be provided with slight color tints, each size being given a different color, to allow quick identification of which size the band is. The band is substantially rigid, with some amount of flexibility such that when the strap is tightened, the U-shaped legs will move towards each other somewhat to take up slack in the fit on the patient's wrist. Examples of suitable material to use in construction of the band includes PVC, ABS, Poly Urethane, or a blend thereof.

A strap assembly 20' connects to the ends of the band brace, suitably by means of upper and lower buckles 22' and 24', which removably connect to the band brace at the 'ends' of the U-shape of the band

brace. A strap member 26' is received by the buckles, substantially permanently yet flexibly attached at one of the buckles, lower buckle 24', for example, and removably looped through upper buckle 22'. Hook and
5 loop fasteners 28' are provided on the strap member to allow adjustment tightening of the tension on the strap and then securing the strap with the desired tension, allowing the band to be removably secured to the patient's wrist. A band pad 114' may be installed
10 at an inner portion of the radial band brace to provide added comfort to the patient and stability to the band and to assist in providing pressure against the patient's arm.

The device 10' includes a radial band bubble
15 assembly 64' and an ulnar band bubble assembly 170, the bubble assemblies being slidably movable along an extent of the band, being defined by slots which extend from the top to the underside portion of the band from positions in the illustrated embodiment. The
20 bubble assemblies may be moved to desired positions along the extent provided by the slots, suitably to be positioned over the radial and ulnar arteries, or puncture sites made to access these arteries. On the inner side of the band, the bubble assemblies
25 comprises inflatable bubbles 64' and 170, being of corresponding construction to the bubble 64 described above. The bubbles are in pneumatic communication via tubes 65' and 172 with connectors 67 and 174 that
30 allows an inflation source to be connected to inflate or deflate the respective bubbles. Connectors 67' and 174 suitably comprise luer locks. Valves (not shown) may be provided to allow inflation/deflation of the bubbles as desired, while maintaining the state of inflation of the bubbles in absence of inflation

pressure or deflation suction. In use, inflation/deflation is provided by attachment of a syringe to the connectors 67' and/or 174 to allow a desired amount of inflation of the bubble 64' or 170.

5 The insertion of the syringe operates the valve to allow inflation or deflation of the bubbles. Removing the syringe causes the valve to close, maintaining the desired pressure. The bubbles may be configured to be inflated separately as in the illustrations, or
10 inflated together, as desired.

The shape of the bubble portion that directly contact's the patient's arm for either the single or dual bubble versions may be modified for different pressure application profiles. Considering FIGs. 21-
15 25, which are side views of single bubble bands without the strap installed, the bubbles can have, for example, a square profile bubble 126 (FIG. 21) for a more flat contact surface 128, a triangular profile bubble 130 providing a narrower contact surface 132
20 (FIG. 22), a modified square profile 134 with one side longer to provide a wider contact region 136 (FIG. 23), a curved side profile 138 providing a wider more curved contact profile 140 (FIG. 24), and a curved edge rectangular shape 142 providing yet another
25 curved contact surface profile 144. Other shapes may of course be employed to provide desired contact pressure profiles against the patient's arm. The various shapes of the bubbles allow targeted application of pressure to the wrist site along an
30 axis of the bubble, and can be line, oval, rectangular or other shape pressure application profiles, depending on the bubble configuration.

Bubbles having greater length along the direction of the arm's length can be provided for use in

applications where a longer incision has been made in the patient, so that pressure is applied over a greater length.

In use of the device, the band portion is slid
5 over the patient's wrist and the strap portions are snapped in place. The bubble or bubbles are approximately positioned over the insertion site(s) of the catheter(s), and the strap is tightened. A syringe is attached to the luer lock of one of the bubbles (or
10 a pair of syringes may be used in the dual bubble version, or the dual bubbles may be connected to use the same inflation source simultaneously). The bubble assembly (or assemblies) is slid to be in an optimal position, with use of the optional guide mark if
15 desired, and the bubble is inflated, locking the slide against unintended movement. The locking can be accomplished by inflation of the bubble causing a portion of the bubble to press against the brace. The individual catheter is removed. If bleeding starts
20 immediately, the bubble is inflated further. If no bleeding is observed, pressure is released until just the point that bleeding starts, whereupon 2 cc of air (or other fluid) are added, the syringe is removed from the luer lock, and after 30-60 minutes, as
25 determined by the medical personnel, then 2 cc are removed from the bubble every 5 minutes. Once it is determined that hemostatis has been achieved, the bubble is deflated and slid away from the site. The sideward movement of the bubble reduces the chance of
30 tearing the clotted seal on the artery away as opposed to pulling directly upwardly as with prior art solutions.

The disclosed band has numerous benefits over prior solutions. The attachment of the band to the arm

is separate from final positioning of the bubble over the site. The slidable bubble assembly allows precise positioning of the bubble for maximum effect. The bubble is typically smaller than prior art devices, and can provide a pinpoint focus of pressure. The pressure applied by the inflated bubble pushes off axis, as indicated by arrow 158 in FIG. 2A, pushing the artery directly into the patient's bone, not merely pushing the artery in a direction that might not be normal to the bone, which would be less effective. The angle at which the pressure is applied can be varied in accordance with the disclosure. The number of surfaces through which the site is viewed is reduced over prior solutions. When deflated, the bubble retracts into itself and forms a concavity relative to the skin to keep the bubble away from contact with the skin. Unlike prior devices, the band and bubble location will not substantially rotate when the bubble is inflated. The device is easily put onto a patient's wrist by sliding the band onto the wrist from the side, then the strap may be clipped in and tightened to secure the band on the patient. The patient's wrist need not be lifted to install the band. While traditional devices tend to constrict the patient's entire wrist, almost acting like a tourniquet, the relatively rigid material of the band of the present device instead acts as a hinge, keeping pressure from being applied to the entire wrist, allowing specific pressure application where needed by the bubble, which mimics pressure applied by a finger by medical personnel, as is done when no radial band is available. The bubble in the illustrated configurations is suitably inflatable to 10 psi, which is more than sufficient. While the illustrated

inflation medium is air, fluid or other gases may be employed to inflate the bubble. The bubble can be provided with a slow rate leak, such that it will slowly deflated over time on its own without
5 intervention, so that after a sufficient time to allow hemostasis, the bubble pressure is released. The skin contact surface of the bubble can be provided with a medication or other substance to assist with the function.

10 The illustrated application of the device is with radial/ulnar artery procedures, but other uses are possible, such as with stopping bleeding in dialysis procedures, for example.

While plural preferred embodiments of the
15 technology have been shown and described, it will be apparent to those skilled in the art that many changes and modifications may be made without departing from the broader aspects. The appended claims are therefore intended to cover all such changes and modifications
20 as fall within the true spirit and scope of the technology.

25

30

Claims

What is claimed is:

1. A hemostasis device, comprising:
5 an attachment device for securing the hemostasis
device to a patient; and
 a positionable pressure application device for
positioning over a site independent of securing of the
attachment device.
10
2. The hemostasis device according to claim 1,
wherein said attachment device comprises a band
adapted to be secured to the patient's wrist.
- 15 3. The hemostasis device according to claim 2
wherein said attachment device is substantially rigid.
4. The hemostasis device according to claim 2
wherein said attachment device comprises a band that
20 is substantially rigid to maintain a pressure applied
to the patient's wrist.
5. The hemostasis device according to claim 1,
wherein said positionable pressure application device
25 comprises an inflatable member adapted to press
against the patient when inflated.
6. The hemostasis device according to claim 5
wherein said pressure member includes a substantially
30 clear viewing portion for enabling viewing of the
position on the patient where said inflatable member
presses when inflated.
7. The hemostasis device according to claim 1

wherein said positionable pressure application device slides along a portion of the attachment device for positioning thereof.

5 8. The hemostasis device according to claim 5 wherein said inflatable member collapses to retract away from the patient when deflated.

10 9. The hemostasis device according to claim 1, said pressure application device further comprising a receptacle for holding a substance wherein the substance is dispensed to the patient by pressure provided by the pressure application device.

15 10. The hemostasis device according to claim 9, wherein said substance comprises a hemostatic substance.

20 11. The hemostasis device according to claim 9, wherein said receptacle comprises a removable sterile sealing layer.

25 12. The hemostasis device according to claim 1, wherein the positionable pressure application device comprises a first and a second pressure application device.

30 13. The hemostasis device according to claim 12, wherein the first and a second pressure application devices are for pressing against a radial and an ulnar puncture site respectively.

 14. A method of forming a hemostasis pressure bubble, comprising:

nesting 4 bubble layers together; and
sealing the bubble layers together to form an air
tight bubble member.

5 15. The method according to claim 14, wherein a
central portion of the 2 center most layers of said
nested bubble layers comprise an opening and said
sealing comprises sealing together the inner
peripheries of the openings of said 2 center layers.

10

 16. The method according to claim 15, comprising
after sealing the inner peripheries, sealing together
the outer peripheries of the 2 top most layers and
sealing together the outer peripheries of the two
15 bottom most layers.

 17. The method according to claim 16, comprising
providing a protection layer between the two center
layers to prevent sealing of the peripheries of the
20 two center layers to one another when said steps of
sealing the outer peripheries of the 2 top most and 2
bottom most layer is performed.

 18. The method according to 16 comprising sealing
25 an inflation tube to the bubble member to allow
inflation and deflation thereof.

 19. The method according to claim 14 wherein said
bubble layers have a concave form and the nesting
30 comprises nesting said concavities together in the
same orientation.

 20. A hemostasis wrist band comprising:
a wrist engaging portion adapted for placement on

a patient's wrist; and

a positionable pressure bubble member adapted to slide along a portion of the wrist engaging portion for positioning of the pressure bubble member over a
5 desired pressure application location.

21. The hemostasis wrist band according to claim 20, wherein said pressure bubble member has a viewing portion that is substantially clear to enable viewing
10 of a pressure application site through the pressure bubble member.

22. The hemostasis wrist band according to claim 20, wherein said wrist engaging portion is
15 substantially rigid.

23. The hemostasis wrist band according to claim 20 further comprising a locking device for substantially locking said positionable pressure
20 bubble in location when positioned to a desired location.

24. The hemostasis wrist band according to claim 20, further comprising an inflation member for
25 allowing inflation/deflation of the pressure bubble.

25. The hemostasis wrist band according to claim 24 wherein said inflation member comprises a leur lock attachment for connection to a pressure source.

30

26. The hemostasis wrist band according to claim 20, wherein said pressure bubble further comprising a receptacle for holding a substance wherein the substance is dispensed to the patient by pressure

provided by the pressure bubble.

27. The hemostasis wrist band according to claim
26, wherein said substance comprises a hemostatic
5 substance.

28. The hemostasis wrist band according to claim
26, wherein said receptacle comprises a removable
sterile sealing layer for sealing the receptacle
10 against contamination until use.

29. The hemostasis wrist band according to claim
20, further comprising a second positionable pressure
bubble member adapted to slide along a portion of the
15 wrist engaging portion for positioning of the second
pressure bubble member over a second desired pressure
application location.

20

25

30

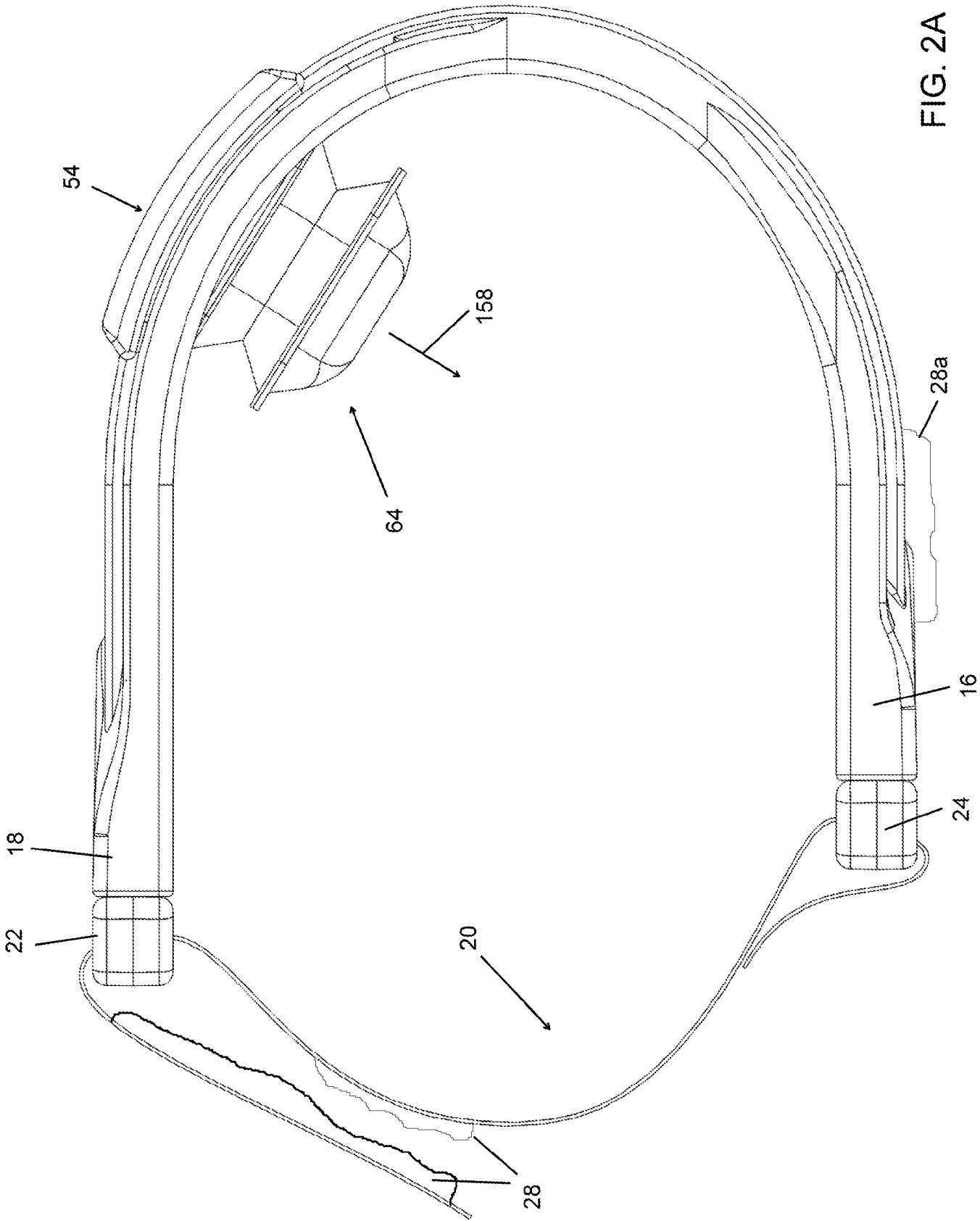


FIG. 2A

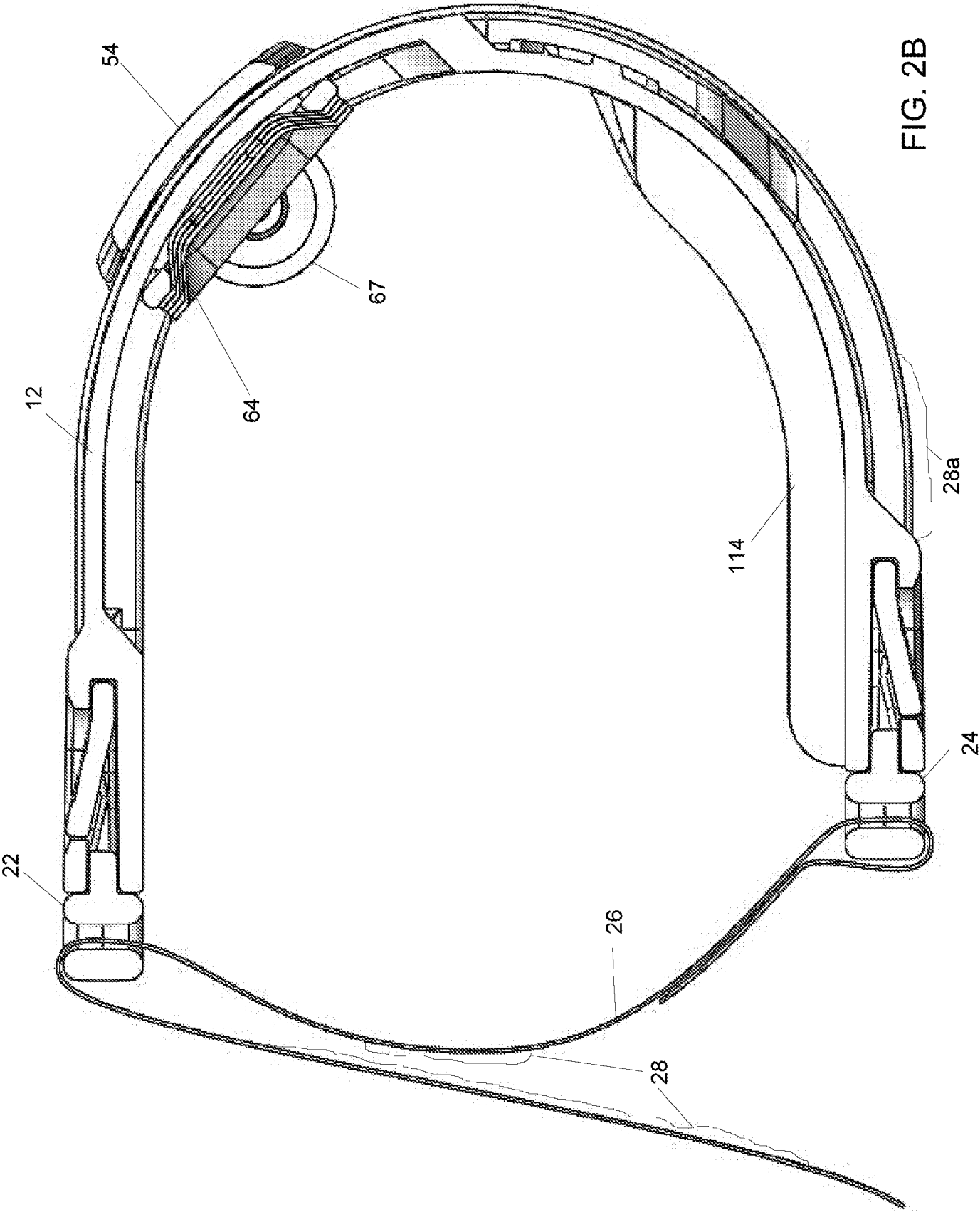


FIG. 2B

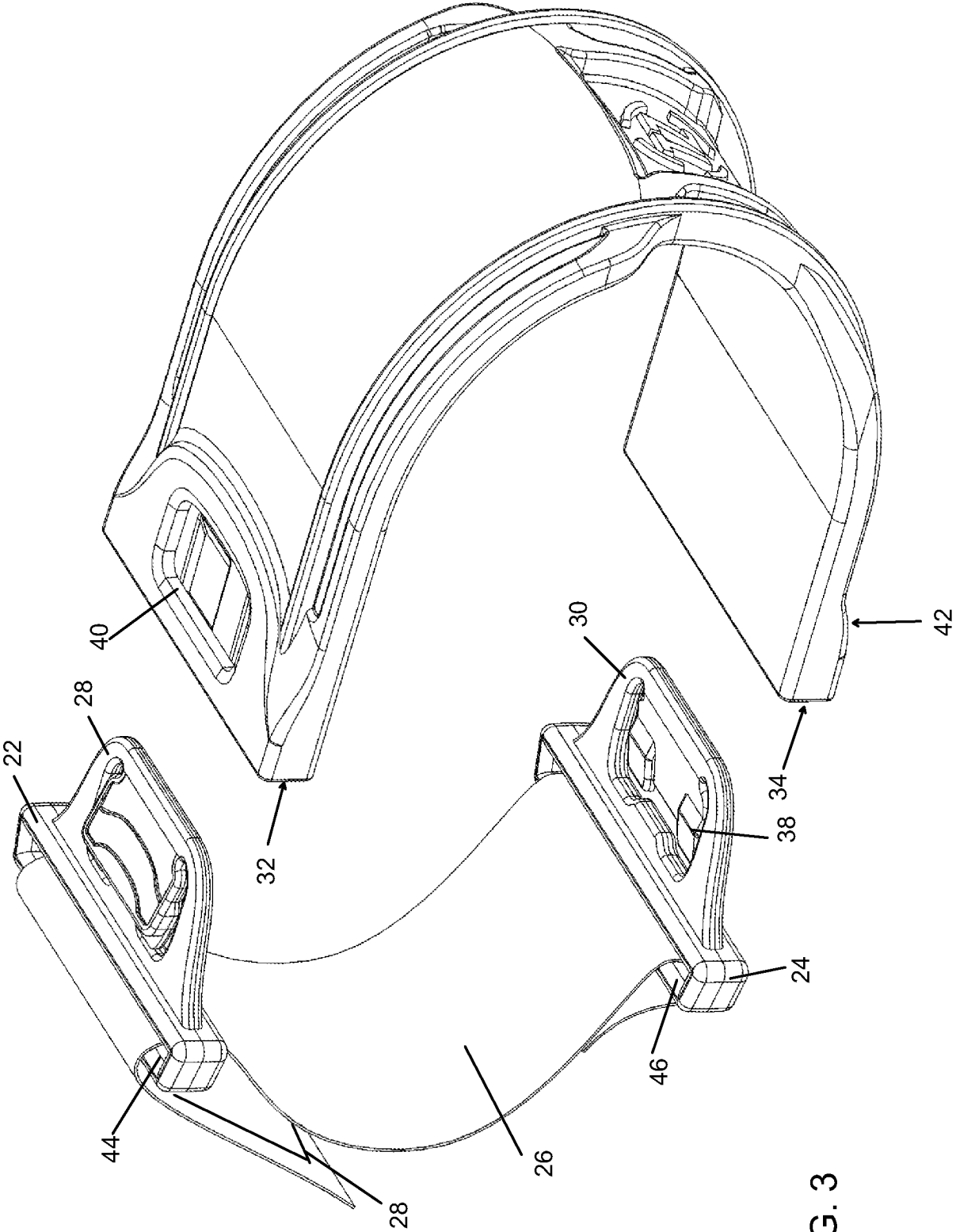


FIG. 3

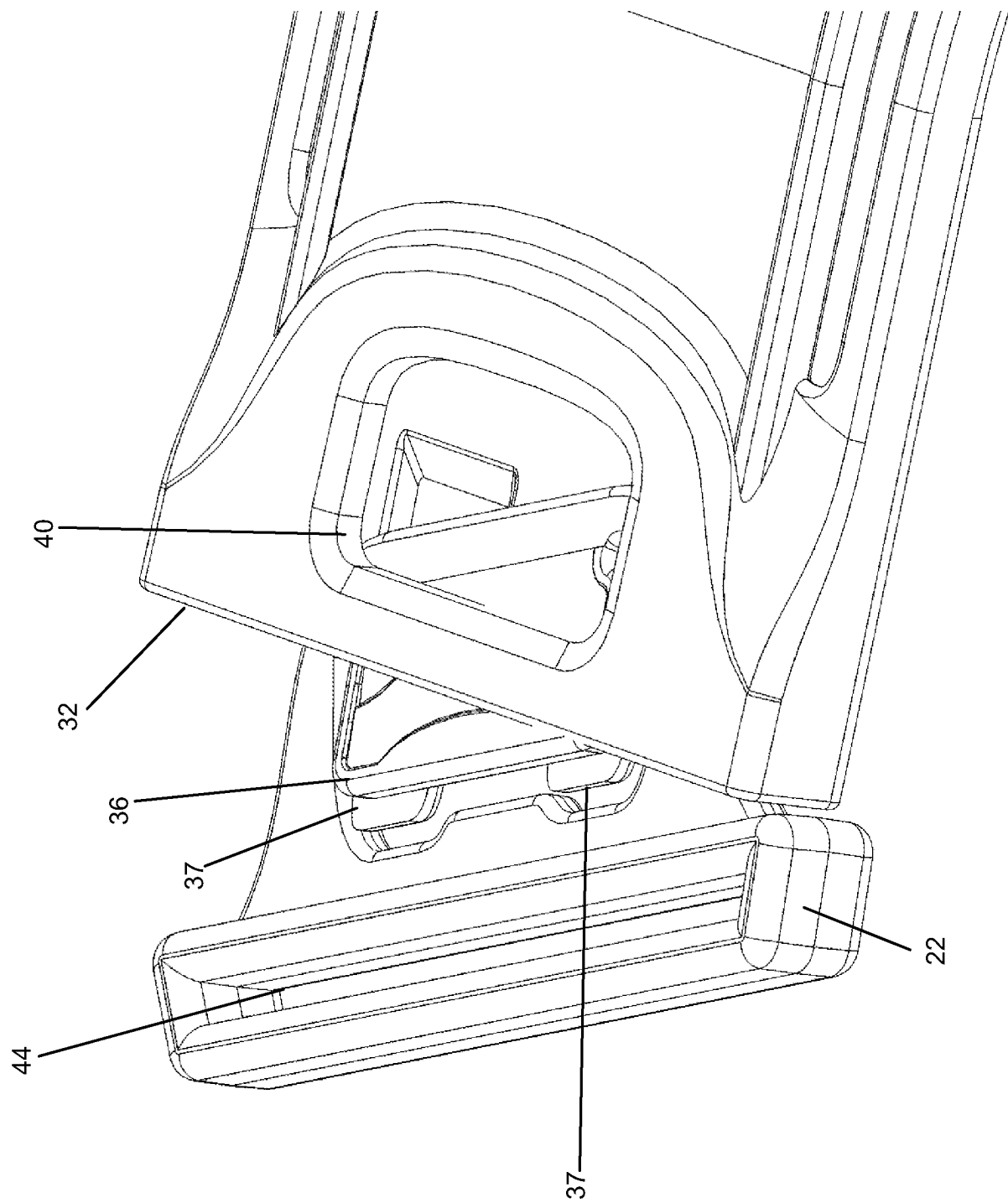


FIG. 4

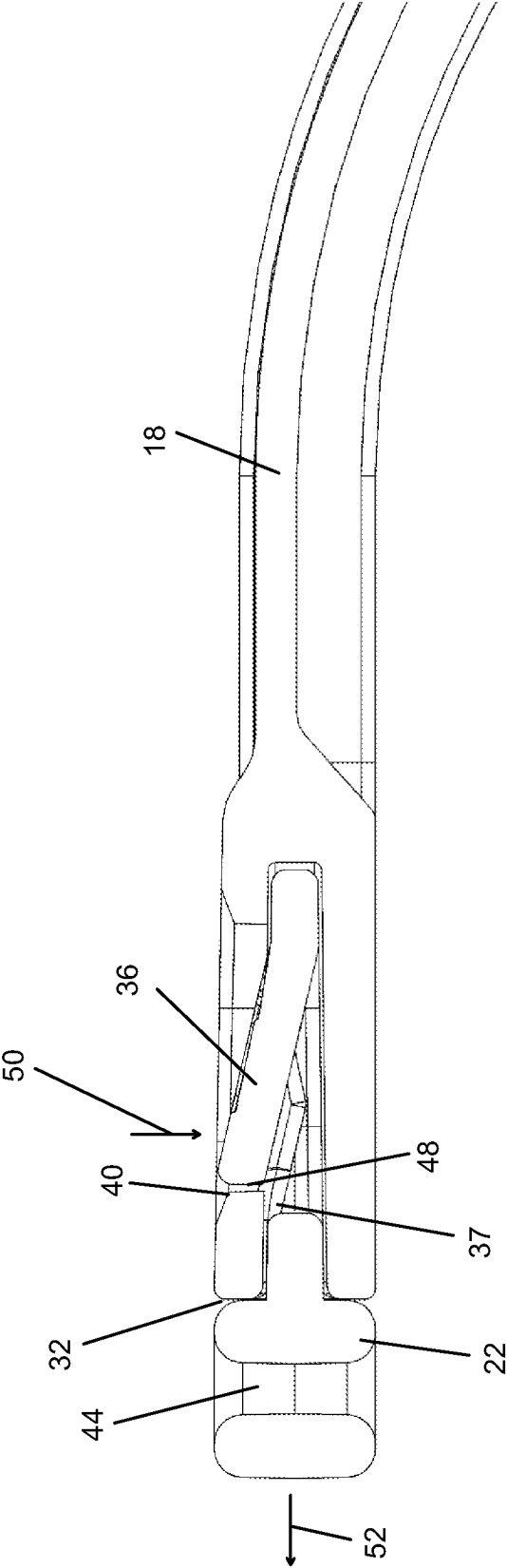


FIG. 5

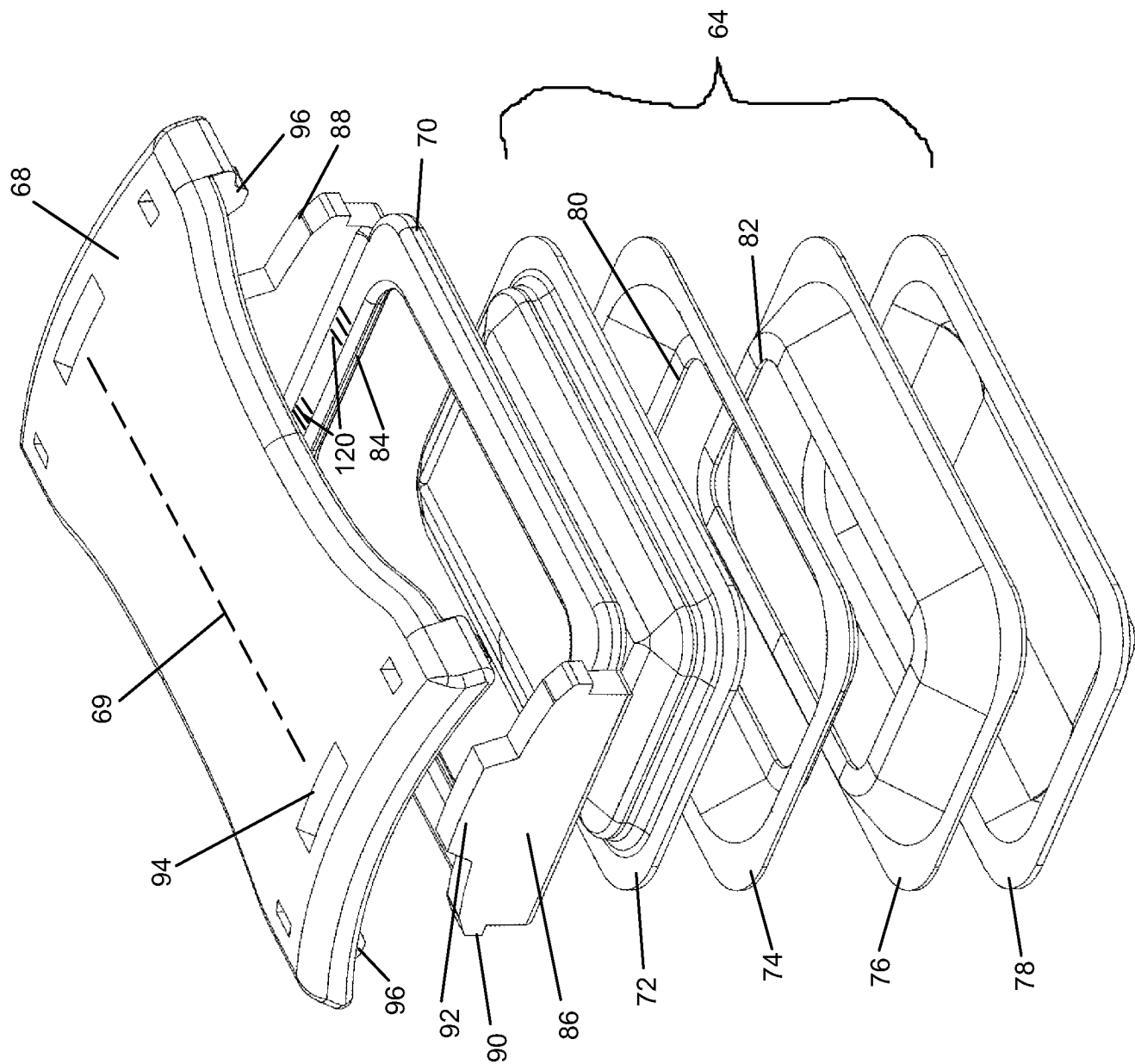


FIG. 6

FIG. 7

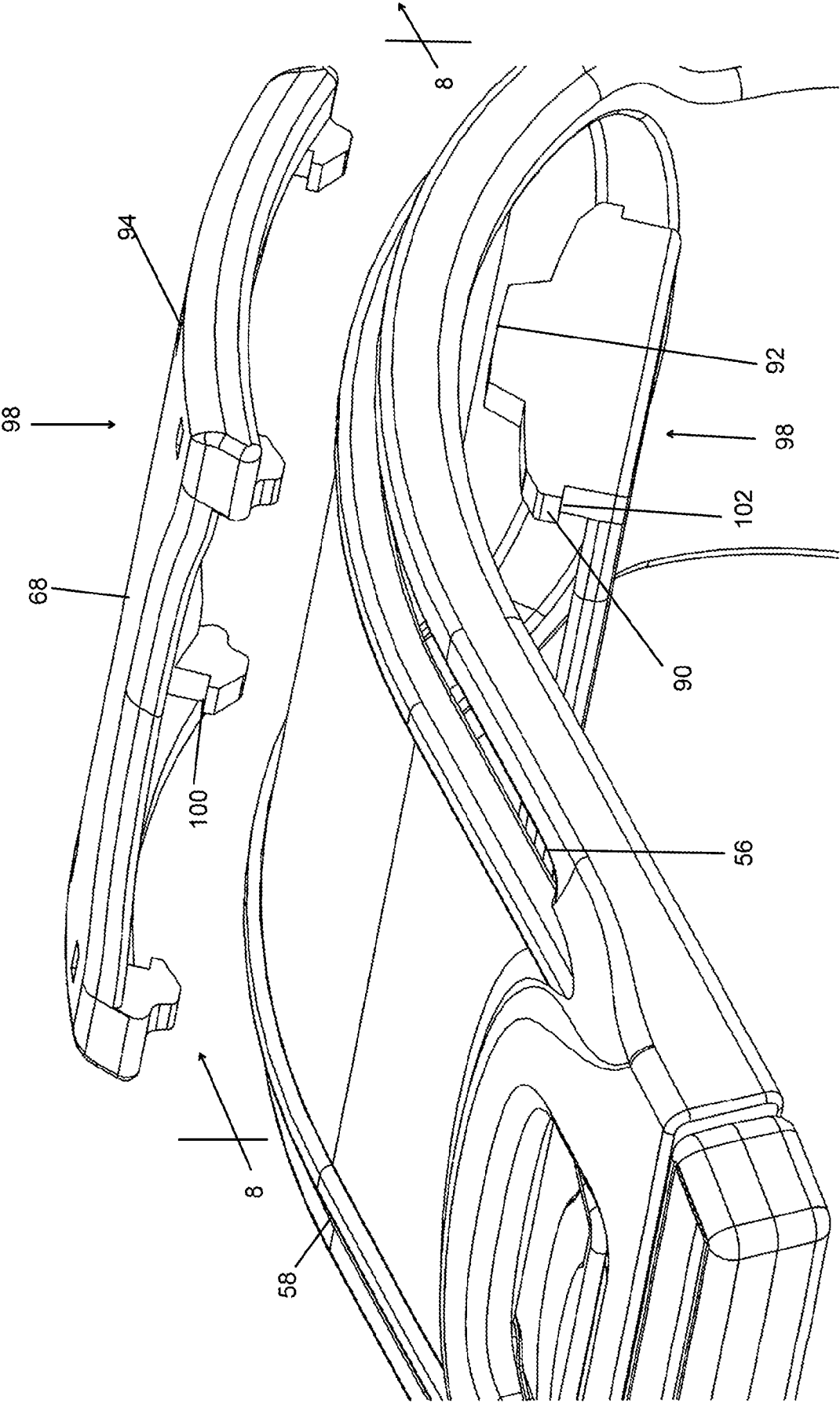


FIG. 8

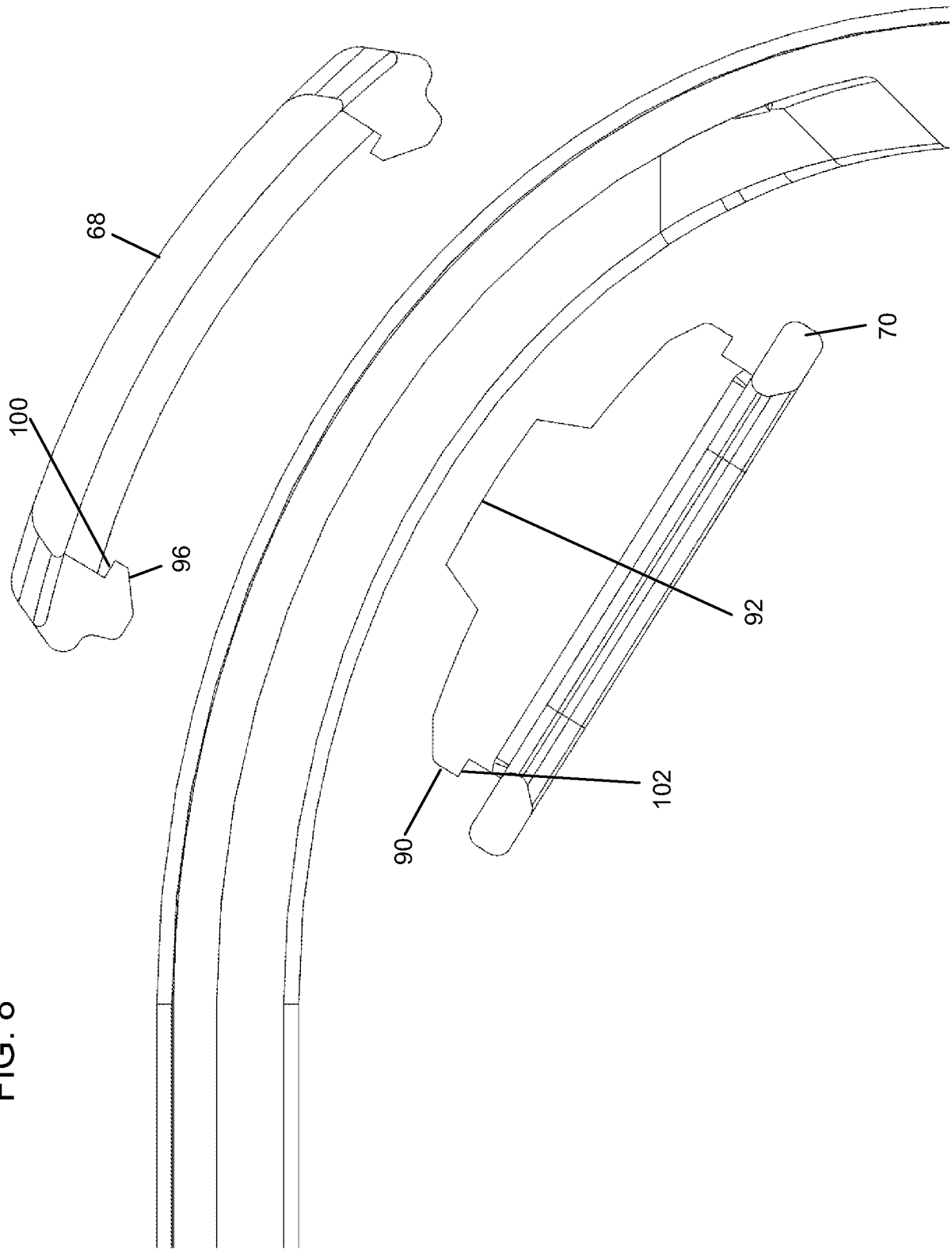
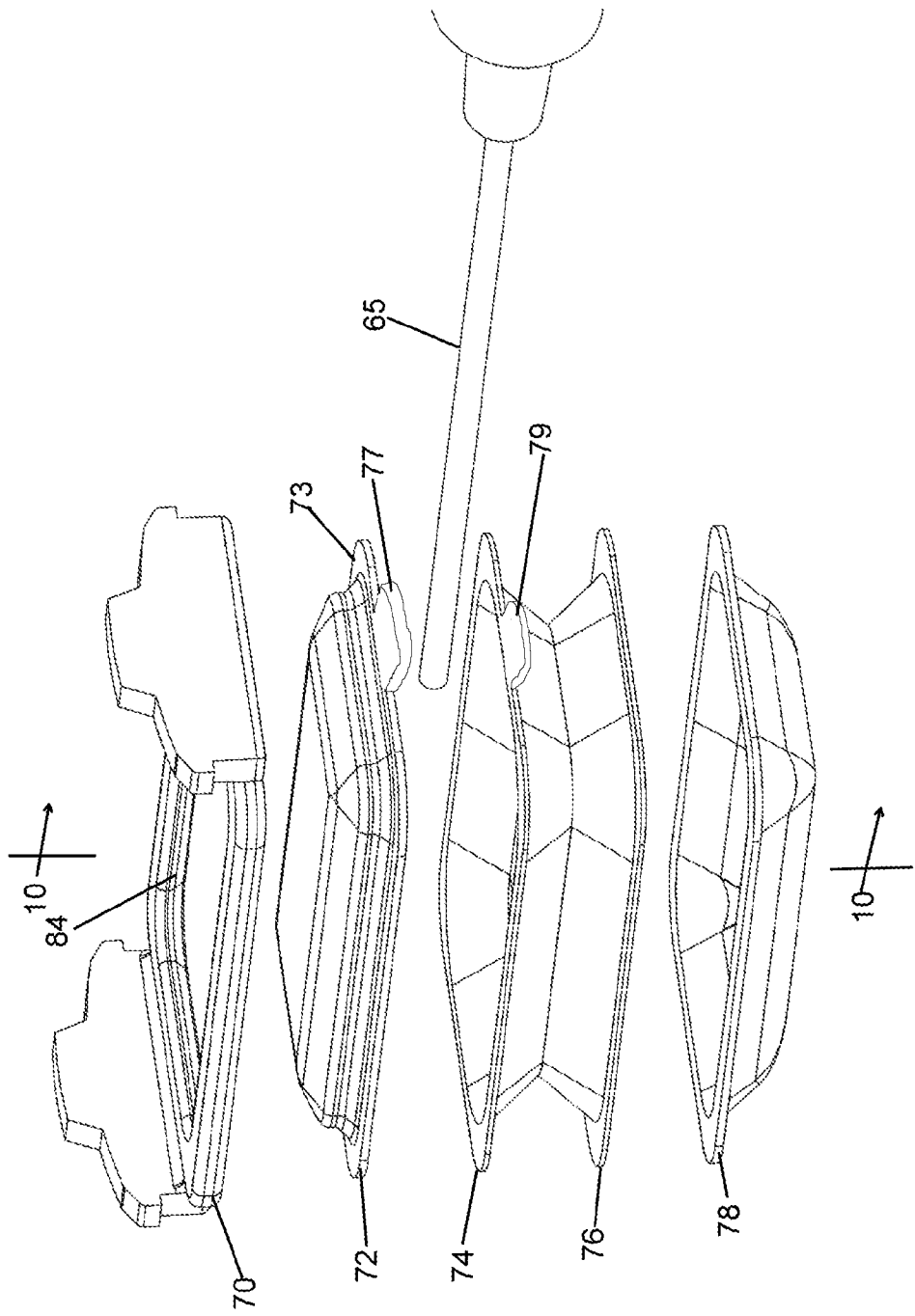


FIG. 9



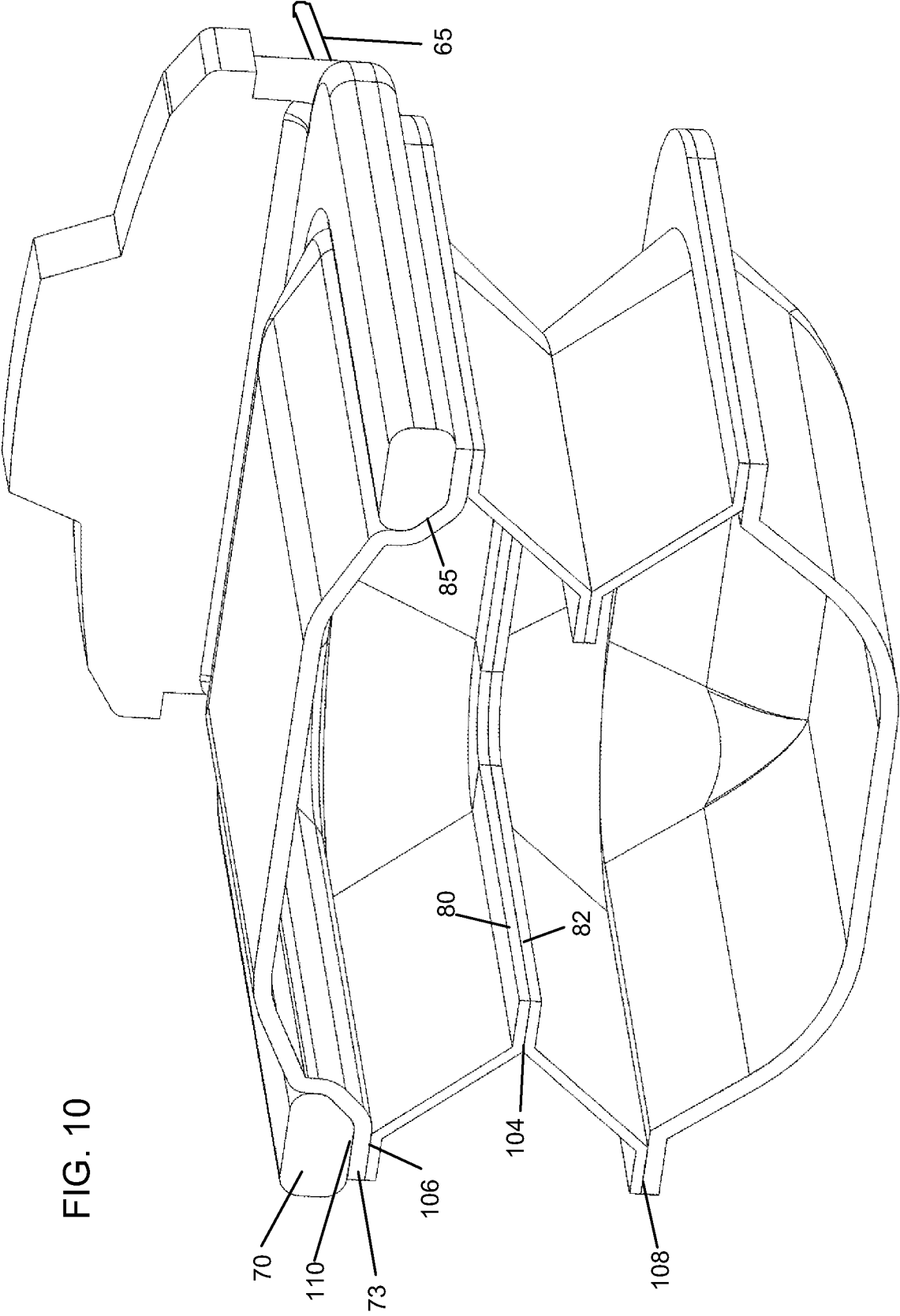
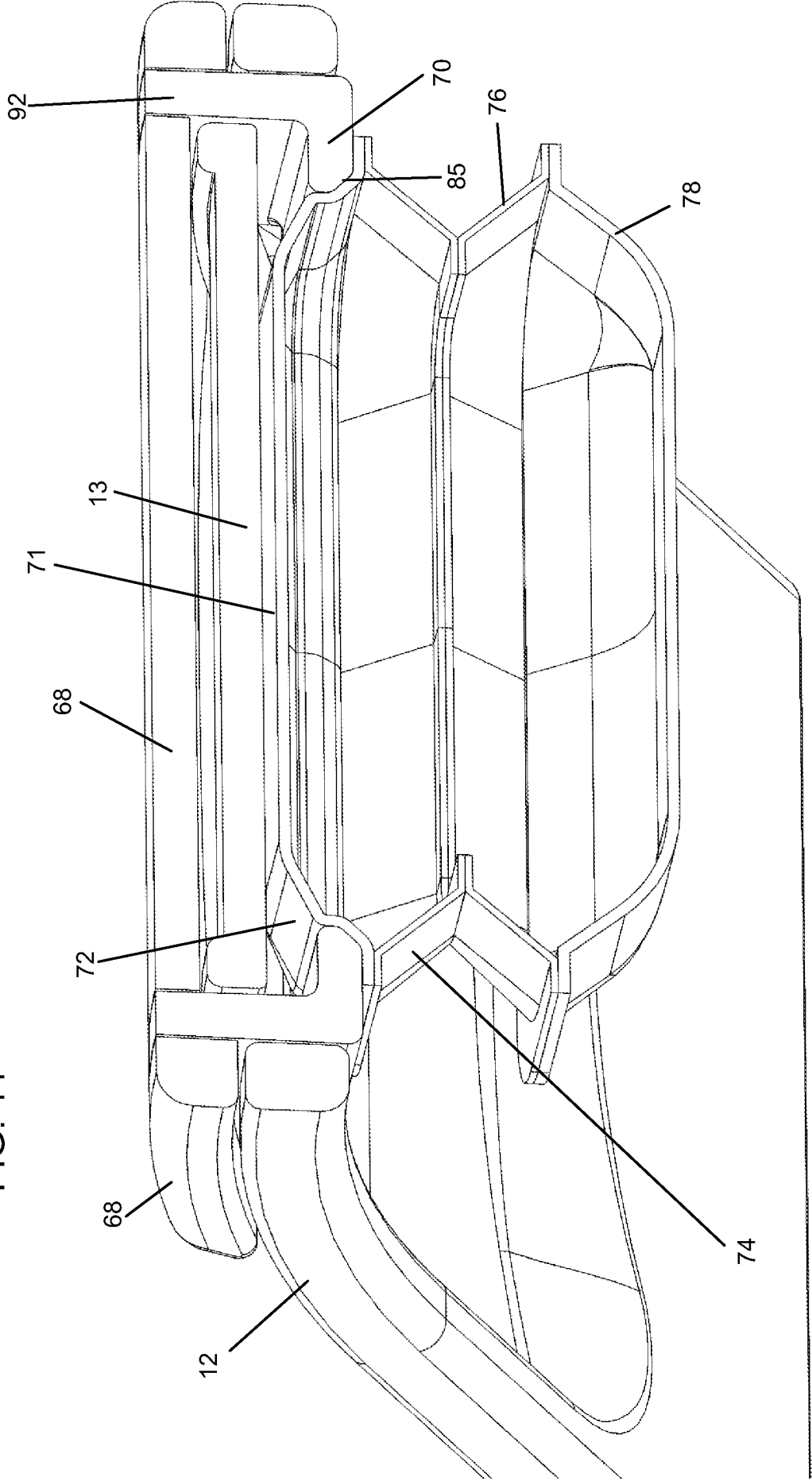


FIG. 11



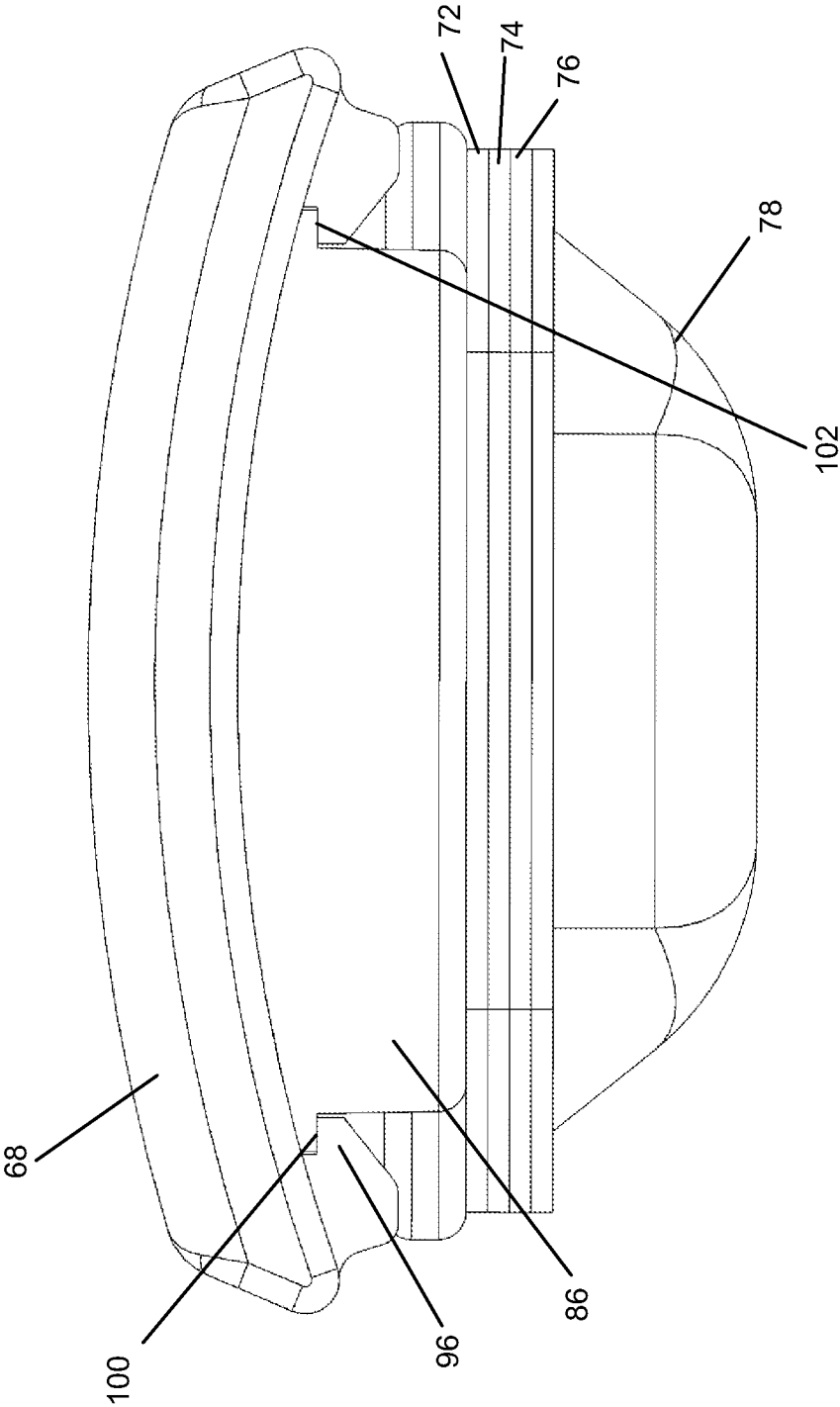
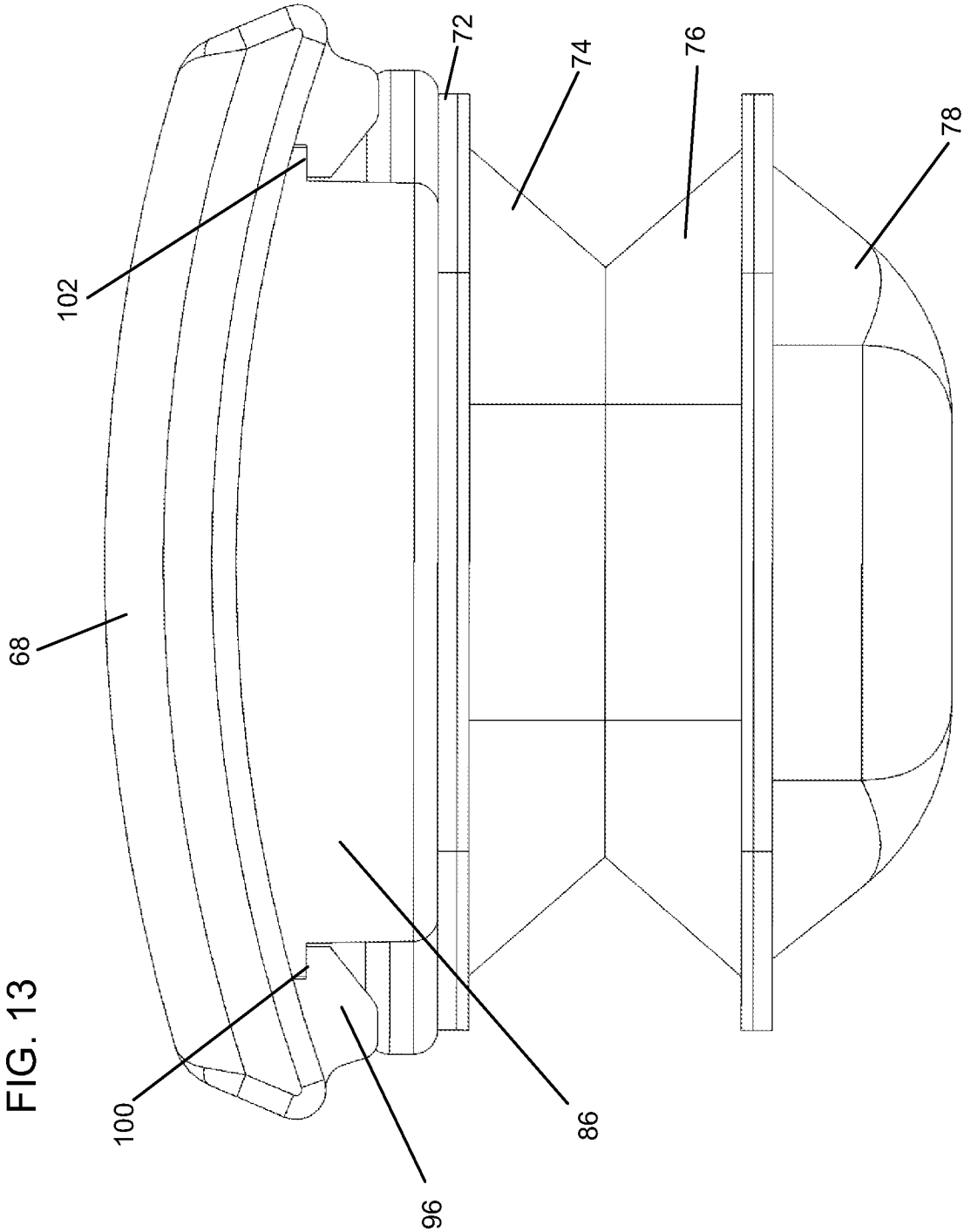


FIG. 12



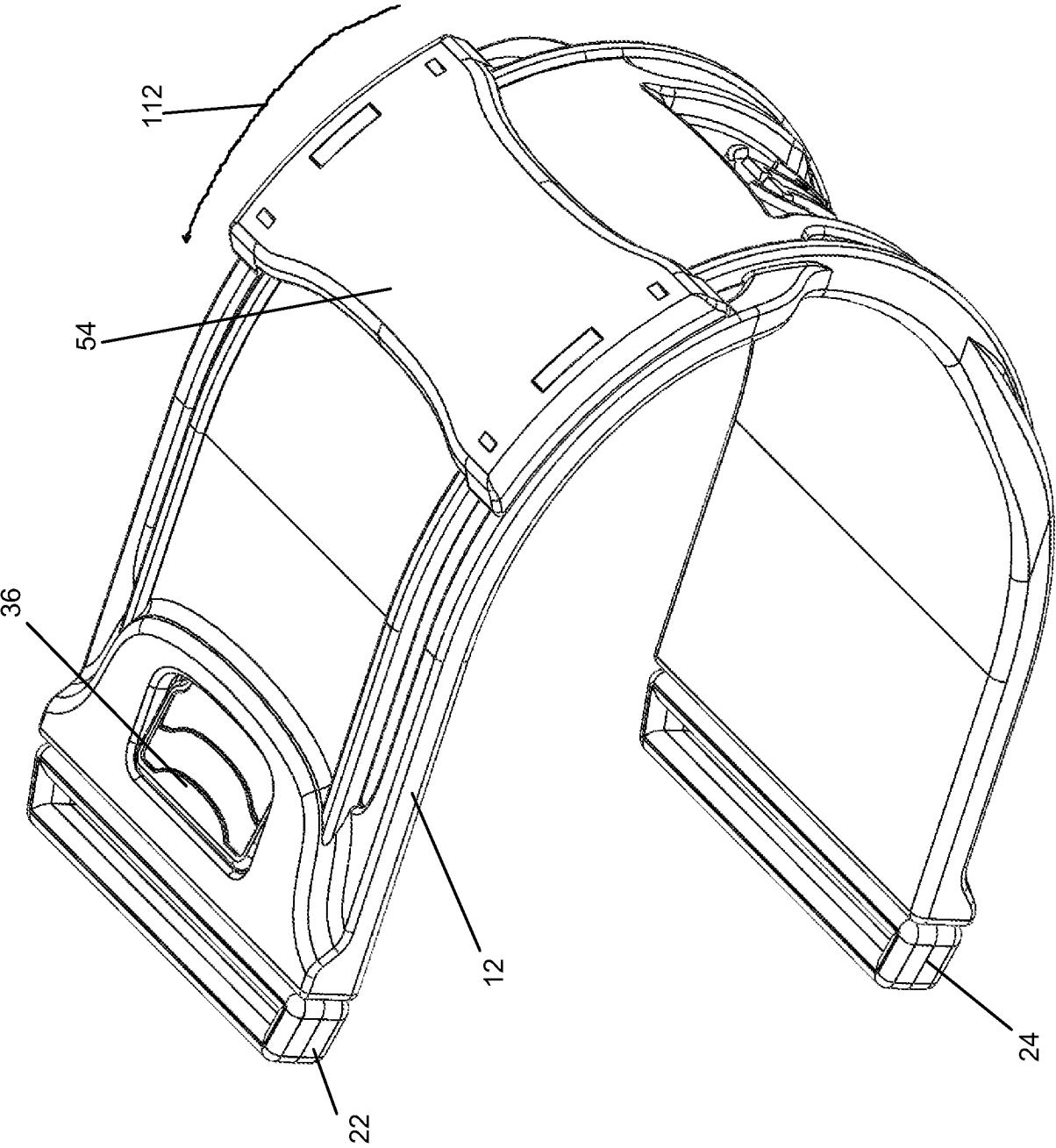


FIG. 14

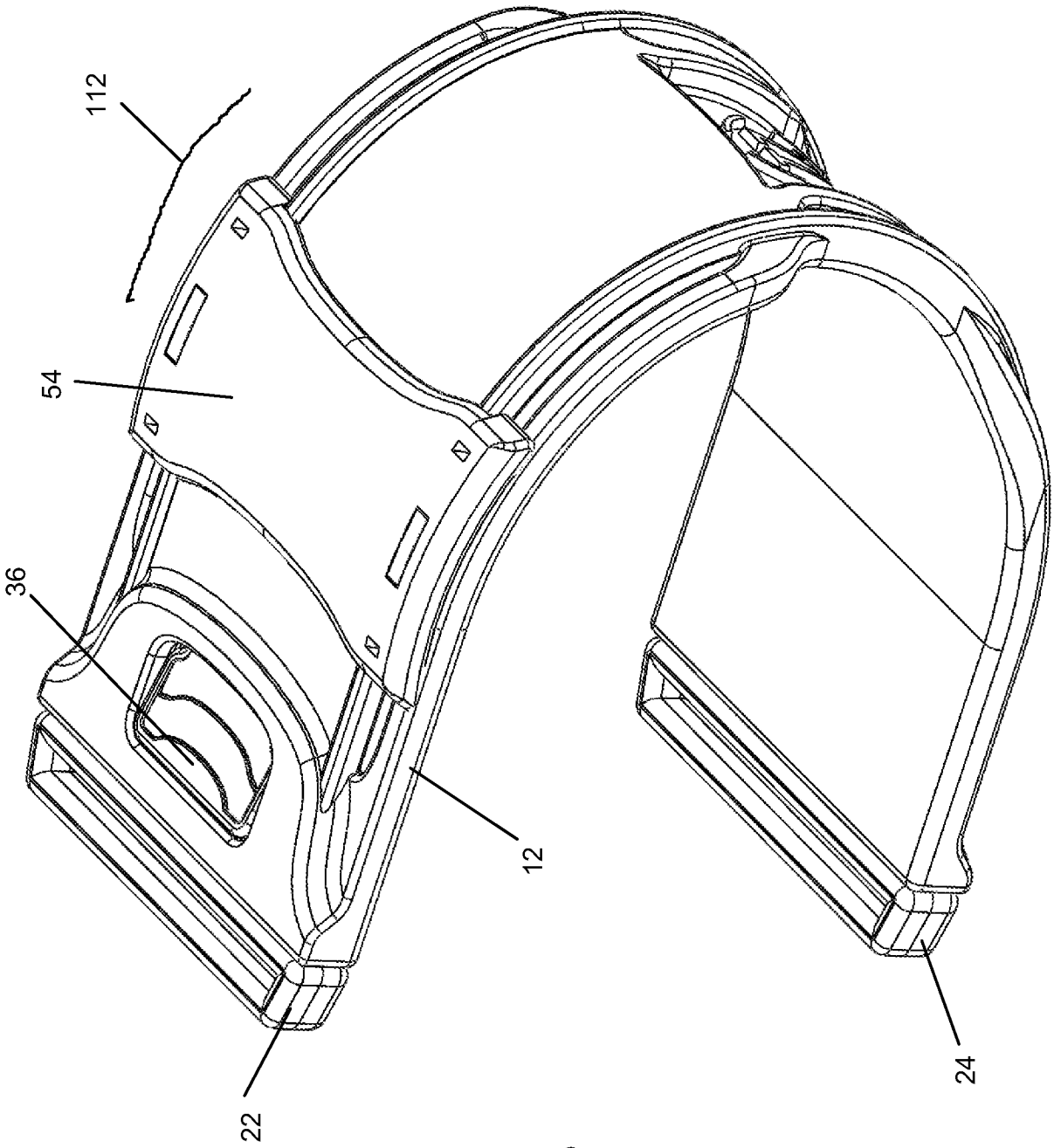


FIG. 15

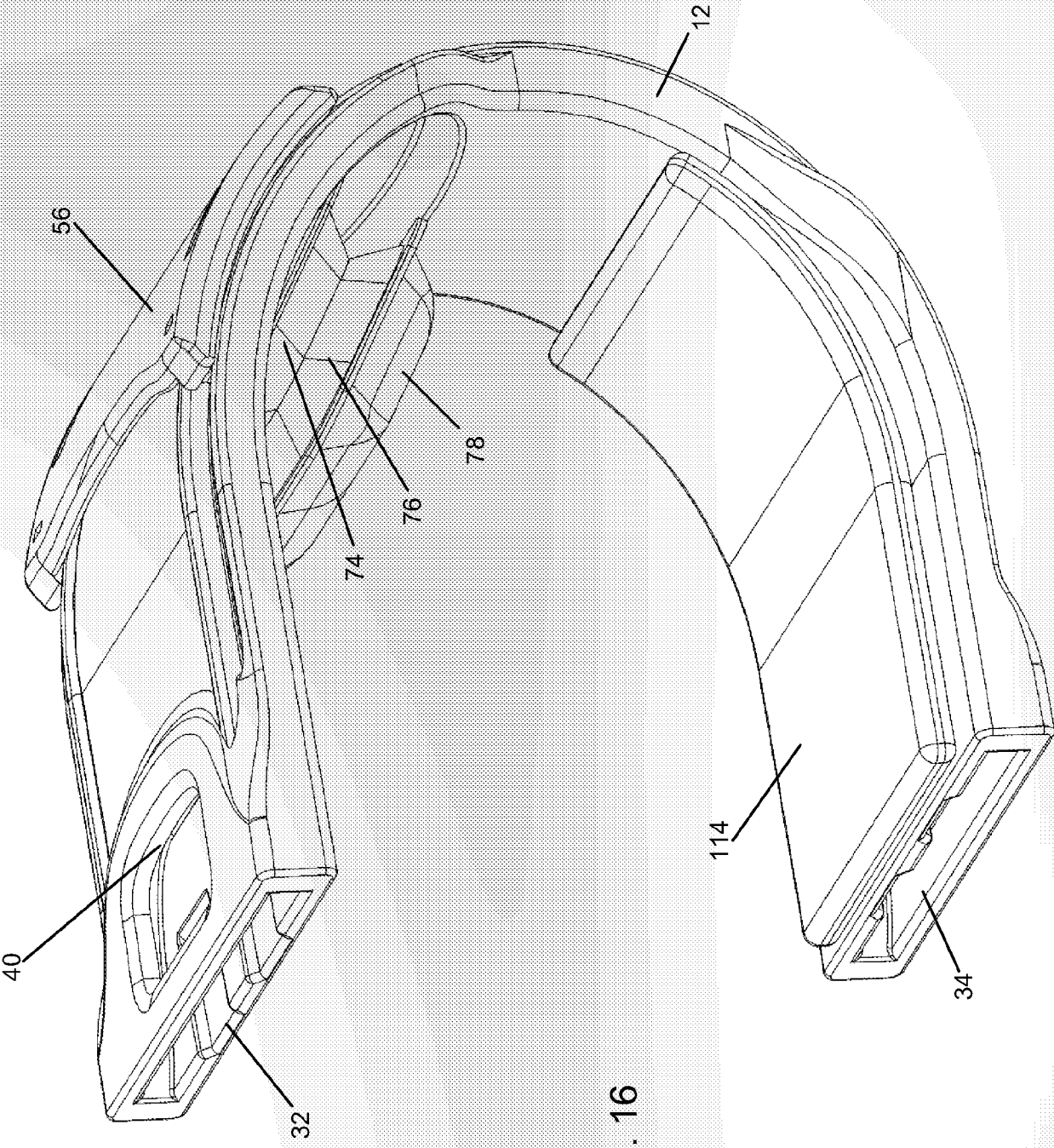


FIG. 16

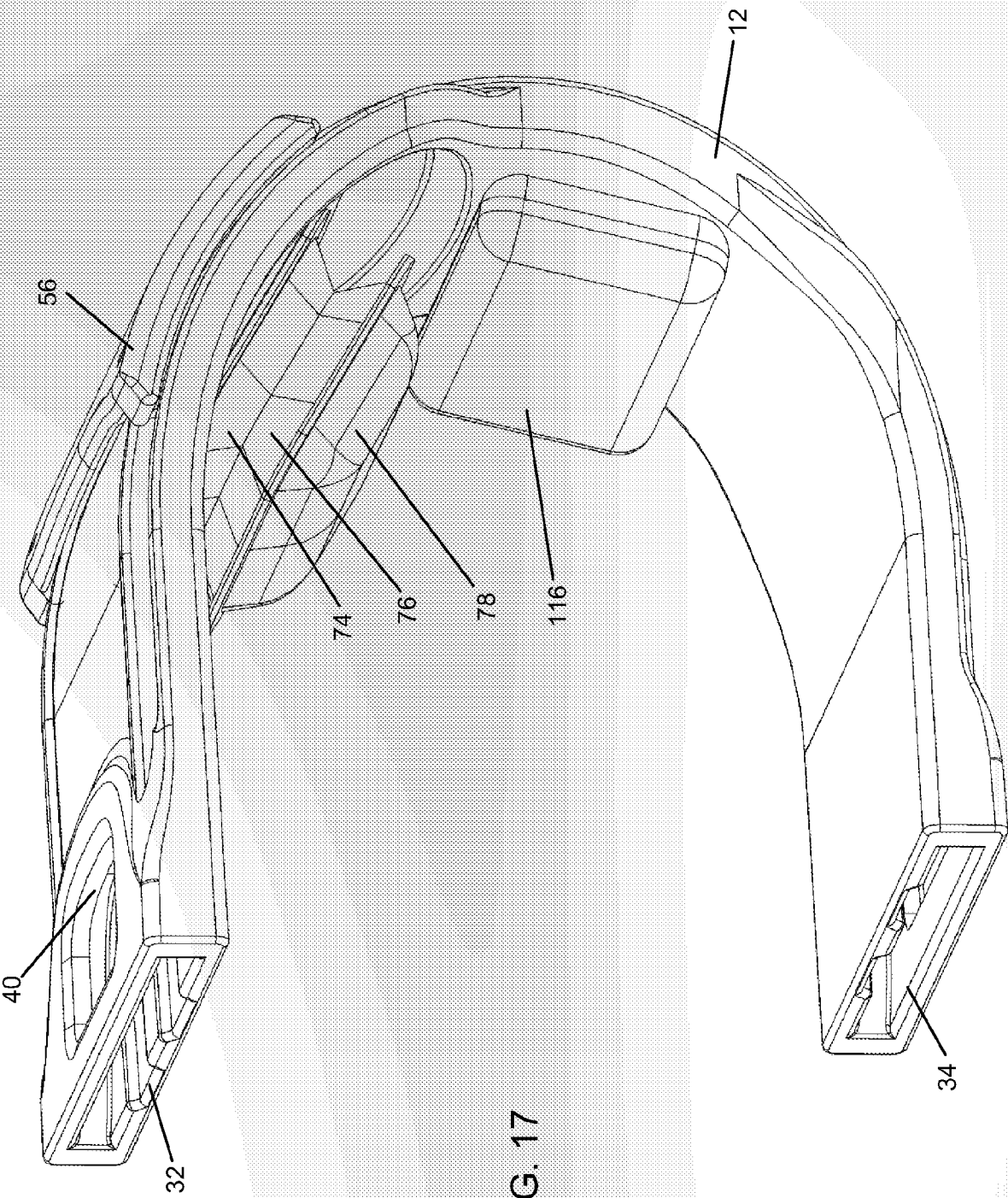


FIG. 17

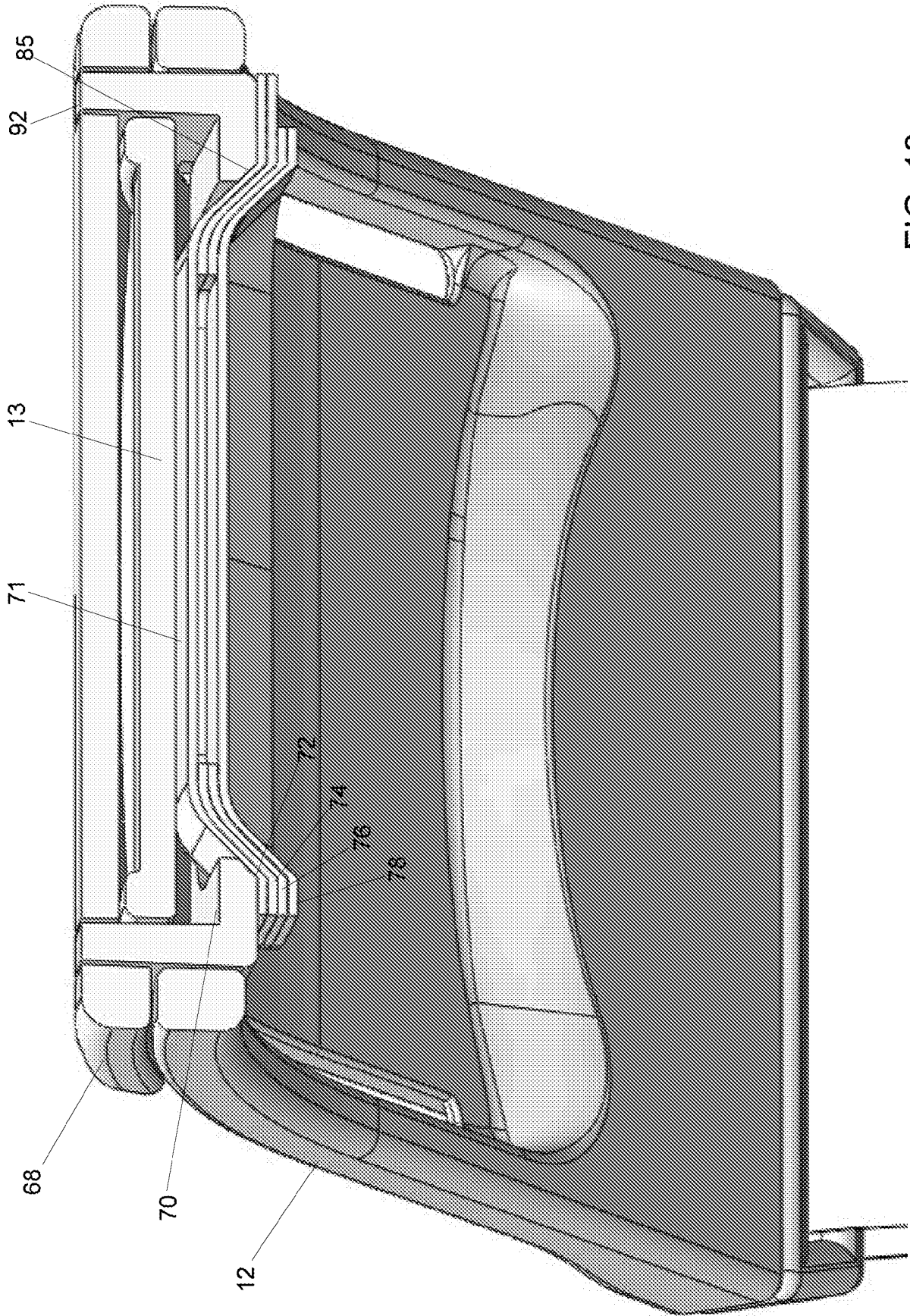


FIG. 18

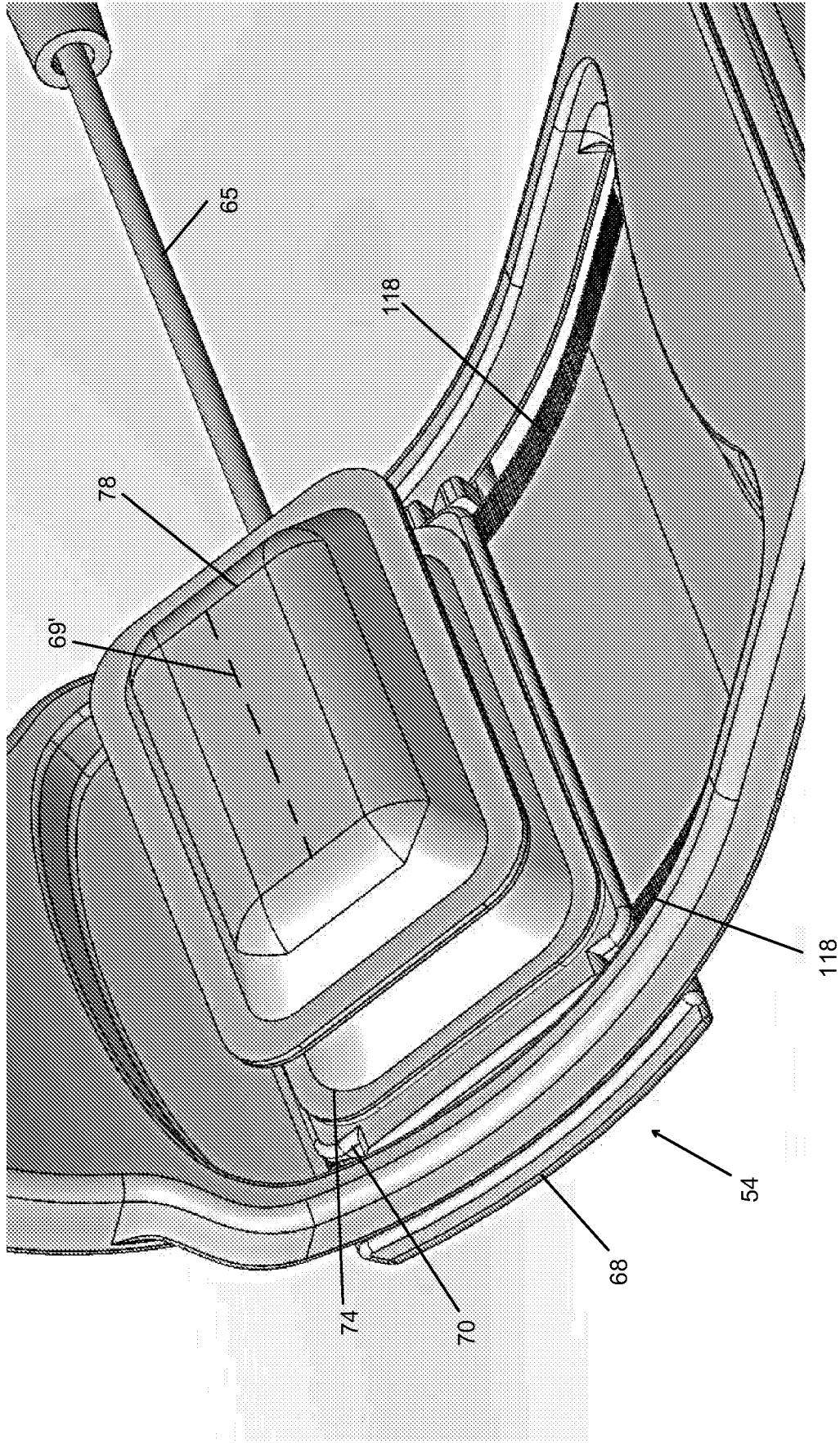


FIG. 19

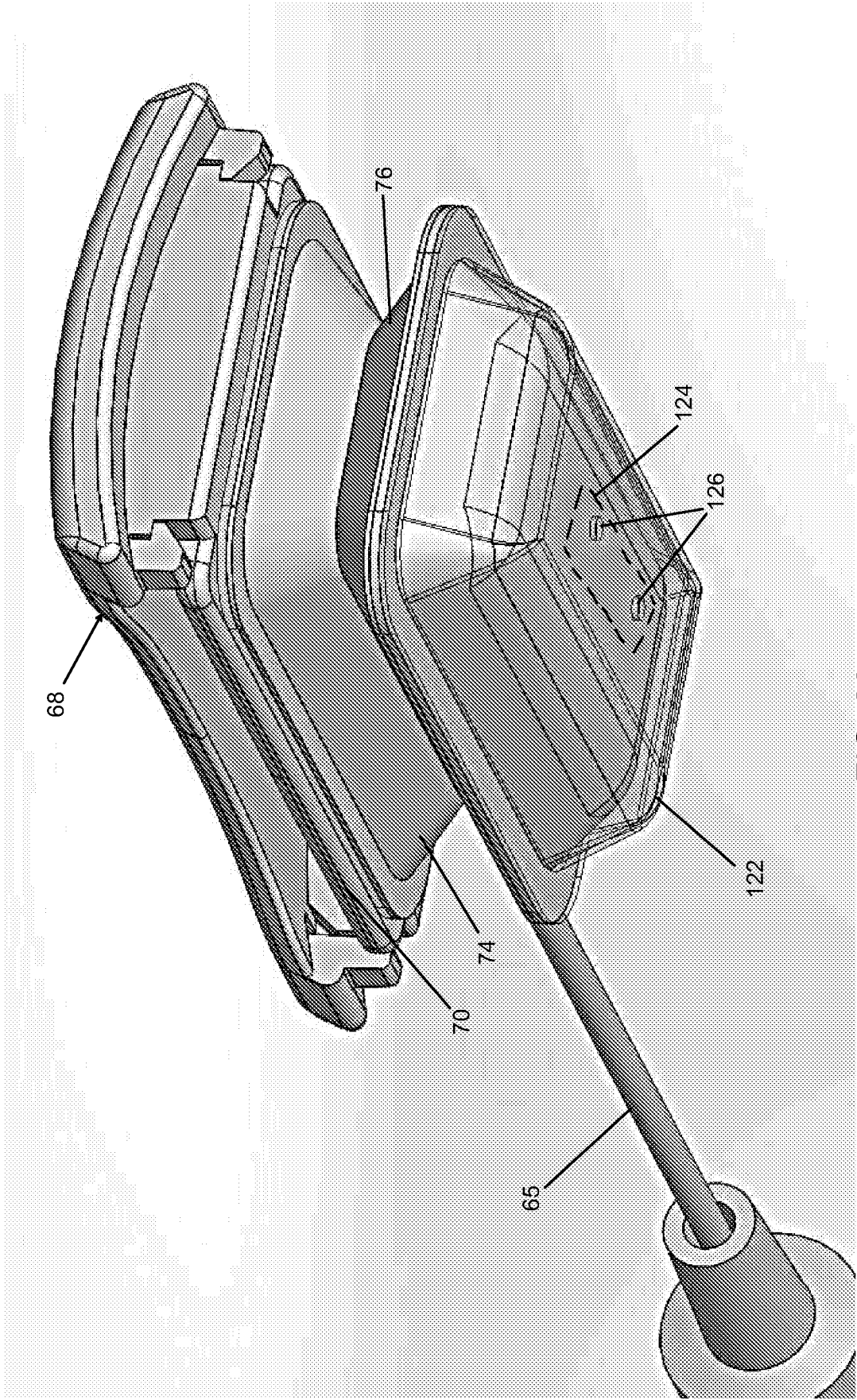
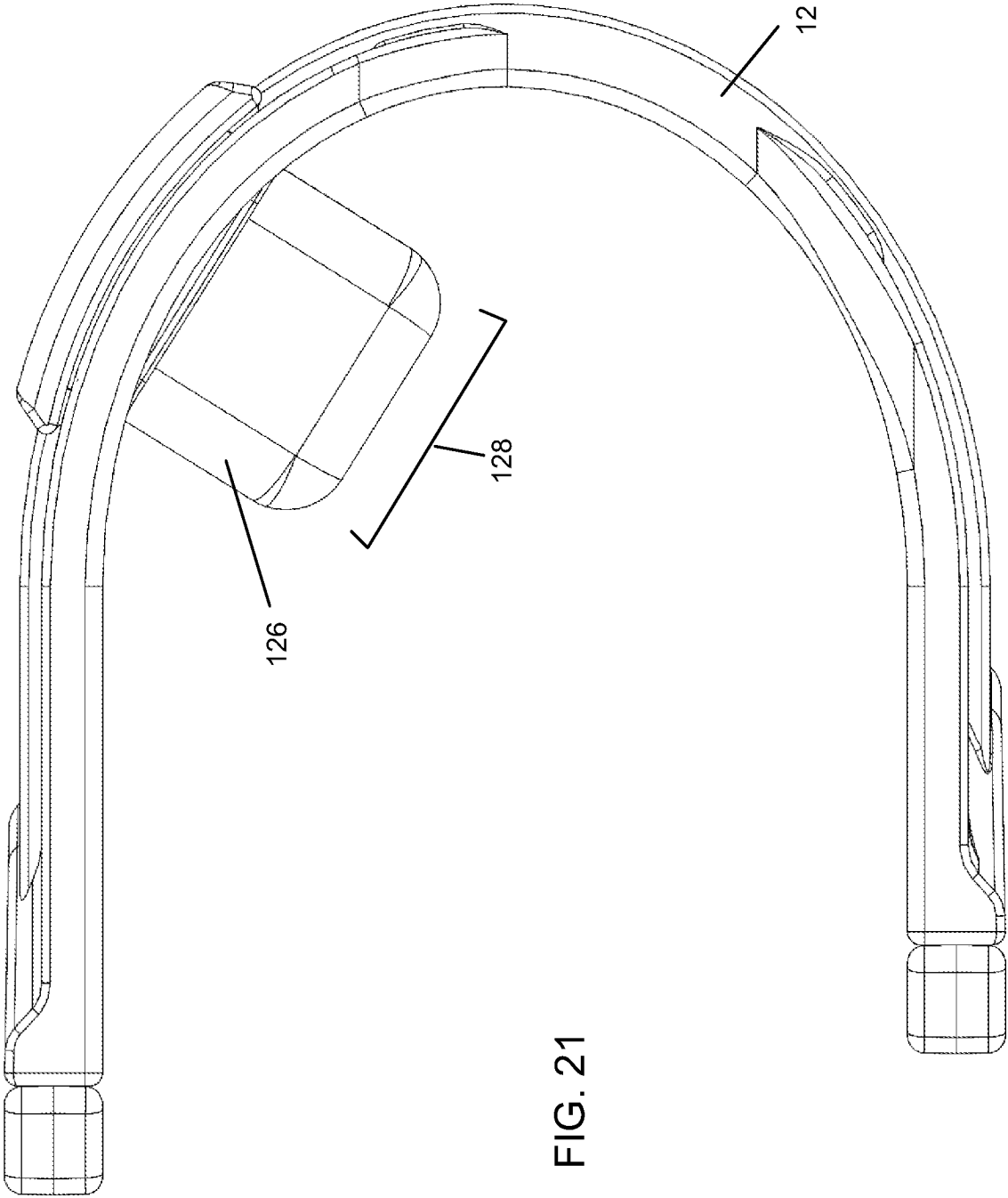


FIG. 20



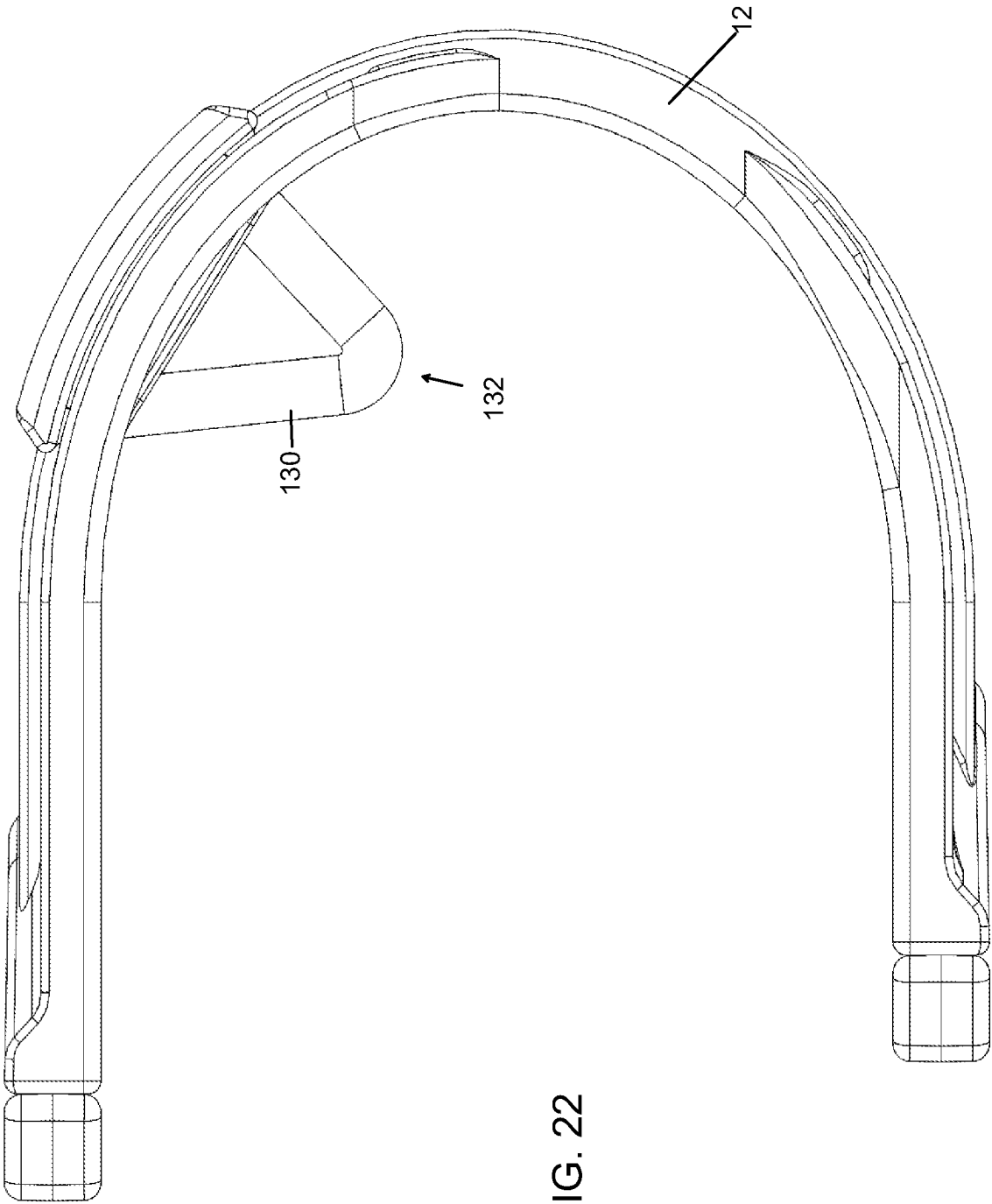
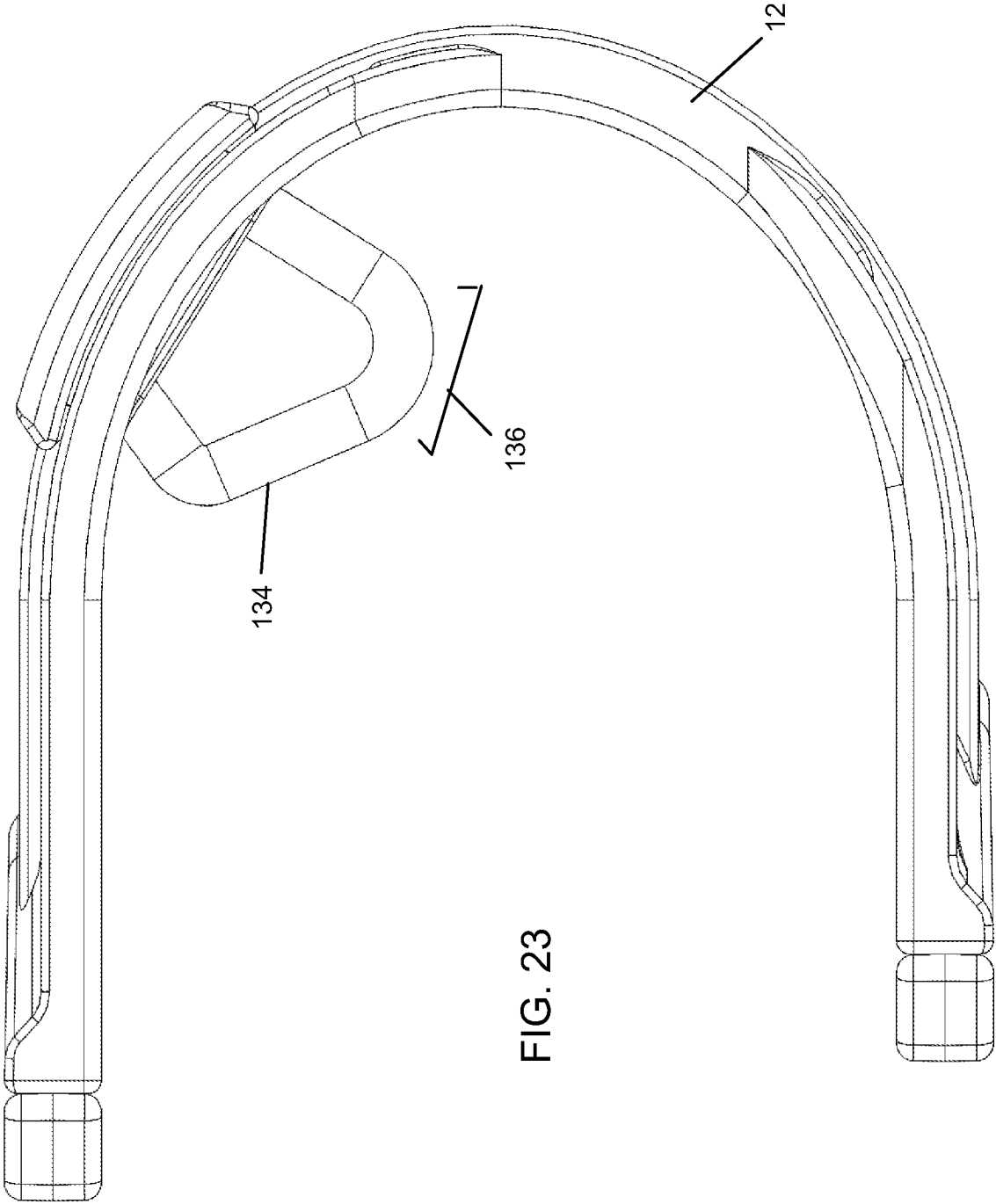


FIG. 22



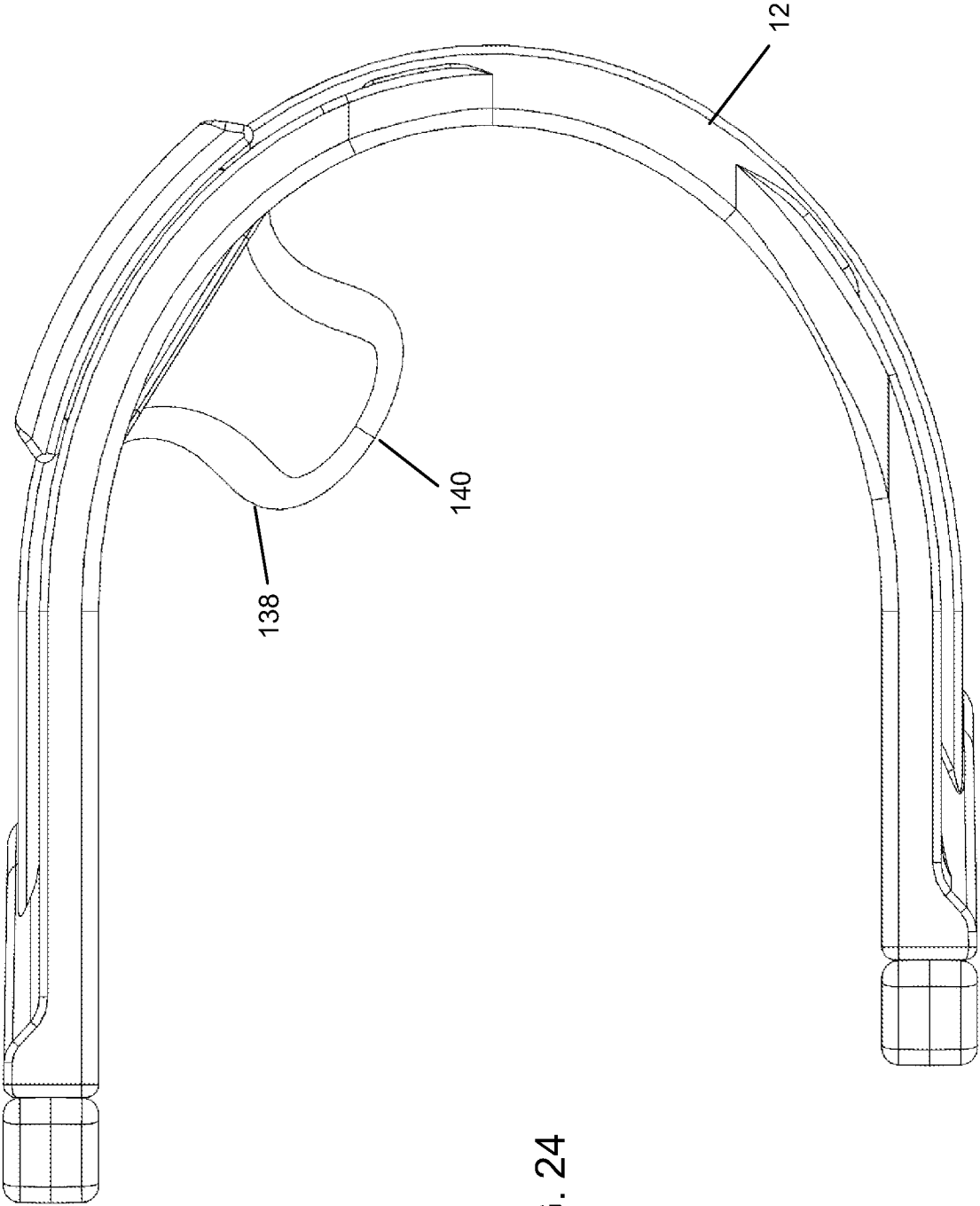


FIG. 24

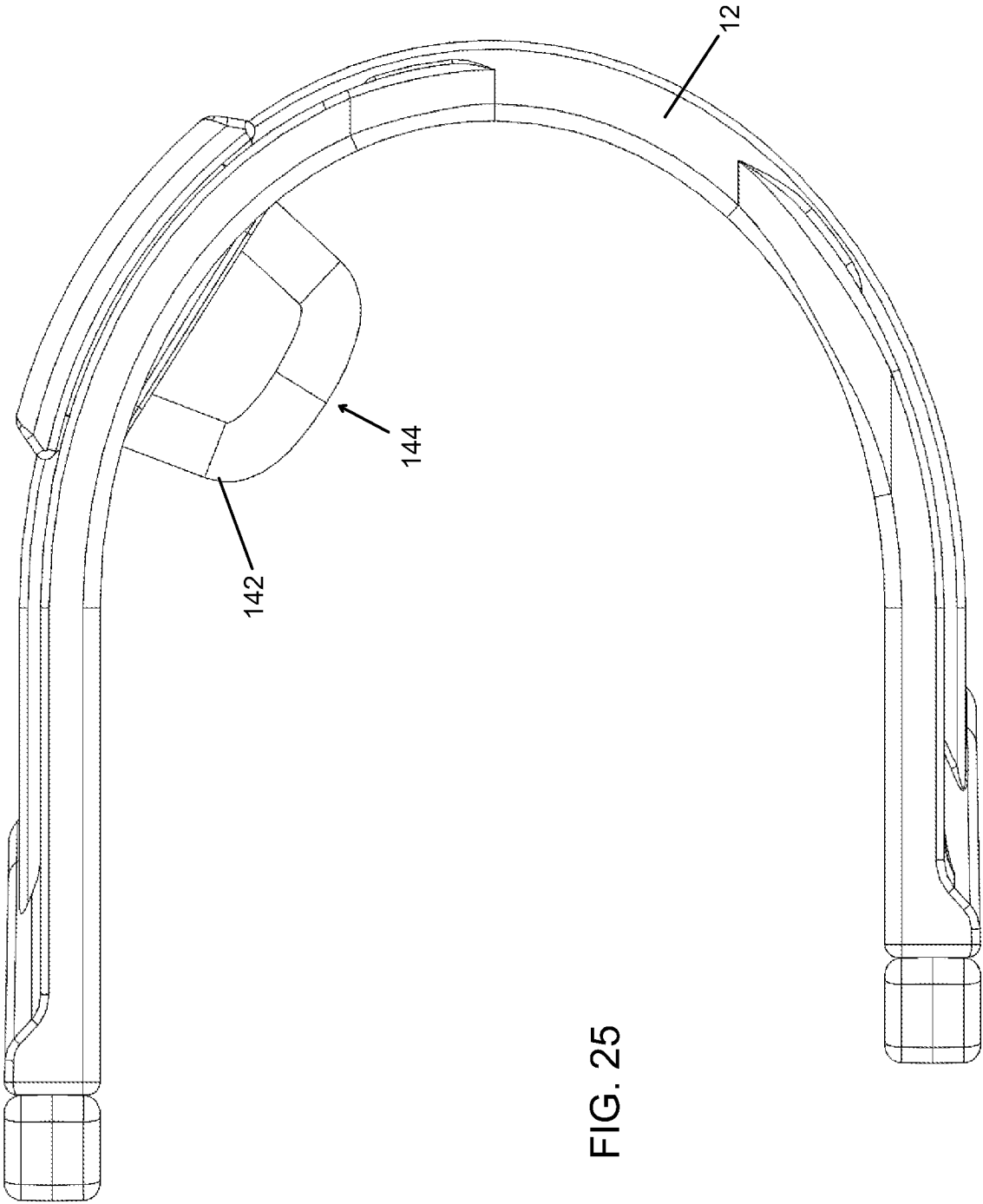


FIG. 25

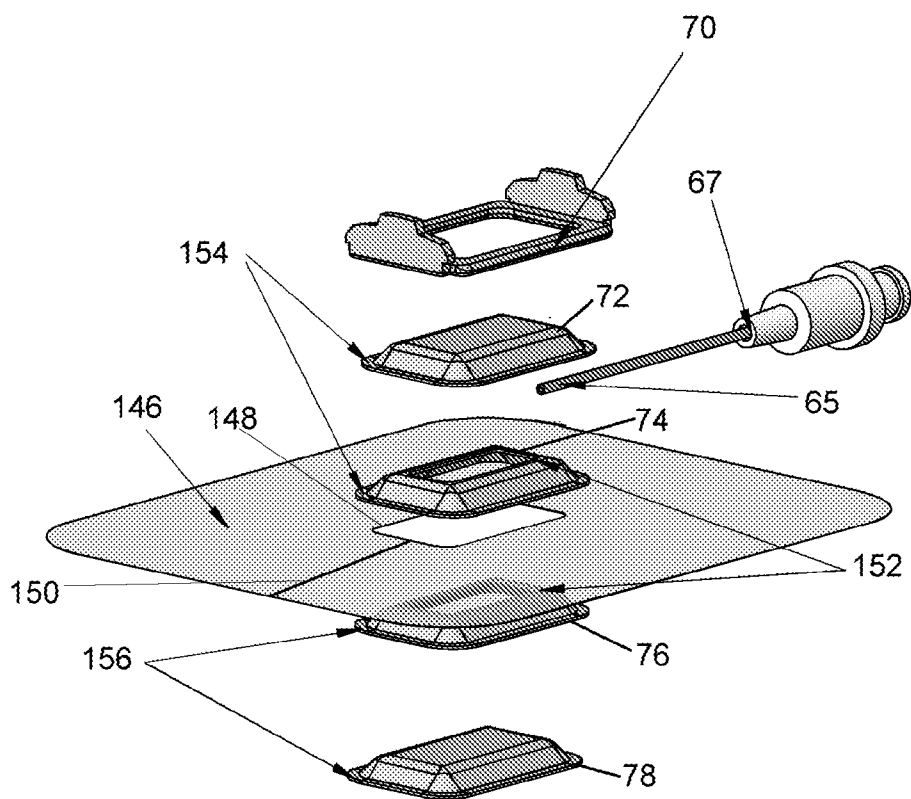


FIG. 26

FIG. 27A

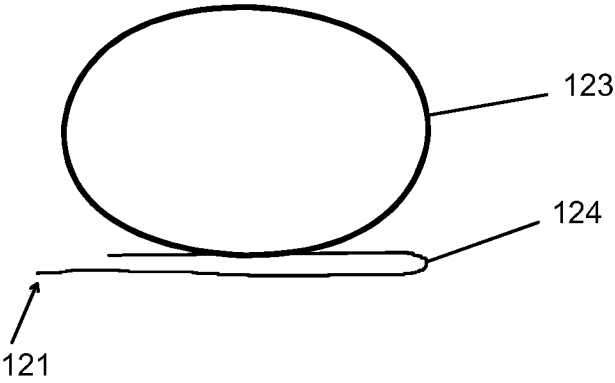


FIG. 27B

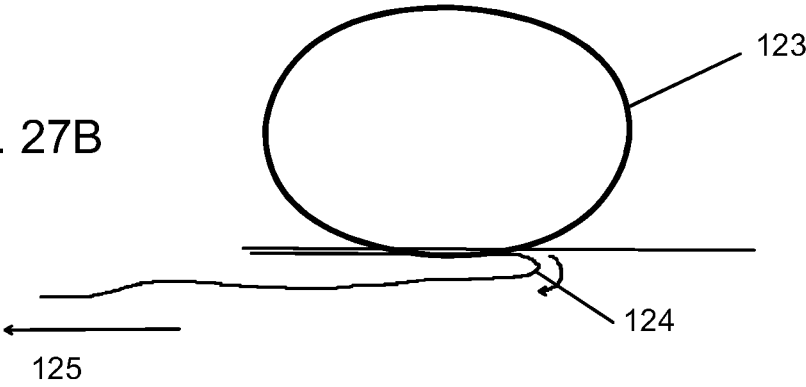


FIG. 27C

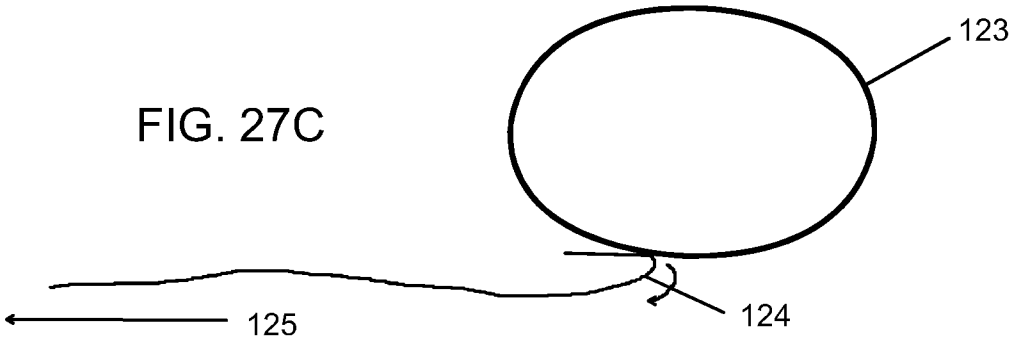
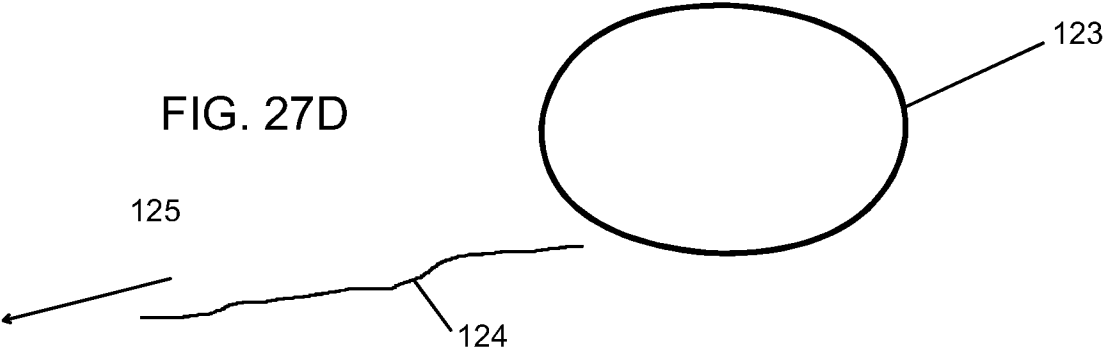


FIG. 27D



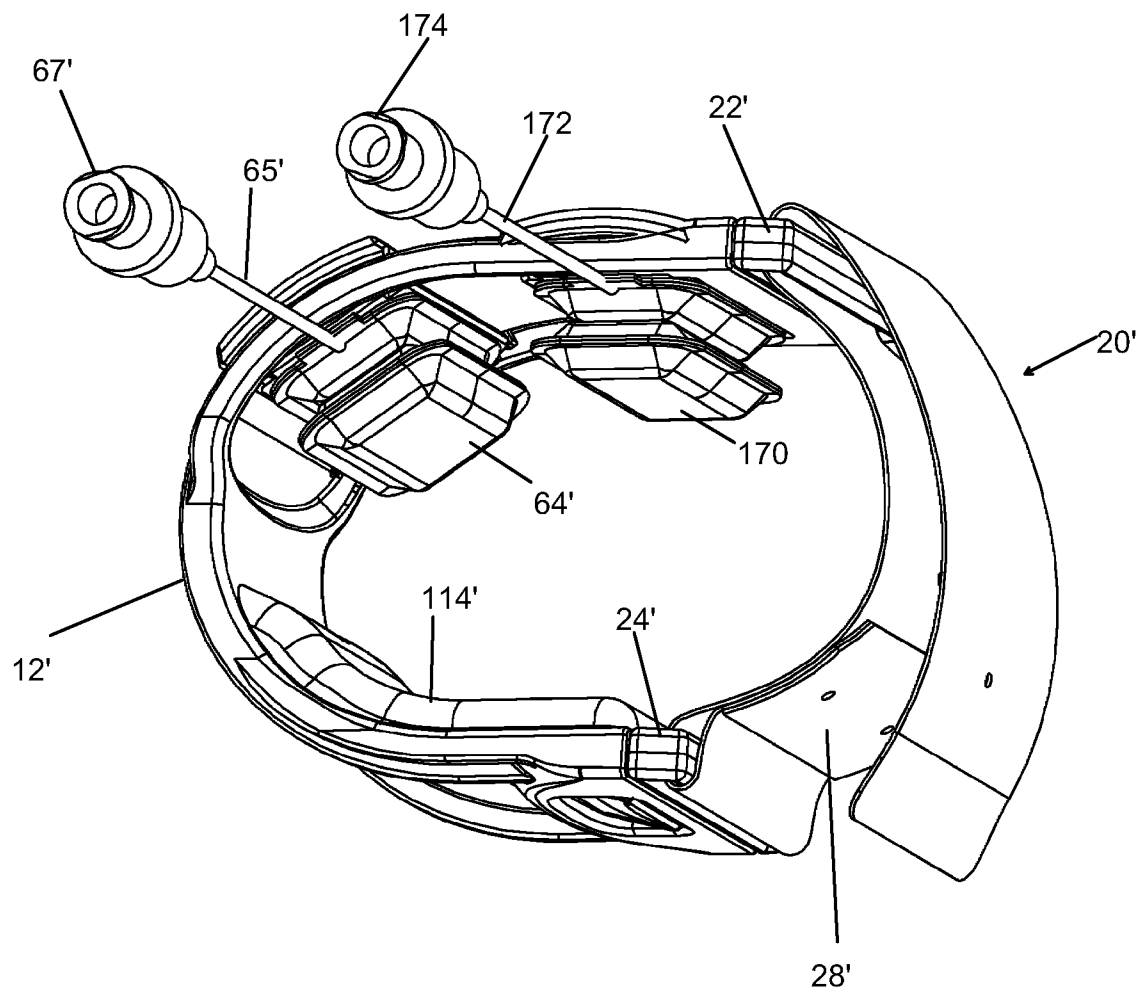


FIG. 28

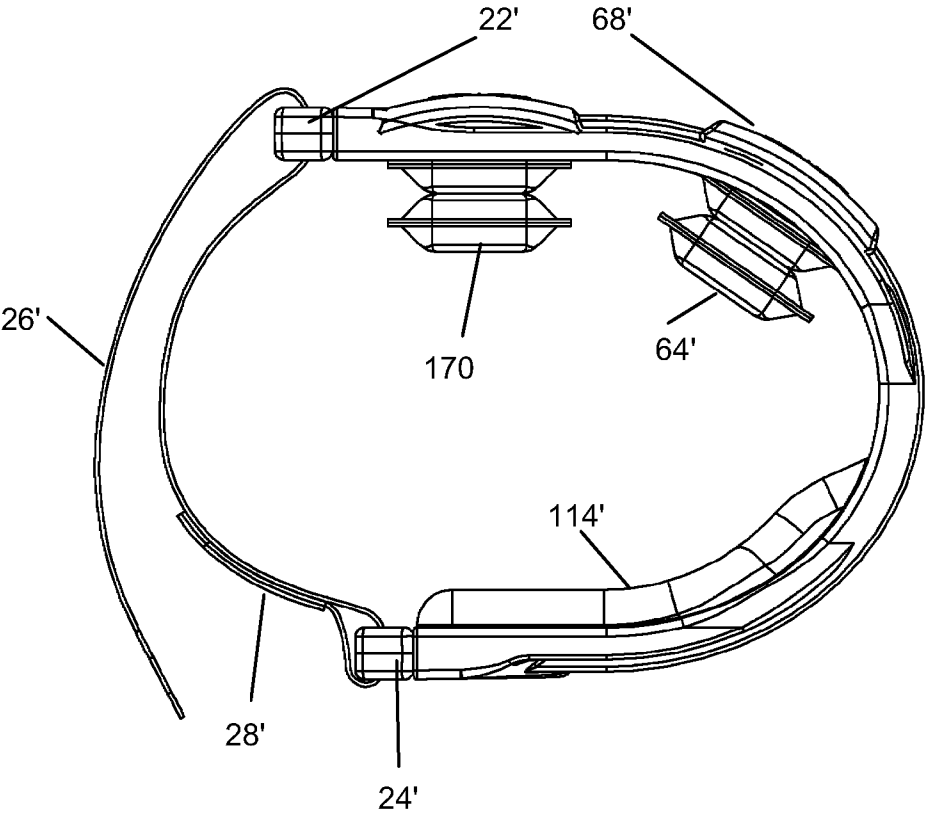


FIG. 29

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2017/020992

A. CLASSIFICATION OF SUBJECT MATTER		
Int.Cl. A61B17/135 (2006.01) i		
According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED		
Minimum documentation searched (classification system followed by classification symbols)		
Int.Cl. A61B17/135		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Published examined utility model applications of Japan 1922-1996 Published unexamined utility model applications of Japan 1971-2017 Registered utility model specifications of Japan 1996-2017 Published registered utility model applications of Japan 1994-2017		
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	JP 2015-66032 A (TERUMO CORPORATION)	1-5, 7-8, 12,
Y	2015.04.13, paragraphs [0012]-[0059], [0093], Figs. 1-8 (No Family)	20, 22-24 6, 9-11, 13, 21, 25-29
Y	JP 2005-218593 A (TERUMO CORPORATION) 2005.08.18, paragraph [0032], Fig. 1 (No Family)	6, 21
Y	US 2015/0327870 A1 (ABBOTT CARDIOVASCULAR SYSTEMS, INC.) 2015.11.19, paragraph [0039], Fig. 1A (No Family)	9-11, 26-28
<input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/> See patent family annex.		
* Special categories of cited documents: "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier application or patent but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family		
Date of the actual completion of the international search		Date of mailing of the international search report
20.06.2017		04.07.2017
Name and mailing address of the ISA/JP		Authorized officer
Japan Patent Office		KONDO, Toshimitsu
3-4-3, Kasumigaseki, Chiyoda-ku, Tokyo 100-8915, Japan		3I 4022
		Telephone No. +81-3-3581-1101 Ext. 3386

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2017/020992

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2015/0018869 A1 (SEMLER TECHNOLOGIES, INC.) 2015.01.15, paragraph [0045], Figs. 2, 4 (No Family)	13, 29
Y	JP 8-71077 A (ZEON CORPORATION) 1996.03.19, paragraph [0010], Figs. 1, 3, 5 (No Family)	25
E, Y	WO 2017/039005 A1 (TERUMO CORPORATION) 2017.03.09, Fig. 7 (No Family)	13, 29
X A	WO 2015/060967 A1 (MEDTRONIC VASCULAR INC.) 2015.04.30, page 33, lines 18-27, page 37, lines 9-32, Figs. 9A, 17 & JP 2016-535615 A & US 2015/0119773 A1	14-16, 18 17, 19

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2017/020992

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

See an extra sheet.

1. ☒ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☒ No protest accompanied the payment of additional search fees.

D1: JP 2015-66032 A (TERUMO CORPORATION)
2015.04.13, paragraphs [0018]-[0019],[0027], Figs. 3-7
(No Family)

The claims can be grouped into two inventions as explained below:

(Invention 1) claims 1-13 and 20-29

Document D1 discloses "a hemostasis device, comprising: a curved plate (12) (corresponding to "an attachment device" of claim 1) for securing the hemostasis device to a patient; and a balloon (13) (corresponding to "a positionable pressure application device" of claim 1) for positioning over a site independent of securing of the curved plate (12)" (see especially paragraph [0027], Figs. 3-7), "said curved plate (12) comprises a band adapted to be secured to the patient's wrist" (see especially paragraph [0018]), and "said curved plate (12) is substantially rigid" (see especially paragraph [0019]). Then, claims 1-3 lack novelty over D1 and include no special technical features. Therefore, claims 1-3 are grouped into Invention 1.

Further, claims 4-13 and 20-29 have an inventive link to claim 1, thus they are grouped into Invention 1.

(Invention 2) claims 14-19

Claims 14-19 are not dependent claims of claim 1. Those claims 14-19 are neither substantially identical, nor similarly closely related, with any claim grouped into Invention 1.

Therefore, claims 14-19 cannot be grouped into Invention 1.

Then, claims 14-19 include "a method of forming a hemostasis pressure bubble, comprising: nesting 4 bubble layers together; and sealing the bubble layers together to form an air tight bubble member" as a technical feature, thus they are grouped into Invention 2.