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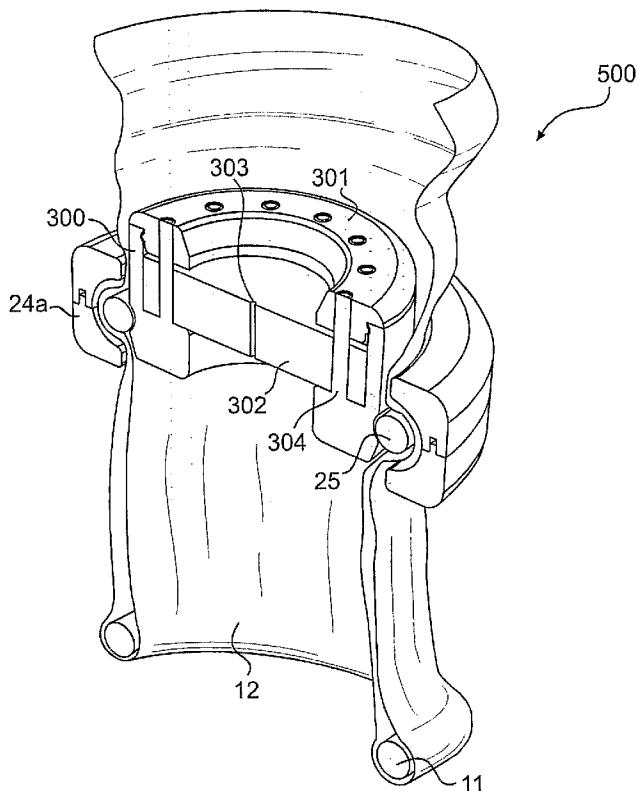
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(54) Title: AN INSTRUMENT ACCESS DEVICE



(57) Abstract: An instrument access device (500) comprises a distal O-ring (11) for insertion into a wound interior, a proximal member for location externally of a wound opening and a sleeve (12) extending in two layers between the distal O-ring (11) and the proximal member. The proximal member comprises an inner proximal ring member (25) and an outer proximal ring member (24) between which the sleeve (12) is led. A seal housing (300) is mounted to the inner proximal ring member (25). A gelatinous elastomeric seal (302) with a pinhole opening (303) therethrough is received in the housing (300). An instrument may be extended through the seal (302) to access the wound interior through the retracted wound opening in a sealed manner.



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"An Instrument Access Device"Introduction

5 Accessing the abdominal cavity while preserving the abdominal wall as much as possible is the aim of any surgical or exploratory procedure. Retraction devices have been used to this end. A retractor can help to expose an operative site and minimise the incision required to carry out the operation.

10 Minimally invasive surgery is an evolving surgical method that similarly attempts to reduce the size of incisions required, in many cases dramatically. By using a so-called "keyhole" or cannula, the surgeon can gain access with instruments into the abdominal cavity to carry out an operation through a very small series of holes in the abdominal wall. Unlike in the case of "open surgery", primary retraction then must be accomplished by lifting the abdominal wall away from the abdominal viscera. This is most often accomplished with the use of gas in a technique known as insufflation.

20 The use of a cannula to gain access as a means to see inside the abdomen or introduce surgical instruments has existed since the late 19th century. A cannula comprises a rigid tube, which is inserted through the abdominal wall and is held in place by the tension of the abdominal wall itself around the inserted cannula. The tube must accommodate various thicknesses of abdominal wall and extend significantly both inside and outside the abdomen to avoid slipping out of the incision, and thereby causing gas pressure to escape.

25 The basic construction of a cannula, however, presents significant limitations in carrying out a surgical procedure. Some of these limitations are as follows.

1. A cannula is held in place, and thus prevents the escape of gas, by tissue tension. This tension can vary depending on the way the cannula is introduced or weaken during the operation under normal surgical manipulation.
- 5 2. A cannula extends significantly into the abdominal cavity taking up precious space and interfering with other instruments.
3. A cannula restricts the movement of instruments as they are rigid structures.
- 10 4. A rigid cannula presents significant limitations on the design of the instrument which must be passed through the cannula.
5. A cannula takes up a significant space outside of the abdomen, shortening the effective length, and therefore reach, of the surgical instrument.

15

This invention is directed towards providing an instrument access device which will address at least some of these problems.

Statements of Invention

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According to the invention there is provided an instrument access device comprising:-

25

a distal anchoring member for insertion into a wound interior;
an elongate member extending proximally from the distal anchoring member to retract laterally the sides of a wound opening; and

30

an instrument working channel through which an instrument may extend to access the wound interior.

In one embodiment of the invention the device comprises a proximal member for location externally of a wound opening. The proximal member may comprise a ring member. The proximal member may comprise a proximal inner element and a proximal outer element. The elongate member may be led between the proximal inner element and the proximal outer element. The proximal inner element and/or the proximal outer element may comprise a ring element. The proximal outer element may be mounted to the proximal inner element. The proximal outer element may be demountable from the proximal inner element.

10 In one case the proximal outer element comprises an engagement surface for resting upon the proximal inner element to mount the proximal outer element to the proximal inner element. The engagement surface may comprise a curved surface. The engagement surface may extend in cross-section for substantially a quarter-revolution. The engagement surface may be configured to engage a proximal side of
15 the proximal inner element.

20 In another case the device comprises a clamp for clamping the instrument working channel in position. The clamp may be configured to clamp the elongate member to the instrument working channel. The clamp may comprise a proximal clamp. The clamp may be defined by the proximal outer element and the proximal inner element. The proximal outer element may comprise a proximal outer ring. The proximal inner element may comprise a proximal inner ring. The proximal inner element may be defined by a portion of the instrument working channel.

25 In another embodiment the device comprises at least one instrument seal or valve. The seal or valve may comprise a gelatinous elastomeric material. The seal or valve may comprise at least one opening extending therethrough through which an instrument may be extended. The opening may be biased towards a closed configuration. The opening may comprise a pinhole opening.

- In one case the seal or valve is piercable to create at least one opening extending therethrough through which an instrument may be extended. The seal or valve may be piercable by an instrument to create an opening extending therethrough.
- 5 In another case the seal or valve comprises an insufflation lumen extending therethrough. The longitudinal axis of the insufflation lumen may be substantially parallel to the longitudinal axis of the device.
- 10 In another embodiment the device comprises a housing for an instrument seal or valve. The housing may comprise a reception space for receiving an instrument seal or valve. The reception space may have an inlet through which an instrument seal or valve may be located in the reception space. The inlet may face proximally.
- 15 In one case the housing comprises a retainer to retain an instrument seal or valve in the reception space. The retainer may comprise a cap for at least partially closing the inlet. The retainer may comprise an opening to facilitate access to an instrument seal or valve in the reception space. The retainer may be substantially annular in shape.
- 20 In another case the housing comprises a locator to assist in locating a seal or valve in the reception space. The locator may comprise at least one male member for cooperative association with at least one corresponding female member.
- 25 In one embodiment the housing comprises an insufflation lumen extending therethrough. The longitudinal axis of the insufflation lumen may be substantially parallel to the longitudinal axis of the device. The housing insufflation lumen may be aligned with an insufflation lumen of an instrument seal or valve. The device may comprise an insufflation seal or valve for the insufflation lumen. The insufflation seal or valve may be provided at a proximal end of the insufflation lumen. The insufflation seal or valve may be pierceable by an insufflation tube.

In one case the access device comprises an intermediate connector to connect the insufflation lumen in communication with an insufflation tube. The intermediate connector may be configured to connect an insufflation tube in communication with the insufflation lumen with the longitudinal axis of the insufflation tube at a distal end of the insufflation tube inclined relative to the longitudinal axis of the insufflation lumen. The intermediate connector may be configured to connect an insufflation tube in communication with the insufflation lumen with the longitudinal axis of the insufflation tube at a distal end of the insufflation tube substantially perpendicular to the longitudinal axis of the insufflation lumen.

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In a further case the housing is mounted to the proximal member. The housing may be mounted to the proximal inner element. The housing may extend distally of the proximal inner element. The housing may be located radially inwardly of the proximal inner element. The housing may be demountable from the proximal inner element.

15

In one case the device comprises a seal across the proximal inner element. The seal may be piercable by the housing and/or by the instrument working channel upon mounting of the housing to the proximal inner element.

20

In a further embodiment the housing is formed integrally with the proximal inner element.

The housing may define the proximal inner element.

25

In one case the device comprises a sleeve extending from the proximal inner element to the housing. The sleeve may be formed integrally with the elongate member.

30

In one embodiment the housing at least in part defines the instrument working channel. The instrument working channel may be mounted to the housing. The

instrument working channel may be demountable from the housing. In one case the instrument working channel is formed integrally with the housing.

In one embodiment the instrument working channel is defined by a tubular member.

5 The tubular member may be substantially rigid over at least part of its length. The tubular member may define a lumen extending therethrough through which an instrument may be extended. The tubular member may have a distal opening at a distal end of the tubular member. The distal opening may be inclined relative to the longitudinal axis of the tubular member. The plane of the distal opening may be
10 inclined relative to the longitudinal axis of the tubular member. The tubular member may have a low-profile leading end. The leading end may be tapered. The leading end may be tapered to a point. The distal end of the tubular member may be skived.

15 In another embodiment the instrument working channel is mounted to the proximal member. The instrument working channel may be mounted for controlled movement relative to the proximal member. The device may comprise a sleeve extending between the instrument working channel and the proximal member to mount the instrument working channel to the proximal member.

20 In one case the elongate member comprises a sleeve. At least a portion of the sleeve may comprise two material layers. The sleeve may be wrapped around the distal anchoring member. The sleeve may be slidably movable relative to the distal anchoring member. The sleeve may comprise a single material layer. An end of the sleeve may be fixed to the distal anchoring member.

25 In a further case the elongate member extends from the distal anchoring member to at least the proximal member. The elongate member may be slidably movable over at least a portion of the proximal member. The elongate member may be slidably movable over the proximal inner element. An end of the elongate member may be fixed to the proximal member. An end of the elongate member may be fixed to the housing. The elongate member may be fixed to the proximal member at one end, the

elongate member may extend from the proximal member to the distal anchoring member to define an inner material layer, and the elongate member may extend from the distal ring anchoring member to the proximal member to define an outer material layer.

5

In one case the distal anchoring member comprises a distal ring. The distal ring may be formed from an elastomeric material.

10 The device may comprise at least one proximal handle for manipulating the device, in situ.

In another aspect of the invention there is provided an instrument access device comprising: -

15 a distal ring;

a proximal ring;

20 a sleeve having a portion between the distal ring and the proximal ring that includes two material layers; and

an instrument seal or valve mounted to the proximal ring.

25 In one embodiment the sleeve is fixed to the proximal ring at one end, the sleeve extends from the proximal ring to the distal ring to define an inner material layer, and the sleeve extends from the distal ring to the proximal ring to define an outer material layer. The sleeve may be slidingly received over a portion of the proximal ring.

30 In one case the proximal ring comprises an inner proximal ring member and an outer proximal ring member between which the sleeve is led.

The instrument also provides in another aspect an instrument access device comprising:-

5 a distal ring;

a proximal ring;

10 a sleeve having a portion between the distal ring and the proximal ring; and

an instrument seal or valve comprising a gelatinous elastomeric material for receiving an instrument.

15 The gelatinous elastomeric material may have a pinhole to receive an instrument.

In a further aspect, the invention provides an instrument access device comprising:-

a distal anchoring member for insertion into a wound interior;

20 a proximal member for location externally of a wound opening;

a sleeve extending in two layers at least between the distal anchoring member and the proximal member; and

25 an instrument seal or valve comprising a gelatinous elastomeric material for receiving an instrument.

The invention also provides in another aspect an instrument access device comprising:-

- a distal anchoring member for insertion into a wound interior;
- a proximal member for location externally of a wound opening;
- 5 an elongate member extending at least between the distal anchoring member and the proximal member;
- the proximal member comprising a proximal inner element and a proximal outer element between which the elongate member is led;
- 10 and
- an instrument seal or valve mounted to the proximal inner element.
- According to another aspect of the invention there is provided a method of accessing
- 15 a wound interior with an instrument, the method comprising the steps of: -
- inserting a distal anchoring member through an incision, the distal anchoring member having an elongate member attached thereto;
- 20 presenting an instrument working channel member to the incision;
- pulling the elongate member upwardly relative to the instrument working channel member to at least partially insert the instrument working channel member into the incision; and
- 25 inserting an instrument through the incision.

In one embodiment the elongate member lies at least in part between the instrument working channel member and the walls of the incision.

In one case the incision is a laparoscopic incision. The sides of the incision may be retracted to a diameter of less than 40 mm. The sides of the incision may be retracted to a diameter of between 3 mm and 35 mm. The sides of the incision may be retracted to a diameter of between 5 mm and 12 mm.

5

In another case the sides of the incision are retracted to a diameter substantially equal to a diameter of the instrument working channel member.

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The sides of the incision may be at least partially retracted by insertion of the instrument working channel member into the incision. The sides of the incision may be at least partially retracted by pulling of the elongate member upwardly relative to the instrument working channel member.

15

In one case the instrument is a laparoscopic instrument. The instrument may have a diameter of less than 40 mm. The instrument may have a diameter of between 3 mm and 35 mm. The instrument may have a diameter of between 5 mm and 12 mm.

20

In one case after insertion of the instrument working channel member into the incision, the distal end of the instrument working channel member is located within the wound interior distally of the incision. In another case after insertion of the instrument working channel member into the incision, the distal end of the instrument working channel member is located within the incision proximally of the wound interior.

25

In one embodiment the leading end of the instrument working channel member is guided into the incision. The instrument working channel member may be configured to automatically guide the leading end into the incision.

30

The method may comprise the step of sealing the incision. The method may comprise the steps of insufflating the wound interior. The wound interior may be

insufflated after insertion of the instrument working channel member into the incision.

5 In another aspect the invention provides a method of retracting a wound opening, the method comprising the steps of: -

inserting a distal anchoring member through a wound opening into a wound interior;

10 locating a proximal member externally of the wound opening with an elongate member extending at least between the distal anchoring member and the proximal member;

locating a guide member externally of the wound opening;

15 moving the guide member and the proximal member relative to the elongate member to retract laterally the sides of the wound opening; and

20 removing the guide member while the distal anchoring member, the proximal member and the elongate member remain in position retracting the wound opening.

In one case the elongate member is led between the proximal member and the guide member.

The elongate member may extend in two layers between the proximal member and the distal anchoring member.

30 In another case the proximal member is moved by pushing the guide member which engages the proximal member.

The invention also provides in a further aspect a method of retracting a wound opening, the method comprising the steps of: -

5 inserting a distal anchoring member through a wound opening into a wound interior;

10 locating a proximal member externally of the wound opening with an elongate member extending at least between the distal anchoring member and the proximal member;

 moving the proximal member relative to the elongate member to retract laterally the sides of the wound opening; and

15 mounting a first seal or valve to the proximal member.

In one embodiment the first seal or valve is mounted to the proximal member after retraction of the wound opening. The first seal or valve may be mounted to the proximal member before retraction of the wound opening.

20

In one case the method comprises the step of piercing a second seal. The second seal may be pierced upon mounting of the first seal or valve to the proximal member.

25

In a further aspect of the invention there is provided a method of retracting a wound opening, the method comprising the steps of:-

 inserting a distal anchoring member through a wound opening into a wound interior;

locating a proximal member externally of the wound opening with an elongate member extending at least between the distal anchoring member and the proximal member; and

5 by means of a single actuation step, moving the proximal member relative to the elongate member to retract laterally the sides of the wound opening.

10 In one embodiment the entire circumference of the proximal member is moved together relative to the entire circumference of the elongate member.

15 The proximal member may be pushed distally relative to the elongate member. The elongate member may be pulled proximally relative to the proximal member. The proximal member may be moved relative to the elongate member in a single direction. The proximal member may be moved relative to the elongate member in a direction substantially parallel to the longitudinal axis of the wound opening.

20 In one case the method comprises the step of gripping the proximal member. The proximal member may be gripped by a single hand of a user. Opposite sides of the proximal member may be gripped by a single hand of a user. The method may comprise the step of gripping the elongate member. The elongate member may be gripped by a single hand of a user. The entire circumference of the elongate member may be gripped by a single hand of a user.

25 Brief Description of the Drawings

The invention will be more clearly understood from the following description of some embodiments thereof, given by way of example only, with reference to the accompanying drawings, in which:-

Fig. 1 is a perspective view of a liner part of an instrument access device of the invention;

5 Fig. 2 is a cross sectional, side view of the liner part of Fig. 1 inserted in an incision;

Fig. 3 is a perspective view of a tubular member defining an instrument working channel of the access device;

10 Fig. 4 is a cross sectional, side view of the access device in place in an incision;

Fig. 5 is a cross-sectional, side view similar to Fig. 4 illustrating clamping or anchoring of the tubular member;

15 Figs. 6 and 7 are views similar to Figs. 1 and 2 of an alternative liner part with a proximal valve or seal;

20 Figs. 8 and 9 are views similar to Figs. 4 and 5 with the liner part of Figs. 6 and 7, in use;

Figs. 10 and 11 are views similar to Figs. 4 and 5 of an alternative tubular member with a proximal valve or seal, in use;

25 Fig. 12 is a cross sectional, side view of an instrument access device of the invention; in use;

Fig. 13 is a cross sectional, side view of another instrument access device of the invention, in use;

Figs. 14 to 16 are cross sectional, side views of a further instrument access device of the invention, in use;

5 Figs. 17 to 19 are cross sectional, side views of alternative instrument access devices of the invention, with different tubular members;

Fig. 20 is a perspective view of one of the tubular members of Figs. 17 to 19;

10 Fig. 21 is a cross sectional, perspective view of the tubular member of Fig. 20;

Fig. 22 is a perspective view of a housing part of the access device of the invention;

15 Fig. 23 is a cross sectional, perspective view of the housing part of Fig. 22;

Figs. 24 and 25 are exploded, perspective views of an outer proximal ring and housing part assembly of the access device of the invention;

20 Figs. 26 to 28 are cross sectional, side views of another instrument access device of the invention, in use;

Figs. 29 and 30 are cross sectional, side views of a further instrument access device of the invention, in use;

25 Figs. 31 and 32 are cross sectional, side views of another instrument access device of the invention;

30 Figs. 33 to 37 are cross-sectional, side views of a further instrument access device of the invention;

Figs. 38 and 39 are cross sectional, side views of a still further instrument access device of the invention;

5 Figs. 40 to 42 are cross sectional, side views of another instrument access device of the invention;

Fig. 43 is a cross sectional, side view of a further instrument access device of the invention;

10 Figs. 44 to 46 are cross sectional, side views of another instrument access device of the invention;

Figs. 47 to 49 are cross sectional, side views of a further instrument access device of the invention;

15 Figs. 50 to 55 are views of another instrument access device of the invention;

Figs. 56 to 58 are cross sectional, side views of a further instrument access device of the invention;

20 Fig. 58(a)(i) is a cut-away, perspective view of another instrument access device according to the invention;

25 Fig. 58(a)(ii) is an exploded, perspective view of a part of the device of Fig. 58(a)(i);

Fig. 58(b) is an assembled, perspective view of the part of the instrument access device of Fig. 58(a)(ii);

30 Fig. 58(c)(i) is a cut-away, perspective view of the part of the instrument access device of Fig. 58 (a)(ii);

Figs. 58(c)(ii) and 58(c)(iii) are cross-sectional, side views of the device of Fig. 58(a)(i), in use;

5 Figs. 58(d) and 58(e) are views similar to Figs. 58(a)(ii) and 58(c)(i) of part of another instrument access device according to the invention;

Figs. 58(f) and 58(g) are partially cross-sectional, side views of another instrument access device according to the invention, in use;

10 Figs. 58(h) and 58(i) are partially cross-sectional, side views of a further instrument access device according to the invention, in use;

15 Figs. 59 to 61 are cross sectional, side views of another instrument access device of the invention;

Figs. 62 to 64 are cross sectional, side views of a further instrument access device of the invention;

20 Fig. 65 is a cross sectional, side view of another instrument access device according to the invention;

Fig. 66 is a cut-away, perspective view of a part of the device of Fig. 65;

25 Fig. 67 is an end view of the part of Fig. 66;

Figs. 68 to 70 are cross-sectional, side views of the device of Fig. 65, in use;

30 Figs. 70(a) to 70(f) are cross-sectional, side views of another instrument access device according to the invention, in use;

Figs. 70(g) to 70(i) are cross-sectional, side views of another instrument access device according to the invention, in use; and

5 Figs. 71 to 73 are cross-sectional, side views of a further instrument access device according to the invention, in use.

Detailed Description

10 Referring to the drawings there are illustrated various instrument access devices of the invention for an incision 1, for example in an abdominal wall 2. The construction of the various components and their attributes will be explained in detail below. In some cases, the instrument access device is used as a substitute for a conventional rigid tubular cannula. The instrument access devices of the invention may be used
15 to provide access to the abdominal cavity by an instrument 3, which in this case has an operating element 4, such as a surgical stapler, mounted at the distal end of a flexible shaft 5.

It will be noted that the devices have a very low profile, especially with respect to the
20 inside of the incision 1. The devices are positively retained in the incision 1 against pull-out forces. Because of the low profile the shaft 5 of the instrument 3 can begin bending immediately after entering the abdominal cavity. The amount of free space required to manipulate the instrument 3 is minimised. This is in contrast to a conventional cannula, in which the rigid tube of the cannula must be extended
25 significantly into the abdomen to ensure that it remains anchored in the abdomen, otherwise gas pressure may cause it to become dislodged. In conventional systems, because of the cannula length extending into the abdomen, the shaft 5 of the instrument 3 cannot be steered until the steerable section has exited the cannula. Thus, there are severe limitations on the use of such instruments using a
30 conventional cannula. These problems are overcome at least in part using the instrument access devices of the invention.

Referring initially to Figs. 1 and 2 there is illustrated a liner part 10 of the access device. The liner part 10 comprises a distal anchoring member 11 and an elongate member 12 extending proximally of the distal anchoring member 11.

5

In this case, the elongate member is provided in the form of a sleeve 12 of flexible, polymeric film material which lines the sides of the wound opening 13, in use. The distal anchoring member 11 in this case comprises a resilient O-ring.

10 An instrument working channel is in this case defined by a tubular member 15 which may be substantially rigid along at least portion of the length thereof.

15 In use, a relatively small incision 1 is made in an abdominal wall 2 to form the wound opening 13. A typical length for the incision 1 is in the range of from 12mm to 30mm. The resilient distal O-ring 11 is then manipulated into an elongate, oblong shape by squeezing the distal O-ring 11 to facilitate insertion of the distal O-ring 11 through the wound opening 13, until the distal O-ring 11 is fully located within the abdominal cavity and the sleeve 12 lines the wound opening 13. The tubular member 15 is then presented to the wound opening 13 inside the sleeve 12. The
20 sleeve 12 is then pulled upwardly relative to the tubular member 15 to cause the tubular member 15 to enter the wound opening 13 and to cause the distal O-ring 11 to engage with the internal surface of the abdominal wall.

25 The tubular member 15 is clamped or anchored to the sleeve 12 by a suitable clamp such as a proximal clamp 17.

30 The use of the tubular member 15 provides an enhanced instrument working channel through the wound opening 13. It assists in preventing collapse of the sides of the wound opening 13. There is less friction as the instrument 3 is inserted and manipulated. Importantly, the tubular member 15 assists in providing a device that

has a very low profile with the consequent advantages of maximising the surgeon's freedom of movement.

Any suitable valve or seal or combinations of valves and/or seals may be provided for an instrument. Such valve or valves are generically indicated by an X and by the reference numeral 20 in the drawings. In one arrangement (Figs. 6 to 9) a valve 20 is provided at a proximal end of the sleeve 12. In another arrangement a valve 20 is provided at a proximal end of the tubular member 15 (Figs. 10 and 11). Indeed valves 20 may be provided both on the sleeve 2 and on the tubular member 15.

10

The sleeve 12 may be a single layer sleeve or may have two layers at least in the section which lines the wound opening 13. One such arrangement is illustrated in Fig. 12 in which the sleeve 12 is wrapped around the distal ring 11 and has an outer layer 22 which lines the wound opening 13 and an inner layer 23. A clamp is in this case a proximal clamp comprising an outer proximal ring member 24 and an inner proximal ring member 25 between which the sleeve 12 extends. In this case the inner proximal clamp is mounted to or provided by part of a housing 27 for a valve 20. The sleeve 12 is mounted at one end to the ring member 25 or housing 27 and extends to form the inner layer 23, is wrapped around the distal ring 11 and extends to form the outer layer 22. The sleeve 12 is slidable on at least portion of the inner proximal clamp ring 25 and the sleeve 12 is slidable relative to the distal ring 11.. On pulling of the sleeve 12 upwardly the wound opening 13 is retracted. Because of the sleeve pathway a free end of the sleeve 12 is external of the valve 20 and can be readily removed, if desired. In this case the proximal ring member 25 is formed integrally with the housing 27.

Referring now to Figs. 13 to 16 there is illustrated an instrument access device having a valve housing 27 and an instrument working channel defined by a tubular member or stub 40 which extends into the wound opening 13 from the valve housing 27. The tubular member 40 need not necessarily extend fully into the wound opening. In the arrangement of Fig. 13 it is shown extending only partially through

30

the wound opening whilst in Figs. 14 to 16 the tubular member 40 extends fully the thickness of the abdomen. The valve housing 27 in this case also has an insufflation port 42. In this case the tubular member 40 is formed integrally with the housing 27.

5 The tubular member 40 may be detachably mounted to the valve housing 27 as illustrated particularly in Figs. 17 to 25. In this way the access device may be adapted for different situations such as different sized abdomens or depending on the degree of access required by the surgeon. The tubular members 40 may be of varying lengths, as illustrated. Any suitable mounting may be provided between the
10 tubular member 40 and the valve housing 27 such as adhesive, an interference fit, a spigot and socket, screw threaded, or bayonet type fitting.

15 Referring to Figs. 24 and 25 the outer proximal clamp ring member may be split into sections 24a, 24b for ease of assembly, disassembly. The ring sections 24a, 24b can be assembled and fixed using any suitable means such as adhesive or the like.

20 Referring to Figs. 26 to 28 there is illustrated a further instrument access device according to the invention. In this case a seal in the form of a sheet 50 of film material is extended across the inner proximal ring 25 to maintain pneumoperitoneum. The tubular member 40 has a tapered distal end 55 for ease of breaking through the film 50 as illustrated in Fig. 27. The valve housing 27 in this case is configured at 56 to snap fit over an outer proximal ring 24 for assembly of the valve housing 27 to the retractor base. The access device is illustrated in use in Fig. 28.

25 Referring to Figs. 29 and 30 the access device in this case has a gripper or handle provided by an anchor eye 57 and a lifting wire 58. On pulling of the lifting wire 58 upwardly as indicated by the arrow in Fig. 30 the device can be easily tilted providing easier access to more areas of the abdomen. The force on the lifting wire 58 can be varied to increase or decrease the angle alpha to provide further desired access.

Referring to Figs. 31 and 32 there is illustrated another instrument access device which is similar to those described above and like parts are assigned the same reference numerals. In this case the tubular member 40 is detachable and a suitable tubular member 40 is attached to the valve housing 27 prior to deployment in a patient.

Referring to Figs. 33 to 37 there is illustrated the method of using a device such as the device of Figs. 31 and 32. The surgeon first selects the detachable tubular member 40 of desired length, for example based on the abdominal wall thickness. The tubular member 40 is attached (Fig. 34) so that the device is ready for deployment. The distal ring 11 is deployed in the abdomen as described above. The sleeve 12 is pulled upwardly in the direction of the arrow A whilst pushing down on the proximal ring 24 in the direction of the arrow B. Retraction of the incision 1 commences and the tubular member 40 begins to enter the margin of the incision 1 (Fig. 36). As the pulling and pushing action is continued the tubular member 40 is fully deployed creating an instrument working channel in the wound opening 13 (Fig. 37). The device is extremely low profile, easy to deploy, and creates an excellent working channel which provides maximum flexibility in instrument manipulation.

Referring to Figs. 38 and 39 there is illustrated another instrument access device which is similar to those described above and like parts are assigned the same reference numerals. In this case the valve housing 27 is connected to the inner proximal ring 25 by a suitable connection such as a flexible sleeve or corrugated tube 60. In use, the tubular member 40 is flexible relative to the proximal anchor which may be beneficial in reducing drag / friction.

Another access device of the invention is illustrated in Fig. 40. In this case, the free end of the sleeve 12 is external of a valve such as a lipseal valve 70 which is connected to the inner proximal ring 25 by means of a flexible connecting sleeve 75.

The retractor is easily deployed as the free end of the sleeve 12 which is pulled on for deployment is readily accessible. The operation of this device is illustrated in Figs. 41 and 42. It will be noted that in view of the flexible connection 75 tilting of the instrument does not cause a leak path. This arrangement may be used with any suitable valve(s) and/or seal(s) 20, as illustrated in Fig. 43.

5

Another access device similar to that of Figs. 40 to 42 is illustrated in Figs. 44 to 46. In this case the flexible connection is provided by a corrugated tube 80.

10 A further access device of the invention is illustrated in Figs. 47 to 49. It will be noted that in this case a proximal inner ring 85 is undersized with respect to the receiver of an outer proximal ring 86. As illustrated in Fig. 49 when the instrument 3 is tilted off its vertical axis, the valve housing 27 can move due to this clearance without compromising the seal between the lipseal 70 and the instrument 3. Thus, 15 off-axis movement is accommodated without compromising the seal to the instrument 3.

20

Referring to Figs. 50 to 55 a self locking retractor of the type described above has a valve / seal provided by a body of gelatinous elastomeric material 90 which in this case is simply illustrated as extending across the inner proximal ring 25. The gelatinous elastomeric body 90 may have a pin hole 91 for ease of insertion of an instrument 3. The gel 90 deforms as the instrument 3 is inserted. If there is a pre-made pinhole 91, this facilitates entry. If there is no pinhole, the leading edge of the instrument 3 will eventually pierce the material. In use the gel 90 seals around the instrument shaft 5. Upon withdrawal of the instrument 3, the hole 91 in the gel 90 self-seals closed.

25

30 Figs. 56 to 58 illustrate the use of a gelatinous elastomeric seal / valve 95 as described above with reference to Figs. 50 to 55 with a valve housing 96 of the type described above.

Referring to Figs. 58(a)(i) to 58(c)(iii) there is illustrated another instrument access device 500 according to the invention, which is similar to the instrument access device of Figs. 56 to 58, and similar elements in Figs. 58(a)(i) to 58(c)(iii) are assigned the same reference numerals.

5

In this case the seal / valve housing of the device 500 comprises a housing body 300 and a housing cap 301.

The housing body 300 comprises a reception space 305 for receiving the gelatinous elastomeric seal 302 with the pinhole opening 303 extending therethrough. As illustrated in Fig. 58(a)(ii), the reception space 305 has an open proximal end which acts as an inlet through which the seal 302 may be located in the reception space 305. The housing body 300 comprises a plurality of upstanding male pins 304 which may be co-operatively associated with corresponding female openings 306 in the seal 302 to control location of the seal 302 in the reception space 305.

In this case the seal 302 is formed separately to the housing body 300. For example, the seal 302 may be formed by casting.

20 The housing body 300 is mounted to the proximal ring member 25 in a snap-fit arrangement (Fig. 58(c)(i)). When mounted to the proximal ring member 25, the distal end of the housing body 300 extends distally of the proximal ring member 25 and the housing body 300 is located radially inwardly of the proximal ring member 25.

25

The housing cap 301 is mounted to the housing body 300 in a snap-fit arrangement to partially close the proximal end inlet of the reception space 305. In this manner the housing cap 301 retains the seal 302 in position in the reception space 305. The housing cap 301 is substantially annular in shape with a central opening to facilitate access to the seal 302 in the reception space 305.

30

The housing body 300 may be mounted to the proximal ring member 25 before or after retraction of a wound opening.

In use, a wound opening 13 is made in the abdominal wall 2 and the distal O-ring 11 is inserted through the wound opening 13 into the wound interior. The seal housing and the proximal ring members 24, 25 are located externally of the wound opening 13 (Fig. 58(c)(ii)). The seal housing may be mounted to the inner proximal ring member 25 before or after insertion of the distal O-ring 11 through the wound opening 13.

10

To retract laterally the sides of the wound opening 13, the outer proximal ring member 24 is pushed distally, which causes the inner proximal ring member 25 and the seal housing to move distally, while the free, proximal end of the sleeve 12 is pulled proximally (Fig. 58(c)(iii)). An instrument may then be inserted through the pinhole opening 303 of the seal 302 to access the wound interior in a sealed manner.

15

The excess proximal portion of the sleeve 12 may be removed, for example by cutting away, after retraction of the wound opening 13, as illustrated in Fig. 58(c)(iii).

20

Alternatively the excess proximal portion of the sleeve 12 may be sealed to the outer proximal ring member 24 or to the housing body 300, for example using a clamp, to enhance the sealing effect of the instrument access device 500.

25

As noted previously, the instrument access device 500 is particularly suitable for retracting relatively small wound openings, for example wound openings having a diameter of less than 40mm, such as between 3mm and 35mm, typically between 5mm and 12mm. The instrument access device 500 is thus suitable to facilitate access of relatively small laparoscopic instruments, for example instruments having a diameter of less than 40mm, such as between 3mm and 35mm, typically between 5mm and 12mm.

30

Because of the relatively small size of the instrument access device 500, the wound opening 13 may be retracted by moving the sleeve 12 relative to the proximal ring members 24, 25 in a single actuation step. In particular the entire circumference of the sleeve 12 may be gripped by a single hand of a user, and opposite sides of the outer proximal ring member 24 may be gripped by the other hand of the user. The sleeve 12 may then be pulled proximally while the outer proximal ring member 24 is pushed distally to retract the wound opening 13 in a single actuation step.

It will be appreciated that more than one opening may be provided extending through the seal 302. For example, two pinhole openings may be provided, spaced-apart from one another, extending through the seal 302. In this case access may be gained to the wound interior with more than one instrument by extending an instrument through each opening in the seal 302.

15

Figs. 58(d) and 58(e) illustrate a seal / valve housing of another instrument access device according to the invention, which is similar to the seal / valve housing of Figs. 58(a)(i) to 58(c), and similar elements in Figs. 58(d) and 58(e) are assigned the same reference numerals.

20

In this case, the housing body 300 has an insufflation lumen 313 extending therethrough, the seal 302 has an insufflation lumen 312 extending therethrough, and the housing cap 301 has an insufflation lumen 311 extending therethrough. As illustrated in Fig. 58(e), the three insufflation lumena 313, 312, 311 are in alignment, and the longitudinal axis of each insufflation lumen 313, 312, 311 is parallel to the longitudinal axis of the instrument access device. An insufflation tube 310 may be inserted into the insufflation lumen 311 of the housing cap 301 to insufflate a wound interior (Fig. 58(e)).

25

In Figs. 58(f) and 58(g) there is illustrated another instrument access device 320 according to the invention comprising a seal / valve housing, which is similar to the

seal / valve housing of Figs. 58(d) and 58(e), and similar elements in Figs. 58(f) and 58(g) are assigned the same reference numerals.

In this case the instrument access device 320 comprises a temporary insufflation seal 321 fixed to the housing cap 301 at the proximal end of the housing cap insufflation lumen 311. The seal 321 seals the insufflation lumena 311, 312, 313 to prevent discharge of gas from the insufflated wound interior. The seal 321 may be pierced by a pointed distal end of the insufflation tube 310, for example if it is required to further insufflate the wound interior.

10

Once the access device 320 has been fired, and the excess sleeve 12 removed, the insufflation tube 310 can be connected by piercing the temporary seal 321 which maintains pneumoperitoneum.

15

The distal ring 11 of the device 320 is configured to be sufficiently flexible for ease of insertion of the distal ring 11 through the wound opening 13 prior to retraction. The distal ring 11 is also configured to be sufficiently rigid to anchor the device 320 in position in the wound opening 13 during retraction of the wound opening 13. The sleeve 12 has sufficient strength to facilitate transmission of the retraction force required to retract the wound opening 13.

20

It will be appreciated that the distal ring may be provided in any suitable configuration for ease of insertion through the wound opening 13 prior to retraction. For example at least part of the distal ring 11 may be provided in the form of a shape-memory material, such as Nitinol.

25

Referring to Figs. 58(h) and 58(i) there is illustrated a further instrument access device 330 according to the invention, which is similar to the instrument access device 320 of Figs. 58(f) and 58(g), and similar elements in Figs. 58(h) and 58(i) are assigned the same reference numerals.

30

In this case the instrument access device 330 comprises an intermediate connector 331 to connect the insufflation tube 310 in communication with the insufflation lumena 311, 312, 313. As illustrated the intermediate connector 331 is substantially "L"-shaped. In this manner the insufflation tube 310 may be connected in communication with the insufflation lumena 311, 312, 313 with the longitudinal axis A-A of the insufflation tube 310 at the distal end of the insufflation tube 310 substantially perpendicular to the longitudinal axes B-B of the insufflation lumena 311, 312, 313.

10 The access device 330 has an alternative insufflation connection means in the form of a tube 331 with an angle and a valve connector. The valve connector may be closed when not connected to the insufflation supply 310 (Fig. 58(h)).

15 Figs. 59 to 61 illustrate a still further instrument access device of the invention which in this case has a sheet of film material 100 extending across the inner proximal ring 25. A valve housing 101 is mounted to an outer proximal ring 104, for example by snap fitting and a gelatinous elastomeric seal 102 seals to an instrument 3 which in use pierces through the gel 102 and through the proximal film 104.

20 Referring to Figs. 62 to 64 there is illustrated another instrument access device with valve(s) 20. Again, as in some previous embodiments the sleeve 13 is pulled upwardly on deployment, leaving the valve 20 free of sleeve material.

25 Referring to Figs. 65 to 70 there is illustrated another instrument access device 200 according to the invention, which is similar to the devices of Figs. 13 to 16 and Figs. 56 to 58, and similar elements in Figs. 65 to 70 are assigned the same reference numerals.

30 In this case the sleeve 12 is fixedly attached at one end to the inner proximal ring 25, extends distally in a first layer to the distal ring 11, is looped around the distal ring

11, extends proximally in a second layer to the proximal rings 25, 24, and passes proximally between the inner proximal ring 25 and the outer proximal ring 24.

5 The tubular member 40 is integrally formed with the housing 27, and the housing 27 is mounted to the inner proximal ring 25.

10 The seal / valve 95 is provided in the form of a gelatinous elastomeric material which is mounted to the housing 27. The seal / valve 95 has a pinhole opening 196 extending therethrough through which an instrument 3 may be extended. The opening 196 is biased towards a closed configuration.

15 A lumen 150 extends through the tubular member 40 through which an instrument 3 may be extended. The tubular member 40 has a distal opening 142 at a distal end 141 of the tubular member 40.

20 The tubular member 40 has a skived distal end 141, in this case. In particular the plane of the distal opening 142 is inclined relative to the longitudinal axis of the tubular member 40, for example inclined at an angle of 45°. This configuration results in a low-profile, tapered leading end for the tubular member 40 which tapers to a point 143.

25 The benefit of having the truncated / skived tubular member is that the point 143 on the leading edge of the truncated member 40 more easily finds the narrow, unretracted hole of the incision 1. As it advances downwards, the taper 141 gradually spreads the incision 1 open.

30 The distal end 141 of the tubular member 40 is truncated, e.g. at an angle of 45°. This yields a narrow leading edge 143 on the tubular member 40 which more easily locates the incision 1, through which the distal ring 11 and the sleeve 12 have already been passed. Furthermore the taper will aid the retraction of the incision 1 as it advances downwards.

The length of the tubular member 40 relative to the abdominal wall thickness may vary.

- 5 Upon pulling of the sleeve 12 proximally and pushing of the tubular member 40 distally, the incision 1 is retracted by a combined action of the skived distal end 141 of the tubular member 40 forcing the sides of the incision 1 apart and of the sleeve 12 pulling the sides of the incision 1 laterally, as illustrated in Fig. 69. The skived distal end 141 of the tubular member 40 assists in guiding the point 143 of the
10 tubular member 40 to the unretracted incision 1, for subsequent advancement of the tubular member 40 through the incision 1.

After insertion of the tubular member 40 into the incision 1, the point 143 of the tubular member 40 is located within the wound interior distally of the incision 1.
15 However it will be appreciated that the length of the tubular member 40 may be adjusted to suit the particular anatomy of a patient and/or to suit the preferences of a surgeon. In certain cases after insertion of the tubular member 40 into the incision 1, the distal end of the tubular member 40 may be located within the incision 1 proximally of the wound interior.

- 20 Figs. 70(a) to 70(f) illustrate another instrument access device 400 according to the invention, which is similar to the instrument access device 200 of Figs. 65 to 70, and similar elements in Figs. 70(a) to 70(f) are assigned the same reference numerals.

- 25 In this case the inner proximal ring 25 has a seal 401 extending across the inner proximal ring 25. The seal 401 prevents gas leakage from the insufflated wound interior when the wound opening has been retracted (Fig. 70(b)).

30 The housing 27 is mountable to and demountable from the inner proximal ring 25 in a snap-fit arrangement (Figs. 70(e) and 70(f)). Upon mounting of the housing 27 to

the inner proximal ring 25 after the wound opening has been retracted, the pointed tip 143 of the tubular member 40 pierces the seal 401 (Figs. 70(d) and 70(e)).

Mounting of the housing 27 to the inner proximal ring 25 proceeds in a manner similar to that described previously with reference to Figs. 26 to 28.

Figs. 70(a) to 70(f) illustrate a modular instrument access device 400. The gel valve 95 has been separated from the retractor base 25. It may be easier to introduce a cannulated gel housing 27 into an incision this way, rather than trying to do it at the same time as the retracting phase. Fig. 70(a) illustrates the disc of film 401 mounted in the proximal 'O' ring 25 to maintain pneumoperitoneum. When pneumoperitoneum has been established, the film 401 prevents pressure loss. Fig. 70(d) illustrates the leading tip 143 of the truncated cannula 40 beginning to pierce the disc of film 401. In Fig. 70(e) the disc of film 401 has been pierced. Fig. 70(f) illustrates the snap-fit connection between the gel housing 27 and the proximal 'O' ring 25 of the retractor 400.

Referring to Figs. 70(g) to 70(i) there is illustrated another instrument access device 410 according to the invention, which is similar to the instrument access device 400 of Figs. 70(a) to 70(f), and similar elements in Figs. 70(g) to 70(i) are assigned the same reference numerals.

In this case, the sleeve 12 extends distally from the inner proximal ring 25 to the distal ring 11, loops around the distal ring 11, extends proximally from the distal ring 11 to the proximal rings 24, 25, extends between the inner proximal ring 25 and the outer proximal ring 24, and extends proximally to the housing 27 to which the sleeve 12 is fixedly attached. Before the housing 27 is mounted to the inner proximal ring 25, any gas leakage from the wound interior through the retracted wound opening is contained within the sleeve 12, and thus pneumoperitoneum is maintained (Fig. 70(h)). No seal is provided, in this case, extending across the inner proximal ring 25.

Figs. 70(g) to 70(i) illustrate another modular instrument access device, the gel housing 27 with the cannula 40 is fixed to the proximal end of the sleeve 12. A snap fit connection is used to secure the gel housing 27 to the proximal 'O' ring 25 of the retractor 410.

5

In Figs. 71 to 73 there is illustrated another instrument access device 340 according to the invention, which is similar to the instrument access device 200 of Figs. 65 to 70, and similar elements in Figs. 71 to 73 are assigned the same reference numerals.

10 In this case no tubular member is provided extending distally from the housing 27.

The outer proximal ring 341 is releasably mounted to the inner proximal ring 25, in this case. In particular the outer proximal ring 341 has a curved engagement surface which extends in cross-section for a quarter-revolution, as illustrated in Figs. 71 and 15 72. The curved engagement surface rests upon the proximal side of the inner proximal ring 25, with the sleeve 25 extending between the inner proximal ring 25 and the outer proximal ring 341, to mount the outer proximal ring 341 to the inner proximal ring 25. This arrangement enables the outer proximal ring 341 to be removed after retraction of the wound opening (Fig. 73).

20

In use, the distal ring 11 is inserted through the wound opening into the wound interior, and the inner proximal ring 25 is located externally of the wound opening with the sleeve 12 extending from the distal ring 11 to the inner proximal ring 25 in the double-layer arrangement. The outer proximal ring 341 is then mounted to the inner proximal ring 25 with the sleeve 12 extending therebetween (Fig. 71).
25

The sleeve 12 is then pulled proximally while pushing the outer proximal ring 341 distally. The outer proximal ring 341 engages the inner proximal ring 25 and thus the housing 27, the inner proximal ring 25 and the outer proximal ring 341 all move 30 distally to retract laterally the sides of the wound opening (Fig. 72).

After retraction of the wound opening, the outer proximal ring 341 may be removed while the distal ring 11, the inner proximal ring 25 and the sleeve 12 remain in position retracting the wound opening (Fig. 73).

- 5 The outer proximal ring 341 acts as a guide to guide movement of the inner proximal ring 25 relate to the sleeve 12. In this case, the outer proximal ring 341 does not act as a locking mechanism to lock the sleeve 12 with the wound retracted.

10 Figs. 71 to 73 show how only half an outer proximal ring 341 is needed to provide support when firing the instrument access device 340. The device 340 functions to retract the wound opening without the outer proximal ring 341 (Fig. 73).

15 The access ports of the invention can be used in a number of ways. In one method the retractor is used as described above, the distal inner ring 11 being inserted into an incision 1, the outer ring being slid to controllably radially expand the incision 1. The retractor may then be locked in position. If necessary, the outer ring can be moved further downwardly to create a larger incision.

20 In some arrangements an instrument may be bent manually outside the body and the bent instrument is delivered through the access port to readily access the operative site.

25 In a further embodiment an instrument is inserted into the access port and the surgeon uses the abdominal wall itself to bend the instrument and then insert the bent section further into the abdomen.

It will be appreciated that the instrument access device of the invention may have a valve or seal in the form of a gelatinous elastomeric material, or in any other suitable form, for example a lip seal.

The access ports of the invention have at least some of the following advantages:

Controlled Radial Expansion

1. Greater access using smaller incision
2. Can vary incision size as need be (e.g. specimen removal during lap col.)

Greater Sealing Capabilities

1. No gas leakage from the wound margins
2. Cannot be inadvertently pulled out of the incision
3. Will seal any incision and never require secondary sealing method (suture, Hassan port, etc.)

Eliminate Intra-abdominal Profile

1. Gives back more working space in the abdomen (critical in pelvic surgery)
2. Perineal access for operations such as Radical Prostatectomy.

Protection of Wound from Infection and Cancer Seeding

1. Tight seal with no "chimney stack" effect
2. Upon removal all areas of potential contamination are isolated from the incision

20

Reduced Extra-abdominal Profile

1. Will increase the effective working length of an instrument
2. Greater working area outside the abdomen

25

Increase the freedom of movement of conventional laparoscopic instruments

The instrument access device of the invention enables a surgeon to gain access to a wound interior using an instrument while minimising the incision size at the wound interior to minimise the possibility of post-operative herniation.

30

The retractor of the invention may be inserted through the abdominal wall as described below. An initial thin incision may be made in the abdominal wall and an inner distal ring of the retractor may be attached to an insertion tool. The ring is flexible and can be stretched or bent for ease of insertion through the incision.

5

In some cases the ring may be inserted through the incision using a blunted or round-nosed obturator tool.

Alternatively the ring may be inserted using an obturator/trocår tool with a leading cutting blade. In this case the tool itself makes an incision in the abdominal wall, allowing the distal ring of the retractor to be delivered and deployed.

Further means and methods suitable for introducing the instrument access device of the invention into a wound opening, and suitable for withdrawing the instrument access device of the invention from a wound opening are described in International patent application published under Nos. WO 2004/026153, WO 2004/030547, WO 2004/054456, and WO 2005/009257, the relevant contents of which are incorporated herein by reference.

20 The invention is not limited to the embodiments hereinbefore described, with reference to the accompanying drawings, which may be varied in construction and detail.

25

Claims

1. An instrument access device comprising: -

5 a distal anchoring member for insertion into a wound interior;

an elongate member extending proximally from the distal anchoring member to retract laterally the sides of a wound opening; and

10 an instrument working channel through which an instrument may extend to access the wound interior.

2. An access device as claimed in claim 1 wherein the device comprises a proximal member for location externally of a wound opening.

15

3. An access device as claimed in claim 2 wherein the proximal member comprises a ring member.

4. An access device as claimed in claim 2 or 3 wherein the proximal member

20

comprises a proximal inner element and a proximal outer element.

5. An access device as claimed in claim 4 wherein the elongate member is led between the proximal inner element and the proximal outer element.

25

6. An access device as claimed in claim 4 or 5 wherein the proximal inner element and/or the proximal outer element comprises a ring element.

7. An access device as claimed in any of claims 4 to 6 wherein the proximal outer element is mounted to the proximal inner element.

30

8. An access device as claimed in claim 7 wherein the proximal outer element is demountable from the proximal inner element.
9. An access device as claimed in claim 7 or 8 wherein the proximal outer element comprises an engagement surface for resting upon the proximal inner element to mount the proximal outer element to the proximal inner element.
10. An access device as claimed in claim 9 wherein the engagement surface comprises a curved surface.
11. An access device as claimed in claim 10 wherein the engagement surface extends in cross-section for substantially a quarter-revolution.
12. An access device as claimed in any of claims 9 to 11 wherein the engagement surface is configured to engage a proximal side of the proximal inner element.
13. An access device as claimed in any of claims 1 to 12 wherein the device comprises a clamp for clamping the instrument working channel in position.
14. An access device as claimed in claim 13 wherein the clamp is configured to clamp the elongate member to the instrument working channel.
15. An access device as claimed in claim 13 or 14 wherein the clamp comprises a proximal clamp.
16. An access device as claimed in any of claims 13 to 15 wherein the clamp is defined by the proximal outer element and the proximal inner element.
17. An access device as claimed in claim 16 wherein the proximal outer element comprises a proximal outer ring.

18. An access device as claimed in claim 16 or 17 wherein the proximal inner element comprises a proximal inner ring.
19. An access device as claimed in claim 16 or 17 wherein the proximal inner element is defined by a portion of the instrument working channel.
5
20. An access device as claimed in any of claims 1 to 19 wherein the device comprises at least one instrument seal or valve.
- 10 21. An access device as claimed in claim 20 wherein the seal or valve comprises a gelatinous elastomeric material.
22. An access device as claimed in claim 20 or 21 wherein the seal or valve comprises at least one opening extending therethrough through which an
15 instrument may be extended.
23. An access device as claimed in claim 22 wherein the opening is biased towards a closed configuration.
- 20 24. An access device as claimed in claim 22 or 23 wherein the opening comprises a pinhole opening.
25. An access device as claimed in claim 20 or 21 wherein the seal or valve is piercable to create at least one opening extending therethrough through which an instrument may be extended.
25
26. An access device as claimed in claim 25 wherein the seal or valve is piercable by an instrument to create an opening extending therethrough.
- 30 27. An access device as claimed in any of claims 20 to 26 wherein the seal or valve comprises an insufflation lumen extending therethrough.

28. An access device as claimed in claim 27 wherein the longitudinal axis of the insufflation lumen is substantially parallel to the longitudinal axis of the device.

5

29. An access device as claimed in any of claims 1 to 28 wherein the device comprises a housing for an instrument seal or valve.

- 10 30. An access device as claimed in claim 29 wherein the housing comprises a reception space for receiving an instrument seal or valve.

31. An access device as claimed in claim 30 wherein the reception space has an inlet through which an instrument seal or valve may be located in the reception space.

15

32. An access device as claimed in claim 31 wherein the inlet faces proximally.

33. An access device as claimed in any of claims 30 to 32 wherein the housing comprises a retainer to retain an instrument seal or valve in the reception space.

20

34. An access device as claimed in claim 33 wherein the retainer comprises a cap for at least partially closing the inlet.

25

35. An access device as claimed in claim 33 or 34 wherein the retainer comprises an opening to facilitate access to an instrument seal or valve in the reception space.

36. An access device as claimed in claim 35 wherein the retainer is substantially annular in shape.

30

37. An access device as claimed in any of claims 29 to 36 wherein the housing comprises a locator to assist in locating a seal or valve in the reception space.
38. An access device as claimed in claim 37 wherein the locator comprises at least one male member for co-operative association with at least one corresponding female member.
5
39. An access device as claimed in any of claims 29 to 38 wherein the housing comprises an insufflation lumen extending therethrough.
10
40. An access device as claimed in claim 39 wherein the longitudinal axis of the insufflation lumen is substantially parallel to the longitudinal axis of the device.
15
41. An access device as claimed in claim 39 or 40 wherein the housing insufflation lumen is aligned with an insufflation lumen of an instrument seal or valve.
42. An access device as claimed in any of claims 39 to 41 wherein the device comprises an insufflation seal or valve for the insufflation lumen.
20
43. An access device as claimed in claim 42 wherein the insufflation seal or valve is provided at a proximal end of the insufflation lumen.
44. An access device as claimed in claim 42 or 43 wherein the insufflation seal or valve is pierceable by an insufflation tube.
25
45. An access device as claimed in any of claims 39 to 44 wherein the access device comprises an intermediate connector to connect the insufflation lumen in communication with an insufflation tube.
30

46. An access device as claimed in claim 45 wherein the intermediate connector is configured to connect an insufflation tube in communication with the insufflation lumen with the longitudinal axis of the insufflation tube at a distal end of the insufflation tube inclined relative to the longitudinal axis of the insufflation lumen.
5
47. An access device as claimed in claim 46 wherein the intermediate connector is configured to connect an insufflation tube in communication with the insufflation lumen with the longitudinal axis of the insufflation tube at a distal end of the insufflation tube substantially perpendicular to the longitudinal axis of the insufflation lumen.
10
48. An access device as claimed in any of claims 29 to 47 wherein the housing is mounted to the proximal member.
15
49. An access device as claimed in claim 48 wherein the housing is mounted to the proximal inner element.
50. An access device as claimed in claim 49 wherein the housing extends distally of the proximal inner element.
20
51. An access device as claimed in claim 49 or 50 wherein the housing is located radially inwardly of the proximal inner element.
52. An access device as claimed in any of claims 49 to 51 wherein the housing is demountable from the proximal inner element.
25
53. An access device as claimed in any of claims 49 to 52 wherein the device comprises a seal across the proximal inner element.
30

54. An access device as claimed in claim 53 wherein the seal is piercable by the housing and/or by the instrument working channel upon mounting of the housing to the proximal inner element.
- 5 55. An access device as claimed in any of claims 29 to 47 wherein the housing is formed integrally with the proximal inner element.
56. An access device as claimed in any of claims 29 to 47 wherein the housing defines the proximal inner element.
- 10 57. An access device as claimed in any of claims 29 to 47 wherein the device comprises a sleeve extending from the proximal inner element to the housing.
58. An access device as claimed in claim 57 wherein the sleeve is formed integrally with the elongate member.
- 15 59. An access device as claimed in any of claims 29 to 58 wherein the housing at least in part defines the instrument working channel.
- 20 60. An access device as claimed in any of claims 29 to 58 wherein the instrument working channel is mounted to the housing.
61. An access device as claimed in claim 60 wherein the instrument working channel is demountable from the housing.
- 25 62. An access device as claimed in any of claims 29 to 58 wherein the instrument working channel is formed integrally with the housing.
63. An access device as claimed in any of claims 1 to 62 wherein the instrument working channel is defined by a tubular member.

64. An access device as claimed in claim 63 wherein the tubular member is substantially rigid over at least part of its length.
- 5 65. An access device as claimed in claim 63 or 64 wherein the tubular member defines a lumen extending therethrough through which an instrument may be extended.
- 10 66. An access device as claimed in any of claims 63 to 65 wherein the tubular member has a distal opening at a distal end of the tubular member.
- 15 67. An access device as claimed in claim 66 wherein the distal opening is inclined relative to the longitudinal axis of the tubular member.
68. An access device as claimed in claim 67 wherein the plane of the distal opening is inclined relative to the longitudinal axis of the tubular member.
- 15 69. An access device as claimed in any of claims 63 to 68 wherein the tubular member has a low-profile leading end.
- 20 70. An access device as claimed in claim 69 wherein the leading end is tapered.
71. An access device as claimed in claim 70 wherein the leading end is tapered to a point.
- 25 72. An access device as claimed in claim 71 wherein the distal end of the tubular member is skived.
73. An access device as claimed in any of claims 2 to 72 wherein the instrument working channel is mounted to the proximal member.

74. An access device as claimed in claim 73 wherein the instrument working channel is mounted for controlled movement relative to the proximal member.
- 5 75. An access device as claimed in claim 73 or 74 wherein the device comprises a sleeve extending between the instrument working channel and the proximal member to mount the instrument working channel to the proximal member.
- 10 76. An access device as claimed in any of claims 1 to 75 wherein the elongate member comprises a sleeve.
- 15 77. An access device as claimed in claim 76 wherein at least a portion of the sleeve comprises two material layers.
78. An access device as claimed in claim 77 wherein the sleeve is wrapped around the distal anchoring member.
- 20 80. An access device as claimed in claim 76 wherein the sleeve comprises a single material layer.
81. An access device as claimed in claim 80 wherein an end of the sleeve is fixed to the distal anchoring member.
- 25 82. An access device as claimed in any of claims 2 to 81 wherein the elongate member extends from the distal anchoring member to at least the proximal member.
- 30 83. An access device as claimed in claim 82 wherein the elongate member is slidably movable over at least a portion of the proximal member.

84. An access device as claimed in claim 83 wherein the elongate member is slidably movable over the proximal inner element.
- 5 85. An access device as claimed in any of claims 82 to 84 wherein an end of the elongate member is fixed to the proximal member.
86. An access device as claimed in any of claims 82 to 84 wherein an end of the elongate member is fixed to the housing.
- 10 87. An access device as claimed in claim 85 wherein the elongate member is fixed to the proximal member at one end, the elongate member extends from the proximal member to the distal anchoring member to define an inner material layer, and the elongate member extends from the distal ring anchoring member to the proximal member to define an outer material layer.
- 15 88. An access device as claimed in any preceding claim wherein the distal anchoring member comprises a distal ring.
- 20 89. An access device as claimed in claim 88 wherein the distal ring is formed from an elastomeric material.
90. An access device as claimed in any preceding claim wherein the device comprises at least one proximal handle for manipulating the device, in situ.
- 25 91. An instrument access device comprising: -
 - a distal ring;
 - 30 a proximal ring;

a sleeve having a portion between the distal ring and the proximal ring that includes two material layers; and

an instrument seal or valve mounted to the proximal ring.

5

92. An access device as claimed in claim 91 wherein the sleeve is fixed to the proximal ring at one end, the sleeve extends from the proximal ring to the distal ring to define an inner material layer, and the sleeve extends from the distal ring to the proximal ring to define an outer material layer.

10

93. An access device as claimed in claim 92 wherein the sleeve is slidingly received over a portion of the proximal ring.

15

94. An access device as claimed in any of claims 91 to 93 wherein the proximal ring comprises an inner proximal ring member and an outer proximal ring member between which the sleeve is led.

95. An instrument access device comprising: -

20

a distal ring;

a proximal ring;

25

a sleeve having a portion between the distal ring and the proximal ring; and

an instrument seal or valve comprising a gelatinous elastomeric material for receiving an instrument.

30

96. An access device as claimed in claim 95 wherein the gelatinous elastomeric material has a pinhole to receive an instrument.

97. An instrument access device comprising:-

a distal anchoring member for insertion into a wound interior;

5

a proximal member for location externally of a wound opening;

a sleeve extending in two layers at least between the distal anchoring member and the proximal member; and

10

an instrument seal or valve comprising a gelatinous elastomeric material for receiving an instrument.

98. An instrument access device comprising:-

15

a distal anchoring member for insertion into a wound interior;

a proximal member for location externally of a wound opening;

20

an elongate member extending at least between the distal anchoring member and the proximal member;

the proximal member comprising a proximal inner element and a proximal outer element between which the elongate member is led; and

25

an instrument seal or valve mounted to the proximal inner element.

99. An instrument access device substantially as hereinbefore described with reference to the accompanying drawings.

30

100. A method of accessing a wound interior with an instrument, the method comprising the steps of: -

5 inserting a distal anchoring member through an incision, the distal anchoring member having an elongate member attached thereto;

presenting an instrument working channel member to the incision;

10 pulling the elongate member upwardly relative to the instrument working channel member to at least partially insert the instrument working channel member into the incision; and

inserting an instrument through the incision.

- 15 101. A method as claimed in claim 100 wherein the elongate member lies at least in part between the instrument working channel member and the walls of the incision.

20 102. A method as claimed in claim 100 or 101 wherein the incision is a laparoscopic incision.

25 103. A method as claimed in claim 102 wherein the sides of the incision are retracted to a diameter of less than 40 mm.

104. A method as claimed in claim 103 wherein the sides of the incision are retracted to a diameter of between 3 mm and 35 mm.

20 105. A method as claimed in claim 104 wherein the sides of the incision are retracted to a diameter of between 5 mm and 12 mm.

106. A method as claimed in any of claims 100 to 105 wherein the sides of the incision are retracted to a diameter substantially equal to a diameter of the instrument working channel member.

5 107. A method as claimed in any of claims 100 to 106 wherein the sides of the incision are at least partially retracted by insertion of the instrument working channel member into the incision.

10 108. A method as claimed in any of claims 100 to 107 wherein the sides of the incision are at least partially retracted by pulling of the elongate member upwardly relative to the instrument working channel member.

15 109. A method as claimed in any of claims 100 to 108 wherein the instrument is a laparoscopic instrument.

110. A method as claimed in claim 109 wherein the instrument has a diameter of less than 40 mm.

20 111. A method as claimed in claim 110 wherein the instrument has a diameter of between 3 mm and 35 mm.

112. A method as claimed in claim 111 wherein the instrument has a diameter of between 5 mm and 12 mm.

25 113. A method as claimed in any of claims 100 to 112 wherein after insertion of the instrument working channel member into the incision, the distal end of the instrument working channel member is located within the wound interior distally of the incision.

30 114. A method as claimed in any of claims 100 to 112 wherein after insertion of the instrument working channel member into the incision, the distal end of the

instrument working channel member is located within the incision proximally of the wound interior.

115. A method as claimed in any of claims 100 to 114 wherein the leading end of
5 the instrument working channel member is guided into the incision.

116. A method as claimed in claim 115 wherein the instrument working channel member is configured to automatically guide the leading end into the incision.

10 117. A method as claimed in any of claims 100 to 116 wherein the method comprises the step of sealing the incision.

118. A method as claimed in any of claims 100 to 117 wherein the method comprises the steps of insufflating the wound interior.

15 119. A method as claimed in claim 118 wherein the wound interior is insufflated after insertion of the instrument working channel member into the incision.

20 120. A method of accessing a wound interior with an instrument substantially as hereinbefore described with reference to the accompanying drawings.

121. A method of retracting a wound opening, the method comprising the steps of: -

25 inserting a distal anchoring member through a wound opening into a wound interior;

locating a proximal member externally of the wound opening with an elongate member extending at least between the distal anchoring member and the proximal member;

30 locating a guide member externally of the wound opening;

moving the guide member and the proximal member relative to the elongate member to retract laterally the sides of the wound opening; and

5

removing the guide member while the distal anchoring member, the proximal member and the elongate member remain in position retracting the wound opening.

10 122. A method as claimed in claim 121 wherein the elongate member is led between the proximal member and the guide member.

15 123. A method as claimed in claim 121 or 122 wherein the elongate member extends in two layers between the proximal member and the distal anchoring member.

124. A method as claimed in any of claims 121 to 123 wherein the proximal member is moved by pushing the guide member which engages the proximal member.

20

125. A method of retracting a wound opening, the method comprising the steps of: -

inserting a distal anchoring member through a wound opening into a wound interior;

25

locating a proximal member externally of the wound opening with an elongate member extending at least between the distal anchoring member and the proximal member;

30

moving the proximal member relative to the elongate member to retract laterally the sides of the wound opening; and

mounting a first seal or valve to the proximal member.

126. A method as claimed in claim 125 wherein the first seal or valve is mounted to
5 the proximal member after retraction of the wound opening.
127. A method as claimed in claim 125 wherein the first seal or valve is mounted to
the proximal member before retraction of the wound opening.
- 10 128. A method as claimed in any of claims 125 to 127 wherein the method
comprises the step of piercing a second seal.
129. A method as claimed in claim 128 wherein the second seal is pierced upon
mounting of the first seal or valve to the proximal member.
- 15 130. A method of retracting a wound opening, the method comprising the steps of:-

inserting a distal anchoring member through a wound opening into a
wound interior;
- 20 locating a proximal member externally of the wound opening with an
elongate member extending at least between the distal anchoring
member and the proximal member; and
- 25 by means of a single actuation step, moving the proximal member
relative to the elongate member to retract laterally the sides of the
wound opening.
- 30 131. A method as claimed in claim 130 wherein the entire circumference of the
proximal member is moved together relative to the entire circumference of the
elongate member.

132. A method as claimed in claim 130 or 131 wherein the proximal member is pushed distally relative to the elongate member.

5 133. A method as claimed in any of claims 130 to 132 wherein the elongate member is pulled proximally relative to the proximal member.

134. A method as claimed in any of claims 130 to 133 wherein the proximal member is moved relative to the elongate member in a single direction.

10 135. A method as claimed in claim 134 wherein the proximal member is moved relative to the elongate member in a direction substantially parallel to the longitudinal axis of the wound opening.

15 136. A method as claimed in any of claims 130 to 135 wherein the method comprises the step of gripping the proximal member.

137. A method as claimed in claim 136 wherein the proximal member is gripped by a single hand of a user.

20 138. A method as claimed in claim 137 wherein opposite sides of the proximal member are gripped by a single hand of a user.

139. A method as claimed in any of claims 130 to 138 wherein the method comprises the step of gripping the elongate member.

25 140. A method as claimed in claim 139 wherein the elongate member is gripped by a single hand of a user.

141. A method as claimed in claim 140 wherein the entire circumference of the
30 elongate member is gripped by a single hand of a user.

142. A method of retracting a wound opening substantially as hereinbefore described with reference to the accompanying drawings.

143. A method of retracting a wound opening, the method comprising the steps of:-

5

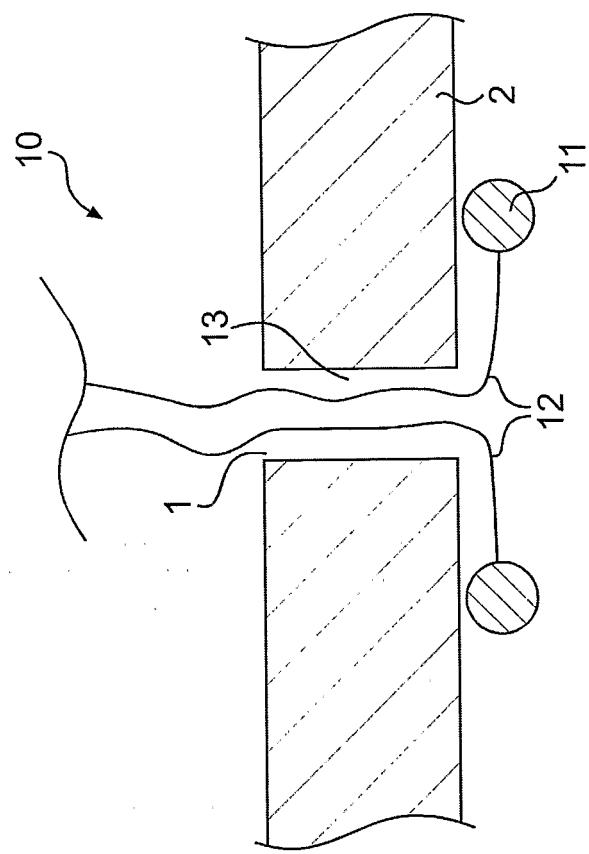
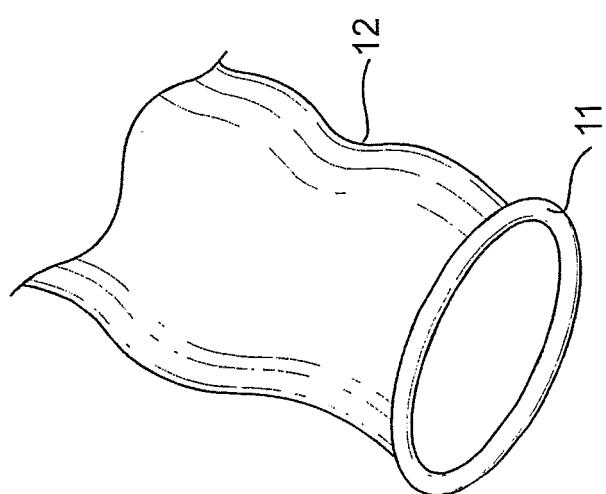
inserting a distal anchoring member through a wound opening into a wound interior;

10 locating a proximal member externally of the wound opening with an elongate member extending at least between the distal anchoring member and the proximal member; and

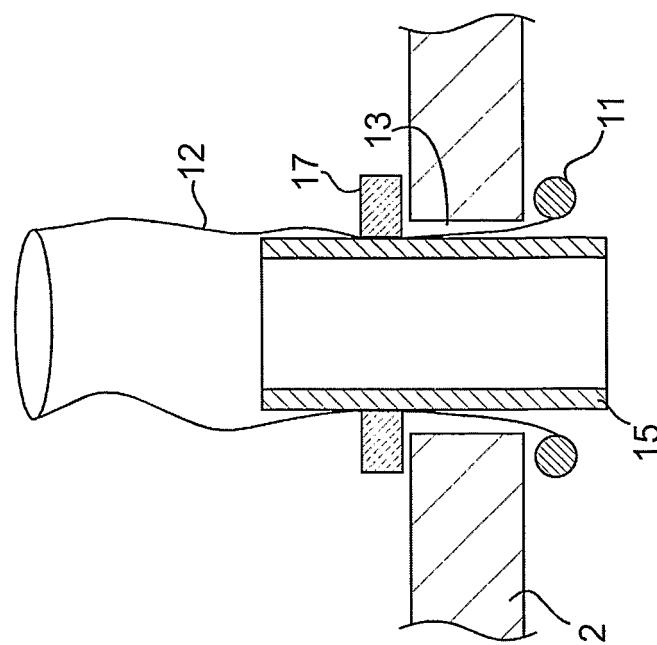
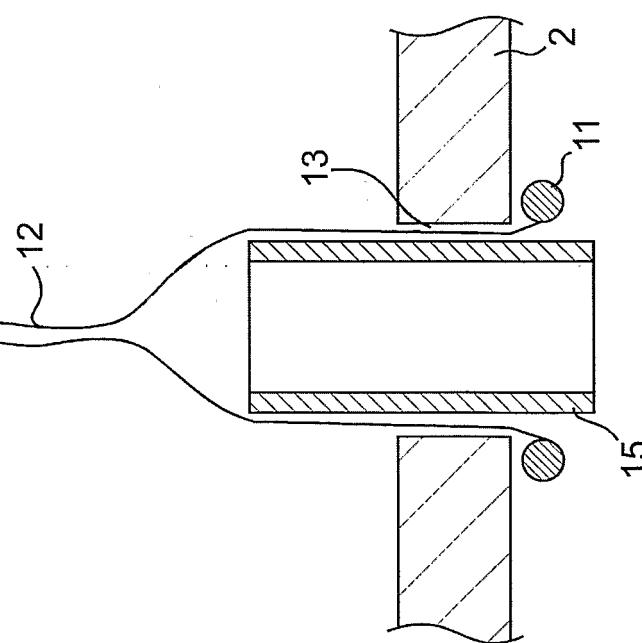
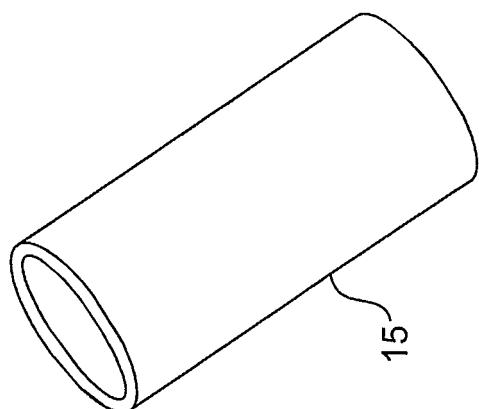
15 moving the entire periphery of the proximal member together relative to the entire periphery of the elongate member to retract laterally the sides of the wound opening.

20

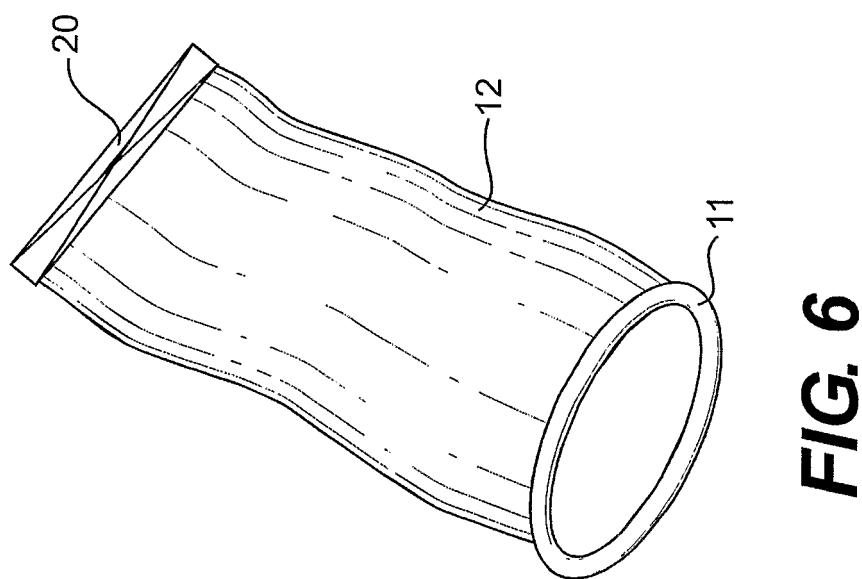
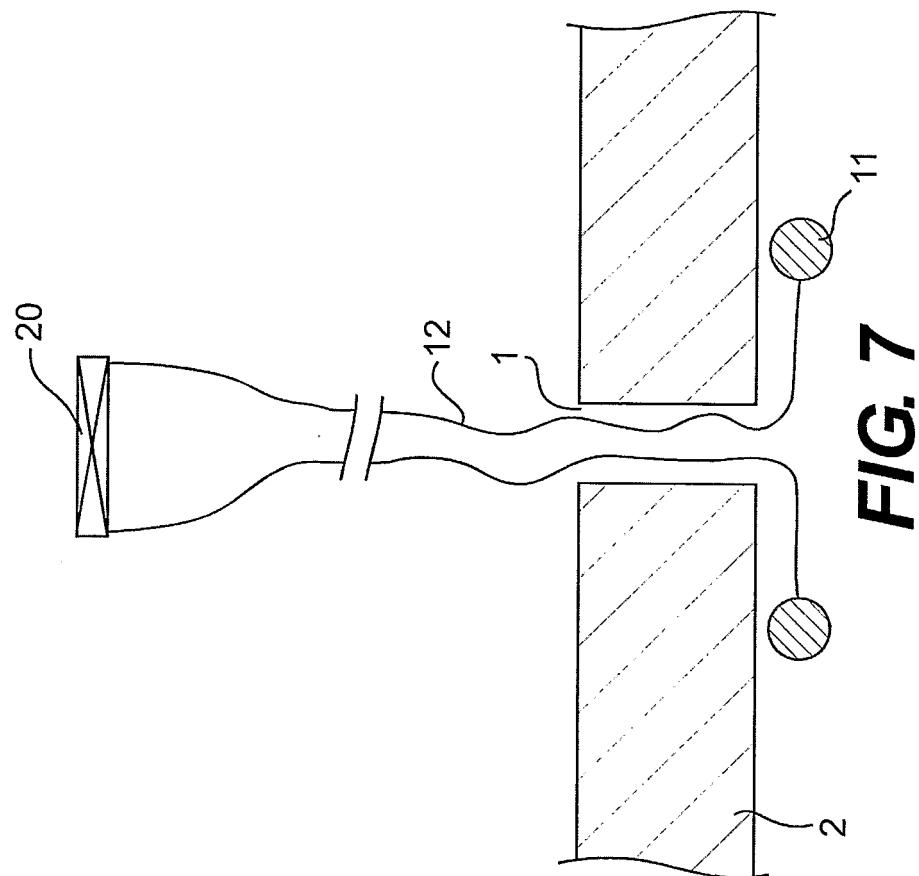
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**FIG. 2****FIG. 1**

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**FIG. 5****FIG. 4****FIG. 3**

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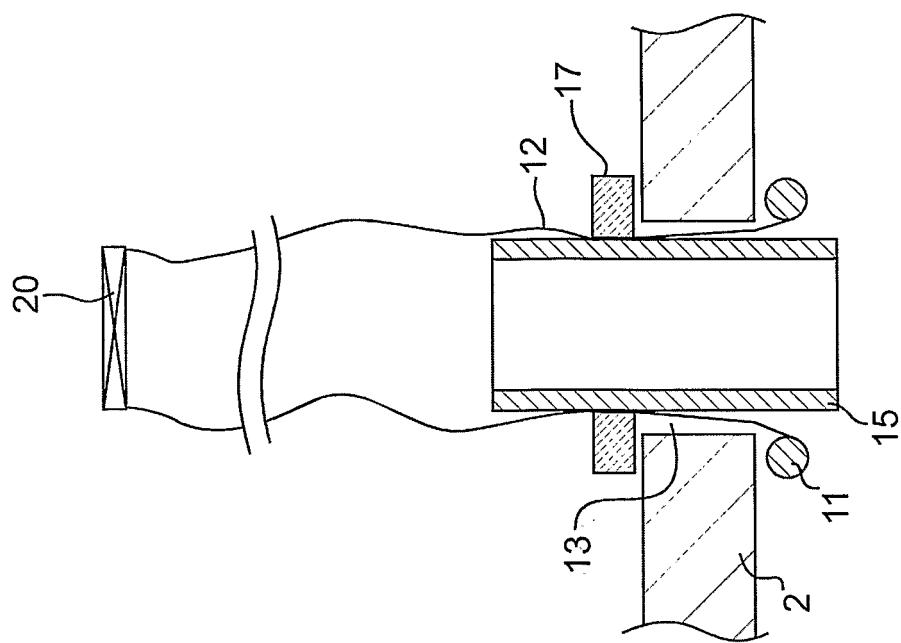


FIG. 9

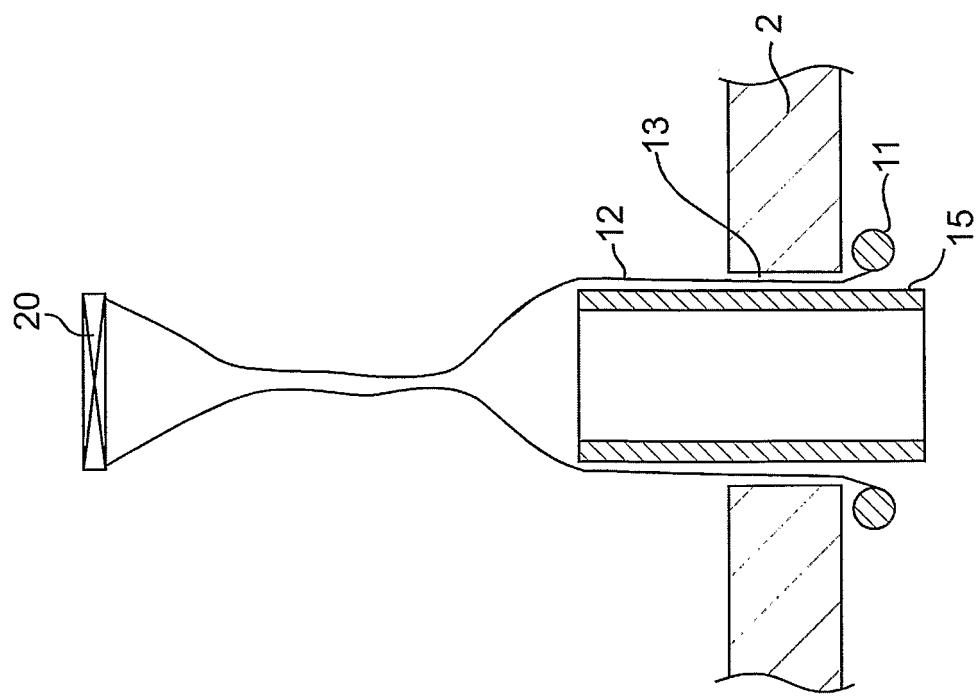
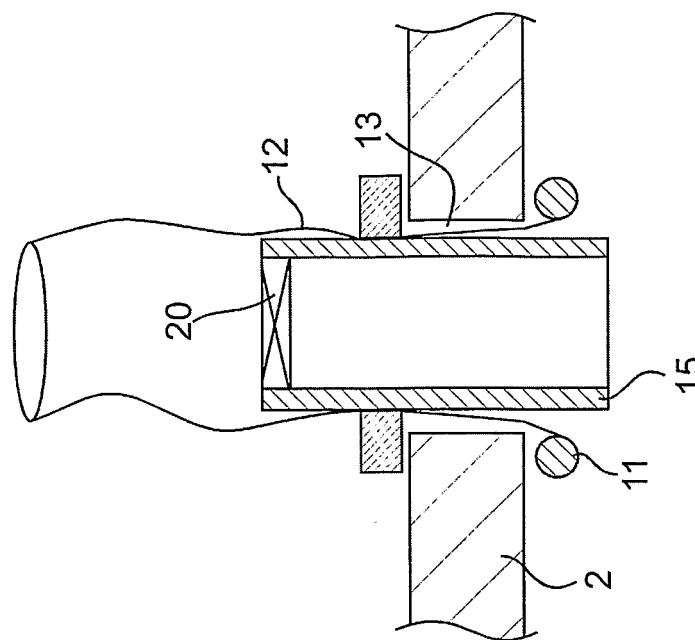
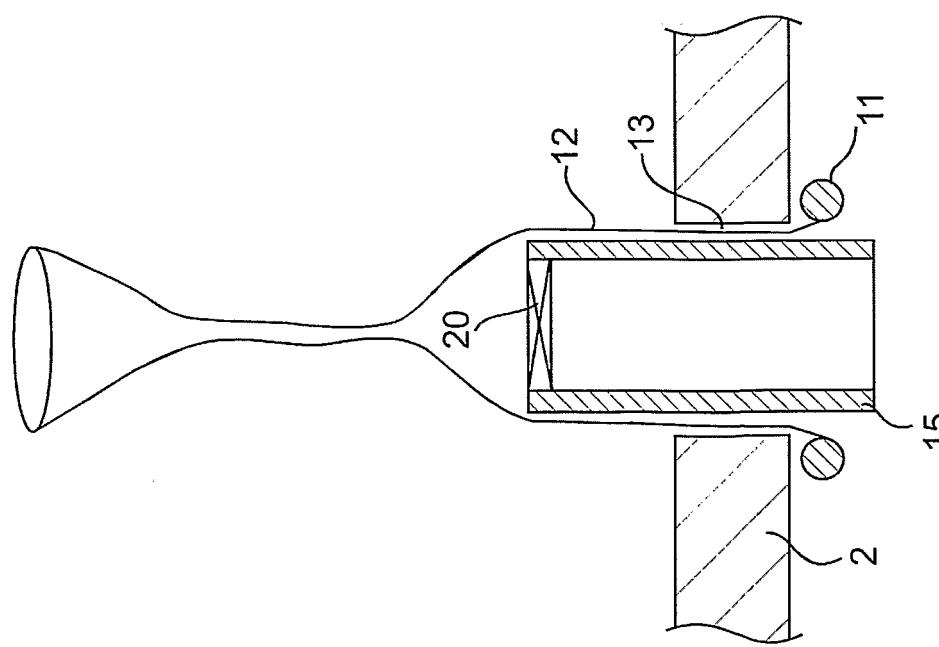
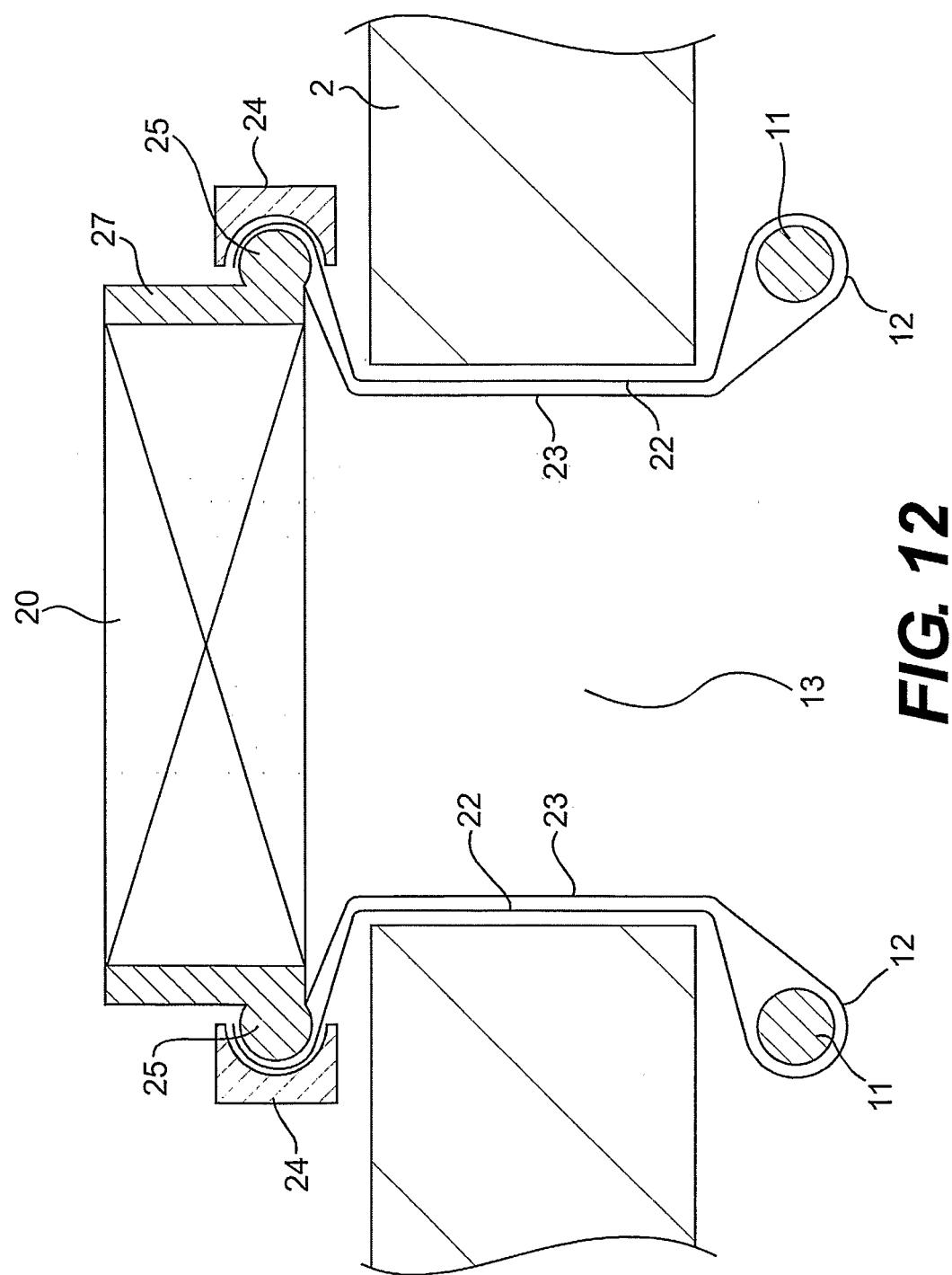


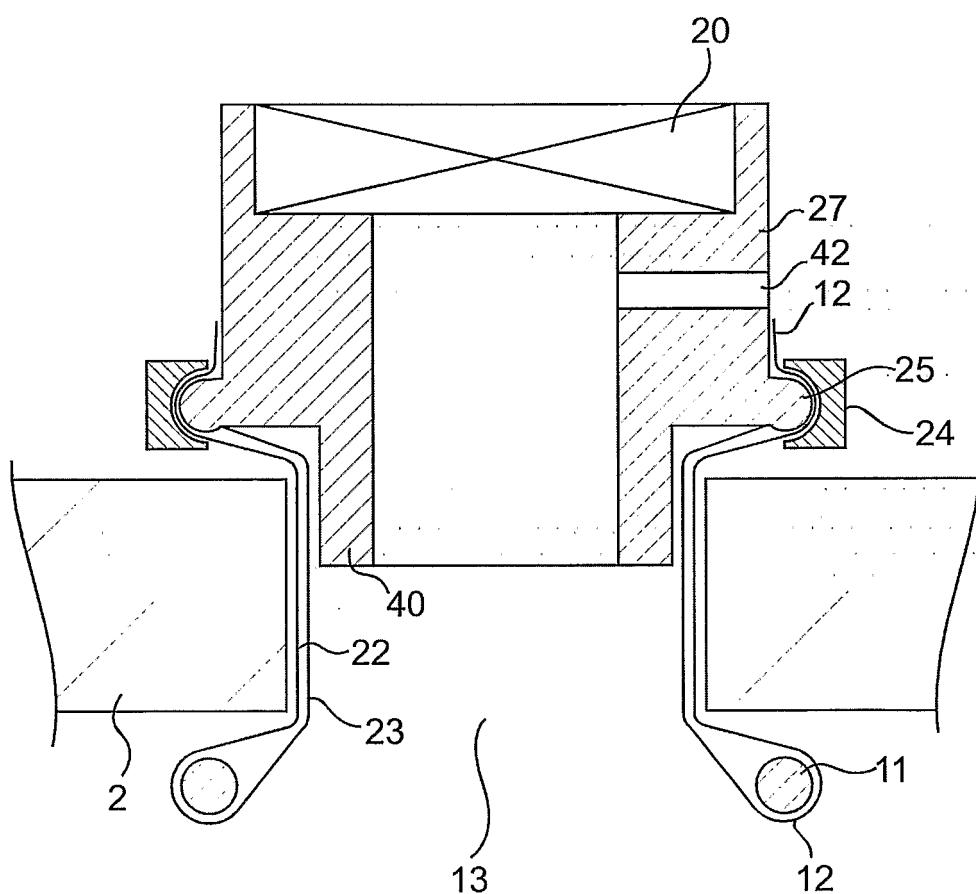
FIG. 8

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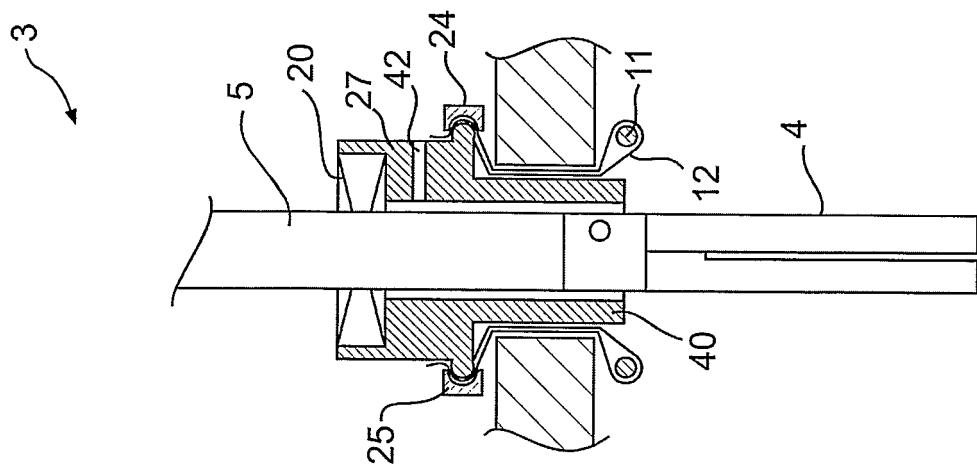
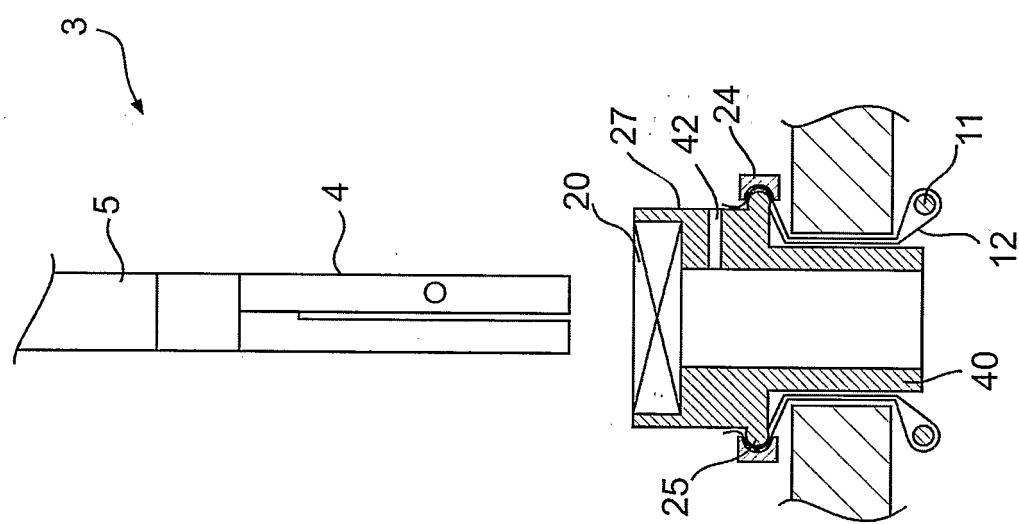
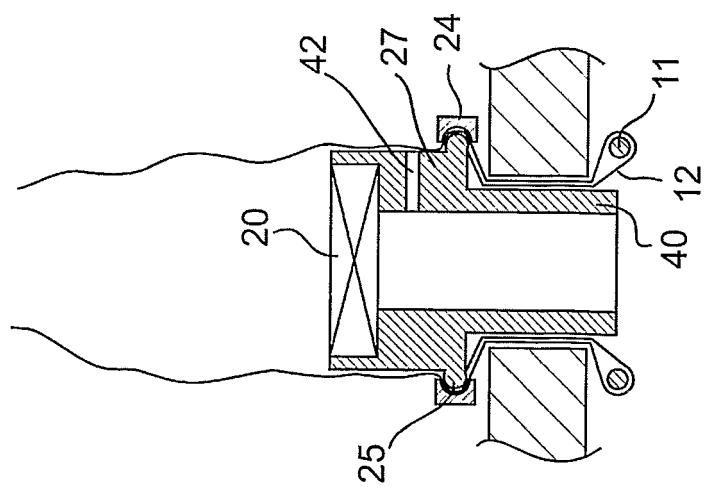
**FIG. 11****FIG. 10**

**FIG. 12**

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**FIG. 13**

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**FIG. 16****FIG. 15****FIG. 14**

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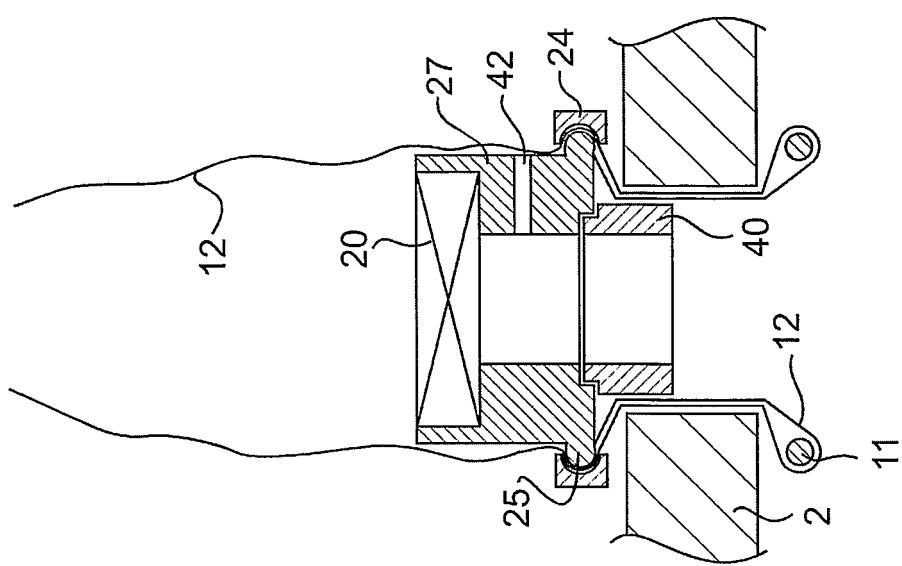


FIG. 19

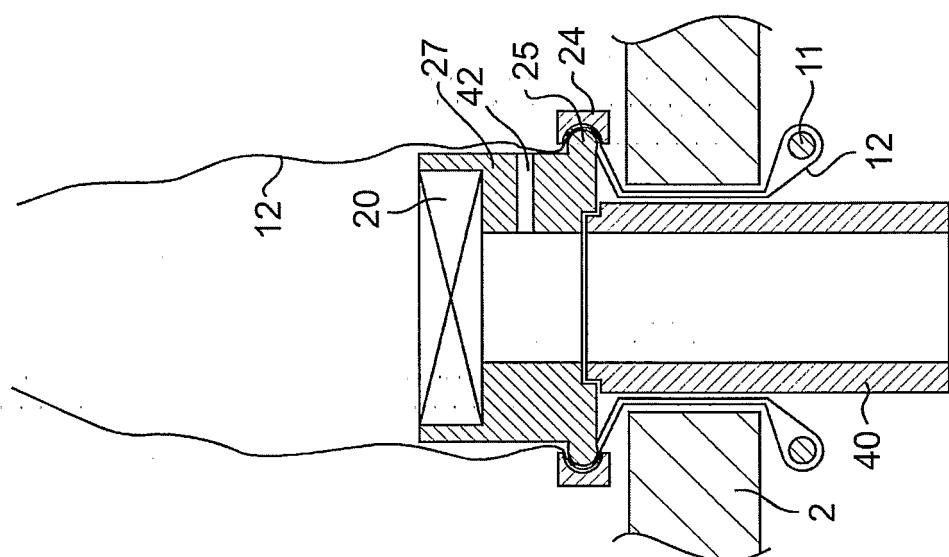


FIG. 18

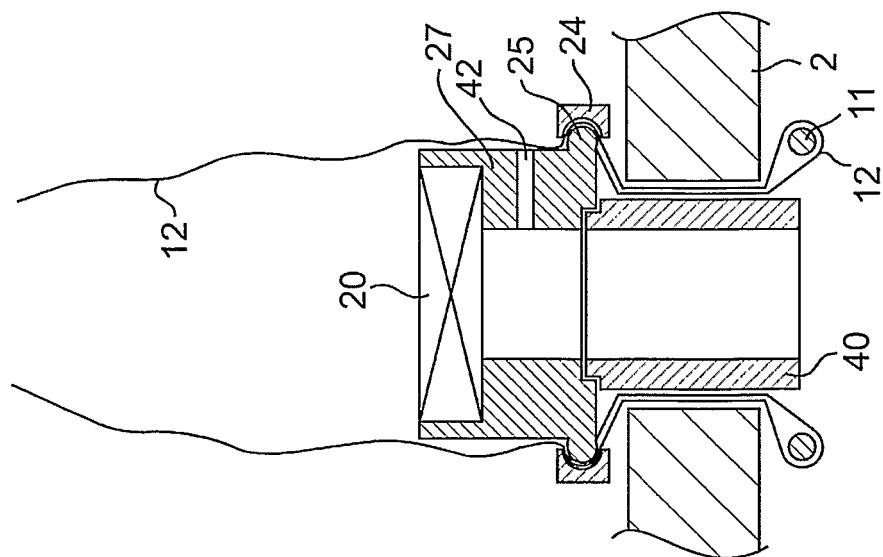
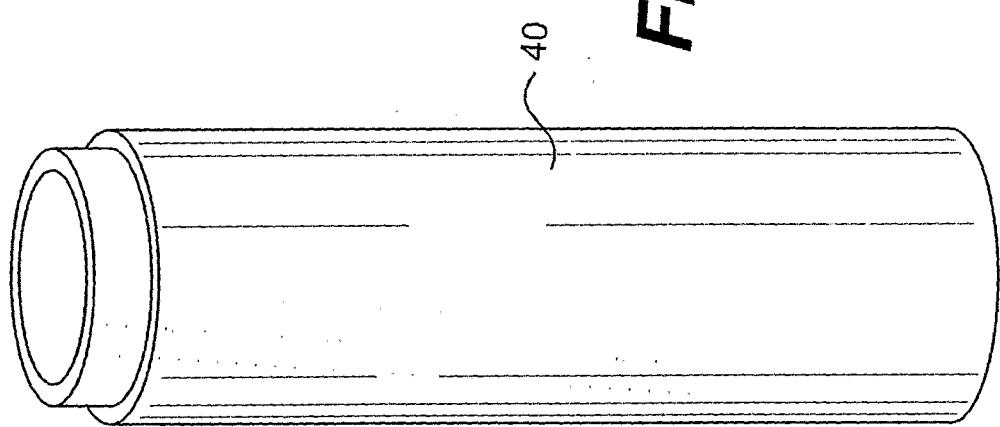
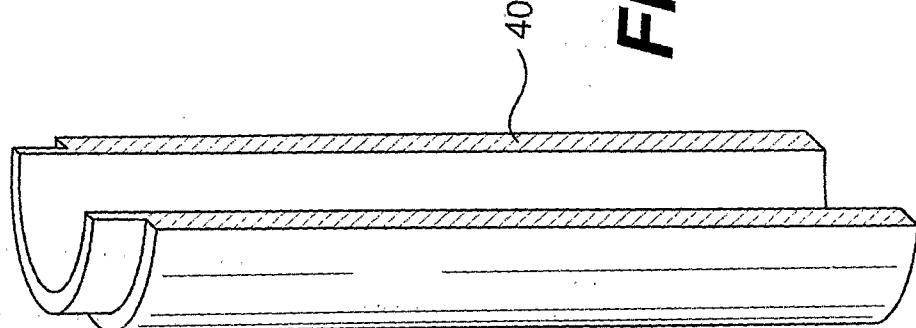


FIG. 17

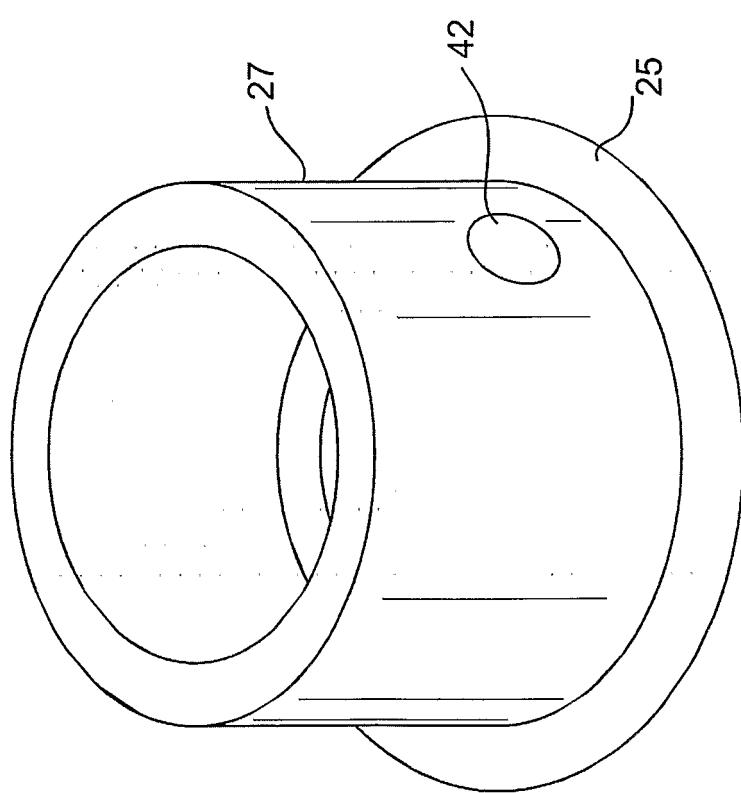
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FIG. 20

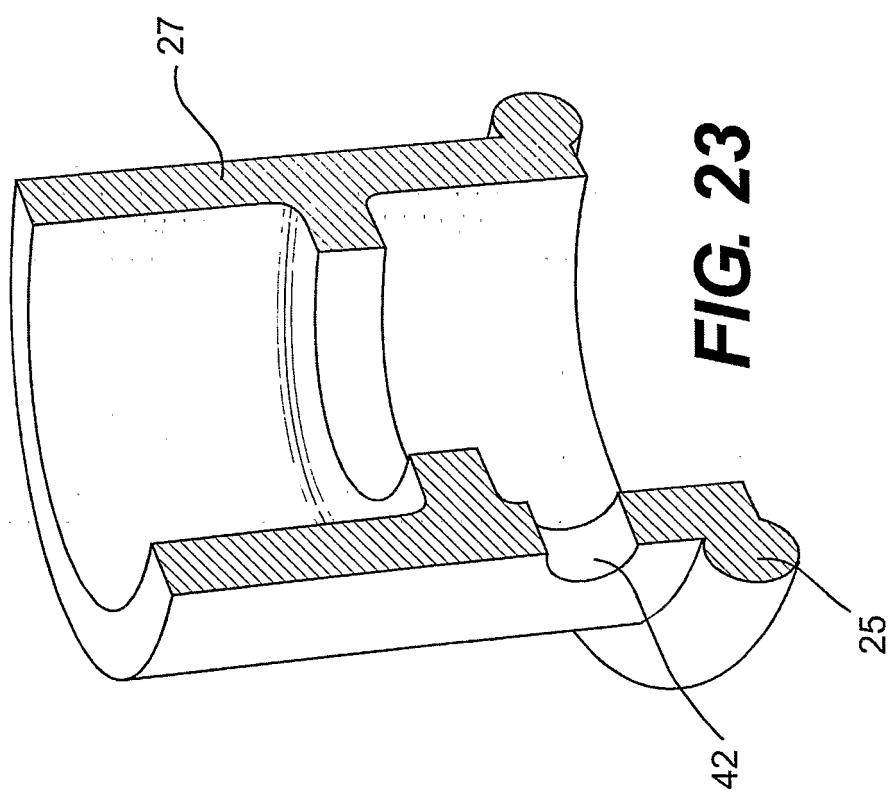
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FIG. 21

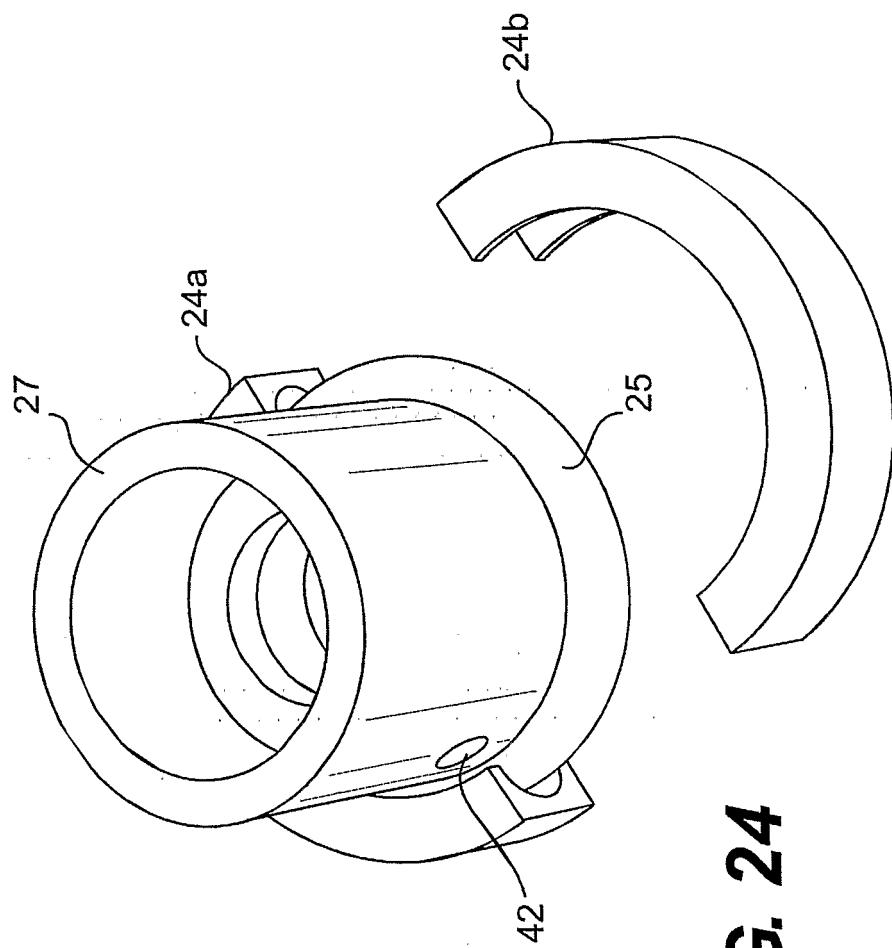
12/54

**FIG. 22**

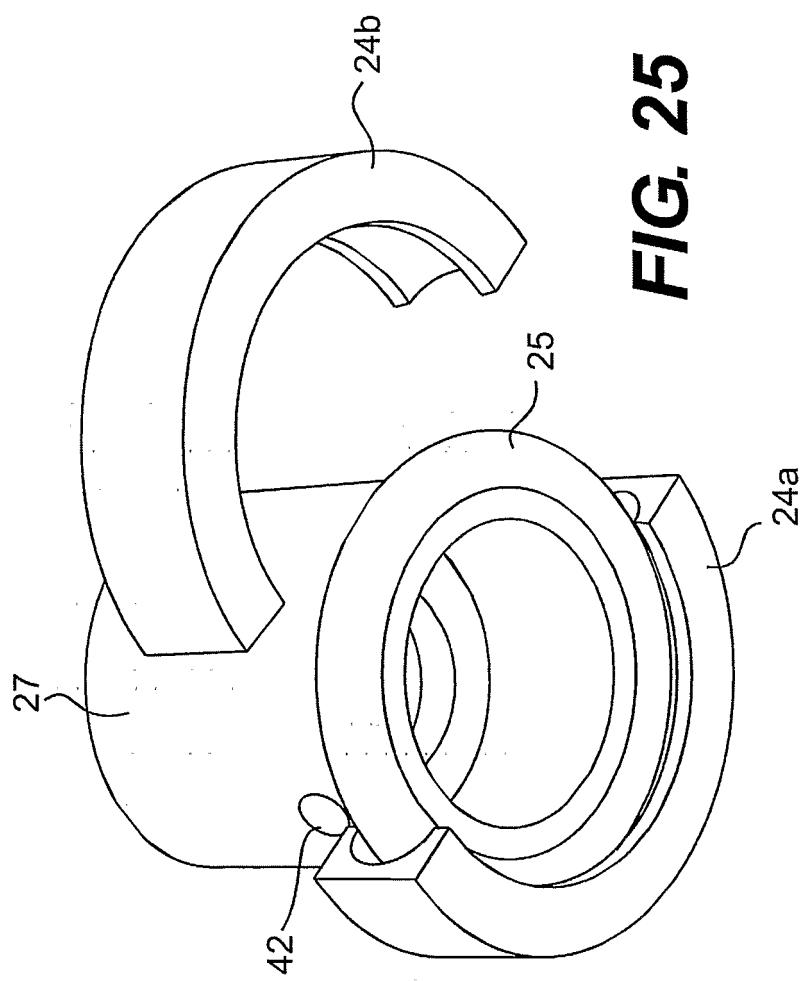
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FIG. 23

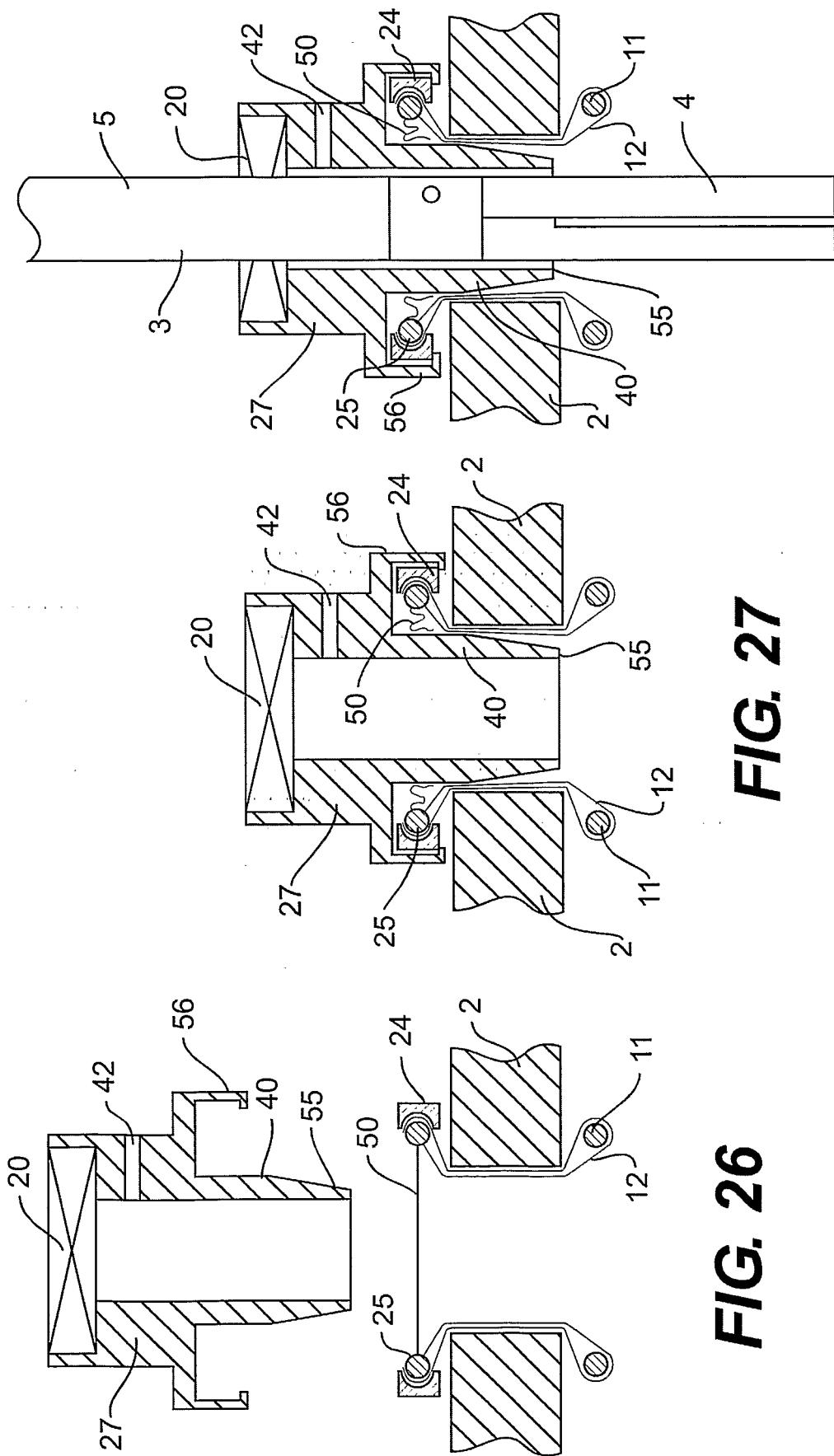
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**FIG. 24**

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FIG. 25

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**FIG. 27****FIG. 28**

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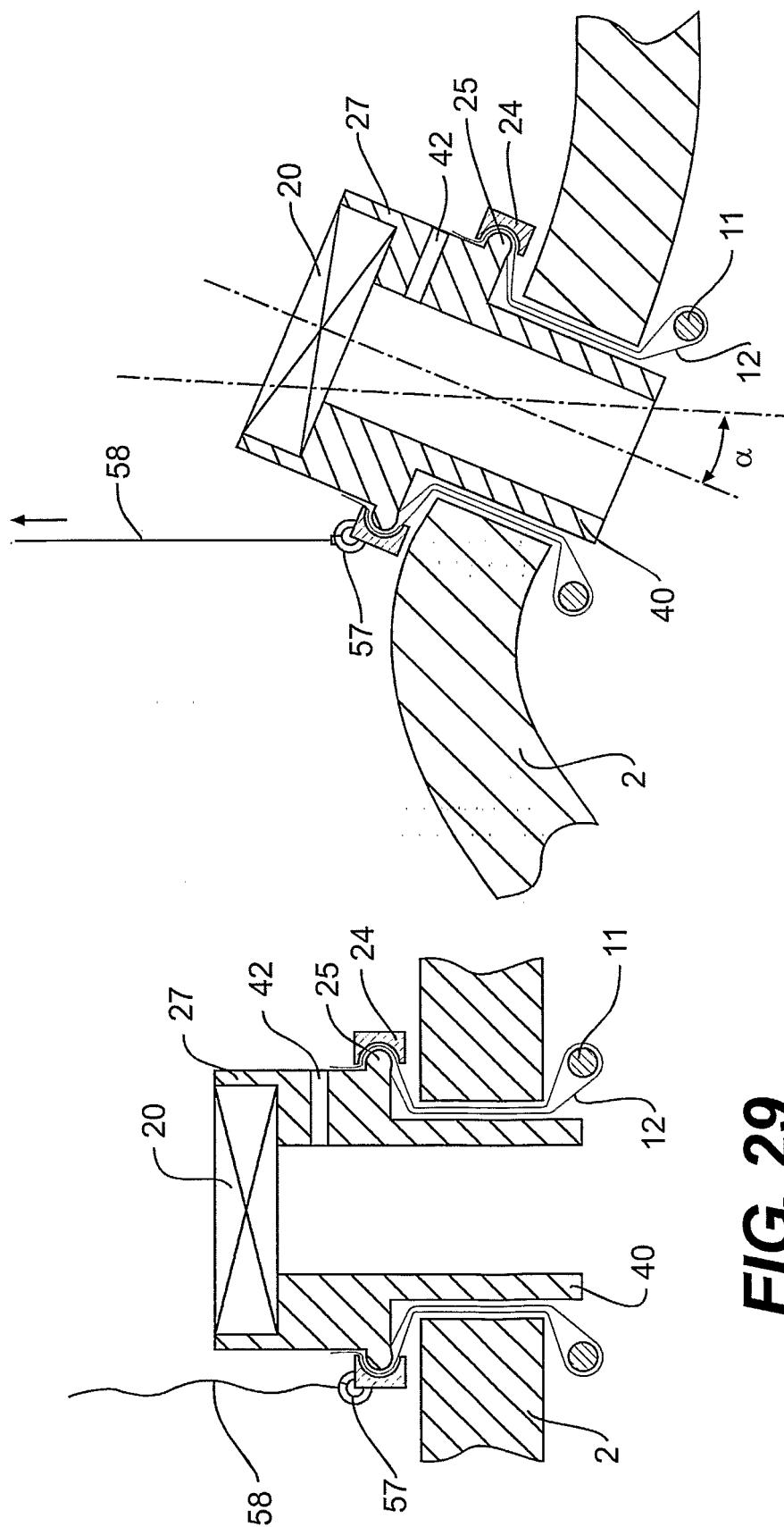
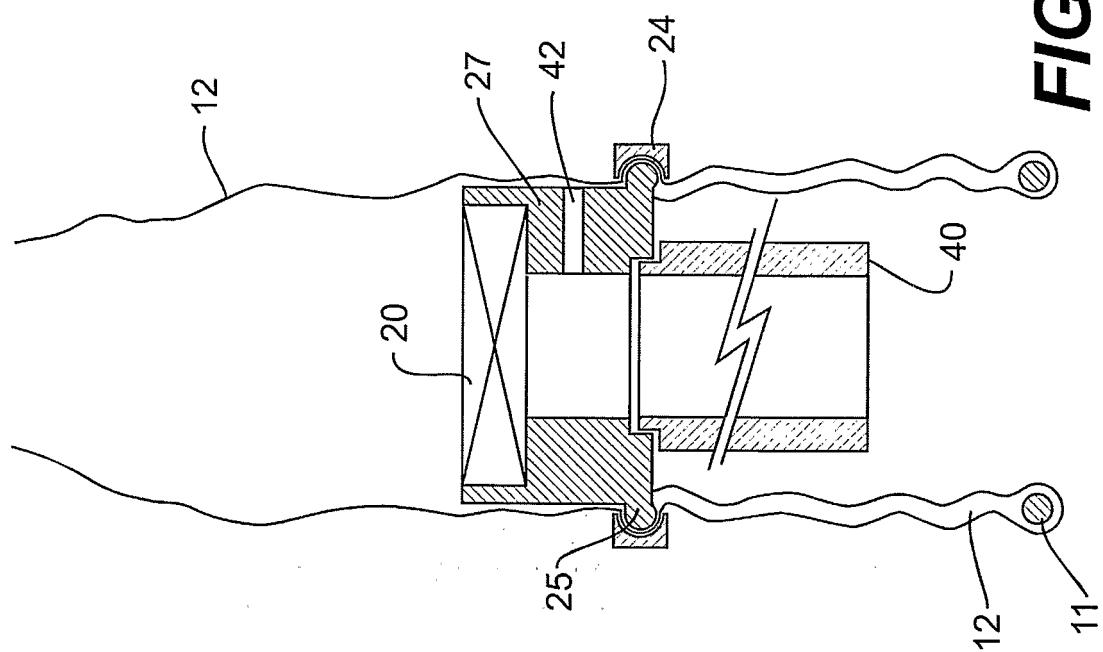
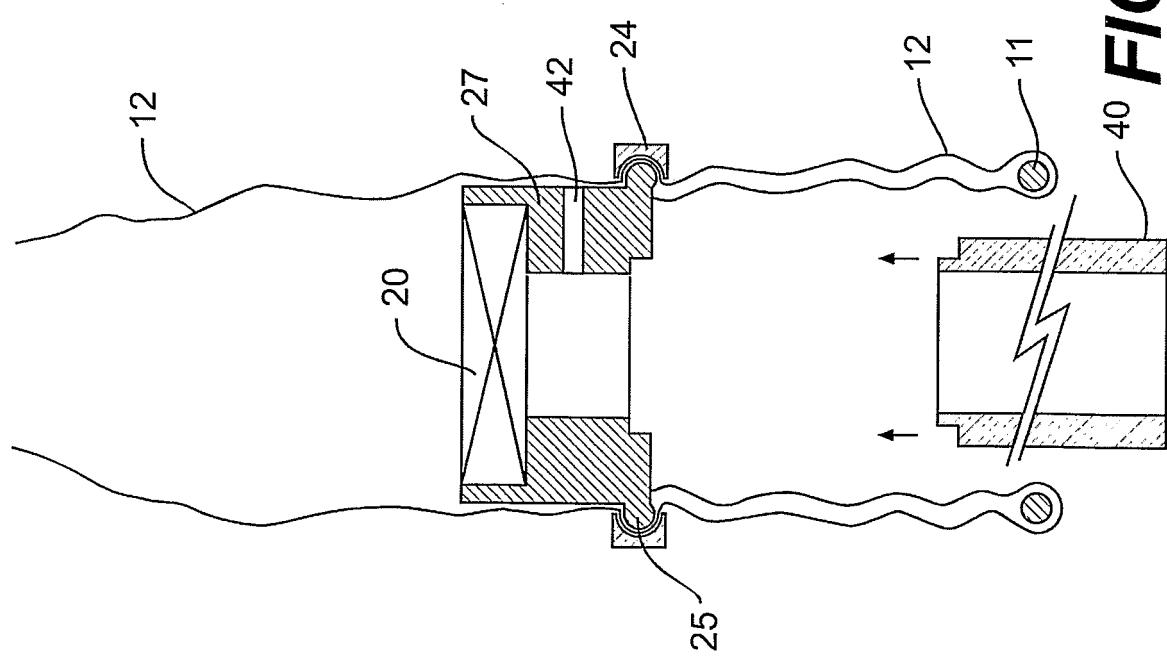


FIG. 29

FIG. 30

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FIG. 32**FIG. 31**

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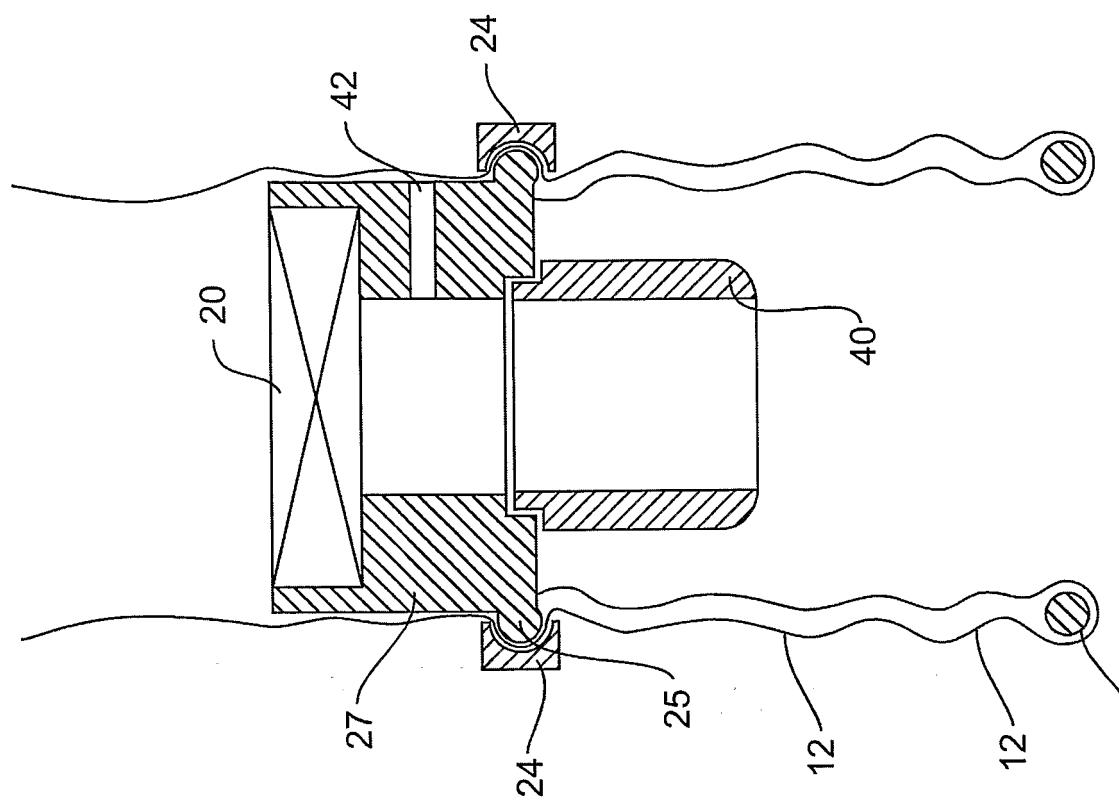


FIG. 34

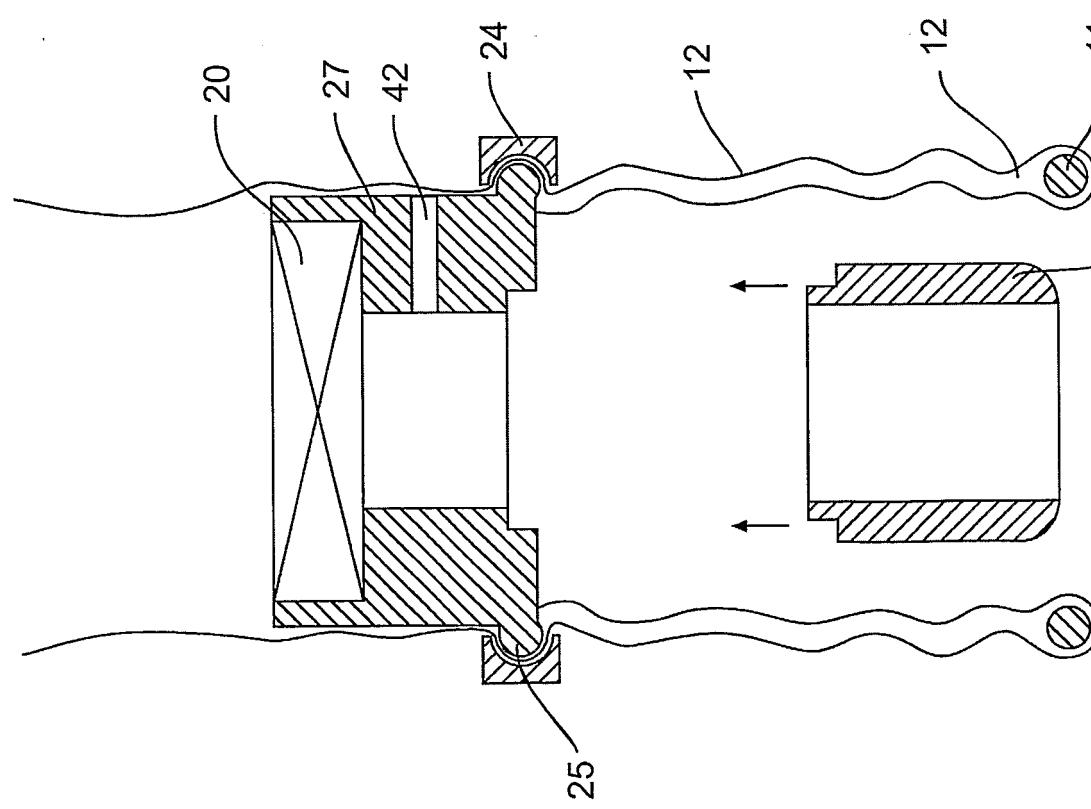


FIG. 33

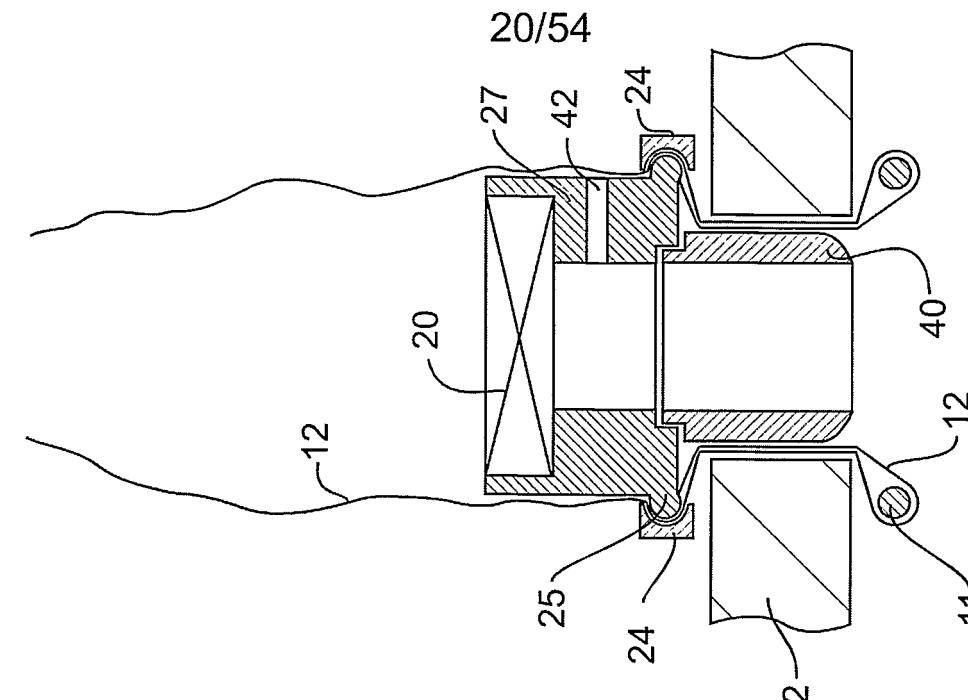


FIG. 37

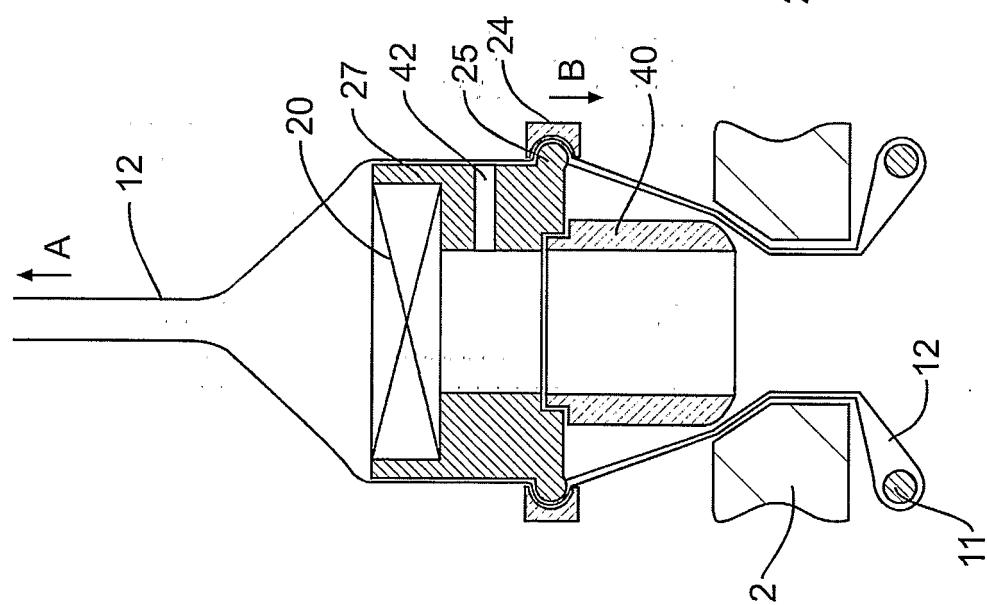


FIG. 36

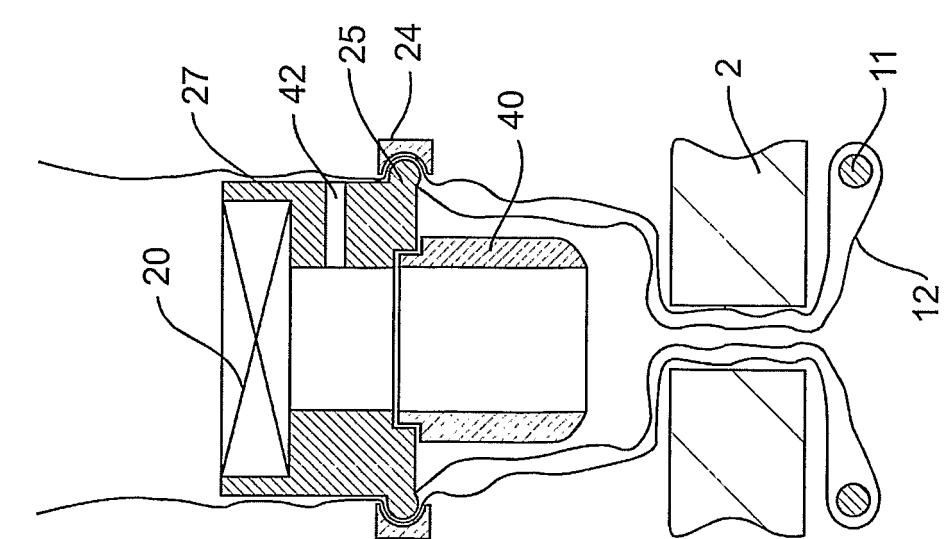


FIG. 35

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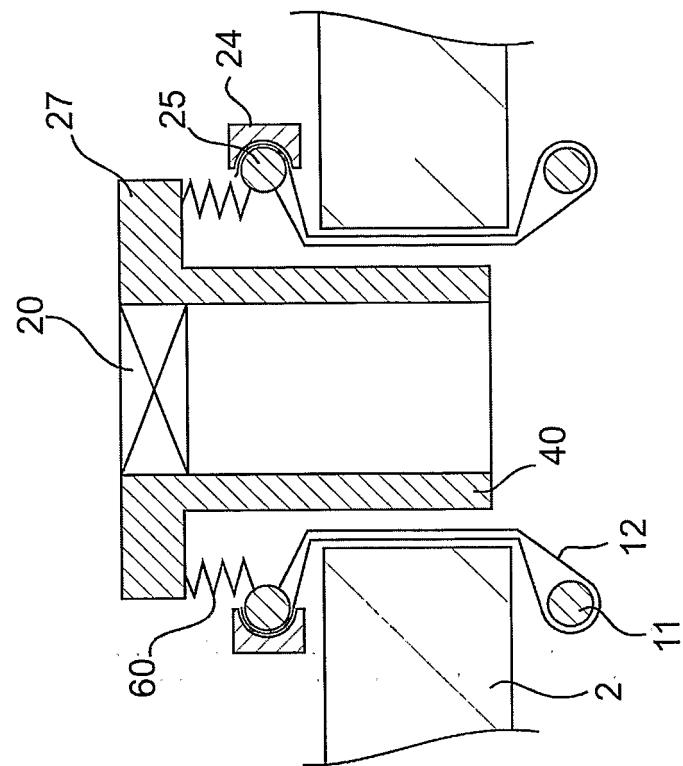


FIG. 39

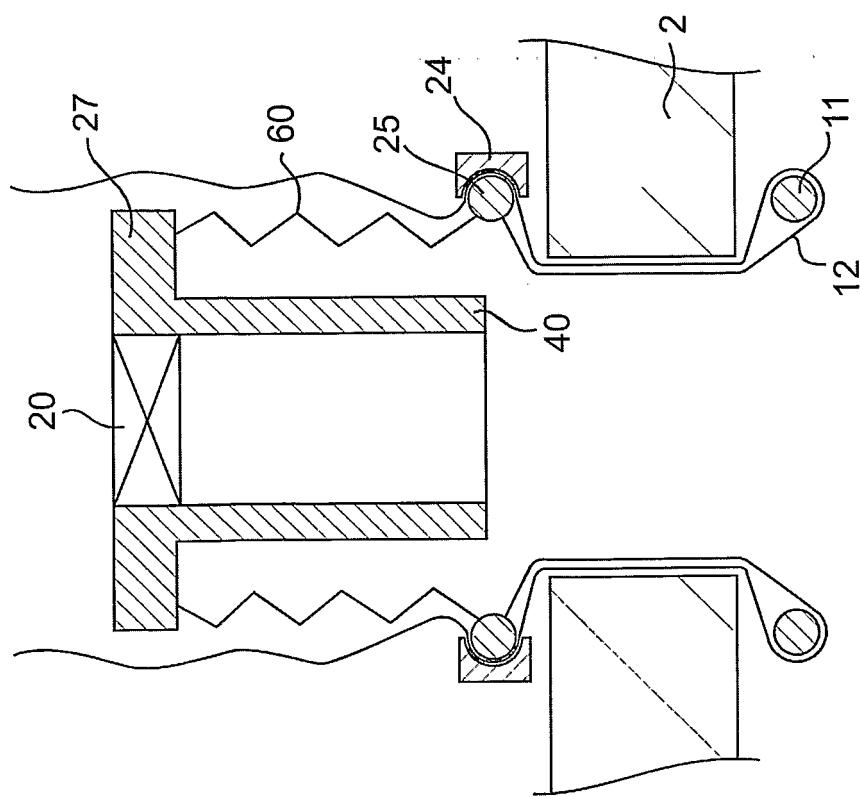
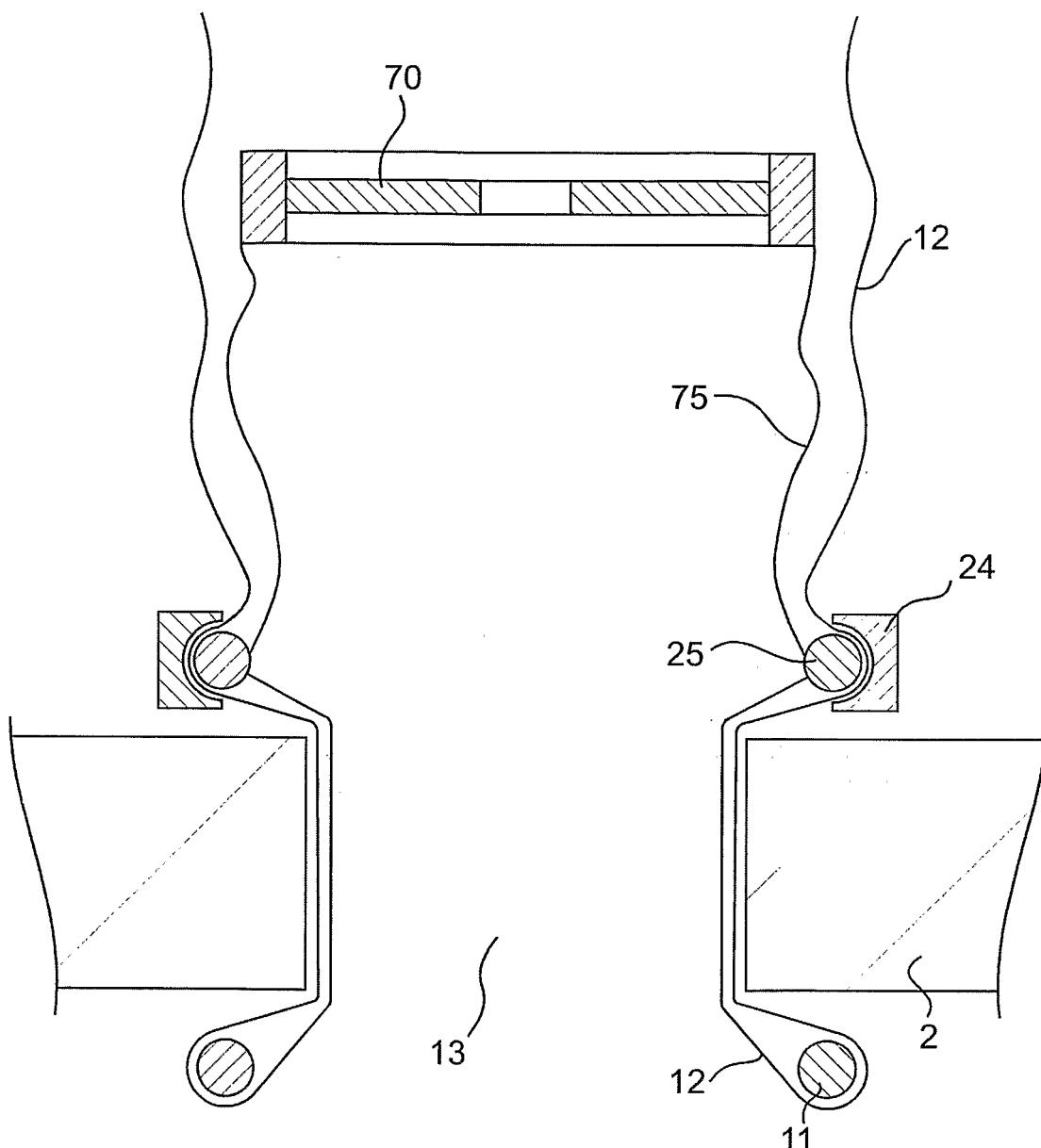
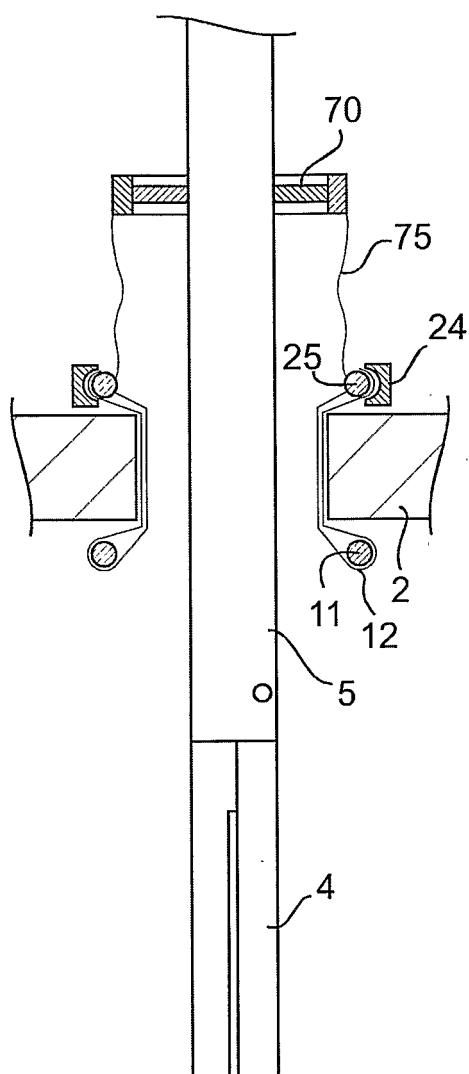
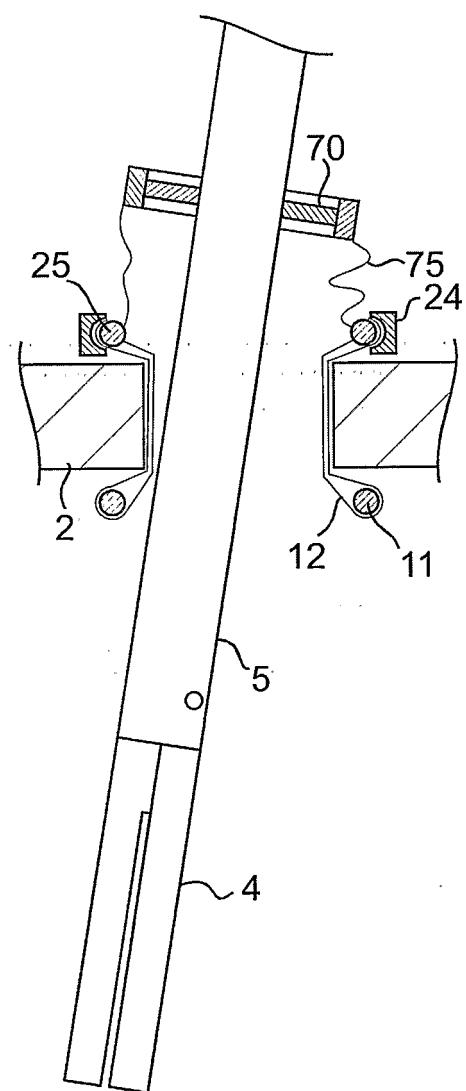


FIG. 38

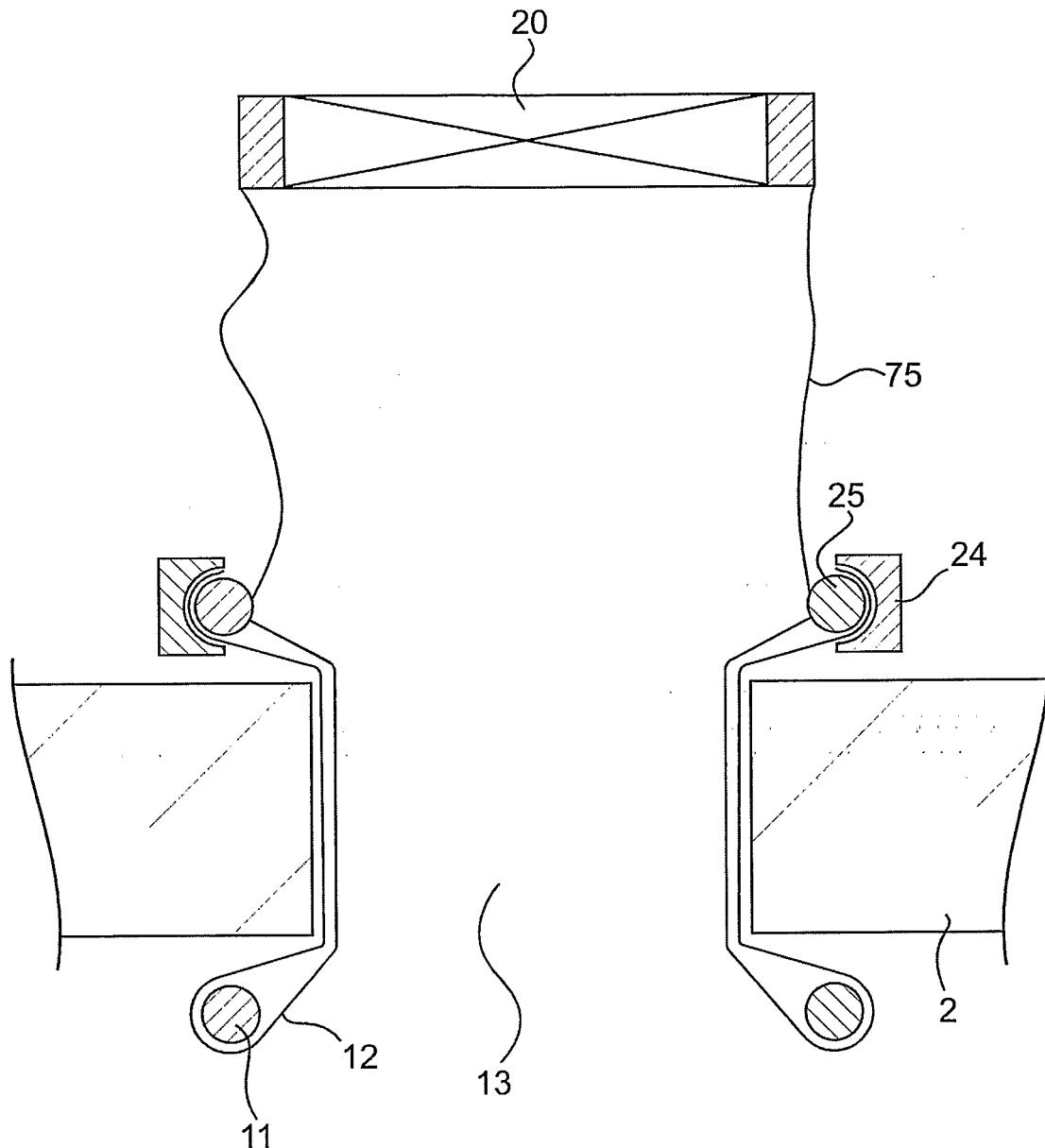
22/54

**FIG. 40**

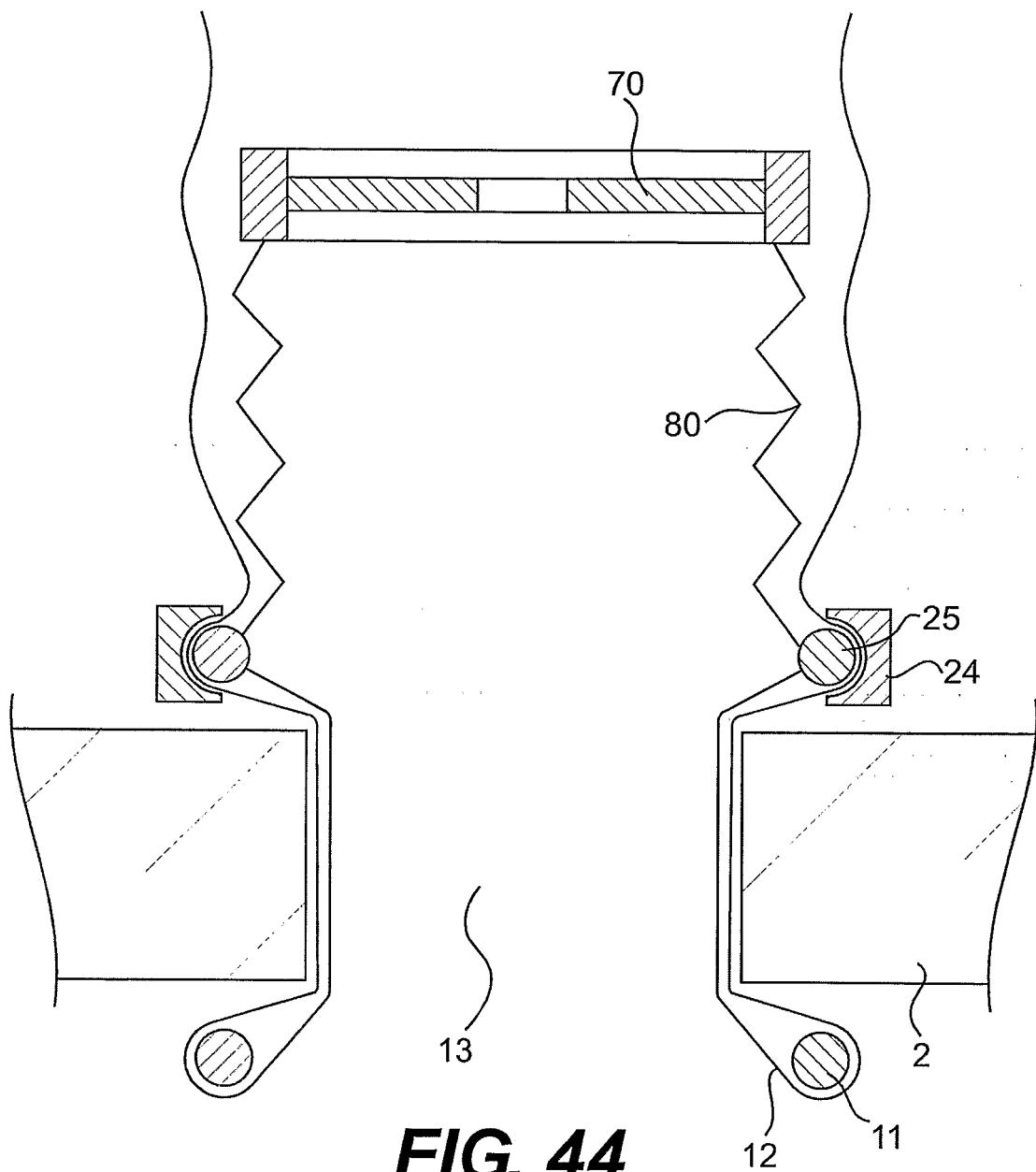
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**FIG. 41****FIG. 42**

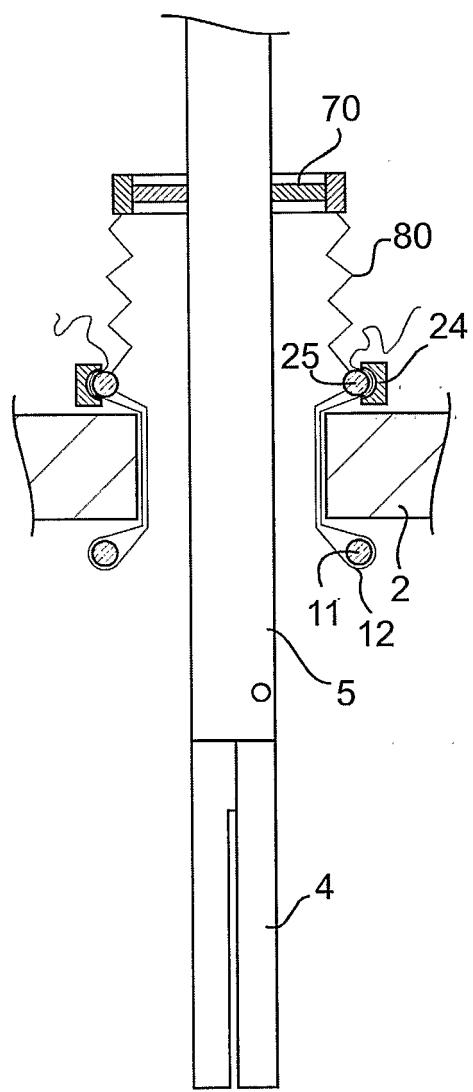
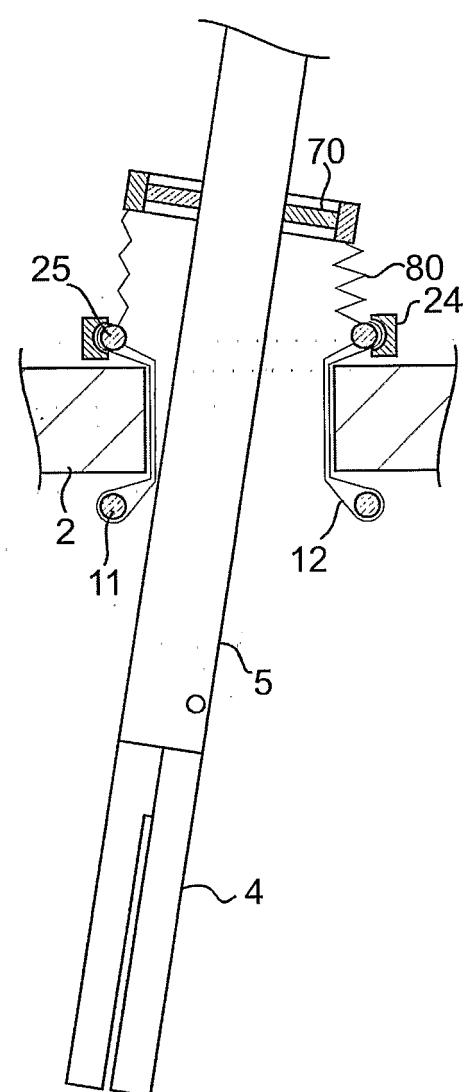
24/54

**FIG. 43**

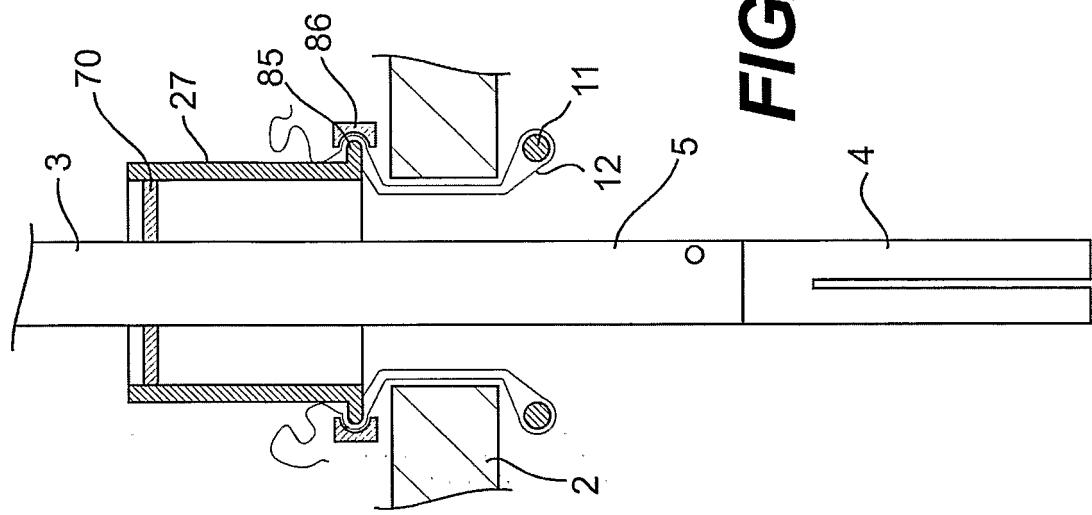
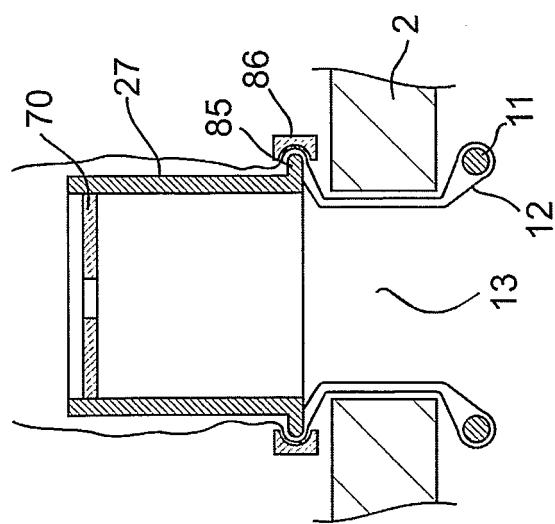
25/54

**FIG. 44**

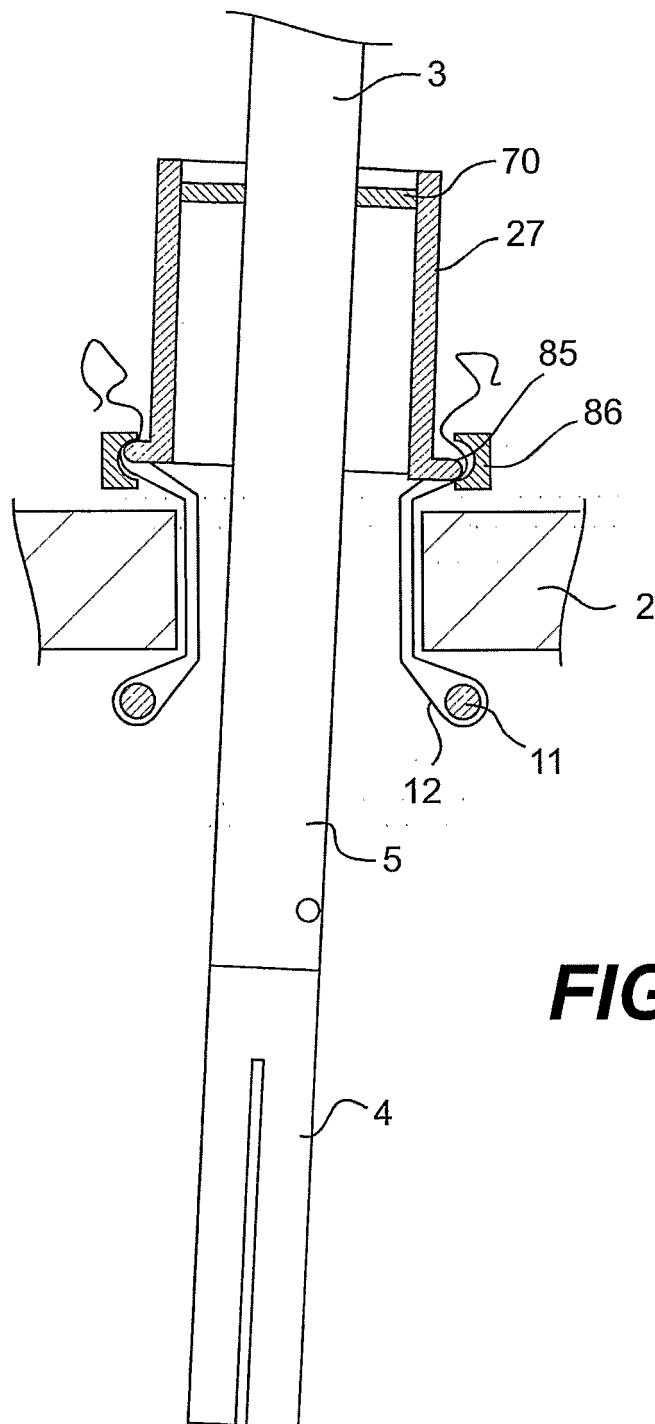
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**FIG. 45****FIG. 46**

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FIG. 48**FIG. 47**

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**FIG. 49**

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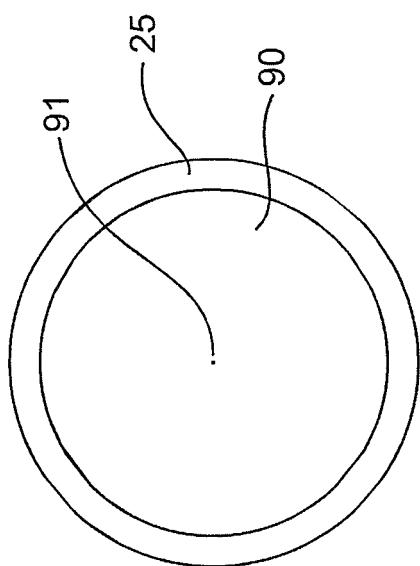


FIG. 52

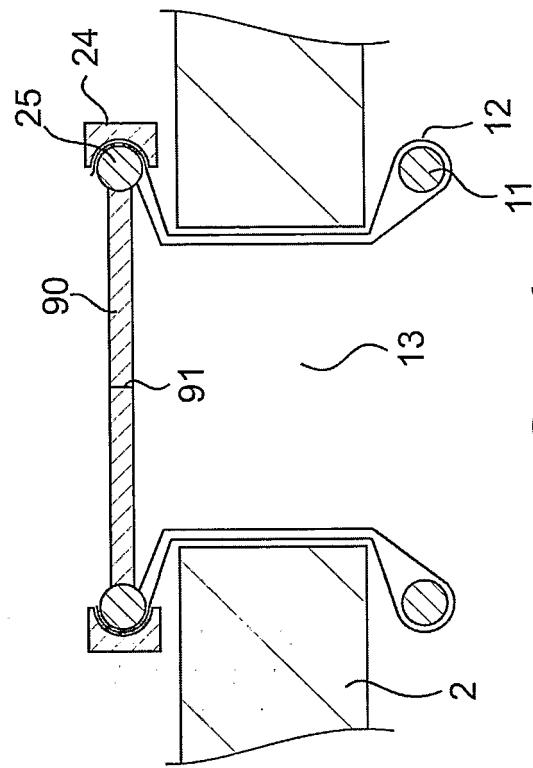


FIG. 51

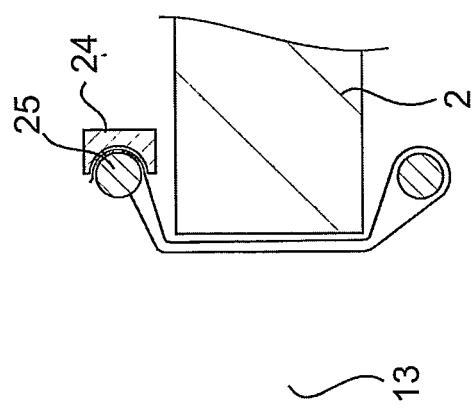
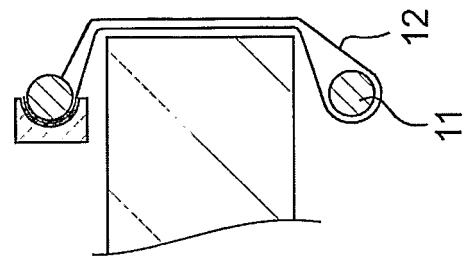
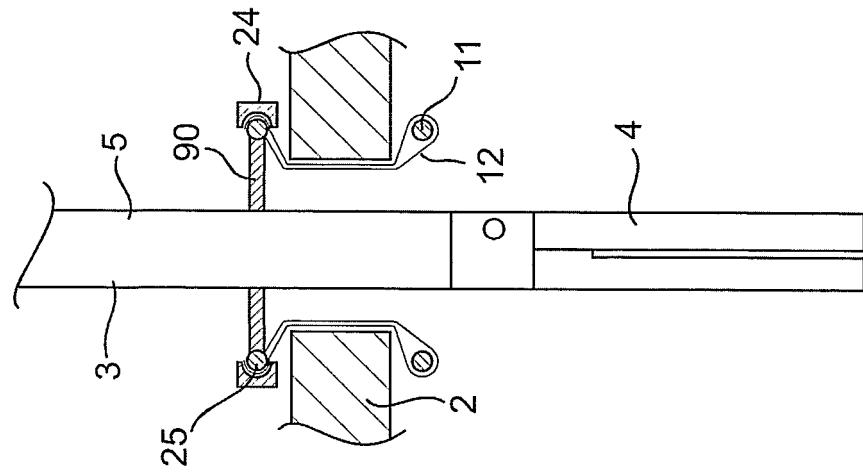
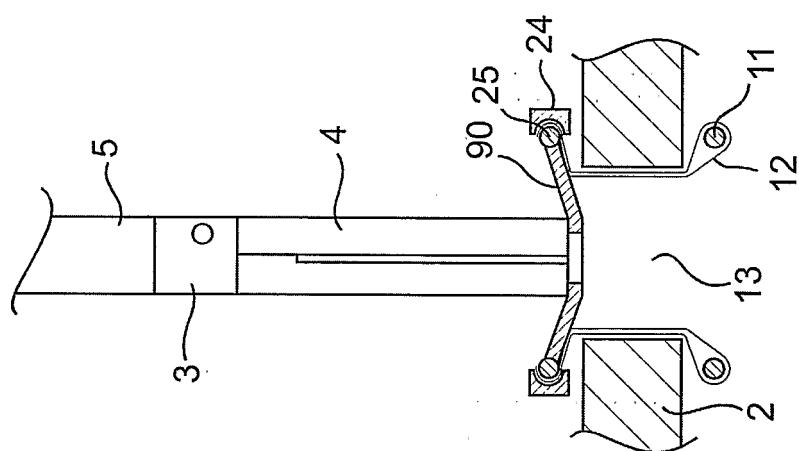
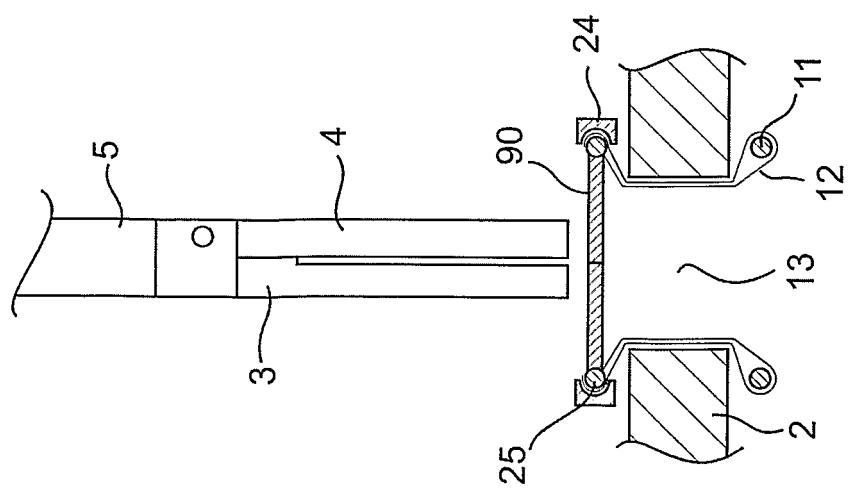


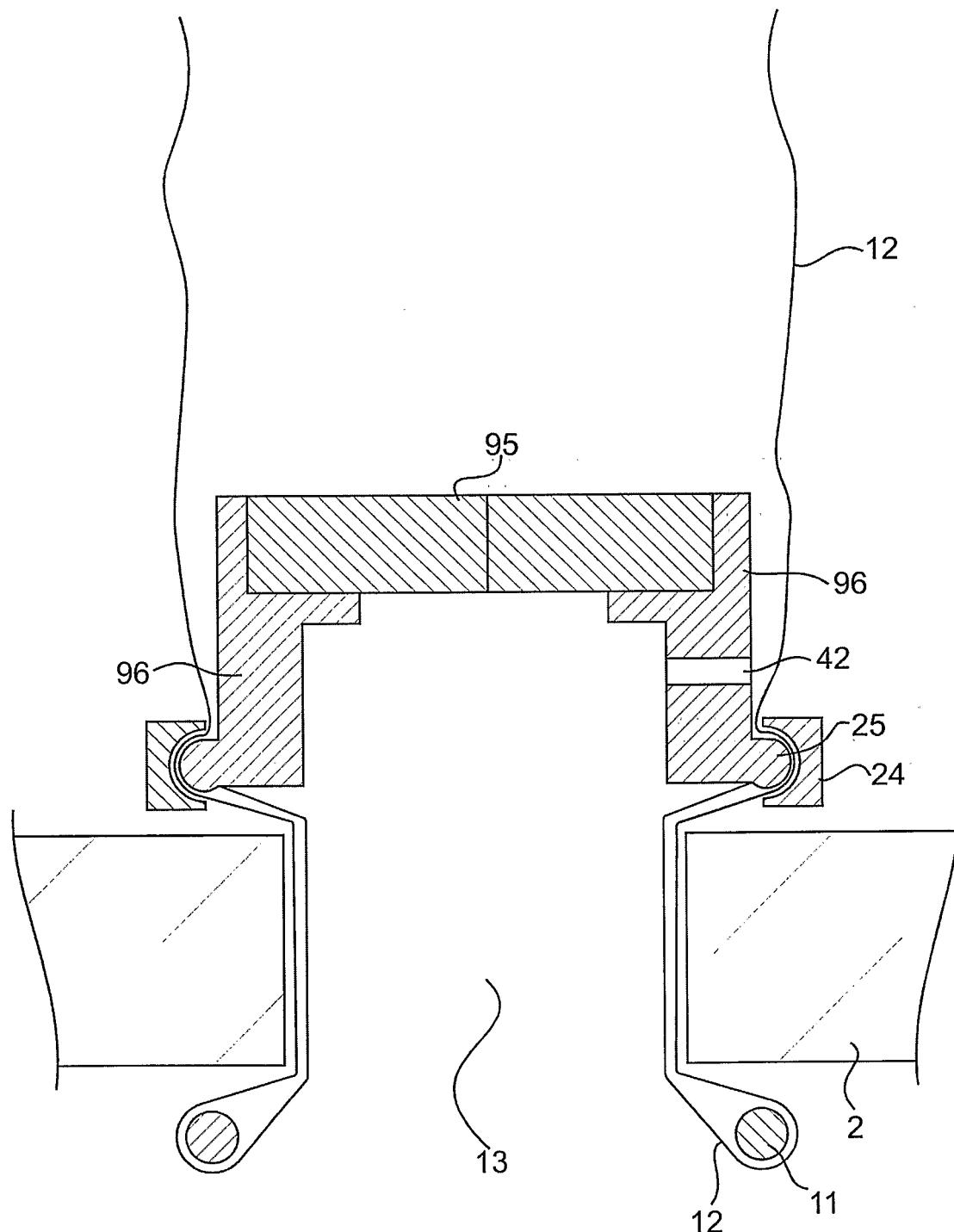
FIG. 50



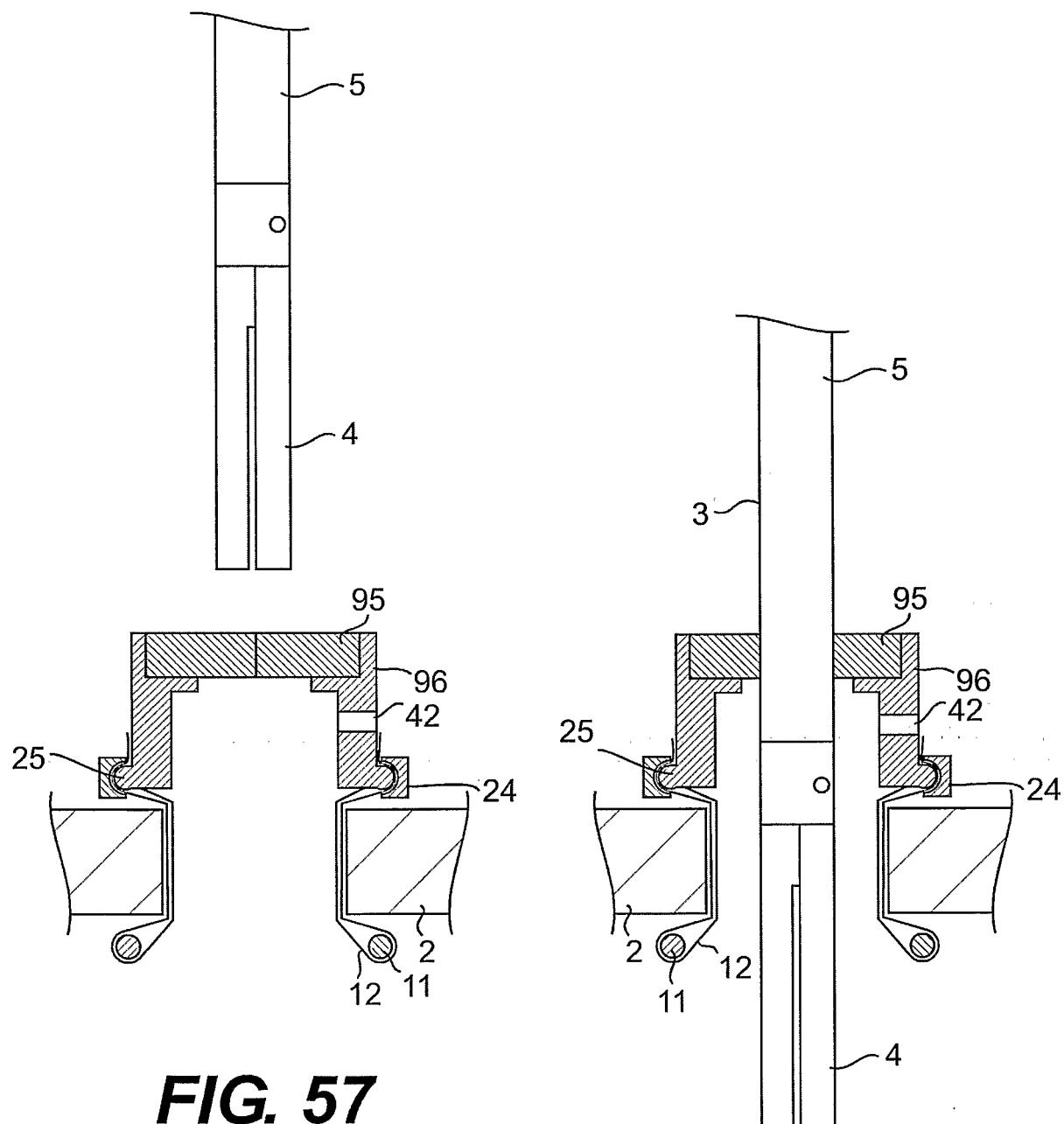
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**FIG. 54****FIG. 53****FIG. 55**

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**FIG. 56**

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**FIG. 58**

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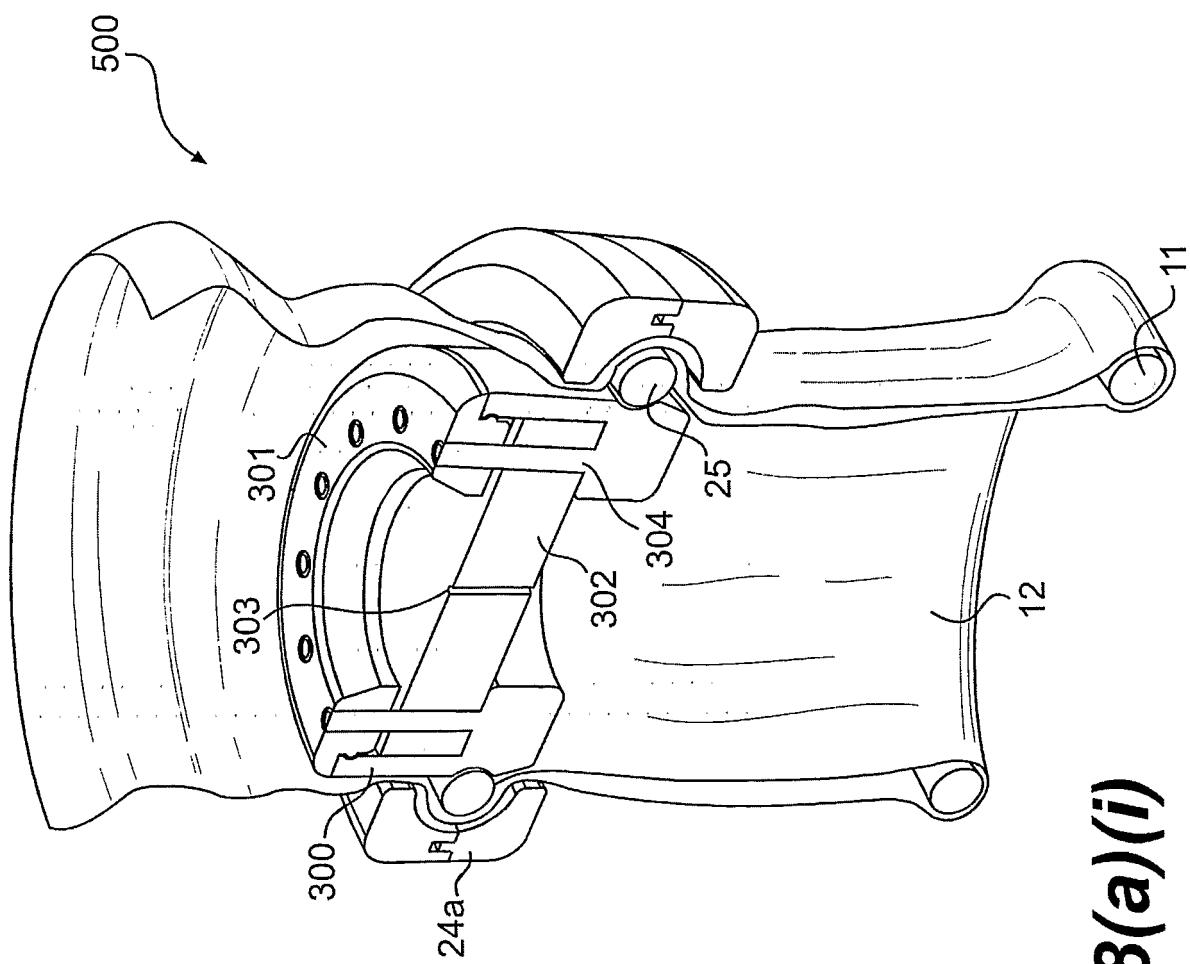
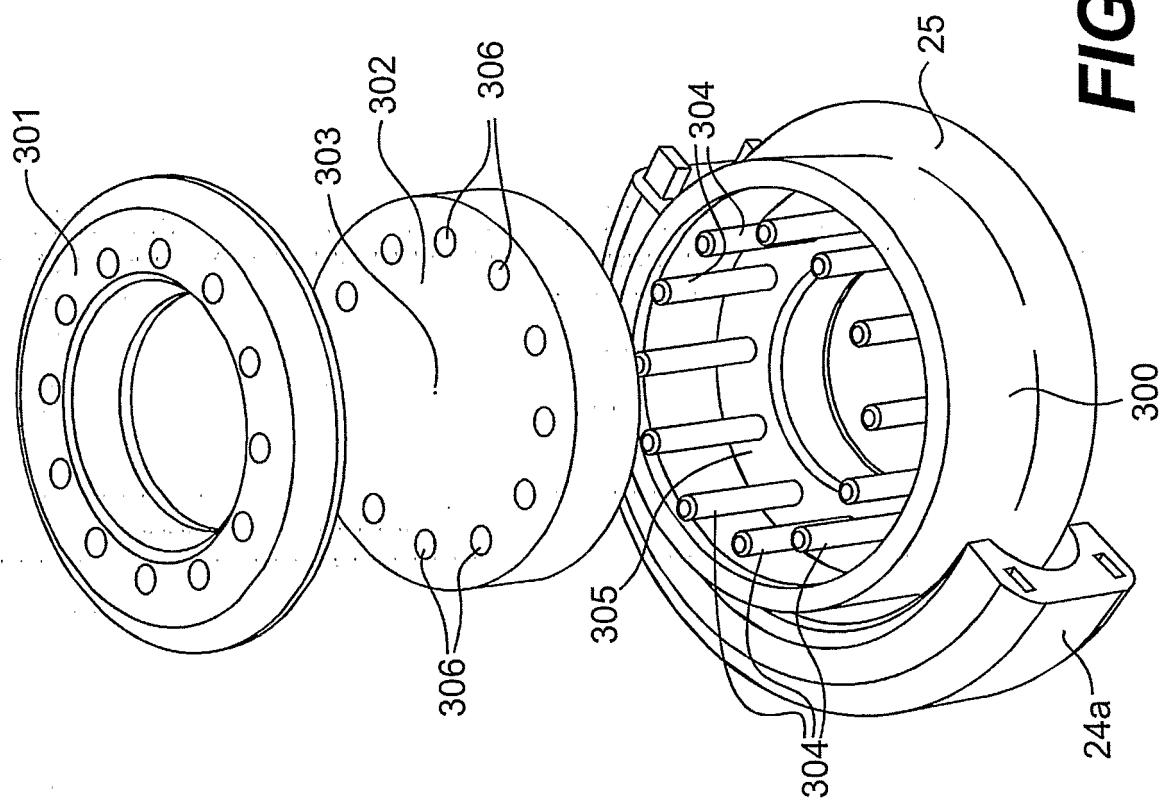


FIG. 58(a)(i)

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FIG. 58(a)(ii)

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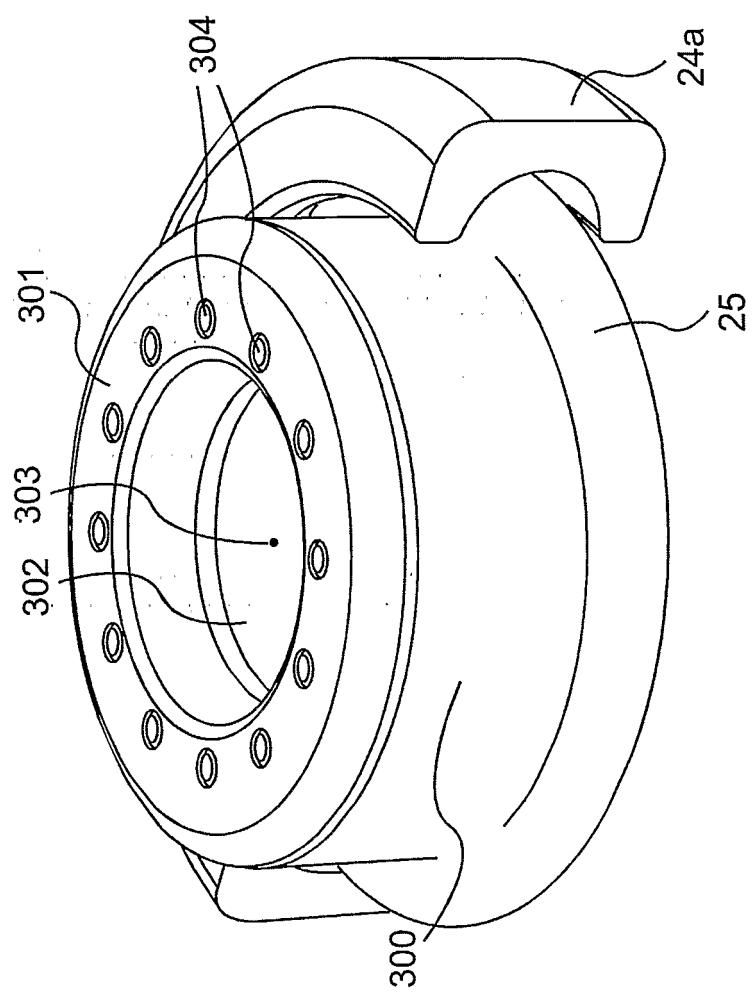
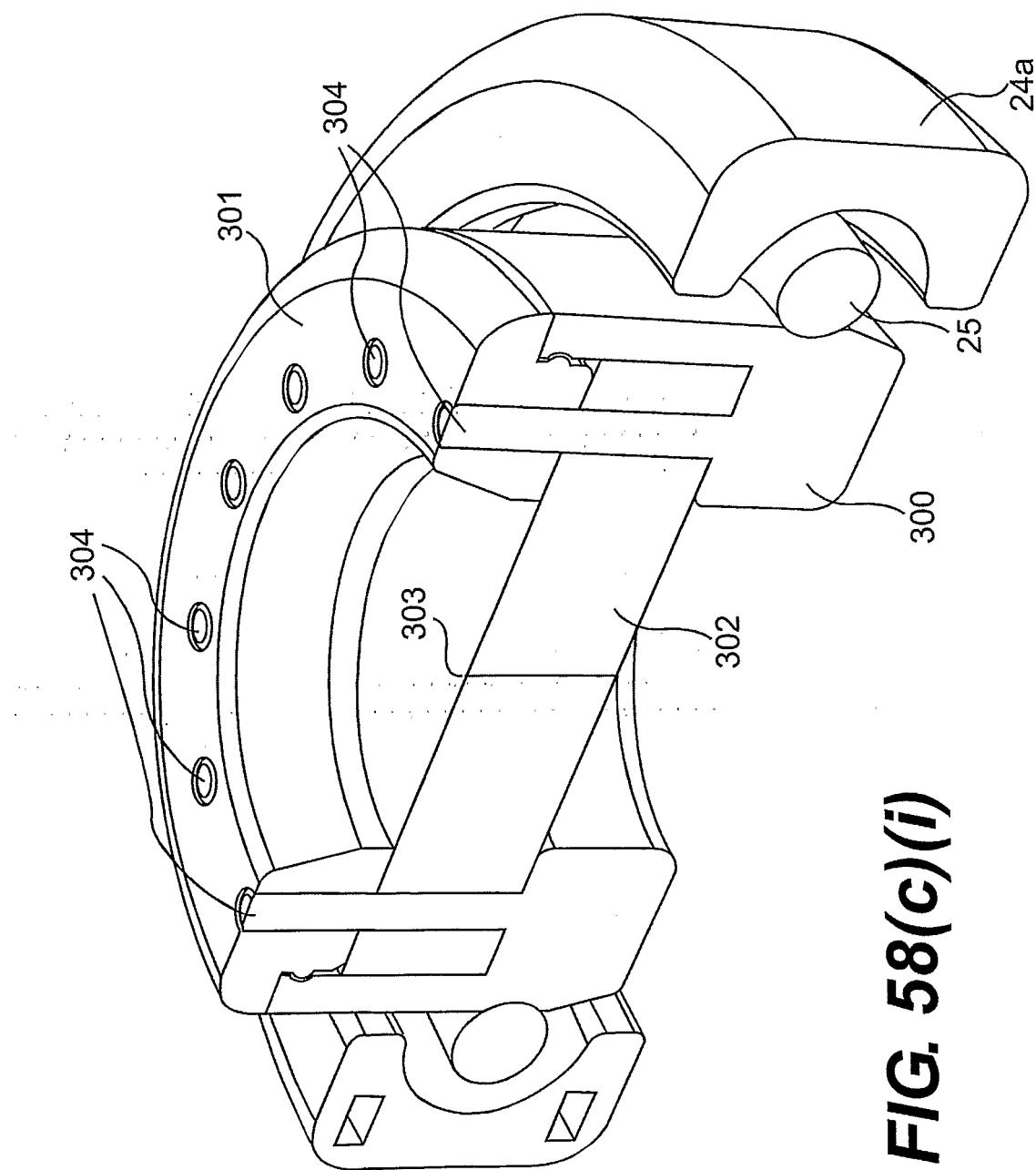
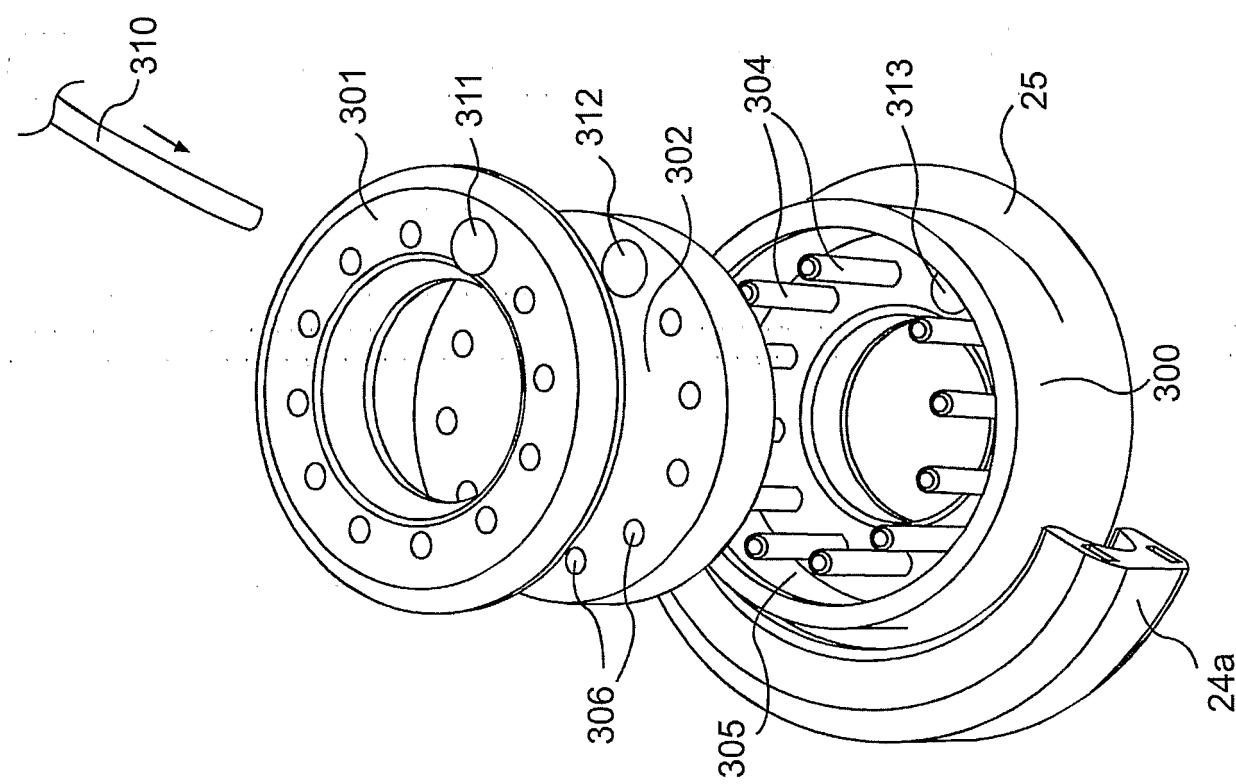


FIG. 58(b)

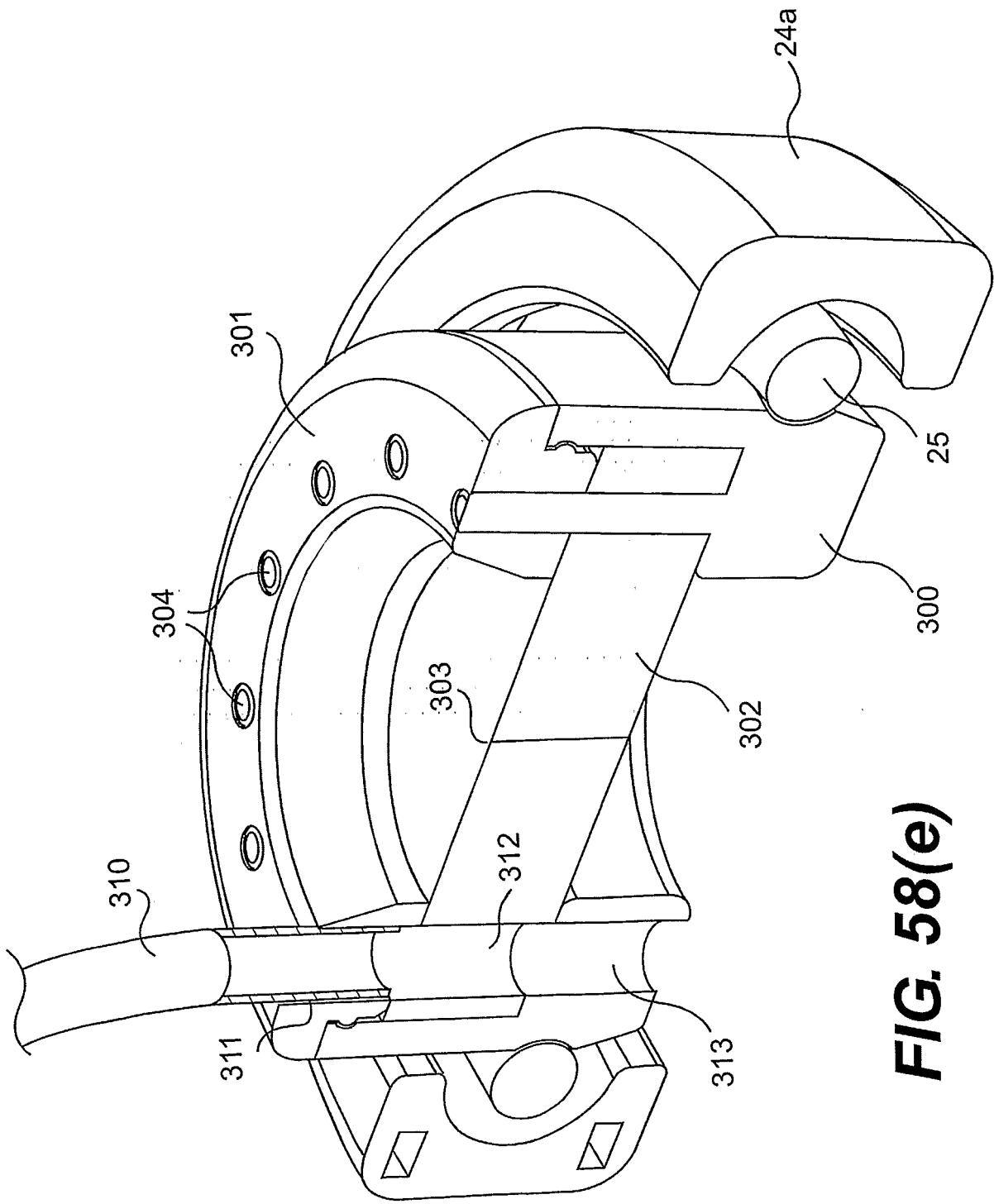
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**FIG. 58(c)(i)**

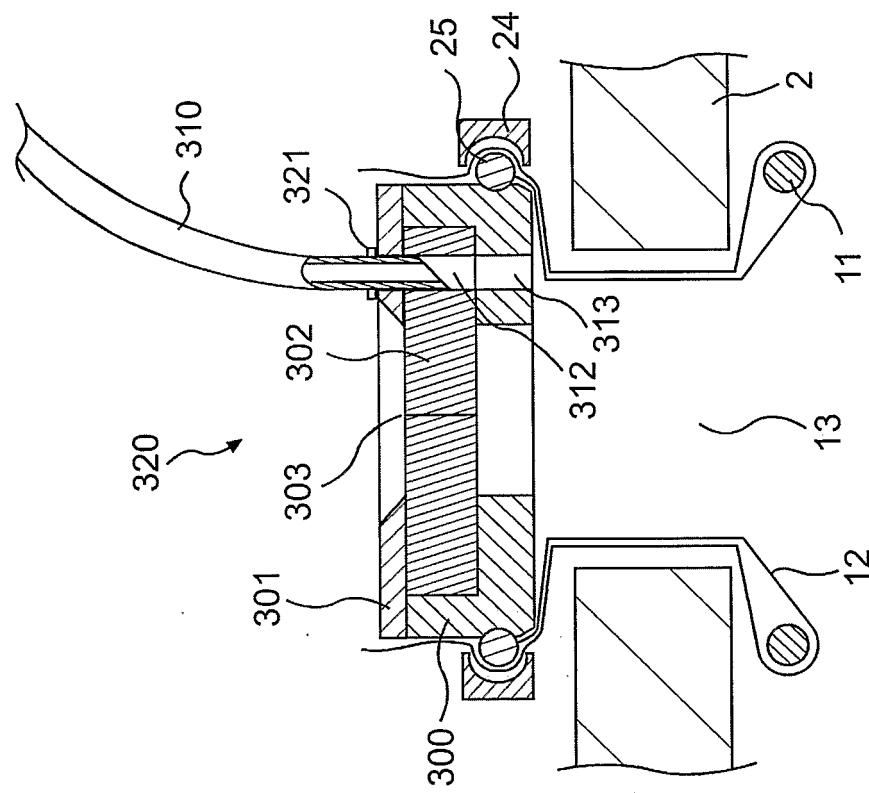
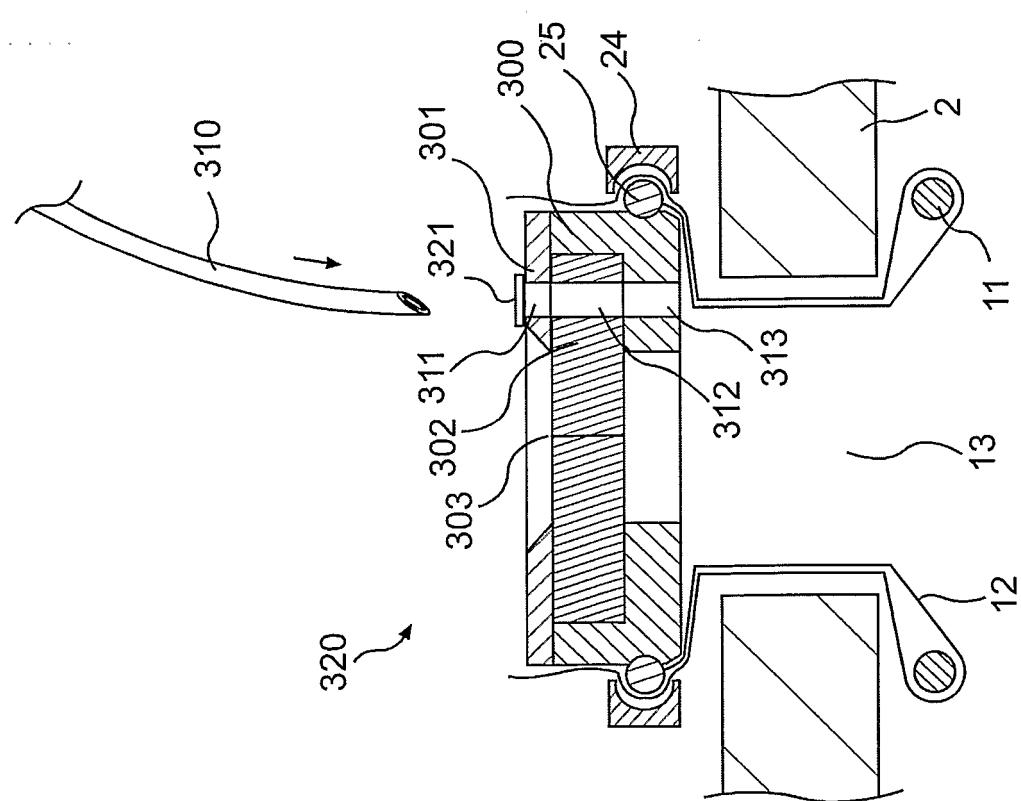
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FIG. 58(d)

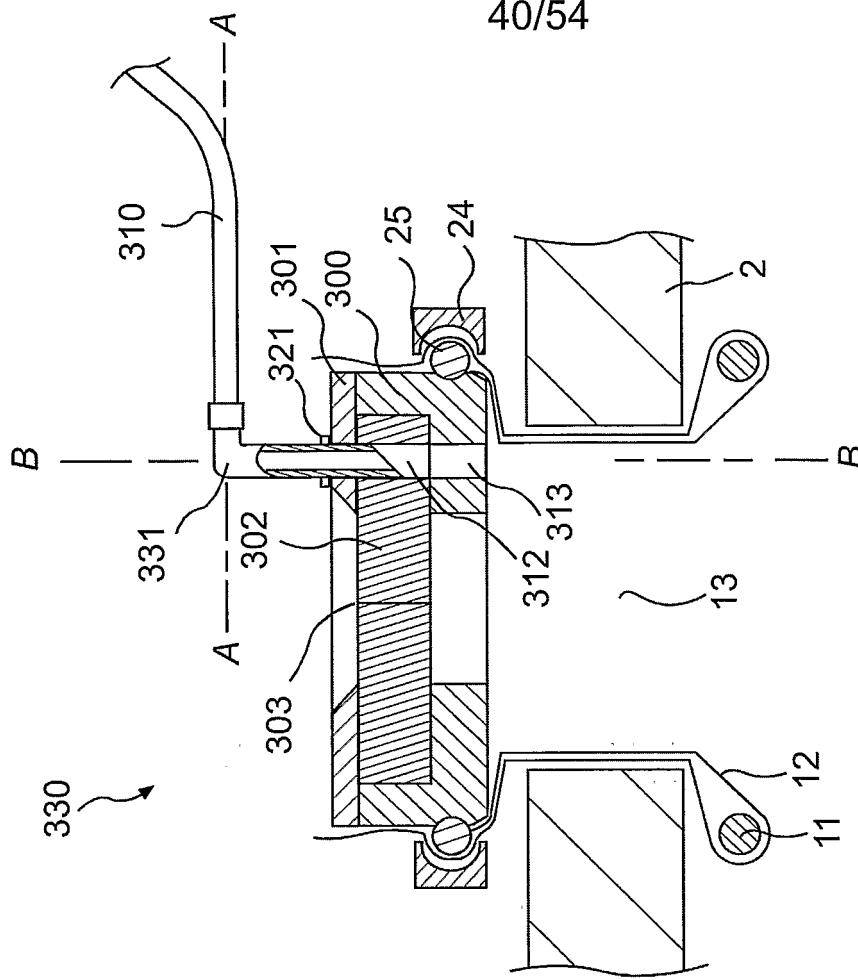
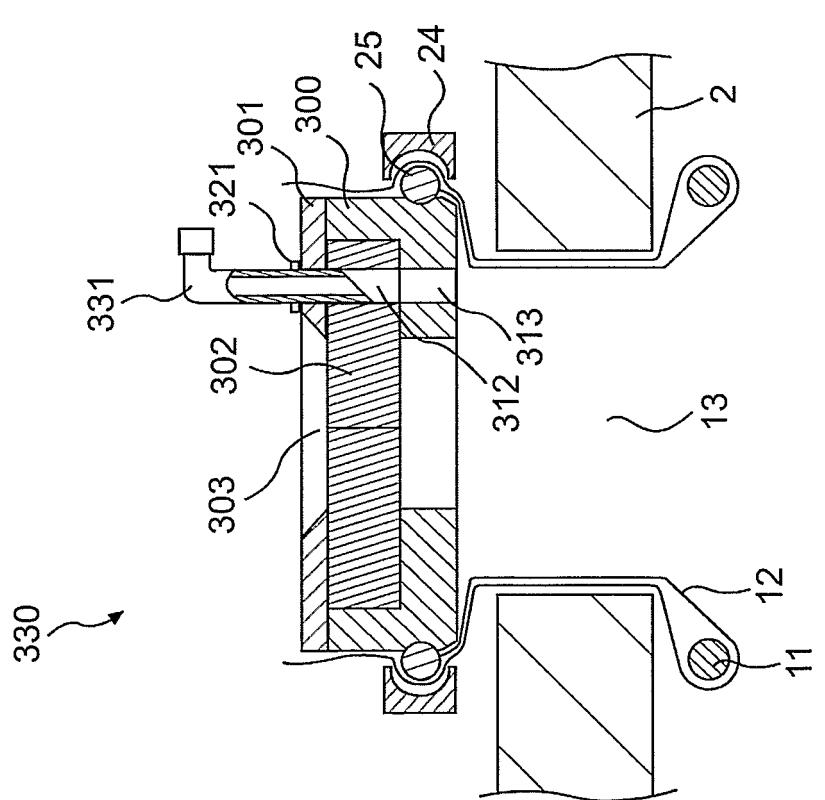
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**FIG. 58(e)**

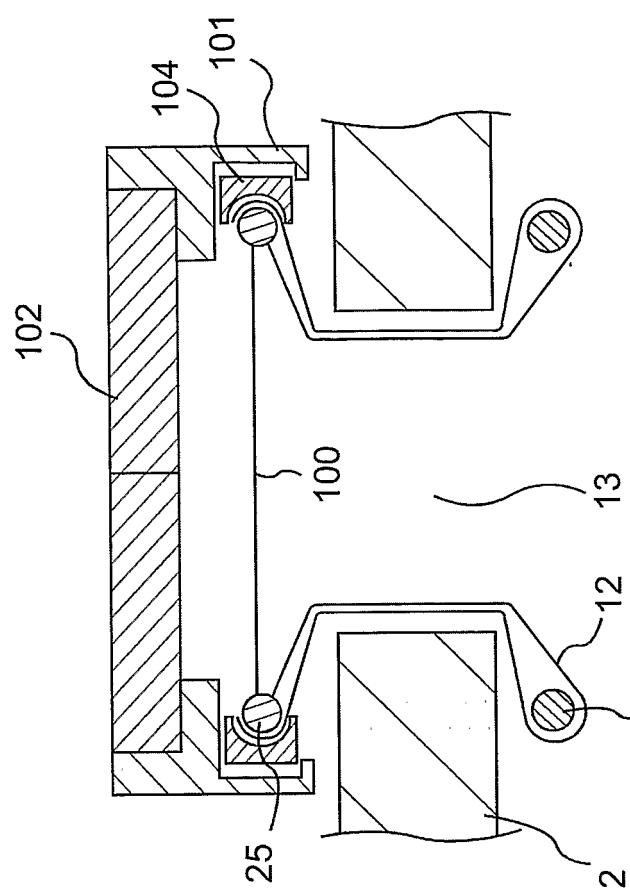
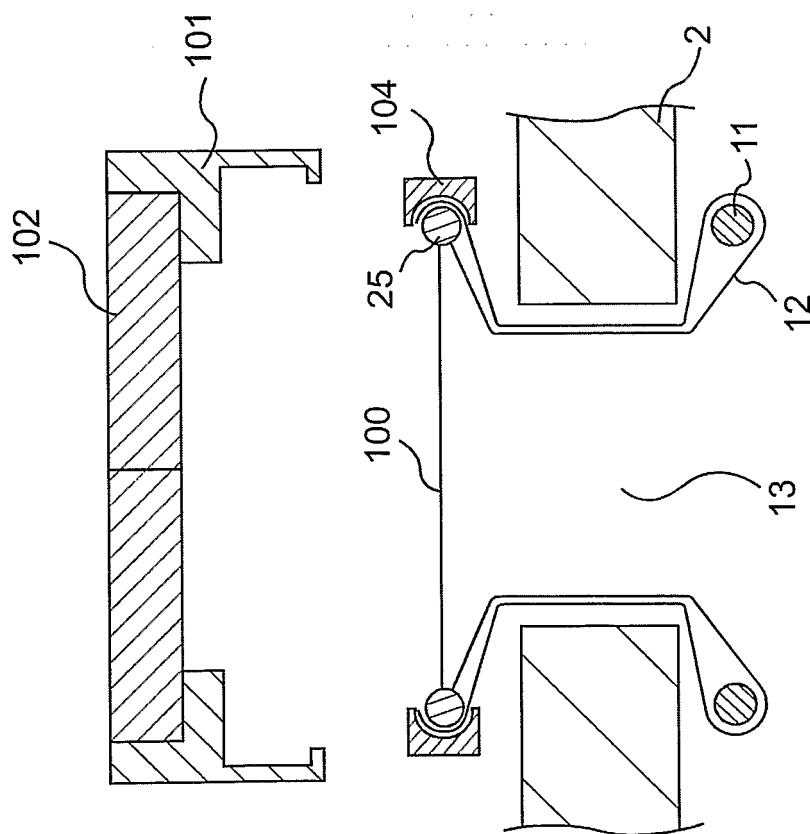
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**FIG. 58(g)****FIG. 58(f)**

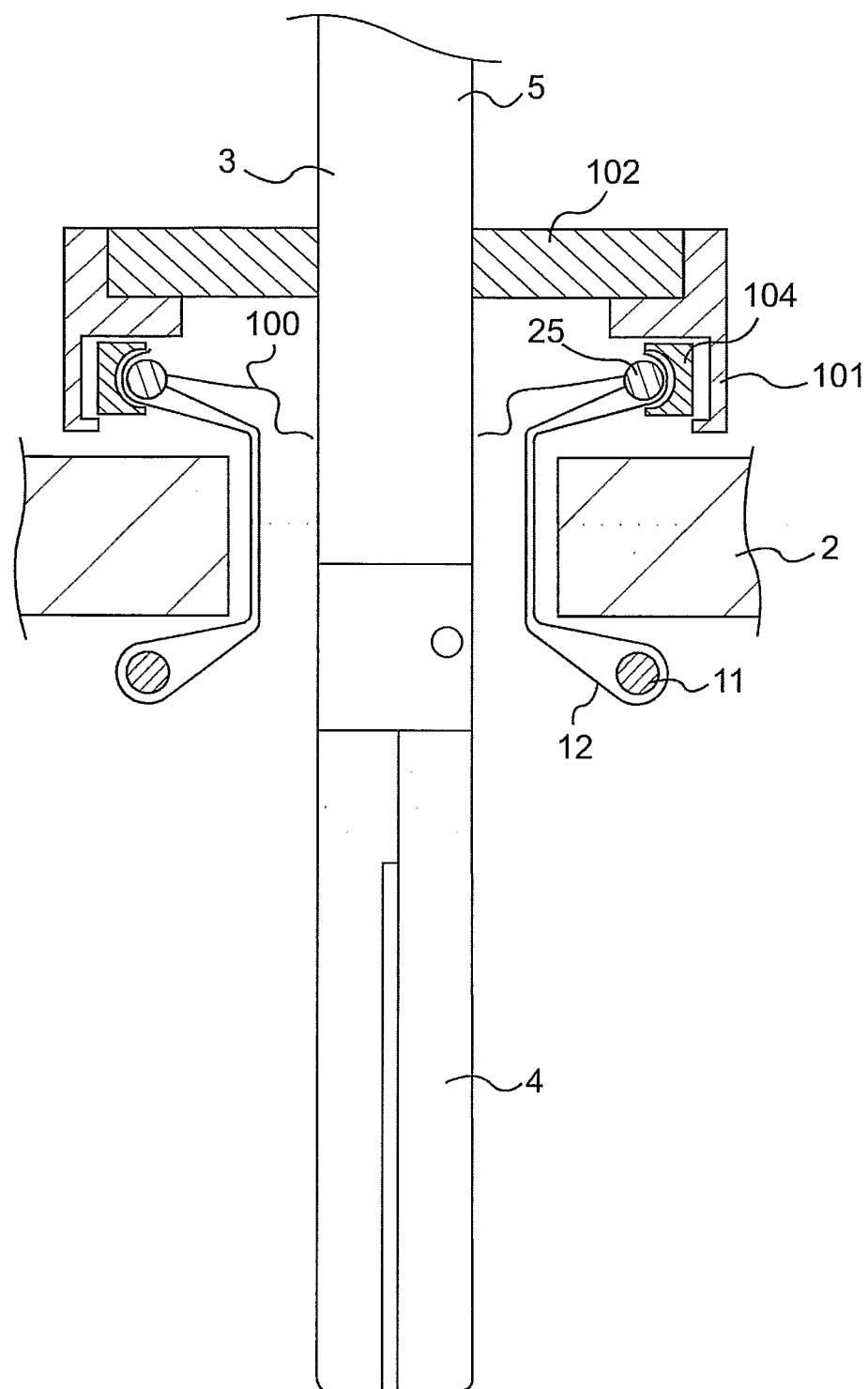
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**FIG. 58(i)****FIG. 58(h)**

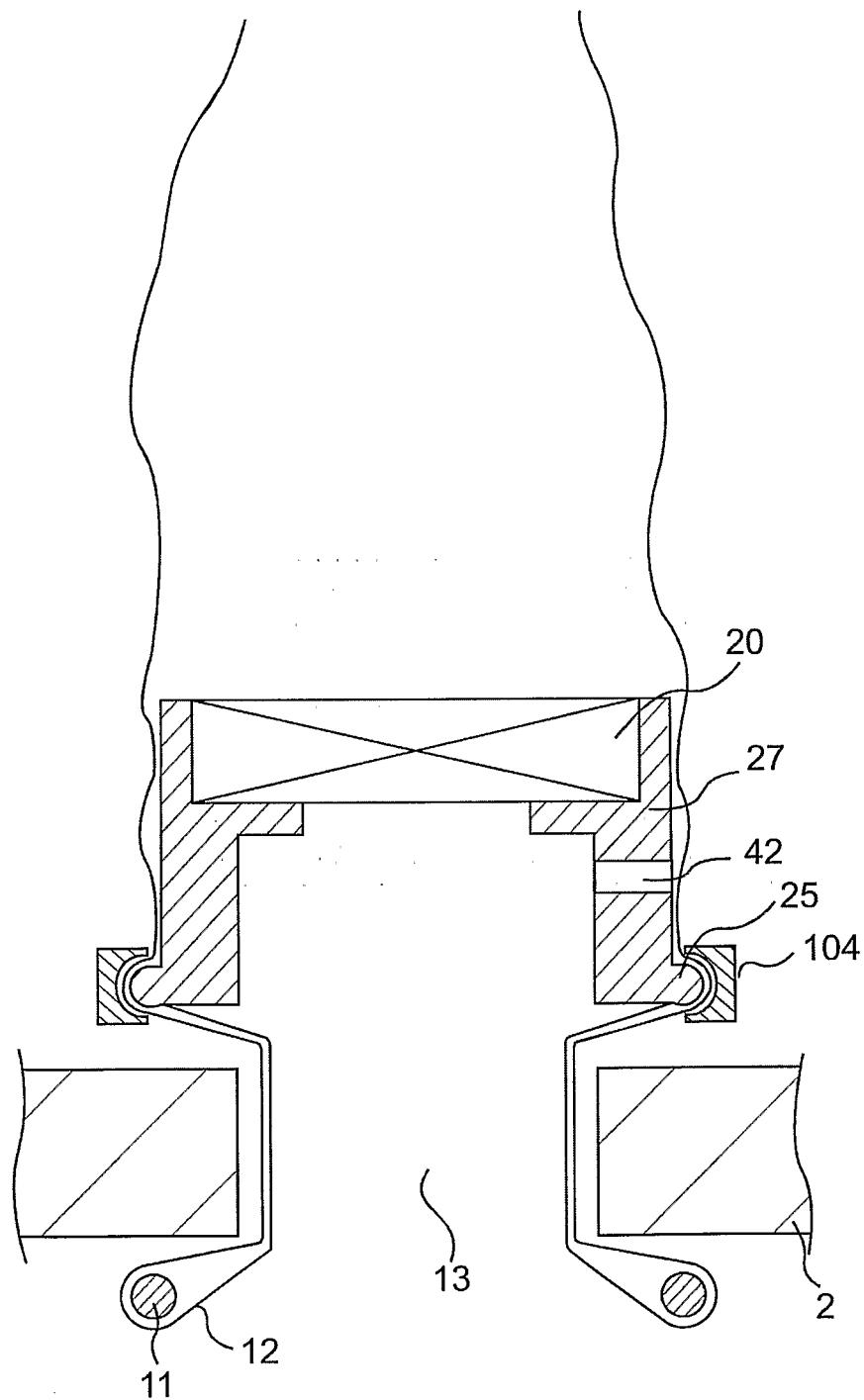
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**FIG. 60****FIG. 59**

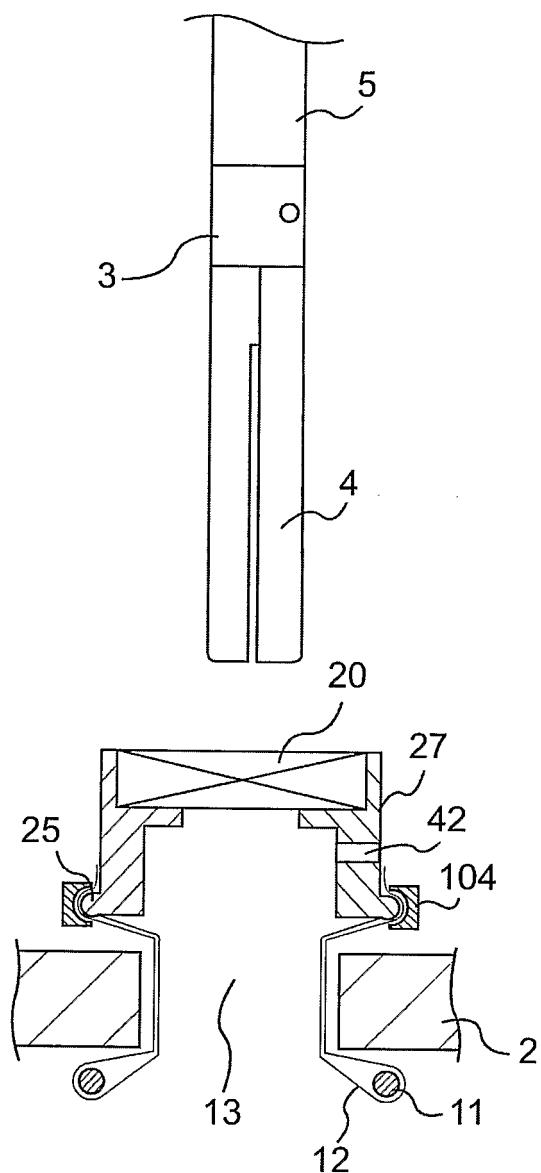
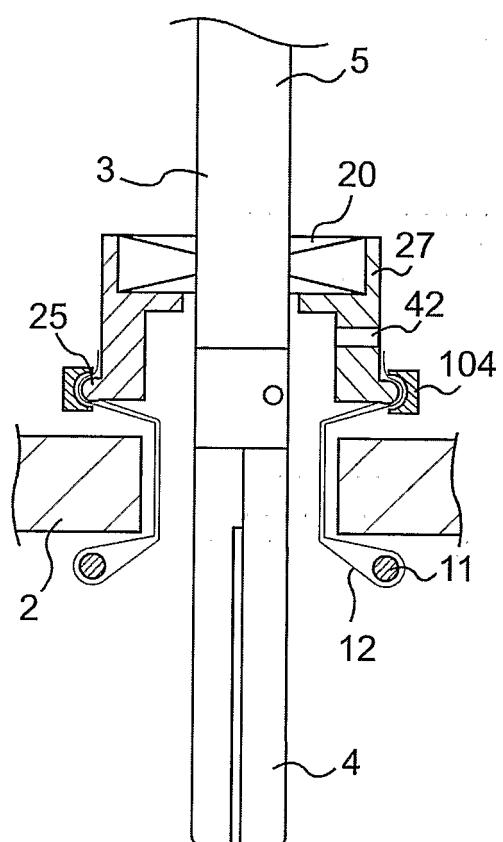
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**FIG. 61**

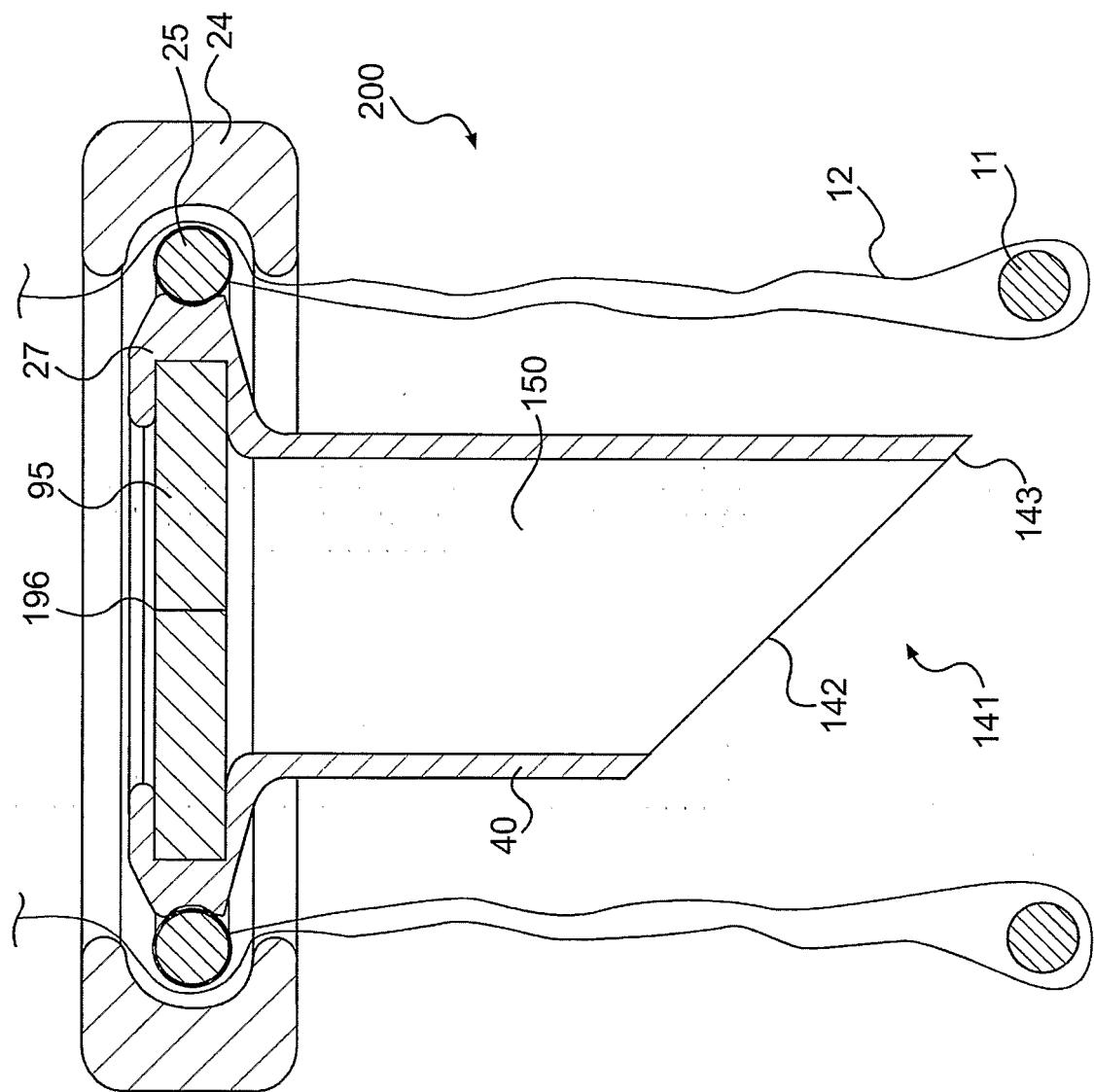
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**FIG. 62**

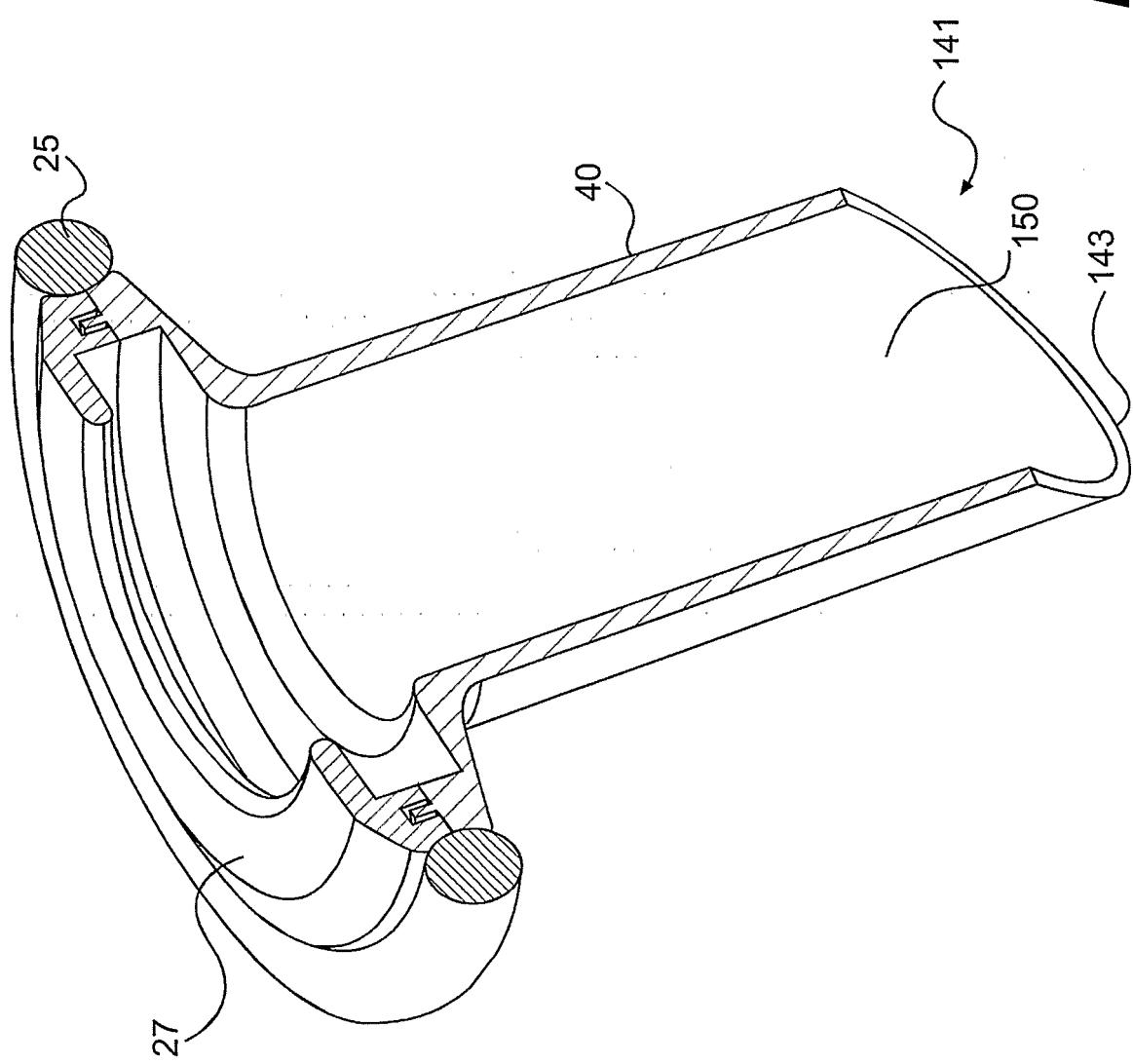
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**FIG. 63****FIG. 64**

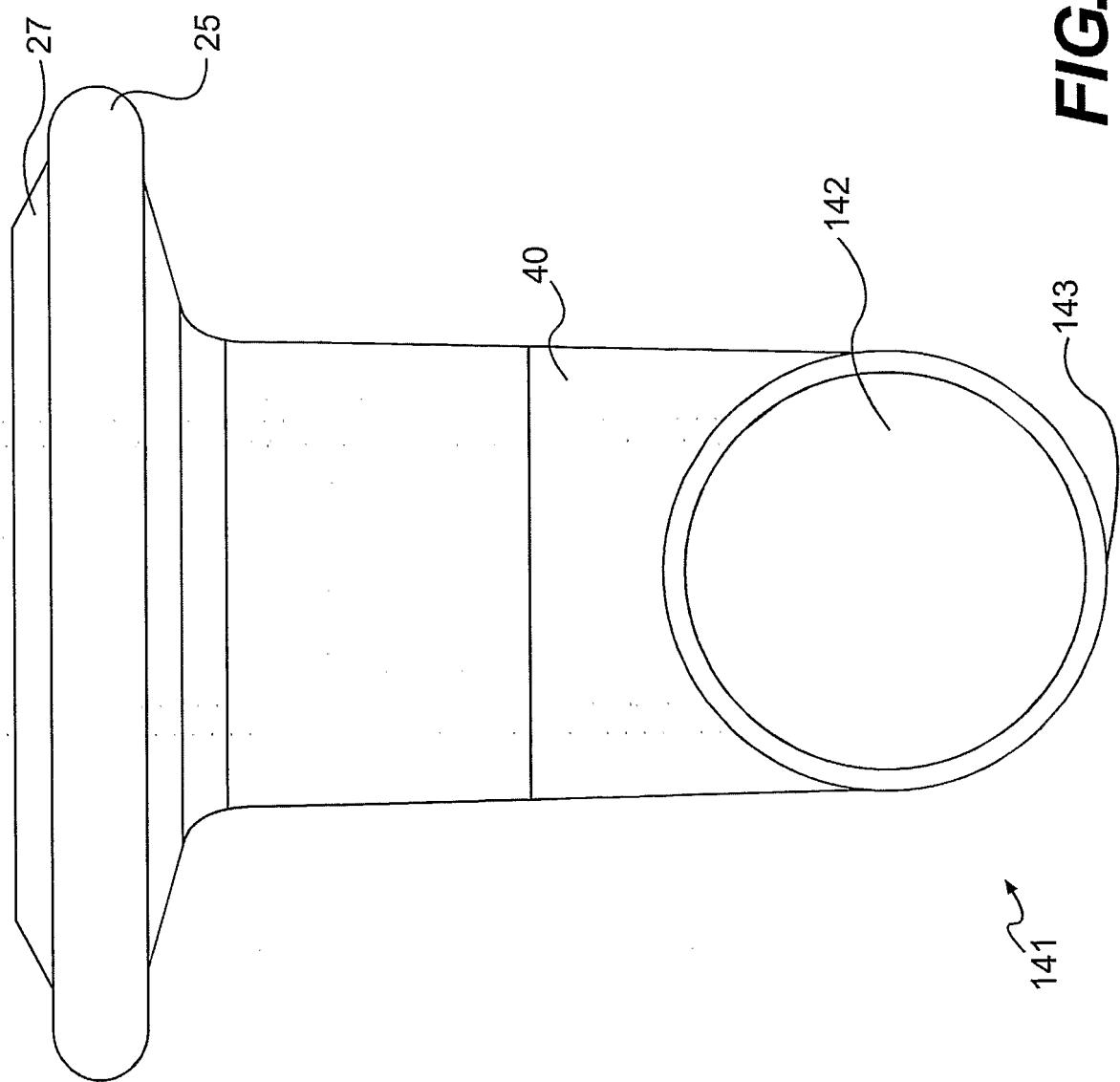
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**FIG. 65**

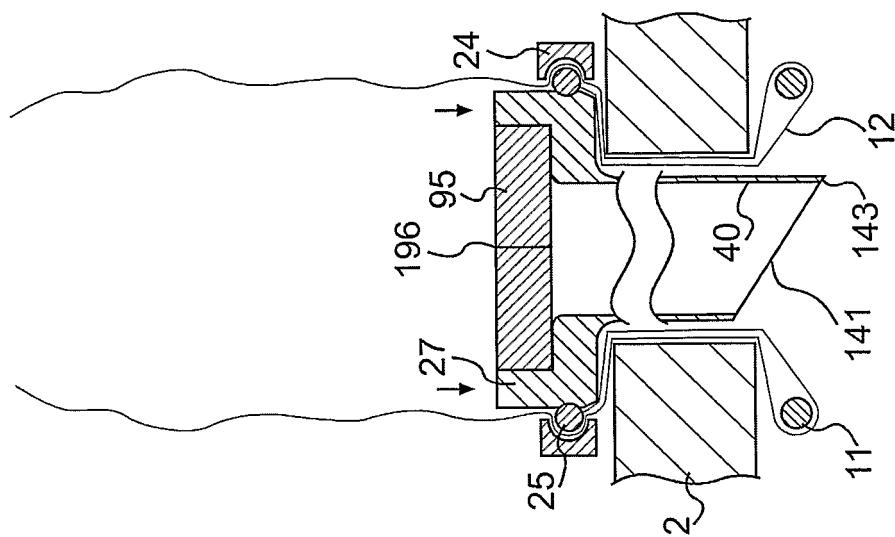
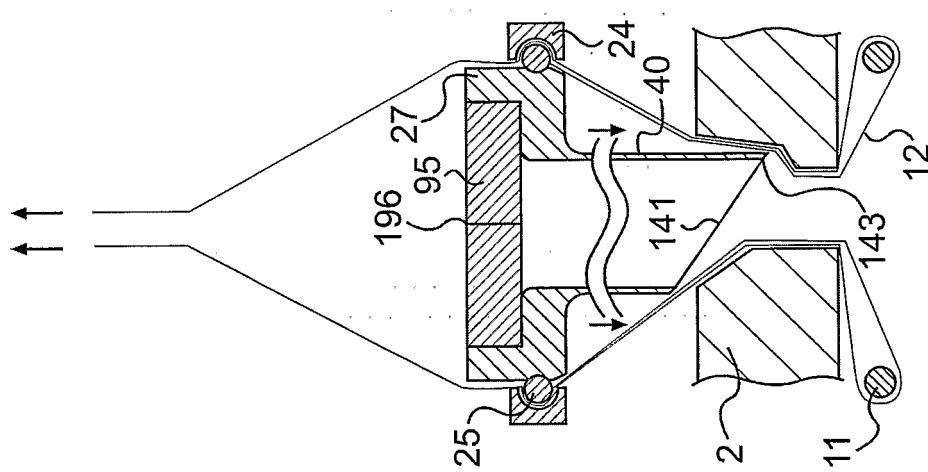
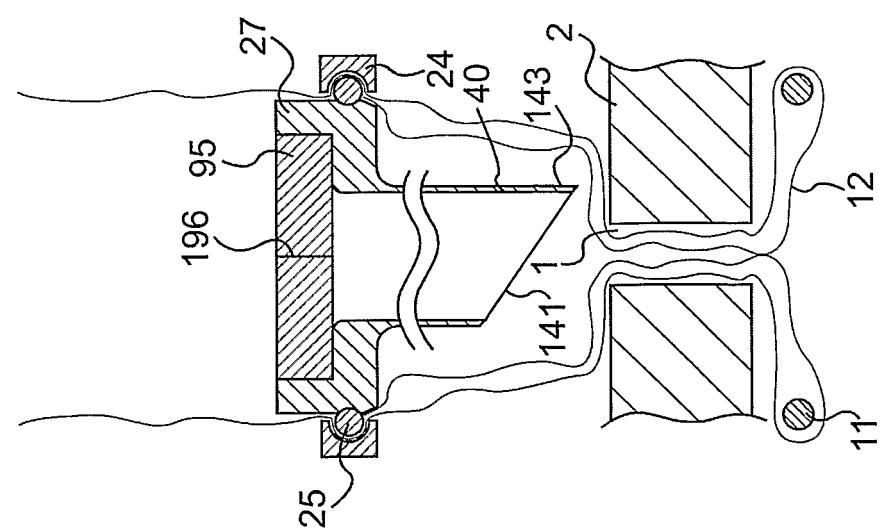
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FIG. 66

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FIG. 67

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**FIG. 70****FIG. 69****FIG. 68**

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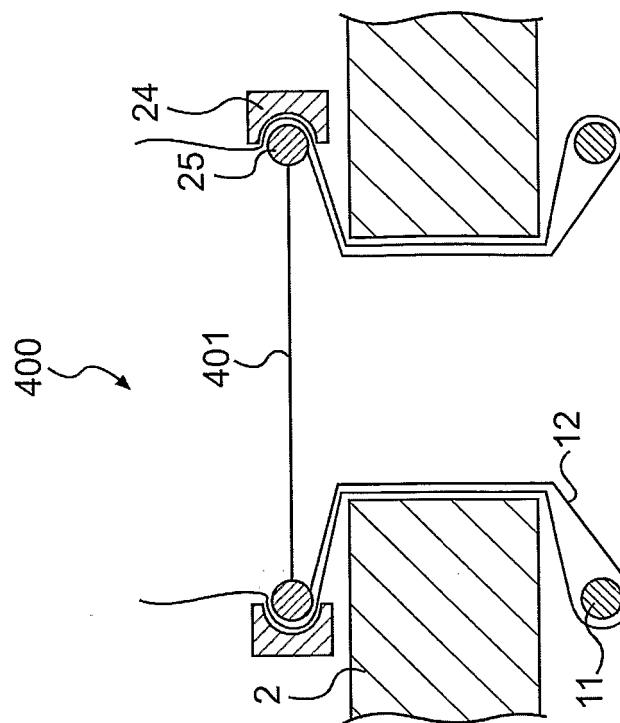


FIG. 70(b)

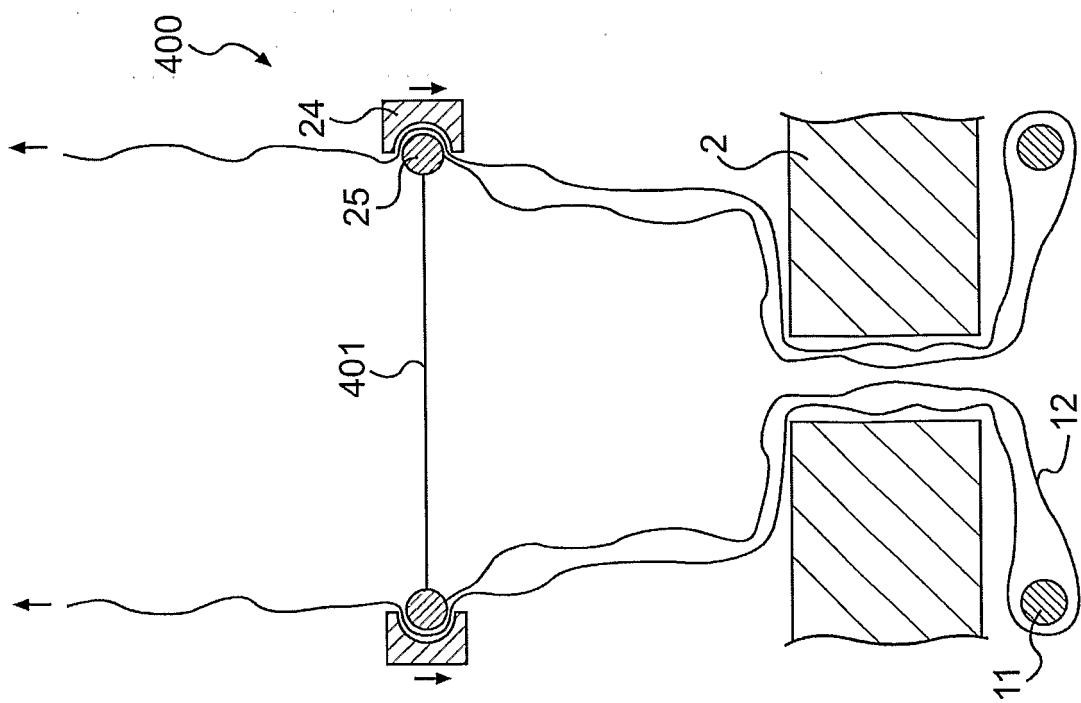
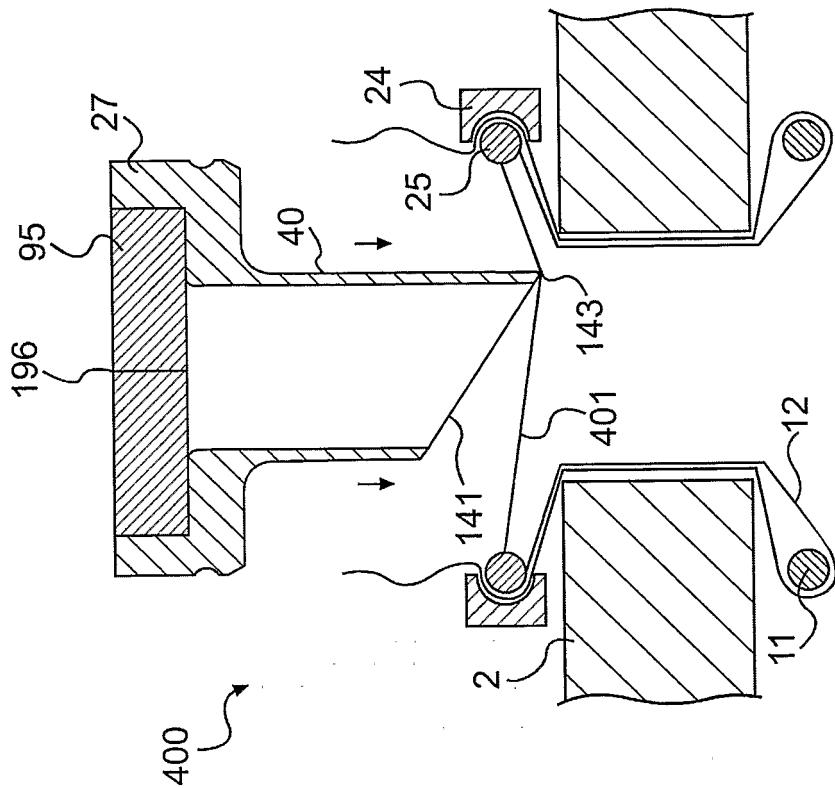
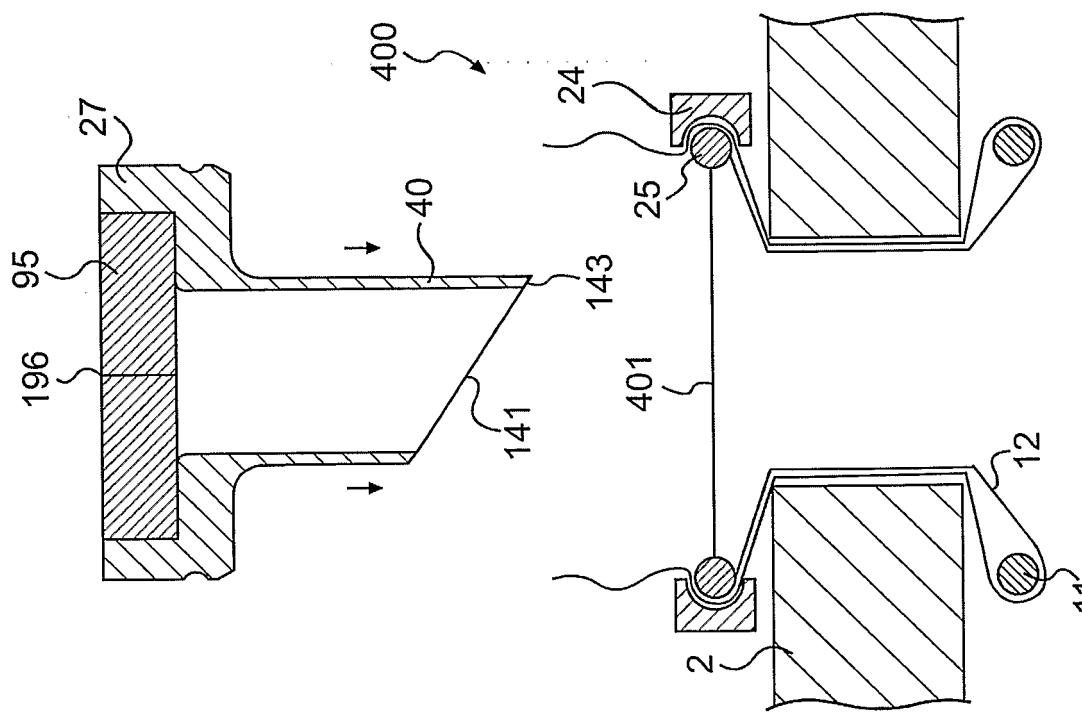


FIG. 70(a)

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**FIG. 70(d)****FIG. 70(c)**

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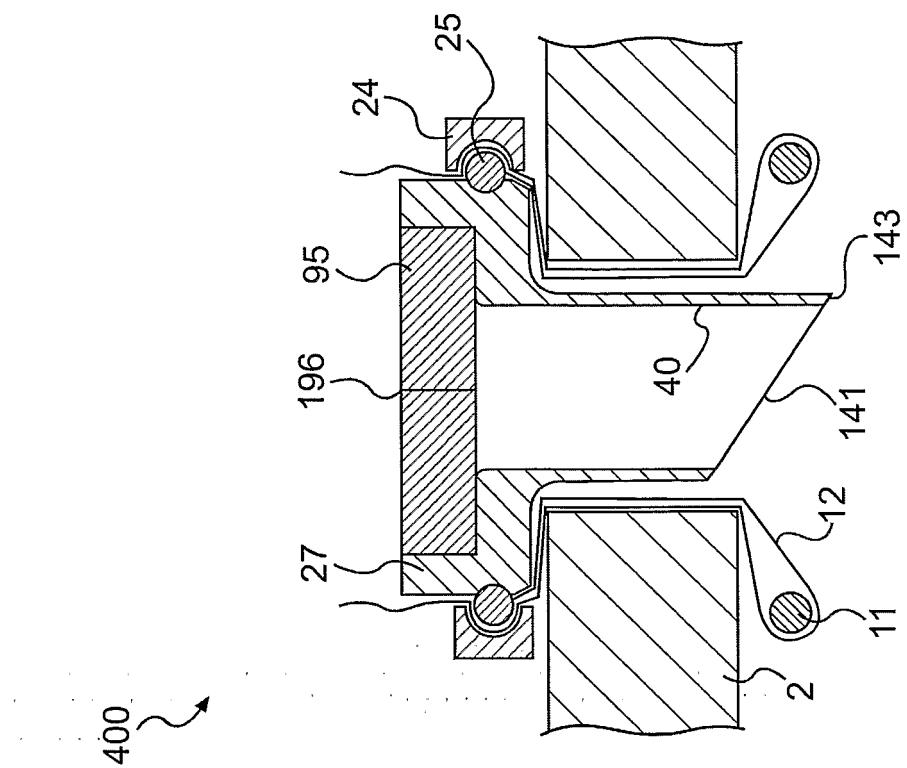


FIG. 70(f)

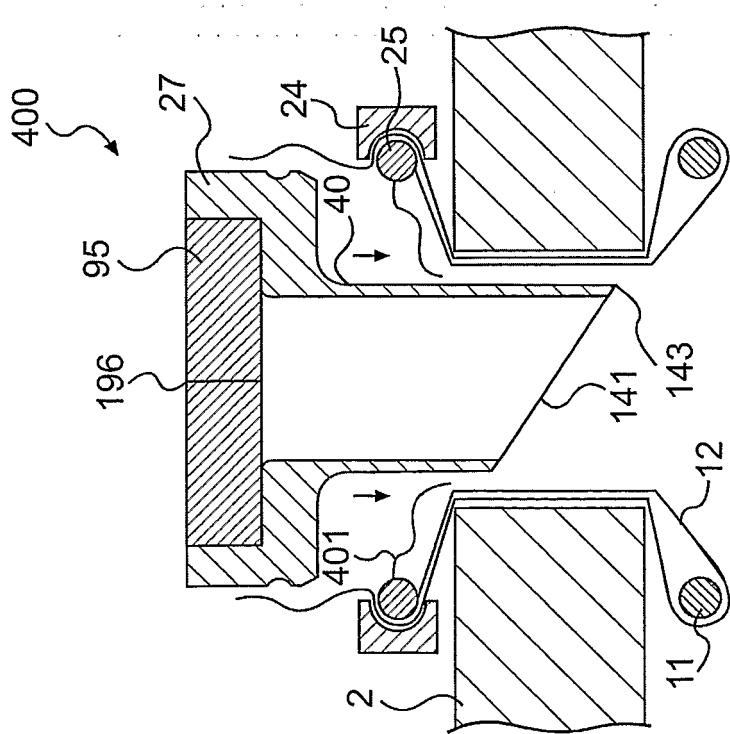
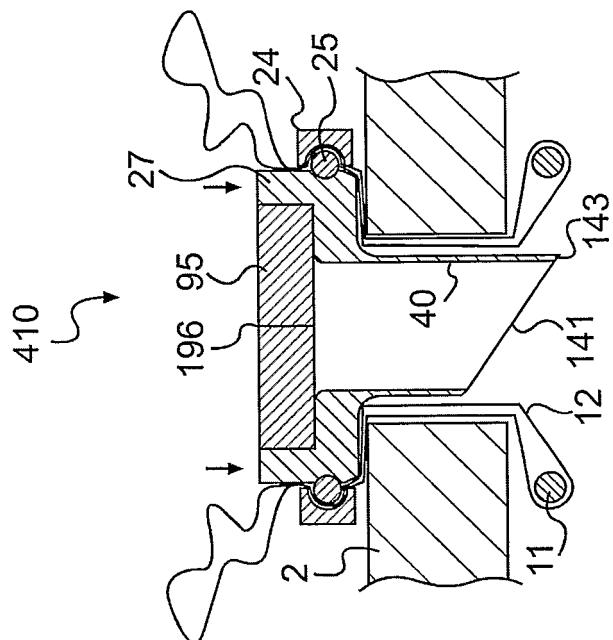
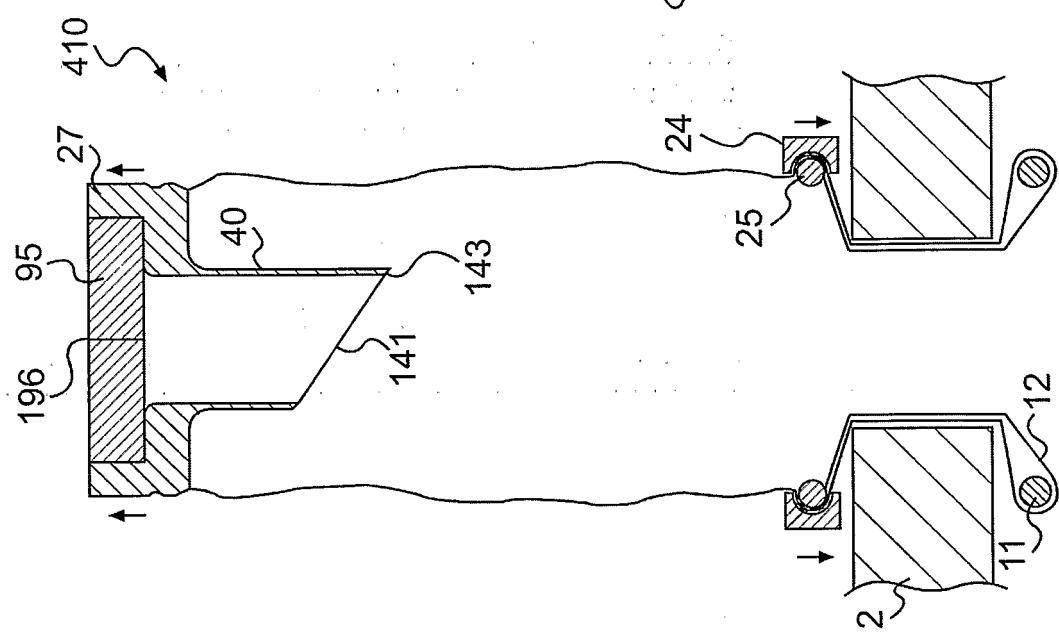
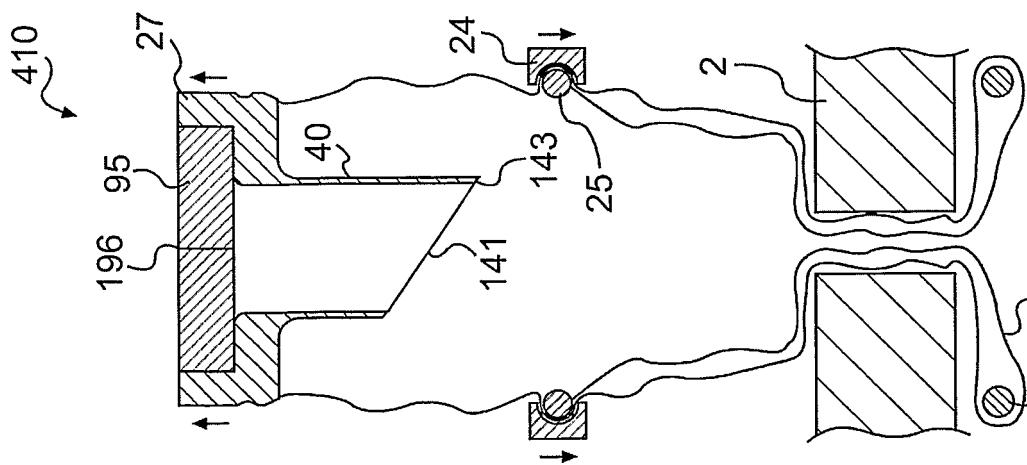
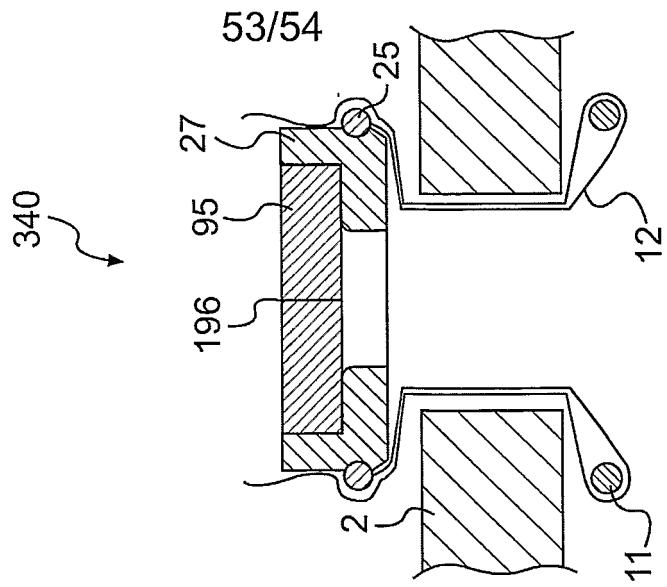
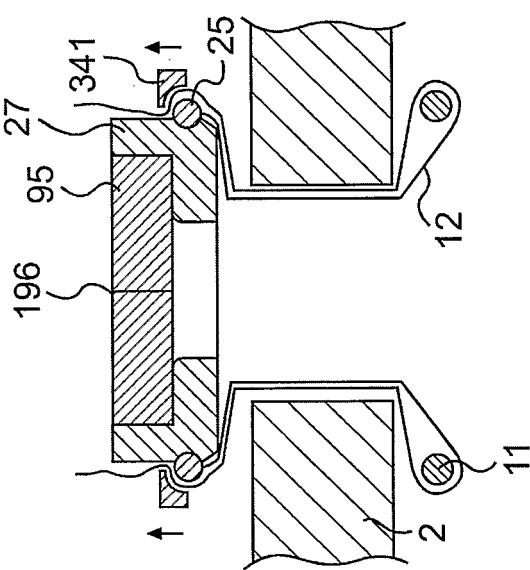
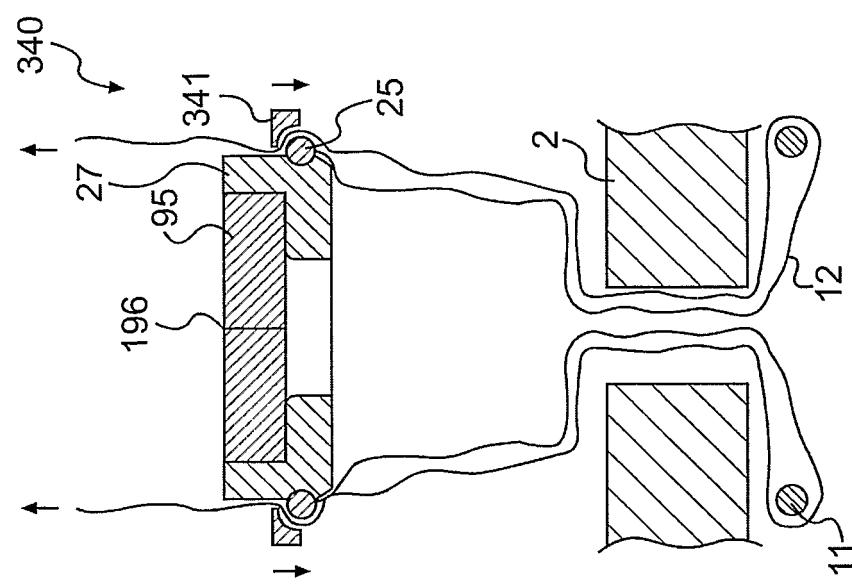


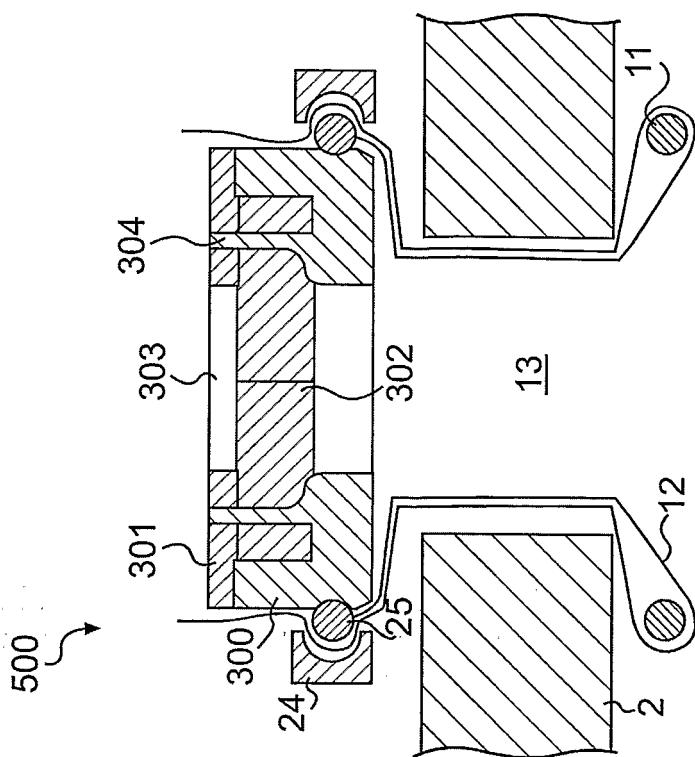
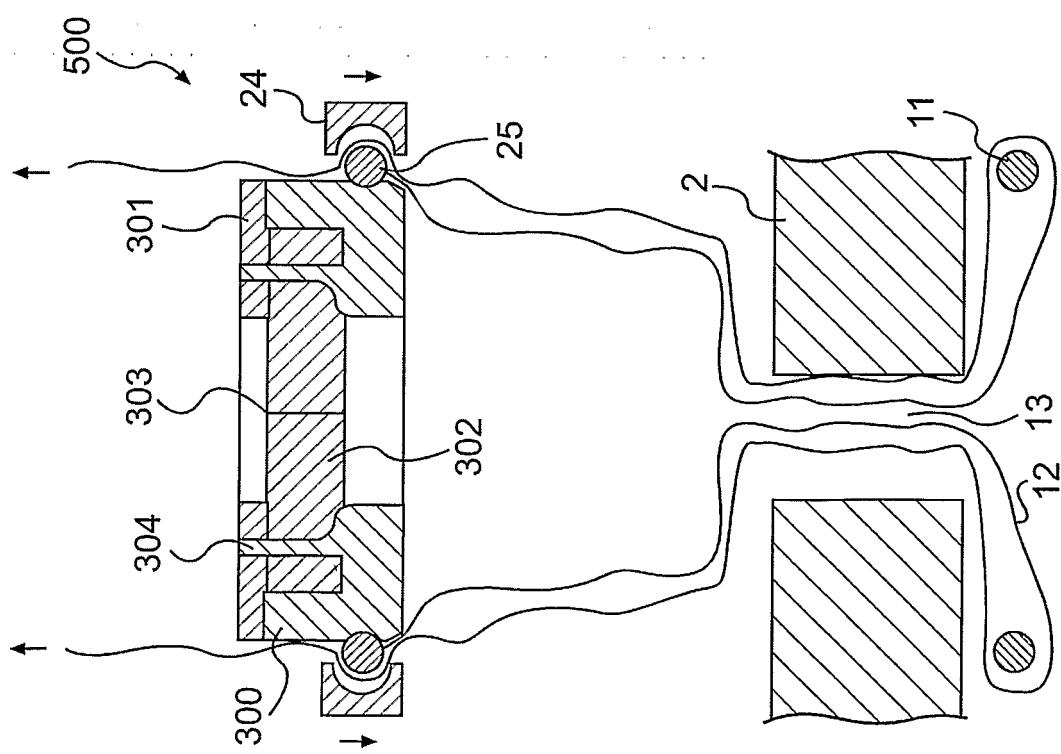
FIG. 70(e)

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FIG. 70(i)**FIG. 70(h)****FIG. 70(g)**

**FIG. 73****FIG. 72****FIG. 71**

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FIG. 58(c)(iii)**FIG. 58(c)(ii)**

INTERNATIONAL SEARCH REPORT

International application No
PCT/IE2005/000113

A. CLASSIFICATION OF SUBJECT MATTER
A61B17/34

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)
A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2004/030547 A (ATROPOS LIMITED; BUTLER, JOHN; VAUGH, TREVOR; BONADIO, FRANK; MACNALLY) 15 April 2004 (2004-04-15) the whole document	1-12, 20-28, 76-85, 87-98
X	US 6 059 816 A (MOENNING ET AL) 9 May 2000 (2000-05-09) column 7, line 50 – column 15, line 65 figures 1-10,27,28	1,2, 63-68, 73-75
X	US 2001/039430 A1 (DUBRUL WILLIAM R ET AL) 8 November 2001 (2001-11-08) page 3, paragraph 39 – page 6, paragraph 59 figures 4-7	1,63-66, 69-72
		-/-

Further documents are listed in the continuation of Box C.

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 document 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

13 February 2006

23.02.2006

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
NL – 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Compos, F

INTERNATIONAL SEARCH REPORT

International application No
PCT/IE2005/000113

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 589 167 B1 (SHIMOMURA KAZUYUKI ET AL) 8 July 2003 (2003-07-08) column 3, line 3 – column 5, line 22 figures 3-8 -----	1,29,37, 38, 48-62,86
X	US 5 957 913 A (DE LA TORRE ET AL) 28 September 1999 (1999-09-28) column 12, line 12 – column 13, line 6 column 15, line 9 – column 17, line 33 figures 27,30-32 -----	1,29-36

INTERNATIONAL SEARCH REPORT

Box 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.: **99–143**
because they relate to subject matter not required to be searched by this Authority, namely:
Claim 99: Contrary to Article 6 PCT, the features of the claims are disclosed as the contents of the figures, this indicates a limitless range of possible device variations which is impossible to search.**Claims 100–143:** Rule 39.1(iv) PCT – Method for treatment of the human or animal body by surgery.
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:
see FURTHER INFORMATION sheet PCT/ISA/210
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 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 additional 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 an additional fee, this Authority did not invite payment of any additional fee.
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.:
1–12, 20–98
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.
 No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-12, 20-28, 63-85, 87-98

An instrument access device having a distal ring to be placed in a wound; a proximal ring to be placed outside the wound; a sleeve portion between said rings; an instrument seal or valve; and an elongate tubular instrument guide passing from the proximal end of the device to the distal end of the device.

2. claims: 1,13-19

An instrument access device having a distal ring to be placed in a wound; a sleeve portion extending proximally from said ring; and a clamp for clamping a working channel in said sleeve.

3. claims: 1,29-62,86

An instrument access device having a distal ring to be placed in a wound; a sleeve portion extending proximally from said ring, a working channel within said sleeve; and a housing for an instrument seal.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 99-143

Claim 99: Contrary to Article 6 PCT, the features of the claims are disclosed as the contents of the figures, this indicates a limitless range of possible device variations which is impossible to search.

Claims 100-143: Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery.

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guideline C-VI, 8.5), should the problems which led to the Article 17(2) declaration be overcome.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/IE2005/000113

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
WO 2004030547	A 15-04-2004	AU 2003272042 A1	BR 0315045 A	23-04-2004
		CA 2499835 A1		23-08-2005
		EP 1545348 A1		15-04-2004
				29-06-2005
US 6059816	A 09-05-2000	NONE		
US 2001039430	A1 08-11-2001	NONE		
US 6589167	B1 08-07-2003	NONE		
US 5957913	A 28-09-1999	NONE		

专利名称(译)	仪器访问设备		
公开(公告)号	EP1804695A1	公开(公告)日	2007-07-11
申请号	EP2005791930	申请日	2005-10-11
[标]申请(专利权)人(译)	阿特波斯有限公司		
申请(专利权)人(译)	阿特洛波斯有限公司		
当前申请(专利权)人(译)	阿特洛波斯有限公司		
[标]发明人	BONADIO FRANK BUTLER JOHN VAUGH TREVOR		
发明人	BONADIO, FRANK BUTLER, JOHN VAUGH, TREVOR		
IPC分类号	A61B17/34		
CPC分类号	A61B17/0293 A61B1/32 A61B17/0218 A61B17/3421 A61B17/3423 A61B17/3431 A61B17/3462 A61B17/3474 A61B17/3498 A61B90/40 A61B2017/00477 A61B2017/00557 A61B2017/0225 A61B2017 /3429 A61B2017/3435 A61B2017/3443 A61B2017/347 A61B2017/3482 A61B2017/3492 A61M13/003		
优先权	60/617094 2004-10-12 US 20040686 2004-10-11 IE 60/699370 2005-07-15 US		
外部链接	Espacenet		

摘要(译)

器械进入装置 (500) 包括用于插入伤口内部的远侧O形环 (11) , 用于位于伤口开口外部的近侧构件和在远侧O形环之间以两层延伸的套管 (12) (11) 和近端构件。近端构件包括内近端环构件 (25) 和外近端环构件 (24) , 套管 (12) 在所述外近端环构件之间被引导。密封壳体 (300) 安装在内近端环构件 (25) 上。具有穿过其中的针孔开口 (303) 的凝胶状弹性体密封件 (302) 容纳在壳体 (300) 中。器械可以延伸穿过密封件 (302) , 以密封的方式通过缩回的伤口开口进入伤口内部。