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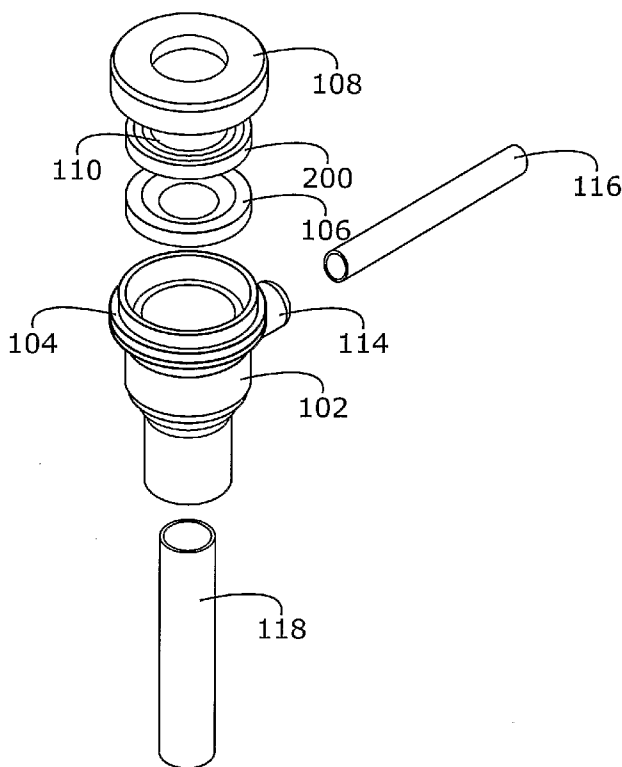
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(54) Title: TWO PART HEMOSTATIC VALVE FOR A CATHETER INTRODUCER



(57) Abstract: A catheter introducer having a secondary hemostatic seal formed from a resilient material and having a flange. A downwardly-depending conic section has an orifice in its apex. The cross sectional area of the secondary hemostatic seal decreases between the flange and the orifice. Compressive radial forces on an introduced catheter and, acting collaboratively with a primary hemostatic valve, forms an effective, leak-resistant hemostatic seal around the catheter. This seal better restricts the backflow of fluids, typically blood, around a catheter inserted into a blood vessel through an introducer. In one embodiment a unique upper auxiliary valve is provided to be placed adjacent an existing hemostatic valve in a catheter introducer. The novel configuration of the auxiliary valve and the lower valve provides a vastly improved hemostatic seal that prevents blood loss from leakage around the catheter during procedures such as angiography or other endovascular interventions.

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TWO PART HEMOSTATIC VALVE
FOR A CATHETER INTRODUCER

5 Related Applications:

This patent application is a continuation-in-part application of U.S. Provisional Patent Application Serial No. 60/737,700, filed November 17, 2005.

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Field of the Invention:

The present invention pertains to valves for hemostatic catheter introducing appliances and more particularly, to a two or more stage valve that minimizes or eliminates fluid leakage therefrom during repeated introductions of diverse catheters and the like.

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BACKGROUND OF THE INVENTION

Hemostatic catheter introducers are used to provide an entry into body cavity, blood vessels etc. Such devices include a valve that allows the passage of a catheter into the blood vessel but prevents fluid flow outwardly therefrom. When a catheter is to be inserted into a blood vessel, particularly an artery, the blood under pressure tends to flow outward around the perimeter of the catheter because the seal within the introducer is ineffective.

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Discussion of Related Art:

Catheter introducers are well known in the prior art. An exemplary prior art introducer may be seen in United States Patent No. 6,352,520 for "HEMOSTATIC VALVE FOR A CATHETER INTRODUCER", issued March 5, 2002 to Miyazaki. MIYAZAKI provides a valve for a catheter comprising multiple layers configured to interactively and cooperatively close around the catheter.

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Patterns are formed in different layers of the MIYAZAKI valve to provide such interaction.

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SUMMARY OF THE INVENTION

In accordance with the present invention, there are provided improvements to better restrict the backflow of fluids, typically blood, around a catheter inserted into a blood vessel. In one
10 embodiment a unique upper auxiliary valve is provided to be placed adjacent an existing hemostatic valve in a catheter introducer. The novel configuration of the auxiliary valve and the lower valve provides a vastly improved hemostatic seal that prevents blood loss from leakage around the catheter during
15 procedures such as angiography or other endovascular interventions.

It is, therefore, an object of the invention to provide a hemostatic seal for use in a catheter introducer.

20

It is a further object of the invention to provide a hemostatic seal in a catheter introducer for use in inserting a guidewire, catheter or other endovascular devices.

It is another object of the invention to provide a hemostatic seal for a catheter introducer that minimizes backward blood flow around the inserted catheter or other device.

It is an additional object of the invention to provide a
30 hemostatic seal for use in a catheter introducer that provides minimal resistance to the passage of a catheter or endovascular devices through the seal.

It is yet another object of the invention to provide a
35 hemostatic seal for use in a catheter introducer that accommodates repeated insertions and withdrawals of diverse catheters and devices while maintaining its ability to seal.

It is a further object of the invention to provide a hemostatic seal for use in a catheter introducer that comprises an auxiliary upper seal and a bottom seal or multiples of seals.

5

BRIEF DESCRIPTION OF THE DRAWINGS

A complete understanding of the present invention may be obtained by reference to the accompanying drawings, when considered in conjunction with the subsequent detailed description, in which:

10

15

FIGURE 1 is an exploded perspective view of a conventional catheter introducer;

FIGURES 2a, 2b and 2c are top plan, side elevational, and cross-sectional views respectively of the upper auxiliary valve of the instant invention;

20

FIGURES 3a and 3b are respectively an exploded, perspective view and cross sectional view of an assembly of a catheter introducer showing the placement of the upper auxiliary hemostatic valve of FIGURES 2a, 2b and 2c in a first possible configuration; and

25

FIGURES 4a, 4b and 4c are top plan, side elevational, and cross-sectional views respectively of the bottom hemostatic valve of the invention.

30

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Generally speaking, the present invention is directed to a hemostatic valve in a catheter introducer. The incorporation of a uniquely designed auxiliary valve is shown to increase the sealing efficiency and prevent reverse flow of fluids from around the catheter.

35

This may be understood with reference to FIGURE 1 which is an exploded, perspective view of a conventional catheter device

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of prior art, generally at reference number 100. Catheter introducer 100 has a body portion 102 having an externally-threaded upper region 104 adapted to receive a hemostatic seal 106 therein. Cap 108 has a catheter-receiving orifice 112
5 disposed centrally therein and is received on an externally-threaded upper region 104 thereby retaining hemostatic seal 106 within the body portion 102. Hemostatic seal 106 is typically formed from a resilient material and contains a feature (e.g. a slit) 110 to allow passage of a catheter 120 therethrough. Slit
10 110 provides closure around the catheter 120 thereby preventing passage of blood.

A branch tube 114 allows attachment of a side tube 116 for diverse purposes known to those of skill in the medical arts.
15

A sheath portion 118 extends downward from a lower region of body portion 102 of catheter introducer 100.

Typically the single seal (also referred to as a valve hereinafter) 106 is ineffective in preventing leakage of blood or other bodily fluids around catheter 120.
20

It has been discovered that placement of two discrete adjacent valves in the upper region 104 of the body portion 102 greatly improves the hemostatic seal. The present invention incorporates an auxiliary valve of unique design placed adjacent the primary valve thereby increasing the leak resistance of the hemostatic seal.
25

Referring now to FIGURES 2a, 2b and 2c, there are shown top plan, side elevational, and side cross-sectional views, respectively of an auxiliary valve in accordance with the present invention, generally at reference number 200.
30

Auxiliary valve 200, has a substantially circular flange having an outer diameter 202 sized to fit within the seal-receiving interior portion of the upper region 104 (FIGURE 1) of body portion 102 (FIGURE 1). A second, concentric diameter 204 defines a point wherefrom a downwardly directed conical portion
40 206 emerges from the flange. As may be seen in FIGURE 2c, the

downwardly directed conical portion has a continuously decreasing cross-section towards the apex, a unique feature of the invention. A second unique feature of the invention is that, unlike conventional valves of the prior art, the conical portion
5 206 terminates in a circular orifice 208. Conventional valves of the prior art are characterized by orifices configured as slits or slots that provide an opening for the introduction of the catheter. The diameter of orifice 208 is designed to be smaller than that of the narrowest/thinnest catheter, not shown, intended
10 to be used in a surgical procedure.

A relieved feature 210 is present in the flange of the valve 200 to accommodate protrusions in the cap 108 (FIGURE1).

15 Valve 200 is made from a compliant, resilient material suitable for medical applications. Additionally the material must be suitable for sterilization and must be non-allergenic. Elastomeric materials such as Neoprene™, butadiene, latex, silicone rubber and the like, which lend themselves to easy
20 fabrication are suitable valve materials and are known in the art. Such materials are capable of repeated elastic expansion of 200% to 1200% in the diameter of the opening without failure (tearing, permanent set or the like).

25 In operation, the auxiliary valve 200 exerts a compressive radial force on an introduced catheter and, acting collaboratively with the primary hemostatic valve 106, forms an effective, leak-resistant hemostatic seal around the catheter.

30 The auxiliary valve 200 is intended to be used in conjunction with a primary valve. Referring now to FIGURE 3a and 3b, there is shown respectively an exploded, perspective view and cross sectional view of an assembly of a catheter introducer 300 showing the placement of the upper auxiliary hemostatic valve 200
35 of FIGURES 2a, 2b and 2c in a first possible configuration. In the embodiment of FIGURES 3a and 3b, only one auxiliary valve 200 is shown adjacent and above the primary valve 106. An auxiliary valve 200 of the instant invention placed below the primary valve would be equally effective in forming a hemostatic seal. It will
40 also be recognized that two auxiliary valves 200 may be used, one

each above and below the primary valve 106 to improve the hemostatic sealing efficiency.

The mode of employing the auxiliary valve of the instant invention in conjunction with a primary valve is shown in FIGURES 5 3a and 3b. FIGURE 3a is an exploded, perspective view and 3b is a cross-sectional elevational view of a catheter introducer showing the configuration of the auxiliary valve 200 adjacent the primary valve 106. In these FIGURES 3a and 3b similar reference numbers 10 refer to similar parts of the introducer previously discussed with reference to FIGURE 1 and are not explained in further detail.

Referring now to FIGURES 4a, 4b cross-sectional views, 15 respectively of another embodiment of a hemostatic seal or valve designed to replace primary valve 106 (FIGURE 1), generally at reference number 400. The valve comprises a substantially circular flange 404 with a downwardly convex portion 406 emerging from it and terminating in a cylindrical portion 408. An opening 20 410 is provided for the introduction of the catheter. Modified valve 400 may substitute for valve 106 as shown in FIGURES 3a and 3b.

The mode of employing the auxiliary valve of the instant invention in conjunction with a primary valve is shown in FIGURES 25 3a and 3b. FIGURE 3a is an exploded, perspective view and 3b is a cross-sectional elevational view of a catheter introducer showing the configuration of the auxiliary valve 200 adjacent the primary valve 400. In these FIGURES similar reference numbers refer to 30 similar parts of the introducer previously discussed with reference to FIGURE 1 and are not explained in further detail.

Without reliance on any particular theoretical model, inventors believe that the design of the auxiliary valve with the 35 two unique characteristics viz. decreasing thickness of the cross section of the conical portion 206 of the valve and the "under-sized" opening 208 of the valve provide for a more effective seal than conventional valves with flaps and slits.

When an "oversized" catheter or device is introduced through the auxiliary valve, the outward expansion of the elastomeric material results in continuous, inward, compressive radial forces on the catheter. This results in a more conformal seal between
5 the valve and the catheter and a more effective prevention of leakage or "bleed-out". The decreasing wall-thickness results in a more compliant valve which combined with the elasticity of the material permits multiple introductions (and removal) of catheters of different sizes.

10

Since other modifications and changes varied to fit particular operating requirements and environments will be apparent to those skilled in the art, this invention is not considered limited to the example chosen for purposes of this
15 disclosure, and covers all changes and modifications which does not constitute departures from the true spirit and scope of this invention.

Having thus described the invention, what is desired to be
20 protected by Letters Patent is presented in the subsequently appended claims.

What is claimed is:

1. An auxiliary valve for use adjacent a primary valve in a hemostatic seal in a catheter introducer, comprising:

5

a) a substantially circular flange; and

b) a conical section depending from said flange and having a decreasing wall-thickness and a circular orifice disposed at an apex thereof, a wall-thickness of said conical section decreasing from said flange towards said apex.

10

2. The auxiliary valve according to claim 1, wherein said auxiliary valve comprises a compliant, resilient elastomeric material capable of repeated expansions of said orifice without failure.

15

3. The auxiliary valve according to claim 2, wherein said repeated expansions of said orifice are in the range of between approximately 200% to 800% of the diameter of said orifice.

20

4. The auxiliary valve according to claim 1, wherein the introduction of a catheter results in radial compressive forces exerted on the catheter by the valve thereby forming an effective hemostatic seal.

25

5. The auxiliary valve according to claim 1, wherein said elastomeric materials are selected from the group: Neoprene™, butadiene, latex, and silicone rubber.

30

6. A hemostatic seal in a catheter introducer comprising:

5 a) an auxiliary valve, characterized by a substantially circular flange, a downwardly facing conical section attached thereto, said conical section having a wall-thickness decreasing from said circular flange to an apex of said conical section;

10 b) a circular orifice disposed the apex of the conical section, wherein the wall-thickness of the conical section decreases towards the apex of the conical section; and

15 c) a primary hemostatic valve disposed adjacent said auxiliary valve.

7. A catheter introducer comprising:

20 a) an auxiliary valve, characterized by a substantially circular flange, a downwardly facing conical section depending therefrom, said conical section having a decreasing wall-thickness between said circular flange and said apex, said apex having a circular orifice disposed therein; and

25 b) a primary hemostatic valve disposed adjacent said auxiliary valve;

30 whereby a compressive radial force exerted by said auxiliary valve on an introduced catheter, acts collaboratively with said primary hemostatic valve to form an effective, leak-resistant hemostatic seal around said catheter.

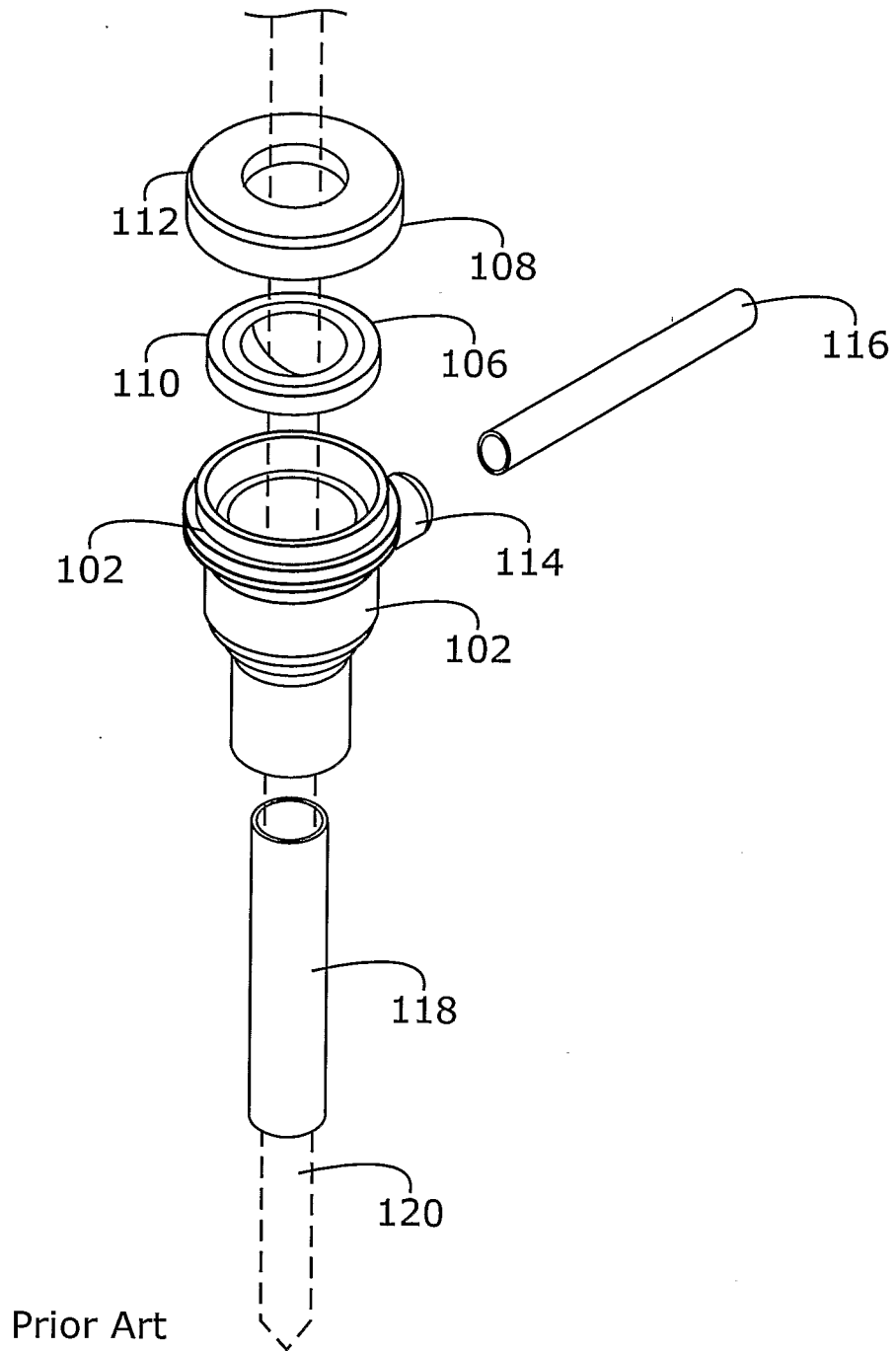


Figure 1

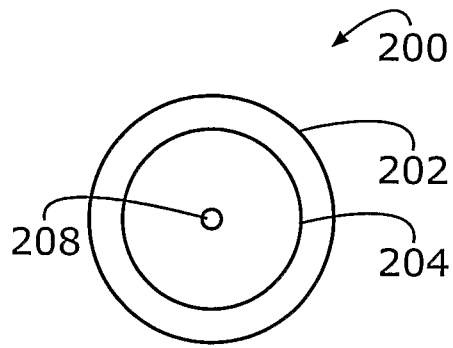


Figure 2a

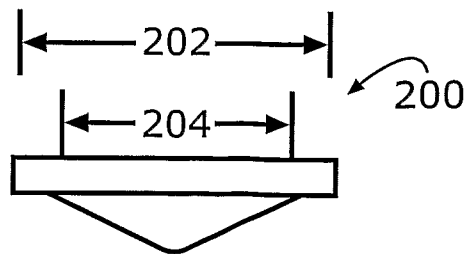


Figure 2b

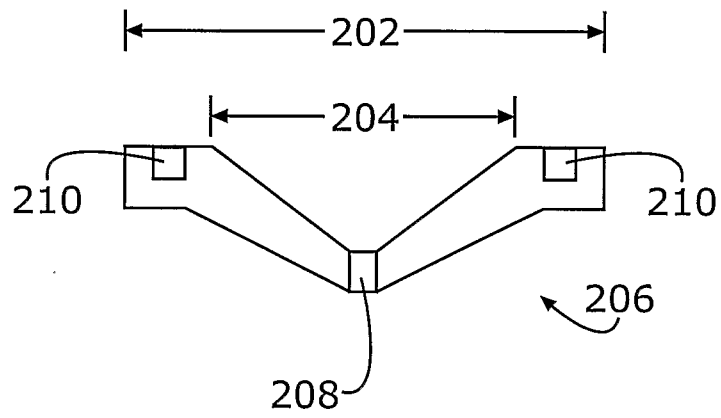


Figure 2c

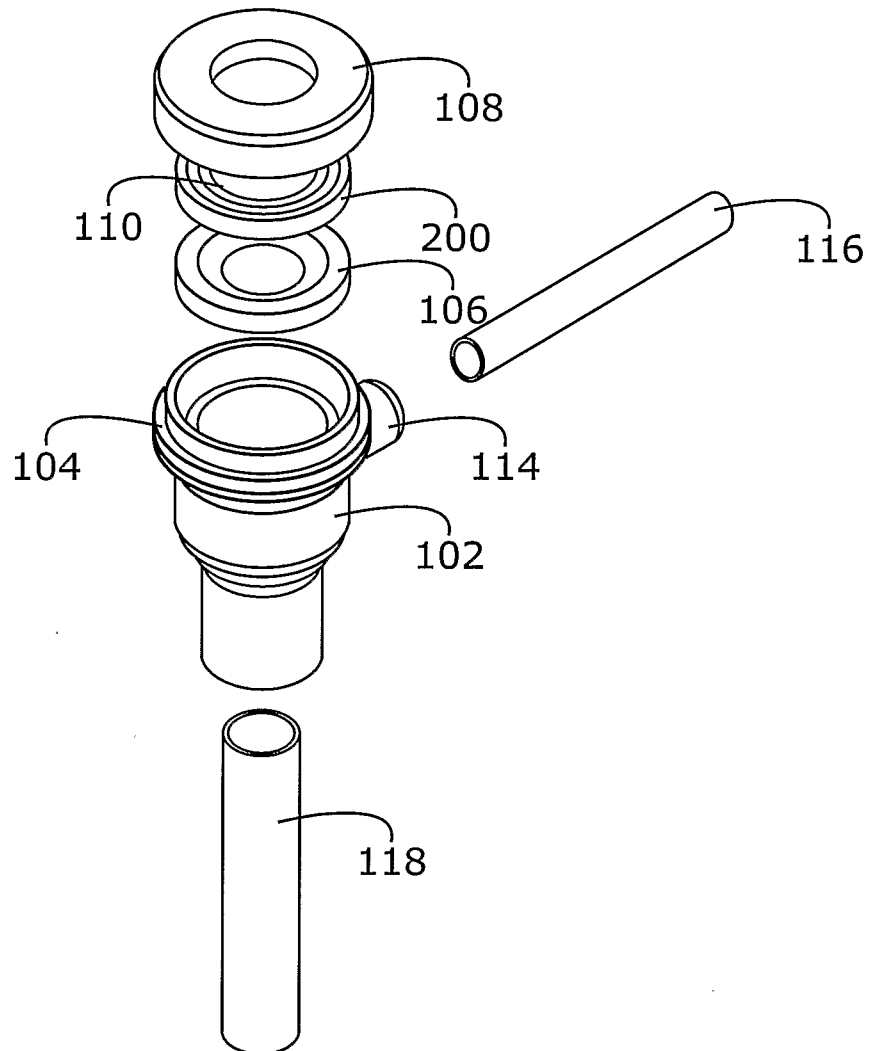


Figure 3a

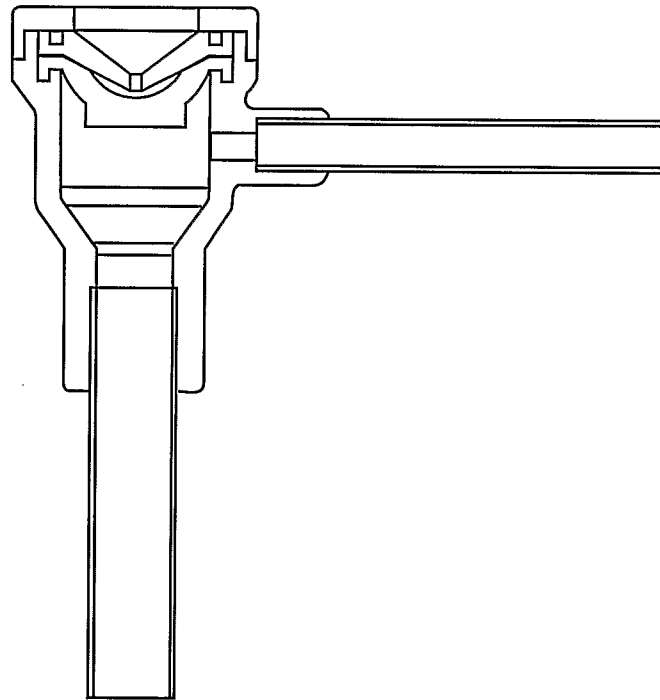


Figure 3b

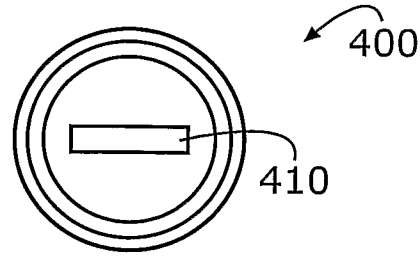


Figure 4a

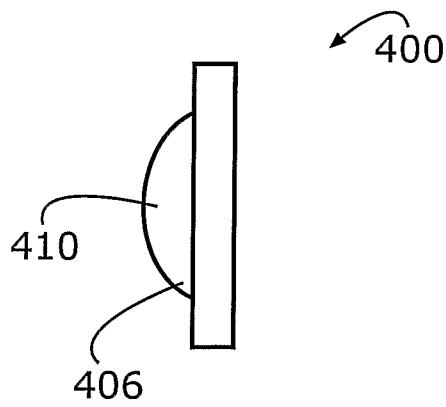


Figure 4b

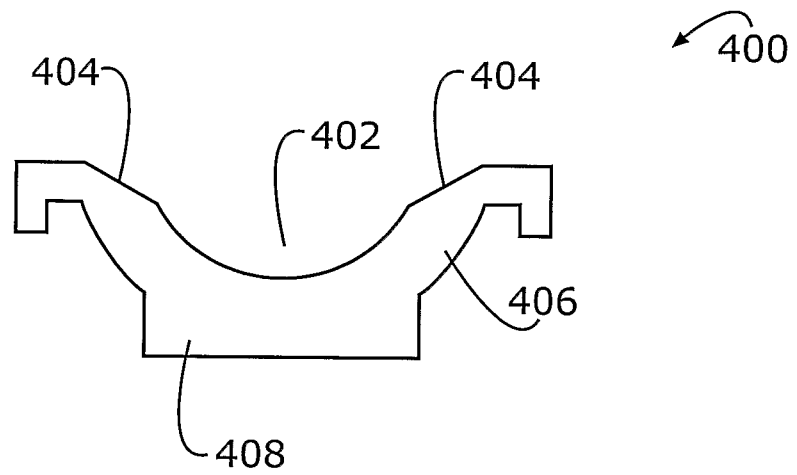


Figure 4c