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(54) **Title:** HAEMOSTATIC VALVE DEVICE

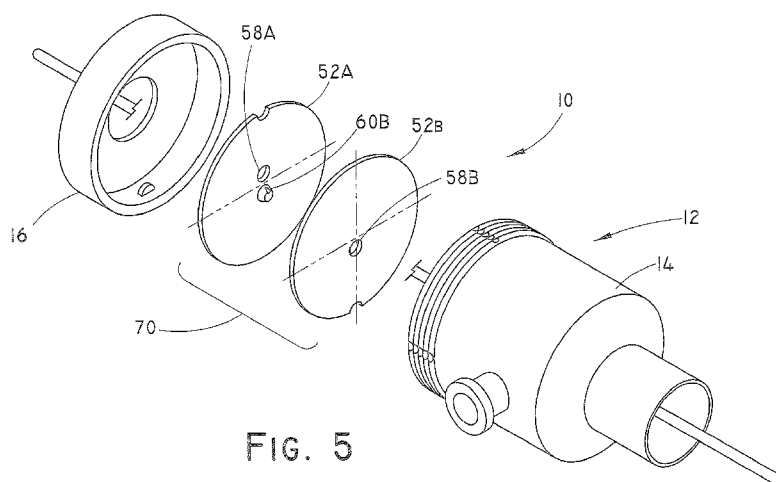


FIG. 5

(57) **Abstract:** A haemostatic valve device (10) comprises a disk valve (52a) having a valve body with a first surface facing in a first direction, a second surface facing in a second direction opposite the first direction, and an opening (58a) formed in the valve body for providing communication through the disk valve. In some examples, the disk valve comprises a nipple (60b), axially offset from the opening, extending outwardly and away from at least one of the first and second surfaces. The haemostatic valve device may further comprise a second disk valve (52b) and the nipple (60b) may be removably disposed within, and sealingly engage, an opening (58b) of the second disk valve.



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## HAEMOSTATIC VALVE DEVICE

### Field of the Invention

The present invention relates to haemostatic valves, devices, and  
5 systems, and methods of making and using same.

### Background of the Invention

Numerous procedures have been developed that involve the  
percutaneous insertion of a medical device into a vessel. Such a device may be  
introduced into the vessel by a variety of known techniques. For example, a wire  
10 guide may be introduced into a vessel using the Seldinger technique. This  
technique involves making a surgical opening in a vessel by a needle and inserting  
a wire guide into the vessel through a bore in the needle. The needle can be  
withdrawn, leaving the wire guide in place. An introducer device is then inserted  
over the wire guide and into the vessel. The introducer device may be used in  
15 conventional fashion to insert a variety of types of medical devices, such as  
catheters, cardiac leads, balloons, stents, stent grafts, and the like.

One of the challenges associated with endoluminal procedures is  
controlling the flow of bodily fluids within the introducer device during the  
procedure. Haemostatic devices and valve systems control the flow of blood  
20 through an introducer. US-A-2007/0078395 entitled "Haemostatic Valve System",  
the disclosure of which is incorporated herein by reference, discloses numerous  
examples of haemostatic valve devices and systems that use disk valves to  
control fluid flow. US-A-2007/0078395 discloses, among other things, disk valves  
with holes that are offset from the radial center of the disk. In some examples, a  
25 valve system includes several such disks, aligned so that the holes are not  
substantially overlapping. Additional valve disks may be added to improve the  
pressure rating of such a valve system.

Using a large number of disk valves to provide a desired seal can  
present challenges. For example, as the number of disk valves increases, the  
30 total force required to insert a medical device through the valve system may  
increase. In addition, even when the valves are in a "closed" configuration, the

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holes in the disk valves remain open and may provide a pathway for leakage through the haemostatic device.

#### Summary of the Invention

The present invention seeks to provide an improved haemostatic valve, valve and medical introducer or deployment device incorporating such a valve.

According to an aspect of the present invention, there is provided a haemostatic valve device including a disk valve including a valve body with a first surface facing in a first direction, a second surface facing in a second direction opposite the first direction, an opening formed in the valve body for providing communication through the disk valve, and a nipple extending outwardly and away from at least one of the first and second surfaces; wherein the nipple is axially offset from the opening.

According to another aspect of the present invention, there is provided a haemostatic valve device including a first disk valve having a valve body with an opening therein for providing communication through the first disk valve; and a second disk valve having a valve body with an opening therein for providing communication through the second disk valve, and a plug removably disposed within, and sealingly engaging, the opening of the first disk valve to limit fluid flow through the first disk valve.

Various examples of valve devices and systems are described throughout the specification and depicted in the drawings. In one example, a haemostatic valve device is provided and comprises a disk valve having a valve body with a first surface facing in a first direction, a second surface facing in a second direction opposite the first direction, an opening formed in the valve body for providing communication through the disk valve, and a nipple extending outwardly and away from at least one of the first and second surfaces of the valve body.

Such a disk valve may be used, for example, in combination with a second disk valve to provide a haemostatic valve device with superior haemostatic properties. In these examples, the valves are arranged so that the nipple is removably disposed within, and sealingly engages, an opening of the second disk valve. The nipple acts as a stopper or plug for the opening of the second disk

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valve, thereby limiting fluid flow through the opening. A medical device, such as a guide wire, may be inserted through the opening of the second disk valve to displace the nipple, break the sealing engagement, and allow the wire to pass through the openings. Such devices have a more robust sealing structure and may result in a better pressure rating than devices that use only traditional disk valves.

In some embodiments, the nipple has a tapered contour. The nipple may be attached to the valve body by any means. For example, the nipple and the valve body may comprise a monolithic structure. In examples comprising a second disk valve, the second disk valve may comprise a nipple that is removably disposed within, and sealingly engages, the opening of the first disk valve.

In another embodiment, a haemostatic valve device is provided and comprises a first disk valve and a second disk valve. Each disk valve has a valve body with an opening formed in the valve body for providing communication through the disk valve. The second disk valve may have a plug removably disposed within, and sealingly engaging, the opening of the first disk valve to limit fluid flow through the first disk valve. The first disk valve may, likewise, have a plug removably disposed within, and sealingly engaging, the opening of the second disk valve. In preferred examples, the opening of the first disk valve is axially offset from the opening of the second disk valve.

Guiding a device through first and second openings in such devices can be more challenging than in examples where the openings are axially aligned. Therefore, structures are disclosed herein for guiding a medical device between the first and second openings. For example, the plug of the second disk valve may have a dent with a contour that slopes towards the opening of the second disk valve. The plug of the second disk valve and the opening of the first disk valve may cooperate to form a niche having a contour that slopes towards the opening of the second disk valve. When a medical device, for example a guide wire, is inserted into the chamber, the dent and/or niche acts as a locator for the sealed opening of the first disk valve, biases the manner in which the medical device passes through the opening, and causes the opening to stretch in a

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predetermined direction, thereby deflecting and guiding the medical device towards the opening of the second disk valve.

#### Brief Description of the Drawings

Embodiments of the present invention are described below, by way of example only, with reference to the accompanying drawings, in which:

FIG 1 is a perspective view of a haemostatic device;

FIG 2 is an exploded view of the device shown in FIG 1;

FIG 3 is a perspective view of an embodiment of valve device;

FIG 4 is a perspective view of another embodiment valve device;

FIG 5 is an exploded view of an embodiment of haemostatic device including a valve device similar to the one shown in FIG 4;

FIG 6 is a cross-sectional view of the valve device shown in FIG 4;

FIG 7A is a perspective view of an embodiment of nipple for the valve devices disclosed herein;

FIG 7B is a cross-sectional view of the nipple of FIG 7A;

FIG 8 is a perspective view of the valve device shown in FIG 4; and

FIGS 9A-9D depict various views of a valve device in stages of use.

#### Terminology

Throughout the specification, when referring to a medical device, or a portion of a medical device, the terms "distal" and "distally" shall denote a position, direction, or orientation that is generally towards, or in the direction of, the patient when the device is in use. The terms "proximal" and "proximally" shall denote a position, direction, or orientation that is generally away from the patient, or closer to the operator, during use of the device.

The term "medical device" refers to any device, object, or structure, that supports, repairs, or replaces, is configured to support, repair, or replace, or that may be used, alone or in combination with other devices, objects, or structures, to support, repair, or replace a body part or a function of that body part. Examples of medical devices include, but are not limited to, sheaths, catheters, guide wires, cardiac leads, vessel occlusion devices, filters, stents, stent grafts, and delivery and deployment devices.

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The term "opening" includes one or more apertures, perforations, gaps, spaces, holes, slits, slots, or the like.

The term "monolithic" refers to structures, or portions of structures, that are formed as a single integral piece, rather than being separately formed and  
5 attached.

The term "disk" describes structures with circular contours, as well as structures with contours that would not be described as circular (such as square, octagonal, and the like). Thus, the term "disk valve" describes valve structures that are circular, as well as structures that are not circular.

10 The term "niche" refers to a dent, detent, depression, cut, score, notch, line, recess, dimple, or other like structure in a surface.

#### Description of the Preferred Embodiments

Figures 1 and 2 illustrate a perspective view and exploded view, respectively, of one embodiment of introducer device 10. Various features of this  
15 device are described in detail in US-A-2007/0078395 where more specific details can be found. The device 10 includes a valve housing 12 having a main body 14 and an end cap 16. Main body 14 and end cap 16 may be joined in any conventional fashion, such as by a screw fit or a snap fit. As can be seen in FIG 2, main housing body 14 has one or more screw threads 17 that correspond with a  
20 lip or other suitable structure in the end cap. Housing 12 may also include a side-arm spout 18 extending in a generally transverse direction from main housing body 14. Spout 18 may be used for transmitting or aspirating a fluid or drug in a conventional fashion, and preferably includes a lip 19 sized and shaped for threaded or like engagement with a tube or other device (not shown). The distal  
25 end of main housing body 14 comprises a smaller diameter portion 22. A removable sheath 24 extends distally from smaller diameter portion 22 of housing 12 in conventional fashion. A wire guide 25 extends through device 10.

The device comprises a plurality of disk valves 26, 30, 34, 38, as shown in FIG 2, disposed within a chamber of the housing 12. The valves 26, 30, 34, 38  
30 are axially aligned between main body 14 and end cap 16. Each valve has an opening 27, 31, 35, 39 (depicted, in this example, as a generally circular hole) that allows communication through the valve of fluids, such as blood. The openings

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27, 31, 35, 39 are preferably sized to enable communication or passage of a medical device, such as a catheter. In this example, the openings are each axially offset from the radial center of the respective disk. To improve the pressure rating of the valve system, the valves are arranged so that openings in immediately adjacent disks are not substantially overlapping. The device shown in FIGS 1 and 2 includes numerous other features that are described in US-A-2007/0078395.

The use of disks in haemostatic valve systems is well known. The disks preferably comprise a material with sufficient elasticity to enable an opening formed in the disk to stretch to the extent required to allow a medical device to pass through the disk, and to enable the disk and opening to substantially return to a pre-stretched condition when the medical device is removed. Examples of suitable materials include silicone and urethane, although any other suitable composition known in the art for such purposes may also be used.

Figure 3 depicts an embodiment of disk valve 50 that may be used along with, or instead of, a conventional disk valve. The valve 50 includes a valve body 52 having a first surface 54 facing a first direction, a second surface 56 facing a second direction, opposite the first direction, and an opening 58 between the first and second surfaces. The valve body 52 preferably comprises an elastic material, as described above, and is fluid impermeable.

Opening 58 provides a path for communication through the valve 50. Opening 58 is preferably sized and configured to allow passage of a medical device (not shown) through the valve 50, as described above. In some examples, opening 58 may have a generally circular shape and have an unexpanded diameter of approximately 0.1 mm. Such an opening may expand to 50 or 60 times its diameter, depending on the elasticity of the disk material. In other embodiments, opening may have a non-circular shape and/or may have an unexpanded dimension that is less than, or greater than, 0.1 mm.

In the embodiment of FIG 3, opening 58 is axially offset from the radial center C of the valve body 52. In other embodiments, valve 50 may have an opening disposed at the radial center of the valve body. Opening 58 is depicted in FIG 3 as a generally circular aperture, however other structures and configurations are also contemplated. For example, opening may comprise one or more slits.

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Disk valve 50 has a nipple 60 that extends outwardly and away from the first surface 54 of the valve body 52. Nipple 60 has a base B attached to the valve body 52 and extends outwardly towards head H (see FIG 7A). Nipple 60 and opening 58 are each axially offset from the radial center C of the valve body 52 and are axially offset from each other. The distance between nipple 60 and opening 58 may vary by design. Thus, in some examples, nipple 60 and opening 58 may be axially aligned.

Nipple 60 is sized and configured to engage and seal an opening in a valve to limit communication through the valve (described further below). The shape, size, and configuration of the nipple can vary. To facilitate engagement of the nipple 60 with the opening, the head H preferably has a radial dimension that is less than, or equal to, the radial dimension of the opening to be sealed (see for example FIG 4, described below). To facilitate sealing, at least a portion of the nipple should preferably have a radial dimension that is equal to, or greater than, the radial dimension of the opening to be sealed. This "sealing" region is denoted in FIG 7A as "S."

In the embodiments of FIGS 3, 7A, and 7B, the nipple 60 is generally frustoconical and has a diameter that increases towards the base B. The cone or frustum may have a circular cross-section, as shown, or a non-circular cross-section (for example, a square contour). In some examples, a nipple may be provided with a "snap-fit" structure (not shown), such as one or more annular depressions, ridges, crests, or the like, that cooperate with a valve opening to form a reversible mechanical interlock between the nipple and opening. Such a structure may further enhance the integrity of the seal.

Nipple 60 may be attached to the valve body 52 by conventional means such as fusing, welding, adhering, or the like. In preferred examples, the nipple 60 and valve body 52 have a monolithic structure and may be formed, for example, by casting, molding, thermoforming, pressure forming, or like technique.

Figure 4 depicts an exploded view of a valve device 70 with disk valves 52A, 52B. Valve 52A comprises a valve body 53A having a first surface 54A, a second surface 56A, and an opening 58A between the first and second surfaces. Valve 52B comprises a valve body 53B having a first surface 54B, second surface

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56B, and opening 58A between the first and second surfaces. Openings 58A, 58B are each axially offset from the radial center C of the disks 52A, 52B. Each valve body 53A, 53B comprises a nipple 60B, 60A. The valves 52A, 52B are arranged so that nipple 60A is axially aligned with opening 58A and nipple 60B is axially aligned with opening 58B. In this arrangement, nipples 60A, 60B each define a plug that is capable of entering, and sealingly engaging, a respective opening 58A, 58B. The nipples 60A, 60B are each designed so that, in use, their length is at least equal to the spacing distance D (shown in FIG 6) between valves 52A, 52B. In preferred examples, each nipple has a length that is greater than the spacing distance D. In some examples, a nipple may be provided with a length of 0.1 mm or greater, 0.2 mm or greater, or 0.5 mm or greater.

Figure 5 depicts an exploded view of a device 10, similar to the introducer device depicted in FIGS 1 and 2 that includes a valve 70, similar to the valve depicted in FIG 4. In this example, two disk valves 52A, 52B are used instead of the four disk valves depicted in FIG 2. Valves 52A, 52B are arranged so that nipple 60A (hidden) is axially aligned with opening 58A and nipple 60B is axially aligned with opening 58B. Valves 52A, 52B are assembled within the valve housing 12 in relatively close proximity so that nipple 60A can plug opening 58A and nipple 60B can plug opening 58B. In use, fluid pressure within the haemostatic device 10 forces the valves 52A, 52B into intimate contact so that plug 60A penetrates and covers the perimeter of opening 58A and plug 60B penetrates and covers the perimeter of opening 58B.

Figure 6 depicts a cross-sectional view of a portion of valve device 70 with nipple 60A removably disposed within, and sealingly engaging, valve opening 58A. This sealing structure results in a more robust seal between valves 52A, 52B than is possible with previously-known disk valves only, where fluid pockets may form due to decreased surface tension between the disks. As a result of this unique sealing structure, a two-body valve, like the one depicted in FIG 4, may have an improved pressure rating over a device using two, three, four, or more previously-known disk valves.

In the embodiments shown in FIGS 4 and 5, opening 58A is axially offset from opening 58B. These unaligned openings may present a challenge to

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the operator in navigating a medical device along multiple axes through the valve assembly. To facilitate this, the valve 70 system preferably has a structure that can guide a medical device between adjacent openings 58A, 58B. For example, nipple 60A may have a dent 62 (shown in FIGS 4, 7A, and 7B) with a contour O  
5 that slopes outwardly and away from the center axis A of the nipple and towards opening 58B (see also FIGS 7 and 7A). In the embodiment shown in FIGS 7A and 7B, dent 62 has a tapered conical contour, although other contours may be provided or desired. Nipple 60A and opening 58A may cooperate to form a niche 64, as shown in FIG 8. Niche 64 is formed by the adjacent radial surfaces of the  
10 dent 62A and opening 58A. In other embodiments, an opening may be provided with a dent (not shown), and a niche may be formed by adjacent radial surfaces of the dent and nipple.

Dent 62A and niche 64 facilitate guiding a medical device, such as a guide wire, between openings 58A, 58B. In particular, the niche 64 structure is  
15 designed to locate and receive at least a portion of the medical device. Once the device is received in the niche 64, the dent 62A deflects it outwardly, and towards opening 58B. This causes opening 58A to stretch in a predetermined direction towards opening 58B.

Figures 9A–9D depict a haemostatic valve device 10 in stages of use.  
20 The device includes a valve housing 12 and two disk valves 52A, 52B disposed within the housing. Valve 52A comprises a nipple 60B that is removably disposed within, and sealingly engages, opening 58B of valve 52B. Likewise, valve 52B comprises a nipple 60A that is removably disposed within, and sealingly engages, opening 58A of valve 52A. Each of the nipples 60A, 60B has a dent 62A, 62B  
25 which, in cooperation with openings 58A, 58B, defines a niche 64A, 64B.

Figure 9A depicts the valves in a sealing configuration where nipple 60A sealingly engages opening 58A, and nipple 60B sealingly engages opening 58B, to limit fluid flow through the device. A guide wire 25 is shown disposed within the housing 12 and the tip of the guide wire is received within niche 64A.  
30 When the guide wire 25 is pushed through opening 58A, dent 62A deflects and guides the tip of the guide wire toward and through opening 58B.

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In FIG 9B, the guide wire 25 is pushed through valve openings 58A, 58B, and displaces nipples 60A, 60B, thereby breaking the sealing engagement between nipples 60A, 60B and openings 58A, 58B. The wire 25 stretches opening 58A radially in the direction of opening 58B and opening 58B radially in the  
5 direction of opening 58A. The openings 58A, 58B deform about the wire 25 and create two opposing generally parabolic shapes that seal the curvature of the wire. The nipples 60A, 60B are displaced and, in some examples, may slide behind the facing valve. Figures 9C and 9D depict views of the valve system with guide wire 12 passing through the valves 52A, 52B.

10 When the guide wire 25 is removed from the valve device, the openings 58A, 58B relax and contract towards their unexpanded configurations. As the openings contract, the nipples 60A, 60B sealingly engage a respective opening 58A, 58B, preventing fluid flow through the disks and, thereby, sealing the valve system. Due to their designed contour (shown, for example, in FIGS 7A and 7B),  
15 the nipples 60A, 60B will fall in place naturally. Moreover, any pressure on either valve (such as fluid pressure on valve 58B) will tend to force the nipples 60A, 60B into further engagement with the openings 58A, 58B, further improving the seal.

Throughout this specification various indications have been given as to preferred and different embodiments of the invention. However, it should be  
20 understood that the invention is not limited to any one of these. It is therefore intended that the foregoing detailed description be regarded as illustrative rather than limiting. Moreover, the features of different embodiments may be combined together as no embodiment described above is intended to be an alternative of another.

25 It is to be understood that although the examples described above show the nipples being spaced from the apertures on the same disk, in some embodiments the nipples may be immediately adjacent these apertures. Such an arrangement provides a less tortuous path through the valve assembly for, for instance, a medical device.

30 The disclosures in United States patent application no. 61/221,343, from which this application claims priority, and in the abstract accompanying this application are incorporated herein by reference.

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CLAIMS

1. A haemostatic valve device including:  
a disk valve including a valve body with a first surface facing in a first direction, a second surface facing in a second direction opposite the first direction,  
5 an opening formed in the valve body for providing communication through the disk valve, and a nipple extending outwardly and away from at least one of the first and second surfaces;  
where the nipple is axially offset from the opening.
2. A device as claimed in claim 1, including a second disk valve including a  
10 valve body with a first surface facing in a first direction, a second surface facing in a second direction opposite the first direction, and an opening formed in the second valve body for providing communication through the second disk valve, wherein the first and second disk valves are arranged so that the nipple is removably disposed within, and sealingly engages, the opening of the second disk  
15 valve.
3. A device as claimed in claim 2, wherein the second disk valve includes a nipple, and wherein the second disk valve nipple is removably disposed within the opening of the first disk valve.
4. A device as claimed in claim 3, wherein the nipple and substantially  
20 sealingly engages the opening of the first disk valve.
5. A device as claimed in claim 2, 3 or 4, wherein the first and second disk valves are separated by a spacing, and the nipple has a length that is equal to, or greater than, the spacing.
6. A device as claimed in any preceding claim, wherein the or each nipple and  
25 its respective valve body comprise a monolithic structure.
7. A device as claimed in any preceding claim, wherein the or each nipple has a tapered contour.
8. A device as claimed in any preceding claim, wherein the or each nipple comprises a dent including a contour that slopes towards the opening.
- 30 9. A device as claimed in any preceding claim, wherein the or each nipple is generally frusto-conical in shape.

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10. A device as claimed in any preceding claim, wherein the nipple or each extends a distance of 0.1 mm or greater from the surface of the disk valve.
11. A haemostatic valve device including:  
a first disk valve having a valve body with an opening therein for providing  
5 communication through the first disk valve; and  
a second disk valve having a valve body with an opening therein for providing communication through the second disk valve, and a plug removably disposed within, and sealingly engaging, the opening of the first disk valve to limit fluid flow through the first disk valve.
- 10 12. A device as claimed in claim 11, wherein the opening of the first disk valve is axially offset from the opening of the second disk valve.
13. A device as claimed in claim 12, wherein the valve includes a structure for guiding a medical device between the opening of the first disk valve and the opening of the second disk valve.
- 15 14. A device as claimed in any one of claims 11 to 13, wherein the first disk valve includes a plug removably disposed within, and sealingly engaging, the opening of the second disk valve.
15. A device as claimed in claim 14, wherein the plug comprises a dent having a contour that slopes towards the opening of the second disk valve.
- 20 16. A device as claimed in claim 14 or 15, wherein the plug and the opening of the first disk valve cooperate to form a niche having a contour that slopes towards the opening of the second disk valve.
17. A device as claimed in claim 14, 15 or 16, wherein the first and second disk valves are separated by a spacing, and the plug has a length that is equal to, or  
25 greater than, the spacing.
18. A haemostatic valve device including:  
a first disk valve having a valve body and an opening therein for providing communication through the first disk valve;  
a second disk valve having a valve body and an opening therein for  
30 providing communication through the second disk valve, where the opening of the first disk valve is axially offset from the opening of the second disk valve; and

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a structure for guiding a medical device between the opening of the first disk valve and the opening of the second disk valve, the structure having a contour that slopes from the opening of the first disk valve towards the opening of the second disk valve.

5 19. A device as claimed in claim 18, wherein the second disk valve includes a plug removably disposed within, and sealingly engaging, the opening of the first disk valve.

20. A device as claimed in claim 18 or 19, wherein the plug includes a dent having a contour that slopes towards the opening of the second disk valve.

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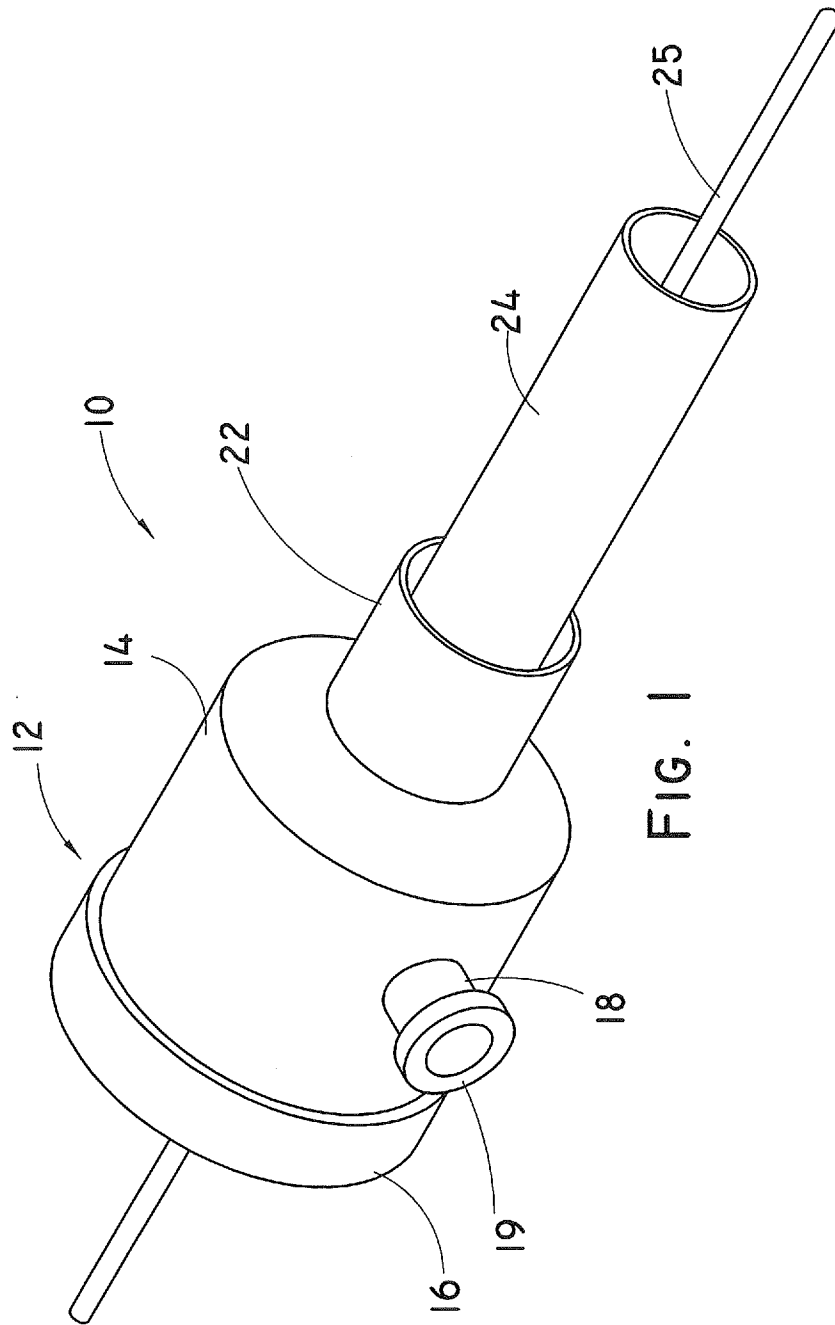


FIG. 1

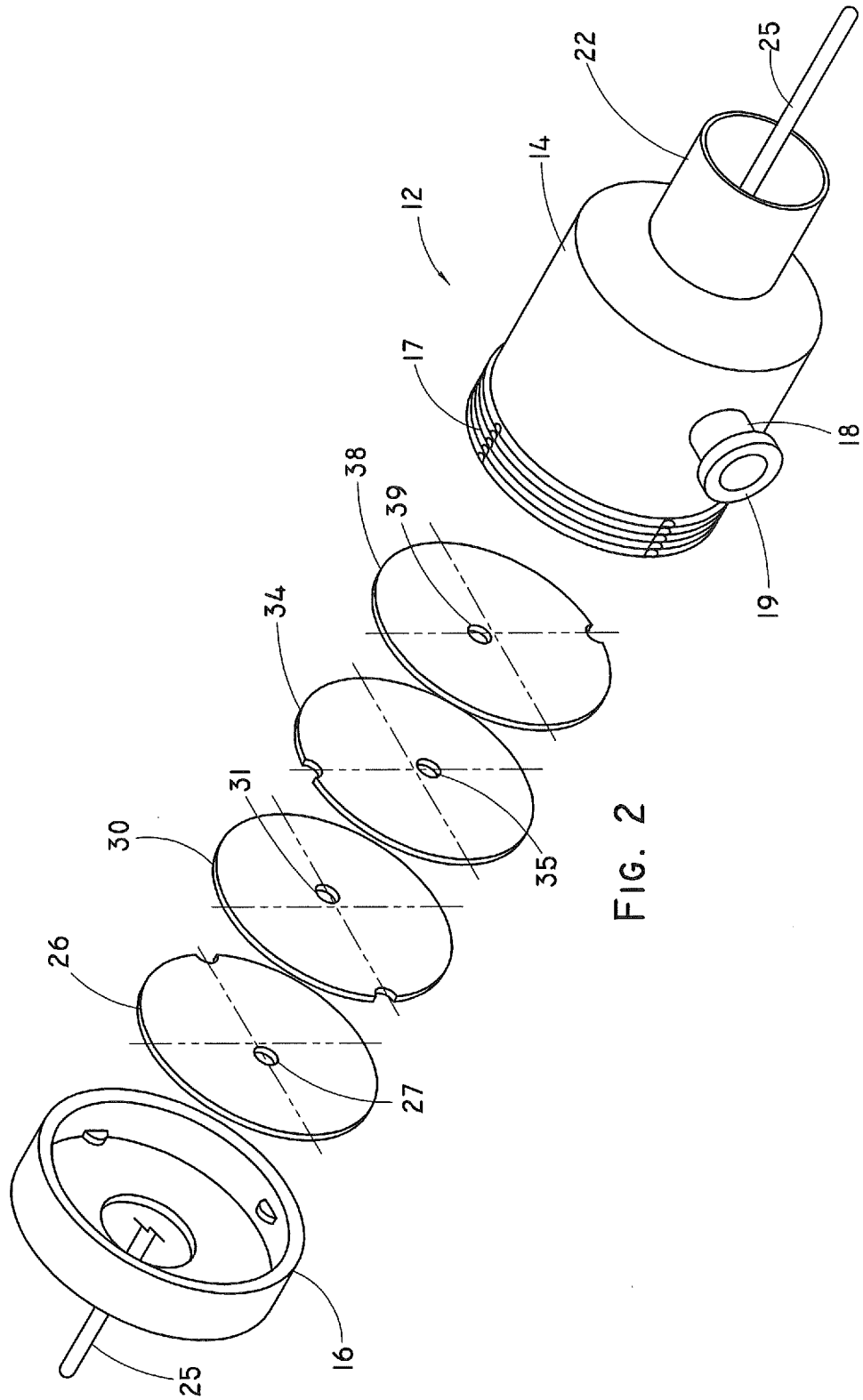


FIG. 2

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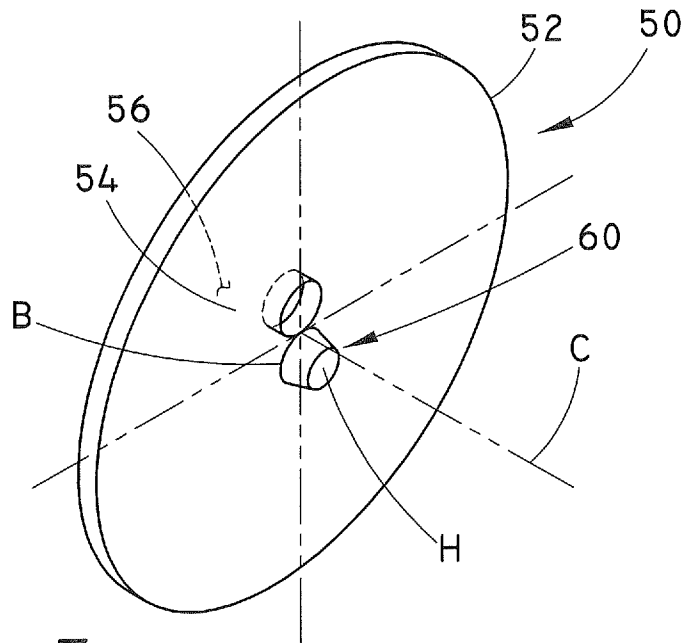


FIG. 3

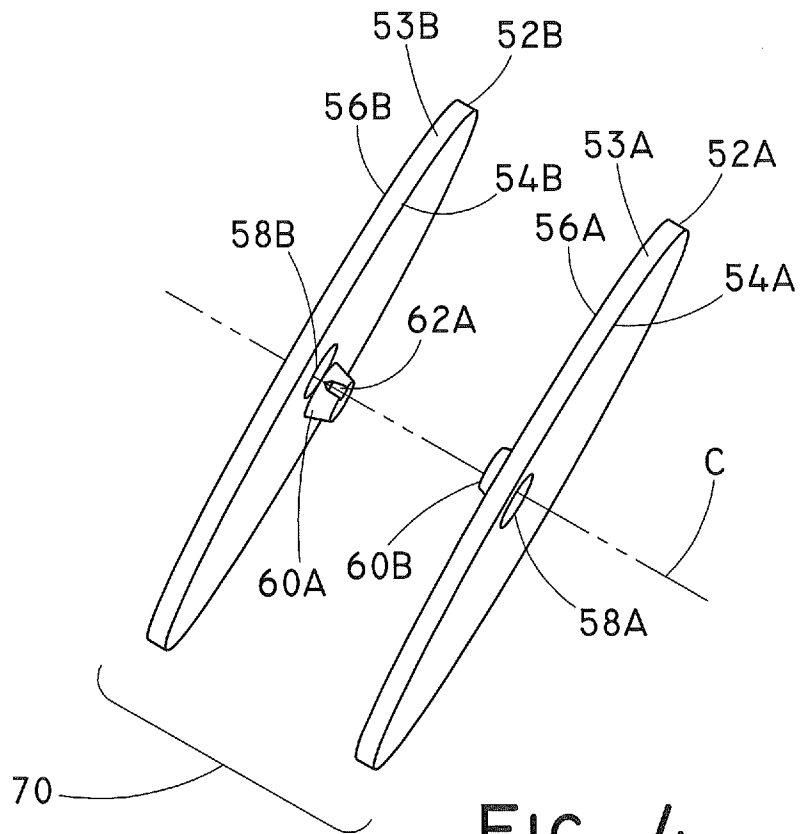


FIG. 4

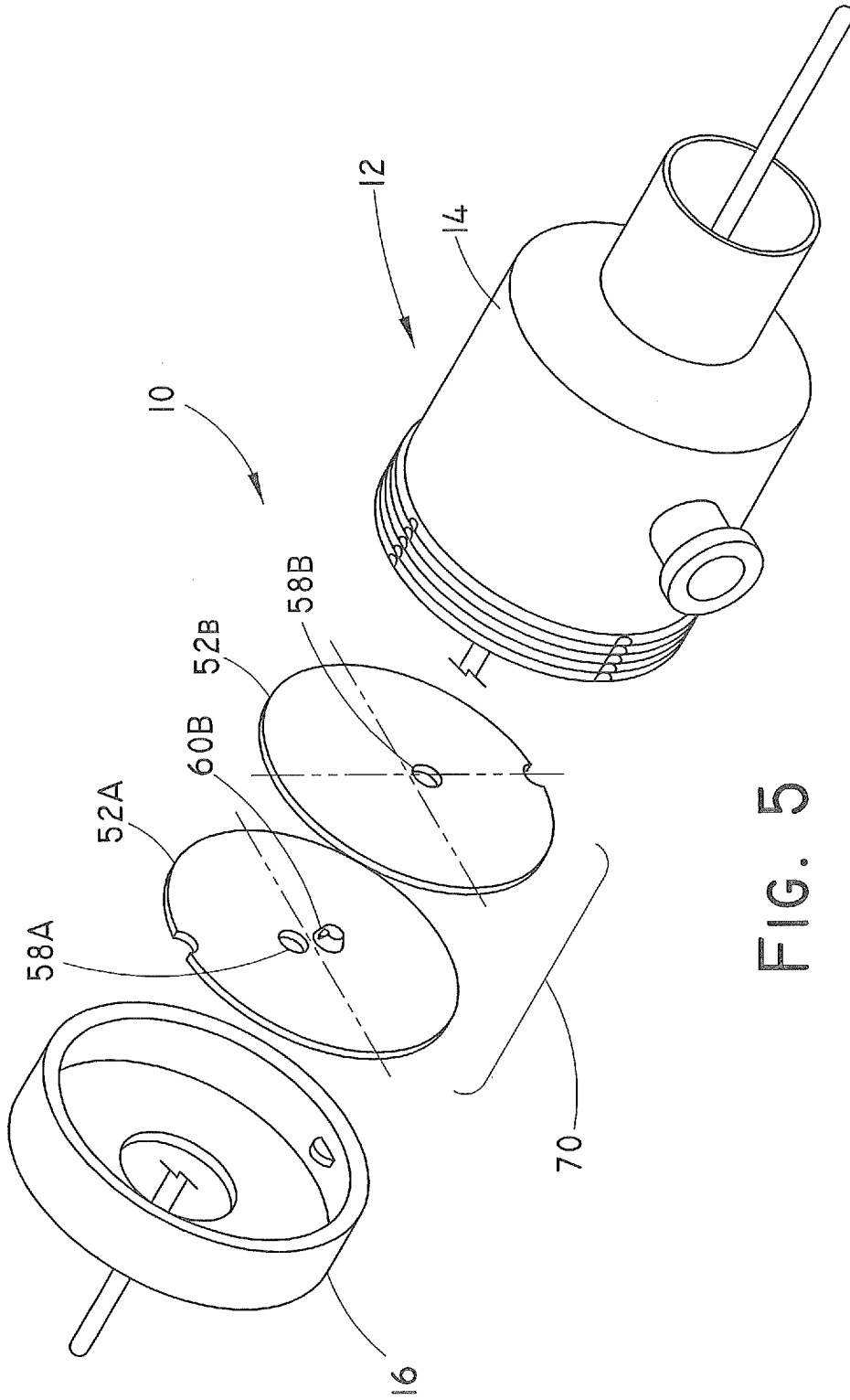
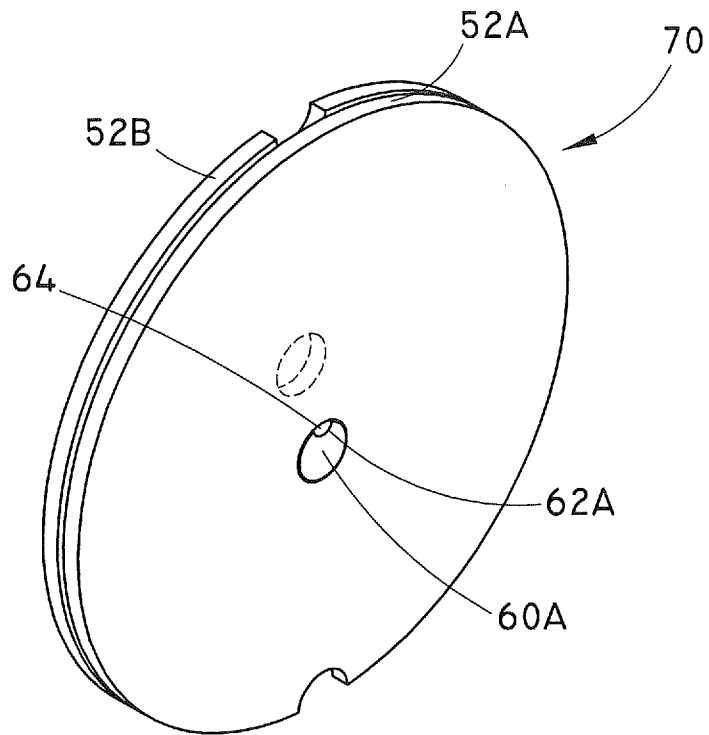
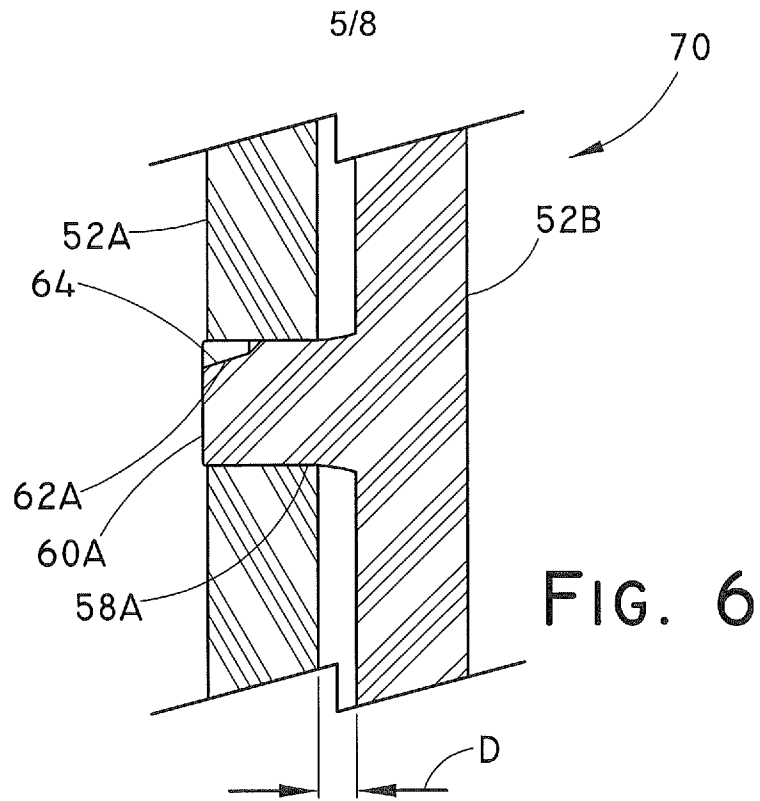


FIG. 5



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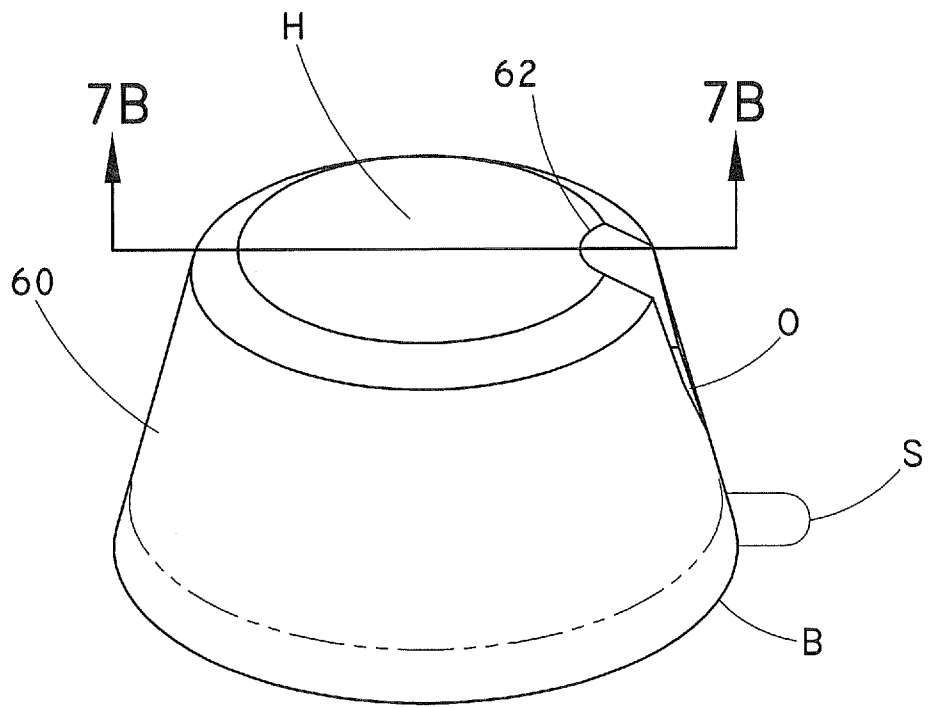


FIG. 7A

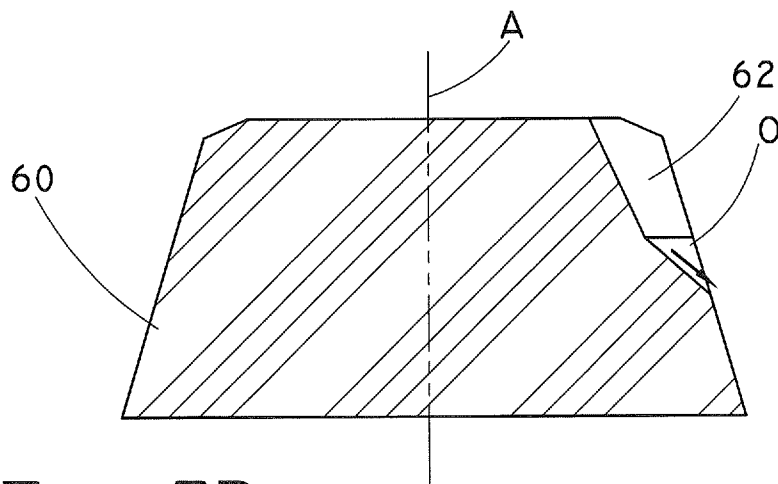


FIG. 7B

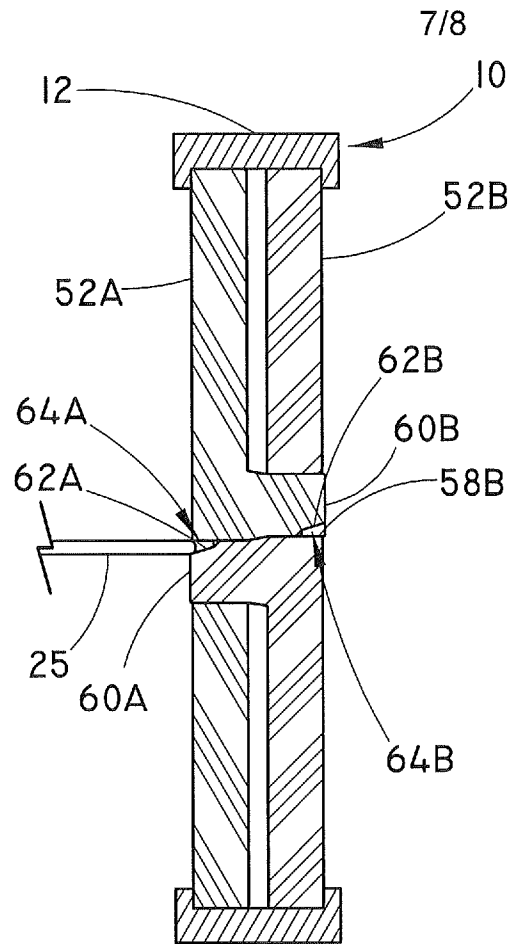


FIG. 9A

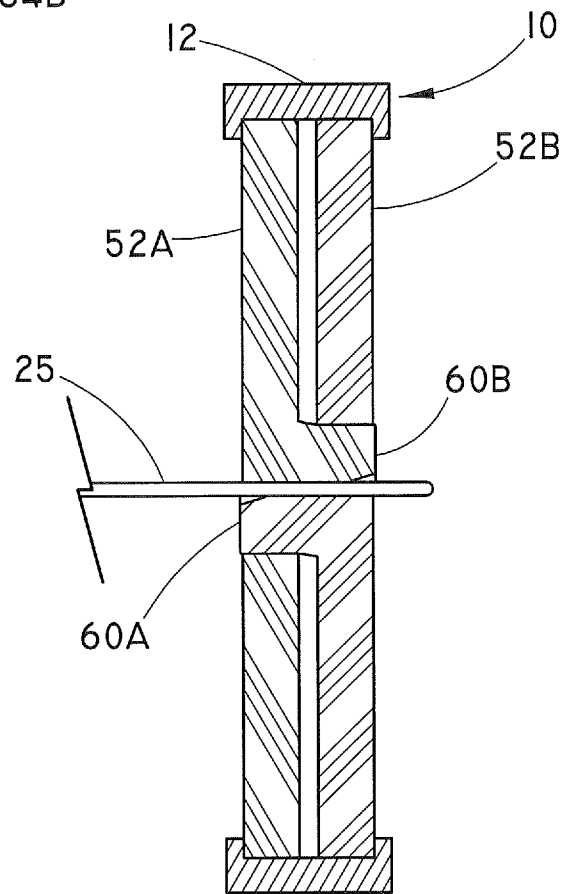


FIG. 9B

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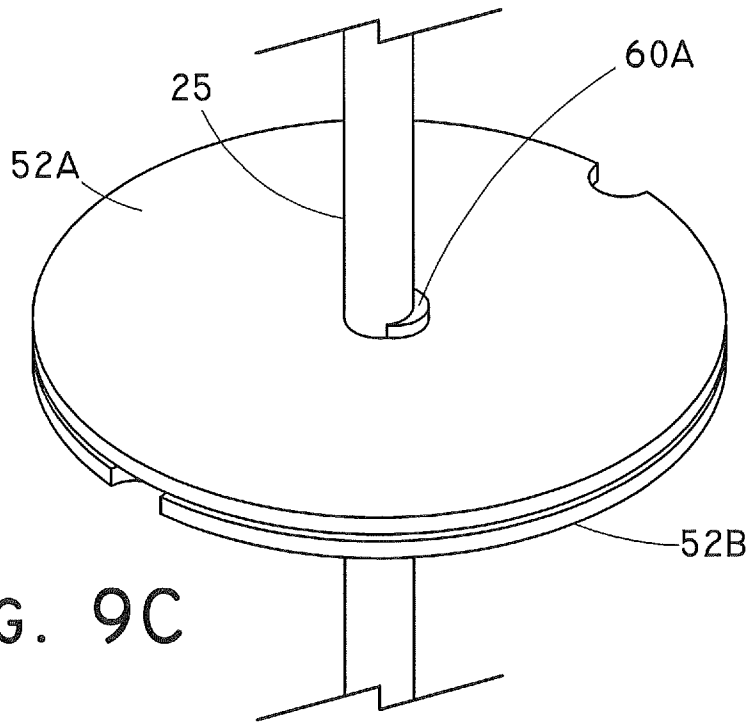


FIG. 9C

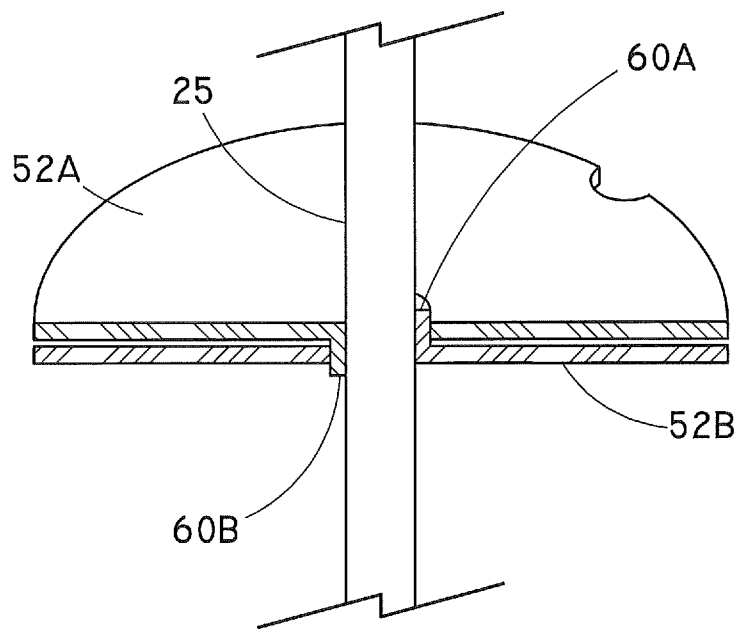


FIG. 9D

## INTERNATIONAL SEARCH REPORT

International application No  
PCT/US2010/040380

## A. CLASSIFICATION OF SUBJECT MATTER

INV. A61M39/06  
ADD.

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)  
A61M

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	EP 0 247 824 A2 (PACESETTER INFUSION LTD [US] IVAC CORP [US]) 2 December 1987 (1987-12-02) column 1, line 39 - line 51 column 7, line 21 - line 39; figures 3,4	1,7,9,10
X	US 5 356 381 A (ENSMINGER WILLIAM D [US] ET AL) 18 October 1994 (1994-10-18)	2-6, 11-14, 17-19
A	column 17, line 34 - line 42 column 20, line 21 - column 22, line 12; figures 34-38, 41-47	7,9
A	WO 2007/030746 A1 (COOK INC [US]; VALAIE ARMAN H [US]) 15 March 2007 (2007-03-15) figure 2	2,4, 12-14,19

 Further documents are listed in the continuation of Box C. See patent family annex.

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"&" document member of the same patent family

Date of the actual completion of the international search

26 October 2010

Date of mailing of the international search report

03/11/2010

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# INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2010/040380

Patent document cited in search report	Publication date	Patent family member(s)	Publication date	
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			DE 3751314 T2	11-04-1996
			US 4712583 A	15-12-1987
US 5356381	A	18-10-1994	NONE	
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