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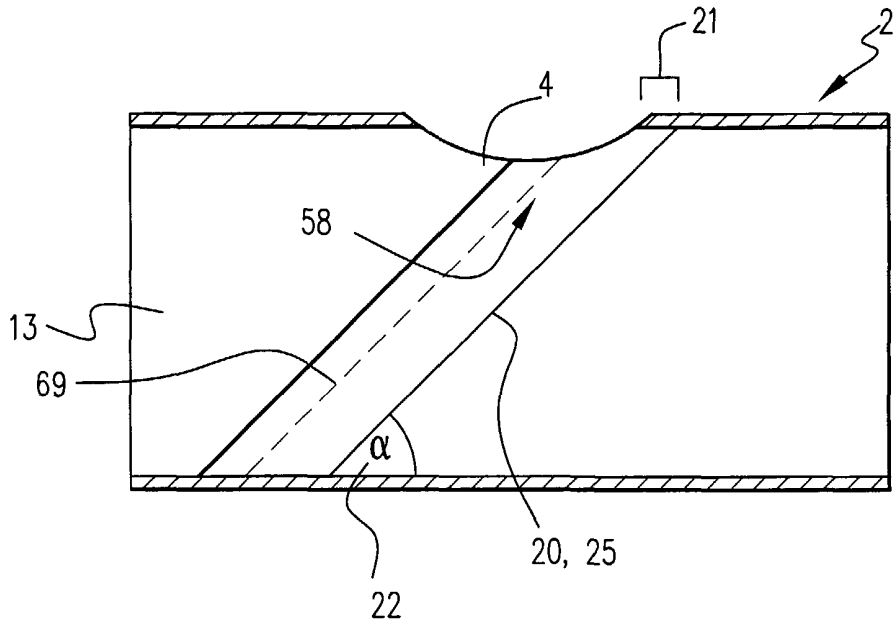
(54) Title: IMPLANTABLE FLOW DIVERSION DEVICE



(57) Abstract: This is an implantable device intended generally for at least partially diverting flows of fluids within a body lumen to another lumen defined by a graft member. The device is made up of a stent, often radio-opaque, and a sheet-like member which is coupled to the stent and configured to form a side port through which fluids may be diverted. The device may comprise various configurations of end walls which are configured to at least partially occlude the main lumen of the stent. The device may also comprise a sew ring or expandable t-graft configured to facilitate formation of an end to side anastomoses between the vessel containing the device and a graft at the location of the side port.

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IMPLANTABLE FLOW DIVERSION DEVICE

TECHNICAL FIELD

The present invention relates to an intravascular expandable implant to maintain vascular patency in lumens of humans and animals while providing a construct for controlling and diverting flow to other body lumens.

BACKGROUND ART

Intravascular expandable implants such as stents and stent grafts have long been applied to maintain vascular patency. Many intravascular stents are used in conjunction with balloon angioplasty wherein a balloon is inflated to expand a constricted vessel in order to restore proper blood flow. The intravascular stent is then positioned inside the expanded vessel to ensure the vessel maintains the enlarged diameter.

Widespread use of intravascular stents and stent grafts has lead to the development of safe and reliable procedures for endolumenally positioning and implanting them using relatively noninvasive methods into tissue lumens at various locations of the body. There is a need to provide an endolumenally implantable device capable of controlling flow in a lumen and diverting flow from the lumen to another surgically established lumen which may lead to another device, organ, or vessel. A number of patents have been found describing various stent designs as well as methods for delivering stents to desired positions within the body. These patents include:

U.S. Patents Nos. 3,868,956 and 4,503,569, each of which describes methods wherein a stent comprising a

temperature responsive device is implanted in a damaged vessel and thereafter expanded by means of an external heat source.

U.S. Patent No. 4,553,545, which discloses a method whereby a complex mechanical rotating device and coaxial cables are employed to increase the diameter of the implanted stent.

U.S. Patent No. 4,580,568, which describes a stent wherein a single wire forming a closed loop is expanded in a damaged vessel to maintain vascular patency. The loop of wire is compressed to form a series of straight segments and bends, the bends storing energy in the compressed state. Upon removal of a compression means the stent expands and exhibits a circular configuration.

U.S. Patent No. 4,649,992, which describes a stent device in combination with a catheter. The stent is a compression spring retained by a partially inflated balloon and an abutment immediately behind the balloon on the catheter shaft. The spring prosthesis is transported to the desired location and released by totally evacuating the balloon, thereby allowing the spring prosthesis to expand linearly.

U.S. Patent No. 4,681,110, which describes a catheter for delivery of a stent comprising woven plastic strands forming a tube which can be compressed radially. The orientation of the plastic strands provides resilience for the tube to expand from a compressed state.

U.S. Patent No. 4,768,507, which discloses a catheter comprising an outer cylinder and inner core. The inner core has spiral grooves for holding a coil

spring stent. Pliers are used to facilitate the loading of the coil spring into the grooves. Upon completion of the loading of the outer cylinder, it is placed over the inner core thereby retaining the coil in the compressed state until the coil is released.

U.S. Patents Nos. 4,690,684, and 4,720,176, each of which discloses a stent for aligning the ends of the vessel during anastomosis by thermal bonding. The stent comprises an integral solid of biologically compatible material to align the vessel ends together during anastomosis. Upon completion of the anastomosis the stent fully melts into the fluid flowing through the vessel. U.S. Patent No. 4,770,176 also discloses a method of anastomosing a vessel utilizing the stent described in U.S. Patent No. 4,690,684.

U.S. Patent No. 4,878,906, which describes a prosthesis comprising a flexible thin-walled plastic sleeve for repairing damaged vessels. The sleeve has sufficient length to cover the damaged area of the vessel by forming a sealed interface between its outer peripheral ends and the inner peripheral surface of the vessel. A bridge is thereby provided to bypass the damaged area of the vessel.

U.S. Patent No. 4,830,003, which discloses a cylindrical stent comprising angled wires of bio-compatible metal. The angled wires are connected obliquely at alternate ends to form a compressible open ended tube.

U.S. Patent No. 4,866,062, which discloses a radially expandable coronary stent. The stent comprises a flat expandable wire band which is preformed in a

zigzag pattern to provide expansion capability. The band is wound into a cylindrical shape and is inflated by means of a variable diameter device. The band expands radially into a cylindrical shape with increasing diameter.

U.S. Patents Nos. 4,800,882, 4,739,762 and 4,733,665, each of which discloses an expandable intraluminal graft. These grafts are made of wire or a thin balled tubular member and may be expanded by an angioplasty balloon associated with a catheter.

U.S. Patent No. 4,760,849, which discloses a planar blank which may be made into a helical coil spring stent.

U.S. Patent No. 4,665,918, which describes a system and method for implanting a generally tubular prosthesis member having an unobstructed central passageway into a blood vessel. The prosthesis member is positioned in a contracted condition between a delivery catheter and outer sheath, and expands outwardly in response to the removal of the sheath.

U.S. Patent No. 5,855,597, which discloses a stent valve and stent graft for percutaneous surgery. A star-shaped stent and replacement valve or replacement graft for use in repairing a damaged cardiac valve includes two to eight star-shaped members interconnected into a chain.

U.S. Patent No. 5,571,173, which discloses an aortic graft for intraluminal delivery to repair an abdominal aortic aneurysm with at least one wire which is woven into the distal, or lower, end of the graft, which wire permits the distal end of the graft to conform to, and sealingly engage, within the aortic bifurcation region of the aneurysm.

U.S. Patent No. 5,676,697, which discloses an intraluminal graft and method and apparatus for installing an intraluminal graft in relation to a bifurcation of a trunk vessel into two branch vessels to bypass an aneurysm defect or injury, wherein the intraluminal graft is formed of two cooperating graft prostheses.

None of the foregoing patents, however, disclose an intravascular device configured to control flow within an existing lumen and divert flow from the existing lumen to another surgically-established lumen.

SUMMARY OF THE INVENTION

This invention is an implantable device for placement in a body lumen which generally comprises an expandable stent and a sheet-like member coupled to the expandable stent in a configuration wherein a flow diversion side port is formed in the side of the construct. The stent has a compressed delivery state and an expanded implantation state, and is preferably configured for delivery using a catheter.

Many variations of side ports may be formed in the device, although a substantially circular side port geometry is preferred. The side port may have a relatively small area, such as 1/10 of the stent inlet lumen area, or it may have a relatively large area, such as 1/2 of the stent inlet lumen area or greater.

The expandable stent has two ends, an upstream end and a downstream end, defining the flow input lumen and flow output lumen, respectively. The inlet lumen remains opened, or un-occluded, after expansion of the stent. In

some variations the outlet lumen remains opened, and in others it is closed to facilitate flow diversion through the side port.

In one variation, at least a portion of the expandable stent is radio-opaque, and radio-opaque markers are disposed around the perimeter of the side port to facilitate accurate delivery and orientation of the implantable device using a catheter or similar endolumenal device. An annulus of the sheet-like member defining the side port may be reinforced, preferably by an additional folded-over layer of the sheet-like member. In such a variation, radio-opaque markers may be encapsulated within the two layers comprising the reinforced annulus defining the side port. A sew ring or expandable T-graft may be attached to the annulus to facilitate formation of an end-to-side anastomoses using stitching techniques, glues, or other end-to-end fastening techniques. The T-graft may be delivered in a low-profile configuration, such as an accordion shape or folded and flattened elongate shape, and may be pulled into a roughly cylindrical expanded implantation shape configured to facilitate formation of an anastomoses between a graft member and said implantable device.

The sheet-like member may comprise a semi-permeable material such as ePTFE to allow for flow-based nutrition of tissues, such as endothelial tissues, adjacent to the implantable device, while directing the vast majority of the flow through the stent lumen and/or side port after the device has been installed. The sheet-like member may be attached to the expandable stent using adhesive,

stitching, weaving, encapsulation, or a combination thereof.

The implantable device may further comprise a flexible wall member which is coupled to the device and configured to form an end wall when the stent is in its expanded implantation state. The end wall is configured to substantially block the flow of fluids through one end of the stent lumen, thus helping to divert flows through the side port in a flow diversion configuration. The flexible wall member may be coupled to the expandable stent or sheet-like member using adhesives, stitching, weaving, encapsulation, or a combination thereof. The flexible wall member may also comprise a portion of the sheet-like member.

In one variation, the end wall is configured to form a relatively flat surface perpendicular to a longitudinal axis of the stent lumen. In another variation, the end wall may be configured to divert flow through the side port using a relatively flat end wall positioned at an angle such as 45 degrees. The end wall may also be configured to divert flow through the side port using a curved end wall. The curved end wall may have a substantially constant radius of curvature. Angled and curved end wall variations are configured to minimize flow turbulence and the possibility of zero-velocity dead spots within and near the implanted device.

The implantable device may further comprise a valve having an open position and a closed position, the valve being configured to controllably allow or prevent flow through a valve door in the sheet-like member. The valve

may be located upon an end wall, and may have a remote shut-off mechanism to permanently close the valve door.

The remote shut-off mechanism may comprise an electrolytically dissolvable mechanical link interfaced with the valve so that the valve door cannot be closed until the link has been controllably dissolved. The device may further comprise a remote valve lock-down mechanism having a pin which is operational to lock the valve into its closed position after the shut-off mechanism has allowed the valve door to close.

The implantable device may also comprise more than one side port for multiple flow diversions.

BRIEF DESCRIPTION OF THE DRAWINGS

Figures 1A and 1B depict orthogonal and front views, respectively, of a variation of the inventive device.

Figure 2A depicts a partial side view of a variation of the inventive device having a reinforced side port.

Figure 2B depicts a partial side view of a variation of the inventive device showing an attachment location for a sew ring or T-graft section.

Figure 2C depicts a top view of a variation of the device showing a T-graft section coupled to said device in an accordion delivery configuration.

Figure 2D depicts a top view of a variation of the device showing a T-graft section coupled to said device in a bent and flattened elongate delivery configuration.

Figure 3A depicts an orthogonal view of a variation of the inventive device.

Figure 3B is an orthogonal view of a variation of the sheet-like member.

Figure 4A depicts an orthogonal view of a variation of the inventive device having a long sheet-like member.

Figure 4B depicts an orthogonal view of a variation of the inventive device having a relatively small sheet-like member.

Figure 4C depicts an orthogonal view of a variation of the inventive device having a relatively small sheet-like member.

Figure 4D depicts an orthogonal view of a variation of the inventive device having an expanded T-graft section coupled to the sheet-like member.

Figure 5A depicts a sectional side view of a variation of the inventive device having an angled end wall.

Figure 5B depicts a sectional side view of a variation of the inventive device having a curved end wall.

Figure 5C depicts a side view of a variation of the inventive device having a perpendicular end wall.

Figure 5D depicts an orthogonal view of a dual-lumen variation of the inventive device.

Figure 5E depicts an orthogonal view of a venturi lumen variation of the inventive device.

Figure 5F depicts a sectional side view of a variation of the inventive device having a curved end wall and sensors.

Figure 6 depicts a sectional side view of a variation of the inventive device having an end wall with a valve.

Figure 7 depicts a sectional side view of a variation of the inventive device having an end wall with a valve.

Figure 8 depicts a sectional side view of a variation of the inventive device having an end wall with a valve.

Figure 9A depicts a sectional side view of a variation of the inventive device having an end wall with a valve.

Figure 9B depicts a close-up partial side view of a variation of the inventive device having an end wall with a valve.

Figure 9C depicts a close-up partial orthogonal view of a variation of the inventive device having an end wall with a valve.

Figure 9D depicts a close-up partial orthogonal view of a variation of the inventive device having an end wall with a valve.

Figure 9E depicts a close-up partial orthogonal view of a variation of the inventive device having an end wall with a valve.

Figure 9F depicts a close-up partial side view of a variation of the inventive device having an end wall with a valve.

Figure 10 depicts a close-up partial bottom orthogonal view of a valve door and locking mechanism in a variation of the inventive device having an end wall with a valve.

Figure 11 depicts a close-up partial bottom orthogonal view of a valve door and locking mechanism in

a variation of the inventive device having an end wall with a valve.

Figures 12A-12E depict a method for installing a variation of the inventive device.

DETAILED DESCRIPTION OF THE INVENTION

This invention is an implantable device configured to facilitate the diversion of flows from one lumen to another. Referring to Figures 1A and 1B, an orthogonal view and front view of a variation of the inventive device (2) is depicted. A substantially-cylindrical stent (3) is shown, having a collapsible structure which is preferably self-expanding. The stent (3) is shown as it would appear when implanted into a body conduit with its diameter adjusted beyond the collapsed pre-implantation diameter. The substantially cylindrical expanded shape defines an inner stent lumen (13) into which fluids may flow when the stent is in an implanted configuration. While the stent shown is made from metal wire (15), a polymeric stent or perforated sleeve having perforations of suitable shape, size, and quantity may be used. Various suitable stents are described, for instance, in U.S. Patent No. 4,776,337 to Palmaz and PCT US 92/03481 to Hess. These stents may be made from biocompatible implantable metals such as titanium, stainless steel, or Nitinol.

The stent (3) is preferably configured to have at least one region wherein a side port (4) for flow diversion, free of crossing stent structures, may be formed. Stents with relatively loose structures are suitable, as are stents with structures designed for side

port flow diversion. Stents may be made with such configurations using laser cutting and chemical etching procedures, such as those disclosed in U.S. Patents Nos. 5,879,370 and 5,855,597. The stent is preferably at least partially radio-opaque or marked with radio-opaque markers to facilitate accurate delivery.

Referring again to Figures 1A and 1B, a sheet-like member (14) is shown coupled to the expandable stent (3). The sheet-like member (14) is configured to form a side port (4) through which flow may be diverted, while forming a localized barrier to flow for regions adjacent to the side port (4). The side port is preferably of an approximately circular geometry when viewed from the end, although other geometries, such as approximately rectangular side port shapes when viewed from the end, may be useful depending upon other componentry which may interface with the side port. The diameter (5) of the side port (4) may vary, depending upon the particular application. For small side port flow rates, a diameter as small as 1/10 the size of the stent lumen (13) diameter (7) is preferred. Larger side port diameters (5) which are 1/8, 1/5, 1/4, 1/3, or 1/2 the size of the associated stent lumen (13) diameter (7) are desired for higher flow rates. Larger relative side port diameters (5) may also be preferred for relatively large side port flow rates, although such sizes may require that the stent (3) be significantly reinforced due to the large size of the side port (4).

Figure 2A depicts a close-up partial side view of a variation of the inventive device wherein an approximately circular side port (4) is formed in the sheet-like

member (14). This variation has a reinforced annulus (8) which defines the side port (4), the reinforced annulus (8) having higher stiffness than the other portions of the sheet-like member (14) to facilitate load bearing which may accompany anastomosis formation at the location of the side port (4), depending upon what componentry is coupled to the device and how such componentry is coupled. The reinforced annulus (8) may be formed by a folded-over layer of the sheet-like member (14) which is attached to the substrate layer using stitches, adhesives, thermal bonding, chemical bonding, or other known methods of coupling two relatively flexible flat surfaces. The depicted variation comprises a folded-over layer of the sheet-like member(14) fastened to the substrate layer using a biocompatible polymeric adhesive such as those disclosed in U.S. Patent No. 5,810,870. The depicted variation also comprises several radio-opaque markers (6) positioned around the perimeter of the side port (4) to facilitate imaging and accurate placement of the device (2). These markers (6) may be encapsulated between layers forming a reinforced annulus (8), as in the depicted variation, or they may be attached by adhesives or other means.

Figure 2B depicts a similar variation of the inventive device in close-up partial side view further comprising a sew ring (10) coupled to the portions of the sheet-like member (14) which define the side port. A T-graft section (18), as shown in Figure 2C, may be coupled to the device in the same location as the sew ring (10) in the depicted variation. A sew ring (10) or T-graft (18) may be incorporated to facilitate formation of an

anastomoses at the site of the side port (4). To illustrate these concepts further, Figures 2C and 2D depict top views of variations of the inventive device comprising T-graft sections (18) having T-graft lumens (19). Referring to Figure 2C, an expandable T-graft section (18) is shown in a low-profile accordion compressed configuration (12) which facilitates catheter based delivery. Figure 2D shows a T-graft section (18) against the device in a bent and flattened configuration (23) which also facilitates catheter based delivery. Upon deployment of the device (2), the T-graft section, either accordion compressed (12) or bent and flattened (23), may be pulled by a surgical grasping tool into an generally cylindrical extended configuration having a T-graft lumen (19), as shown in Figure 4D.

Referring to Figures 3A-3B and 4A-4D, the sheet-like member (14) may comprise various geometric configurations in relation to the generally cylindrical deployed stent (3). Figures 3A and 3B depict orthogonal views of a generally cylindrical sheet-like member (14) configuration, Figure 3A showing an apparatus (2) comprising a stent (3) and sheet-like member (14) with side port (4). Figure 3B depicts the sheet-like member of Figure 3A in isolation without the stent to which it is preferably coupled.

Figure 4A depicts a variation wherein the sheet-like member (14) extends the length of the expandable stent (3) and forms a partial cylindrical surface defined by an angle of coverage (16). The depicted variation has an angle of coverage of approximately 90 degrees. The preferred angle of coverage necessary to facilitate

diversion of flows through the side port (4) without significant flow leakage in the region between the sheet-like member (14) and the tissue (64) forming the main lumen (1) varies from 10 degrees to 360 degrees depending upon factors such as endolumenal pressure, endolumenal flow rate, side port (4) diameter, stent lumen (13) diameter, the thrombogenicity of the materials comprising the stent (3) and sheet-like member (14), and the type of junction to be formed between the device and a diversion graft member (not shown) at the side port (4) location.

If a traditional stitched anastomoses is sought between the tissue forming the main lumen (not shown) into which the apparatus (2) is to be implanted and the material forming the graft member (not shown) to which flow may be diverted through the side port (4), then leakage between the sheet-like member (14) and main lumen tissue is less of an issue since such leakage would be contained within the main lumen or diversion graft lumen.

If an anastomoses is formed using an anastomoses device which couples to an implanted stent-like device rather than directly to the main lumen tissue, such as the device disclosed in the copending U.S. Patent application for "Anastomosis Device and Method" (attorney docket number 3659-8) is employed, or a T-graft or sew ring used to form an anastomoses between the tissue forming the main lumen and the material forming the diversion graft member, then it is desirable to minimize leakage between the sheet-like member and main lumen tissue since such leakage would not be contained by the main lumen or flow diversion graft lumen. With such variations, a larger sheet-like member (14) surface area

is desired around the side port (4). Preferably, the sheet-like member (14) extends away from the side port (4) by at least one side port diameter (5) in each direction. In other words, the sheet-like member extends away from the circumference of the side port (4) in each direction a distance equal to at least one times the diameter (5) of the side port (4).

Referring again to Figure 4A, a sheet-like member (14) is shown coupled to an expandable stent (3) in a configuration extending the length of the expandable stent (3) and having an angle of coverage (16) of approximately 90 degrees, resulting in approximately one side port diameter (5) of surface coverage in each direction. Figure 4B is an orthogonal view of a variation of the device in which the sheet-like member (14) has an approximately rectangular shape when viewed from the side. Figure 4C depicts an orthogonal view of a variation of the device in which the sheet-like member (14) has an approximately circular shape when viewed from the side. Figure 4D depicts the variation shown in Figure 4C further comprising a T-graft (18) which is coupled thereto, in this case depicted in an expanded T-graft configuration.

The sheet-like member (14) may be coupled to the expandable stent (3) using sutures, a biocompatible adhesive such as those disclosed in U.S. Patent No. 5,810,870, a woven coupling configuration such as that described in U.S. Patent No. 5,876,432, partial encapsulation of the stent (3) by the sheet-like member (14), or other known methods for attaching a flexible sheet-like member to an expandable structure, such as

those which are employed in the manufacture of stent-grafts. The sheet-like member (14) is comprised of a flexible material, preferably a biocompatible polymer such as PTFE, expanded PTFE, polyethylene, polyethylene terepthalate, or polyurethane.

Referring to Figure 5A, a sectional side view of a variation of the inventive device is depicted, the inventive device having a flexible wall member (25) coupled across the stent lumen (13) to form an end wall (20) positioned at an end wall angle (22). The angled end wall of this variation is designed to divert flow in a flow path (58) through the side port (4) while minimizing flow turbulence in the stent (13) and associated lumens when the device (2) is in an implanted configuration. The end wall angle (22) is preferably approximately 45 degrees for the depicted variation. To prevent the likelihood of zero-velocity or eddy regions, the distance (21) between the edge of the side port and end wall (20) is minimized. This distance (21) may not be entirely eliminated in many cases due to the geometric constraints of certain anastomotic techniques and devices. The anastomosis device (66) depicted in Figures 12D and 12E, for example, may require a small amount of such space (21) to accommodate radial extensions (67). The end wall (20) may be approximately flat when the expandable stent (3) is expanded, or it may form a partial cylindrical shape (69) as in the depicted variation. The phrase "partial cylindrical shape" is meant to describe a gutter-like shape having a substantially straight end wall (20) spine. Variations having an angled end wall (20) with a partial cylindrical

shape are believed to best minimize the occurrence of zero-velocity points or eddies within the stent lumen (13).

Figure 5B depicts a similar variation of the inventive device in sectional side view in which a flexible wall member (25) forms a curved end wall (20) having an approximately constant radius of curvature (26). The curvature of the end wall (20) is designed to minimize flow turbulence and channel flows along a flow path (58) directly out of the side port (4). The curved end wall (20) may be configured to have an additional radius of curvature perpendicular to that of the wall's (20) spine, resulting in a curved gutter-like shape (also described as a shape similar to that of a jai-ali paddle or inverted saddle), or it may not have a curvature in such perpendicular direction so the resultant shape resembles a concave loading ramp rather than an a curved gutter. The preferred shape for minimizing flow turbulence, as depicted in the figure, is the curved gutter shape (70).

Figure 5C depicts a side view of a variation of the inventive device wherein a relatively flat end wall (20) is formed by a flexible wall member (25) across one end of the stent lumen (13). When this and other variations of the inventive device which totally divert or occlude flow are placed in a lumen, significant forces from flow in the associated vessels may cause device destabilization. To prevent such destabilization, sutures may be placed through the associated tissue wall and a portion of the structure of the device to fasten the device to the associated tissue wall. Installation

of a variation of the inventive device is described below.

Referring to Figure 5D, a variation of the inventive device (78) having two end walls (20, 73) defining the ends of two distinct lumens (74, 75) is shown in orthogonal view. A pump lumen (74) contains an implantable fluid pumping mechanism (77) such as that disclosed in U.S. Patent No. 5,707,218. A bypass lumen (75) is configured to allow flow to bypass the pump lumen (74) during installation of the device. In the depicted variation, one end of the bypass lumen (74) has a valve (76) configured to controllably occlude the bypass lumen (74) when the pumping mechanism (77) has been made operational. A control lead (71) configured to place the pumping mechanism (77) in electrical connection with a power source (not shown) and control system (not shown) is depicted extending from the device (78). Also depicted is a controllable valve (78) configured to connect with the control system and be remotely closeable over the opening of the bypass lumen (74), effectively selecting the pump lumen (75) as the only path for flow past the device (78). Remotely-operable valves are further discussed below. Upon implantation of the device (78), an aperture may be surgically created in the associated tissue wall (not shown), the control lead (71) pulled through the aperture, and the aperture sealed around the protruding control lead (71) using a purse-string suture or other standard technique or device.

Referring to Figure 5E, a variation of the inventive device is shown in orthogonal view having a relatively-small side port (4) and a venturi lumen (81) having

tapered entrance (82) and exit (83) surfaces and a venturi throat (84). The venturi throat (84) is configured to provide high velocity flow and associated low pressure at the entrance region (85) of the side port (4), thus providing a pressure gradient which may be operable to augment the flow of fluids into the venturi lumen (81) through the side port (4), depending upon other associated pressures as well as the viscosity of the fluids and other geometric factors.

Referring to Figure 5F, a variation of the inventive device similar to that of Figure 5B is depicted in sectional side view, this variation also having sensors or sensor portions (86) coupled thereto in a configuration where they are operable to monitor fluids flowing through the device (80). In Applicant's copending application for "Instrumented Stent" (attorney docket no. 3659-6), incorporated by reference herein, devices are disclosed having sensors similarly coupled thereto for similar functionality. Also shown in the figure is a control lead (71) extending from the device (80) and configured to establish communication between the sensors (86) and an associated control system (not shown).

The flexible wall members (25) of Figures 5A-5F may be coupled to the stents (3) or sheet-like members (14) or both in the depicted variations using adhesives, stitching, weaving, encapsulation, a combination thereof, or other known coupling techniques. The flexible wall member (25) is comprised of a flexible material, preferably a biocompatible polymer such as PTFE, expanded PTFE, polyethylene, or polyurethane.

Figure 6 depicts a sectional side view of a variation of the inventive device wherein a curved end wall (20) comprises a valve (28) having open and closed positions. When the valve door (30) is in an open position, a bifurcated flow path (58) results when flows exit the side port (4). Various fluid valve configurations known in the cardiovascular arts to be biocompatible and reliable may be used in this variation. A reed-type valve (28) is depicted, having a valve opening (36), a valve door (30) which is rotatable about a valve door hinge point (32), and a valve door retainer (34) which is configured to hold the valve door (30) in open position. The valve door retainer (34) preferably comprises an electrolytically erodable junction (54) like those used in other electrolytic release mechanisms. Examples of such release mechanisms are described in references such as U.S. Patents Nos. 5,122,136, 5,354,295, 5,891,128, and 5,624,449. In the depicted variation, the valve door (30) remains open until the erodable junction (54) has been eroded (56), at which point the valve door (30) may close. The valve door (30) may be biased to stay closed by fluid pressures within the stent lumen (13) or other associated lumens, or forces developed by a valve door closer member (38), such as that which is depicted in Figure 7 in sectional side view. The valve door (30) closer member (38) preferably applies a spring-generated tension force to the valve door (30), operating to pull the valve door (30) shut when said erodable junction (54) has been eroded. The valve door (30) boundary (46) shown in Figures 6-8 is configured to meet the valve door (30) when it is closed.

Figure 8 depicts a variation similar to that depicted in Figure 7, however the variation of Figure 8 has an end wall (20) with valve (28) located across one end of the stent lumen (13), the valve door (30) being associated with a valve closer member (38).

Referring to Figures 9A-9F, variations of the closing and locking operation according to the present invention are described. Figure 9A depicts in sectional side view a device similar to that shown in Figure 6, with the exception that the erodable junction (54) has been eroded (65) and the valve door (30) is shut against the valve door boundary (46).

Figure 9B depicts a variation of the valve door (30) in shut configuration in a close-up partial side view. The depicted reed-type valve (28) variation has a valve door (30) hinge (32), and a lock member aperture (45) which is designed to protrude through and beyond the portion of the end wall (20) with which it interfaces via a valve door lock member slot (48) in the end wall (20). In the depicted variation, the valve door (30) extends beyond the valve door boundary point (46), thus producing an overlap region (47).

Figure 9C depicts a close-up partial orthogonal view of a variation of the inventive device having a locking pin (50) configured to side through a protruding lock member aperture (45) when the valve (28) is in a closed configuration, the locking pin (50) being operational to lock the valve door (30) into a closed position. Figure 9D depicts a more magnified close-up partial orthogonal view of the device depicted in Figure 9C, this view illustrating the interface between the valve door (30)

lock member (44) and the valve door (30) lock member slot (48) in the overlap region (47) of the end wall (not shown).

Figures 9E and 9F are additional close-up partial orthogonal and partial side views, respectively, of the device depicted in Figure 9D which illustrate the configuration and operation of the valve door lock member (44) of this variation. A spring member (52) and an erodable junction (54) are attached in parallel between an end wall (20) attachment base (51) and a locking pin (50).

Figure 9F illustrates that when the erodable junction is eroded (56), the spring member (52) urges the locking pin (50) through the valve door lock member aperture (45), thus locking the valve door (30) into a shut configuration.

Figures 10 and 11 depict close-up partial bottom orthogonal views of further variations of the inventive device wherein a valve door locking member (44) is configured to receive one or more locking pins (50) after an erodable junction (54) has been eroded (56). To ensure proper sealing of the valve (28) in its closed configuration, as well as reliability of small components such as the valve door hinge (32), valve door (30), erodable junctions (54), spring members (52), locking pins (50), and attachment base (51), the valve (28) must be mounted upon a relatively stiff portion (31) of the end wall (20). Figure 10, as well as Figures 9C and 9E, depict such a stiff portion (31), which preferably comprises a layer of a relatively stiff polymeric material such as PET, PETE, or polyethylene coupled to or

forming a portion of the end wall (20) using an adhesive or encapsulation. Since this portion (31) is relatively stiff, it generally may not be compressed to a smaller size during delivery, and thus presents a geometric constraint which may prevent catheter-based delivery of devices which contain end walls (20) having relatively-large valves (28) and thus relatively-large stiff portions (31).

Figures 12A-12E depict a method for installing a variation of the inventive device. Although the preferred method of delivery requires a delivery catheter, non-catheter-based delivery techniques known in the art may also be suitable for installing the inventive device, depending upon the particular application. For example, a variation of the inventive device can be installed by surgically creating an arteriotomy and placing the device therethrough into an artery or other vessel, then suturing the arteriotomy closed.

Figure 12A depicts a catheter-based delivery of the device (2) wherein the device (2) is delivered to a desired location in compressed form within the catheter (60) and is then pushed out the end of the catheter (60) where it may expand to an implanted configuration, as shown in Figure 12B. The depicted variation of the device (2) has an end wall (20) with a valve (28), the valve door (30) being in open position upon delivery, as shown in Figures 12B-12D.

As shown in Figure 12C, a trocar (62) may be used to create a hole in the tissue wall (64) at the location of the side port (4). As shown in Figure 12D, an anastomosis device (66) may then be placed through the

tissue hole and side port (4) where it is locked into a final configuration, as is shown in Figures 12D and 12E. After the anastomosis has been formed, the valve door (30) in the end wall (20) may be closed to facilitate flow diversion through the anastomoses device (66). As is shown in Figure 12E, stabilizing sutures (87) may also be installed to provide additional fastening stability to the implanted construct.

A control lead (71) for providing current to electrolytically erodable junctions (54) is also shown in Figures 12A-12E. During catheterized delivery of the device, the control lead (71) trails behind the implant within the bounds of the tissue wall (64). After the implant has been expanded, as is shown in Figures 12B-12E, a small aperture (72) may be surgically created through the tissue wall (64), through which the control lead (71) may be pulled. The aperture (72) is then closed around the protruding control lead (72) using a purse-string suture (not shown) or other known closure technique or device.

Each of the U.S. patent documents, U.S. patent application documents, foreign patent documents, and scientific reference documents (including texts and scientific journal articles) referred to in the text of this document is incorporated by reference into this document in its entirety.

Many alterations and modifications may be made by those of ordinary skill in the art without departing from the spirit and scope of this invention. The illustrated embodiments have been shown only for purposes of clarity. These examples should not be taken as limiting the

invention defined by the following claims, said claims including all equivalents now or later devised.

WHAT IS CLAIMED IS:

1. An implantable device for placement in a body lumen comprising:

a. an expandable stent having a compressed delivery state and an expanded implantation state, said expandable stent having a roughly cylindrical external shape when in said expanded implantation state, said roughly cylindrical shape having an upstream end and a downstream end and defining a stent lumen having a flow input area at said upstream end through which fluids in said body lumen may enter said stent lumen in said expanded implantation state, and

b. a sheet-like member coupled to said expandable stent;

wherein said sheet-like member is configured to form a surface on said expandable stent, said surface forming a side port through which fluids flowing in said stent lumen may be diverted, said side port having a side port area, said side port area being at least 1/10 as great as said flow input area.

2. The implantable device of claim 1 wherein said side port area is at least 1/8 as great as said flow input area.

3. The implantable device of claim 1 wherein said side port area is at least 1/5 as great as said flow input area.

4. The implantable device of claim 1 wherein said side port area is at least 1/4 as great as said flow input area.

5. The implantable device of claim 1 wherein said side port area is at least 1/3 as great as said flow input area.

6. The implantable device of claim 1 wherein said side port area is at least 1/2 as great as said flow input area.

7. The implantable device of claim 1 wherein said downstream end of said roughly cylindrical shape defines a flow output area through which fluids flowing in said stent lumen may flow to rejoin said body lumen.

8. The implantable device of claim 1 wherein said compressed shape of said expandable stent is small enough to accommodate catheterized delivery of said implantable device to large vessels of the body, said expandable stent being at least partially radio-opaque, said side port having radio-opaque markers disposed around the perimeter thereof, said radio-opaque markers being configured to assist in orientation of said implantable device at a targeted endolumenal destination.

9. The implantable device of claim 1 wherein a reinforced annulus of material defines the side port in said sheet-like member, said reinforced annulus being configured to provide added structural rigidity around said side port.

10. The implantable device of claim 9 wherein said reinforced annulus comprises a folded-over layer of said sheet-like member.

11. The implantable device of claim 1 wherein a sew ring is disposed about said side port and is coupled to said implantable device.

12. The implantable device of claim 1 wherein a T-graft section is coupled to said implantable device and is configured to form a T-graft lumen extending away from said side port in a configuration wherein flows being diverted through said side port will next enter said T-graft lumen.

13. The implantable device of claim 12 wherein said T-graft section comprises a flexible material and is configured to occupy a relatively flat delivery shape during delivery of said implantable device, and a roughly cylindrical implantation shape after said implantable device has reached its implantation configuration and said T-graft section has been pulled from said delivery shape into said implantation shape.

14. The implantable device of claim 13 wherein said delivery shape is a compressed accordion shape.

15. The implantable device of claim 13 wherein said delivery shape is a folded and flattened elongate shape.

16. The implantable device of claim 13 wherein said flexible material comprises a polymer.

17. The implantable device of claim 1 wherein said sheet-like member comprises a semi-permeable material, said semi-permeable material being configured to facilitate flow-based nutrition of tissues adjacent to said implantable device while directing the vast majority of fluid flow through the stent lumen and the side port.

18. The implantable device of claim 17 wherein said semi-permeable material comprises ePTFE.

19. The implantable device of claim 1 wherein said sheet-like member is coupled to said expandable stent using a coupling agent selected from the group consisting of adhesive, stitching, weaving, and encapsulation.

20. The implantable device of claim 1 further comprising a flexible wall member coupled to said implantable device in a configuration wherein an end wall is formed when said stent is in said expanded implantation state, said end wall substantially preventing the flow of fluids through said flow output area, said implantable device being operational to divert the majority of flow passing into said stent lumen out through said side port in a flow diversion configuration.

21. The implantable device of claim 20 wherein said flexible wall member is coupled to said expandable stent using a coupling agent selected from the group consisting of adhesive, stitching, weaving, and encapsulation.

22. The implantable device of claim 20 wherein said flexible wall member is coupled to said sheet-like member

using a coupling agent selected from the group consisting of adhesive, stitching, weaving, and encapsulation.

23. The implantable device of claim 20 wherein said flexible wall member is formed from a portion of said sheet-like member.

24. The implantable device of claim 20 wherein said end wall is configured to taper the stent lumen cross-sectional area from a larger area to a smaller area to minimize flow turbulence and zero-velocity flow spots.

25. The implantable device of claim 20 wherein said end wall is coupled to said stent in a configuration substantially perpendicular to a longitudinal axis of the stent.

26. The implantable device of claim 20 wherein said end wall comprises a relatively flat wall attached across said stent lumen at a flow diversion angle.

27. The implantable device of claim 26 wherein said flow diversion angle is approximately 45 degrees.

28. The implantable device of claim 20 wherein said end wall is curved in shape.

29. The implantable device of claim 28 wherein said end wall has a substantially-constant radius of curvature.

30. The implantable device of claim 20 further comprising a valve having an open position and a closed position, said valve being located upon said implantable device and being configured to controllably allow or prevent flow through a valve door in said sheet-like member when in said open position or said closed position, respectively.

31. The implantable device of claim 30 wherein said valve is located upon said end wall.

32. The implantable device of claim 30 wherein said valve has a remote shut off mechanism.

33. The implantable device of claim 32 wherein said remote shut-off mechanism comprises an electrolytically-dissolvable mechanical link which is interfaced with said valve and is operational to prevent said valve from occupying said closed position until after said dissolvable mechanical link has been controllably dissolved.

34. The implantable device of claim 33 further comprising a remote valve lock-down mechanism having a pin which is operational to lock said valve into said closed position after a second dissolvable mechanical link has been controllably dissolved.

35. The implantable device of claim 1 further comprising at least one additional side port.

36. An implantable device for placement in a body lumen comprising an expandable stent, a side port, and means for selectively diverting all or a portion of flow entering said expandable stent through said side port.

37. An implantable device for placement in a body lumen comprising:

a. a substantially tubular body having first and second opening at the ends of said body;

b. a side port through a wall of said body; and

c. an end wall coupled to said body, said end wall substantially preventing fluid communication between said first and second openings and diverting flow entering said body through said side port.

38. An implantable device for placement in a body lumen comprising:

a. a substantially tubular body having first and second openings at the ends of said body and an inner lumen;

b. a side port through a wall of said body; and

c. a valve movedly mounted to said body in said inner lumen;

wherein said valve is operable to divert some or all of flows entering said body through said side port.

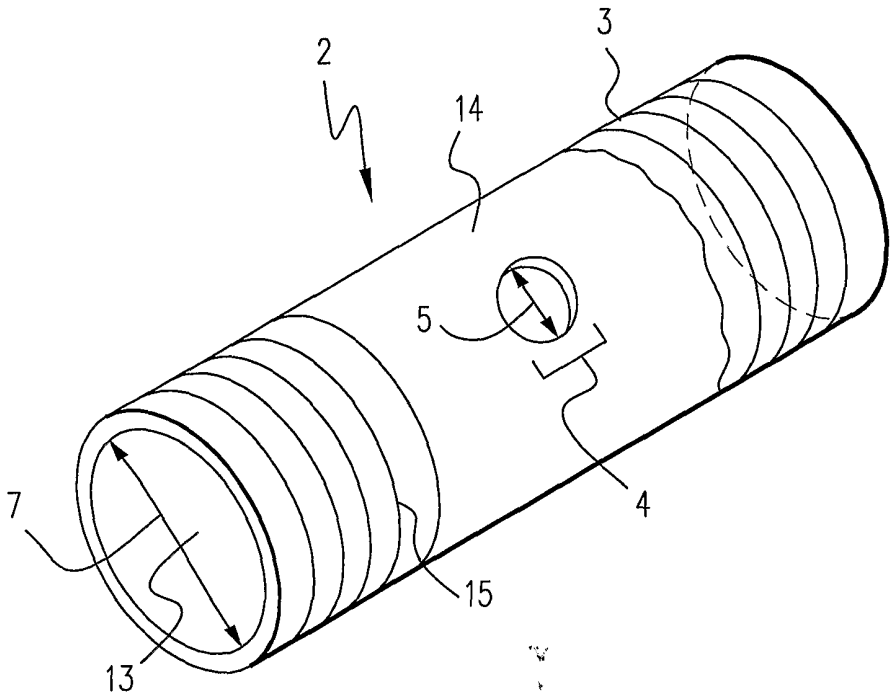


Fig.1A

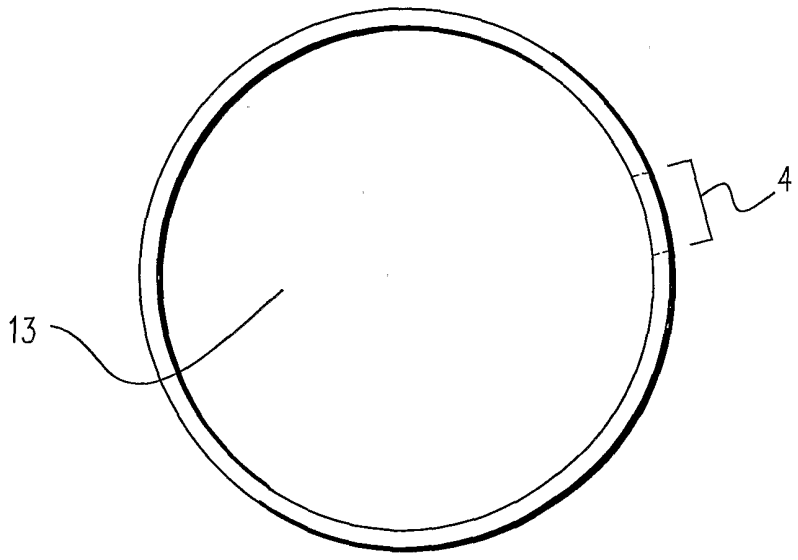


Fig.1B

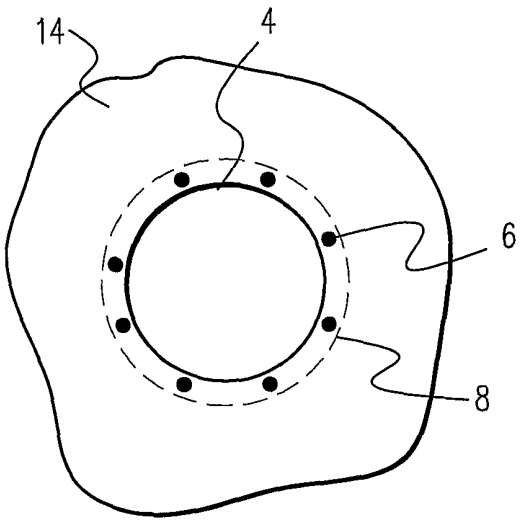


Fig.2A

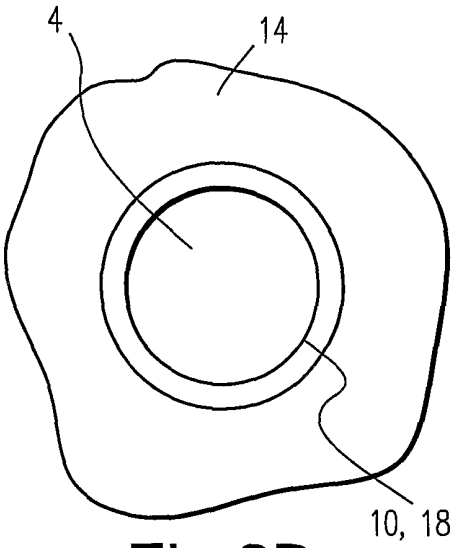


Fig.2B

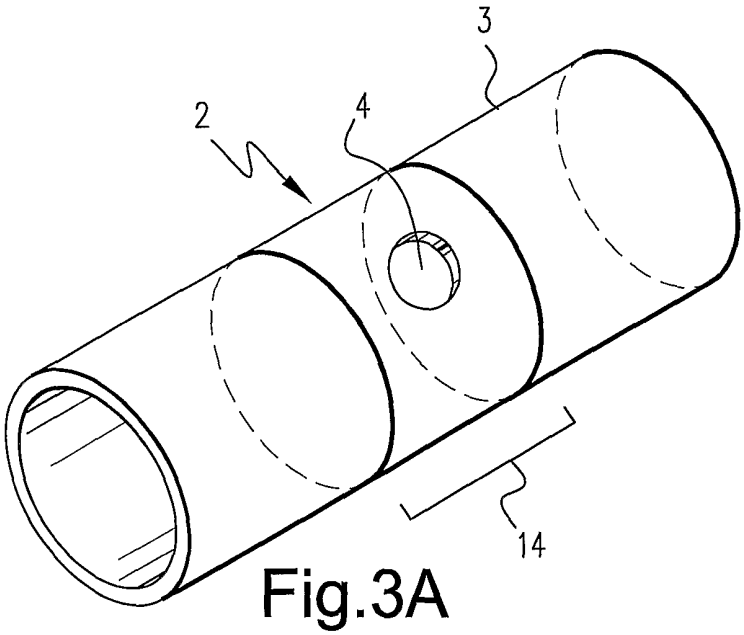


Fig.3A

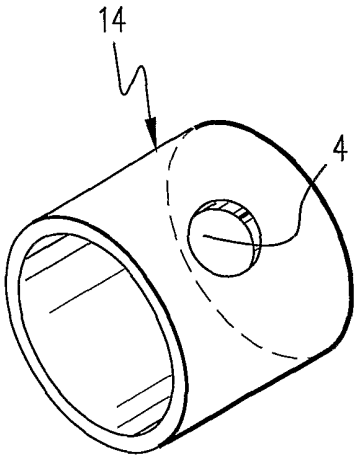


Fig.3B

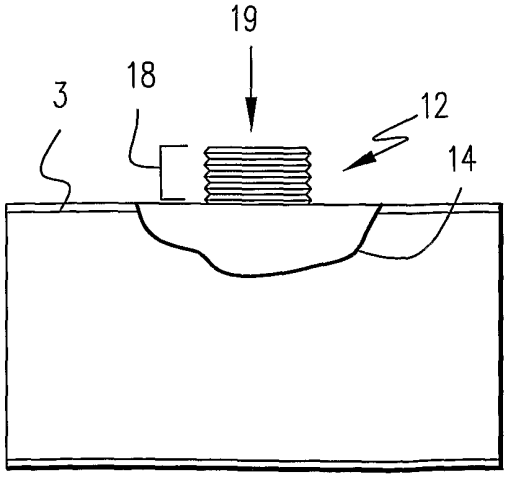


Fig.2C

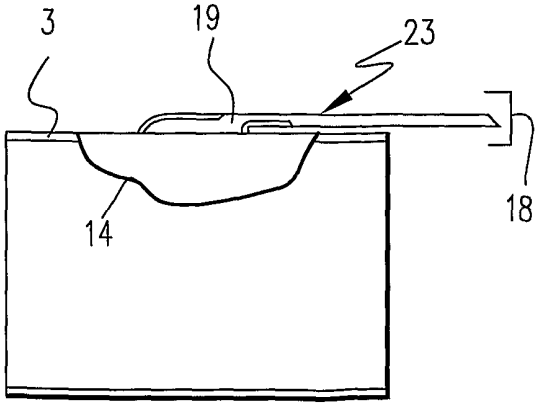


Fig.2D

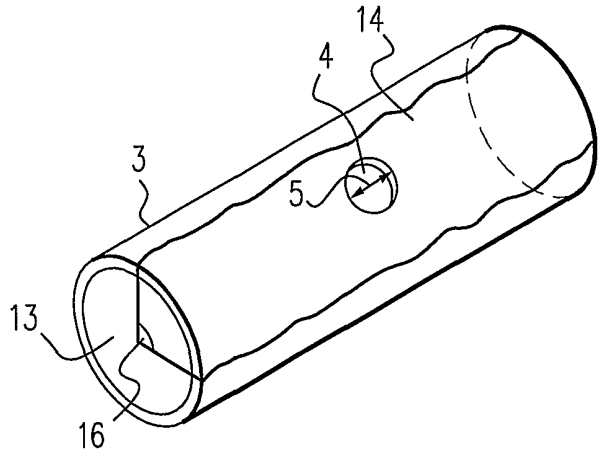


Fig.4A

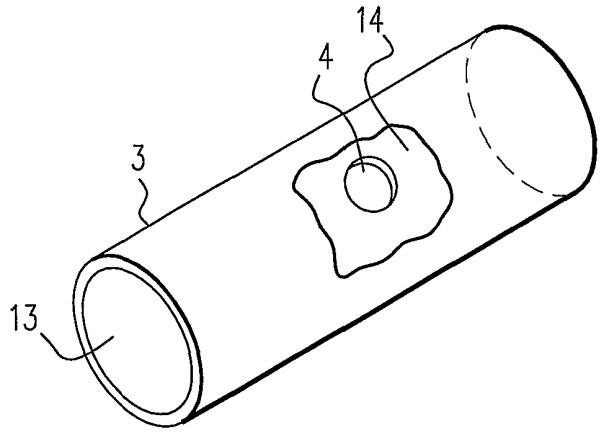


Fig.4B

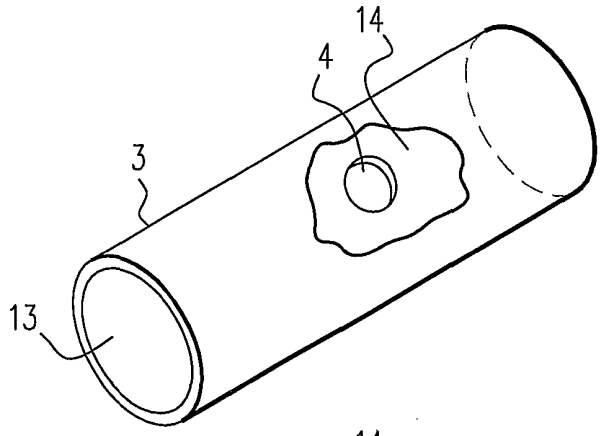


Fig.4C

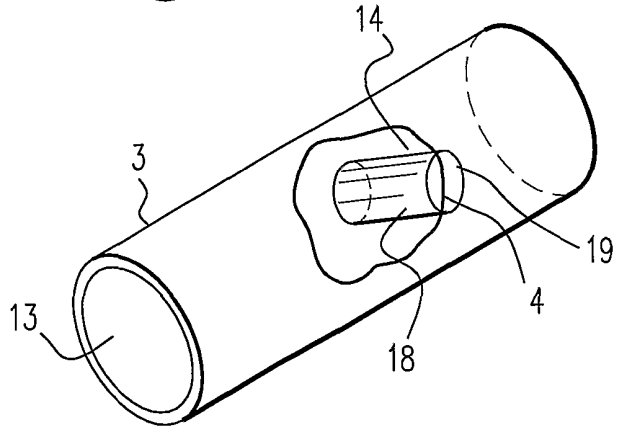


Fig.4D

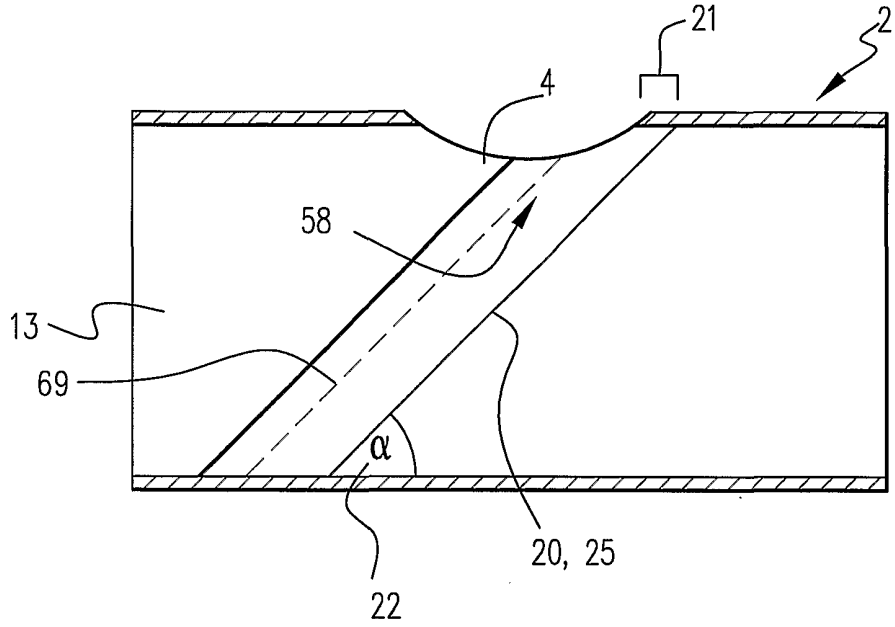


Fig.5A

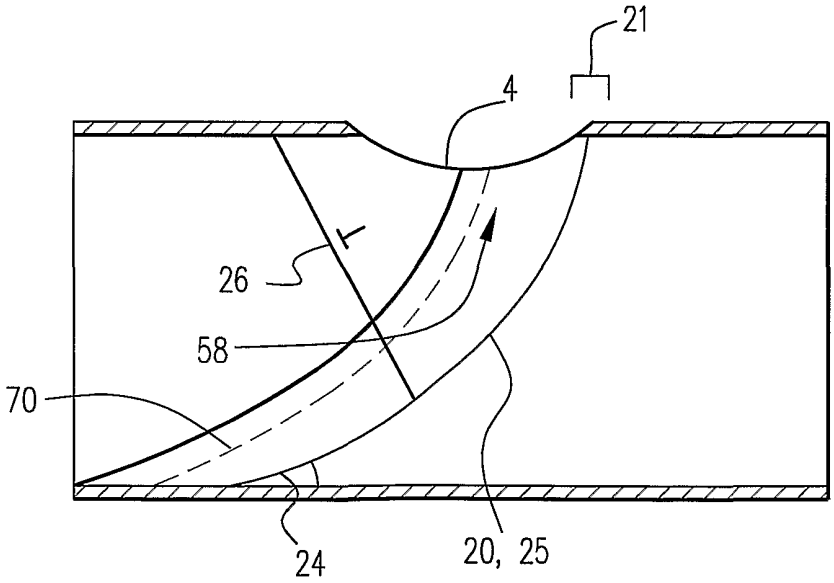


Fig.5B

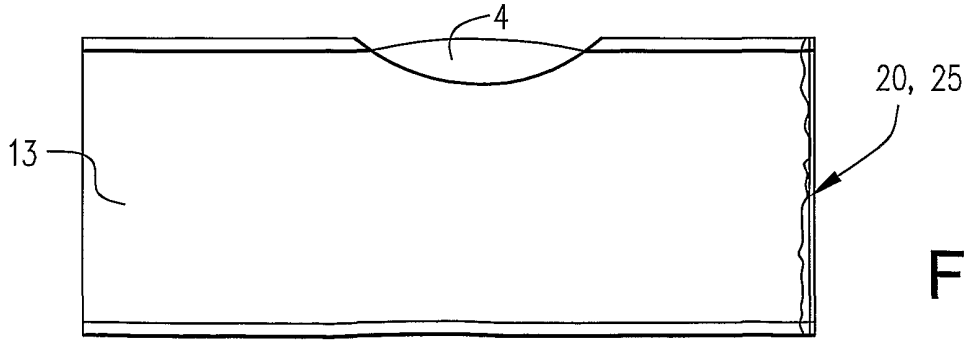


Fig.5C

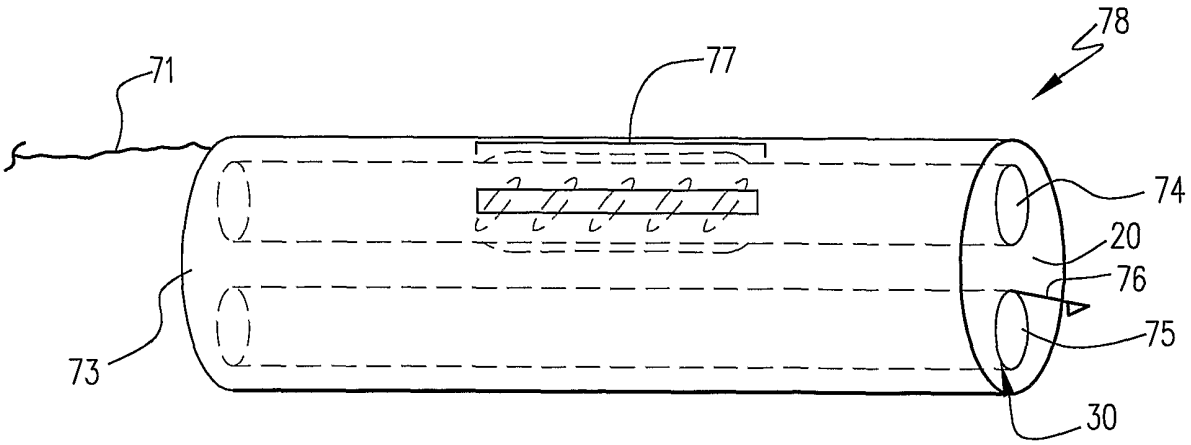


Fig.5D

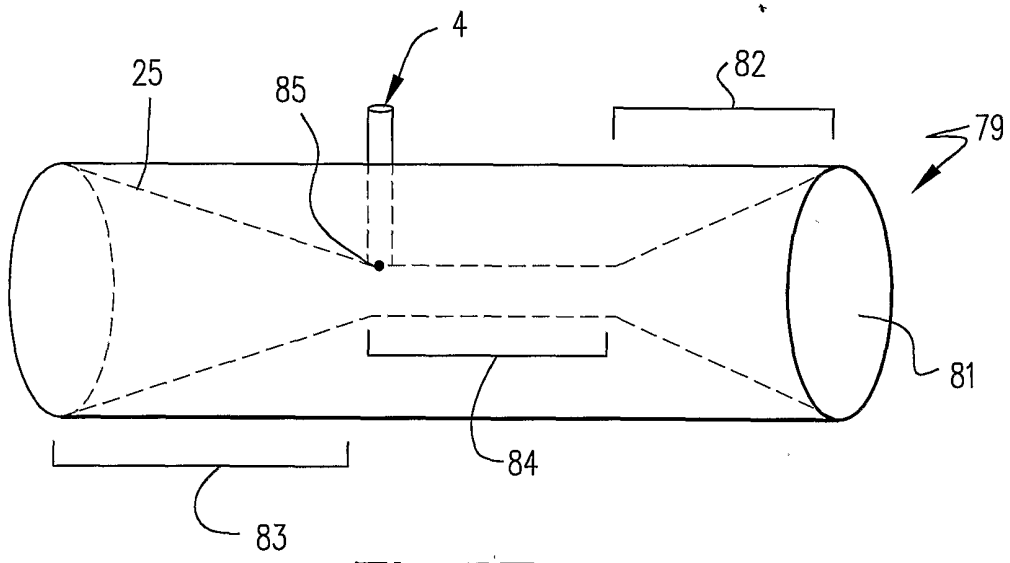


Fig.5E

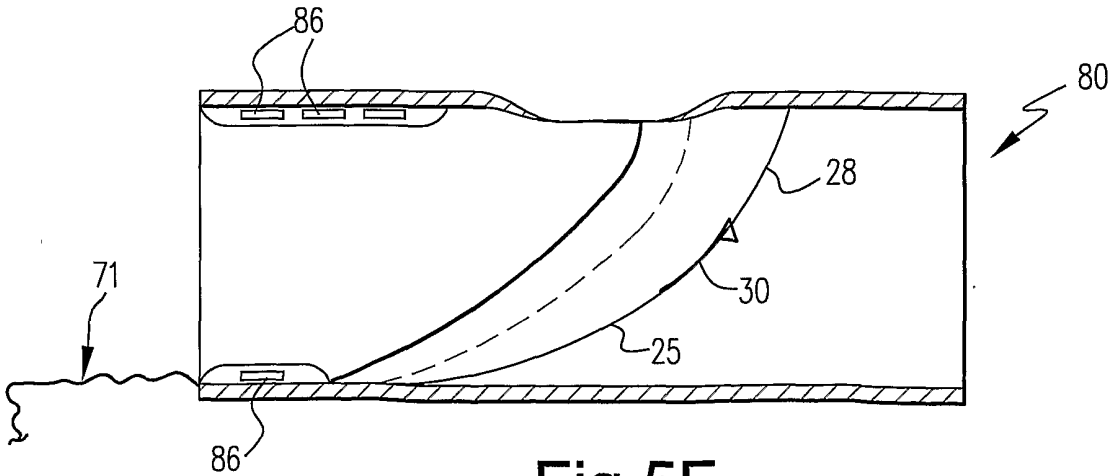


Fig.5F

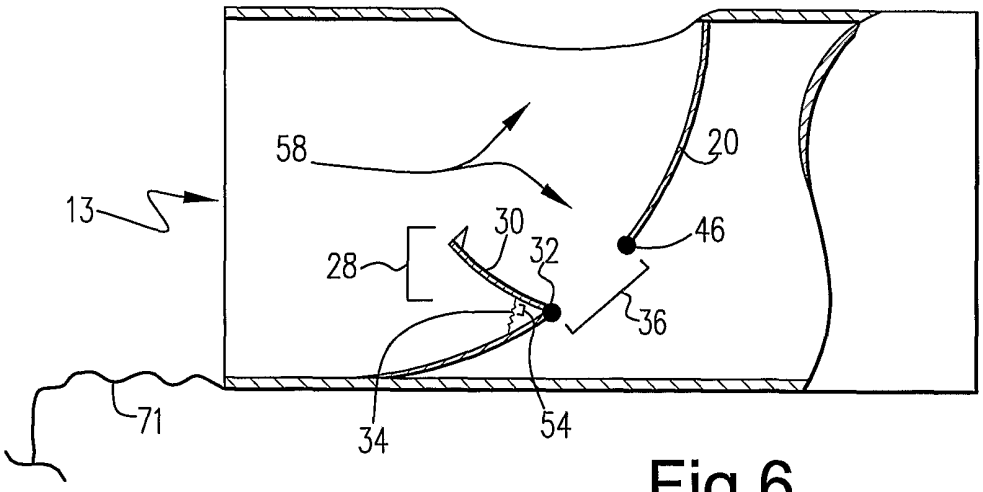


Fig.6

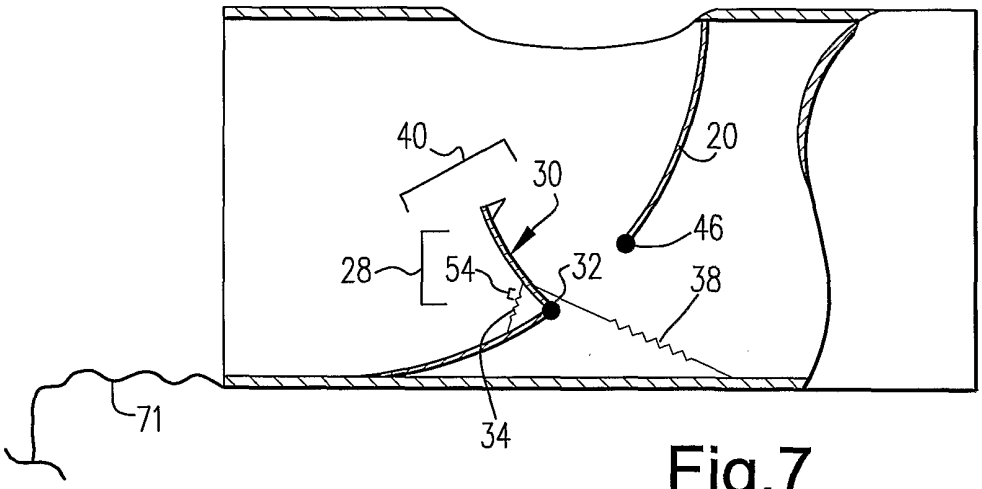


Fig.7

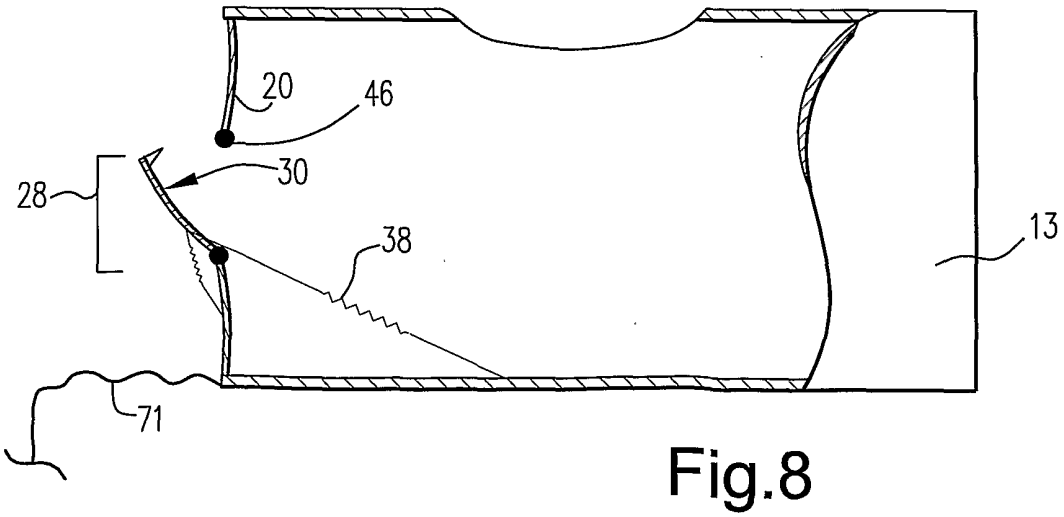


Fig.8

Fig.9A

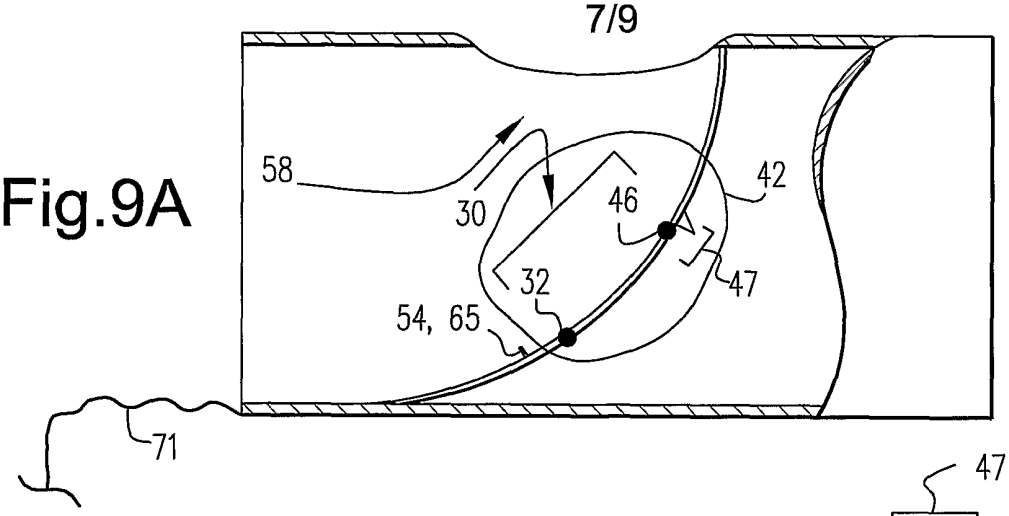
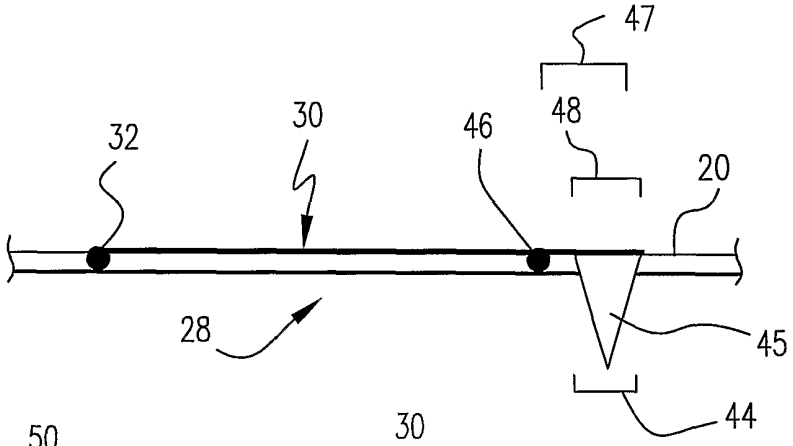


Fig.9B



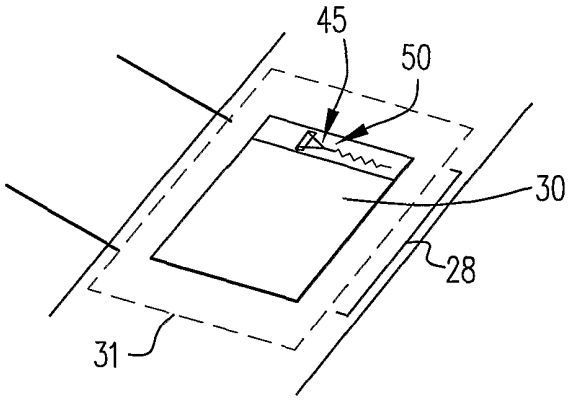


Fig.9C

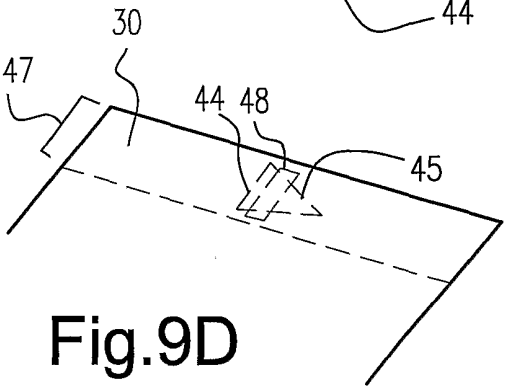


Fig.9D

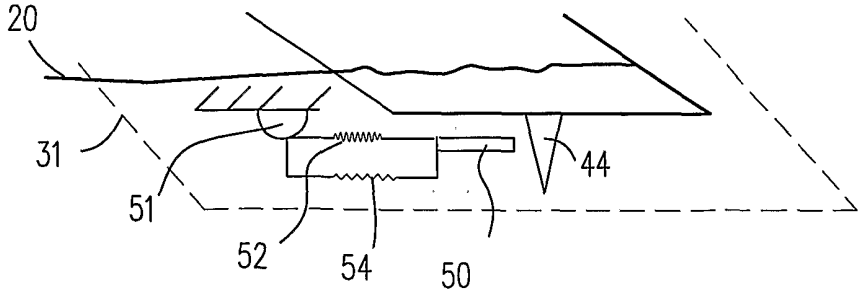


Fig.9E

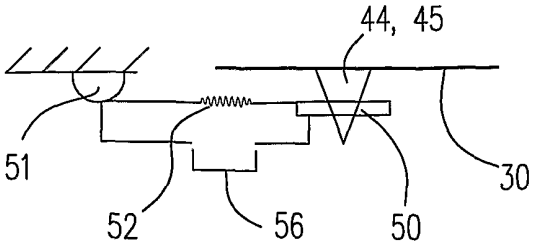


Fig.9F

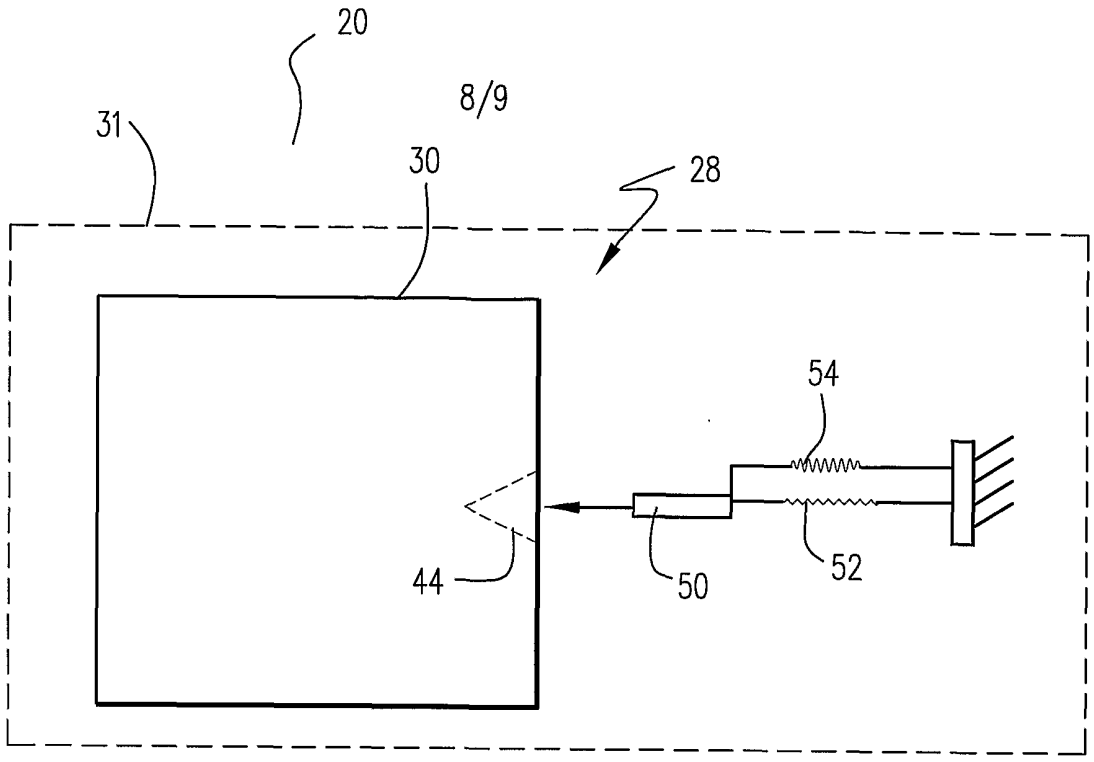


Fig.10

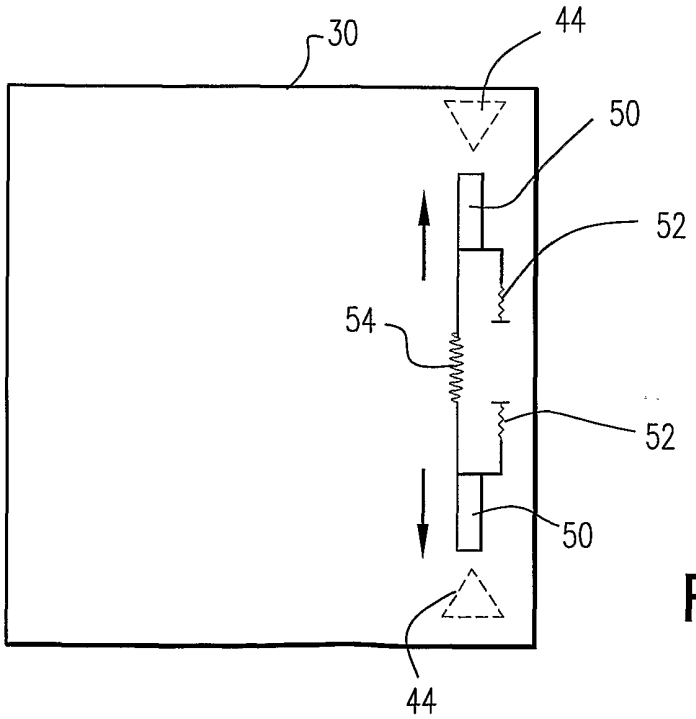


Fig.11

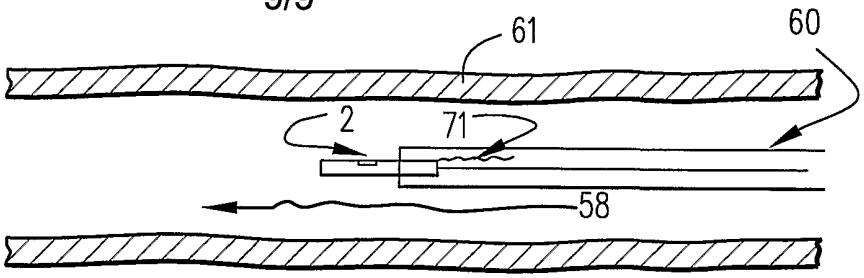


Fig.12A

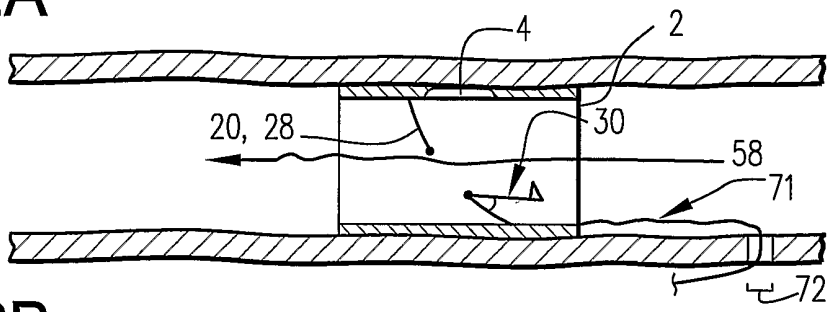


Fig.12B

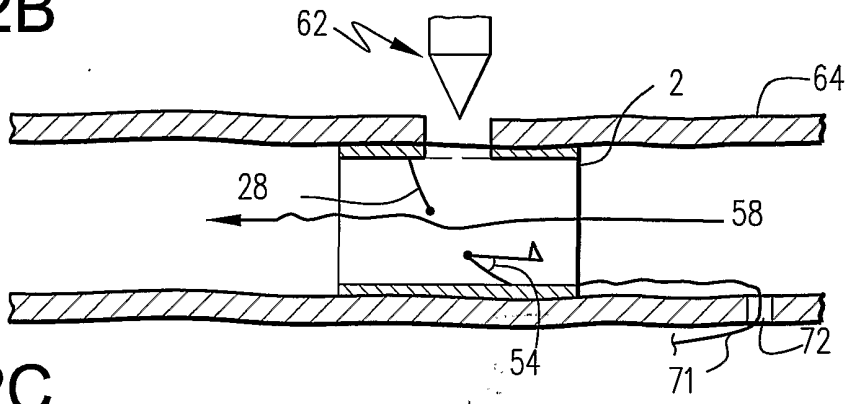


Fig.12C

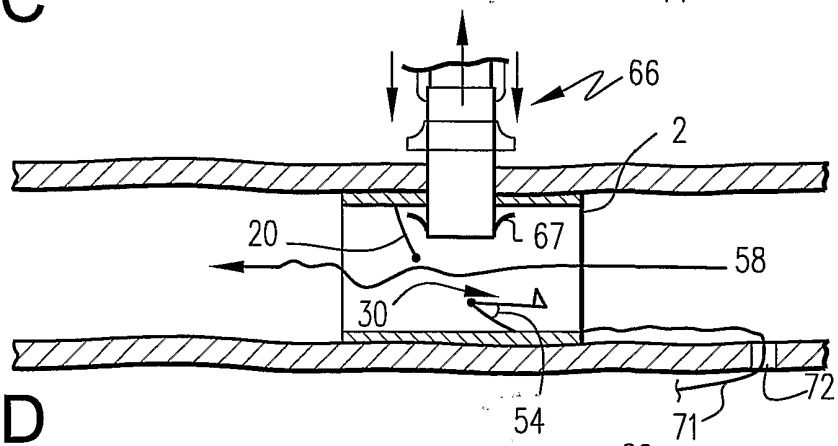


Fig.12D

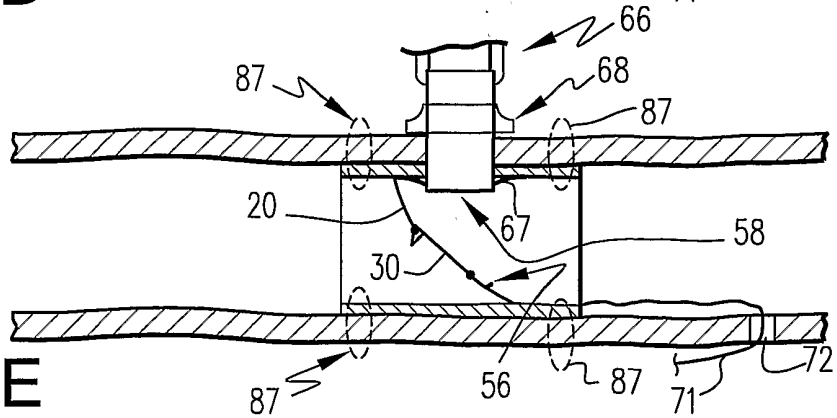


Fig.12E

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 00/17010

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/06

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)
IPC 7 A61F

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)
WPI Data, EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
E	WO 00 53118 A (MINDGUARD LTD.) 14 September 2000 (2000-09-14) the whole document	1,36,37
A	WO 98 06356 A (HEARTSTENT, LLC) 19 February 1998 (1998-02-19) page 21, line 13 -page 22, line 26; figures 18A-19C	1,36-38
A	WO 99 63910 A (ADVANCED BYPASS TECHNOLOGIES, INC.) 16 December 1999 (1999-12-16) page 30, paragraph 2; figures 24G,24H	1,36,37

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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"A" document defining the general state of the art which is not considered to be of particular relevance

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"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

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
22 January 2001	26/01/2001

Name and mailing address of the ISA	Authorized officer
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	Smith, C

INTERNATIONAL SEARCH REPORT

mation on patent family members

Interna[redacted]al Application No
PCT/US 00/17010

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