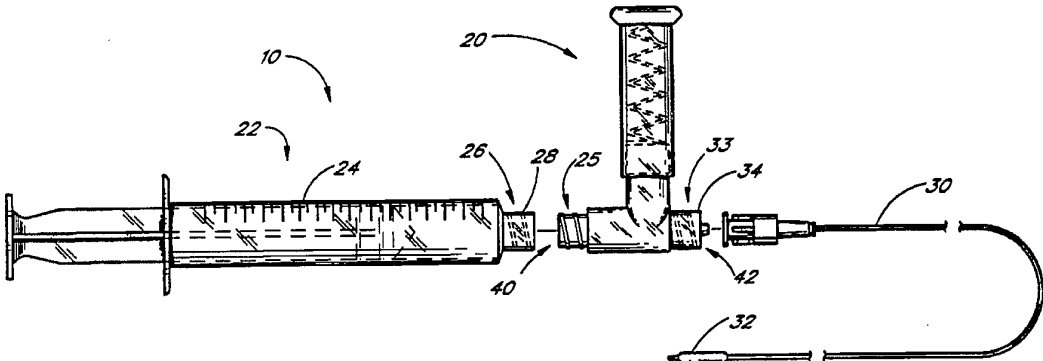


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(21) International Application Number: PCT/US95/07920 (22) International Filing Date: 7 June 1995 (07.06.95) (30) Priority Data: 08/255,097 7 June 1994 (07.06.94) US (71)(72) Applicant and Inventor: WILLIS, Allan [US/US]; 12440 Alderglen Street, Moorpark, CA 93021 (US). (74) Agent: NATAUPSKY, Steven, J.; Knobbe, Martens, Olson and Bear, Suite 1600, 620 Newport Center Drive, Newport Beach, CA 92660 (US).		(81) Designated States: AM, AT, AU, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IS, JP, KE, KG, KP, KR, KZ, LK, LR, LT, LU, LV, MD, MG, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TT, UA, UG, UZ, VN, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG), ARIPO patent (KE, MW, SD, SZ, UG). Published <i>With international search report.</i>
(54) Title: BALLOON CATHETER OVER-INFLATION PROTECTION DEVICE		
		
(57) Abstract There is provided a device (20) for preventing over-inflation of a balloon catheter (10). In one embodiment, a movable wall (48) is attached to a spring (50) for defining a pressure release chamber (46) between the movable wall (48) and a pressure release port (44) of the device. The movable wall (48) is biased in the direction of a pressure source so that increases in pressure above a threshold pressure move the movable wall (48) a variable distance from the pressure release port (44). Over-inflation of the catheter balloon (32) is prevented because pressures exceeding the desired maximum cause the movable wall (48) to move to a position in which the pressure release chamber (46) is placed in communication with a vent (52). There is also provided a method for preventing balloon catheter over-inflation.		

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BALLOON CATHETER OVER-INFLATION PROTECTION DEVICEBackground of the Invention

The present invention relates to over-inflation protection devices and, more particularly, to balloon catheter over-inflation protection devices.

Percutaneous transluminal coronary angioplasty is a procedure for enlarging a narrowed coronary arterial lumen using a balloon catheter. One concern regarding the use of balloon catheters is the possibility of the inflatable dilatation balloon bursting while inside the patient. The purpose of over-inflation protection devices is to ensure that the balloon catheter is not exposed to more than a specific predetermined maximum pressure, which is less than the failure pressure of the balloon.

One of the known over-inflation protection devices involves the use of an externally placed latex balloon. The externally placed latex balloon, however, has inherent burst risk problems similar to those of the dilatation balloon mounted on the catheter tip. Thus, there remains a need for a reliable, yet low-cost, over-inflation protection device for limiting dilatation balloon pressure at a level below the failure pressure of the balloon.

Summary of the Invention

There is provided in accordance with one aspect of the present invention a balloon catheter over-inflation protection device, for minimizing the likelihood of balloon failure during balloon dilatation procedures. The over-inflation protection device comprises a housing, having an effluent port for communication with a pressure source. The housing is further provided with an effluent port for communication with a balloon catheter. The effluent port and influent port are in communication with each other, and with a pressure release port on the housing.

A vent is provided in the housing for releasing inflation media to maintain a predetermined maximum pressure. A movable wall is positioned within the housing for defining a variable volume pressure release chamber between the movable wall and

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the pressure release port. The movable wall is biased in the direction of the pressure source, so that an increase in pressure above a threshold pressure over comes the biasing force and moves the movable wall from a first position
5 disposed towards the pressure, through a second position between the first position and a third position, to the third position in which the vent is placed in communication with the pressure source. In this manner, access inflation media is released through the vent when the movable wall is in the
10 third position, thereby minimizing the likelihood of balloon failure.

In accordance with a further aspect of the present invention, there is provided a method of minimizing balloon catheter over-inflation. In accordance with the method, a
15 balloon catheter over-inflation device as described above is selected, said device having a maximum or vent pressure which is below the failure pressure of the balloon catheter.

The balloon catheter is connected to effluent port of the housing, and a pressure source is connected to the influent port of the housing. The balloon catheter is thereafter
20 percutaneously inserted and transluminally advanced to the desired treatment site in accordance with conventional techniques. The pressure source is activated to inflate the balloon, and access inflation media beyond that required to
25 inflate the balloon to the predetermined maximum pressure is vented through the vent, to minimize the risk of balloon failure. The inflation balloon is thereafter deflated, and the catheter is withdrawn from the treatment site in accordance with conventional techniques.

30 Further features and advantages of the present invention will become apparent to one of skill in the art in view of the detailed description of preferred embodiments which follows, when considered together with the attached figures and claims.

Brief Description of the Drawings

35 Figure 1 is a partially exploded side elevational representation of a balloon catheter system incorporating the over-inflation protection device according to the present

invention.

Figure 2 is a front elevational view of a first embodiment of an over-inflation protection device according to the present invention.

5 Figures 3A, 3B, and 3C are elevational cross-sectional views taken along lines 3-3 of Figure 2.

Figure 4 is an enlarged view of the vent depicted in Figure 3C.

10 Figure 5 is an exploded side elevational view of a second embodiment of an over-inflation protection device according to the present invention.

Figure 6 is a front elevational view of the second embodiment of the over-inflation protection device.

15 Figure 7 is an elevational cross-sectional view taken along line 7-7 of Figure 6.

Figure 8 is an exploded side elevational view of a third embodiment of an over-inflation protection device according to the present invention.

20 Figure 9 is a front elevational view of the third embodiment of the over-inflation protection device.

Figure 10 is an elevational cross-sectional view taken along line 10-10 of Figure 9.

Detailed Description of Preferred Embodiments

25 Referring to Figure 1, there is disclosed a schematically illustrated balloon catheter system 10 incorporating a balloon catheter over-inflation protection device 20. The over-inflation protection device has an influent port 40, which can be connected to any of a variety of known pressure sources 22, such as a source of pressurized carbon dioxide gas, fluid or
30 other media. Other conventional pressure sources, such as an Inflator or a syringe 24, can also be used.

A connector 25 is preferably provided on influent port 40 for releasably placing influent port 40 in communication with pressure source 22. Connector 25 is preferably a standard
35 luer connector, such as for connection to a corresponding luer 28 on effluent port 26 from pressure source 22.

The over-inflation protection device 20 also has an

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effluent port 42, which can be connected to a catheter 30, such as a conventional balloon catheter with an inflatable balloon 32 near the distal tip. The balloon 32 can be made from any of a number of materials, such as latex or polyethylene, depending on the type of procedure being performed. Compressed gas such as pressurized carbon dioxide is preferably used to inflate a latex balloon as may be used in right heart/pulmonary artery catheterization, while a fluid pressure source is preferably used to inflate a polyethylene balloon in other percutaneous transluminal coronary angioplasty procedures.

The catheter 30 is connected to the over-inflation protection device 20 with a connector 33. The catheter connection is preferably a standard luer connection, such as that obtained using a male luer lock 34.

Figures 3A-3C illustrate side elevational cross-sectional views of a first embodiment of the over-inflation protection device 20 in sequential stages of operation. A housing 38 is provided with influent port 40 for communication with a pressure source. An effluent port 42 is provided for connection to a balloon catheter and placing the balloon catheter in communication with influent port 40 through the housing 38 as has been discussed. The housing is also provided with a pressure release port 44. The influent port 40, effluent port 42, and pressure release port 44 are in communication with each other.

A vent 52 is provided in the housing 38 downstream from the release port 44 for releasing inflation media, if necessary, to maintain a precalibrated maximum pressure. The maximum pressure is preferably calibrated during the manufacturing stage of the device using conventional means as will be apparent to one of skill in the art in view of the disclosure herein.

A movable wall 48 is disposed within the housing 38 for defining a variable volume pressure release chamber 46 between the movable wall and the pressure release port 44. Preferably, the movable wall 48 comprises an elastomeric plug

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such as the plunger in a conventional syringe, for providing slidable sealing engagement within a tubular wall. The pressure release chamber 46 is in communication with the pressure release port 44, and normally positioned in between the port 44 and the vent 52.

The movable wall 48 is biased in the direction of the pressure source 22 by a spring 50 in the housing 38. Any of a number of other conventional sources for providing a biasing force can also be used, such as compressible foams, resilient materials and the like. In addition, the movable wall can be biased by a pull spring in the housing positioned on the pressure release port 44 side of the movable wall 48. In the preferred embodiment, the coil 50 is disposed on the downstream side of movable wall 48 as illustrated.

The dimensions and configuration of the over-inflation protection device 20 can be varied considerably to suit the particular design criteria desired for a particular application and still embody the present invention. For example, in a typical percutaneous transluminal coronary angioplasty procedure, the device is adapted for use with a conventional dilatation balloon having a working pressure within the range of from about 120 p.s.i. to about 160 p.s.i. and a failure pressure of greater than 180 p.s.i.

The movable wall 48 is axially movably positioned within a generally cylindrical portion of the housing 38 as illustrated to provide the variable volume chamber 46. The housing can be made using any of a number of techniques known in the art. For instance, the housing can be cast from stainless steel, such as in a sterilizable, reusable model. The housing can also be injection molded from polyethylene, polycarbonate, or other medical grade polymer such as in a disposable model. Use of a clear polymer permits visualization of the position of the movable wall 48 within the chamber. Indicia of pressure can also be provided on the generally cylindrical portion of the housing containing the movable wall.

In the illustrated embodiment, the main manifold portion

of the housing 38 is integrally molded with the portion of the housing which contains the movable wall 48 and chamber 46. The distal end 49 of the housing 38 is provided with an open end, for insertion of the movable wall 48 and spring 50.

5 Following assembly, a separate cap 51 is secured into place such as through the use of conventional adhesives, thermal bonding, solvent bonding or mechanical interfit techniques.

Any of a variety of combinations of housing dimensions and spring constants can be utilized to accomplish the purpose of the present invention. In general, the chamber size and spring constant will be adapted to cooperate with the coefficient of sliding friction of movable wall 48 within the chamber to achieve venting at the appropriate maximum pressure.

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15 In a particular embodiment, the movable wall 48 is a generally cylindrical elastomeric plug having a diameter of about 0.250 inch to 0.400 inch and an axial length of about 0.250 inch. The movable wall 48 is slidably disposed in a generally cylindrical chamber having an axial length of about 1.5 to 2.0 inches. In this embodiment, a coil spring having a coil diameter of about 0.350 inch, a wire diameter of about 0.025 inch, and a relaxed length of about 1.3 to 1.9 inches is used to bias the movable wall 48. In the absence of pressure from the pressure source 22, the spatial orientation of the movable wall within the chamber causes partial compression of the spring so that the spring length in the chamber is somewhat less than the relaxed length of the spring. The stroke length of the spring is generally about 1.00 to 1.50 inches. The chamber preferably has an inside diameter of 0.360 inch, with a pressure release chamber variable volume between 0.75 cc and 1.0 cc.

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Calibration of the device can be readily accomplished by pressurizing the system to the desired maximum pressure, and observing and/or marking the location of the movable wall 48 within the chamber. Following release of pressure, the vent 52 can be conveniently drilled at the appropriate location. Alternatively, the vent 52 can be predrilled or molded if the

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various components of the device are available within acceptable manufacturing tolerances to produce a desired precision in the final product. Preferably, the movable wall has an axial travel of at least about 0.75 inch, and preferably at least about 1.0 inch between the onset of pressure and the release of inflation media through the vent 52.

The aforementioned axial travel of the movable wall creates a damper effect. This damper effect is beneficial for a number of reasons. For example, axial travel of the movable wall ensures gradual inflation of the catheter balloon 32. In addition, the damper effect lowers the peak pressure received by the catheter balloon in response to a given pressure delivered from the pressure source 22. Further, visualization of the axial position of the movable wall enhances the user's ability to gauge the degree of inflation while the balloon is inside the patient.

In Figure 3A the movable wall is in a first position. The movable wall 48 will remain in the first position until being exposed to pressures above a threshold pressure necessary to overcome the initial biasing force and thereby move the wall. When the movable wall 48 is in the first position, the spring 50 is partially compressed (pretensioned) so that the movable wall will return to the first position when the pressure drops below the threshold pressure.

Figure 3B illustrates the movable wall 48 in a second, intermediate position. The second position of the movable wall 48 can be anywhere between the first position and a third position as discussed below. The vent 52 is not in communication with the pressure release chamber 46 when the movable wall 48 is in either the first or second position. Pressure increases above the threshold pressure, however, cause the variable volume of the pressure release chamber 46 to increase. The increased volume of the pressure release chamber 46 allows the over-inflation protection device to absorb excess pressure while the movable wall 48 is advancing through the second position, even though the vent 52 is not

yet in communication with the pressure release chamber 46.

Figure 3C illustrates the movable wall in the third position. When the movable wall reaches the third position, the vent is placed in communication with the pressure release chamber so that inflation media is released through the vent 52, as indicated by the curved arrow in Figure 3C, thereby maintaining a stable maximum inflation pressure within the system.

Figure 4 is an enlarged view of a portion of Figure 3C, illustrating the release of pressure through the vent 52 when the movable wall 48 is in the third position. When fluid is used as the pressure source, fluid escaping through vent 52 can be collected by any of the variety of structures apparent to those skilled in the art.

A procedure for preventing balloon catheter over-inflation within an artery is generally accomplished as follows. The surgeon selects an over-inflation protection device of the present invention having a desired vent pressure. The vent pressure selected depends on the type of procedure being performed. For instance, for use with certain percutaneous transluminal coronary angioplasty catheters, an over-inflation protection device 20 with a vent pressure of at least about 14 atmospheres or less may be used to dilate a highly calcified lesion, while an over-inflation protection device 20 having a vent pressure on the order of about 10 atmospheres may be used to dilate a soft thrombosis or less calcified lesion.

The influent port 40 of the housing 38 is connected to a conventional pressure source 22, such as a syringe 24. A conventional balloon catheter is connected to the effluent port 42 of the housing 38. For example, in right heart/pulmonary artery balloon catheterization, a seven French Swan-Ganz catheter is preferably used for adults, while a five French Swan-Ganz catheter is preferably used for pediatric patients.

The surgeon positions the balloon catheter at a vascular treatment site using conventional techniques.

The surgeon then transmits pressure from the pressure source 22 to inflate the balloon 32 at the treatment site. The seven French Swan-Ganz catheter balloon will normally inflate to its recommended size at a nominal 17 p.s.i., while
5 the corresponding pressure for a five French Swan-Ganz pediatric catheter is approximately 21 p.s.i.

The over-inflation protection device 20 is calibrated so that the catheter balloon is not exposed to more than the preselected vent pressure, which is less than the failure
10 pressure of the balloon 32, thereby preventing over-inflation. In addition, depending on the relative threshold pressures needed for movement of the movable wall 48 and inflation of the catheter balloon 32, the physician can determine whether the balloon 32 is inflated or deflated based on the position
15 of the movable wall. This decreases the risk of the physician unknowingly withdrawing a catheter having a partially inflated balloon. Moreover, visualization of the movable wall enables the physician to assess catheter function. For instance, movement of the movable wall towards the pressure release port
20 in response to a constant pressure from the pressure source 22, may be indicative of catheter malfunction, such as a leak in the catheter system.

Figures 5-7 illustrate a second embodiment of the present invention. Unlike the first embodiment, in which the pressure
25 release chamber 46 of the over-inflation protection device 20 is integrally molded with the manifold portion of the housing, in the second embodiment, a subassembly 56 is releasably attached to pressure release port 44. A standard luer connector 58 or other connector adapted for convenient
30 attachment can be used to bring the subassembly 56 in communication with pressure release port 44. In all other respects, the first and second embodiments are functionally identical.

The procedure for using the second embodiment depicted by
35 Figures 5-7 is the same as that of the first embodiment depicted by Figures 2-4 with the exception of the second embodiment requiring additional steps. The additional steps

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required to use the embodiment of Figures 5-7 involve selecting a subassembly 56 having a desired vent pressure and attaching the subassembly 56 to the pressure-release port 44 before transmitting pressure from the pressure source 22. This releasable attachment can be accomplished using a standard luer connector 58 or other connector adapted for convenient attachment. Alternatively, this step can be accomplished at the point of manufacture of the over-inflation protection device.

Figures 8-10 illustrate a third embodiment of the present invention. In this embodiment, the entire spring, movable wall and pressure release chamber are disposed within a integrally molded cap 60. The cap 60 is press fit to the pressure release port 44 during the manufacturing stage of the device and secured using conventional techniques such as snap fit or net tolerance fit preferably together with any of a variety of ways to maintain a seal such as thermal bonding, solvent bonding or suitable adhesives known in the art.

The procedure for using the third embodiment depicted by Figures 8-10 is identical to the procedure for using the first embodiment depicted by Figures 2-4.

Although this invention has been described in terms of certain preferred embodiments, other embodiments which will be apparent to those of ordinary skill in the art in view of the disclosure herein are also within the scope of this invention. Accordingly, the scope of the invention is intended to be defined only by reference to the appended claims.

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I CLAIM:

1. A balloon catheter over-inflation protection device, comprising:

5 a housing having an influent port for communication with a pressure source, an effluent port for communication with a balloon catheter, and a pressure release port, the influent port, effluent port, and pressure release port being in communication with each other;

10 a vent in the housing for releasing inflation media to maintain a predetermined maximum pressure; and

a movable wall within the housing for defining a pressure release chamber between the movable wall and the pressure release port, the movable wall being biased in the direction of the pressure source so that an increase in pressure above a threshold pressure overcomes the biasing force and moves the movable wall from a first position disposed towards the pressure release port, through a second position between the first position and a third position, to the third position in which the vent is placed in communication with the pressure release chamber, so that excess inflation media is released through the vent when the movable wall is in the third position, thereby preventing over-inflation of the balloon.

25 2. A balloon catheter over-inflation protection device, comprising:

a housing;
an influent port in the housing for communication with a pressure source;

30 an effluent port in the housing for communication with a balloon catheter;

a first flow path for communication between the influent port and the effluent port;

35 a pressure release port in the housing;

a second flow path for communication between the pressure release port and the first flow path;

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a vent in the housing for releasing excess inflation media; and

5 a movable wall normally disposed within the housing in between the pressure release port and the vent, the movable wall being biased in the direction of the pressure source so that an increase in pressure above a threshold pressure overcomes the biasing force and moves the movable wall from a first position disposed towards the pressure release port, to a second position between the first position and a third position, to the third position in which the vent is placed in communication with the pressure release chamber, so that excess inflation media is released through the vent when the movable wall is in the third position, thereby preventing over-inflation of the balloon.

15 3. A balloon catheter over-inflation protection device, comprising:

a housing;
an influent port in the housing for communication with a pressure source;
20 an effluent port in the housing for communication with a balloon catheter;
a pressure release port, the influent port, effluent port, and pressure release port being in communication with each other;
25 a cap on the housing;
a vent in the cap for releasing excess pressure; and
a movable wall for defining a pressure release chamber in the cap between the movable wall and the pressure release port, the movable wall being biased in the direction of the pressure source so that an increase in pressure above a threshold pressure overcomes the biasing force and moves the movable wall from a first position disposed towards the pressure release port to a second position between the first position and a third position to the third position in which the vent is placed in communication with the pressure release

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chamber, so that inflation media is released through the vent when the movable wall is in the third position, thereby preventing over-inflation of the balloon.

4. A method of preventing balloon catheter over-inflation, comprising the steps of:

5 providing a housing having an influent port, an effluent port, and a pressure release port in communication with each other, the housing having a movable wall for defining a pressure release chamber
10 between the movable wall and the pressure release port, the movable wall biased in the direction of a pressure source connected to the influent port so that an increase in pressure from the pressure source above a threshold pressure overcomes the biasing force and moves the
15 movable wall from a first position disposed towards the pressure release port, to a second position between the first position and a third position, to the third position in which the vent is placed in communication with the pressure release chamber, so that inflation
20 media is released through the vent when the movable wall is in the third position, thereby preventing over-inflation of the balloon;

connecting a balloon catheter to the effluent port of the housing;

25 positioning the balloon catheter at a treatment site; and

transmitting pressure from the pressure source to inflate the balloon at the treatment site.

5. A method of preventing balloon catheter over-inflation, comprising the steps of:

30 providing a balloon catheter over-inflation device of the type defined in Claim 3;

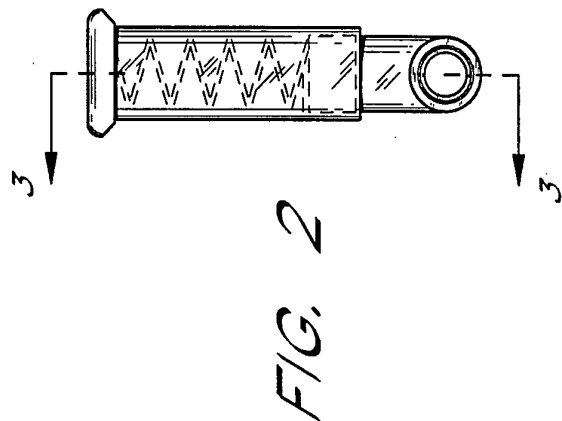
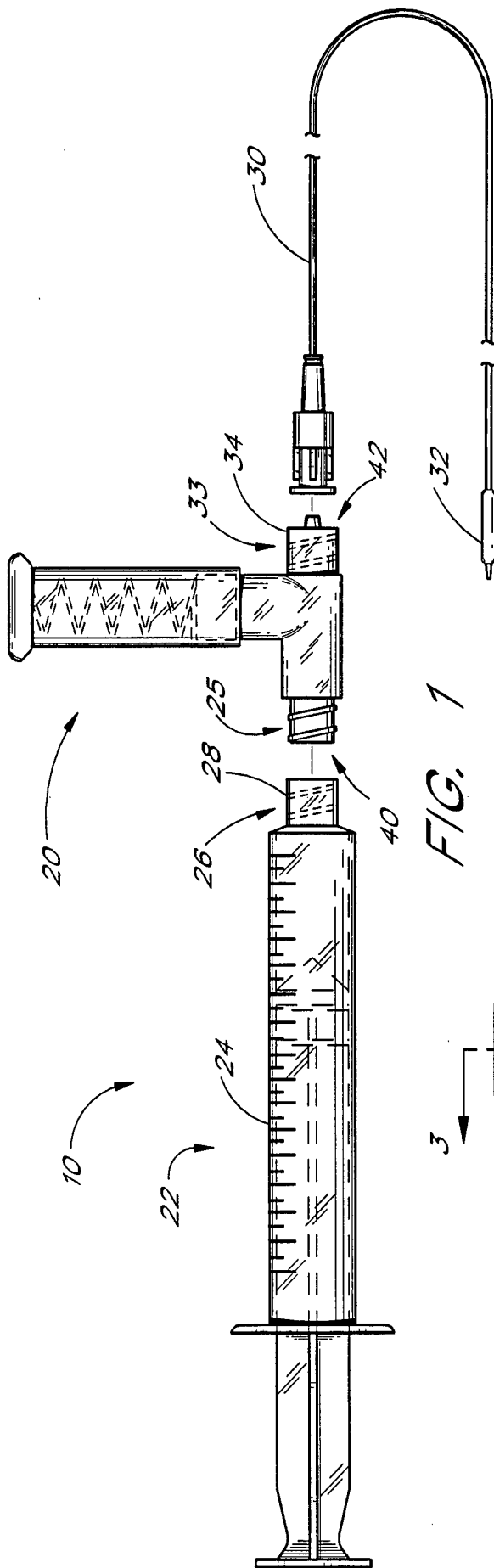
connecting a balloon catheter to the effluent port of the housing;

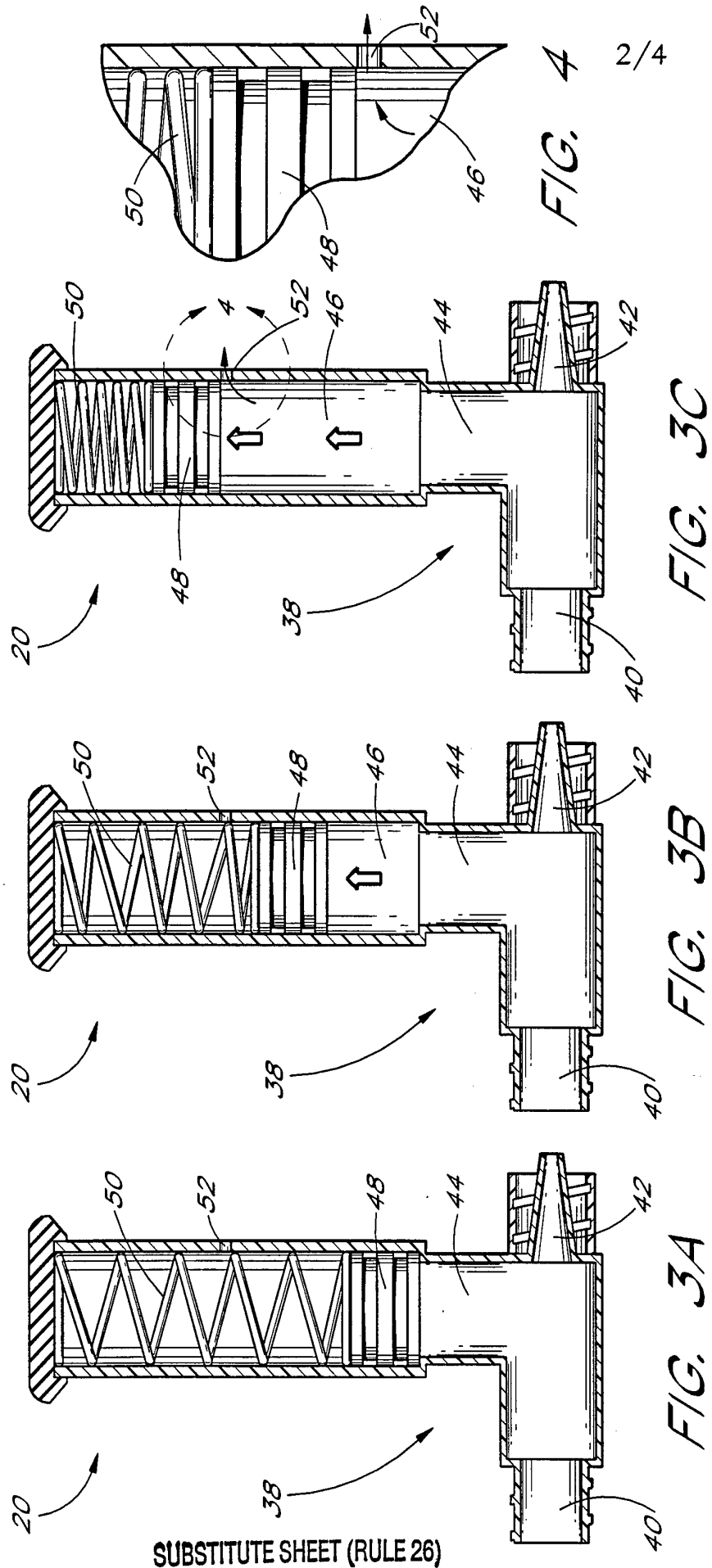
35 positioning the balloon catheter at a treatment site; and

transmitting pressure from the pressure source to

-14-

inflate the balloon at the treatment site.





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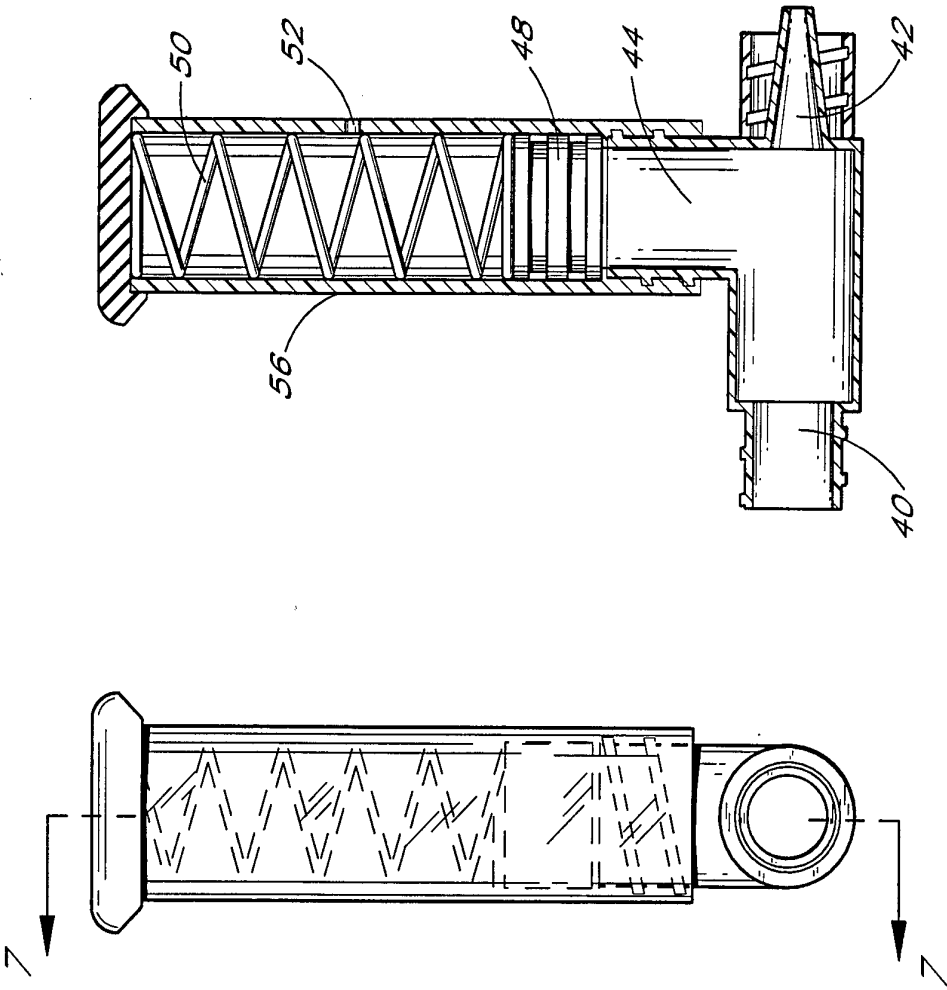


FIG. 5

FIG. 6

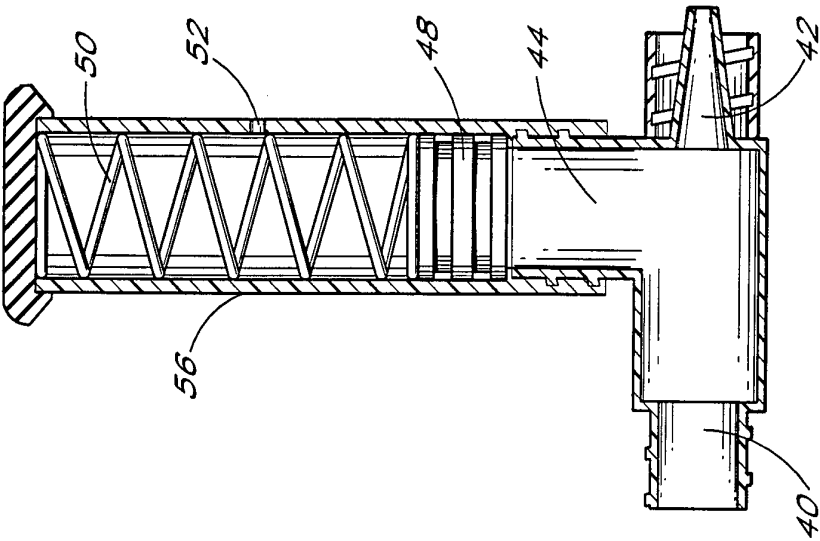


FIG. 7

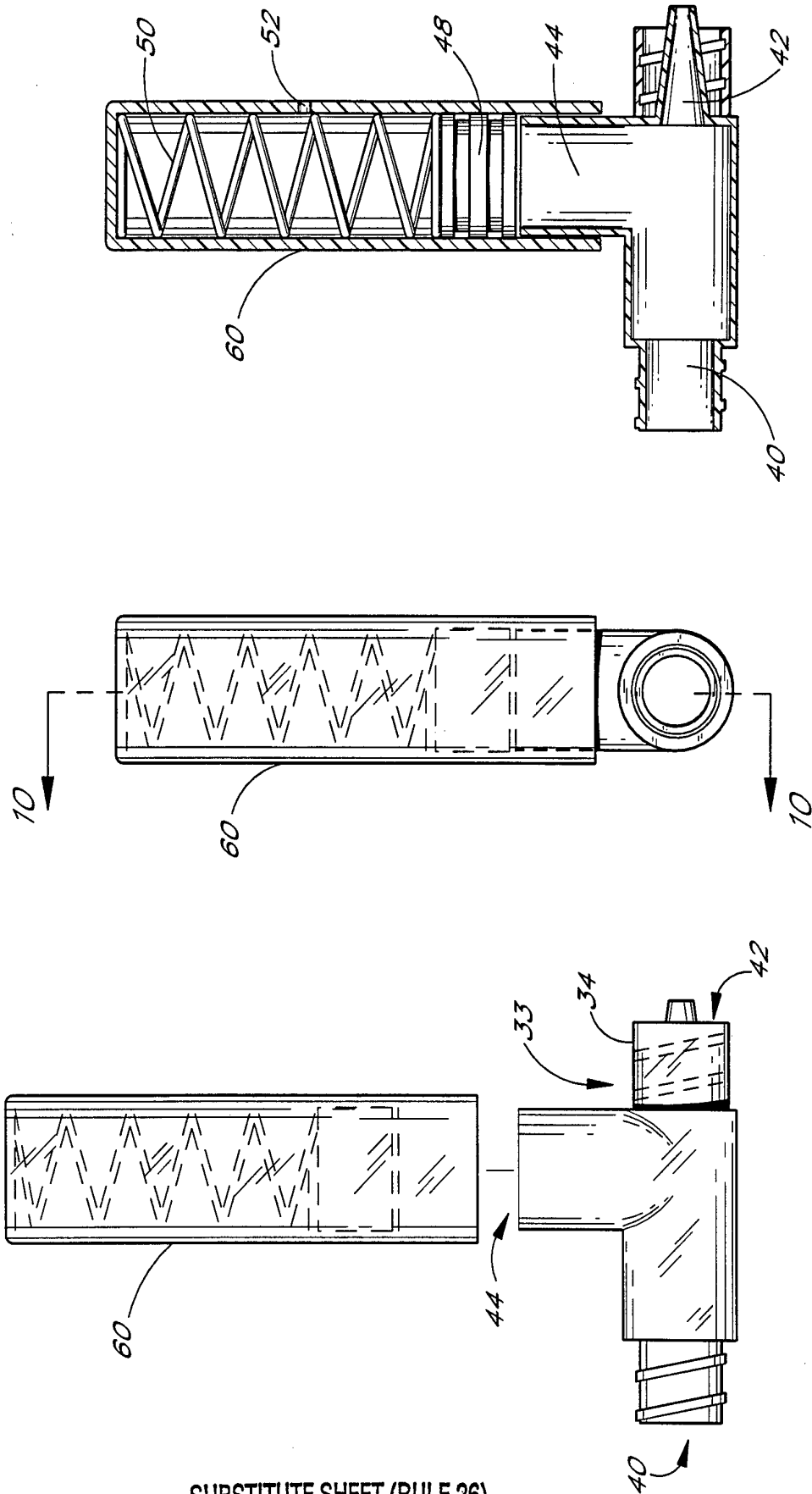


FIG. 10

FIG. 9

FIG. 8

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US95/07920

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61M 29/00

US CL :604/99

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)

U.S. : 137/853, 857; 251/185, 321, 336, 337; 604/97-100, 118, 121, 122, 124, 125

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
NONEElectronic data base consulted during the international search (name of data base and, where practicable, search terms used)
NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US, A, 4,403,988 (BINARD ET AL.) 13 September 1983. Note Fig. 9.	1, 2, 4 ----- 5
X --- Y	US, A, 4,801,293 (JACKSON) 31 January 1989. Note Fig. 2.	1-3 ----- 5



Further documents are listed in the continuation of Box C.



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