

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁵ : A61M 25/01	A1	(11) International Publication Number: WO 92/04932 (43) International Publication Date: 2 April 1992 (02.04.92)
<p>(21) International Application Number: PCT/US91/06517</p> <p>(22) International Filing Date: 9 September 1991 (09.09.91)</p> <p>(30) Priority data: 586,626 21 September 1990 (21.09.90) US</p> <p>(71) Applicant: BAXTER INTERNATIONAL INC. [US/US]; One Baxter Parkway, Deerfield, IL 60015 (US).</p> <p>(72) Inventors: WOODGRIFT, Randal, W. ; 9 Precipice, Laguna Niguel, CA 92677 (US). WELSH, Gregory, P. ; 207 40th Street, Newport Beach, CA 92663 (US).</p> <p>(74) Agents: CANTER, Bruce, M. et al.; 2132 Michelson Drive, Irvine, CA 92715 (US).</p>		<p>(81) Designated States: AT (European patent), BE (European patent), CA, CH (European patent), DE (European patent), DK (European patent), ES (European patent), FR (European patent), GB (European patent), GR (European patent), IT (European patent), JP, LU (European patent), NL (European patent), SE (European patent).</p> <p>Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i></p>
<p>(54) Title: ADJUSTABLE CATHETER CONTAMINATION SHIELD</p>		
<p>(57) Abstract</p> <p>An adjustable contamination shield (10) includes a distal fitting (12), a proximal fitting (14) and a collapsible shield (16), disposed between said distal (12) and proximal (14) fittings for enclosing an adjustable space therebetween and for preventing contact with a portion (20) of the catheter (22) disposed between the distal (12) and proximal (14) fittings. The shield (16) is supported in a collapsed configuration and controlled expansion thereof is provided when the distal (12) and proximal (14) fittings are moved apart from observation through an expanded portion of the collapsible shield (16) when the distal (12) and proximal (14) fittings are moved apart from one another.</p>		

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	ES	Spain	MG	Madagascar
AU	Australia	FI	Finland	ML	Mali
BB	Barbados	FR	France	MN	Mongolia
BE	Belgium	GA	Gabon	MR	Mauritania
BF	Burkina Faso	GB	United Kingdom	MW	Malawi
BG	Bulgaria	GN	Guinea	NL	Netherlands
BJ	Benin	GR	Greece	NO	Norway
BR	Brazil	HU	Hungary	PL	Poland
CA	Canada	IT	Italy	RO	Romania
CF	Central African Republic	JP	Japan	SD	Sudan
CG	Congo	KP	Democratic People's Republic of Korea	SE	Sweden
CH	Switzerland			SN	Senegal
CI	Côte d'Ivoire	KR	Republic of Korea	SU ⁺	Soviet Union
CM	Cameroon	LI	Liechtenstein	TD	Chad
CS	Czechoslovakia	LK	Sri Lanka	TG	Togo
DE*	Germany	LU	Luxembourg	US	United States of America
DK	Denmark	MC	Monaco		

+ Any designation of "SU" has effect in the Russian Federation. It is not yet known whether any such designation has effect in other States of the former Soviet Union.

ADJUSTABLE CATHETER CONTAMINATION SHIELD

5 The present invention generally relates to apparatus for preventing the contamination of a catheter as it is inserted into and withdrawn from a body cavity or lumen. More particularly, the present invention is directed to apparatus including an expandable shield for providing a sterile environment for a catheter enclosed thereby. In
10 view of commonly accepted procedures for the utilization of catheters within a venous lumen, such as balloon-tipped catheters, which include the adjustment of catheter depth, or inserted length, it is most desirable to retain sterility of the exposed catheter portion exterior to the
15 body.

A number of prior art devices have addressed this problem and utilized a protective sheath such as a thin, plastic, flexible and collapsible tube, which is disposed
20 exterior to the catheter and supported between distal and proximal fittings.

In use, the catheter is inserted through the proximal and distal fittings and collapsed sheath before insertion
25 into a venous lumen or the like. The collapsed sheath may have a length of up to ten centimeters, in view of the fact that it is desirable for it to be expanded to lengths as long as one meter for providing a sterile environment for the catheter. To facilitate the insertion of the catheter
30 through the collapsed sheath, prior devices have provided a length of tube approximately equal to the length of collapsed sheath and disposed between the proximal end and distal fittings to provide a clear passage through the collapsed sheath and prevent puncture of the collapsed
35 sheath during insertion of the catheter therethrough. Once the distal and proximal fittings of the prior art device

are pulled apart, thus disconnecting the interconnecting tube, the collapsed shield prevents observation of the catheter disposed therein and consequently makes reinsertion of the catheter through the collapsed shield difficult, if not impossible, due to difficulty in alignment of the proximal and distal ends.

The present invention provides a means for accumulating the excess or unused length of shield as the shield is expanded during separation of the proximal and distal ends of the apparatus. This enables the alignment of the proximal and distal ends without separate interconnection thereof by a tube or the like. Further, the present invention enables tension to be applied to expanded portions of the shield, thus enabling visual observation therethrough of the catheter for enabling alignment of the distal and proximal fittings to facilitate a thread of the catheter through the shield.

SUMMARY OF THE INVENTION

An adjustable catheter contamination shield in accordance with the present invention generally includes a distal fitting having a bushing for coupling to introducer and means, defining a bore through the distal fitting, for enabling the passage of the catheter therethrough. A proximal fitting is provided which also includes means, defining a bore therethrough, for enabling passage of the catheter through the proximal fitting.

A collapsible shield is disposed between the distal and the proximal fittings which provides means for enclosing an adjustable space therebetween and preventing contact with a portion of the catheter disposed between the distal and the proximal fittings.

Means are provided for supporting the shield means and collapsed configuration and for causing the collapsed shield means to expand on a longitudinal axis thereof from a selected number of points along the collapsible configuration. Preferably, the collapsible shield expands from one end of the collapsed configuration when the distal and the proximal fittings are moved apart from one another.

More particularly, the means for supporting the shield means is disposed proximate the proximal fitting and interconnected therewith. The means for supporting the shield may comprise a flange having an outside diameter sufficient to prevent passage of the shield means thereover without movement of the distal and proximal fittings from one another.

Further, the shield means may be formed from a material enabling visual observation of the catheter through an expanded portion thereof when the expanded portion is in a state of tension. In conjunction therewith, the flange, as hereinabove recited, provides a means for causing the expanded portion of the shield to be in a state of tension which enables the visual observation of the catheter therethrough, when the distal and proximal fittings are moved apart from one another.

To prevent stress on the catheter passing through the proximal and distal fittings, each fitting may be provided with a flexible tube connected thereto for preventing forces being applied to the catheter during manipulation of the proximal and distal fittings during insertion of the catheter therethrough and during manipulation of the catheter as it is inserted and withdrawn from a venous lumen.

BRIEF DESCRIPTION OF THE DRAWINGS

A better understanding of the present invention may be had by consideration of the following detailed description, taken in conjunction with the accompanying drawings, in which:

Figure 1 is a side view of an adjustable catheter contamination shield in accordance with the present invention depicting its use with an introducer for introducing a catheter into a heart;

Figure 2 is an exploded pictorial representation of the contamination shield shown in Figure 1;

Figure 3 is a side view of the shield of the present invention, shown in fully collapsed condition;

Figure 4 is a side view of the shield shown in Figure 3 with the catheter inserted therethrough;

Figure 5 is a side view of the shield shown in Figure 3 with a portion of the shield shown in an extended state with the catheter visible therethrough;

Figure 6 is a side view of the shield shown in Figure 3 in a totally expanded condition.

Figure 7 is a cross-sectional view of the catheter shown in Figure 3.

Figure 8 is a partial cross-section of the proximal end of the shield shown in Figure 3 before a cap is inserted thereover to affix the expandable shield thereto;

Figure 9 is a cross-sectional view of a portion of the proximal fitting showing a cap placed for securing the expandable shield thereto; and

5 Figure 10 is an enlarged view of an alternative embodiment of a distal fitting in accordance with the present invention.

DETAILED DESCRIPTION OF THE DRAWINGS

10

Turning now to Figure 1, there is shown an adjustable catheter contamination shield 10 in accordance with the present invention generally including a distal fitting 12, a proximal fitting 14, and a collapsible shield 16, 15 disposed between the distal and proximal fittings 14, 12 which provides means for enclosing an adjustable space 18 therebetween and for preventing contact with a portion 20 of a catheter 22 disposed between the distal and proximal fittings 12, 14. As diagrammatically shown in Figure 1, 20 the catheter contamination shield is positioned for the insertion of the catheter 22 into a heart 28 through an internal jugular vein 30 by means of an introducer 32 which includes an introducer sheath 34 and a fitting 36, the 25 introducer 32, including the sheath 34 and fitting 36 being of conventional design. As shown, the catheter 22 may include a balloon portion 40 disposed proximate a tip 42 commonly used and well-known in the art.

30 Figure 2 is an exploded perspective view of the catheter contamination shield 10 showing in greater detail the distal fitting 12 and the proximal fitting 14. A flange 46 formed as an integral portion of a tube 48 provides a means for supporting the shield 16 in the collapsed configuration and, in addition, causing the collapsed shield to expand

along a longitudinal axis 52 as shown in Figures 3, 4, 5 and 6 and hereinafter described in greater detail.

5 It should be appreciated that, while the flange 46 and tube 48 are shown proximate and connected to the proximal fitting 14, alternatively the flange 46 with tube 48 may be interconnected with the distal fitting 12, such alternative arrangement not being shown in the drawings. The tube 48, which may be formed from any suitable flexible material and may include a ribbed portion 54 proximate the flange 46, not only provides a passage through the collapsed shield 16 but also importantly provides a means for reducing stress on the catheter passing therethrough which may occur through manual manipulation of the catheter contamination shield 10 and catheter 22 as the latter is advanced through a venous lumen such as the jugular vein 30 as shown in Figure 1.

20 A groove 58 disposed in the flexible tube 48 along with an O-ring 60 and a cap 62 provides means for fixing the collapsible shield 16 to the proximal fitting 14 as more clearly shown in cross-section in Figure 7.

25 Coupled to the cap 62 is a threaded fitting 64 enclosing an end bushing 66, having an orifice 68 therethrough sized for fitting into the catheter 22 and held in position by a threaded cap 70 adapted for threaded engagement with the fitting 64 with the bushing 66 there enclosed, as shown in Figure 7.

30 As best shown in Figure 8, the flange 46 has an outside diameter D which is sufficient to prevent the passage of the shield 16 therepast without movement of the distal and proximal fittings 12, 14 from one another. Depending upon the material of construction of the shield 16, this

35

function of the flange 46 in both enabling selected expansion of the shield therepast and for supporting the shield in a collapsed configuration may be obtained when the flange diameter D is greater than the inside diameter of the shield 16. It should be appreciated that while the flange is shown disposed at an end 74, it may be disposed at any intermediate position or a number of flanges, not shown, may be disposed along the tube 48 for controlling the expansion of the shield 16 therepast. The tube 48 provides a clear passage through the collapsed shield 16 and additionally when the shield 16 is collapsed over the tube 48, the flange 46 is coaxially aligned with a flexible distal tube 76 thereby facilitating passage of the catheter 22 therethrough.

The shield 16 may be formed of a polyethylene type material or any other material facilitating the accordion-like collapse thereof over the tube 48 and also, importantly, enabling the visual observation of the catheter 22 through an expanded portion 80 thereof as shown in Figure 5.

The flange 46 hereinabove described in conjunction with providing a means for maintaining the shield in a selected, collapsed configuration also performs the function of providing tension in the expanded portion 80 between the flange 46 and the distal fitting 12 to enable visual observation of the catheter 22 disposed therein. This state of tension is sufficient to remove a pleating 84 of the shield 16 sufficient to enable the hereinabove visual observation. This feature is important in that once the distal and proximal fittings 12, 14 are moved to a spaced apart relationship, the catheter 22 can still be "threaded" or passed from the proximal fitting 14 through the distal fitting 12 by visual alignment thereof through the taut

portion 80 of the shield 16. Hence, the structure of the present invention enables the function of threading the catheter 22 through spaced apart proximal and distal fittings 12, 14 which results in a shield providing far greater capability with regard to movement and withdrawal of a catheter than was heretofore possible.

As shown in Figures 1 and 2, the distal tube 76, which may be formed of a flexible material similar to that utilized in the tube 48 may include a ribbed portion 86 which provides a means for preventing stress on the catheter 22 during manipulation thereof as hereinabove discussed in connection with the distal tube 48 and the ribbed portion thereof 54. The threaded fitting 64 and the distal tube 76 include bores 90, 92 for enabling passage of the catheter 22 therethrough. In addition, the distal fitting 12 includes a bushing 96 sized for passing over the tube 76 and sealably engaging a flange 98 disposed on the tube 76 to the introducer 32 by way of the introducer fitting 36. The bushing 96 may include a slot 100 and detent 102 for engaging a prong 104 on the introducer fitting 36 in a conventional manner. Alternatively, as shown in Figure 10, an alternative bushing 108 may include a bayonet-type slot 110 with detent 112 for engaging the prong 104 in a conventional manner.

A distal end 116 of the shield 16 may be fixed to the distal fitting 12, for a compressed fit between the flange 98 and the bushing 96, as shown in Figure 7.

A procedure in accordance with the present invention, and utilizing the structure thereof, provides a sterile environment exterior to a body, such as a heart 28, for the catheter 22 which includes steps of coupling the distal fitting 12 of the contamination shield 10 to an introducer

32, the introducer being adapted for insertion into a venous lumen such as the jugular vein 30 as hereinbefore described.

5 Thereafter, the procedure in accordance with the present invention includes passing catheter 22 through the proximal fitting 14 and into the sterile area 18 enclosed by the expandable shield 16 disposed between the distal and proximal fittings 12 and 14.

10

 Thereafter, the shield 16 is expanded from the flange 46 to enable visual observation of the catheter portion 20 passing between the distal and proximal fittings 12, 14.

15 Although there has been hereinabove described specific arrangements of a catheter contamination shield and procedure in accordance with the present invention for the purpose of illustrating the manner in which the invention can be used to advantage, it will be appreciated that the invention is not limited thereto. Accordingly, any and all
20 modifications, variations, or equivalent arrangements, which occur to those skilled in the art, should be considered to be within the scope of the invention as defined in the appended claims.

25

WHAT IS CLAIMED IS:

1. An adjustable catheter contamination shield comprising:
- 5 a distal fitting including bushing means for coupling to an introducer and means, defining a bore through the distal fitting, for enabling passage of a catheter therethrough;
- a proximal fitting including means, defining a bore therethrough, for enabling passage of the catheter through
- 10 the proximal fitting;
- collapsible shield means, disposed between said distal and proximal fittings, for enclosing an adjustable space therebetween and for preventing contact with a portion of the catheter disposed between the distal and proximal
- 15 fittings; and
- means for supporting the shield means in a collapsed configuration and for causing the collapsed shield means to expand along a longitudinal axis thereof from one end of the collapsed configuration when the distal and proximal
- 20 fittings are moved apart from one another.
2. The adjustable catheter contamination shield according to claim 1 wherein said means for supporting the shield means is disposed proximate said proximal fitting.
- 25
3. The adjustable catheter contamination shield according to claim 2 when said means for supporting the shield means is interconnected with said proximal fitting.
- 30
4. The adjustable catheter contamination shield according to claim 3 wherein said means for supporting the shield means is disposed within said shield means.
- 35
5. The adjustable catheter contamination shield according to claim 4 wherein said means for supporting the

shield means comprises a flange having an outside diameter sufficient to prevent passage of the shield means thereover without movement of the distal and proximal fittings from one another.

5

6. The adjustable catheter contamination shield according to claim 5 wherein the means for supporting the shield means further comprises a flexible tube means, disposed between said flange and proximal fitting and coaxially aligned therewith, for providing a clear passage through the collapsed shield means and for reducing stress on a catheter passing therethrough.

10

7. The adjustable catheter contamination shield according to claim 6 wherein said distal fitting includes flexible tube means coaxially aligned therewith for reducing stress on a catheter passing therethrough.

15

8. An adjustable catheter contamination shield comprising:

20

a distal fitting including bushing means for coupling to an introducer and means, defining a bore through the distal fitting, enabling passage of a catheter therethrough;

a proximal fitting including means, defining a bore therethrough, for enabling passage of the catheter through the proximal fitting;

25

collapsible shield means, disposed between said distal and proximal fittings, for enclosing an adjustable space therebetween and for preventing contact with a portion of the catheter disposed between the distal and proximal fittings, the shield means being formed of a material enabling visual observation of the catheter through an expanded portion of the shield means, when the catheter is disposed between the distal and proximal fittings; and

30

means for supporting the shield means in a collapsed configuration and for producing the expended portion, through which the catheter is observed, while maintaining a remainder of the shield means in the collapsed configuration, as the distal and proximal fittings are moved apart from one another.

9. The adjustable catheter contamination shield according to claim 8 wherein said means for supporting the shield means is disposed proximate said proximal fitting.

10. The adjustable catheter contamination shield according to claim 9 when said means for supporting the shield means is interconnected with said proximal fitting.

11. The adjustable catheter contamination shield according to claim 10 wherein said means for supporting the shield means is disposed within said shield means.

12. The adjustable catheter contamination shield according to claim 11 wherein said means for supporting the shield means comprises a flange having an outside diameter sufficient to prevent passage of the shield means thereover without movement of the distal and proximal fittings from one another.

13. The adjustable catheter contamination shield according to claim 12 wherein the means for supporting the shield means further comprises a flexible tube means, disposed between said flange and proximal fitting and coaxially aligned therewith, for providing a clear passage through the collapsed shield means and for reducing stress on a catheter passing therethrough.

14. The adjustable catheter contamination shield according to claim 13 wherein said distal fitting includes flexible tube means coaxially aligned therewith for reducing stress on a catheter passing therethrough.

5

15. An adjustable catheter contamination shield comprising:

10 a distal fitting including bushing means for coupling to an introducer and means, defining a bore through the distal fitting, for enabling passage of a catheter therethrough;

a proximal fitting including means, defining a bore therethrough, for enabling passage of the catheter through the proximal fitting;

15 collapsible shield means, disposed between said distal and proximal fittings, for enclosing an adjustable space therebetween and for preventing contact with a portion of the catheters disposed between the distal and proximal fittings; and

20 means for supporting the shield means in a collapsed configuration and for causing the collapsed shield means to expand from a selected number of points along the collapsed configuration.

25 16. The adjustable catheter contamination shield according to claim 15 wherein said selected number of points along the collapsed configuration is one.

30 17. The adjustable catheter contamination shield according to claim 16 wherein the one selected point is disposed at an end of the collapsed configuration.

18. The adjustable catheter contamination shield according to claim 15 wherein said means for supporting the shield means is disposed proximate said proximal fitting.

35

19. The adjustable catheter contamination shield according to claim 18 when said means for supporting the shield means is interconnected with said proximal fitting.

5 20. The adjustable catheter contamination shield according to claim 19 wherein said means for supporting the shield means is disposed within said shield means.

10 21. The adjustable catheter contamination shield according to claim 20 wherein said means for supporting the shield means comprises a flange having an outside diameter sufficient to prevent passage of the shield means thereover without movement of the distal and proximal fittings from one another.

15 22. The adjustable catheter contamination shield according to claim 21 wherein the means for supporting the shield means further comprises a flexible tube means, disposed between said flange and proximal fitting and
20 coaxially aligned therewith, for providing a clear passage through the collapsed shield means and for reducing stress on a catheter passing therethrough.

25 23. The adjustable catheter contamination shield according to claim 22 wherein said distal fitting includes flexible tube means coaxially aligned therewith for reducing stress on a catheter passing therethrough.

30 24. An adjustable catheter contamination shield comprising:

a distal fitting including bushing means for coupling with an introducer and means, defining a bore through the distal fitting, for enabling passage of a catheter therethrough;

a proximal fitting including means, defining a bore therethrough, for enabling passage of the catheter through the proximal fitting;

5 collapsible shield means, disposed between said distal and proximal fittings, for enclosing an adjustable space therebetween and for preventing contact with a portion of the catheter disposed between the distal and proximal fittings, the shield means being formed of a material enabling visual observation of the catheter through an
10 expanded portion thereof when the catheter is disposed between the distal and proximal fittings and the expanded portion is in a state of tension;

means, connected with one of said distal and proximal fittings, for supporting the shield means in a collapsed
15 configuration with said distal and proximal fittings adjacent to one another for enabling the catheter to be threaded through the bores of the distal and proximal fittings, for causing the collapsed shield means to expand along a longitudinal area thereof from one end of the
20 collapsed configuration, when the distal and proximal fittings are moved apart from one another, and for causing the expanded portion of the shield to be in the state of tension enabling visual observation of the catheter therethrough.

25

25. The adjustable catheter contamination shield according to claim 24 wherein said means for supporting the shield means is disposed proximate said proximal fitting.

30

26. The adjustable catheter contamination shield according to claim 25 when said means for supporting the shield means is interconnected with said proximal fitting.

27. The adjustable catheter contamination shield according to claim 26 wherein said means for supporting the shield means is disposed within said shield means.

5 28. The adjustable catheter contamination shield according to claim 27 wherein said means for supporting the shield means comprises a flange having an outside diameter sufficient to prevent passage of the shield means thereover without movement of the distal and proximal fittings from
10 one another.

29. The adjustable catheter contamination shield according to claim 28 wherein the means for supporting the shield means further comprises a flexible tube means,
15 disposed between said flange and proximal fitting and coaxially aligned therewith, for providing a clear passage through the collapsed shield means and for reducing stress on a catheter passing therethrough.

20 30. The adjustable catheter contamination shield according to claim 29 wherein said distal fitting includes flexible tube means coaxially aligned therewith for reducing stress on a catheter passing therethrough.

25 31. An adjustable catheter contamination shield comprising:

 a distal fitting including bushing means for coupling to an introducer and first flexible tube means, coaxially aligned with said distal filter, for enabling passage of a
30 catheter therethrough and preventing stress to said catheter;

 a proximal fitting including second flexible tube means, coaxially aligned with said proximal fitting, for enabling passage of a catheter therethrough and preventing stress to
35 said catheter;

collapsible shield means, disposed between said distal and proximal fittings, for enclosing an adjustable space therebetween and for preventing contact with a portion of the catheter disposed between the distal and proximal fittings, said collapsible shield means being disposed over said first and second flexible tube means.

32. The adjustable catheter contamination shield according to claim 31 wherein the second flexible tube means includes means for supporting the shield means in a collapsed configuration and for causing the collapsed shield means to expand along a longitudinal axis thereof from one end of the collapsed configuration when the distal and proximal fittings are moved apart from one another.

33. The adjustable catheter contamination shield according to claim 32 wherein said means for supporting the shield means is disposed proximate said proximal fitting.

34. The adjustable catheter contamination shield according to claim 33 when said means for supporting the shield means is interconnected with said proximal fitting.

35. The adjustable catheter contamination shield according to claim 34 wherein said means for supporting the shield means is disposed within said shield means.

36. The adjustable catheter contamination shield according to claim 35 wherein said means for supporting the shield means comprises a flange having an outside diameter sufficient to prevent passage of the shield means thereover without movement of the distal and proximal fittings from one another.

37. The adjustable catheter contamination shield according to claim 36 wherein the means for supporting the shield means further comprises a flexible tube means, disposed between said flange and proximal fitting and coaxially aligned therewith, for providing a clear passage through the collapsed shield means and for reducing stress on a catheter passing therethrough.

38. The adjustable catheter contamination shield according to claim 37 wherein said distal fitting includes flexible tube means coaxially aligned therewith for reducing stress on a catheter passing therethrough.

39. A procedure for providing a sterile environment exterior to a body for a catheter comprising the steps of:

- coupling a distal fitting of a contamination shield to an introducer, the introducer being adapted for insertion into a venous lumen;
- passing the catheter through a proximal fitting and into a sterile area enclosed by an expandable shield disposed between said distal and proximal fittings;
- expanding the shield from one end of a collapsed configuration thereof to enable visual observation of a catheter portion passing between the distal and proximal fittings.

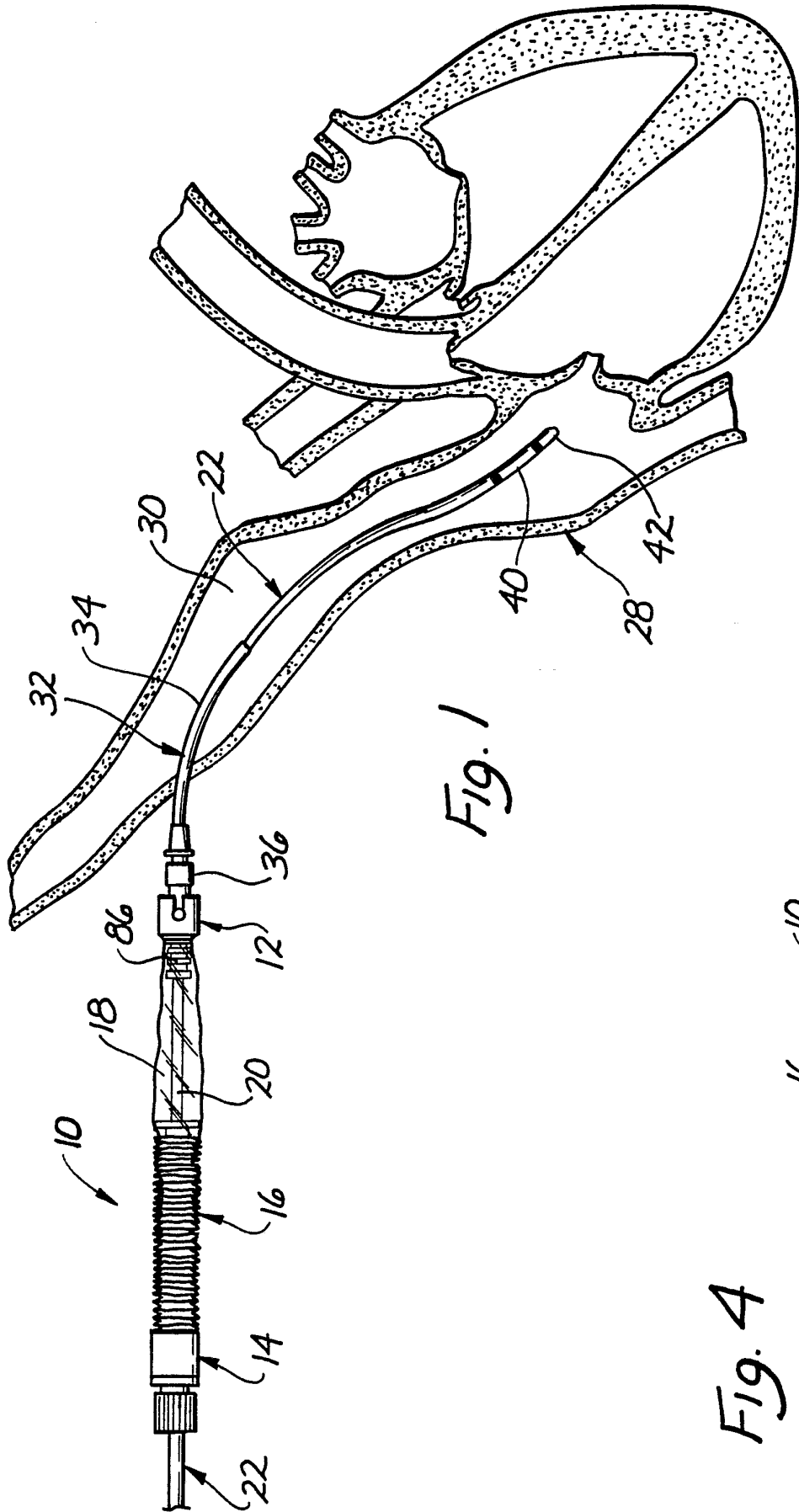
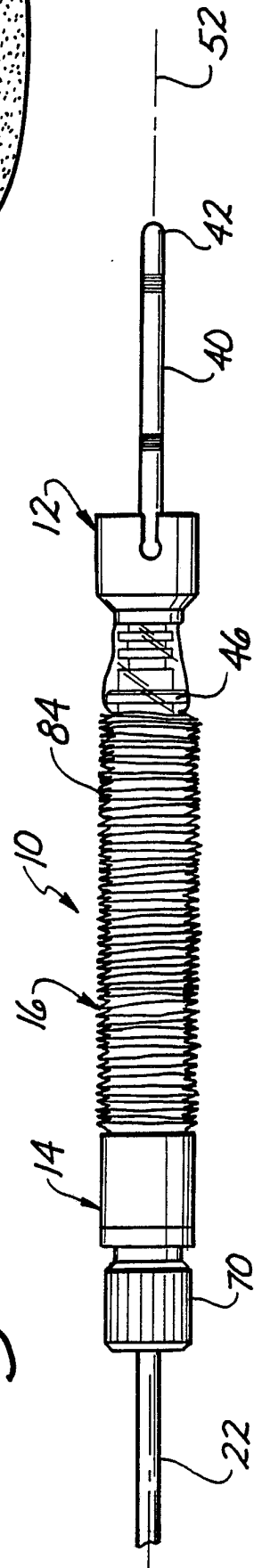


FIG. 1

FIG. 4



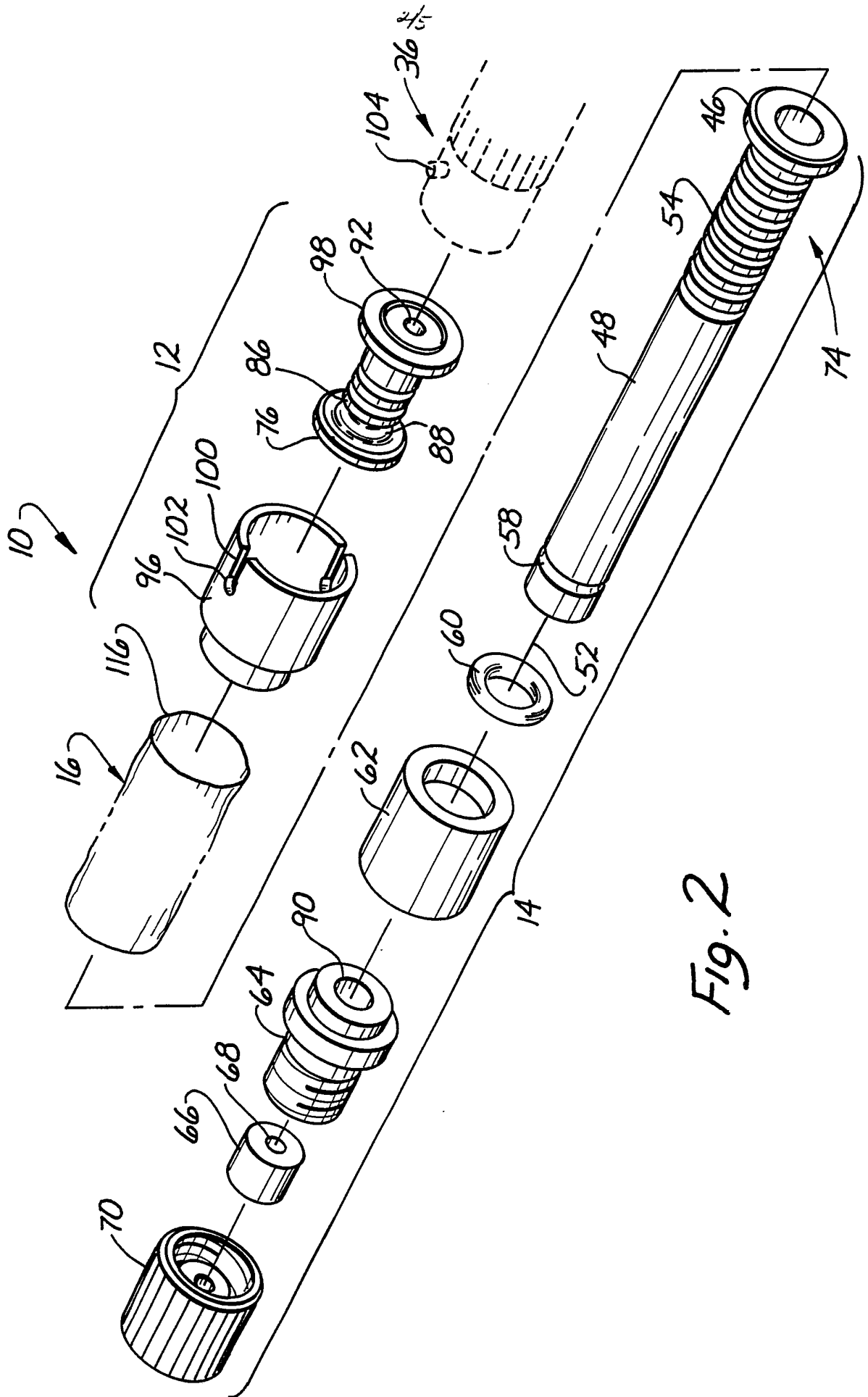


FIG. 2

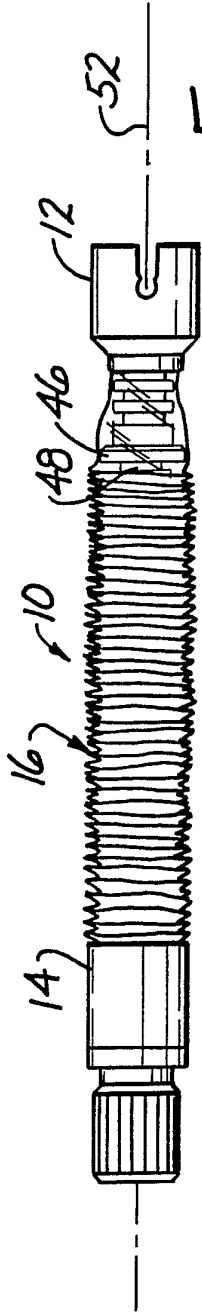


Fig. 3

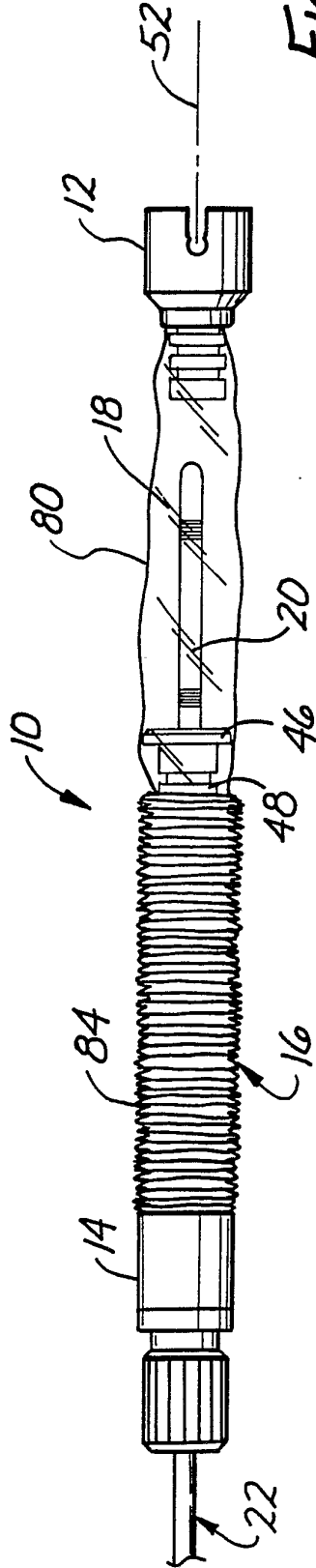


Fig. 5

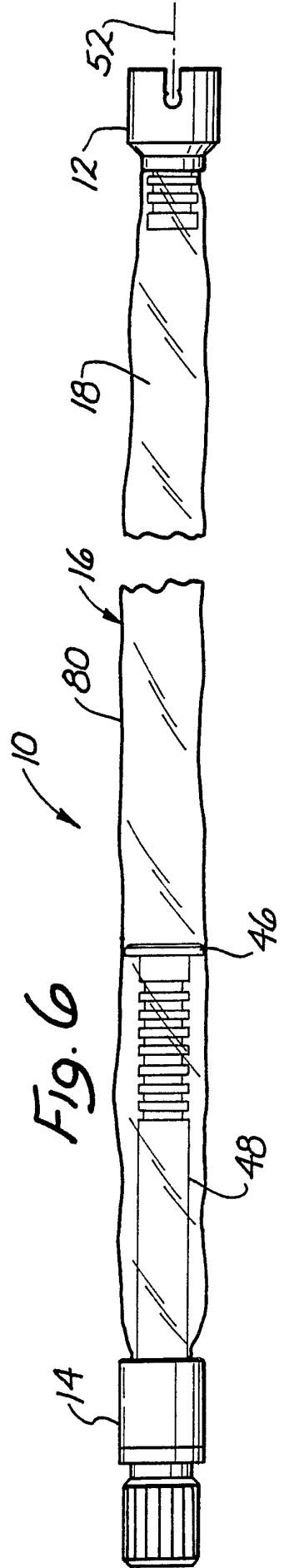


Fig. 6

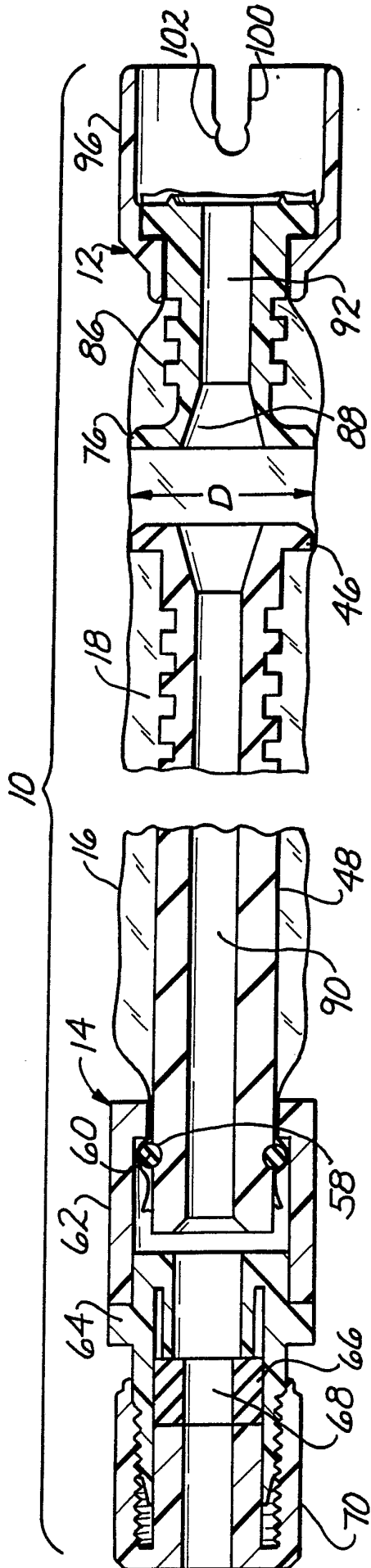


Fig. 7

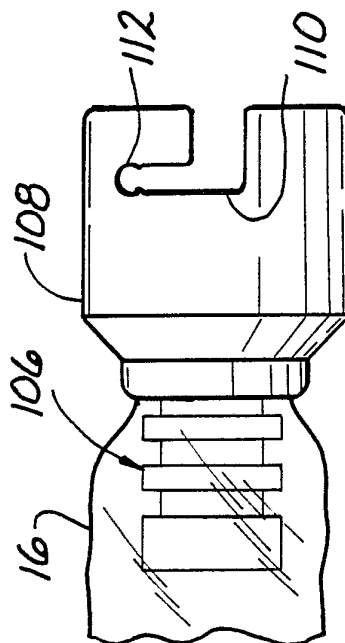


Fig. 8

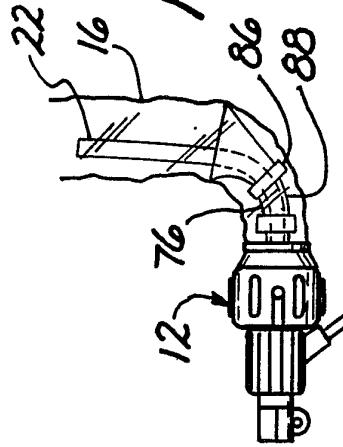


Fig. 9

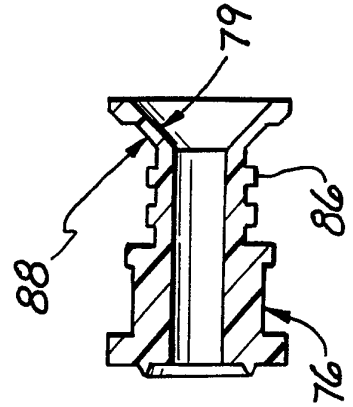
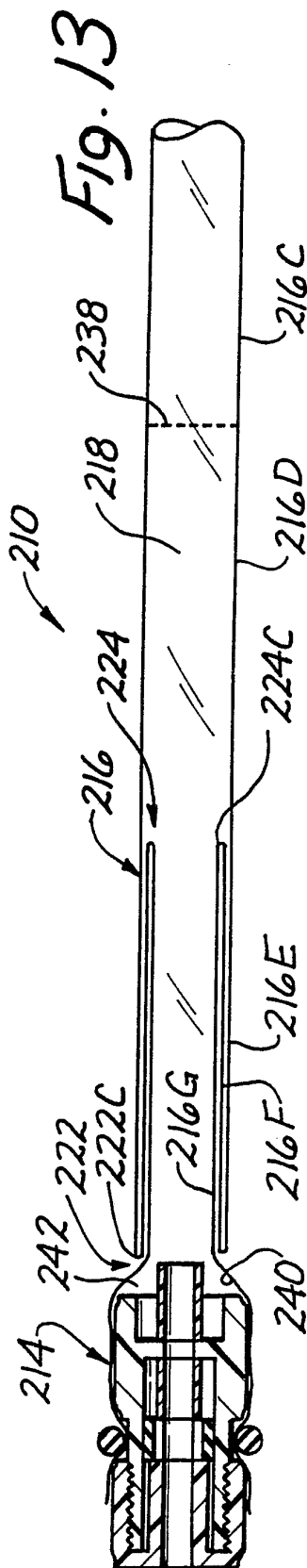
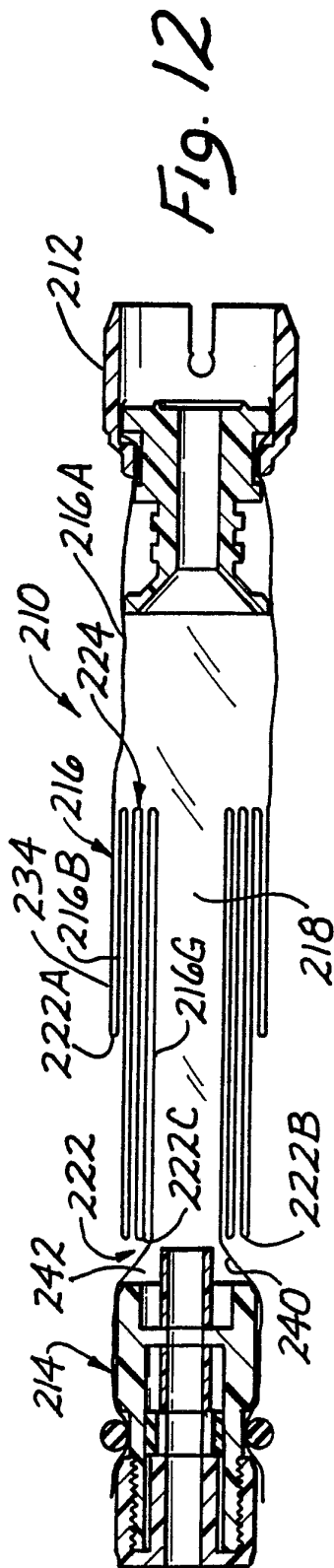
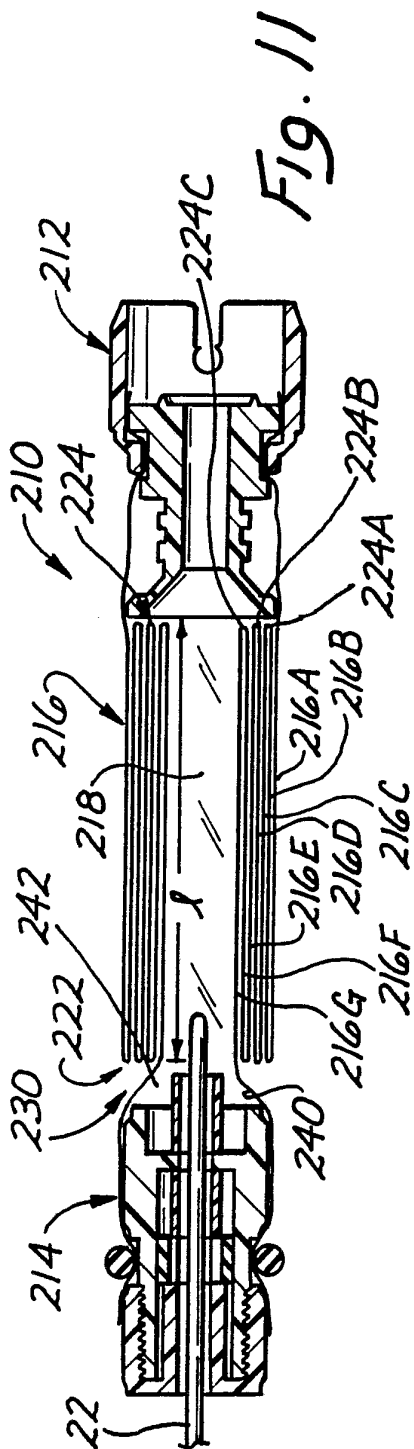


Fig. 10

45



INTERNATIONAL SEARCH REPORT

PCT/US 91/06517

International Application No

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) ⁶				
According to International Patent Classification (IPC) or to both National Classification and IPC Int.Cl. 5 A61M25/01				
II. FIELDS SEARCHED				
Minimum Documentation Searched ⁷				
Classification System	Classification Symbols			
Int.Cl. 5	A61M			
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched ⁸				
III. DOCUMENTS CONSIDERED TO BE RELEVANT⁹				
Category ^o	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³		
X	EP,A,0 311 427 (ARROW INTERNATIONAL INVESTMENT CORP.) 12 April 1989 see column 4, line 10 - column 5, line 13; figures ---	1,8, 15-17, 24,39		
A	US,A,4 767 409 (BROOKS) 30 August 1988 see claims; figures ---	1-3, 8-10, 15-19, 24-26		
A	US,A,4 327 723 (FRANKHOUSER) 4 May 1982 see column 3, line 27 - line 68; figures --- -/--	1-3, 8-10, 15-19, 24-26		
<table style="width: 100%; border: none;"> <tr> <td style="width: 50%; border: none; vertical-align: top;"> ^o Special categories of cited documents :¹⁰ "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed </td> <td style="width: 50%; border: none; vertical-align: top;"> "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art. "&" document member of the same patent family </td> </tr> </table>			^o Special categories of cited documents : ¹⁰ "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art. "&" document member of the same patent family
^o Special categories of cited documents : ¹⁰ "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art. "&" document member of the same patent family			
IV. CERTIFICATION				
Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report			
14 JANUARY 1992	23. 01. 92			
International Searching Authority	Signature of Authorized Officer			
EUROPEAN PATENT OFFICE	MIR Y GUILLEN V.			

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)		
Category °	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No.
A	FR,A,2 120 413 (DURAND) 18 August 1972 see claims; figures ---	1, 4, 6-8, 15-17, 24

**ANNEX TO THE INTERNATIONAL SEARCH REPORT
ON INTERNATIONAL PATENT APPLICATION NO. US 9106517
SA 52083**

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information. 14/01/92

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP-A-0311427	12-04-89	US-A- 4834710 DE-A- 3865164 JP-A- 1141673	30-05-89 31-10-91 02-06-89
US-A-4767409	30-08-88	None	
US-A-4327723	04-05-82	US-A- 4515592	07-05-85
FR-A-2120413	18-08-72	None	