(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
27 December 2001 (27.12.2001)

PCT

(10) International Publication Number
WO 01/97740 A2

(51) International Patent Classification[7]: A61F 200/

(21) International Application Number: PCT/NL01/00454

(22) International Filing Date: 18 June 2001 (18.06.2001)

(25) Filing Language: Dutch

(26) Publication Language: English

(30) Priority Data:

1015504	22 June 2000 (22.06.2000)	NL
1016706	24 November 2000 (24.11.2000)	NL
1016743	29 November 2000 (29.11.2000)	NL

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(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:
— *without international search report and to be republished upon receipt of that report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

WO 01/97740 A2

(54) Title: DEVICE AND METHOD FOR FILLING A BODY CAVITY

(57) Abstract: The present invention relates to a device for filling a body cavity, such as a blood vessel or an abnormal part of a blood vessel, bladder or bowel, comprising: - an elongate sheath; - a balloon member mountable distally on the sheath, -dilating means for bringing the balloon member from a starting position into a dilated position.

DEVICE AND METHOD FOR FILLING A BODY CAVITY

The present invention relates to a device for filling a body cavity, such as a blood vessel or an abnormal part of a blood vessel, bladder or bowel, and to a sheath member for introducing intervention means into the body cavity.

With the device according to the invention a (part of a) body cavity is filled, such as a blood vessel or an abnormal part of a blood vessel, bladder or bowel, such as for instance an abnormally dilated blood vessel (or aneurysm) or vessel connection (such as an arteriovenous malformation). Placing of the device according to the invention results in decrease or disappearance of undesired abnormal blood flow and therefore in an improvement in the haemodynamics. The placing can also ensure that determined abnormal (weak) blood vessel parts are no longer exposed to blood pressure, whereby the chance of rupture at that position decreases or disappears or leakage from a rupture is temporarily reduced. The device can also be used to fill abnormal bulges (diverticula) of other hollow organs, such as bladder or bowel, or postoperative cavities. It may be possible hereby to prevent the presence of residue causing recurring inflammations.

According to a first aspect of the invention a device for filling a body cavity is provided, which device comprises:

- an elongate sheath;
- a balloon member mountable distally on the sheath,
- dilating means for bringing the balloon member from a starting position into a dilated position. Coupled to the sheath, the balloon member is pushed into the body and subsequently dilated so that the balloon member wholly or partially fills the body cavity.

When the body cavity for filling is a blood vessel, the device is suitable for stemming loss of blood from the cardiovascular system to for instance the abdominal

or thoracic region when the blood vessel no longer functions properly, for instance as a result of a rupture of the aorta as a consequence of an aortic aneurysm.

In a first preferred embodiment of the invention the device comprises disconnecting means for disconnecting the sheath and the balloon member in the dilated position. The sheath can hereby be disconnected from the balloon member and wholly or partially removed from the body.

According to a second preferred embodiment the dilating means comprise a feed lumen provided in the sheath for feeding a fluid from the proximal end of the sheath into the balloon member and closing means are arranged on the balloon member for closing the balloon member when the balloon member is disconnected. The balloon member is dilated by carrying fluid therein. When the sheath is disconnected the closing means, preferably in the form of a valve mechanism, ensure that the fluid remains contained in the balloon member.

According to a third preferred embodiment the dilating means comprise moisture-absorbing material (preferably hypophilic, lipophilic and/or hygroscopic material) arranged in the balloon member and the balloon member wall is at least partially moisture-permeable, preferably in that it is manufactured at least partially from permeable material. The balloon member expands by absorbing bodily fluid and thereby acquires the above stated dilated position.

According to a fourth preferred embodiment the dilating means comprise an optionally self-expanding stent arranged on the balloon member. In a particular embodiment the stent is expanded by filling the balloon with liquid or gas. In another embodiment (for instance in the "Wall stent" from the company Boston Scientific) the stent-balloon combination is folded loosely between enclosing membranes (the so-called known rolling membrane principle) and the stent-balloon combination can be expanded (dilated) by retracting the membranes (or by

applying a similar expanding mechanism). Through use of a stent a more stable situation can be effected which also persists in the case of possible leakage of the balloon.

In the third or fourth preferred embodiment no additional lumen is necessary for administering balloon-filling material. As already stated above, one or more additional lumina are however possible if desired.

It is noted that the invention also relates to a combination of one or more of the above stated preferred embodiments. In a combination of the second and third embodiment the balloon is for instance first dilated by feeding fluid; after disconnection of the sheath additional dilation then occurs through the absorption of moisture (supplied via the body or the lumen). The combination of the second embodiment with the third and/or fourth embodiment in the case of a self-expanding stent has the advantage that in the case of further progressive dilation of the relevant body cavity, such as blood vessel, bowel etc., the relevant balloon respectively balloon-stent combination dilates further and thereby adapts itself to said progressive dilation of the body cavity.

According to a further preferred embodiment the sheath extends through the balloon member and the sheath comprises a guide wire lumen extending distally beyond the balloon member for the purpose of guiding guide means, such as a guide wire, inserted from the proximal end of the lumen. In this embodiment the device can be readily guided through the body over a guide wire already arranged in the body. If for instance the balloon member is to be dilated by feeding a fluid therein, the balloon member comprises proximally disposed first closing means and distally disposed second closing means for closing the balloon member when the balloon member is disconnected. In this latter embodiment the device can be arranged over the guide wire and fluid can be fed (simultaneously) into the balloon member. This means that the balloon member can be carried more quickly to the

place of destination in the body without the use of a prearranged wide surrounding guide catheter. The application of less wide catheters is furthermore less traumatic.

According to a further preferred embodiment the guide wire lumen extends over a distance of between 2 and 15 mm relative to the balloon member. A slight protruding of the guide wire lumen (and thereby of the catheter part) means that in the non-inflated situation the end of the catheter can be slightly tapering, which makes introduction of the catheter less traumatic. If the catheter part protrudes too much relative to the balloon member, the catheter becomes more difficult to handle.

In the above stated embodiments a stent is preferably arranged on the balloon member so as to increase the pressure to be exerted on the body cavity in the dilated position. The position will hereby also remain more stable over the years than without this reinforcement or strengthening.

According to another preferred embodiment the balloon member (and thereby also the balloon member-stent combination) is dilatable such that in the dilated position the shape thereof has substantially adapted itself to the shape of the body cavity to be filled. In this embodiment the device can be applied as graft after resectional surgery of for instance tumours so as to fill the created cavities, so that there is less cosmetic deformation after occlusion of upper-lying layers. According to this embodiment an asymmetric filling of the cavities is also possible.

According to another aspect of the present invention there is provided a sheath member for arranging intervention means in a body cavity, preferably in the embodiment of said sheath for arranging an optionally disconnectable balloon member, wherein a guide wire lumen is provided in the sheath member for guiding a guide wire therein, as well as an additional lumen provided with one or more outlet openings for feeding contrast agent along

the outlet openings into the body cavity. Instead of an additional lumen, the guide wire lumen and the additional lumen can be combined in another preferred embodiment, and the combined lumen is provided with a narrowed portion, at the location of which one or more outlet openings are arranged in the sheath wall for supplying contrast agent into the body cavity through the combined lumen over the guide wire via the outlet openings. Owing to this for the greater part wider lumen with opening(s) at the position of the tapering (or the part which tapers) a guide wire can be present and administering of liquid contrast agent can take place simultaneously (so-called over-the-wire contrast administering). The position of an optionally expanded balloon or stent-graft balloon can thereby be monitored without loss of time caused by the guide wire being withdrawn. It may however be necessary for this purpose for either regular or continuous flushing of the lumen to take place in order to prevent thrombosis (for instance by making use of existing pressure bag* systems). Owing to the tapering lumen a reasonably firm or sturdy guide wire can be used without the diameter of the intervention means acquiring a greater size than is strictly necessary.

The narrowed portion is situated just proximally of intervention means, preferably the disconnectable balloon member, mountable on the sheath member. The principle of a wide lumen with tapering portion and an opening therein which is suitable for administering contrast simultaneously with the presence of a guide wire proximally of the sheath end or of a preformed sheath part is appropriate for all types of sheath (catheters), i.e. both non-selective catheters (for instance for application in the aorta) and selective catheters (for instance for application in branches of the aorta) and both with and without intervention means.

The preferred embodiments are also suitable for temporarily blocking lumina, for instance a ruptured aorta, with the use of a non-disconnectable balloon part.

This is the case for instance when the device is applied to stem loss of blood from the cardiovascular system to for instance the abdominal or thoracic region when the blood vessel no longer functions properly, for instance as a result of a rupture of the aorta as a consequence of an aortic aneurysm. Following rupture of an abdominal aortic aneurysm, approximately 60% of patients die before a life-saving emergency operation can be carried out in a hospital. This is due mainly to loss of blood, the resulting fall in blood pressure and the strain on the heart. In order to counter the fall in blood pressure operations have been carried out wherein balloon catheters have been utilized, which balloon catheters are inserted via the arteries in the arm or groin and then expanded upstream of the rupture in the blood vessel wall. As a result of the falling blood pressure this has proven to be a difficult and time-consuming procedure.

Such past operational procedures have however proven to be less successful than envisaged as a consequence of the degree of difficulty in performing thereof and the insignificant gain in time.

By means of a combination of firstly localizing an aortic aneurysm, preferably by means of ultrasound, it is possible for a doctor or first-aid emergency personnel to quickly diagnose and localize an aneurysmal rupture and to then quickly and efficiently arrange an occlusion (stent-graft) balloon percutaneously in the aorta.

Much time is saved in this way, so that a further fall in blood pressure can be lessened or prevented. Accordingly, critical time is gained to prepare for an emergency live-saving operation.

As a result of the thus increased preparation time, the chance of survival and the success of such an operation is expected to be significantly increased.

It is also possible for the assembly and method according to the present invention to be used by emergency ambulance services which can arrange the assembly according to the present invention in the

ruptured aorta using an available mobile ultrasound apparatus. In this way the patient can be kept stable until arrival at the hospital, where the operation can be carried out.

According to another aspect of the present invention there is provided a method for wholly or partially filling a body cavity, comprising of:

- localizing the body cavity to be filled;
- inserting the device of the above stated type, preferably with the sheath member of the above stated type;
- filling the body cavity by dilating the balloon member;
- removing the sheath from the body.

The present invention will now be further elucidated by way of the following description, which refers to the figures, in which:

- Figure 1 shows a perspective view of a material set according to an embodiment of the present invention;
- Figure 2 shows a perspective view of a material set according to a further embodiment of the present invention;
- Figure 3 shows a perspective view of another material set according to the present invention;
- Figure 4 is a partly cut-away perspective view of the device according to the present invention during operational use;
- Figures 5, 6 and 7 show partly cut-away perspective views of a balloon stent graft according to the present invention;
- Figure 8 shows a schematic, partly cut-away perspective view of a preferred embodiment with a disconnectable balloon member according to the invention;
- Figure 9 is a schematic, partly cut-away perspective view of another preferred embodiment provided with a stent;

- Figures 10 and 11 show schematic, partly cut-away views of two preferred embodiments of a catheter according to the invention;

- Figures 12, 13 and 14 show cross-sections through preferred embodiments of a catheter;

- Figure 15 is a view of a preferred embodiment of a catheter provided with an additional lumen for feeding contrast agent;

- Figure 16 is a cut-away perspective view of a further preferred embodiment of the device in starting position;

- Figure 17 is a cut-away perspective view of the preferred embodiment of figure 16 in dilated position;

- Figure 18 is a cut-away perspective view of the preferred embodiment of figure 17, wherein the balloon is provided with a stent;

- Figure 19 is a partly cut-away perspective view of a preferred embodiment provided with a central artificial blood vessel; and

- Figure 20 is a schematic view in perspective of a preferred embodiment suitable for an asymmetrical occlusion.

A first material set of a device according to the present invention (figure 1) consists of a solid metal stylet 4 having a pointed tip, a hollow sheath 6 which fits around stylet 4 and a cylinder part 8 in which the sheath 6 and stylet 4 can be placed.

Sheath 6 provides additional stability* when the device is arranged during use thereof. This sheath 6 is an optional part of the embodiment as shown in figures 1 and 3.

Cylinder 8 has a distal part 10, a body section 12 extending from the distal end 10 to a proximal part 14.

Distal part 10 has a tapering end 16 which is continuous with the inner lumen 18 of cylinder 8.

An outer lumen 20 is arranged in the wall of cylinder 8 and is continuous with valve 22 arranged at the proximal part 14 of cylinder 8, and this outer lumen

is continuous with a balloon catheter 24 arranged at the distal end behind the tapering end 16.

A side port 26 is also arranged in proximal part 14 and is continuous with the inner lumen 18. An entry 28 is also arranged terminally in the proximal part 14 and is also continuous with inner lumen 18.

The side port 26 can be opened and closed using a valve (not shown).

The valve 22, side port 26 and opening 28 of the proximal part 18 are formed as integral three-way tap which fits over the cylinder 8.

The balloon catheter 24 can have a volume of for instance 30-50 cc (cubic centimetres) and can be used for radio opaque balloon tracing*.

A variant of balloon catheter 24 is shown in figure 2, which variant 30 is provided with a series of inflatable ribs 32 in order to provide a further anchoring force when arranged in position in for instance an aorta.

These ribs 32 can be arranged in transverse longitudinal or spiral manner (not shown). It will be apparent that the balloon catheter may have any type of surface which ensures that the anchoring stability is as great as possible at the determined site of use.

The parts of a further preferred assembly according to the present invention are shown in figure 3, whereby the stylet and sheath correspond to those of the first preferred embodiment as shown in figure 1.

An elongate, tapering tube-like dilator 40 is arrangeable over a guide wire and can be replaced by a cylinder 42 which likewise has a tapering distal part 44.

The tapering tube 40 is designed for pre-dilation, whereafter it can be removed. The tapering tube 40 can be a new inflatable type of the present invention, as shown in figure 3, or a commercially available type such as a Coons dilator (dilatatorium or dilating element).

Pre-dilation takes place by filling the outer lumen with liquid, for example a contrast-agent, via a side port (not shown).

Contrast agent, blood and the like can be supplied via lumen 46 of cylinder 42, through a side port 50, or opening 52, of a proximal distribution point 54 arranged on cylinder 42. A commercially available balloon catheter can be introduced through opening 52 over a guide wire and inflated to the desired position (not shown).

The assembly according to the present invention can be utilized as follows, see also figure 4.

The exact location of a ruptured aneurysm is first determined using ultrasound and a monitor (M).

The patient's skin is subsequently disinfected and the surgeon or emergency assistance personnel arrange a sterile surgical blanket provided with a surgical opening over the stomach of the patient.

The procedure described below can be used for direct insertion into the abdominal aorta, although the described materials can also be used to enter the arterial system in known surgical or percutaneous manner in the groin artery, the arm artery, the clavicular artery or any random desired artery.

The skin can subsequently be locally anaesthetized, whereafter an incision of between 3 to 15 mm is made using a scalpel. The assembly consisting of stylet 4, sheath 6 and cylinder 8 according to the present invention is then pushed carefully into the aorta lumen, wherein the route is followed with reference to the ultrasound monitor. The pointed stylet 4 enables a quick and easy passage to the rupture.

Once the assembly is arranged in position, stylet 4 and sheath 6 can be partially or wholly removed, wherein stylet 4 may be completely removed first or removed together with partial or complete removal of sheath 6.

If there is a pulsing backflow of aortic blood, or the trained first aid nurse or doctor has determined by means of the ultrasound monitor that the tapering distal

part 16 of the assembly is lying in the aorta, a guide wire can be inserted through the inner lumen 18 of cylinder 8, preferably using x-rays, until a point is reached lying proximally relative to the aneurysm or at least high in the abdomen.

Without exerting any great pressure, balloon catheter 29, 30 can be filled with contrast agent or any sterile liquid.

Contrast agent can be provided through the inner lumen 18, via the tapering part 16, distally relative to the balloon so as to flow into the aorta in order to determine, with the aid of x-rays, whether the balloon is already occluding the aorta or whether the balloon has to be inflated still further. Depending on the position of the rupture in the aorta, further displacement of the balloon 24 over the guide wire (not shown) is possible if occlusion has not yet been effected.

Blood, artificial blood or liquid medium can if necessary be infused through the inner lumen 18.

When the embodiment of the assembly according to the present invention is used as shown in figure 3, stylet 4 and sheath 6 are arranged in place as above.

Stylet 4 can then be removed, whereafter a guide wire can be inserted upstream into the vessel lumen. Sheath 6 is subsequently removed and dilator 40 is placed in the lumen over the guide wire for the purpose of pre-dilation. Dilator 40 is then removed and cylinder 42 is placed over the guide wire into the vessel lumen. A commercially available balloon catheter or a balloon catheter preferably provided with a suitable surface (ribs, longitudinal, transverse, spiral, bumpy road*) can then be arranged over the wire through cylinder 42 and dilated at the desired location. This introducer-cylinder can likewise be used to carry any type of stent-graft into the vessel lumen over the guide wire. If desired, these balloon catheters can be integrated to form one system with an Intravascular Ultrasound Catheter so as to simplify accurate positioning.

A further two embodiments of the present invention can be utilized to attain a more stable position of the inflated balloon part.

A first such further embodiment comprises a conventionally designed balloon-occlusion catheter of which at least the balloon part or, if necessary, larger parts are made of any type of graft material (= artificial blood vessel-substitute material) with an attached self-expanding stent on the balloon part of the device. This is the first design of any balloon catheter (partially) made of stent-graft material. The stent ensures that the balloon part can withstand a greater pressure, thereby reducing the chance of the balloon part changing position in undesired manner.

The expanding device of this balloon catheter can be identical to or based on the commercially available Wall-stent expanding system (rolling membrane system) which allows re-folding of the partially expanded system and which allows repositioning as well as removal of the device after an operation. Any other commercially available stent-graft system with the stent on the outer part of the stent-graft can also be used for the same purposes. The same type of stent-graft balloon can be used as the balloon part of cylinder 8 of the device, figure 1. It is noted that the metal stent can be situated either on the inside or on the outside of the graft material.

A second further embodiment consists of a self-expandable stent-graft system in which the distal part of the graft part and the stent part are preferably interlaced, therein leaving only a small opening through which a guide wire is insertable, resulting in a tapering cylindrical shape of the graft part.

Another embodiment of the invention comprises the same design wherein both the proximal and the distal part of the graft part are interlaced in the same manner with the relevant stent part. Because the distal and/or proximal part of the graft part are interlaced with the

stent part, a possible flow of blood in longitudinal direction is stemmed.

Both these alternatives with either a graft part or a stent-graft on the outside can be used and arranged in position through cylinder 42. This stent-graft 100 (see figures 5, 6 and 7) comprises an outer sleeve 102 which abuts at a distal end 104 thereof with a conical nose part 106.

The sleeve 102 comprises a support wire-like member 108 upon which an expandable stent 110 is arranged with a covering skin 112 to thus form an inflatable balloon stent-graft system 114, which skin completely insulates the expandable stent 110 except for the small front and rear openings via which the support wire 108 runs through the expandable stent 110 into the nose portion 106.

The expandable stent 110 can be made of any suitable self-expanding material and is released from its folded-up state inside sleeve 102, figure 5, by simply retracting sleeve 102 along guide wire 108.

In this the manner the stent-graft system 100 can be positioned via opening 52 in cylinder 42, as shown in figure 3.

Once arranged in position, sleeve 102 can be wholly or partially retracted along the stent-graft part of the system, depending on which embodiment of the invention is applied. Stent 110 then expands and presses itself in outward direction into position in for instance a blood vessel, the whole thereby functioning as a sort of dam to stem blood loss resulting from a rupture located downstream.

Other preferred embodiments of the invention comprise the same design with integration of a commercially available intravascular ultrasound catheter, the ultrasound part of which extends to either the distal end or just proximally relative to the distal end (for instance at a distance of 0.5 to 4 cm from the distal end). The intravascular ultrasound system (IVUS) is preferably integrated centrally in the invention. The

integration of an IVUS monorail system with the invention can enable a complete interlacing of the stent-graft parts and the distal and/or proximal parts thereof.

The stent-graft 114 can remain in position until an emergency surgical operation has been carried out, whereafter the balloon stent-graft can also be removed by pushing the sleeve 102 over the balloon stent-graft 114 in order to compress this back into its displacement position, as in figure 5, whereafter the system is removed from the body.

If necessary an additional conventional balloon-occlusion catheter can be used to give more support.

Figure 8 shows a body L into which a device 201 according to a preferred embodiment of the invention is placed through an incision I with the purpose of occluding a blood vessel b which has an arteriovenous malformation or an aneurysm. Device 201 comprises a sheath 204 on which a balloon 206 is mounted distally. Sheath 204 is connected to a feed 202 for supplying (P_1) fluid (gas or liquid) and is made from a known material such as high density polyethylene HDPE, polyether block amide PEBA, polyethylene terephthalate PET or nylon.

The balloon 206 is at least partially constructed (for instance only on the inside or one the outside or on both the inside and outside) from a known balloon material, such as for instance nylon, or from optionally semi-permeable artificial blood vessel material.

Provided in the sheath is a lumen 207 with which liquid or gas supplied from the proximal end (P) of sheath 204 can be carried via openings 208 into the balloon 6 arranged at the position of the distal end (D) of sheath 204. The balloon can be inflated to a suitable thickness by feeding a correct quantity of fluid.

A central guide wire lumen 209 is arranged concentrically in sheath 204 relative to lumen 207. In contrast to lumen 207 which debouches in the balloon, the guide wire lumen 209 extends to the distal end of sheath 204. This means that the part of the sheath 204 which

protrudes distally relative to balloon 6 has a smaller diameter, which reduces the chance of damage to the blood vessel. Guide wire lumen 209 has the function of guiding a guide wire V. Device 201 can hereby be introduced into the body L over a guide wire arranged beforehand in the body.

When balloon 206 has been inflated sufficiently to occlude blood vessel b, sheath 204 is disconnected from balloon 206 by means of a schematically shown disconnecting mechanism and then retracted. In order to prevent the fluid carried into balloon 206 from flowing out of the balloon, this latter is provided with a proximal valve mechanism 210 and a distal valve mechanism 211. The valves of these mechanisms are closed as soon as balloon 206 is disconnected. The fluid therefore remains present in balloon 206 and the balloon remains pressed forcefully against the blood vessel walls.

Drawn in figure 9 is an embodiment in which sheath 204 is provided with a single lumen 212 with which fluid supplied via feed 202 can fill the balloon 213 arranged on the distal end of sheath 204. In the drawn embodiment the balloon wall is provided on its distal end with a stent attached thereto. In another embodiment (not shown) the stent can also be arranged on the inner side of the balloon wall. During insertion the stent-balloon can be situated inside a coaxial wider catheter or sheath and can thus be carried to its place of destination.

The application of a stent ensures that the balloon-stent combination can withstand a greater pressure, thereby reducing the chance of this combination being displaced in undesirable manner. The balloon will also remain in place better in the case of leakage out of the balloon which may occur after some years.

In the embodiment of figure 9 it is possible to suffice with a single valve mechanism 212 with which the balloon 213 can be closed when it is disconnected from sheath 204.

A further embodiment (not shown) comprises a balloon-stent part having a first valve mechanism distally as well as a second valve mechanism proximally, with the added advantage that a surrounding, wide guide catheter can be dispensed with for insertion purposes, which increases the maximum speed of insertion and entails less danger of trauma for the patient.

Figure 10 shows an outer end 220 of a catheter. In this preferred embodiment the catheter is provided with two lumina 223 and 224 disposed adjacently of each other. Guide wire lumen 223 extends over a distance a beyond balloon 225. This distance must be large enough to avoid unnecessary damage to the blood vessel, also in that this outer end can be made tapering. It has been found that the device can be readily handled when the distance a is between about 2-15 mm.

In the shown embodiment the guide wire lumen 223 has two functions. Firstly, lumen 223 serves to guide (in direction P_4) a guide wire V (not drawn). Secondly, lumen 223 functions to supply contrast agent. At the proximal end the lumen has a cross-section which is larger than the guide wire cross-section. Just proximally of balloon 225 the lumen 223 narrows to a cross-section substantially corresponding to the cross-section of the guide wire. Openings 221 are provided in the tapering part 226 of the outer end 220 of the catheter. Owing to the oversizing of lumen 223 contrast agent can be fed which is injected into the blood vessel via openings 221 in the catheter wall.

Lumen 224 is intended for the purpose of filling (P_6) the balloon 225 with fluid supplied via the proximal end (P_5).

In figure 10 the mutually adjacent lumina 223 and 224 are realized by arranging a wall 222 in the catheter. In another embodiment (figure 14) mutually adjacent lumina are realized by attaching together two cylindrical tubes 230 and 231 using a wrapping 32.

In the view of figure 11 and the cross-section of figure 12 is shown an embodiment in which three lumina 233, 234 and 235 are disposed concentrically relative to each other. A short outer lumen 233 communicates with openings 221 in the catheter wall and functions as feed lumen for contrast agent. A longer central lumen 234 is connected to opening 236 in balloon 225 and functions as feed lumen for fluid for inflating balloon 225. An inner lumen 235 extends beyond the distal end of balloon 225 and functions as guide wire lumen for guiding a guide wire (not shown).

Figure 13 shows a further variant in which three lumina 240, 241 and 242 are attached together using a wrapping 243.

It is noted that the above described catheter embodiment can be applied not only on a device with intervention means in the form of a balloon, as described with reference to figures 10-14, but also on intervention tools and diagnostic catheters generally which can be introduced into the bloodstream.

Figure 15 shows a catheter provided with a guide wire lumen 243 for guiding a guide wire V and a liquid lumen 244 arranged therearound for feeding liquid, such as contrast agent, wherein the liquid lumen 244 is provided with a narrowed portion in which are provided openings 245 for injecting the supplied liquid into the body cavity. These openings may also be located just proximally of the tapering "narrowed" portion (not shown).

Figure 15A shows a further preferred embodiment which has a single lumen 256 consisting of two parts. The first part of the lumen is intended for administering contrast agent and is relatively short. The first part tapers toward the part of the lumen intended for the guide wire. The part for administering contrast agent can be disposed adjacently of as well as concentrically round the part for the guide wire and contains close to the

distal end a number of openings 257 for administering contrast agent.

Another preferred embodiment of each type of described model can further be manufactured without additional lumen for filling the balloon (figures 16 and 17) or stent-balloon (figure 18, in which the stent is designated with reference numeral 251). In the case a balloon is disconnectable, it must then contain a moisture-absorbing, hygroscopic, hydrophile and/or lipophilic substance 250. If moisture is present, for instance through feed of liquid via sheath 4, although preferably due to the suction action by a balloon wall manufactured at least partially of selectively permeable material, the balloon is filled. Selective is here understood to mean that the wall is permeable by molecules of a determined structure or size. The wall can thus for instance be permeable only by H_2O or larger molecules through a correct choice of the pore size of the wall material, depending on the molecule structure. In this embodiment an additional lumen for filling the balloon can therefore be dispensed with. The material in the balloon is preferably of a type which expands when it becomes moist. Due to the expansion of the material in the balloon (indicated in figures 16 and 18 with arrows), the balloon is inflated when it absorbs the moisture until the outer wall of the balloon assumes the form of the surrounding tissue (figure 17) and is fixed in the blood vessel (or other random body part) by the pressure exerted on the tissue. The sheath 204 with which the balloon is arranged can be disconnected from the balloon immediately after insertion with a disconnecting mechanism and subsequently retracted (in direction P_7) or be removed once the balloon has reached the dilated position.

Use of a selectively permeable membrane, optionally in combination with a hygroscopic/lipophilic substance arranged therein, is an easily applicable method of

filling balloons without an additional lumen being necessary for the purpose.

If in another preferred embodiment of the invention the stent part is manufactured from memory material, the stent part can take on any predetermined shape.

In the case of self-expanding stents an open cylindrical shape or other closed forms can be assumed, for instance a hollow cylinder form covered with graft material. With a hollow form a central lumen remains present after disconnection which can be connected to the blood vessel in the body. The flow of blood along this lumen and the blood circulation is thereby maintained. This preferred embodiment in hollow form, such as for instance a hollow cylinder form, is suitable as permanent prosthesis in an abdominal aortal aneurysm and is less often the cause of complications such as can be caused by backflow from lumbar arteries to the aneurysm (so-called endo-leakage).

Figure 19 shows that an intervention unit in the form of a self-expanding stent is arranged in an aneurysm a in a blood vessel b. The stent comprises an artificial blood vessel with an inner wall 250, an outer wall 251 in addition to an upper wall 252 and a lower wall 253, all manufactured from or at least covered with artificial blood vessel or graft material. The stent (indicated by means of hatching) is once again of the self-expanding type so that the outer wall 251 presses as uniformly as possible against the outer wall of aneurysm a. The expanding inner wall acquires a diameter which is as similar as possible to that of the adjoining lumina. In the shown situation the flow of blood can make its way with the least possible obstruction from the upstream side of the stent via the artificial blood vessel to the downstream side of the stent (indicated with arrows P_8), and the aneurysm a in blood vessel b is simultaneously filled.

This latter embodiment of a stent-balloon can for instance be used as incorporated* adjuvant catheter

sheath which is dilated in the same manner as described above by means of a valve mechanism and through which filling can be arranged.

Because the memory material can be preprogrammed such that a greater pressure can be exerted on the surrounding thrombotic tissue or blood vessel wall with the double-layered hollow stent-balloons than with known aorta stents, sometimes occurring abnormal blood supply via lumbar arteries to the aneurysm, a known complication, is checked. A reduction in the number of complications can therefore be anticipated after placing of such an aorta stent-balloon.

Owing to prior three-dimensional evaluation of a patient (for instance by means of computer tomography, MRI (Magnetic Resonance Imaging) or three-dimensional echography, a balloon with a form and size specific to the patient can be defined, whereafter it can be produced using a mould based on this specific information. An artificial blood vessel (graft) material can subsequently be adhered in known manner to the inside or outside, whereafter the graft-balloon is shrunk or folded together in known manner. The compact form can be retained if a membrane system is placed therearound in known manner until it is removed at the appropriate location inside the patient so that expanding takes place.

In a further preferred embodiment the outer and inner stent-graft parts can be inserted separately of each other and individually into the body, for instance in an aortal aneurysm. This means that the combination of insertion set and insertion materials is less bulky and will therefore be less traumatic. An outer layer is first of all placed carefully against the aneurysm wall. This layer is manufactured from artificial blood vessel material, for instance PTFE, or a combination of a stent and artificial blood vessel material, wherein the stent can be located on the inside as well as on the outside. If the stent is self-expanding and located on the inside, fixation of the second parts to each other can be

dispensed with because the stent is held in place by the outward directed forces. The use of a non-self-expanding stent is also a possibility. Secondly, a stent-graft part can then be placed which forms the inner wall and which is placed both proximally and distally against the outer wall, this such that no blood can flow between the outer and inner wall. For this purpose the outer wall is at least as long as the inner wall, so that placing of the inner wall against the already placed outer wall need take place slightly less precisely in order to still obtain a fully occluded space between the walls.

In the integral design an iliac part can be adhered in known manner as single-walled stent-graft part to the aortal double-walled part. If desired, the iliac part can be at least partly embodied with an outer wall and an inner wall. This latter may be necessary in the case of an iliac continuation of the aortal aneurysm.

Figure 20 shows a preferred embodiment which has the object of being able to perform asymmetrical occlusions. An asymmetrical, closed stent-graft part 255 can be fixed to a stent 254 having the form of the desired, usually central lumen. Use can for instance be made here of a standard open stent 254 to which is attached a closed stent 255 manufactured specially for the relevant body cavity to be filled. This is therefore a combination of the above mentioned closed stent-(balloon)-graft part and a stent with a (permanently) open part. The whole unit can be introduced with a stent-(graft) placing mechanism. The closed stent-graft part 255 is wholly covered with artificial blood vessel material, and is brought into the dilated state by one or more of the above mentioned techniques. The device shown in figure 20 is particularly advantageous in those embodiments where no feed lumen is required to dilate the balloon. In the embodiment of figure 20 a stable position of partially occluding materials is possible due to the support by the open stent part in a normally formed lumen (blood vessel, bowel, bladder etc.)

In embodiments which are not shown and in above described embodiments containing stent parts, the stent part can be provided with an anchoring for anchoring the balloon to the vascular wall. Such an anchoring can be embodied by fixing to the outer surface of the balloon a number of wire-like anchors which adhere to the vascular wall and prevent a movement in flow direction. Radio-opaque markings can also be arranged thereon which facilitate localization during placing.

The present invention is not limited to the above described preferred embodiments. Also possible for instance are optionally hollow, asymmetrical or spherical designs which may be useful in cosmetic improvements after resectional surgery or treatment of asymmetrically formed aneurysm. The rights sought are defined by the following claims, within the scope of which many modifications can be envisaged.

CLAIMS

1. Device for filling a body cavity, such as a blood vessel or an abnormal part of a blood vessel, bladder or bowel, comprising:

- an elongate sheath;
- a balloon member mountable distally on the sheath,
- dilating means for bringing the balloon member from a starting position into a dilated position.

2. Device as claimed in claim 1, comprising disconnecting means for disconnecting the sheath and the balloon member in the dilated position.

3. Device as claimed in claim 2, wherein the dilating means comprise a feed lumen provided in the sheath for feeding a fluid from the proximal end of the sheath into the balloon member, and closing means are arranged on the balloon member for closing the balloon member when the balloon member is disconnected.

4. Device as claimed in claim 2 or 3, wherein the dilating means comprise moisture-absorbing material arranged in the balloon member and the balloon member wall is at least partially moisture-permeable.

5. Device as claimed in claim 2, 3 or 4, wherein at least a part of the balloon member wall is manufactured from permeable material, and hypophilic, lipophilic and/or hygroscopic material is arranged in the balloon member.

6. Device as claimed in any of the claims 1-5, wherein the dilating means comprise a stent, for instance a self-expanding stent, arranged on the balloon member.

7. Device as claimed in any of the foregoing claims, wherein the sheath extends through the balloon member and comprises a guide wire lumen extending distally beyond the balloon member for the purpose of guiding guide means, such as a guide wire, inserted from the proximal end of the lumen.

8. Device as claimed in claim 7, wherein the guide wire lumen extends over a distance of between 2 and 15 mm relative to the balloon member.

9. Device as claimed in claim 7 or 8, wherein the balloon member comprises proximally disposed first closing means and distally disposed second closing means for closing the balloon member when the balloon member is disconnected.

10. Device as claimed in any of the foregoing claims, wherein a stent is arranged on the balloon member for the purpose of increasing the pressure to be exerted on the body in the dilated position.

11. Device as claimed in any of the foregoing claims, wherein the outer wall of the balloon member is at least partially constructed from artificial blood vessel material.

12. Device as claimed in any of the foregoing claims, wherein the balloon member is provided internally with an artificial blood vessel for connection onto a lumen in the body, such as a blood vessel, bowel or bladder.

13. Device as claimed in any of the foregoing claims, wherein the balloon member is dilatable such that in the dilated position the shape thereof has substantially adapted itself to the shape of the body cavity to be filled.

14. Device as claimed in any of the foregoing claims, wherein the feed lumen and the guide wire lumen are disposed adjacently of each other.

15. Device as claimed in any of the claims 1-13, wherein the feed lumen is disposed concentrically relative to the guide wire lumen.

16. Device as claimed in any of the foregoing claims, wherein the balloon member comprises anchoring means, preferably wire-like anchors, for adhering to the wall of the body part for occlusion.

17. Device as claimed in any of the foregoing claims, comprising radio-opaque markings for facilitating the localization during placing.

21. Assembly for stemming the loss of bodily fluid from a damaged body-vessel, for example through collapse or disfunctioning of the aorta following rupture of an aortic aneurysm, said assembly comprising:

- dilation means, dilatable between a displacement position and a dilated position of use, for dilating and occluding a body vessel, and
- support means for supporting the dilating means during the introduction thereof into the body.

22. Assembly as claimed in claim 21, further comprising incision means for making an incision and cutting through body tissue to enable access of the assembly to the damaged body vessel.

23. Assembly as claimed in claim 22, wherein the incision means are combined with the support means.

24. Assembly as claimed in any of the claims 21-23, wherein the dilation means comprise:

- a cylinder-like element having a distal part, which in turn comprises an inflatable balloon-like element or an inflatable tapering tube-like element;
- a proximal part;
- a middle part extending between the proximal part and the distal part and being continuous therewith;
- an internal lumen into which the support means are arrangeable; and
- an external lumen between the balloon and the distal part.

25. Assembly as claimed in any of the claims 21-24, wherein the dilating means comprise a stent.

26. Assembly as claimed in claim 25, wherein the stent is of the self-expanding type.

27. Assembly as claimed in any of the claims 24-26, wherein the balloon member is provided with a skin-like covering, preferably in the form of a stent-graft.

28. Assembly as claimed in any of the claims 24-27, wherein the dilation means taper distally or both distally and proximally.

29. Assembly as claimed in any of the claims 21-28, comprising reinforcing means for reinforcing the assembly during introduction thereof into the body, said reinforcing means comprising a substantially rigid sheath (6) arrangeable around the support means inside the internal lumen.

30. Assembly as claimed in any of the claims 21-29, comprising an integrated locating device, preferably an ultra-sound device connected to a monitor, or an x-ray machine, for determining the position of the assembly in the body.

31. Sheath member for arranging intervention means in a body cavity, preferably a sheath for arranging a balloon member as claimed in any of the claims 1-30, wherein a guide wire lumen is provided in the sheath member for guiding a guide wire therein, as well as an additional lumen provided with one or more outlet openings for feeding contrast agent along the outlet openings into the body cavity.

32. Sheath member as claimed in claim 31, wherein the guide wire lumen and the additional lumen are combined, and the combined lumen is provided with a narrowed portion, at the location of which or just proximally of which one or more outlet openings are arranged in the sheath wall for supplying contrast agent into the body cavity through the combined lumen over the guide wire via the outlet openings.

33. Sheath member as claimed in claim 31 or 32, intended for diagnostic imaging with outer ends which are optionally embodied for selective catheterization.

34. Sheath member as claimed in claim 32 or 33, wherein the narrowed portion is situated just proximally of intervention means, preferably a disconnectable balloon member, mountable on the sheath member.

35. Sheath member as claimed in any of the claims 31-34, comprising a first lumen for guiding a guide wire, a second lumen for feeding fluid into the balloon member and a third lumen for feeding contrast agent into the body cavity.

36. Method for filling a body cavity, comprising of:

- localizing the body cavity to be filled;
- inserting the device as claimed in any of the claims 1-16, preferably with the sheath member as claimed in any of the claims 31-35;
- filling the body cavity by dilating the balloon member;
- removing the sheath from the body.

37. Method as claimed in claim 36, comprising of attaching the artificial blood vessel of the device as claimed in claim 12 to the relevant blood vessel in the body.

38. Assembly for filling a body cavity, comprising one or more devices as claimed in claim 13, in addition to an open stent fixed to the devices and to be arranged in a normally formed body lumen such as a blood vessel, bowel or bladder, for supporting said devices in the body.

39. Method for treating a damaged body-vessel such as a ruptured aorta, said method comprising the steps of:

- localizing the damaged body-vessel;
- making an incision at a predetermined position in the abdomen, the groin, the arm, the armpit, under the collar bone or at a random suitable entry position;
- inserting the assembly as claimed in any of the foregoing claims into the body through the incision and to the treatment site; and
- occluding the damaged body-vessel at or close to this treatment site in order to stem fluid loss*, preferably to stem blood loss from the cardiovascular system from a more distally located part of the vessel.

40. Apparatus for occluding a body vessel, for example a damaged blood vessel, said apparatus comprising

an expandable part expandable between a displacement position and a dilated position, which expandable part is covered with a skin-like layer so as to ensure that during use the apparatus is substantially impermeable to the liquid in the body vessel.

41. Apparatus as claimed in claim 40, wherein the expandable part takes the form of a balloon catheter, and the skin-like covering takes the form of an impermeable stent-graft.

42. Apparatus as claimed in claim 40, wherein the stent material is located on the outer side or on the inner side of the expandable part.

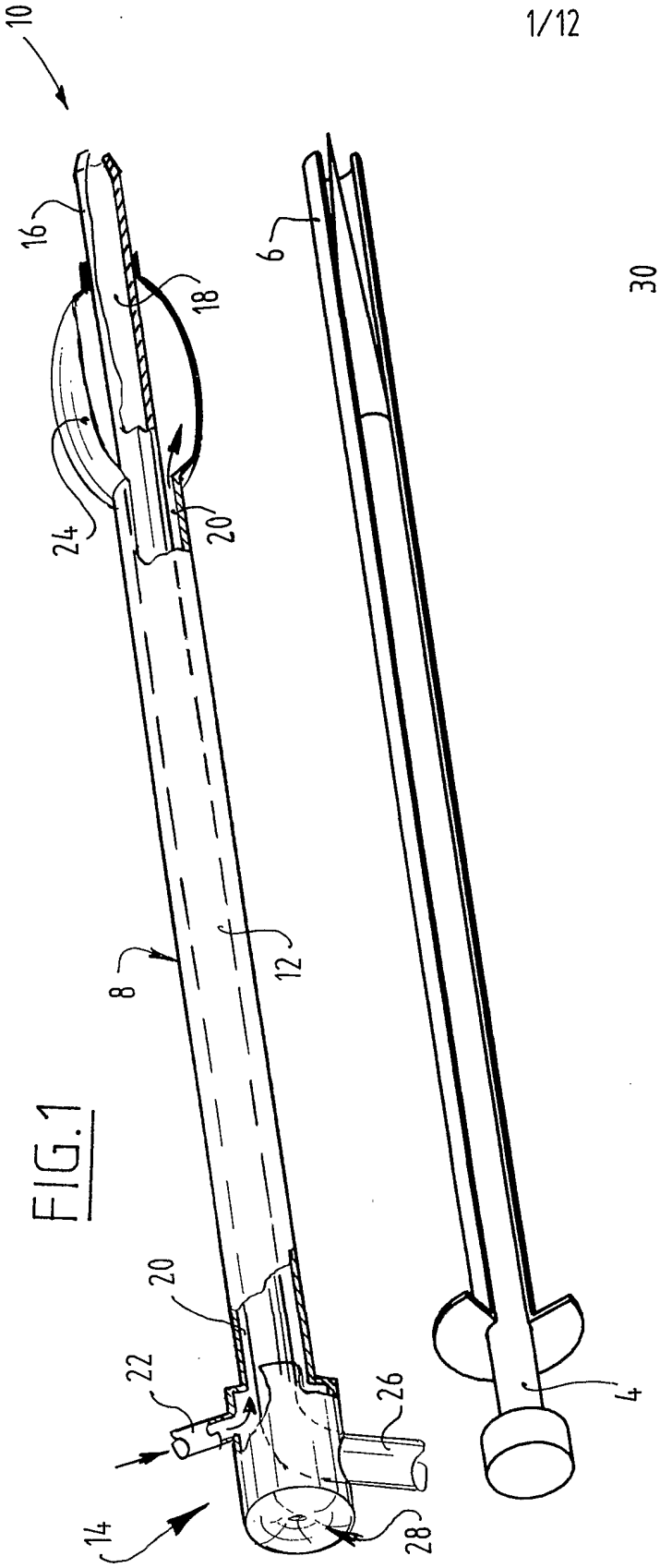


FIG.1

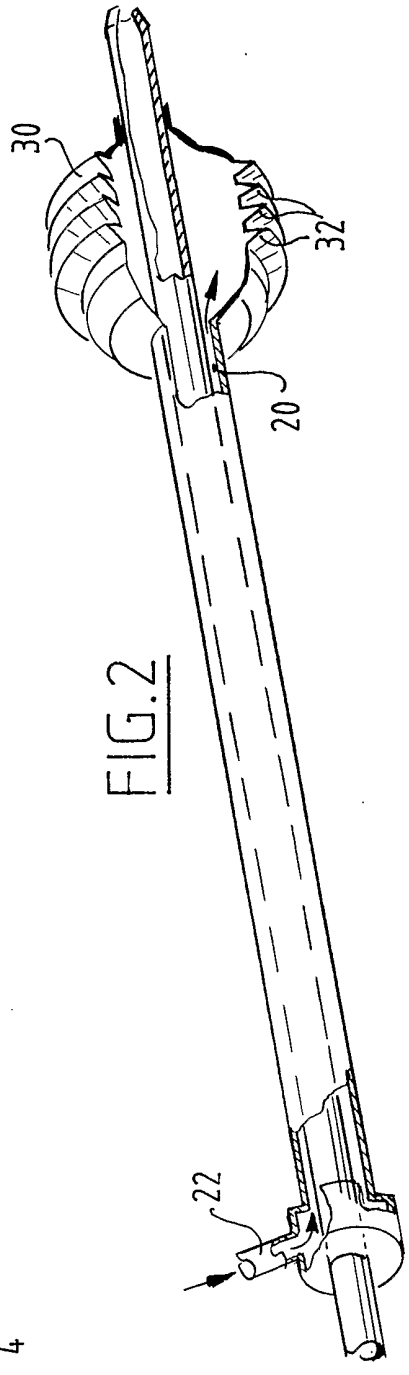


FIG.2

FIG.3

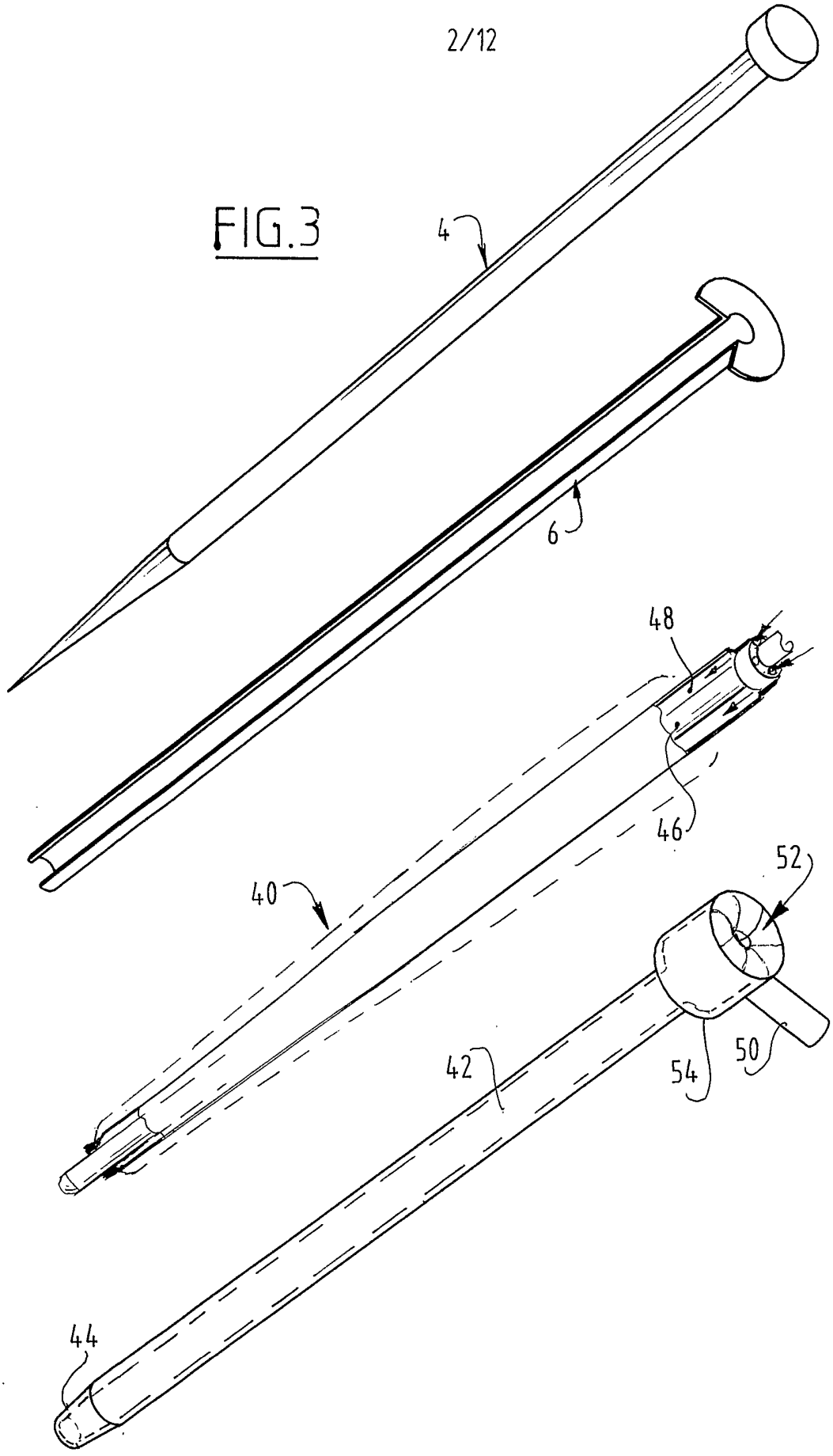
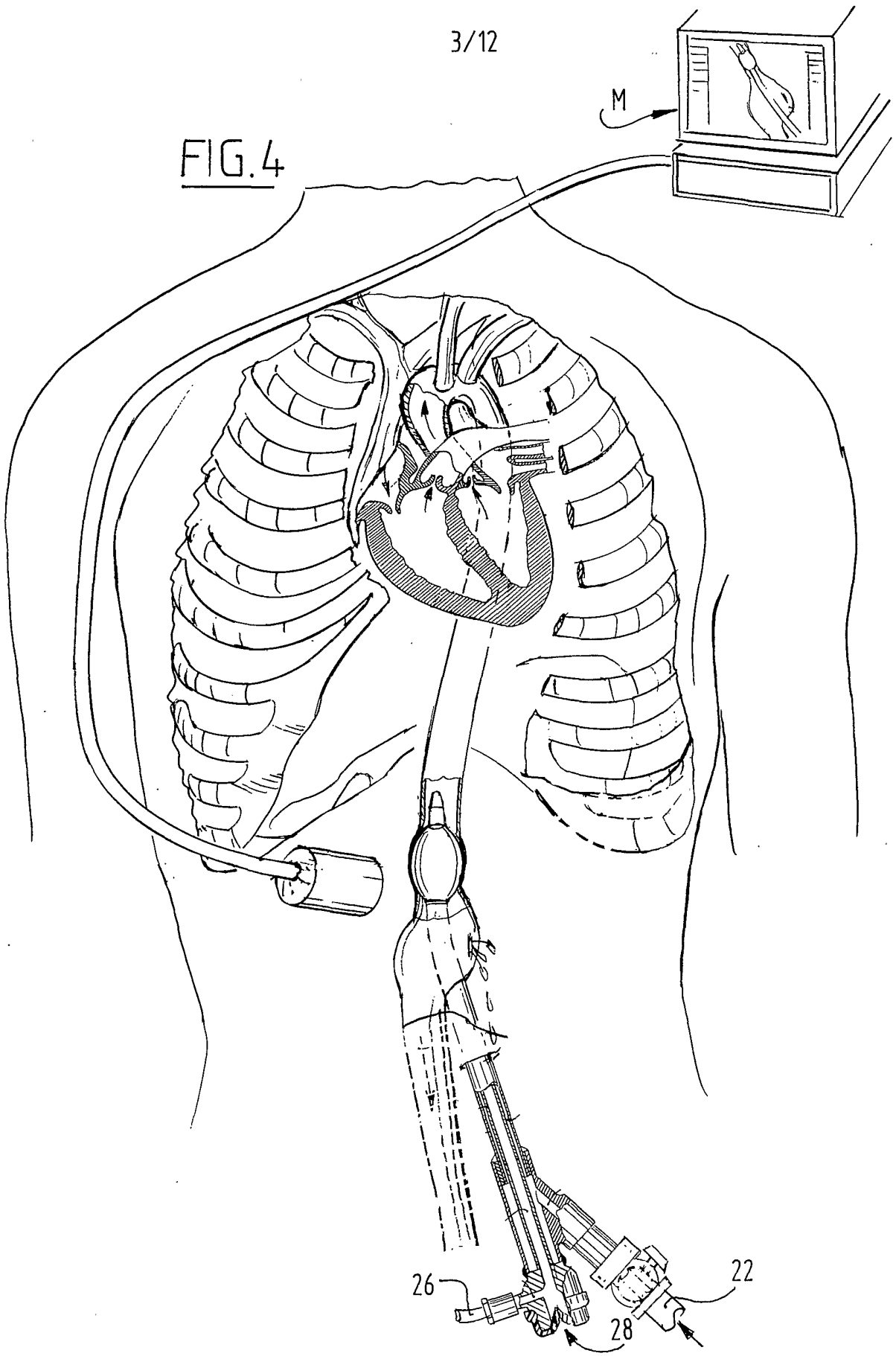


FIG.4



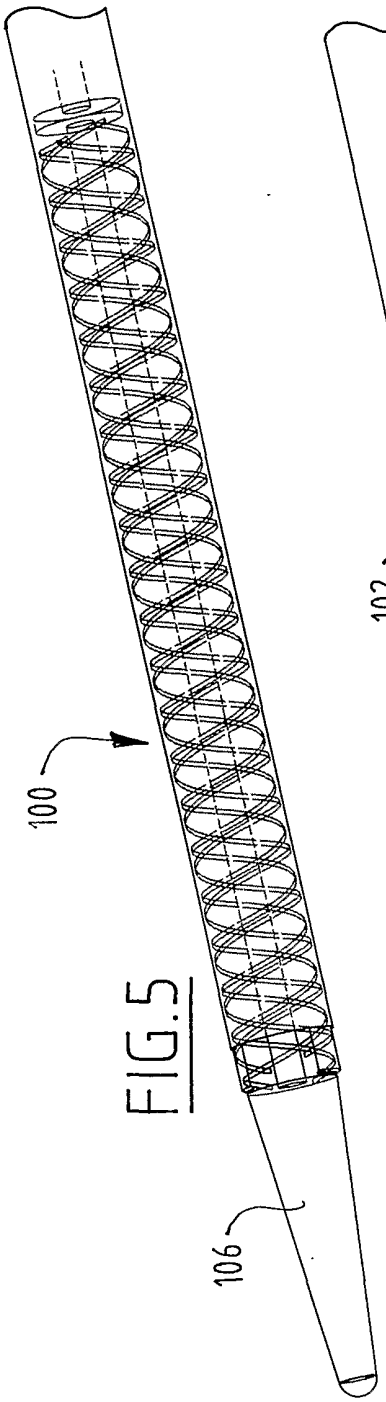


FIG.5

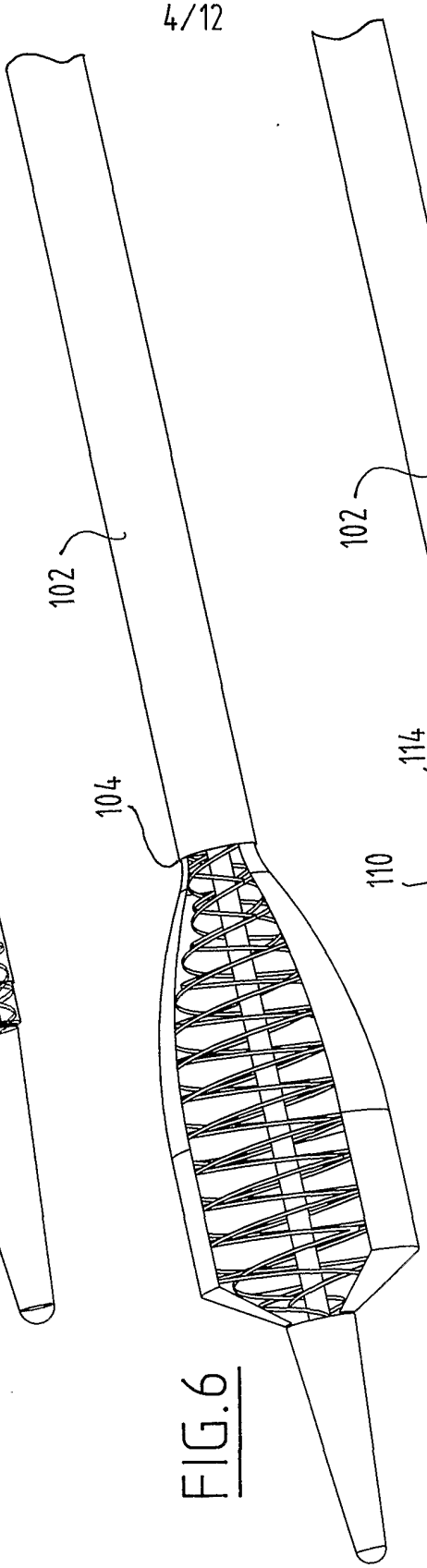


FIG.6

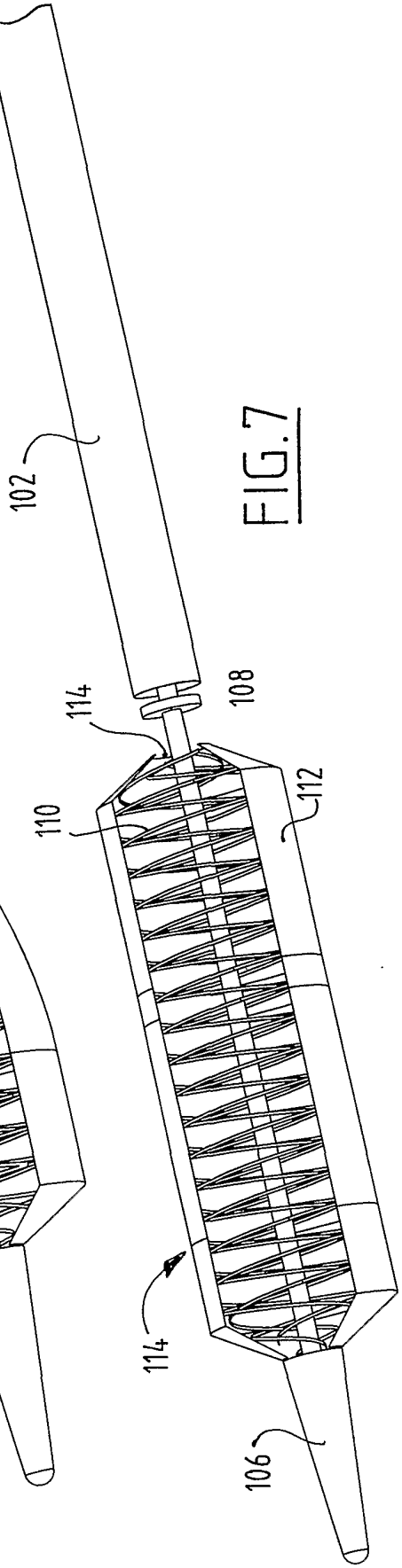


FIG.7

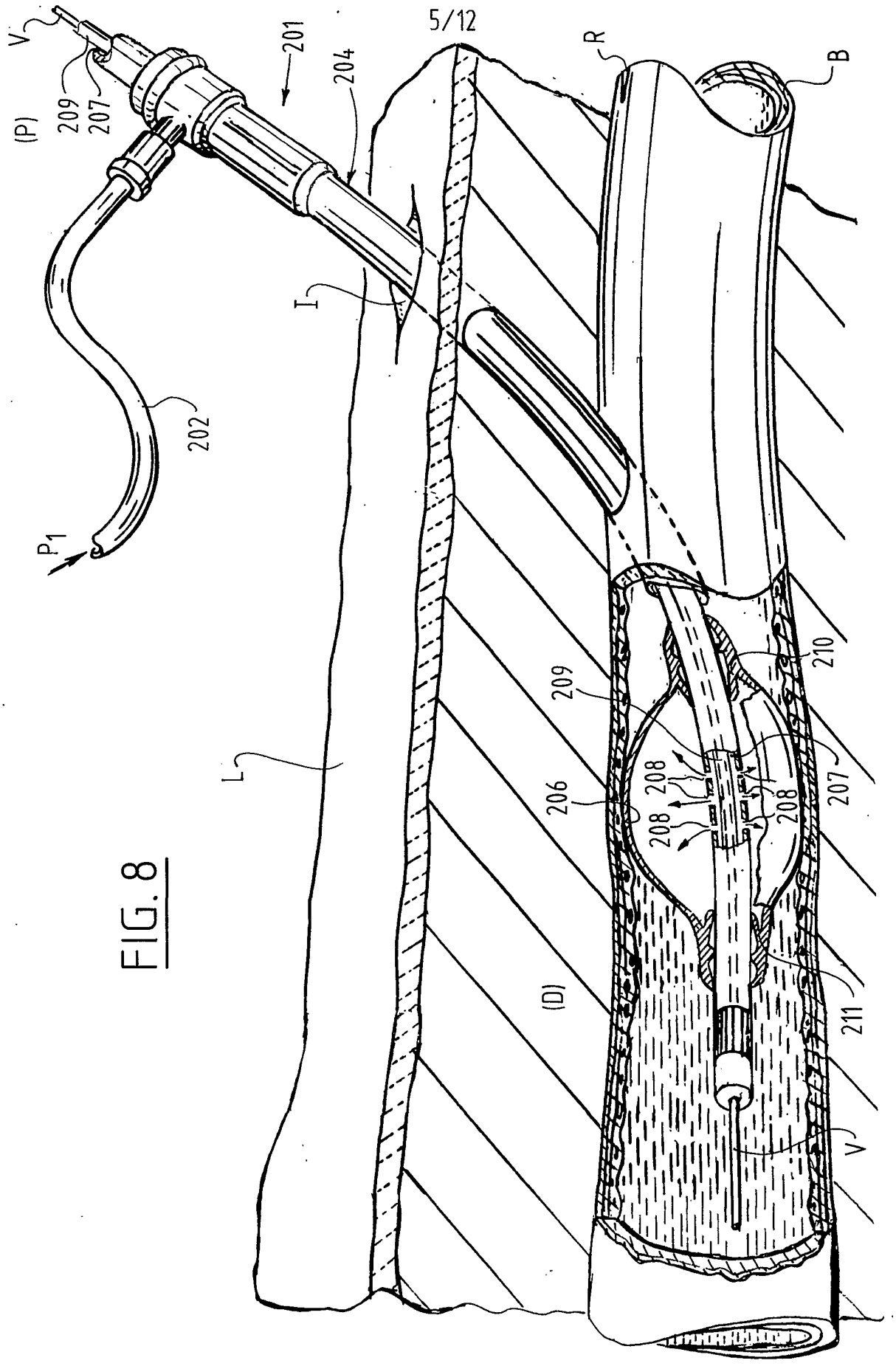


FIG. 8

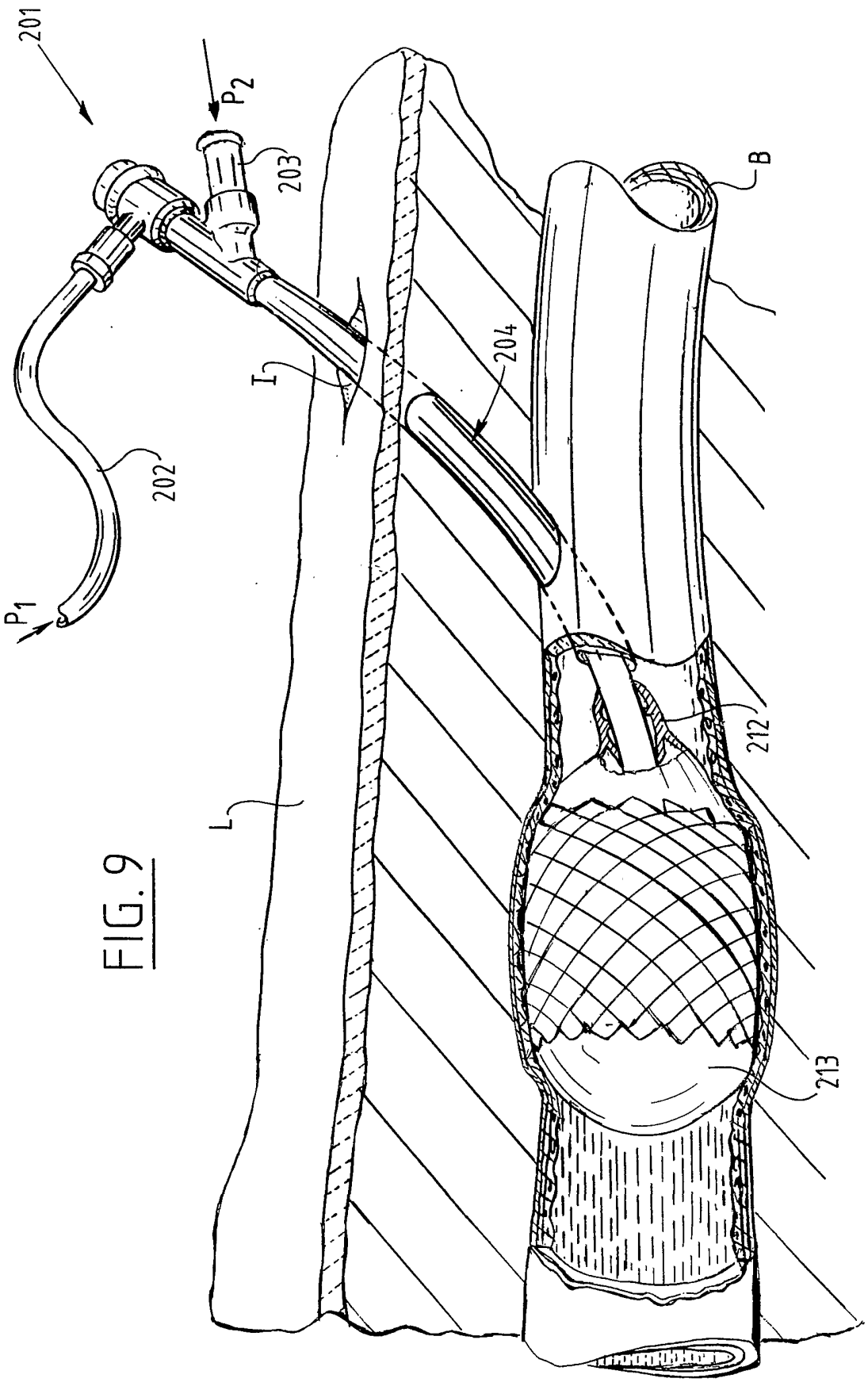


FIG. 9

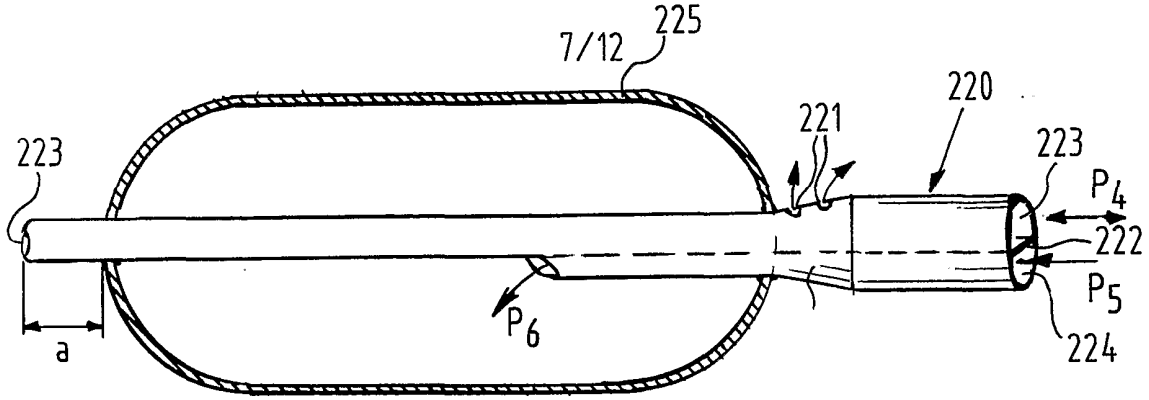


FIG. 10

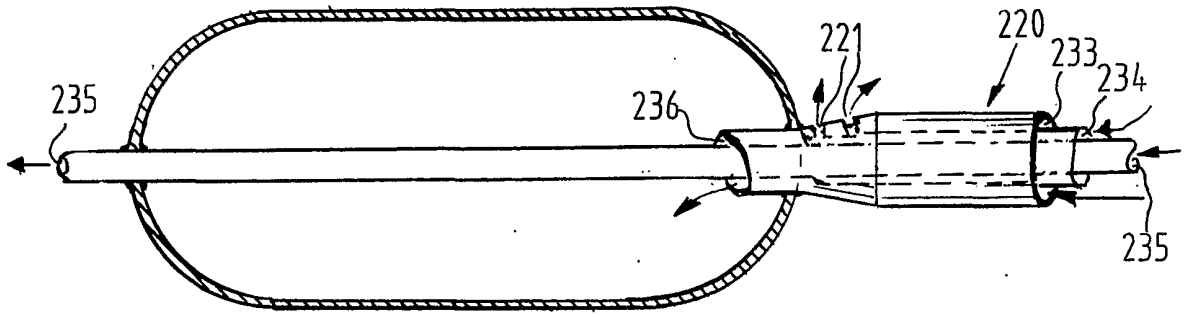


FIG. 11

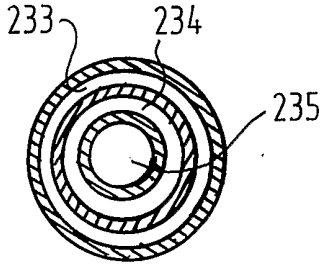


FIG. 12

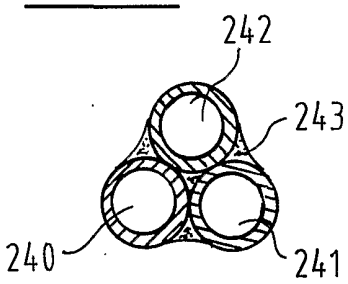


FIG. 13

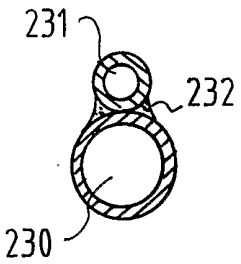


FIG. 14

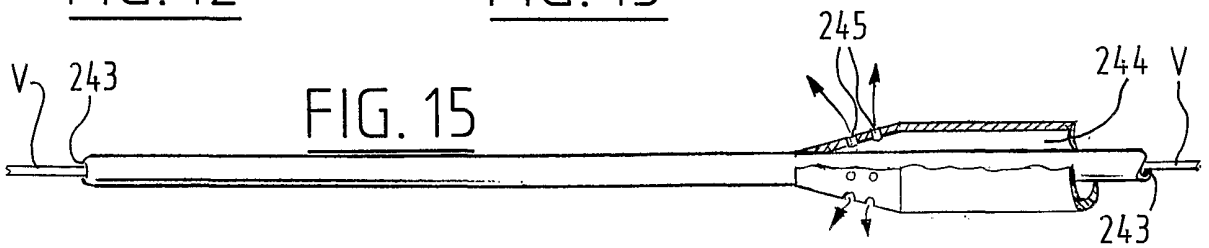


FIG. 15

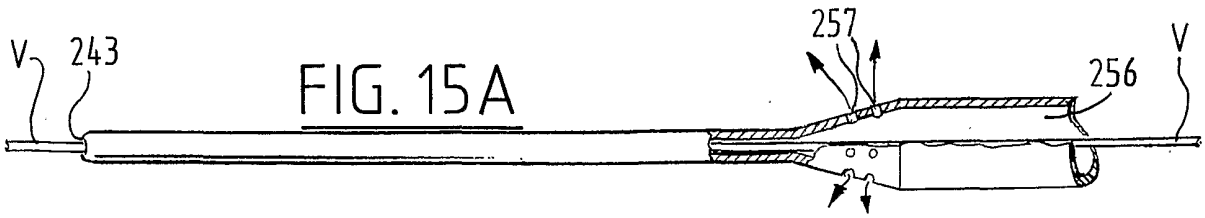


FIG. 15A

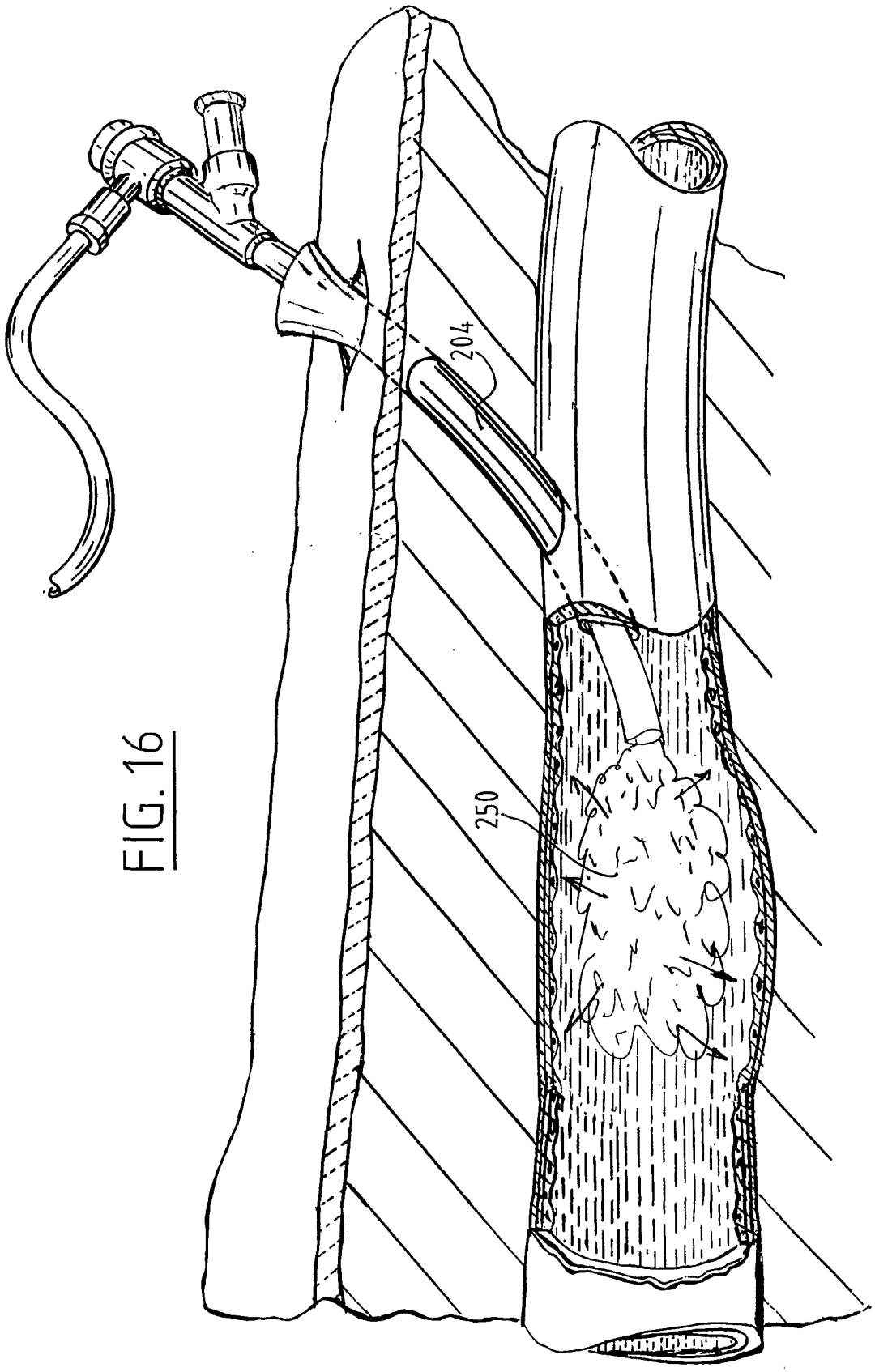


FIG. 16

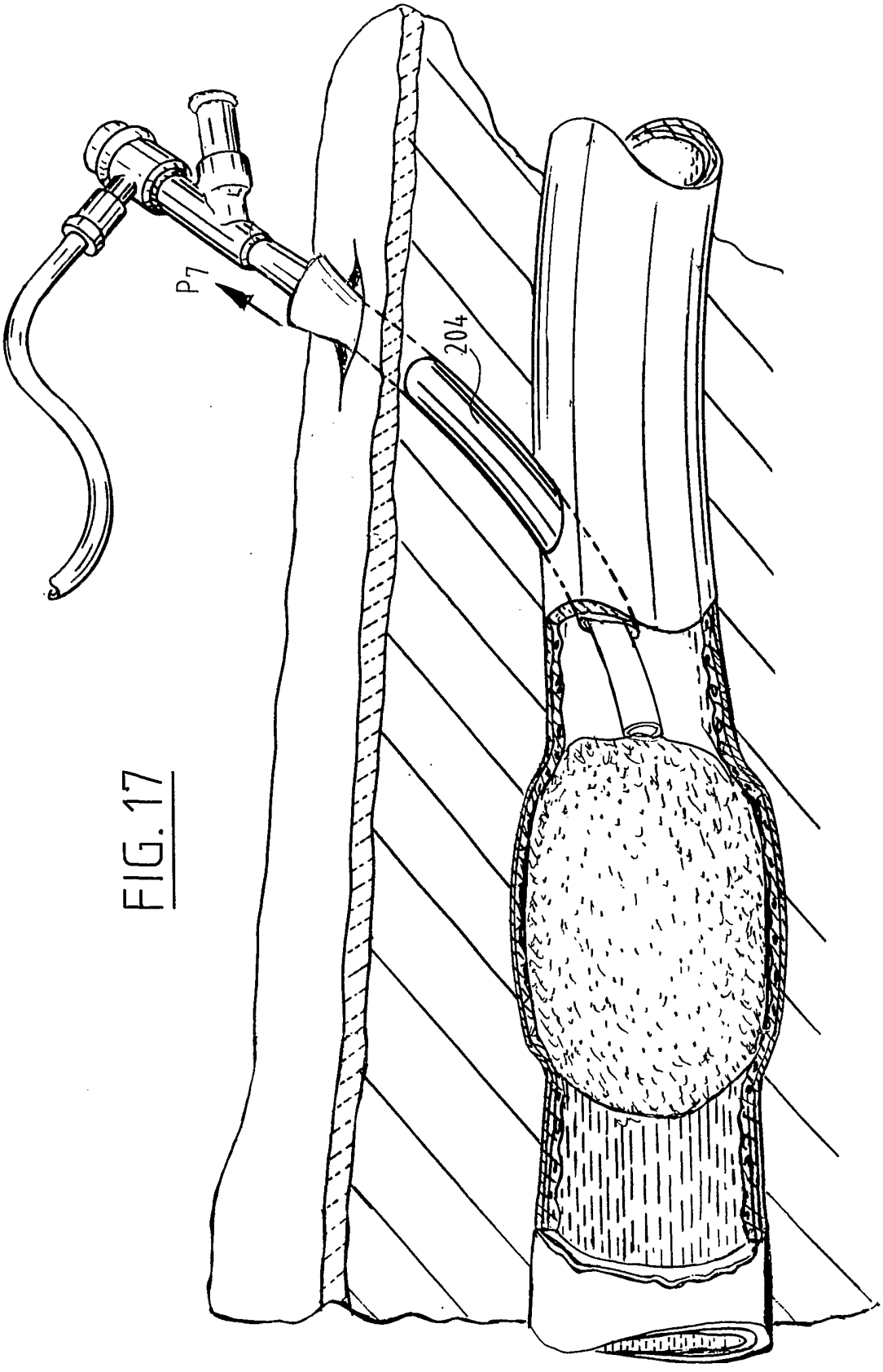


FIG. 17

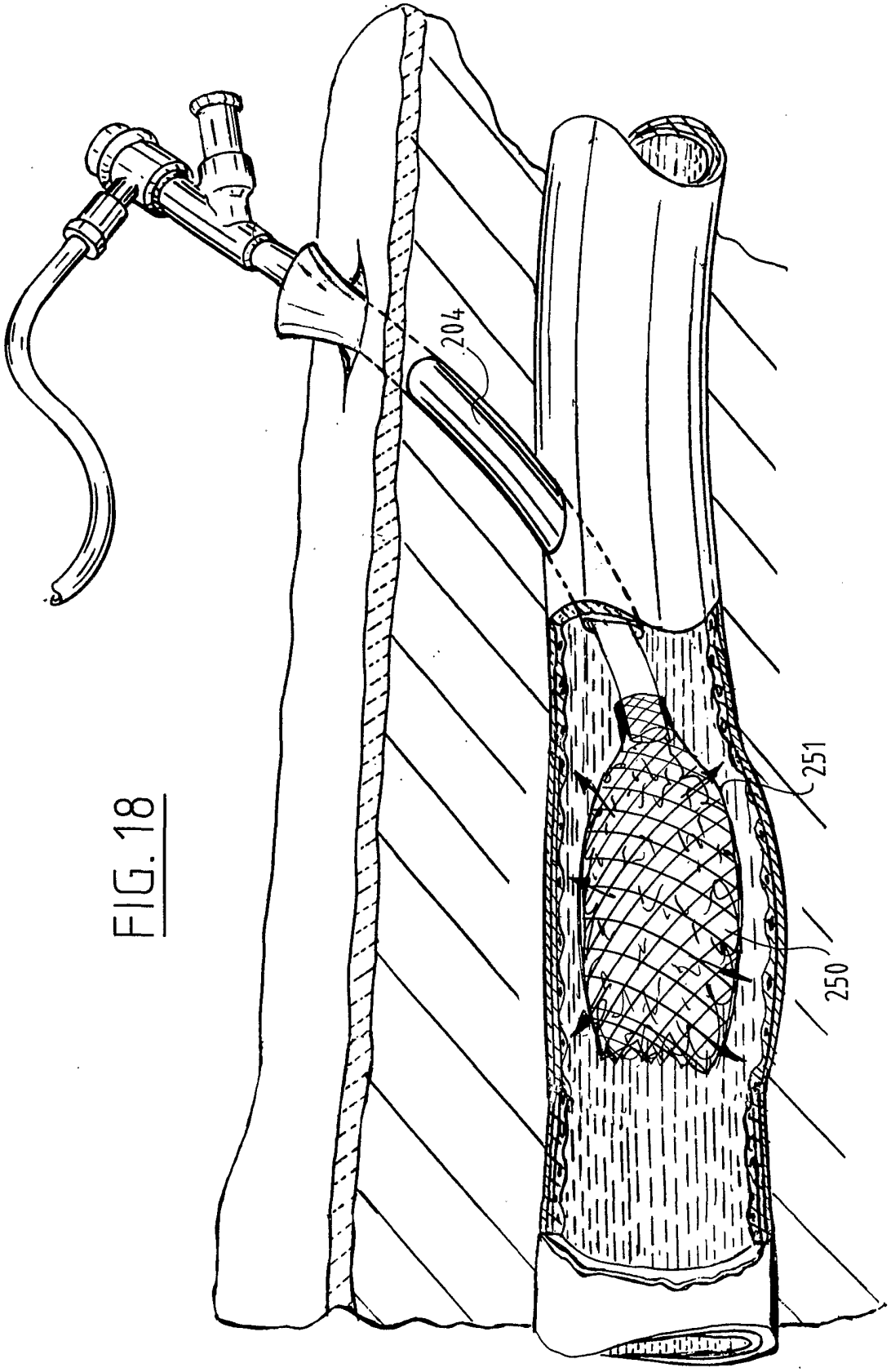


FIG. 18

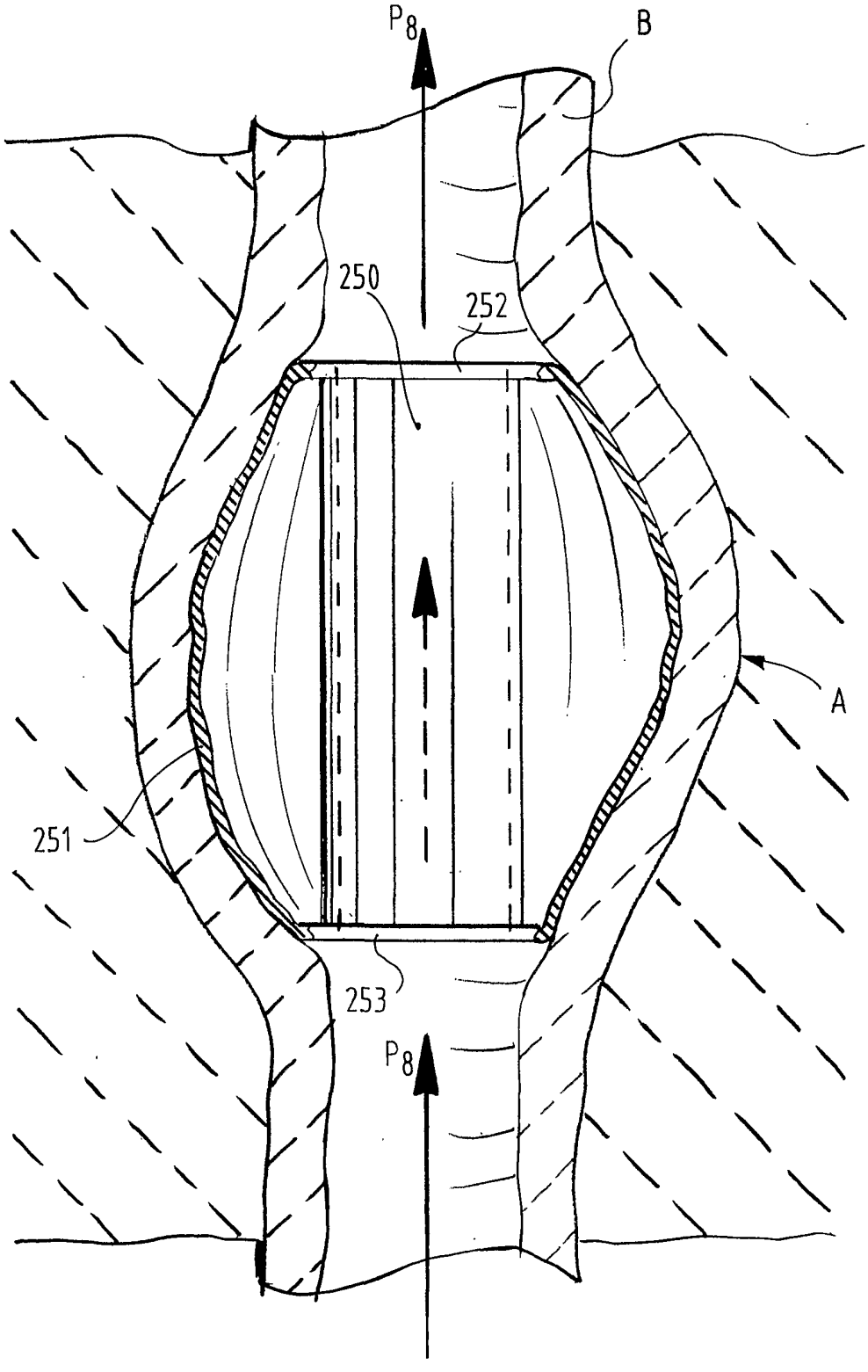


FIG. 19

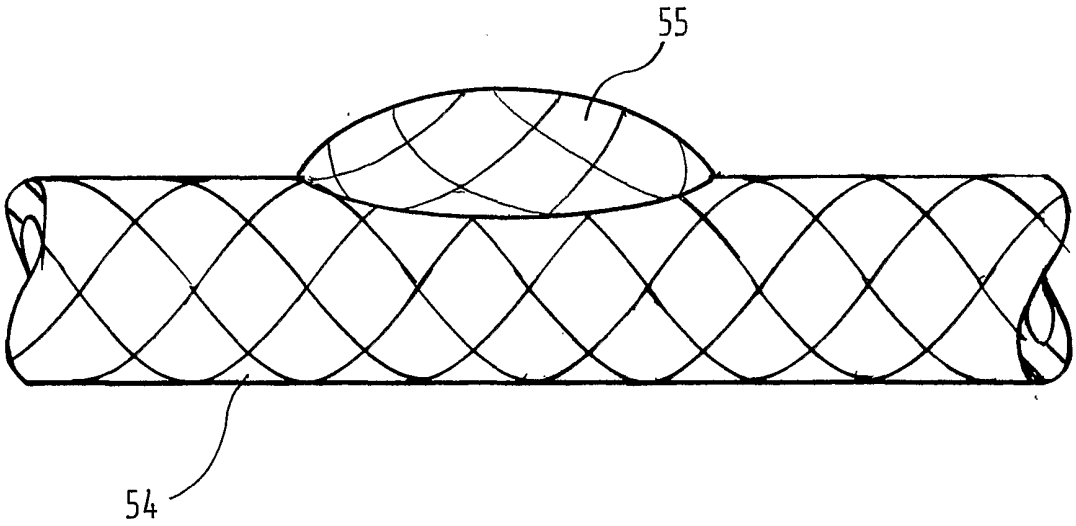


FIG. 20