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CA 2660391 A1 2008/02/21

(21) 2 660 391

(12) DEMANDE DE BREVET CANADIEN
CANADIAN PATENT APPLICATION

(13) A1

(86) Date de dépôt PCT/PCT Filing Date: 2007/08/20
(87) Date publication PCT/PCT Publication Date: 2008/02/21
(85) Entrée phase nationale/National Entry: 2009/02/09
(86) N° demande PCT/PCT Application No.: US 2007/018408
(87) N° publication PCT/PCT Publication No.: 2008/021555
(30) Priorité/Priority: 2006/08/18 (US60/838,964)

(51) Cl.Int./Int.Cl. *A61F 2/84* (2006.01)

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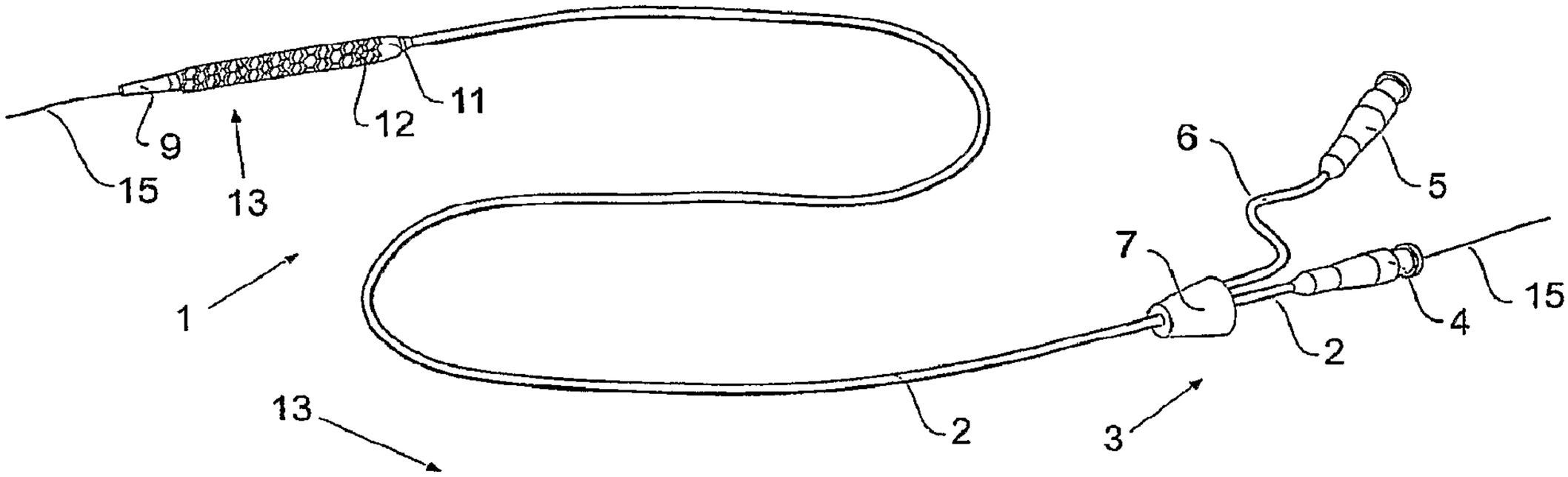
(54) Titre : BALLONNET POUR ELEMENT D'ENDOPROTHESE
(54) Title: BALLOON FOR STENT MEMBER



(57) Abrégé/Abstract:
A balloon expandable stent (12) in its contracted condition is carried on an elongate balloon (10) so that a distal end (11) of the balloon extends beyond the stent, whereby, after deployment of the stent into a side vessel, the end (11) of the balloon is expanded to cause the end of the stent to flare to engage a stent member in a main vessel. The stent (12) and balloon (10) are provided in a balloon catheter having a balloon lumen (16) at a proximal end and a connection arrangement (4) for a source of inflation fluid at a distal end of the balloon catheter. The balloon comprises a compliant or semi-compliant material.

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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
21 February 2008 (21.02.2008)

PCT

(10) International Publication Number
WO 2008/021555 A1

(51) International Patent Classification:
A61F 2/84 (2006.01)

(21) International Application Number:
PCT/US2007/018408

(22) International Filing Date: 20 August 2007 (20.08.2007)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/838,964 18 August 2006 (18.08.2006) US

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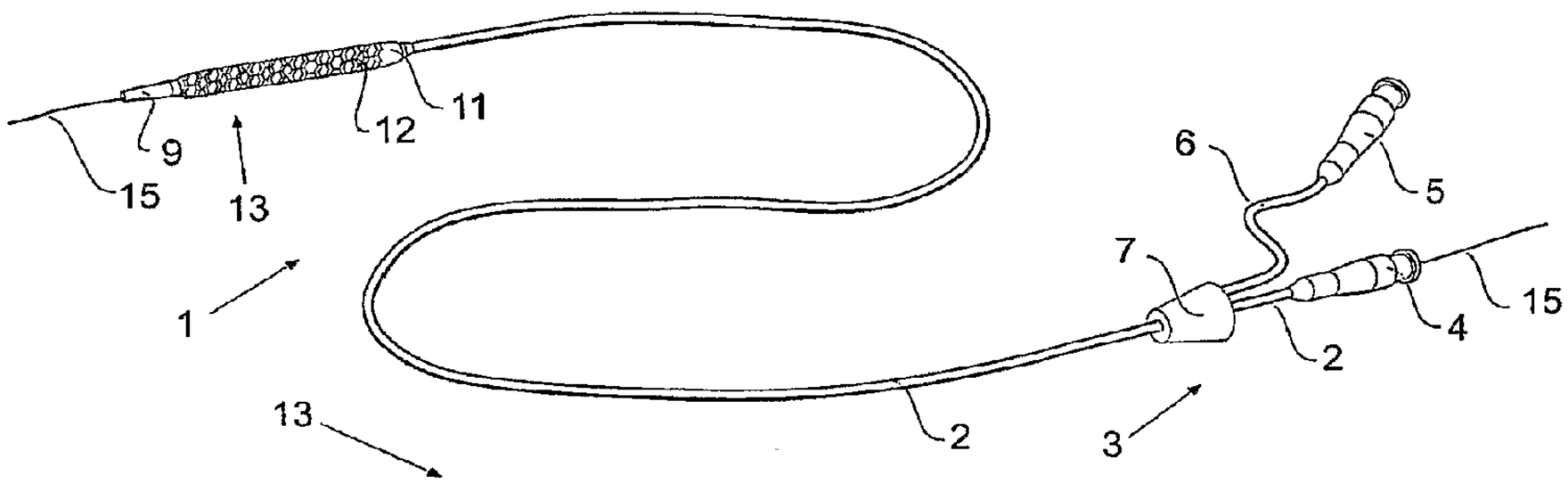
(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, MT, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*
— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

(54) Title: BALLOON FOR STENT MEMBER



(57) **Abstract:** A balloon expandable stent (12) in its contracted condition is carried on an elongate balloon (10) so that a distal end (11) of the balloon extends beyond the stent, whereby, after deployment of the stent into a side vessel, the end (11) of the balloon is expanded to cause the end of the stent to flare to engage a stent member in a main vessel. The stent (12) and balloon (10) are provided in a balloon catheter having a balloon lumen (16) at a proximal end and a connection arrangement (4) for a source of inflation fluid at a distal end of the balloon catheter. The balloon comprises a compliant or semi-compliant material.

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BALLOON FOR STENT MEMBER

Description

Technical Field

This invention relates to the insertion of endovascular stent members, and more particularly to balloon expandable stents. The devices may be used for the placement of branch stents into fenestrated grafts.

Background of the Invention

It is known to place a fenestrated stent graft into the vasculature of a patient and to subsequently place a balloon expandable stent through the fenestration into a branch vessel and to expand the balloon expandable stent in situ to enable a flow path from the lumen of the stent graft into the branch vessel.

US Patent 6,645,242 discloses a bifurcated side-access stent graft in which a balloon catheter may be deployed to expand and hold a stented graft member so as to form a fluid tight seal with a main body vessel.

There have been proposals to subsequently deploy a balloon catheter to flare out a portion of the side branch stent to more firmly lock the branch stent into the fenestration of the stent graft.

Summary of the Invention

For example, WO 2005/034807 discloses an arrangement in which a first balloon is used to expand a portion of a stent against the walls of a side branch artery and a second balloon is used to flare the end of the stent against the inside wall of a main graft. Furthermore, WO 2005/099629 also discloses an arrangement with two balloons which are inflated in separate operations. The balloons may be of different diameters. The flaring balloon can comprise a compliant material and the side branch balloon can comprise a semi-compliant or non-compliant material. The balloons may be separate sections of a "single" balloon.

Operation of the arrangements described in the preceding paragraph is time consuming and aspects of the present invention seek to provide an improved arrangement to simplify the process or to at least provide the practitioner with a useful alternative.

EP 1 475 054 A discloses a combination of an elongate, balloon-expandable stent member and a single elongate balloon arranged therein, the balloon extending throughout substantially all of the stent member and extending beyond at least one end of the stent member.

Throughout this specification the term distal with respect to a portion of the aorta, a deployment device or a prosthesis is the end of the aorta, deployment device or prosthesis further away in the direction of blood flow away from the heart and the term proximal means the portion of the aorta, deployment device or end of the prosthesis nearer to the heart. When applied to other vessels similar terms such as caudal and cranial should be understood.

According to a first aspect of the present invention, there is provided the combination of an elongate, balloon-expandable stent member and a single elongate balloon arranged therein, the balloon extending throughout substantially all of the stent member and extending beyond at least one end of the stent member, characterised in that the material of the balloon where it extends beyond said end is more compliant than the material of the rest of the balloon.

The above arrangement is simpler and cheaper to manufacture and simpler and quicker to deploy.

The balloon preferably extends beyond both ends of the stent member, so that the stent member is firmly held in the side branch artery. It preferably extends further beyond the end of the stent member adjacent the main graft than the other end. It preferably extends beyond the end adjacent the main graft by at least 10% of the length of the stent member, more preferably between 10% and 25% and most preferably between 12% and 15%. This range of lengths enables the protruding portion to bridge any gap between the end of the side branch artery and the main graft and to allow a sufficient length at the end of the stent member to be flared by the balloon to firmly engage the interior of the main graft. The arrangement also allows the portion of the stent member between the end of the side branch artery and the main graft to expand into any remaining space in the main vessel; this assists in holding the stent member in position,

The material of the balloon is preferably of substantially uniform thickness and/or the balloon is of substantially constant size along its length, both when inflated

and non-inflated. Thus a conventional balloon can be employed having a single inlet for inflation, and this involves no additional manufacturing costs

Preferably the balloon is formed from a material which is selected from the group comprising polyurethane, vinyl, latex, silicone rubber or other elastic biocompatible material.

According to a second aspect of the present invention, there is provided a catheter with a combination according to the first aspect at a proximal end thereof, the catheter having a single connection means for a balloon inflation fluid at a distal end thereof and an inflation lumen capable of supplying the inflation fluid to the balloon.

Preferably the catheter includes a guide wire lumen therethrough.

In one embodiment the guide wire lumen may extend from the proximal end of the catheter and exit the catheter intermediate the proximal and distal ends of the catheter such that the catheter can be used with a rapid exchange system.

Preferably the balloon catheter comprises a proximal soft tip to prevent trauma to a vessel during deployment. The proximal tip can be formed from or incorporate a radiopaque material to enable visualisation of the tip of the balloon catheter.

Preferred embodiments of the present invention will now be described, by way of example only, with reference to the accompanying drawings, of which:

Figure 1 depicts a balloon catheter according to one embodiment of the present invention;

Figure 2 shows a detailed view of the balloon portion of the balloon catheter of Figure 1;

Figure 3 shows a longitudinal section view of the embodiment shown in Figure 2;

Figure 4 shows an alternative embodiment of balloon catheter with a rapid exchange system and incorporating a balloon expandable stent according to the present invention;

Figure 5 shows a detailed view of the balloon portion and part of the catheter of the balloon catheter of Figure 4;

Figure 6 shows one view of how a balloon catheter carrying stent graft thereon can be deployed through a fenestration into a renal artery; and

Figure 7 shows a further stage in the deployment process of Figure 6.

Detailed Description

Now looking more closely at the drawing and in particular the embodiment shown in Figures 1 to 3 will be seen that the balloon catheter generally shown as 1 includes a catheter 2 with a distal end 3 which in use remains outside a patient and includes a first female Luer lock connector 4 on the distal end of the catheter 2 and a second female Luer lock connector 5 on a side tube 6 extending from a junction 7 on the catheter 2.

As can be seen in more detail in Figure 2, on a widened part of the proximal portion 13 of the balloon catheter there are provided a balloon 10 and a balloon expandable stent 12 carried on the balloon 10. The expandable stent is in a contracted or compressed condition for deployment. The balloon 10 is of substantially uniform thickness throughout and has substantially the same diameter before inflation along its entire length, except its ends. There is a portion 11 of the balloon 10 which is not covered by the stent 12 at the distal end of the balloon and which is more compliant than the material of the rest of the balloon. When the balloon is expanded (shown in Figure 7) the exposed portion 11 will expand slightly more than the remainder of the balloon which will assist with flaring the end of the stent as discussed below.

5 and the guide wire lumen 8 is in communication with the Luer lock connector 4. Inflation fluid is therefore supplied through the female Luer lock connector 5 and contrast medium to assist with confirmation of placement can be supplied through the Luer lock connector 4 and the guide wire lumen 8.

The tip portion 9 at the proximal end of the balloon catheter 1 terminates in a soft tip 9 to prevent trauma to a vessel during deployment. The proximal tip portion 9 of the balloon catheter is preferably formed from or incorporates a radiopaque material to enable visualisation of the tip of the balloon catheter.

Figures 4 and 5 show an alternative embodiment of balloon catheter according to the present invention.

In this embodiment the balloon catheter 50 has a catheter 58 with a distal end 52 which includes a female Luer lock connector 54. The catheter 58 incorporates a guide wire lumen 60 along part of it length from the proximal end as particularly seen in Figure 5. The guide wire lumen 60 extends completely through the proximal balloon portion 62 but the guide wire lumen exits from the catheter 58 at a point 63 intermediate the proximal and distal ends of the catheter 58 of the so that the proximal portion of the balloon catheter 50 can be deployed over a guide wire 64 as shown schematically in Figure 4. This arrangement is known as a rapid exchange system. A balloon expandable stent 66 is carried on the balloon 68 in a contracted condition for deployment. A portion 69 of the balloon 68 extends beyond the distal end of the balloon expandable stent 66. An inflation lumen 70 in the catheter 58 allows inflation fluids to be supplied through the inflation lumen 70 to a balloon lumen 72 of the balloon 68. The inflation lumen 70 is in fluid communication with the Luer lock connector 54. Inflation fluid is therefore supplied through the female Luer lock connector 54. A further lumen (not shown) and connector may be provided to supply contrast medium to assist with confirmation of placement.

Figure 6 and 7 show various stage in deploying a balloon expandable stent in a fenestration of a stent graft according to one embodiment of the invention.

In this embodiment a main stent graft 30 has been placed into an aorta which has an aorta wall 31 and a renal artery 32 extending from the aorta. The stent graft 30 has been positioned in the aorta such that a fenestration 41 in the wall of the main stent graft 30 opens into the renal artery 32 defined by the artery wall 37. A

guide wire lumen 60 along part of it length from the proximal end as particularly seen in Figure 5. The guide wire lumen 60 extends completely through the proximal balloon portion 62 but the guide wire lumen exits from the catheter 58 at a point 63 intermediate the proximal and distal ends of the catheter 58 of the so that the proximal portion of the balloon catheter 50 can be deployed over a guide wire 64 as shown schematically in Figure 4. This arrangement is known as a rapid exchange system. A balloon expandable stent 66 is carried on the balloon 68 in a contracted condition for deployment. A portion 69 of the balloon 68 extends beyond the distal end of the balloon expandable stent 66 and is more compliant than the rest of the balloon. An inflation lumen 70 in the catheter 58 allows inflation fluids to be supplied through the inflation lumen 70 to a balloon lumen 72 of the balloon 68. The inflation lumen 70 is in fluid communication with the Luer lock connector 54. Inflation fluid is therefore supplied through the female Luer lock connector 54. A further lumen (not shown) and connector may be provided to supply contrast medium to assist with confirmation of placement.

Figure 6 and 7 show various stage in deploying a balloon expandable stent in a fenestration of a stent graft according to one embodiment of the invention.

In this embodiment a main stent graft 30 has been placed into an aorta which has an aorta wall 31 and a renal artery 32 extending from the aorta. The stent graft 30 has been positioned in the aorta such that a fenestration 41 in the wall of the main stent graft 30 opens into the renal artery 32 defined by the artery wall 37. A balloon catheter 36 carrying a balloon expandable stent 34 in a contracted condition thereon according to this embodiment of the invention has been deployed over a guide wire 38 so that the proximal end 39 of the balloon catheter 36 extends through the fenestration 41 into the renal artery 32 and the distal end 40 remains within the main stent graft 30. The balloon 46 of the balloon catheter 36 is then inflated as shown in Figure 7 and this expands the proximal portion 43 of the stent 34 into the renal artery. Simultaneously, the distal portion 48 of the balloon 46 which is less restrained by the stent 34 and the fenestration 41 is expanded to a larger diameter which causes the distal end 44 of the stent 34 to flare out inside the main stent 30 so that the branch

stent 34 is locked into place in the fenestration 41 and extending into the renal artery.

The balloon 46 is then deflated and the balloon catheter 36 is then withdrawn over the guide wire 38 and removed from the patient.

It may be particularly noted in Figure 7 that as the balloon 46 is of a compliant or semi-compliant nature it tends to inflate more where it is less restrained such that the end 44 of the stent 34 is flared out but the adjacent portion 50 of the stent 34 which is just outside the fenestration 41 is also expanded where it is not restrained by the artery wall 37. This gives a very positive locking of the stent 34 into the fenestration.

The above-described embodiments have a number of advantages. In particular, the use of only a single balloon means that assembly of the arrangement is simpler and cheaper. Also, only one inflation path is required. The balloon is of uniform construction, so no special manufacturing techniques are required. In addition, the deployment of the stent member is simpler and quicker because only a single inflation operation is needed. A single balloon simultaneously achieves the desired expansion of the stent in the side branch artery, the flaring of the stent end in the main graft, and also offers the possibility of expanding the stent just outside the fenestration as shown in Figure 7. This last feature is an advantage over WO 2005/099629 in particular, in which any pressure exerted by the flaring balloon at the corresponding location would be taken up by compression of the already-deployed radially-inwardly-disposed side branch balloon.

Various modifications may be made to the above described arrangements. For example, the material of the extending exposed portion 11, 69 of the balloon is arranged to be more compliant than the material of the rest of the balloon by being made of a different material and/or having a lower thickness. For example, the portion 11, 69 may be semi-compliant, with the rest of the balloon being substantially non-compliant.

CLAIMS

1. The combination of an elongate, balloon-expandable stent member and a single elongate balloon arranged therein, the balloon extending throughout substantially all of the stent member and extending beyond at least one end of the stent member, characterised in that the material of the balloon where it extends beyond said end is more compliant than the material of the rest of the balloon.

2. A combination according to claim 1, wherein the balloon extends beyond both ends of the stent member.

3. A combination according to claim 2, wherein the balloon member extends further beyond one end of the stent member than beyond the other end of the stent member.

4. A combination according to any preceding claim, wherein the balloon extends beyond said one end of the stent member by a distance corresponding to at least one tenth of the length of the stent member.

5. A combination according to claim 4, wherein the distance is between 10% and 25% of the length of the stent member.

6. A combination according to claim 5, wherein the distance is between 12% and 15% of the length of the stent member.

7. A combination according to any preceding claim, wherein the material of the balloon is of substantially uniform thickness.

8. A combination according to any preceding claim, wherein, in an uninflated condition, the balloon has a substantially constant diameter along substantially all its length.

9. A combination according to any preceding claim, wherein the balloon is formed from a material which is selected from the group comprising polyurethane, vinyl, latex, silicone, rubber or other elastic biocompatible material.

10. An assembly comprising a balloon catheter with a combination according to any preceding claim at a proximal end thereof, the catheter having a single connection means for a balloon inflation fluid at a distal end thereof and an inflation lumen capable of supplying the inflation fluid to the balloon.

11. An assembly according to claim 10, wherein the catheter includes a guide wire lumen therethrough.

12. An assembly according to claim 11, wherein the guide wire lumen exits the catheter intermediate the proximal and distal ends of the catheter.

13. An assembly according to any of claims 10 to 12, wherein the balloon catheter comprises a proximal soft tip.

14. An assembly according to any of claims 10 to 13, wherein the balloon catheter comprises a proximal tip formed from or incorporating a radiopaque material to enable visualisation of the tip of the balloon catheter.

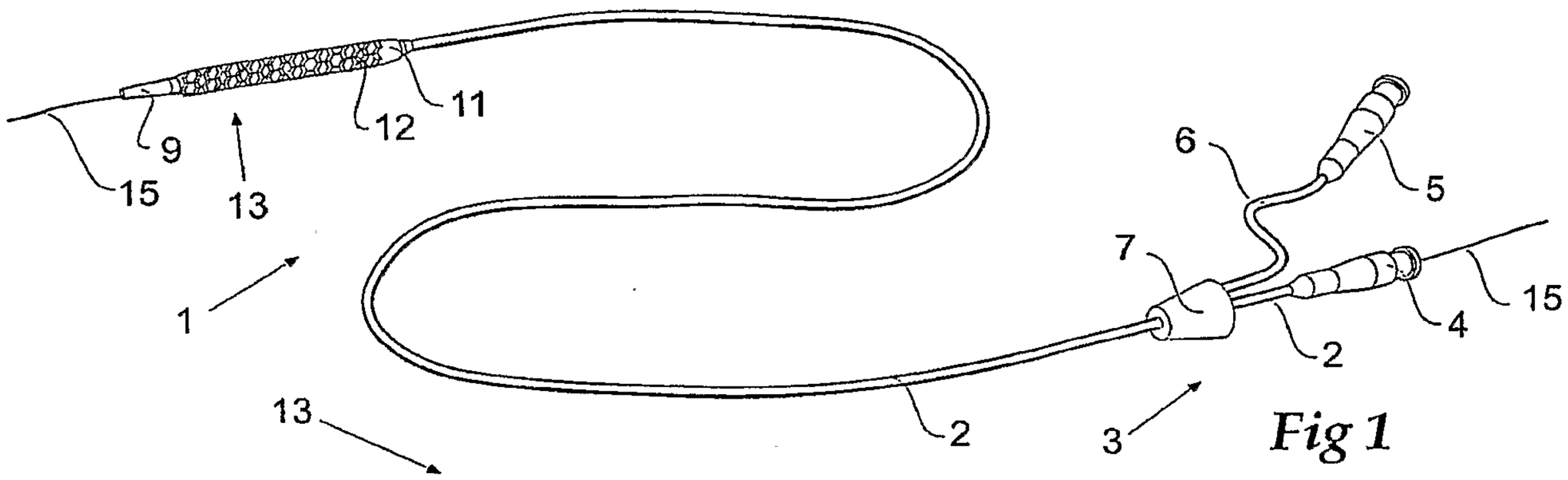

Fig 1

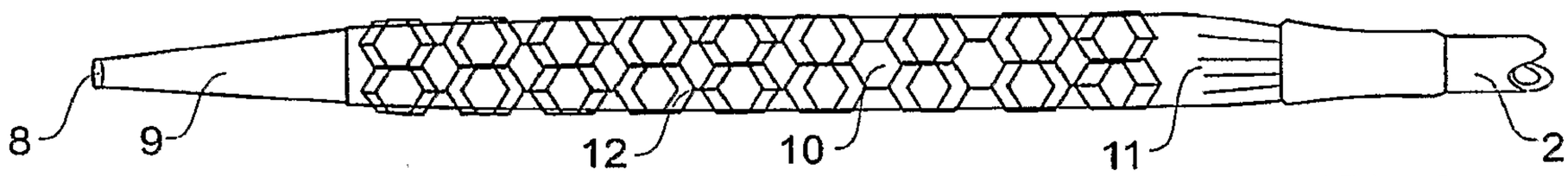

Fig 2

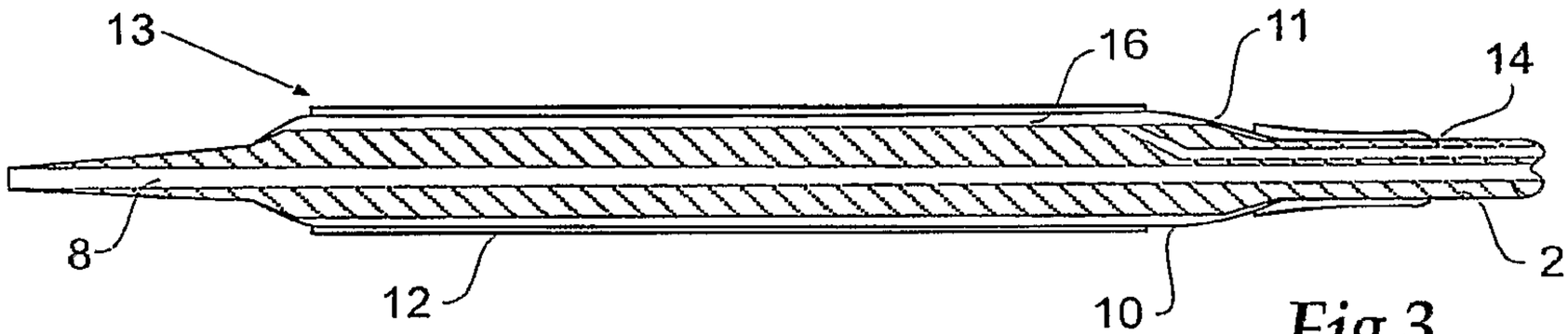

Fig 3

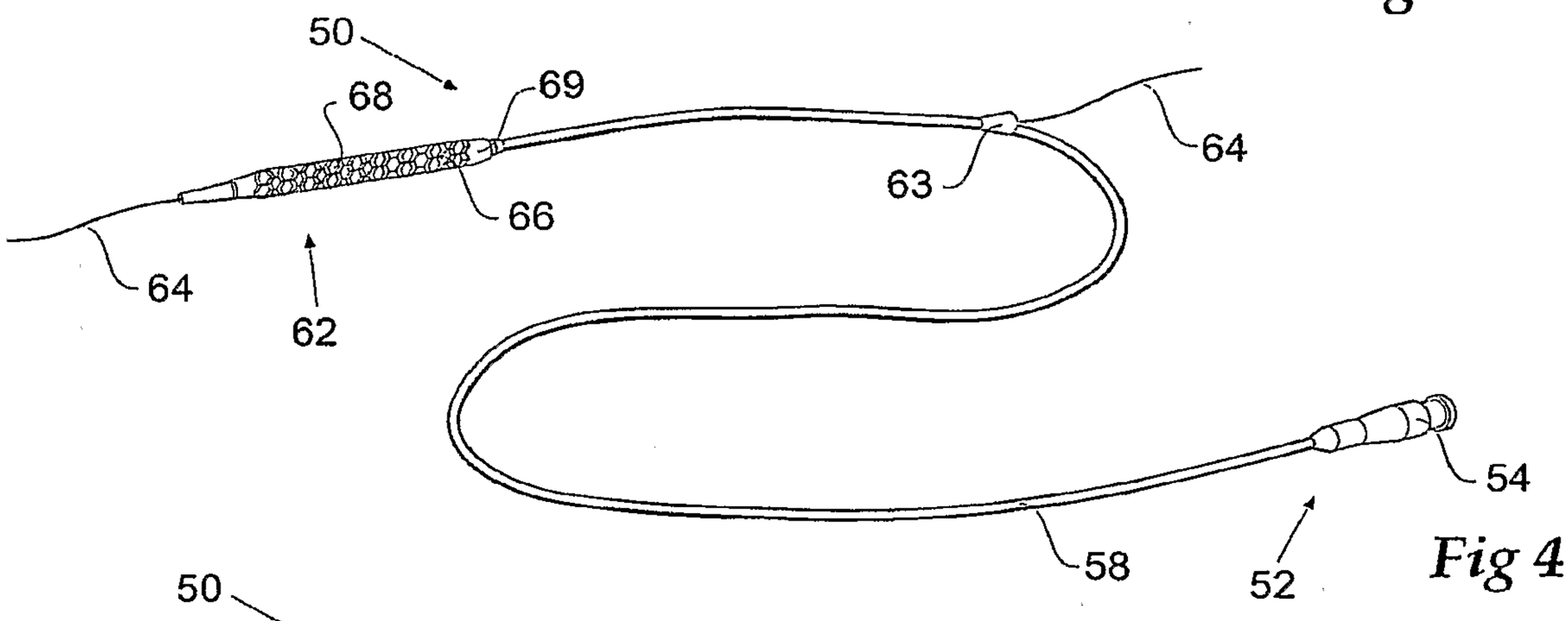

Fig 4

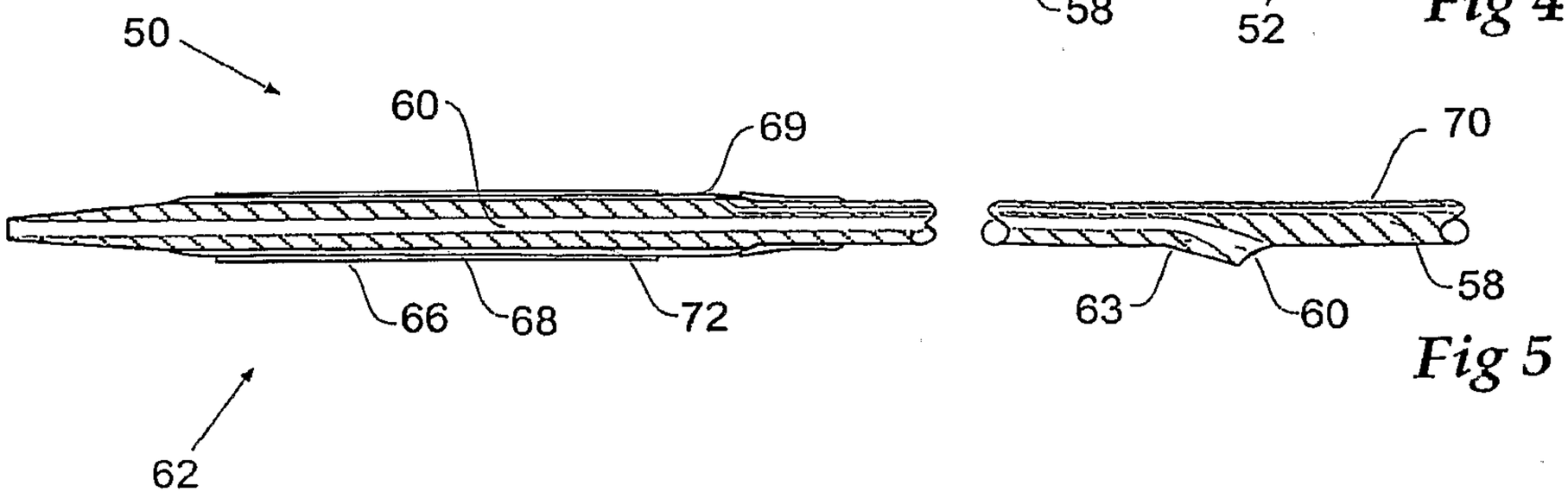

Fig 5

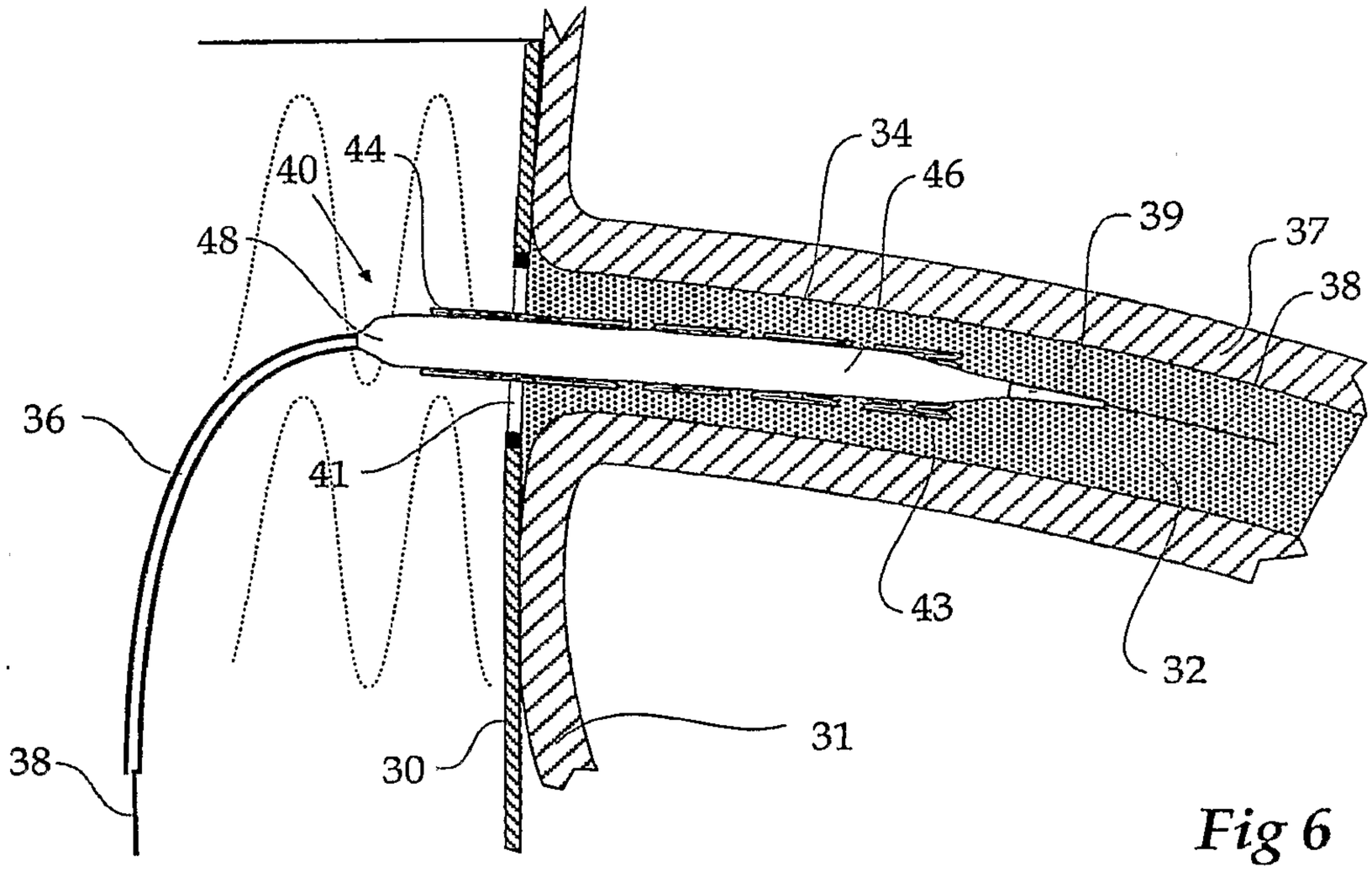
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Fig 6

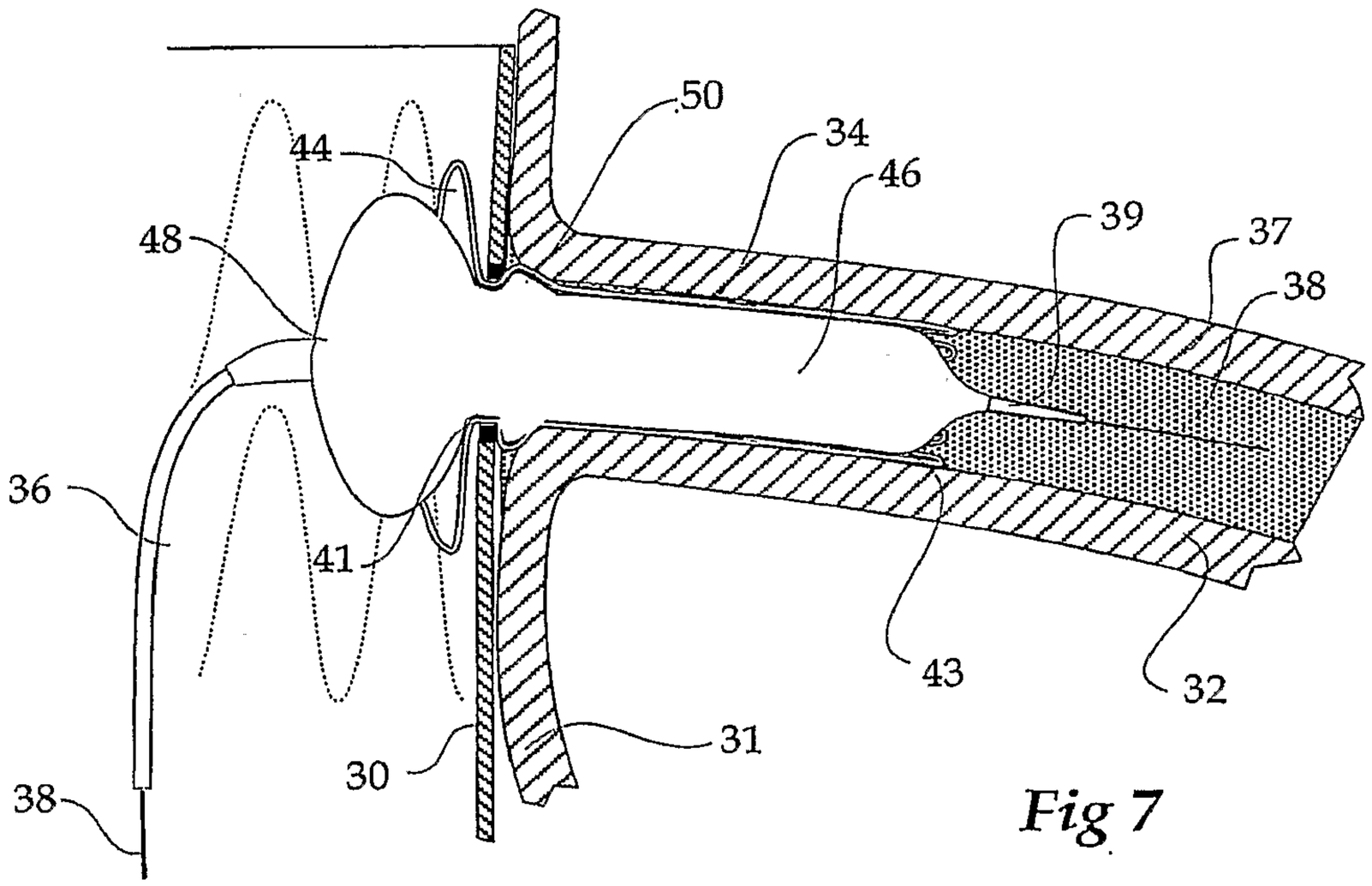
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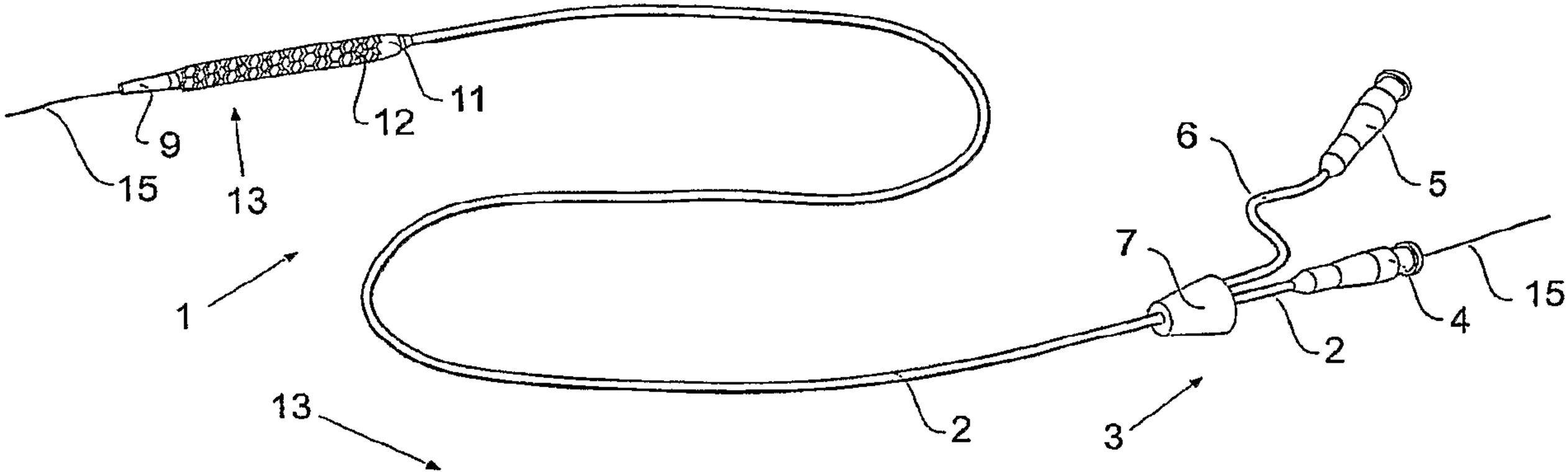
Fig 7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