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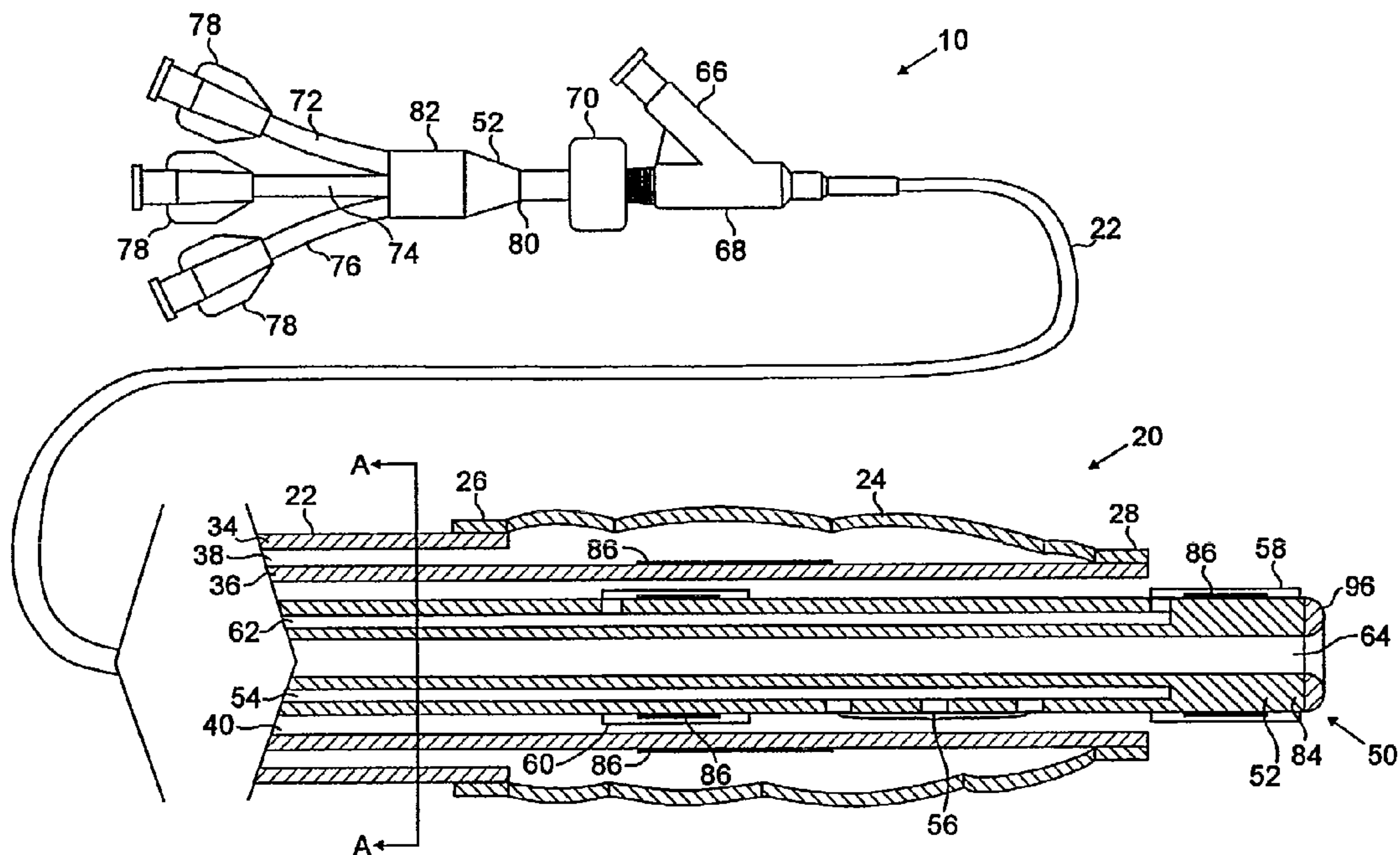
(73) SCHNEIDER (USA) INC., US

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(54) **CATHETER D'APPORT DE MEDICAMENT PAR DILATATION**

(54) **A DILATION-DRUG DELIVERY CATHETER**



(57) Cette invention concerne un cathéter d'apport de médicament par dilatation (10), qui comprend une partie de dilatation (20) servant à dilater une sténose, et une partie d'apport de médicament (50), laquelle sert à libérer à l'endroit de la dilatation un agent antithrombolitique, un agent antiprolifératif ou tout autre type de médicament. La partie d'apport de médicament (50) du cathéter (6) est située à l'intérieur de la partie de dilatation (20), la quelle peut se rétracter pour découvrir ladite partie d'apport de médicament (50), après la dilatation. Des ballons d'occlusion (58, 60) sont de préférence prévus sur la partie d'apport de médicament (50), afin d'isoler l'endroit de la dilatation après la libération du médicament.

(57) A dilation-drug delivery catheter (10) comprises a dilation portion (20) for dilating a stenosis and a drug delivery portion (50) for delivering antithrombolytic, antiproliferative, or any other type of medication, to the dilation site. The drug delivery portion (50) of the catheter (10) is located within the dilation portion (20), which can be retracted to reveal the drug delivery portion (50), after dilation. Occlusion balloons (58, 60) are preferably provided on the drug delivery portion (50) to isolate the dilation site during drug delivery.



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(71) Applicant: SCHNEIDER (USA) INC. [US/US]; 5905 Nathan Lane, Plymouth, MN 55442 (US).

(72) Inventor: FORMAN, Michael, R.; 2026 Pinehurst Avenue, St. Paul, MN 55116 (US).

(74) Agents: SPIEGEL, Allen, J. et al.; Pfizer Inc., Patent Dept., 235 East 42nd Street, New York, NY 10017 (US).

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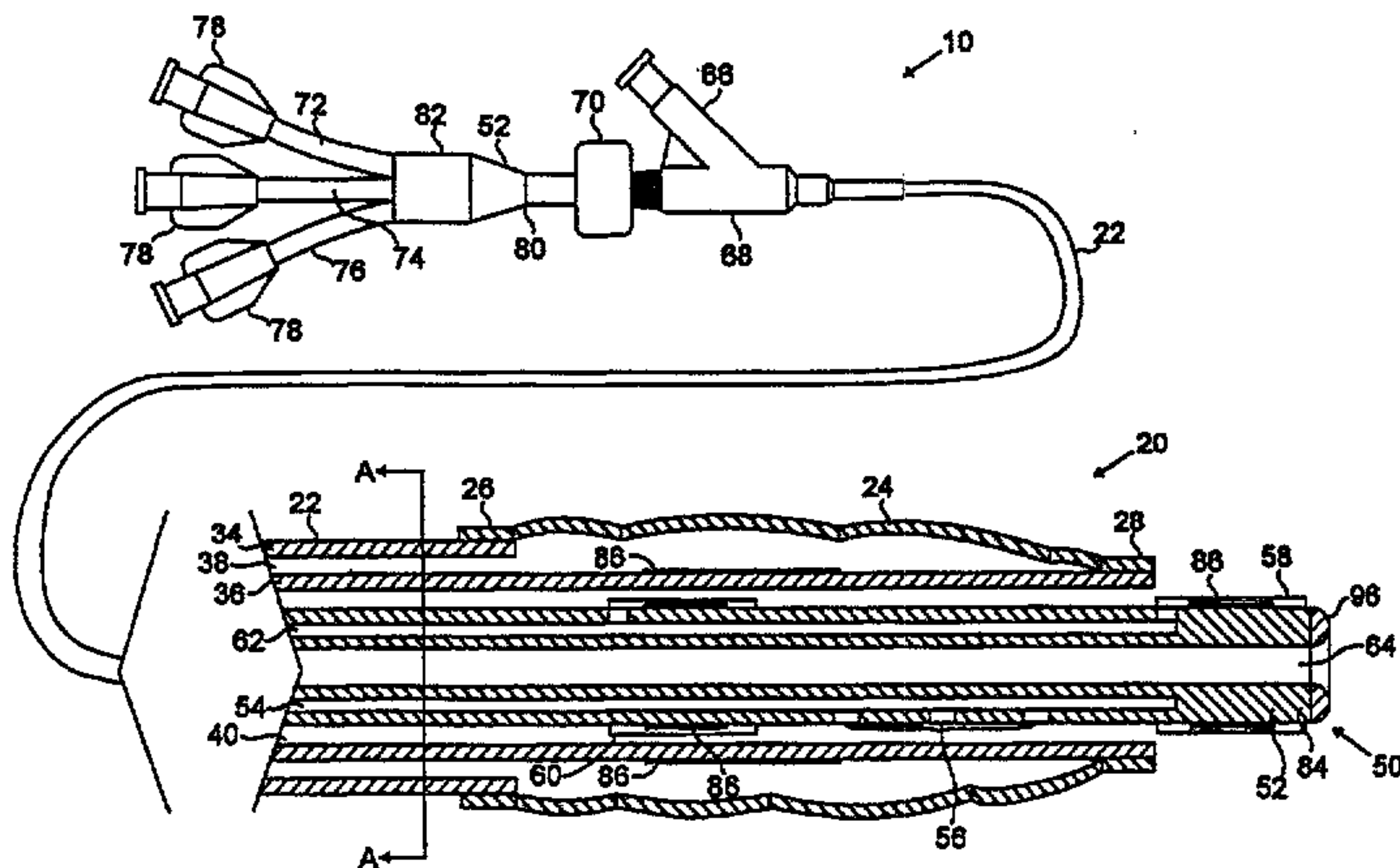
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(54) Title: A DILATION-DRUG DELIVERY CATHETER



(57) Abstract

A dilation-drug delivery catheter (10) comprises a dilation portion (20) for dilating a stenosis and a drug delivery portion (50) for delivering antithrombolytic, antiproliferative, or any other type of medication, to the dilation site. The drug delivery portion (50) of the catheter (10) is located within the dilation portion (20), which can be retracted to reveal the drug delivery portion (50), after dilation. Occlusion balloons (58, 60) are preferably provided on the drug delivery portion (50) to isolate the dilation site during drug delivery.

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A DILATION-DRUG DELIVERY CATHETER

FIELD OF THE INVENTION

A dilation-drug delivery catheter, and, more particularly, a dilation-drug delivery catheter
5 comprising a drug delivery portion within a dilation portion, wherein the dilation portion can be retracted after dilation, revealing the drug delivery portion.

BACKGROUND OF THE INVENTION

10 Percutaneous transluminal angioplasty ("PTA") and percutaneous transluminal coronary angioplasty ("PTCA"), wherein a dilation balloon is advanced through the vascular system to a stenosis and inflated to open the blockage, is now a commonplace
15 procedure. In about one-third of the cases, however, the procedure leads to restenosis that can require another dilation procedure. It is estimated that the total cost of restenosis requiring an additional dilation procedure or some other treatment, is over 2
20 billion dollars per year worldwide.

Various agents that may reduce restenosis can be applied to the dilation site. For example, antithrombolytic agents such as heparin may prevent clotting. Antiproliferative agents, such as
25 dexamethasone, can prevent smooth muscle cell migration and proliferation.

Various methods have been proposed to effectively deliver such agents to the dilation site. For example, in U.S. Patent No. 5,087,244, to
30 Wolinsky, a catheter is disclosed having a thin walled flexible balloon with a plurality of small holes. After an angioplastic procedure, such a balloon can be advanced to the dilation site and inflated with heparin, or some other medication. The

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medication exits the inflated balloon, which is in contact with the arterial wall, through the holes. Such "weeping" balloons may damage the arterial wall, however. In addition, having to insert a second catheter for drug delivery after removal of the
5 dilation catheter is cumbersome and time consuming. It can also be difficult to precisely locate the dilation site after the dilation catheter is removed.

It is, therefore advantageous to provide a catheter which can both dilate the stenosis and immediately thereafter
10 deliver drugs directly to the dilation site. U.S. Patent Nos. 4,824,436 and 4,636,195, also to Wolinsky, disclose a catheter with a dilation balloon and a pair of occlusion balloons proximal and distal to the dilation balloon. A drug delivery conduit is provided between the distal occlusion balloon and
15 the dilation balloon. After dilation of the stenosis, the dilation balloon is deflated, the occlusion balloons are inflated and a drug is delivered. Because of the presence of the dilation balloon, there is only a small region available for drug delivery. Drug delivery may, therefore, be slow and
20 of too low volume to be effective.

SUMMARY OF THE INVENTION

The present invention provides a dilation-drug delivery catheter comprising: a dilation portion comprising an outer catheter shaft, a dilation balloon attached to the outer
25 catheter shaft, the outer catheter shaft comprising a dilation lumen for providing inflation fluid to the dilation balloon and a central lumen; and a drug delivery portion located at least in part within the central lumen, the drug delivery portion comprising an inner catheter shaft having at least one drug
30 delivery port and defining a drug delivery lumen for providing a drug to the drug delivery port, the drug delivery port being located in a portion of the inner catheter shaft lying within

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the central lumen, wherein the dilation portion can move with respect to the drug delivery portion such that the dilation portion can be retracted from the distal end of the drug delivery portion, revealing the drug delivery port, the drug
5 delivery portion further comprising: a first occlusion balloon distal to the drug delivery port; an inflation lumen in fluid communication with the first occlusion balloon; and a second occlusion balloon proximal to the drug delivery port; wherein the dilation portion can be retracted to reveal the first
10 occlusion balloon.

The occlusion balloons maintain the delivered drug in proximity with the dilation site. The same inflation lumen can be in fluid communication with the first and second balloons.

A plurality of drug delivery ports are preferably
15 provided, as are perfusion means for allowing blood to flow through the dilation-drug delivery catheter, beyond the occlusion balloon.

The invention also provides a dilation-drug delivery catheter comprising a dilation portion comprising a dilation
20 balloon and a drug delivery portion having a distal end, wherein the portions can be moved with respect to each other, the catheter having a dilation position, wherein the distal end of the drug delivery portion is located at least in part within the dilation portion, and a drug delivery position, wherein the
25 dilation portion is retracted to reveal the distal end of the drug delivery portion; and wherein the dilation portion further comprises a dilation lumen for providing dilation fluid to the dilation balloon and a central lumen, wherein the drug delivery portion is located at least in part, within the central lumen
30 and wherein the drug delivery portion comprises a catheter shaft comprising an inflation lumen and a drug delivery lumen; and the distal end of the drug delivery portion comprises a

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pair of occlusion balloons in fluid communication with the inflation lumen and a plurality of drug delivery ports between the occlusion balloons, the drug delivery ports being in fluid communication with the drug delivery lumen, wherein, in the
5 drug delivery position, the dilation portion is retracted to reveal the occlusion balloons and the drug delivery ports.

The invention further provides a dilation-drug delivery catheter comprising: an outer catheter shaft, a dilation balloon bonded to the catheter shaft, the catheter
10 shaft having an outer wall and an inner wall defining a lumen for providing dilation fluid to the dilation balloon, the inner wall further defining a central lumen, an inner catheter shaft comprising a pair of occlusion balloons at its proximal end, a lumen in fluid communication with the occlusion balloons to
15 provide inflation fluid to the occlusion balloons, a plurality of drug delivery ports between the occlusion balloons, a lumen in fluid communication with the drug delivery ports to provide drugs to the ports, and a guide wire lumen, wherein at least a portion of the distal end of the inner catheter shaft lies
20 within the central lumen, and the outer catheter shaft can be moved with respect to the inner catheter shaft to reveal the distal end of the inner catheter shaft.

Preferably, the drug delivery ports lie within the central lumen prior to the outer catheter shaft being
25 retracted.

DESCRIPTION OF THE DRAWINGS

FIG. 1 is a view of a dilation-drug delivery catheter in accordance with the present invention, wherein the distal portion of the catheter is shown enlarged and in cross-section,
30 in the dilation position of the catheter;

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FIG. 2 is a cross-sectional view of the distal portion of the catheter of FIG. 1, wherein a dilation balloon is shown inflated;

FIG. 3 is a cross-sectional view of the distal portion of the catheter of FIG. 1, along line AA of FIG. 1;

FIG. 4 is a cross-sectional view of the distal portion of the catheter of FIG. 1, with its dilation portion retracted, showing the drug delivery position of the catheter; and

FIG. 5 is a side view of the distal portion of the catheter of FIG. 1, wherein two occlusion balloons are inflated.

DESCRIPTION OF THE INVENTION

FIG. 1 is a view of a dilation-drug delivery catheter 10 in accordance with the present invention, wherein the distal portion of the catheter 10 is shown enlarged and in cross-section. The dilation-drug delivery catheter 10 comprises a dilation portion 20 and a drug delivery portion 50. The dilation portion 20 comprises a dilation balloon 24 bonded to an outer catheter shaft 22 at sites 26 and 28. In FIGS. 1-2, the catheter 10 is shown in its dilation position. In FIG. 1, the dilation balloon 24 is deflated, while in FIG. 2, a cross-sectional view of the distal portion of the dilation-drug delivery catheter 10 of FIG. 1, the dilation balloon 24 is shown inflated.

The outer catheter shaft 22 has an outer wall 34 and an inner wall 36 which define a dilation lumen 38 for providing dilation fluid to the dilation balloon 22. The inner wall 36 also defines a central lumen 40 for receiving the drug delivery portion 50. FIG. 3 is a cross-sectional view of the dilation-drug

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delivery catheter 10, through line A-A of FIG. 1, showing the outer wall 34, inner wall 36, the dilation lumen 38 and the central lumen 40.

The drug delivery portion 50 of the catheter 10 comprises an inner catheter shaft 52, whose distal end is located at least in part within the second lumen 40. The inner catheter shaft 52 includes a drug delivery lumen 54, which communicates with the exterior of the shaft 52 through drug delivery ports 56. There are preferably between 2-20 circular or oval shaped ports 56 with a diameter or length, respectively, of between about 0.003-0.020 inches. Three drug delivery ports 56 are provided in this embodiment. A plurality of such ports are preferably provided to ensure the delivery of adequate drug to the dilation site. The drug delivery ports 56 preferably lie within the central lumen 40 during dilation. FIG. 3 shows that the drug delivery lumen 54 is preferably semi-circular.

Returning to FIGS. 1-2, a distal occlusion balloon 58 and a proximal occlusion balloon 60 are preferably provided to isolate the dilation site during drug delivery. The occlusion balloons 58, 60 are shown inflated in the side view of Fig. 5. The occlusion balloons 58, 60 maintain the drug in proximity with the portion of the arterial wall which has been dilated, improving the absorption and efficacy of the drug. An inflation lumen 62 in the inner catheter shaft 52 is provided to convey inflation fluid to the occlusion balloons 58, 60. The inner catheter shaft 52 also typically includes a guide wire lumen 64. The inflation lumen 62 and guide wire lumen 64 are shown in cross-section in Fig. 3. The inflation lumen 62 is also preferably

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semi-circular and in the same radial plane as the drug delivery lumen 54. To deliver an adequate amount of drug in the time allowed, the drug delivery lumen 54 will generally need to be larger than the inflation lumen 62. In the embodiment illustrated, the portion of the inner catheter shaft 52 including the distal occlusion balloon 58 extends beyond the distal tip of the dilation portion 20 while the catheter is in its dilation position. The distal occlusion balloon 58 can lie within the second lumen 40 in the dilation position, as well.

In FIGS. 4 and 5, the dilation-drug delivery catheter 10 of the present invention is shown in its drug delivery position. In FIG. 4, the dilation portion 20 is shown retracted to fully reveal the distal end of the drug delivery portion 50 of the catheter 10, which comprises the occlusion balloons 58, 60, and the drug delivery ports 56. FIG. 5 is a side view of the catheter 10, showing the occlusion balloons 58, 60, inflated as they would be immediately prior to and during drug delivery. The present invention enables a plurality of drug delivery ports 56 to be provided between the occlusion balloons 58, 60, better ensuring the delivery of an adequate quantity of drug. Perfusion openings 88 are preferably provided through the walls of the inner catheter shaft 52 to the guide wire lumen 64 as shown in FIG. 5, to provide a path for blood to flow beyond the occluded site. There are preferably between 2-20 circular or oval perfusion openings 88 with a diameter or length, respectively, of between about 0.003-0.020 inches. Three perfusion openings 88 are provided in this embodiment.

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Returning to FIG. 1, the proximal end of the catheter 10 includes a Y-adaptor 68 including a port 66, as is known in the art. A tube (not shown) is connected to the dilation lumen 38 of the outer catheter shaft 22 and extends through the port 66. The outer catheter shaft ends within the Y-adaptor 68, proximate the base of the port 66. A syringe can be used to supply the dilation fluid through the port 66 into the dilation lumen 38, also as is known in the art. A Tuohy-Borst adapter 70 is threaded on the central port of the Y-adaptor 68. The inner catheter shaft 52 extends through the Y-adaptor 68 and Tuohy-Borst adapter 70. In this embodiment, three tubes 72, 74, and 76 are connected to the drug delivery lumen 54, inflation lumen 62 and guide wire lumen 64, respectively, of the inner catheter shaft 52. Hubs 78 are connected to each tube. The guide wire can be inserted into the guide wire lumen 64, through tube 76. Syringes can also be used to supply inflation fluid for the occlusion balloons 58, 60 and any desired drug through tubes 74 and 72, respectively.

The outer diameter of the catheter 10 and the deflated dilation balloon 24 is preferably no greater than about 0.042-0.050 inches, so that it can be used with a 7 or 8 French guiding catheter. To accommodate the tubes 72, 74, 76, the portion of the inner catheter shaft 52 which extends out of the Tuohy-Borst adapter 68 flares to an outer diameter of about 0.200 inches at about point 80. The tubes 72, 74, 76, are held together by a heat shrink tubing 82.

The distal end 84 of the inner catheter shaft 52 preferably includes a resilient tip 96 which comprises a material softer than that of the inner catheter shaft 22. The tip 96 spreads or bends when

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it contacts body tissue, easing the catheter's passage through the vascular system and helping to avoid tissue damage. The tip 96 can be made of ultra low density polyethylene 4603 from Dow Chemical Corporation, which has a melt flow rate at 190°C (ASTM D-1238) of 0.7-0.9 g/10 min. and a density (ASTM D-792) of 0.9030-0.9070 g/cc. The tip 96 can also be a nylon, such as PEBA 25D from Elf Atochem Deutschland GmbH, which has an ultimate tensile strength (ASTM D-638) of 4950 psi min., an ultimate elongation (ASTM-638) of 640% min., a flexural modulus (ASTM D-790) of 2100 psi min., a Durometer (ASTM D-2240) of 25D $\pm$ 4D, and a melting point (ASTM D-3418) of 142°-153°C. The tip 96 can be connected to the inner catheter shaft 22 by an adhesive or thermal bonding.

Radiopaque markers 86 of gold or tantalum, for example, are also preferably provided on the inner catheter shaft 52 within the occlusion balloons 58, 60, and on the outer catheter shaft 22 within the dilation balloon 24, as shown, to assist in monitoring the position of the catheter on a fluoroscope during a PTA or PTCA procedure, as is known in the art. The inner catheter shaft 52 and occlusion balloons 58, 60, are preferably coated with a lubricous material, such as silicone, acrylicimide, or a hydrophilic polyurethane coating, to ease retraction of the dilation portion 20 after dilation. The outer catheter shaft 22 and dilation balloon 24 can be similarly coated to ease its advance through a guiding catheter and a lesion, as is known in the art.

The inner and outer catheter shafts can be of any material suitable for catheters, such as linear

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low density or high density polyethylene, nylon, polyurethane, polypropylene, silicone rubber, or other non-thrombogenic materials. A linear low density polyethylene which can be used for the outer catheter shaft 22 is Dowlex 2038 from Dow Chemical Company, which has a melt flow rate at 190°C (ASTM D-1238) of 0.85-1.15 g/10 min. and a density (ASTM D-792) of 0.9330-0.9370 g/cc. A high density polyethylene which can be used for the outer catheter shaft 22 is LB 8320-00 from Quantum Chemical Corporation, which has a melt flow rate at 190°C (ASTM D-1238) of 0.20-0.36 g/10 min. and a density (D-1505) of 0.9566 g/cc min.

A nylon which can be used for the inner or outer catheter shafts 22, 52 is nylon 12, such as L2101F Vestamed from Hüls America Inc., which has a relative viscosity (ISO 307) of 2.05-2.22 and a water content (ASTM D-4019) of 0.10 maximum. Another nylon which can be used is PEBA 70D from Elf Atochem, which has an ultimate tensile strength (ASTM D-638) of 8300 psi min., an ultimate elongation (ASTM D-638) of 400% min., a flexural modulus (ASTM D-790) of 67,000 psi min., a Durometer (D-2240) of 69D $\pm$ 4D and a melting point (ASTM D-3418) of 160°-180°C.

A high density polyethylene which can be used for the inner catheter shaft 52 is LM6007 from Quantum Chemical Corporation, which has the following characteristics:

30	Ultimate Tensile Strength (ASTM D-638)	4400 psi min.
	Ultimate Elongation % at break (ASTM D-638)	600% min.
	Durometer D Scale (ASTM D-2240)	68 $\pm$ 4.5

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	Melt Flow Rate at 240°C 2160g (ASTM D-1238)	0.070 (REF)
5	Flexural Modulus at Room Temperature (ASTM D-790, Procedure B)	220,000 psi min.
	Vicat Softening Point °C (ASTM D-1525)	125°C (REF)

The outer catheter shaft 22 and inner catheter
10 shaft 52 are extruded separately. To form the flared
portion of the inner catheter shaft 52, a bump
extrusion process can be used, as is known in the
art. After extrusion of the inner catheter shaft 52,
the tubes 72, 74 and 76 are inserted into the shaft's
15 wider portion and thermally bonded in place. An
adhesive can be used, as well. A tube (not shown) is
inserted and similarly bonded to the dilation lumen
38 of the outer catheter shaft 22. That tube extends
through the port 66 of the Tuohy-Borst adaptor 70.
20 After formation of the inner catheter shaft 52,
the perfusion openings 88 and drug delivery ports 56
are made. Passages through the shaft 52 to the
inflation lumen 62 proximate the intended location of
the occlusion balloons, are also made. The
25 radiopaque markers 86 are added to the inner and
outer catheter shafts, as well. All these procedures
are known in the art.

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The dilation balloon 24 can be of any type and size appropriate for PTA and PTCA procedures. For example, the balloon 22 can be of polyethylene, polyethylene terephthalate, nylon, polyurethane or any other material suitable for a dilation balloon. The balloon 24 can be compliant, non-compliant or semi-compliant. The dilation balloon 24 can be attached to the outer catheter shaft 22 through thermal bonding, including laser bonding or ultrasonic bonding, or with an adhesive, as is known in the art. An apparatus and process for laser bonding angioplasty balloon catheters is disclosed in U. S. Patent No. 5,267,959 which was filed on November 29, 1991 by the inventor of the present invention and is assigned to the assignee of the present invention. The balloon 22 is preferably of the same or compatible material as the catheter shaft 28 to enable thermal bonding.

A low density polyethylene which can be used for the dilation balloon 24 is P. E. 1031 from Rexene Corporation, which has a melt flow rate at $190 \pm 0.2^\circ\text{C}$ (ASTM D-1238) of 0.4-1.4 g/10 min., a density (ASTM D-1505) of 0.93 ± 0.02 g/cc and a melt point (ASTM D-3417, D-3418) of $104-140^\circ\text{C}$. A linear low density polyethylene which can be used is Dowlex 2247A LLDPE from Dow Chemical Corporation, which has a melt index at $190^\circ\text{C}/2.16$ kg (ASTM D-1238) of 2.0-2.6 g/10 min., a density (ASTM D-1505) of 0.9150-0.9190 g/cc, and a melt point (D-3417, D-3418 (REF)) of $122-125^\circ\text{C}$.

The occlusion balloons 58, 60 can be nylon, polyamide copolymer, polyethylene, polyethylene terephthalate,

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polyurethane, Kraton (Trade-mark), silicone, latex or any other soft, non-thrombogenic material which will seal against, but not expand, the arterial wall when inflated. The balloons can be tubes which expand on inflation or blow molded balloons.

5 If the balloon material is compatible with the inner catheter shaft 52, the occlusion balloons 58, 60 can be attached by the thermal bonding techniques discussed above. If not, an adhesive may be used. A nylon which can be used for the occlusion balloons 58, 60 is L25 G Grilamid from EMS-Chemie
10 AG, which has a melting point of 178°C, a density (DIN 53479) of 1.01 kg/dm³, a tensile strength (DIN 53455) of 40 N/mm², an elongation at yield (DIN 53455) of 10% and a Shore D hardness (DIN 53505) of 72.

The dilation-drug delivery catheter 10 of the
15 present invention can be introduced into the vascular system and advanced to the site of the stenosis by a guiding catheter, as would an ordinary dilation catheter. After a guide wire is advanced through the stenosis, the catheter 10 is advanced from the guiding catheter, over the guide wire, through the
20 stenosis. Dilation fluid is injected with a syringe through the port 66 of the Y-adapter 68, to the dilation lumen 38, to dilate the balloon 24 as shown in FIG. 2, opening the stenosis, as would an ordinary dilation catheter. After the stenosis is opened, the dilation balloon 24 is deflated and the dilation
25 portion 20 of the catheter 10 is retracted far enough to reveal the drug delivery ports 56, the proximal occlusion balloon 60 and the perfusion openings 88, if present, putting the catheter

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into the drug delivery position of FIG. 3. The dilation portion can be retracted by loosening the Tuohy-Borst adapter 70 and withdrawing the outer catheter 22 a suitable distance. After the dilation portion 20 is retracted, the Tuohy-Borst adapter is tightened.

If the perfusion openings 88 are present, the guide wire is also preferably retracted to a position proximal to the perfusion openings 88 to allow blood to flow through the inner catheter shaft 52. If active perfusion is required, the guide wire can be completely removed and blood or perfluorochemicals such as Fluosol[®] can be injected with a syringe through tube 76, as is known in the art.

Inflation fluid is then injected with a syringe through the tube 74 to inflate the distal and proximal occlusion balloons 58, 60, until the occlusion balloons meet and seal the arterial wall, isolating the dilated region. Antithrombolytic, antiproliferative, or any other type of drug can now be injected through tube 72, drug deliver lumen 54

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and drug delivery ports 56, via a syringe, to the dilation site.

After the drug has been applied at the desired pressure and for the desired length of time (typically
5 from about 20 seconds to 3 minutes), the occlusion balloons are deflated and the dilation-drug delivery catheter 10 is withdrawn from the blood vessel. One drug formulation which may be promising is dexamethasone absorbed in poly-lactic/poly-glycolic particles with
10 diameters substantially less than 100 microns. Such particles can adhere to or penetrate the arterial wall. The surface of the particles can be treated with cell adhesion proteins and peptides based peptides to improve the adhesion of the particles with the arterial wall.
15 An arginine glycine aspartic acid based peptide which can be used is Teptite 2000® from Telios Pharmaceuticals, Inc.

The dilation-drug delivery catheter of the present invention provides a single catheter which can perform
20 dual functions, saving time and enabling delivery of drug directly to the dilation site.

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CLAIMS:

1. A dilation-drug delivery catheter (10) comprising:

a dilation portion (20) comprising an outer catheter shaft (22), a dilation balloon (24) attached to the outer catheter shaft (22), the outer catheter shaft (22) comprising a
5 dilation lumen (38) for providing inflation fluid to the dilation balloon (24) and a central lumen (40); and

a drug delivery portion (50) located at least in part within the central lumen (40), the drug delivery portion (50)
10 comprising an inner catheter shaft (52) having at least one drug delivery port (56) and defining a drug delivery lumen (54) for providing a drug to the drug delivery port (56), the drug delivery port (56) being located in a portion of the inner catheter shaft (52) lying within the central lumen (40),

15 wherein the dilation portion (20) can move with respect to the drug delivery portion (50) such that the dilation portion (20) can be retracted from the distal end of the drug delivery portion (50), revealing the drug delivery port (56),

20 the drug delivery portion (50) further comprising:

a first occlusion balloon (58) distal to the drug delivery port;

an inflation lumen (62) in fluid communication with the first occlusion balloon (58); and

25 a second occlusion balloon (60) proximal to the drug delivery port (56);

wherein the dilation portion (20) can be retracted to reveal the first occlusion balloon (58).

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2. The dilation-drug delivery catheter (10) of claim 1, wherein the inflation lumen (62) is in fluid communication with the first (58) and second (60) occlusion balloons.

3. The dilation-drug delivery catheter (10) of claim 1
5 or claim 2 wherein there are a plurality of drug delivery ports (56), at least some of which lie within the central lumen (40) prior to the drug delivery portion (50) being retracted.

4. The dilation-drug delivery catheter (10) of any one of claims 1 to 3 further comprising a lubricious layer between
10 a wall of the central lumen (40) and the inner catheter shaft (52).

5. The dilation-drug delivery catheter (10) of any one of claims 1 to 4 wherein the occlusion balloons (58, 60) comprise inflatable plastic tubes.

15 6. The dilation-drug delivery catheter (10) of any one of claims 1 to 5 wherein the occlusion balloons (58, 60) are blow molded.

7. The dilation-drug delivery catheter (10) of any one of claims 1 to 6 further comprising perfusion means for
20 allowing blood to flow through the dilation-drug delivery catheter (10), beyond the occlusion balloon (58).

8. The dilation-drug delivery catheter (10) of any one of claims 1 to 7 wherein the inner catheter shaft (52) further comprises a guide wire lumen (64) and the perfusion means
25 comprise at least one passage through the inner catheter shaft (52) to the guide wire lumen (64).

9. A dilation-drug delivery catheter (10) comprising a dilation portion (20) comprising a dilation balloon (24) and a drug delivery portion (50) having a distal end, wherein the
30 portions can be moved with respect to each other, the catheter

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having a dilation position, wherein the distal end of the drug delivery portion (50) is located at least in part within the dilation portion (20), and a drug delivery position, wherein the dilation portion (20) is retracted to reveal the distal end
5 of the drug delivery portion (50); and

wherein the dilation portion (20) further comprises a dilation lumen (38) for providing dilation fluid to the dilation balloon (24) and a central lumen (40), wherein the drug delivery portion (50) is located at least in part, within
10 the central lumen (40) and

wherein the drug delivery portion (50) comprises a catheter shaft comprising an inflation lumen (62) and a drug delivery lumen (54); and the distal end of the drug delivery portion (20) comprises a pair of occlusion balloons (58, 60) in
15 fluid communication with the inflation lumen (62) and a plurality of drug delivery ports (56) between the occlusion balloons (58, 60), the drug delivery ports (56) being in fluid communication with the drug delivery lumen (54), wherein, in the drug delivery position, the dilation portion (20) is
20 retracted to reveal the occlusion balloons (58, 60) and the drug delivery ports (56).

10. A dilation-drug delivery catheter (10) comprising:
an outer catheter shaft (22), a dilation balloon (24) bonded to the catheter shaft (22), the catheter shaft (22)
25 having an outer wall and an inner wall defining a lumen for providing dilation fluid to the dilation balloon (24), the inner wall further defining a central lumen,

an inner catheter shaft (52) comprising a pair of occlusion balloons (58, 60) at its proximal end, a lumen in
30 fluid communication with the occlusion balloons (58, 60) to provide inflation fluid to the occlusion balloons (58, 60), a plurality of drug delivery ports (56) between the occlusion

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balloons (58, 60), a lumen in fluid communication with the drug delivery ports (56) to provide drugs to the ports (56), and a guide wire lumen (64),

wherein at least a portion of the distal end of the
5 inner catheter shaft (52) lies within the central lumen (40),
and the outer catheter shaft (22) can be moved with respect to
the inner catheter shaft (52) to reveal the distal end of the
inner catheter shaft (52).

11. The dilation-drug delivery catheter (10) of claim 10
10 wherein all of the drug delivery ports (56) lie within the
central lumen (40).

12. The dilation-drug delivery catheter (10) of claim 10
or 11, wherein the inner catheter shaft (52) further comprises
perfusion passages proximal to the occlusion balloons (58, 60),
15 the perfusion passages being in fluid communication with the
guide wire lumen (64).

SMART & BIGGAR

OTTAWA, CANADA

PATENT AGENTS

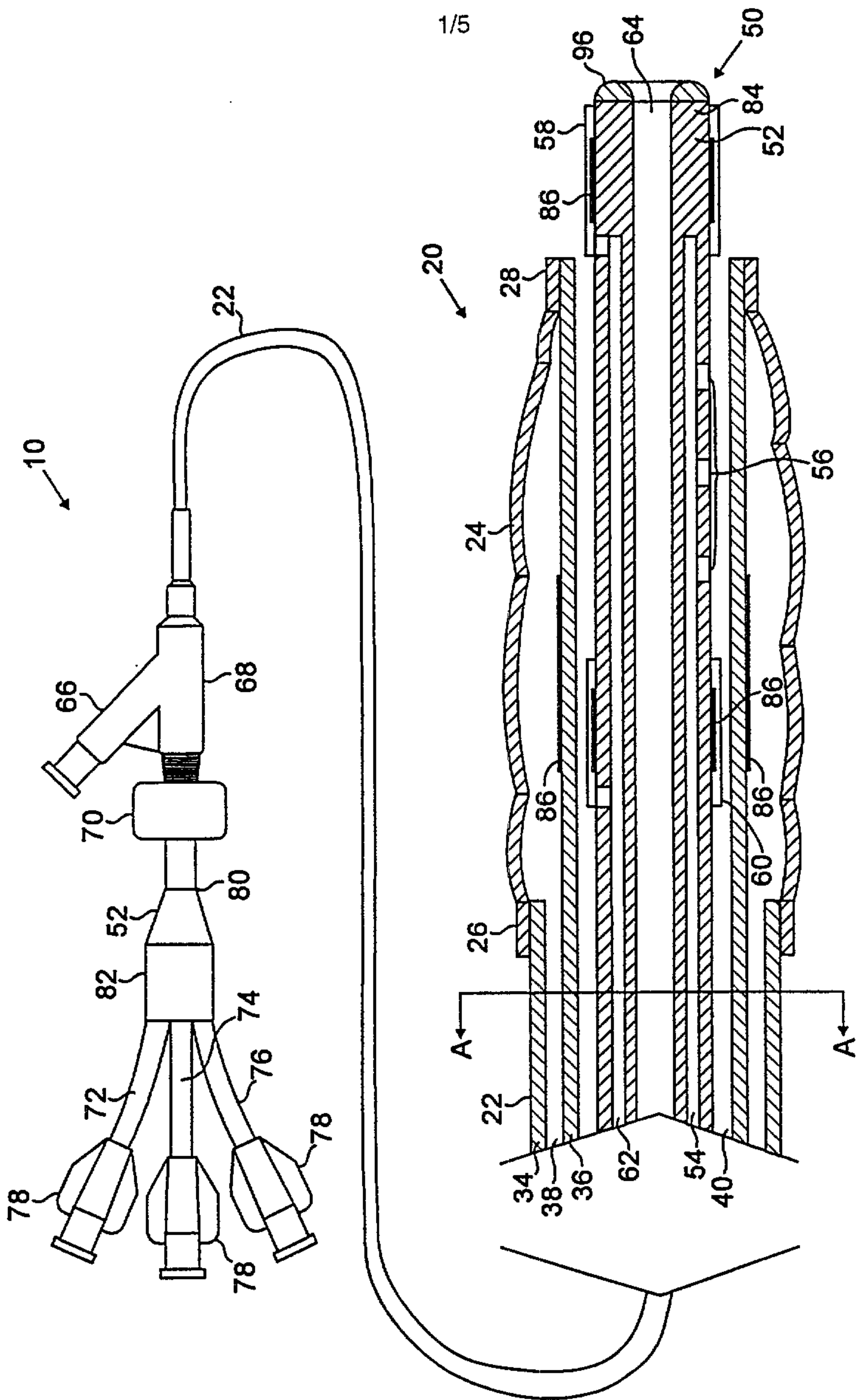


FIG. 1

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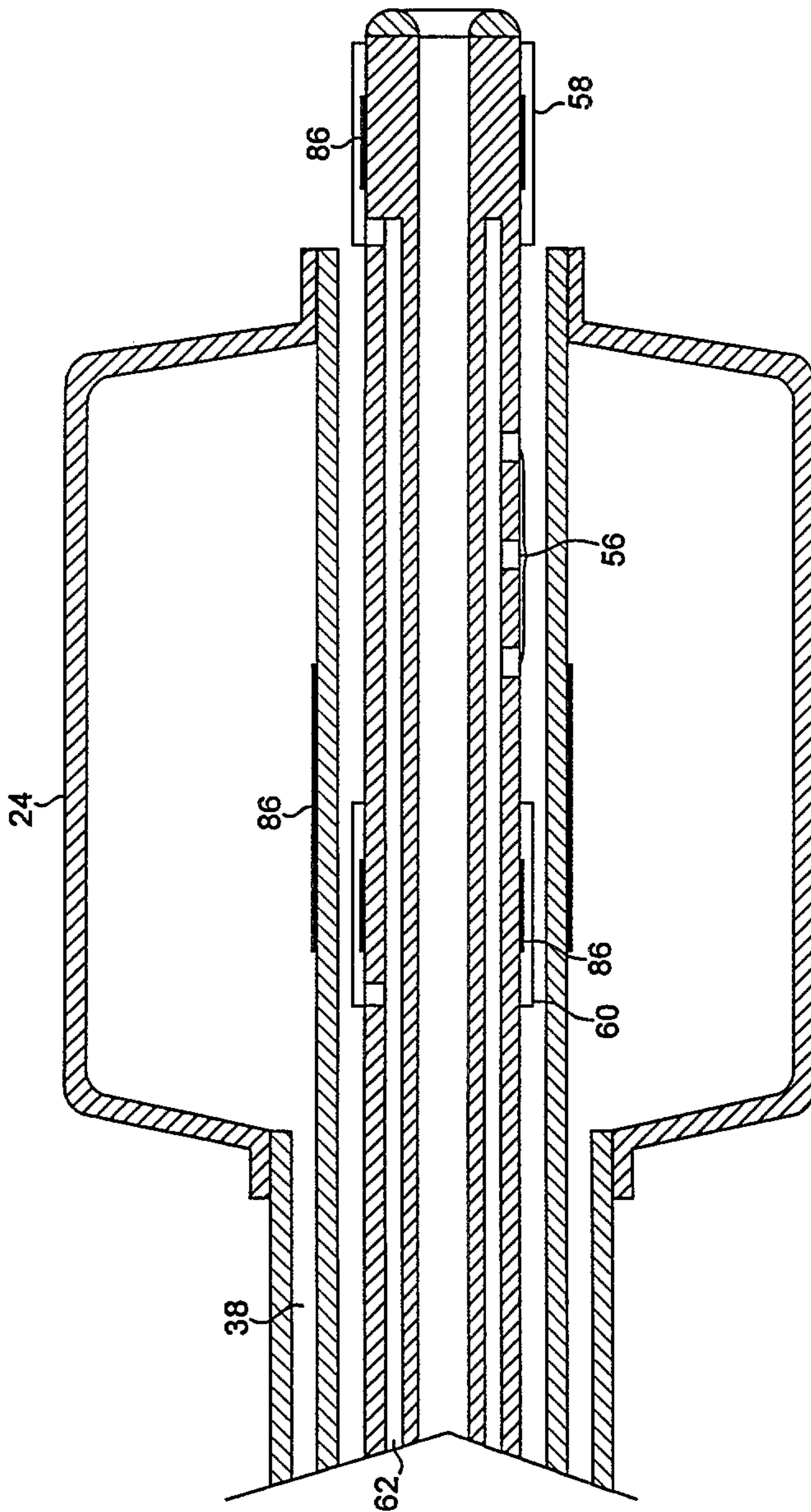


FIG. 2

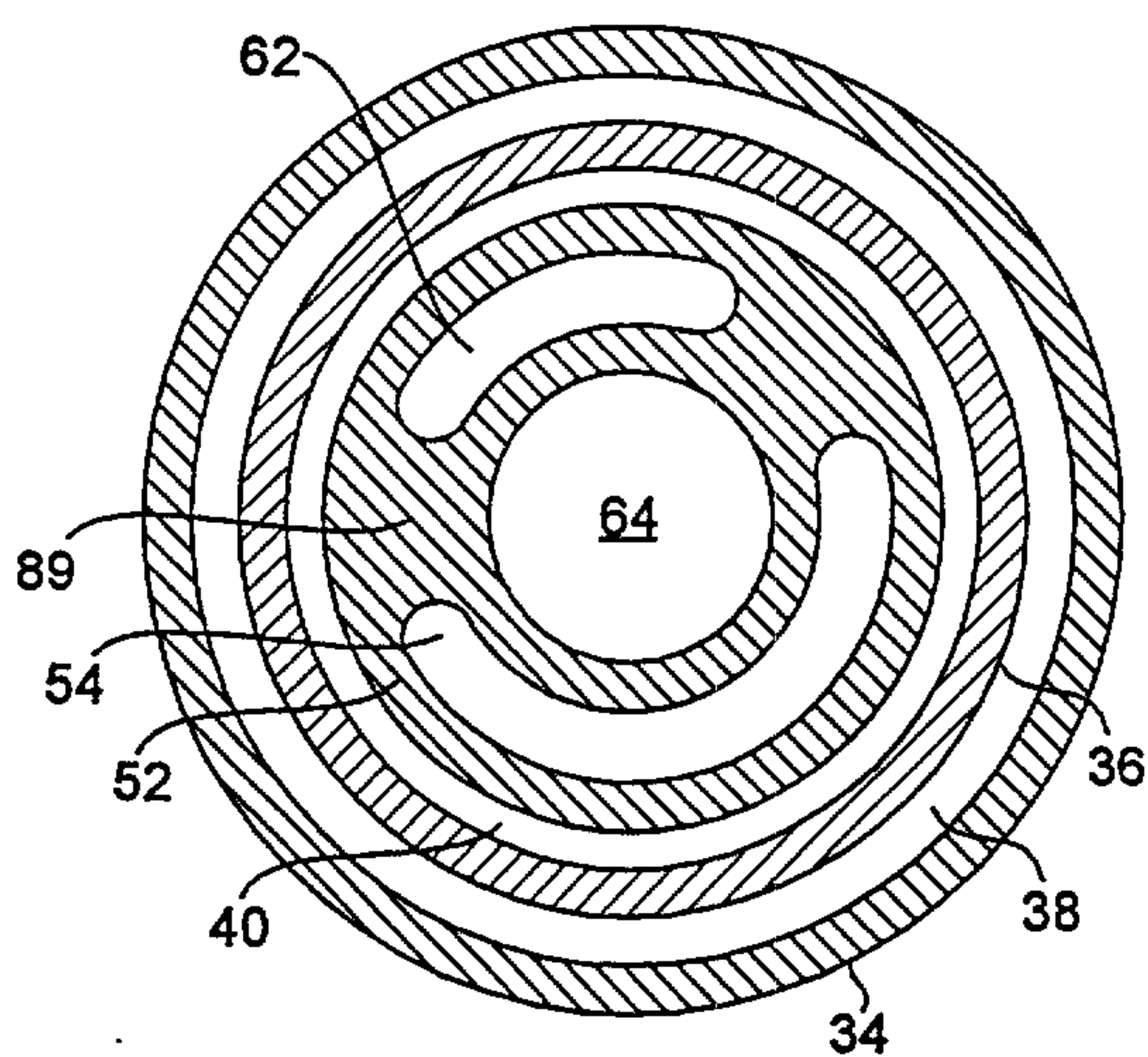


FIG. 3

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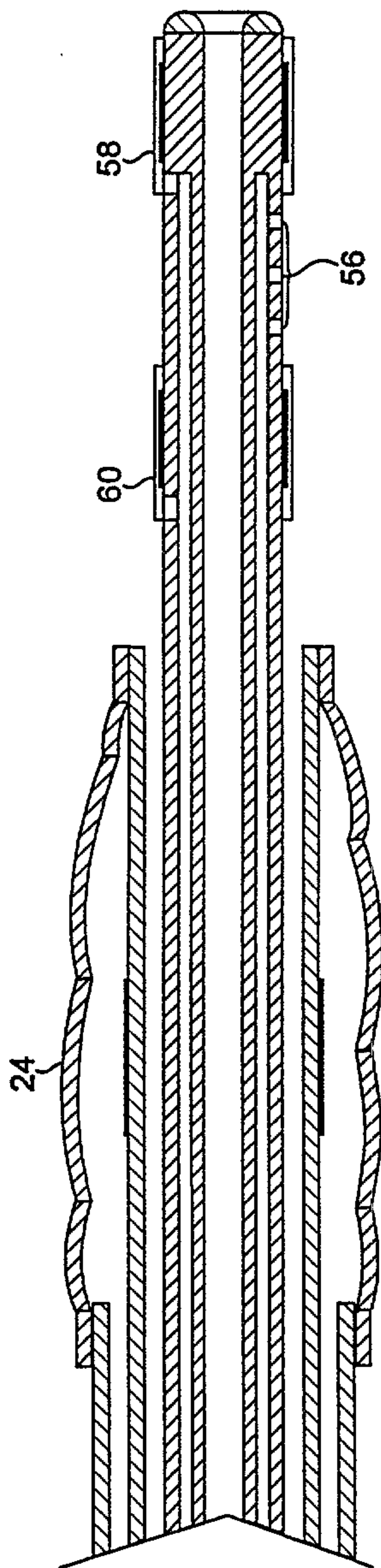


FIG. 4

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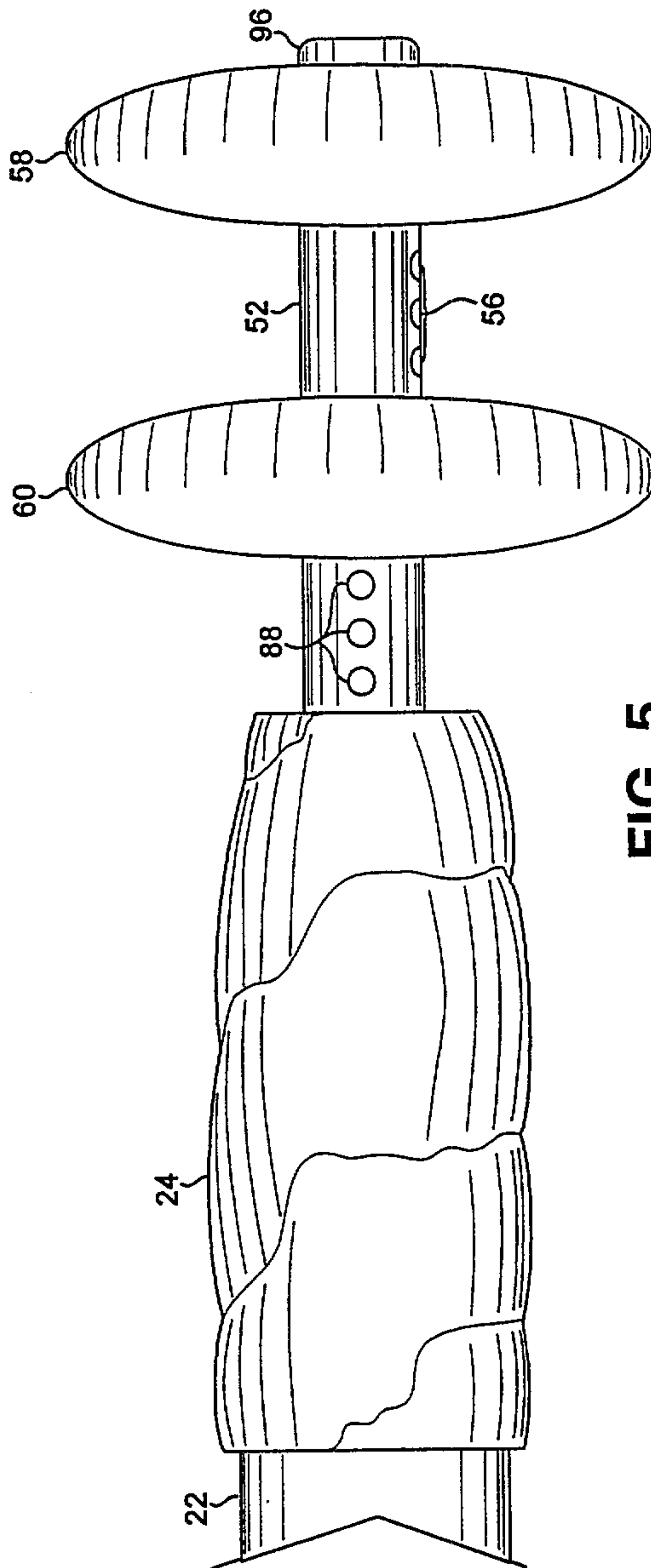


FIG. 5

