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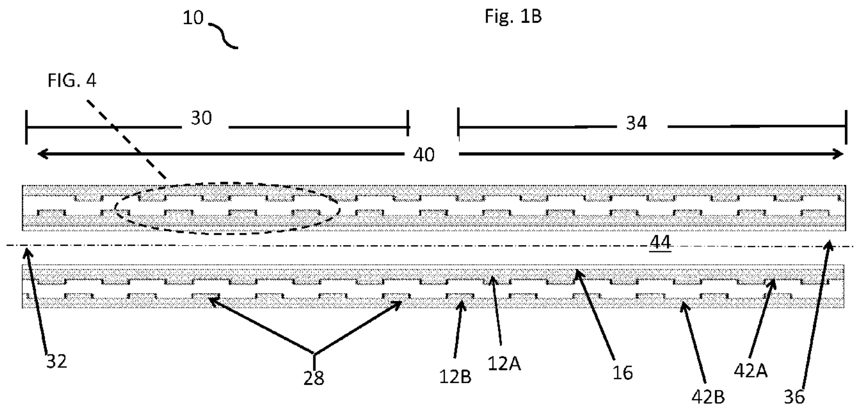

(57) Abstract: A medical device such as a catheter may have an elongate shaft that includes a hypotube having a cut formed therein. The elongate shaft may define a lumen that extends within the elongate shaft. A polymer may be disposed over at least a portion of the hypotube. A medical device may include a cut hypotube having a constant pitch and may be configured to reversibly and temporarily alter the pitch of at least a portion of the cut hypotube. In some cases, the medical device may be configured to reversibly and/or temporarily alter a compressive strength of at least a portion of the cut hypotube.

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HYPOTUBE CONSTRUCTION

CROSS REFERENCE TO RELATED APPLICATION

This application takes priority from and claims the benefit of United States Provisional Patent Application Serial No. 62/030,435 filed on July 29, 2014 and United States Provisional Patent Application Serial No. 62/055,712 filed on September 26, 2014, the contents of which are herein incorporated by reference.

BACKGROUND OF THE SYSTEM

Field of the System

The instant system relates generally to medical devices, and more particularly to a hypotube construction that may form part of a delivery device or catheter construction.

Description of the Related Art

Presently, numerous micro catheter designs exist that possess hypotubes utilized within the construction. In general, a hypotube is a long metal tube with micro-engineered features along its length. Additionally, a hypotube is a critical component of minimally-invasive catheters, utilized in conjunction with balloons and stents to open up clogged arteries for example. In many embodiments, the balloon portion of the catheter is attached to a head of the hypotube. Additionally, both full length hypotubes and partial length hypotubes (normally located at the proximal end of the catheter) may be utilized.

Typically hypotubes may possess some form of inside or internally located liner, which provides a low friction interface with the devices being pushed through the hypotube. These liners may slightly undersized as opposed to a laser cut hypotube so they slide inside a catheter or other medical device during manufacturing. In other embodiments, a hypotube may have a reinforcement which may give the liners more support and integrity as the catheters navigate the vasculature to a treatment location. In some instances, a polymer jacket is distributed on an outer diameter of the hypotube to provide a seal and also to minimize any surface roughness imparted by the laser cutting of the hypotube while still providing flexibility. As a result, this outer layer of the hypotube may also act as a tie layer to enable the application of coatings to enhance lubricity.

Moreover, medical devices such as hypotubes catheters may be subject to a number of often conflicting performance requirements such as flexibility, strength, minimized exterior diameter, maximized interior diameter, and the like. In particular, often times there is a balance between a need for flexibility and a need for strength. Therefore, a need remains for improved medical devices such as catheters that incorporate hypotube constructions which are configured for an optimal balance between flexibility, strength, and other desired properties.

SUMMARY OF THE SYSTEM

The instant apparatus and system, as illustrated herein, is clearly not anticipated, rendered obvious, or even present in any of the prior art mechanisms, either alone or in any combination thereof. A versatile system, method and series of apparatuses for creating and utilizing a hypotube system as part of a delivery device and other like systems is disclosed.

The present system pertains to improved medical devices providing advantages in flexibility, strength and other desired properties. Accordingly, an illustrative but non-limiting example of the present system may be found in a medical device such as a catheter that has an elongate shaft that includes a hypotube having cutting formed within the hypotube. The elongate shaft may define a lumen that extends within the elongate shaft.

Another illustrative but non-limiting example of the present system may be found in a medical device that includes a hypotube middle liner, a Teflon inner liner, and a powdered polymer coat. Thus, herein achieved is a system of a hypotube incorporated within a catheter to allow for a larger interior diameter working lumen than conventional designs while still maintaining the stiffness properties of the catheter shaft. These hypotube systems may be utilized in Neurovascular, Peripheral and cardiovascular procedures and/or in any other nonvascular procedure requiring a catheter which offers the largest interior diameter profile while also providing the lowest outer diameter profile possible.

It is an object of the present system to provide a hypotube with a customizable stiffness profile along its length to allow for a multitude of applications.

It is further object of the present system to provide a hypotube with a low friction interior surface.

It is a further object of the present system to provide a hypotube encapsulated in a dip coated polymer allowing for lower wall thickness.

It is a further object of the present system to provide a hypotube with a low wall thickness to allow for easier maneuverability and increased usages during medical procedures.

It is a further object of the present system to maintain superior stiffness properties overtime while exposed to the internal body temperature of an individual during a medical procedure .

It is a further object of the present system to provide a hypotube with a stiff proximal region to allow for increased pushability of a catheter incorporating the hypotube system.

It is a further object of the present system to provide a hypotube with a soft distal region for increased maneuverability during a medical procedure.

It is a further object of the present system to provide a hypotube for use in a variety of catheter applications.

Therefore, through the construction of the hypotube it is possible to achieve superior stiffness and support while also eliminating any issues relating to the softening of the hypotube body as a function of time exposed to an individual's internal body temperature during a medical procedure. A user may choose any cut pattern to provide the stiffness profile desired and achieve this stiffness with a wall thickness that is thinner than conventional braided or coiled constructions.

Further, the hypotube catheter shafts may be made from nitinol. Shafts made from nitonol tend to be an excellent choice for minimally-invasive catheter procedures because they can be designed with varying degrees of trackability and torque. This design flexibility allows the hypotube to be made to resist kinking in the most intricate, demanding medical procedures.

There has thus been outlined, rather broadly, the more important features of a hypotube construction and incorporation into a delivery device so the description thereof that follows may be better understood, and in order that the present contribution to the art may be better appreciated. There are additional features of the system that will be described hereinafter and which will form the subject matter of the claims appended hereto.

In this respect, before explaining at least one embodiment of the system in detail, it is to be understood that the system is not limited in its application to the details of construction and to the arrangements of the components set forth in the following description or illustrated in the drawings. The system is capable of other embodiments and of being practiced and carried out in various ways. Also, it is to be understood that the phraseology and terminology employed herein are for the purpose of description and should not be regarded as limiting.

These together with other objects of the system, along with the various features of novelty, which characterize the system, are pointed out with particularity in the claims annexed to and forming a part of this disclosure. For a better understanding of the system, its operating advantages and the specific objects attained by its uses, reference should be made to the accompanying drawings and descriptive matter in which there are illustrated preferred embodiments of the system.

BRIEF DESCRIPTION OF THE DRAWINGS

The system may be more completely understood in consideration of the following detailed description of various embodiments of the system in connection with the accompanying drawings, in which:

FIG. 1A is a simple cross-sectional view shown lengthwise of a hypotube in accordance with one embodiment of the present system.

FIG. IB is a detailed cross-sectional view shown lengthwise of a hypotube in accordance with one embodument of the present system .

FIG. 2 is a cross-sectional view shown along line 5-5 of the hypotube shown in Fig. 1A, in accordance with one embodiment of the present system.

FIG. 3 illustrates a side perspective view of one example of a known in the art catheter system.

FIG. 4A illustrates an exploded longitudinal cross-sectional view of a portion of the hypotube system shown in FIG. IB.

FIG. 4B illustrates a perspective view of one embodiment of the hypotube body.

FIG. 4C illustrates a perspective cutaway view of one embodiment of the hypotube body with a polymer coating.

FIG. 4D illustrates a perspective view of an alternate embodiment of the hypotube body.

FIG. 4E illustrates a perspective cutaway view of one embodiment of the hypotube body with a polymer coating.

FIG. 4F illustrates a perspective view of an embodiment of the hypotube body.

FIG. 4G illustrates a perspective cutaway view of an embodiment of the hypotube body with a polymer coating.

FIG. 5 illustrates a cross-sectional view of a hypotube contained within the catheter system in FIG. 3 possessing a dip-coated polymer layer within a plurality of interstices.

FIG. 6 illustrates a cross-sectional view of a hypotube incorporating a mandrel support guidewire within a cavity of the hypotube construction for the delivery of a medical device to a treatment area.

FIG. 7 illustrates a cross-sectional, longitudinal view of a longitudinal segment of one embodiment of the enhanced hypo-tube catheter system.

While the system is amenable to various modifications and alternative forms, specifics thereof have been shown by way of example in the drawings and will be described in detail. It should be understood, however, that the intention is not to limit the system to the particular embodiments described. On the contrary, the intention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the system.

DETAILED DESCRIPTION OF THE SEVERAL EMBODIMENTS

For the following defined terms, these definitions shall be applied, unless a different definition is given in the claims or elsewhere in this specification. All numeric values are herein assumed to be modified by the term "about", whether or not explicitly indicated. The term "about" generally refers to a range of numbers that one of skill in the art would consider equivalent to the recited value (i.e., having the same function or result) . In many instances, the terms "about" may include numbers that are rounded to the nearest significant figure.

As used in this specification and the appended claims, the singular forms "a", "an", and "the" include plural referents unless the content clearly dictates otherwise. As used in this specification and the appended claims, the term "or" is generally employed in its sense including "and/or" unless the content clearly dictates otherwise.

The following description should be read with reference to the drawings wherein like reference numerals indicate like elements throughout the several views. The drawings, which are not necessarily to scale, depict illustrative embodiments of the claimed system.

FIG. 1A illustrates a simple cross-sectional view shown lengthwise of a hypotube 10, wherein the hypotube 10 preferably is utilized in construction with micro-catheter designs (see **FIG. 3**). In one embodiment, the hypotube system **10** comprises a pair of polymer layers **12A** and **12B**, wherein the pair of polymer layers **12A** and **12B** surround a hypotube body **14.** Additionally, a liner **16** may be secured against an inside surface (see **FIG. IB)** of the hypotube body **14.** In one embodiment, a first polymer layer **12A** encapsulates the inside surface of the hypotube body **14**, while a second polymer layer encapsulates an outside surface (see **FIG. IB)** of the hypotube body **14.** Furthermore, the liner **16** is secured against the second polyer layer **12B** on the inside surface of the hypotube body **14.**

The polymer layers **12A** and **12B** may be formed of any suitable polymeric material. In particular embodiments, the polymer layer **12** is formed of a material such as the ELAST-EON™ materials commercially available from AORTECH BIOMATERIALS , of Australia. The ELAST-EON™ materials generally are polyurethanes that include a polysiloxane component. While these materials encompass both elastomeric and non-elastomeric polymers, elastomeric polymers are useful in particular embodiments of the present system. In some instances, useful elastomeric polymers may exhibit an elongation of at least about 500 percent.

FIG. IB illustrates a more detailed cross-sectional view shown lengthwise of a hyptoube, **10.** The hypotube system **10** comprises the pair of polymer layers **12A** and **12B,** wherein the polymer layers **12A** and **12B** surround the hypotube body **14.** In another embodiment, a cut pattern 28 (see FIGS. 4B-4D for more detail) may be formed within the hypotube body 14; the cut pattern 28 may be cut in a number of ways to provide a desirable stiffness profile to a user. Different cut patterns may impart different degrees of support at specific sections along the length of the hypotube 10. Types of cut patterns 28 include, but are not limited to, C-cuts, spiral cuts, interrupted spiral cuts which may be varied numerous ways in a cut pitch or cut density to provide any stiffness profile desired in a catheter.

The hypotube 10 preferably comprises a proximal region 30 defining a proximal end 32, and a distal region 34 defining a distal end 36. The hypotube 10 may be cut in any number of ways to provide a desirable stiffness profile over an entire working length 40 of the hypotube 10. The cut pattern 28 may comprise any number of variations to impart different degrees of support at specific sections along the length 40 of the hypotube 10.

The hypotube body 14 further comprises an inside surface 42A and an outside surface 42B; preferably the inside surface 42A faces a lumen 44 formed by the hypotube body 14. In one embodiment, the liner 16 is placed against the inside surface 42A of the hypotube body 14 and secured in place by the first polymer layer 12A. The liner 16 may be a low friction material which provides a low friction interface desired to allow a variety of medical devices to be pushed through the hypotube 10 during a medical procedure.

In one embodiment, the liner **16** is a material which includes, but is not limited to: Teflon, PD Slick (i.e. a blend of PTFE and polyimide) , a high density polyethylene or any other similar low friction materials. PTFE, polytetraf luoroethylene may be used as a lubricant-like material and reduce friction. When used in hypotube structures, PTFE has a low coefficient of friction for ease of navigation in intravenous procedures. A wide variety of coating technologies are available to maximize hypotube trackability including the PTFE coatings and polymer jackets.

In yet another embodiment, the hypotube **10** further comprises a pair of dip-coated polymer layers **12A** and **12B,** wherein the polymer layers **12A** and **12B** is preferably a solution that encapsulates a plurality of interstices **50** (see **FIG. 4**) located on the inside surface **42A** and outside surface **42B** of the hypotube body **14** created by the cut pattern **28.** Furthermore, the polymer layers **12A** and **12B** preferably serve the dual purpose of providing a smooth outside surface **42B** to the hypotube **10,** while at the same time securing the liner **16** in place against the inside surface **42A** of the hypotube body **14.**

FIG. 2 illustrates a cross-sectional view along line **5-5** of the hypotube **10** shown in **FIG. 1**, wherein the hypotube **10** possesses an inside diameter **20** and a corresponding outside diameter **18.** In practice, medical practitioners desire a larger inside diameter **20** working lumen **44** while keeping the outside diameter **18** of the hypotube **10** as close to the inside diameter 20 as possible to create a larger area for medical devices to pass through. The problem with this type of construction utilizing traditional catheter designs is through the expense of wall thickness which in turn affects shaft stiffness. Typically the longer a medical procedure case takes, traditional braided polymer catheters soften and lose their support properties.

The instant system eliminates these issues by providing a hypotube **10** construction, wherein the thickness of the inside diameter **20** and the outside diameter **18** is nearly identical, while being able to possess superior stiffness and flexibility properties .

Preferably, the liner **16** possesses a thickness in the range of .00025 inches to .001 inches, and more preferably possesses a thickness of one-one thousandth of an inch. Moreover, in one embodiment, the diameter of the lumen **44** is roughly seven-one hundredths of an inch; therefore, in practice the inside diameter **20** of the hypotube body **14** is almost identical to the diameter of the lumen **44** as the thickness of the liner **16** and the polymer layer **12** between the liner **16** and the inside surface **42A** of the hypotube body **14** is minimal. In a preferred embodiment, the ratio of the thickness of the outer diameter 18 to the thickness of the inner diameter is in the range of 1.15:1 to 1.5:1.

In further embodiments, the hypotube may possess a range in the stiffness profile wherein the stiffest profile would equate to an uncut stainless steel tube (located near the proximal region **30)** to as flexible as desired, which may be a function of the softest durometer polymer utilized (around 65A on the durometer scale) combined with a high density cut pattern **28** (located near the distal region **34)** which the hypotube body **14** may tolerate (distally **34)** . In yet another embodiment, the stiffness profile of the hypotube **10** may be in the range of 65A to 75D in accordance with the durometer scale as known in the art.

In further embodiments of the hypotube 10, the thickness of the hypotube body 14 may be in the range of one one-thousandths (.001) of an inch to three one-thousandths (.003) of an inch. Additionally, the first polymer layer 12A preferably includes a thickness in the range of five ten-thousandths (.0005) of an inch to fifteen ten-thousandths of an inch (.0015), and more preferably one one-thousandth of an inch (.001) to fifteen ten-thousandths (.0015) of an inch. Moreover, the second polymer 12B preferably includes a thickness in the range of three ten-thousandths (.0003) of an inch to three thousandths (.003) of an inch. Lastly, the lumen 44 of the hypotube body 14 may have an inner diameter 20 in the range of thirty-four ten-thousandths (.0034) of an inch to thirty-six ten-thousandths (.0036) of an inch; conversely the outer diameter 18 of the hypotube 10 may be in the range of fortyone ten thousandths (.0041) of an inch to forty-three ten thousandths (.0043) of an inch.

In one embodiment, the hypotube body **14** is preferably constructed of a material including, but not limited to stainless steel, cobalt chrome, nitinol, and any similar metallic compound which is not polymeric in nature. In other embodiments, part or all of the hypotube body may be formed of a metal or a metal alloy. Some examples of suitable metals and metal alloys include stainless steel, such as 304V, 304L, and 316L stainless steel; alloys including nickel-titanium alloy such as linear elastic or superelastic (i.e. pseudoelastic) nitinol; nickel-chromium alloy; nickel-chromium-iron alloy; cobalt alloy; tungsten or tungsten alloys; MP35-N (having a composition of about 35% Ni, 35% Co, 20% Cr, 9.75% Mo, a maximum 1% Fe, a maximum 1% Ti, a maximum 0.25% C, a maximum 0.15% Mn, and a maximum 0.15% Si); hastelloy; monel 400; inconel 825; or the like; or other suitable material. The particular material used can be chosen in part based on the desired characteristics of the hypotube body **14**, for example flexability, pushability, torqueability, and the like.

In even further embodiments, the hypotube body may be formed from a superelastic or linear elastic nickel-titanium alloy, for example, linear elastic or superelastic (i.e. pseudoelastic) nitinol .

Within the family of commercially available nitinol alloys, is a category designated "linear elastic" which, although is similar in chemistry to conventional shape memory and superelastic varieties, exhibits distinct and useful mechanical properties. By skilled applications of cold work, directional stress, and heat treatment, the wire is fabricated in such a way that it does not display a substantial "superelastic plateau" or "flag region" in its stress/strain curve. Instead, as recoverable strain increases, the stress continues to increase in an essentially linear relationship until plastic deformation begins. In some embodiments, the linear elastic nickel-titanium alloy is an alloy that does not show any martensite/austenite phase changes that are detectable by DSC and DMTA analysis over a large temperature range.

Preferably, the hypotube body **14** is constructed of a higher modulus metal which allows for a thinner hypotube body **14** construction which may be utilized to achieve a higher stiffness profile of the hypotube **10**. Furthermore, the hypotube body **14** may comprise a cut pattern **28** including, but not limited to C-cut, spiral cut, interrupted spiral, and any combination/blend thereof. Additionally, the cut pattern **28** may vary along the length **40** of the hypotube body **14** such that the spacing of the cut pattern **28** in one embodiment may be equidistantly disposed along the length **40**, whereas in another embodiment the spacing between the cut pattern **28** may be random or in a specified pattern that provides for unequal spacing. Additionally, the cut pitch and/or cut density of the cut pattern **28** may vary along the length **40** of the hypotube body **14** to incorporate various stiffness profiles depending on the medical procedure and requirement by physicians. Lastly, the polymer layers **12A** and **12B** may be a polymer including, but not limited to PEBAX, nylons, polyurethanes and other polymers that possess similar properties. In one embodiment, the polymer layers **12A** and **12B** may be a material that may be dissolved in solution and subsequently applied to the hypotube body **14** and liner **16** via a dip-coating process.

FIG. 3 illustrates a known in the art catheter system **60** which may incorporate the hypotube **10** of the present system; in this embodiment the catheter system **60** comprises a catheter **62** (shown schematically) , a stent **64**, a guidewire **66**, and an expandable balloon **68**, with the balloon **68** in an inflated or deflated configuration. In a deflated or delivery configuration, the balloon **68** and stent **64** will have an outer diameter close to the outer diameter of a shaft **70** of the catheter **62**. The catheter **62** includes a distal guidewire portion **72** at a distal end **76** of the catheter **62** and a proximal guidewire portion **74** proximal of the balloon **64**.

FIG. 4A illustrates an enlarged cross-sectional view taken from the dotted circle in **FIG. IB.** The hypotube **10** further comprises a pair of polymer layers **12A** and **12B**, wherein the polymer layers **12A** and **12B** are preferably dip-coated and is a solution that encapsulates a plurality of interstices **50** created by the cut pattern **28.**

The hyptotube system preferably possesses a desired cut pattern **28** (see **FIG. IB)** to provide the stiffness profile wanted and to achieve this stiffness with a wall thicknesses that is thinner than conventional braided or coiled constructions. Types of cut patterns **28** include, but are not limited to, C-cuts, spiral cuts, interrupted spiral cuts which may be varied numerous ways in a cut pitch or cut density to provide any stiffness profile desired in a catheter. Cuts used in an embodiment of the present system may be constant or varied depending upon the stiffness transition characteristics desired. For example, the pitch may be increased for more flexibility or decreased for less flexibility. Further, the cut pattern may extend partially through or all the way through the hypotube body. As stated, the cut pattern creates a set of interstices **50** filled with a low stiffness polymer that gives a smooth outer surface to the laser cut hypotube while at the same time securing a liner **16** in place. In this embodiment, the first polymer layer **12A** and the second polymer layer **12B** encapsulate the plurality of interstices **50** created by the cut pattern **28** in the hypotube body **14.** In alternate embodiments, the cut pattern **28** and corresponding interstices **50** may be located on the outer surface **42B** of the hypotube body **14** only, or the inside surface **42A** of the hypotube body **14** only, so some combination thereof.

Additionally, the cut pattern **28** of the hypotube **10** may vary depending on the medical procedure involved and utilizing the hypotube **10**. For example, the cut pattern 28 may vary as a function of the size of the medical device, location of the anatomy of a patient, and the length required to reach the target location from the insertion point.

One important element of the hypotube **10** described herein, is the ability to cut any stiffness profile over any discreet length, short or long. As such, it may be possible to start on the distal end of the hypotube body and go from stiff to soft and stiff again or any other permutation of those until the proximal end. However, the type of cut pattern **28** employed, and in turn the associated stiffness profile, may be anatomy specific and application specific. Moreover, in one embodiment, the maximum cut density per unit length will be dictated by how much the hypotube **10** being cut is affected by the heat generated by a laser, however in one embodiment a one hundredth (.01) inch of gap separation in the consecutive cuts may be utilized.

FIG. 4B illustrates a perspective view of one embodiment of the hypotube body **14.** In this embodiment the hypotube body **14** has a plurality of external grooves **202** that extend from a main body **200** of the hypotube body **14.** In this embodiment the grooves **202**

are externally oriented, however in other embodiments they may be internally oriented as depressions. In this embodiment the external grooves 202 are vertically oriented, however in other embodiments they may be oriented diagonally, horizontally or in a broken pattern.

FIG. 4C illustrates a perspective cutaway view of an embodiment of the hypotube body 14 with a polymer coating 204. In this embodiment the polymer coating 204 fills a plurality of cavities 201 between the external grooves 202, however in other embodiments the polymer coating 204 may cover the entire hypotube body 14.

FIG. 4D illustrates a perspective view of an embodiment of the hypotube body 14. In this embodiment the hypotube body 14 has a plurality of diagonal grooves 208 that extend from the main body 200 of the hypotube body 14. In this embodiment the diagonal grooves 208 are externally oriented however in other embodiments they may be internally oriented as depressions. In this embodiment the diagonal grooves 208 are diagonally oriented, however in other embodiments they may be oriented vertically, horizontally or in a broken pattern.

FIG. 4E illustrates a perspective cutaway view of an embodiment of the hypotube body 14 with a polymer coating 210. In this embodiment the polymer coating 210 fills a plurality of diagonal cavities 207 between the the plurality of diagonal grooves

208, however in other embodiments the polymer coating 210 may cover the entire hypotube body 14.

FIG. 4F illustrates a perspective view of an embodiment of the hypotube body 14. In this embodiment the hypotube body 14 has a plurality of diagonal cuts 214 that extend from the main body 200 of the hypotube body 14. In this embodiment the plurality of diagonal cuts 214 are externally oriented however in other embodiments they may be internally oriented as depressions. In this embodiment the plurality of diagonal cuts 214 are diagonally oriented, however in other embodiments they may be oriented vertically, horizontally or in a broken pattern.

FIG. 4G illustrates a perspective cutaway view of an embodiment of the hypotube body 14 with a polymer coating 216. In this embodiment the polymer coating 210 fills the plurality of diagonal cuts 214 and the entire hypotube body 14.

FIG. 5 illustrates a longitudinal cross-sectional view of a portion of the catheter 62 illustrated in FIG. 3, incorporating yet another embodiment of the hypotube system. The catheter shaft 70 includes a hypotube shaft 80 including a proximal portion 82 and a distal portion 88, with the proximal 82 and distal 88 portions being joined together near the distal end 86 of the proximal portion and the proximal end 84 of the distal portion 88. An inflation lumen 78 extends through the hypotube shaft 80 into an interior of the balloon 68. In an exemplary embodiment, the two portions of the hypotube **80** are joined at a telescoping connection, that is, the distal end **86** of the proximal portion **82** is positioned distally of the proximal end **84** of the distal portion **88**, and one of the two portions has an outer dimension.

Another advantageous, optional feature of the present system includes that the hypotube **80** comprises one or more cuts **50** formed therein, which increases the flexibility of the hypotube in the area of the cut **50.** By way of example and not of limitation, the shape of the cut **50** may be C-cut, spiral cut, interrupted spiral cut, as well as other shapes and orientations of one or more cuts **50**, so that a desired stiffness profile may be achieved by a user of a catheter. Additionally, the cut **50**, or the density of cuts **50**, may be non-uniform, and advantageously may be formed so that the configuration of the cut **50** contributes to the increasing flexibility of the catheter shaft **70.** The plurality of cuts form a cut pattern **28.** By way of non-limiting example, a spiral cut, such as that illustrated herein, may be formed, e.g., by laser cutting .

Yet another advantageous, optional feature of the present system is the further inclusion of a polymer jacket **92** over the hypotube **80.** By forming the jacket **92** of a polymer material, the catheter shaft **70** may be made fluid tight to the inflation fluid passing through inflation lumen **78**, relatively low friction to assist in passing the catheter **62** through the vasculature of a patient, and the flexibility of the catheter shaft **70** may further be modified. More specifically, the jacket **92** may be formed of a material, and having thicknesses, so that the flexibility of the shaft **70** increases distally.

In practice, the hypotube **10** may form a catheter construction in the range of one-and-a-half to twenty French, and more preferably in the range of three to six French. Furthermore, in one embodiment, the proximal region **30** will possess a stiffer profile in comparison to the distal region **34**, which will be softer in nature. As such, the stiffer proximal region facilitates better pushability while in turn the softer distal region **34** assists navigating a vessel tortuosity. However, in alternate embodiments, the stiffness profiles between the proximal end **32** and the distal end **36** may comprise an infinite number of profiles depending on the properties required for treating a specific disease where more or less support is required at certain locations over the length of the hypotube **10.**

In alternate embodiments, the hypotube **10** in accordance with the present system, may be of any of variety of different catheters. In some embodiments, the hypotube **10** may be an intravascular catheter; examples of intravascular catheters include balloon catheters, atherectomy catheters, drug delivery catheters, stent delivery catheters, diagnostic catheters and guide catheters. Furthermore, the intravascular hypotube **10** may be sized in accordance with its intended use. Furthermore, the hypotube 10 may be utilized in a variety of procedures, including but not limited to: Neurovascular, Peripheral, Cardiovascular, and in any non-vascular procedure requiring a catheter which offers the largest inside diameter of the lumen **44** while keeping the outside diameter profile low.

Therefore, having the ability to deliver larger lumen devices with superior support profiles, physicians do not need to worry about having to insert a supporting sheath(s) over the guide catheter outside diameter for enhanced support or insert a stiff buddy wire inside the guide lumen to enhance its support. As such, the instant system provides a novel hypotube solution, for use with a variety of micro catheter designs, wherein the hypotube 10 allows for large catheters to behave as small catheters from a functionality and usage standpoint, and conversely to allow small catheters to behave as large catheters during use.

FIG. 6 illustrates one embodiment wherein a balloon with mandrel support guidewire is loaded within the hypotube body. The removable mandrel support guidewire **104** runs concentrically along the length of a reinforced single lumen shaft and is pushed through the hyptotube body **14**.

In one embodiment, within the hypotube body **14** is a reinforced single lumen shaft **108;** a removable mandrel support guidewire **104;** a bonded balloon **106** that is deflated; the bonded balloon **106** may include a bonded tip **110** and an attached soft atraumatic tip **112.** The reinforced single lumen shaft **108** may be comprised of a reinforced polymer outer layer **114.**

Furthermore, a distal head **112** of the guidewire **104** preferably remains free-floating relative to an extreme distal end of the catheter **100** but is anchored to the catheter **100** at a more proximal location (not shown). This anchoring helps ensure that the distal head of the guidewire **104** will not break off from the catheter **100** during use. Any suitable anchoring device may be used and is contemplated within the scope of the system.

FIG. 7 illustrates a cross-sectional, longitudinal view of a longitudinal segment of one embodiment of the enhanced hypo-tube catheter system **300,** wherein the base hypotube catheter **310** comprises a substantially spiral cut body. Similar to many other embodiments disclosed herein, the hypotube catheter system **300** further comprises an outer polymer layer **320,** which may be a dip-coated polymer layer, wherein the outer polymer layer **320** comprises a solution that encapsulates the outside hypotube catheter surface.

The hypotube catheter system **300** further comprises a first inner polymer layer **330** which comprises a solution that encapsulates the inner hypotube catheter surface. The hypotube catheter system **300** further comprises an interstices polymer layer **340** wherein interstices polymer layer **340** comprises a solution that encapsulates the surfaces of the set, or plurality, of interstices **313** of the spiral cut hypotube body **300.**

The hypotube catheter system **300** further comprises a second inner polymer layer **350,** wherein the polymer layer may comprise a composition of polytetraflouroethylene (PTFE) or other Teflon™ derivative.

In conclusion, herein is presented a hypotube construction, preferably for use in forming a catheter. The system is illustrated by example in the drawing figures, and throughout the written description. It should be understood that numerous variations are possible, while adhering to the inventive concept. Such variations are contemplated as being a part of the present system.

CLAIMS

What is claimed is:

1. A hypotube comprising:

a hypotube body;

a pair of polymer layers, wherein a first polymer layer encapsulates an inside surface of the hypotube body, and wherein a second polymer layer encapsulates an outside surface of the hypotube body;

a liner, wherein the liner is secured to the inside surface of the hypotube body by the first polymer layer; and

a cut pattern, wherein the cut pattern is formed on the hypotube body.

2. The hypotube of claim 1, wherein the inside surface of the hypotube body faces a lumen formed by the hypotube body.

3. The hypotube of claim 1, wherein the liner is a material selected from the group consisting of: Teflon, PD Slick, a high density polyethylene, and any other similar low friction material.

4. The hypotube of claim 2, wherein a plurality of interstices is formed by the cut pattern on the hypotube body.

5. The hypotube of claim 4, wherein the polymer layer encapsulates the plurality of interstices on the hypotube body.

6. The hypotube of claim 1, wherein the hypotube body is a material selected from the group consisting of: stainless steel, cobalt chrome, nitinol, and any similar metallic compound which is not polymeric in nature.

7. The hypotube of claim 1, wherein the hypotube body is constructed of a higher modulus metal to allow for a thinner hypotube body to achieve a higher stiffness profile of the hypotube .

8. The hypotube of claim 1, wherein the cut pattern is selected from the group consisting of: a c-cut, a spiral cut, an interrupted cut, and any combination/blend thereof.

9. The hypotube of claim 1, wherein the cut pitch and cut density of the cut pattern varies along the length of the hypotube to incorporate various stiffness profiles.

10. The hypotube of claim 1, wherein the polymer layer is selected from the group consisting of: PEBAX, nylons, polyurethanes , and any other polymers that possess similar properties.

11. The hypotube of claim 1, wherein the hypotube forms a catheter construction in the range of one-and-a-half to twenty French.

12. The hypotube of claim 1, wherein the hypotube forms a catheter construction in the range of three to six French.

13. The hypotube of claim 1 further comprising:

a proximal region; and

a distal region;

wherein the proximal region possesses a stiffer profile in comparison to the distal region.

14. A catheter comprising:

a hypotube, wherein the hypotube further comprises:

a hypotube body, wherein the hypotube body defines a lumen, wherein the hypotube body further comprises:

an inside surface, wherein the inside surface faces the lumen; and

an outside surface;

a liner comprising a low friction material, wherein the liner is placed against the inside surface; and, a polymer layer, wherein the polymer layer is placed over the hypotube body.

15. The hypotube of claim 14 wherein the liner is a low friction material is selected from the group consisting of Teflon®, PD-Slick® and High Density Polyethylene.

16. The hypotube of claim 14, wherein the hypotube comprises a set of laser cut interstices filled with a low stiffness polymer that give a smooth outer surface to the laser cut hypo tube while at the same time securing the PTFE liner in place inside.

17. A method of programming a stiffness profile for a catheter utilizing the hypotube of claim 1:

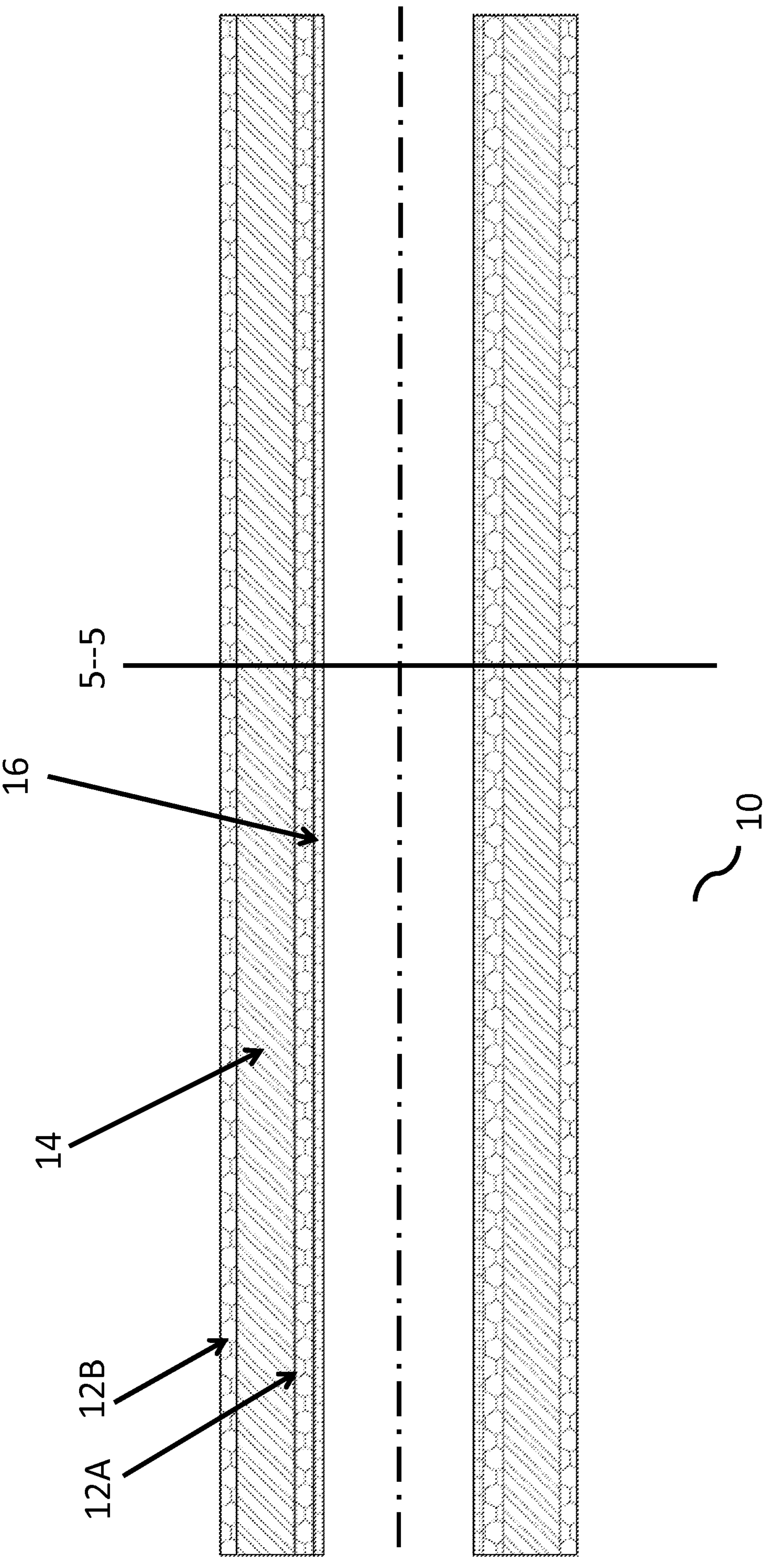
selecting a medical procedure for use with the catheter;

selecting a cut pattern for the hypotube;

selecting a polymer for the polymer layer; and

selecting a material for the hypotube.

FIG 1A



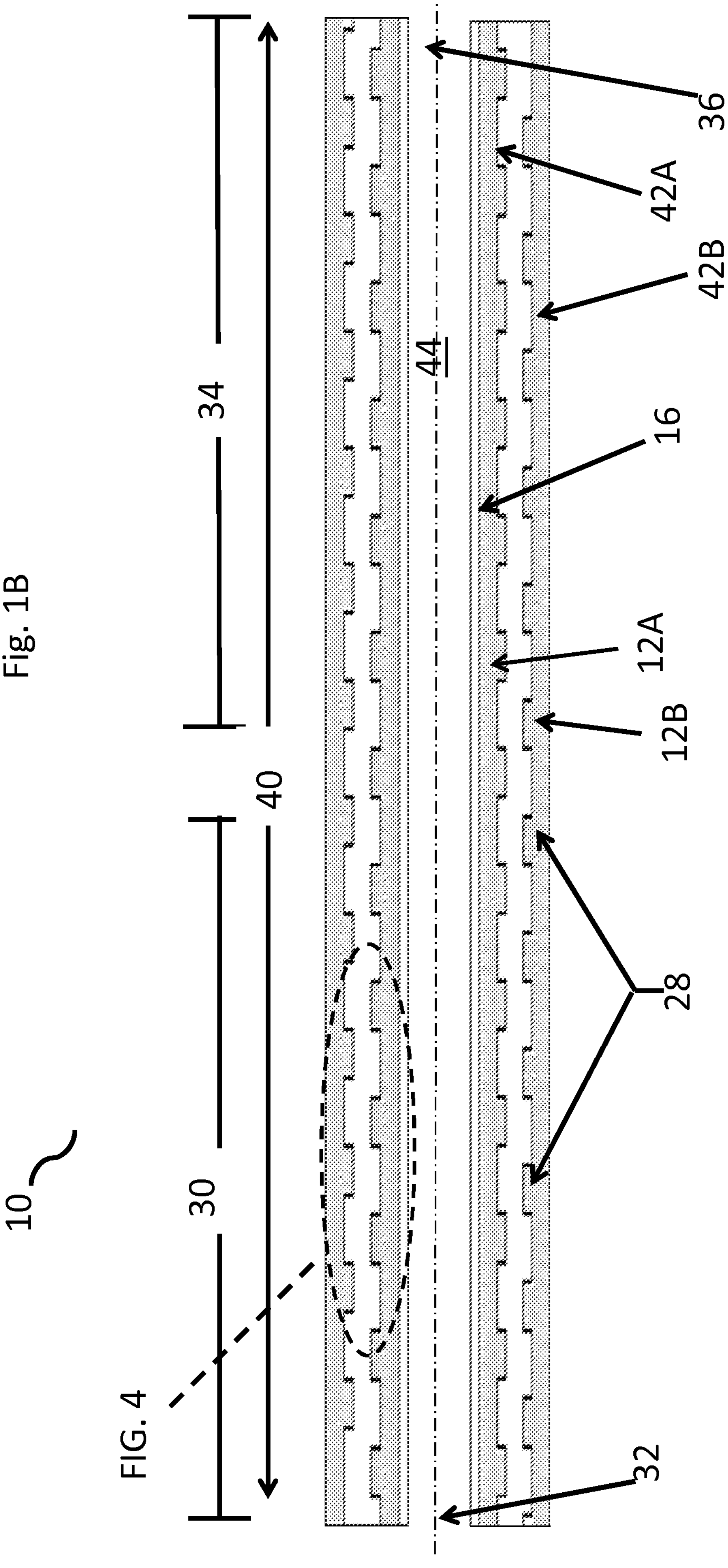


Fig. 1B

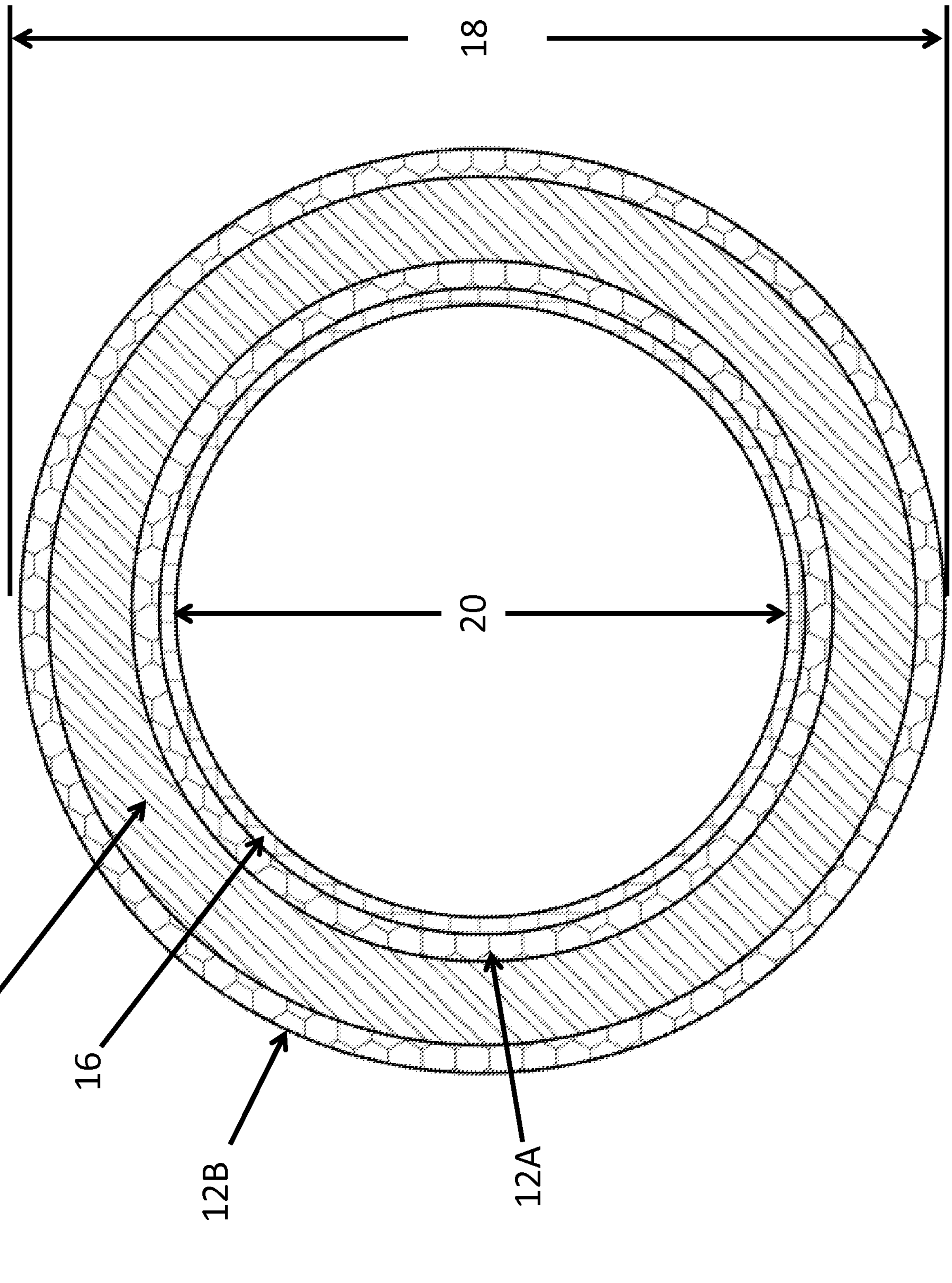


FIG 2

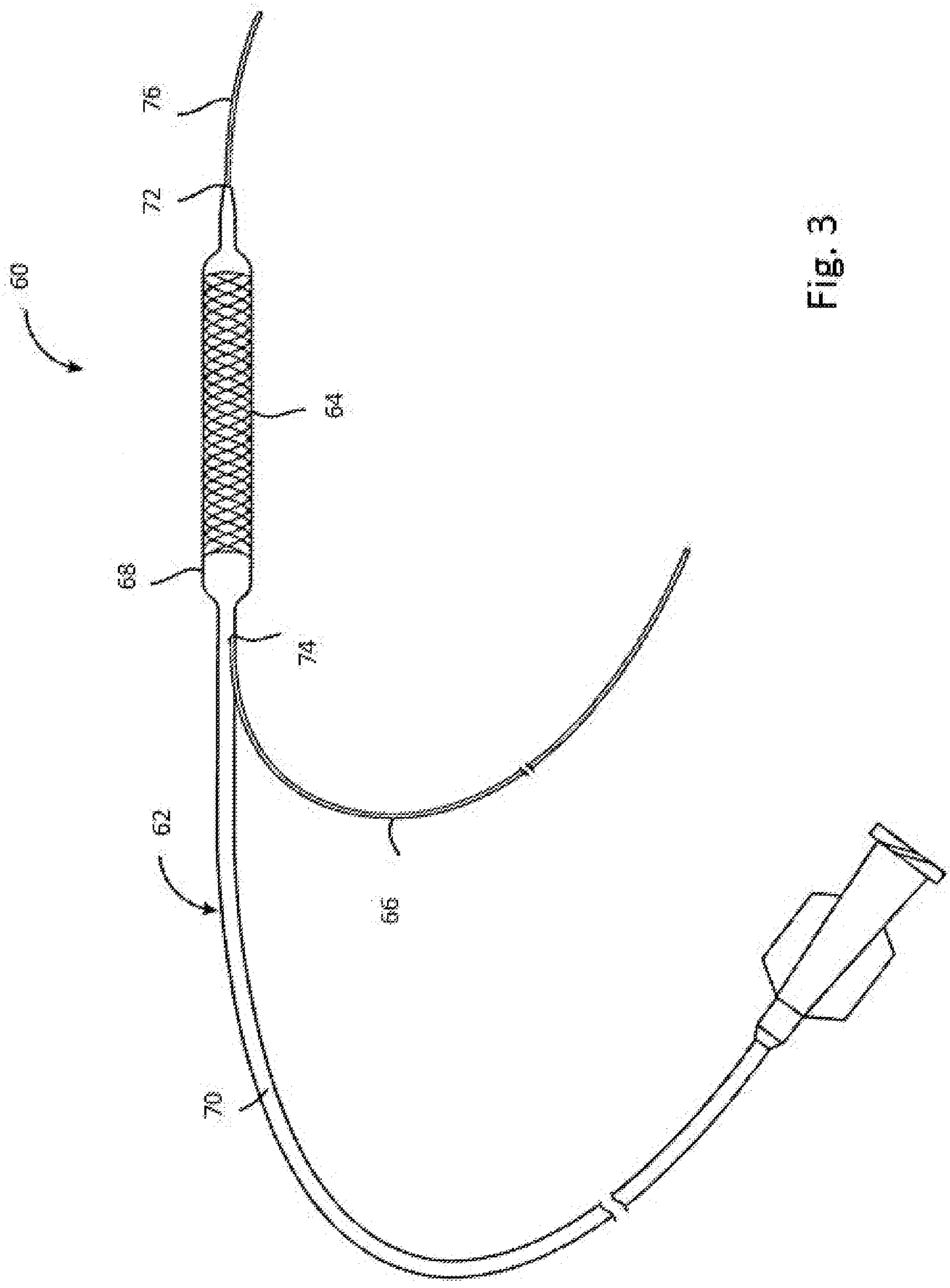


Fig. 3

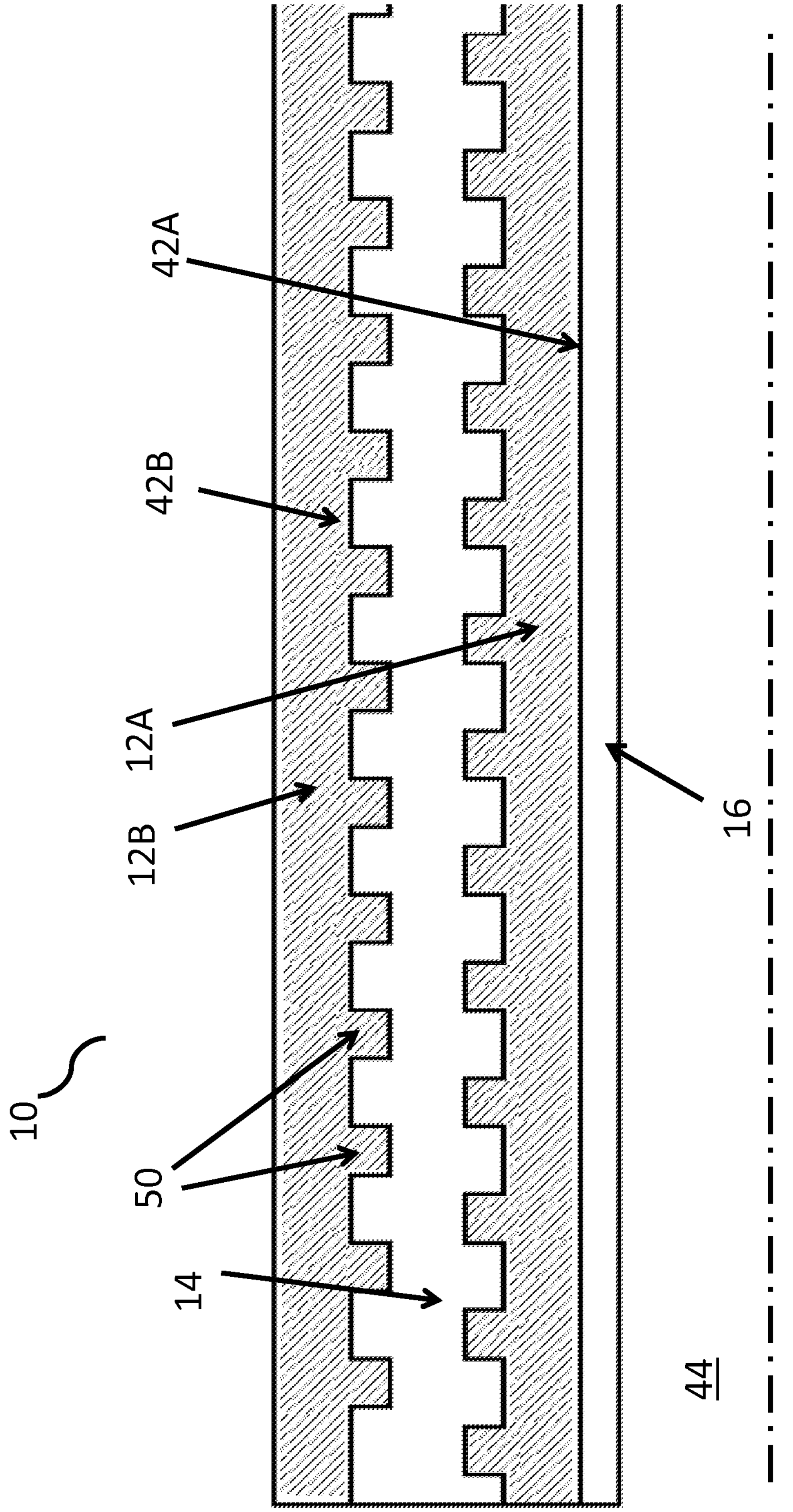


Fig. 4A

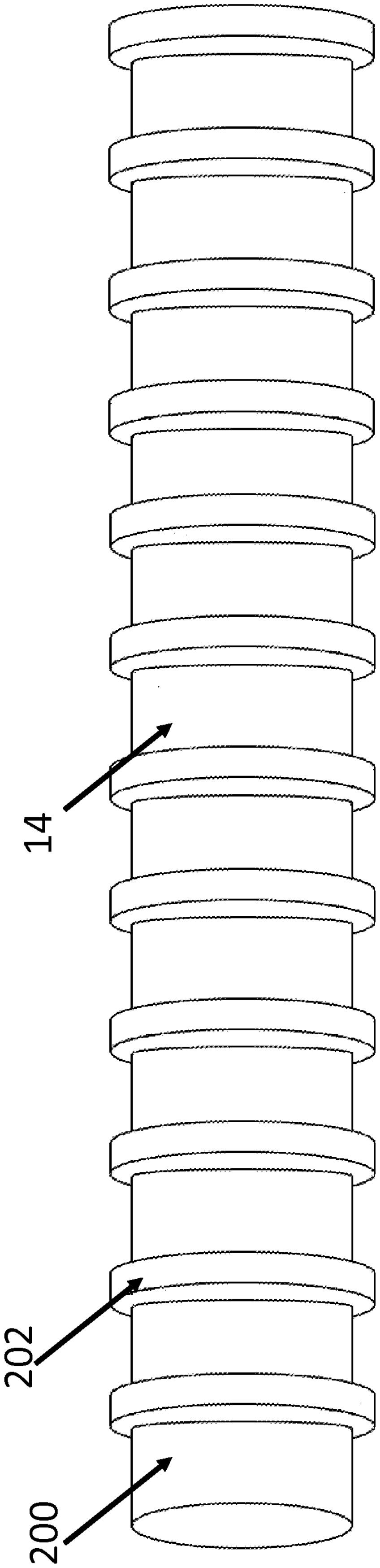


Fig. 4B

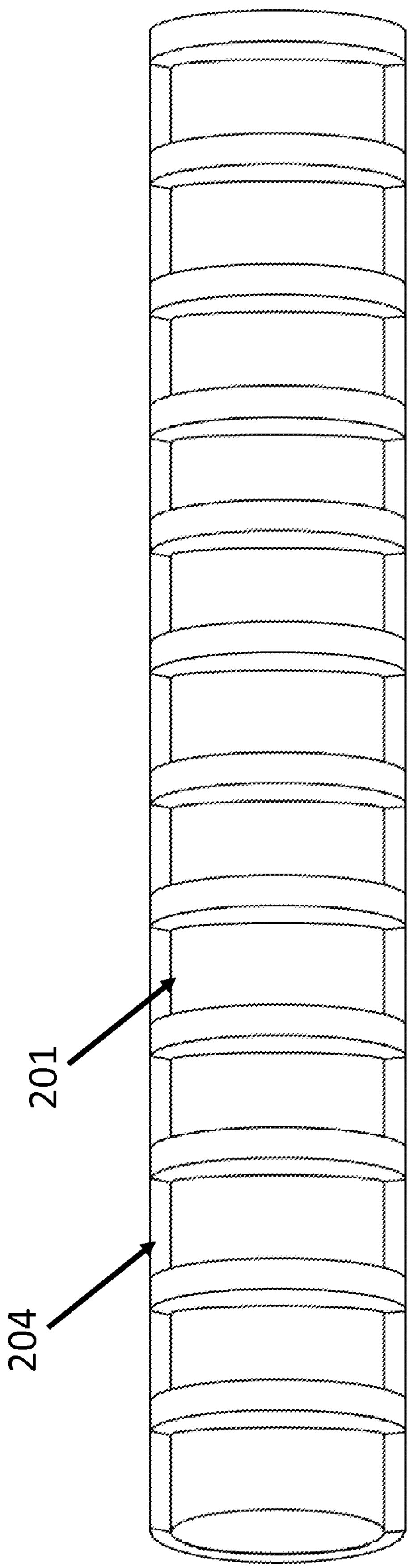


Fig. 4C

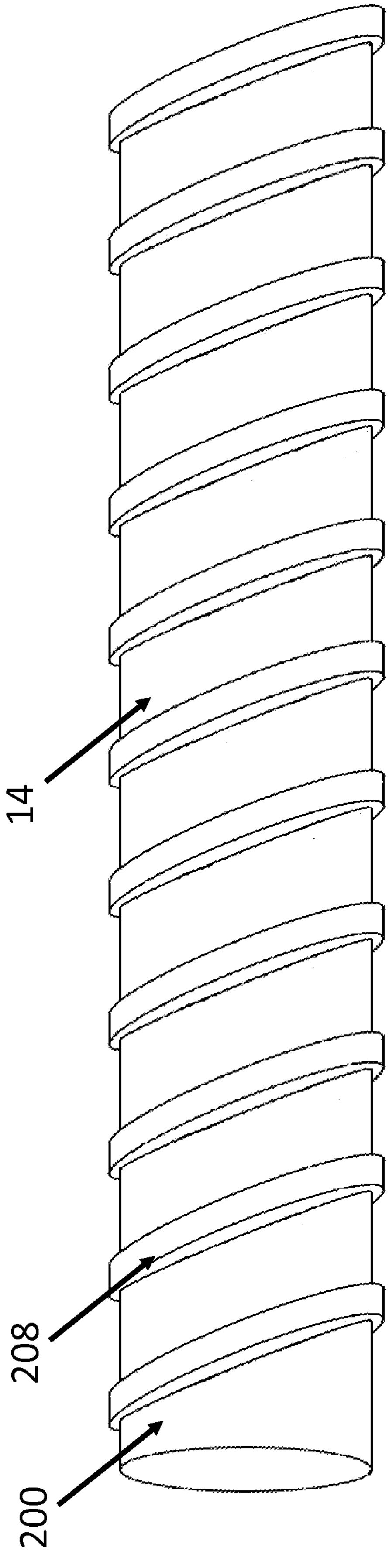


Fig. 4D

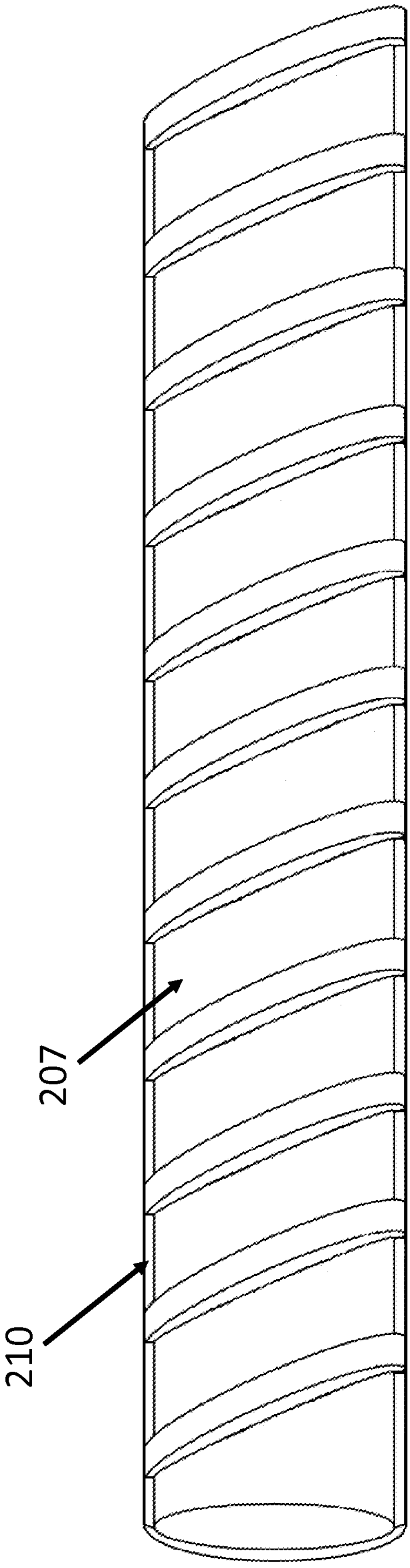


Fig. 4E

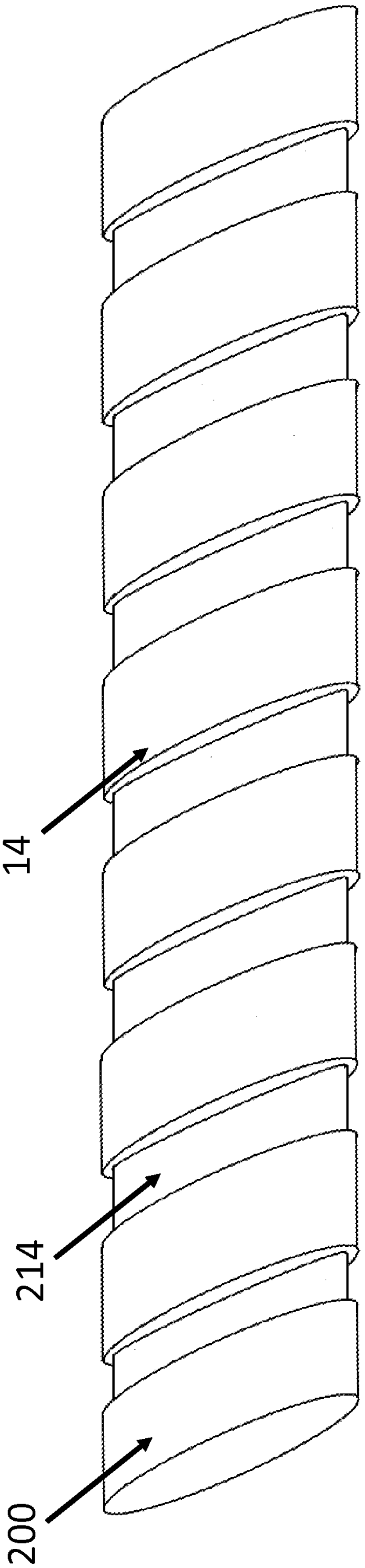


Fig. 4F

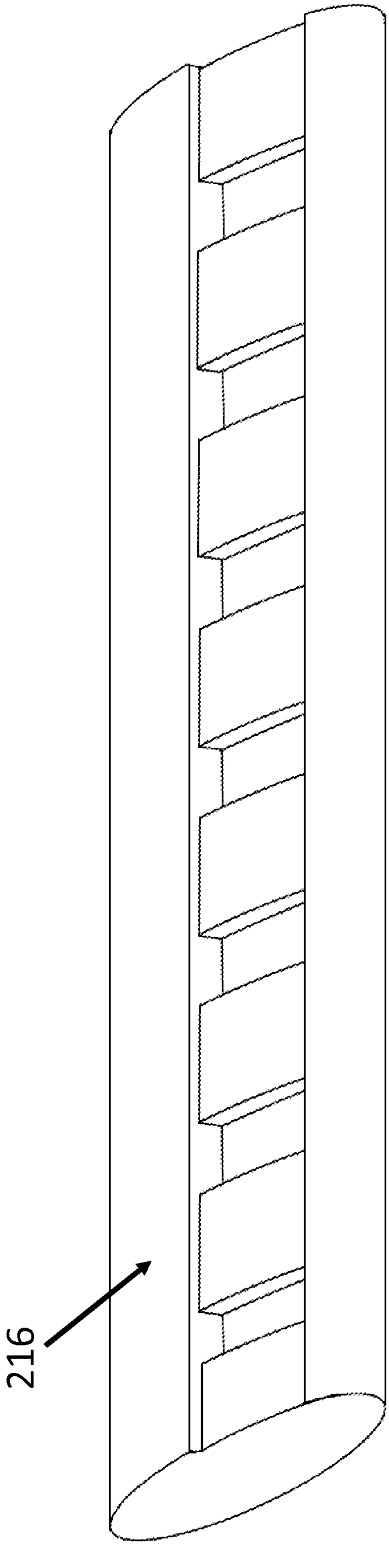


Fig. 4G

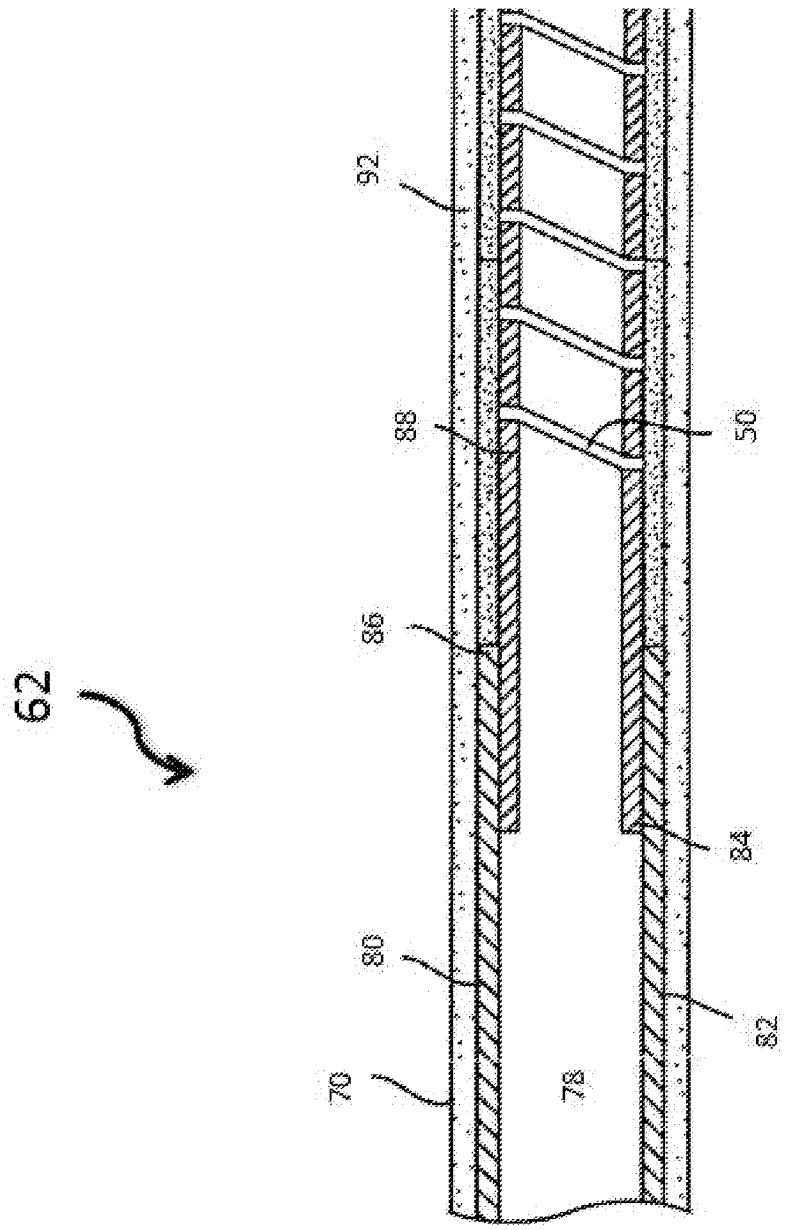


FIG. 5

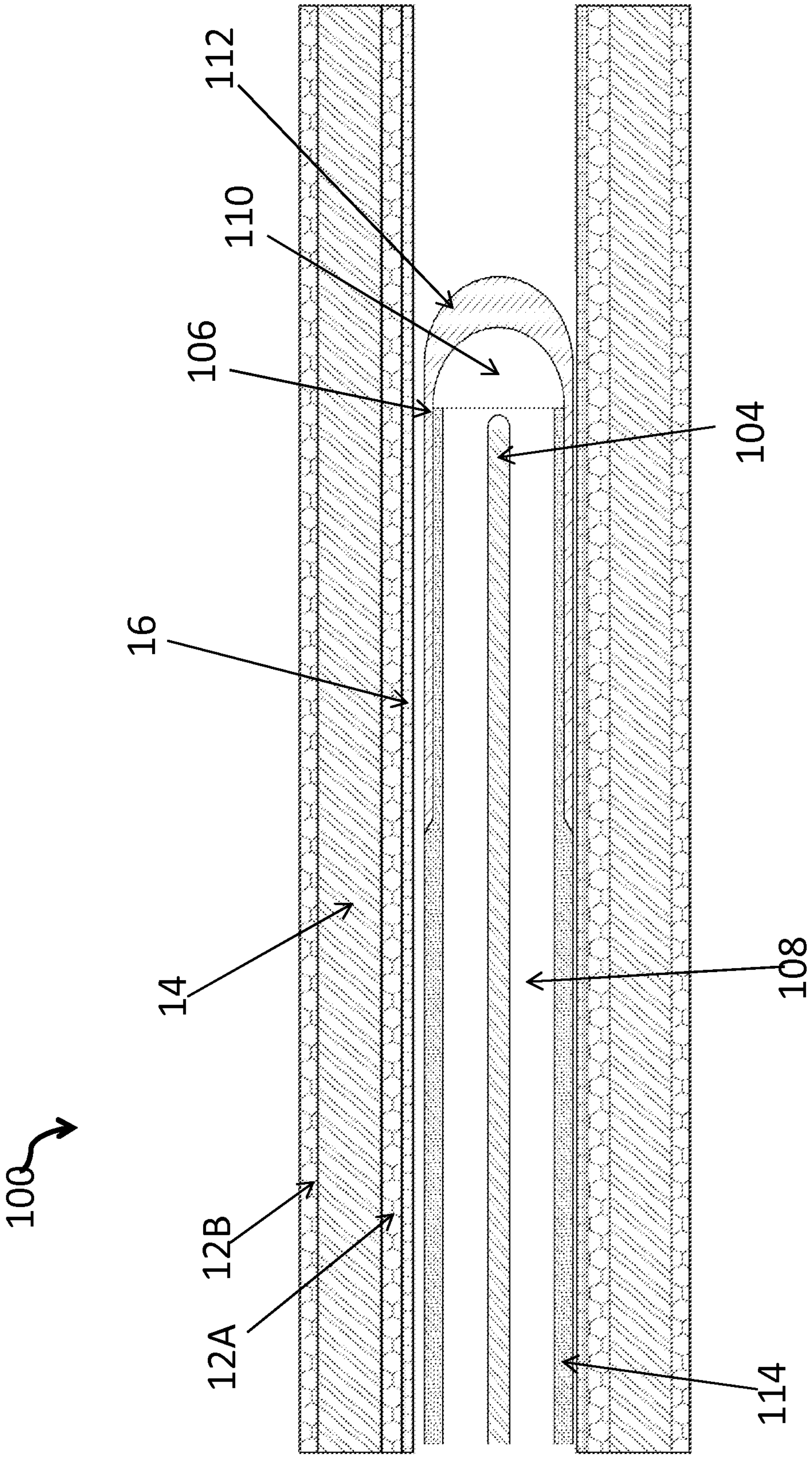


Figure 6

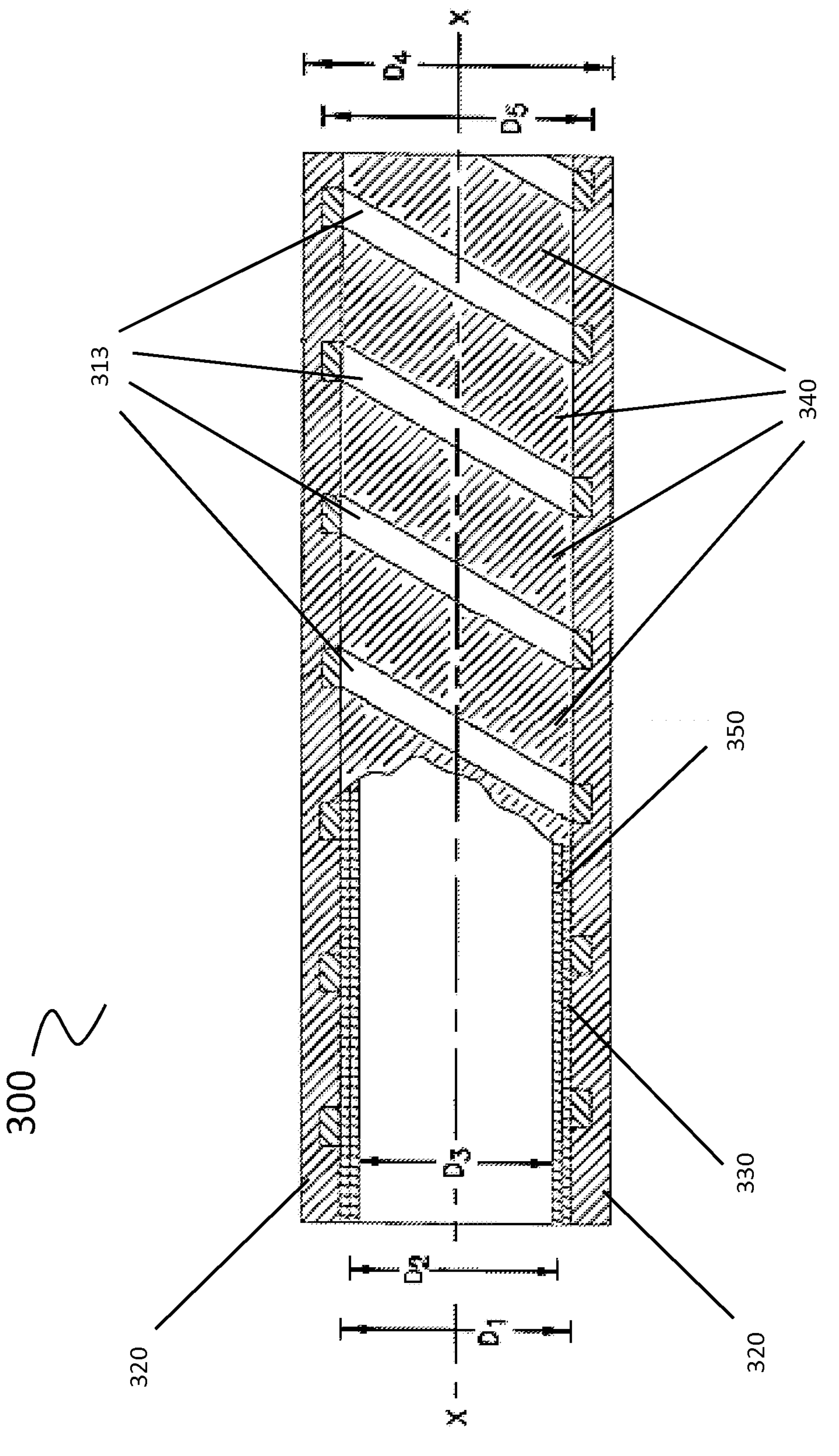


Fig. 7

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 15/42676

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. Ill Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

Group I: Claims 1-13 and 17 are directed toward a hypotube with a cut pattern and liner, encapsulated with polymers.

Group II: Claims 14-16 are directed toward a catheter comprising a coated hypotube and liner.

The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the special technical features of Group I a hypotube body; a pair of polymer layers, wherein a first polymer layer encapsulates an inside surface of the hypotube body; wherein a second polymer layer encapsulates an outside surface of the hypo tube body a liner, wherein the liner is secured to the inside surface of the hypotube body by the first polymer layer; and a cut pattern, wherein the cut pattern is formed on the hypotube body, which are not present in Group II; and the special technical features of Group II include a catheter comprising a liner comprising a low friction material, wherein the liner is placed against the inside surface, which are not present in Group I.

-*"-Continued Within the Next Supplemental Box-***-

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-13, 17

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 15/42676

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61B 17/94; A61L 29/14; B32B 1/08 (2015.01)
CPC - A61L 29/14; A61M 25/0021; Y10T 428/1393
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
-'''-Continued Within the Next Supplemental Box-'''-

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PatSeer (US, EP, WO, JP, DE, GB, CN, FR, KR, ES, AU, IN, CA, INPADOC Data); Google Scholar; ProQuest; IP.com: hypotube, cut, pattern, polymeric, metal, coat, layer, liner, catheter, stiffness

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X -- Y	US 2003/0093059 A1 (GRIFFIN, S et al.) 15 May 2003; figure 2; paragraphs [0003], [0009H0013], [0015], [0019]	I-10, 13, 17 -- I I-12
Y	US 2014/0046297 A1 (SHIMADA, L et al.) 13 February 2014; paragraphs [0008]-[0009], [0046]	11-12
A	US 2013/0046285 A1 (GRIFFIN, S et al.) 21 February 2013; entire document	1-13, 17
A	US 7,989,042 B2 (OBARA, RZ et al.) 02 August 2011; entire document	1-13, 17
A	US 2009/0043283 A1 (TURNLUND, TH et al.) 12 February 2009; entire document	1-13, 17

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
22 September 2015 (22.09.2015)	**30 DEC 2015**

Name and mailing address of the ISA/	Authorized officer
Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Shane Thomas PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/US 15/42676

-'"-Continued from Box III: Observations where unity of invention is lacking-*"-

The common technical features of Groups I-II are a hypotube comprising: a hypotube body; a polymer on an outside surface of the hypotube body; and a liner on the inside of the hypotube body.

These common technical features are disclosed by US 7,989,042 B2 to Obara, et al. (hereinafter Obara'). Obara discloses a hypotube (a coated hypotube 22; figures 2-3, 6; column 4, lines 54-64; column 7, lines 41-51); a polymer on an outside surface of the hypotube body; and a liner a polymer on an outside surface of the hypotube body (polymer layer 24 is applied to the hypotube 10 covering all of the surface elements; column 4, lines 65-67; column 5, lines 1-7); and a liner on the inside of the hypotube body (coated hypotube 22 used as a catheter has an inner polymeric layer 36 (liner); figure 6; column 7, lines 41-51).

Since the common technical features are previously disclosed by Obara, these common features are not special and so Groups I-II lack unity.

-*"-Continued from Box B. FIELDS SEARCHED -***-

IPC(8): A61B 17/00, 17/94; A61L 29/00, 29/02, 29/08, 29/12, 29/14; A61M 25/00, 25/14, 25/16; B32B 1/08, 3/20 (2015.01)

CPC: A61B 17/00234, 2017/00292, 17/3415; A61L 29/00, 29/02, 29/08, 29/12, 29/14; A61M 25/00, 2025/0007, 25/0009, 25/0021; Y10T 428/00, 428/1321, 428/1352, 428/139, 428/1393