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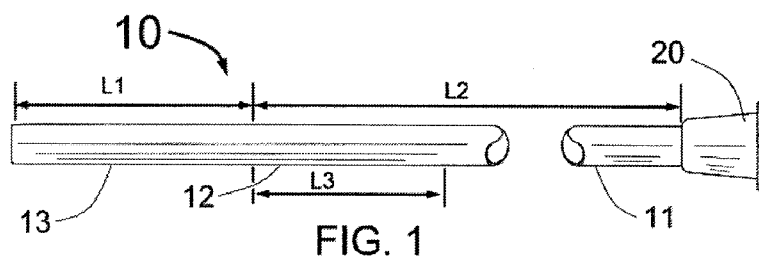
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- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))

(54) Title: CAROTID SHEATH WITH FLEXIBLE DISTAL SECTION



(57) Abstract: The present invention is a carotid sheath that has a proximal portion that is stiffer than the distal portion of the sheath as a result of the proximal portion having a higher durometer of the outer plastic coating of the sheath's proximal portion with a lower durometer for the plastic coating on the more flexible distal portion of the sheath. Another means to increase the flexibility of the sheath's distal portion compared to a stiffer proximal portion is by having a slightly smaller outside diameter for the outer plastic coating of the distal portion of the sheath. A more flexible distal portion of the sheath allows easier access for angiography, angioplasty or stenting when the sheath is used to access the tortuous path encountered when entering the carotid arteries.



CAROTID SHEATH WITH FLEXIBLE DISTAL SECTION

Field of Use

[0001] This invention is in the field of devices to assist in the placement of catheters through the skin to treat carotid artery obstructive disease.

Background of the Invention

[0002] At the present time, physicians often treat carotid artery obstructive disease with the placement of a stent. This stent is typically placed in the internal carotid artery, in the common carotid artery, or spanning both arteries with the distal portion of the stent in the internal carotid artery and the proximal portion of the stent in the distal common carotid artery. The start of this procedure necessitates the placement of either a long sheath or a guiding catheter into the common carotid artery proximal to the carotid stenosis to be treated. The placement of such a sheath or guiding catheter can often be extremely challenging due to the tortuous course for access from the aortic arch into the common carotid artery. This is particularly an issue when accessing the right common carotid artery, which typically arises as a proximal branch from the innominate artery. Many different “tricks” are used to try to place relatively stiff sheaths and guiding catheters into the carotid circulation. One such “trick” is to have the sheath track over a “super-stiff” guidewire. Even with the best of equipment, it can be technically challenging, or even impossible to access the common carotid artery in order to stent a stenosis at that location when using any existing carotid sheath that has a uniform flexibility along its entire length. If stenting is not possible, then the more invasive and potentially life threatening procedure of a surgical endarterectomy may be required. Therefore, there is an important need for an improved carotid sheath that allows for more successful guidance through the tortuous vascular anatomy that is encountered when attempting to stent a stenosis in a carotid artery.

[0003] Another problem with the current approach for carotid stenting is that it requires the placement of a relatively large sheath (typically 8 French) or a thick walled 7 French carotid sheath system to deliver the relatively high profile carotid stent delivery catheter. The use of these larger diameter sheaths can lead to an increased likelihood of vascular access bleeding after the sheath has been removed. In general, there is a relationship between the outer diameter of the inserted sheath and the risk of bleeding complications. Thus, sheaths with thinner walls would have

a smaller outside diameter. This would decrease the size of the hole at the vascular entry site which would reduce the risk of serious bleeding complications.

Summary of the Invention

[0004] A sheath diameter is typically expressed in FR (read “French”), which is the diameter of the sheath in millimeters multiplied by three. So a 6 FR sheath has a diameter of 2 mm. Using the currently available technology for carotid stenting, it is typical to use a relatively small sized (5 FR or 6 FR) sheath and diagnostic catheter (e.g., Simmons, or Headhunter, etc.) to access into the proximal common carotid artery. A relatively stiff (exchange length) guidewire is then placed through this 5 FR or 6 FR diagnostic catheter. The guidewire is then advanced through the common carotid artery, and distally into the external carotid artery to “anchor” this wire. Once the stiff guidewire is in place, it allows the exchange over this wire of a guiding catheter or a long carotid “guiding” sheath. For the purposes of this specification, we will refer to this guiding catheter or long carotid sheath merely as a “sheath” or a “carotid sheath.”

[0005] The present invention is a thin-walled, flat wire reinforced sheath with a differential in sheath flexibility from the proximal portion to the distal portion of the sheath. Specifically, the carotid sheath described herein would have a greater stiffness along most of its proximal length and more flexibility in the distal portion of the sheath in order to enhance sheath tracking over a guidewire, a diagnostic catheter, or a dilator. At this time, there is no sheath that exists that has a comparatively long (about 75 cm) and stiff proximal portion to provide “pushability” combined with a comparatively short (about 15 cm) distal portion that is highly flexible to provide ready tracking through the highly curved vascular anatomy that must often be navigated in order to successfully place a stent in a carotid stenosis. Such a novel carotid sheath would make stenting of a carotid stenosis a more predictably successful procedure.

[0006] Another important aspect of the present invention is the construction of the tubular shaft of the sheath. Existing sheaths have a wall thickness that is typically greater than 13 mils where 1.0 mil = 0.001 inch. By using a flat wire helical coil with a wire thickness of approximately 1 mil to 3 mils, which coil has a very thin coating of plastic placed onto its inner and outer surfaces, it is possible to reduce the wall thickness of the tubular shaft to less than 7 mils and preferably to around 5 mils. Such a novel construction would reduce the outside diameter of the introducer

sheath by approximately one French size compared to existing sheaths. Such a reduction in the diameter of the sheath would be advantageous in reducing the risk of bleeding at the groin that sometimes occurs after removal of sheaths having a larger outside diameter. Any method to decrease the requirement for surgical repair and/or a blood transfusion often needed for a major bleeding complication would be highly advantageous for the patient and could significantly decrease the morbidity, mortality and cost associated with catheterization procedures.

[0007] The present invention also envisions that the shaft of the sheath could employ a thin-walled, flat wire helical coil to be fabricated from a shape memory alloy such as Nitinol to prevent the possibility of kinking of the tubular shaft of the introducer sheath. Still further the present invention envisions a shaft made from two to four separate helical metal coils, one of a cobalt chromium alloy (e.g., the alloy L605) to enhance the strength and radiopacity of the shaft and the other coil(s) to be made from stainless steel for cost economy. This novel design would be very advantageous for providing a thin-walled shaft for the sheath that is also radiopaque and reasonably economical to build. It is also envisioned that just using one or more stainless steel and/or cobalt chromium alloy flat wires wound onto an inner layer of PTFE plastic and then coated in a plastic such as Pebax could be an excellent design. An important feature of any flat wire used for such a sheath is that they would be annealed to be either half hard or quite soft so as to more easily place the flat wires into the sheath shaft. Another novel design aspect is to have a differential in sheath flexibility with greater flexibility in the distal portion by either changing the durometer, or the thickness of the plastic components from the sheath's proximal portion to its distal portion (i.e., higher durometer or thicker in the proximal portion rather than distal portion) and/or changing the winding frequency of the helical coil of flat wire as one moves from proximal to distal end of the sheath, such that the distal portion of the sheath is more flexible and trackable than the proximal portion of the sheath.

[0008] Thus, one object of this invention is to use thin-walled flat wire within the sheath to decrease the outer diameter of the sheath, which decreases the size of the vascular entry hole and potentially reduces access site bleeding complications.

[0009] Another object of this invention is to create a carotid sheath that has a differential in sheath flexibility such that the distal portion of the sheath is more flexible than the proximal portion of the sheath which provides greater trackability of

the distal portion of the sheath into the common carotid artery or any other target vessel requiring access for percutaneous intervention.

[0010] Still another object of the invention is to have a carotid sheath that is quite stiff for most of its proximal length to enhance its pushability with a distal portion that is much more flexible to enhance trackability and to ease its passage into the carotid arteries.

[0011] Still another object of the invention is to have a carotid sheath that has a proximal portion that is stiffer than the distal portion of the sheath as a result of the proximal portion having a higher durometer of the plastic on the outer layer of the sheath's proximal portion with a lower durometer for plastic covering on the more flexible distal portion of the sheath.

[0012] Still another object of the invention is to have a carotid sheath that has a proximal portion that is stiffer than the distal portion of the sheath as a result of the proximal portion having a slightly thicker outer coating of the plastic on the sheath's proximal portion with a thinner coating of plastic covering the more flexible distal portion of the sheath.

[0013] These and other objects and advantages of this invention will become obvious to a person of ordinary skill in this art upon reading the detailed description of this invention including the associated drawings as presented herein.

Brief Description of the Drawings

[0014] FIG. 1 illustrates the present invention having a proximal portion with a length L2, the proximal portion being quite inflexible and a distal portion having a length L1 that is highly flexible.

[0015] FIG. 2 is a cross section of the carotid sheath showing the construction details for its proximal portion.

[0016] FIG. 3 is a cross section of a distal portion of the carotid sheath showing a means to increase the flexibility of the distal portion of the sheath.

Detailed Description of the Invention

[0017] FIG. 1 shows a sheath 10 having a comparatively flexible distal portion 13 having a length L1, a comparatively long and stiff proximal portion having a length L2 and a comparatively short transitional section 12 with length L3. Typical lengths L1, L2 and L3 would be $L1 = 15 \pm 5$ cm, $L2 = 75 \pm 10$ cm and $L3 = 3 \pm 3$ cm. The total length of the carotid sheath should be about 90 cm. FIG. 1 also shows a Luer fitting at the proximal end of the sheath 10 which is typically used for injecting liquids

through the sheath 10 or for connecting a Touhy-Borst fitting for performing carotid stenting. The Luer fitting with the Touhy-Borst fitting also allows for the passage of a dilator. Though it is not shown in FIG. 1, the present invention also envisions having a Touhy-Borst fitting fixedly attached at the sheath's proximal end instead of the Luer fitting. This would save one step for the operator by not requiring the attachment of a separate Touhy-Borst fitting to the Luer fitting.

[0018] FIG. 2 shows a typical construction for the proximal portion 11 of the sheath 10. This portion of the sheath tubing would have an interior plastic coating 14 that would typically be formed from a lubricious plastic such as PTFE with a thickness that would typically be less than 1.0 mil, and an exterior plastic coating 15P on the proximal portion of the sheath 10 that would typically be formed from a Nylon type plastic such as Pebax with a thickness between 2 mils to 5 mils. Either or both coatings could be treated with a hydrophilic or other coating, to enhance their lubricity. The thickness of the Pebax could be thinned a bit in the distal portion, compared to the proximal portion of the sheath in order to enhance distal flexibility.

[0019] Between the interior and exterior plastic coatings 14 and 15, an optimum sheath would utilize one or several flat wire helical coils to create tubing that was non-kinking and also radiopaque. At least one helical coil 16 could be formed from a tough, radiopaque metal such as the cobalt chromium alloy L605. At least one additional helical coil 17 would be formed from stainless steel for additional non-kinking resistance and for cost economy. An optimum design might have as many as three separate helical coils of stainless steel and one helical coil of cobalt chromium.

[0020] It is also conceived to have just one to as many as four helical coils 17 formed from stainless steel. These flat wires would typically have a wall thickness of about 2.0 ± 1.5 mils and a width that could be between 3 and 50 mils. An optimum flat wire would be approximately 2.0 mils thick and about 10 to 20 mils wide. The space between the wires that is occupied by the exterior plastic coating 15 would be approximately 10 ± 5 mils wide for the comparatively stiff proximal portion 11 of the sheath 10. The inside diameter of the sheath would typically be formed to have a small clearance that allows for the passage of catheters that would have diameters between 4 FR and 9 FR. The outside diameter of the sheath would typically be approximately 1.0 FR size greater than the inside diameter of the sheath.

[0021] FIG. 3 is a cross section of the distal portion 13 of the sheath 10 showing a tapered radiopaque marker band 19 placed within a tapered tip 18. The distal portion 13 would typically have the same interior plastic coating 14 as is used for the proximal portion 11 of the sheath 10. The exterior plastic coating 15D for the flexible distal portion of the sheath would have a lower durometer as compared to the durometer for the proximal portion 11 of the sheath 10. The increased flexibility of the distal portion 13 can be achieved by a greater separation of the coils of the helical coils 16 and 17 as illustrated in FIG. 3. A greater separation of the flat wire helical coil 16, with the elimination of the helical coil 17 could also be used to provide the desired increased flexibility. Alternatively, the pitch angle of both helical coils 16 and 17 of the proximal portion 11 (as shown in FIG. 3) could be changed to provide increased separation of the coils as another means to provide the increased flexibility that is desired for the distal portion 13. It is certainly envisioned that the sheath 10 would have a single helical coil formed from flat wire with a tight spacing in the proximal portion 11, increased spacing through the transitional section 12 and a comparatively wide spacing of the flat wire helical coil for the sheath's distal portion 13. The separation between the flat wire coils for the distal portion 13 could be as great as 100 ± 90 mils in order to achieve the desired degree of flexibility.

[0022] Still another means to improve the flexibility of the distal portion 13 would be to use an exterior plastic coating 15D on the distal portion 13 that has a decreased plastic durometer as compared to a higher durometer that would be used for the exterior plastic coating 15P of the proximal portion 11 of the sheath 10. For example, the harder plastic coating 15P could have a durometer of 75 ± 10 and the softer plastic coating 15D could have a durometer of 45 ± 10 . Although it would be typical for the outside diameter of both plastic coatings 15P and 15D to have the same diameter, it is also envisioned that the proximal portion 13 could have a slightly smaller diameter to further improve the flexibility of the distal portion of the sheath 10. For example, the outer coating 15D of the distal portion 13 could have an outside diameter that is between 0.1 mil and 2 mils smaller than the outer diameter of the outer coating 15P of the proximal portion 11. Still further, it is envisioned that the transitional portion having a length L3 could have a variable durometer from being quite hard where it joins the proximal portion plastic coating 15P to a much softer durometer where it joins the distal portion plastic coating 15D.

[0023] Exemplary embodiments of the present disclosure include:

[0024] A first exemplary embodiment of a sheath for accessing a patient's vascular system where most of the length of the sheath is the proximal portion that is stiffer as to its bending characteristic as compared to a shorter distal portion of the sheath that has increased flexibility, the increased flexibility of the distal portion of the sheath being accomplished by having a decreased durometer, and/or thickness for the outer plastic coating compared to a harder durometer and/or thicker layer of plastic coating on the longer, proximal portion of the sheath.

[0025] The sheath of the first exemplary embodiment where the tubing of the sheath has a comparatively lubricious interior plastic coating and an exterior plastic coating formed from a different plastic material and there is at least one flat wire helical coil situated between the two layers of plastic. The sheath of this paragraph is referred to as the second exemplary embodiment below.

[0026] The sheath of first exemplary embodiment where the length of the stiffer proximal portion is approximately 75 + 10 cm and the length of the distal portion of the sheath is approximately 15 + 10 cm.

[0027] The sheath of the second exemplary embodiment where at least one flat wire between the plastic coatings is formed from stainless steel.

[0028] The sheath of the second exemplary embodiment where at least one flat wire between the plastic coatings is formed from an alloy of a high density metal such as cobalt chromium.

[0029] The sheath of the second exemplary embodiment where at least one of the flat wire helical coils is formed from stainless steel and at least one other helical coil is formed from a metal alloy that is more highly radiopaque.

[0030] The sheath of the second exemplary embodiment where the increased flexibility of the distal portion of the sheath is achieved by a greater separation between the coils of at least one helical coil of flat wire that is situated between the interior plastic coating and the exterior plastic coating.

[0031] The sheath of the second exemplary embodiment where the interior plastic coating is formed from PTFE or an equivalent lubricious plastic.

[0032] The sheath of the second exemplary embodiment where the exterior plastic coatings of the sheath are formed from Pebax or an equivalent plastic material.

[0033] The sheath of the second exemplary embodiment where the exterior plastic coating of the sheath's distal portion is approximately 0.1 mil to as much as 2

mils smaller in outside diameter as compared to the outside diameter of the exterior plastic coating of the proximal portion of the sheath so as to improve the flexibility of the distal portion of the carotid sheath compared to the flexibility of the proximal portion of the sheath.

[0034] The sheath of the second exemplary embodiment where there is a transitional section of the sheath between the proximal portion and the distal portion, the transitional section having a tighter spacing of at least one flat wire helical coil near the proximal portion of the sheath and a greater separation between the flat wires of the at least one helical coil near the distal portion of the sheath.

[0035] The sheath of the second exemplary embodiment where there is a transitional section of the sheath between the proximal portion and the distal portion, the transitional section having a higher durometer near the proximal portion of the sheath and a decreased durometer of the plastic coating as it reaches the distal portion of the sheath.

[0036] A thirteenth exemplary embodiment of a sheath for accessing a patient's vascular system, the sheath having a tapered distal end from a plastic material with a tapered radiopaque marker band situated within the tapered distal end.

[0037] A fourteenth exemplary embodiment of a sheath for accessing a patient's vascular system, the sheath having a Touhy-Borst fitting formed integral with the sheath's proximal portion.

Claims

What is claimed is:

1. A vascular access sheath comprising:
a first portion having a first length and
a second portion having a second length, the second portion disposed distal of the first portion;
wherein the first portion is stiffer than the second portion and the first length is greater than the second length.
2. The vascular access sheath of claim 1, wherein the second portion has durometer hardness which is lower than the durometer hardness of the first portion.
3. The vascular access sheath of claim 1, wherein the first portion comprises an outer plastic coating which is thicker than an outer plastic coating of the second portion.
4. The vascular access sheath of claim 1, further comprising a lubricious interior plastic coating;
an exterior plastic coating comprising a different plastic material than the interior plastic coating; and
a flat helical wire coil disposed between the interior plastic coating and the exterior plastic coating.
5. The vascular access sheath of claim 1, wherein the first length is about 75 ± 10 cm and the second length is about 15 ± 10 cm.
6. The vascular access sheath of claim 4, wherein the flat helical wire coil comprises stainless steel.
7. The vascular access sheath of claim 4, wherein the flat helical wire coil comprises a high density metal alloy such as a cobalt chromium alloy.

8. The vascular access sheath of claim 6, further comprising a second flat helical wire coil disposed between the interior plastic coating and the exterior plastic coating, the second flat helical wire coil comprising an alloy of a radiopaque metal.

9. The vascular access sheath of claim 4, wherein the distance between adjacent coils of the flat helical wire coil is greater in the second portion than in the first portion.

10. The vascular access sheath of claim 4, wherein the lubricious interior plastic coating comprises PTFE.

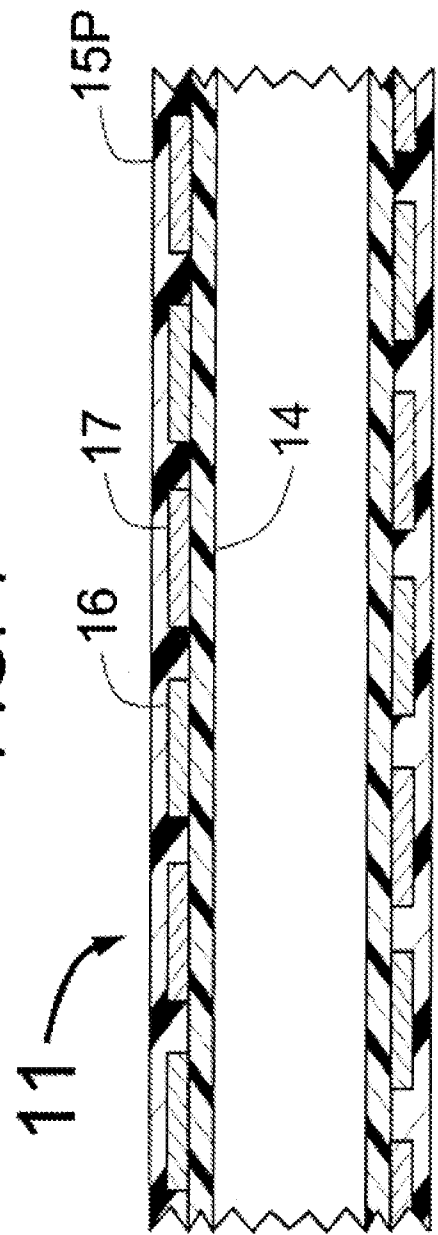
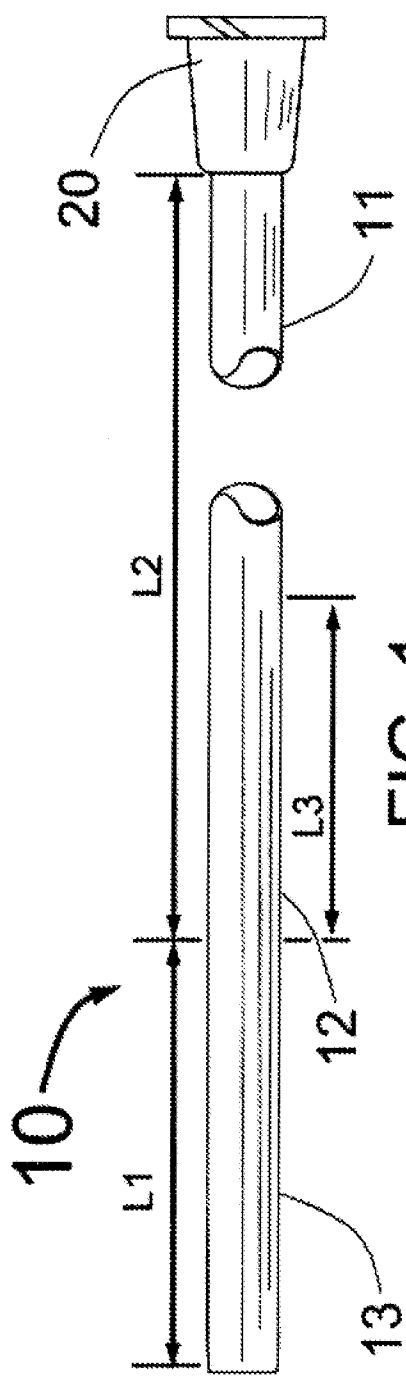
11. The vascular access sheath of claim 4, wherein the exterior plastic coating comprises Pebax.

12. The vascular access sheath of claim 4, wherein the second portion comprises an exterior plastic coating with an outside diameter between about 0.1 mil to about 2 mils smaller than an outside diameter of an exterior plastic coating of the first portion.

13. The vascular access sheath of claim 4, further comprising a transitional section disposed between the first portion and the second portion, wherein the distance between adjacent coils of the flat helical wire coil within the transitional section is greater near a proximal portion of the transitional section than in a distal portion of the transitional section.

14. The vascular access sheath of claim 4, further comprising a transitional section disposed between the first portion and the second portion, the transitional section having a higher durometer hardness near a proximal portion of the transitional section than in a distal portion of the transitional section.

15. A vascular access sheath comprising:
a tapered distal end comprising a plastic material and
a tapered radiopaque marker band disposed within the tapered distal end.
16. A vascular access sheath comprising a Touhy-Borst fitting integrally formed with a proximal portion of the sheath.



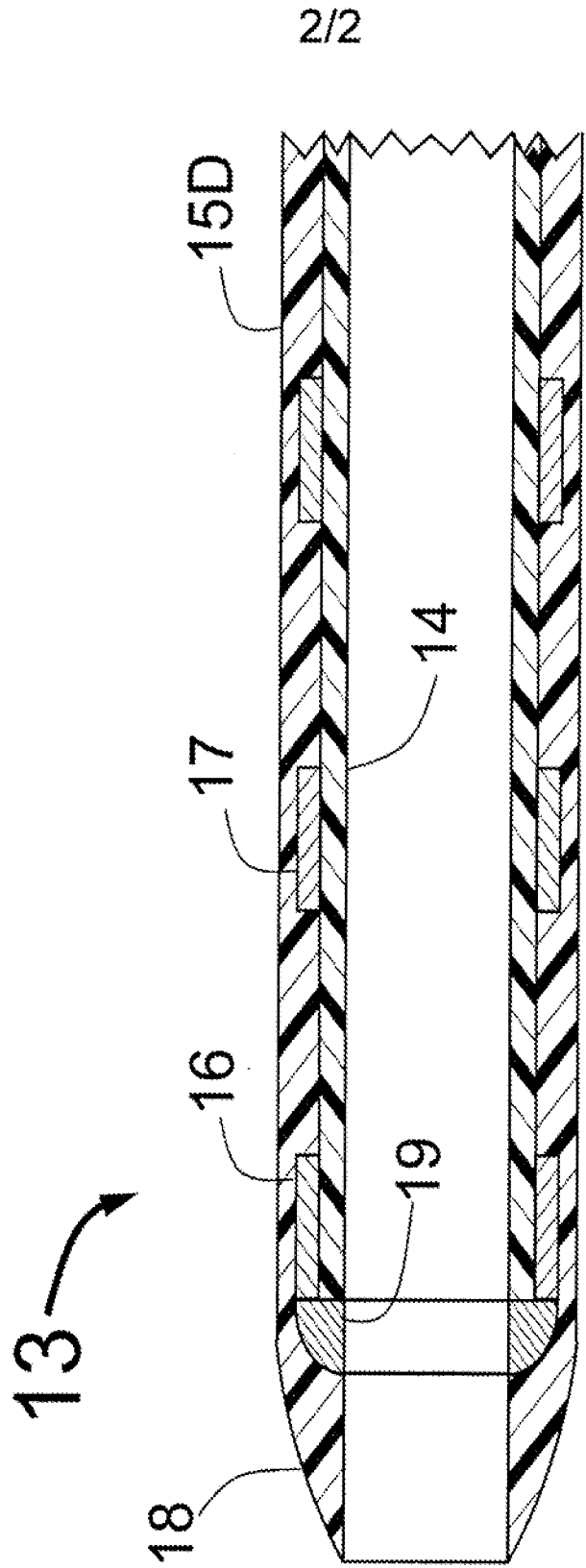


FIG. 3

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 12/40391

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61M 25/00 (2012.01)

USPC - 604/525, 526

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)

IPC(8) - A61M 25/00 (2012.01)

USPC - 604/525, 526

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
604/48, 93.01, 171, 172, 264, 265, 275, 523-526(Search term limited; see below)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

PubWest (PGPB, USPT, EPAB, JPAB); Google

Search Terms: Catheter, sheath, introducer, vary\$, different, variable, durometer, stiff\$, flexib\$, proximal, distal, section, portion, helical, coil, wire, spring, spacing, lubric\$, PTFE, Pebax,

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6,152,912 A (JANSEN et al.) 28 November 2000 (28.11.2000) Entire document, especially Abstract, col 9, ln 29- col 9, ln 41, col 9, ln 49-65, col 10, ln 60- col 11, ln 16 and FIGS. 1, 2A-2F.	1, 2, 4-6, 8, 10, 11 and 14
X	US 2006/0155302 A1 (SISKEN et al.) 13 July 2006 (13.07.2006) Entire document, especially Abstract, para[0025], para[0029]- para[0033] and FIG. 2.	1, 2, 4, 7, 9 and 13
X	US 2003/0093060 A1 (KEMPF) 15 May 2003 (15.05.2003) Entire document, especially Abstract, para[0018]- para[0020], para[0025]- para[0030] and FIGS. 1, 4.	1, 3-4, 6, 10-12
X	US 2006/0089618 A1 (MCFERRAN et al.) 27 April 2007 (27.04.2007) Entire document, especially Abstract, para[0005]-[0006], [0015]-[0018].	1
X	US 2009/0157162 A1 (CHOW et al.) 18 June 2009 (18.06.2009) Entire document, especially Abstract, para[0007]-[0015] and FIGS. 23-28.	1
X	US 7,905,877 B1 (JIMENEZ et al.) 15 March 2011 (15.03.2011) Entire document	1
X	US 6,939,337 B2 (PARKER et al.) 06 September 2005 (06.09.2005) Entire document.	1
X	US 5,704,926 A (SUTTON) 06 January 1998 (06.01.1998) Entire document.	1

☐ Further documents are listed in the continuation of Box C.

* 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

24 October 2012 (24.10.2012)

Date of mailing of the international search report

08 NOV 2012

Name and mailing address of the ISA/US

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PCT Helpdesk: 571-272-4300
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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 12/40391

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. III 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 1-14, drawn to vascular access sheaths, more specifically to those with two sections, with the first section being stiffer and longer than the second section.

Group II: Claims 15-16, drawn to vascular access sheaths, more specifically to those with a tapered distal end, radiopaque markers and Touhey-Borst connectors.

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 shared technical features for the two groups comprises the vascular access sheaths, with different first and second ends. However, vascular sheaths (12, FIG. 1) with two sections (28, 30; FIG. 1), including tapered distal ends (26, FIG. 1; col 5, ln 35-58) are known in the art (see US 6,508,790 B1 to Lawrence). Groups I-II therefore lack unity under PCT Rule 13 because they do not share a same or corresponding special technical feature.

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.:
1-14

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.