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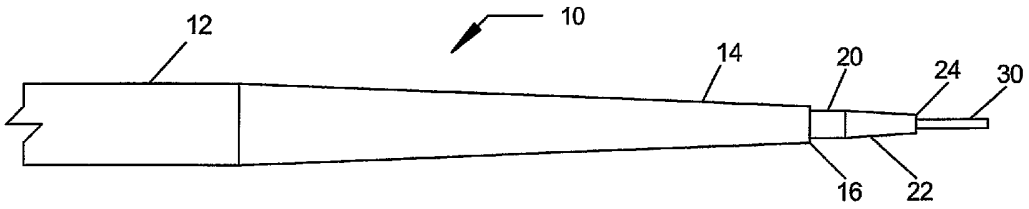
(54) Title: LOW PROFILE INTRODUCER APPARATUS



(57) Abstract: An introducer apparatus includes an outer sleeve (12) and an inner cannula (20) received within the lumen (15) of the outer sleeve. The outer sleeve has a profile such that at least a portion of the distal end of the outer sleeve tapers in the distal direction at an angle not exceeding about 2.5° relative to a longitudinal axis of the apparatus. The distal open end of the outer sleeve has a wall thickness not exceeding about 0.003 inch, and is sized such that a first wire guide is receivable therethrough. The inner cannula includes a tapered distal end portion. The inner cannula distal open end is sized such that a second wire guide is receivable therethrough, and the first wire guide is not receivable therethrough. The tapered distal portion of the inner cannula extends distal to the distal open end of the outer sleeve, such that a generally smooth diametrical transition is provided between the outer sleeve tapered portion and the open distal end of the inner cannula.

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LOW PROFILE INTRODUCER APPARATUS

Description

Technical Field

This invention relates to the field of percutaneous access to the vascular system. More specifically, this invention relates to a low profile apparatus used to introduce catheters and other interventional devices into the vascular system with small gauge needles.

Background of the Invention

Many medical procedures require the percutaneous placement of an interventional medical device, such as a catheter, into an artery or vein. Such interventional devices are used for, among other things, blood pressure monitoring, blood sampling, and the administration of fluids and medicaments to a patient.

Typically, such devices are introduced using the well-known Seldinger percutaneous entry technique. The Seldinger technique for percutaneous entry into the vascular system has been in widespread use in diagnostic and interventional medicine for many years. In the Seldinger technique, the physician makes an oblique entry into the artery or vein with a beveled needle. A wire guide is passed into the proximal end of the needle, through the length of the needle and into the artery or vein. The needle is thereafter withdrawn, leaving the wire guide in place. The catheter or other interventional device is then passed over the wire guide, through the puncture, and into the artery or vein at the needle puncture site. Once the catheter is in place, the wire guide can be withdrawn.

One of the disadvantages of this procedure is that the initial needle stick must be made with a needle that is large enough to accept the wire guide through its central bore. Conventional wire guides are normally comprised of a tightly wound helical stainless steel wire coil. In order to have sufficient rigidity to properly support and lead many standard catheters and other interventional devices in common use in modern medicine, such wire guides are typically constructed to have an outer diameter (O.D.) in the range of about 0.035 to 0.038 inch (0.89 or 0.97 mm). This diameter of wire guide will typically pass through an

18 gauge thinwall needle. An 18 gauge needle typically has a 0.050 inch (1.27 mm) outer diameter and a 0.042 inch (1.07 mm) inner diameter.

The 18 gauge needle is the most common sized needle used for initial vascular access, and has become a standard needle for use with the Seldinger technique for percutaneous catheterization. However, the outer diameter of an 18 gauge needle is just large enough to damage tissue or cause excessive bleeding if it does not enter the vessel correctly, or if it inadvertently penetrates an organ or other unintended body structure. As a result, it is desirable to utilize a smaller gauge needle to effect the initial entry. Needles of 21 gauge thinwall (.32 in O.D., .022 in I.D.), or smaller, are considered small enough that they do not damage tissue or organs, or cause excessive bleeding if inserted off target. In addition, needles having smaller outer diameters generally have correspondingly shorter bevels at the needle tip compared to the size of the bevel tip of an 18 gauge needle. Thus, it is much easier to get a short bevel into the lumen of a small vessel than the longer bevel of the 18 gauge needle.

Unfortunately, the bore of a needle of 21 gauge, or smaller, is not large enough to pass a standard 0.035 inch or 0.038 inch (0.89 mm or 0.97 mm) diameter wire guide therethrough. The largest wire guide that can be easily introduced into such small gauge needles is normally a wire of 0.018 inch (0.46 mm) outer diameter. However, many diagnostic and interventional devices need at least a 0.035 inch (0.89 mm), and more preferably a 0.038 inch (0.97 mm), diameter wire guide to provide sufficient support to optimally introduce and manipulate such devices through the vasculature. Thus, unless and until a larger diameter wire guide is introduced into the vasculature, many such devices cannot be introduced.

U.S. Patent No. 4,650,472 ("the '472 patent"), assigned to the assignee herein, describes a catheterization apparatus which allows a smaller gauge needle, such as a 22 gauge (0.028 inch; 0.72 mm O.D.) needle, to be used for the initial puncture through the skin of the patient in place of the larger conventional 18 gauge needle. The '472 patent is incorporated by reference herein. A 0.018 inch (0.46 mm) outer diameter wire guide is initially inserted through the bore of the small gauge (e.g. 22 gauge) needle. The needle is thereafter withdrawn, and a removable inner

cannula, or dilator, is provided over the wire guide but inside an outer sleeve portion of the catheterization apparatus. This removable inner cannula has a tapered tip, and provides a transition between the large distal opening of the outer sleeve and the 0.018 inch wire guide. The inner cannula is generally about 0.038 inch (0.97 mm) O.D., and the outer sleeve is sized to fit over the inner cannula.

The outer sleeve and the inner cannula of the apparatus disclosed in the '472 patent are normally inserted into the blood vessel in tandem. The diametrical transition of the leading end of this tandem is intended to minimize the trauma that may otherwise be caused by the insertion of a large diameter outer sleeve over a small diameter wire guide. Once the outer sleeve is properly positioned within the blood vessel, the inner cannula and the smaller wire guide can be withdrawn, leaving the outer sleeve in place. A larger (0.035 to 0.038 inch) (0.89 to 0.97 mm) wire guide can then be introduced through the outer sleeve and into the vessel. The outer sleeve can thereafter be removed from the patient, leaving the larger wire guide in the vessel ready to accept a catheter or other interventional device, as in the standard Seldinger technique. The apparatus of the '472 patent has been successfully used to percutaneously insert a catheter having a large diameter O.D. into a blood vessel when the initial insertion is made with an introducer needle and a wire guide which are much smaller in diameter than the distal opening of the catheter.

The apparatus of the '472 patent thus enables the physician to introduce larger diagnostic and interventional devices into a vessel than would otherwise be possible when the initial vessel entry is made with a small gauge needle. When the apparatus is inserted into the vessel as described, however, the physician must exert sufficient force to overcome the resistance provided at the "bump" that is present at the transition between the distal end of the outer sleeve and the underlying portion of the inner cannula. In addition, if the amount of force is not carefully controlled, the side of the vessel opposite the initial stick may be punctured. Although such insertions may be safely performed, it is nonetheless desired to further minimize the amount of force required to insert the outer sleeve

into the vessel, and to reduce the possibility that the physician may inadvertently puncture any portion of the vessel wall.

Brief Description of the Drawing

Fig. 1 is a side view of a prior art apparatus for effecting catheterization of a body vessel using a small gauge introducer needle;

Fig. 2 is a sectional view of the outer sleeve of the apparatus of Fig. 1;

Fig. 3 illustrates one embodiment of a wire guide exchange apparatus of the present invention;

Fig. 4 is a sectional view of the outer sleeve of the apparatus of Fig. 3;

Fig. 5 is a graph illustrating the relationship between compressive extension and compressive load for specimens 1-15 of an embodiment of the inventive apparatus;

Fig. 6 is a graph illustrating the relationship between compressive extension and compressive load for specimens 16-30 of an embodiment of the inventive apparatus;

Fig. 7 is a graph illustrating of relationship between compressive extension and compressive load for specimens 1-15 of a reference apparatus; and

Fig. 8 is a graph illustrating the relationship between compressive extension and compressive load for specimens 16-30 of a reference apparatus

Detailed Description

For the purposes of promoting an understanding of the principles of the invention, reference will now be made to the embodiments illustrated in the drawings, and specific language will be used to describe the same. It should nevertheless be understood that no limitation of the scope of the invention is thereby intended, such alterations and further modifications in the illustrated device, and such further applications of the principles of the invention as illustrated therein being contemplated as would normally occur to one skilled in the art to which the invention relates.

In the following discussion, the terms "proximal" and "distal" will be used to describe the opposing axial ends of the inventive apparatus, as well as the axial ends of various related components. The term "proximal" is used in its

conventional sense to refer to the end of the apparatus (or component) that is closest to the operator during use of the collar. The term "distal" is used in its conventional sense to refer to the end of the apparatus (or component) that is initially inserted into the patient, or that is closest to the patient.

Fig. 1 illustrates one embodiment of a prior art apparatus 100 for effecting catheterization of a body vessel using a small gauge introducer needle. The apparatus shown in Fig. 1 is further described in U.S. Patent No. 4,650,472. Fig. 1 illustrates the dimensional relationship between outer sleeve 102, inner cannula 110 and wire guide 120 at the distal end portion of prior art apparatus 100. Outer sleeve 102 includes a distal portion 104 that tapers to outer sleeve distal end 106. Inner cannula 110 also includes a distal portion 112 that tapers to inner cannula distal end 114. Wire guide 120 extends from inner cannula distal end 114 in the normal fashion.

Fig. 2 is a sectional view of outer sleeve 102, shown removed from apparatus 100. Generally, tapered area *a* in this prior art apparatus is approximately 4 (±1) mm long. The thickness *b* of the wall of sleeve 102 at distal end 106 is about 0.004 (±0.0005) inch.

Fig. 4 is a sectional view of the outer sleeve of the apparatus of Fig. 3;

Fig. 5 is a graph illustrating the relationship between compressive extension and compressive load for specimens 1-15 of an embodiment of the inventive apparatus;

The thickness *e* of the wall of sleeve 12 at distal end 16 is less than 0.003 inch. Preferably, thickness *e* is between about 0.0005 and 0.003 inch, more preferably between about 0.0005 and 0.0015 inch, and most preferably, about 0.001 inch. The angle *f* of taper of tapered area 14 from the longitudinal axis is less than about 2.5°, preferably between about 0.5° and about 2°, and more preferably between 0.5° and 2°, or from about 1° to about 1.5° and most preferably about 1°. The exact angle of taper will preferably correspond to the remaining dimensions of the outer sleeve and inner cannula such that a generally smooth transition is provided between the distal end of the sleeve and the outer surface of the inner cannula.

The inventive apparatus 10 can be of any conventional size for its intended purposes. Preferably, however, the outer sleeve 12 is between about 4 and 6 French, and most preferably, about 5 French. The lumen 15 of the outer sleeve preferably has a diameter of about 0.04 inch. Inner cannula 20 is sized to fit within the lumen of outer sleeve 12 in conventional fashion for such devices. Those skilled in the art will appreciate that the dimensions provided hereinabove are only examples of acceptable dimensions for a particular sheath to be used for a particular purpose, and that sheaths of other dimensions may be similarly made within the scope of the invention.

One example of the gradual transition of the outer surface of outer sleeve 12 of the inventive apparatus to the inner cannula 20 is shown in Fig. 3. This transition is much smoother, avoids the substantial shoulder represented by the dimension b of Figure 2, and occurs in a much more gradual manner over a greater tapered length 14 of the outer sleeve, when compared to the much more abrupt transition of the tapered portion 104 of the prior art device shown in Fig. 1. The smooth, gradual transition of the inventive apparatus provides a very sleek profile that enables the apparatus to be smoothly inserted into, and passed through, the initial body opening and the underlying tissue. This results in a reduction of the trauma experienced by the patient at the insertion point.

The step or shoulder represented by the wall thickness of the outer sleeve at the distal end is preferably 10% or less than the external radius of the outer sleeve at its full (non-tapered) diameter, more preferably 5% or less, still more preferably 3% or less.

To further illustrate this reduction in trauma, tests were performed to simulate the force required to be exerted by a physician during the insertion of an inventive introducer apparatus through the skin at a body opening. For comparison, similar tests were performed utilizing a conventional introducer apparatus. A sheet of 0.038 inch duro silicone with a translucent color (available from AAA-Acme Rubber Company of Tempe, Arizona), was provided to simulate the skin of a patient. In each case, the initial puncture through the silicone sheet was made with a conventional 21 gauge needle. A 0.018 inch wire guide was inserted

through the bore of the needle in conventional fashion. The needle was thereafter withdrawn over the wire guide, and the sheath/cannula apparatus was inserted over the wire guide. Each apparatus included a 5 French outer sleeve, and a 3 French inner cannula (dilator).

The inventive apparatus included an outer sleeve having a tapered portion of about 15 mm, and forming an angle of about 1° with the longitudinal axis. The thickness of the wall of the outer sleeve at its distal end was about 0.001 inch. The comparative reference apparatus included an outer sleeve having a tapered portion of about 4 mm, and forming an angle of about 3° with the longitudinal axis. The thickness of the wall of the outer sleeve at its distal end was about 0.004 inch.

Simulations were performed on thirty specimens of the inventive apparatus and thirty specimens of the conventional apparatus. The testing conditions were identical on all specimens, with the exception of the structural differences in the outer sleeves of the respective apparatuses as described. The tests were designed to simulate the compressive load (in lbf) that is exerted on the skin as the introducer apparatus initially enters the skin through the puncture, and as the introducer apparatus is continuously inserted to a depth (or compressive extension) of about 50 mm.

The results of the tests on the 30 specimens of the inventive apparatus are shown below in Table 1.

TABLE 1:

Specimen Label	Maximum Load (lbf)	Compressive extension at Maximum Comp. load (mm)	Compressive load at 47 mm (lbf)	Comment
1	0.31	4.47458	0.27933	Pushed without incident
2	0.35	4.18979	0.32828	Pushed without incident
3	0.32	32.73474	0.28809	Pushed without incident
4	0.40	36.24515	0.26727	Pushed without incident
5	0.39	5.53499	0.24153	Pushed without incident
6	0.33	5.00999	0.23552	Pushed without incident
7	0.36	35.05036	0.20435	Pushed without incident
8	0.29	4.70999	0.23899	Pushed without incident
9	0.28	47.49513	0.24798	Pushed without incident
10	0.36	5.23041	0.23015	Pushed without incident
11	0.35	41.46015	0.18996	Pushed without incident
12	0.43	22.76017	0.25893	Pushed without incident
13	0.37	5.86520	0.18430	Pushed without incident
14	0.34	4.84437	0.26116	Pushed without incident
15	0.29	46.74514	0.22182	Pushed without incident
16	0.33	34.20495	0.24218	Pushed without incident
17	0.35	5.20999	0.25428	Pushed without incident
18	0.36	5.63499	0.21307	Pushed without incident
19	0.36	5.34978	0.21285	Pushed without incident
20	0.37	47.17951	0.18557	Pushed without incident
21	0.36	46.88972	0.24057	Pushed without incident
22	0.36	5.47499	0.22677	Pushed without incident
23	0.38	6.07978	0.19394	Pushed without incident
24	0.33	5.61041	0.18142	Pushed without incident
25	0.28	4.99520	0.19651	Pushed without incident
26	0.33	41.46952	0.19551	Pushed without incident
27	0.39	5.98520	0.16382	Pushed without incident
28	0.37	36.46015	0.15755	Pushed without incident
29	0.38	5.68999	0.20767	Pushed without incident
30	0.34	40.59056	0.17002	Pushed without incident
Mean	0.35	19.97250	0.22398	
Standard Deviation	0.03480	17.70996	0.03969	
Minimum	0.28	4.18979	0.15755	
Maximum	0.43	47.49513	0.32828	

Rate 1150.0 mm/min
Data captureManual
Control mode 1Compressive extension
Start of test Temperature (deg C)21.0
Start of Test Relative Humidity (%)37.0
End of test Temperature (deg C)21.0
End of test Relative Humidity (%)29.0

The data of Table 1 is illustrated graphically in Fig. 5 for specimens 1 to 15, and in Fig. 6 for specimens 16 to 30 of the inventive apparatus. In the figures, the "zero point" ("0") of the "compressive extension" and the "compressive load" represents the point where the inner cannula initially touches the sheet as it is urged forwardly for insertion.

The results of the tests on the 30 specimens of the conventional, reference apparatus are shown below in Table 2.

TABLE 2:

Specimen Label	Maximum Load (lbf)	Compressive extension at Maximum Comp. load (mm)	Compressive load at 42 mm (lbf)	Comment
1	0.60	11.28040	0.17221	Pushed without incident
2	0.62	11.46957	0.13470	Pushed without incident
3	0.61	9.84978	0.21689	Pushed without incident
4	0.61	10.67436	0.17909	Pushed without incident
5	0.57	9.78998	0.24985	Pushed without incident
6	0.61	9.47436	0.28167	Pushed without incident
7	0.59	10.46415	0.21618	Pushed without incident
8	0.59	11.01998	0.14473	Pushed without incident
9	0.57	9.48040	0.28587	Pushed without incident
10	0.63	10.59957	0.19785	Pushed without incident
11	0.60	10.93436	0.15891	Pushed without incident
12	0.62	10.51498	0.18479	Pushed without incident
13	0.59	10.62915	0.18130	Pushed without incident
14	0.61	11.20019	0.16731	Pushed without incident
15	0.57	10.39457	0.18708	Pushed without incident
16	0.67	10.64936	0.22800	Pushed without incident
17	0.58	9.64540	0.28844	Pushed without incident
18	0.57	10.12457	0.21000	Pushed without incident
19	0.57	9.97436	0.21853	Pushed without incident
20	0.63	10.49519	0.20705	Pushed without incident
21	0.59	10.71936	0.17773	Pushed without incident
22	0.61	11.48415	0.12394	Pushed without incident
23	0.60	9.99478	0.23544	Pushed without incident
24	0.60	10.29978	0.22631	Pushed without incident
25	0.57	10.59540	0.21824	Pushed without incident
26	0.57	10.41957	0.18823	Pushed without incident
27	0.57	11.18477	0.09785	Pushed without incident
28	0.53	9.67999	0.26979	Pushed without incident
29	0.58	10.18103	0.26243	Pushed without incident
30	0.62	10.91498	0.16288	Pushed without incident
Mean	0.60	10.47128	0.20244	
Standard Deviation	0.02679	0.57158	0.04818	
Minimum	0.53	9.47436	0.09785	
Maximum	0.67	11.48415	0.28844	

Rate 1150.0 mm/min
Data captureManual
Control mode 1Compressive extension
Start of test Temperature (deg C)21.0
Start of Test Relative Humidity (%)32.0
End of test Temperature (deg C)21.0
End of test Relative Humidity (%)30.0

The data of Table 2 is illustrated graphically in Fig. 7 for specimens 1 to 15,and in Fig. 8 for specimens 16 to 30 of the reference apparatus.

As demonstrated by the simulations, considerably more force is required to enter the skin and underlying tissue when utilizing the reference apparatus when compared to the inventive apparatus. This is particularly true at the point where the outer sleeve initially penetrates the skin. This is illustrated by the respective curves shown in Figs. 5-8. The x-axis of the graphs represents the compressive extension, or in other words, the length of insertion (in mm) of the apparatus through the skin. The y-axis of the graph represents the compressive load, or in other words, the force (in lbf) that is exerted by the physician upon insertion of the apparatus through the skin. As shown in each of the graphs of Figs. 5-8, the compressive load gradually builds as the apparatus is advanced into the skin until the inner cannula has initially penetrated the skin. This is represented by the first peak in each of the figures. In both the reference apparatus and the inventive apparatus (e.g., in each of the Figs. 5-8), the first peak indicates a maximum compressive load in the vicinity of about 0.35 lbf.

Upon insertion of this cannula through the skin an immediate decrease in force is observed once the initial penetration, or puncture, has been completed. As the apparatus is further inserted, the force once again builds, to represent the force required for the outer sleeve to penetrate the skin. As illustrated in Figs. 7 and 8, and as documented in Table 2, a maximum compressive load that varies from 0.53 to 0.63 lbf is required in the thirty reference specimens when the outer sleeve penetrates the skin. The mean value of maximum compressive load of all thirty reference specimens is indicated as 0.60 lbf. This is best shown in the figures as the large (second) peak in the vicinity of 0.60 lbf.

For comparison, as illustrated in Figs. 5 and 6, and as documented in Table 1, a much smaller maximum compressive load is required when the outer sleeve penetrates the skin with the inventive apparatus. This graphically shown by viewing the second peak in each of these figures. This peak illustrates that a compressive load of only about 0.20 to 0.30 lbf is generally required at the insertion point of the outer sleeve. The reduction in force required with the

inventive apparatus when compared to the reference apparatus is dramatically indicated by the absence of the large second peak in the inventive specimens (Figs. 5 and 6). This indicates a much smoother insertion when compared to the reference apparatus. The mean value of the maximum compressive load of all thirty of the inventive specimens is indicated as 0.35 lbf. In most of the inventive specimens, the maximum compressive load does not even occur at this insertion point (second peak), but rather, later during the insertion procedure as the tapered outer sleeve continues to be pushed through the skin.

Appendices 1 and 2 attached hereto provide raw data that corresponds to the curves of Figs. 5-8. Specifically, Appendix 1 includes data from reference Specimens 1-30. This data is graphically illustrated in Fig. 7 (reference specimens 1-15) and Fig. 8 (reference specimens 16-30). Appendix 2 includes data from Specimens 1-30 of the inventive apparatus. This data is graphically illustrated in Fig. 5 (inventive apparatus specimens 1-15) and Fig. 6 (inventive apparatus specimens 16-30). The "load" column in the appendices is specified in units of kgf. The data in the appendices could also be averaged and plotted in that manner. In this event, one averaged curve corresponds to the data for the reference apparatus, and one averaged curve corresponds for readings related to the inventive apparatus.

The inventive apparatus comprising the outer sleeve and inner cannula can be provided as a combination, or as separate components. Similarly, all of the components discussed herein can be provided as a kit, or as separate components. The individual components are well known, and, other than the distinctions specified hereinabove, may be formed in conventional manner and of well known compositions. Although the outer sleeve and inner cannula can be formed of any materials suitable for their intended use, preferably they will be formed from a suitable polymer, such as polyethylene.

It is therefore intended that the foregoing detailed description be regarded as illustrative rather than limiting, and that it be understood that it is the following claims, including all equivalents, that are intended to define the spirit and scope of this invention.

Claims

1. A low profile introducer apparatus, comprising:

an outer sleeve having proximal and distal open ends, and having a lumen extending longitudinally therethrough, said outer sleeve having a profile such that at least a portion of said outer sleeve tapers diametrically inwardly toward said outer sleeve distal end at an angle not exceeding about 2.5° relative to the longitudinal axis of the apparatus, said outer sleeve having an outer diameter that does not exceed about 6 French and having a distal open end sized such that a first wire guide is receivable therethrough, said distal open end of said outer sleeve having a wall thickness less preferably not exceeding about 0.003 inch; and

an inner cannula having proximal and distal open ends, and having a lumen extending longitudinally therethrough, said inner cannula sized to be receivable within the lumen of said outer sleeve, said inner cannula having a portion that tapers toward the inner cannula distal end, said inner cannula distal open end sized such that a second wire guide is receivable through said inner cannula distal open end and said first wire guide is not receivable through said inner cannula distal open end, said tapered distal portion of said inner cannula extending distal to the distal open end of said outer sleeve and having a profile such that a generally smooth diametrical transition is provided between said outer sleeve tapered portion said inner cannula open end.

2. The apparatus of claim 1, wherein said outer sleeve tapered portion comprises between about the distal 5 and 50 mm of said outer sleeve.

3. The apparatus of claim 2, wherein said outer sleeve tapered portion comprises about the distal 15 mm of said outer sleeve.

4. The apparatus of claim 2, wherein said outer sleeve tapered portion is tapered at an angle of between about 0.5° and 2°.

5. The apparatus of claim 4, wherein said outer sleeve tapered portion is tapered at an angle of about 1°.

6. The apparatus of claim 1, wherein said distal open end of said outer sleeve has a wall thickness of between about 0.0005 and 0.0015 inch, and

preferably about 0.001 inch.

7. The apparatus of claim 1, wherein said outer sleeve has an outer diameter between about 4 and 6 French.

8. The apparatus of claim 8, wherein said diameter is about 5 French.

9. The apparatus of any of claims 1 to 8 wherein the load that is exerted on simulated skin on entry of the outer sleeve is less than the load exerted on entry of the inner cannular.

10. An introducer kit comprising:

an introducer needle, said introducer needle having an outer diameter that does not exceed about 21 gauge (0.032 inch; 0.81 mm), and an inner diameter that does not exceed about 0.018 inch (0.46 mm);

a first wire guide, said first wire guide having an outer diameter not less than about 0.35 inch (0.89 mm);

a second wire guide, said second wire guide having an outer diameter not greater than about 0.018 inch (0.46 mm), said second wire guide receivable in a bore of said introducer needle;

an outer sleeve, said outer sleeve having proximal and distal open ends and having a lumen extending longitudinally therethrough, said outer sleeve having a profile such that a distal portion of said outer sleeve tapers diametrically inward toward said outer sleeve distal end at an angle not exceeding about 2.5° relative to the longitudinal axis of the apparatus, said outer sleeve having an outer diameter that does not exceed about 6 French and having a distal open end sized such that said first wire guide is receivable therethrough, said distal end of said outer sleeve preferably having a wall thickness not exceeding about 0.003 inch; and

an inner cannula, said inner cannula having proximal and distal open ends and having a lumen extending longitudinally therethrough, said inner cannula sized to be receivable within the lumen of said outer sleeve, said inner cannula having a portion that tapers toward the inner cannula distal end, said inner cannula distal open end sized such that said second wire guide is receivable through said inner cannula open end a said first wire guide is not

receivable through said inner cannula open end, said tapered distal portion of said inner cannula extending distal to the distal open end of said outer sleeve and having a profile such that a generally smooth diametrical transition is provided between said outer sleeve tapered portion said inner cannula open end.

11. The kit of claim 10, wherein said outer sleeve tapered portion comprises the distal 5 to 50 mm of said outer sleeve.

12. The kit of claim 11, wherein said outer sleeve tapered portion comprises the distal 15 mm of said outer sleeve.

13. The kit of claim 11, wherein said distal open end of said outer sleeve has a wall diameter of about 0.001 inch (0.0254 mm).

14. The apparatus of claim 12, wherein said outer sleeve has an outer diameter that does not exceed about 5 French.

15. A method of catheterizing a body vessel, comprising:

providing an introducer system, said system comprising an introducer needle having an outer diameter that does not exceed about 21 gauge (0.032 inch; 0.81 mm) and an inner diameter that does not exceed about 0.018 inch (0.46 mm); a first wire guide having an outer diameter not less than about 0.35 inch (0.89 mm); a second wire guide having an outer diameter not greater than about 0.018 inch (0.46 mm) and being receivable in said introducer needle; and an introducer apparatus comprising an outer catheter and an inner cannula, said inner cannula removably received in a lumen of said outer catheter, said outer catheter having proximal and distal open ends and a profile such that a distal portion of said outer catheter tapers toward said catheter distal end at an angle not exceeding about 2.5° with the longitudinal axis of the catheter, said outer catheter distal open end sized such that said first wire guide is receivable therethrough, said inner cannula having proximal and distal open ends and a lumen extending therethrough, and having a portion that tapers toward the inner cannula distal end, said inner cannula distal open end sized such that said second wire guide is receivable therethrough and said first wire guide is not receivable therethrough, said tapered distal portion of said inner cannula

extending distal to the distal open end of said outer cannula and having a profile such that a generally smooth diametrical transition is provided between said outer catheter tapered portion and said inner cannula open end;

injecting said needle into said body vessel;

guiding said second wire guide through said needle inner diameter such that a distal end of said wire guide extends beyond said needle in said body vessel;

withdrawing said needle from said body vessel over said second wire guide;

introducing said introducer apparatus over said wire guide such that the respective distal ends of said outer catheter and inner cannula are in said body vessel;

withdrawing said second wire guide from said introducer apparatus while maintaining the introducer apparatus in the body vessel;

separating the inner cannula from the outer catheter, and removing the inner cannula while maintaining the outer catheter in the body vessel; and

guiding said first wire guide through said outer catheter such that a distal end of said first wire guide extends beyond said outer catheter in said body vessel.

16. The method of claim 15, further comprising:

withdrawing said outer cannula over said first wire guide, and

guiding an interventional device over said first wire guide into said body vessel.

17. The method of claim 16, wherein said angle is about 1°.

18. The method of claim 16, wherein said distal open end of said outer catheter has a thickness not exceeding about 0.003 inch and preferably about 0.001 inch.

19. The method of claim 16, wherein said outer sheath and said inner cannula comprise polyethylene.

20. A kit according to any one of claims 10 to 14 in combination with instructions prescribing the method of any one of claims 15 to 19.

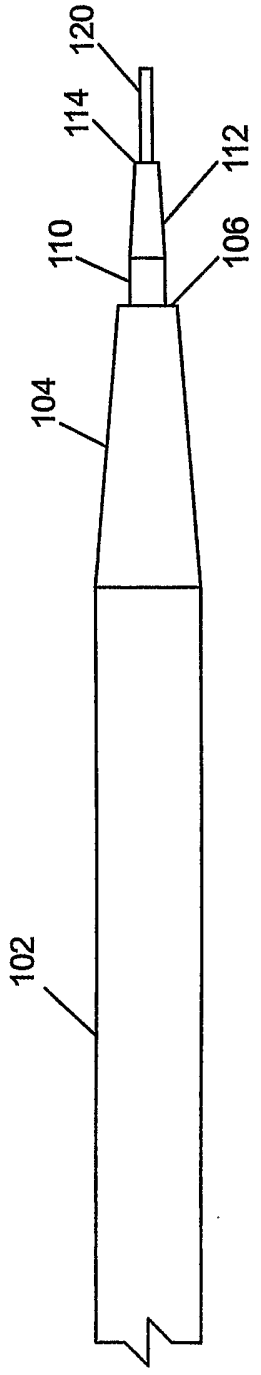


FIG. 1 - PRIOR ART

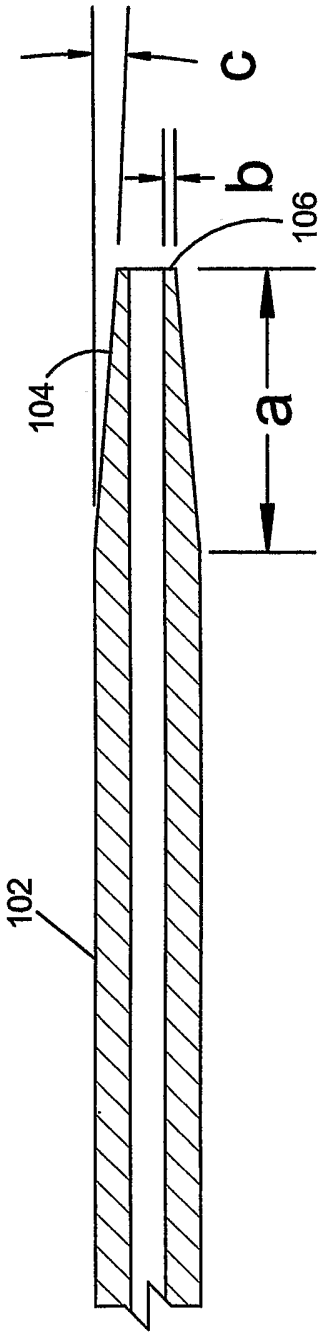


FIG. 2 - PRIOR ART

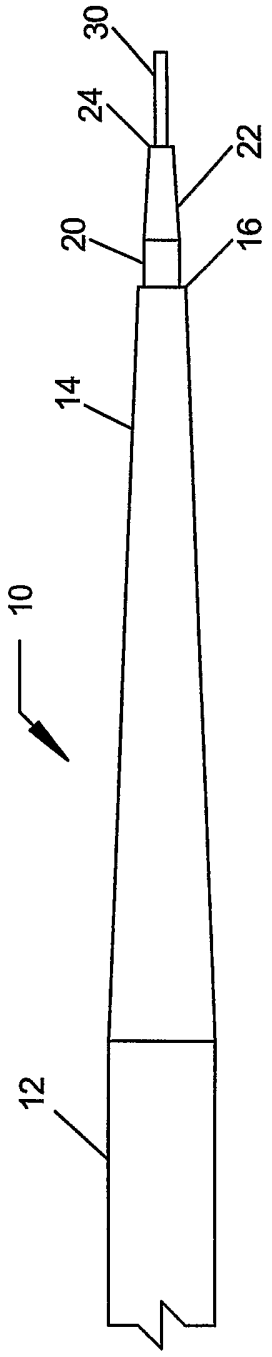


FIG. 3

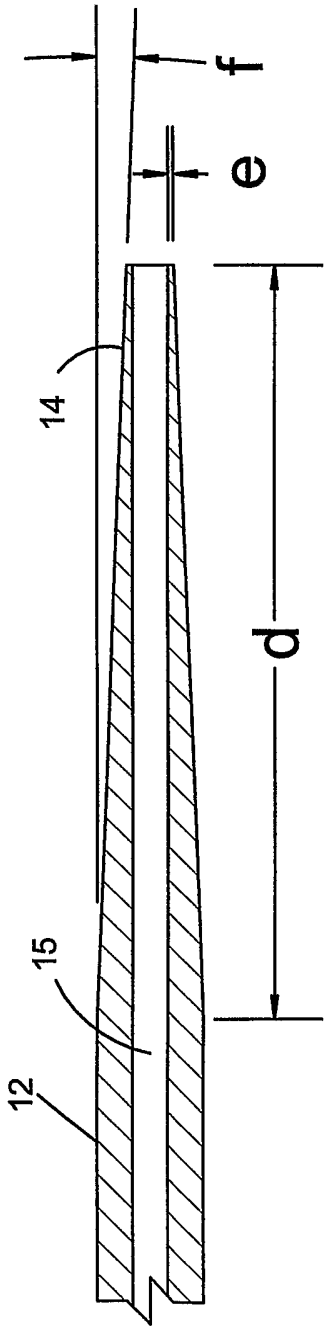
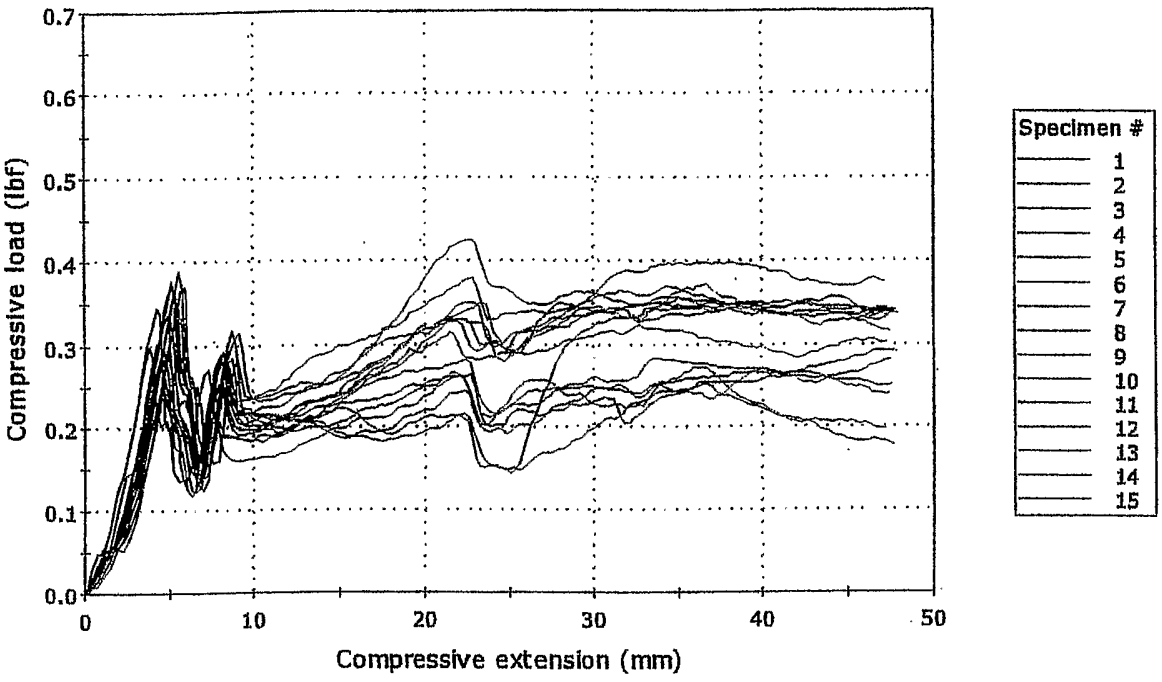


FIG. 4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30
40
50
Compressive extension (mm)
Specimen #
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3
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5
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7
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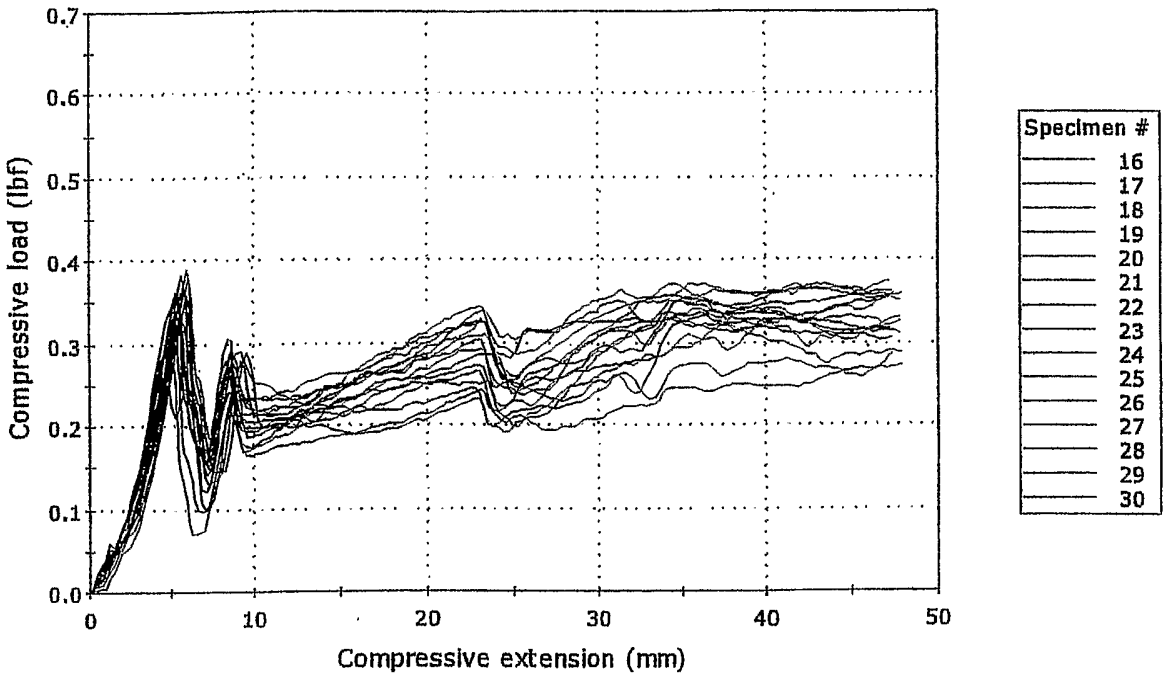
11
12
13
14
15

FIG. 5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Compressive extension (mm)
Specimen #
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18
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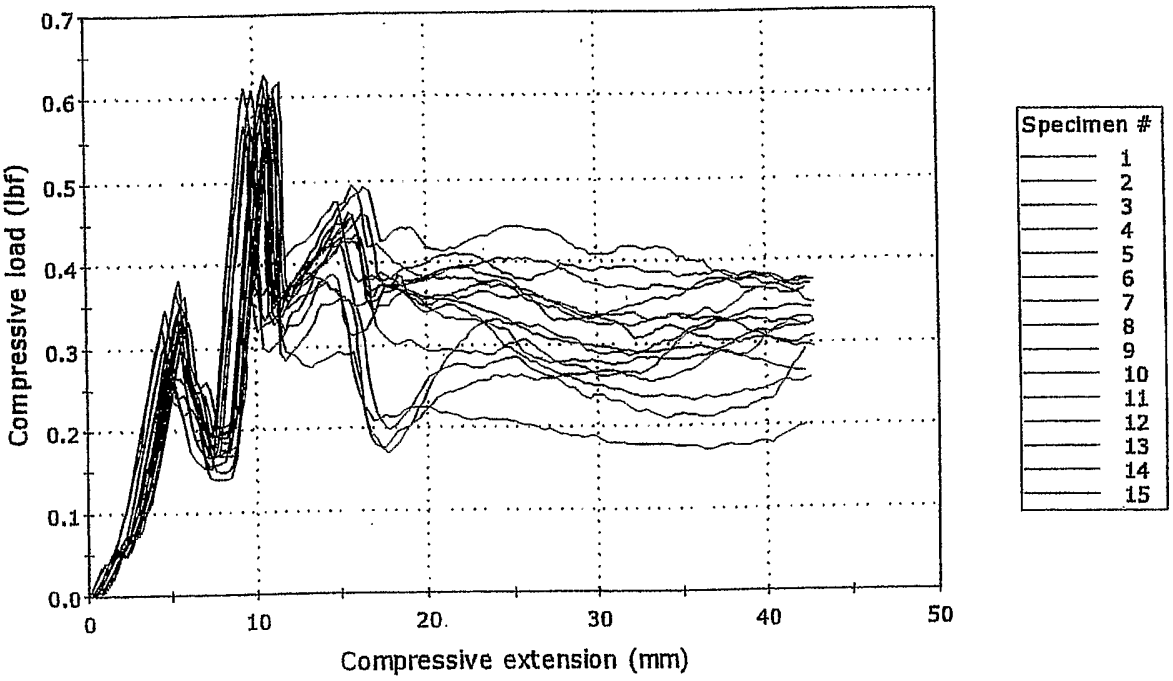
FIG. 6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0.0
Compressive load (lbf)
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20
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50
Compressive extension (mm)
Specimen #
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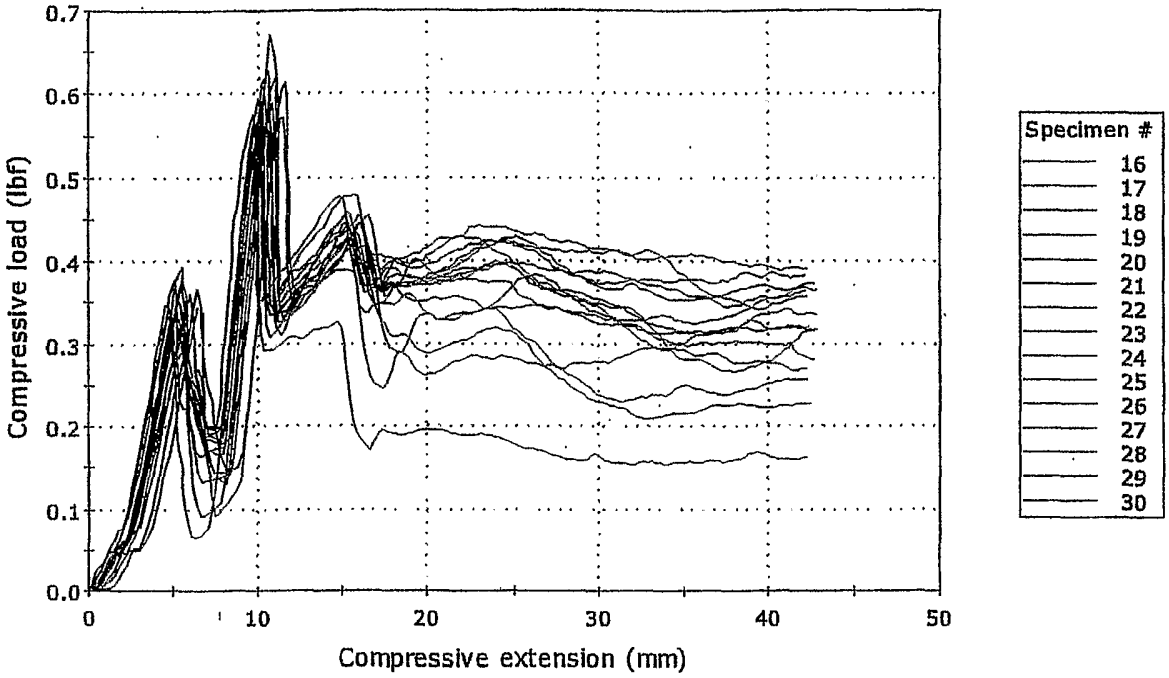
FIG. 7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0.2
0.3
0.4
0.5
0.6
0.7
0
10
20
30
40
50
Compressive extension (mm)
Specimen #
16
17
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FIG. 8

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2006/020368

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M25/09 A61M25/06

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)
A61M A61B

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 practical, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4 650 472 A (BATES ET AL) 17 March 1987 (1987-03-17) cited in the application the whole document	1-14
A	US 4 404 159 A (MCFARLANE ET AL) 13 September 1983 (1983-09-13)	1,4,6, 10,12,13
A	EP 1 092 449 A (USAMINANOTECHNOLOGY, INC) 18 April 2001 (2001-04-18) paragraph [0066] - paragraph [0067]; figure 7	1-3,6, 10-13
A	US 4 405 314 A (COPE ET AL) 20 September 1983 (1983-09-20) column 2, line 65 - column 3, line 21; figure 1	1,10

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[X] Further documents are listed in the continuation of Box C.

[X] 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 document 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
25 September 2006	02/10/2006

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Jameson, Patricia

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Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2006/020368

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 2005/004967 A (COOK INCORPORATED) 20 January 2005 (2005-01-20) paragraph [0026] - paragraph [0031]; figures 1-6	1,10
A	US 6 053 904 A (SCRIBNER ET AL) 25 April 2000 (2000-04-25) column 7, line 68 - column 10, line 26; figures 7-11	1,10
A	US 4 629 450 A (SUZUKI ET AL) 16 December 1986 (1986-12-16) column 4, line 14 - column 5, line 42; figures 1-3	1,10
A	WO 93/02735 A (MED-PRO DESIGN, INC) 18 February 1993 (1993-02-18) abstract; figure 1 page 1, lines 17-33	1,10
A	EP 0 778 045 A (NISSHO CORPORATION; NIPRO CORPORATION) 11 June 1997 (1997-06-11) column 4, line 4 - column 5, line 16	1-14

2

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2006/020368

Box 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. [X] Claims Nos.: 15-20
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

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 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:

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 an additional fee, this Authority did not invite payment of any additional fee.

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.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2006/020368

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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