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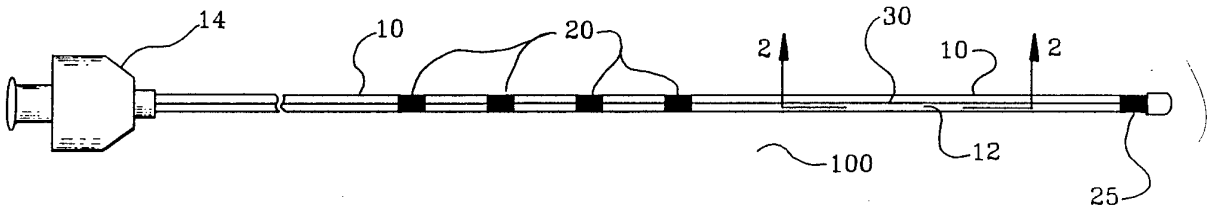

(57) Abstract

Flexible tip epidural catheters are provided having a soft, flexible outer tube (10) overlying a relatively stiff inner tube (12) so as to provide an extended portion of the outer tube at the distal end of the catheter. Methods for using the epidural catheters of this invention to provide local anesthesia and methods for constructing the epidural catheters are also provided as herein described.

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UNIBODY CONSTRUCTION DUAL DUROMETER EPIDURAL CATHETER

Field of the Invention

This invention relates to lengthy catheters of small diameter used for infusing small quantities of liquids into a body, and more particularly, to epidural anesthesia catheters having a soft flexible tip.

Background of the Invention

Epidural anesthesia has gained widespread acceptance in surgery, chronic pain management, and obstetrics. Obstetricians have been increasingly relying upon the accuracy and flexibility of epidural catheters for providing both single doses or continuous infusion of anesthesia. Continuous epidural anesthesia applied through a small epidurally-located catheter has provided safe and efficacious pain relief during labor and delivery. The epidural administration of anesthesia operates by producing a regional dermatomal band of anesthesia spreading toward the head and the feet from the site of the injection.

Continuous epidural anesthesia is not without associated drawbacks, however, which are known to include paresthesia, blood vessel puncture, dural puncture, and inadequate anesthesia, which may be related to epidural catheter design flaws. The anesthesiologist must ensure that the needle tip or the catheter is in the epidural space during insertion and infusion. If the catheter has been incorrectly

inserted and does not lie within the spinal canal, then nerve block will not result from the injection of the local anesthesia. The anaesthetist must be able to diagnose both dural tap and inadvertent intravenous or intravascular placement of the needle or catheter.

Insertion into the subarachnoid space by needles or the catheter itself is almost always recognized by the rapid escape of cerebrospinal fluid. Injecting anesthesia into the subarachnoid space causes accidental total spinal blocks which may produce an apnoeic, unconscientious, and hypo-tensive patient, which may complicate the birth or intended surgical procedure.

Intravascular placement of the needle or catheter is another complication associated with epidural catheter placement. Prior art nylon epidural catheters have been favored over softer polymers, such as PTFE, because of their superior kink resistance. However, these nylon catheters have been known to puncture blood vessels with greater frequency than softer polymeric catheters, because of the higher flexural modulus of nylon makes it easier to pierce the vessel wall, rather than meandering around it. The incidence of trauma is also greater with these harder and stiffer catheter materials.

Trauma is probably the most common cause of neurological impairment and usually involves a single spinal nerve. A stiff catheter can enter a nerve and if an injection is made directly into the nerve, some disruption of the fibers can occur. This may lead to a degree of neuritis which can last for some weeks to months, and in certain cases, permanent nerve damage can result.

In an effort to overcome the deficiencies associated with hard nylon catheters, catheters have been designed with bonded or "welded" soft distal tips. Such catheters include a smooth polyurethane body with a soft polyurethane tapered tip adhered in abutting relationship. These soft polyurethane, distal tips are considerably softer than nylon and are more pliable during epidural insertion. The flexibility of this

design makes it more convenient for the catheter to be placed through a plastic introducer sheath, as opposed to an internal stylet.

Such catheters have received significant commercial success, but in certain cases, the adhesion between the soft polyurethane tip and the stiffer polyurethane body may not be as strong as the remainder of the catheter. If such a bond fails during use, the soft flexible tip may, unfortunately, remain within the patient.

Accordingly, there is a present need to provide an epidural catheter having a soft flexible tip with a relatively rigid proximal portion for providing steerability, and kink resistance during the application of a fluid connector. This catheter should also provide reliable adherence of the flexible tip to the rigid proximal portion to prevent severing of the tip during use.

Summary of the Invention

This invention provides dual durometer epidural catheters, methods for making these catheters, and methods of using the catheters to apply local anesthesia. The epidural catheters of this invention include a stiff inner tube having a proximal and distal end and a softer outer tube co-axially disposed over the inner tube and having a distal portion which extends beyond the distal end of the inner tube so as to form a soft, flexible distal tip. The catheters further include radio opaque portions disposed axially along their length to provide fluoroscopic contrast and connection means for connecting the proximal end of the catheter to a fluid injection means suitable for injecting liquid anesthesia.

Accordingly, "unibody" epidural catheters are provided having a soft, flexible tip and a relatively rigid proximal portion, with a high degree of adherence between these respective portions. The softer outer tubes of this invention are adhered or laminated substantially over the entire length of the stiff inner tube so as to provide a large contact area of adherence for resisting failure. The unified

design of this invention lacks both the trauma-threatening hardness of nylon epidural catheters as well as the bonding failure risk of the welded tip designs, and can be manufactured with conventional solvents and over-extrusion equipment.

In the process aspects of this invention, the catheters can be produced by one of two preferred methods. In a first preferred method, the softer outer tube is treated with a solvent to expand its dimensions sufficiently to insert the stiff inner tube. The solvent is then permitted to evaporate so that the outer tube attempts to regain its original dimensions and tightly constricts upon the stiff inner tube.

In a second preferred method of manufacturing the epidural catheters of this invention, an over-extrusion process is used in which long, stiff inner tube sections of catheter polymer are joined together with fluorocarbon-coated metallic links and then overextruded with molten polymer to form a softer outer tube over the linked inner tubes similar to a conventional tube-on wire drawing process. This process offers the advantage of permitting smaller soft distal tip inner diameters having improved kink resistance.

Brief Description of the Drawings

The accompanying drawings illustrate preferred embodiments of the present invention as well as other information which is pertinent to the disclosure, and in which:

FIG. 1: is a side elevation of a preferred dual durometer epidural catheter of this invention;

FIG. 2: is a side cross-sectional view, taken through line 2-2 of the catheter of FIG. 1, illustrating the telescopic arrangement between the stiff inner tube and the softer outer tubes of this invention;

FIG. 3: is a transverse, cross-sectional view, taken through line 3-3 of the catheter of FIG. 2, showing the preferred concentric nature of the inner and outer tubes;

FIGS. 4a-c: are diagrammatic views of a human thoracic spine showing sequential steps for introducing the epidural catheter of this invention through a telescopic introducer sheath into the epidural space; and

FIG. 5: is a cross-sectional view of a preferred over-extrusion segment including a preferred PTFE-coated metallic link connecting a pair of stiff inner tube segments.

Detailed Description of the Invention

Epidural catheters have proved to be one of the major factors in the present severity of complications during continuous epidural anesthesia. The catheters of this invention promote a lower incidence of blood vessel puncture, paresthesia, and dural puncture, without the risk of weld failure of the distal tip associated with earlier soft-tip catheter designs.

With reference to FIGS. 1-3, there is shown a preferred dual durometer epidural catheter 100 having a stiff inner tube 12 and a softer outer tube 10 co-axially disposed over the inner tube 12 and having a distal portion which extends beyond the distal end of the inner tube so as to form a soft, flexible tip at the distal end of the epidural catheter 100. The catheter can also include inked or printed portions, such as depth indicators 20, tip indicator 25, and radio opaque means, shown here as stripe 30. A suitable female connector 14 is provided at the proximal end of the catheter 100 for fluidly connecting the catheter to a syringe for the administration of gases or fluids, such as medicines or anesthesia.

The preferred epidural catheter 100 is about 91.4 cm (36 in.) in length with an outer diameter of about .984 mm (.0388 in.) and an inner diameter of about .476 mm (.0188 in.). The soft, flexible distal tip of the catheter is preferably at least about 1.0 cm (.4 in.), more preferably about 3-10 cm (1.2-4 in.), and typically about 7.6 cm (3 in.) in length.

With reference to the cross-sectional views of FIGS. 2 and 3, the telescoping nature of the inner and outer tubes 12 and 10 becomes readily apparent. The inner tube 12 of this invention desirably includes a higher flexural modulus than the softer outer tube 10 so as to provide a stiff, torsion-resistant proximal end to the catheter. Preferably, the inner tube 12 has a flexural modulus which is at least about 50% more than the flexural modulus of the outer tube 10, and more preferably is at least about 10 times greater than the flexural modulus of the outer tube 10.

The stiff inner tube 12 should be constructed of a polymeric material, such as a thermoplastic polymer capable of forming a substantially rigid structure. These rigid polymeric materials provide in combination with the softer outer tube substantial rigidity in the transverse direction, so as to resist kinking, and retain longitudinal flexibility during use. The inner tube 12 can preferably possess a flexural modulus of greater than about 1 GPa (.15 X 10^6 psi), and preferably of about 2-10 GPa (.29-1.5 X 10^6 psi). Such polymers include polyamides (nylon), polyetherimide (PEI), polyaryletherketone (PAEK), polyetheretherketone (PEEK), polyethylene terephthlates (PET), polyacetals, polycarbonates, and polyether/polyamide co-polymers, although PEEK is presently preferred. Suitable properties for the preferred polymeric materials for the inner tubes of this invention are found in Table I below.

Table I: Approximate Mechanical Properties of Selected Polymers

Material	Tensile Strength MPa (X 10^3 psi)	Tensile/ Flexural Modulus* GPa (X 10^6 psi)	Flexural Strength MPa (X 10^3 psi)
Nylon 6 (polyamide)	81.4 (11.8)	2.76 (0.40)	113 (16.4)
PAEK	121 (17.6)	8.96 (1.30)	138 (20.0)
PEEK	93.8 (13.6)	3.5 (0.51)	110 (16.0)

* At low strains the Tensile and Flexural Modulus are considered equivalent for comparative purposes.

The softer outer tube 10 of this invention, in contrast with the stiff inner tube 12, should be formed of a soft, flexible polymeric material. Such materials preferably include soft thermoplastics having a hardness of about 35 A-80 D Shore, preferably about 50 A-60 D Shore, and most preferably about 80-100 A Shore. Thermoplastics also having a flexural modulus of less than about 1 GPa (.15 X 10^6 psi), more preferably less than about .34 GPa (.050 X 10^6 psi), and ideally about .1-.17 GPa (.015-.025 X 10^6 psi) are most suited to forming a flexible, trauma reducing tip. Such materials are known to include various soft thermoplastic polyolofins, such as polyethylene and polypropylene, polyurethanes, polyesters, and similar polymers. The selected polymer should also be non-thrombogenic and otherwise biologically compatible. In a preferred embodiment of this invention, transparent, aromatic polyurethane having a flexural modulus of about .1 GPa (.015 X 10^6 psi) is employed, such as Pellethane® and Tecothane® which are commercially available.

The preferred soft distal tip of this invention comprises an extended length of about 3-10 cm of the soft polyurethane outer tube. The preferred softer outer tube 10 also desirably includes a hydrophilic coating for reducing the friction associated with inserting the preferred epidural catheters of this invention into sensitive epidural sites which include blood vessels and nerves. Such hydrophilic coatings are known to include lubricants of water-soluble, high molecular weight compounds or their derivatives, for example, those including polyurethane elastomer, ultra-high molecular weight polyethylene oxide (100,000 MW), maleic anhydride, polyacrylamide, water-soluble nylon, cellulosic polymers, or silicone oil. See U.S. Patent No. 4,943,460, 5,091,205 and EP-A 0 166 998, which are hereby incorporated by reference. Preferred lubricous coatings include mixtures of polyurethane elastomer and 100,000 MW polyethylene oxide, and maleic anhydride copolymer-based lubricants. The preferred lubricous coating provides a relatively low co-efficient of friction, which is desirably less than about .05, and more

preferably about .01-.03. This co-efficient of friction is nearly an order of magnitude better than current coatings employing high molecular weight polyethylene or PTFE, although these materials could be suitable alternatives for the lubricous coatings of this invention.

The outer surface of the softer outer tube 10 of epidural catheter 100 also can include an anti-coagulant, such as heparin, urokinase, or the like, or an anti-thrombin, such as silicone rubber, block copolymer of urethane, or silicone hydroxyethylmthacrylate styrene polymer, or the like.

Also with reference to FIG. 1, the preferred radio opaque means of this invention will now be described. The radio opaque configurations of this invention should be sufficient to locate the epidural catheter with fluoroscopy during placement procedures. Radio opaque metals are known to include both solid forms, such as springs and sleeves, as well as filled portions of the polymeric materials. Radio opaque materials include barium sulfate, tungsten, gold, tantalum, platinum and mixtures of these. To provide a light color for blood contrast, pigments such as TiO_2 can be added.

In the preferred embodiments of this invention, powdered barium sulfate is employed at selected locations, and preferably integrally within, the preferred polyurethane outer tube. As described in FIG. 1, the filled locations can include a radio opaque stripe 30 located along a portion of the catheter's length, and preferably located continuously along the softer outer tube 10 of this invention. The stripe 30 when used in conjunction with the preferred translucent or transparent inner and outer tubes of this invention, can be used as a cerebrospinal fluid indicator. When the radio opaque stripe 30 is located on the far side of the catheter, and cerebrospinal fluid is tapped through the epidural catheter 100, the inner and/or outer tubes magnify the stripe through the cerebrospinal fluid, which produces a visible verification of its presence within the central lumen 11 of the catheter, much the same way as mercury in a thermometer provides an indication of temperature. The cerebrospinal

fluid filling the inner lumen 11 of the catheter becomes apparent because the tube or tubes behave like a high-powered cylindrical convergent lens that suddenly magnifies the preferred white, barium sulfate, radio opaque stripe on the far side. The tapping of cerebrospinal fluid can be further confirmed by physically touching the fluid which is released through the syringe connector 14. If the clear fluid is warm, it is most likely cerebrospinal fluid, if the fluid is cool or room temperature, it is most likely injected saline.

The epidural catheters 100 of this invention can be constructed by known manufacturing processes for producing thermoplastic products, such as extrusion, drawing, and the like. Two preferred methods include "solvent swelling" and "over-extrusion". In the first method, the softer outer tube is exposed to a solvent, such as by dipping the preferred polyurethane tube into a 60/40 vol. % solvent mixture containing tetrahydrofuran/heptane, so that the polyurethane tube swells isotopically, i.e. in a uniform way in all directions. Other suitable solvents can be employed, especially if they have high OSHA TLV, low density, low cost, and lack halogen or CFC constituents. Preferably, a tubular extrusion or sleeve of polyurethane is enlarged in all directions by the swelling effect of the solvent, and the inner diameter of the sleeve becomes just large enough to receive the stiff inner tube, the solvent hydrodynamically lubricating its insertion. The solvent is then permitted to evaporate, and the polyurethane sleeve attempts to revert to its original dimensions and tightly grips the inner tube. Preferably, the stiff inner tube is slightly larger than the dry, inner diameter of the polyurethane sleeve, and prevents the sleeve from realizing complete recovery after the evaporation of the solvent.

Following the lamination of the outer and inner tubes, the catheter 100 can be subjected to a post-coating annealing operation at a temperature of less than about 400°F, and preferably about 250-350°F for a time sufficient to release any residual stresses caused by the preferred

polyurethane coating operation. After stress relieving to stabilize the length of the exposed soft tip, the catheter is pad printed and cut to final length.

The second method of manufacturing the preferred epidural catheters of this invention includes a process commonly referred to as "over-extrusion". This process represents a modification of over-extrusion wire coating equipment. In the preferred process, a chain of 32 in. long stiff inner tubes 58 are spliced together as shown in FIG. 5, using link means, preferably fluorocarbon coated metallic links, such as PTFE coated Ni-Ti links 61 having helical or corrugated ends 59 for retaining the spliced sections together. These links 61 preferably include a central 4 in. PTFE-coated section 56 having an outer diameter of about .020-.022 in. The metallic member 54 preferably includes stainless steel or Ni-Ti alloy, so that it can be reused often, without corrosion. The corrugated ends 59 of the preferred link embodiment are desirably pushed into the preferred 0.0185 in. PEEK or PAEK stiff inner tube diameter with greater than about .05 lb., and preferably about .5-1 lbs. of force.

The linking of the 32 in. length strips 58 of inner tube material together produces a semi-continuous core onto which the barium sulfate-polyurethane outer tube 52 can be extruded. While it is envisioned that the linked inner tube material may lack the tensile strength necessary for conventional wire coating equipment, specially designed "soft-handling" equipment can be employed to provide a suitable industrial over-extrusion process. Such specialized equipment can include, for example, an active spool payoff, a dancer control of the "slack loop", and coordinated feed rollers located before the cross head die and just into the water trough of a conventional tubular extrusion operation.

The coated length of inner tube material 50 can then be unspooled, printed, inspected, and cut to length. The soft tip should be readily apparent upon extracting the fluorocarbon-coated metallic links 61. It is noted that the over-extrusion process can provide flexible tips of different

inner diameters depending on diameter of the links employed, so as to provide customized kink resistance and resistance to deflection depending on the thickness of the material which remains.

The epidural catheters of this invention are uniquely suitable for infusing epidural anesthesia into the epidural space of a patient. The epidural space of a human body contains fat and blood vessels. The fat is rather gelatinous at body temperature and is tightly packed in the epidural space. This space is limited laterally since the dura is attached to the connective tissue covering the vertebrae and the ligamenta flava, the inner and outer layers of the spinal dura mater fuse. Thus, the epidural space is considered a closely confined compartment limited by the dura internally, and by the connective tissue lining the spinal canal externally.

Possible sites of the application of local anesthetic drugs administered into the epidural space include the spinal nerve trunks in the paravertebral space, the dorsal root ganglia, the dorsal and ventral spinal roots, and the spinal cord itself. It is known that local anesthetic agents injected into the epidural space rapidly reach the cerebrospinal fluid and penetrate into the peripheral areas of the spinal core.

In the preferred method of employing the epidural catheters 100 of this invention shown in FIGS 4 a-c, an injection needle 28, such as a syringe needle, is employed to locate the epidural space 35 before insertion of the catheter 100. There are many variations of this technique, some using the hands and others employing medical aids. After penetration of the ligamentum flavum, it becomes relatively easy to inject saline or air, at which time it becomes evident that the epidural space has been entered, as shown in FIG. 4a. The flow of fluid or air from the syringe as the needle enters the epidural space, pushes the dura 37 away from needle point. Other needle insertion techniques include the "hanging drop" technique, or lateral, or paramedian approach.

The catheter 100 is thereafter inserted through the needle 28 and into the epidural space 35 as shown in FIG. 4b. The catheter 100 can be located during fluoroscopy by the radio opaque stripe 30, and the depth of the catheter can be readily determined by depth indicators 20, which are preferably now located outside of the needle 28. The catheter is preferably rolled up in a spiral plastic package, or held in one hand, to prevent it from falling into an unsterile area as it is inserted through the needle. A slight resistance is felt as the catheter passes through the tip of the needle when the second depth indicator will just be visible at the hub of the needle 28. By turning the needle, its point can be directed to a preferred position. The catheter can thereafter be advanced in either direction along the epidural space 35. About 5 cm of catheter is preferably advanced into the epidural space 35, when the third depth indicator will be at or near the needle hub. The needle is then withdrawn carefully without removing the catheter 100, which is gently pushed forwardly as the needle is retracted. The needle is then completely removed from the patient, and anesthetic is delivered to a localized region 36 through the catheter 100. A bacterial filter can also be attached to the free end of the catheter 100 so that all fluid injected down the catheter 100 is sterile. Water-resistant strapping can also be employed to keep the catheter in place during injections.

From the foregoing, it can be realized that this invention provides improved epidural catheters having a soft, flexible tip and a unibody construction. The catheters of this invention can safely deliver fluids even if tied in small knots, e.g., having a bending radius of less than about 5 mm (.2 in.), and are highly resistant to kinking. The unified construction of the catheters of this invention sufficiently overcomes the deficiencies of prior art hard nylon and welded flexible tip catheters. Although various embodiments have been illustrated, this was for the purpose of describing, and not limiting the invention; for example, the concept of telescoping laminated tubes of different flexural moduli could

be equally applied to peripheral, interplural (or other regional anesthesia applications), central venous, multi-lumen, thermodilution, thoracic and emergency/trauma catheters. Various other modifications, which will become apparent to one skilled in the art, are within the scope of this invention described in the attached claims.

What is claimed is:

1. A dual durometer epidural catheter, suitable for infusing anesthesia into the epidural space of a body, said catheter comprising:

a stiff inner tube having a proximal and distal ends;

a softer outer tube co-axially disposed over said inner tube and having a distal end portion which extends beyond the distal end of said inner tube so as to form a soft, flexible, distal tip on said epidural catheter;

radio opaque means disposed along said catheter for providing fluoroscopic contrast; and

connection means for fluidly connecting a proximal end of said catheter to fluid injection means.

2. The epidural catheter of claim 1, wherein said stiff inner tube comprises a flexural modulus which is greater than about 50% of the flexural modulus of the softer outer tube.

3. The epidural catheter of claim 2, wherein said outer tube comprises a hardness of about 35 A-80 D Shore.

4. The epidural catheter of claim 1, wherein said inner tube comprises a flexural modulus which is at least about 10 times the flexural modulus of the softer outer tube.

5. The epidural catheter of claim 4, wherein said softer outer tube comprises a hardness of about 50 A-60 D Shore.

6. The epidural catheter of claim 1, wherein said flexible distal tip of said catheter extends about 3-10 cm from the distal end of said inner tube.

7. The epidural catheter of claim 6, wherein said flexible distal tip comprises a hydrophilic coating.

8. The epidural catheter of claim 1, wherein said stiff inner tube comprises a flexural modulus of at least about 1 GPa (.15 X 10^6 psi).

9. The epidural catheter of claim 8, wherein said softer outer tube comprises a hardness of about 80-100 A Shore and a flexural modulus of about .1-.17 GPa (.015-.025 X 10^6 psi).

10. The epidural catheter of claim 1, wherein said softer outer tube comprises a plurality of axially-spaced printed portions.

11. The epidural catheter of claim 10, wherein at least of one said axially-spaced printed portions comprises a portion of said flexible distal tip.

12. The epidural catheter of claim 1, wherein radio opaque means comprises a substantially continuous radio opaque stripe located axially along a portion of the length of said softer outer tube.

13. The epidural catheter of claim 12, wherein said stripe comprises tungsten, barium-sulfate, gold, tantalum, or platinum.

14. The epidural catheter of claim 1, wherein said radio opaque means comprises a longitudinal, barium-sulfate-impregnated stripe axially located substantially along the length of said epidural catheter.

15. The epidural catheter of claim 14, wherein said softer outer tube and said stiff inner tube are transparent.

16. The epidural catheter of claim 1, wherein said stiff inner tube comprises PEEK, PAEK, or nylon, and said softer outer tube comprises polyurethane.

17. A method of manufacturing a dual durometer catheter, comprising:

(a) providing a stiff inner tube having proximal and distal ends;

(b) disposing a softer outer tube co-axially over said stiff inner tube whereby a portion of said softer outer tube extends beyond the distal end of said inner tube so as to form a soft, flexible, distal tip on said epidural catheter; and

(c) applying a radio opaque material along a portion of said catheter to provide fluoroscopic contrast.

18. The method of claim 17, wherein said disposing step (b) comprises adhering said outer tube to said inner tube by expanding said outer tube with a solvent, inserting said inner tube into said expanded outer tube, and permitting said solvent to evaporate, whereby said outer tube compresses tightly around said inner tube.

19. The method of claim 18, wherein said outer tube comprises polyurethane and said inner tube comprises a flexural modulus of at least about 50% greater than the flexible modulus of said polyurethane.

20. The method of claim 17, wherein said outer tube and inner tube are laminated together by an over-extrusion process.

21. The method of claim 20, wherein said over-extrusion comprises joining long segments of stiff inner tube material together by link means prior to over-extruding said softer outer tube onto said linked, stiff inner tube segments.

22. The method of claim 21, wherein said link means comprises a fluorocarbon coated metallic member having a diameter greater than an inner diameter of said stiff inner tube segments.

23. The method of claim 22, wherein said coated metallic member comprises corrugated portions extending therefrom.

24. The method of claim 21, wherein said link means comprises a Ni-Ti metal core having a fluorocarbon coating thereon.

25. The method of claim 21, wherein said co-extrusion comprises removing said link means to provide an extruded segment consisting essentially of said softer outer tube.

26. A method of infusing epidural anesthesia into a patient, comprising:

providing a dual durometer epidural catheter including a stiff inner tube having proximal and distal ends and a softer outer tube co-axially disposed over said inner tube and having a distal portion which extends beyond the distal end of said inner tube so as to form a soft, flexible, distal tip on said epidural catheter, said epidural catheter further comprising radio opaque means disposed along said catheter for providing fluoroscopic contrast, and connection means for fluidly connecting said proximal end of said catheter to fluid injection means;

inserting said epidural catheter into a epidural space of said patient; and

injecting a local anesthesia into said epidural space through said epidural catheter.

27. The method of claim 26, wherein said inserting step comprises inserting a needle into said epidural space; telescoping said epidural catheter through an interior lumen of said needle; and withdrawing said needle whereby at least a distal portion of said epidural catheter remains in said epidural space.

28. The method of claim 26, wherein a proximal end of said epidural catheter is connected to a syringe for injecting said local anesthesia.

29. A dual durometer catheter suitable for delivering localized anesthesia, comprising a stiff inner tube having an internal lumen exiting at a proximal and distal end region of said catheter; a softer outer tube laminated to said inner tube and extending at least about 1.0 cm (.4 in.) from said distal end of said stiff inner tube, said outer tube having a flexural modulus of at least about 50% less than the flexural modulus of said stiff inner tube.

30. The catheter of claim 29, wherein said stiff inner tube and said softer outer tube are transparent and said catheter further comprises a longitudinal radio-opaque stripe.

31. The catheter of claim 29, wherein said softer outer tube is laminated to said stiff inner tube by a solvent swelling process.

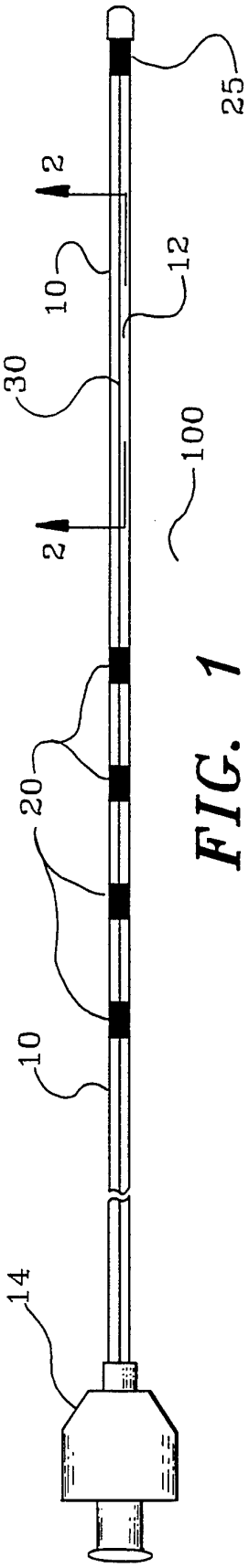

FIG. 1

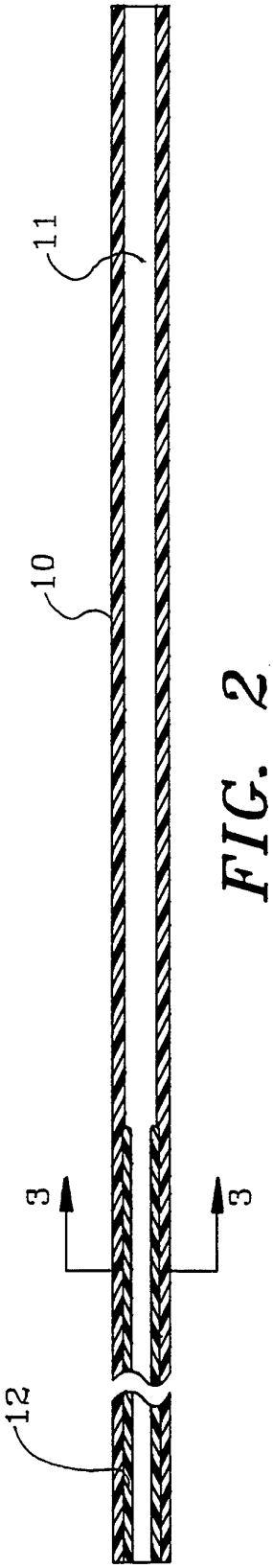

FIG. 2

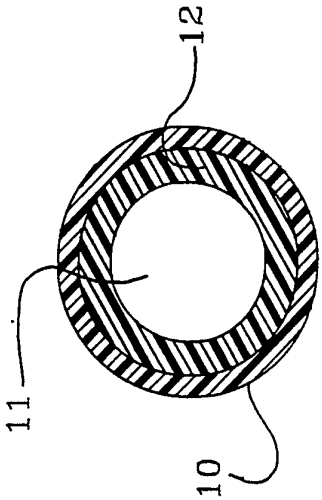

FIG. 3

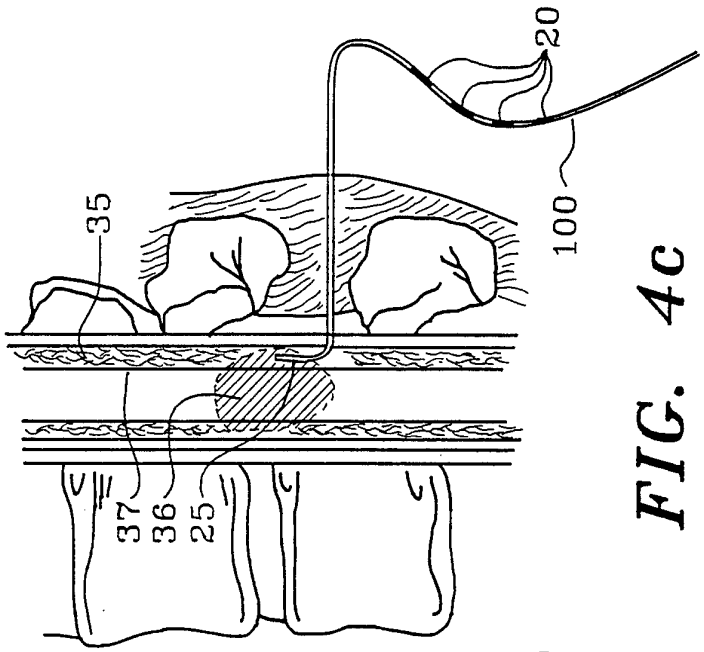

FIG. 4c

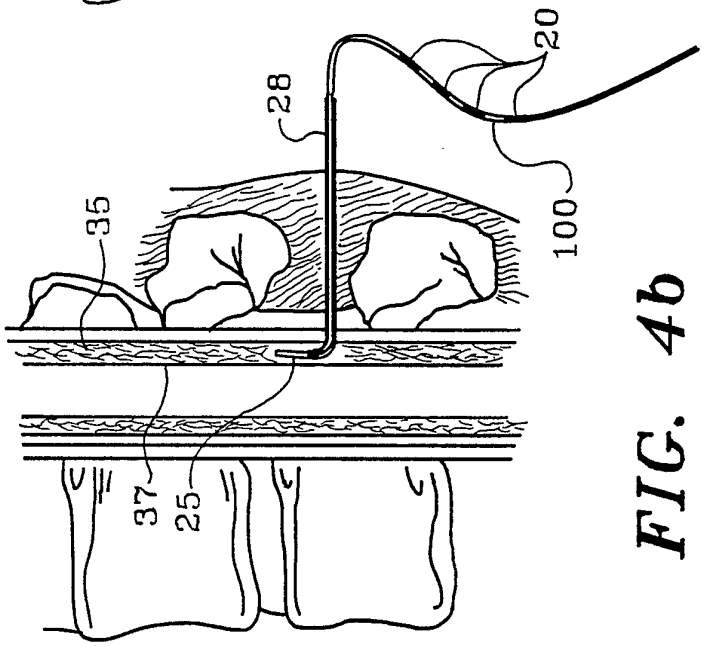

FIG. 4b

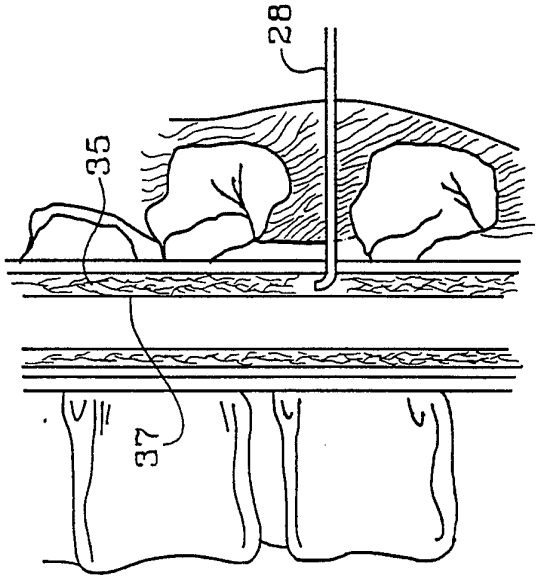

FIG. 4a

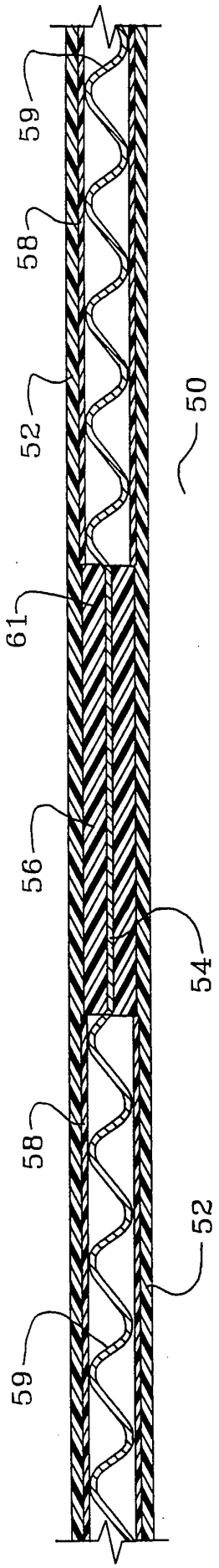

FIG. 5

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US93/06022

A. CLASSIFICATION OF SUBJECT MATTER

IPC(5) :A61M 25/00
US CL :604/264

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)

U.S. : 604/264, 280

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

None

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

None

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US, A, 5,078,702 (Pomeranz) 07 January 1992, see entire patent.	1-31
Y	US, A, 4,863,442 (DeMello et al.) 05 September 1989, see entire patent.	1-31
Y	US, A, 4,385,635 (Ruiz) 31 May 1983, see entire document.	1-31

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

*	Special categories of cited documents:	"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
"A"	document defining the general state of the art which is not considered to be part of particular relevance	"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
"E"	earlier document published on or after the international filing date	"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
"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)	"&"	document member of the same patent family
"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		

Date of the actual completion of the international search 20 September 1993	Date of mailing of the international search report OCT 19 1993
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. NOT APPLICABLE	Authorized officer Manuel Mendez Telephone No. (703) 308-2221

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