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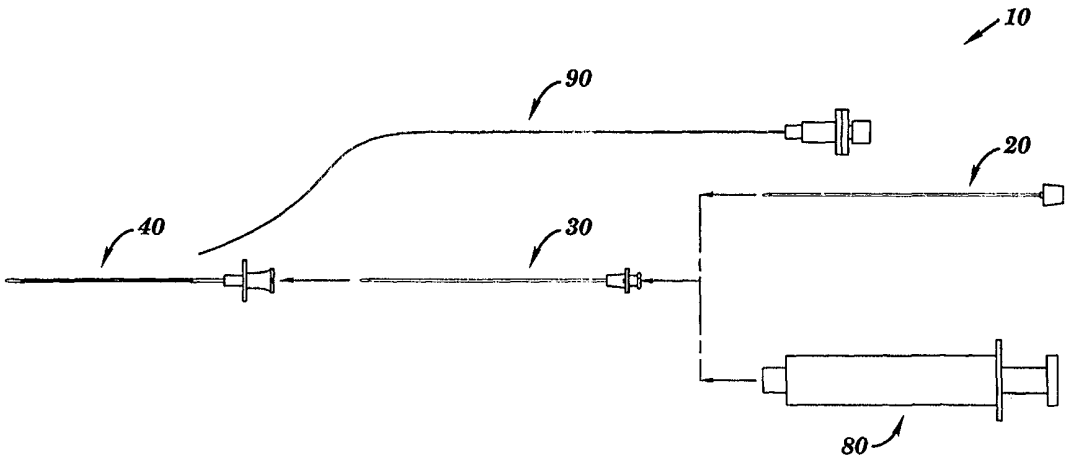

(57) Abstract

An epidural catheter system (10) for inserting a catheter tube (90) into an epidural space of a patient that includes a stylet (20), an epidural needle (30), a sheath (40), a glass syringe (80), and a catheter tube (90). The system (10) allows a physician, e.g., an anesthesiologist, to insert the catheter tube (90) into an epidural space in a patient without the need to slide the epidural needle (30) over the catheter tube (90) when removing the epidural needle (30) from the patient. The sheath (40) includes a generally elongated body (42) comprising a first end having a point (45), a second end (46), an outer surface, and an inner surface defining a passageway extending from the first end to a second end (46). A slot (56) extends from the outer surface to the inner surface from the first end, and adjacent to the second end (46).

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SHEATH, EPIDURAL CATHETER SYSTEM, AND METHOD FOR INSERTING A CATHETER

TECHNICAL FIELD

This invention relates to an epidural catheter, and more particularly, to a sheath, an epidural catheter system, and a method for inserting a catheter tube into an epidural space in a patient.

BACKGROUND INFORMATION

An epidural catheter is typically inserted into an epidural space in a spinal column of a patient for delivery of an anesthetic for the relief of pain secondary to surgery, labor, etc. The process typically involves inserting a hollow epidural needle having a solid stylet (e.g., a thin wire inserted into the hollow epidural needle to maintain patency) through the patient's skin adjacent to the epidural space. The stylet is then removed and the epidural needle is attached to a syringe containing air or fluid. The syringe allows identifying the epidural space using the "loss of resistance" technique, i.e., the epidural needle and syringe are slowly advanced and the syringe is tested for a "bounce" in the plunger. When the "bounce" or loss of resistance in the syringe is gone, the end of the needle has entered the epidural space.

The syringe is then detached from the hollow epidural needle and a first end of a catheter tube is inserted into and fed through the hollow space in the epidural needle until the first end of the catheter exits the epidural needle and enters the epidural space. Once the first end of the catheter is positioned in the epidural space, the epidural needle is then removed from the patient by sliding the epidural needle over the second end of the catheter tube which extends from the patient so that the catheter tube remains in the patient.

The end of the catheter tube is then attached to a leur lock so that the catheter tube can be attached to a large syringe or of an anaesthetic supply pump. Typically, an antimicrobial filter is placed between the hub and the patient to inhibit bacterial migration along the catheter tube toward the exit site in the patient.

A drawback with the above-noted procedure for inserting a catheter tube in a patient is that the catheter tube is easily sheared in half by the end of the epidural needle when the catheter is pulled back through the hollow epidural needle while the needle tip remains in the epidural space of the patient. Another drawback is that this procedure requires that a physician, in order to utilize the epidural catheter, must attach the hub to the end of the catheter tube. Routinely this catheter is inserted into the hub and can subsequently become disconnected, thus, opening the catheter and patient to possible bacterial contamination.

Therefore, there is a need for a sheath for a epidural catheter system and method for inserting a catheter tube into an epidural space in a patient wherein the likelihood of shearing the catheter tube is reduced, if not eliminated, and wherein a hub may be attached to the end of a catheter tube during manufacturing prior to inserting the catheter tube into the patient. Thus creating a one piece hub/catheter system that will not disconnect. Also, such an epidural catheter system would allow the manufacturing of a catheter of various diameters as one unit, not dictated by the diameter of the epidural needle.

SUMMARY OF THE INVENTION

The above-mentioned needs are met by the present invention which relates, in one aspect, to a sheath for use in inserting a catheter tube into an epidural space in a patient. The sheath includes a generally elongated body having a first end having a point, a second end, an outer surface, and an inner surface defining a passageway extending from the first end to the second end. The body includes a slot extending

from the outer surface to the inner surface and from the first end to adjacent to the second end. The passageway is sized to allow a catheter tube to be fed therethrough, and the slot is sized to allow the catheter tube to pass therethrough.

In another aspect of the present invention, an epidural catheter system for inserting a catheter tube into an epidural space of a patient includes a sheath as noted above, a needle receivable in the sheath, and a stylet slidably receivable in the needle. Desirably, the sheath and the needle each include a beveled end, and means for aligning the beveled end of the sheath and the beveled end of the needle. The needle and the stylet may also include a beveled end and means for aligning the beveled end of the needle with the beveled end of the stylet. Advantageously, the system also includes a catheter tube having a hub attached to one end of the catheter tube.

In another aspect of the present invention a method for inserting a catheter tube into an epidural space of a patient is provided in which the method includes the steps of forming an assembly comprising a sheath as noted above having a passageway and a slot, a needle slidably received in the sheath, and a stylet slidably received in the needle. The assembly is inserted into the patient adjacent to the epidural space and the stylet is removed from the assembly. A syringe is attached to the needle and a portion of the sheath and the needle are positioned into the epidural space of the patient, e.g., using the "loss of resistance" technique. The needle is removed from the sheath and a catheter tube is inserted through the slot and fed through the passageway in the sheath and into the epidural space in the patient. The sheath is removed from the patient wherein the catheter tube passes through the slot in the sheath.

BRIEF DESCRIPTION OF THE DRAWINGS

The subject matter which is regarded as the invention is particularly pointed

out and distinctly claimed in the claims at the conclusion of the specification. The foregoing and other objects, features, and advantages of the invention will be readily understood from the following detailed description of preferred embodiments taken in conjunction with the accompanying drawings in which:

FIG. 1 is an exploded plan view of an epidural catheter system according to the present invention;

FIG. 2 is an enlarged, exploded plan view of the epidural catheter system shown in FIG. 1;

FIG. 3 is a partial, enlarged, cross-sectional view of an assembly of the sheath, the epidural needle, and the stylet shown in FIGS. 1 and 2;

FIG. 4 is a partial, enlarged, cross-sectional view of an assembly of the sheath, the epidural needle, and the glass syringe shown in FIG. 1 and 2;

FIG. 5 is a partial, enlarged, cross-sectional view of an assembly of the catheter tube inserted through the sheath shown in FIGS. 1 and 2;

FIG. 6 is a perspective view of the assembly shown in FIG. 3 prior to insertion of the assembly into a patient;

FIG. 7 is a perspective view of the removal of the stylet from the assembly shown in FIG. 6 after insertion into the patient;

FIG. 8 is a perspective view of the attachment of a glass syringe to the epidural needle shown in FIG. 7;

FIG. 9 is a cross-sectional view of the insertion of the sheath and needle,

shown in FIG. 8, into the epidural space of the patient while monitoring for the loss of resistance in the syringe;

FIG. 10 is a cross-sectional view of removal of the glass syringe and epidural needle from the sheath, shown in FIG. 9;

FIG. 11 is a cross-sectional view of insertion of a catheter tube through the slot and the passageway in the sheath, shown in FIG. 10, and into the epidural space;

FIG. 12 is a perspective view of removal of the sheath, shown in FIG. 11, from the patient wherein the catheter tube passes through the slot in the sheath;

FIG. 13 is a cross-sectional view of the assembly shown in FIG. 3;

FIG. 14 is a cross-sectional view of the sheath and the catheter tube shown in FIG. 5;

FIG. 15 is an enlarged, partial, plan view of the sheath and key hole slot shown in FIGS. 1 and 2;

FIG. 16 is an enlarged, partial, cross-sectional view of the catheter tube (shown in phantom) inserted through the keyhole into the passageway in the sheath shown in FIG. 15; and

FIGS. 17-19 are cross-sectional views of alternative sheaths according to the present invention.

DETAILED DESCRIPTION OF THE PRESENT INVENTION

FIGS. 1 and 2 illustrate one embodiment of a multicomponent epidural

catheter system 10 according to the present invention. In this exemplary embodiment, system 10 includes a stylet 20, an epidural needle 30, a sheath 40, a glass syringe 80, and a catheter tube 90. System 10 allows a physician, e.g., an anesthesiologist, to insert catheter tube 90 into an epidural space in a patient without requiring epidural needle 30 to be slid over the length of the catheter tube 90 when removing epidural needle 30 from the patient.

As best shown in FIG. 2, stylet 20 includes a solid, cylindrical, elongated body 22 having a first beveled end 24, e.g., a slanted or an inclined surface which defines a point 25, and a second end 26 attached to a stop 28 having a thumb rest 27.

Epidural needle 30 includes a hollow, cylindrical, elongated body 32 having a first beveled end 34, e.g., a slanted or an inclined surface which defines a point 35, and a second end 36 attached to a stop 38. Stop 38 includes a fusto conically-shaped portion 31, a finger flange 33 and a Luer-Lock tip 37. A recess 39a in Leur-Lock tip 37 receives a tab 29 on stylet 20, e.g., when stylet 20 is slidably inserted and received in epidural needle 30 for maintaining beveled ends 24 and 34 in alignment.

Sheath 40 includes a generally hollow elongated body 42 having a first beveled end 44, e.g., a slanted or an inclined end which defines a point 45, and a second end 46 attached to a stop 48. Stop 48 includes a finger flange 43 and an conically-shaped recess 41 (shown in dashed lines). A recess 49 on stop 48 receives a tab 39b of epidural needle 30, e.g., when epidural needle 30 is slidably receivable in sheath 40 for maintaining beveled ends 35 and 45 in alignment. From the present description, it will be appreciated by those skilled in the art that other configurations may be employed to align stylet 20 to epidural needle 30, and epidural needle 30 to sheath 40, e.g., detents and/or snap-fit engaging portions.

As best shown in FIGS. 2 and 13-16, in this exemplary embodiment of sheath 40, elongated body 42 includes a sidewall having an outer surface 50 (FIG.

14), and an inner surface 52 (FIG. 14) defining a longitudinally extending passageway 54 (FIG. 14). An elongated aperture or slot 56 extends from inner surface 52 of sheath 40 to outer surface 50 of sheath 40 so that sheath 40 has a generally C-shaped cross-sectional configuration. Elongated slot 56 opens onto beveled end 44 (FIG. 2) and extends longitudinally along the length of elongated body 42 to terminated at an aperture or keyhole 55 (FIG. 2) disposed adjacent to stop 48. Desirably, sheath 40 comprises a C-shaped cross-section which defines an arc extending at least 180 degrees.

FIGS. 6-12 illustrate the procedure according to the present invention for inserting catheter tube 90 into an epidural space in a spinal column of a patient. Initially, as shown in FIGS. 3 and 6, an assembly 60 comprises stylet 20 slidably received within epidural needle 30, and stylet 20 and epidural needle 30 together slidably received in sheath 40. Stylet 20 provides support and maintains the rigidity of epidural needle 30, as well as maintains patency of epidural needle 30 as assembly 60 is inserted through a patient's skin and into the lumbar region of a patient's spine, e.g., in the ligamentum flavum, adjacent to the epidural space.

As shown in FIG. 7, once assembly 60 is inserted into the patient, stylet 20 is removed from assembly 60 leaving epidural needle 30 and sheath 40 embedded in the patient. Glass syringe 80 is attached to Luer-Lock tip 37 of epidural needle 30, as shown in FIGS. 4 and 8, to form an assembly 70 comprising sheath 40, epidural needle 30, and glass syringe 80.

Assembly 70 is further inserted into the patient, as shown in FIG. 9, using the "loss of resistance" technique, e.g., wherein a pressure is applied to thumb rest 87 to test glass syringe 80 for bounce in plunger 82. When the bounce is gone, end 44 of sheath 40 and end 34 (FIG. 2) of epidural needle 30 (FIG. 10) have entered an epidural space 12.

As shown in FIG. 10, epidural needle 30 and glass syringe 80 are removed leaving sheath 40 in epidural space 12. As shown in FIG. 11, catheter 90 is placed through keyhole 55 (FIGS. 5, 15, and 16) and fed into passageway 54 (FIG. 14) in sheath 40 and into epidural space 12. Catheter tube 90 desirably includes a hub 98 attached to end 92 of catheter tube 90. Hub 98 allows catheter tube 90 to be readily attached to a tube of a local anaesthetic supply pack (not shown). Advantageously, the tube 90 can have a greater diameter at hub 98 than the diameter of the catheter tube inserted through sheath 40 into the epidural space 12.

Once catheter 90 is positioned in epidural space 12 (FIG. 11), sheath 40 is removed from the patient as shown in FIG. 12. Desirably, sheath 40 is removed from the patient by catheter tube 90 passing through slot 56 of sheath 40. As shown in FIG. 14 slot 56 of sheath 40 is desirably sized to allow catheter tube 90 to readily pass therethrough. From the present description, it will be appreciated by those skilled in the art that hub 98 (FIG. 11) of catheter tube 90 does not interfere or prevent sheath 40 from being removed from the patient.

Desirably, hub 98 may be securely attached prior to surgery by a physician or may be fixedly attached by a manufacturer as a unit which advantageously reduces the time required for connecting catheter tube 90 to hub 98 and which reduces the likelihood of the hub and catheter tube becoming disconnected and subsequently contaminated. An antimicrobial cuff (not shown) may be manufactured to catheter tube 90 between end 92 and hub 98 if catheter is implanted into patient to prevent bacterial migration.

Also, tube 90 can be manufactured with various diameters, i.e., 20 gauge (end inserted into 12) to 10 french end 92 into hub 98. This allows for ease of handling of tube 90 with larger size by patient and professionals and allows tube 90 to be manufactured as one piece not spliced together. Lastly, by being manufactured as one piece, this eliminates need to splice catheter of various diameters together and

eliminates the possibility of the catheter coming apart or contamination thereof once implanted or utilized for patient use.

FIGS. 18 and 19 illustrate alternative cross-sectional views of a sheath 140 and sheath 240, respectively, according to another aspect of the present invention for use in the above-described epidural catheter system.

As shown in FIG. 17, another aspect of the present invention includes a sheath 340 which may include a first arcuate half 342 and a second arcuate half 344 which together form a passageway 346. By rotating first half 342 relative to 344, the arcuate halves defines a longitudinally extending slot along the length of sheath 340.

Although preferred embodiments have been depicted and described in detail herein, it will be apparent to those skilled in the relevant art that various modifications, additions, substitutions and the like can be made without departing from the spirit of the invention and these are therefore considered to be within the scope of the invention as defined in the following claims.

WHAT IS CLAIMED:

1. A sheath for use in inserting a catheter tube into an epidural space in a patient, said sheath comprising:

a generally elongated body comprising a first end having a point, a second end, an outer surface, and an inner surface defining a passageway extending from said first end to said second end; and

a slot extending from said outer surface to said inner surface and from said first end to adjacent to said second end.

2. The sheath according to claim 1, wherein said passageway is sized to allow a catheter tube to be fed therethrough, and said slot is sized to allow the catheter tube to pass therethrough.

3. The sheath according to claim 1, wherein said slot opens onto an enlarged aperture extending from said outer surface to said inner surface.

4. The sheath according to claim 1, wherein said first end comprises a beveled end.

5. The sheath according to claim 1, further comprising a stop attached to said second end.

6. The sheath according to claim 1, wherein said stop comprises a finger flange.

7. The sheath according to claim 5, wherein said stop comprises means for aligning a beveled edge of an epidural needle with said beveled edge of said sheath.

8. The sheath according to claim 1, wherein said elongated body comprises a generally C-shaped cross-section.

9. The sheath according to claim 8, wherein said elongated body comprises an arc extending at least 180 degrees.

10. The sheath according to claim 1 wherein said elongated body comprises a first arcuate portion and a second arcuate portion which are rotatable with respect to each other to define said slot.

11. An epidural catheter system for inserting a catheter tube into an epidural space of a patient, said system comprising:

a sheath according to claim 1;

a needle receivable in said sheath; and

a stylet slidably receivable in said needle.

12. The system according to claim 11, wherein said sheath and said needle each comprise a beveled end, and further comprising means for aligning said beveled end of said sheath and said beveled end of said needle.

13. The system according to claim 11, wherein said needle and said stylet each comprise a beveled end, and further comprising means for aligning said beveled end of said needle with said beveled end of said stylet.

14. The system according to claim 11, further comprising a catheter tube.

15. The system according to claim 11, wherein said catheter tube comprises a hub attached to one end of the catheter tube.

16. A method for inserting a catheter tube into an epidural space of a patient, said method comprising the steps of:

forming an assembly comprising a sheath according to claim 1 having a passageway and a slot, a needle slidably received in said sheath, and a stylet slidably received in said needle;

inserting said assembly into the patient adjacent to an the epidural space;

removing said stylet from said assembly;

attaching a syringe to said needle;

positioning a portion of said sheath and said needle into the epidural space of the patient;

removing said needle from said sheath;

inserting a catheter tube through said slot and feeding said catheter tube through said passageway in sheath and into the epidural space in the

patient;

removing said sheath from the patient wherein said catheter tube passes through said slot in the sheath.

17. The method according to claim 16, wherein the step of positioning a portion of said sheath and said needle comprises monitoring the syringe for loss of resistance.

* * * * *

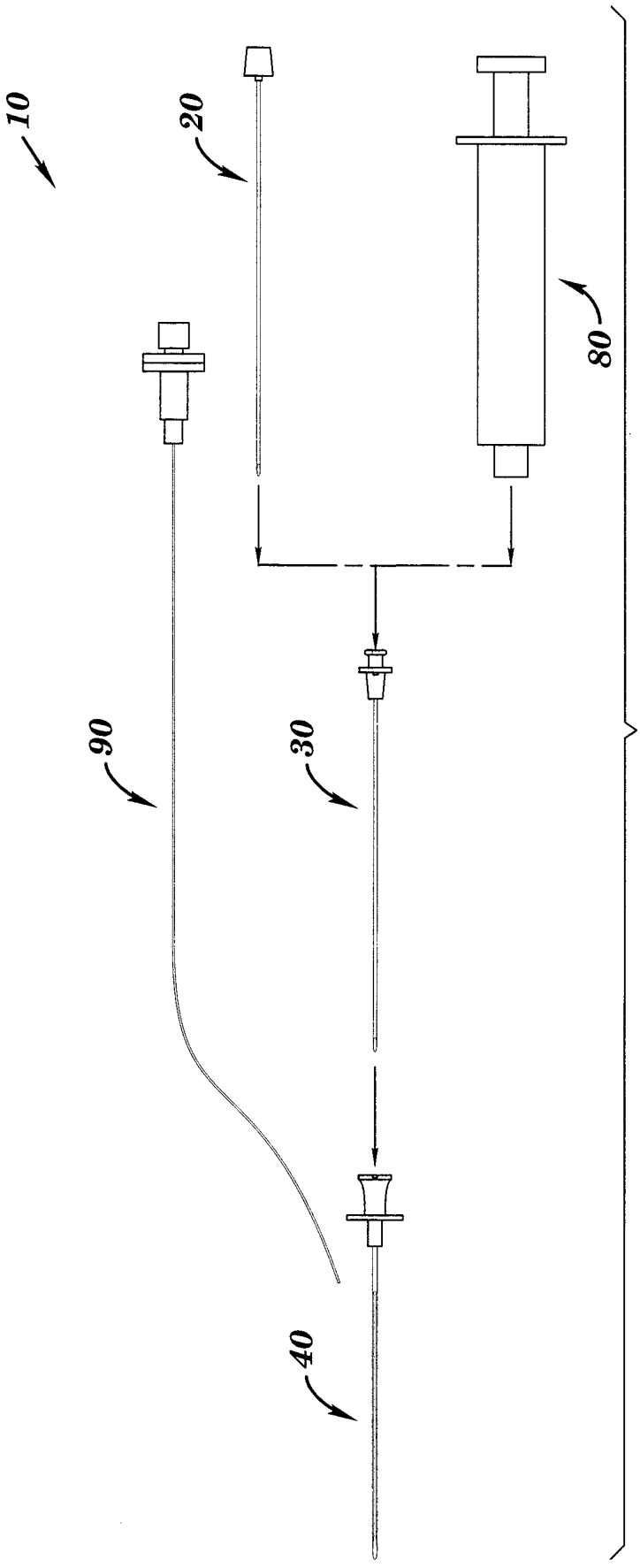

FIG. 1

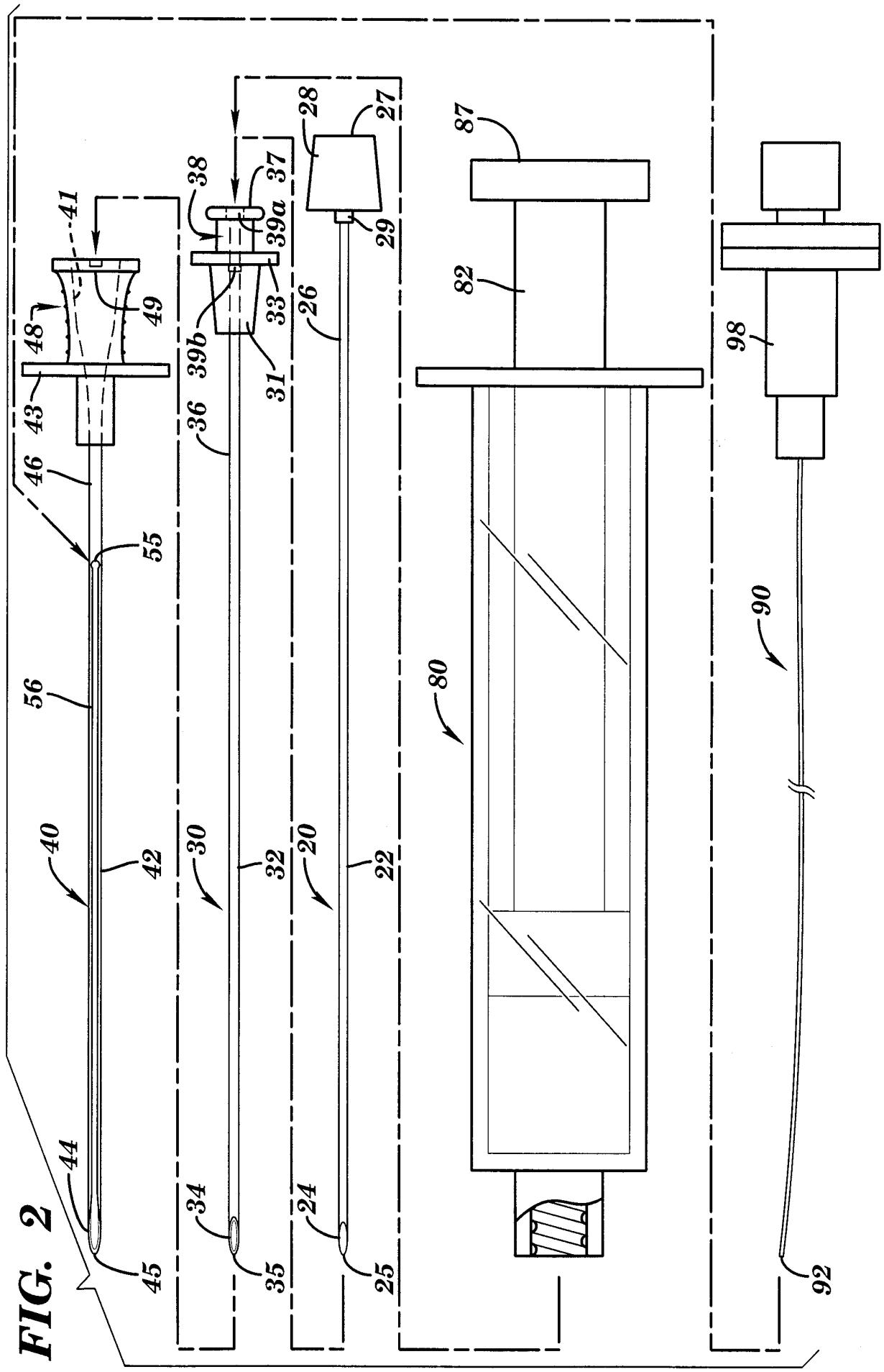
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FIG. 2

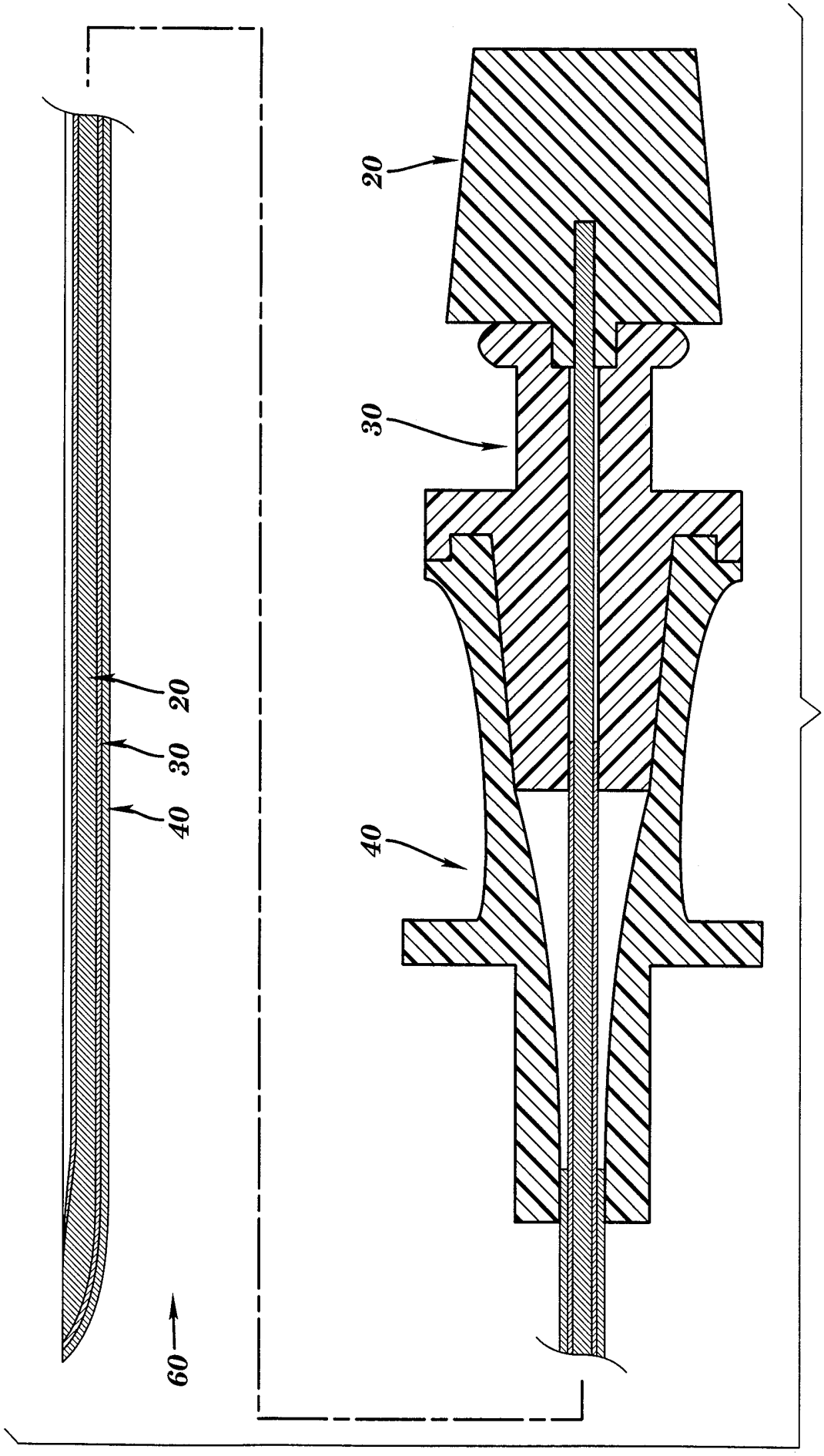


FIG. 3

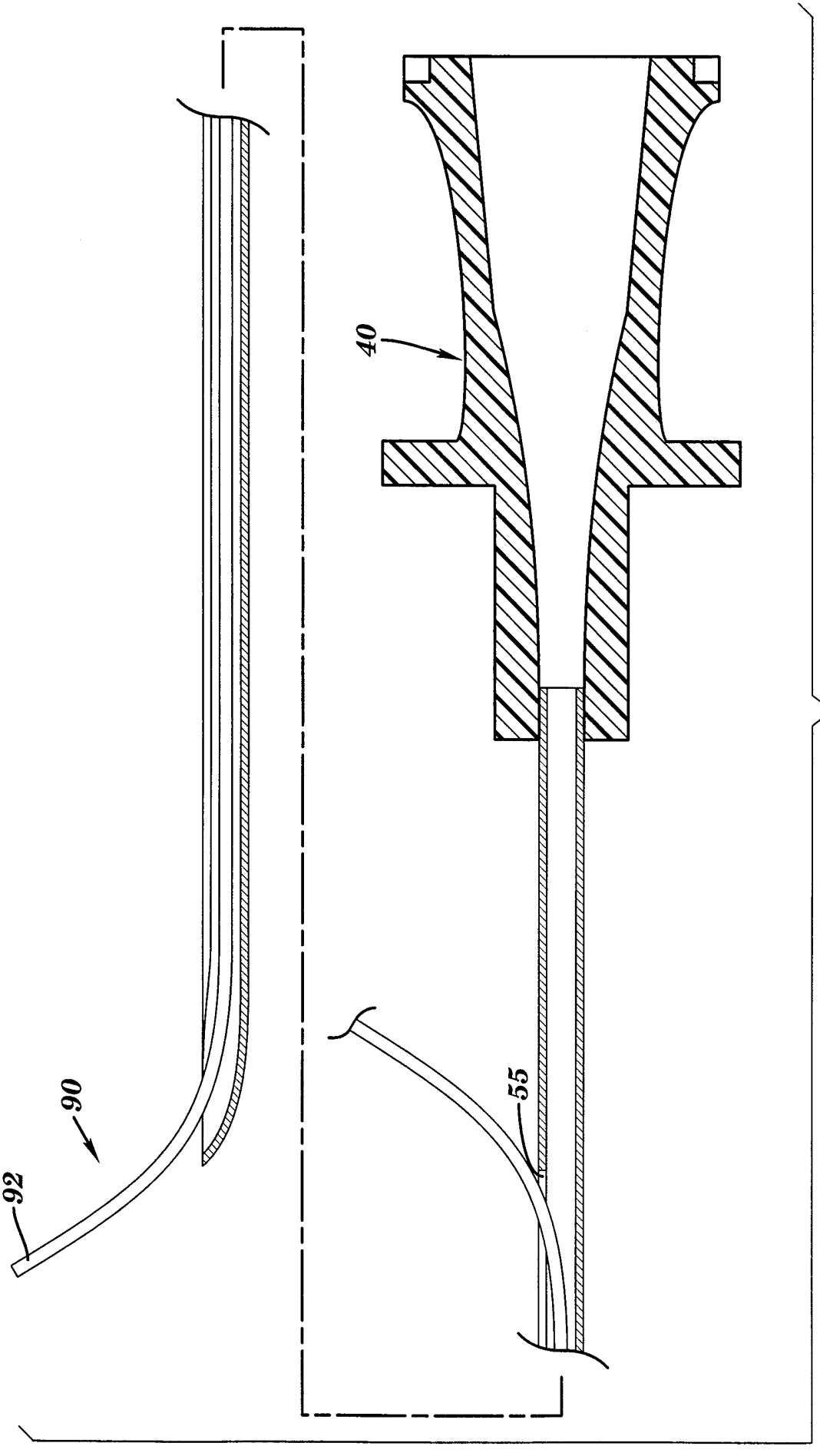


FIG. 5

FIG. 6

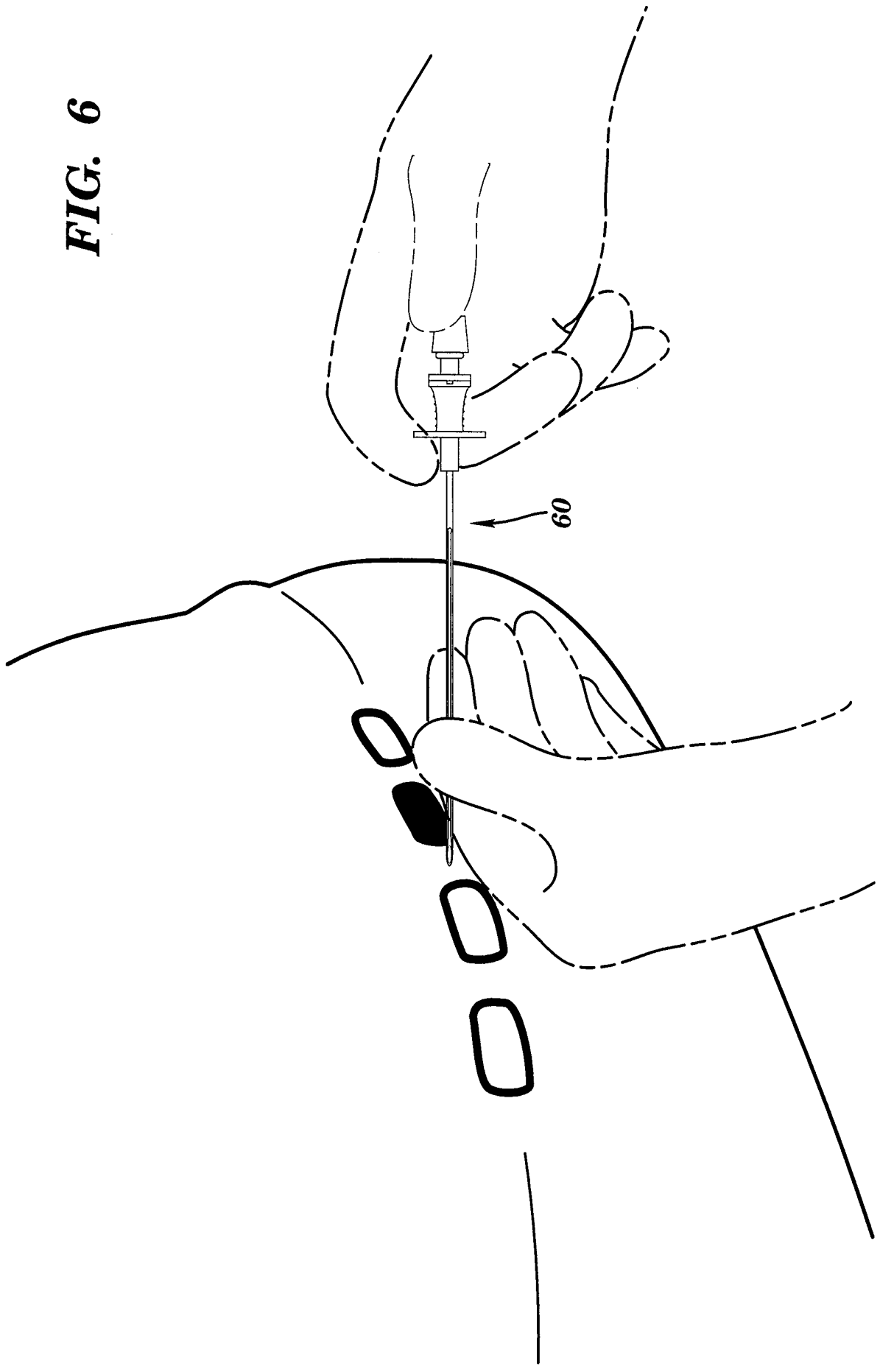
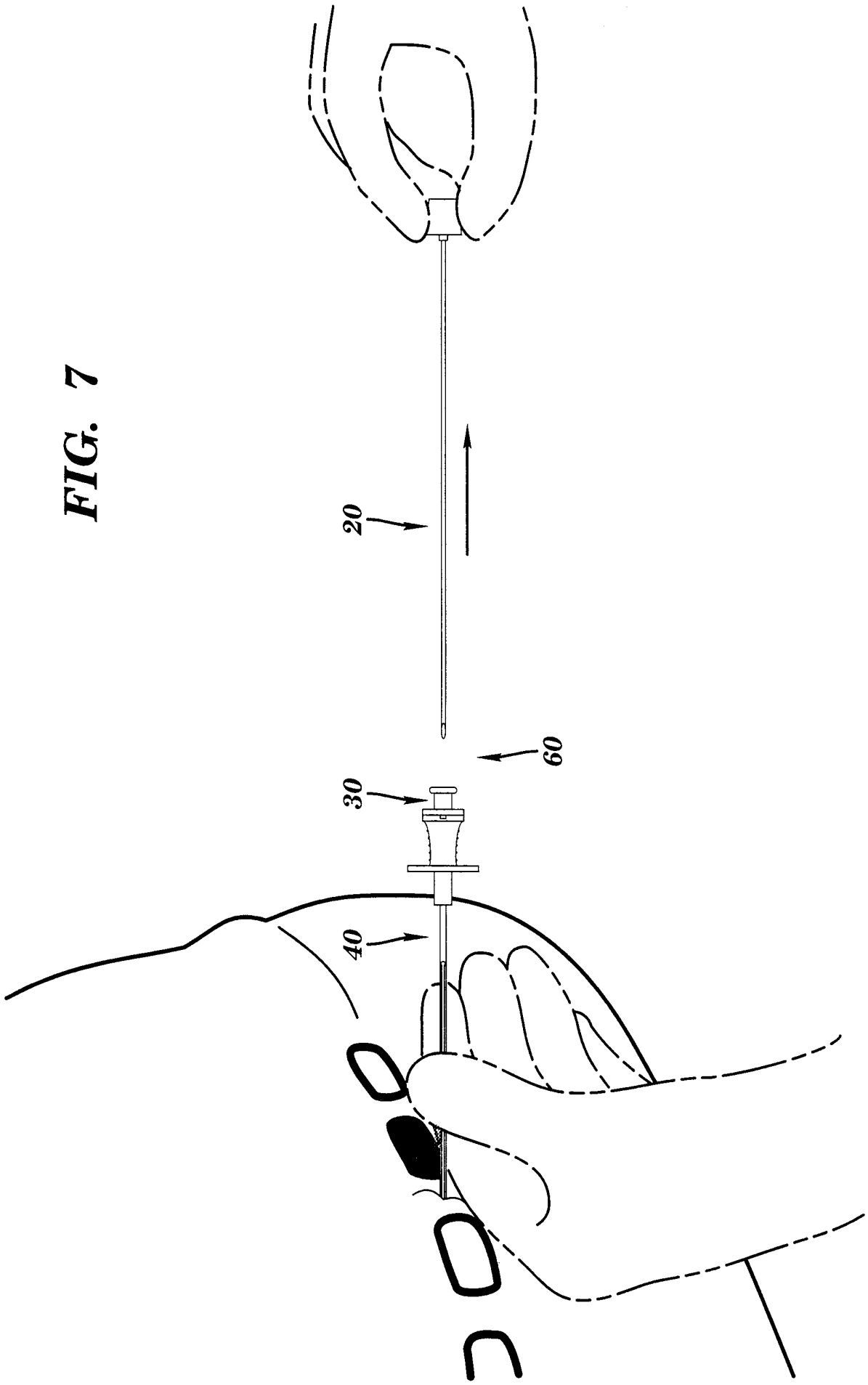


FIG. 7



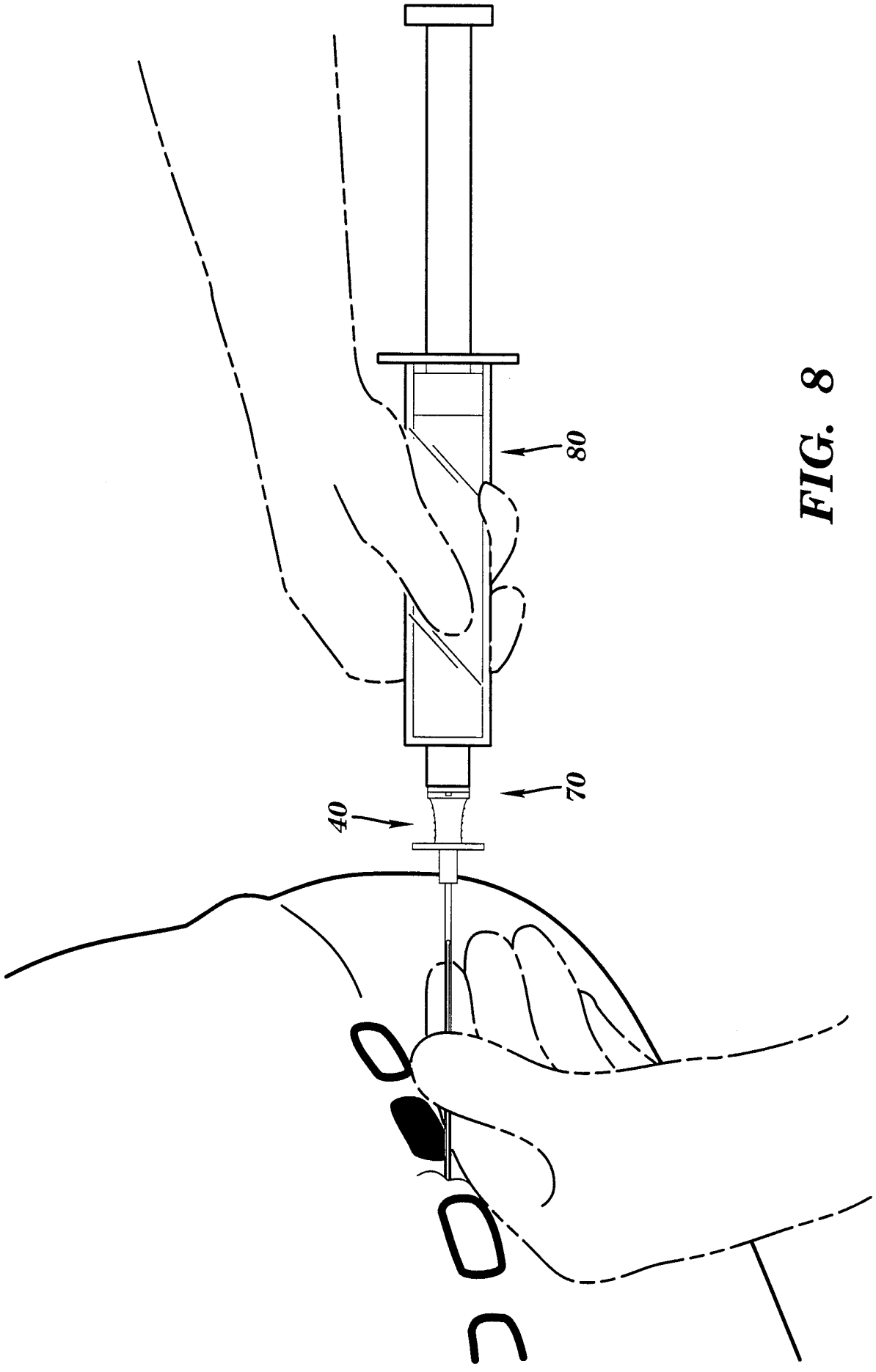
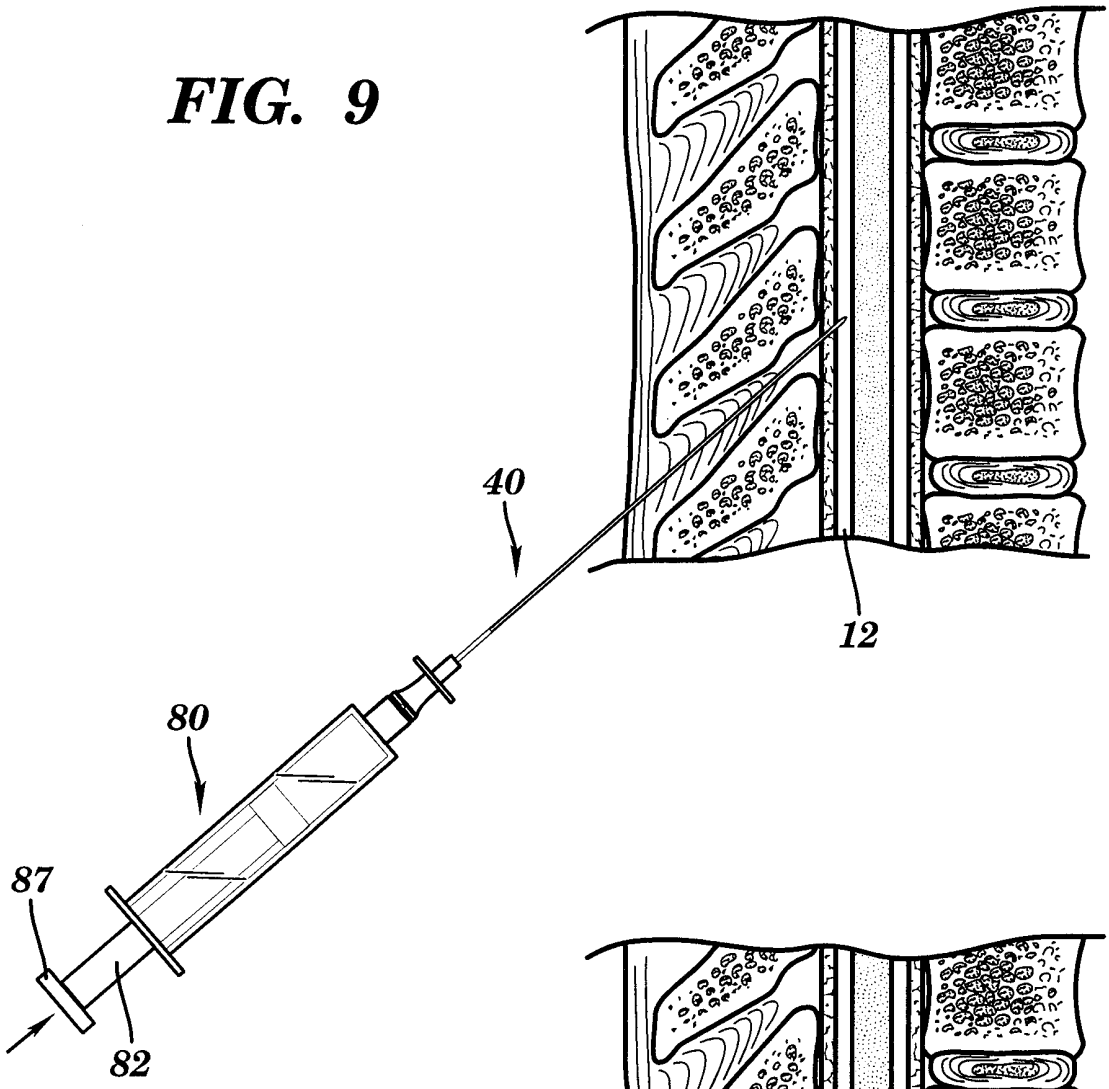


FIG. 8

FIG. 9



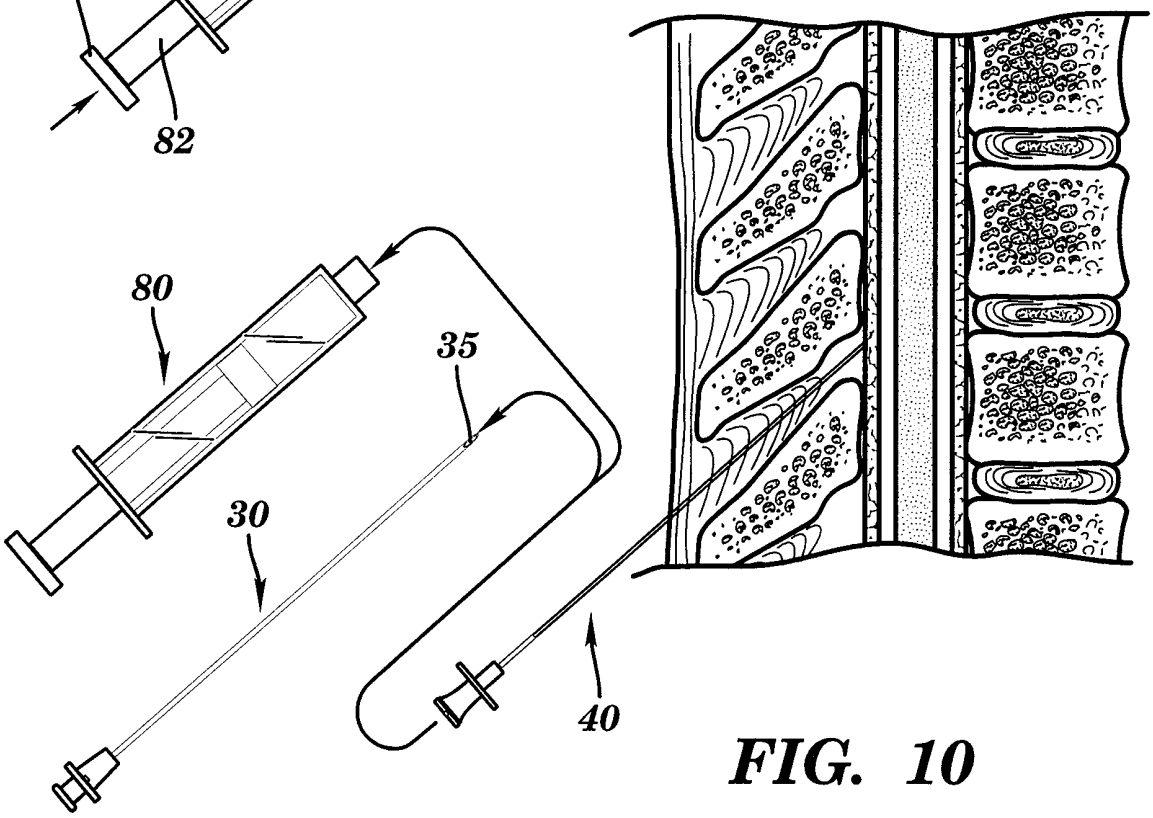


FIG. 10

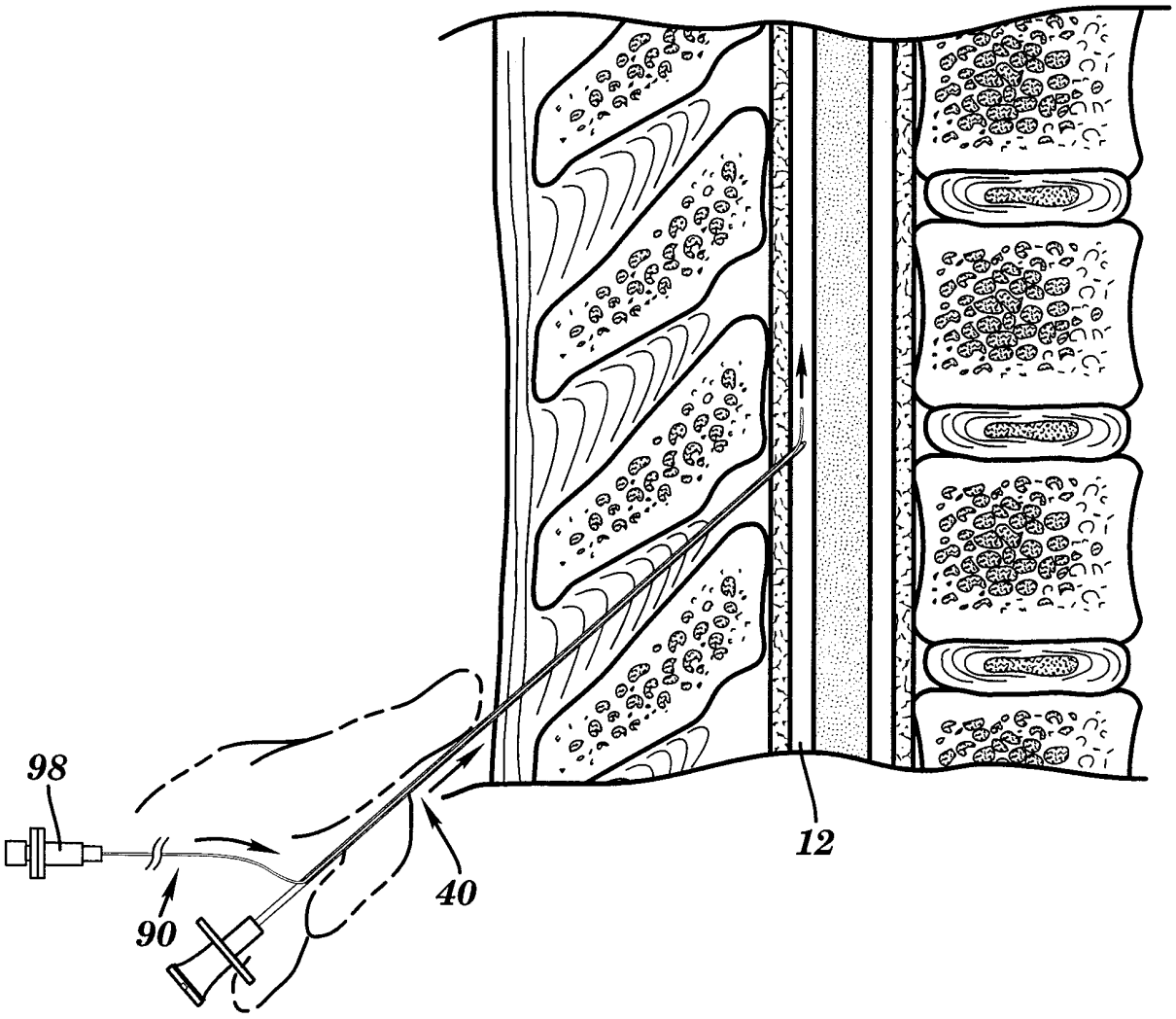


FIG. 11

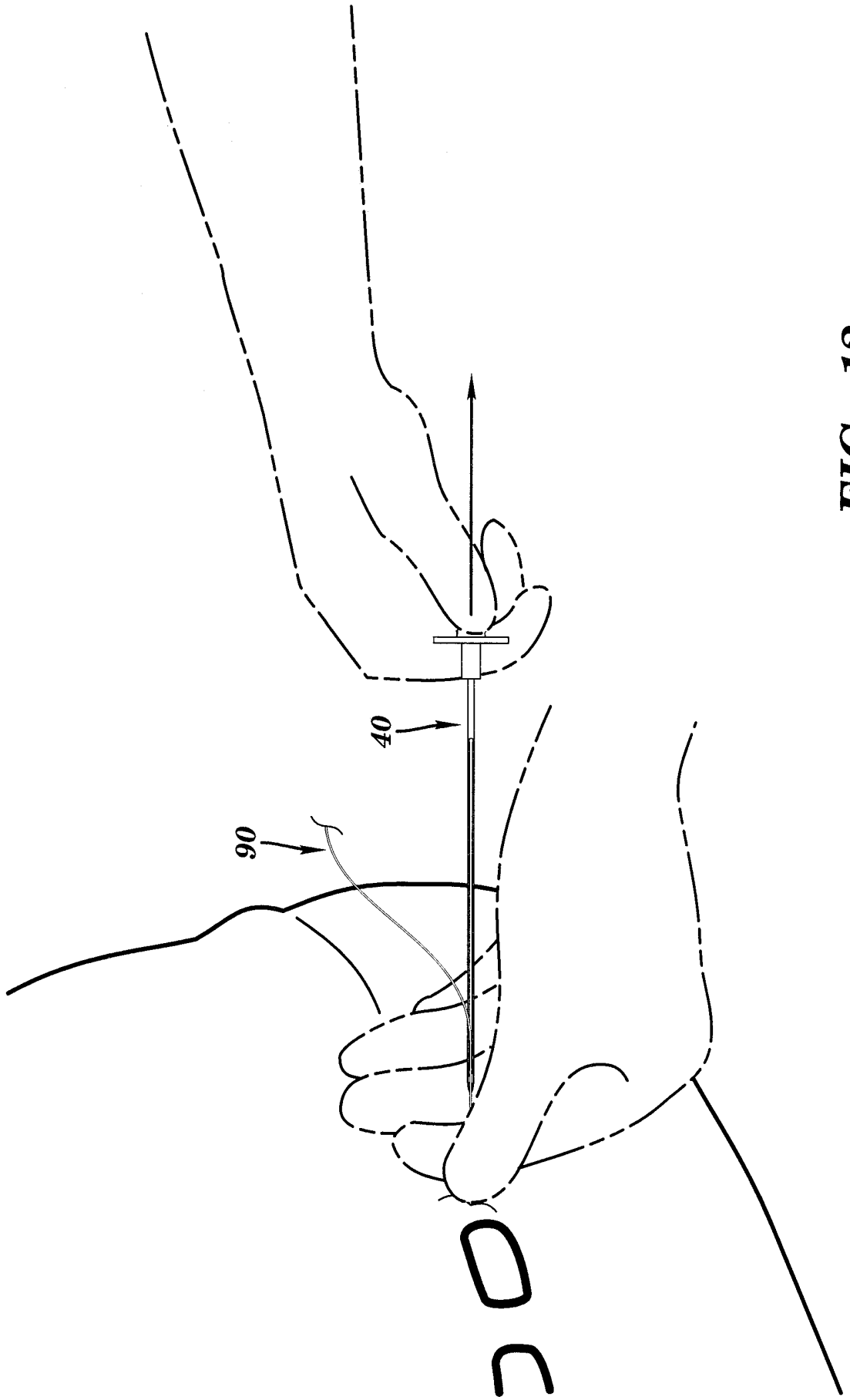


FIG. 12

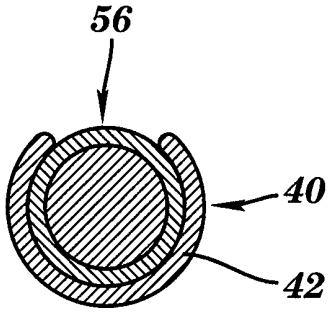


FIG. 13

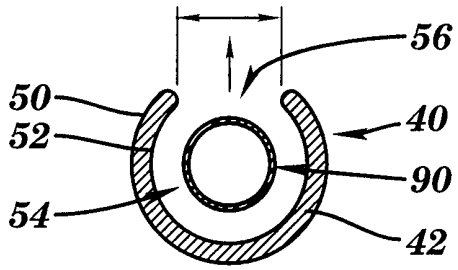


FIG. 14

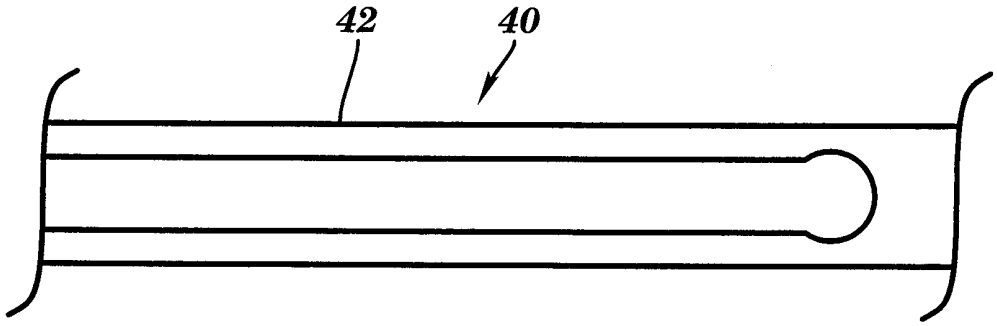


FIG. 15

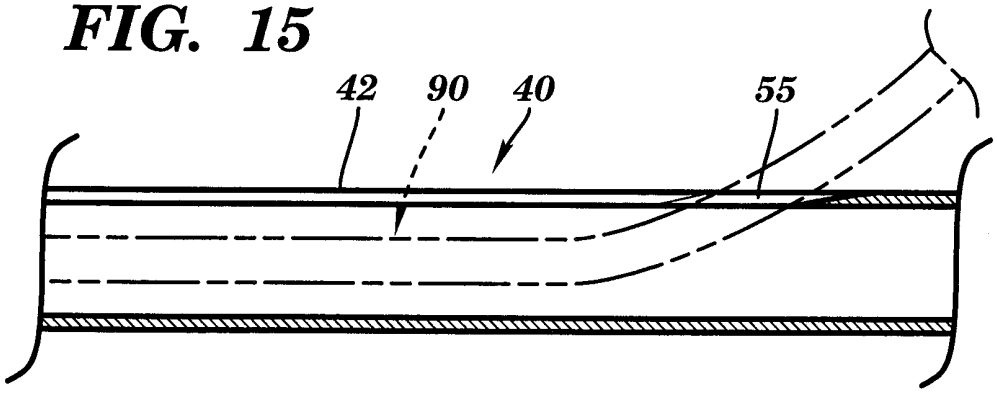


FIG. 16

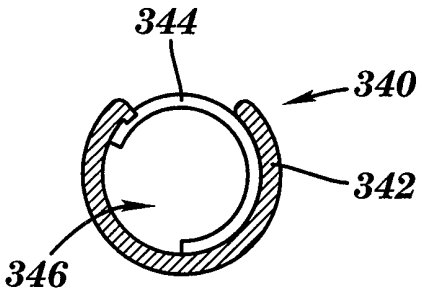


FIG. 17

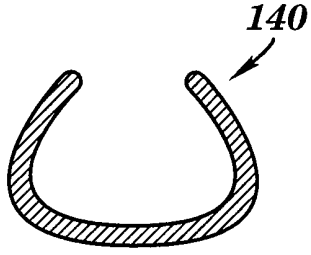


FIG. 18

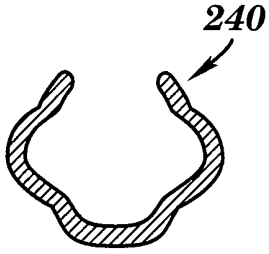


FIG. 19

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/00762

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) :A61M 5/178
US CL :604/160

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. : 604/158, 160, 161, 164.01, 164.06, 164.07, 164.09, 170.01, 170.02, 264, 272-274, 512

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

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

EAST
Serch Terms: (CLAS/SUB and slot; and needle and stylet; and anest$)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,380,290 A (MAKOWER et al.) 10 January 1995, specification.	1-5
Y	US 5,667,514 A (HELLER) 16 September 1997, specification.	1, 2, 4-6
Y	US 3,827,434 A (THOMPSON et al.) 06 August 1974, specification.	1-4
A	US 3,835,854 A (JEWETT) 17 September 1974, specification.	1
A	US 5,057,085 A (KOPANS) 15 October 1991, specification.	1, 11, 12
A	US 4,354,491 A (MARBRY) 19 October 1982, specification.	1, 2, 4, 5

[X] 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 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 04 APRIL 2000	Date of mailing of the international search report 25 APR 2000
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer CRIS L. RODRIGUEZ Telephone No. (703) 308-2194

Form PCT/ISA/210 (second sheet) (July 1998) ★

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/00762

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No
A	US 5,139,486 A (MOSS) 18 August 1992, specification.	1