CORRECTED VERSION *

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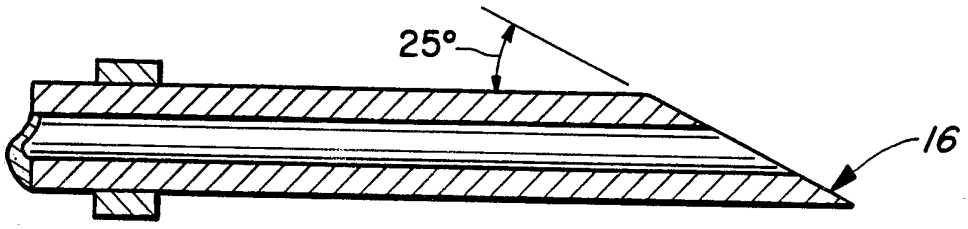
Published
With international search report.

(54) Title: CANNULA



(57) Abstract

A microcannula (12) having a tip (16) beveled at an angle of about 25° is provided with a pointed trochar (10) in the lumen of the cannula. The trochar (10) is removable but tightly held within the lumen of the cannula (12) and helps confer rigidity to the device comprised of the cannula (12) and trochar (10). The point of the trochar (10) contained within the lumen protrudes beyond the end of the cannula (12) and may be used to pierce small vessels (18) or hollow structures and guide the cannula (12) into the interior of vessel (18) or hollow structure without the need for prior incision in the vessel (18) or hollow structure.

* (Referred to in PCT Gazette No. 20/1993, Section II)

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Cannula

Field of the Invention

The present invention relates to the field of surgical devices.

Background of the Invention

Cannulas are hollow tube instruments used to deliver fluids or remove fluids from blood vessels, ducts or other hollow organs of animals. While many sizes of cannulas are available commercially, microcannulas suitable for use in surgery on small animals are of limited design and utility, The smallest available cannulas are generally flat tipped and are large enough to accommodate a 14 to 24 gauge needle in the lumen of the cannula, which needle is used as a trochar. Small cannulas are generally made of small bore polyethylene tubing and are supplied with a hypodermic needle which is used to block a cannula to prevent fluid contained in the vessel of the hollow organ from draining until the cannula is in place in a pre-made incision in the vessel or other hollow organ.

As cannulas decrease in size, they are more flexible and easily bent and therefor difficult to manipulate. The flexibility of small cannulas occurs because of the decreasing absolute wall thickness of the cannula as they get smaller in diameter, and concomitant loss of rigidity of the cannula wall.

Conventional cannulas are supplied with trochars that move freely in the lumen of the cannula since it is conventionally desirable to be able to quickly remove the trochar once a

vessel is cannulated.

Conventional small cannulas appropriate for use in cannulation of small blood vessels in microsurgery are notoriously difficult to use. The smallest cannulas available frequently require many minutes of patient and skilled manipulation to prepare a micro- incision in a blood vessel and properly place the cannula in small blood vessels.

Summary and Objects of the Invention

The present invention comprises a very small bore cannula having a beveled tip with a sharp pointed trochar tightly, but removably placed in the lumen of the cannula. This cannula or microcannula and associated trochar have sufficient rigidity to be relatively easily manipulated. Furthermore by means of using a sharp pointed trochar and bevel tipped cannula, it is possible to cannulate a small blood vessel with out the necessity of incising the blood vessel wall before inserting the cannula and trochar.

It is an object of the invention to provide in easily manipulated cannula which can be used to cannulate small hollow organs and blood vessels in a short period of time.

It is another object of the invention to provide a microcannula and trochar that function together as a unit to provide rapid cannulation with a minimum of blood loss.

I397Xisyet another object of the invention to provide a microcannula and trochar that can be used to cannulate a blood vessel without making a preparatory incision before inserting the trochar and cannula into the blood vessel.

Brief Description of the Figures

Figure 1 is a side view of the trochar according to the invention.

Figure 2 is a cross-section of the microcannula according to the invention.

Figure 3 shows the trochar and microcannula in use as a unit just prior to penetration of a blood vessel wall or other hollow tube by the point of the trochar.

Figure 4 shows the microcannula in place in a blood vessel or other hollow tube with the trochar in the process of being with- drawn.

Figure 5 shows the microcannula in place in a blood vessel or other hollow tube with the blood vessel tied off around the proximal end of the microcannula and the microcannula secured in place.

Detailed Description of the Invention

In greater detail, the microcannula according to the invention comprises a hollow tube 12 having a cross sectional size smaller that a 24 gauge needle. More precisely the outside diameter of said tube which comprises the body of the microcannula is about 0.016 inch. The outside diameter of the tubing will vary slightly but in general the outside diameter

of the tube will be between 0.018 and 0.014 inch. Usually the outside diameter of the tubing will be 0.016" +/- 0.001 inch.

The microcannula according to the invention will have a simple beveled tip. The angle of said bevel is about 25°. The angle of the bevel may vary between 23 and 27 degrees, but the best performance of the microcannula is achieved when the bevel is 25°+/- 0.5°.

The microcannula of the invention will generally be made of bio-compatible polymer tubing. It is preferred that the bio-compatible polymer be perfluorocarbon material.

The microcannula described above is highly flexible and delicate and is difficult to insert into the lumen of a blood vessel 18
or other hollow organ requiring cannulation. In order to facilitate manipulation of the microcannula, a trochar 10 is provided for use with the microcannula. The trochar fits in the lumen of the microcannula tube and may be removed therefrom. It is preferred that the trochar be of a size that fits tightly in the lumen of the microcannula tube and does not move freely in the lumen; however, the trochar must also be small enough to be removed from the lumen of the microcannula when the side of the microcannula is grasped and held and the trochar is pushed or pulled from the lumen of the tube. The preferred performance of the trochar is best obtained when the outside diameter of the trochar is slightly smaller than the inside diameter of the tube.

The trochar used with the cannula is pointed and the point forms an angle of about 8°. The angle of the point of said

trochar may vary between about 11° and 5°. An angle of 8° is preferred. The length of the point of the trochar is about six times the diameter of said trochar. Lengths substantially greater that about six times the diameter of the trochar lead to undesirable delicate points that can flex and break. Therefore, it is preferred that the length of the trochar point is about six times the diameter of the trochar or less.

The trochar may be made of any strong wire stock. It is preferred that the wire is not of a ductile metal since the trochar confers rigidity on the microcannula when it is inserted into the lumen thereof. Furthermore ductile wires cannot be easily inserted into the lumen of the microcannula with the required tight fit without bending or breaking. It is preferred that the trochar is made of stainless steel.

The microcannula of the invention further comprises a segment of the microcannula tube located distal to the tip of the microcannula that has an expanded outside diameter. The expanded outside diameter of shoulder 14 may be in the form a ring of tubing or an "O" ring adhered to the outside wall of the microcannula tube, dried plastic glue or a thickening in the wall for the microcannula itself.

When in use, the shoulder is used to secure the distal end of the microcannula using a ligature 20, one end of which is tied around the distal end of the microcannula and the other end of which is tied around the blood vessel 18 surrounding the end of the microcannula proximal to the beveled tip, as depicted in Figure 5.

The distal end of the microcannula, which is the end of the microcannula away from the beveled tip, may be secured

optionally within the lumen of a larger tube which may in turn be secured to the tip of a needle or still larger piece of tubing. The distal end of the microcannula can in this fashion be conveniently connected to conventional fittings for tubing or syringes such as luer lock fittings and the like.

Tubing of the type used to make the microcannula according to the invention can be obtained from suppliers of laboratory wares such as Cole-Parmer, Chicago, Illinois U.S.A.. Wire suitable for the fabrication into the trochar described here in can be obtained from National Standard Company, Santa Fe Springs, California, U.S.A.

The present invention further comprises that microcannula described hereinabove with the trochar described herein above placed in the lumen of the tube forming the microcannula.

When in use to cannulate a small blood vessel or hollow organ the trochar 10 and microcannula 12 are used as a unit. The trochar 10 is placed tightly fitting in the lumen of the microcannula 12 with the trochar tip 11 protruding beyond the microcannula bevel's leading edge 16. The trochar tip 11 is used to pierce the wall of the blood vessel 18. The microcannula bevel's leading edge comes into contact with the outside of the blood vessel 18 outer wall slightly displacing the wall of the blood vessel and stretching the hole punctured in the blood vessel wall. By further advancing the microcannula and trochar together, the microcannula is easily threaded through the hole into the lumen of the blood vessel.

As a result of the tight fit of the trochar and microcannula the cannulation of small blood vessels can be accomplished without the necessity of first incising a blood vessel

followed by insertion of a cannula and trochar. By using the trochar and microcannula as a unit, bleeding can be minimized and the possibility of damaging the blood vessel with an incision that is too large is eliminated.

We Claim:

1. A microcannula comprising a hollow tube haveing a cross sectional size smaller that a 24 gauge needle, said microcannula having a beveled tip wherein the angle of said bevel is about 25°.

2. The microcannula of claim 1 wherein said bevel is 25° +/- 0.5°.

3. The microcannula of claim 1 wherein the outside diameter of said tube is about 0.016 inch.

4. The microcannula of claim 1 wherein the outside diameter of said tube is about 0.016 inch +/- 0.001 inch.

5. The microcannula of claim 1 wherein the inside diameter of said tube is about 0.008 inch.

6. The microcannula of claim 1 wherein the inside diameter of said tube is about 0.008 inch +/- 0.001 inch.

7. The microcannula of claim 1 wherein the walls of said tube are a biocompatible polymer.

8. The microcannula of claim 7 wherein the walls of said tube are a biocompatible perfluorocarbon material.

9. The microcannula of claim 1 further comprising a pointed trochar that fits in the lumen of the microcannula tube.

10. The microcannula of claim 9 wherein the point of said trochar forms an angle of about 8°.

11. The microcannula of claim 9 wherein the point of said trochar forms an angle of about 8O +/- 3O.

12. The microcannula of claim 9 wherein the point of said trochar is about six times the diameter of said trochar.

13. The microcannula of claim 9 wherein the outside diameter of said trochar is slightly smaller than the inside diameter of said tube.

14. The microcannula of claim 9 wherein said trochar is removable from said microcannula but fits tightly in the lumen of said microcannula.

15. The microcannula of claim 9 wherein the trochar is made of stainless steel.

16. A device comprising the microcannula of claim 1 and a pointed trochar fitted in the lumen of the microcannula tube.

17. The microcannula of claim 1 further comprising a segment thereof distal to the tip wherein said segment has an expanded outside diameter.

18. The device of claim 16 further comprising a segment thereof distal to the tip wherein said segment has an expanded outside diameter.

19. The microcannula of claim 17 wherein the expanded outside diameter of said segment is provided by a ring around the outside of said tube.

20. The device of claim 18 wherein the expanded outside

diameter of said segment is provided by a ring around the outside of said tube.

FIG._1

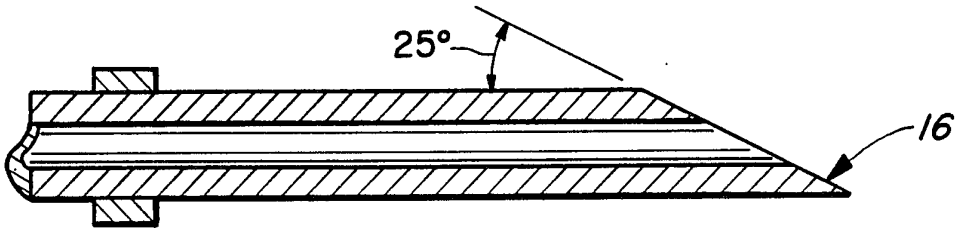

FIG._2

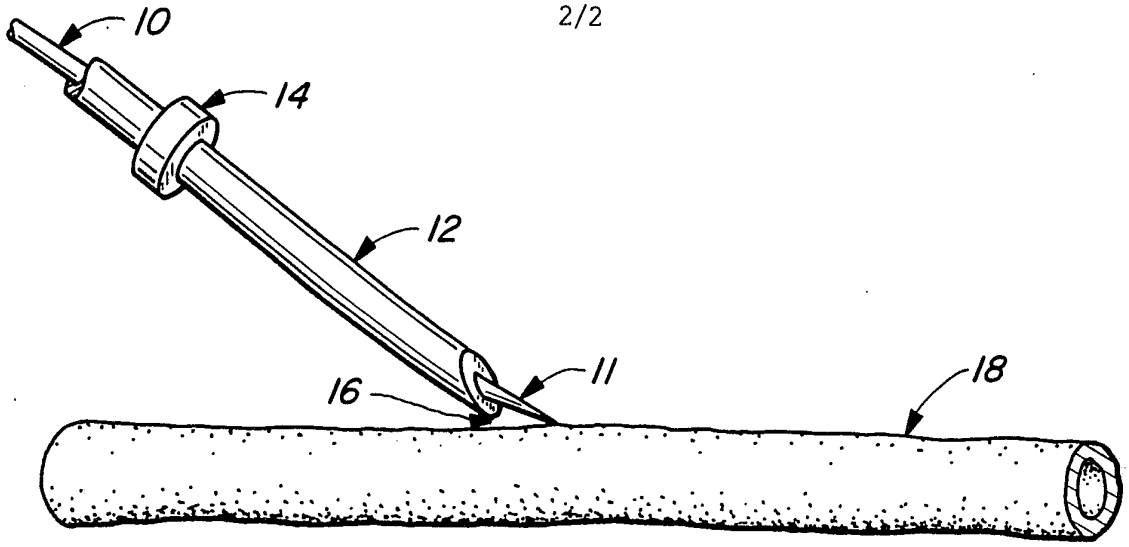

FIG._3

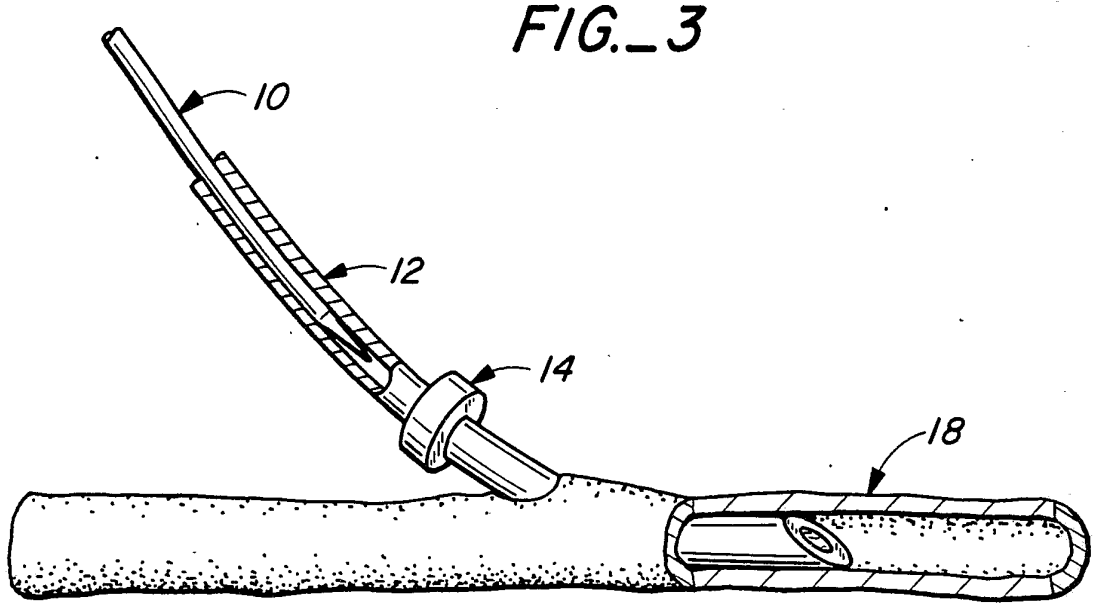

FIG._4

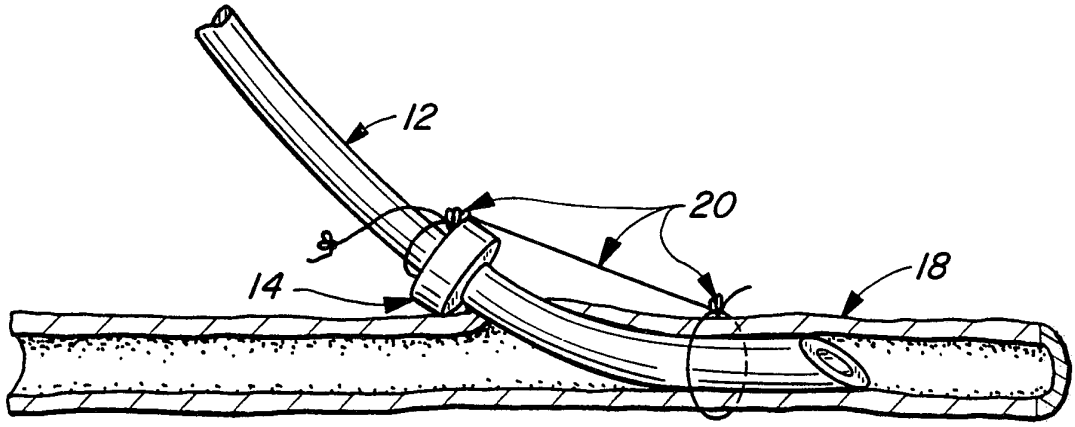

FIG._5

INTERNATIONAL SEARCH REPORT

International Application No. PCT/US92/03239

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all)[3]

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC (5): A61M 5/00
US CL : 604/272

II. FIELDS SEARCHED

Minimum Documentation Searched[4]	
Classification System	Classification Symbols
U.S.	604/164-169, 264, 272-274, 280 128/656-658, 772

Documentation Searched other than Minimum Documentation to the extent that such Documents are included in the Fields Searched[6]

III. DOCUMENTS CONSIDERED TO BE RELEVANT[14]

Category*	Citation of Document,[16] with indication, where appropriate, of the relevant passages[17]	Relevant to Claim No.[18]
Y	US, A 4,917,670 (HURLEY) 17 April 1990, Teaches a microcannula assembly for spinal anesthesia; a microcatheter of biocompatible polymeric material such as a fluoropolymer (3:21-23) having an external diameter of less than 0.0130" and an internal diameter of greater than 0.0065" (3:34-49); a reinforcing steel stylet having an outer diameter small enough to fit snugly in said microcatheter (3:56-66).	1-8,16-20
Y	US, A 3,788,119 (ARRIGO) 29 January 1974, Teaches a spinal catheter (14) having a bevelled tip between 20-23 degrees providing smoother entrance, preventing spinal trauma.	1-8,16-20
Y	US, A 4,808,170 (THORTON, ET AL) 28 February 1989, Teaches a bevelled cannula for use in ophthalmic surgery, said cannula (22) having a low profile with a bevelled slope of 20 degrees; allows easy penetration (see abstract).	1-8,16-20
Y	US, A 4,411,657 (GALINDO) 25 October 1983, Teaches a cone shaped pointed portion of a spinal needle (14:9-12); said needle having a distal point six times the diameter of the needle (see figure 2); (see abstract).	9-15

* Special categories of cited documents:[15]

"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
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"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step
"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

IV. CERTIFICATION

Date of the Actual Completion of the International Search[2]	Date of Mailing of this International Search Report[2]
19 JUNE 1992	3 JUL 1992
International Searching Authority[1]	Signature of Authorized Officer[20]
ISA/US	CHALIN SMITH

FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

A	US, A 4,413,993 (GUTTMAN) 08 November 1983, See entire document.	1-20
A	US, A 4,994,036 (BISCOANG ET AL.) 19 February 1991, Spinal catheter having bevelled, angled distal tip; see figurs 1a-1d).	1-20
A	US, A 4,588,398 (DAUGHERTY) 13 May 1986, See entire document.	1-20
A	US, A 4,808,156 (DEAN) 28 February 1989, Catheter having bevelled, angled distal top; see abstract.	1-20

V. ☐ **OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE**[1]

1. ☐ Claim numbers , because they relate to subject matter (1) not required to be searched by this Authority, namely:

2. ☐ Claim numbers _, 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 (1), specifically:

3. ☐ Claim numbers _, because they are dependent claims not drafted in accordance with the second and third sentences of PCT Rule 6.4(a).

VI. ☐ **OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING**[2]

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 of the international application.

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

3. ☐ 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 claim numbers:

4. ☐ As all searchable claims could be searched without effort justifying an additional fee, the International Search Authority did not invite payment of any additional fee.

Remark on protest

☐ The additional search fees were accompanied by applicant's protest.

☐ No protest accompanied the payment of additional search fees.

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)

Category*	Citation of Document,[16] with indication, where appropriate, of the relevant passages [17]	Relevant to Claim No.[18]
A	US, A 4,565,545 (SUZUKI) 21 January 1986, See entire document.	1-20