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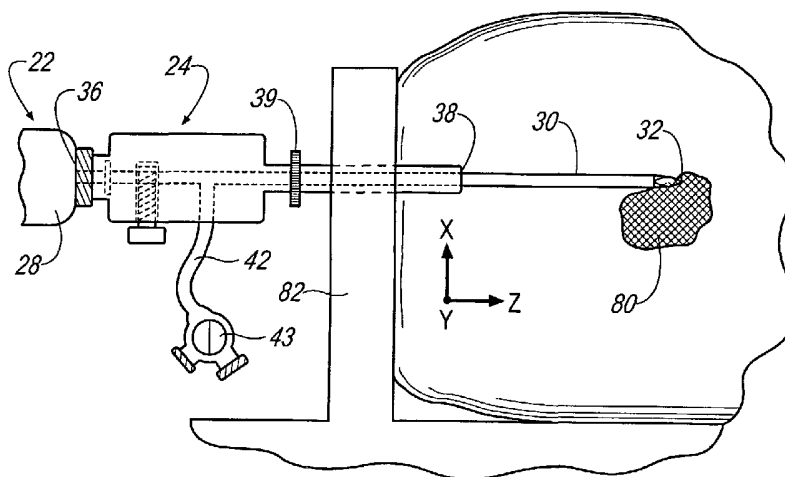
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- (74) Agents: **DIEDRICH, Bradley, J.** et al.; Rader, fishman & Grauer PLLC, Suite 140, 39533 Woodward Avenue, Bloomfield Hills, MI 48304 (US).
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- (71) Applicant (*for all designated States except US*): **SUROS SURGICAL SYSTEMS, INC.** [US/US]; Suite 3, 9502 Angola Court, Indianapolis, IN 46268 (US).
- (72) Inventors; and
- (75) Inventors/Applicants (*for US only*): **MARK, Joseph, L.** [US/US]; 5154 N. Capitol Avenue, Indianapolis, IN 46208 (US). **MILLER, Michael, E.** [US/US]; 4560 West Woodpecker, Trafalgar, IN 46181 (US). **GOEDDE, Timothy, A.** [US/US]; 8180 Clearvista Parkway #100, Indianapolis, IN 46236 (US).
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(54) Title: INTRODUCTION SYSTEM FOR MINIMALLY INVASIVE SURGICAL INSTRUMENTS



(57) Abstract: A medical system (20) is disclosed that includes a cannula (24), an introducer stylet (22) removably disposed within the cannula (24) and a target confirmation device (26) selectively insertable within the cannula (24). In an embodiment of the invention, the introducer stylet (22) is configured for insertion into a patient's body. The outer cannula (24) is sized to fit over the introducer stylet (22) and is positionable at least partially within the patient's body after insertion and removal of the introducer stylet (22). The target confirmation device (26) is insertable into the outer cannula (24) after removal of the introducer stylet (22) and is configured to confirm the position of the outer cannula (24) relative to the target site. A medical procedure using the medical system of the present invention is also disclosed.

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INTRODUCTION SYSTEM FOR MINIMALLY INVASIVE SURGICAL INSTRUMENTS

BACKGROUND OF THE INVENTION

Field of the Invention

[0001] The present invention relates to the field of medical devices and more particularly to a medical system for introducing, among other things, minimally invasive surgical instruments and other medical treatments into a patient's body.

Description of the Related Art

[0002] Medical procedures have advanced to stages where less invasive or minimally invasive surgeries, diagnostic procedures and exploratory procedures have become desired and demanded by patients, physicians, and various medical industry administrators. To meet these demands, improved medical devices and instrumentation have been developed, such as cannulas or micro-cannulas, medical introducers, vacuum assisted biopsy apparatus, and other endoscopic related devices.

[0003] In the field of tissue biopsy, minimally invasive biopsy devices have been developed that require only a single insertion point into a patient's body to remove one or more tissue samples. One such biopsy device incorporates a "tube-within-a-tube" design that includes an outer piercing needle having a sharpened distal end and a lateral opening that defines a tissue receiving port. An inner cutting member is slidably received within the outer piercing needle, which serves to excise tissue that has prolapsed into the tissue receiving port. A vacuum is used to draw the excised tissue into the tissue receiving port and aspirates the excised tissue from the biopsy site once severed.

[0004] Exemplary "tube-within-a-tube" biopsy devices are disclosed in pending U.S. Patent Applications, Serial Nos. 09/707,022 and 09/864,031, which are owned by the assignee of the present invention. Among other features, the exemplary biopsy devices can be used in conjunction with Magnetic Resonance Imaging (MRI). This compatibility is due to the fact that many of the components of the biopsy devices are made of materials that do not interfere with operation of MRI apparatus or are otherwise compatible therewith. It is desirable to perform biopsies in conjunction with MRI because it is currently the only non-invasive visualization modality capable of defining the margins of a tumor.

[0005] While the exemplary MRI compatible biopsy devices have proven effective in operation, in some procedures it is desirable to create a pathway to the biopsy site for precise introduction of the biopsy device and other medical treatments into the patient. For these and other reasons, an MRI compatible medical introduction system is desirable for use with minimally invasive biopsy devices, such as those employing a “tube-within-a-tube” design.

SUMMARY OF THE INVENTION

[0006] A medical system is disclosed that includes a cannula, an introducer stylet removably disposed within the cannula and a target confirmation device selectively insertable within the cannula. In an embodiment, the introducer stylet is configured for insertion into a patient’s body. The outer cannula is sized to fit over the introducer stylet and is positionable at least partially within the patient’s body after insertion and removal of the introducer stylet. A target confirmation device is insertable into the outer cannula after removal of the introducer stylet and is configured to confirm the position of the outer cannula relative to the target site. A medical procedure using the medical system of the present invention is also disclosed.

BRIEF DESCRIPTION OF THE DRAWINGS

[0007] Embodiments of the invention will now be described, by way of example, with reference to the accompanying drawings, wherein:

[0008] FIG. 1 is a side view of an introducer stylet according to an embodiment of the present invention;

[0009] FIG. 2 is side view of an outer cannula and fluid conduit according to an embodiment of the present invention;

[0010] FIG. 3 is a side view of a target confirmation device according to an embodiment of the present invention;

[0011] FIGS. 3A and 3B are side views of a target confirmation device according to alternate embodiments of the present invention;

[0012] FIG. 4 is a side view of an exemplary biopsy device for use with the introduction system of the present invention;

[0013] FIG. 5 is a detailed cross-sectional view of a cutting element of the biopsy device of FIG. 4;

[0014] FIG. 6 is a side view of an aspiration wand suitable for insertion into the outer cannula; and

[0015] FIGS. 7-11 are elevational views illustrating a medical procedure using the medical system of the present invention.

DETAILED DESCRIPTION

[0016] Referring now to the drawings, the preferred illustrative embodiments of the present invention are shown in detail. Although the drawings represent some preferred embodiments of the present invention, the drawings are not necessarily to scale and certain features may be exaggerated to better illustrate and explain the present invention. Further, the embodiments set forth herein are not intended to be exhaustive or otherwise limit or restrict the invention to the precise forms and configurations shown in the drawings and disclosed in the following detailed description.

[0017] Referring to FIGS. 1-3, a medical system 20 is shown that includes an introducer stylet 22, an outer cannula 24 and a target confirmation device 26. As will be described in detail, system 20 is particularly, but not necessarily, suited for use in biopsy procedures that identify the target biopsy site using Magnetic Resonance Imaging (MRI) or comparable medical imaging modality.

[0018] In an embodiment, introducer stylet 22 includes a handle 28 and a stylet 30 having a distal end 32 and a proximal end 34 connected to handle 28. Handle 28 may be made of a medical grade resin or other MRI compatible material. Stylet 30 may also be made of an MRI compatible, medical grade material, such as 316 stainless steel or inconel 625.

[0019] In a particular configuration, a distal end 32 of stylet 30 includes a tissue piercing tip, such as a trocar tip, to facilitate penetration of stylet 30 into a patient's tissue. In addition to a trocar tip, it will be appreciated that stylet 30 may include other devices for piercing the patient's tissue, including without limitation, devices that use a laser or radio frequencies (RF) to pierce the tissue. The length of stylet 30 is generally denoted by the reference character "A" in FIG. 1.

[0020] Referring to the embodiment shown in FIG. 2, outer cannula 24 extends from an open proximal end 36 to an open distal end 38, which is separated from proximal end 36 by a distance "B." Like introducer stylet 30, outer cannula 24 may be made from a medical grade resin or other MRI compatible material. In some configurations, proximal end 36 may include a luer-style fitting or other suitable configuration for interfacing, but not necessarily connecting, outer cannula 24 with target confirmation device 26. A depth limiting member 39, such as a rubber o-ring, may be moveably disposed on outer cannula 24 to limit the insertion depth of outer cannula 24 into the patient's body.

[0021] In an embodiment, outer cannula 24 also includes an inner lumen 40 therethrough, which is open to communication with a fluid conduit 42 for supplying fluids, such as saline and anesthetics, or removing fluids, such as blood, from the patient's body. Fluid conduit 42 communicates with inner lumen 40 via a port in outer cannula 24. In some configurations, outer cannula 24 may include a haemostatic valve, depicted generally as element 41, or a manually operable valve 41' that can be selectively closed to prevent the escape of fluid from proximal end 36. Fluid conduit 42 may also include a directional valve 43 to selectively control the supply and removal of fluid to and from inner lumen 40, respectively.

[0022] In the embodiment shown in FIG. 3, target confirmation device 26 is an elongated member that is sized to fit within inner lumen 40 of outer cannula 24. Target confirmation device 26, which may be made of a medical grade resin or other MRI compatible material, extends from a connecting end 44 to a distal end 46. Connecting end 44 may be configured with a cap 47 that abuts outer cannula 24. In some configurations, cap 47 may include a luer-style fitting or other suitable feature for interfacing, but not necessarily connecting, target confirmation device 26 with outer cannula 24.

[0023] Distal end 46 of target confirmation device 26 is generally rounded to facilitate entry into the patient's body. In an embodiment, a portion of target confirmation device 26 is configured with a magnetic resonance imaging (MRI) identifiable material, such as inconel 625, titanium or other material with similar magnetic characteristics. In one particular configuration, a targeting band 48 is provided a distance "C" from connecting end 44, as shown in FIG. 3; the distance C being measured from the approximate center of targeting band 48 to connecting end 44 (or the inside of cap 47), for example. Targeting band 48 provides a reference point in an MR image relative to the target biopsy tissue.

[0024] In another embodiment of the present invention, the tip of target confirmation device itself may be used to provide the reference point in the MR image, provided the target confirmation device material exhibits a relatively low artifact during MR imaging. As used herein, the term “artifact” describes a material’s tendency to distort an MR image. A material exhibiting a relatively high artifact will render the body tissue surrounding the material unreadable in an MR image. Conversely, a material with a relatively low artifact will allow the material to be readily identified in the MR image and will not significantly distort the MR image of the surrounding tissue.

[0025] As shown in the embodiments of FIGS. 3A and 3B, the distal end 46 of target confirmation device 26 may include a particular shape to help identify the location of target confirmation device 26 relative to the surrounding tissue. In the embodiment of FIG. 3A, a portion of target confirmation device 26 adjacent the distal end 46 has a smaller diameter relative to the remaining length. In the embodiment of FIG. 3B, a portion of target confirmation device 26 is tapered to provide an hour glass like image when viewed under MR. It will be appreciated that the embodiments represented in FIGS. 3A and 3B are not limited to the configurations shown, and that other configurations are within the scope of the present invention.

[0026] In still another embodiment, introducer stylet 30 may function as a target confirmation device. In this embodiment, introducer stylet 30, and more particularly stylet 30, may be made of an MRI compatible material that preferably, but not necessarily, exhibits a relatively low artifact.

[0027] An exemplary biopsy apparatus 50, which is suitable for use with medical system 20 of the present invention, is generally shown in FIG. 4 and in more detail in FIG. 5. Apparatus 50 includes a cutting element 52 sized for introduction into the patient’s body and a hand piece 54. The exemplary biopsy apparatus 50 is configured as a “tube-within-a-tube” cutting device. More particularly, cutting element 52 includes an outer cannula 56 having an outer lumen 57 and an inner cannula 58 sized to fit concentrically within the outer lumen. A motor or other motion generating device is provided within hand piece 54 to rotate and/or translate inner cannula 58 within outer cannula 56. Biopsy apparatus similar to apparatus 50 can be seen by way of example in pending U.S. Patent Applications, Serial Nos. 09/707,022 and 09/864,03, which are owned by the assignee of the present invention and are incorporated herein by reference in their entirety.

[0028] A particular embodiment of the working end of cutting element 52 is depicted in FIG. 5. In the illustrated embodiment, outer cannula 56 defines a tissue-receiving opening 60, which communicates with outer lumen 57. The working end of cutting element 52 further includes a cutting board 64 that is disposed within outer lumen 57 at the distal end of outer cannula 56. Inner cannula 58 defines an inner lumen 65 that is hollow along its entire length to provide for aspiration of the biopsy sample (tissue). Inner cannula 58 terminates in a cutting edge 66 that may be formed by an inwardly beveled surface having a razor-sharp edge.

[0029] Referring to FIG. 6, an aspirating wand 68 is shown that can be inserted into outer cannula 24. In an embodiment, aspirating wand 68 extends from a connecting end 70 to an insertion end 72 and includes an inner lumen 74 that extends from connecting end 70 to insertion end 72. Connecting end 70 may include a luer interface or other suitable fitting for connecting aspirating wand 68 to a vacuum source (not shown). Aspirating wand 68 may also include a cap 76 that can be placed onto connecting end 70 to inhibit fluid leakage when aspirating wand 68 is inserted into the patient. The haemostatic valve 41 in outer cannula 24 seals against aspirating wand 68, as it does against target confirmation device 26 and biopsy device 50, when inserted into outer cannula 24. Additionally, the outside diameter of aspirating wand 68 is less than the inside diameter of inner lumen 40 to allow saline or other fluids introduced through fluid conduit 40 to pass into the patient's body. When cap 76 is removed and aspirating wand 68 is connected to a vacuum source, fluids, such as blood and saline, can be aspirated from the biopsy site.

[0030] Referring to FIGS. 7-11, a medical procedure using system 20 of the present invention will be described. In an embodiment, system 20 is employed to conduct a biopsy of a lesion within a patient's body. The target tissue or lesion to be biopsied and/or removed from the patient's body (denoted generally by mass 80 in FIG. 7) is located using a medical imaging system, such as MRI or other suitable imaging modality. A reference structure 82 may be positioned adjacent the patient to assist in locating the target tissue. The location of the target tissue 80 relative to reference structure 82 may be determined along one or more axis. In the illustrated embodiment, the target tissue location relative to reference structure 82 is determined along the X and Y axes; however, the target tissue location may also be determined along all three of the X, Y and Z axes. While the

described method employs a reference structure 82 to locate the target tissue, the reference structure is not necessarily required and a more “free-hand” approach may be utilized.

[0031] In an embodiment, reference structure 82 includes a support grid having a number of holes therethrough. Each hole is sized to allow passage of outer cannula 24. The hole through which outer cannula 24 is ultimately inserted is determined by the location of target tissue 80 relative to reference structure 82 along the X and Y axes. The patient and reference structure 82 are viewed using a medical imaging system, such as MRI, to determine the location of the target tissue relative to reference structure 82.

[0032] After application of anesthesia, the stylet portion of introducer stylet 22 and a portion of outer cannula 24 are inserted through the support grid and into the patient's body, creating a pathway 84 to the target tissue 80 (see, e.g., FIG. 7). Introducer stylet 22 is then removed from the patient's body leaving behind outer cannula 24 (see, e.g., FIG. 8).

[0033] Fluids may be inserted into or removed from the patient's body through inner lumen 40 via fluid conduit 42. These fluids may include, for example, additional anesthetics and/or saline solution to cleanse pathway 84 and remove blood. Accumulated blood and other fluids within pathway 84 may be aspirated through fluid conduit 42 or by inserting aspirating wand 68 prior to insertion of target confirmation device 26.

[0034] Once introducer stylet 22 is removed from outer cannula 24, target confirmation device 26 may be inserted into the patient's body through the port created by outer cannula 24 (see, e.g., FIGS. 8 and 9). With target confirmation device 26 properly inserted into outer cannula 24, an image of the target site is again taken to determine the location of targeting band 48 in relation to the target tissue and reference structure 82. If targeting band 48 is in the desired position adjacent target tissue 80 along the Z-axis, targeting device 26 is removed from outer cannula 24. However, if targeting band 48 is not in the desired position, then the position of target confirmation device 26 and outer cannula 24 is modified along the Z-axis until the desired position is achieved.

[0035] Once the desired position is achieved, depth limiting member 39 is moved against reference structure 82 to inhibit movement of outer cannula 24 further into the patient. When no reference structure 82 is used, depth limiting member may be moved directly against the patient's skin. Target confirmation device 26 is then removed from outer cannula 24 and biopsy device 50 is inserted into outer cannula 24 until handpiece 54 abuts proximal end 36 of outer cannula 24. In the embodiment illustrated in FIG. 10, one

or more samples of target tissue 80 are removed from the patient through tissue-receiving opening 60. The correct position of tissue-receiving opening 60 is ensured because the distance "C" between proximal end 44 of target confirmation device 26 and targeting band 48 (see, e.g., FIGS. 3 and 9), or the distance between proximal end 44 and the predetermined location on target confirmation device 26 (FIGS. 3A and 3B), is approximately equal to the distance between the center of tissue receiving opening 60 and handpiece 54 of biopsy device 50.

[0036] After completion of the biopsy, the biopsy site can be aspirated using aspirating wand 68 (see, e.g., FIG. 11). During or after aspiration, a final image of the biopsy site can be taken to confirm removal of the target tissue. Finally, an MRI identifiable marker, such as a collagen plug, or other medical treatment can be inserted into the biopsy site through outer cannula 24.

[0037] Among other features, the medical system of the present invention localizes the target biopsy site in a manner that allows confirmation of the target biopsy site under MRI or other visualization modality, and allows positioning of a biopsy device to ensure the cutting element of the biopsy device can be accurately placed at the target biopsy site. The medical system of the present invention also facilitates the introduction and removal of fluids from the target site, including without limitation, anesthesia and blood, but minimizes the exposure of the fluids to the adjacent equipment and medical staff. In addition to allowing the medical staff to identify the presence of significant bleeding and to introduce a biopsy device into the patient, the medical system provides access to the target site to introduce a medical treatment, such as a site marker, tamponade or other haemostatic agent, after removal of the tissue.

[0038] The present invention has been particularly shown and described with reference to the foregoing embodiments, which are merely illustrative of the best modes for carrying out the invention. It should be understood by those skilled in the art that various alternatives to the embodiments of the invention described herein may be employed in practicing the invention without departing from the spirit and scope of the invention as defined in the following claims. It is intended that the following claims define the scope of the invention and that the method and apparatus within the scope of these claims and their equivalents be covered thereby. This description of the invention should be understood to include all novel and non-obvious combinations of elements described herein, and claims

may be presented in this or a later application to any novel and non-obvious combination of these elements. Moreover, the foregoing embodiments are illustrative, and no single feature or element is essential to all possible combinations that may be claimed in this or a later application.

CLAIMS

What is claimed is:

1. A medical targeting and device introduction system, comprising:
a cannula;
an introducer stylet removably disposed within the cannula; and
a target confirmation device selectively insertable within the cannula.
2. The system of claim 1, wherein the cannula is configured to introduce at least one of a biopsy device, a site marker, an anesthesia, a fluid, a tamponade, and a hemostatic agent.
3. The system of claim 1, wherein the introducer stylet is the target confirmation device.
4. The system of claim 1, wherein the target confirmation device includes a magnetic resonance imaging (MRI) identifiable material.
5. The system of claim 4, wherein the magnetic resonance imaging (MRI) identifiable material is a band disposed proximate a distal end of the target confirmation device.
6. The system of claim 1, wherein the system is magnetic resonance imaging (MRI) compatible.
7. A biopsy system suitable for use with a magnetic resonance imaging (MRI) device, comprising:
a cannula insertable into a patient's tissue;
an introducer stylet removably disposed within the cannula and configured for tissue penetration;
a target confirmation device selectively insertable within the cannula, the target confirmation device including a magnetic resonance imaging (MRI) identifiable material;
and

a biopsy device selectively insertable within the cannula.

8. The system of claim 7, wherein the cannula is configured to introduce at least one of a site marker, an anesthesia, a fluid, a tamponade and a hemostatic agent into the patient.

9. The system of claim 7, wherein the magnetic resonance imaging (MRI) identifiable material is shaped to distinguish the target confirmation device from the patient's tissue.

10. The system of claim 7, wherein the magnetic resonance imaging (MRI) identifiable material is a band disposed proximate a distal end of the target confirmation device.

11. The system of claim 7, wherein the biopsy system is magnetic resonance imaging (MRI) compatible.

12. A medical system, comprising:
an introducer stylet configured for insertion into a patient's body proximate a target site;
an outer cannula sized to fit over the introducer stylet and positionable at least partially within the patient's body after insertion and removal of the introducer stylet; and
a target confirmation device insertable into the outer cannula after removal of the introducer stylet, the target confirmation device configured to confirm the position of the outer cannula relative to the target site.

13. The system of claim 12, wherein a distal end of the introducer stylet includes a tissue piercing member.

14. The system of claim 12, wherein the outer cannula includes an inner lumen and a fluid conduit provided in communication with the inner lumen.

15. The system of claim 14, wherein the fluid conduit includes a directional valve.

16. The system of claim 12, wherein the target confirmation device includes a proximal end having a first fitting interface that engages a second fitting interface on the outer cannula upon insertion of the target confirmation device into the outer cannula.

17. The system of claim 12, wherein the outer cannula includes a haemostatic valve.

18. The system of claim 12, wherein the target confirmation device includes a magnetic resonance imaging (MRI) identifiable material.

19. The system of claim 12, wherein the target confirmation device includes a relatively low artifact generating material.

20. The system of claim 12, further including a biopsy device that includes a handpiece and a cutting element, the cutting element defining a tissue-receiving opening for removing tissue from the target site.

21. The system of claim 20, wherein the distance between a proximal end and a distal end of the target confirmation device is approximately equal to the distance between the center of the tissue receiving opening and the handpiece of the biopsy device.

22. The system of claim 20, wherein the target confirmation device includes a targeting band.

23. The system of claim 22, wherein the distance between a proximal end of the target confirmation device and the targeting band is approximately equal to the distance between the center of the tissue receiving opening and the handpiece of the biopsy device.

24. The system of claim 20, wherein the length of the cutting element is approximately equal to the length of the introducer stylet.

25. The system of claim 20, wherein the length of the target confirmation device is approximately equal to the length of the introducer stylet.

26. A medical procedure, comprising:
inserting an introducer stylet having an outer cannula disposed thereon into a patient's body creating a pathway to a target tissue;
removing the introducer stylet from the patient's body leaving behind the outer cannula; and

inserting a target confirmation device into the patient's body through the outer cannula and confirming the location of the target tissue relative to the outer cannula.

27. The method of claim 26, further including the step of providing an image of the target tissue prior to or contemporaneous with inserting the introducer stylet into the patient's body.

28. The method of claim 26, further including the step of providing an image of the target confirmation device within the patient's body.

29. The method of claim 26, further including the step of removing the target confirmation device and inserting a biopsy device through the outer cannula to a position adjacent the target tissue.

30. The method of claim 29, further including the step of performing a biopsy of the target tissue.

31. The method of claim 30, further including the step of aspirating a biopsy site formed after removing the target tissue.

32. The method of claim 31, further including the step of inserting a medical treatment into the biopsy site through the outer cannula.

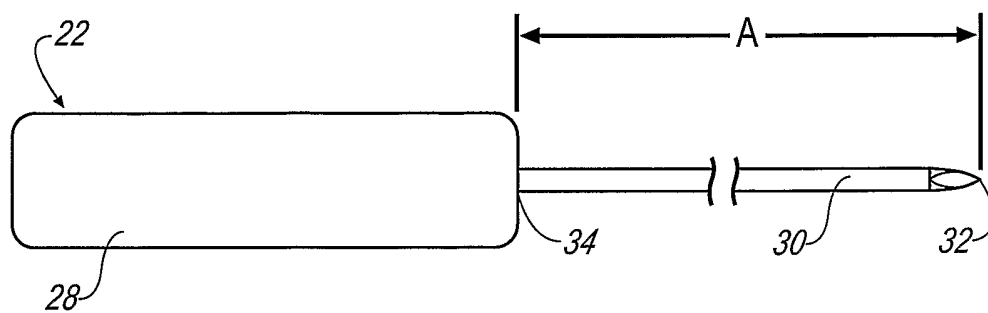


FIG. 1

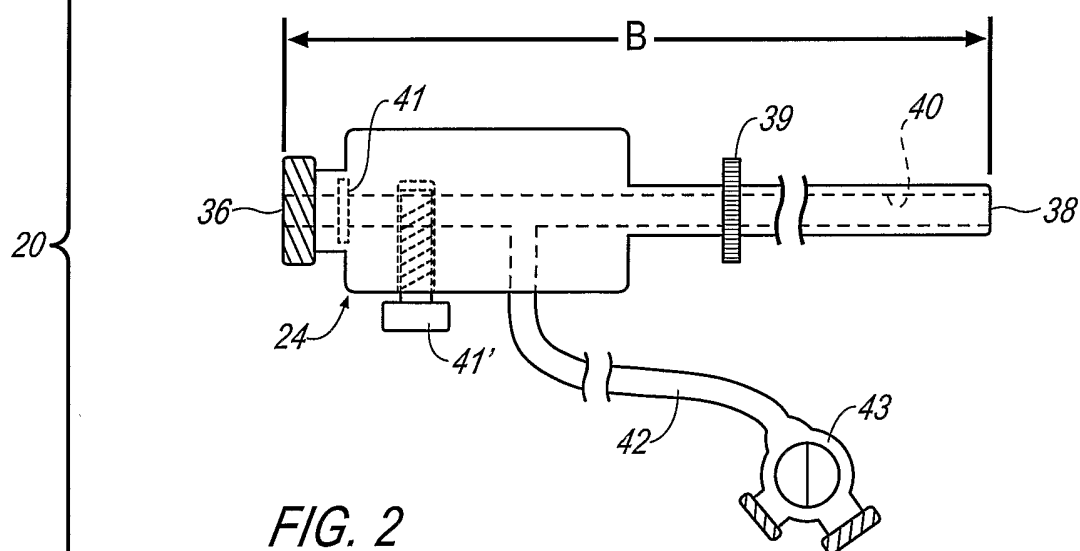


FIG. 2

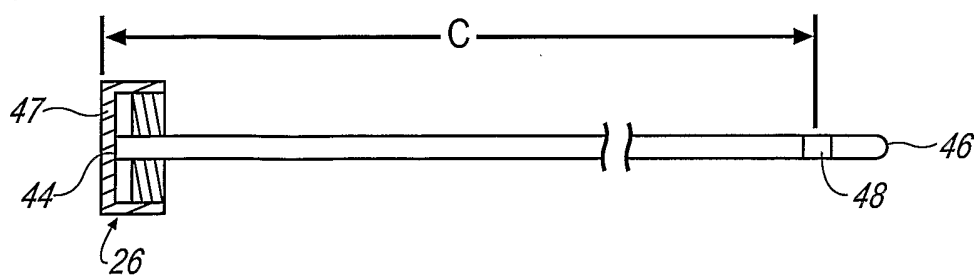


FIG. 3

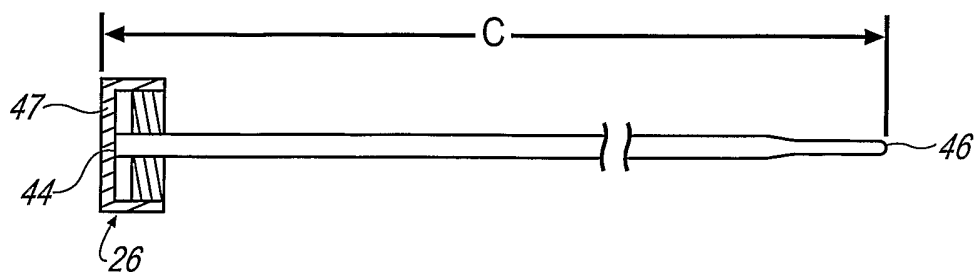


FIG. 3A

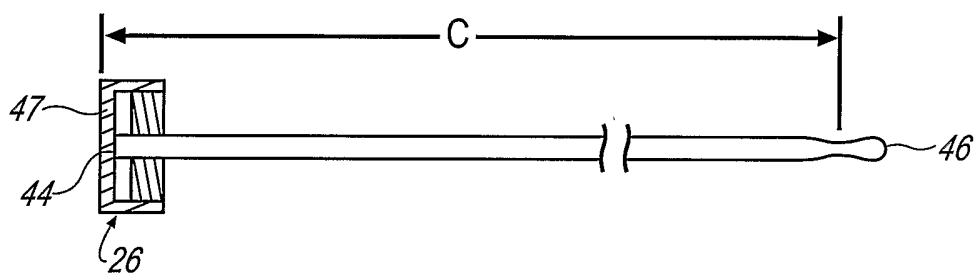


FIG. 3B

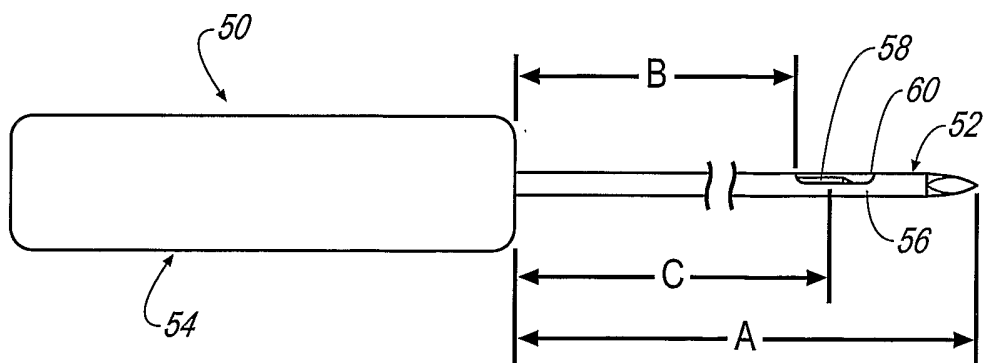


FIG. 4

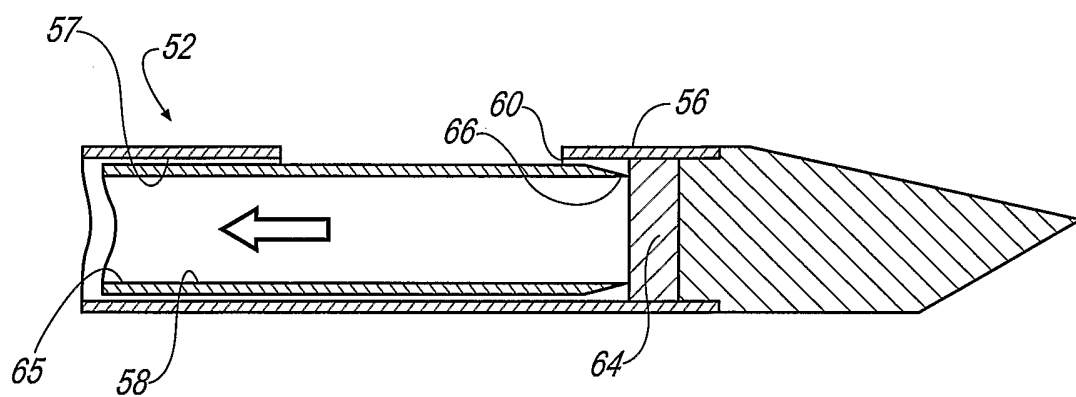


FIG. 5

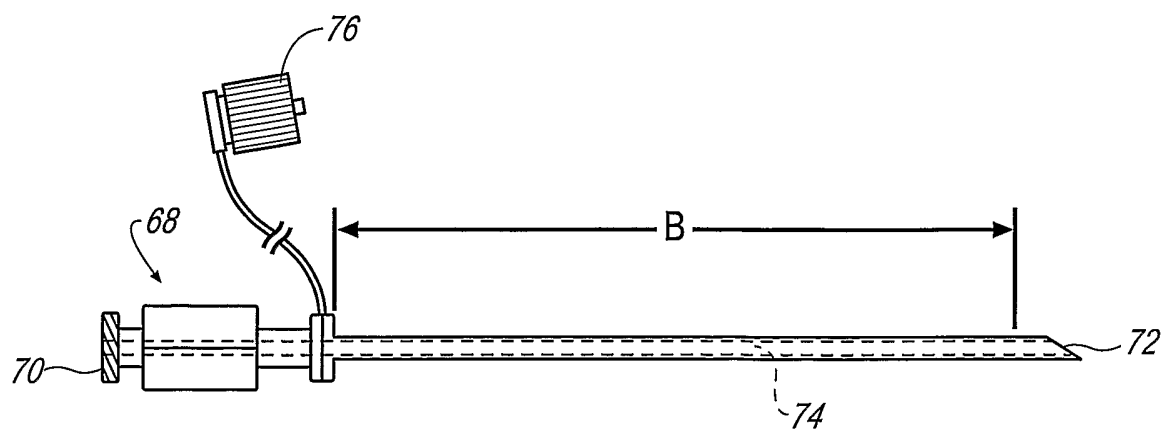


FIG. 6

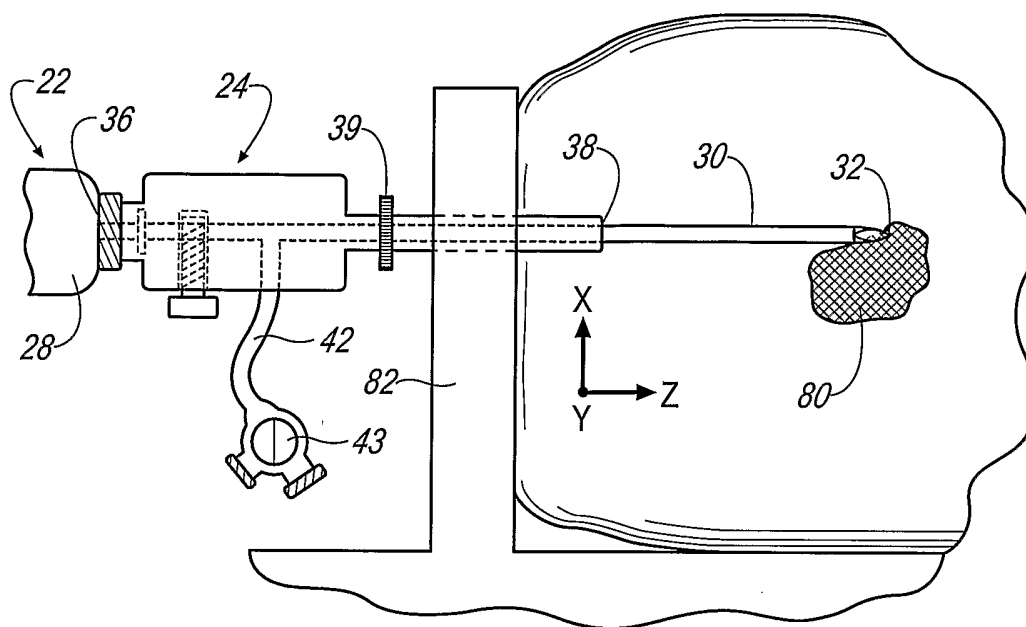


FIG. 7

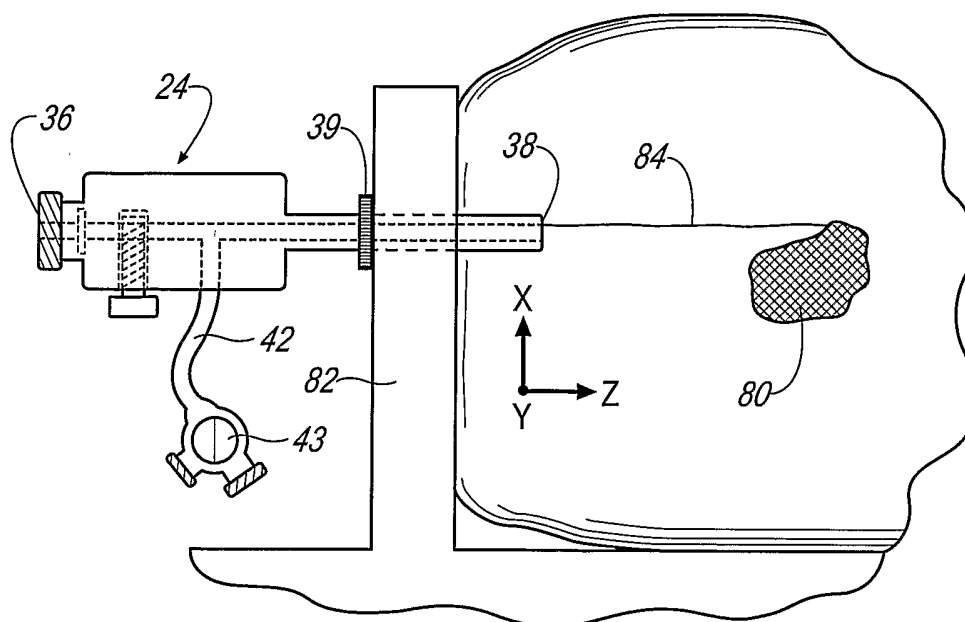


FIG. 8

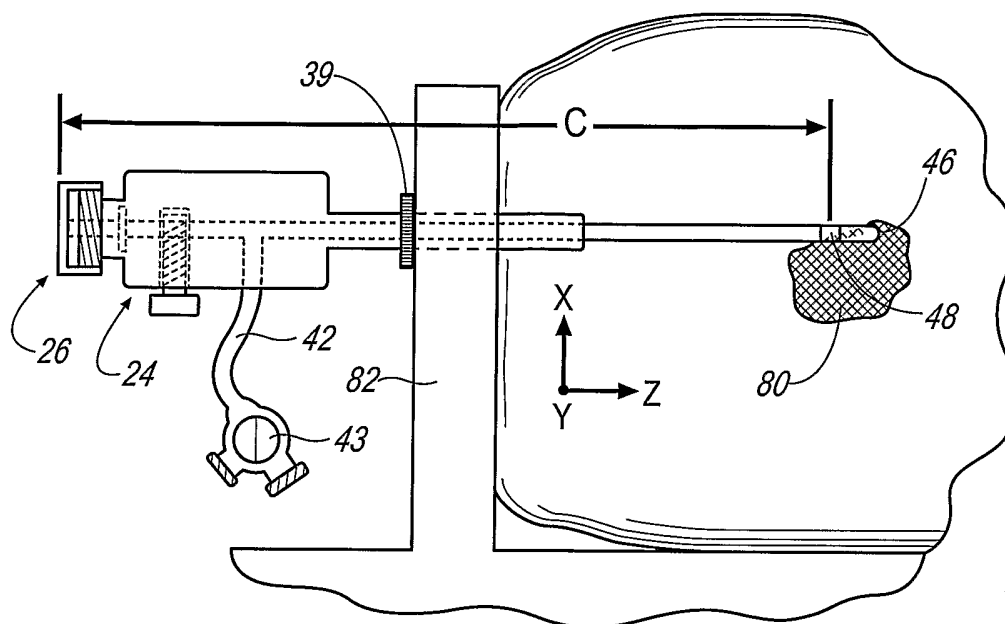


FIG. 9

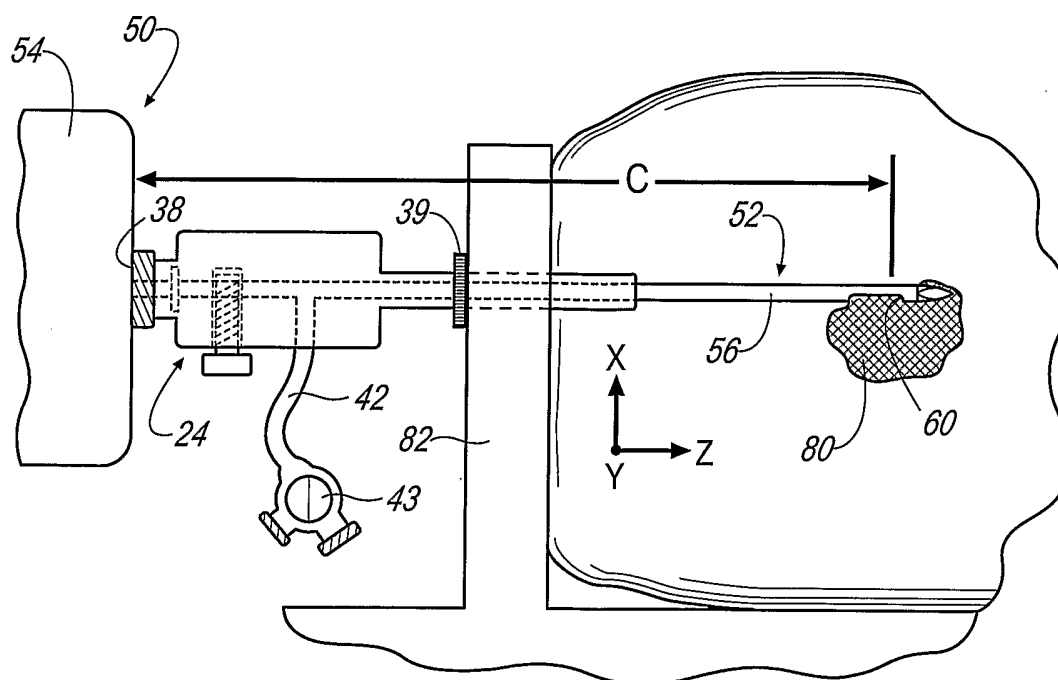


FIG. 10

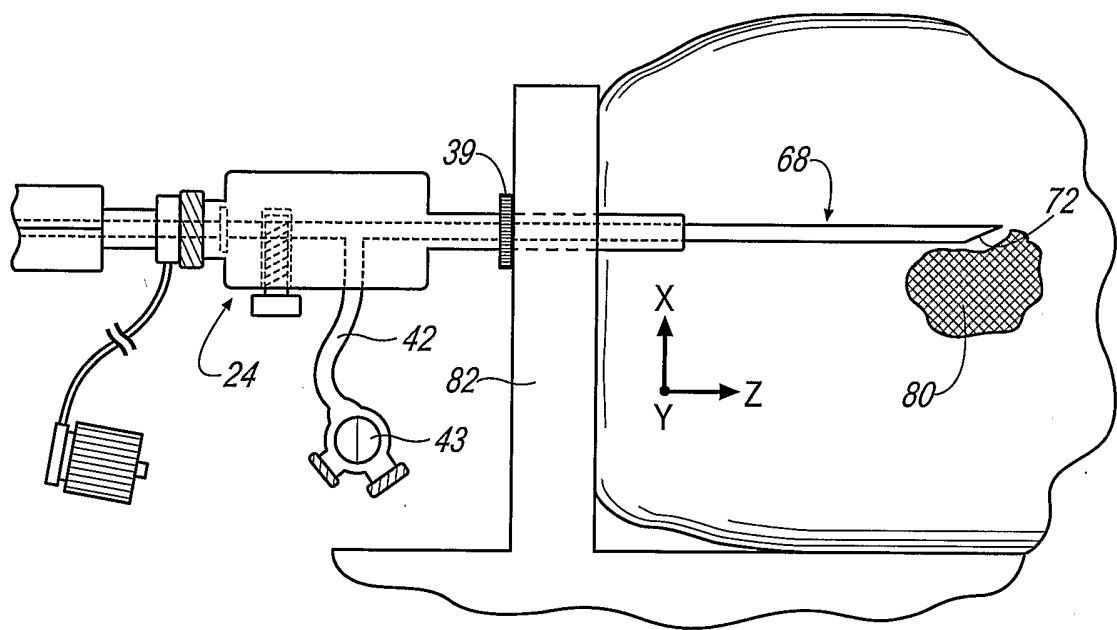


FIG. 11

INTERNATIONAL SEARCH REPORT

Int'l Application No
PCT/US 03/26958

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B10/00 A61B17/34

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B A61M

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)

EP0-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 98 22022 A (ITI MEDICAL TECHNOLOGIES INC) 28 May 1998 (1998-05-28)	1-13, 16-25
Y	page 13 -page 24-25; figures 4D,8,9	14,15
Y	US 2002/120212 A1 (BURBANK FRED H ET AL) 29 August 2002 (2002-08-29)	14,15
	paragraph '0052!; figures 6,7	
A	US 2002/082519 A1 (MARK JOSEPH L ET AL) 27 June 2002 (2002-06-27)	1,2,7, 12,16
	paragraphs '0062!, '0069!, '0074!; figures 1,5	
A	US 2001/032649 A1 (NAGANO SHIGEO) 25 October 2001 (2001-10-25)	5,6,9, 10,19
	paragraphs '0003!, '0093!, '0094!; figure 5	
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☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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Date of the actual completion of the international search

19 January 2004

Date of mailing of the international search report

04/02/2004

Name and mailing address of the ISA

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

Authorized officer

Assion, J-C

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 03/26958

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 2002/016544 A1 (HAREYAMA NORIHIKO ET AL) 7 February 2002 (2002-02-07) paragraph '0135!; figures 6,7,10,13 -----	5,6,9, 10,19
A	WO 01 54763 A (DAIG CORP) 2 August 2001 (2001-08-02) abstract figure 1 -----	17

INTERNATIONAL SEARCH REPORT

national application No.
PCT/US 03/26958

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 26-32
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 II Observations where unity of invention is lacking (Continuation of item 2 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/US 03/26958

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