

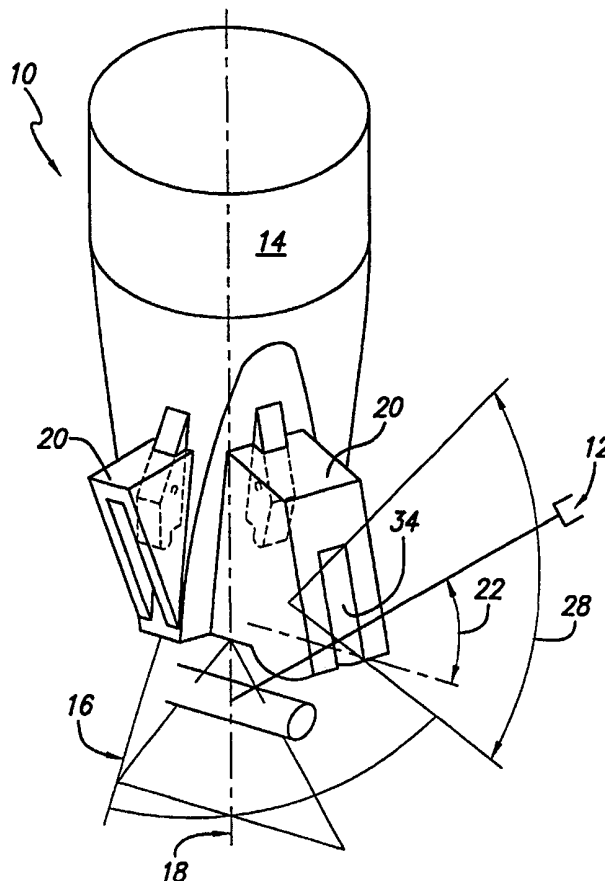


## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<b>(51) International Patent Classification <sup>7</sup> :</b>  <b>A61B 8/08</b>	<b>A1</b>	<b>(11) International Publication Number:</b> <b>WO 00/40155</b>  <b>(43) International Publication Date:</b> 13 July 2000 (13.07.00)
<b>(21) International Application Number:</b> PCT/US99/31255 <b>(22) International Filing Date:</b> 30 December 1999 (30.12.99)  <b>(30) Priority Data:</b> 09/231,399 1 January 1999 (01.01.99) US  <b>(71) Applicant:</b> DYMAX CORPORATION [US/US]; 271 Kappa Drive, Pittsburgh, PA 15238 (US). <b>(72) Inventor:</b> SKOLNICK, Leon, M.; 5415 Albermarle Avenue, Pittsburgh, PA 15217 (US). <b>(74) Agents:</b> KIRCHANSKI, Stefan, J. et al.; Graham & James LLP, 14th Floor, 801 S. Figueroa Street, Los Angeles, CA 90017-5554 (US).	<b>(81) Designated States:</b> CA, JP, MX, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).  <b>Published</b> <i>With international search report.          Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>	

**(54) Title:** SLOTTED NEEDLE GUIDE**(57) Abstract**

A needle guiding system (10) for guiding a needle (12) into a patient. The system includes an ultrasonic scanning apparatus (14) having a scan plane (16) and a central ray (18). The system includes a needle guide (20) having a slot (22) which receives the needle. The slot has a first side (24) and an opposed second side (26). The needle is free to move in a path within an arc (18) of at least  $\pi/16$  in the slot, but the needle is prevented from moving in a direction between the first side and the second side by the first side and second side.



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## SLOTTED NEEDLE GUIDE

FIELD OF THE INVENTION

The present invention is related to a needle guide for use with  
5 a scanning apparatus. More specifically, the present invention is related to a  
needle guide for use with a scanning apparatus where the needle is free to  
move within an arc of at least  $\pi/16$  in the slot.

BACKGROUND OF THE INVENTION

10 Needle guides are used to assist the operator in the insertion  
of a needle into a desired location in a patient. In U.S. Patents 4,363,326,  
4,402,324 and 5,235,987, the needle is constrained by the needle guide to  
move essentially only in an "axial" direction. The present invention, among  
other features, allows the needle while in the slot of the needle guide, to  
15 move along an arc to have a range of paths for insertion into a patient while  
the scanning apparatus, to which the guide is attached, remains still.  
Because the operator can move the needle within the slotted guide through  
an arc, the operator can make corrections in the path of the needle by  
partially pulling back the needle from the body and reinserting it at a slightly  
20 different angle.

SUMMARY OF THE INVENTION

The present invention pertains to a needle guiding system for  
guiding a needle into a patient. The system comprises an ultrasonic  
scanning apparatus having a scan plane and a central ray. The system  
25 comprises a needle guide having a slot which receives the needle. The slot  
has a first side and an opposed second side. The needle is free to move in a  
path within an arc of at least  $\pi/16$  in the slot, but the needle is prevented  
from moving in a direction between the first side and the second side by the  
first side and second side.

30 The present invention pertains to a method for guiding a  
needle into a patient. The method comprises the steps of placing an  
ultrasonic scanning apparatus in a desired position adjacent a patient. Next

there is the step of inserting the needle into a slot of a needle guide attached to the scanning apparatus. The slot has a first side and an opposing second side. Then there is the step of moving the needle in the slot while maintaining the needle guide and scanning apparatus still to arrange the angle the needle extends from the skin surface of the patient to a desired angle over an arc of at least  $\pi/16$  in the slot, but where the needle guide prevents the needle from moving in a direction between the first side and the second side. Next there is the step of pushing the needle through the skin surface at the arranged angle while the scanning apparatus is imaging the needle as it moves.

#### BRIEF DESCRIPTION OF THE DRAWINGS

In the accompanying drawings, the preferred embodiment of the invention and preferred methods of practicing the invention are illustrated in which:

Figure 1 is a schematic representation of a perspective view of a needle guiding system of the present invention.

Figure 2 is a schematic representation of a side view of a needle guiding system within the image plane of the present invention.

Figure 3 is a schematic representation of a cross-sectional view of the superior surface of a slot.

Figure 4 is a schematic representation of a biopsy guide of the present invention.

Figure 5 is a schematic representation of a needle guide with lips on the present invention.

#### DETAILED DESCRIPTION

Referring now to the drawings wherein like reference numerals refer to similar or identical parts throughout the several views, and more specifically to figures 1, 2 and 3 thereof, there is shown a needle guiding system 10 for guiding a needle 12 into a patient. The system 10 comprises an ultrasonic scanning apparatus 14 having a scan plane 16 and a central

ray 18. The system 10 comprises a needle guide 20 having a slot 22 which receives the needle 12. The slot 22 has a first side 24 and an opposed second side 26. The needle 12 is free to move in a path within an arc 28 of at least  $\pi/16$ , but the needle 12 is prevented from moving in a direction  
5 between the first side 24 and the second side 26 by the first side 24 and second side 26.

Preferably, the needle guide 20 is disposed such that the slot 22 causes the needle 12 to always stay in a plane perpendicular to or within the scan plane 16. The scanning apparatus 14 preferably has a skin surface  
10 30 and the needle guide 20 has an inferior edge 38 which extends beyond the skin surface 30 of the scanning apparatus 14.

Preferably, the needle guide 20 has a superior edge 32 with an entrance 34 with beveling 37 to facilitate entry of the needle 12 through the entrance 34. The exit 39 of the inferior edge 38 preferably has lips 36 to  
15 prevent the needle 12 from falling out of the slot 22, as shown in figure 5. Preferably, the needle guide 20 is releasably attached to the scanning apparatus 14.

The present invention pertains to a method for guiding a needle 12 into a patient. The method comprises the steps of placing an  
20 ultrasonic scanning apparatus 14 in a desired position adjacent a patient. Next there is the step of inserting the needle 12 into a slot 22 of a needle guide 20 attached to the scanning apparatus 14. The slot 22 has a first side 24 and an opposing second side 26. Then there is the step of moving the needle 12 in the slot 22 while maintaining the needle guide 20 and scanning  
25 apparatus 14 still to arrange the angle the needle 12 extends from the skin surface 30 of the patient to a desired angle over an arc 28 of at least  $\pi/16$ , but where the needle guide 20 prevents the needle 12 from moving in a direction between the first side 24 and the second side 26. Next there is the step of pushing the needle 12 through the skin surface 30 at the arranged  
30 angle while the scanning apparatus 14 is imaging the needle 12 as it moves.

In the operation of the preferred embodiment, a needle guide 20 is a device that encompasses a needle 12 and directs the needle 12

either within (figs. 2 and 4) or through (fig. 1) the ultrasound beam of the scanning apparatus 14 to which it is attached so that the needle 12 can traverse a target area displayed by the ultrasound beam. In the usual needle guide 20, the needle 12 is free to only move into or out of the tissue. The  
5 guide prevents the needle 12 from moving from side to side or to change its angle of approach to the target.

When the guide 20 is mounted so that the needle travels through the ultrasound beam, the needle is directed at the central ray which should be displayed on the ultrasound image as a vertical line. The guide  
10 constrains the course of the needle 12 to this path. Any target in the tissue to be traversed by the needle 12 must lie within the displayed vertical line representing the central ray as shown on the TV monitor. The operator places the vertical line representing the central ray through the target region in the tissue and then pushes the needle 12 through the guide (the needle  
15 12 having been previously inserted in the guide) until the tip of the needle is seen entering the target. The guide may have a release mechanism (such as the split lips 36 used in U.S. Patent No. 5,235,987) which permits the user to separate the guide and scanning apparatus 14 from the needle 12 so that the needle 12 may remain in the target region of the patient without its  
20 remaining attached to the guide. Alternatively, if there are no split lips, the needle can be released from the guide by having the operator lift the probe 14 vertically off the subject so that the needle guide slides over the needle.

In the apparatus, the needle 12 lies within a slot 22 in the guide so that it is free to move in an arcuate manner within or through the  
25 ultrasound beam to change the angle of approach to the target. However, it is prevented from moving from side to side so that it always stays within the same plane (either within the beam or through the beam) depending upon how the guide is attached to the scanning apparatus 14. Because the operator can change the angle of approach of the needle 12 within the guide  
30 while the needle 12 is being directed to the target, the operator can make adjustments in the needle 12 path to improve its course. When the needle 12 travels within the ultrasound beam, at least the needle tip is usually

displayed on the monitor as the operator manipulates the needle 12 position and direction. If the needle 12 travels through the beam, a vertical row of dot markers may continue to be displayed to define the central ray 18 of the ultrasound image (fig. 1) that the needle 12 will intersect. Creation of the electronic dot marker display of the central ray 18 itself is well known to one skilled in the art and is available with the Siterite scanning apparatus sold by Dymax Corporation, Pittsburgh, Pennsylvania. (Siterite is a registered trademark of Dymax Corporation).

The slot 22 is open on the surface touching the skin. In operation, the scanning apparatus 14 is pressed against the skin so that the skin acts as the inferior closing surface of the slot 22, capturing the needle 12 within it. However, when one wants to separate the needle 12 from the guide, one only lifts the guide and scanning apparatus 14 off the skin, leaving the needle 12 within the patient. This is the preferred embodiment. One could, however, attach plastic lips 36 to close the lower end of the guide (lips 36 similar to those used in U.S. Patent No. 5,235,987, incorporated by reference herein) to provide a more secure closure of the slot 22 and still allow the needle 12 to be easily separated from the scanning apparatus 14. The needle 12 parts the lips 36 as the scanning apparatus 14 and guide are lifted off the skin.

This slotted guide should be especially useful for operators who are accustomed to freehand (no guide used) directing needles into superficial vessels (within 1-2 cm of the skin) but who appreciate the difficulties of the freehand approach. The slotted guide continues to provide the operator freedom to vary the angle of needle 12 approach while either having the needle 12 travel within the ultrasound beam or intersecting the central ray 18 of the beam.

In an alternate embodiment for breast biopsy, as shown in figure 4, a biopsy guide indents the skin of one side of the breast so that the needle 12 can be directed horizontally to the mass minimizing the chance that the needle 12 will be directed toward the lung 51 and possibly puncture the lung 51.

In an alternate embodiment with lips, as shown in figure 5, the same embodiment as the preferred embodiment is used except that lips 36 project from the inferior edge 32 of the slot to prevent the needle 12 from easily falling out of the slot.

5           Although the invention has been described in detail in the foregoing embodiments for the purpose of illustration, it is to be understood that such detail is solely for that purpose and that variations can be made therein by those skilled in the art without departing from the spirit and scope of the invention except as it may be described by the following claims.



CLAIMS

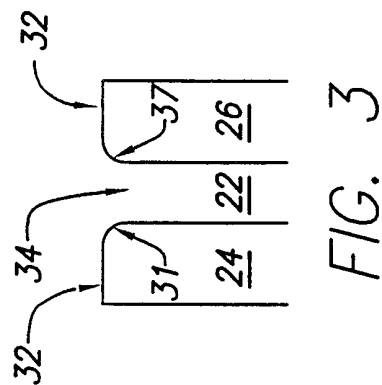
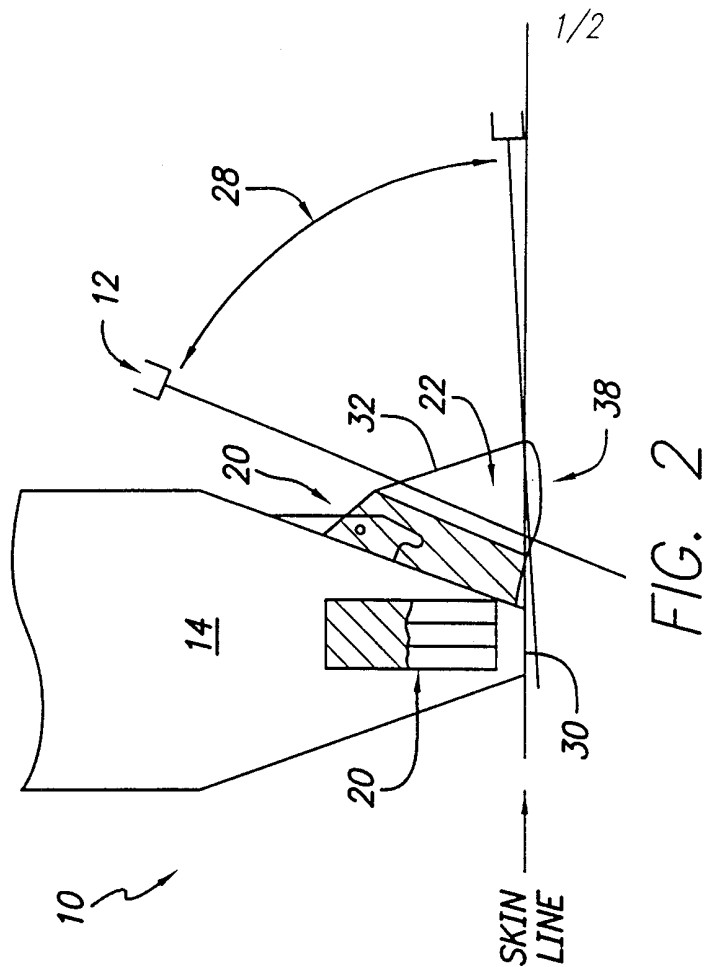
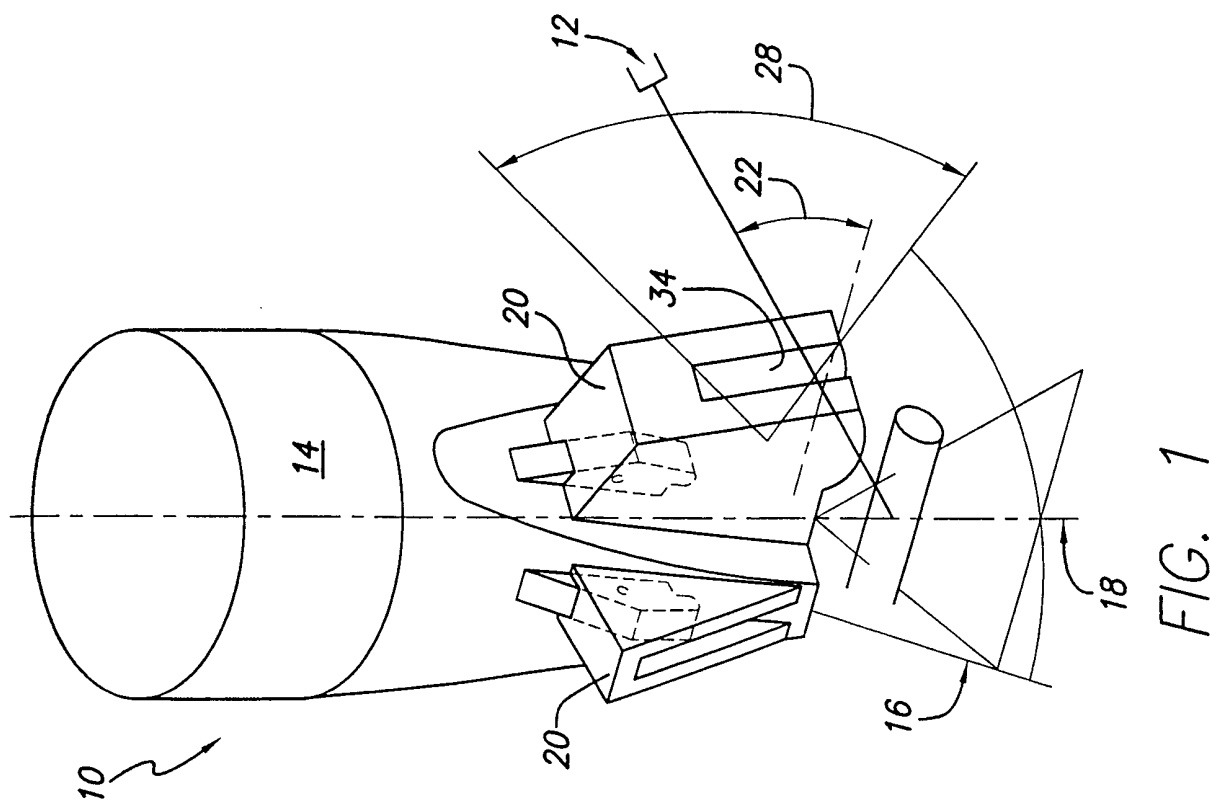
1. A needle guiding system for guiding a needle into a patient comprising:
  - an ultrasonic scanning apparatus having a scan plane and a
  - 5 central ray; and
  - a needle guide having a slot which receives the needle, said slot having a first side and an opposed second side, said needle free to move in a path within an arc of at least  $\pi/16$ , but said needle is prevented from moving in a direction between the first side and the second side by the
  - 10 first side and second side.
2. A system as described in Claim 1 wherein the needle guide is disposed such that the slot causes the needle to always stay in a plane perpendicular to or within the scan plane.
- 15 3. A system as described in Claim 2 wherein the scanning apparatus has a skin surface and wherein the needle guide has an inferior edge which extends beyond the skin surface of the scanning apparatus.
- 20 4. A system as described in Claim 3 wherein the needle guide has a superior edge with an entrance with beveling to facilitate entry of the needle through the entrance.
5. A system as described in Claim 4 wherein the exit of the
- 25 inferior edge has lips to prevent the needle from falling out of the slot.
6. A system as described in Claim 5 wherein the needle guide is releasably attached to the scanning apparatus.
- 30 7. A method for guiding a needle into a patient comprising the steps of:
  - placing an ultrasonic scanning apparatus in a desired position

adjacent a patient;

inserting the needle into a slot of a needle guide attached to the scanning apparatus, said slot having a first side and an opposing second side;

5 moving the needle in the slot while maintaining the needle guide and scanning apparatus still to arrange the angle the needle extends from the skin surface of the patient to a desired angle over an arc of at least  $\pi/16$ , but where the needle guide prevents the needle from moving in a direction between the first side and the second side; and

10 pushing the needle through the skin surface at the arranged angle while the scanning apparatus is imaging the needle as it moves.



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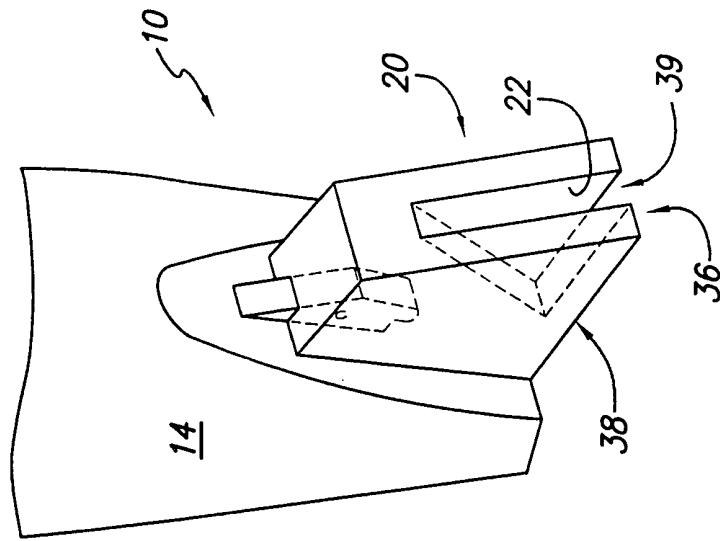


FIG. 5

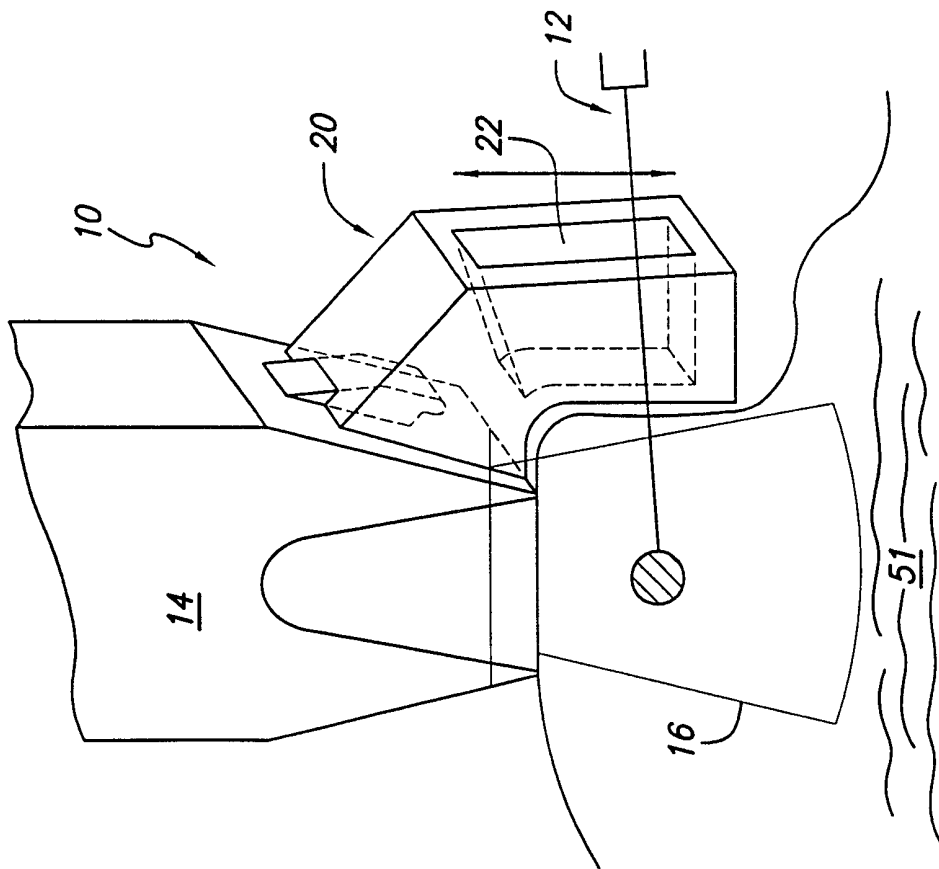


FIG. 4

# INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 99/31255

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61B8/08

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

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)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4 838 506 A ( W. I. COOPER ) 13 June 1989 (1989-06-13)	1,2
A	column 1, line 53 -column 2, line 43 ----	3-6
Y	DE 29 42 405 A ( SIEMENS AG ) 30 April 1981 (1981-04-30) page 5, line 33 -page 7, line 6 ----	1-6
Y	US 4 635 644 A ( YUKIHIRO YAGATA ) 13 January 1987 (1987-01-13) the whole document ----	1-6
Y	WO 84 03034 A ( H. R. C. DRUE ET AL ) 16 August 1984 (1984-08-16) page 6, line 6 -page 7, line 2 ----- -/--	1-6

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

\* Special categories of cited documents :

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Date of the actual completion of the international search

16 May 2000

Date of mailing of the international search report

24/05/2000

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# INTERNATIONAL SEARCH REPORT

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## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 4 899 756 A ( J. D. SONEK ) 13 February 1990 (1990-02-13) column 2, line 14 - line 48	1,2
A	column 4, line 57 -column 6, line 4 -----	3-6
Y	EP 0 102 800 A ( ADVANCED TECHNOLOGY LABORATORIES, INC. ) 14 March 1984 (1984-03-14)	1,2
A	page 2, line 20 -----	6

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 99/31255

### 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.: 7  
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.
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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

Int. Application No

PCT/US 99/31255

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