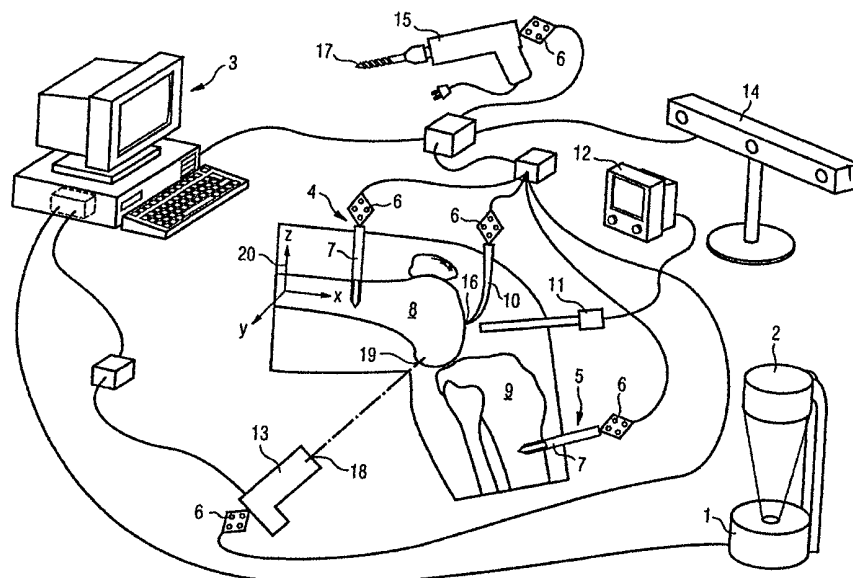


INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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<p>(21) International Application Number: PCT/EP99/01778</p> <p>(22) International Filing Date: 17 March 1999 (17.03.99)</p> <p>(71) Applicant (for all designated States except CA US): SYNTHES AG CHUR [CH/CH]; Grabenstrasse 15, CH-7002 Chur (CH).</p> <p>(71) Applicant (for CA only): SYNTHES (U.S.A.) [US/US]; 1690 Russell Road, P.O. Box 1766, Paoli, PA 19301-1222 (US).</p> <p>(72) Inventors; and</p> <p>(75) Inventors/Applicants (for US only): SATI, Marwan [CA/CH]; Hausmattrain 44, CH-4600 Olten (CH). NOLTE, Lutz, Peter [CH/CH]; Wartbodenstrasse 1 K, CH-3626 Hünibach (CH).</p> <p>(74) Agent: LUSUARDI, Werther; Dr. Lusuardi AG, Kreuzbühlstrasse 8, CH-8008 Zürich (CH).</p>		<p>(81) Designated States: AU, CA, JP, NZ, US, ZA, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).</p> <p>Published With international search report.</p>

(54) Title: IMAGING AND PLANNING DEVICE FOR LIGAMENT GRAFT PLACEMENT



(57) Abstract

Device for realtime computerized in-situ planning and guidance of ligament graft placement comprising: A) two rigid reference bodies (4; 5) with at least three markers (6) each and screws (7) or pins to attach the reference bodies (4; 5) to the femur (8) respectively to the tibia (9); B) a pointer (10) with at least three markers (6); C) an endoscope (11); D) a computer (3); E) a position measurement device (14) connected to the computer (3) in order to determine the position of the markers (6); F) an X-ray source (1) that may be used pre-operatively or intra-operatively; G) an X-ray receiver (2) for gathering medical image data which is transferred to the computer (3) either directly in numerical format or by scanning the radiographic film into the computer (3); and H) an A-mode ultrasound device (13) which is connected to the computer (3) and provided with at least three markers (6).

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IMAGING AND PLANNING DEVICE FOR LIGAMENT GRAFT PLACEMENT

The present invention relates to a device for realtime computerized in-situ planning and guidance of ligament graft placement as defined in the preamble of claim 1 and a method for realtime computerized in-situ planning and guidance of ligament graft placement as defined in the preamble of claim 8.

Anterior Cruciate Ligament (ACL) rupture is a very common sports-related injury. Reconstruction with autogenous graft using a minimal invasive endoscopic approach has become standard in ACL replacement. This has the advantage that surgery causes minimal trauma.

Unfortunately, according to the state of the art knowledge on proper ACL placement, approximately 40% of ACL ligaments are currently being misplaced. This exposes a serious problem in the quality of a procedure that, if not performed correctly, can result in premature degeneration of knee structures that eventually requires total knee replacement.

These misplacements can partially be attributed to the restricted local endoscopic view that does not give the surgeon a global overview of ligament position as seen in standard

postoperative X-rays. These limits of endoscopically-identified landmarks for consistent ligament placement have lead some experienced surgeons to strongly advocate the use of fluoroscopy as a quantitative method to verify positioning intraoperatively.

Proper ligament positioning involves many factors such as:

- a) Proper drill tunnel placement with respect to anatomical landmarks;
- b) Avoidance of impingement;
- c) Ensuring that ligament elongation does not exceed 10% (collagen fibre rupture beyond 10% elongation);
- d) Proper graft tension and position to restore knee stability; and
- e) Proper graft fixation in good quality bone.

A method for the determination of the femoral point of the graft attachment in case of ACL replacement is known from the EP 0 603 089 CINQUIN. This known method concerns the determination of a femoral point of graft attachment with respect to the tibial graft attachment point such that the distance between these two points remains invariant during knee flexion and extension. This known method includes the use of a reference and a pointer both provided with energy emitting markers whose position within an on-site three-dimensional coordinate system is determined by means of a three-dimensional position measurement system e.g. an optical custom position measurement system OPTOTRAK, Northern Digital, Waterloo, On. The position measurement system

measures the position of the markers with respect to the on-site three-dimensional coordinate system. Therewith, the position of the tip of the pointer is determinable by means of a computer. The method comprises the steps of:

- 1) Attachment of a first reference at the tibia;
- 2) Positioning of the pointer tip at a previously determined point T_1 and measure the position of the pointer tip with respect to the first reference;
- 3) Positioning of the pointer tip at several points P_i at the trochlea of the femur close to that position where the invariant point is expected;
- 4) Calculation of the distances of point T_1 and each of the points P_i ;
- 5) Displacement of the femur with respect to the tibia and calculation of the variations of the distances between T_1 and each of the points P_i ;
- 6) Selection of that point P_1 among points P_i which shows the most invariant distance.

This method measures knee movement to obtain a "functional" placement of the ligament that respects certain elongation criteria.

The disadvantage of this known method is that anatomical placement criteria such as a general overview of graft position with respect to the whole anatomy of the joint is not possible.

On this point, the invention intends to provide remedial measures.

The objective of the invention is to provide a device that can support both functional and anatomical criteria for a variety of graft types, surgical philosophies and surgical techniques.

The invention solves the posed problem with a device for realtime computerized in-situ planning and guidance of ligament graft placement offering the features of claim 1 and a method for realtime computerized in-situ planning and guidance of ligament graft placement offering the features of claim 8.

Additional advantageous embodiments of the invention are characterized in the dependent claims.

The device according to the invention provides the advantage that the device provides a versatility that allows anterior cruciate ligament insertion for very different surgical techniques.

The device according to the invention comprises

- A) two rigid reference bodies with at least three markers each and screws or pins to attach the reference bodies one to the femur and one to the tibia;
- B) a pointer with at least three markers;
- C) an endoscope;
- D) a computer;
- E) a position measurement device connected to the computer in order to determine the position of the markers;
- F) an X-ray source that may be used pre-operatively or intra-operatively;
- G) an X-ray receiver for gathering medical image data which is transferred to the computer either directly in numerical format or by scanning the radiographic film into the computer; and
- H) an ultrasound device which is connected to the computer and provided with at least three markers.

The markers may be energy emitting, receiving or reflecting means depending on the position measurement device being used. For instance as energy emitting means:

- Light sources;
- Light emitting diodes (LED's);
- Infrared light emitting diodes (IRED's);
- Accoustic transmitters; or
- Coils in order to establish a magnetic field;

or as energy receiving means:

- Photodiodes;
- Microphones; or
- Hall-effect components;

may be installed.

Furthermore, the device may comprise a drilling device which is provided with at least three markers as well. The markers attached to the drilling device allow to determine the in-situ position of the drilling device, particularly of the drill tip. Such the drill tip may be positioned on the bone as previously planned at the computer. The path of the hole being bored by the drill may be controlled at the computer therewith allowing a guidance of the drilling device according to the holes previously planned at the computer. The planning of the positions of the holes may be performed with use of the medical images.

In a preferred embodiment of the device according to the invention the pointer and the endoscope are configured as a one-piece computer-integrated endoscopic instrument.

Preferably, the ultrasound device is an A-mode ultrasound device emitting and receiving an ultrasound beam along an axis such allowing a realtime signal processing.

Particular software allows the computer to display a three-dimensional representation of the connection between ligament attachment points previously determined via the pointer. Moreover, when using the ligament attachment points the computer can display a ligament during knee flexion and extension.

The method according to the invention comprises the steps

- A) making at least one X-ray of the knee sections of the femur and the tibia as a medical image;
- B) transfer of the medical image to a computer;
- C) measurement of points on the surface of the femur respectively of the tibia by means of a pointer and within a on-site three-dimensional coordinate system;
- D) measurement of points on the surface of the femur respectively of the tibia by means of an ultrasound device and within a on-site three-dimensional coordinate system; and
- E) functional and anatomical determination of the ligament graft placement by means the data received under A), C) and D).

The points intraoperatively measured on the surface of the femur respectively of the tibia may be used to establish a mathematical relationship between the patient's intraoperative position and the data of the X-rays.

The X-rays may be made preoperatively or intraoperatively and are used to help decide where to place the ligament.

Furthermore, the method may comprise the step of determination of the image magnification by the computer.

Preferably the X-rays are prepared as templates. Such allowing a direct planning of the desired ligament graft placement with respect to anatomical landmarks on the medical image displayed at the computer through manipulation of the templates.

The method may also comprise the implantation of fiducial markers at the femur respectively at the tibia.

The invention is explained in more detail with reference to the partially schematic illustration of the preferred embodiment.

Shown are:

Fig. 1 the preferred embodiment of the device according to the invention.

Fig. 1 shows the device according to the invention comprising:

- An X-ray source 1 that may be used pre-operatively or intra-operatively;
- An X-ray receiver 2 for gathering medical image data;

- A computer 3 whereto the medical image data is transferred either directly in numerical format or by scanning the radiographic film into the computer 3;
- Two rigid reference bodies 4;5 with four markers 6 each and screws 7 or pins to attach the reference bodies 4;5 to the femur 8 respectively to the tibia 9;
- A pointer 10 with twelve markers 6;
- An endoscope 11 which is provided with a display 12;
- An A-mode ultrasound device 13 which is connected to the computer 3 and provided with four markers 6;
- A position measurement device 14 connected to the computer 3 in order to determine the position of the markers 6; and
- A drilling device 15 which is provided with four markers 6.

X-rays may be established pre-operatively or intra-operatively by means of the X-ray source 1 and the X-ray receiver 2. If pre-operative X-rays are taken, these may be available in numerical format or as a radiographic film. If available in numerical format, the X-ray is directly transferred to the computer 3, otherwise the radiographic film is scanned into the computer 3. If intra-operative X-rays are taken, a fluoroscope is used with an X-ray source 1 and an X-ray receiver 2. X-rays

should be taken in standard orientations, for example anterior-posterior and medial-lateral, and contain a ruler with radio-opaque markings placed at the side of the knee. The radio-opaque markings on the ruler appear on the image and are digitised in the computer 3 to determine image magnification. The X-rays can be prepared as templates. Desired ligament placement with respect to anatomical landmarks, e.g. the medial and lateral condyles or the trochlea, can be planned directly on the medical image displayed at the computer 3 through manipulations of the templates.

To perform the functional considerations the position measurement of the femur 8, the tibia 9, and the pointer 10 is performed by the position measurement device 14. In the preferred embodiment of the device according to the invention the position measurement device 14 is an optoelectronic navigation system (Optotrak 3020, Northern Digital, CAN.). The markers 6 are infrared light emitting diodes (IRED's) that are detected by the position measurement device 14 therewith allowing to calculate the position of the reference bodies 4;5, the pointer tip 16, the drill tip 17 and the head 18 of the ultrasound device 13.

The pointer 10 can be used to digitise structures of the femur 8 respectively of the tibia 9 under direct visual control by means of the endoscope 11. In the preferred embodiment of the

device according to the invention the pointer 10 is a computer-integrated endoscopic palpation hook such that the endoscope 11 is integrated in the pointer 10.

Certain landmarks, such as the posterior femoral and tibial condyles, are difficult to obtain by direct digitization with the pointer 10. For this reason, the device according to the invention also incorporates an A-mode ultrasound device 13 equipped with markers 6. The ultrasound device 13 and the computer 3 allow to calculate the distance between the ultrasound device head 18 and the point of intersection 19 of the ultrasound beam with the surface of a bone. Since the position of the ultrasound device head 18 and the direction of the ultrasound beam within the on-site three-dimensional coordinate system 20 are determined by the position measurement device 14 the position of the point of intersection 19 may be determined within the on-site three-dimensional coordinate system 20 by means of a coordinate transformation performed via the computer 3.

The points intraoperatively measured on the surface of the femur 8, respectively on the tibia 9 may be used to establish a relationship between the patient's intraoperative position and the data of the medical images. Such a transformation of coordinates on the medical image may be computed into coordinates within the on-site three-dimensional coordinate system 20 therewith allowing functional and anatomical considerations of the graft placement.

CLAIMS

1. Device for realtime computerized in-situ planning and guidance of ligament graft placement comprising
 - A) two rigid reference bodies (4;5) with at least three markers (6) each and screws (7) or pins to attach the reference bodies (4;5) to the femur (8) respectively to the tibia (9);
 - B) a pointer (10) with at least three markers (6);
 - C) an endoscope (11);
 - D) a computer (3); and
 - E) a position measurement device (14) connected to the computer (3) in order to determine the position of the markers (6), characterized in that the device further comprises
 - F) an X-ray source (1) that may be used pre-operatively or intra-operatively;
 - G) an X-ray receiver (2) for gathering medical image data which is transferred to the computer (3) either directly in numerical format or by scanning the radiographic film into the computer (3); and
 - H) an ultrasound device (13) which is connected to the computer (3) and provided with at least three markers (6).
2. Device according to claim 1, characterized in that the device further comprises a drilling device (15) which is provided with at least three markers (6).

3. Device according to claim 1 or 2, characterized in that the pointer (10) and the endoscope (11) are configured as a one-piece computer-integrated endoscopic instrument.

4. Device according to one of the claims 1 through 3, characterized in that the ultrasound device (13) is an A-mode ultrasound device.

5. Device according to one of the claims 1 through 4, characterized in that the computer (3) can display a three-dimensional representation of the connection between ligament attachment points previously determined via the pointer (10).

6. Device according to claim 5, characterized in that using the ligament attachment points the computer (3) can display a ligament during knee flexion and extension.

7. Device according to one of the claims 1 through 6, characterized in that the X-ray source (1) and the X-ray receiver (2) are configured as a fluoroscope.

8. Method for realtime computerized in-situ planning and guidance of ligament graft placement with the use of the device according to one of the claims 1 through 7, characterized in that it comprises the steps

A) making at least one X-ray of the knee sections of the femur (8) and the tibia (9) as a medical image;

- B) transfer of the medical image to a computer (3);
- C) measurement of points on the surface of the femur (8) respectively of the tibia (9) by means of a pointer (10) and within an on-site three-dimensional coordinate system (20);
- D) measurement of points on the surface of the femur (8) respectively of the tibia (9) by means of an ultrasound device (13) and within a on-site three-dimensional coordinate system (20);
- E) establish a mathematical relationship between the patient's intraoperative position and the data of the medical images by using the points on the surface of the femur (8) respectively of the tibia measured under steps C) and/or D); and
- F) functional and anatomical determination of the ligament graft placement by means the data received under A), C) and D).

9. Method according to claim 8, characterized in that the at least one X-ray is made preoperatively and used to help decide where the ligament is placed.

10. Method according to claim 8, characterized in that the at least one X-ray is made intraoperatively and used to help decide where the ligament is placed.

11. Method according to one of the claims 8 through 10, characterized in that it further comprises the step of determination of the image magnification by the computer (3).

12. Method according to one of the claims 8 through 11, characterized in that the at least one X-ray is prepared as template.

13. Method according to claim 12, characterized in that the desired ligament graft placement with respect to anatomical landmarks is planned directly on the medical image displayed at the computer (3) through manipulation of the templates.

14. Method according to one of the claims 8 through 13, characterized in that it further comprises the implantation of fiducial markers at the femur (8) respectively at the tibia (9).

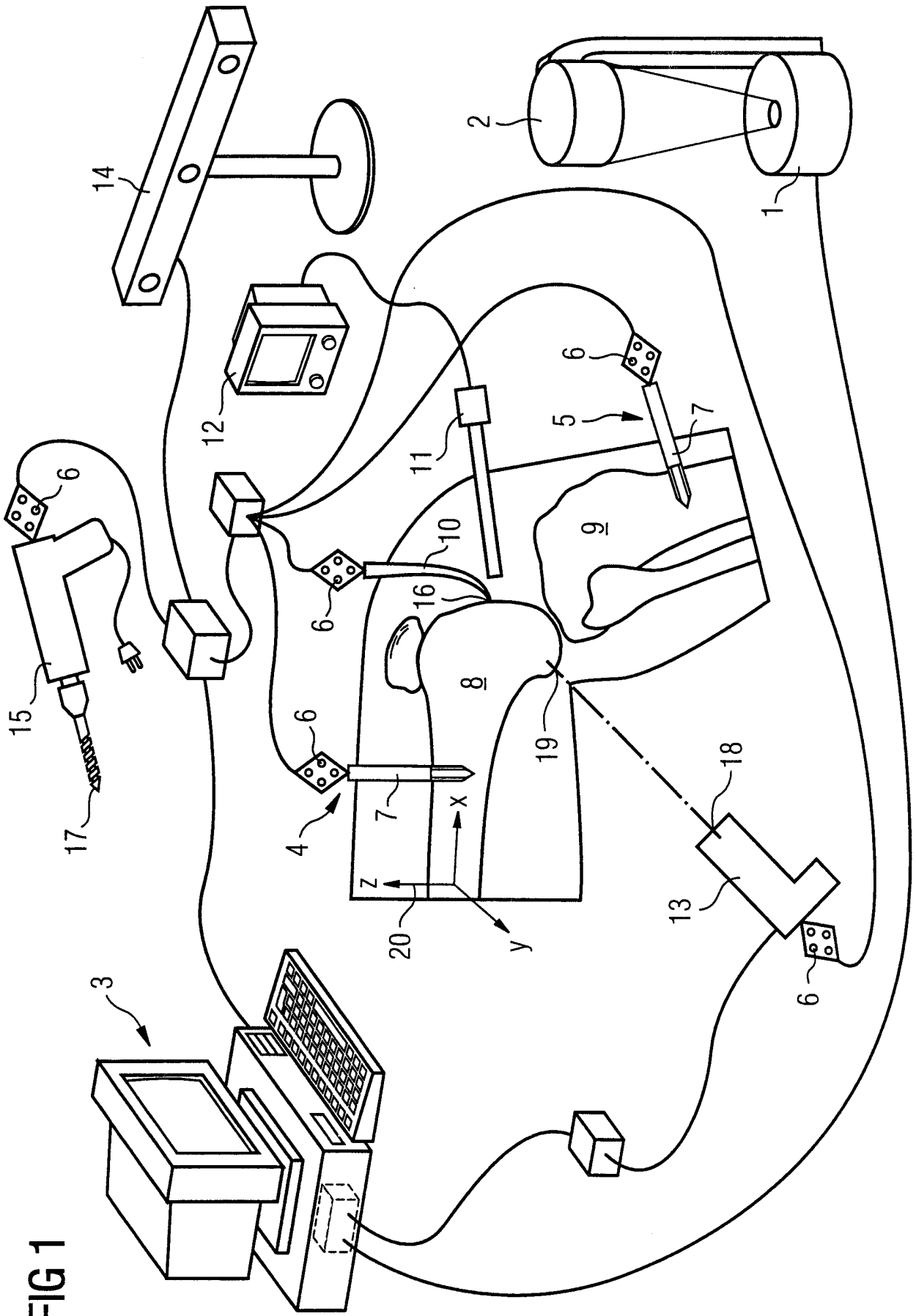


FIG 1

INTERNATIONAL SEARCH REPORT

International Application No PCT/EP 99/01778

A. CLASSIFICATION OF SUBJECT MATTER
 IPC 7 A61B19/00 A61B17/17

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.
Y	EP 0 603 089 A (UNIV JOSEPH FOURIER) 22 June 1994 (1994-06-22) cited in the application column 3, line 41 - line 47 column 4, line 5 - line 15 column 4, line 32 - line 44; figure 1 ---	1,2,4-6
Y	US 5 817 022 A (VESELY IVAN) 6 October 1998 (1998-10-06) column 4, line 25 - line 35 column 6, line 8 - line 18 column 7, line 7 - line 26; figure 4 ---	1,2,4-6
A	US 5 682 886 A (WONG ARTHUR Y ET AL) 4 November 1997 (1997-11-04) column 8, line 32 - line 39 column 15, line 18 - line 21 column 16, line 21 - line 25 ---	1,5-7
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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 :

<p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"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)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p>	<p>"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</p> <p>"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</p> <p>"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.</p> <p>"&" document member of the same patent family</p>
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Date of the actual completion of the international search 17 November 1999	Date of mailing of the international search report 25/11/1999
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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 Mayer, E
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INTERNATIONAL SEARCH REPORT

International Application No PCT/EP 99/01778

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 5 810 008 A (HALL CHARLES RYAN ET AL) 22 September 1998 (1998-09-22) column 4, line 10 - line 20; figure 1 -----	1,3,4
A	WO 97 29679 A (BEN HAIM SHLOMO ;BIOSENSE INC (US)) 21 August 1997 (1997-08-21) page 11, line 3 - line 10; figure 1 -----	1,3

INTERNATIONAL SEARCH REPORT

International application No.

PCT/EP 99/01778

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.: 8-14
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/EP 99/01778

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