

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
29 December 2005 (29.12.2005)

PCT

(10) International Publication Number
WO 2005/122899 A1

(51) International Patent Classification⁷: **A61B 5/22**,
G01L 1/22, A61F 2/46

(21) International Application Number:
PCT/CH2004/000361

(22) International Filing Date: 15 June 2004 (15.06.2004)

(25) Filing Language: English

(26) Publication Language: English

(71) Applicant (for all designated States except CA, US): **SYNTHES AG CHUR** [CH/CH]; Grabenstrasse 15, CH-7002 Chur (CH).

(71) Applicant (for CA only): **SYNTHES (USA)** [US/US]; 1690 Russell Road, P.O.Box 1766, Paoli, PA 19301-1222 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): **CROTTET, Denis** [CH/CH]; Les Grandseys, CH-1564 Domdidier (CH).

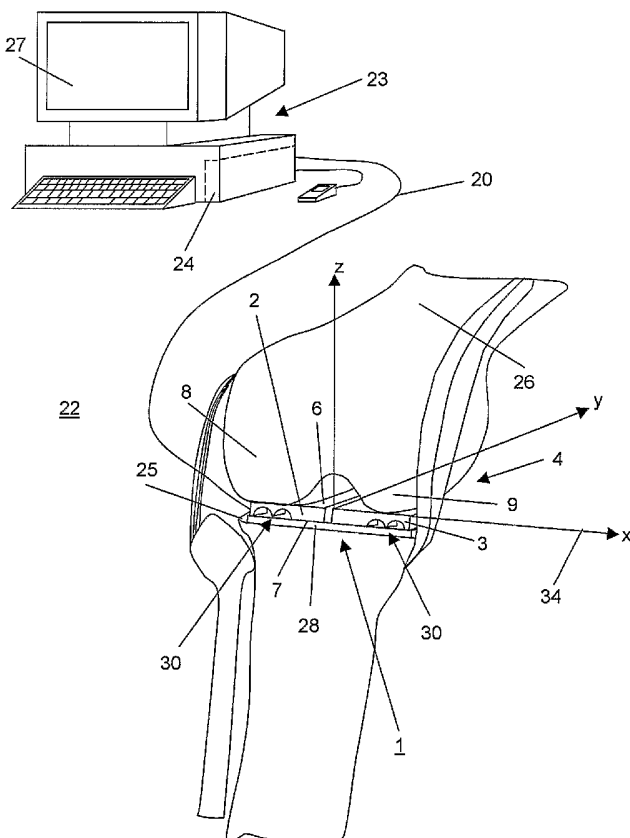
PAPPAS, Ion, Petros [GR/CH]; Tschannerstrasse 36, CH-3007 Bern (CH). **MAEDER, Thomas** [CH/CH]; Chemin des Bosquets 5, CH-1315 La Sarraz (CH). **JACQ, Caroline** [FR/CH]; Avenue d'Epenex 21, CH-1024 Ecublens (CH). **BLEULER, Hannes** [CH/CH]; Chemin des Etaloges 1, CH-1164 Buchillon (CH).

(74) Agent: **LUSUARDI, Werther**; Dr. Lusuardi AG, Kreuzbühlstrasse 8, CH-8008 Zürich (CH).

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

[Continued on next page]

(54) Title: DEVICE FOR MEASURING TIBIO-FEMORAL FORCE AMPLITUDES AND FORCE LOCATIONS IN TOTAL KNEE ARTHROPLASTY



(57) Abstract: Probe (1) used during a total knee arthroplasty for measuring forces and locations of their points of application and thereby moments comprising A) two load sensitive plates (2; 3) apt to be inserted in one joint-compartment of a knee joint each and each being provided with a top surface (6) and a bottom surface (7); B) at least two load sensors (10) situated on the top surfaces (6) and/or the bottom surface (7) of each load sensitive plate (2; 3).



(84) **Designated States** (*unless otherwise indicated, for every kind of regional protection available*): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

Published:

— *with international search report*

Device for measuring tibio-femoral force amplitudes and force locations in total knee arthroplasty.

The invention relates to a probe for measuring force amplitudes and force locations and moments according to the concept of claim 1.

During a Total Knee Arthroplasty (TKA), the surgeon balances the collateral knee joint ligaments in order to ensure a stable artificial joint. Conventionally, the balance assessment is based on the surgeon's perception and experience by manually manipulating the knee joint. Assessing the ligament forces and moments acting in the knee "by hand" is subjective, and can lead to relatively large errors and repeatability problems.

From EP 1 304 093 GOUGEON a probe is known, which allows the measurement of the compressive forces between each condyle of the femur and the tibial plateau. This known probe comprises two load sensors, one for each condyle, and is attached to a plate like support. This known probe shows the disadvantage that the determination of the point of application of the compressive force is not possible. The moments which are important for the ligament balancing remain unknown.

On this point, the invention intends to provide remedial measures. The invention is based on the objective of providing a probe allowing to measure the amplitude and location of the compressive force generated by each condyle.

The invention solves the posed problem with a probe that displays the features of claim 1.

Additional advantageous embodiments of the invention are characterized in the subclaims.

The advantages achieved by the invention are essentially to be seen in the fact that the probe according to the invention allows

- measuring the force amplitude and location separately for each condyle and therefore
- computing the moments acting on the knee joint to better assess the ligament balance;
- measuring in real-time time; and
- keeping the patella at its anatomical place during the measurement, which is closer to the postoperative situation.

In a preferred embodiment the first and second load sensitive plate comprise at least three load sensors each that are non-colinearly arranged allowing to measure the force amplitudes and locations with respect to two perpendicular axes, preferably one extending in a medio-lateral direction and the other one extending in a antero-posterior direction.

In another preferred embodiment the probe further comprises a tibial base plate. Therewith, the advantage of a fixed and defined reference surface for the probe is obtainable.

In a further embodiment the probe further comprises a set of wedges allowing a variation of the tibio-femoral gap according to the patient anatomy and ligament releasing procedure.

In yet another embodiment the first and second load sensitive plates have adjoining inner lateral side walls and are connected at these adjoining inner lateral side walls. Therewith, an easier insertion of the probe into the tibio-femoral gap is obtainable. Preferably the first and second load sensitive plate are flexibly connected at their adjoining inner lateral side walls therewith allowing that the tibio-femoral gap may be varied by means of the above wedges.

Preferably, each load sensor comprises a bridge-shaped structure and at least one piezoresistive sensor attached thereto. The bridge-shaped structures may be configured such that each load sensor provides measurement at one discrete point. Preferably, the discrete point measurements of the load sensors are spaced apart relative to one another by a distance greater than 2 mm.

The measured parameters may be used as inputs to a computational biomechanical model of the knee joint acting as an assistive expert system.

Instead of electrically connecting the load sensitive sensors with the data processing instrument, (e.g. the computer) by means of cables, wireless telemetry may be used to transmit the measurement signals of the load sensors to the data processing instrument, e.g. the computer. Therewith, the ergonomics of the probe may be improved and the handling may be facilitated as well.

The invention and additional configurations of the invention are explained in even more detail with reference to the partially schematic illustration of several embodiments.

Shown are:

Fig. 1 a perspective view of a human knee joint with inserted probe according to one embodiment of the invention and a computer;

Fig. 2 a perspective view on the embodiment of the probe shown in fig. 1.

Fig. 1 represents the measuring apparatus 22 comprising a probe 1 being situated between the tibial plateau 25 and the two condyles 8;9 of a human knee joint 4. Furthermore, the measuring apparatus 22 comprises a data acquisition and processing instrument 24 connected cableless or by means of cables 20 to the probe 1 and a computer 23. The probe 1 comprises two load sensitive plates 2;3 whose bottom surfaces 7 are in contact with the top surface of a tibial base plate 28 lying on the tibial plateau 25 and whose top surfaces 6 are in contact with one condyle 8;9 of the femur 26 each. Each load sensitive plate 2;3 is situated in one knee-compartment and experiences the forces of one condyle 8;9. Furthermore, each load sensitive plate 2;3 comprises three bridge-shaped structures 30 (Fig. 2) being elastically deformable with respect to the load applied onto the top surfaces 6 of the load sensitive plates 2;3.

Fig. 2 depicts a perspective view on an exemplary embodiment of the probe 1 comprising two load sensitive plates 2;3 each for one condyle 8;9 of a human knee joint

4. Each plate 2;3 has a top surface 6 and a bottom surface 7. In the top view the two plates 2;3 have polygon-like shape with rounded corners. Each plate 2;3 contains three load sensors 10 that are situated on the top surface 6 next to the periphery of the plates 2;3. The peripheries of the plates 2;3 are configured so that the shape of the probe 1 is adapted to the shape of the tibial plateau 25. The two load sensitive plates 2;3 are connected to each other by means of a flexible joining element 19 being attached at the top surfaces 6 next to the adjoining inner lateral side walls 14a;14b of the load sensitive plates 2;3. In the exemplary embodiment shown in Fig. 2 the load sensors 10 are provided with cables 20 that are combined to a cable form 21 near the periphery of the first or second load sensitive plate 2;3 whereby each cable 20 is connected to the data acquisition and processing instrument 24 (Fig. 1). At the gap between the inner lateral side walls 14a;14b the cable 20 of the load sensors 10 situated on the first load sensitive plate 2 are integrated in the flexible joining element 19. Instead of using cables 20 the measurement signals could be wirelessly transmitted as well.

The load sensors 10 are realised through elastically deformable bridge-shaped structures 30 near the periphery of each plate 2;3 and instrumented with thick-film piezoresistive sensors 33. The bridge-shaped structures 30 are spaced apart from each other whereby at least two of the bridge-shaped structures 30 are situated at an angle relative to each other. Furthermore, each bridge-shaped structure 30 is provided with a central pillar 32 which is convexely, preferably spherically shaped at the bottom. The piezoresistive sensors experience an electric resistance change depending on the force applied. Arranging the piezoresistive sensors in a Wheatstone bridge allows converting the resistance change into an electric signal being measurable by means of the data acquisition and processing instrument 24 (Fig. 1). According to the measurement device 22 shown in Fig. 1 the amplitude and the location x;y within the reference system 34 of the compressive force on the probe 1 that is generated by each condyle 8;9 may be computed by means of the computer 23 using the values of the electric signals measured by the data acquisition and processing instrument 24.

Once the probe 1 has been inserted in the knee-joint the surgeon may display the computed parameters, i.e. the amplitude and location of the compressive forces and the resulting moments, which characterise the degree of ligament force balance in real-

time on the monitor 27 of the computer. The relevant parameters may be computed during flexion/extension of the knee joint 4 (Fig. 1).

Each load sensitive plate 2;3 contains three deformable bridge-shaped structures 30 instrumented with thick-film piezoresistive sensors 33. The contact between the load sensitive plates 2;3 and the tibial base plate 28 or the wedges (not shown) occurs at the bottom of the pillar center 32 of each bridge-shaped structure 30. In that way, three reaction forces $R_1;R_2;R_3$ orthogonal to the tibial base plate 28 are generated at the pillars 32 of the bridge-shaped structures 30 when a force F is applied on the respective load sensitive plate 2;3. These reaction forces $R_1;R_2;R_3$ being measured by the piezoresistive sensors 33, the amplitude and location of the initial load F can be computed thanks to the equations of mechanical equilibrium.

Description of the surgical procedure:

Following a standard opening of the knee joint 4, a tibial precut is performed in order to obtain a flat reference surface and enough room for the probe 1. The probe 1 is inserted into the knee joint 4 and the measuring system as well as the computer 23 is prepared for the acquisition, processing and display of the measurements. The amplitude and location of the compressive contact force as well as the moments of each femoral condyle 8;9 are then measured in real-time at various knee flexion angles. The computer 23 displays the raw measurements and an interpretation of these measurements based on a computational biomechanical model of the knee joint 4, which acts as an assistive expert system. The ligamentous balance is then corrected according to the measurements and to the biomechanical interpretation. The measurement and correction procedure is repeated until the ligaments are balanced. Finally, the probe 1 is removed and the prosthetic components are inserted. Alternatively, the probe 1 can be used after the insertion of the femoral and/or tibial prosthetic component.

Claims

1. Probe (1) used during a total knee arthroplasty for measuring force amplitudes and force locations
characterised in that it comprises
two load sensitive plates (2;3) apt to be inserted in one joint-compartment of a knee joint each and each being provided with a top surface (6) and a bottom surface (7); whereby each load sensitive plate (2;3) comprises at least two load sensors (10).
2. Probe (1) according to claim 1, wherein at least two load sensors (10) are situated on the top surface (6).
3. Probe (1) according to claim 1 or 2, wherein at least two load sensors (10) are situated on the bottom surface (7).
4. Probe (1) according to one of the claims 1 to 3, wherein at least one load sensor (10) is situated on the top surface (6) and at least one load sensor (10) is situated on the bottom surface (6;7).
5. Probe (1) according to one of the claims 1 to 4, wherein the first and second load sensitive plate (2;3) comprise at least three load sensors (10) each that are non-colinearly arranged.
6. Probe (1) according to one of the claims 1 to 5, wherein it further comprises a tibial base plate.
7. Probe (1) according to one of the claims 1 to 6, wherein it further comprises a set of wedges.
8. Probe (1) according to one of the claims 1 to 7, wherein the first and second load sensitive plate (2;3) have adjoining inner lateral side walls (14) and are connected at their adjoining inner lateral side walls (14).

9. Probe (1) according to claim 8, wherein the first and second load sensitive plate (2;3) are flexibly connected at their adjoining inner lateral side walls (14)
10. Probe (1) according to one of the claims 1 to 9, wherein each load sensor (10) comprises a bridge-shaped structure (30) and at least one piezoresistive sensor (33).
11. Probe (1) according to one of the claims 1 to 10, wherein the measured parameters are used as inputs of a computational biomedical model of the knee joint acting as an assistive expert system.
12. Probe (1) according to one of the claims 1 to 11, wherein wireless telemetry is used to transmit the measurement signals emitted by the load sensors (10) to a computer (23).
13. Probe (1) according to one of the claims 1 to 12, wherein each load sensor (10) provides measurement at one discrete point.
14. Probe (1) according to claim 13, wherein the discrete point measurements of the load sensors (10) are spaced apart relative to one another by a distance greater than 2 mm.

1 / 2

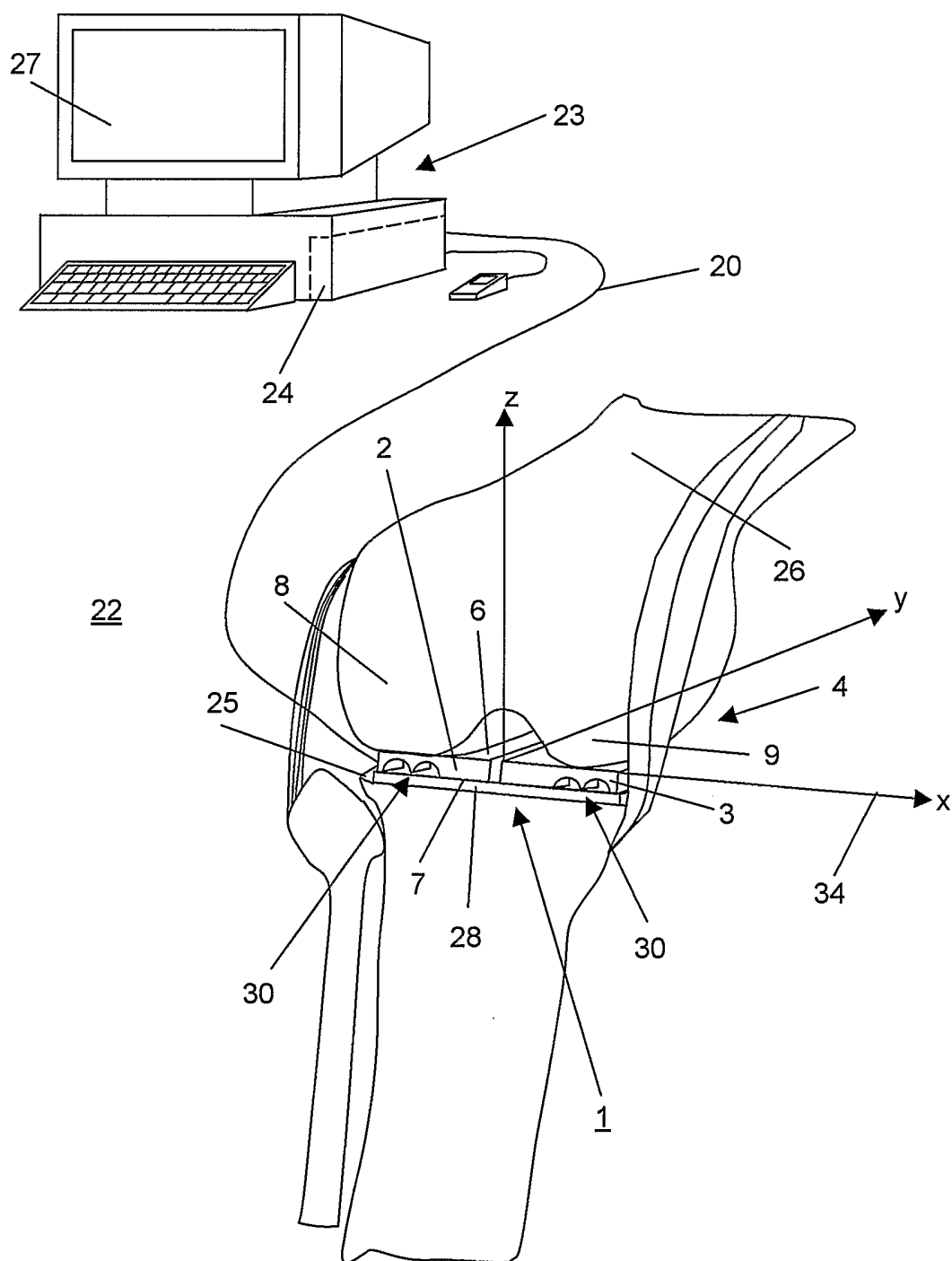


Fig. 1

2 / 2

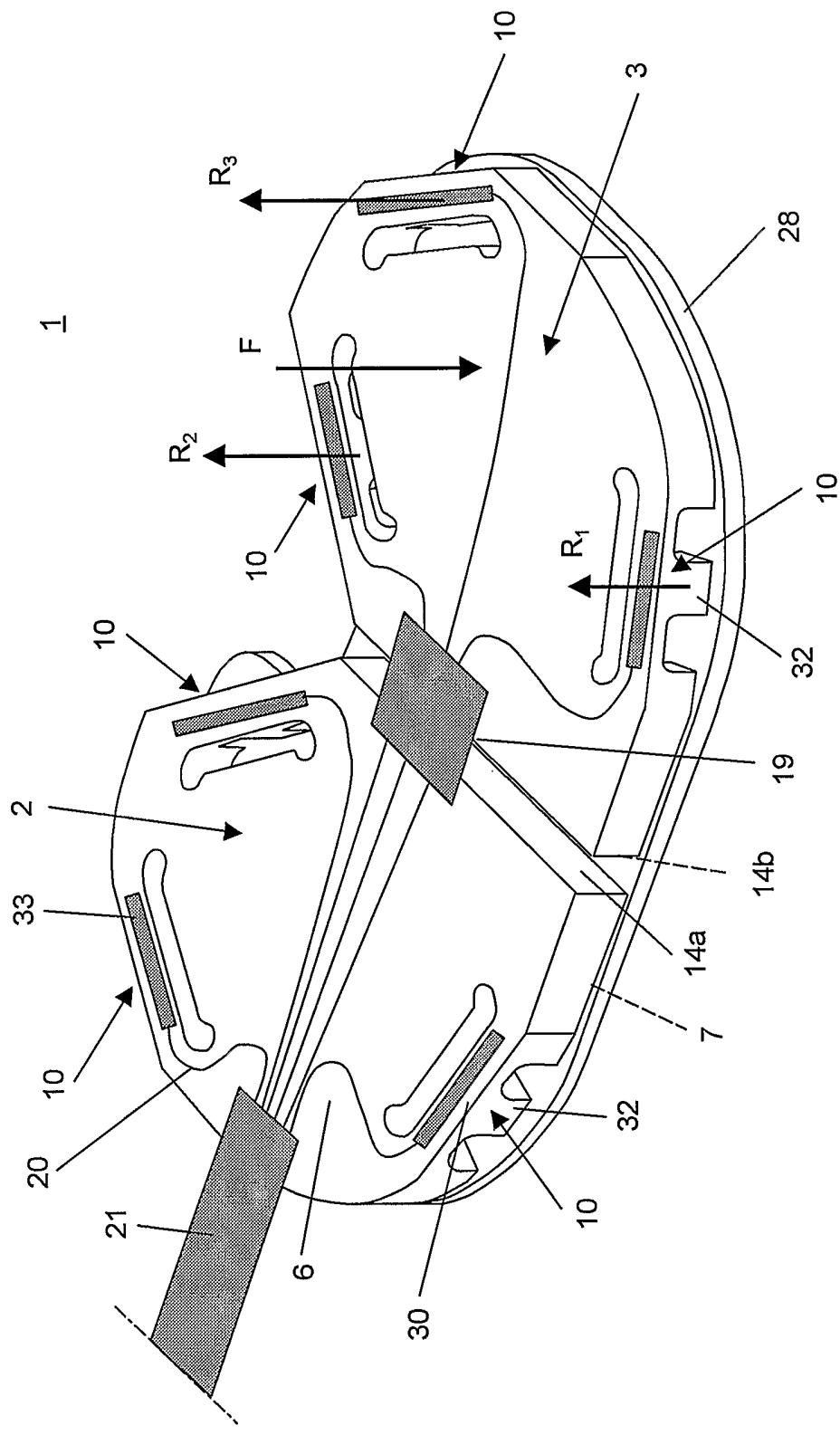


Fig. 2

INTERNATIONAL SEARCH REPORT

International Application No
PCT/CH2004/000361

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61B5/22 G01L1/22 A61F2/46

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 G01L A61F

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)

EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 03/079940 A (THE BOARD OF TRUSTEES OF THE UNIVERSITY OF ILLINOIS) 2 October 2003 (2003-10-02) paragraphs '0035!, '0037! - '0043!, '0049! - '0053!, '0056!, '0063! - '0068!; claims 1,3,4,6,7,11; figures 2-5	1,3,5,6, 11-14
X	US 5 360 016 A (KOVACEVIC ET AL) 1 November 1994 (1994-11-01) column 2, line 22 - column 3, line 12 column 3, line 51 - column 5, line 37 column 6, line 1 - line 50; claims 1,2,4-6; figures 1,2,4-7,11 ----- -/--	1,3,6, 10,13

☒ 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
- *E* earlier document but published on or after the international filing date
- *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)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *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
- *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
- *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

Date of the actual completion of the international search

10 February 2005

Date of mailing of the international search report

21/02/2005

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

Rick, K

INTERNATIONAL SEARCH REPORT

International Application No
PCT/CH2004/000361

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 470 354 A (HERSHBERGER ET AL) 28 November 1995 (1995-11-28) column 2, line 23 - line 48 column 3, line 28 - line 43 column 6, line 52 - column 7, line 19 column 8, line 20 - column 9, line 5 column 9, line 65 - column 10, line 16; figures 3,20	1,2,6,7, 13
A	----- EP 1 304 093 A (SOFINORDEST, S.A.S; GOUGEON, FRANCOIS; TILLIE, BRUNO) 23 April 2003 (2003-04-23) cited in the application paragraphs '0031! - '0040!, '0050! - '0054!; claims 1,2,4; figures 1-4 -----	1-14

INTERNATIONAL SEARCH REPORT

International Application No
PCT/CH2004/000361

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 03079940	A	02-10-2003	AU 2003228341 A1 EP 1487385 A2 WO 03079940 A2 US 2004019382 A1	08-10-2003 22-12-2004 02-10-2003 29-01-2004
US 5360016	A	01-11-1994	US 5197488 A WO 9217113 A1	30-03-1993 15-10-1992
US 5470354	A	28-11-1995	NONE	
EP 1304093	A	23-04-2003	FR 2831053 A1 EP 1304093 A1	25-04-2003 23-04-2003