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(54) **Title:** SUTURE THREAD

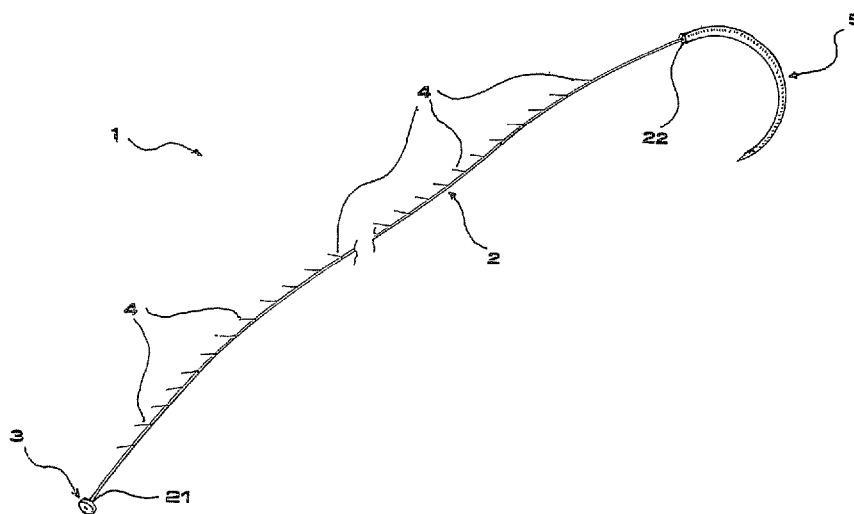


FIG.1

(57) **Abstract:** A suture thread (1), comprising: - a thread-shaped main body (2) having spikes; and - a stopper cylinder (3) having a diameter enlarged with respect to the main body (2), which stopper cylinder (3) is arranged in correspondence of a longitudinal end (21) of the main body (2) to block said end in abutment against a tissue flap.

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SUTURE THREADDESCRIPTION

The present invention refers to a thread, especially for use as a suture thread.

5

The operation of surgical nature most frequently performed in operating room and outpatient clinic surgery is certainly that of suturing by thread. In spite of the frequency and the "historicity" of use of the suture threads, the *in situ* blocking modes of the ends thereof have not been optimized yet. In particular, in order to secure one end of the thread against a portion of biological tissue, the same thread is generally knotted on itself.

10

However, this blocking mode is intrinsically less than reliable as the knot, over time, tends to come undone; this entails that, for each suturing operation that proves necessary during surgery, the operator is forced to make a high number of knots in sequence. Therefore, the entire suturing operation carried out through the knotting technique requires a non-negligible time significantly affecting the total length of the intervention, with the associated consequences for the patient's wellbeing.

15

Therefore, the technical problem set and solved by the present invention is that of providing a thread - and in particular a suture thread - allowing to overcome the drawbacks mentioned above with reference to the known art.

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Such a problem is solved by a thread according to claim 1.

Preferred features of the present invention are set forth in the dependent claims thereof.

25

The present invention provides some relevant advantages. The main advantage lies in the fact that the thread of the invention, by being equipped with a stopper included in correspondence of a longitudinal end of the thread itself, allows to reduce surgical times, eliminating the need to make plural knots, and concomitantly improving the reliability of the sutures, since the block is not subject to the drawback of coming undone. Moreover, by eliminating the need to knot the main body of the thread on itself, the

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invention allows a greater variety of choice for the rigidity level of the latter and for the materials of which it is made, thereby allowing to meet any type of suturing and surgery need.

5 Other advantages, features and operation steps of the present invention will be made apparent in the following detailed description of some embodiments thereof, given by way of example and not for limitative purposes. Reference will be made to the figures of the annexed drawings, wherein:

- 10 ▪ Figure 1 shows a perspective view of a first preferred embodiment of the suture thread according to the present invention;
- Figure 1A shows an enlarged view of a detail of the thread of Figure 1;
- Figure 2 shows a perspective view of a second preferred embodiment of the suture thread according to the present invention;
- 15 ▪ Figure 3 shows a perspective view of the suture thread of Figure 1, in use during surgery; and
- Figures 4A, 4B and 4C show schematic front views illustrating three respective steps of a preferred method for manufacturing the suture thread of Figure 1.

20 Referring initially to Figures 1 and 1A, a suture thread according to a first preferred embodiment of the invention is generally denoted by 1.

The thread 1 comprises first of all an elongated main body 2 having just a thread-like shape. The main body 2 is preferably flexible and extends, in a straight and extended configuration, along a longitudinal axis A.

25 On the main body 2 there are preferably provided holding spikes 4, i.e. thread portions arranged obliquely with respect to the prevalent direction of development of the main body 2 and apt, by virtue of said tilt, to engage the tissue sutured by the thread itself so as to prevent the unthreading of the latter along a given pull direction. Also the length and the thickness of the spikes 4 can be selected depending on the selected cutting tilt.

30 The spikes 4 can be applied on the main body 2 in a monolateral way, as in the depicted example, or in a plurilateral way. In both cases they can be manufactured in a monodirectional way, as in the depicted example, or in a

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pluridirectional way, i.e. have a tilt along a single direction or along plural divergent directions. Moreover, the spikes 4 can be applied on the main body 2 even along a helical path or a spiral-like path.

5 In correspondence of a first longitudinal end 21 of the main body 2, the thread 1 provides a stopper 3 having a section enlarged with respect to the main body 2 itself.

Preferably, the stopper 3 has a substantially cylindrical shape, preferably with an axis of the cylinder aligned with the axis A of the main body 2.

10 Always according to a preferred embodiment, the stopper 3 has a diameter D of about 4 mm and a thickness S comprised in a range of about 1-2 mm.

During suturing, and as shown in Figure 3, the stopper 3, by virtue of its own section enlarged with respect to the main body 2, can block the corresponding longitudinal end 21 of the latter in abutment against a tissue flap.

15 Main body 2 and stopper 3 can be made both of a same material and of different materials, preferably of absorbable synthetic type.

In the present example, the stopper 3 and/or the main body 2 can be made of a material selected from a group comprising: glycolide polymer (PGA), copolymer of glycolide and lactide (PGLA), Poly(p-dioxanone) (PDO),
20 copolymer of glycolide and epsilon-caprolactone (PGCL), and copolymer of Poly(L-lactide) and epsilon-caprolactone P(LA-CL).

The stopper 3 can be fixed to the main body 2 by heat-sealing.

In particular, a preferred embodiment schematically illustrated in Figures 4A, 4B and 4C envisages that the stopper 3 be made by melting of poly(p-dioxanone) polymer in suitable moulds 60 of cylindrical shape of the above-
25 mentioned dimensions, preferably made in the form of openings shaped on a metal plate 61 resting on a board 62 heated to about 130°C.

The connection between stopper 3 and main body 2 is then obtained by the following steps:

30 - sealing of the "free" end 21 of the thread into the polymer paste still molten in the mould 60 (the correct positioning of the thread at the center of the cylindrical element can be guaranteed by a truing device positioned on the plate 61) - this step is schematically shown in Figure 4A;

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- removing the metal plate 61 from the heated board 62, in order to obtain the cooling of the plate itself - this step is schematically shown in Figure 4B; and
- separating the stopper from the metal plate - this step is schematically shown in Figure 4C.

Advantageously, the thread 1 is then prearranged, in correspondence of a second longitudinal end 22 of the main body 2 opposite to that associated to the stopper 3, with a suture needle 5 having a substantially straight or curved shape. Such a needle can be made of stainless steel (e.g. AISI 300 series or AISI 400 series).

According to a second preferred embodiment shown in Figure 2, a suture thread, denoted herein by 100, has a main body, denoted herein by 200, which comprises a pair of thread-shaped members 201, 202, apt to define a generally ring-shaped or loop-like structure of the thread itself.

The thread 100 comprises a stopper 3 analogous to that already described above, and in this case as well it is prearranged with a suture needle, here substantially straight, denoted by 50.

It will be understood that a plurality of suture threads, each as described above with reference to Figures 1 and 2, may be provided in various calibers, preferably comprised in the range USP 6/0 - 8, and in various lengths.

It will also be understood that a plurality of suture threads, each as described above with reference to Figures 1 and 2, may be provided in the form of a reel. In particular, in that case threads will be arranged in a longitudinal sequence and removably connected in correspondence of respective ends.

It will be understood that although the invention has been described with specific reference to suture applications, it can advantageously be used for any type of surgical need in which the use of a thread to be blocked *in situ* be required.

Moreover, in a broader meaning the invention can find application also in a

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field different from the surgical one, for instance that of threads for sewing, especially in specialized fields like those of sewing or stitching technical fabrics, such as for use in fishing, motorcycling, etc.

- 5 The present invention has been hereto described with reference to preferred embodiments thereof. It is understood that other embodiments might exist, all falling within the concept of the same invention, as defined by the protective scope of the claims hereinafter.

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CLAIMS

1. A thread (1) for suture or other sewing or stitching applications, comprising:

- an elongated main body (2); and

5 - a stopper (3) having a section enlarged with respect to said main body (2), arranged in correspondence of a longitudinal end (21) of the latter to block said end in abutment against a tissue flap.

2. The thread (1) according to claim 1, having, in correspondence of said main body (2), a plurality of holding spikes (4).

10 3. The thread (1) according to the preceding claim, wherein said holding spikes (4) are arranged on said main body (2) in a monolateral way, in a plurilateral way and/or along a helical path.

4. The thread (1) according to claim 2 or 3, wherein said holding spikes (4) are arranged on said main body (2) in a monodirectional or pluridirectional way.
15

5. The thread (100) according to any one of the preceding claims, having a substantially ring-shaped or loop-like configuration.

6. The thread (100) according to any one of the preceding claims, wherein said main body (200) comprises a pair of thread-shaped members (201 ,
20 202).

7. The thread (1) according to any one of the preceding claims, wherein said stopper (3) has a substantially cylindrical shape, preferably with an axis (A) of the cylinder aligned with the direction of longitudinal development of said main body (2).

25 8. The thread (1) according to the preceding claim, wherein said stopper (3) has a diameter (D) of about 4 mm.

9. The thread (1) according to any one of the preceding claims, wherein said stopper (3) has a thickness (S) comprised in a range of about 1-2 mm.

30 10. The thread (1) according to any one of the preceding claims, wherein said stopper (3) is fixed to said main body (2) by heat-sealing.

11. The thread (1) according to any one of the preceding claims, wherein

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said stopper (3) and/or said main body (2) are made of a material selected from a group comprising: glycolide polymer (PGA), copolymer of glycolide and lactide (PGLA), Poly(p-dioxanone) (PDO), copolymer of glycolide and epsilon-caprolactone (PGCL), and copolymer of Poly(l-lactide) and epsilon-caprolactone P(LA-CL).

12. The thread (1) according to any one of the preceding claims, comprising a suture needle (5; 50) having a substantially straight or curved shape, arranged in correspondence of another longitudinal end (22) of said main body (2) opposite to that associated to said stopper (3).

13. A reel, comprising a plurality of threads (1), each according to any one of the preceding claims, which threads (1) are arranged in a longitudinal sequence and removably connected in correspondence of respective ends.

14. A method for manufacturing a thread (1) according to any one of the claims 1 to 12, comprising the steps of:

- providing the main body (2) of the thread;
- providing a mould having a shape corresponding to that of said stopper (3), preferably in the form of a seat (60) obtained in a plate (61);
- melting inside of said mould a selected material for manufacturing said stopper (3); and
- heat-sealing said main body (2) to said stopper (3) by inserting one end (21) of said main body (2) into said molten material and a subsequent cooling of the assembly.

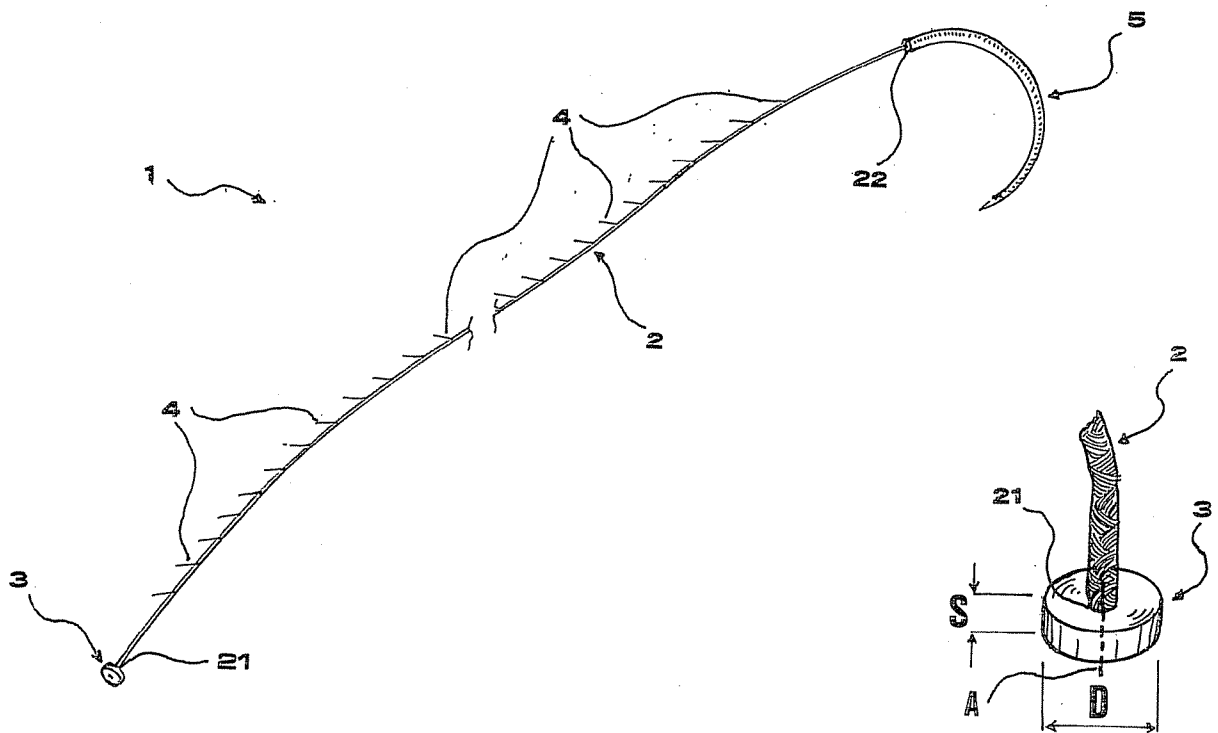


FIG. 1

FIG. 1A

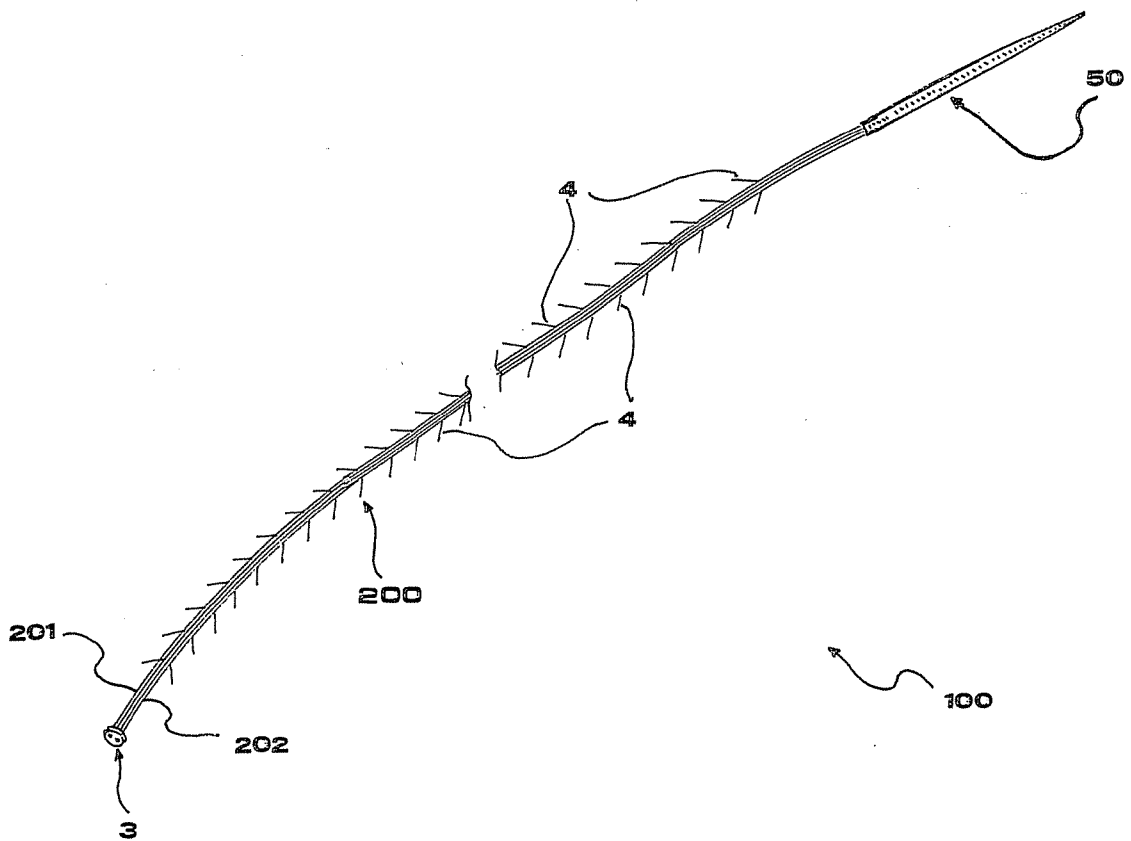


FIG. 2

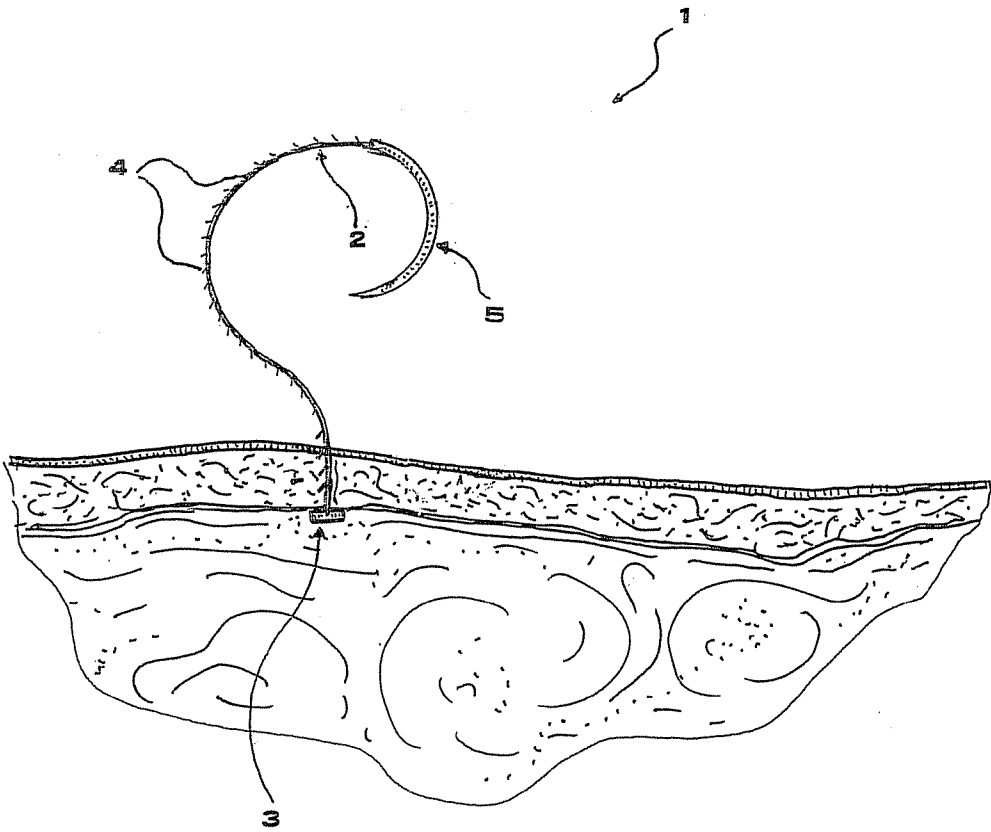


FIG.3

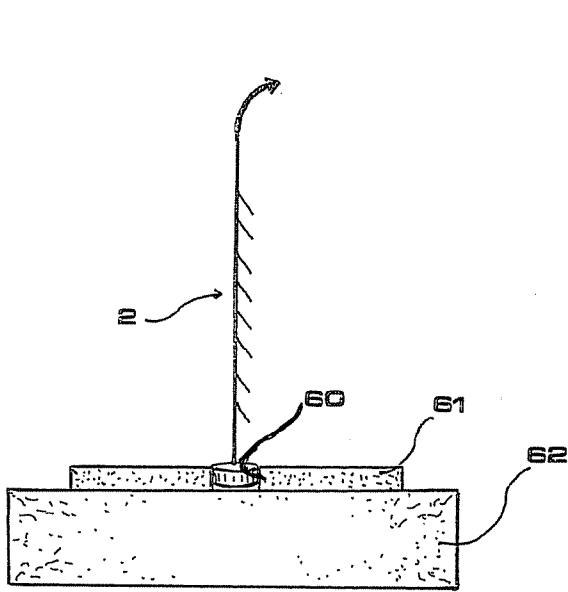


FIG. 4A

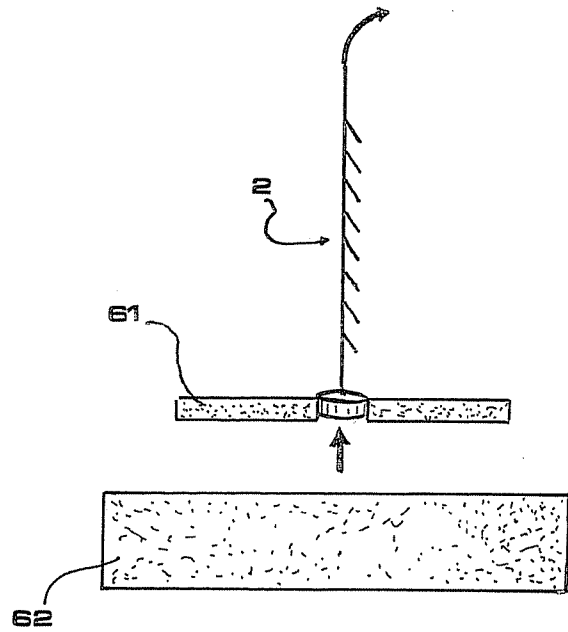


FIG. 4B

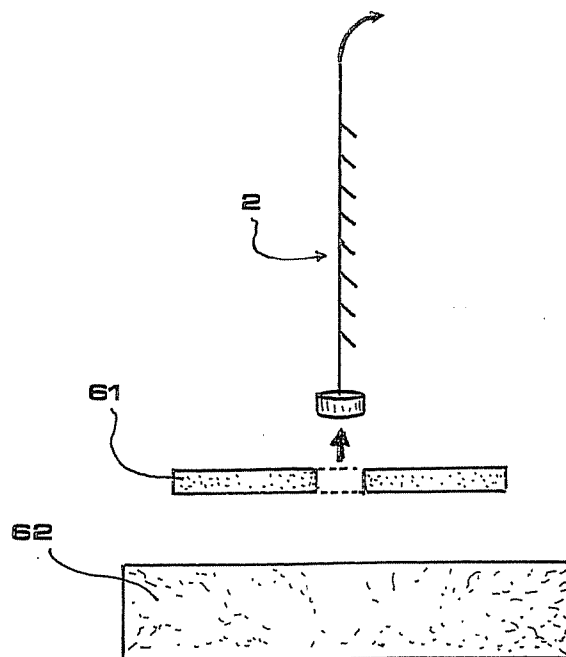


FIG. 4C

INTERNATIONAL SEARCH REPORT

International application No

PCT/IB2011/053016

A. CLASSIFICATION OF SUBJECT MATTER
 INV. A61B17/04 A61B17/06
 ADD.

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)

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)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2009/248067 A1 (MAIORINO) 1 October 2009 (2009-10-01)	1-6, 9-12, 14
Y	abstract; claims; figures paragraphs [0052], [0059] - [0063] -----	13
Y	W0 97/09935 A1 (Y00N) 20 March 1997 (1997-03-20) abstract; figures 1,6,7, 13-23,31-33 page 18, line 18 - page 20, line 8 -----	13
X	W0 2005/016176 A2 (LEIBOFF) 24 February 2005 (2005-02-24) abstract; figures 6,20,27 page 8, lines 19-26 page 11, lines 8-14 page 14, lines 8-10 -----	1-4,7-9 , 11, 12
	-/- .	



Further documents are listed in the continuation of Box C.



See patent family annex.

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Date of the actual completion of the international search

14 September 2011

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INTERNATIONAL SEARCH REPORT

International application No

PCT/IB2011/053016

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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X	US 6 506 197 B1 (ROLLER0 ET AL.) 14 January 2003 (2003-01-14) abstract; figures 1,4A-6C,9 -----	1,5-9,12
X	US 6 596 014 B2 (LEVINSON ET AL.) 22 July 2003 (2003-07-22) abstract; figures column 20, lines 12-38 -----	1,10,14

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

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