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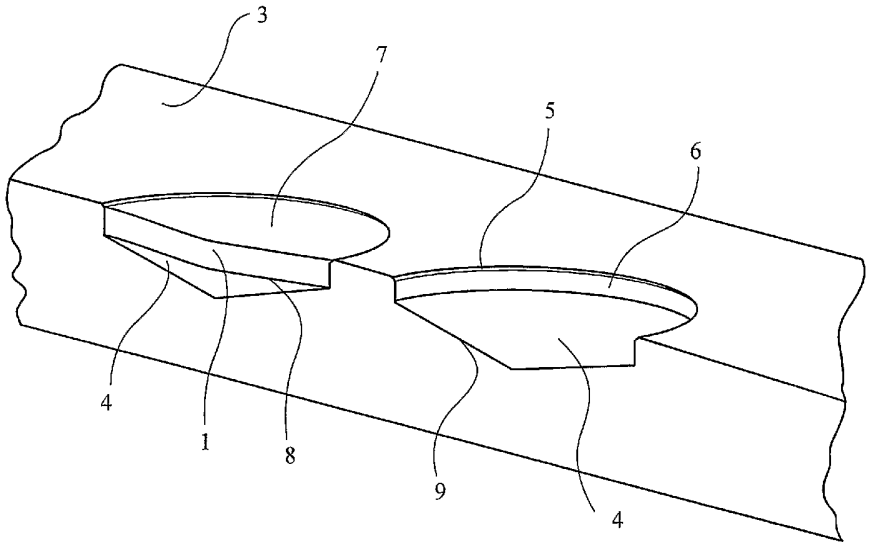
(54) Title: LABELLING SYSTEM



(57) Abstract: A method of labelling a surgical instrument comprising the steps of: -providing a recess (4, 10) in a surface of the surgical instrument; -pushing a resilient disc (1, 12A, 12B) into said recess so that hoop stress in said disc retains said disc within said recess.

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Declaration under Rule 4.17:

— *of inventorship (Rule 4.17(iv)) for US only*

Published:

— *with international search report*

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

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.

LABELLING SYSTEM

This invention relates to the field of labelling medical instruments, in particular those for use in sterile surgical conditions.

Surgical instruments may be colour-coded with a label in order to visually indicate their size, purpose, left or right-handedness or other characteristics. A non-exhaustive list of instruments having such labelling includes: hip, knee, toe, spinal, shoulder, elbow and tibial instruments, femoral reamers, rasps, graters and cutting blocks.

The colour-coded labels generally comprise one or more regions of colour, whose meaning is determined with reference to a key.

Such colour-coded labels must be:

1. non-toxic, as the instrument is obviously intended to be used in a sterile environment;
2. permanently fixed to the instrument as it is clearly very undesirable for the label to become detached and fall into the operating area;
3. durable so that there is substantially no colour fading or corrosion over time;
4. substantially unaffected by sterilisation processes, autoclaves, ultrasound treatment, heat treatment etc.

A known method of colour-coded labelling for surgical instruments comprises using one or more coloured plastic rings, plugs, press-pins or tags. Such labels are physically attached to the surgical instruments and

occasionally suffer the problem of becoming undesirably detached from the instruments, not only creating a medical risk to the patient but also meaning the unlabelled instrument cannot be sterilised and used again.

Furthermore, it is not always possible to conveniently attach such a label to some instruments. Those instruments which are particularly small or thin may not comprise enough material to which a label could be attached.

It is labour-intensive and therefore expensive to attach physical colour-coded labels to each surgical instrument.

Finally, it is undesirable to have the colour-coded label physically protruding from (i.e. not flush with) the surface of the instrument, creating a risk that the label may be broken off.

As an alternative to a physically-attached label, it is known to create a depression or recess at a convenient location on the instrument and then fill this recess with a coloured epoxy resin which, when cured, forms a solid coloured label within the recess. This has the advantage of the label being flush with the surface of the instrument.

However, any epoxy resin to be used in a surgical environment must be subjected to rigorous tests as to its non-toxicity. Furthermore, there is a significant risk that, during heat treatment in an autoclave for example, the epoxy resin label may expand at a different rate to the instrument and become loosened or detached from the recess in which it is located. The label may then fall

off the instrument in the autoclave or, even more undesirably, during a surgical procedure.

It is therefore an object of the present invention to provide apparatus and a method for colour-coding surgical instruments which seeks to alleviate the above-described problems.

According to a first aspect of the present invention there is provided a method of labelling a surgical instrument comprising the steps of:

providing a recess in a surface of the surgical instrument;

pushing a resilient disc into said recess so that hoop stress in said disc retains said disc within said recess.

The hoop stresses in the disc cause the disc to be firmly retained within the recess, making it difficult to remove deliberately and very unlikely to fall out accidentally. The top surface of the disc is preferably concave so that no part of the disc protrudes above the surface of the surgical instrument.

The coloured disc therefore provides a clear and durable colour-coded label for the surgical instrument which can withstand the repeated sterilisation and/or heat treatment processes to which a surgical instrument is typically subjected.

Preferably, said recess has an inwardly-tapered wall.

Preferably, said disc and said recess are substantially circular.

In a preferred form, a lowermost surface of the recess is generally conical.

Preferably, the disc is provided with at least one edge blend radius.

Preferably, the recess is provided with at least one edge blend radius.

The edge blend radiuses on the disc and/or recess facilitate the pressing of the disc into the recess.

In a preferred form, said disc is pushed into said recess using a hydraulic press.

Preferably, said disc is made from acetal. Alternatively, the disc is made from PEEK [PolyEtherEtherKetone].

Preferably, the disc is manufactured using injection moulding techniques.

In a preferred form, two or more recesses are provided on the surgical instrument.

According to a second aspect of the invention there is provided a surgical instrument labelled using the method of any of the preceding paragraphs.

According to a third aspect of the invention there is provided a colour-coded label comprising a resilient disc used in the method of any of the preceding paragraphs.

Preferred embodiments of the present invention will now be more particularly described by way of example only,

with reference to the accompanying drawings wherein:

Figure 1 shows a chamfer cutter including a colour-coded label;

Figure 2 is a perspective view of a disc label embodying one aspect of the present invention;

Figure 3 is a side view of the disc shown in Figure 2;

Figure 4 is a schematic perspective view of a section of a surgical instrument, showing two recesses and one disc label in place;

Figure 5 is a schematic side view of the section of the surgical instrument shown in Figure 4; and

Figure 6 is a schematic perspective view of an alternative embodiment of the invention.

Throughout this description, reference to the term "disc" is not limited to meaning a strictly circular disc.

Figure 1 shows a chamfer cutter which includes a colour-coded label 20.

Referring to Figures 2 and 3, the colour-coded label comprises a substantially planar plastics disc 1 which can be of any desired colour. The lowermost edge of the disc has an edge blend radius 2.

The disc is made from a plastic having a relatively high melting point. The disc must be capable of withstanding repeated autoclave operations at temperatures in the region of 135°C and it is therefore preferable to utilise

a plastic with a melting point significantly higher than this. Acetal, which may be used, has a melting point in the region of 150-160°C. Alternatively, PEEK [PolyEtherEtherKetone] can be used which has a much higher melting point - in the region of 300°C. Other suitable materials may be envisaged.

The selected material is formed into a disc using injection moulding techniques. The disc so formed is pressed into the stainless steel of the surgical instrument. The disc needs to be resilient, i.e. must be capable of flexing to at least some extent. The disc is coloured according to a standard key to give a predefined meaning thereto and, optionally, may be provided with text and/or numerals thereon.

The surgical instrument 3 is provided with one or more recesses 4 of a suitable size to receive the disc 1. The recesses 4 may be created by using a pre-formed drill sink to the desired depth then, using an oscillating specific angle dovetail cutter, enlarging the recess to the desired diameter. The uppermost edge of each recess has an edge blend radius 5. The side walls 6 of each recess are tapered inwardly, as best shown in Figure 5.

In order to label the surgical instrument 3, a downward force is applied to the disc 1 so that it is pushed downwardly into the recess 4. As the edge 2 of the disc contacts the uppermost edge 5 of the recess 4, the disc is guided into the recess. Once edge 2 (on the disc) and edge 5 (on the recess) have passed one another, the tapered walls 6 of the recess cause the disc 1 to flex inwardly, as best shown in Figure 4.

Once the disc 1 is fully engaged in the recess 4, the

upper surface 7 of the disc is slightly concave and hoop stresses in the disc retain it in position.

The lowermost surface of the recess needs to be shaped so that there is sufficient space for the slightly convex lower surface 8 of the disc to fit therein. For example, the lowermost surface 9 of the recess may be conical as illustrated in Figure 4.

The slightly concave upper surface of the disc is advantageous as it means that no part of the colour-coded label (i.e. the disc) protrudes beyond the surface of the surgical instrument 3, eliminating the risk that any part of the colour-coded label could be broken off.

Furthermore, the extremely tight fit of the disc within the recess reduces the risk of loosening of the label over time and during repeated heat treatment of the surgical instrument.

The downward force necessary to apply the disc into the recess is typically of the order of 4-5kg. This force could be applied by a hydraulic press in a straightforward manner, when compared with the labour-intensive application of conventional coloured plastic rings, plugs, press-pins or tags.

An alternative embodiment of the invention is shown in Figure 6. In this embodiment, a recess 10 is provided in the surface of the surgical instrument 3; the recess includes an internal ridge 11 which is inwardly-protruding. The ridge 11 need not be continuous as illustrated in Figure 6, but may comprise one or more discrete ridges.

The disc 12 is provided with a peripheral groove 13 of suitable dimensions to locate over the ridge 11. The peripheral groove 13 is deep enough to, effectively, divide the disc into two (joined) parts 12A and 12B, the extremities of which are capable of some movement or flexibility with respect to one another.

In use, the disc 12 is pushed into the recess 10, causing part 12A of the disc to flex relative to part 12B so that it can ride over the ridge 11.

Once part 12A is past the ridge 11, the ridge is located within the groove 13 and the disc 12 is firmly retained within the recess 10. Again, since the disc is flush with the surface of the surgical instrument 3, there is no risk of part of the colour-coded label (i.e. the disc) being broken off.

The disc and recess may be of any suitable alternative shape to that illustrated in Figure 6, so long as a ridge and groove are provided, as discussed above.

CLAIMS

1. A method of labelling a surgical instrument comprising the steps of:

providing a recess in a surface of the surgical instrument;

pushing a resilient disc into said recess so that hoop stress in said disc retains said disc within said recess.

2. A method as claimed in claim 1 wherein said recess has an inwardly-tapered wall.

3. A method as claimed in claim 1 or claim 2 wherein said disc and said recess are substantially circular.

4. A method as claimed in any of the preceding claims wherein a lowermost surface of the recess is generally conical.

5. A method as claimed in any of the preceding claims wherein the disc is provided with at least one edge blend radius.

6. A method as claimed in any of the preceding claims wherein the recess is provided with at least one edge blend radius.

7. A method as claimed in any of the preceding claims wherein said disc is pushed into said recess using a hydraulic press.

8. A method as claimed in any of the preceding claims wherein said disc is made from acetal.

9. A method as claimed in any of the preceding claims wherein said disc is made from PEEK [PolyEtherEtherKetone].

10. A method as claimed in any of the preceding claims wherein said disc is manufactured using injection moulding techniques.

11. A method as claimed in any of the preceding claims wherein two or more recesses are provided on the surgical instrument.

12. A method of labelling a surgical instrument substantially as described herein with reference to any appropriate combination of the accompanying drawings.

13. A surgical instrument labelled using the method of any of the preceding claims.

14. A colour-coded label comprising a resilient disc used in the method of any of the preceding claims.

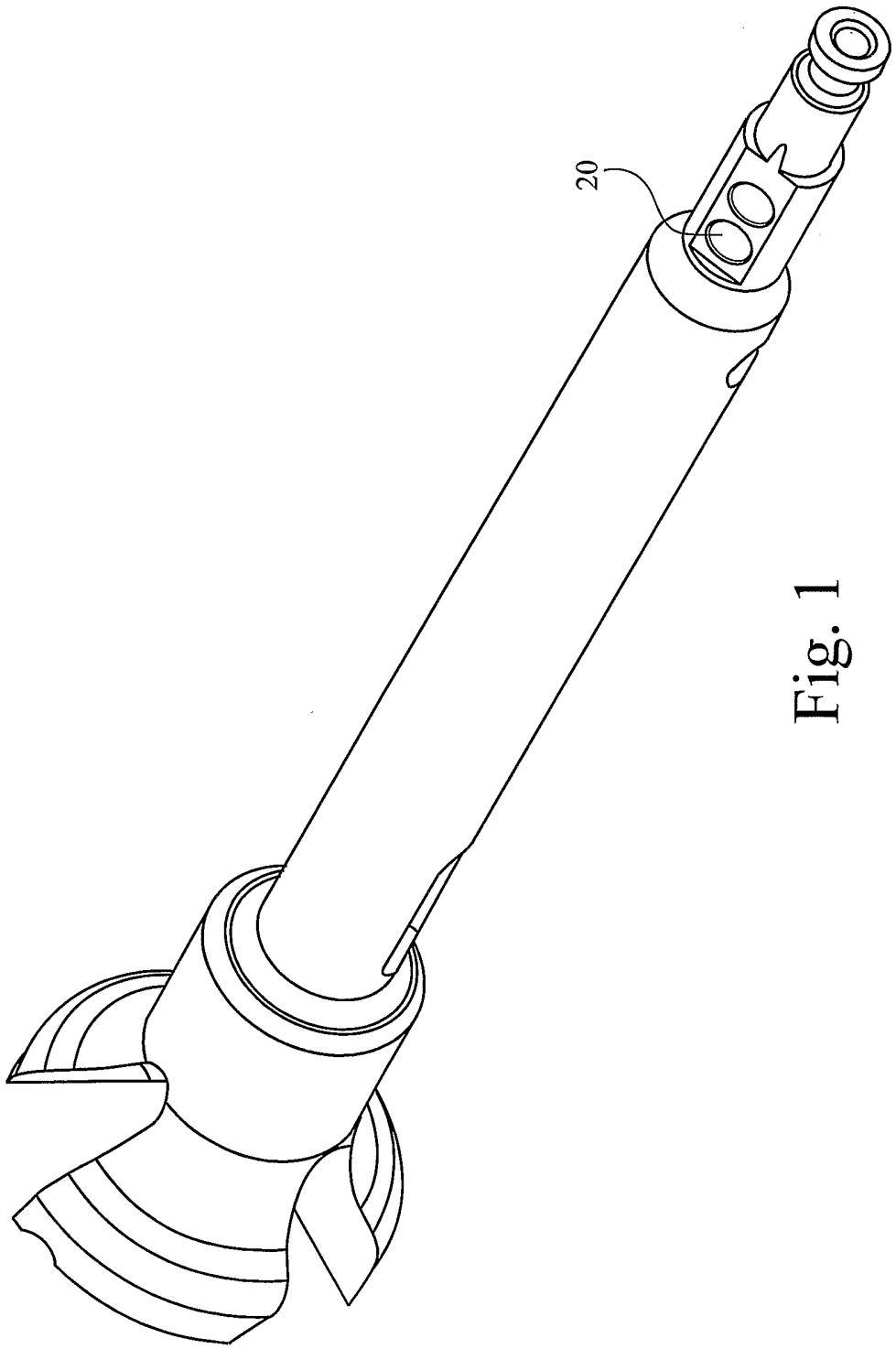

Fig. 1

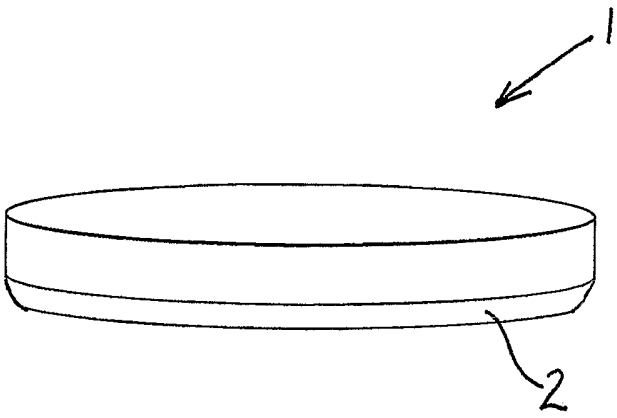

FIGURE 2

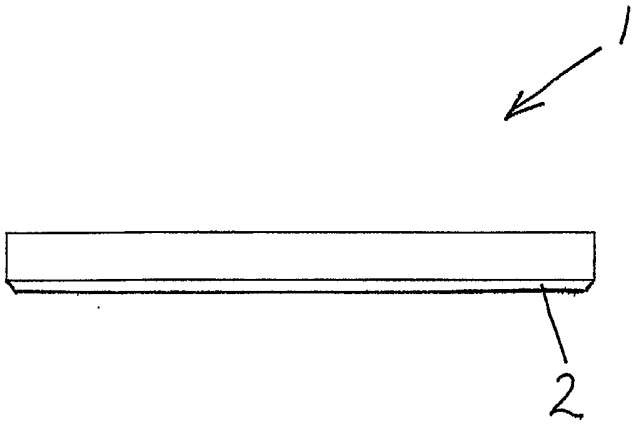

FIGURE 3

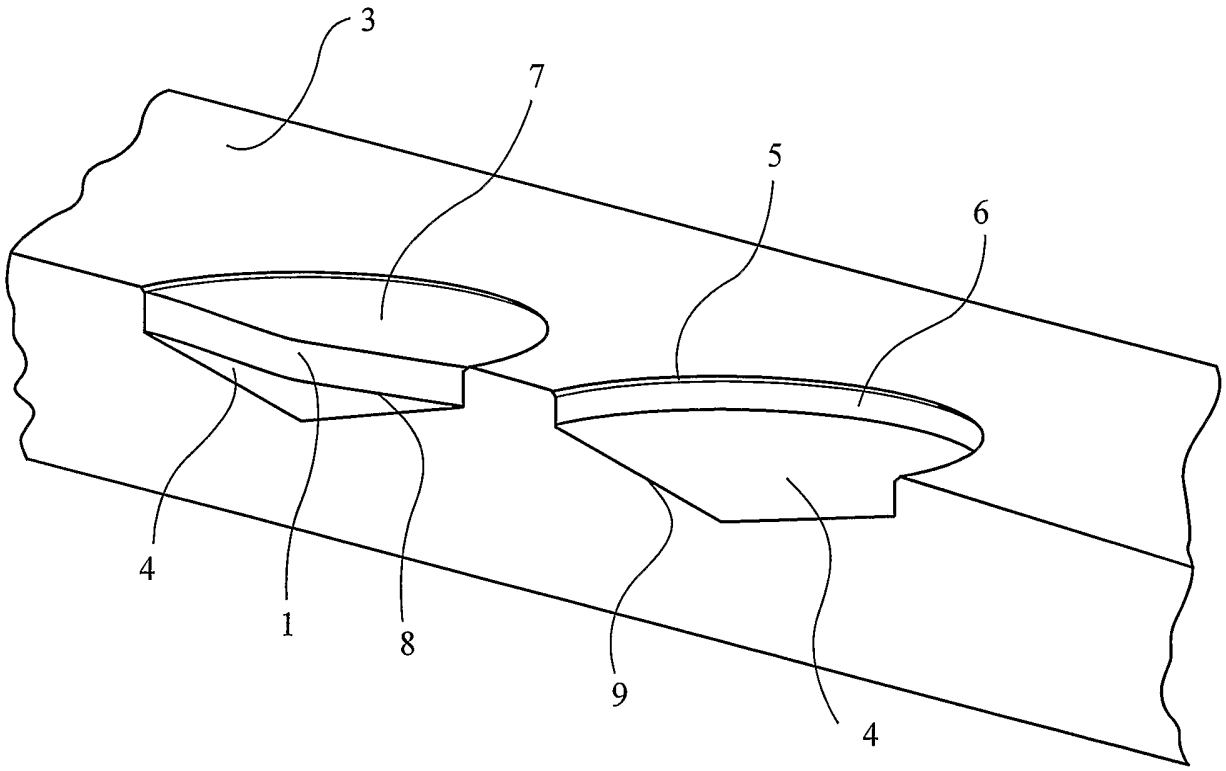

Fig. 4

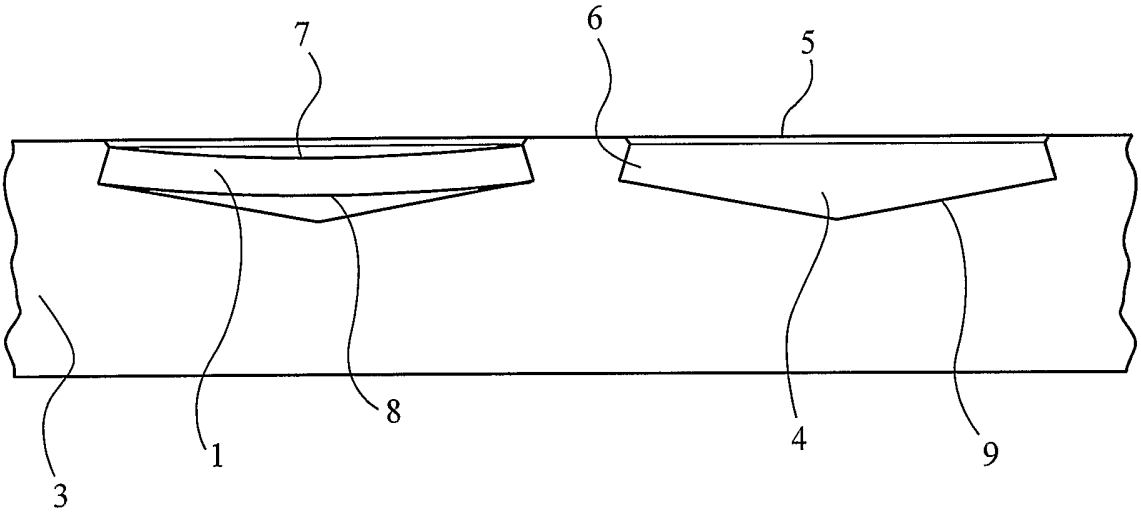

Fig. 5

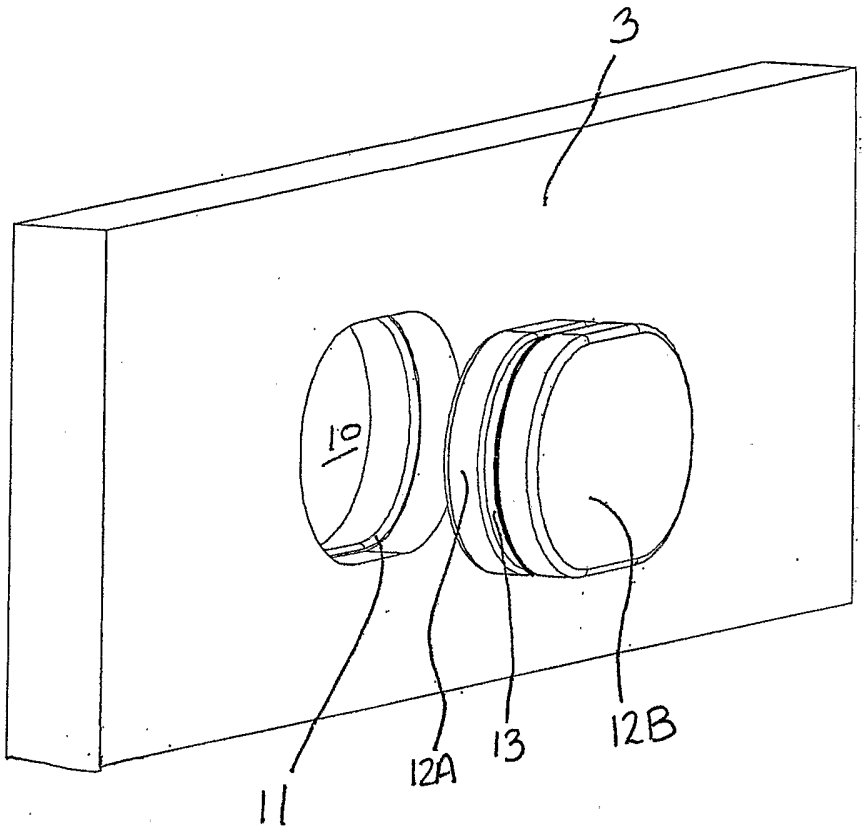

FIGURE 6

INTERNATIONAL SEARCH REPORT

Application No
PCT/GB2004/005388

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B19/00 G09F3/04

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 G09F

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.
Y	EP 1 238 636 A (ORTHOFIX S.R.L) 11 September 2002 (2002-09-11) figures 3,7,9,11	1-6, 8-11,13, 14
Y	DE 196 35 994 A1 (ADOLF WUERTH GMBH & CO. KG, 74653 KUENZELSAU, DE) 12 March 1998 (1998-03-12) column 2, lines 22-31 column 3, lines 36-39 column 4, line 42	1-3,9, 11,13,14
Y	FR 2 770 127 A (OURY GUYE ET FILS) 30 April 1999 (1999-04-30) page 4, line 21 figures 2,3	4,8

-/--

[X] Further documents are listed in the continuation of box C.

[X] 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	Date of mailing of the international search report
28 April 2005	10/05/2005

Name and mailing address of the ISA	Authorized officer
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	Schießl, W

Form PCT/ISA/210 (second sheet) (January 2004)

INTERNATIONAL SEARCH REPORT

Application No
PCT/GB2004/005388

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	EP 0 829 842 A (ADOLF WUERTH GMBH & CO. KG) 18 March 1998 (1998-03-18) figure 1	5,6,10
A	US 6 030 386 A (TAYLOR ET AL) 29 February 2000 (2000-02-29) figure 5	1

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.2

Claims Nos.: 12

Due to unspecific reference to the description, the features of claims 12 are entirely unclear.

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guideline C-VI, 8.5), should the problems which led to the Article 17(2) declaration be overcome.

INTERNATIONAL SEARCH REPORT

application No.
PCT/GB2004/005388

Box II Observations where certain claims were found unsearchable (Continuation of item 2 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.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☒ Claims Nos.: 12
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:
see FURTHER INFORMATION sheet PCT/ISA/210

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 III Observations where unity of invention is lacking (Continuation of item 3 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

Application No
PCT/GB2004/005388

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