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(54) Title: MEDICAL DEVICE AND METHOD

(57) Abstract: A device and method for cutting and collecting bone debris. The device comprises a receptacle having an opening, the receptacle opening being disposed with respect to a cutting tool such that, in use, bone debris produced by the cutting tool is received by the receptacle. The opening of the receptacle may have dimensions corresponding to those of the cutting tool. The receptacle may be shaped so that it does not extend beyond the outer periphery of the cutting tool.

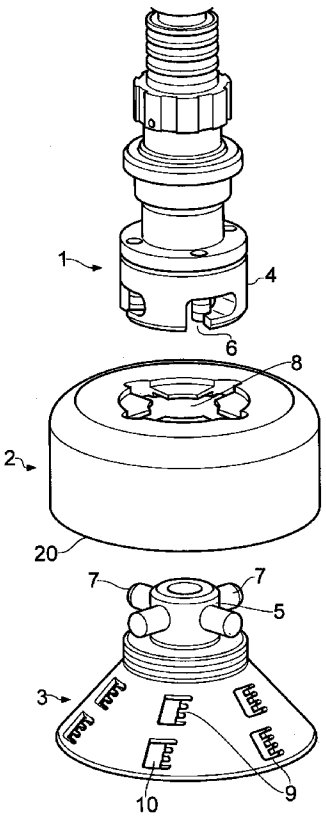

FIG. 1

WO 2009/024798 A1

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, HR, HU, IE, IS, IT, LT, LU, LV, MC, MT, NL, NO, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

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— *with international search report*

Medical Device and Method

The present invention relates to medical devices, in particular devices for collecting bodily matter created during a surgical operation. Devices in accordance with the present invention may collect debris generated during cutting of a bone.

During orthopaedic surgery, debris from bone and cartilage is created by the instruments used to prepare the bone, for example cutting tools such as reamers. For example, during a hip resurfacing operation, bone debris is created from the instruments used to prepare the femoral head to the required dimensions. Hip resurfacing procedures involve reaming the femoral head and drilling a centralised stem hole. These procedures produce a significant amount of bone debris which is dispersed widely in the surrounding tissues. The greatest amount of debris is created when using a chamfer cutter.

Bone debris is problematic in a surgical site for a number of reasons. The debris can obstruct the surgeon's view of the surgical site, which may compromise the operation. The debris can also compromise the operation of surgical instruments, for example by getting caught in any moving parts. It is also essential during surgery to keep the wound clean. Bone debris may lead to heterotopic ossification. Moderate to severe heterotopic ossification can negate the benefits of replacement surgery and reducing bone debris has been shown to reduce the incidence of heterotopic ossification.

It is known to cover the surgical site with swabs in order to minimise the amount of bone debris entering the surgical site. For example, during hip resurfacing the area below the femoral neck is commonly covered using swabs in order to minimise the amount of bone debris entering the acetabulum. However, swabs can also obstruct the surgeon's view of the surgical site. Swabs can also compromise the operation of surgical instruments because the fibres of the swab can get caught in moving parts, for example a femoral reamer.

In addition to the use of swabs, the wound needs to be fully cleaned on completion of the operation in order to remove any bone debris or swab fibres.

It is an aim of the present invention to provide a device for collecting bodily matter such as bone debris from a surgical site that overcomes the problems associated with known surgical techniques.

According to a first aspect of the present invention, there is provided a device for collecting bone debris, comprising: a receptacle having an opening, the receptacle opening being disposed with respect to a cutting tool such that, in use, bone debris produced by the cutting tool is received by the receptacle.

According to a second aspect of the present invention, there is provided a device for collecting bone debris, comprising: a receptacle having an opening, the receptacle opening being disposed with respect to the cutting tool such that, in use, bone debris produced by the cutting tool is received by the receptacle, wherein the opening of the receptacle has dimensions corresponding to those of the cutting tool.

According to some embodiments of the present invention, the receptacle may have an outer periphery that matches the outer periphery of the cutting tool.

According to some embodiments of the present invention, the cutting tool has a substantially circular outer periphery and the receptacle has a substantially circular outer periphery, wherein the diameter of the outer periphery of the cutting tool is substantially the same as the diameter of the outer periphery of the receptacle.

According to a third aspect of the present invention, there is provided a device for collecting bone debris, comprising: a receptacle having an opening, the receptacle opening being disposed with respect to the cutting tool such that, in use, bone debris produced by the cutting tool is received by the receptacle, wherein the cutting tool has an outer periphery and the receptacle is shaped so that it does not extend beyond the outer periphery of the cutting tool.

According to some embodiments of the present invention, the diameter of the receptacle does not extend beyond the diameter of the cutting tool.

According to some embodiments of the present invention, the diameter of the receptacle is substantially the same or less than the diameter of the cutting tool.

According to a fourth aspect of the present invention, there is provided a kit of parts, comprising: a receptacle according to the first, second or third aspects of the present invention; and a plurality of cutting tools according to the first, second or third aspects of the present invention, the cutting tools differing in size.

The kit of parts provides a modular system in which a particular receptacle fits (is compatible with) multiple cutting tools of different sizes. Modular systems may also be provided comprising a plurality of receptacle sizes, each receptacle being compatible with a plurality of cutting tools. For example, the or each receptacle may be compatible with three different size cutting tools.

According to a fifth aspect of the present invention, there is provided a device for cutting bone, comprising:

a cutting portion having a distal surface and a proximal surface, wherein the distal surface has at least one cutting means; and

a receptacle disposed with respect to the proximal surface of the cutting portion such that, in use, bone debris produced by the cutting portion is received by the receptacle.

According to some embodiments of the present invention, the cutting portion comprises at least one conduit disposed such that bone can move through the cutting portion from the distal surface to the receptacle via the or each conduit.

According to some embodiments of the present invention, at least one conduit forms a cutting means on the distal surface of the cutting portion.

Devices according to the present invention have a number of advantages. They collect bone debris as it is produced by the cutting tool. Accordingly, bone debris is not dispersed into the surgical site and surrounding tissues. The surgeon therefore does not have to rely on swabs and thorough cleaning. The surgeon can also perform the operation without

obstruction of his view of the surgical site. The risk of bone debris becoming caught in moving parts is also minimised, if not eliminated. Furthermore, the risk of heterotopic ossification is also minimised, if not eliminated.

Devices according to the present invention also have the advantage that the receptacle is securely connected to the cutting tool during operation of the instrumentation. There is therefore no risk of the receptacle becoming detached accidentally and discarding the bone debris into the surgical site. The rigid and secure connections provided by devices according to the present invention optimise repeated operation of the cutting devices.

Embodiments of the present invention wherein the opening of the receptacle has dimensions corresponding to those of the cutting tool and/or wherein the receptacle is shaped so that it does not extend beyond the outer periphery of the cutting tool, have an advantage in that they are optimal for a less invasive surgical approach. Such embodiments of the present invention add the minimum amount of bulk to the cutting tool, thereby optimising them for minimally invasive surgery.

Furthermore, according to some embodiments of the present invention, the devices are reusable after appropriate sterilisation.

The following features and embodiments may apply to the first, second, third, fourth and fifth aspects of the present invention, as appropriate.

According to some embodiments of the present invention, the device is a receptacle that is releasably attachable to a cutting tool.

According to some embodiments of the present invention, the device comprises a receptacle fixedly attached to a cutting tool.

The cutting tool may comprise one or more cutting surfaces and a drive shaft. The device may be disposed between the cutting surface(s) and the drive shaft.

The receptacle and the cutting tool may be formed as a single piece. That is, the receptacle, cutting surface and drive shaft may be formed as a single piece.

The receptacle and the cutting surface may be formed as a single piece. The drive shaft may be attachable to the receptacle and cutting surface.

The cutting tool may be a reamer. The reamer may be a chamfer cutter. The reamer may be a profile cutter.

The receptacle opening may be shaped so as to mate with the peripheral edge of the proximal surface of a reamer.

The cutting tool may be a sleeve cutter.

The receptacle opening may be shaped so as to mate with the peripheral edge of the proximal end of the sleeve cutter.

The receptacle may be fixedly attached to the cutting surface.

The receptacle may be fixedly attached to the cutting surface and the drive shaft.

The receptacle may be releasably attached to at least one of the cutting surface and the drive shaft.

The receptacle may comprise a second opening, or further openings, for removal of bone debris from the receptacle.

The receptacle may comprise a cylinder. The cylinder may be an open cylinder. The cylinder may be partially closed at one or both ends. The cylinder may be closed at a first end and open at a second end.

The cylinder may have an outside diameter in the range 45 to 75 mm. The cylinder may have an outside diameter in the range 50 to 70 mm. The cylinder may have an outside

diameter in the range 55 to 65 mm. The cylinder may have an outside diameter of around 60 mm.

The cylinder may have a length (height) in the range 15 to 50 mm. The cylinder may have a length in the range 15 to 45 mm. The cylinder may have a length in the range 20 to 45 mm. The cylinder may have a length in the range 20 to 40 mm. The cylinder may have a length in the range 20 to 35 mm. The cylinder may have a length in the range 20 to 30 mm. The cylinder may have a length of around 25 mm.

The device may be made of metal. The device may be made of metal alloy. The device may be made of titanium. The device may be made of a titanium alloy. The device may be made of stainless steel. The device may be made of cobalt chrome alloy.

The device may be made of plastic. The device may be made of polyethylene. The device may be made of polypropylene. The device may be made of polyacetal. The device may be made of polyphenylsulfone.

According to a sixth aspect of the present invention, there is provided a method of cutting a bone, comprising the steps of:

providing a cutting tool;

providing a receptacle, the receptacle having an opening;

disposing the receptacle with respect to the cutting tool such that, in use, bone debris produced by the cutting tool is received by the receptacle via the opening; and

cutting the bone with the cutting tool and thereby collecting bone debris in the receptacle.

According to a seventh aspect of the present invention, there is provided a method of cutting a bone, comprising the steps of:

providing a receptacle and cutting tool according to any of the first, second, third or fourth aspects of the present invention;

engaging the cutting tool with a bone; and

cutting the bone and thereby collecting bone debris in the receptacle.

According to an eighth aspect of the present invention, there is provided a method of cutting a bone, comprising the steps of:

providing a device for cutting bone according to the fifth aspect of the present invention;

engaging the cutting portion with a bone; and

cutting the bone and thereby collecting bone debris in the receptacle.

Reference will now be made, by way of example, to the accompanying drawings, in which:

Figure 1 shows a disassembled device according to an embodiment of the present invention;

Figure 2 shows the device of figure 1 when assembled;

Figure 3 shows a cross-sectional view of the device shown in figure 2; and

Figure 4 shows a device according to another embodiment of the present invention.

As shown in figures 1 to 3, the device comprises a modular drive shaft (1), a receptacle (2), and a cutting tool (3), which is a chamfer cutter in this particular embodiment. Other types of reamers or cutting instruments are in accordance with the present invention. For example, the cutting tool may be a reamer, such as an acetabular reamer. The cutting tool may be a sleeve cutter. The cutting tool may be a profile cutter.

In the embodiment shown in figures 1 to 3, the components (1-3) are separable. The modular drive shaft (1) has a connector (4) at its distal end that engages with a connector (5) on the proximal end of the cutting tool (3). The connectors (4,5) may be in the form of a bayonet type connection, as shown in figures 1 to 3. Connector (4) comprises one or more slots (6) or the like, and connector (5) comprises one or more pegs (7) or the like. When assembled, the one or more slots (6) receive the one or more pegs (7), thus forming the bayonet connection. In the embodiment shown in figures 1 to 3, connector (4) comprises four slots (6) and connector (5) comprises four pegs (7). Other types of connection, such as a screw fit or friction fit, are also in accordance with the present invention.

The receptacle (2) has an opening (20) on its distal end that is shaped such that it fits over and accommodates the reverse face (proximal side) of the cutting tool (3), as shown in figure 3. The receptacle (2) has an opening (8) on its proximal end that is shaped such that the connector (5) of the cutting tool (3) passes through the opening (8) and engages with connector (4) such that the receptacle (2) is locked in place between the drive shaft (1) and the cutting tool (3), as shown in figures 2 and 3. Drive shaft (1) imparts a torque to receptacle (2) and cutting tool (3) such that the cutting tool (3) rotates, causing the cutting means (serrated edge) (9) to cut bone when engaged with the bone. As shown in figure 3, bone debris will pass through the holes (10) and be collected in the space (11) formed between the cutting tool (3) and the receptacle (2).

Figure 4 shows an alternative embodiment of the invention in which a receptacle (12) is fixedly attached to a cutting tool (13), which is a chamfer cutter in this particular embodiment. The receptacle (12) is attached to the peripheral edge of the proximal surface of the cutting tool (13). The cutting tool (13) has a connector (5) as in the embodiment shown in figures 1 to 3 for connecting the cutting tool/receptacle (12,13) to a drive shaft (not shown).

Devices according to the present invention minimise, if not eliminate, the amount of bone debris entering the surgical site, by capturing the debris directly as it is produced from the cutting tool. The device is attached between the modular connection of the cutting tool and the drive shaft in order to ensure it is securely connected during the procedure. On completion of the cutting process the device can be removed and the debris discarded. This enables easy cleaning of the device and the cutting tool.

The procedure for using the device shown in figures 1 to 3 comprises the following steps:

1. Position the receptacle (2) over the drive connector (5) on the reverse face (proximal side) of the cutting tool (3).
2. Connect the modular drive shaft (1) connector (4) to the cutting tool (3) connector (5), thereby securing the receptacle (2) in place.

3. Connect drive shaft (1) to a power tool and use the cutting tool (3) to prepare the bone, for example a femoral head. During this process the receptacle (2) will collect the bone debris created.
4. Remove the drive shaft (1), cutting tool (3) and receptacle (2) from the surgical site.
5. Remove the receptacle (2) and discard the bone debris.

The same principle of collecting bone debris could be easily adapted to use in other types of reamers or cutting instruments, including acetabular reamers, sleeve cutters and profile cutters.

CLAIMS

1. A device for collecting bone debris, comprising: a receptacle having an opening, the receptacle opening being disposed with respect to a cutting tool such that, in use, bone debris produced by the cutting tool is received by the receptacle.

2. A device according to claim 1, wherein the opening of the receptacle has dimensions corresponding to those of the cutting tool.

3. A device according to claim 1 or 2, wherein the receptacle has an outer periphery that matches the outer periphery of the cutting tool.

4. A device according to any preceding claim, wherein the cutting tool has a substantially circular outer periphery and the receptacle has a substantially circular outer periphery, and wherein the diameter of the outer periphery of the receptacle is substantially the same as the diameter of the outer periphery of the cutting tool.

5. A device according to claim 1, wherein the cutting tool has an outer periphery and the receptacle is shaped so that it does not extend beyond the outer periphery of the cutting tool.

6. A device according to claim 5, wherein the diameter of the receptacle does not extend beyond the diameter of the cutting tool.

7. A device according to claim 5 or 6, wherein the diameter of the receptacle is substantially the same or less than the diameter of the cutting tool.

8. A device according to any preceding claim, wherein the receptacle is fixedly attached to the cutting tool.

9. A device according to any of claims 1 to 7, wherein the receptacle is reversibly attached to the cutting tool.

10. A device according to any preceding claim, wherein the receptacle is a cylinder closed at a first end and open at a second end.

11. A device according to any preceding claim, wherein the cutting tool has a cutting surface and a drive shaft, and the receptacle is disposed between the cutting surface and the drive shaft.

12. A device according to claim 11, wherein the cutting tool has a proximal surface, a distal cutting surface and a drive shaft, and wherein the receptacle is disposed between the proximal surface and the draft shaft.

13. A device according to claim 12, wherein the proximal and distal surfaces of the cutting surface comprise at least one conduit disposed such that bone can move through the cutting tool from the distal cutting surface to the receptacle via the or each conduit.

14. A device according to claim 13, wherein at least one conduit forms a cutting surface on the distal surface of the cutting tool.

15. A device according to any preceding claim, wherein the cutting tool is a reamer.

16. A device according to claim 15, wherein the receptacle opening is shaped so as to mate with the peripheral edge of the proximal surface of the reamer.

17. A device according to claim 15 or 16, wherein the reamer is a chamfer cutter.

18. A device according to claim 15 or 16, wherein the reamer is a profile cutter.

19. A device according to any of claims 1 to 14, wherein the cutting tool is a sleeve cutter.

20. A device according to claim 19, wherein the receptacle opening is shaped so as to mate with the peripheral edge of the proximal end of the sleeve cutter.

21. A device according to any of claims 14 to 20, wherein the receptacle is fixedly attached to the cutting surface.

22. A device according to any of claims 14 to 20, wherein the receptacle is fixedly attached to the cutting surface and the drive shaft.

23. A device according to any of claims 14 to 20, wherein the receptacle is releasably attached to at least one of the cutting surface and the drive shaft.

24. A device according to any preceding claim, wherein the receptacle further comprises a second opening for removal of bone debris from the receptacle.

25. A kit of parts, comprising: a receptacle according to any preceding claim; and a plurality of cutting tools according to any preceding claim, the cutting tools differing in size.

26. A device for cutting bone, comprising:

a cutting portion having a distal surface and a proximal surface, wherein the distal surface has at least one cutting means; and

a receptacle disposed with respect to the proximal surface of the cutting portion such that, in use, bone debris produced by the cutting portion is received by the receptacle.

27. A device according to claim 26, wherein the cutting portion comprises at least one conduit disposed such that bone can move through the cutting portion from the distal surface to the receptacle via the or each conduit.

28. A device according to claim 27, wherein at least one conduit forms a cutting means on the distal surface of the cutting portion.

29. A device substantially as hereinbefore described with reference to the drawings.

30. A method of cutting a bone, comprising the steps of:

providing a cutting tool;

providing a receptacle, the receptacle having an opening;

disposing the receptacle with respect to the cutting tool such that, in use, bone debris produced by the cutting tool is received by the receptacle via the opening; and

cutting the bone with the cutting tool and thereby collecting bone debris in the receptacle.

31. A method of cutting a bone, comprising the steps of:
providing a receptacle and cutting tool according to any of claims 1 to 25 and 29;
engaging the cutting tool with a bone; and
cutting the bone and thereby collecting bone debris in the receptacle.

32. A method of cutting a bone, comprising the steps of:
providing a device for cutting bone according to any of claims 26 to 29;
engaging the cutting portion with a bone; and
cutting the bone and thereby collecting bone debris in the receptacle.

33. A method substantially as hereinbefore described with reference to the drawings.

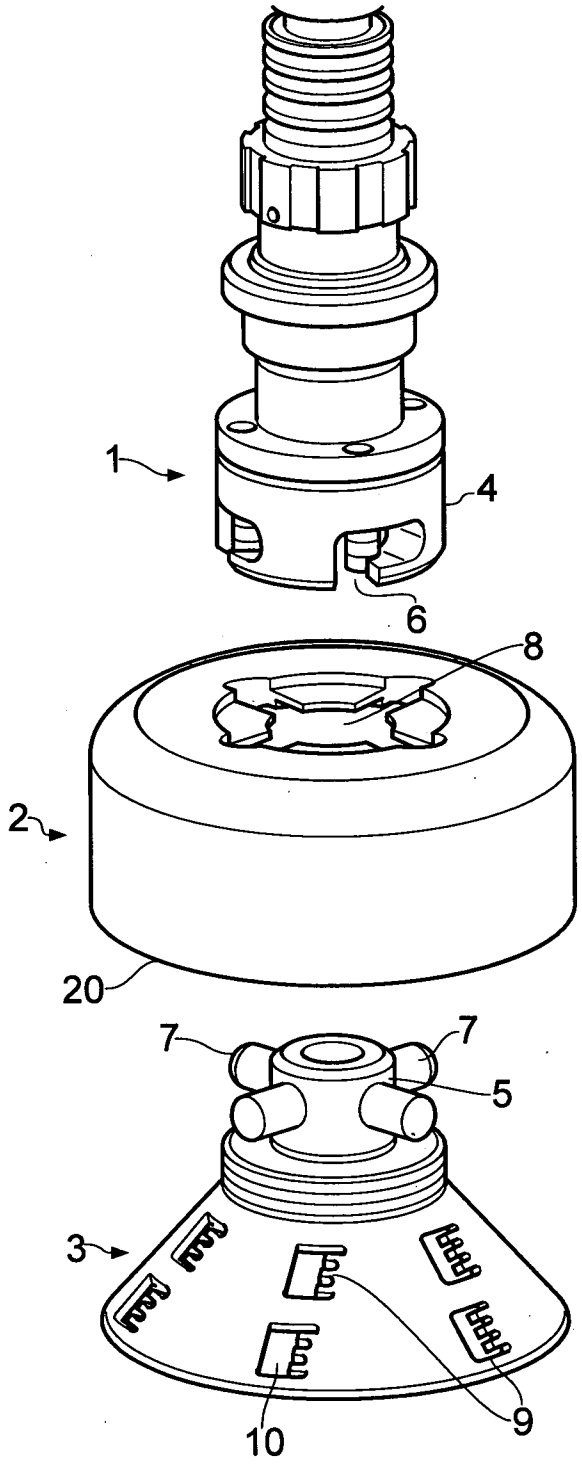

FIG. 1

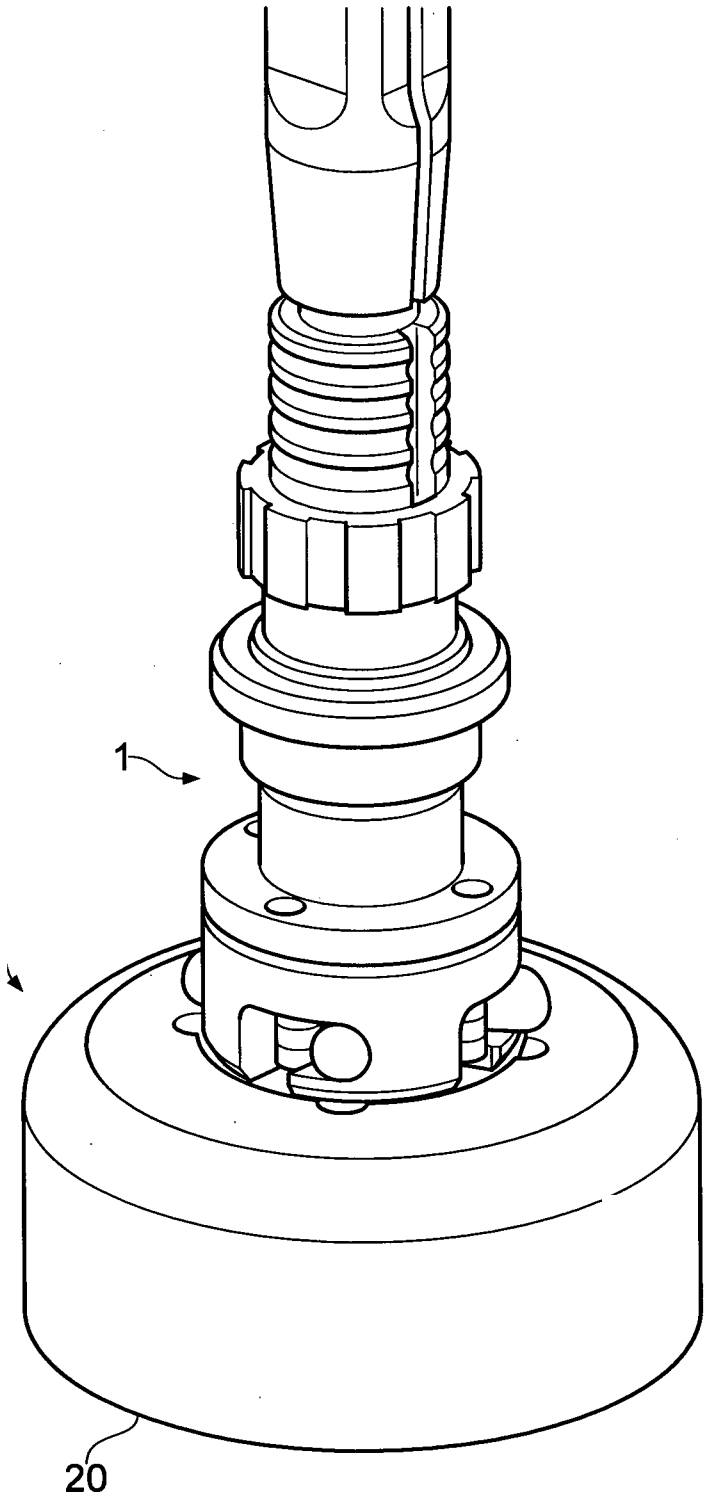

FIG. 2

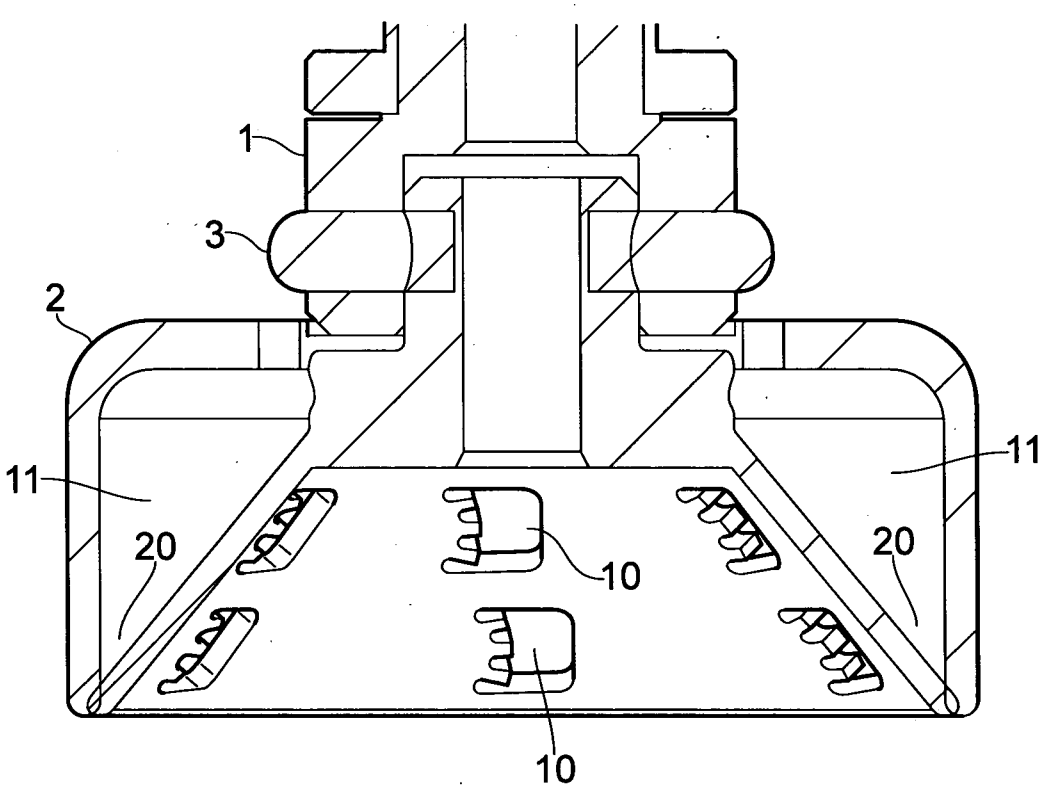

FIG. 3

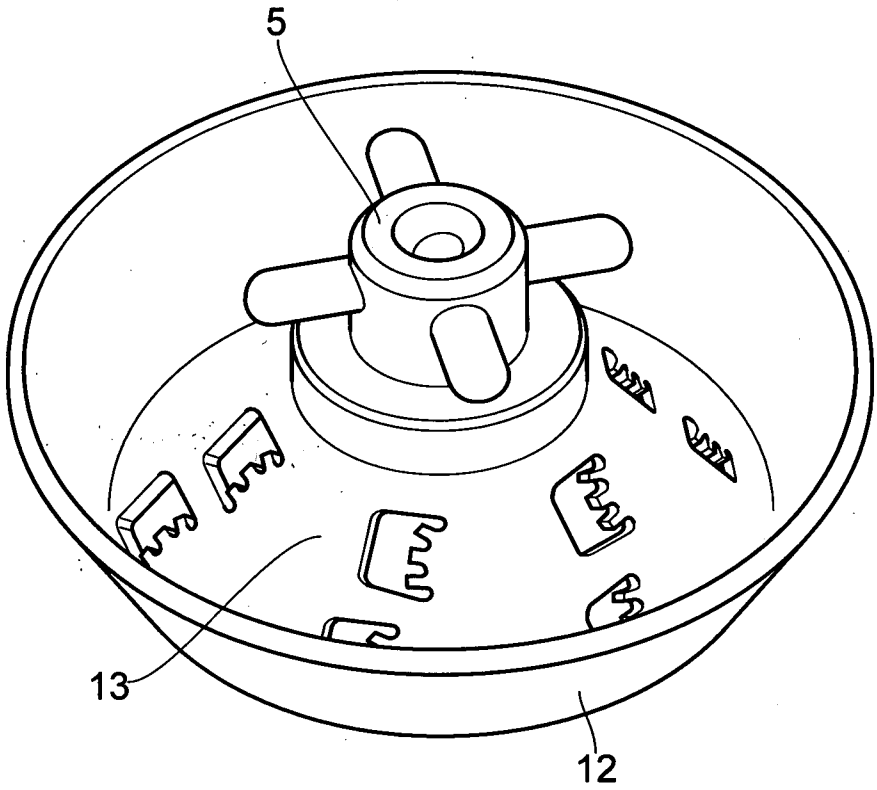

FIG. 4

INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2008/002865

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/16

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 4 116 200 A (BRAUN KARL ET AL) 26 September 1978 (1978-09-26) figure 1	1-29
X	WO 99/47051 A (FISHBEIN MEYER [US]; WHITE PATRICK MICHEL [US]) 23 September 1999 (1999-09-23) figure 22	1
X	EP 1 764 046 A (FINSBURY DEV LTD [GB]) 21 March 2007 (2007-03-21) figure 17	1
X	US 5 489 310 A (MIKHAIL W E MICHAEL [US]) 6 February 1996 (1996-02-06) figure 15	1

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

[X] See patent family 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
13 November 2008	27/11/2008

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, Fax: (+31-70) 340-3016	Fernández Arillo, J

Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2008/002865

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 5 885 298 A (HERRINGTON STEPHEN MICHAEL [US] ET AL) 23 March 1999 (1999-03-23) figures 4,5	1
X	US 6 325 806 B1 (FOX WILLIAM CASEY [US]) 4 December 2001 (2001-12-04) figure 3b	1
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X	US 6 162 227 A (ECKHARDT HARALD [DE] ET AL) 19 December 2000 (2000-12-19) figure 3	1
X	US 6 283 971 B1 (TEMELES RANDY S [US]) 4 September 2001 (2001-09-04) figures 3a,3b	1

INTERNATIONAL SEARCH REPORT

International application No.
PCT/GB2008/002865

Box No. 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. [X] Claims Nos.: 30-33
because they relate to subject matter not required to be searched by this Authority, namely:

Pursuant to Rule 39.1(iv) PCT, the subject-matter of claims 30-33 has not been searched, since it is directed to a method for treatment of the human body by surgery (cutting a bone).

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 No. 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 allsearchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search reportcovers 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 and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/GB2008/002865

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