

Cutting instruments for ultrasonic bone surgery

The present invention relates to cutting instruments for use in ultrasonic bone surgery. The instruments according to the invention are intended for use, particularly but not
5 exclusively, in the fields of orthopaedic surgery, neurosurgery, otorhinolaryngologic surgery, maxillofacial surgery, dental surgery and veterinary surgery.

The ultrasonic technique is widespread in bone surgery, where it is generally used also because it does not cause undesired cuts in the flesh. There are known surgical devices
10 containing electrically supplied piezoelectric transducers which cause vibration of a metal instrument that can cut the bone or separate biological tissues. See, for example, patent publications US-2 984 241, US-4 188 952 and EP-0 238 667.

It is an object of the invention to provide a cutting instrument capable of reaching more
15 easily inner zones of the human body which are difficult to access, such as narrow and deep recesses. Another object of the invention is to provide a cutting instrument allowing the surgeon to have a clear vision of both the cutting end of the instrument and the whole operating zone.

20 These objects are achieved, in accordance with the present invention, by a surgical instrument having the features defined in claim 1. Preferred embodiments of the invention are defined in the dependent claims.

The advantages of the invention will become apparent from the following detailed
25 specification, given by way of example, reference being made to the accompanying drawings, in which:

figure 1 is a side view of a first embodiment of a surgical cutting instrument according to the present invention;

figure 2 is a partial view of the free end of the instrument of figure 1 looking in the
30 direction of arrow II in figure 1;

figure 3 is a partial view similar to that of figure 2, of a second embodiment of an instrument according to the invention;

figure 4 is a side view of a third embodiment of a surgical instrument according to the invention;

figures 5 and 6 are partial views similar to those of figures 2 and 3, of a fourth and a fifth embodiment of the surgical instrument;

5 figures 7 and 8 are side views of a sixth and a seventh embodiment of the surgical instrument according to the invention;

figure 9 is a perspective view schematically showing an apparatus for vibrating the instruments of figures 1 to 9 at ultrasonic frequencies, and

figure 10 schematically shows a control panel of the apparatus of figure 9.

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A first embodiment of a surgical instrument for ultrasonic bone surgery according to the invention, shown in figures 1 and 2, is indicated as a whole at 10. The instrument 10, consisting of an elongate body made of titanium alloy, preferably titanium grade 5 alloy, extends along a central axis x having a succession of straight and curved lengths lying in a plane herein defined "vertical". The instrument 10 comprises a proximal length or locking tang 11 of rectilinear shape, a thin, straight distal length 12 with a sharp cutting end 13 and an intermediate length 14 which includes three successive curved portions with respective alternating concavities, as described in detail hereinafter.

20 The tang 11, substantially cylindrical and having an increased diameter with respect to that of the distal length 12, is adapted to be clamped or screwed or otherwise steadily mounted onto a cylindrical handpiece M (shown only in part) that the surgeon will grip. The handpiece is part of a medical ultrasonic apparatus which electrically supplies a set of piezoelectric transducers housed in the handpiece, so as to vibrate the instrument 10 at a frequency in the ultrasonic range. The constructional and functional features of the
25 aforementioned apparatus are not *per se* relevant for the understanding of the invention and will not therefore be described in detail. Suffice it here to say that said apparatus allows to adjust the input power and the frequency of the vibrations imparted to the instrument.

30 Figure 9 shows by way of example an ultrasonic apparatus A with a handpiece M connected through a cable C. Indicated F is a flowmeter for measuring the flow rate of a cooling physiological solution supplied by means of a peristaltic pump P. Apparatus A is

equipped with an on/off foot pedal B and a control panel CP (figure 10) comprised of keys 1, 2, 3 for selecting frequency channels as a function of the type of instrument being used, keys 4, 5, 6 for adjusting the flow rate supplied by the pump P, a knob 8 for selecting the frequency of the instrument mounted on the handpiece. By acting on the knob 8, one varies the frequency of the electric power supply, with a consequent impedance variation that causes a change in the frequency of vibration of the instrument. Keys B1 and B2 allow to select the power level supplied to the handpiece M, whereas displays D1 and D2 show the selected power and flow rate levels. A further display D3 shows the time the apparatus has been used. It can be reset by a key 9.

Vibrations are transmitted to the tang 11 in form of pulses along the axis x and are propagated and amplified through the intermediate length 14 and transmitted to the distal length 12 and the cutting end 13 that is brought in contact with the biological tissue to cut.

The distal length 12 extends in a direction substantially parallel to or coincident with that of the tang 11. As shown, while the tang 11 has a substantially uniform thickness, the intermediate and distal lengths 14 and 12 are progressively flattened and get thinner when measured in directions y1, y2, y3 which are perpendicular, in each point, to the central axis x and lie in the aforesaid vertical plane.

The intermediate length 14 has a first curved portion 14a with its concavity directed upwardly in the vertical plane, a second curved portion 14b with a downwardly facing concavity and a third curved portion 14c with an upwardly directed concavity radiused to the distal length 12 so that the latter is substantially aligned with or parallel to the tang 11.

The bending radius of the third curved portion 14c is comparable to that of the first curved portion 14a, but definitely greater than that of the second curved portion 14b.

Preferably the thickness S1, as measured in direction y at the junction between the tang 11 and the intermediate length 14, ranges between 2.0 and 3.0 mm, whereas the thickness S2 of distal length 12, near the sharp cutting end 13 is preferably ranging between 0.4 and 0.6 mm. The overall length of the instrument, without the tang, is preferably of about 30 mm.

The instruments shown in figures 3 to 8 differ from those of figures 1 and 2 in the particular shape of the sharp cutting end 13, which may take different shapes according to the special purpose of the instrument (for example saw-toothed, chisel-like, triangular, with a perforating tip, etc.).

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Tests carried out so far by the Applicant have proven that, owing to the shape of the instrument as described herein above, the instrument allows to cut bone located in sites otherwise difficult to reach, while letting the surgeon clearly observe the position and motion of the cutting end. More particularly, instruments made of titanium alloy have displayed surprising performances if used with ultrasonic apparatus of the above mentioned type within a frequency range between about 22 kHz and about 36kHz. Best results have been attained using on the apparatus an input power ranging between 20 and 90 W, particularly between 42 and 90 W, with a sinusoidal wave. It has been noted that the cut resulting from the use of an instrument of the invention is particularly accurate and thin.

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The above results have been attained with instruments manufactured by chip-forming machining from a blank. The same instruments are then subjected to a normalizing step in order to preserve the molecular properties of the titanium alloy. It is believed that this machining and this treatment confer better elastic properties to the instrument in terms of wider oscillations of its free cutting end.

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The invention is not intended to be limited to the embodiments described and illustrated herein, which should be considered as examples of a surgical cutting instrument; rather, the invention may be modified with regard to constructional and functional details, particularly concerning the shape of the sharp cutting end.

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CLAIMS

1. A surgical instrument (10) for cutting bone by vibrating at ultrasonic frequencies, including an elongate metal body extending along a central axis (x), the body lying in a plane and having a succession of straight and curved lengths, characterised in that the instrument comprises:
- 5
- a straight tang (11) adapted to be locked to a surgical device (M) capable of imparting to the instrument vibrations at frequencies ranging between about 22 kHz and about 36 kHz,
 - 10 - a straight distal length (12) substantially aligned with or parallel to the tang (11) but thinner than the tang and having a sharp free end (13),
 - an intermediate length (14) between the tang (11) and the distal length (12), the intermediate length having three successive curved portions (14a, 14b, 14c) with respective concavities facing towards directions which are alternate and substantially opposite and perpendicular to the central axis (x), wherein the intermediate (14) and distal (12) lengths are progressively flattened and get thinner when measured in directions (y1, y2, y3) which are perpendicular, in each point, to the central axis (x) and lie in said plane.
 - 15
2. A surgical instrument according to claim 1, characterised in that the instrument (10) is made of titanium alloy.
- 20
3. A surgical instrument according to claim 2, characterised in that the instrument (10) is made of titanium grade 5 alloy.
- 25
4. A surgical instrument according to any one of the preceding claims, characterised in that
- the thickness (S1) of the instrument, measured in said perpendicular direction (y) at the junction between the tang (11) and the intermediate length (14) ranges between about 2.0 and about 3.0 mm, and that
- 30
- the thickness (S2) of the distal length (12) near the sharp free end (13) ranges between about 0.4 and about 0.6 mm.

5. A surgical instrument according to any one of the preceding claims, characterised in that the overall length of the instrument (10), without the tang (11), is about 30 mm.

6. A method of vibrating a sharp surgical instrument so as to cut bone, the method including the steps of:

- providing a surgical instrument according to claim 1;
- provide apparatus electrically supplying at least one piezoelectric transducer located in a handpiece mechanically connected with the surgical instrument;
- selecting on the apparatus a frequency of said electric supply so as to cause the instrument to vibrate at a frequency ranging between about 22 kHz and about 36 kHz;
- selecting on the apparatus a level of electric power supplied to the handpiece ranging between about 20 W and about 90 W;
- electrically supplying the piezoelectric transducer with the selected frequency and power through the apparatus, thereby causing the surgical instrument to vibrate at an ultrasonic frequency ranging between about 22 kHz and about 36 kHz.

Fig.1

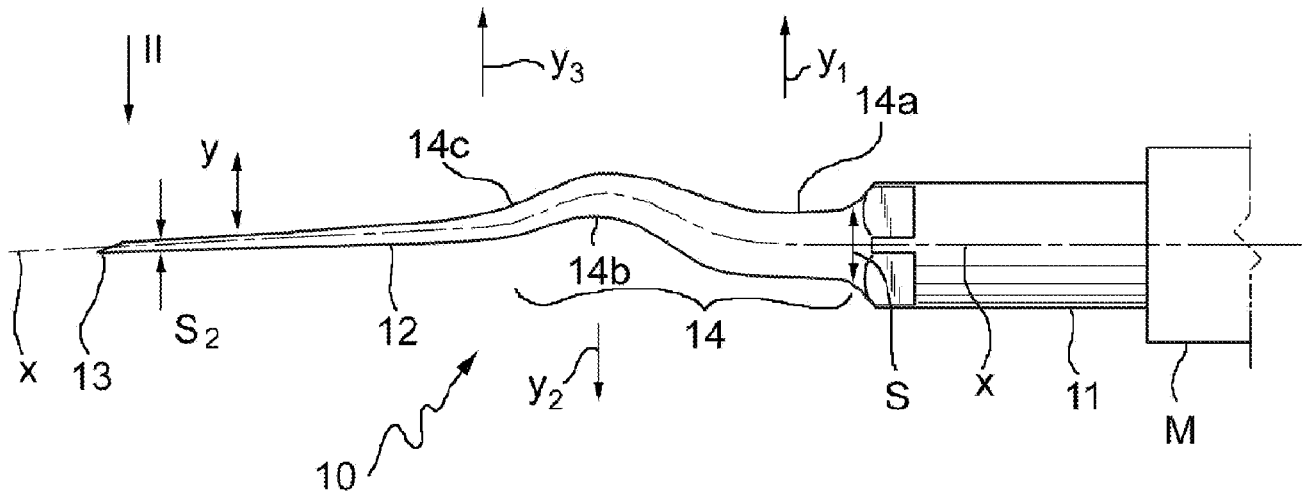


Fig.2

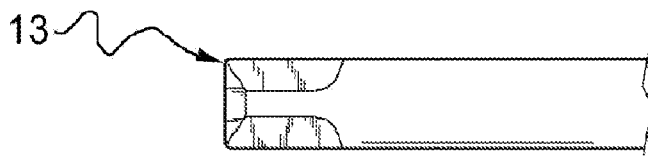


Fig.3



Fig.4

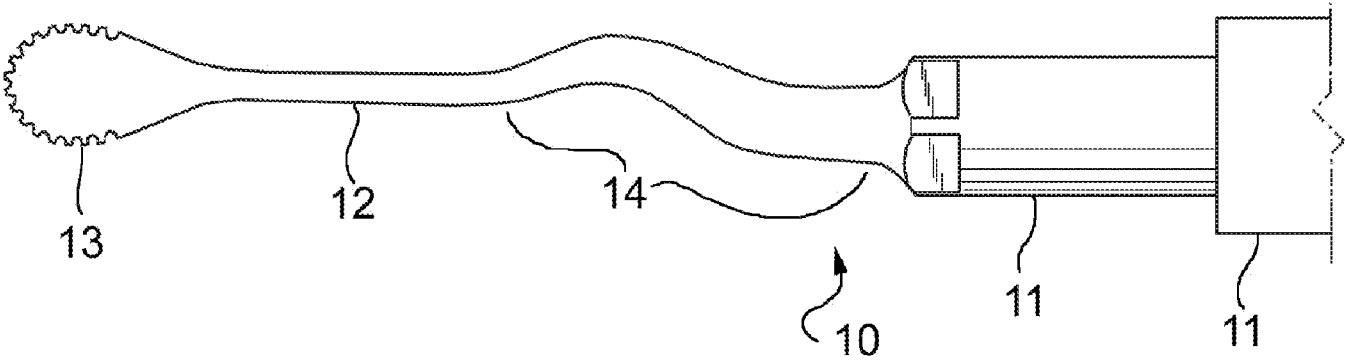


Fig.5

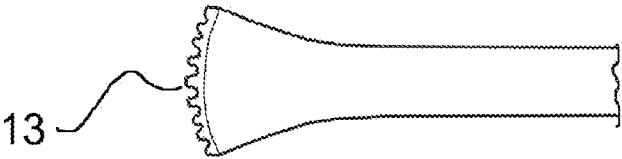


Fig.6



Fig.7

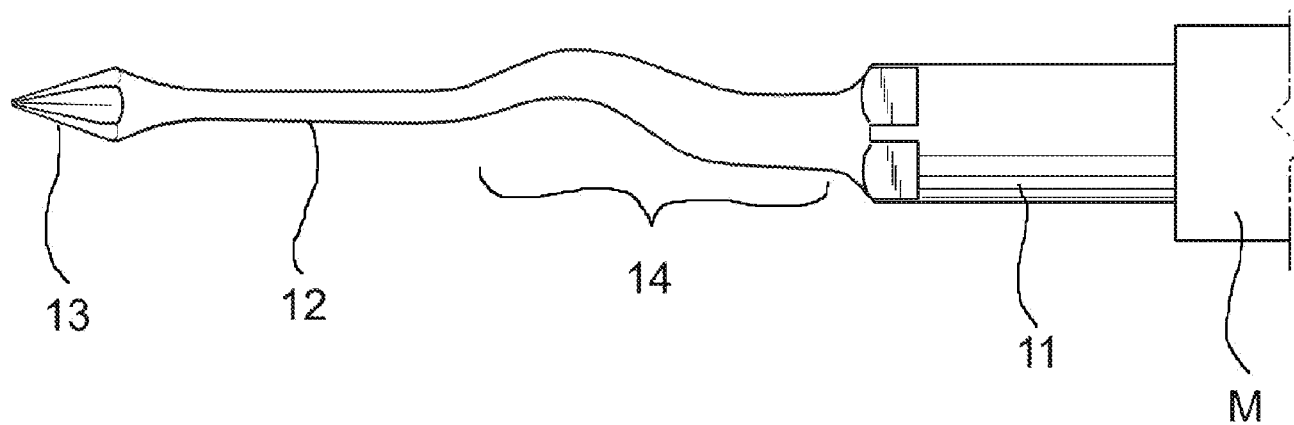


Fig.8

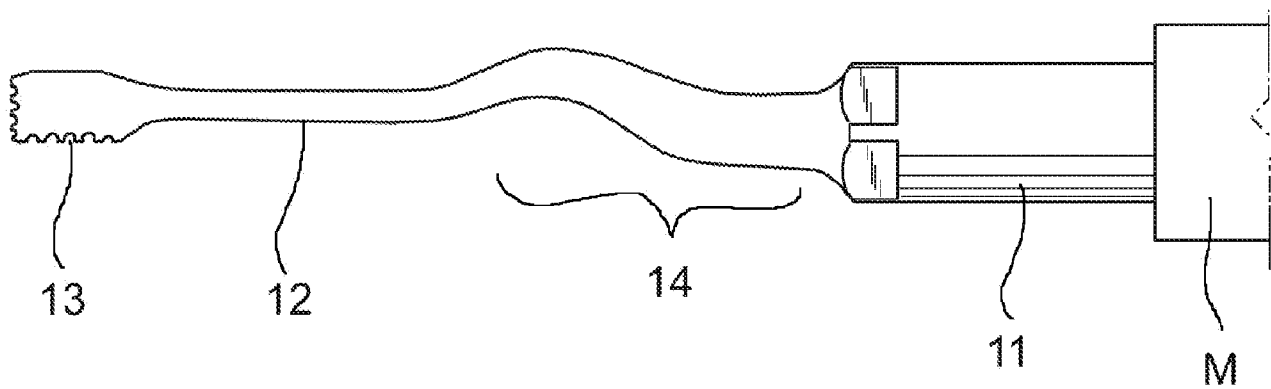


Fig.9

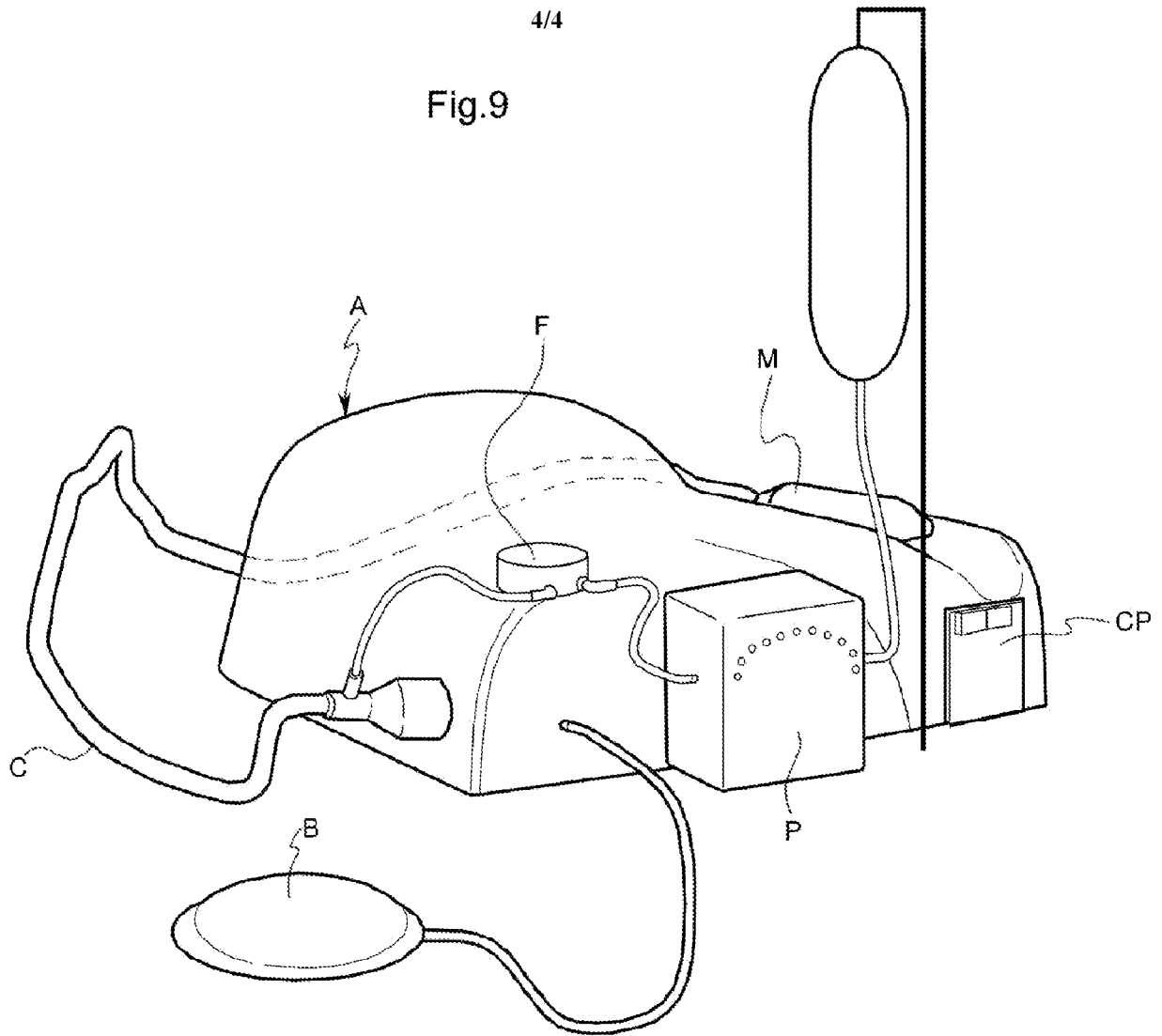
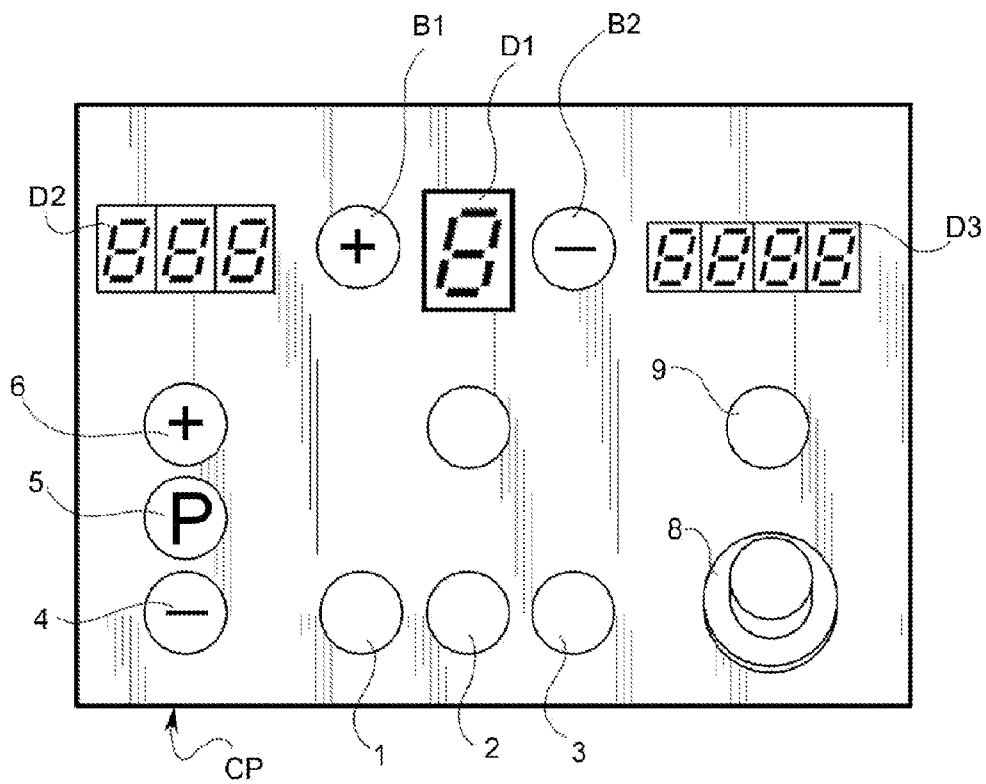


Fig.10



INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2007/057761

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61B17/32

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 A61F B06B

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)

EP0-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>WO 2006/052903 A (CRESCENDO TECHNOLOGIES LLC [US]; BEAUPRE JEAN [US]) 18 May 2006 (2006-05-18) abstract; claims 1,2,4,8,9,11,15,16,18; figure 6 page 3, lines 26-30 page 5, lines 28-30 page 7, line 11 - page 8, line 7 page 10, line 3 - page 12, line 29 page 13, line 14 - page 15, line 9</p> <p style="text-align: center;">----- -/--</p>	1-5

☒ Further documents are listed in the continuation of Box C.

☒ 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
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- *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.
- *Z* document member of the same patent family

Date of the actual completion of the international search

14 November 2007

Date of mailing of the international search report

23/11/2007

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INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2007/057761

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>WO 2006/059120 A (ORTHOSONICS LTD [GB]; YOUNG MICHAEL JOHN RADLEY [GB]) 8 June 2006 (2006-06-08) figures page 3, line 6 - page 7, line 7 page 8, lines 13-17 page 10, lines 11,12 page 11, line 5 - page 12, line 5 page 13, line 1 - page 14, line 5</p>	1-5
A	<p>EP 0 456 470 A (SUMITOMO BAKELITE CO [JP]) 13 November 1991 (1991-11-13) abstract; figures column 1, lines 4-7 column 2, line 7 - column 4, line 39</p>	1-5
A	<p>US 2006/030797 A1 (ZHOU ZHAOYING [CN] ET AL) 9 February 2006 (2006-02-09) abstract; figures paragraphs [0009] - [0015], [0044], [0045]</p>	1-5
A	<p>EP 1 138 264 A (ETHICON ENDO SURGERY INC [US]) 4 October 2001 (2001-10-04) abstract; figures paragraphs [0009] - [0014], [0016]</p>	1-5
A	<p>EP 1 110 509 A (VERCELLOTTI TOMASO [IT]; BIANCHETTI FERNANDO [IT]; VERCELLOTTI DOMENIC) 27 June 2001 (2001-06-27) figures</p>	

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2007/057761

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. ☒ Claims Nos.: 6
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 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 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 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/EP2007/057761

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 2006052903	A	18-05-2006	EP 1814479 A2	08-08-2007
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			JP 2001204735 A	31-07-2001
			US 2001004695 A1	21-06-2001

专利名称(译)	用于超声骨手术的切割器械		
公开(公告)号	EP2051643A1	公开(公告)日	2009-04-29
申请号	EP2007787976	申请日	2007-07-27
[标]申请(专利权)人(译)	背光模组CORNELIO		
申请(专利权)人(译)	背光模组， CORNELIO		
当前申请(专利权)人(译)	背光模组， CORNELIO		
[标]发明人	BLUS CORNELIO		
发明人	BLUS, CORNELIO		
IPC分类号	A61B17/32		
CPC分类号	A61B17/320068 A61B17/142 A61B17/144 A61B2017/320078		
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其他公开文献	EP2051643B1		
外部链接	Espacenet		

摘要(译)

手术器械 (10) 用于通过在22kHz和36kHz之间的超声频率下振动来切割骨。该仪器包括具有直柄脚 (11) 的钛合金体，具有尖锐自由端 (13) 的直的远端长度 (12)，以及柄脚 (11) 和远端长度 (12) 之间的中间长度 (14)。)。中间长度具有三个连续的弯曲部分 (14a， 14b， 14c)，其具有面向交替方向的凹面，交替方向与仪器的中心轴线 (x) 交替相对并垂直。中间件 (14) 和远端 (12) 长度逐渐变平并从柄脚 (11) 朝向端部 (13) 变薄。