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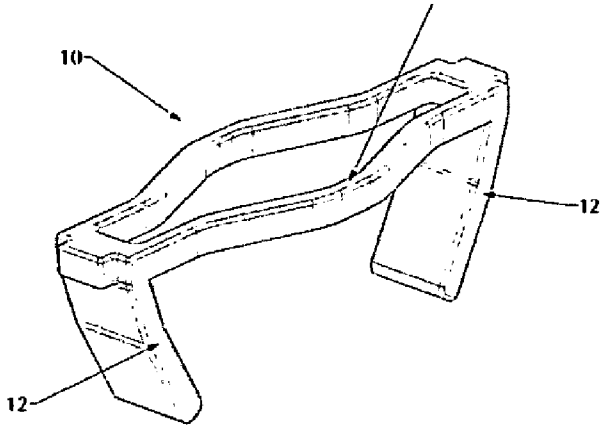

FIG. 1

(57) Abstract: A fixing device is described, for closing a sternum (S) opened following a sternotomy incision (T) in the field of heart surgery or torax surgery, comprising a staple (10) made of an elastic plastic material, wherein the fixing device consists in a central segment or cortical riser (11) with a rhomboidal shape eguipped with a central opening that extends at its two opposite ends in two side segments or roots (12). A process and instruments for applying such fixing device are also described.

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ELASTIC FIXING DEVICE FOR CLOSING THE STERNUM AFTER A STERNOTOMY, PROCESS AND INSTRUMENTS FOR APPLYING SUCH DEVICE

The present invention refers to an elastic fixing device for closing the sternum, after a sternotomy in the field of heart surgery or torax surgery, and to a process and instruments for applying such device.

Currently, the most widely used system for bone synthesis that follows a sternotomy provides for the use of steel wires, that are passed through and behind the sternum to be then linked to the front part of the sternum itself. The use of such steel wires however generates several problems. In fact, it often happens that steel wires are not able to guarantee an optimum bone synthesis, since, due to the tensions generated by muscular movements, coughs or even only the respiration movement, slight diastases and dislodgings can occur in sternum segments, that generate an unstable bone synthesis. Steel wires, therefore,

not being elastic at all, are not able to comply with such movements and therefore create bone lysis. In some cases, even a displacement and lifting of the steel wire node can occur, this generating the decubitus of soft tissues.

In order to solve the above problems, the art has then proposed closing systems based on the use of staples made of NITINOL® (like those disclosed in patents US-A-6 783 531 in the name of ALLEN Drew, US-A-6 969 391 in the name of the Applicant and FR-A-2 874 166 in the name of SURGE FOOT) that are able to embrace the sternum and guarantee an adequate closing force and, at the same time, capable of allowing the absorption of tensions generated by movements. The components made of NITINOL® in fact have the feature of being malleable at low temperatures and to get their original shape again at body temperature. Such staples therefore are a valid solution in many situations, including the most difficult ones, like when there is ostheoporosis, but have the need, in order to allow their application, to remove the cortex from the sternum in spaces between ribs, in order to create an adequate seat, this operation appearing as extremely cumbersome and invasive.

Moreover, existing staples are ofter characterised by extremely complex functional geometries and, also due to this latter reason, they have too high costs to be able to be used on a large scale.

Therefore, object of the present invention is solving the above prior art problems, by providing an elastic device that can be applied for closing the sternum after a sternotomy without the need of a previous bone cortex removal in spaces between ribs.

Another object of the present invention is providing an elastic fixing device that is cheaper than what has been proposed by the art and therefore can be used on a large scale.

A further object of the present invention is providing a process and instruments for applying the fixing device as cited above.

The above and other objects and advantages of the invention, as will result from the following description, are obtained with an elastic device for closing the sternum, with a process and with instruments for applying such device as described in the respective independent claims.

Preferred embodiments and non-trivial variations of the present invention are the subject

matter of the dependent claims.

The present invention will be better described by some preferred embodiments thereof, provided as a non-limiting example, with reference to the enclosed drawings, in which:

- Figure 1 shows a perspective view of a preferred embodiment of the fixing device 1 according to the present invention;
- Figure 2 shows a front view of the fixing device of FIG. 1;
- Figure 3 shows a top view of the fixing device of FIG. 1 and 2;
- Figure 4 shows a schematic front view of a human sternum before a sternotomy intervention;
- Figures 5 to 8 show sectional views of a human sternum during some steps of the process according to the present invention;
- Figure 9 shows a schematic front view of a human sternum after the application of the fixing devices through the process according to the present invention;
- Figure 10 shows a schematic side view of a container for a plurality of devices as shown in Figure 1;
- Figure 11 shows a perspective view of a

preferred embodiment of the instrument for taking from the container in Figure 10 and inserting in the sternum of Figure 2 a device as shown in Figure 1;

- Figure 12 is a side view of the instrument of Figure 11;
- Figure 13 schematically shows the various operating steps of the instrument of Figure 11; and
- Figure 14 is a schematic block diagram of a perforating instrument to be used in the process of the present invention.

With reference in particular to Figures 1, 2 and 3, it is possible to note that the fixing device according to the present invention is composed of a clip or staple (these two terms are used interchangeably) 10, made of an elastic plastic material, comprising a central segment 11 substantially with a rhomboidal shape, equipped with a central opening suitable for creating the future compression, also called cortical riser, that elongates at its two opposite ends in two side segments 12, also called roots.

Figure 10 shows a schematic side view of a container 15 in which a plurality (in this case

preferably five) staples 10 are placed in a rest position and ready for being taken for.

Figures 11 and 12 show a preferred embodiment of an instrument 16 for taking and inserting the staples 10. Such instrument 16 in general, is equipped with means 18, 24, 26 for enlarging the fixing device, means 28, 30 for taking the fixing device, means 28, 30 for placing the fixing device in its operating position and means 18, 20 for pushing the fixing device in the sternum S.

As instead shown in a practical, non-limiting example of an embodiment, such instrument 16 is composed of a central tube 18 around which an abutment spring 20 is wound and that is equipped, at an end, with a pressing mushroom 22 and, at the other end, with two arms 24, hinged to the tube 18 in 23 and hinged in 25 to two respective jaws 26 suitable to open the staple 10, as can be better seen below. A pressure on the mushroom 22, preferably through the palm of a hand, in contrast with the force of the spring 20, will be transmitted, through the tube 18 and the arms 24, to the jaws 26 that will move away one from the other and will be opened in order to enlarge the roots 12 of the staple 10. Once having reached the

enlargement position, through a safety stopper mechanism 27, the instrument 16 will be blocked in such position, being unlocked only when the staple 10 will be inserted in the sternum S; after such unlocking, the spring 20 will take back the instrument 16 in it rest position with its jaws 26 closed, waiting for a subsequent withdrawal of another staple 10.

The instrument 16 is further equipped with an envelope 28 in which the arms 24 and part of the jaws 26 are contained, and inside which also two guides 30 are made, that are used to keep the roots 12 parallel once they have been opened. Finally, in Figures 11 and 12, it is possible to see grips 32 for fingers of a hand, suitable to provide a contrast when the pressing force is applied onto the mushroom 22.

Finally, Figure 14 is a schematic diagram of the perforating instrument 40 to be used in the process of the present invention, described herein below. The perforating instrument 40 is substantially composed of a rear mass 42 equipped at an end with an inlet 44 for water to be used when perforating, and connected, at the other end thereof, to a front mass 48, piezoelectric ceramics

46 being interposed in the connection. The perforating instrument 40 further comprises a transducing support 52 coupled with the front mass by interposing a suitable gasket 50, for example of the O-Ring type, to prevent vibrations when operating. Finally, the perforating instrument 40 comprises a single or double working bit 54 that ends with nozzles 55 for making water go out and that projects outside the plane of the head 56 when operating.

The present invention also refers to a process for applying at least one fixing device for closing a sternum opened due to a sternotomy. With reference to Figures 4 to 9, it is possible to note that the process according to the present invention comprises the steps of:

a) approaching two bone sections of sternum S separated due to a sternotomy incision T (Figures 4 and 5); approaching the two parts of sternum S to be joined is performed through the use of suitable pliers (of the Backhaus type or the like, not shown);

b) making at least one hole F on every section (Figure 6), the distance between such two holes F being at least equal to the length of a

cortical riser 11 during the compression of the central rhombus and/or at the distance between the roots 12 when made parallel; in particular, the holes F should be parallel to the sternum sections S, symmetrical with respect to the sternotomy incision T and be two for every staple 10 to be applied. The holes F can be made by using a perforating device 40, of a mechanical or ultrasound type;

c) providing at least one staple 10 of the previously-described type, preferably placed in a container 15 (Figure 13a);

d) by means of the instrument 16 for taking and inserting, taking from the container 15 a staple 10, enlarging and making parallel the roots 12 and simultaneously squashing the rhombus of the cortical riser 11 to obtain a longer distance between the roots 12: such distance will have to be equal to the distance between the holes F previously obtained in the sections of sternum S (Figures 13b to 13d);

e) inserting the staple 10 assembled on the instrument 16 in the sternum S: the roots 12 of the staple 10 cross the cortex part and are closed back into the sponge part Sp creating an

undercut (Figures 13e to 13g). In this way, they exert an elastic compression on the cortex part itself and on the sponge part Sp inside the holes F in which they are applied and therefore on the portions of the sternum S that are required to be sinthesized;

f) repeating steps a) to e) for every staple 10 to be applied (Figure 9); it is clear that such step, and consequently the global number of staples 10 to be applied, is mostly dependent on the length of the incision T and on the bone consistency of the sections of sternum S to be consolidated.

As can be well seen in Figures 13a to 13g, the instrument 16 substantially operates as follows:

- Figure 13a: the instrument 16 is actuated through a pulling force exerted by the hand palm (for example of the surgical room operator) on the mushroom 22 by resting onto the grips 32: the guides 30 go out of the envelope 28 and the spring 20 is compressed, loaded and fixed by the safety stopper 27 in its loading position;
- Figure 13b: the instrument 16 is approached to the container 15 and the jaws 26 are inserted into the rhomboidal opening of one of the fixing

devices to be taken from the container 15;

- Figure 13c: through a pressure onto the mushroom 22, the tube 18 and the guide 30 are pushed along the direction of the container 15 and, through this pushing, the jaws 26 are opened and the roots 12 are enlarged, simultaneously making them mutually parallel;
- Figure 13d: the fixing device is extracted from the container 15, is engaged by the envelope 28, by the guides 30 and by the jaws 26, so that the ends of the roots 12 slightly project from the envelope 28 itself (this will make it easier to perform the following insertion operation of the roots 12 into the respective holes F);
- Figure 13e: the operator passes the instrument to the surgeon that rests the fixing device onto the holes F to be fixed, inserting the ends of the roots 12 projecting from the envelope 28;
- Figure 13f: through a final pressure towards the holes F, the insertion of the roots 12 into the holes F is then automatically completed;
- Figure 13g: the device 16 is then extracted and taken back to its rest position by unlocking the stopper 27: the staple 10 in the meantime, due to its elasticity, has moved to its gripping

position in which the roots 12 are bent one towards the other at such an angle as to guarantee the gripping on the sponge part Sp of the sternum S.

The advantages deriving from the use of the staple 10 according to the present invention and/or its related application process are numerous: some of them are as follows:

- diasthasis, dislocation and the consequent bone-synthesis instability are prevented. Such instability, present in cases in which steel wires are used for closing, moreover generates sliding and lifting of closing nodes and therefore the decubitus of soft tissues. Due to their elasticity, instead, the staples 10 according to the present invention keep their elastic compression;
- the staples 10 according to the present invention further determine, in the cortex segment, a minimum encumbrance and avoid disturbances to patients;
- the possibility for a patient to move is made easier, this without impairing the bone synthesis quality;
- lysis phenomena, typical instead of the

closure with metal wires, are reduced;

- the staples 10 according to the present invention do not create image distortions in radiologic surveys (RX, TAC, RMN);
- the staples 10 according to the present invention have a greater application and removal ease with respect to known fastening systems.

CLAIMS

1. Fixing device for closing a sternum (S) opened following a sternotomy incision (T) in the field of heart surgery or torax surgery, comprising a staple (10) made of an elastic plastic material, characterised in that said fixing device consists in a central segment or cortical riser (11) with a rhomboidal shape equipped with a central opening that extends at its two opposite ends in two side segments or roots (12).
2. Instrument (16) for taking and inserting a fixing device for closing a sternum (S) opened following a sternotomy incision (T) in the field of heart surgery or torax surgery, characterised in that it is equipped with means (18, 24, 26) for enlarging said fixing device, means (28, 30) for grasping said fixing device, means (28, 30) for placing said fixing device in an operating position and means (18, 20) for pushing said fixing device in the sternum (S).
3. Instrument (16) according to claim 2, characterised in that it is composed of a central tube (18) around which an abutment spring (20) is wound, and that is equipped, at an end, with a pressing element (22) and, at

another end, with two arms (24), hinged to the tube (18) in (23), and hinged, in (25), to two respective jaws (26) adapted to open the staple (10), said instrument (16) being further equipped with an envelope (18) in which arms (24) and part of the jaws (26) are contained, and inside which two guides (30) are also made, that are used for keeping the fixing device open and for taking it.

4. Instrument (16) according to claim 2 or 3, characterised in that it is further equipped with at least one safety stopper mechanism (27) adapted to block said instrument (16) in position for enlarging said fixing device and adapted to be unlocked after having inserted said fixing device in the sternum (S).

5. Perforating instrument (40) for a sternum (S) for placing therein a fixing device for closing a sternum (S) opened following a sternotomy incision (T) in the field of heart surgery or torax surgery, said perforating instrument (40) comprising: at least one rear mass (42) equipped on at least one end with an inlet (44) for water to be used when perforating, and connected on another end thereof to at least one front mass

(48), piezoelectric ceramics (46) being interposed in the connection, said perforating instrument (40) further comprising a transducing support (52) and a single or double working bit (54) that ends with nozzles (55) for making water go out and that projects from a plane of the head (56) for its operation.

6. Process for applying at least one fixing device for closing a sternum (S) opened following a sternotomy incision (T) in the field of heart surgery or torax surgery, said fixing device comprising a staple (10) made of an elastic plastic material, and consisting in a central segment or cortical riser (11) with a rhomboidal shape equipped with a central opening that extends at its two opposite ends in two side segments or roots (12), said process comprising the steps of:

a) approaching two bone sternum sections (S) separated due to a sternotomy incision (T);

b) making at least one hole (F) on every section, a distance between said two holes (F) being at least equal to a length of a cortical riser (11) when compressing the central rhombus and/or a distance between

the roots (12) made parallel, said holes (F) being in particular adapted to be made parallel with the sternum sections (S), symmetrical with respect to the sternotomy incision (T) and to be two for every staple (10) to be applied;

c) providing at least one staple (10), preferably placed in a container (15);

d) taking one staple (10), enlarging and making parallel the roots (12) and simultaneously squashing the rhombus of the cortical riser (11) to obtain a greater distance between the roots (12), said distance being equal to the distance between the holes (F) previously obtained in the sternum sections (S);

e) inserting the staple (10) in the sternum (S): the roots (12) of the staple (10) cross the cortex part and are closed back in the sponge part (Sp) creating an undercut (Figures 13e to 13g), the roots (12) exerting in this way an elastic compression on the cortex part itself and on the sponge part (Sp) inside the holes (F) in which they are applied and therefore on sternum

sections (S) that require to be synthesized; and

f) repeating steps a) to e) for every staple (10) to be applied (FIG. 9).

7. Process according to claim 6, characterised in that said approaching in step a) of said two sternum sections (S) is performed through Backhaus pliers.

8. Process according to claim 6, characterised in that said holes (F) are parallel to said sternum sections (S), symmetrical with respect to said incision (T) and are two for every one of said staples (10) to be applied.

9. Process according to claim 6 or 8, characterised in that said holes (F) are made by means of a perforating instrument according to claim 5.

10. Process according to claim 9, characterised in that said perforating instrument is of a mechanical or ultrasound type.

11. Process for operating an instrument (16) for taking and inserting a fixing device for closing a sternum (S) opended following a sternotomy incision (T) in the field of heart surgery or torax surgery according to claim 4, said process comprising the steps of:

- triggering the instrument (16) through a pulling force on a mushroom (22) by abutting onto abutment grips (32), the guides (30) going out of the envelope (28) and the spring (20) being compressed, loaded and fixed to the safety stopper (27) in its loading position;
- approaching the instrument (16) to a staple (10) of a fixing device, in particular a staple (10) contained in a container (15), and inserting the jaws (26) in the rhomboidal opening of the fixing device to be taken;
- through pressure on the mushroom (22), pushing the tube (18) and the guide (30) along the direction of the container (15) and, through this thrust, opening the jaws (26) and enlarging the roots (12), simultaneously making them mutually parallel;
- extracting the fixing device engaged by the envelope (28), from the guides (30) and the jaws (26), so that the ends of the roots (12) slightly go out of the envelope (28);
- resting the fixing device on the holes (F) to be fixed, inserting therein the ends of the roots (12) going out of the envelope (28);
- through a final pressure towards the holes (F),

automatically completing the insertion of the roots (12) in the holes (F); and

- extracting the device (16) and taking it back to its rest position by unlocking the stopper (27).

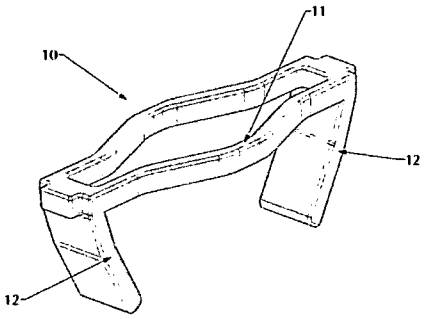


FIG. 1

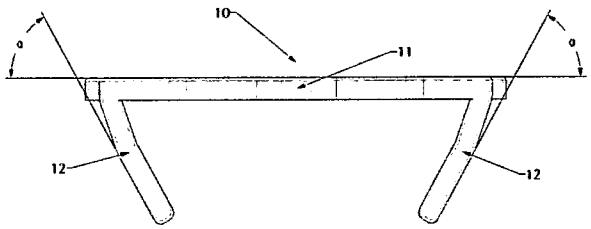


FIG. 2

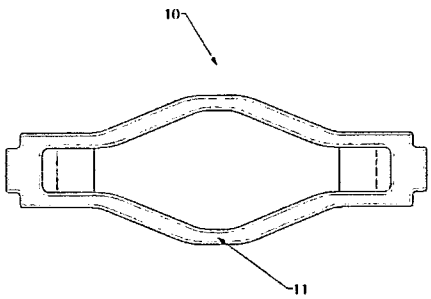
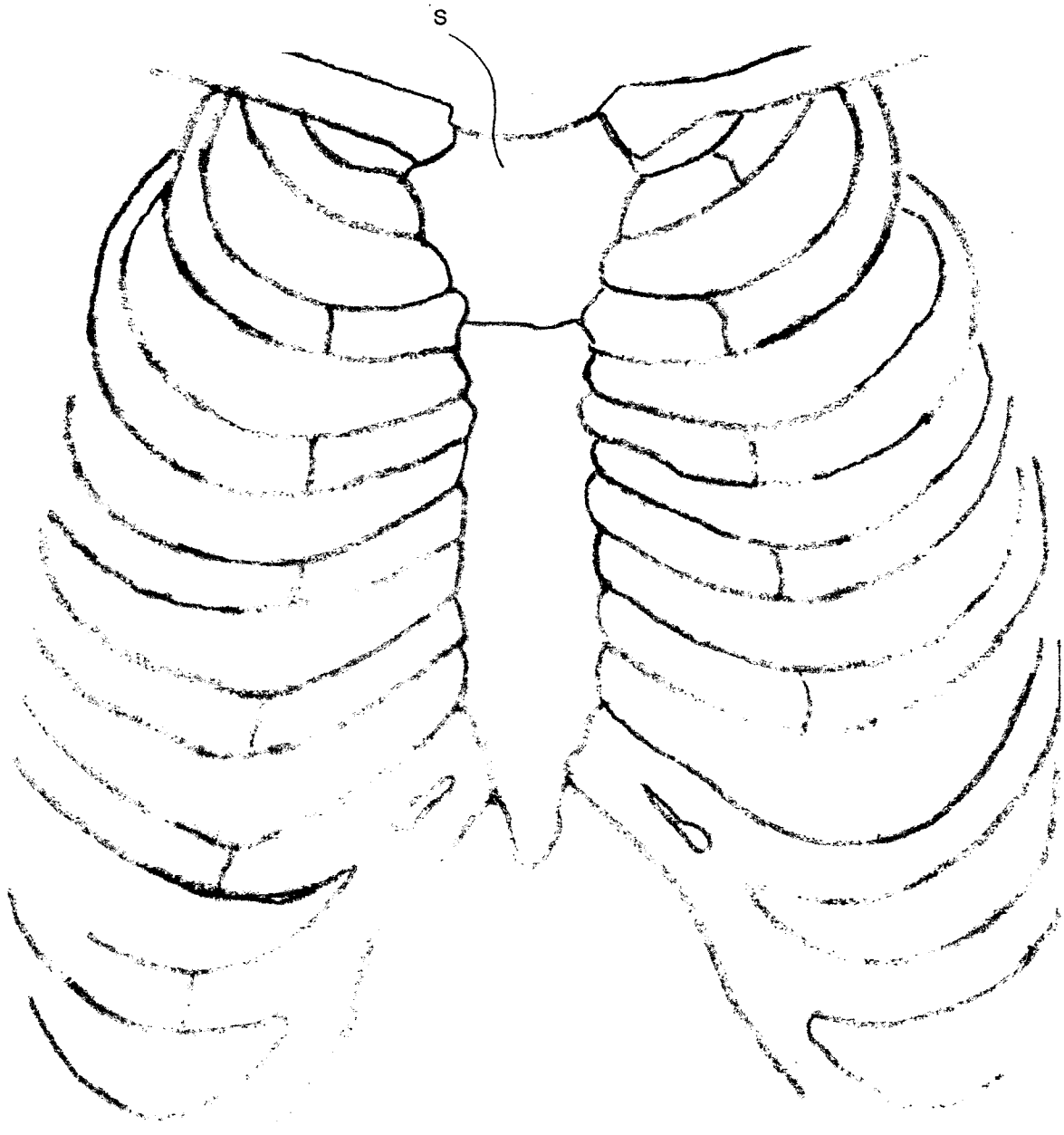


FIG. 3

FIG. 4



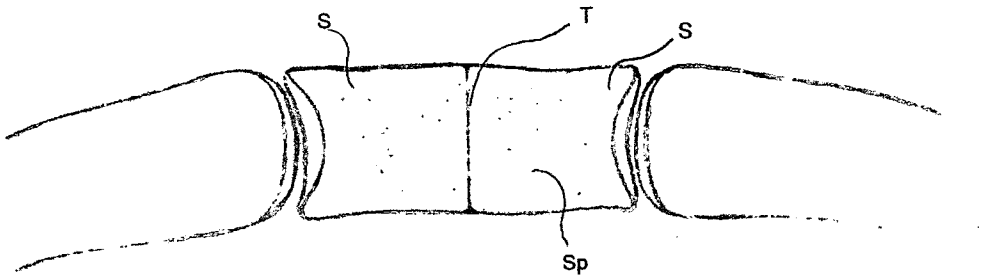


FIG. 5

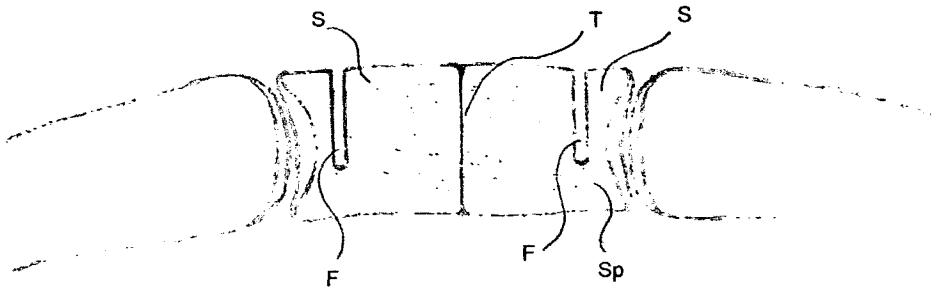


FIG. 6

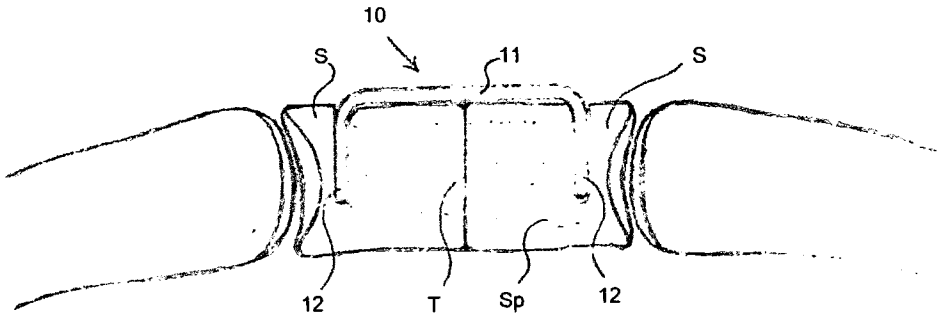


FIG. 7

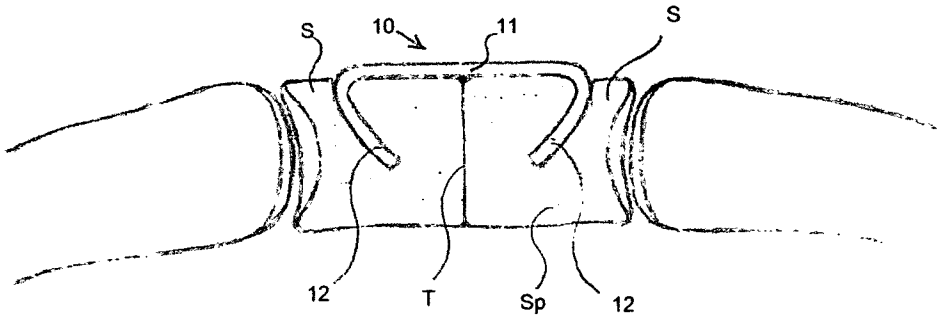


FIG. 8

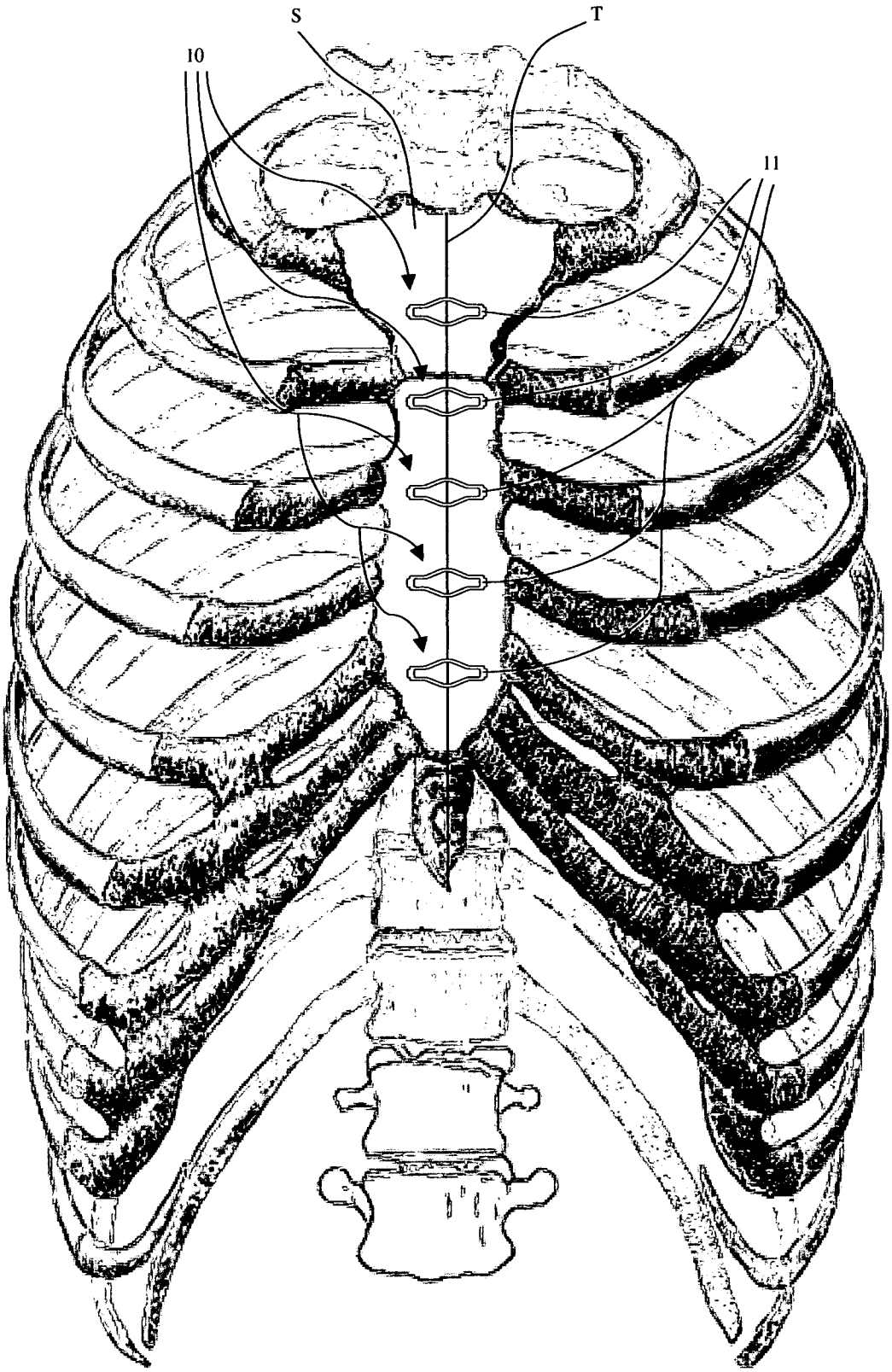


FIG. 9

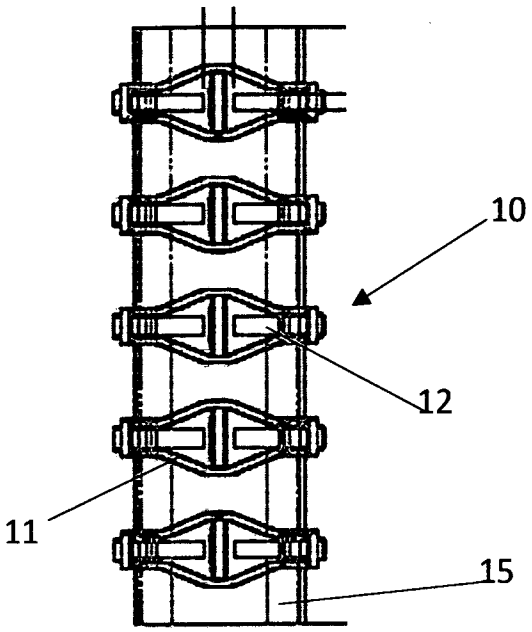


FIG. 10

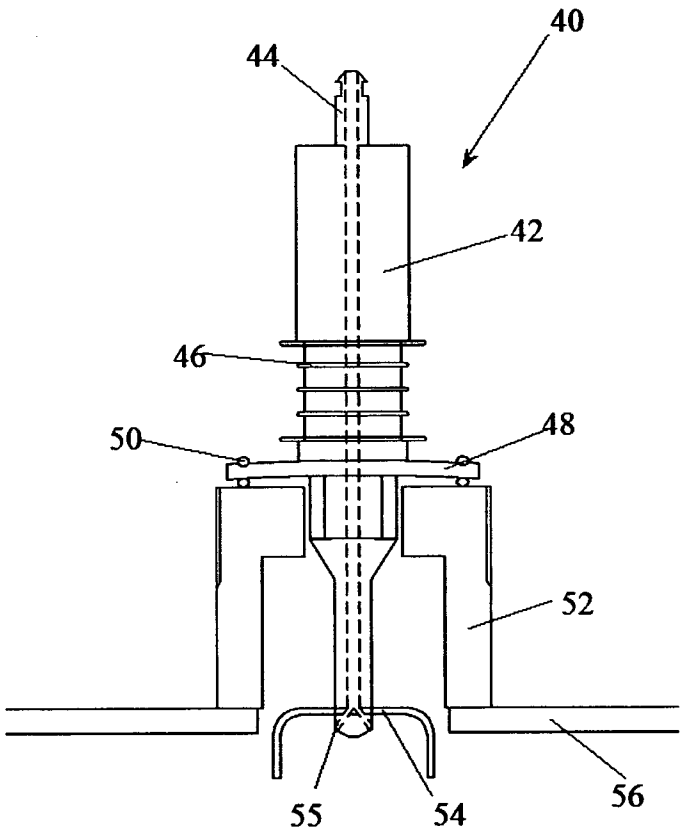


FIG. 14

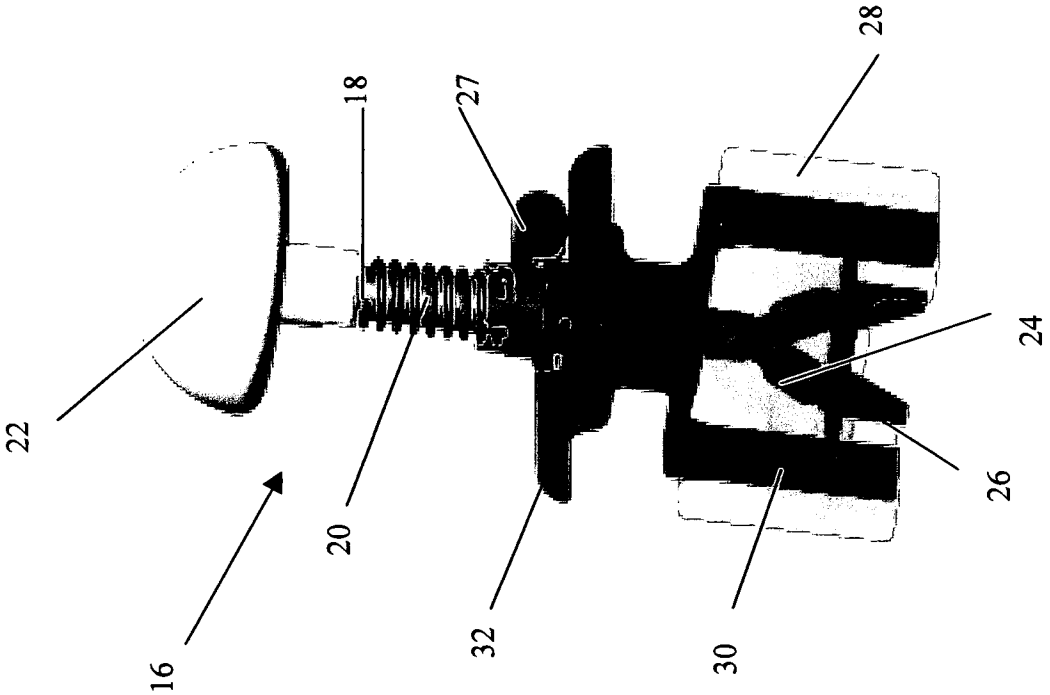


FIG. 11

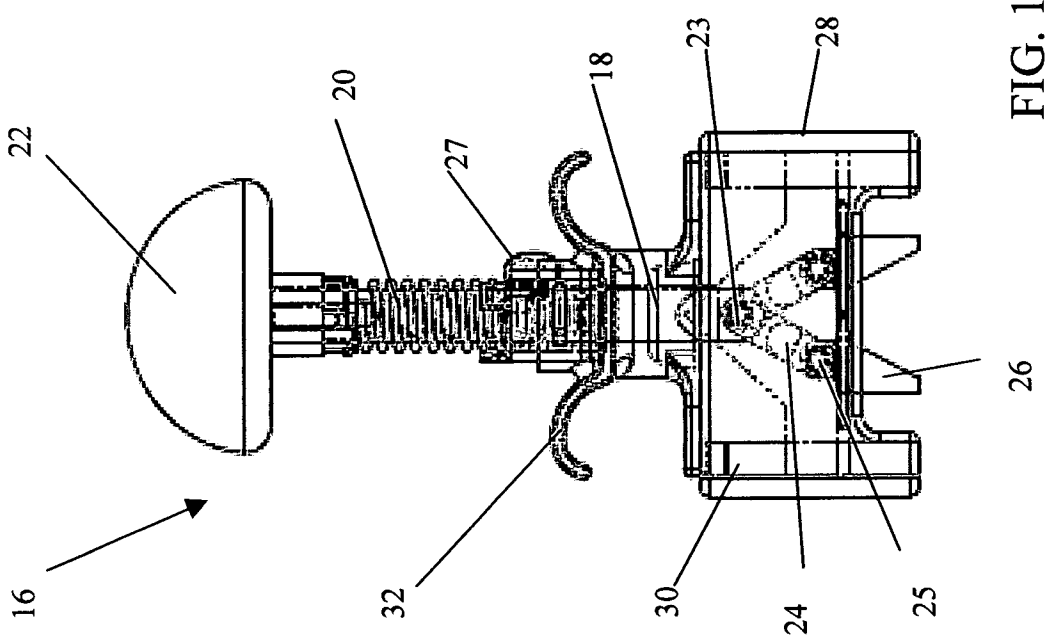


FIG. 12

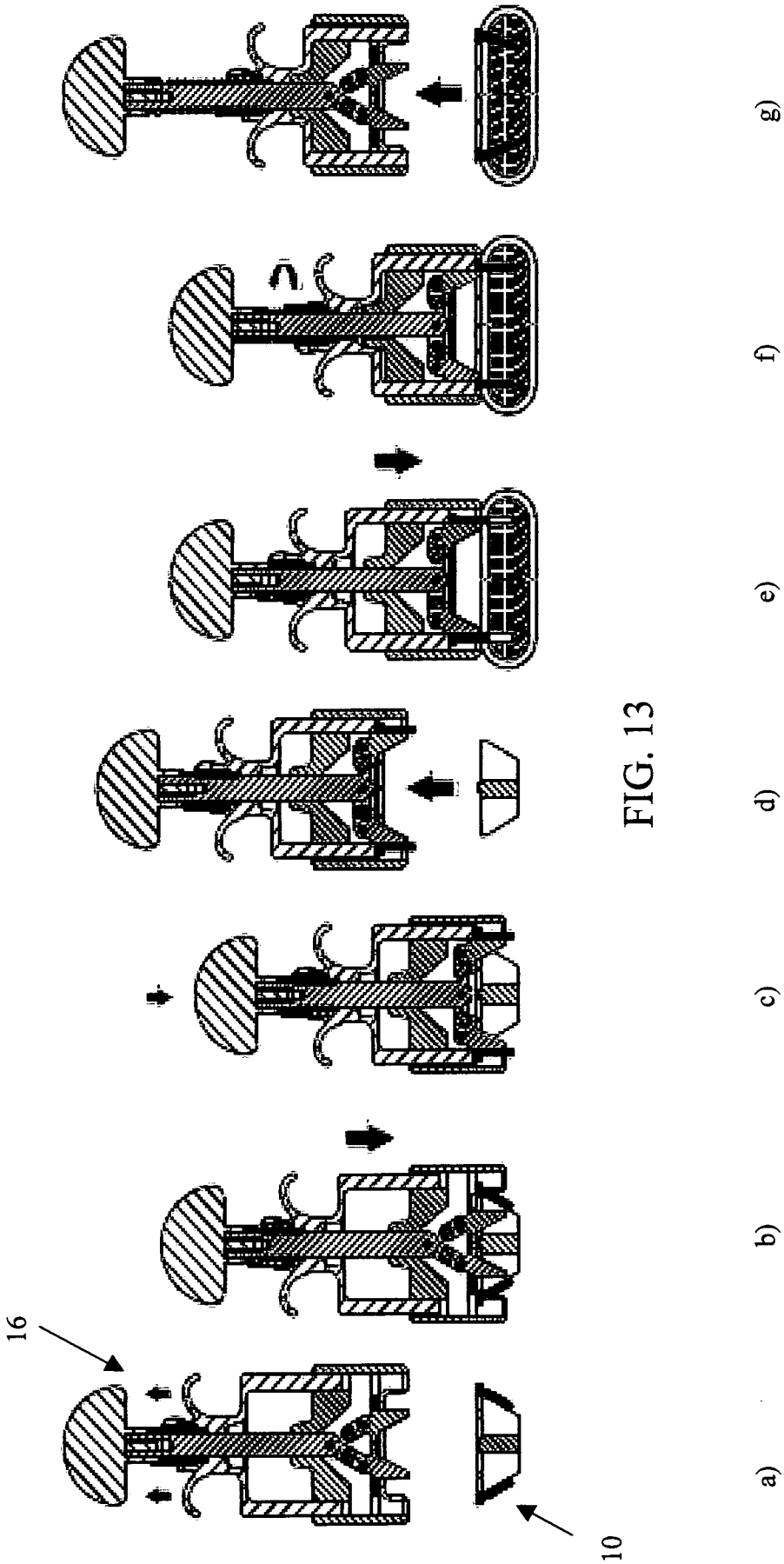


FIG. 13

INTERNATIONAL SEARCH REPORT

International application No
PCT/IT2009/000202

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/064 A61B17/82

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	EP 0 852 128 A (GROISO JORGE A [AR] S C I DIGO [LU]) 8 July 1998 (1998-07-08) figures 1-3,25,31	1
X	US 3 960 147 A (MURRAY WILLIAM M) 1 June 1976 (1976-06-01) figures 1,2	2-4
X	US 5 026 390 A (BROWN ALAN W [US]) 25 June 1991 (1991-06-25) figures 5,6,8,9	2-4
A	US 5 449 359 A (GROISO JORGE A [AR]) 12 September 1995 (1995-09-12) the whole document	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
29 September 2009	11/12/2009

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	Cuiper, Ralf

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

INTERNATIONAL SEARCH REPORT

International application No
PCT/IT2009/000202

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2002/029044 A1 (MONASSEVITCH LEONID [IL] ET AL) 7 March 2002 (2002-03-07) figure 10a	1
A	US 6 030 410 A (ZURBRUEGG HEINZ ROBERT [CH]) 29 February 2000 (2000-02-29) figure 9	2

3

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

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IT2009/000202

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.: 6-11
because they relate to subject matter not required to be searched by this Authority, namely:

see FURTHER INFORMATION sheet PCT/ISA/210

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:

see additional sheet

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 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. [X] 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.:

see annex

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.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-4

sternum staple and device for insertion

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2. claim: 5

Perforating instrument for sternum

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 6-11

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery.
Claim 6 includes i.a. the step b) making at least one hole on every section [of the sternum] and e) inserting the staple in the sternum.
Claim 11 includes i.a. step of resting the fixing device on the holes [of the sternum] to be fixed, inserting therein the ends of the roots.
These are clearly surgical steps performed inside the human body.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/IT2009/000202

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 0852128 A	08-07-1998	AT 202687 T	15-07-2001
		DE 69705489 D1	09-08-2001
		DE 69705489 T2	23-05-2002
		DK 852128 T3	22-10-2001
		ES 2161421 T3	01-12-2001
		GR 3036806 T3	31-01-2002
		PT 852128 E	28-12-2001
		US 5993476 A	30-11-1999
		US 5947999 A	07-09-1999
US 3960147 A	01-06-1976	NONE	
US 5026390 A	25-06-1991	NONE	
US 5449359 A	12-09-1995	NONE	
US 2002029044 A1	07-03-2002	AU 8802701 A	22-03-2002
		EP 1333765 A2	13-08-2003
		WO 0219888 A2	14-03-2002
		IL 138320 A	20-11-2005
US 6030410 A	29-02-2000	NONE	