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(54) Title: FIXING DEVICE FOR CLOSING THE STERNUM AFTER A STERNOTOMY AND INSTRUMENT FOR APPLYING SUCH DEVICE

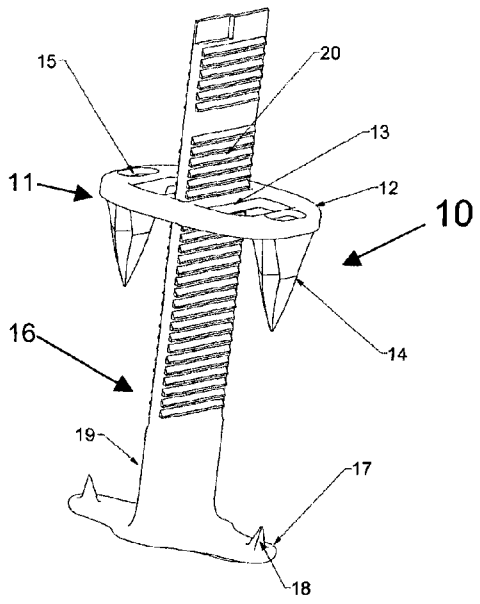


FIG. 1

(57) Abstract: A fixing device (10) made of plastic material is described for closing a sternum (S) after a sternotomy, comprising: at least one staple (11); at least one clamping element (16) operatively coupled with the staple (11); and optionally at least one handle (21') operatively coupled with the clamping element (16). An instrument (21) is also described for applying, by tightening, this fixing device (10) to a sternum (S), consisting in pliers (21) made of levers (25) equipped with a base (22) adapted to push down the staple (11) and an upper part (23) for grasping the stem (19) of the clamping element (16), the base (22) reproducing the shape of the staple (11) and being provided with two thin plates (24) to be inserted in the respective small cavities (15) of the staple (11). The use of the above instrument (21) for fixing a sternum (S) with the above fixing device (10) is also described.

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Declarations under Rule 4.17:

— *of inventorship (Rule 4.17(iv))*

Published:

— *with international search report (Art. 21(3))*

FIXING DEVICE FOR CLOSING THE STERNUM AFTER A STERNOTOMY AND INSTRUMENT FOR APPLYING SUCH DEVICE

The present invention refers to a fixing device for closing the sternum after a sternotomy in the case of heart surgery or torax surgery, and to an instrument for applying such device, in addition to the use of such device and instrument.

Currently, the most widely used system for bone synthesis that follows a sternotomy is based on 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, in fact, 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 mentioned 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 place for the

insertion, this operation appearing as extremely invasive.

Moreover, existing staples are often characterized 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.

EP-A-2063799 discloses a fixing device according to the preamble of claim 1.

Therefore, object of the present invention is the creation of a system able to solve the above prior art problems, by providing a 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 and able to comply with physiological micro-movements.

Another object of the present invention is providing a 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 an easy application of 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 a 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 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 according to the present invention;
- Figure 1A shows a perspective view of a variation of the fixing device of Figure 1;
- Figure 2 shows an exploded view of the fixing device of Figure 1;
- Figure 2A shows an exploded view of the fixing device of Figure 1A;
- Figure 3 shows a lateral view of the fixing device of Figure 1;
- Figure 4 shows a front sectional view of the fixing device of Figure 1;

- Figure 4A shows a detail of part of Figure 4;
- Figures 5 and 6 show a perspective and a side view of a first embodiment of the instrument to tighten the device of Figure 1;
- Figures 5A and 6A show two perspective views of a second embodiment of the instrument in ita opening and closing positions;
- Figure 7 shows a schematic front view of a human sternum before a sternotomy intervention; and
- Figures 8 to 14 show perspective views of a human sternum during some steps of the process according to the present invention.

With reference in particular to Figures 1, 2, 3 and 4, it is possible to note that the fixing device 10 according to the present invention substantially comprises the following elements:

- a staple 11, made of plastic material, comprising an outer contact element 12 substantially with an elliptic shape, equipped with at least two transverse rods 13, preferably extending along the minor radius of the ellipse, and with not more than two first sharpened tips 14 perpendicular to

the contact element 12. Each first sharpened tip 14 has a small cavity 15 used as a guide for an instrument 21; and

- a clamping element 16 made of plastic material, comprising a lower contact element 17 equipped with at least two small second sharpened tips 18, whose size is much smaller than the first sharpened tips 14, and with a clamping stem 19 projecting vertically therefrom and provided with small teeth 20 for matching with the transverse teeth 13' inside the transverse rods 13 of staple 11.

According to a variation of the invention as shown in Figures 1A and 2A, the fixing device can further comprise a handle 21' made of plastic material, connected with the vertical stem 19 of the clamping element 16 and provided with a counterpart 22' to be grasped by a suitable instrument (not shown).

Figures 5 and 6 show a preferred embodiment of an instrument for tightening the fixing device 10. Such instrument, in general, consists in special pliers 21 formed of levers 25 and equipped with a base 22 to push down the staple 11 and an upper part 23 for grasping the clamping stem 19. The base

22 reproduces the shape of the staple 11 and is provided with two thin plates 24 to be inserted in the respective small cavities 15 of the staple 11.

The present invention also refers to a process for applying at least one fixing device for closing a sternum S opened due to a sternotomy. With reference to Figures 8 to 14, it is possible to note that the process according to the present invention comprises the steps of:

a) approaching two bone sections of the sternum S divided due to a sternotomy incision until they are separated by a gap G of about 1.5 cm; approaching the two parts of the sternum S to be joined is performed through the use of suitable pliers or rib contractors (not shown);

b) inserting a fixing device 10 along the gap G, with the clamping stem 19 perpendicular to the bone surface and the longest side of the staple 11 oriented in the same direction of the length of the incision;

c) when the fixing device 10 is in the desired position along the gap G, rotating the fixing device 10 by 90 degrees;

d) repeating steps b) and c) for each fixing device used. It is clear that the global number of fixing devices 10 to be applied is mostly dependent on the length of the incision and on the bone consistency of the sections of sternum S to be consolidated;

e) completely approaching the two bone sections of the sternum S;

f) manually pushing down the staple 11 until the first sharpened tips 14 touch the surface of the sternum S, while pulling up the clamping stem 19 in order to keep the lower contact element 17 in contact with the inner side of the sternum S. This leads the small second sharpened tips 18 in the lower contact element 17 to grip the soft tissues surrounding the bone;

g) repeating step f) for each fixing device 10;

h) matching the instrument 21 to each fixing device 10: inserting the clamping stem 19 into the upper part 23 and coupling the base 22 with the outer contact element 12 and the thin plates 24 with the cavities 15 of the first sharpened tips 14;

i) starting the action on the levers 25 of the pliers 21, until the clamping stem 19 is grasped into the upper part 23 of the pliers 21;

j) acting thoroughly and repeatedly on the levers 25 of the pliers 21 in order to tighten each fixing device 10 onto the sternum S. This causes the traction of the clamping stem 19, the perforation of the sternum S through the first sharpened tips 14 and the descent of the staple 11. In this way, the two bone sections are blocked through the compression exerted by the first sharpened tips 14 on the cortex part and on the sponge part of the sternum S. The bigger section of the first sharpened tips 14 compared with traditional steel wires, the use of plastic material and the design of the fixing device 10 prevent the generation of the tensions and the cut of the bone tissue, and allow an optimum bone synthesis.

The advantages deriving from the use of the fixing device 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;
- the staples 11 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 of the closure with metal wires, are reduced;
- the fixing device 10 according to the present invention does not create image distortions in radiologic surveys (RX, CAT, RMN);
- the fixing device 10 according to the present invention shows unmatched easiness of application and removal in respect to previously known fastening systems.

CLAIMS

1. Fixing device (10) for closing a sternum (S) after a sternotomy, comprising:

- at least one staple (11) made of plastic material;
- at least one clamping element (16) made of plastic material operatively coupled with said staple (11);

characterised in that:

- said staple (11) comprises an outer contact element (12) equipped with at least two transverse rods (13), and with not more than two first sharpened tips (14) perpendicular to the contact element (12); and
- said clamping element (16) comprises an inner contact element (17) equipped with at least two small second sharpened tips (18), whose sizes are much smaller than said first sharpened tips (14), and with a clamping stem (19) projecting vertically therefrom and provided with small teeth (20) for matching with transverse teeth (13') inside the transverse rods (13) of the staple (11).

2. Fixing device (10) according to claim 1, characterised in that it further comprises at least one handle (21') made of plastic material

operatively coupled with said clamping element (16).

3. Fixing device (10) according to claim 1 or 2, characterised in that said outer contact element (12) has a substantially elliptic shape.

4. Fixing device (10) according to claim 1, 2 or 3, characterised in that each first sharpened tip (14) has a small cavity (15) used as a guide for an instrument (21) for applying said fixing device (10).

5. Fixing device (10) according to claim 2, characterised in that said handle (21') is connected with the vertical stem (19) of the clamping element (16) and is provided with a counterpart (22') to be grasped by an instrument for applying said fixing device (10).

6. Instrument (21) for applying, by tightening, the fixing device (10) according to any one of claims 1 and 3 to 4 to a sternum (S), characterised in that said instrument consists in pliers (21) made of levers (25) and equipped with a base (22) adapted to push down the staple (11) and an upper part (23) for grasping the clamping stem (19), the base (22) reproducing the shape of the staple (11) and being provided with two thin plates (24) to be inserted

in the respective small cavities (15) of the staple (11).

7. Use of at least one fixing device (10) according to any one of claims 1 to 5, by employing an instrument (21) according to claim 6, for closing a sternum (S) opened due to a sternotomy, through the following steps:

a) approaching two bone sections of the sternum (S) divided due to a sternotomy incision until they are separated by a gap (G);

b) inserting a fixing device (10) along the gap (G), with the clamping stem (19) perpendicular to the bone surface and the longest side of the staple (11) oriented in the same direction of the length of the incision;

c) when the fixing device (10) is in the desired position along the gap (G), rotating the fixing device (10) by 90 degrees;

d) repeating steps b) and c) for each fixing device (10) used;

e) completely approaching the two bone sections of the sternum (S);

f) manually pushing down the staple (11) until the first sharpened tips (14) touch the surface of the sternum (S), while pulling up

the clamping stem (19) in order to keep the lower contact element (17) in contact with the inner side of the sternum (S), the small second sharpened tips (18) in the lower contact element (17) being led to grip the soft tissues surrounding the bone;

g) repeating step f) for each fixing device (10);

h) matching the instrument (21) to each fixing device (10) by inserting the clamping stem (19) into the upper part (23) and coupling the base (22) with the outer contact element (12) and the thin plates (24) with the cavities (15) of the first sharpened tips (14);

i) starting the action on the levers (25) of the pliers (21), until the clamping stem (19) is grasped into the upper part (23) of the pliers (21);

j) acting thoroughly and repeatedly on the levers (25) of the pliers (21) in order to tighten each fixing device (10) onto the sternum (S), this step causing a traction of the clamping stem (19), a perforation of the sternum (S) through the first sharpened tips (14) and a descent of the staple (11), the two

bone sections being blocked through the compression exerted by the first sharpened tips (14) on the cortex part and on the sponge part of the sternum (S).

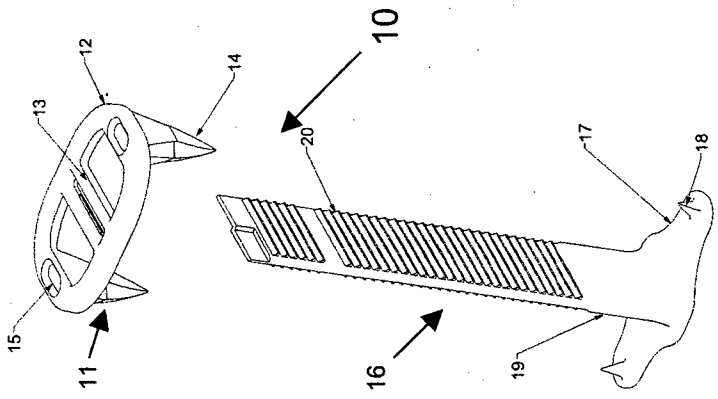


FIG. 2

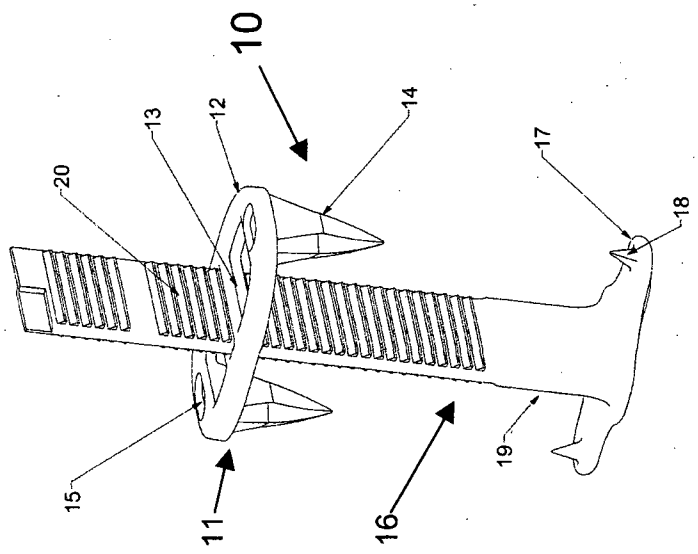


FIG. 1

FIG. 2A

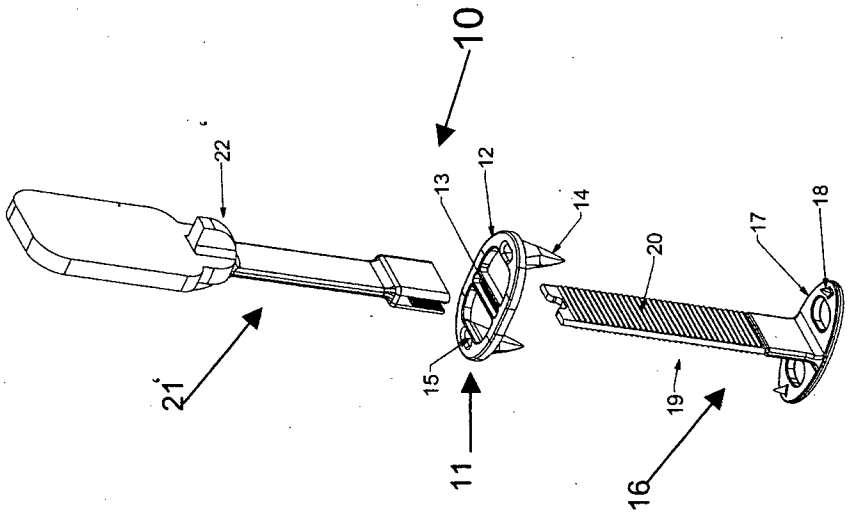
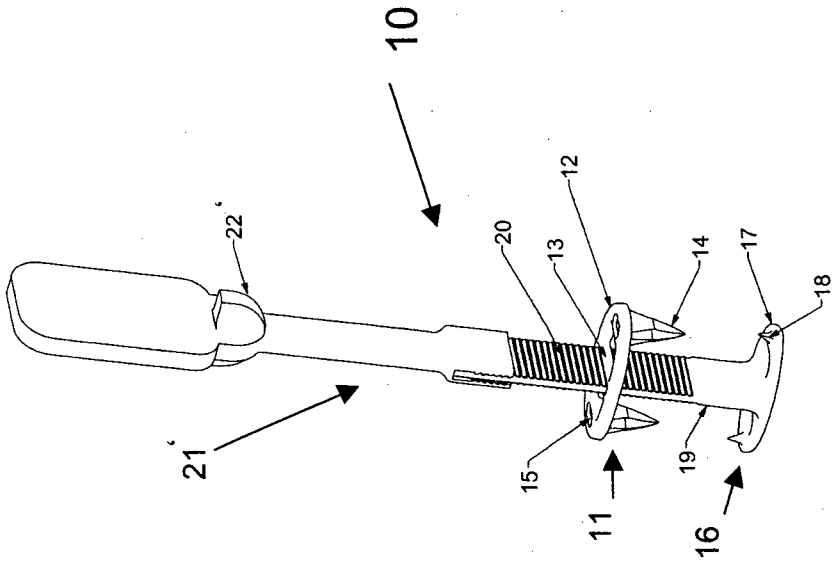

10
22'
21'
13
12
14
15
11
20
17
18
19
16

FIG. 1A


10
22'
21'
20
13
12
14
17
18
15
11
19
16

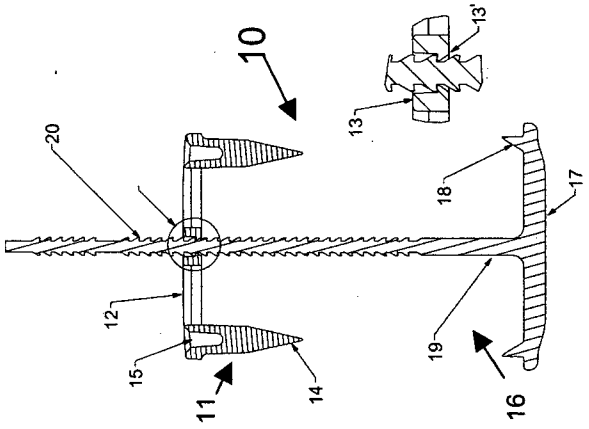


FIG. 4A

FIG. 4

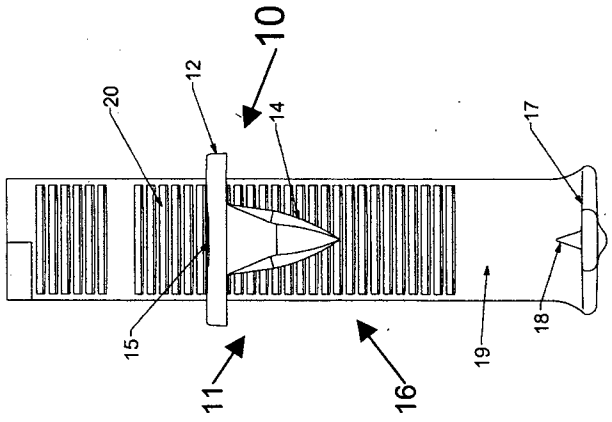


FIG. 3

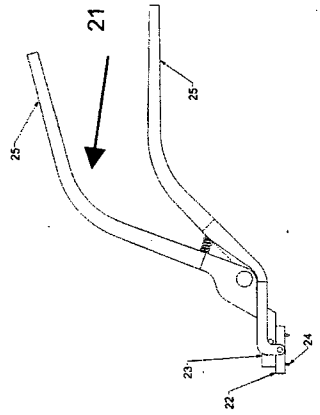


FIG. 6

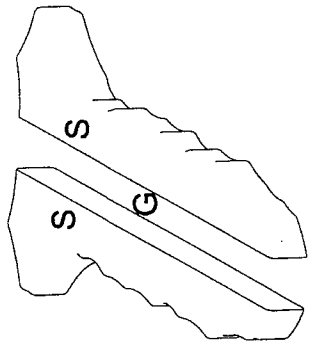


FIG. 8

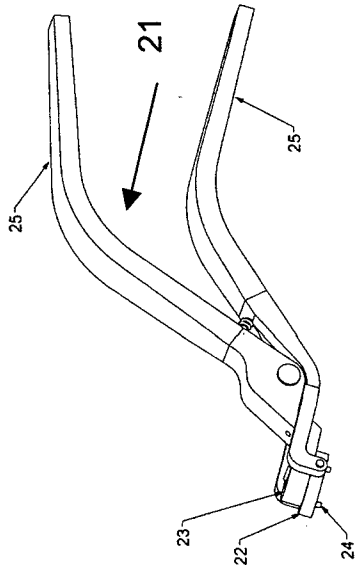


FIG. 5

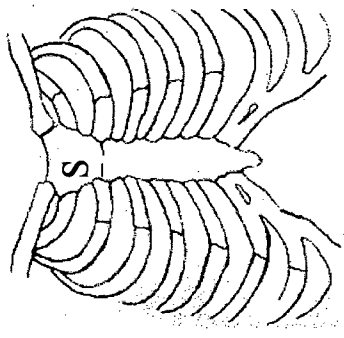


FIG. 7

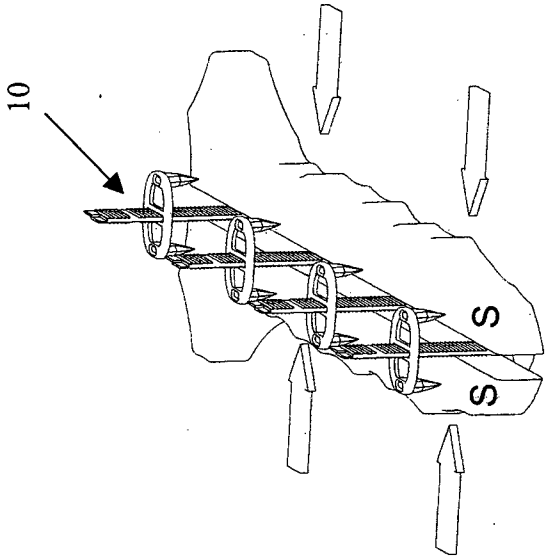


FIG. 10

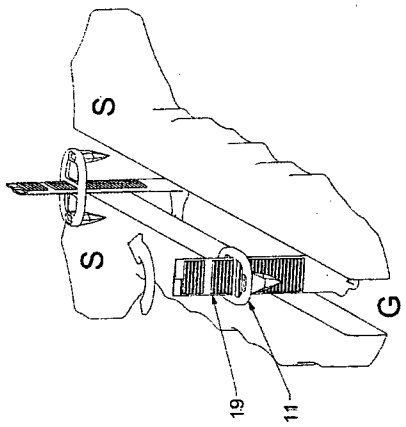


FIG. 9

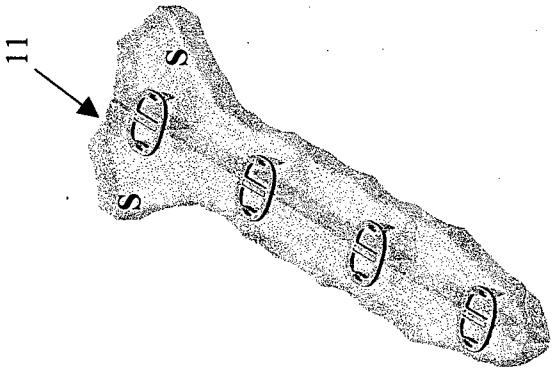


FIG. 14

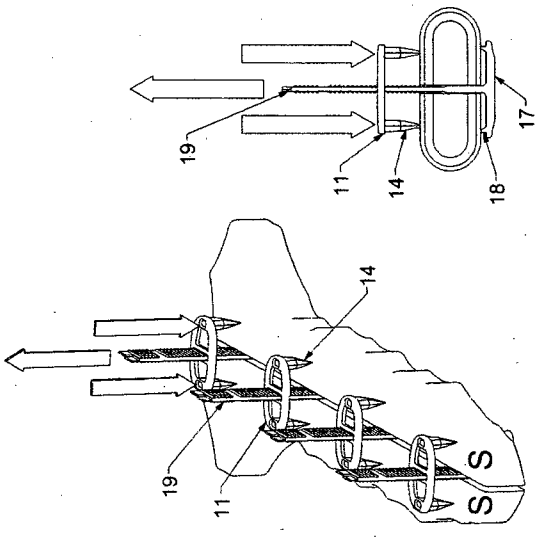
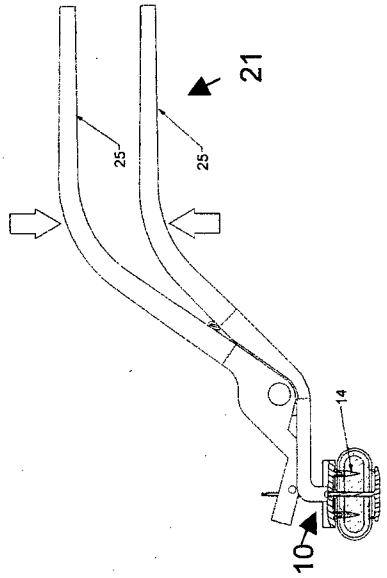


FIG. 11

FIG. 13



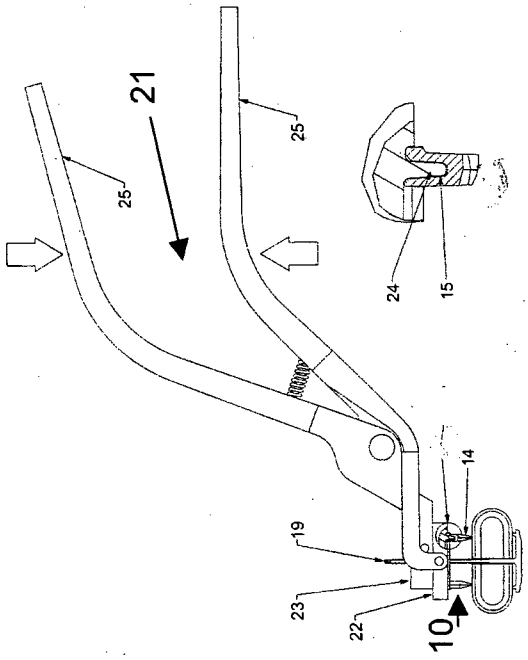


FIG. 12

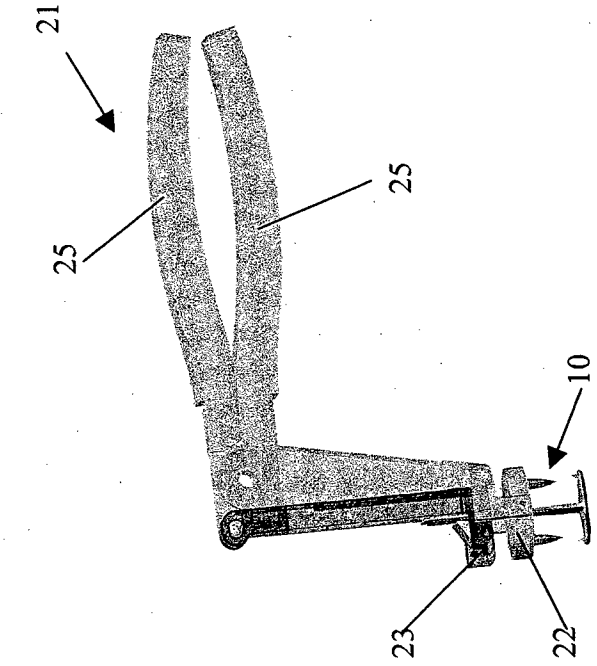


FIG. 6A

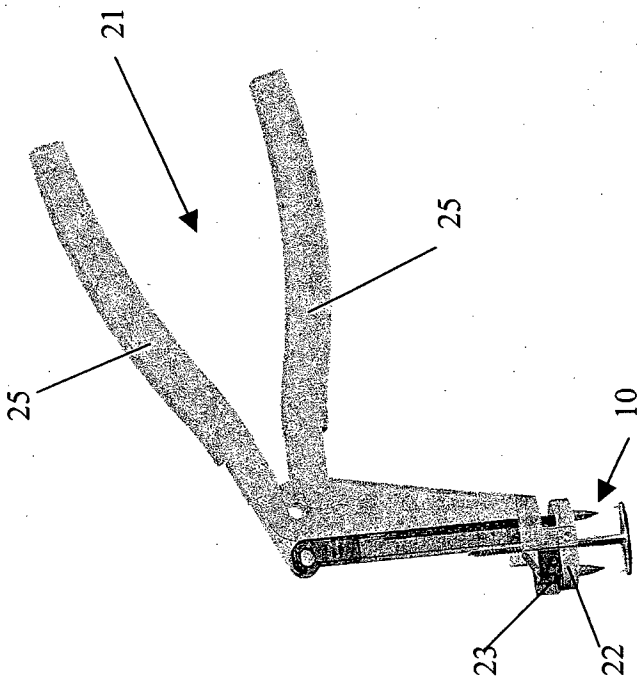


FIG. 5A

INTERNATIONAL SEARCH REPORT

International application No
PCT/IT2011/000051

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/82 A61B17/80
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2009/234357 A1 (MORALES PEDRO [DE] ET AL) 17 September 2009 (2009-09-17) figures 1,4,5 -----	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

"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
7 October 2011	20/12/2011

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

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IT2011/000051

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.: 7
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 claim 7 has not been searched, since the use of the fixing device of any one of claims 1-5 implies surgical steps (see e.g. the step of "approaching two bone sections of the sternum ..." in claim 7).

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.:

1-5

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: 1-5

A fixing device comprising a plastic staple and a plastic clamping element, both the staple and the clamping element having corresponding teeth for solving the problem of providing a device capable of efficiently closing a sternum after a sternotomy.

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2. claim: 6

An instrument for applying by tightening a fixing device for closing a sternum after a sternotomy, the instrument consisting in pliers made of levers, thereby solving the problem of providing an instrument capable of efficiently implanting a sternum closing fixing device.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/IT2011/000051

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2009234357 A1	17-09-2009	AT 529062 T	15-11-2011
		DE 102006046428 A1	03-04-2008
		EP 2063797 A1	03-06-2009
		JP 2010503502 A	04-02-2010
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		WO 2008034489 A1	27-03-2008