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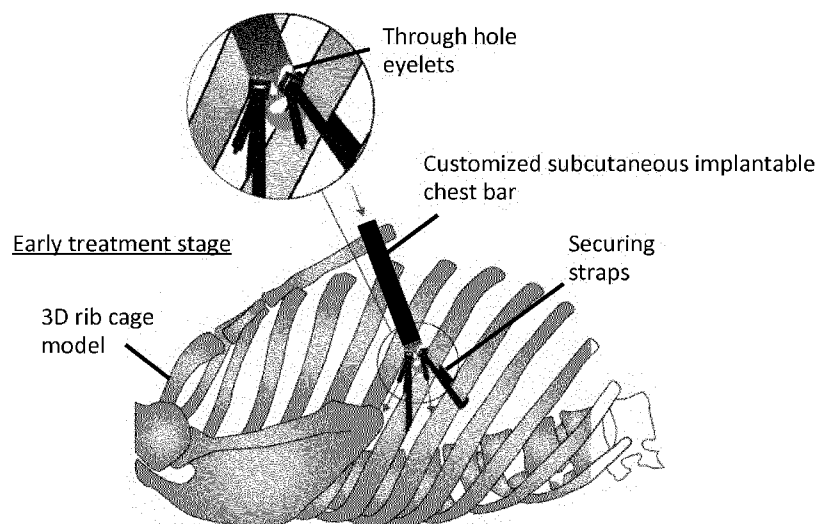
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(54) Title: ZIP FOR A RIB STERNAL PULL-BACK SYSTEM



(57) Abstract: A pectus carinatum sternal pull-back device is provided that includes an implantable subcutaneous chest bar, where a size, a curve, a length and a width of the implantable later chest bar are customized according to predetermined sternum and rib cage dimensions of a pectus carinatum patient, where the customized implantable subcutaneous chest bar includes through holes at the ends of the customized implantable subcutaneous chest bar, and at least a pair of securing straps, where the securing strap includes a channeled head element at a first securing strap end, a semi-ribbed strap, and a curved solid insertion element at a second end, where the channeled head element includes a barb for receiving and locking the semi-ribbed strap, where the securing strap is configured for insertion through the through holes of the implantable subcutaneous chest bar.



ZIP FOR A RIB STERNAL PULL-BACK SYSTEM

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FIELD OF THE INVENTION

This invention relates to pectus carinatum treatment. More particularly, the invention relates to minimally invasive surgery for pectus carinatum.

BACKGROUND OF THE INVENTION

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Pectus carinatum is a deformity of the chest characterized by a protrusion of the sternum and ribs.

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Currently, surgically implanted orthotic braces are used for some cases of pectus carinatum. With the cases of children, teenagers, and young adults that wish to avoid surgery, a chest-wall brace has been used that is configured to apply direct pressure on the protruding area of the chest, where the brace is essential for the success of this treatment approach. In one instance, the brace includes front and back compression plates that are anchored to aluminum bars. These bars are bound together by a tightening mechanism, which varies from brace to brace. This device is easily hidden under clothing and must be worn from 14 to 24 hours a day. The wearing time varies with each brace manufacturer and the managing physicians protocol, which could be based on the severity of the carinatum deformity and if it is symmetric or asymmetric.

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In some instances, the brace may be worn on the skin or it may be worn over a body 'sock' or sleeve specifically designed to be worn under braces.

For patients with severe pectus carinatum, surgery may be necessary. Minimally invasive
5 surgery for pectus carinatum (PC) has shown to be an effective surgical procedure, although with current approaches the mayor drawback is implant fixation.

What is needed is a surgical technique and apparatus that uses dedicated custom-made implants and an efficient reduced complexity fixation system.

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SUMMARY OF THE INVENTION

To address the needs in the art, a pectus carinatum sternal pull-back device is provided that includes an implantable subcutaneous chest bar, where a size, a curve, a length and a width of the implantable subcutaneous chest bar are customized according to predetermined
15 sternum and rib cage dimensions of a pectus carinatum patient, where the customized implantable subcutaneous chest bar includes through holes at the ends of the customized implantable subcutaneous chest bar, and at least a pair of securing straps, where the securing strap includes a channeled head element at a first securing strap end, a semi-ribbed strap, and a curved solid insertion element at a second end, where the channeled head
20 element includes a barb for receiving and locking the semi-ribbed strap, where the securing strap is configured for insertion through the through holes of the implantable subcutaneous chest bar.

According to one aspect of the invention, the implantable subcutaneous chest bar includes material selected such as titanium, or surgical steel.

In another aspect of the invention, the predetermined sternum and rib cage dimensions
5 include a 3D digital image of the sternum and rib cage dimensions from a patient according to output from a CT scan of the patient. Here, a 3D plastic printed test bar is configured from the 3D digital image of the sternum and rib cage dimensions for test fitting the implantable subcutaneous chest bar.

10 In a further aspect of the invention, the through holes include oval through holes or elongated through holes, where the through holes are a pattern of the through holes, where the pattern is configured to direct tension forces exerted on the through holes in a splayed direction from the pattern of through holes.

15 In yet another aspect of the invention, the semi-ribbed strap includes a narrowed material region that is proximal to a middle of the semi-ribbed strap, where the semi-ribbed strap is ribbed along a span from proximal to the channeled head to proximal to the narrowed material region and is un-ribbed from proximal to the narrowed material region to the curved solid insertion element.

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According to a further aspect of the invention, the securing strap has the strap portion made of a polymer plastic and the curved solid insertion element includes a material such as stainless steel.

According to one embodiment of the invention, a method of pectus carinatum sternal pull-back is provided that includes marking bar entry and exit sites on a patient rib cage, selecting intercostal spaces on the patient rib cage, making bilateral skin incisions at the selected intercostal spaces, creating a submuscular tunnel from an anterior aspect of the bilateral incisions to a highest point of a pectus carinatum sternal defect, advancing a subcutaneous dissector into the submuscular tunnel from a proximal side of the rib cage to a distal side of the rib cage, pulling a customized implantable subcutaneous chest bar, using an umbilical tape, through the submuscular tunnel to a predetermined position on the rib cage, placing securing straps around selected ribs of the rib cage, where the selected ribs are located on each side of the rib cage, where the securing straps are passed through eyelets of the customized implantable subcutaneous chest bar, applying a pressure to the anterior chest wall while tightening the securing straps for correcting the pectus carinatum sternal defect, and closing the bilateral skin incisions.

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BRIEF DESCRIPTION OF THE DRAWINGS

- FIGs. 1A-1C** show drawings of a pectus carinatum sternal pull-back device being implemented to a patient, according to one embodiment of the invention.
- FIGs. 2A-2B** show (2A) a 3D printed plastic test bar, and (2B) a customized pectus carinatum sternal pull-back bar (implantable subcutaneous chest bar), according to one embodiment of the invention.
- FIGs. 3A-3E** show pectus carinatum sternal pull-back securing straps, according to one embodiment of the invention.

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DETAILED DESCRIPTION

Experience accumulated with non-surgical treatment by means of dynamic compression, providing a better understanding of the mechanics of the thoracic chest in pectus carinatum patients. The present invention provides a new surgical technique using dedicated custom-
5 made implants and a new fixation system.

Before surgery, a test corrective bar is designed using digital 3D design software to output a plastic 3D printed test bar of the subcutaneous bar to be later implanted, where the process starts with 3D software processing of the patient's CT scan to produce a 3D digital image
10 of the rib cage of the pectus carinatum patient. The 3D digital image is used to print a 3D plastic test bar that is used to fit the customized implantable subcutaneous chest bar in the patient and check if the design, size, curve, length and width of the bar is correct when placed exactly at the level of the thorax where the real and final implant made out of metal (surgical steel or titanium depending on the patient's need) will be placed. A clinic
15 template fitting session to the patient is scheduled prior to surgery prior to the final manufacture of a personalized metal bar implant.

In one embodiment of the invention, a pectus carinatum sternal pull-back device is provided that includes an implantable subcutaneous chest bar, where a size, a curve, a
20 length and a width of the implantable later chest bar are customized according to predetermined sternum and rib cage dimensions of a pectus carinatum patient, where the customized implantable subcutaneous chest bar includes through holes at the ends of the customized implantable subcutaneous chest bar, and at least a pair of securing straps, where the securing strap includes a channeled head element at a first securing strap end, a semi-

ribbed strap, and a curved solid insertion element at a second end, where the channeled head element includes a barb for receiving and locking the semi-ribbed strap, where the securing strap is configured for insertion through the through holes of the implantable subcutaneous chest bar.

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FIGs. 1A-1C show drawings of a customized pectus carinatum sternal pull-back device (implantable subcutaneous chest bar) being implemented to a patient, according to one embodiment of the invention.

10 In another aspect of the invention, the predetermined sternum and rib cage dimensions include a 3D digital image of the sternum and rib cage dimensions from a patient according to output from a CT scan of the patient. Here, a 3D plastic printed test bar is configured from the 3D digital image of the sternum and rib cage dimensions for test fitting the implantable subcutaneous chest bar (see **FIG. 2A**).

15

In a further aspect of the invention, the through holes include oval through holes or elongated through holes, where the through holes are a pattern of the through holes, where the pattern is configured to direct tension forces exerted on the through holes in a splayed direction from the pattern of through holes (see **FIG. 2B**). **FIGs. 2A-2B** shown a 3D
20 printed plastic test bar and the customized subcutaneous chest bar having the associated eyelet through holes, respectively, according to one embodiment of the invention.

In yet another aspect of the invention, the semi-ribbed strap includes a narrowed material region that is proximal to a middle of the semi-ribbed strap, where the semi-ribbed strap is

ribbed along a span from proximal to the channeled head to proximal to the narrowed material region and is un-ribbed from proximal to the narrowed material region to the curved solid insertion element. **FIGs. 3A-3E** show pectus carinatum sternal pull-back securing straps, according to one embodiment of the invention. According to a further aspect of the invention, strap portion is made of a polymer plastic and the curved solid insertion element includes a material such as stainless steel. In implementation, the securing straps are threaded around the ribs and through the through hole eyelets using the curved solid insertion element, then the securing straps are cut at the narrowed material region to allow for insertion of the ribbed portion through the channeled head to interlock with the barb for securing.

According to one embodiment of the invention, a method of pectus carinatum sternal pull-back is provided that includes marking bar entry and exit sites on a patient rib cage, selecting intercostal spaces on the patient rib cage, making bilateral skin incisions at the selected intercostal spaces, creating a submuscular tunnel from an anterior aspect of the bilateral incisions to a highest point of a pectus carinatum sternal defect, advancing a subcutaneous dissector into the submuscular tunnel from a proximal side of the rib cage to a distal side of the rib cage, pulling a customized implantable subcutaneous chest bar, using an umbilical tape, through the submuscular tunnel to a predetermined position on the rib cage, placing securing strap around selected ribs of the rib cage, where the selected ribs are located on each side of the rib cage, where the securing straps are passed through eyelets of the customized bar, applying a pressure to the anterior chest wall while tightening the securing straps for correcting the pectus carinatum sternal defect, and closing the bilateral skin incisions.

The present invention has now been described in accordance with several exemplary embodiments, which are intended to be illustrative in all aspects, rather than restrictive. Thus, the present invention is capable of many variations in detailed implementation, which
5 may be derived from the description contained herein by a person of ordinary skill in the art. All such variations are considered to be within the scope and spirit of the present invention as defined by the following claims and their legal equivalents.

CLAIMS

What is claimed:

- 1) A pectus carinatum sternal pull-back device, comprising:
 - a) an implantable subcutaneous chest bar, wherein a size, a curve, a length and a
5 width of said implantable subcutaneous chest bar are customized according to predetermined sternum and rib cage dimensions of a pectus carinatum patient, wherein said customized implantable subcutaneous chest bar comprises through
holes at the ends of said customized implantable subcutaneous chest bar; and
 - b) at least a pair of securing straps, wherein said securing strap comprises a
10 channeled head element at a first securing strap end, a semi-ribbed strap, and a curved solid insertion element at a second end, wherein said channeled head element comprises a barb for receiving and locking said semi-ribbed strap, wherein said securing strap is configured for insertion through said through
holes of said implantable subcutaneous chest bar.
- 15 2) The pectus carinatum sternal pull-back device of claim 1, wherein said implantable subcutaneous chest bar comprises material selected from the group consisting of titanium, and surgical steel.
- 20 3) The pectus carinatum sternal pull-back device of claim 1, wherein said predetermined sternum and rib cage dimensions comprise a 3D digital image of said sternum and rib cage dimensions from a patient according to output from a CT scan of said patient.

4) The pectus carinatum sternal pull-back device of claim 4, wherein a 3D plastic printed test bar is configured from said 3D digital image of said sternum and rib cage dimensions.

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5) The pectus carinatum sternal pull-back device of claim 1, wherein said through holes comprise oval through holes or elongated through holes, wherein said through holes comprise a pattern of said through holes, wherein said pattern is configured to direct tension forces exerted on said through holes in a splayed direction from said pattern of through holes.

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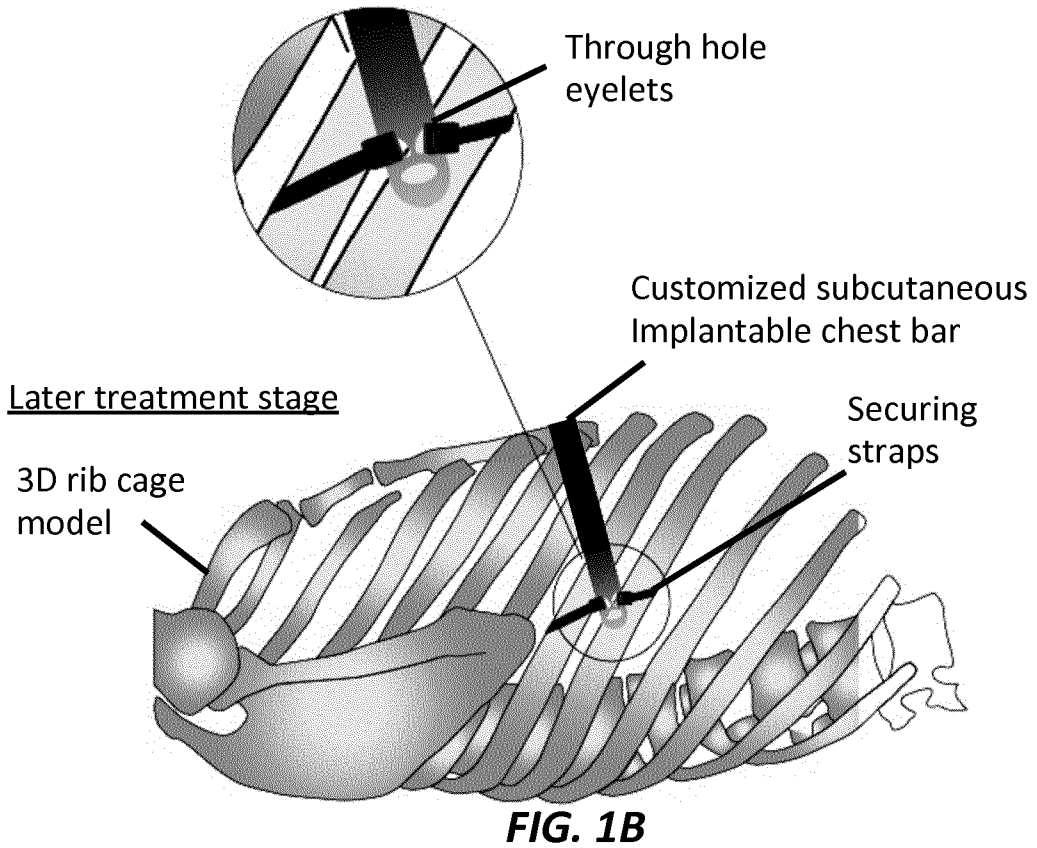
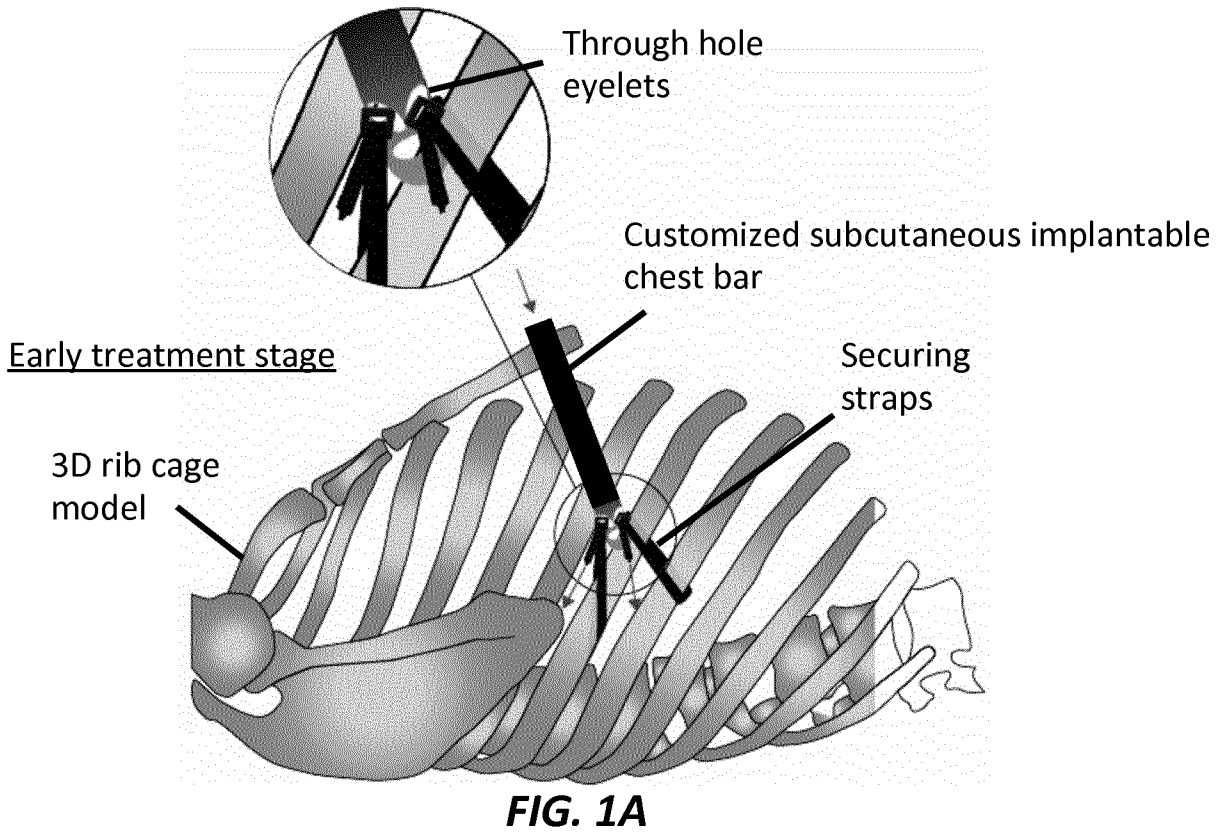
6) The pectus carinatum sternal pull-back device of claim 1, wherein said semi-ribbed strap comprises a narrowed material region that is proximal to a middle of said semi-ribbed strap, wherein said semi-ribbed strap is ribbed along a span from proximal to said channeled head to proximal to said narrowed material region and is un-ribbed from proximal to said narrowed material region to said curved solid insertion element, wherein said channeled head and said semi-ribbed strap are made from a polymer plastic.

15

7) The pectus carinatum sternal pull-back device of claim 1, said curved solid insertion element of said securing strap comprises a material made from stainless steel.

20

- 8) A method of pectus carinatum sternal pull-back, comprising
- a) marking bar entry and exit sites on a patient rib cage;
 - b) selecting intercostal spaces on said patient rib cage;
 - c) making bilateral skin incisions at said selected intercostal spaces;
 - 5 d) creating a submuscular tunnel from an anterior aspect of said bilateral incisions to a highest point of a pectus carinatum sternal defect;
 - e) advancing a subcutaneous dissector into said submuscular tunnel from a proximal side of said rib cage to a distal side of said rib cage;
 - f) pulling a customized bar, using an umbilical tape, through said submuscular
10 tunnel to a predetermined position on said rib cage;
 - g) placing securing straps around selected ribs of said rib cage, wherein said selected ribs are located on each side of said rib cage, wherein said securing straps are passed through eyelets of said customized bar;
 - h) applying a pressure to said anterior chest wall while tightening said securing
15 straps for correcting said pectus carinatum sternal defect; and
 - i) closing said bilateral skin incisions.



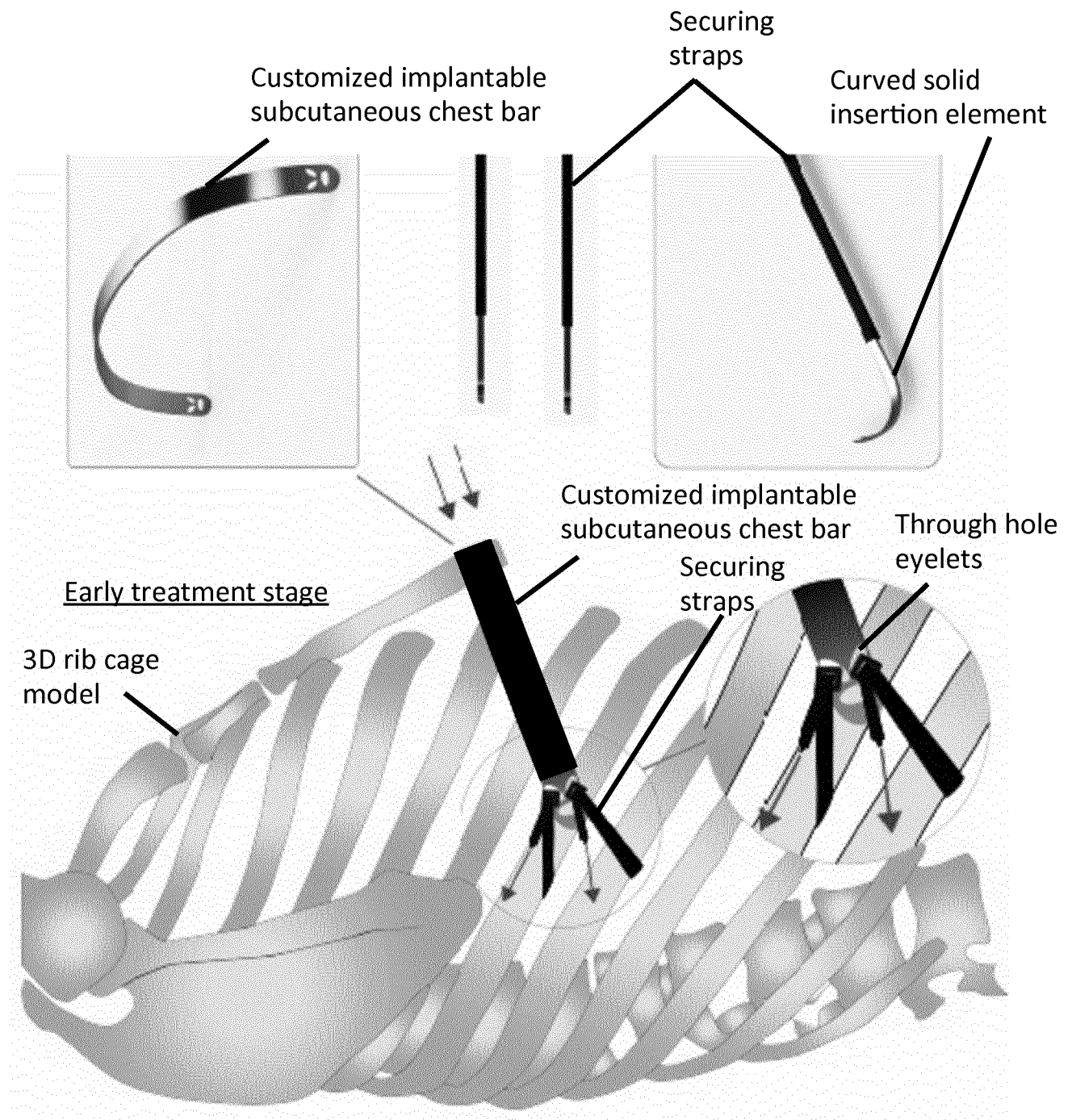


FIG. 1C

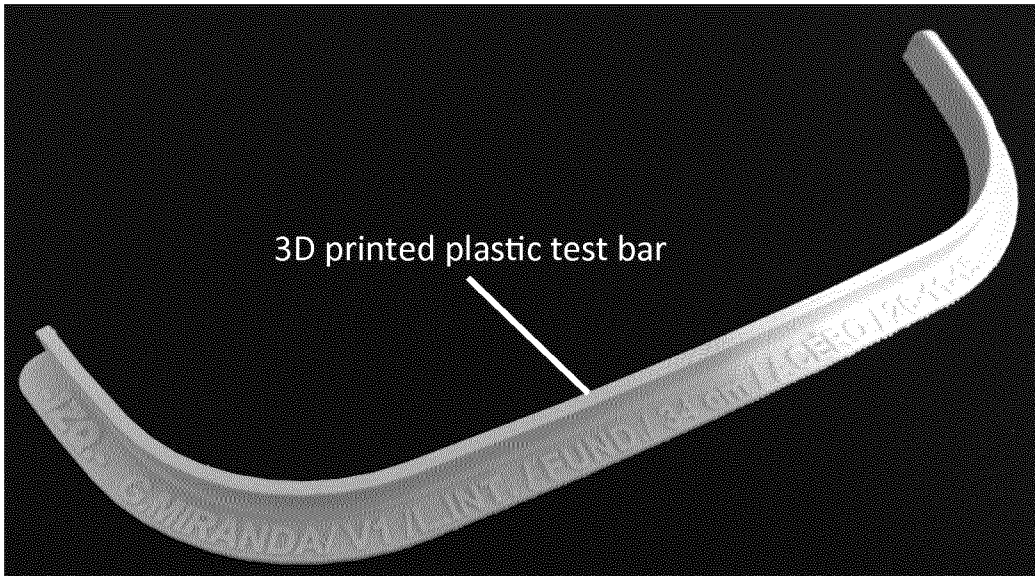


FIG. 2A

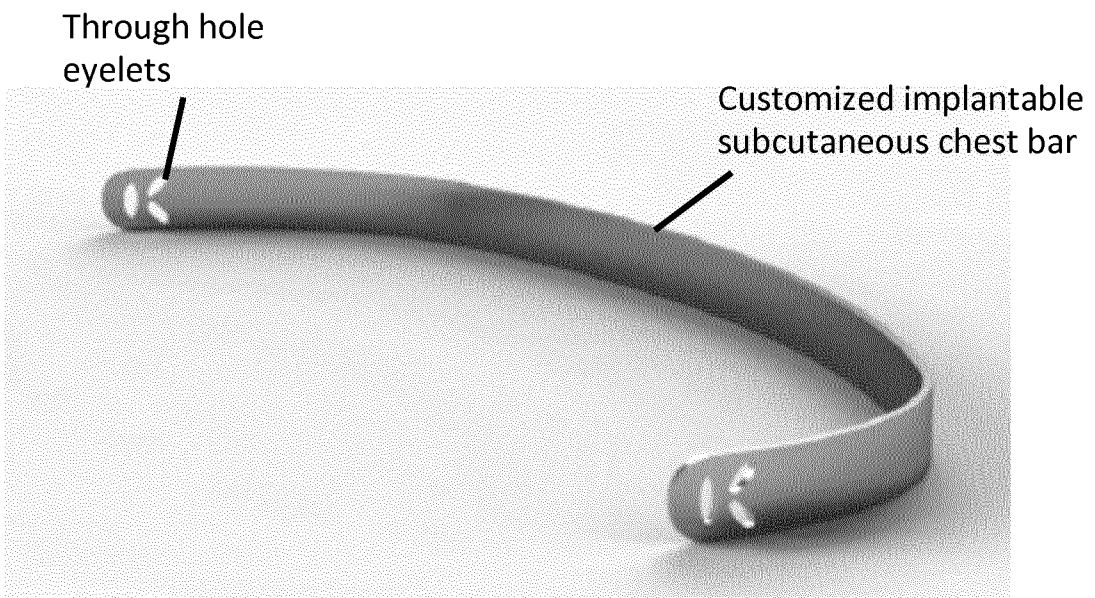
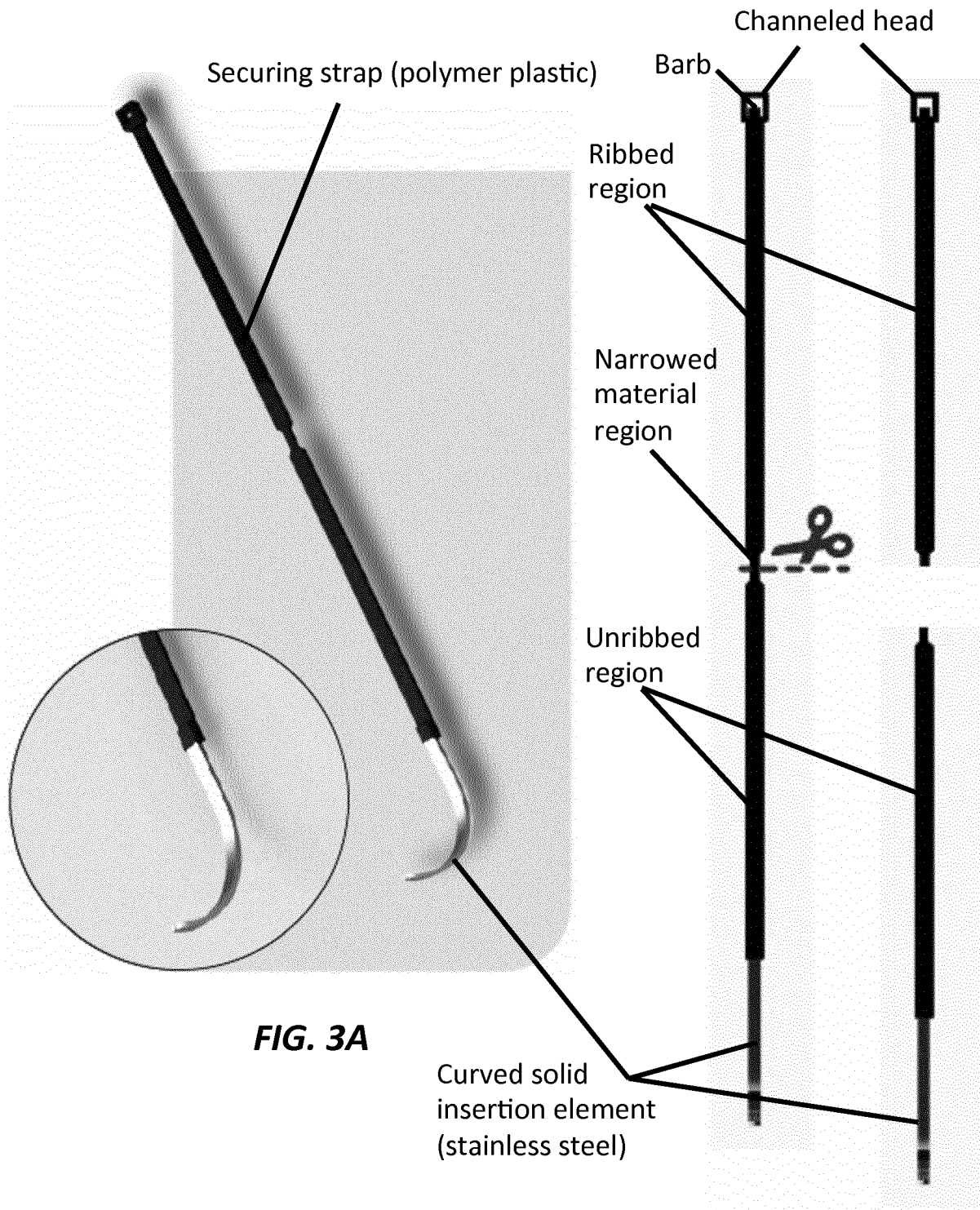


FIG. 2B



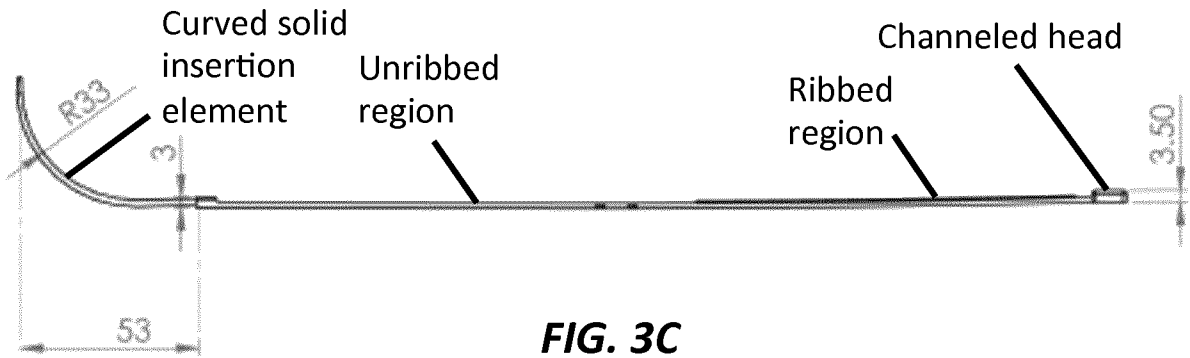


FIG. 3C

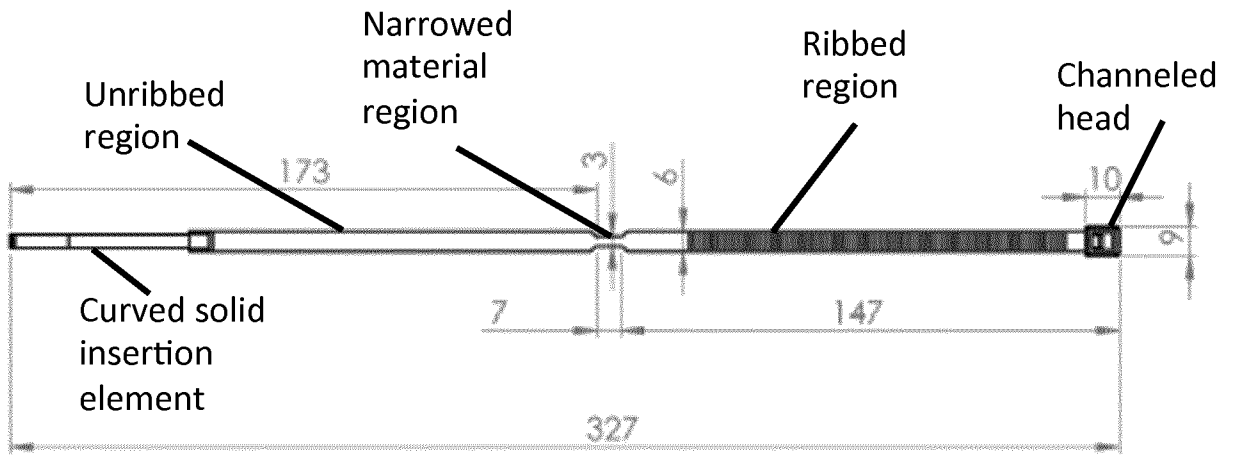


FIG. 3D

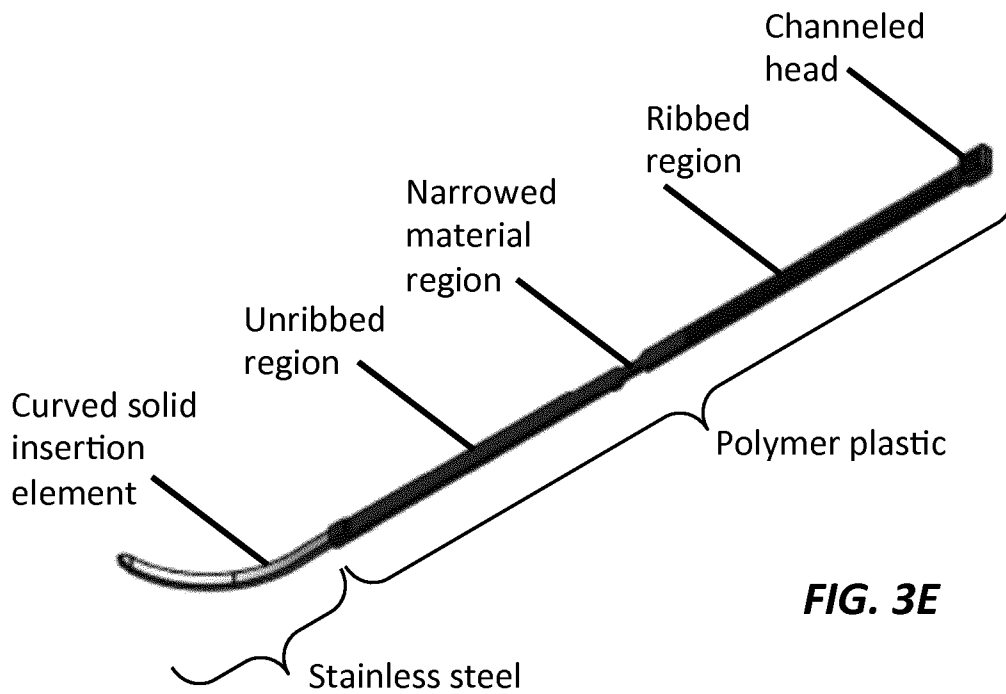


FIG. 3E

INTERNATIONAL SEARCH REPORT

International application No PCT/EP2017/055718

A. CLASSIFICATION OF SUBJECT MATTER INV. A61B17/82 A61B17/84 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 practicable, 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 2004/117016 A1 (ABRAMSON HORACIO [AR]) 17 June 2004 (2004-06-17) figures 1, 8, 10 -----	1-7		
A	EP 0 238 219 A1 (PFIZER HOSPITAL PROD [US]) 23 September 1987 (1987-09-23) figures 1, 2 -----	1		
<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input checked="" type="checkbox"/> See patent family annex.				
* Special categories of cited documents : <table style="width: 100%; border: none;"> <tr> <td style="width: 50%; border: none; vertical-align: top;"> "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier application or patent 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 </td> <td style="width: 50%; border: none; vertical-align: top;"> "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 </td> </tr> </table>			"A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier application or patent 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
"A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier application or patent 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			
27 April 2017	10/05/2017			
Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Authorized officer Fernández Arillo, J			

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2017/055718

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.: 8
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 8 has not been searched, since it is directed to a method for treatment of the human 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 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. 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/EP2017/055718

Patent document cited in search report		Publication date		Patent family member(s)	Publication date
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