(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
6 September 2013 (06.09.2013)

WIPO | PCT

(10) International Publication Number
WO 2013/127406 Al

(51) International Patent Classification:
A61B 17/86 (2006.01) *A61B 17/88* (2006.01)

(21) International Application Number:
PCT/EP20 12/000880

(22) International Filing Date:
29 February 2012 (29.02.2012)

(25) Filing Language: English

(26) Publication Language: English

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(81) Designated States *(unless otherwise indicated, for every kind of national protection available):* AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available):* ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

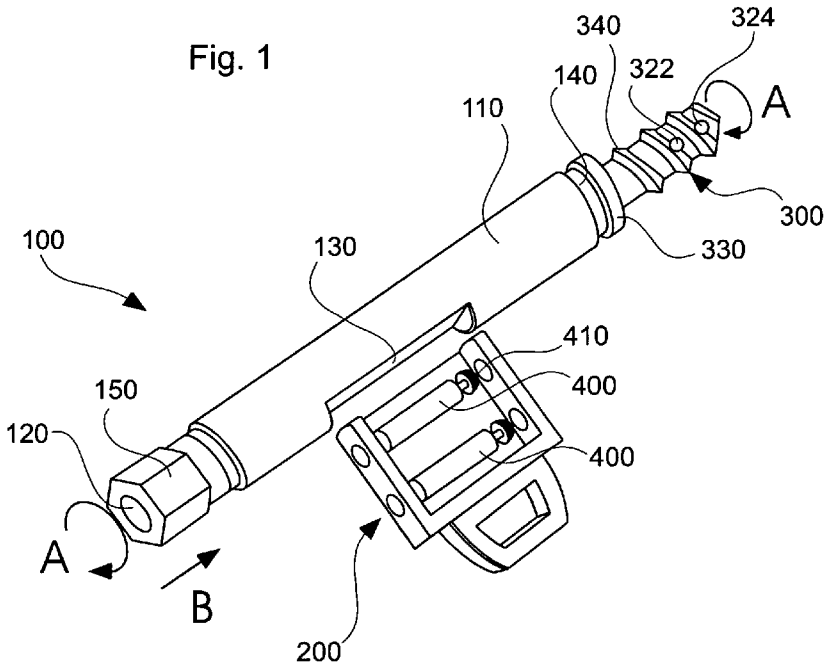
Published:

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

WO 2013/127406 A1

(54) Title: SYSTEM FOR HANDLING AN AUGMENTATION IMPLANT

Fig. 1



(57) Abstract: A handling device for handling an augmentation implant is proposed, comprising an elongated housing having an axial through-bore for accommodating a sonotrode of an ultrasound applicator, and a lateral opening for inserting a pin magazine with an augmentation pin, wherein the axial through-bore and the lateral opening are connected to each other. The handling device further comprises a distal implant portion for fastening a proximal end of the augmentation implant at the housing, and a proximal tool portion for driving and/or augmenting the augmentation implant.

System for handling an augmentation implant

FIELD OF THE DISCLOSURE

The invention relates to a handling device for handling an augmentation implant. Furthermore, the invention relates to a corresponding method including driving in of the implant into an object and augmenting the same within the object.

BACKGROUND INFORMATION

Known from US 4,653,489 is a system wherein fixation cement is introduced through a screw into a portion of a bone afflicted by osteoporoses. Femoral neck fractures as well as distal femoral fractures can be fixated by means of this device.

The system in accordance with prior art comprises a screw having a flow cavity, i.e. an axial through-bore through which bone cement can be introduced into the portion at the tip of the screw. The bone cement is advanced by a device which is releasably attached to the subsequent end of the screw. This device is similar to commercially available syringes. In use of this prior art device, the fixation cement is injected in an already fluidized state into the axial through-bore of the screw. Due to the pressure, the fixation cement is adequately fluidized, so that it can pass through the proximal end of the screw into the bone, as a result of which the screw is augmented in the bone.

This system has a drawback that the distribution of the fixation cement within the portion of the bone at the tip of the screw is neither reliable nor even.

SUMMARY OF THE INVENTION

WO 201 1/054122 A1 describes a medical device which may be an augmentation implant or may be an augmentation device for strengthening human or animal hard tissue for subsequently implantation of a separate implant. The disclosure of this document is incorporated herein by reference.

An object of the invention may be to provide a device and a method by means of which a handling of an augmentation implant is facilitated. Another object may be to provide a device and a method by means of which a reliable and even augmentation of an augmentation implant in an installation site can be assured. This is achieved by the subject-matter of the respective independent claims. Further embodiments are described in the dependent claims.

According to an exemplary embodiment of the invention, a handling device for handling an augmentation implant comprises an elongated housing having an axial through-bore and a lateral opening in communication with each other, a distal implant portion and a proximal tool portion.

As used herein, in addition to the plain and ordinary meaning, the term "augmentation" can, for example, encompass any kind of anchoring. The term "augmentation" can, for example, encompass an anchoring by way of material which is arranged between an implant and an object, like a dowel between a screw and a wall. Furthermore, the term "augmentation" can, for example, encompass an anchoring by providing material which engages the implant as well as the surrounding tissue, but which material is introduced after the implant is inserted into the object.

Consequently, an "augmentation implant" can be any kind of an implant which may be anchored by providing material between the implant and tissue surrounding the implant, i.e. which may be augmented. Accordingly, the overall volume of the augmentation implant is increased after the implant is inserted into tissue of an object, for example bone, wood or another porous material.

As used herein, in addition to the plain and ordinary meaning, the verb "to augment" can, for example, encompass any kind of anchoring or fixating of an implant in an object by providing material and thus increasing the overall volume of the implant, for example with a material which can be pressed from the implant into at least one cavity or into pores in tissue of an object, with the material being fluidized, wherein the material is capable of subsequently hardening.

A material for augmenting an implant may be provided in form of an augmentation pin. An augmentation pin may be, for example, a small pin of approximately 3cm to 4cm, length with a few millimetres in diameter. It will be understood, that the dimensions of the augmentation pin depend upon the intended application, i.e. depends on the amount of material which is needed for a reliable augmentation of a particular implant.

It is noted, that the material of the augmentation pin may be a polymer material being fluidizable and biocompatible, wherein a biocompatible material may be a material which does not negatively interfere with human or animal tissue. Additionally, the material may also be bioabsorbable.

In this text the expression "polymer material being fluidizable e.g. by mechanical vibration" or in short "fluidizable polymer material" or "fluidizable material" is used for describing a material comprising at least one thermoplastic component, which material becomes liquid or flowable when heated, in particular when heated through friction i.e. when arranged at one of a pair of surfaces (contact faces) being in contact with each

other and vibrationally or rotationally moved relative to each other, wherein the frequency of the vibration may be between 2 kHz and 200 kHz, preferably 20 to 40 kHz and the amplitude between 1 μm and 100 μm, preferably around 10 to 30 μm. Such vibrations may be e.g. produced by ultrasonic devices as e.g. known for dental applications. For being able to constitute a load-bearing connection to the tissue, the material at the time of insertion may have an elasticity coefficient of more than 0.5 GPa, preferably more than 1 GPa. The elasticity coefficient of at least 0.5 GPa also ensures that the fluidizable or liquefiable material may be capable of transmitting the ultrasonic oscillation with such little damping that inner fluidization or liquefaction and thus destabilization of the liquefiable element does not occur, i.e. liquefaction occurs only where the liquefiable/fluidizable material is at the liquefaction interface to the stop face. The plastification temperature is preferably of up to 200°C, between 200°C and 300°C or even more than 300°C.

Suitable resorbable polymers are e.g. based on lactic acid and/or glycolic acid (PLA, PLLA, PGA, PLGA etc.) or polyhydroxyalkanoates (PHA), polycaprolactones (PCL), polysaccharides, polydioxanones (PD), polyanhydrides, polypeptides or corresponding copolymers or blended polymers or composite materials containing the mentioned polymers as components are suitable as resorbable liquefiable materials. Thermoplastics such as for example polyolefins, polyacrylates, polymetacrylates, polycarbonates, polyamides, polyesters, polyurethanes, polysulphones, polyaryl ketones, polyimides, polyphenyl sulphides or liquid crystal polymers (LCPS), polyacetals, halogenated polymers, in particular halogenated polyoelefins, polyphenylene sulphides, polysulphones, polyethers, polypropylene (PP), or corresponding copolymers or blended polymers or composite materials containing the mentioned polymers as components are suitable as non-resorbable polymers. Examples of suitable thermoplastic material include any one of the polylactide products LR708 (amorphous Poly-L-DL lactide 70/30), L209 or L210S by Bohringer Ingelheim.

Specific embodiments of degradable materials are Polylactides like LR706 PLDLLA 70/30, R208 PLDLA 50/50, L210S, and PLLA 100% L, all of Bohringer. A list of suitable degradable polymer materials can also be found in: Erich Wintermantel und Suk-Woo Haa, "Medizinaltechnik mit biokompatiblen Materialien und Verfahren", 3. Auflage, Springer, Berlin 2002 (in the following referred to as "Wintermantel"), page 200; for information on PGA and PLA see pages 202 ff., on PCL see page 207, on PHB/PHV copolymers page 206; on polydioxanone PDS page 209. Discussion of a further bioresorbable material can for example be found in CA Bailey et al., J Hand Surg [Br] 2006 Apr;31(2):208-12.

Specific embodiments of non-degradable materials are: Polyetherketone (PEEK Optima, Grades 450 and 150, Invibio Ltd), Polyetherimide, Polyamide 12, Polyamide 11, Polyamide 6, Polyamide 66, Polycarbonate, Polymethylmethacrylate, Polyoxymethylene, or polycarbonateurethane (in particular Bionate® by DSM, especially Bionate 75D and Bionate 65D; according information is available on datasheets publicly accessible for example via www.matweb.com by Automation Creations, Inc.). An overview table of polymers and applications is listed in Wintermantel, page 150; specific examples can be found in Wintermantel page 161 ff. (PE, Hostalen Gur 812, Hochst AG), pages 164 ff. (PET) 169ff. (PA, namely PA 6 and PA 66), 171 ff. (PTFE), 173 ff. (PMMA), 180 (PUR, see table), 186 ff. (PEEK), 189 ff. (PSU), 191 ff. (POM - Polyacetal, tradenames Delrin, Tenac, has also been used in endoprostheses by Protec).

The fluidizable/liquefiable material having thermoplastic properties may contain foreign phases or compounds serving further functions. In particular, the thermoplastic material may be strengthened by admixed fillers, for example particulate fillers that may have a therapeutic or other desired effect. The thermoplastic material may also contain components which expand or dissolve (create pores) in situ (e.g. polyesters, polysaccharides, hydrogels, sodium phosphates) or compounds to be released in situ and having a therapeutic effect, e.g. promotion of healing and regeneration (e.g. growth

factors, antibiotics, inflammation inhibitors or buffers such as sodium phosphate or calcium carbonate against adverse effects of acidic decomposition). If the thermoplastic material is resorbable, release of such compounds is delayed.

The material of the liquefiable element(s), i.e. of an augmentation pin, may contain an additional substance, for example for promoting healing or regeneration of for furthering x-ray visibility. For example, the additional substance may be a growth factor, an antibiotic, an inflammation inhibitor or a buffer. More particularly, the additional substance be a drug promoting healing, in particular growth, differentiation and/or regeneration such as a proteinaceous drug like a growth and/or differentiation factor, e.g. of the Bone Morphogenic Protein family (especially BMP 2, 6, 7, for certain applications also BMP 12, 13), an Insulin Growth Factor (e.g. IGF 1), a Platelet Derived Growth Factor (PDGF), a Growth and Differentiation Factor (e.g. GDF 5) etc. and also combinations thereof and/or other an other drug including a non-proteinaceous drug including small molecules (e.g. biphosphonates), possibly in combination with a proteinaceous drug, etc..

Fillers used may include degradable, osseostimulative fillers to be used in degradable polymers, including: β-Tricalciumphosphate (TCP), Hydroxyapatite (HA, < 90% crystallinity; or mixtures of TCP, HA, DHCP, Bioglasses (see Wintermantel). Osseo-integration stimulating fillers that are only partially or hardly degradable, for non degradable polymers include: Bioglasses, Hydroxyapatite (>90% cristallinity), HAPEX® , see SM Rea et al., J Mater Sci Mater Med. 2004 Sept; 15(9):997-1 005; for hydroxyapatite see also L. Fang et al., Biomaterials 2006 Jul; 27(20):3701-7, M. Huang et al., J Mater Sci Mater Med 2003 Jul; 14(7):655-60, and W. Bonfield and E. Tanner, Materials World 1997 Jan; 5 no. 1:18-20. Embodiments of bioactive fillers and their discussion can for example be found in X. Huang and X. Miao, J Biomater App. 2007 Apr; 21(4):351-74), JA Juhasz et al. Biomaterials, 2004 Mar; 25(6):949-55. Particulate filler types include: coarse type: 5-20μm (contents, preferentially 10-25% by volume),

sub-micron (nanofillers as from precipitation, preferentially plate like aspect ratio > 10, 10-50 run, contents 0.5 to 5% by volume).

A specific example of a material with which experiments were performed was PLDLA 70/30 comprising 30% (weight percent) biphase Ca phosphate that showed a particularly advantageous liquefaction behaviour.

The material of the sheath element (which may be a screw, especially pedicle screw) may be any material that does not melt at the melting temperatures of the liquefiable material. Especially, the sheath element may be of a metal, for example a titanium alloy. A preferred material is titanium grade 5. This material, in addition to being generally suited for implantable devices, has a comparably low heat conduction. Because of this low heat conduction, the melting zone arising in liquefiable material and at the interface to the directing structure is heated quickly, without the surroundings being heated to too high temperatures. Alternative materials for the sheath element are other metals like other titanium alloys, stainless steel, ceramics like Zirconium oxides or Aluminum oxides, or hard plastics such as PEEK etc.

An augmentation pin may or may not include a closing plug, wherein the closing plug may be fixedly attached to a leading end of a pin made of augmentation material or may be provided as a separate element so that a combination of a closing plug with a pin made of augmentation material may be formed within an augmentation implant by inserting firstly the closing plug and secondly the pin.

An augmentation pin may be inserted through the lateral opening of the elongated housing of the handling device according to the invention so that the augmentation pin is aligned with the axial through-bore, and may be pushed for example by a sonotrode of an ultrasound applicator through the axial through bore in a direction to the distal implant portion. At the distal implant portion a proximal end of an augmentation implant may be coupled to the elongated housing, wherein the augmentation implant

may be provided with an axial bore so that the augmentation pin may be pushed out of the distal implant portion and into the axial bore in the augmentation implant.

For example, the augmentation implant may be an augmentation screw, wherein the augmentation material may be pressed from the inside of the screw to the outside so as to surround at least partially the outer thread of the screw. According to another example, the augmentation implant may be any kind of nail or bolt the outer surface of which is not provided with a thread, but which may be provided with ribs or protrusions, thus being also non-circular. It is noted, that the augmentation implant may also be a plate for stabilizing for example a fractured object at an outer surface thereof, wherein additional material may be provided so as to extend from the plate into at least one cavity formed in the object beneath the plate.

The proximal tool portion of the elongated housing of the handling device is designed so that the augmentation implant can be easily handled by means of the handling device, i.e. can be held and accurately positioned at an installation site at an object and/or can be driven in into the object. In other words, the proximal tool portion may serve as a grip of a screwdriver or as a grip for holding the handling device and thus an augmentation nail while punching the nail into an object.

According to an embodiment of the invention, the handling device further comprises an ultrasound applicator having an ultrasound transducer and a sonotrode, wherein the ultrasound applicator is arranged so that the sonotrode extends from the ultrasound transducer in a direction toward the distal implant portion. The ultrasound applicator may be capable of fluidizing the material of the augmentation pin within the augmentation implant by means of a combination of pressure and ultrasound vibrations, and pressing the fluidized material through at least one bore out of the implant. It will be understood that at least the sonotrode of the ultrasound applicator is movably arranged to be capable of pushing an augmentation pin through the elongated housing

and of pressing the material of the augmentation pin out of the implant when the material of the augmentation pin is fluidized.

According to an embodiment of the invention, the ultrasound applicator may be integrated into the proximal tool portion of the handling device.

According to a further embodiment of the invention, the proximal tool portion may be adapted for releasably connecting the ultrasound applicator at the elongated housing. In this case, the handling device may further comprise a driving tool with a distal driving end, wherein the distal driving end is adapted to be coupled at the proximal tool portion when the ultrasound applicator is released from the proximal tool portion. For example, the driving tool may be an active screwdriver providing appropriate torque wherein the active screwdriver may be driven electrically, pneumatically or hydraulically.

According to another embodiment, the distal implant portion of the handling device, i.e. the connection between the distal implant portion and the augmentation implant, is adapted to transmit forces from the elongated housing to the augmentation implant, for driving in the augmentation implant into an object, wherein these forces may be rotational forces or translational forces as well as a combination thereof, depending on the kind of the implant.

The distal implant portion of the handling device may include a quick-fastener.

In accordance with a further embodiment, the handling device may further comprise a locking element for blocking a lateral movement of the augmentation pin, when the augmentation pin is placed in the lateral opening and is aligned with the axial through-bore. The functionality of the handling device may be further enhanced in that the lateral opening of the elongated housing is a through-opening and a projection projects into the lateral opening, so that the augmentation pin is automatically aligned with the

axial through-bore, when the augmentation pin is placed in the lateral opening and abuts the projection.

According to yet another embodiment, the handling device may further comprise a pin-magazine, wherein at least one pin-retainer may be provided in that pin magazine for holding at least one augmentation pin. The pin-magazine may be adapted to be placed in the lateral opening of the housing and may be adapted to align the augmentation pin with the axial through-bore in the housing, so that the augmentation pin may be inserted into an augmentation implant.

It will be understood that the pin-magazine may be designed corresponding to the shape of the lateral opening in the housing of the handling device in order to be placed in the lateral opening only with a specific orientation and direction.

In accordance with a further embodiment of the invention, the handling device is adapted to augment an implant by means of a plurality of augmentation pins, wherein these pins may be provided in one pin magazine. Each of the augmentation pins may be pushed from the elongated housing into an augmentation implant by means of the sonotrode of the ultrasound applicator. For this, the ultrasound applicator may be movable between a first position and a second position. The distal tip of the sonotrode may be located proximal to the lateral opening, i.e. the location at which an augmentation pin can be inserted into the elongated housing, when the ultrasound applicator is in the first position. On the other hand, the distal tip of the sonotrode may be located at or beyond the distal implant portion, i.e. within an augmentation implant, when the ultrasound applicator is in the second position. Accordingly, the sonotrode may be capable of pushing an augmentation pin from the lateral opening through the axial through bore and into the augmentation implant.

According to an embodiment, the sonotrode of the ultrasound applicator may include a section with reduced diameter. In a case in which an augmentation pin is provided in a

pin magazine, the sonotrode will extend more or less through the pin magazine, when the sonotrode has pushed the augmentation pin to the distal implant portion of the handling device and into an augmentation implant. The section with reduced diameter is adapted so as to ensure that there is no contact between the shaft of the sonotrode and the pin magazine, when ultrasound vibrations are transmitted by the sonotrode. By way of this, any loss of transmitted energy can be avoided during the fluidization and pressing out of the material of the augmentation pin.

According to a further embodiment, a kit may be provided including a handling device as described above together with an augmentation implant.

A description in more detail of the steps performed while using the handling device in accordance with the invention may be followed in conjunction with the detailed description of an exemplary embodiment below.

It has to be noted that embodiments of the invention are described with reference to different subject-matters. In particular, some embodiments are described with reference to method-type claims, whereas other embodiments are described with reference to apparatus-type claims, however, a person skilled in the art will gather from the above and the following description that, unless otherwise notified, in addition to any combination of features belonging to one type of subject-matter, also any combination of features relating to different subject-matters is considered to be disclosed with this application.

These and other objects, features and advantages of the exemplary embodiments of the present invention will become apparent upon reading the following detailed description of exemplary embodiments, when taken in conjunction with the appended claims.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will now be detailed by way of exemplary embodiments with reference to the attached drawings.

Figure 1 is a schematically illustration of an exemplary handling device according to the invention.

Figure 2 is a sectional view of an exemplary handling device according to the invention.

Figure 3 is an illustration of an exemplary handling device with an ultrasound applicator being releasably connected to the elongated housing.

Figures 4a and 4b are illustrations of an exemplary handling device with an ultrasound applicator being fixedly connected to the elongated housing.

Figure 5 is a detail view of the lateral opening in the elongated housing.

Figure 6 is a detail view of an exemplary pin magazine.

Figure 7 is a sectional view of a leading end of an augmentation screw with a closing Plug-

Figure 8 is an isometrical illustration of a closing plug.

Figure 9 shows a sequence illustrating the augmentation of an implant using a plurality of augmentation pins.

Figure 10 is a flowchart representing method steps in accordance with the invention.

It is noted that the illustration in the drawings is only schematically and not to scale. Throughout the drawings, the same reference numerals and characters, unless otherwise stated, are used to denote like features, elements, components, or portions of the illustrated embodiments. Moreover, while the present invention will now be described in detail with reference to the figures, it is done so in connection with the illustrative embodiments and is not limited by the particular embodiments illustrated in the figures, as defined by the appended claims.

DETAILED DESCRIPTION OF EXEMPLARY EMBODIMENTS

Figure 1 provides an isometric illustration of the handling device 100 according to an exemplary embodiment of the invention, including an elongated housing 110, an axial through-bore 120, a lateral opening 130, a distal implant portion 140, and a proximal tool portion 150.

The lateral opening 130 is asymmetrically shaped to assure that a pin-magazine 200 which may be correspondingly formed, can be inserted into the lateral opening 130 only in one predetermined way. In the pin magazine 200, two augmentation pins 400 are shown, wherein each of the augmentation pins comprises a closing plug 410 arranged at the leading end of the pin. Each of the augmentation pins can be inserted into the elongated housing 110 so that the closing plug rests within the axial through-bore 120 at a predetermined position allowing the material of the augmentation pin to flow out of a predetermined lateral bore 322 and/or 324, when fluidized.

It is noted, that the pin-magazine may be a rotary cylinder with augmentation pins arranged like bullets in a revolver, instead of the straight and flat pin-magazine shown in the figures.

Further shown in figure 1 is an augmentation screw 300 the proximal end portion 330 being connected to the distal implant portion 140 of the handling device 100. The augmentation screw comprises an outer thread 340, wherein two lateral bores 322, 324 are formed in the portion of the outer thread. The lateral bores are provided with a different distance to the distal tip of the augmentation screw 300.

As indicated by the arrows A and B, appropriate rotational and translational forces can be applied on the augmentation screw 300 by means of the handling device 100.

Figure 2 is a sectional side view of the handling device 100 together with a pin magazine 200 and an augmentation screw 300. Figure 2 illustrates a situation in which a first augmentation pin 400 is pushed by means of a sonotrode 610 out of the pin magazine 200 and into the augmentation screw 300, and is already fluidized and pressed through lateral bores 324 out of the augmentation screw 300.

The sonotrode as shown in figure 2 comprises a tip 612 and a section 614 with reduced diameter. The section 614 has a length which is sufficient to ensure that the sonotrode shaft will be not in contact with the pin magazine 200 when the sonotrode tip 612 fluidizes an augmentation pin 400 in an augmentation screw 300, wherein the closing plug 410 prevents any flowing out of fluidized material out of the augmentation screw 300 in an axial direction.

Further schematically illustrated in figure 2, is a connection between a distal implant portion 140 of the handling device 100 and the proximal portion 330 of the augmentation screw 300, with the distal implant portion 140 engaging inside the proximal portion 330.

Figure 3 illustrates an exemplary embodiment within ultrasound applicator 600 which can be releasably coupled to the proximal tool portion 150 of the handling device 100. A sonotrode 610 protrudes from the housing of the ultrasound applicator so that the sonotrode 610 can be introduced into the axial through bore 120 in the proximal tool portion 150, can be moved through the axial through bore 120 until then tip 612 is in contact with a augmentation pin 400 to push the augmentation pin 400 in a direction to the distal implant portion of the augmentation handling device 100 when the sonotrode 610 is further moved through the axial through bore 120.

The length of the sonotrode 610 may be adapted so that the augmentation pin 400 is located within an augmentation implant and at the same time the housing of the

ultrasound applicator 600 can be coupled to the proximal tool portion 150 of the handling device 100.

Figures 4a and 4b show another exemplary embodiment in which the housing of the ultrasound applicator 600 can be fixedly connected to the proximal tool portion of the handling device 100. In this case, the sonotrode 610 may be movable within the housing of the ultrasound applicator. Thus, the sonotrode 610 can be moved in a direction to the distal implant portion (arrow C) so as to push an augmentation pin 400 to and into an augmentation implant, as shown in figure 4a. After fluidizing a first augmentation pin, the sonotrode 610 can be pulled back (arrow D) so that the tip of the sonotrode 610 is located proximal to the lateral opening, i.e. proximal to the pin magazine 200, as shown in figure 4b. Then, the pin magazine 200 can be further inserted (arrow E) until a second augmentation pin 400 is aligned with the axial through bore of the handling device 100.

Figure 5 shows an exemplary embodiment of the handling device 100 including a locking element 160 as well as a projection 170.

The locking element 160 may include at least one locking pin (not shown) which protrudes into the lateral opening 130 and which is adapted to engage for example in a notch 240 formed at a pin-magazine 200 to lock the pin-magazine within the lateral opening. Further the locking element 160 may include a resilient element (not shown) for biasing the locking element 160 in a locking position. That is, a pin-magazine 200 may only be inserted into the lateral opening 130, when the locking element 160 is moved against the force of the resilient element, for example by hand or by a structural element at the pin-magazine, when the pin-magazine is inserted into the lateral opening. The locking pin may engage into the notch in the pin-magazine, when the locking element 160 is released. This will result in a locked positioning of the pin-magazine in the housing of the pin-inserter.

The projection 170 which is shown in accordance with this embodiment, projects from one side into the lateral opening 130. The projection 170 may be a substantially flat element, which provides an abutment for an augmentation pin, so that the augmentation pin will be reliably aligned with the axial through-bore in the elongated housing, when the augmentation pin abuts at the projection 170.

Figure 6 shows an exemplary embodiment of a pin-magazine 200. The pin-magazine 200 includes a grip portion 210, a body 220, and a recess 230. Transverse to the grip portion 210, two pin-retainers 260 are formed. Each pin-retainer is realized by a sequence of recesses within and bores through the body 220 of the pin-magazine. A first pin-retainer is formed at a position away from the grip portion 210, and a second pin-retainer is formed nearby the grip portion 210.

By way of the distinct arrangement of the pin-retainers 260 relative to the grip portion 210, it can be assured, that the pin-magazine 200 will be inserted into the lateral opening 130 of the handling device in a correct way, when the pin-magazine 200 is gripped at the grip portion 210.

The recess 230 is formed in the pin-magazine 200 nearby or at the pin-retainers 260, so that on the one hand, when the pin-magazine is placed in the lateral opening of the housing, a projection 170 at the housing may protrude into the recess, and on the other hand, when the augmentation pin is located in the pin-retainer, a portion of the augmentation pin 400 is laterally exposed for an abutment at the projection. That is, an augmentation pin which is accommodated within the pin-retainer of the pin-magazine, may be easily handled and introduced from the side into the housing of the pin-inserter, wherein an abutment of the augmentation pin at a projection within the housing indicates the correct position of the pin-magazine as well as the augmentation pin inside the housing of the pin-inserter. An automatic alignment of the augmentation pin with the axial through-bore of the pin-inserter can thus be assured.

In the body 220 of the pin-magazine 200, notches 240 may be formed, which are provided for an engagement with respective locking pins of the locking element 160 of the handling device. Such locking pins may be press to a side by means of chamfers 250 provided at the body 220, so that the locking element may be passively actuated when the pin-magazine is inserted into the lateral opening of the handling device. By way of this, the pin-magazine may be fixated at a predetermined position and it may be avoided that the pin-magazine falls accidentally out of the pin-inserter.

Further, signs like arrows may be provided at the body, indicating for example a direction for an insertion of the magazine into the pin-inserter, or numbers (shown in figures 3, 4a, 4b) referring to the sequence for the augmentation pins.

In Figure 6, also augmentation pins 400 are visualized within the pin-retainers 260, wherein one of the augmentation pins 400 is pushed half way out of the respective pin retainer 260.

An augmentation implant 300 which may be preferably used with a handling device 100 as described above, may comprise an axial bore for receiving an augmentation pin 400, the axial bore may include at least a first step between a first section with a first diameter and a second section with a second diameter, with the second diameter being greater than the first diameter. The augmentation implant may further comprise a second step between for example the second section and a third section with a third diameter, with the third diameter being greater than the second diameter. At the second section and adjacent the first step, at least one first lateral bore may be provided. At the third section and adjacent the second step, at least one second lateral bore may be provided. Depending on the diameter of the closing plug of the augmentation pin, the closing plug and thus the augmentation pin may rest on the first step or the second step, when inserted into the axial bore of the augmentation implant. Having two steps in the axial bore provides the advantage that such an implant may be utilized in different applications by use of different and/or additional augmentation pins. It will be

understood, that also an augmentation implant with more than two steps may be provided if appropriate in a particular application.

The augmentation implant may further comprise a portion with an outer thread, wherein the first lateral bore as well as the second lateral bore are located in that portion. Figure 7 shows a distal portion of such an augmentation implant 300, i.e. an augmentation screw with at least first lateral bores 324 (two bores with the same distance from the distal end of the implant). A closing plug 410 is located within an axial through-bore of the augmentation screw and is closing the axial through-bore so that any fluidized material may be pressed only out of the lateral bores 324, as indicated by the arrows in figure 7.

Figure 8 shows an exemplary embodiment of a closing plug 410 comprising ribs 412 forming recesses 414 leading fluidized material to lateral bores, as shown in figure 7. Furthermore, the closing plug includes a tapered leading end portion 416 so that the closing plug will fixedly clamp at a step in an axial through-bore of an augmentation implant, as described above and shown in figure 7.

With a closing plug 410 as shown in figures 7 and 8, it may be possible to utilize more than one augmentation pin made only by fluidizable material.

Furthermore, it may be possible to alternate such a closing plug with an augmentation pin made only by fluidizable material, i.e. inserting a closing plug without augmentation material and subsequently inserting a pin made of augmentation material. It will be understood that, in this case, the lateral bores may be provided at the augmentation implant with a distance in an axial direction, corresponding to the length of a closing plug so that with each further closing plug augmentation material may be pressed out of further proximally arranged lateral bores.

According to another exemplary embodiment the closing plug is fixedly attached to the leading end of a pin like element made of fluidizable material.

In a case in which the augmentation implant includes at least two steps with different diameters, the pin-magazine may comprise two pin-retainers adapted to hold two augmentation pins with closing plugs having corresponding different diameters. With this particular embodiment, an augmentation of for example a screw fixating a femur nail may be realized in two or more steps. The difference of both plugs (and possibly pins) will be a diverse diameter in a range of a 10th of a millimeter. Since this diverse diameters are not directly visible, it is appropriate to use a pin magazine to separate the pins.

Since the pin-magazine may fit in a specific way into the lateral opening of the handling device, the two different pins located in the pin-retainers of the pin-magazine can only be introduced into the handling device in a predetermined sequence. Thus, no mistake is possible by inserting the pins.

Figure 9 illustrates an exemplary sequence of handling an augmentation screw.

In a first instance, shown down left in figure 9A, and augmentation implant 300 is coupled to the distal implant portion of the handling device 100 and a driving tool 500 is releasably connected to the proximal tool portion of the handling device 100. As indicated by arrow A, torque is transmitted by the handling device 100 from the driving tool 500 to the augmentation implant 300 with the aim to insert the augmentation implant into an object.

In a second instance, shown in the middle in figure 9B, a pin magazine 200 is inserted into the handling device, as indicated by arrow E. With the pin magazine 200 inserted such that an augmentation pin 400 is aligned with the axial through bore in the handling device 100, an ultrasound applicator with the sonotrode 610 is inserted into the

proximal tool portion and is capable of pushing the augmentation pin 400 out of the pin magazine and into the augmentation implant.

In a third instance, shown up right in figure 9C, the ultrasound applicator 600 is connected to the handling device and the pin magazine is fully inserted into the handling device. That is, a last of a plurality of augmentation pins is pushed into the augmentation implant and may be fluidized and pressed out of the augmentation implant so that the augmentation of the implant is completed.

The flow-chart in Fig. 10 illustrates the principles of using the handling device according to the invention, i.e. Illustrates the principles of handling and augmentation implant. It will be understood that the steps described with respect to the method, and also with respect to figure 9, are major steps, wherein these major steps might be differentiated or divided into several sub-steps. Furthermore, there might be also sub-steps between these major steps. Therefore, a sub-step is only mentioned if that step may be important for the understanding of the principles of the method according to the invention.

In step SI, in implant is connected to the distal implant portion of the handling device.

In step S2, a driving tool is connected to the proximal tool portion of the handling device.

In step S3, a force is applied to the implant via the handling device and thus the implant is introduced or implanted at an installation site. For example, it may be an augmentation screw which is implanted protruding through a transverse bore in a gamma nail.

In step S4, the driving tool is removed from the handling device.

In step S5, a pin-magazine with at least one augmentation pin is placed within the lateral opening of the housing of the handling device so that one augmentation pin is aligned with an axial through-bore in the handling device. This alignment may be achieved by an abutment of the augmentation pin at a projection protruding into the lateral opening in the housing of the handling device.

In step S6, an ultrasound applicator is connected to the proximal tool portion of the handling device. By introducing the sonotrode of the ultrasound applicator into the axial through bore of the elongated housing, the augmentation pin is pushed out of the pin-magazine, through the elongated housing of the handling device and into the augmentation implant. The length of the sonotrode fits to the distance between the proximal end of the housing of the handling device and the proximal end of the augmentation pin inside the augmentation implant.

According to an exemplary embodiment in which altematingly a closing plug and a pin made only from fluidizable material, i.e. augmentation material, are inserted into the axial through-bore of the augmentation implant, steps S5 and S6 will be performed twice to achieve a combination of a closing plug and a pin made of augmentation material within the augmentation implant. It will be understood that, to achieve this, a pin magazine may be provided with a closing plug followed by a pin made of augmentation material, wherein the closing plug and the pin may be provided in separate retainers of the pin magazine. This case is indicated by the arrow going from step S6 back to step S5.

In step S7, ultrasonic vibrations together with a predetermined force is applied by the sonotrode to the augmentation material so that the material is fluidized and pressed out of at least one bore of the augmentation implant.

In step S8, at least the sonotrode of the ultrasound applicator is pulled back to enable an insertion of a further augmentation pin aligned with the axial through bore in the handling device.

If more than one augmentation pin, i.e. a combination of a closing plug and a pin made of augmentation material, should be utilized, the method steps S5 to S8 will be repeated, which is illustrated by the arrow going from step S8 back to step S5.

After the fluidization of all augmentation pins, in step S9, the ultrasonic applicator is removed from the proximal tool portion of the handling device.

In step S10, the handling device will be removed from the proximal end of the augmentation implant.

It is noted, that steps S2, S4, S6 and S8 may be omitted in case of an exemplary embodiment in which the ultrasound applicator is integrated in the elongated housing and the proximal tool portion is adapted to be gripped so that the elongated housing serves as a driving tool, wherein an augmentation pin may be either provided in the distal implant portion of the elongated housing or in the augmentation screw which can be coupled to the distal implant portion. Only steps S2, S4 and S6 may be omitted in case more than one augmentation pin is to be used.

While the invention has been illustrated and described in detail in the drawings and foregoing description, such illustration and description are to be considered illustrative or exemplary and not restrictive. The invention is not limited to the disclosed embodiments. Other variations to the disclosed embodiments can be understood and effected by those skilled in the art in practising the claimed invention, from a study of the drawings, the disclosure, and the appended claims.

In the claims, the word "comprising" does not exclude other elements, and the indefinite article "a" or "an" does not exclude a plurality.

The mere fact that the certain measures are recited in mutually different dependent claims does not indicate that a combination of these measures cannot be used to advantage. Any reference signs in the claims should not be construed as limiting the scope.

LIST OF REFERENCE SIGNS

100	Handling device
110	Housing
120	Axial through-bore
130	Lateral opening
140	Distal implant portion
150	Proximal tool portion
160	Locking element
170	Projection
200	Pin-magazine
210	Grip portion
220	Body
230	Recess
240	Notch
250	Chamfer
260	Pin-retainer
300	Augmentation screw
322, 324	Lateral bore
330	Proximal end portion
340	Outer thread
400	Augmentation pin

410	Closing plug
412	Rib
414	Recess
416	Tapered end portion
500	Driving tool
600	Ultrasonic applicator
610	Sonotrode
612	Tip of sonotrode
614	Section with reduced diameter

CLAIMS

1. A handling device (100) for handling an augmentation implant (300), comprising:

an elongated housing (110) having an axial through-bore (120) for accommodating a sonotrode of an ultrasound applicator, and a lateral opening (130) for inserting an augmentation pin, wherein the axial through-bore and the lateral opening are connected to each other,

a distal implant portion (140) for fastening a proximal end (330) of the augmentation implant (300) at the housing (110), and

a proximal tool portion (150) for driving and/or augmenting the augmentation implant.

2. The handling device (100) of claim 1, further comprising an ultrasound applicator (600) having an ultrasound transducer and a sonotrode(610), wherein the ultrasound applicator is arranged so that the sonotrode extends from the ultrasound transducer in a direction to the distal implant portion (140).

3. The handling device (100) of claim 2, wherein the proximal tool portion (150) is adapted for releasably connecting the ultrasound applicator (600) at the elongated housing (110).

4. The handling device (100) of claim 3, further comprising a driving tool (500) with a distal driving end, wherein the distal driving end is adapted to be coupled at the proximal tool portion (150) when the ultrasound applicator (600) is released from the proximal tool portion.

5. The handling device (100) of any one of claims 1 to 4, wherein the distal implant portion (140) is adapted to transmit forces from the elongated housing (110) to the augmentation implant (300), for driving in the augmentation implant into an object.

6. The handling device (100) of any one of claims 1 to 5, wherein the distal implant portion (140) includes a quick-fastener.

7. The handling device (100) of any one of claims 1 to 6, further comprising a locking element (160) for blocking a lateral movement of the augmentation pin (400) when the augmentation pin is placed in the lateral opening (130) and is aligned with the axial through-bore (120).

8. The handling device (100) of any one of claims 1 to 7, wherein the lateral opening (130) is a through-opening and wherein the elongated housing (110) further comprises a projection (170) projecting into the lateral opening (130), so that the augmentation pin (400) is automatically aligned with the axial through-bore (120), when the augmentation pin is placed in the lateral opening (130) and abuts the projection (170).

9. The handling device (100) of any one of claims 1 to 8, further comprising a pin-magazine (200) for holding the at least one augmentation pin (400), wherein the pin-magazine (200) is designed to be at least partially accepted in the lateral opening (130) of the elongated housing (110).

10. The handling device (100) of any one of claims 2 to 9, wherein the ultrasound applicator (600) is movable between a first position and a second position, wherein the distal tip (612) of the sonotrode (610) is located proximal to the lateral opening when the ultrasound applicator is in the first position, and wherein the distal tip of the sonotrode is located at the distal implant portion (140) when the ultrasound applicator is in the second position, the sonotrode being capable of pushing an augmentation pin through the axial through bore and into the augmentation implant (300).

11. The handling device (100) of any one of claims 2 to 10, wherein the sonotrode (610) of the ultrasound applicator (600) includes a section (614) with reduced diameter.

12. The handling device (100) of any one of claims 1 to 11, further comprising an augmentation implant, wherein the augmentation implant is an augmentation screw, wherein the distal implant portion (140) is adapted to transmit torque from the elongated housing (110) to the augmentation screw, for screwing in the augmentation screw into an object.

13. A method for augmenting an augmentation implant, the method comprising the steps of

(a) connecting a handling device (100) in accordance with any one of claims 1 to 12 with the augmentation implant (300),

(b) placing an augmentation pin (400) in a lateral opening (130) of the handling device,

(c) aligning the augmentation pin with an axial through-bore (120) of the handling device,

(d) pushing the augmentation pin into the augmentation implant,

(e) fluidizing the material of the augmentation pin, and

(f) pressing the fluidized material at least partially out of the augmentation implant.

14. The method of claim 13, wherein steps (b) to (f) are repeated with at least one further augmentation pin.

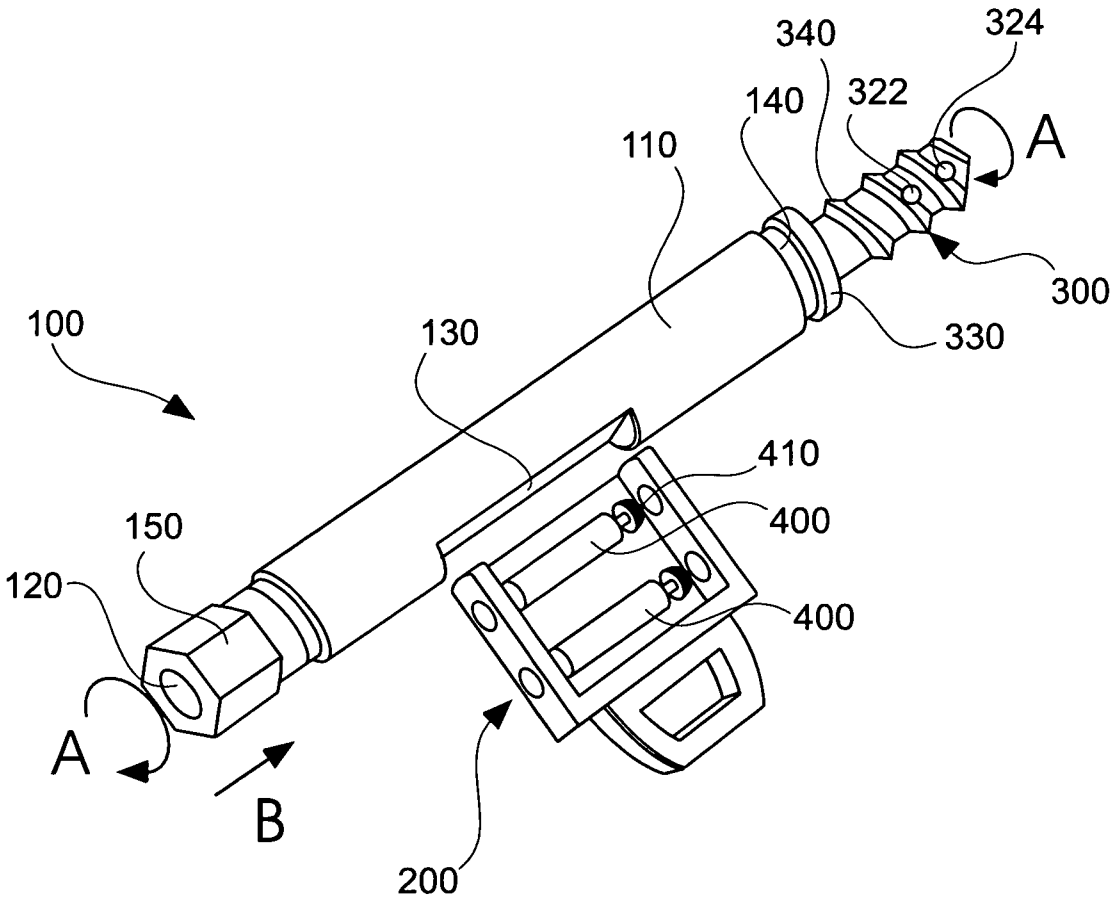


Fig. 1

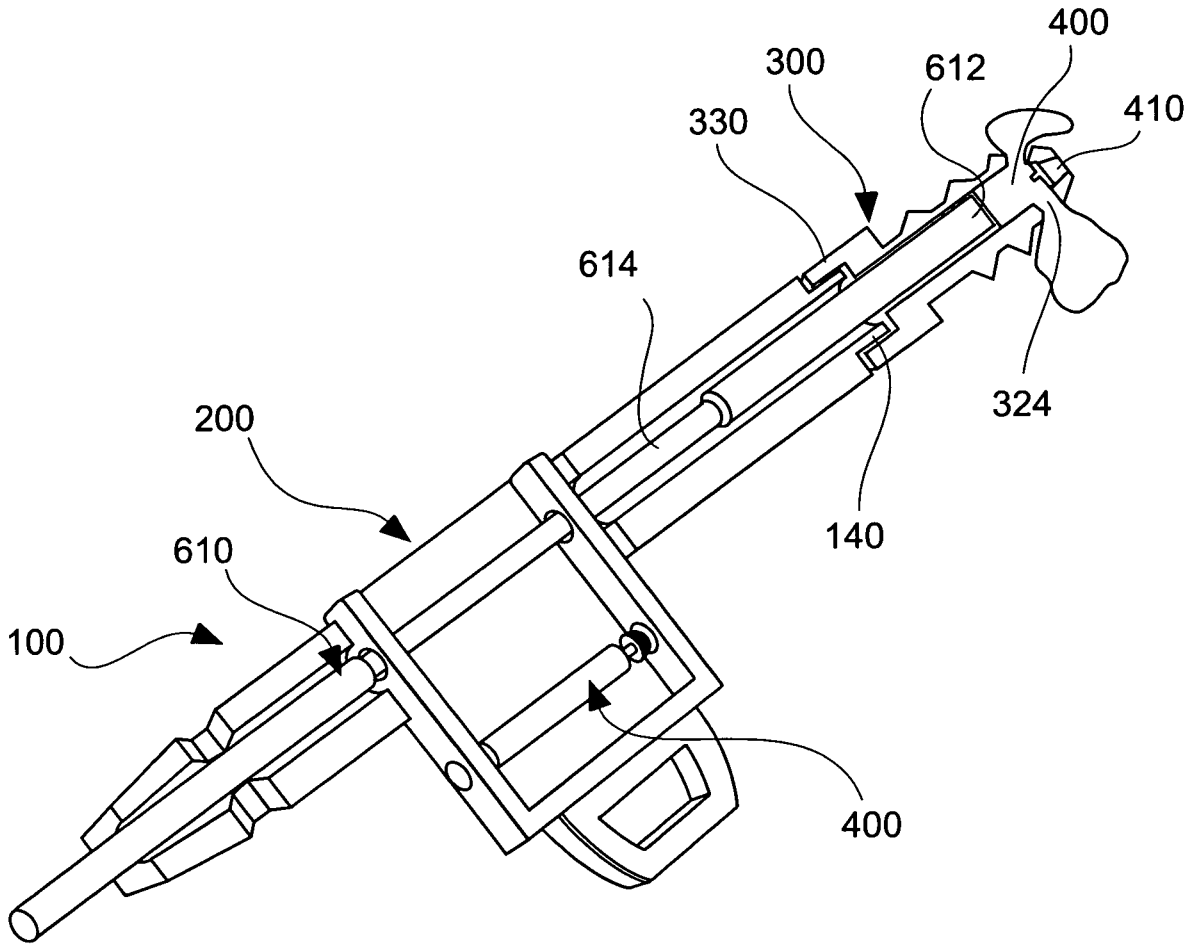


Fig. 2

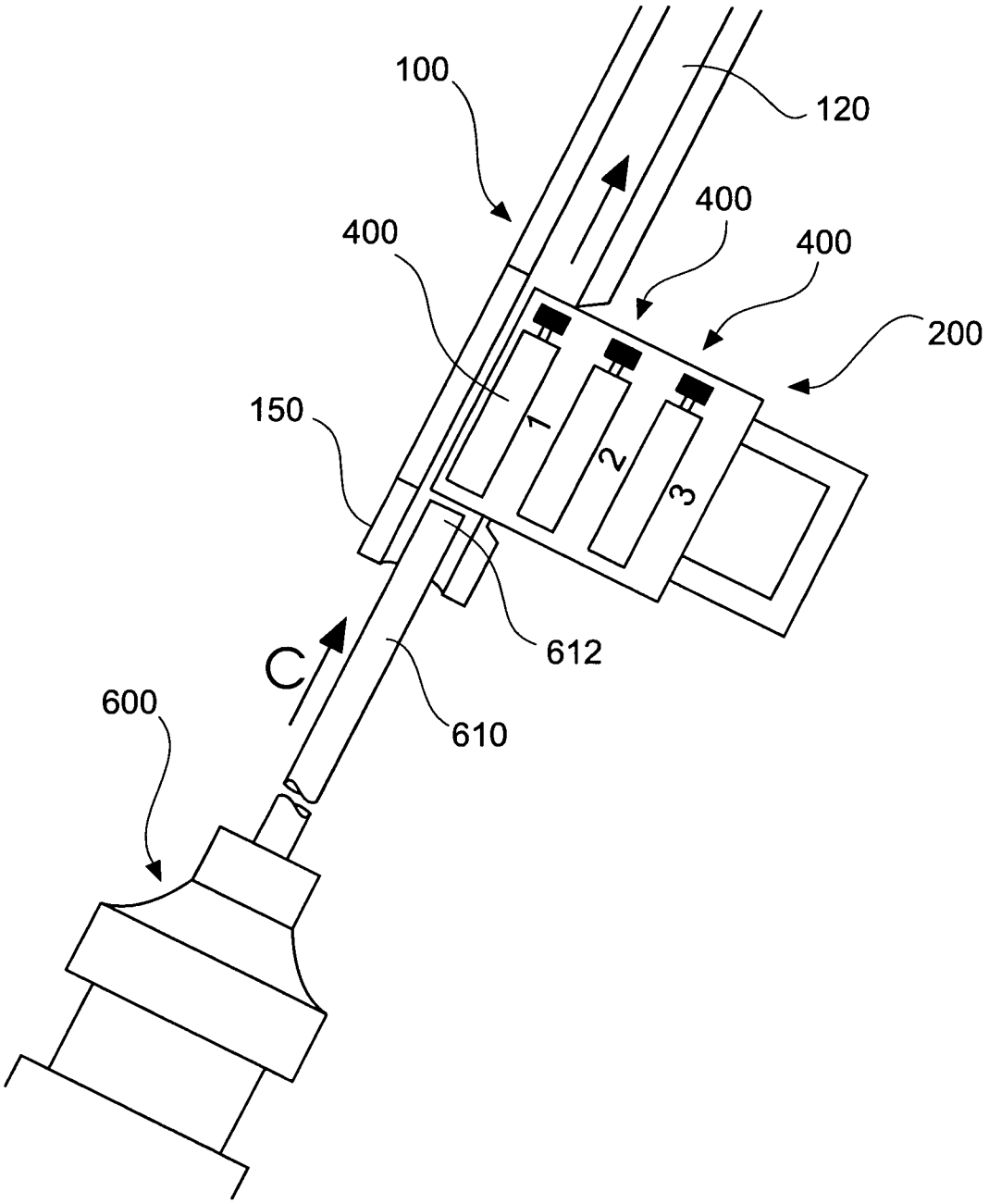


Fig. 3

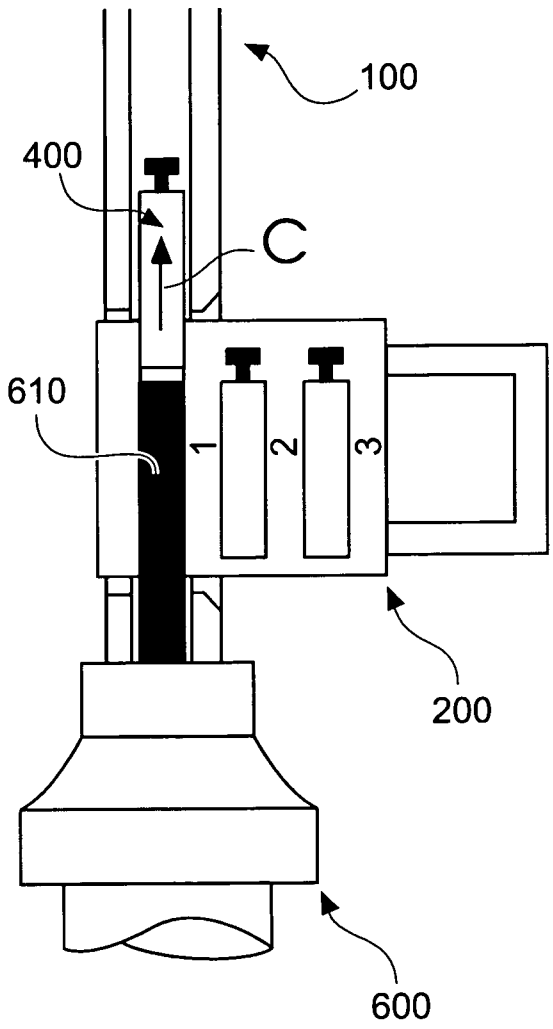


Fig. 4a

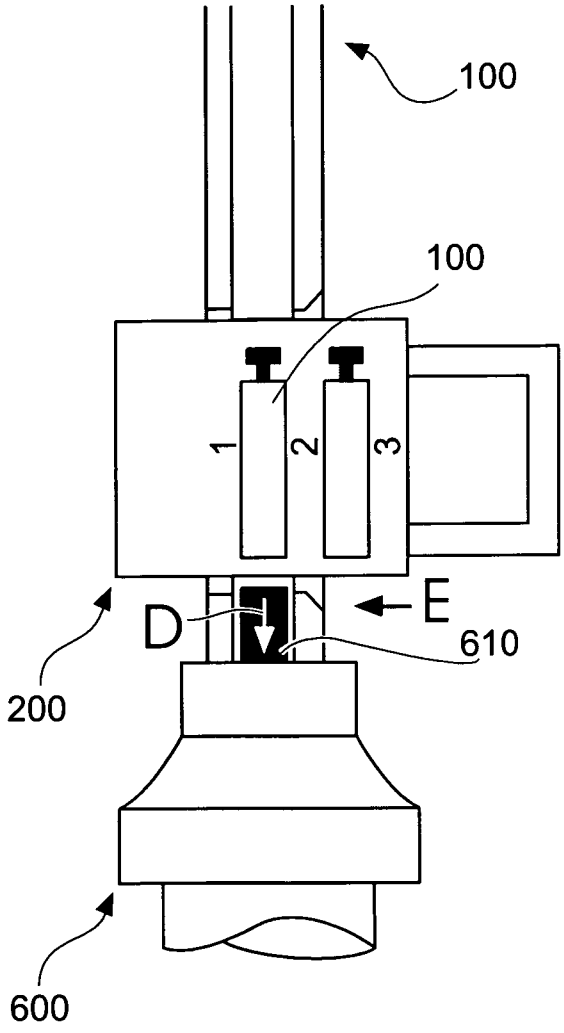


Fig. 4b

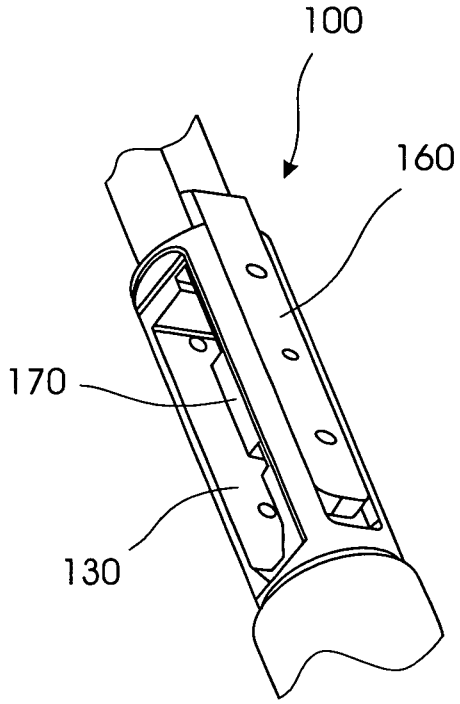


Fig. 5

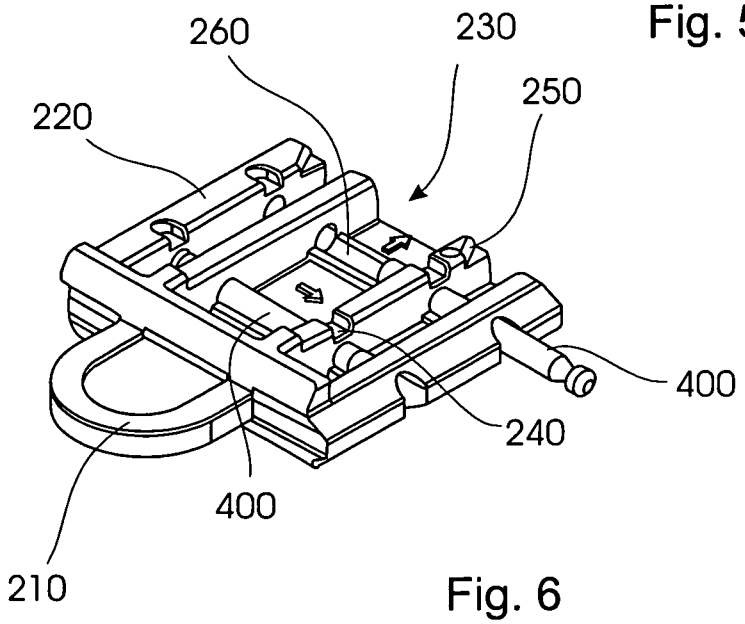


Fig. 6

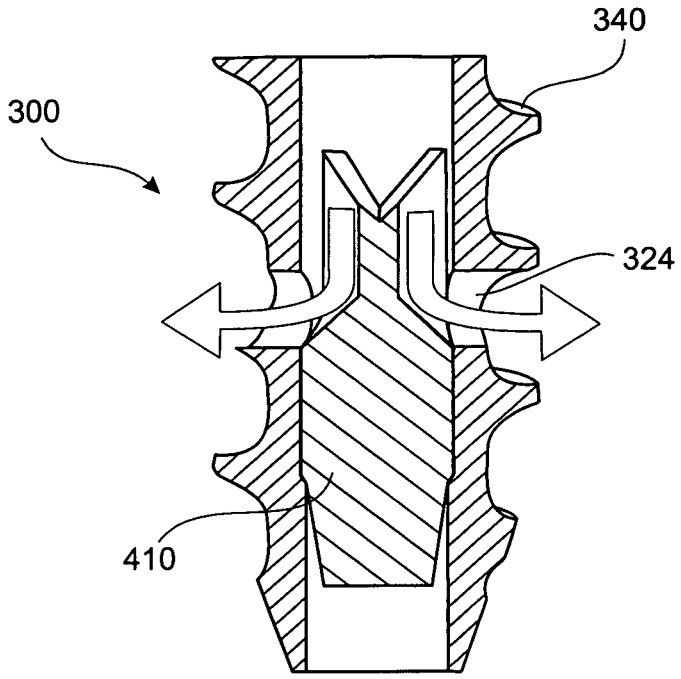


Fig. 7

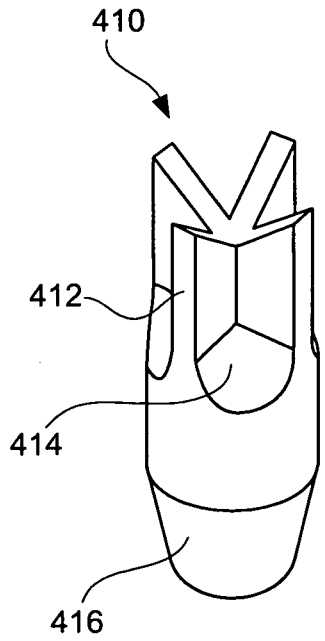


Fig. 8

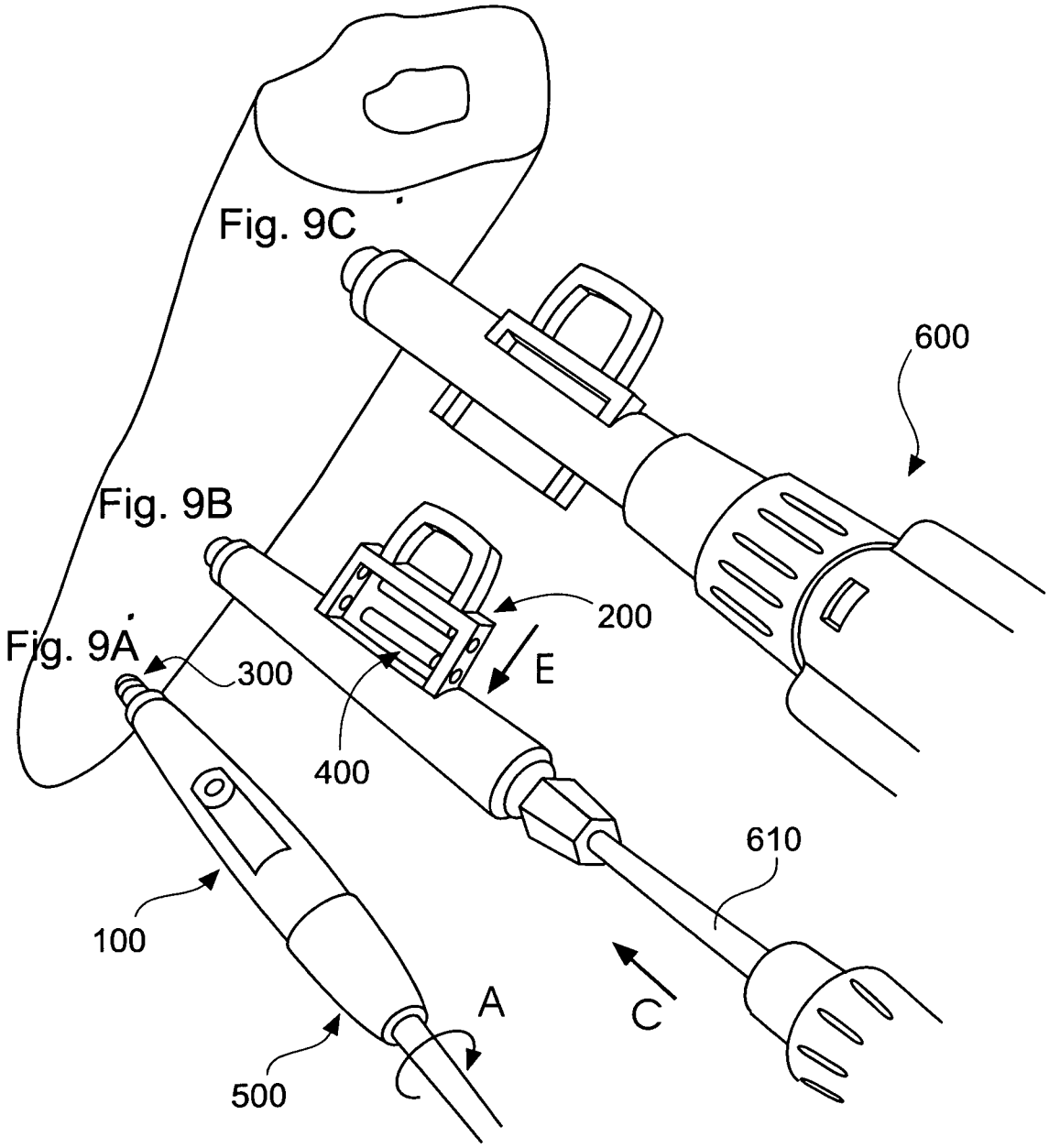


Fig. 9

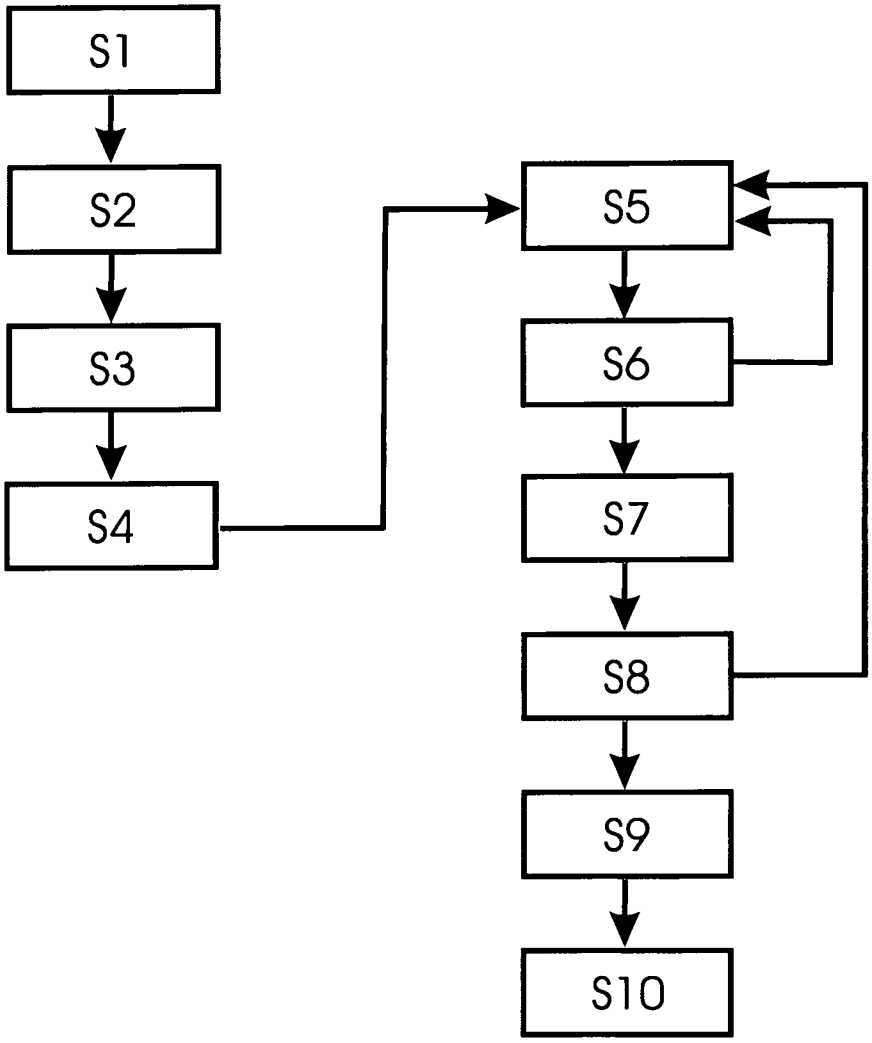


Fig. 10

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2012/000880

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/86 A61B17/88
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.
Y	EP 2 236 101 Al (STRYKER TRAUMA GMBH [DE]) 6 October 2010 (2010-10-06) paragraph [0009] - paragraph [0014] paragraph [0017] - paragraph [0019] paragraph [0021] - paragraph [0022] paragraph [0027] - paragraph [0029] paragraph [0036] - paragraph [0037] ; figure 1 paragraph [0039] - paragraph [0044] ; figures 3, 4	1-12
Y	US 2005/187559 Al (RAYMOND SPANKY A [US] ET AL) 25 August 2005 (2005-08-25) paragraph [0063] - paragraph [0067] ; figures 6-9	1-12

-/- .

[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 application or patent but published on or after the international filing date

"L" documentwhich may throw doubts on priority claim(s) orwhich 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
31 October 2012	07/11/2012

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	Filali, Salima

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

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 2011/054122 A1 (SPINEWELDING AG [CH] ; WENGER ANDREAS [CH] ; MAYER JOERG [CH]) 12 May 2011 (2011-05-12) cited in the application page 17, line 4 - page 21, line 25; figures 1a, 2 page 21, line 26 - page 23, line 13; figures 3-5 page 23, line 14 - page 25, line 4; figures 6-8 -----	1-12

1

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2012/000880

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.: 13, 14
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 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/EP2012/000880

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