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(54) Title: SCREW FOR CORRECTING FLAT FOOT DEFORMITY

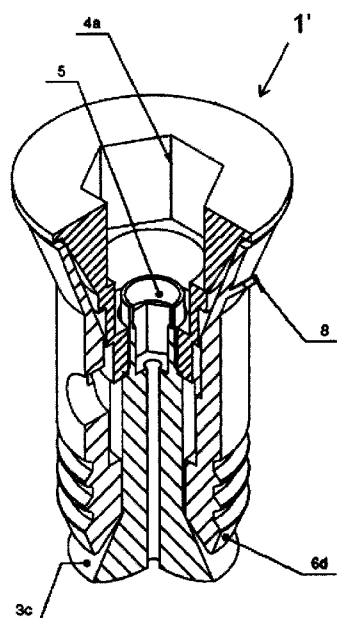


Fig. 2b

(57) Abstract: Endo-sinus-tarsal screw (1;1') comprising an internal metallic part (2, 3), formed by two components (2, 3) that can be moved with respect to each other, as well as an expandable external sleeve (6), the latter having a proximal conical part (6a) and a substantially cylindrical body (6b). The second component (3), by pushing against the distal end (6d) of the expandable sleeve (6), causes the expansion of the sleeve itself. Preferably, an annular abutment (7) is provided for the expandable sleeve, which facilitates the expansion of the sleeve on the proximal side and allows better anchorage to the wall of the tarsal sinus.



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“Screw for correcting flat foot deformity”

Description

5 Field of the art

The present invention generally regards the devices used in medicine in surgical operations, and more particularly those devices which remain inside the body of the patient after the operation, in order to treat specific undesired characteristics, in the present case an incorrect position of the bones of the foot. Specifically, the present invention regards an improvement
10 of the so-called endo-sinus-tarsal screws, which are implanted in the body of the patient (child or even adult) in order to treat the deformity of the so-called “flat foot”.

Prior art

As is already known in the field, the endo-sinus-tarsal screws are introduced in the channel
15 or cavity referred to as tarsal sinus, which is substantially cylindrical-shaped and located between two bones, i.e. between the calcaneum and the astralagus. Normally, in order to carry out the operation of correction of the flat foot deformity, in the prior art various (titanium) metal screws are provided, with different caliber/diameter (e.g.: from 9 to 14 mm) and a certain subset thereof is used on the basis of the size of the enlargement to be carried
20 out in said channel. The enlargement of the tarsal sinus in fact produces a lifting of the astragalus which consequently cancels the flat shape of the arch of the foot.

Hence, according to the prior art, screws of progressive size must be introduced in the foot, increasingly enlarging the channel until the desired effect is attained. The entirely metallic (titanium) screws used to be threaded on the walls of the channel, and this was particularly
25 invasive. In addition, the doctor would be obliged to use a luminance amplifier for verifying the penetration of the (cylindrical) screw in the channel, with consequent exposure to radiation, dangerous both for the doctor and the patient.

Description of the invention

The object of the present invention is to eliminate the problems of the prior art.

First, the endo-sinus-tarsal screw of the invention is globally substantially cylindrical-shaped, though conical at least in the proximal part. Such configuration of the screw of the invention allows it to be immediately adapted to the shape – also substantially cylindrical but slightly conical - of the tarsal sinus, so as to avoid an excessive insertion thereof. Hence, the radiation doses deriving from the use of the luminance amplifier will be considerably lower, since the (final) position of the endo-sinus-tarsal screw shall be verified only at the end of the operation.

10 In addition, the screw of the present invention has an expansion function. It must be inserted only once in the tarsal sinus, and the expansion – similar to a stop to be inserted in a wall – will occur gradually by allowing the surgeon to visually observe the variation of the valgus angle of the hindfoot.

Since the screw of the invention externally (or laterally) has a flexible sleeve that is uniformly expanded, it is impossible that the expansion will occur in just some zones, as it unfortunately used to occur in the case of several types of expansion screws of the prior type, with expansion tabs separate from each other.

In addition, the screw of the invention is substantially expanded in a uniform manner even with respect to the axial direction, i.e. both in the proximal part and in the distal part, due to the fact that a second component thereof – which is movable with respect to a first component and couplable to a screwdriver - pushes, by means of a tapered portion (3c) thereof, the flexible sleeve against the proximal conical part (2a) of the first component, causing a lateral expansion of the flexible sleeve (6). In order to accentuate or optimize the expansion of the sleeve (6), especially in its proximal part, a preferred embodiment of the invention provides for a kind of stop (7) of the sleeve. The stop is preferably formed by an annular projection (7) provided on the conical part (2a) of the first component (2). Such stop (7), besides improving the expansion of the sleeve, also prevents, in this preferred embodiment of the invention, a possible unthreading of the flexible sleeve from the central metallic body

of the screw (formed by the two components that are movable with respect to each other). The two metallic components (normally made of titanium alloy) do not come into contact with the bones, rather only the flexible sleeve (for example made of HDPE: high-density polyethylene) does. The operation is therefore less invasive than other operations of the prior art.

Preferably, the distal cylindrical part of the screw has structures (6c) (ribs or the like) for facilitating the adherence of the expandable sleeve to the wall of the channel (tarsal sinus).

In a particularly preferred embodiment of the screw of the invention, also on the conical proximal part (6a) of the sleeve there will be elements for anchoring to the wall of the tarsal sinus. Preferably, such anchoring elements are constituted by one or more oblique tabs (8), directed towards the proximal end of the endo-sinus-tarsal screw. The obliqueness of the tabs ensures that the more the sleeve tends to exit, the more the tabs tend to penetrate in the tissues, thus ensuring the reliability of the screw (which is not “spit” out of the channel).

Preferably, the first component is threaded on the second component. By acting with a screwdriver on the second component (3), the latter is axially moved with respect to the first component (2), by pushing on the expandable sleeve. Obviously, the use of other mechanical means can also be assumed, in order to obtain the same relative axial movement between the two components (2, 3). Nevertheless, this would probably complicate the screw production process.

In the preferred embodiment of the invention, the two components (2, 3) are monolithic (single cast pieces) and are preferably metallic. Also the flexible sleeve is preferably obtained by molding preferably plastic material in a single piece.

The present invention also comprises a set, or instruments, constituted by the screwdriver, the endo-sinus-tarsal screw described above, and by a support that is coupled to the endo-sinus-tarsal screw and serves to introduce and laterally support the stem with hexagonal tip of the screwdriver which is engaged in a hexagonal hole of the second component of the screw. Said support, part of the instruments provided to the surgeon, obviously serves to avoid that the whole screw rotates around its own axis (it is driven in rotation) when the screwdriver is used,

i.e. to ensure the rotation of only the second component that pushes against the front distal part of the expandable sleeve.

Brief description of the drawings

5 The present invention will now be described more in detail by way of non-limiting example, by means of two specific embodiments, illustrated in the enclosed drawings wherein:

Fig. 1a shows a vertical axial section of the endo-sinus-tarsal screw of the present invention,
10 according to a first embodiment;

Fig. 1b shows a perspective view in partial section of the endo-sinus-tarsal screw of the present invention, according to the first embodiment;

Fig. 1c shows the relative top plan view;
15

Fig. 2a shows a vertical axial section of the endo-sinus-tarsal screw of the present invention, for the second embodiment;

Fig. 2b shows a partial section perspective view of the endo-sinus-tarsal screw of the present
20 invention, for the second embodiment;

Fig. 2c shows the top plan view of the endo-sinus-tarsal screw of the second embodiment of the invention;

25 Fig. 3 shows two instruments used for the correction operation according to the present invention, also part of the object of the invention;

Fig. 4 shows the two instruments of Fig. 3 inserted inside each other and in the endo-sinus-tarsal screw of the invention.
30

Description of the preferred embodiments of the invention

The following detailed description of the invention will focus on the description of the single components, the overall structure and the functioning of the endo-sinus-tarsal screw, without entering into detail on the manufacturing process, the materials employed for the different components etc. Such manufacturing processes, materials, etc. are indeed to be considered as within the reach of an average man skilled in the art, and they can be selected by such man on the basis of his experience and in accordance with the circumstances.

In addition, it is clear that even though the following detailed description illustrates the structural details of the various screw components, other equivalent components and/or those with different but appropriate and equivalent shapes can be used without departing from the protective scope of the invention, so long as they reflect the same inventive concept.

Therefore, even if the two described embodiments are those currently preferred, they are of course neither limiting nor binding.

With reference to the first embodiment (Figs. 1a, 1b, 1c), the endo-sinus-tarsal screw 1 comprises a first component 2 made of rigid, resistant, biocompatible and preferably metallic material, normally made of titanium alloy, and a second component 3, also made of rigid, resistant and biocompatible material and preferably made of titanium alloy. The first component 2 comprises a proximal conical part 2a and a distal substantially cylindrical part 2b which forms various steps (different diameters). The first component 2 has an axial through hole, indicated in its entirety with the reference number 4. The "upper" part (in Fig. 1a) of the through hole 4 constitutes a hexagonal hole 4a, the intermediate part of the through hole 4 is indicated with 4b and it is cylindrical, whereas the "lower" part (in Fig. 1a) of the through hole 4 is threaded and it is indicated with 4c. It is observed that the holes 4a, 4b, 4c have progressively decreasing diameters, forming respective steps.

With regard instead to the second component 3, it has a form similar to the shank 3a of a nail (constant diameter) whose head 3b (lower part 3b in Fig. 1a) has a tapered lateral surface 3c and a convex frontal surface 3d. At the end of the shank 3a, opposite the head 3b, the component 3 has a hole 5, comprising a cylindrical hole 5a and a hexagonal hole 5b with a

smaller diameter with respect to the cylindrical hole 5a. The hexagonal hole 5b in one embodiment of the invention ends on the lower part with the through hole 3e which centrally traverses the entire component 3, until it reaches the front convex surface 3d. In this embodiment of the invention, the through hole 3e serves for inserting and guiding the endo-sinus-tarsal screw along a previously positioned common rigid guide wire. This endo-sinus-tarsal screw, in this embodiment of the invention, is screwed with a cannulated screwdriver 10 in a manner so as to receive at its interior the rigid guide wire which will be inserted inside the through hole 3e upon the positioning of said screw. "On the upper part" (still with reference to Fig. 1a), the shank 3a is externally threaded in order to be screwed in the threaded hole 4c of the first component 2.

Externally, a sleeve 6 is fit on the two components 2, 3; such sleeve is made of material having a certain flexibility that allows the same to be expanded within certain predetermined limits. The sleeve 6 can be made of high-density polyethylene (HDPE) for an improved distribution of the load forces that act on the sleeve 6 (see below). The sleeve 6 has an overall cylindrical shape with "upper" conical part 6a and intermediate cylindrical part 6b equipped "on the lower part" with ribs 6c or other structures that allow a grip/anchorage of the sleeve 6 on the tissues of the walls of the tarsal sinus.

In its "lower" conical-converging part 6d, opposite its conical part 6a, the sleeve 6 has a flared frontal hole 6e for receiving and housing the head 3b of the second component 3 substantially shaped as a nail. It is observed that the tapered lateral surface 3c is in contact or comes into contact, i.e. interacts, with the flared frontal hole 6e of the flexible sleeve 6. This is of fundamental importance, as will be seen, for causing the expansion of the flexible sleeve 6.

Given that the functioning of the endo-sinus-tarsal screw of the first embodiment of the invention is similar – if not equivalent – to that of the second embodiment, in order to simplify the description of the invention, such functioning will be elucidated only after having illustrated the structure of the second embodiment of the endo-sinus-tarsal screw as well (Figs. 2a, 2b, 2c).

With reference to the second embodiment of the invention, shown in Figures 2a to 2c, this substantially comprises the same components and parts already illustrated in the first embodiment (Figs. 1a to 1c), so it is an obvious choice to use the same reference numbers for indicating such parts and components. Nevertheless, in order to simplify the figures, only
5 some components/parts are marked with the respective numeric reference in Figures 2a, 2b, 2c, whereas other numeric references were omitted. The reference numbers 7 and 8 are indicated as well; these constitute the modifications distinguishing the second embodiment from the first. In substance, these are:

- an anchorage or tab element 8, integral with the flexible sleeve 6, and
- 10 - an annular projection 7 (for the abutment of the sleeve 6) which enlarges the “upper” diameter of the conical part 2a of the first metallic component 2 (e.g. made of titanium alloy), such annular projection 7 preferably being made integral with the conical part 2a itself when casting the first component 2.

The elements 7 and 8 provide further very significant advantages with respect to the first
15 embodiment, as will be clear from the description of the functioning of the screw 1' (the prime indicates the screw of the second embodiment, while the screw of the first embodiment was indicated by the reference number 1).

Therefore, by means of simple expedients which do not involve any further difficulty in the manufacturing productive process (molding and/or casting and assembly of the components
20 2, 3, 6) of the endo-sinus-tarsal screw, it is possible to significantly improve the effect produced by the screw 1', with respect to the screw 1, in correcting and limiting over time the excessive pronation of the flat foot in adults and children. Specifically, the elements 7, 8 prevent in a reliable manner, separately or in combination, any movement or even the exit of the screw 1' after surgical operation. Indeed, in some cases (fortunately infrequent), the
25 screw 1 of the first embodiment tended over time to unthread from the tarsal sinus of the patient. Such drawback can now be avoided, as observable from the following description of the functioning of the endo-sinus-tarsal screw.

Functioning and advantages with respect to the prior art

By means of a special metallic support tool (Fig. 3, reference 9), provided with grip handle 9a and tubular part 9b for coupling and insertion, integral with the same grip handle 9a, the surgeon draws the endo-sinus-tarsal screw 1 (or 1') from a loader and inserts it into the tarsal sinus after the operation preparatory steps (anesthesia, incision etc.). Specifically (see Fig. 4), the surgeon grasps the tool or instrument 9 by the handle 9a and introduces the end with hexagonal tip 9b (tube for coupling and insertion of the screw, Fig. 3) in the hexagonal hole 4a of the first component 2. Then, he introduces the screw 1 (or 1') in the tarsal sinus, between the astragalus and the calcaneum, up to the end stop. Then, slowly and progressively, he enlarges the diameter of the channel (tarsal sinus) until the deformity is corrected, in the following manner. He introduces the stem of a second tool or screwdriver 10, with hexagonal tip 10a (see Figs. 3 and 4), in the axial through hole of the tube 9b, until the hexagonal tip 10a of the screwdriver 10 is engaged with the hexagonal hole 5b of the second component 3. By turning the screwdriver 10 like a screwdriver, by acting on its handle, the surgeon moves the second component 3 progressively "upward" (with reference to Fig. 1a or 2a respectively), i.e. in the direction directed toward the exterior of the patient's foot. Thus doing, the tapered lateral surface 3c of the second component 3 pushes against the wall of the flared frontal hole 6e or better yet (as in the drawing) against the innermost circumference of the hole 6e itself. The flexible sleeve 6 is expanded, being anchored to the internal wall of the tissues of the tarsal sinus and pressing against such wall. The anchorage occurs due to the circular ribs 6c. Once the desired expansion diameter has been attained, the instruments 9 and 10 are extracted.

The expansion diameter of the flexible sleeve 6 is clearly correlated to the number of complete turns of the (possibly cannulated) screwdriver 10. A mechanical revolution counter device 10b could be provided (with rigid disc connected to the screwdriver 10 and cooperating with a reference needle 9c on the tool 9) or the like (encoder: magnetic, with Hall effect, optical or potentiometric) adapted to determine the absolute rotation angle of the screwdriver 10, possibly displaying it on a display together with the relative value of the temporary diameter

of the sleeve. Other mechanical systems could serve for the same purpose as revolution counter devices according to the present invention. The arrangement of the reference needle 9c and the rigid disc 10b could naturally also be reversed.

Nevertheless, the preferred and less expensive method simply consists of obtaining (by means of incision, coloring etc.) a graduated scale of values on the stem of the screw 10, to be compared with the reference point fixed on the instrument 9 at the entrance of the tubular part 9b.

The endo-sinus-tarsal screw of the present invention has the particular characteristic that with only one device, it is possible to correct the deformity of the foot and immediately control the correction, either visually (graduated scale) or by means of a suitable revolution counter (encoder, or the like). Another particular characteristic is that the screw reproduces the substantially cylindrical but more particularly conical form of the tarsal sinus, so that by being uniformly expanded (both distally and proximally) it is able to be anchored to the walls of the tarsal sinus, ensuring an optimal grip, thus preventing its exit and consequent loss of the correction. Specifically, in the case of the second embodiment of the invention, the tab (or tabs) 8 is/are fixed in the wall of the tarsal sinus in proximal position; in addition, it is clear that the proximal expansion of the flexible sleeve 6 (and hence the anchorage to the wall of the channel) is optimized by the presence of the annular projection 7 on the head 2a of the screw 1', when the flexible sleeve 6 abuts against the annular projection 7 itself.

It is thus evincible that the elements 7 (annular projection) and 8 (tab or tabs) of the second embodiment constitute improvements with respect to the first embodiment.

The endo-sinus-tarsal screw according to the present invention could be defined "double expansion screw" since it ensures – unlike the prior art – a uniform distal as well as proximal expansion.

The screw of the invention eliminates the entire drawback of an expansion screw type of the prior art which only expanded at the intermediate part.

It also ensures a stable anchorage inside the cavity of the foot referred to as tarsal sinus, arranged between the astragalus and the calcaneum; by acting in said cavity, the screw of the

invention is adapted to raise the astralagus on the calcaneum (correcting the foot deformity) as if it were a jack for vehicles, whereas the expansion as such is similar to that obtained by inserting a stop in a wall.

5 While in the described embodiments the screwer 10 acts on the second component 3 (the internal one), of course it would also be possible to act on the first component 2 (the external one), leaving the second component 3 stationary; nevertheless, in order to prevent a driving (rotation) of the sleeve 6, anti-rotation elements could be necessary between the second component 3 (which in this case remains stationary) and the sleeve 6, so as to render them “integral”.

10 A possible further development of the present invention consists of equipping the screwer with a dynamometric electronic instrument, i.e. a torque transducer, with setting of the final torque and continuous detection of the instantaneous torque (twisting moment) acting on the conical head 2a of the endo-sinus-tarsal screw.

Claims

1. Endo-sinus-tarsal screw of expansion type, comprising an internal part (2, 3) made of rigid biocompatible material, preferably metal and in particular a titanium alloy, and a laterally-
5 expandable flexible external part (6), for example made of plastic and in particular high-density polyethylene (HDPE), **characterized in that** the internal part (2, 3) comprises a first component (2) and a second component (3) that are at least axially movable with respect to each other, wherein
- the first component (2) has a proximal end constituting a first substantially conical part
10 (2a), as well as a second part (2b) for connecting to a proximal end of said second component (3),
 - the second component (3) has a proximal end inserted in the first component (2) and a distal end (3b) with tapered walls (3c) adapted to come into contact with said laterally-expandable flexible external part (6) at the distal end (6d) of the latter,
 - 15 - the laterally-expandable flexible external part (6) constitutes an expandable sleeve (6), whose proximal end (6a) forms a conical part (6a) adapted to come into contact with said conical part (2a) of the first component (2), and wherein
 - the first component (2) and the second component (3) have portions (4a, 5b) for applying
20 tools (9, 10) insertable from the outside, adapted to cause a relative motion between such components (2, 3), in a manner so as to move the second component (3) in the proximal direction, towards the conical part (2a) of the first component (2), **and in that**
during the movement thereof, the second component (3) pushes the expandable sleeve (6) in proximal direction by acting with its tapered walls (3c) against the distal end (6d) of the expandable sleeve (6), causing both the proximal and distal expansion of the sleeve (6)
25 which comes into contact with its conical part (6a) against the conical part (2a) of the first component (2).
2. Endo-sinus-tarsal screw according to claim 1, characterized in that it has a through hole (3e) which, starting from a floor of the hexagonal hole (5b), centrally traverses the entire

component (3) until it reaches a convex frontal surface (3d), said through hole (3e) being obtained in a manner so as to receive a rigid guide wire at its interior, previously positioned in the patient's limb.

5 3. Endo-sinus-tarsal screw according to claim 1, characterized in that the second part (2b) of the first component (2) is screwed on the proximal end of the second component (3), so that the movement of the second component (3) occurs by means of a simultaneous rotation thereof.

10 4. Endo-sinus-tarsal screw according to claims 1, 2 or 3, characterized in that the portions (4a, 5b) for applying the tools insertable from the outside (9, 10), form non-circular seats, e.g. hexagonal, octagonal or the like, for the insertion of a tip of the tool (9 or 10).

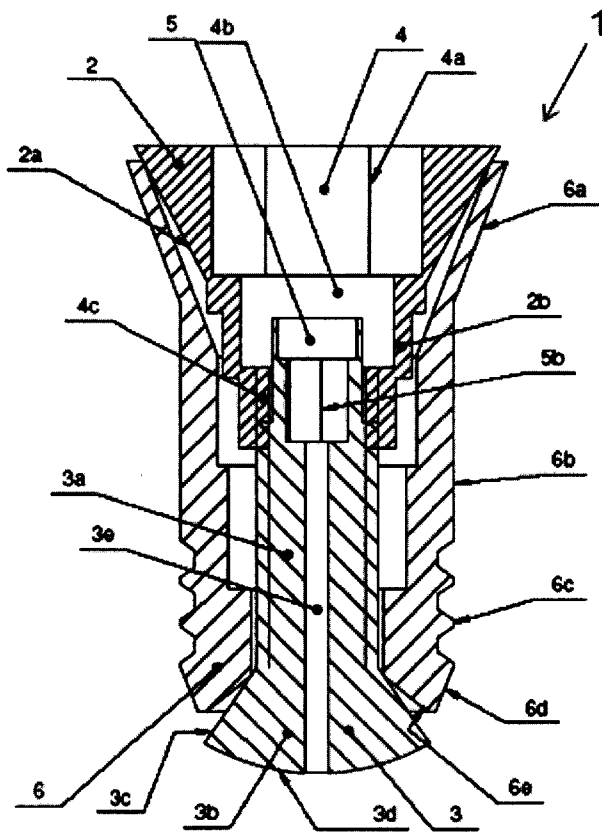
15 5. Endo-sinus-tarsal screw according to any one of the preceding claims, characterized in that said first conical part (2a) laterally has a stop or end stop (7) which stops the axial movement of the expandable sleeve (6), forming a continuous annular projection (7) or a plurality of reliefs spaced from each other, and which forces the expandable sleeve (6) to be expanded in the proximal zone.

20 6. Endo-sinus-tarsal screw according to any one of the preceding claims, characterized in that the expandable sleeve (6) has lateral ribs (6c) and/or oblique tabs (8), or similar anchoring means, for anchoring the expandable sleeve (6) to the wall of the tarsal sinus.

25 7. Endo-sinus-tarsal screw according to any one of the preceding claims, wherein – in the distal end (6d) of the expandable sleeve (6) there is obtained a flaring (6e) the tilt of whose walls (6e) is greater than that of the tapered walls (3c) of the distal end (3b) of the second component (3), in a manner so as to have a substantially linear contact which limits the friction between the expandable sleeve (6) and the second component (3).

8. Set of tools (9, 10) for inserting, in the tarsal sinus of a patient, an endo-sinus-tarsal screw (1; 1') according to the preceding claims, comprising:
- a support tool (9) having a handle (9a) and a tubular part (9b), the tubular part (9a) receiving, in its longitudinal through hole, the stem of a screw (10);
 - the screw (10), bearing a handle and a non-circular tip.
9. Set of instruments according to claim 8, wherein such set of instruments (9, 10) comprises a system for measuring and possibly displaying, or for visually controlling, the total rotation angle of the screw, and the system can be an angular coder, a graduated scale, a sensor or the like and also a torque transducer and a torque limiter.
10. Set of instruments according to claim 8 or 9, wherein said handle (9a) of the support tool (9) first forms a right angle with said tubular part (9b) of the tool, and then it is laterally extended in an oblique manner, so as to ensure maximum ergonomics and ease of use for the operator.
11. Set of instruments according to any one of the claims from 8 to 10, wherein said stem of the screw (10) has a channel at its interior adapted to receive a rigid wire previously positioned in the patient's limb.

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SECTION A-A

Fig. 1a

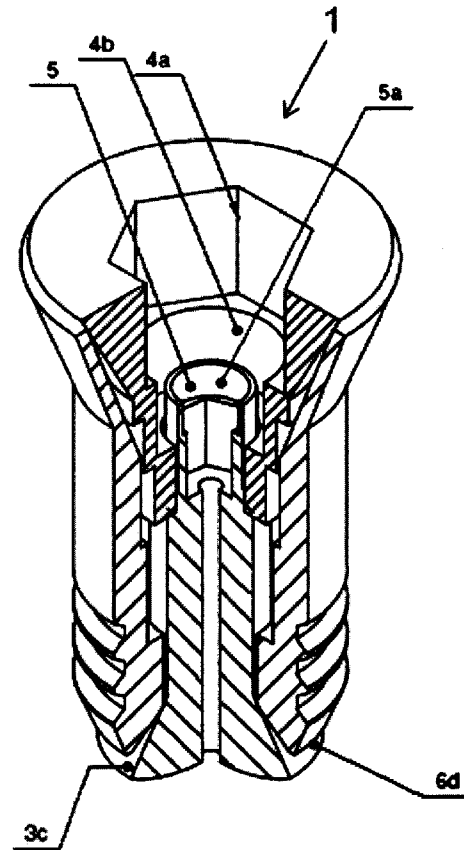


Fig. 1b

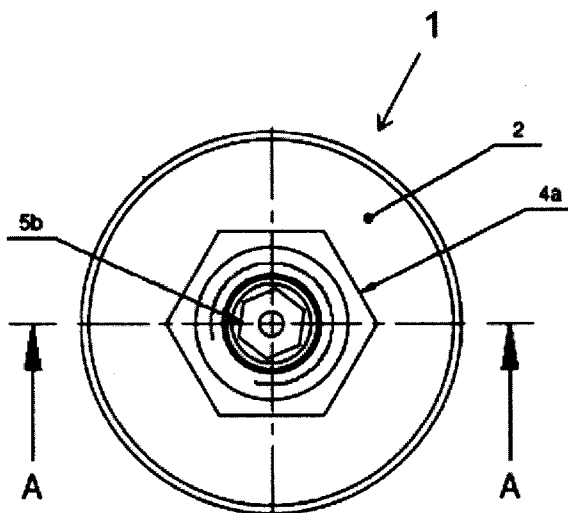
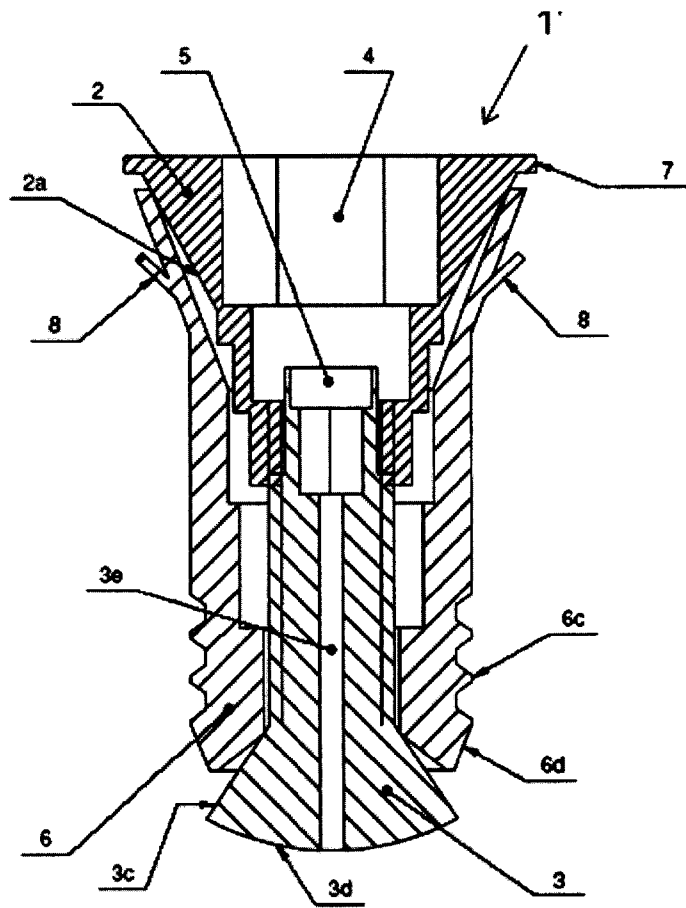


Fig. 1c

2/4



SECTION A-A

Fig. 2a

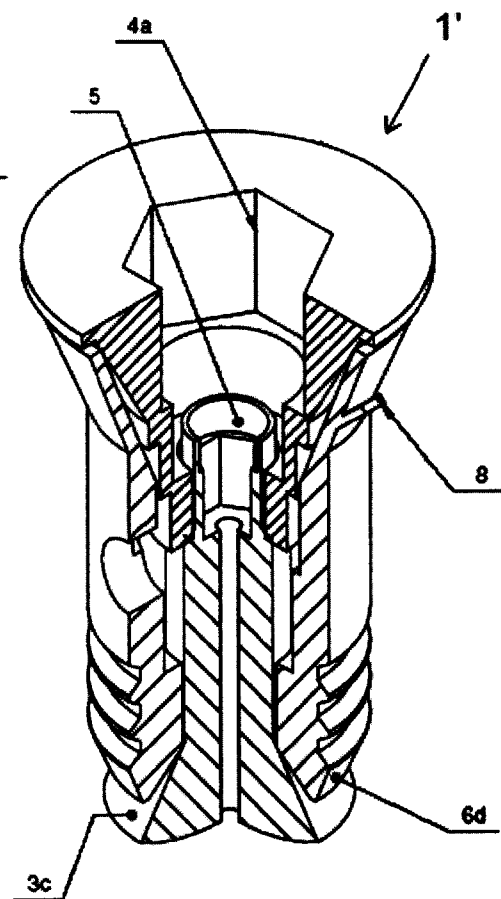


Fig. 2b

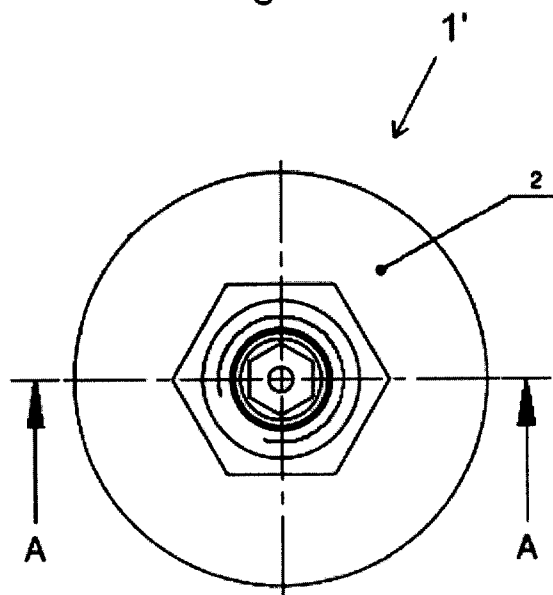


Fig. 2c

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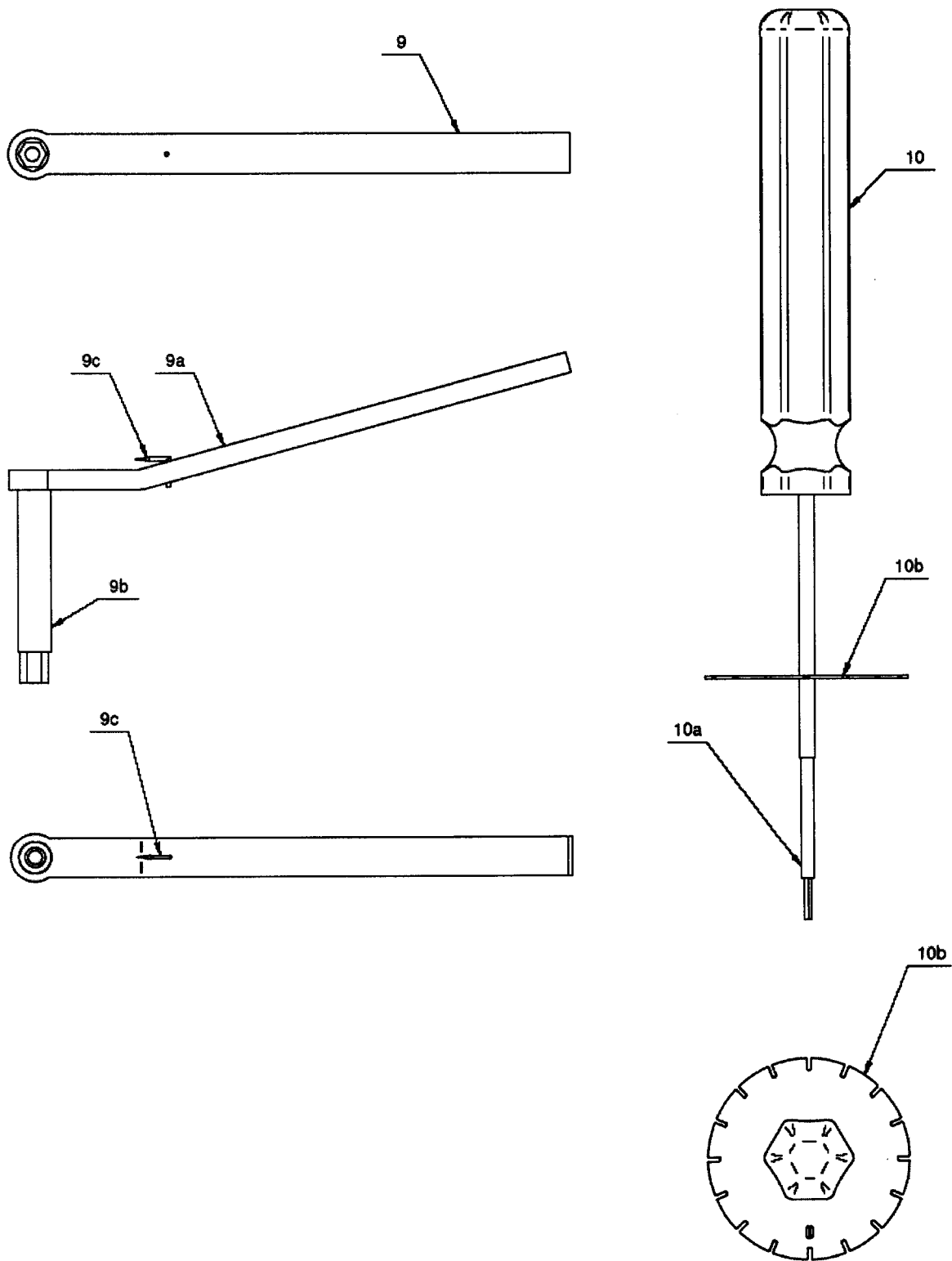


Fig. 3

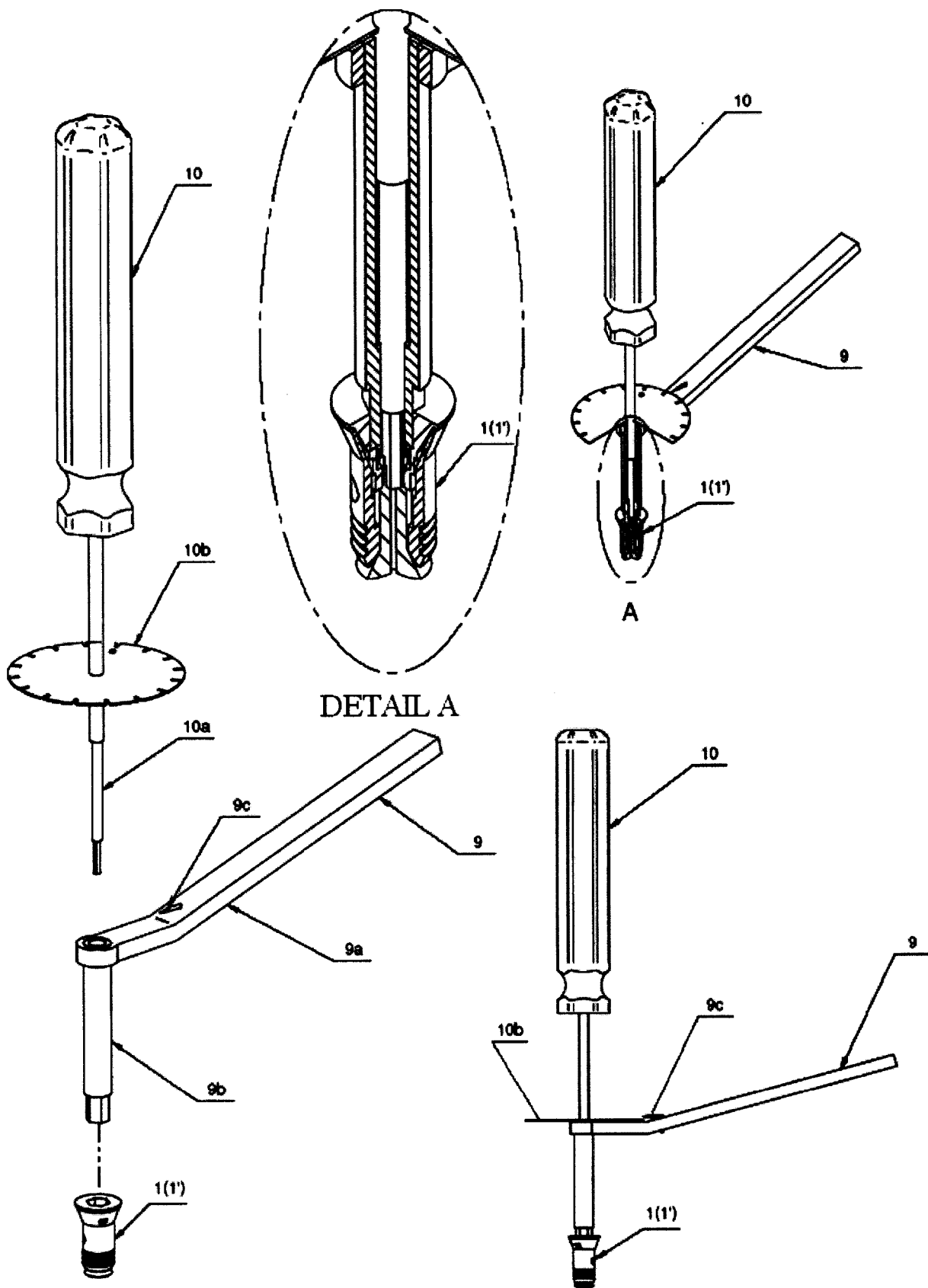


Fig. 4

INTERNATIONAL SEARCH REPORT

International application No
PCT/IT2013/000012

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F2/42
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)
A61F 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	WO 2009/154781 A1 (UNIV YALE [US]; REACH JOHN S [US]) 23 December 2009 (2009-12-23) pages 12,14-16 -----	1-4,6,7
Y	US 6 136 032 A (VILADOT PERICE RAMON [ES] ET AL) 24 October 2000 (2000-10-24) column 3, line 45 - column 5, line 60 -----	1-4,6,7
A	EP 2 213 263 A1 (TEXTILE HI TEC T H T [FR]) 4 August 2010 (2010-08-04) paragraphs [0020] - [0028] -----	1-7
A	EP 1 728 491 A1 (NEWDEAL [FR]) 6 December 2006 (2006-12-06) paragraph [0016] -----	1-7



Further documents are listed in the continuation of Box C.



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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

16 April 2013

Date of mailing of the international search report

24/06/2013

Name and mailing address of the ISA/

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Authorized officer

Buchmann, Gerhard

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IT2013/000012

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

1-7

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: 1-7

Endo-sinus-tarsal screw comprising an internal part comprising two components (2, 3) and a laterally expandable external part (6) wherein both internal components have portions for applying tools insertable from the outside, adapted to cause a relative motion between the two components in order to expand the external part.

2. claims: 8-11

A set of tools comprising a support tool having a handle and a tubular part, and comprising a screwdriver having a handle and a non-circular tip, the screwdriver received in the tubular part.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/IT2013/000012

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