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(54) Title: DENTAL OR OSSEOUS IMPLANT

(57) Abstract: Dental or osseous implant, comprising a stem (3) and a thread obtained on the outer surface of said stem, by means of which the latter is adapted to be anchored to an osseous tissue. The thread comprises a first threaded section (11) adjacent to a tip end (7) of the stem (3), the thread of the first threaded section having a cup-shaped profile, in which both the flanks (11a, lib) of the thread have an arcuate profile having its convex side facing toward said tip end, and a second threaded section (13) spaced from the tip end of the stem, the thread of the second threaded section having a triangular profile. The implant is preferably made of ceramic material.

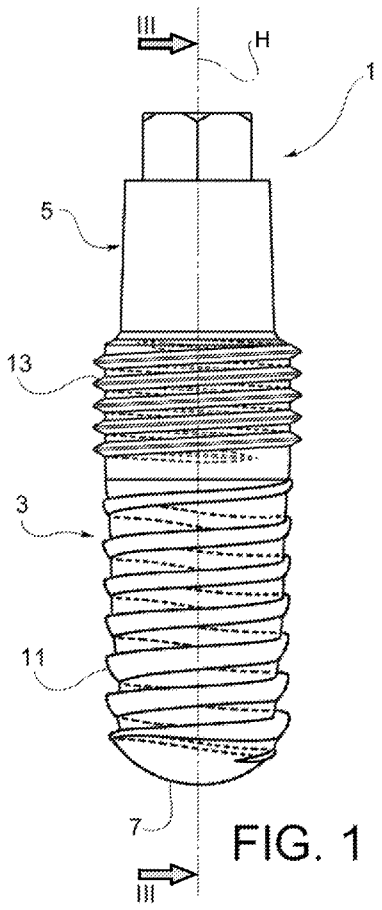

FIG. 1

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DENTAL AND OSSEOUS IMPLANT

TECHNICAL FIELD

The present invention refers to a dental implant or, more generally, an osseous implant, comprising a stem and a thread obtained on the outer surface of said stem, by means of which the latter is adapted to be anchored to an osseous tissue.

BACKGROUND ART

A dental implant is a device designed to be surgically positioned inside the mandibular or maxillary bone to support a dental prosthesis which must guarantee the patient correct biofunctionality. The fundamental requirements of dental implants currently used are biocompatibility, the ability to integrate with the bone, long-term duration and functional recovery of the organs (teeth) replaced, if possible ensuring a harmonious aesthetic result.

The morphology and components of dental implants are determined by the mechanical characteristics of the base material most widely used for production of the implants: titanium, with its alloys, covers approximately 97% of the market in this sector.

In general grade 4 pure titanium is used to produce the fixture, i.e. the endo-osseous part of the implant, while for the abutment, i.e. the part that will be covered by the dental prosthesis, and the connection screw between abutment and fixture, grade 5 titanium is used. Grade 4 titanium is considered pure (4 is the index of the presence of oxygen, carbon, iron and other impurities in residual percentage in the titanium matrix) while grade 5 titanium is an alloy consisting of 6% by weight of aluminium and 4% by weight of vanadium plus other impurities as in grade 4 titanium.

Commercially pure titanium is used as it is necessary to avoid the release of metal ions in contact with the biological tissues, while ensuring the prescribed mechanical

characteristics. The use of grade 5 titanium is prescribed exclusively by the implant manufacturers to ensure the implant system a wide margin of mechanical safety vis-à-vis the action of the masticatory loads. The relationship between the accumulation of metals such as aluminium and serious degenerative pathologies like Alzheimer's disease is of more than just academic interest in this context, since the prosthetic components of the implants are subject to the erosive action of the oral environment. The clear need to control the bioavailability of the potentially toxic elements has been satisfied, for the moment only at experimental level, by means of containment barriers (e.g. surface coatings) or by selecting different materials. In this regard, massive ceramic materials, such as alumina (Al_2O_3) and zirconium (ZrO_2), have recently been proposed as an alternative to metallic materials. Furthermore, in biomechanical terms the use of ceramic materials is particularly suitable for avoiding the transmission of stress between prosthesis and surrounding biological tissue.

Success in the development of a dental implant depends not only on the use of a correct material, but on its integration in the tissue in which it is positioned. In fact, a dental implant should not be considered as a device only able to replace the natural tooth, but a system for rehabilitation of the entire stomatognathic system. In terms of the patient's quality of life, it is important for this rehabilitation to be effected as quickly as possible, and last as long as possible. The application of anatomical, biomechanical, bioengineering and surface chemistry knowledge to the design and production of an implant is a key aspect of the integration characteristics.

It has been clinically demonstrated that implant stability plays a significant role in determining the success of the treatment. In particular, it has been observed that high percentages of success are the result of high levels of implant

stability, in combination with specific clinical parameters (both of a surgical nature and connected with the individual patient), and with a given treatment protocol.

Implant stability is determined by a combination of:
a) mechanical stability, which is the result of cooperation (understood as exchange of forces) between implant and bone tissue which maintains the implant in situ; and
b) biological stability, which is the result of the formation of new bone cells at the implant site and osseointegration.

Mechanical stability is generally high immediately after insertion of the implant (primary stability). This stability is due to the compressive load exerted by the implant on the bone tissue when the implant is inserted, and tends to diminish over time.

Biological stability, on the other hand, is absent immediately after positioning. It becomes evident only when new bone cells are formed at the implant site and increases over time (secondary stability).

In other words, due to the effect of the osseointegration process, the initial mechanical stability is strengthened and/or replaced by biological stability and the level of final stability of an implant is given by the sum of these two elements. Generally, the overall stability of an implant does not have a constant pattern: after insertion of the implant, an initial reduction is observed, followed by a subsequent significant increase once biological (secondary) stability has been established.

Due to the particular mechanical stress to which a dental implant is subject and the complexity of the physiological responses at the interface between implant and tissue, the development of innovative devices having appropriate structural

characteristics and capable of ensuring rapid and lasting integration with the host tissue continues to be an objective of primary importance in the dental sector.

Dental implants designed in order to improve primary stability, for example in view of application in protocols for immediate load, are known, for example from US 2008/0286720, WO 2006/035011, US 2007/0037123 and US 2010/0261141.

For example, the implant of US 2008/0286720 is provided with a connection thread, extending throughout the longitudinal development of the portion intended, in use, to cooperate with the bone tissue of the patient. Said thread is characterised by a V-shaped profile defining a first and a second flat upper contact surface which form, with the implant axis, respectively, a first and a second angle different from each other; and a lower contact surface, also flat, and forming with the implant axis a third angle, the first angle being greater than the second and third angle. Due to this configuration, the implant of US 2008/0286720 is able to effectively oppose radially directed occlusive loads, since the result of the forces which the bone tissue exerts on the upper and lower surfaces of the above-mentioned thread has a centring effect (radial stabilisation).

Analogously, US 2007/0037123 illustrates an implant provided, at a relative median portion, with a thread in which the upper buttress surface is flat and configured so as to form with a plane orthogonal to the axis of the implant itself an angle of 1 to 10° in order to give the implant just inserted in the bone tissue optimal resistance to a compressive type occlusive load. US 2007/0037123 furthermore illustrates a configuration with upturned thread, in which the lower buttress surface forms with a plane orthogonal to the axis of the implant itself a negative angle of 1 to 10°, with the effect of improving the (primary) stability of the plant in the sense of lift-resistance

stabilization.

However, although well-designed in order to maximise their primary (mechanical) stability immediately after insertion, the implants described above do not provide optimal performance in terms of secondary (biological) stability. In fact, it has been observed during tests aimed at evaluating the effectiveness and entity of the physiological processes of new bone tissue generation and osseointegration, that said implants require a particularly long time, in the order of months, to reach fully satisfactory levels of secondary stability.

In the dental sector and in implantology in general, the need is therefore felt to provide a dental or osseous implant that combines sufficient primary stability values with improved properties in terms of secondary stability. In particular, the need is felt in the sector to provide a dental or osseous implant that can promote more rapid triggering and easier progress of the physiological processes connected with the development of secondary stability, in order to achieve more quickly a fully satisfactory overall implant stability.

DISCLOSURE OF INVENTION

It is therefore an object of the present invention to meet at least one of the above-mentioned needs as simply and inexpensively as possible.

The above-mentioned object is achieved by the present invention which concerns a dental or osseous implant as defined in claim 1.

In greater detail, in view of the needs indicated above, the subject of the invention is a dental or osseous implant of the type comprising a stem and a thread obtained on the outer surface of said stem, by means of which the latter is adapted to be anchored to an osseous tissue, in which said thread comprises

a first threaded section adjacent to a tip end of the stem, the thread of said first threaded section having a cup-shaped profile, in which both flanks of the thread have an arcuate profile with convex side facing toward said tip end, and

a second threaded section spaced from said tip end of the stem, the thread of said second threaded section having a triangular profile.

According to said solution, the triangular thread of the second thread section guarantees correct load transfer to the cortical bone tissue, and has the function of giving the plant primary stability immediately after insertion, while the cup-shaped thread of the first thread section, while correctly deforming the spongy osseous tissue of the patient, cooperates (exchanges forces) with it to a significantly reduced extent, to the point that it does not substantially contribute to the primary stability of the implant. In particular the cup-shaped profile has above all the function of collecting, during insertion, bone fragments which perform an important role in the regeneration of new osseous tissue at the peri-implant site.

According to a preferred embodiment of the invention, said stem is made of ceramic material.

As will be appreciated, the implant according to the invention can be applied not only in the dental sector but also in other medical sectors, for example in orthopaedics.

BRIEF DESCRIPTION OF THE DRAWINGS

Further characteristics and advantages of the implant according to the invention will be evident from the following detailed description, with reference to the accompanying drawings, provided purely by way of non-limiting example, in which:

- figures 1 and 2 are different lateral views of a dental implant according to the invention;
- figure 3 is a section view of the implant of figures 1 and 2, taken along the line III-III of figure 1;

- figure 4 is an enlarged scale view of a detail of the implant, indicated by the arrow IV in figure 3;
- figure 5 is a lateral view of a variation of the dental implant according to the invention;
- figure 6 is an enlarged scale section view of a detail (second thread) of the dental implant of figure 5;
- figure 7 is an enlarged scale section view of a further detail (first thread) of the dental implant of figure 5;
- figure 8 is a perspective view of the dental implant of figure 5;
- figure 9 is an enlarged scale lateral view of a detail of the first thread of figure 7; and
- figure 10 is an enlarged scale section view of a detail of the first thread of figures 7 and 9.

BEST MODE FOR CARRYING OUT THE INVENTION

With reference to the figures, an implant according to the invention, in particular a dental implant, is indicated overall by 1.

The dental implant 1 comprises a stem 3 with axis H, commonly known as fixture, which in use constitutes the endo-osseous part of the implant, and a head portion 5, commonly known as abutment, which in use is covered by the dental prosthesis. In the case of an implant for a different use, for example for orthopaedic use, the head portion of the implant can be shaped, according to requirements, differently from the manner shown in the figures. The form of the head portion of the implant is not essential, however, for the purposes of the invention.

The stem 3 has a thread obtained on its outer surface, by means of which it is adapted to be anchored to an osseous tissue, and a tip end 7, opposite the head portion 5. Preferably, the tip end 7 of the stem 3 is calotte-shaped.

The thread of the stem 3 comprises a first threaded section 11 adjacent to the tip end 7 of the stem 3. As can be seen better

in figure 4 and in figure 7, the thread of the first threaded section 11 has a cup-shaped profile, in which both the flanks 11a, 11b of the thread have an arcuate profile with convex side facing toward the tip end 7 of the stem 3.

More specifically, as illustrated in further detail in figures 8 and 9, the cup-shaped profile of the first threaded section 11 comprises an upper surface 111 and a first and a second lower surface 112 and 113. The upper surface 111 is concave towards the top and the first lower surface 112 is convex towards the bottom.

Again more specifically, as shown in the detail of figure 9 which schematically illustrates a section of the cup-shaped profile of the first threaded section 11, the upper surface 111 and the first and second lower surface 112 and 113 identify, in a plane belonging to the bundle of planes passing through the axis H of the stem 3, respective arcs of a circle.

In one embodiment, the arc of a circle identified by the upper surface 111 can extend outwards from the outer surface of the stem 3 forming, at the branch from the stem 3, a substantially right angle with the axis H. In other words, the concavity defined by the upper surface 111 can have a substantially horizontal tangent at the point where the upper surface 111 branches from the stem 3.

Preferably, identifying:

- L_1 as the depth, in the axial direction, of the cavity defined by the upper surface 111, measurable substantially from the bottom of said cavity to the upper end of the arc of a circle identified by the upper surface 111;
- L_2 as the overall radial development of the cavity defined by the upper surface 111, measurable substantially from the upper end of the arc of a circle identified by the upper surface 111 to the outer surface of the stem 3; and

- L_3 as the thread pitch of the first threaded section 111,

the following relations exist:

- L_1 is 0.1 mm to 0.25 mm;
- L_2 is 0.3 mm to 0.6 mm; and
- L_3 is 0.15 mm to 0.25 mm.

Figure 10 illustrates an example of an implant according to the invention in which depth and radial development of the cavity defined by the upper surface 111 have been maximised in order to accentuate the cavity.

The thread of the stem 3 comprises a second threaded section 13 spaced from the tip end 7 of the stem 3, arranged successively to the first threaded section 11 according to a direction which goes from the tip end 7 to the head portion 5. The thread of the second threaded section 13 has a triangular profile.

The thread with triangular profile of the second threaded section 13, adjacent to the head portion 5 of the implant 1, guarantees correct load transfer to the cortical osseous tissue.

As illustrated in figures 5 and 8, a variation of the implant 1 according to the present invention can comprise only the stem (fixture) 3, the extreme portion 14 of the stem 3 on the side opposite the tip end 7 comprising a coaxial recess 15, optionally provided with a thread 16, adapted to receive partially and engage with (or be fixed in another way to) an abutment of known type.

Furthermore, the stem 3 of the implant 1 can comprise, between the first and the second threaded section 11 and 13, a non-threaded connecting section or, as in the case illustrated in figures 5 and 8, a section in which the thread is shaped so as to uninterruptedly connect the first and the second threaded section 11 and 13.

The thread with cup-shaped profile of the first threaded section 11, adjacent to the tip end 7 of the implant 1, transfers a correct deformation to the spongy osseous tissue. Unlike profiles defining flat surfaces, the cup-shaped profile of the first threaded section 11 causes the first threaded section 11 to cooperate mechanically only to a reduced extent with the spongy osseous tissue. In practice, due to the arcuate profile (or profile defined by sections of arcs of a circle), the forces exchanged between first threaded section 11 and spongy osseous tissue are uniformly distributed along an infinite number of directions, their resultant of stabilisation of the implant being thus significantly diminished compared to conventional threads defining flat and angled surfaces with respect to the implant stem axis. Consequently, the implant section 1 provided with the first threaded section contributes only minimally to giving the plant primary stability.

In particular, the cup-shaped profile has the primary function of collecting, during insertion of the implant, the bone fragments which form as the implant penetrates into the spongy osseous tissue, and which perform an important function in the regeneration of new bone around the implant, as will be seen in greater detail in the example below.

The calotte shape of the tip end 7 of the implant permits a more controlled and less point-specific discharge of stress than flat and/or pointed profiles, allowing a 30% reduction in the stress at the bone-implant interface both in the cortical area and in the spongy area of the bone. Furthermore it increases the contact surface with the spongy osseous tissue, facilitating rapid osseointegration.

The ratio between the extent of the first section 11 with cup-shaped profile and the second section 13 with triangular profile can vary according to the patient and the quantity of

soft tissue, cortical bone and spongy bone.

The profile angle of the triangular thread and the curvature of the cup-shaped thread can also vary, according to the type of cortical and spongy bone.

It should be noted that, in particular, the second section 13 could also have a profile that is not strictly triangular, as long as it is such as to sufficiently stabilise, radially and axially, the implant 1 during insertion.

The profile of curvature of the tip end 7 of the implant can vary, according to the density of the spongy bone, from flat to elliptical with any value of the two radiuses of the ellipsoid, parallel and perpendicular to the axis of extension of the implant (if said radiuses are equal, a semi-spherical calotte is obtained).

The above-mentioned geometrical combination of profiles allows significantly improved structural characteristics to be obtained with respect to the known devices, independently of the material used for the implant, for example medical metal, metal alloy or ceramic material. In particular, as will be shown in further detail in the following example, with the implant 1 according to the invention, secondary stability appears much more quickly and to a greater extent compared to the implants of known type.

The positive characteristics of the implant are moreover further increased when said implant is made of ceramic material.

Lastly, it is clear that the implant described and illustrated can be subject to modifications and variations that do not depart from the protective scope of the independent claims.

Comparative example

A commercial Ti-Unite™ (Nobel Biocare Italy, Agrate Brianza, Italy) commercial implant was used as a reference implant. It is an implant provided with a standard thread of triangular type, having diameter 4.25 mm and length 12 mm.

Example 1

An implant according to the invention was used. In particular, an implant having diameter 4.25 mm and length 12 mm was used.

Experimental tests

The experiments were conducted on 16 mini pigs. For each animal, at least 4 implants were inserted at the level of the tibia: 2 implants according to the invention and 2 comparative implants as defined above.

4 animals were sacrificed after 7, 14, 28 and 56 days respectively. The tibias were dissected and underwent histomorphometric and biomolecular analysis. The results were analysed in terms of contribution of new bone (bone to implant contact, also indicated by the acronym BIC) and RNA profiling.

Animals

In the experiment (CISRA, Turin, Italy) sixteen adult mini pigs (weighing approximately 65 kg) were used. The pigs were fed on standard pellet cereals and received water *ad libitum*. The animals had a period of acclimatization of 1 week before the surgery was performed. In full compliance with the Italian laws, all the experiments on the animals were approved by an academic ethics committee.

Surgical procedure

After pre-anaesthetic sedation with xylazine 2% (Rompun 2%, Bayer, Milan, Italy; 2.3 mg/kg) and tiletamine/zolazepam (Zoletil 100-Virbac 20%, Laboratoires Virbac, Carros, France; 6.3 mg/kg), the surgery was performed under anaesthetic with

intubation with isoflurane/halothane and oxygen. The front right leg was prepared according to a standard sterile procedure. After exposing the tibia, the implants were inserted applying a torque of 40Ncm. The lip was then closed and the surgical access sutured so as to completely cover the implants, the head of which reached the level of the bone. Each tibia received 4 implants: two implants according to the invention (Example 1) and 2 implants in traditional titanium (Comparative example). Samples of tibia bone were collected in this phase to determine reference values at time 0. At the pre-established times, the animals were euthanized with 2% xylazine (Rompun 2%, Bayer) (2.2 mg/kg) and tiletamine/zolazepam (6.6 mg/kg) and an intracardiac injection of embutramide, mebezonium iodide and tetracaine hydrochloride (70 mg/kg). Lastly, the tibias were exposed and dissected for analysis.

Histological analysis of the peri-implant bone

In order to evaluate healing and remodelling of the bone, histological analysis was performed after 7, 14 and 56 days from insertion of the implants. After removing the implants, the samples were fixed in formalin 4% for 24 hours, decalcified for 3 to 4 weeks in a mixture of formic acid 50% and tribasic sodium citrate 10%, incorporated in paraffin wax and cut into sections of 3 microns, along the longitudinal axis of the implant, using a motorised microtome. Slides coated with polylysine were used to improve adhesion of the section of tissue during the staining procedures. The histological structure of the peri-implant bone was evaluated by traditional staining with hematoxyline and eosin and optical microscopy.

The bone to implant contact (BIC%) was determined manually using image processing software (Olympus Dot Slide BX51) on the virtual histological slide. Furthermore, morphometric parameters such as the presence of necrotic or fibrous tissue, the quantity of osteoclasts grouped and organised and osteoblasts together with blood vessels and neo-formed bone

were evaluated by two independent pathologists.

Results

Histological analysis

The presence of osteoid at the bone-implant interface was noted at the first of the time instants (7 days) while for all the other time instants, no presence of interfacial non-mineralised matrix was observed, or was observed only in traces, both for the implant according to the invention and for the reference implant.

Consequently, the osteocyte bone score determined as quantity of osteocyte or necrotic cortical bone adjacent to the implant revealed the presence, only after 7 days, of a minimum quantity of necrotic osteocytes near the surface of the implant, both for the implant according to the invention and for the reference implant. The cell remodelling of bone fragments was similar in the implant according to the invention and the reference implant, and the activity reached a peak after 7 days had elapsed from the insertion.

Both treatment groups showed a constant increase in the overall BIC during the study up to 56 days. For the BIC values (see Table 1 below) statistically significant differences were found between the implant according to the invention and the reference implant after 56 days, whereas in the first phase (after 28 days) no important differences were observed.

Table 1

	BIC % (after 28 days)	BIC % (after 56 days)
Implant according to the invention	35.4 ± 3.5	53.3 ± 6.5
Reference implant	32.1 ± 6.4	35.3 ± 1.9

The results show that the implant according to the invention

favours a significant increase in secondary stability much more quickly than the reference (conventional) implant. In particular, 56 days after insertion of the implants, the bone to implant contact is increased by over 50%. It is the opinion of the inventors that this surprising effect can be related to the fact that the cup-shaped structure with arcuate profiles of the thread of the implant according to the invention facilitates, during insertion of the implant in the bone tissue, the collection of a greater number of bone fragments, at the same time reducing the load on the surrounding spongy tissue compared to an implant of known type. According to the inventors, in fact, said distinctive characteristics promote a more rapid and effective osseointegration and, consequently, more rapid development of important and reliable secondary stability of the implant.

CLAIMS

1. A dental or osseous implant comprising a stem (3) having a longitudinal axis (H) and a thread formed on an outer surface of said stem, by means of which the latter is adapted to be anchored to an osseous tissue, characterized in that said thread comprises

a first threaded section (11) adjacent to a tip end (7) of the stem (3), the thread of said first threaded section having a cup-shaped thread form, wherein both flanks (11a, 11b) of the thread have an arcuate profile having its convex side facing toward said tip end, and

a second threaded section (13) spaced out from said tip end of the stem, the thread of said second threaded section having a triangular profile.

2. The implant as claimed in claim 1, characterised in that said cup-shaped profile of said first threaded section (11) comprises an upper surface (111) and a first and a second lower surface (112, 113), said upper surface (111) being concave towards the top and said first lower surface (112) being convex towards the bottom.

3. The implant as claimed in claim 2, characterised in that said upper surface (111) and said first and second lower surfaces (112, 113) identify, in a plane belonging to the bundle of planes passing through said axis (H) of said stem (3), respective arcs of a circle.

4. The implant as claimed in claim 3, characterised in that, identifying:

- L_1 as the depth, in the axial direction, of the cavity defined by said upper surface (111) and measurable from the bottom of said cavity to the upper end of said arc of a circle identified by said upper surface (111);
- L_2 as the overall radial development of said cavity

defined by said upper surface (111) and measurable from the upper end of said arc of a circle identified by said upper surface (111) to said outer surface of said stem (3); and

- L_3 as the thread pitch of said first threaded section (111),

the following relations exist:

- L_1 is 0.1 mm to 0.25 mm;
- L_2 is 0.3 mm to 0.6 mm; and
- L_3 is 0.15 mm to 0.25 mm.

5. The implant as claimed in any one of the claims from 1 to 4, wherein said tip end of the stem adjacent to said first threaded section is calotte-shaped.

6. The implant as claimed in any one of the claims from 1 to 5, wherein the extreme portion (14) of said stem (3) on the opposite side to the tip end (7) comprises a coaxial recess (15), optionally provided with a thread and adapted to partially receive and engage with, or be otherwise fixed to, an abutment element.

7. Implant as claimed in any one of the claims from 1 to 6, wherein said implant is of ceramic material.

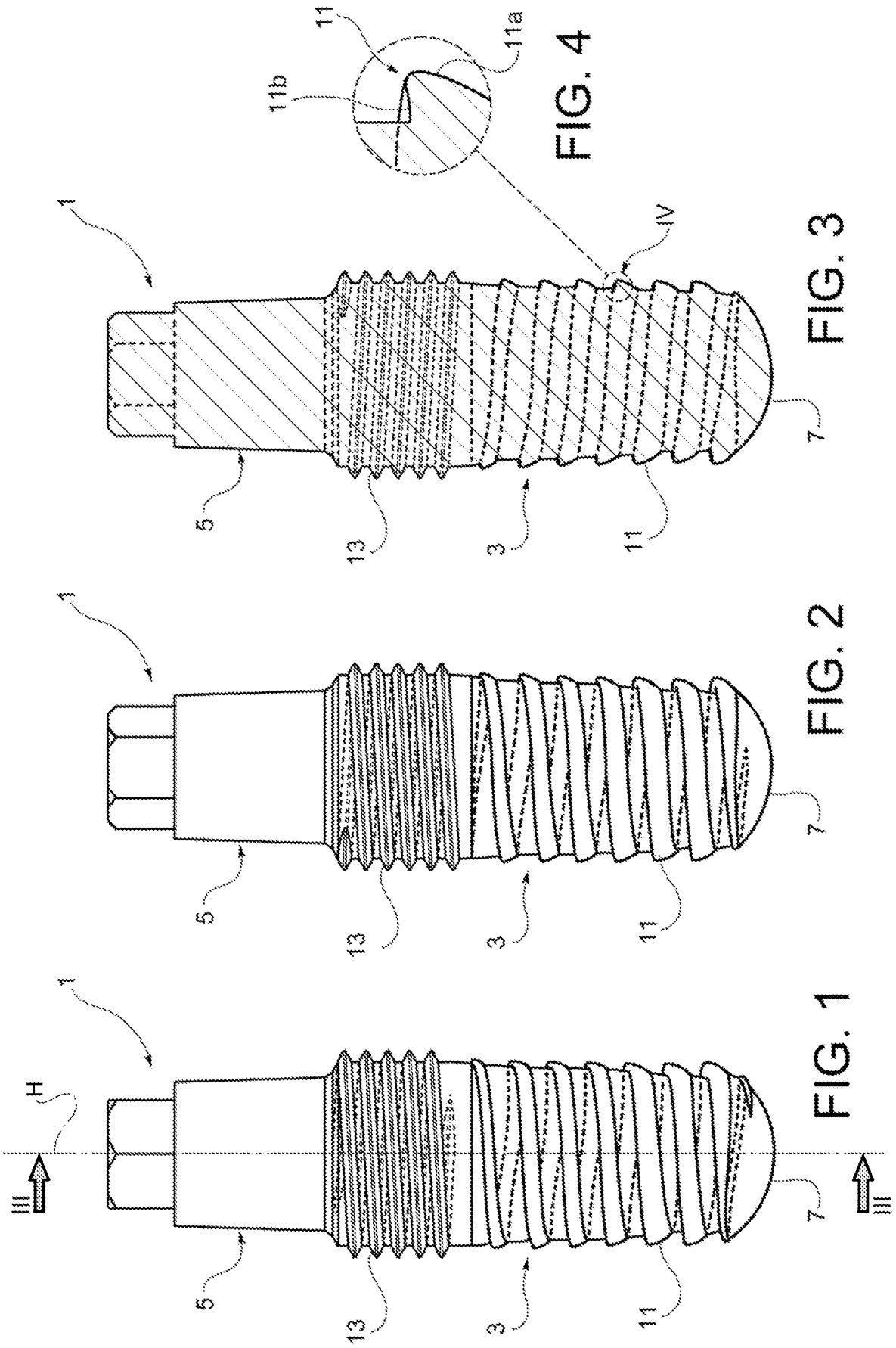


FIG. 4

FIG. 3

FIG. 2

FIG. 1

FIG. 5

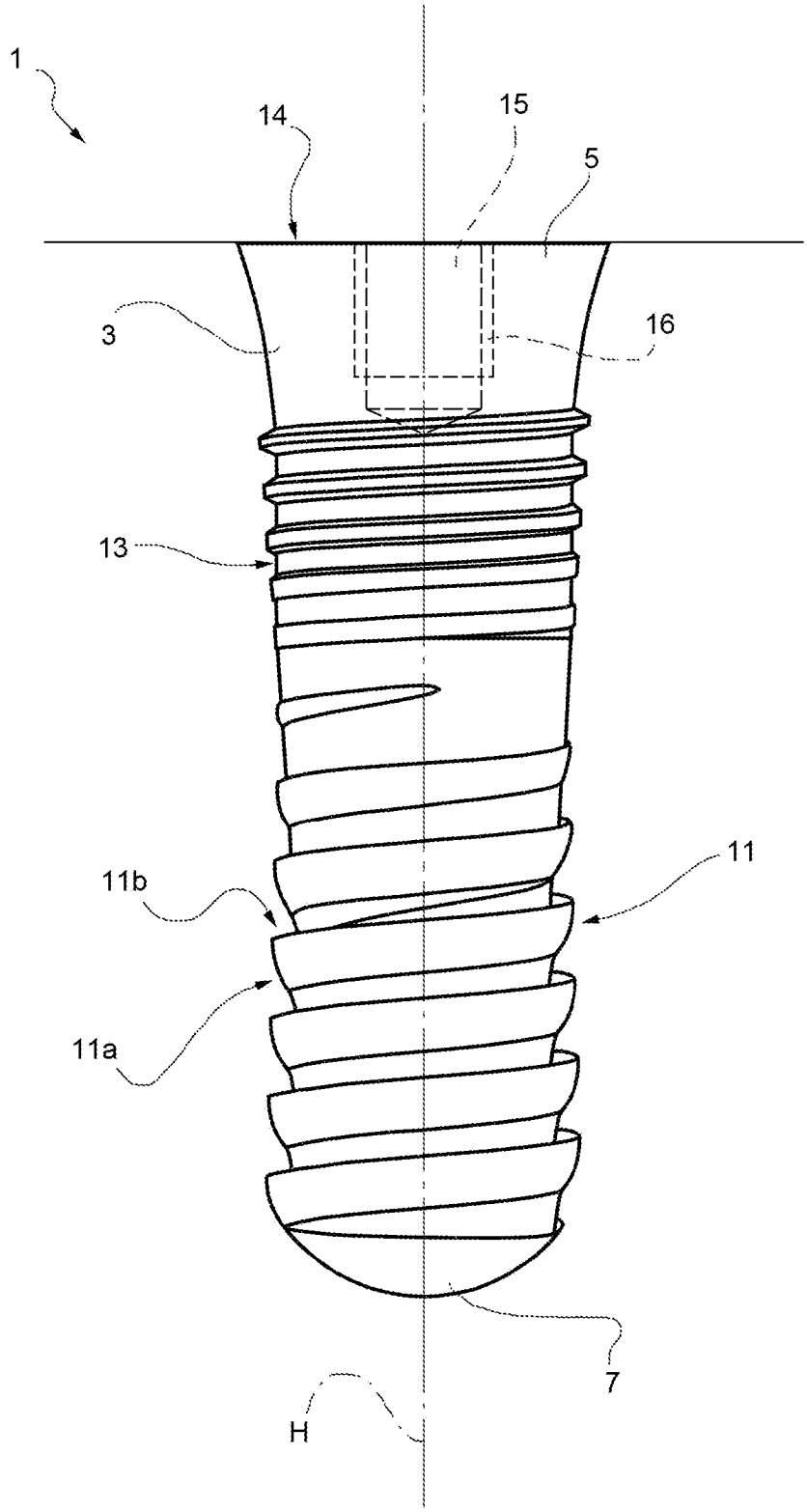


FIG. 6

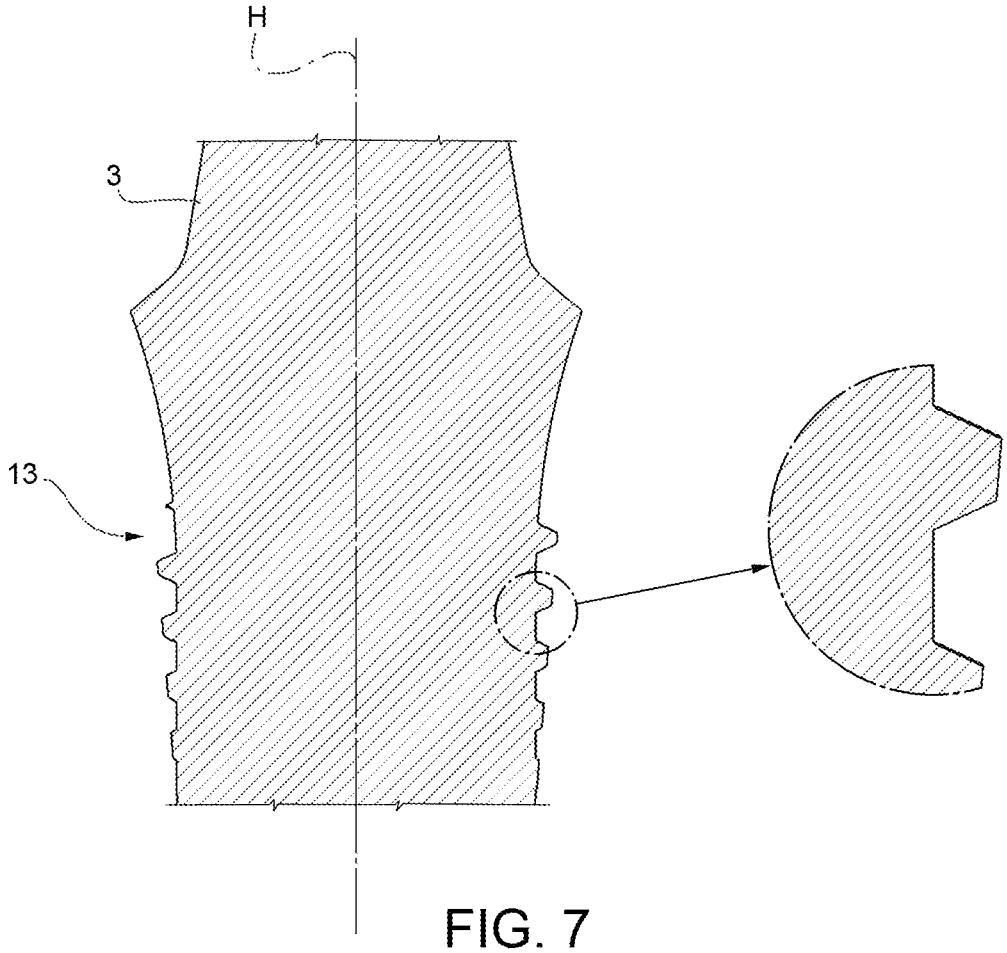


FIG. 7

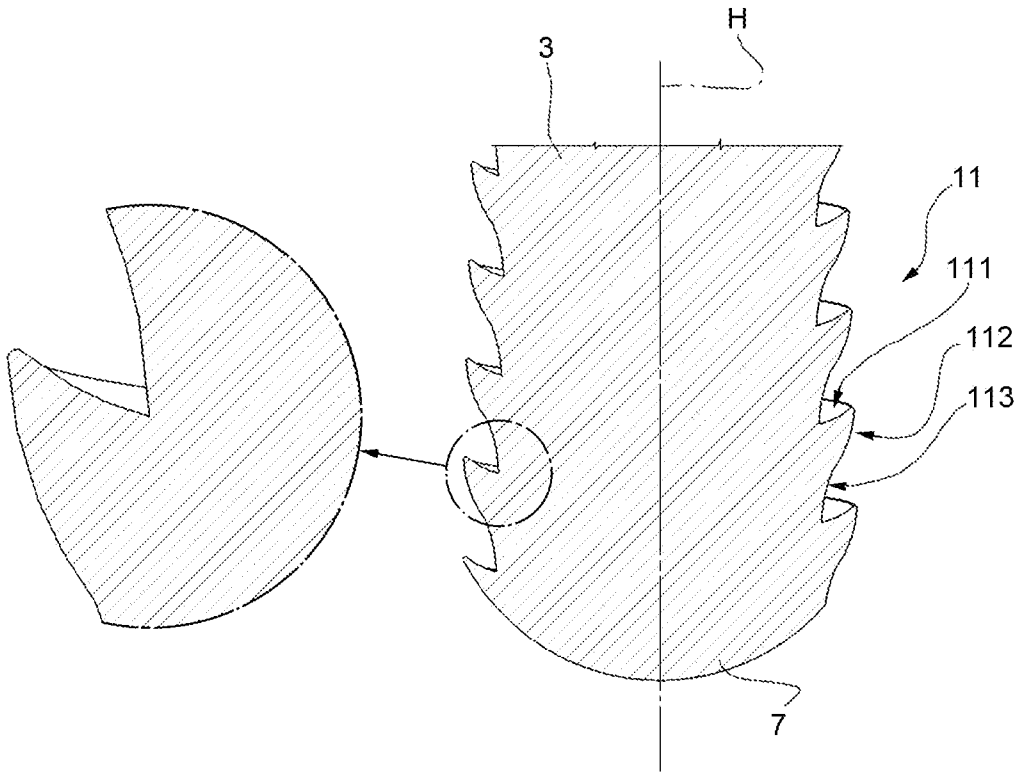


FIG. 8

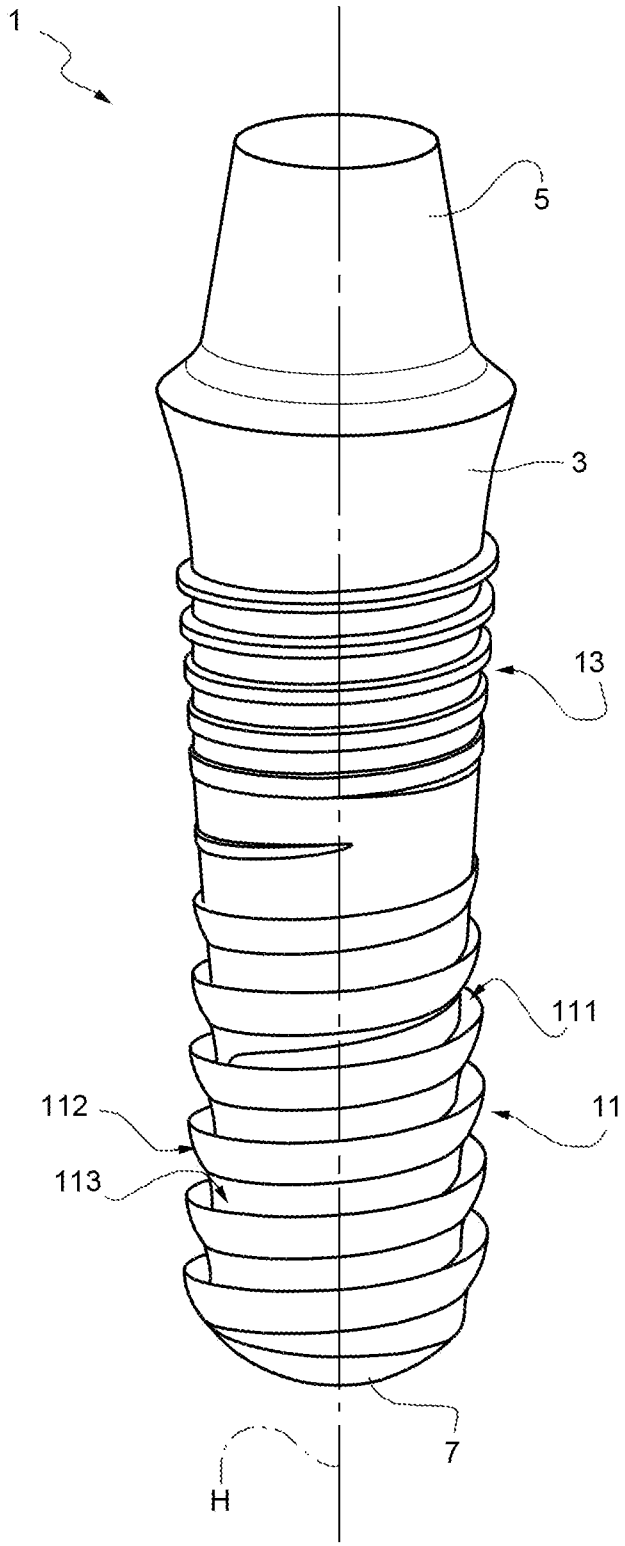


FIG. 9

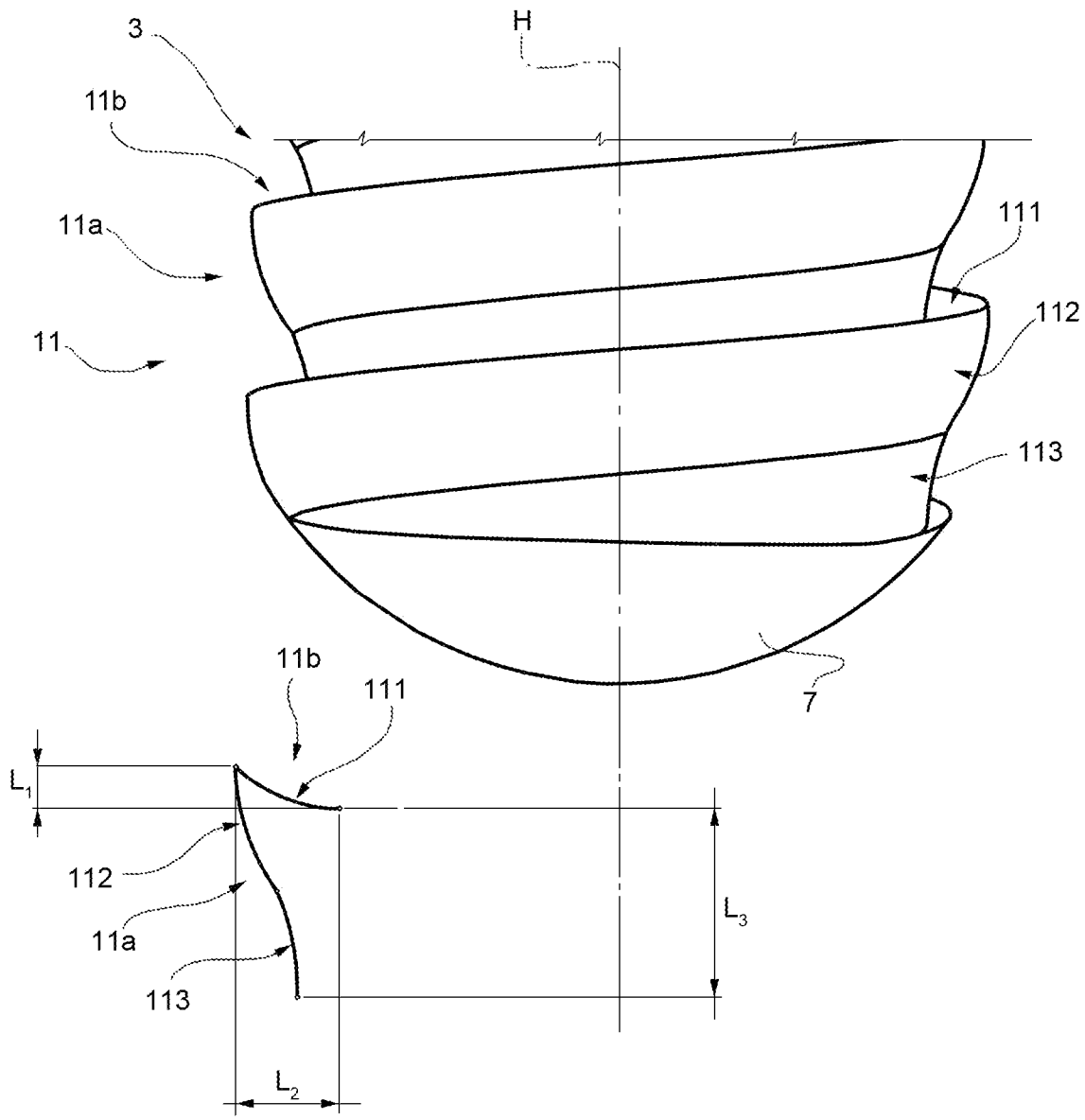
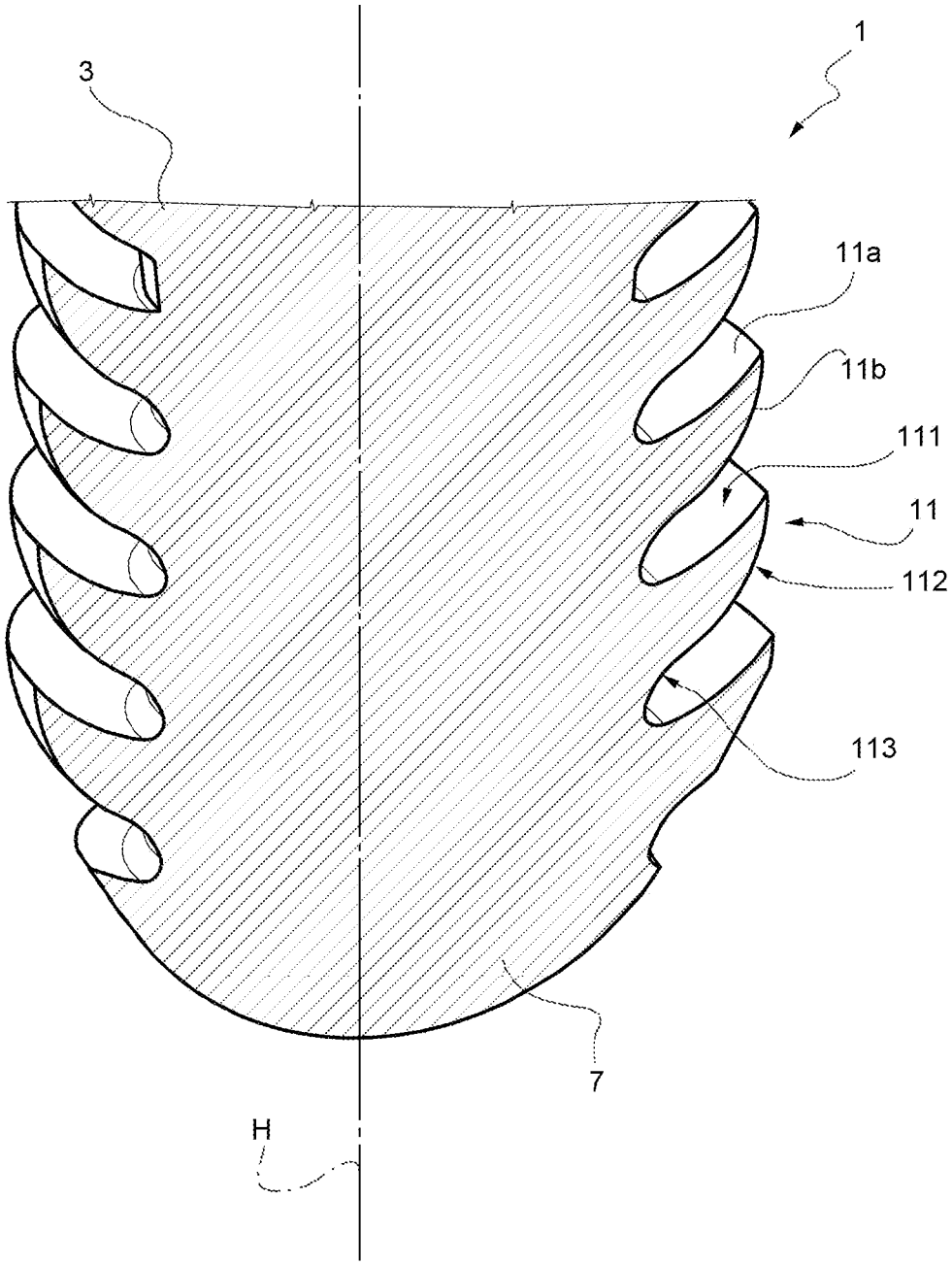


FIG. 10



INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2013/051069

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61C8/00
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)
A61C 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, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2008/286720 A1 (REED GARY J [US]) 20 November 2008 (2008-11-20) cited in the application paragraphs [0050] - [0052], [0057] figures 2A, 3, 5, 6, 7A	1-7
X	US 6 129 730 A (BONO FRANK S [US] ET AL) 10 October 2000 (2000-10-10) column 3, lines 5-60 figures 3, 4	1,2,5,6
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[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
3 July 2013	09/07/2013

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	Chabus, Hervé

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2013/051069

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

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Y	US 2010/261141 A1 (AJLOUNI RAED [US] ET AL) 14 October 2010 (2010-10-14) paragraph [0090] figure 18	1,5-7

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