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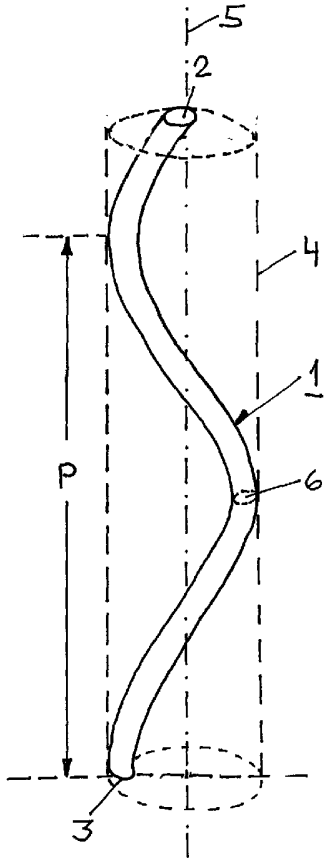
(54) Title: OSTEOSYNTHETIC DEVICE

(57) Abstract: The osteosynthetic device (1) in form of an intramedullary nail has a longitudinal shape with a central axis (5), a first end (2) and a second end (3). The shape of the device (1) is based on the form of a helix.



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patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

OSTEOSYNTHETIC DEVICE

This invention relates to an osteosynthetic device according to the preamble of claim 1.

For the insertion of intramedullary nails the intramedullary canal has to be prepared first. Prior art intramedullary nails have therefore the following major disadvantages:

- the opening is bigger than the nail cross-section because of the bend of the nail; and
- the single bend at one point of the nail does not correspond to the anatomical shape of the medullary cavity of long bones.

Conventional nails forces the surgeon to use in proximal humerus a medial entry point which is located too medially, almost at the articular surface of the humerus, i.e. far from ideal from mechanical and vascular aspects of proximal humerus.

The present invention is designed to overcome the foregoing problems by providing an osteosynthetic device, particularly an intramedullary nail, which is capable of following the shape of the medullary cavity of long bones of humans. No oversized

opening is needed because the helix shape makes it possible to turn the nail during its insertion into the medullary cavity. The entry point of unreamed nails is optimised especially at the femur and the tibia but also in the humerus.

The main advantages of the device according to the invention are the following:

- it allows for a better placement of the entry hole of the nail into the bone avoiding risky points, as for instance, the danger of injuring the vascular supply of the femoral head; this lowers the complication rate and makes humerus nailing easier to perform;
- it does not require an entry hole larger than the cross-section of the nail; and
- it allows easy removal of the nail after bone healing.

Elastic intramedullary nails are not so useful in the adolescent/older child because they may be slightly unstable, requiring often the use of postoperative splints. The use of conventional nails in older children and adolescents is associated to a high risk of femoral head necrosis. A lateral entry points, of a thin constant section (no proximal thick part) can be a high bonus for these patents.

In the case of plates and/or of internal fixators according to the invention the main advantage is the possiblity to allow the implant to be - for instance - anterior in distal humerus and lateral in proximal humerus, avoiding the risk of radial nerve injury.

While one of the principal applications of the invention is as an intramedullary nail, the invention can also be applied to extramedullary devices, e.g. bone plates or internal fixators.

In the modification of a bone nail the device according to the invention may be used in the femur, humerus, tibia and radius.

In a preferred embodiment the envelope of the helix is a circular cylinder having the same central axis as the helix and the helix is running over less than 540°, preferably over less than 360°. The radius r of the circular cylinder purposefully is in the range of 10 to 50 mm, preferably in the range of 15 to 30 mm. The pitch p of the helix should be in the range of 100 to 1'500 mm, preferably in the range of 300 to 1000 mm.
The cross-section orthogonal to the central axis of the helix is preferably a circle, square or star.

In a further preferred embodiment the second end of the nail is pointed, which allows easier introduction into the bone.

In a further preferred embodiment the cross-section orthogonal to the central axis of the helix is essentially a rectangle with the sides a and b, the larger sides b being oriented to the outer and inner side of the helix. Purposefully the ratio of a:b is smaller than 0,50, preferably smaller than 0,35. Preferably the essentially rectangular cross-section is trimmed at its smaller sides a.

In a further preferred embodiment the portion of the helix nearer to the first end is thicker than the portion of the helix nearer to the second end. this allows for attachment of a handle to hold and manipulate the helix nail.

In a further preferred embodiment the central axis of the helix is a straight line.

In a further preferred embodiment the cross-section orthogonal to the central axis has a maximum dimension in the range of 5 to 14 mm and the length of the cylinder or of the helix is in the range of 200 to 500 mm.

In a further preferred embodiment the implant may be provided with lateral holes for locking screws.

The invention will be further described with reference to the accompanying drawings in which:

Fig. 1 is a perspective view of a device according to the

invention in the form of a helical nail;

Fig. 2 is a perspective view of a device according to the invention in the form of a helical plate;

Fig. 3 is a detail of the nail according to Fig. 1;

Fig. 4 is a detail of the plate according to Fig. 2;

Fig. 5 is a an orthogonal cross section through the nail according to Fig. 1;

Fig. 6 is a variation of the orthogonal cross section; and

Fig. 7 is a further variation of the orthogonal cross section.

The osteosynthetic device 1 according to the invention is represented in Fig. 1 in the form of an intramedullary nail. It has a longitudinal shape with a central axis 5, a first end 2 an a second end 3. The shape of the device 1 is based on the form of a helix which in geometry is a well-known configuration. The envelope of the helix as shown in Fig. 1 is a circular cylinder 4 having the same central axis 5 as the helix. The central axis 5 of the helix is a straight line. The helix is running over less than 540°, preferably over less than 360°. Typically the helix is running over 240°. The radius r of

the circular cylinder 4 is in the range of 10 to 50 mm, preferably in the range of 15 to 30 mm. The pitch p of the helix is range of 100 to 1'500 mm, preferably in the range of 300 to 1000 mm. As shown in Fig. 5 the cross-section orthogonal to the central axis 5 of the helix is a circle, i.e. the helix is made of a cylindrical rod. Alternatively as shown in Figs. 6 and 7 the cross-section may also have the shape of a square or a star (or may be fluted).

Another embodiment of the invention is represented in Fig. 2. It differs from the embodiment of Fig. 1 by the cross-section orthogonal to the central axis 5 which is not circular but rectangular, i.e. the helix is made of a flattened rod. In particular the cross-section 6 orthogonal to the central axis 5 of the helix is essentially a rectangle with the sides a and b, the larger sides b being oriented to the outer and inner side of the helix. Instead of a rectangular shape the cross-section could have an ellipsoidal shape, where a/2 and b/2 would be the half-axis of the ellipse. The ratio of a:b should be smaller than 0,50, preferably smaller than 0,35.

The portion of the helix nearer to the first end 2 is thicker than the portion of the helix nearer to the second end 3 this allowing attachment of a handle to hold and manipulate the device 1.

The cross-section orthogonal to the central axis 5 has a maximum dimension in the range of 5 to 14 mm.

As shown in Fig. 3 the second end 3 of the device 1 is pointed for easier introduction into the bone.

As shown in Fig. 4 the essentially rectangular cross-section of the device 1 is trimmed at its smaller sides a.

Figs. 5 to 7 show different cross-sections of the nail according to the invention.

The devices according to the invention may be made of any appropriate material, depending on the purpose to be served. They may be made of metals, for example an appropriate stainless steel, titanium or polymeric material in particular of composite nature.

Claims

1. An osteosynthetic device (1), in particular an intramedullary nail, having a longitudinal shape with a central axis (5), a first end (2) and a second end (3)
characterized in that
the shape of the device (1) is based on the form of a helix.

2. Device (1) according to claim 1, characterized in that the envelope of the helix is a circular cylinder (4) having the same central axis (5) as the helix.

3. Device (1) according to claim 1 or 2, characterized in that the helix is running over less than 540°, preferably over less than 360°.

4. Device (1) according to claim 2 or 3, characterized in that the radius r of the circular cylinder (4) is in the range of 10 to 50 mm, preferably in the range of 15 to 30 mm.

5. Device (1) according to one of the claims 1 to 4, characterized in that the pitch p of the helix is range of 100 to 1'500 mm, preferably in the range of 300 to 1000 mm.

6. Device (1) according to one of the claims 1 to 4, characterized in that the pitch p of the helix is larger than 400 mm, preferably larger than 600 mm.

7. Device (1) according to one of the claims 1 to 6, characterized in that a cross-section (6) orthogonal to the central axis (5) of the helix is a circle.

8. Device (1) according to one of the claims 1 to 6, characterized in that a cross-section (6) orthogonal to the central axis (5) of the helix is a square or star.

9. Device (1) according to one of the claims 1 to 8, characterized in that the second end (3) is pointed.

10. Device (1) according to one of the claims 1 to 9, characterized in that a cross-section (6) orthogonal to the central axis (5) of the helix is essentially a rectangle with the sides a and b, the larger sides b being oriented to the outer and inner side of the helix.

11. Device (1) according to claim 10, characterized in that the ratio of a:b is smaller than 0,50, preferably smaller than 0,35.

12. Device (1) according to claim 10 or 11, characterized in that the essentially rectangular cross-section is trimmed at its smaller sides a.

13. Device (1) according to one of the claims 1 to 12, characterized in that the portion of the helix nearer to the first end (2) is thicker than the portion of the helix nearer to the second end (3).

14. Device (1) according to one of the claims 1 to 13, characterized in that the central axis (5) of the helix is a straight line.

15. Device (1) according to one of the claims 1 to 14, characterized in that the cross-section orthogonal to the central axis (5) has a maximum dimension in the range of 5 to 14 mm, preferably in the range of 7 to 11 mm.

16. Device (1) according to one of the claims 1 to 15, characterized in that the length of the cylinder or of the helix is in the range of 200 to 500 mm, preferably in the range of 250 to 400 mm.

17. Device (1) according to one of the claims 1 to 16, characterized in that it is provided with through-going holes (7) for locking screws, preferably near the second end (3).

18. Device (1) according to one of the claims 1 to 17, characterized in that it is provided with at least two, preferably with at least three trough-going holes (7) for locking screws.

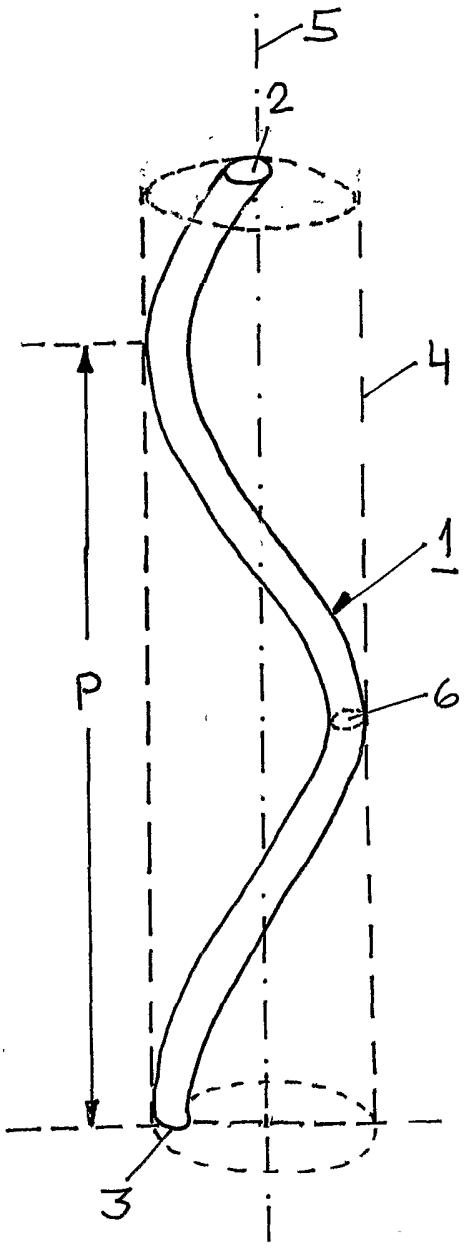

Fig. 1

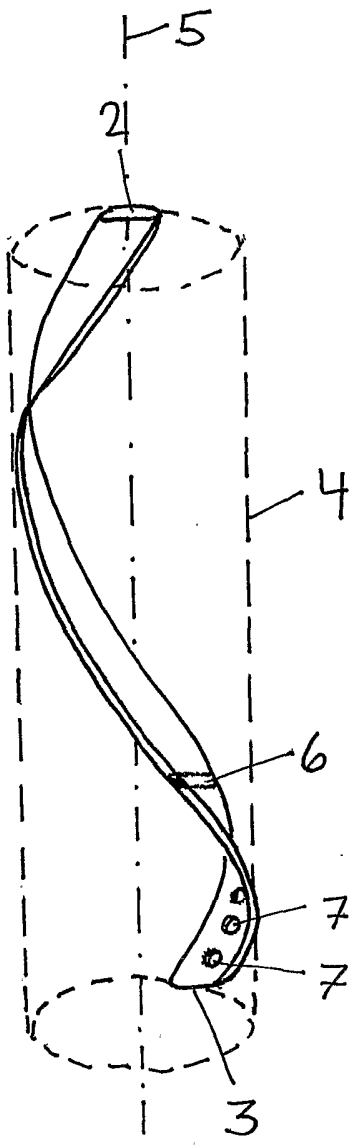

Fig. 2

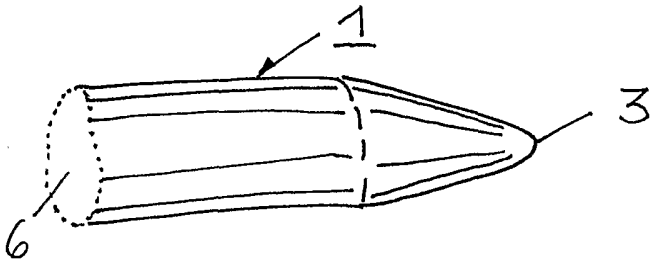

Fig. 3

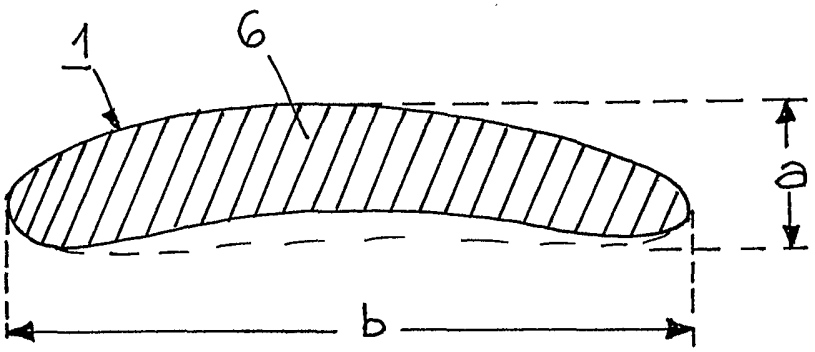

Fig. 4

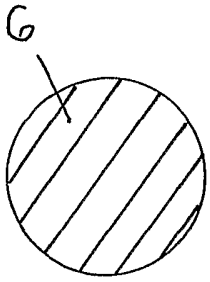

Fig. 5

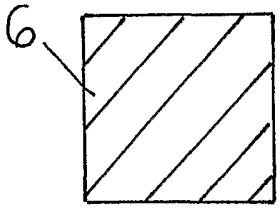

Fig. 6

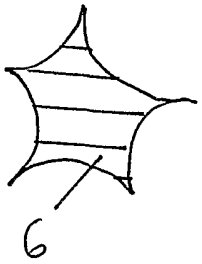

Fig. 7

INTERNATIONAL SEARCH REPORT

Int ional Application No
PCT/CH 01/00276

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/72

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)
IPC 7 A61B

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 094 039 A (SCAGLIETTI OSCAR) 16 November 1983 (1983-11-16) page 2, line 24 -page 3, line 17 page 4, line 5 - line 8 figure 1	1-3,14, 16,17
Y		8-10,18

Y	GB 1 274 470 A (HALLORAN) 17 May 1972 (1972-05-17) page 4, line 81 - line 84; figures 19-23	8-10
A		1

Y	US 3 709 218 A (HALLORAN W) 9 January 1973 (1973-01-09) figure 2	18

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
12 December 2001	20/12/2001

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, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Ducreau, F

INTERNATIONAL SEARCH REPORT

In onal Application No
PCT/CH 01/00276

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 174 312 B1 (LAMINGER KARL) 16 January 2001 (2001-01-16) column 2, line 3 - line 38; figures 1-5 ---	1-4,7,9, 14
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INTERNATIONAL SEARCH REPORT

information on patent family members

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