Office de la Propriété Intellectuelle du Canada
Un organisme d'Industrie Canada

Canadian Intellectual Property Office
An agency of Industry Canada

CA 2416334 C 2008/10/28

(11)(21) 2 416 334

(12) BREVET CANADIEN
CANADIAN PATENT

(13) C

(86) Date de dépôt PCT/PCT Filing Date: 2000/06/09
(87) Date publication PCT/PCT Publication Date: 2001/12/13
(45) Date de délivrance/Issue Date: 2008/10/28
(85) Entrée phase nationale/National Entry: 2003/01/15
(86) N° demande PCT/PCT Application No.: CH 2000/000315
(87) N° publication PCT/PCT Publication No.: 2001/093768

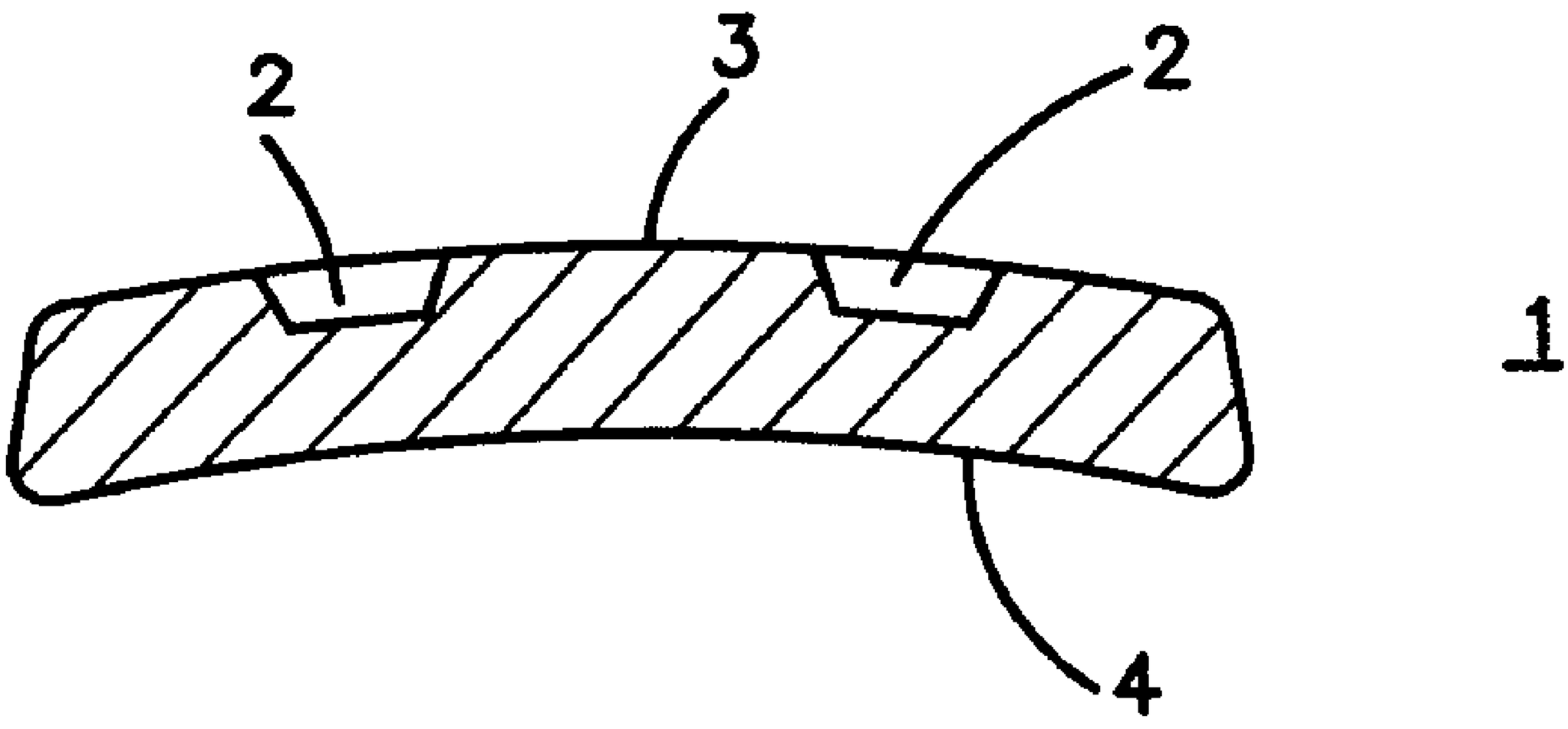
(51) Cl.Int./Int.Cl. *A61B 17/80* (2006.01),
A61B 17/72 (2006.01), *A61B 17/86* (2006.01),
A61B 17/17 (2006.01)

(72) Inventeurs/Inventors:
HEHLI, MARKUS, CH;
FREI, RETO, CH;
DUDA, GEORG, DE

(73) Propriétaire/Owner:
SYNTHES (U.S.A.), US

(74) Agent: OSLER, HOSKIN & HARCOURT LLP

(54) Titre : IMPLANT EN MATIERE PLASTIQUE POUR OSTEOSYNTHESE
(54) Title: OSTEOSYNTHESIS IMPLANT FROM A PLASTIC MATERIAL



(57) Abrégé/Abstract:
The invention relates to an osteosynthesis implant (1) that preferably consists of a bioresorbable plastic material. The inventive implant receives the longitudinal fixation elements (10) to be anchored in the bone, especially in the form of wires, nails, pins or screws. The openings destined to receive the fixation elements (10) do not completely extend through the implant (1) like in conventional bone plates or intramedullary nails but are degenerated to indents (2) in the surface of the implant (1) so that they may serve as a guide for the fixation elements (10) to be guided through the implant (1). The inventive implant (1) allows insertion of the fixation elements (10) in the bone t diverging angles and crossing one another, so that the fixation elements (10) extending intramedullarly or in the spongiosa are primarily prevented from migrating in a proximal or distal direction.

(12) NACH DEM VERTRAG ÜBER DIE INTERNATIONALE ZUSAMMENARBEIT AUF DEM GEBIET DES PATENTWESENS (PCT) VERÖFFENTLICHTE INTERNATIONALE ANMELDUNG

(19) Weltorganisation für geistiges Eigentum
Internationales Büro

(43) Internationales Veröffentlichungsdatum
13. Dezember 2001 (13.12.2001)

PCT

(10) Internationale Veröffentlichungsnummer
WO 01/93768 A1

(51) Internationale Patentklassifikation[7]: A61B 17/80, 17/72

(21) Internationales Aktenzeichen: PCT/CH00/00315

(22) Internationales Anmeldedatum: 9. Juni 2000 (09.06.2000)

(25) Einreichungssprache: Deutsch

(26) Veröffentlichungssprache: Deutsch

(71) Anmelder *(für alle Bestimmungsstaaten mit Ausnahme von CA, US)*: **SYNTHES AG CHUR** [CH/CH]; Grabenstrasse 15, CH-7002 Chur (CH).

(71) Anmelder *(nur für CA)*: **SYNTHES (U.S.A.)** [US/US]; 1690 Russell Road, P.O. Box 1766, Paoli, PA 19301-1222 (US).

(72) Erfinder; und

(75) Erfinder/Anmelder *(nur für US)*: **HEHLI, Markus** [CH/CH]; Junkerboden, CH-7276 Davos Frauenkirch (CH). **FREI, Reto** [CH/CH]; Tobelmühlestrasse 3, CH-7270 Davos Platz (CH). **DUDA, Georg** [DE/DE]; Verlängerte Georgenstrasse 41, D-12209 Berlin (DE).

(74) Anwalt: **LUSUARDI, Werther**; Dr. Lusuardi AG, Kreuzbühlstrasse 8, CH-8008 Zürich (CH).

(81) Bestimmungsstaaten *(national)*: CA, JP, US.

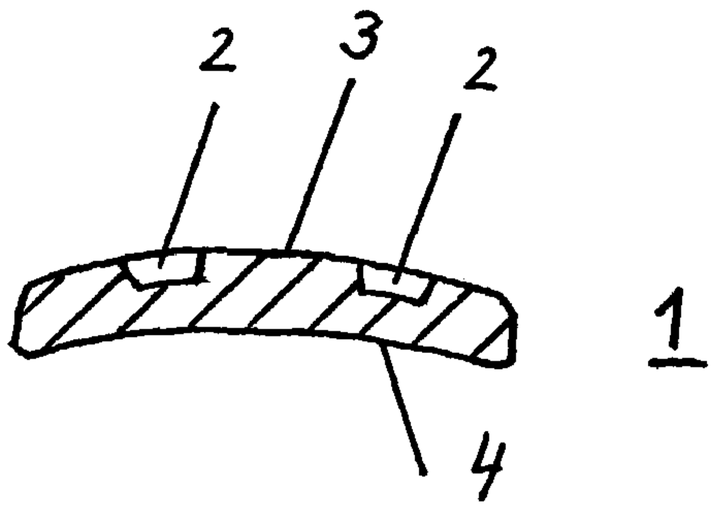
(84) Bestimmungsstaaten *(regional)*: europäisches Patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Veröffentlicht:
— *mit internationalem Recherchenbericht*

Zur Erklärung der Zweibuchstaben-Codes und der anderen Abkürzungen wird auf die Erklärungen ("Guidance Notes on Codes and Abbreviations") am Anfang jeder regulären Ausgabe der PCT-Gazette verwiesen.

(54) **Title:** OSTEOSYNTHESIS IMPLANT FROM A PLASTIC MATERIAL

(54) **Bezeichnung:** IMPLANTAT AUS KUNSTSTOFF FÜR DIE OSTEOSYNTHESE



(57) Abstract: The invention relates to an osteosynthesis implant (1) that preferably consists of a bioresorbable plastic material. The inventive implant receives the longitudinal fixation elements (10) to be anchored in the bone, especially in the form of wires, nails, pins or screws. The openings destined to receive the fixation elements (10) do not completely extend through the implant (1) like in conventional bone plates or intramedullary nails but are degenerated to indents (2) in the surface of the implant (1) so that they may serve as a guide for the fixation elements (10) to be guided through the implant (1). The inventive implant (1) allows insertion of the fixation elements (10) in the bone t diverging angles and crossing one another, so that the fixation elements (10) extending intramedullarly or in the spongiosa are primarily prevented from migrating in a proximal or distal direction.

(57) Zusammenfassung: Das vorzugsweise aus einem bioresorbierbaren Kunststoff bestehende Implantat (1) ist für die Osteosynthese bestimnt. Es dient der Aufnahme von in den Knochen zu verankernden longitudinalen Fixationselementen (10), insbesondere in Form von Drähten, Nägeln, Stiften oder Schrauben. Die zur Aufnahme der Fixationselemente (10) bestimmten Öffnungen durchdringen das Implantat (1) nicht vollständig wie bei konventionellen Knochenplatten oder Marknägeln, sondern sind zu Vertiefngen (2) in der Oberfläche des Implantats (1) degeneriert, so dass sie als Führungshilfe für die durch das Implantat (1) hindurchzuführenden Fixationselemente (10) dienen können. Das Implantat (1) erlaubt es, Fixationselemente (10) unter divergierenden Winkeln und sich gegenseitig kreuzend in den Knochen einzuführen, so dass primär ein Wandern der intramedullär oder in der Spongiosa verlaufenden Fixationselemente (10) sowohl nach proximal als auch nach distal verhindert wird.

WO 01/93768 A1

OSTEOSYNTHESIS IMPLANT FROM A PLASTIC MATERIAL

The invention relates to a plastic implant for osteosynthesis and to fixation devices using such plastic implants.

The implant can be formed as a bone plate or an intramedullary nail. In its plate-like embodiment it can act as an internal fixation means for osteosynthesis, for example, to the proximal humerus or other areas near the joint of tubular bones.

From US 5,476,467 BENOIST, a guiding template that has shafts in the manner of a fan is known for guiding Kirschner wires. The disadvantages of this arrangement result from the fact that the fixation elements (Kirschner wires) can only be guided parallel to one another through the guiding template. Due to the shaft structure of the template, it does not lie directly on the bone so that the length of the wires to be introduced is unnecessarily extended.

Here the invention aims to provide a remedy. The objective of the invention is to provide an osteosynthetic implant which has no penetrating holes to receive longitudinal fixation elements to be anchored in the bone, but rather only a number of indentations in its surface that serve as an aid to positioning and guiding to introduce the fixation elements, at diverging angles and crossing one another, first through the implant and then into the bone.

The implant permits the introduction of fixation elements, at diverging angles and crossing one another, into the bone so that primarily a migration of the fixation elements running intramedullarily or in the spongiosa is preventing proximally as well as distally.

The invention realizes the objective with an implant for osteosynthesis which serves to receive longitudinal fixation elements that may be in the form of wires, nails, pins, or screws to be anchored in bone. The implant has openings intended to receive the fixation elements. The openings do not penetrate the implant completely, but rather are indentations in the surface of the implant. The indentations serve as an aid in positioning and guiding the fixation elements through the implant -- at diverging angles and crossing one another, if desired. The invention also realizes the objective with a fixation device for bone surgery that includes an implant as described above and at least one fixation element for fastening the implant on or in a bone.

The indentations, preferably formed conically or cylindrically, in the upper side of the implant serve as centering elements for the penetrating holes of the guiding plate, for example, with Kirschner wires. The Kirschner wires have, on their front part, a drill bit whose length corresponds preferably to at least the thickness of the plate-like implant or to the diameter of the implant in the form of an intramedullary nail. Furthermore, the Kirschner wires have an outer thread that serves to secure against axial displacement in the implant so that a migration of the Kirschner wires in the implant is prevented. The Kirschner wires can be drilled into the implant at angles to its surface that can be freely chosen by the surgeon, preferably in directions skewed relative to one another in order to achieve an optimal fracture fixation. The position and angle of the Kirschner wires can thus be chosen according to the fracture to be cared for. Thus the advantage can be achieved that a minimally invasive operation technology can be applied, with implant material to be inserted minimally. The implant according to the invention is suitable in particular, due to the possibility of arranging the fixation elements in three dimensions, to osteosynthesis of bones that are osteoporotic or weakened by disease. The stability of the osteosynthesis is thus produced primarily by the bolts/wires and their crosswise

positioning in the bone. Due to the fact that the implant lies directly on the bone, the free length of the wires to be introduced is reduced to a minimum. Thereby an early load of the fracture site is possible, and thus an earlier utilization of the affected connective masses and, in the ideal case, quicker healing.

A preferred extension consists of the case wherein the implant consists of a bioresorbing or biodegradable plastic that is preferably chosen from the group of polylactates. The indentations are expediently disposed in a regular grid on the upper side of the implant.

In a development as a bone plate or as plate-like guiding bodies, the implant preferably has an approximately circular upper side with indentations disposed in concentric circles. The number of indentations is between 3 and 100, preferably between 7 and 40. Typically 10 indentations are provided. Expediently the indentations expand conically toward the upper side. The conical indentations advantageously have a conical angle ranging from 30° to 120°, preferably from 40° to 100°. The indentations have on the upper side a diameter ranging from 1.0 to 3.0 mm, preferably between 1.5 to 2.2 mm (typically 2 mm). The depth of the indentations is in the 0.6 to 1.5 mm range, preferably between 0.8 to 1.2 mm (typically 1 mm).

In the preferred embodiment as plate-like implant, its upper side is preferably formed convexly in order to achieve a better conformity to the surface of the bone. Its thickness is in the 2 to 6 mm range, preferably between 2.5 to 4.0 mm. The upper side expediently has a surface area ranging from 3 to 15 cm^2, preferably between 4 to 10 cm^2 (typically 4.5 cm^2).

In a preferred form of embodiment, the fixation element used as implant has a drill bit with a length from 4 to 10 mm, preferably from 5 to 8 mm. The drill bit should preferably correspond at least to the thickness of the implant.

The fixation element is expediently provided with an outer thread, preferably over a length from 30 to 80 mm. It preferably has no head at its back end and has a uniform diameter, seen over its entire length, preferably in the 1 to 6 mm range (typically in the 2 to 5 mm range).

The invention and extensions of the invention are explained in more detail in the following with the aid of the partially schematic representations of an embodiment example. Shown are:

Figure 1 a perspective representation of a plate-like implant formed as a guiding body,

Figure 2 a cross-section through the implant along the line II-II in Figure 1 in the area of two indentations,

Figure 3 a view of a fixation element in the form of a Kirschner wire, and

Figure 4 a view of a fractured humerus with an implant that is fastened to the bone with a plurality of Kirschner wires drilled therein.

The implant 1 represented in Figures 1 and 2 consists of a 3-mm-thick, arched plate of a biodegradable plastic, in particular a polylactate, suitable for implantation in the human body. The implant 1 has a convex upper side 3 and a concave lower side 4 intended for contact with the bone. In the upper side 3 a plurality of indentations 2 in the form of funnels expanding conically toward the upper side 3 are introduced.

The lower side 4 of the implant 1 is preferably made to conform to the bone surface to be applied in order to achieve as good and broad a bone contact surface as possible.

Represented in Figure 3, the fixation element 10 in the form of a customary Kirschner wire has no head at its back end 13 so that it has a uniform diameter over its entire length. At its front end the fixation element 10 has a drill bit 11 as well as an outer thread 12.

The implant 1 can be introduced through a minimal incision in the body, for example, in the area of the proximal humerus 20 (Figure 4) to which it can be fastened with the fixation means 10. In so doing, the additional use of bone cement is not ruled out. Since the plate-like implant 1 has sufficient indentations 2, they can serve to fasten bands to bone fragments of the humerus 20. In so doing, the three-dimensional, skewed arrangement of the fixation means 10 prevents their loosening so that on the whole a greatly improved stability of fixation results.

The embodiments of the invention in which an exclusive property or privilege is claimed are defined as follows:

1. A fixation device for bone surgery comprising:

a longitudinal fixation element in the form of a wire, nail, pin, or screw to be anchored in a bone; and

an implant having a top surface and a bottom surface, the top surface having at least one indentation that partially penetrates the implant, the indentation sized and shaped to serve as an aid in positioning and guiding the fixation element through the implant, wherein:

the fixation element is adapted to fasten the implant on or in the bone,

the fixation element has a front end and a back end, the back end having no head, and

the indentation is sized to receive the back end such that no portion of the back end protrudes above the top surface when the fixation element is driven through the implant and into the bone.

2. The fixation device according to claim 1, wherein the implant is formed as a plate with the bottom surface intended for contact with the bone.

3. The fixation device according to either claim 1 or 2, wherein the top surface of the implant has a convex cross section and the bottom surface has a concave cross section.

4. The fixation device according to any one of claims 1-3, wherein the implant has an oval or polygonal top surface.

5. The fixation device according to any one of claims 1-4, wherein the top surface has a surface area ranging from 3 square cm to 15 square cm.

6. The fixation device according to any one of claims 1-5, wherein the implant has a thickness ranging from 2 mm to 6 mm.

7. The fixation device according to any one of claims 1-6, wherein the implant is made from a plastic material.

8. The fixation device according to any one of claims 1-7, wherein the implant is made from a polylactate.

9. The fixation device according to any one of claims 1-8, wherein the implant is made from a bioresorbing material.

10. The fixation device according to any one of claims 1-9, wherein the implant is completely devoid of any holes that initially penetrate completely through the implant.

11. The fixation device according to any one of claims 1-10, further comprising a plurality of indentations disposed on the top surface wherein the implant has a circular configuration and the indentations are disposed in concentric circles.

12. The fixation device according to any one of claims 1-10, further comprising a plurality of indentations disposed in a regular grid on the top surface of the implant.

13. The fixation device according to any one of claims 1-12, wherein the implant includes between 3 and 100 indentations.

14. The fixation device according to any one of claims 1-13, wherein the at least one indentation has a diameter ranging from 1.0 mm to 3.0 mm.

15. The fixation device according to any one of claims 1-14, wherein the at least one indentation has a depth ranging from 0.6 mm to and 1.5 mm.

16. The fixation device according to any one of claims 1-15, wherein the at least one indentation extends conically toward the top surface.

17. The fixation device according to claim 16, wherein the at least one indentation has a conical angle ranging from 30 degrees to 120 degrees.

18. The fixation device according to any one of claims 1-17, wherein the fixation element has a uniform diameter over substantially the entire length of the fixation element.

19. The fixation device according to any one of claims 1-18, wherein the fixation element has a diameter ranging from 1 mm to 6 mm.

20. The fixation device according any one of claims 1-19, wherein the fixation element includes an outer thread having a length ranging from 30 mm to 80 mm.

21. The fixation device according to any one of claims 1-20, wherein the fixation element has a drill bit on one end, the bit sized to be received within the indentation and configured to penetrate through the remaining portion of the implant.

22. The fixation device according to claim 21, wherein the length of the drill bit corresponds to the thickness of the implant.

23. The fixation device according to any one of claims 1-22, wherein the length of the drill bit ranges from 4 mm to 10 mm.

24. The fixation device according to claim 1, wherein the implant is formed as an intermedullary nail.

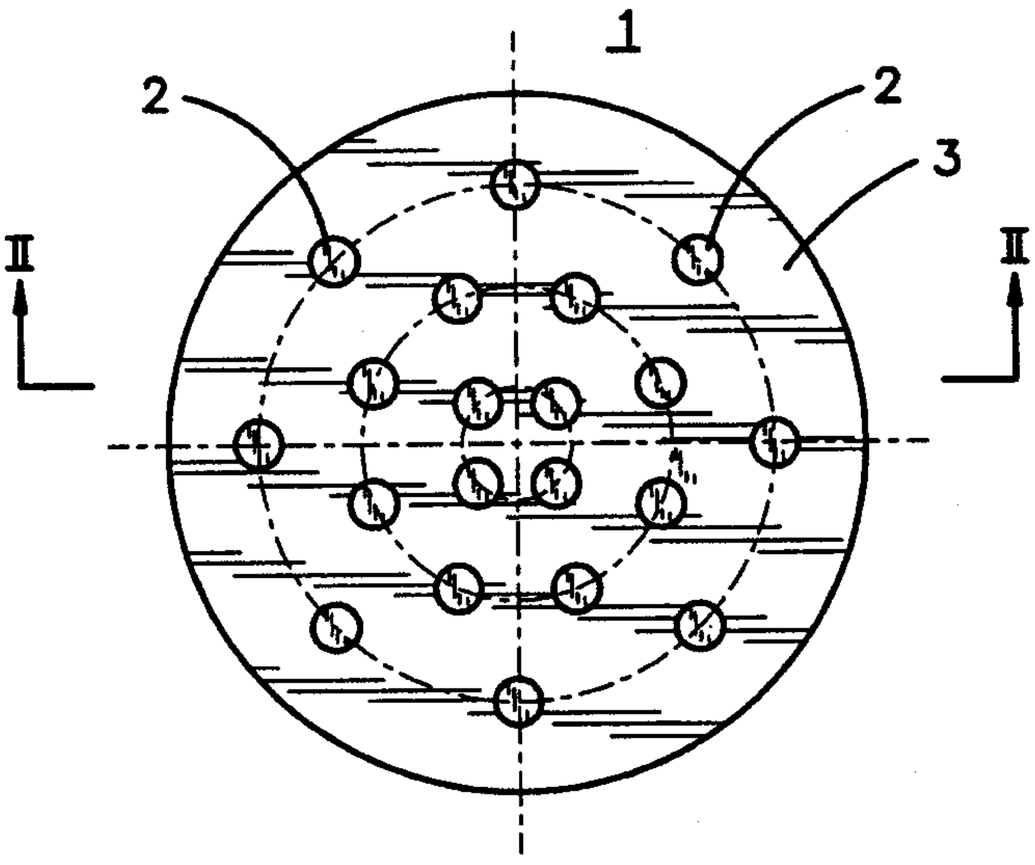


Fig.1

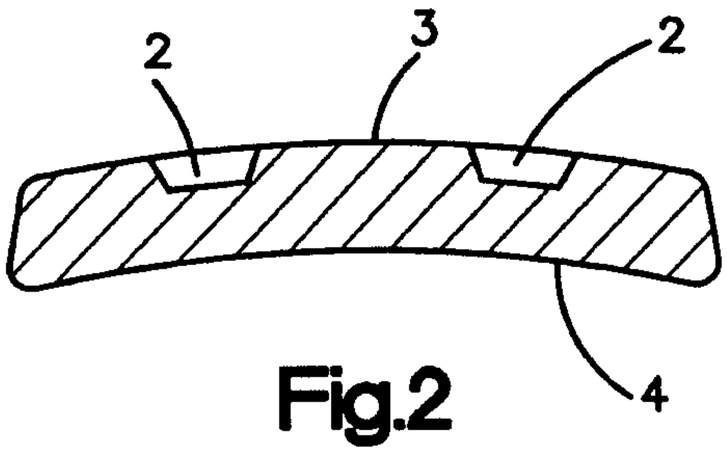


Fig.2

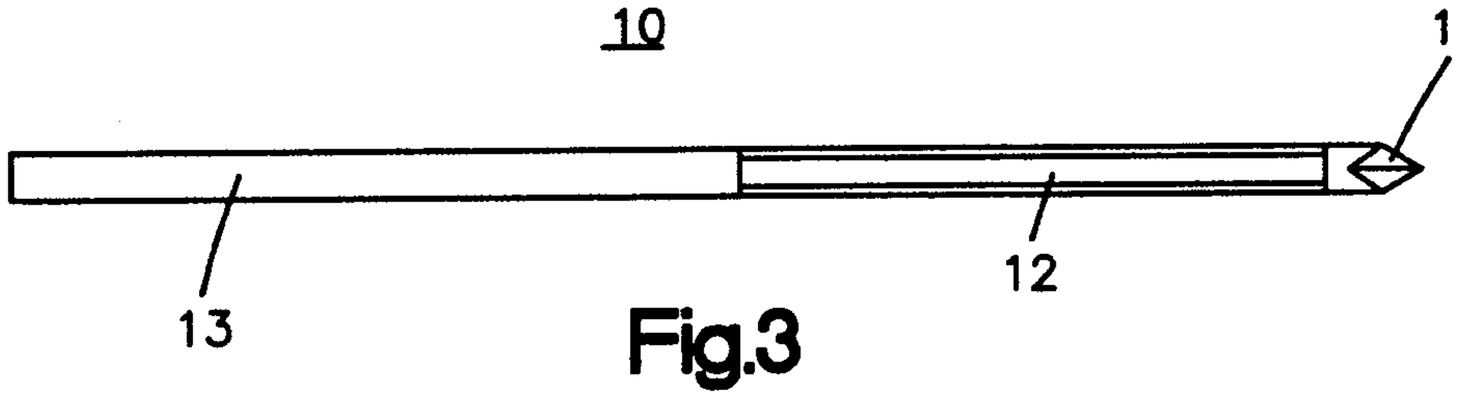


Fig.3

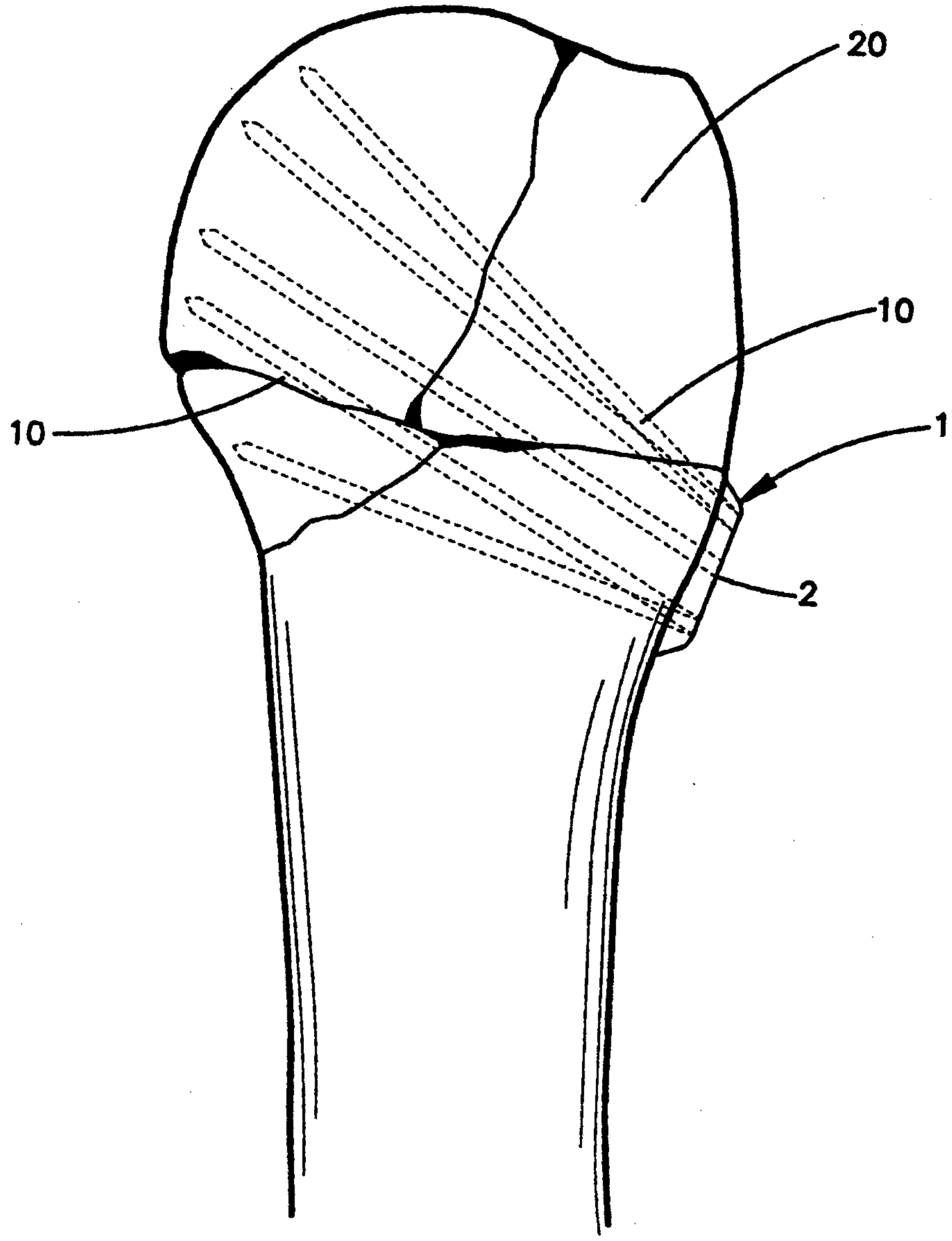
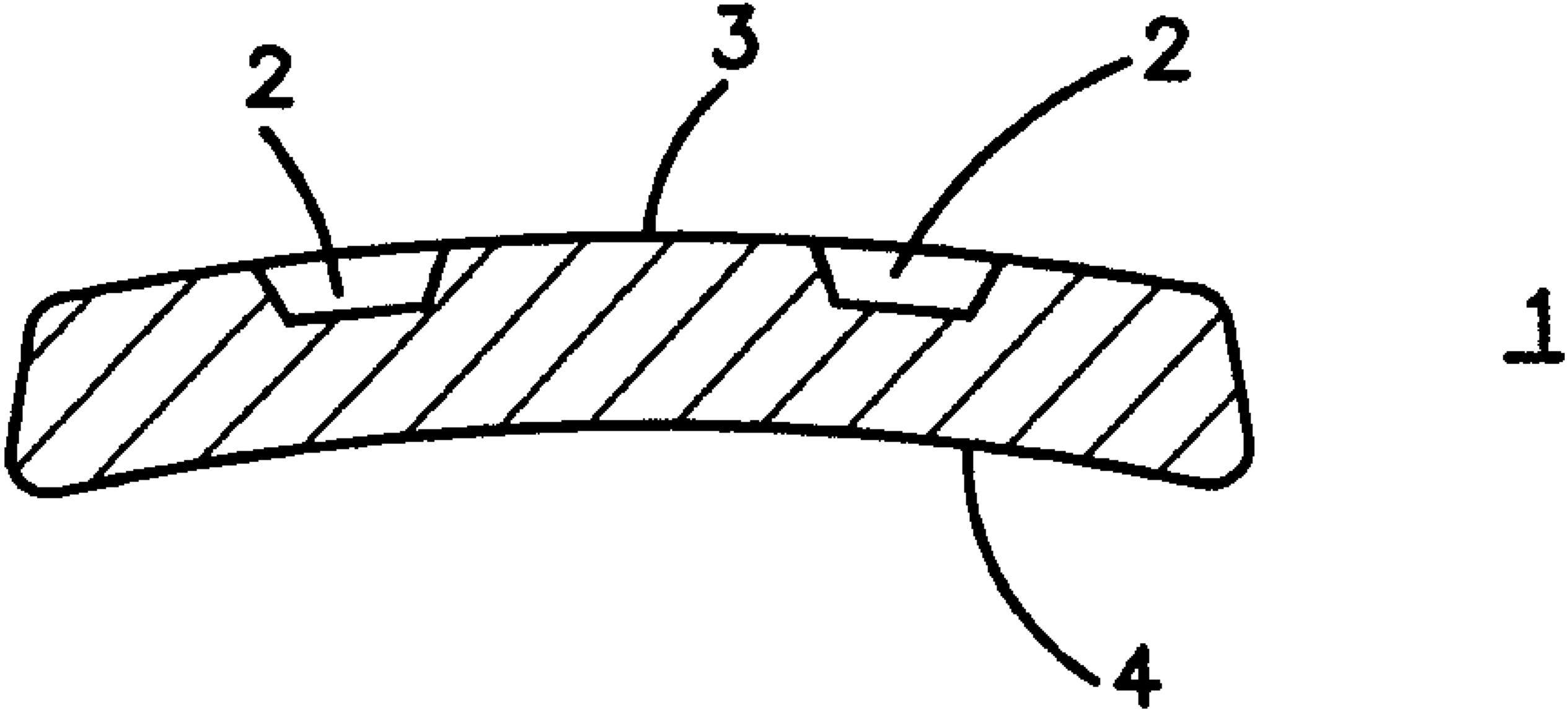


Fig.4


2
3
2
1
4