Form P.8

(To be lodged in duplicate)

REPUBLIC OF SOUTH AFRICA
PATENTS ACT, 1978

PUBLICATION PARTICULARS AND ABSTRACT
(Section 32(3)(a) - Regulations 22(1)(g) and 31)

REFERENCE : AP37971ZA00

OFFICIAL APPLICATION NO.	LODGING DATE	ACCEPTANCE DATE
(21) (01) 2004/7708	22/23 23 September 2004	43 17.05

INTERNATIONAL CLASSIFICATION

51 A61F

NOT FOR PUBLICATION

CLASSIFIED BY :

FULL NAME(S) OF APPLICANT(S)

71 MATHYS MEDIZINALTECHNIK AG

FULL NAME(S) OF INVENTOR(S)

72 STOLL, Thierry

EARLIEST PRIORITY CLAIMED	COUNTRY	NUMBER	DATE
NOTE : The country must be indicated by its International Abbreviation - see Schedule 4 of the Regulations	33 DE	31 202 05 016.5	32 30 March 2002

TITLE OF INVENTION

54 SURGICAL IMPLANT

57 ABSTRACT (NOT MORE THAN 150 WORDS)

NUMBER OF PAGES 22

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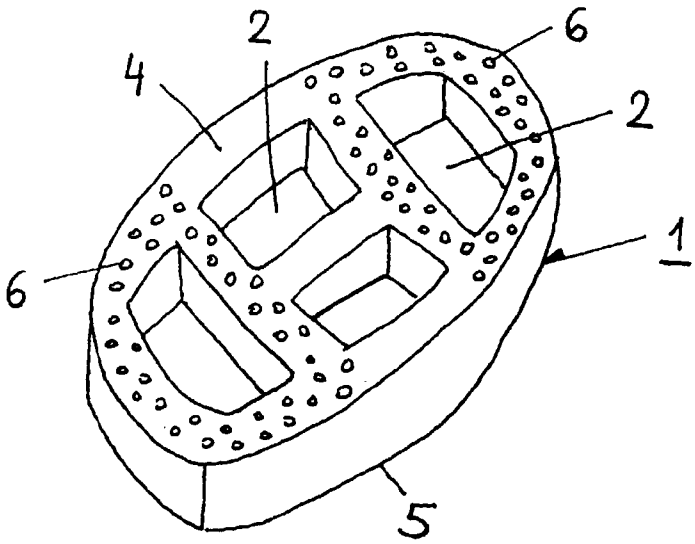
WO 03/082160 A1



(57) Abstract: The invention relates to a surgical implant (1) in the form of an intervertebral implant comprising several cavities (2) for receiving bone substitute material of completely synthetic origin. The advantages of the invention are that there is no longer the risk of infection with the choice of a bone substitute material of natural origin and that in addition, the physical characteristics of a synthetic bone substitute material are not exposed to fluctuations (porosity, pore size, resistance to mechanical pressure).

(57) Zusammenfassung: Das chirurgische Implantat (1) in Form eines Zwischenwirbelimplantates weist mehrere Kavitäten (2) zur Aufnahme von Knochenersatzmaterialien auf. Das Knochenersatzmaterial ist voll-synthetischen Ursprungs. Damit ist der Vorteil erzielbar, dass die Infektionsgefahr mit der Wahl eines Knochenersatzmaterials natürlichen Ursprungs nicht mehr besteht und dass mit der Wahl eines synthetischen Knochenersatzmaterials zusätzlich dessen physikalische Eigenschaften keinen Schwankungen ausgesetzt sind (Porosität, Porengrösse, mechanische Druckfestigkeit).

1928/PCT
14.1.2003

English translation of the specification of the International Patent Application No. PCT/CH03/00020 "Surgical implant" in the name of Mathys Medizinaltechnik AG

A SURGICAL IMPLANT.

The present invention relates to a surgical implant defined in the preamble of claim 1, in particular to an intervertebral implant, an intramedullary pin or an intrajoint prosthesis.

Intervertebral implants or other surgical implants comprising cavities designed to be traversed by bones in most instance will be filled during surgery with bones or bony materials in order to allow optimal bone growth through them (the so-called fusion of two vertebras in the case of two vertebras).

The state of the art includes the following procedures:

(a) filling with autologuous bone chips removed from the patient's iliac crest; this procedure frequently correlates with additional patient morbidity,

(b) filling the implants with autologuous bone removed from the adjacent vertebra as regards intervertebral implantations with anterior access,

(c) implant filling using a bony material; this material may be natural or entirely synthetic; if natural, there is a residual danger of infection both for an allogenic and a xenogenic material; moreover the physical properties of a bone-replacement material may fluctuate substantially when involving the various donor individuals and body removal sites.

The above state of the art is merely cited as background of the present invention and should not be construed having been actually published or being widely known at the time this application was filed.

The objective of the present invention is palliation. It aims to create an implant which when being implanted already contains an entirely synthetic bone replacement material even in the form of a composite product.

The above problem is solved by the present invention by an implant defined by the features of claim 1.

By resorting to an entirely synthetic bone replacement material, the invention allows averting all above cited drawbacks. As a result it also offers the advantage that

-- compared to natural bone replacement products -- the danger of disease communication is precludes because of the absence of pathogenic proteins, germs, viruses or bacteria.

Preferably the entirely synthetic bone replacement material is made of a calcium phosphate, typically a beta tricalcium phosphate. This feature offers the advantage of using a ceramic of which the stoichiometric composition substantially corresponds to that of the human bone. Furthermore the time of degradation of beta tricalciumphosphate is neither too short nor too long, and consequently cavities or implant residues are averted in the course of degradation.

Also the present invention offers further advantages to the patient. In particular, on account of simplified surgery,

(a) the time of surgery is substantially shortened,

(b) the time under anesthesia is less, and

(c) the patient suffers less loss of blood,

and, by selecting a synthetic bone replacement material, the properties of said material (porosity, pore size, mechanical compressive strength) are not subjected to fluctuations.

The bone replacement material may be in the form of a rigid element corresponding to the cavity geometry or alternatively in the form of a plastically deforming mass that can be introduced into said cavity.

In a particular embodiment mode, the implant cavity flares conically or cuneately toward the top or the bottom implant surface. As a result the entirely synthetic bone replacement material element inserted into said cavity is press-fitted into the cavity.

However the element also may be affixed by an appropriate fastener, preferably a screw or pin or a stop in the said cavity.

The implant of the invention may comprise a single cavity or several, typically in the latter case from two to eight mutually separate cavities.

Preferably the implant is designed as an intervertebral implant, though it also may be an intramedullary pin or in the form of another osteosynthetic implant or an intrajoint prosthesis.

In one embodiment of the present invention in the form of an intervertebral implant, same is preferably designed as a spacer unit comprising a top and a bottom

surface which are appropriate to rest against the end plates of two adjacent vertebras. In this design the cavity does link the spacer unit's top surface to its bottom surface. Appropriately the top surface and/ or the bottom surface of said spacer unit are structured in three dimensions, for instance being fluted, grooved, nubbed or in the form of other elevations or indentations.

Preferably the implant shall be transparent to x-rays, in particular consisting of a polymer such as PEEK. The advantage is that fusion may be assessed clinically.

In a further embodiment mode of the present invention, the bone replacement material is resorbing, preferably being hydroxyl apatite or tricalcium phosphate. This feature offers the advantage that because of material resorption, new bone tissue may grow back and need not force itself through the permanent material's pores.

The bone replacement material element advantageously exhibits a porosity of at least 25 %, typically at least 35 % , at least 50 % of the pores exhibiting a diameter preferably in the range of 200 to 500 µ.

In a further embodiment mode, the bone replacement material exhibits connections between the individual pores having diameters in the range of 10 to 500 µ, preferably 200 to 400 µ.

Illustratively the implant may be implemented in that a rigid element corresponding to the cavity geometry and made of an entirely synthetic bone replacement material is pressed into the implant cavity or affixed therein by appropriate fasteners. In another procedure, a moldable and preferably kneadable mass of an entirely synthetic bone replacement material preferably in granular form is introduced into the cavity where it shall be left in the uncured or cured state. This latter procedure also is appropriate for filling the cavities with bone replacement material during surgery.

The invention and its further embodiments are elucidated below in relation to the partly diagrammatic representation of an illustrative embodiment.

Fig. 1 is a perspective of the implant in its unfilled state,

Figs. 2 is a perspective of the implant in its filled state, and

Fig. 3 is a longitudinal section along line III-III through the implant of Fig. 2.

The implant shown in Figs. 1 through 3 is an intervertebral implant in the form of a spacer unit comprising four mutually separate cavities 2 that connect the top surface 4 to the bottom surface 5 of the spacer unit. The top surface 4 and the bottom

surface 5 are designed to rest against the end plates of two adjacent vertebras and are fitted in part with a 3-dimensional structure 6 in the form of nubs.

As shown by Fig. 3, the cavities 2 flare conically or cuneately or in the form of pyramidical frustra toward the surface 4 of the implant 1 and they contain, as shown in Fig. 2, geometrically corresponding elements 3 made of an entirely synthetic bone replacement material. The elements 3 rest in press-fitted manner in the cavities 2.

The spacer unit is made of PEEK whereas the elements 3 are made of porous hydroxyl apatite.

CLAIMS

1. A surgical implant (1) comprising at least one cavity (2) designed to receive bone replacement materials,,

characterized in that

the bone replacement material is entirely synthetic.

2. Implant as claimed in claim 1, characterized in that the bone replacement material (1) assumes the form of a rigid element (3) corresponding to the geometry of the cavity (2).

3. Implant (1) as claimed in claim 1, characterized in that the bone replacement material (1) is in the form of a plastically deforming mass that can be filled into the cavity (3).

4. Implant (1) as claimed in one of claims 1 through 3, characterized in that the cavity (2) flares conically or cuneately toward the top surface (4) or toward the bottom surface (5) of the implant (1)..

5. Implant (1) as claimed in either of claims 2 and 4, characterized in that the element (3) rests in the cavity (2) in firmly press-fitted manner.

6. Implant (1) as claimed in either of claims 2 and 4, characterized in that the element (3) is affixed by a fastener, preferably a screw or a pin, in the cavity (2).

7. Implant (1) as claimed in one of claims 1 through 6, characterized in that it comprises from two to eight mutually separated cavities (3).

8. Implant as claimed in one of claims 1 through 7, characterized in that it is designed as an intervertebral implant.

9. Implant (1) as claimed in claim 8, characterized in that it assumes the form of a spacer unit comprising a top surface (4) and a bottom surface (5) and designed to rest against the end plates of two adjacent vertebras.

10. Implant (1) as claimed in claim 9, characterized in that the top surface (4) is linked through the cavity (3) to the bottom surface (5).

11. Implant (1) as claimed in either of claims 9 and 10, characterized in that the top surface (4) and/or the bottom surface (5) are fitted with a three-dimensional structure (6),

12. Implant (1) as claimed in one of claims 1 through 11, characterized in that it is made of an x-ray transparent material, preferably a polymer.

13. Implant (1) as claimed in claim 12, characterized in that the polymer is PEEK.

14. Implant as claimed in one of claims 1 through 13, characterized in that the element (3) consists of a bone replacement material comprising at least in part a bioresorbing material preferably hydroxyl apatite or tricalcium phosphate.

15. Implant (1) as claimed in one of claims 1 through 14, characterized in that the element (3) is made of a bone replacement material having a porosity of at least 25 %, preferably at least 35 %.

16. Implant (1) as claimed in one of claims 1 through 14, characterized in that the element (3) is made of a bone replacement material of which at least 50 % of the pores have a diameter in the range of 200 to 500 µ.

17. Implant (1) as claimed in one of claims 1 through 16, characterized in that the element (3) is made of a bone replacement material exhibiting a connection

between the individual pores that have a diameter in the range of 10 to 500 µ, preferably 200 to 400 µ.

18. A method for manufacturing an implant as claimed in one of claims 1 through 17,

characterized in that

a rigid element (3) made of an entirely synthetic bone replacement material and corresponding to the geometry of the cavity (2) is pressed into the implant cavity (2) or is affixed in it by fasteners.

19. Method of manufacturing an implant as claimed in one of claims 1 through 17, characterized in that a moldable and preferably kneadable entirely synthetic mass of bone replacement material preferably in granular form is introduced into the cavity (2).