(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
1 May 2003 (01.05.2003)

PCT

(10) International Publication Number
WO 03/034951 A1

(51) International Patent Classification: A61F 2/30

(21) International Application Number: PCT/GB02/04699

(22) International Filing Date: 17 October 2002 (17.10.2002)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
0125298.0 20 October 2001 (20.10.2001) GB
0127860.5 21 November 2001 (21.11.2001) GB

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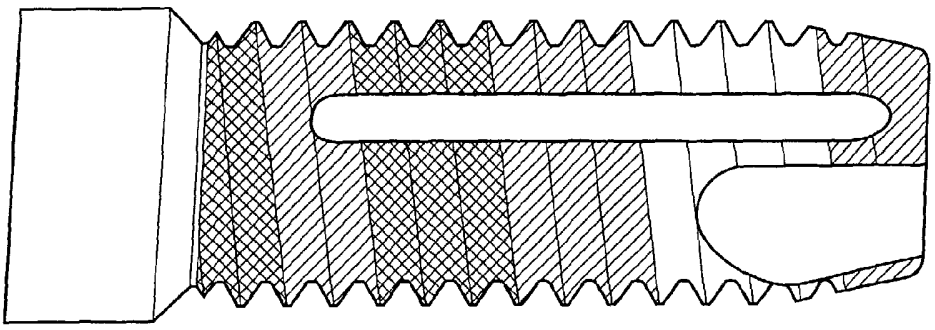
(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZM, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*
— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

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.

(54) Title: IMPLANT AND METHOD OF MANUFACTURING THEREOF



(57) Abstract: The present invention is directed to an implant for use in connection with a bone or tissue structure, comprising surface deformations characterised in that the deformations comprise a plastically controlled pattern of deformations. There is also described a method of manufacturing such an implant.

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IMPLANT AND METHOD OF MANUFACTURING THEREOF

The present invention is directed to a novel implant and to a novel method of treatment related thereto.

More particularly, the present invention relates to the creation of a surface pattern on an implant which is suitable for insertion in bone or tissue structure. The invention relates to the implant which comprises such a surface pattern and to a method for application of the pattern to an implant.

The invention relates to implant devices meant to be implanted into the skeletal system by direct bone apposition to the device surface and essentially to their surface preparation in terms of pattern, i.e. structure, and favourable chemical properties, which can enhance the bonding between device and bone.

The traditional methods for fixation of an implant device to the skeletal system fall into several categories. These include mechanical fixation to bone using nails or screws, impaction of the device into hard tissue, and the use of bone cement, e.g. polymethylmethacrylate, as a grouting agent between an endoprosthesis and bone. New alternative methods comprise fixation by bone ingrowth into porous surfaced devices, by chemical bonding between bone and surface-active ceramic devices, e.g. having a hydroxyapatite coating, and by direct bone apposition to the surface of a titanium-base metal device. As to the latter form of fixation, Brånemark has coined the term "osseointegration" and defines it as direct structural and functional connection between ordered, living bone and the surface of a load-carrying implant.

The structural and functional connection between bone and an implant device can be achieved by fixation rationales of; (a) macrointerlock, e.g. devices with large threads or grooves cut into the surface or with macroporous sintered bead coatings; and (b) microinterlock, e.g. devices with special surface textures. The dental implant market today holds a large variety of methods to create surface textures, i.e. surface

modifications of the original machined titanium surface, for the bone to implant interface, which is shown by the following examples; machining by turning or milling (Nobel Biocare), blasting (Astra Tech), chemical etching (3i) in combination of blasting (Straumann), plasma spraying (Straumann) and anodising (Nobel Biocare, Hati). The anchorage of such devices to bone can be assessed by mechanical measurements such as shear tests (push-out and release torque) or tensile tests (tear-off) and by measurements of the bone-device contact area in histological preparations. Many experiments indicate that these properties are connected with the surface texture of the device, in particular with its roughness (see review by Brunski, Clinical Materials, Vol. 10, 1992, pp. 153-201).

These surface modification methods all include expensive and complex manufacturing processes. At the launches of these modified surfaces no long term clinical effect was known and in some cases it is still not known. Yet, in other cases the long term clinical effect is showing a continuing decrease in success rate, which is in contradiction to a machined surface.

Fracture healing processes are cell mediated and the same mechanisms are active in, for example, osseointegration of a titanium-based implant device. Thus, surface characteristics can influence the needed cellular activity.

Considering surface texture, *in vitro* experiments with human osteoblast-like cells indicate that surface roughness alters cell proliferation, differentiation, and matrix mass production. Further, it is expected that roughness plays a role in determining phenotypic expression of cells *in vivo*, i.e. the observable characteristics of cells and tissue differ from those of its genotype (Boyan et al., Biomaterials, Vol. 17, 1996, pp.137-146).

Thus, rough surfaces are applied to implant devices in the belief that this would aid cell adhesion to the implant. But the question of the reaction of cells to surface roughness is an intriguing one. There are problems at the simple level of defining

roughness and there are difficulties in the quantification of this roughness. No work has yet discovered convincing rules for topography; e.g. roughness height or roughness spacing to which a bone cell will rapidly and efficiently react (see review by Curtis and Wilkinson, Biomaterials, Vol. 18, 1997, pp. 1573-1583) except that the surface structure does influence the cell adhesion as shown by references above.

The vast difference in morphology of the existing implant surfaces suggests that the implant surface texture is of little importance within a very large range of surface roughness values (Ra), as has been shown by Wennerberg et al, (where Ra is an extremely coarse term in defining a surface). It is also recognised that there are no methods available for producing well defined surfaces, or for screenings such outfaces, even though initial have been made using lasers, Gold et al, but where the method in itself has set extensive limitations.

The question of whether the bone cells are reacting to the topography directly and/or to a patterned substratum chemistry formed on the topography, must be raised in view of Brånemark's definition of osseointegration. The wording "functional connection" suggests to also consider factors beyond surface texture, in particular, surface area and surface chemistry, which truly determine the size of bonding forces between the living bone and the load-carrying device. These surface properties of the metallic device clearly depend on the mechanical and chemical preparation techniques used, which, for example, are out-lined in European Patent Application No. 1,023,910 and where an hypothesis about hydrophilic and hydrophobic surfaces is presented. This aspect is also clear in the light of the packaging and cleanliness of the Astra Tech implants.

Customary surface preparations, such as etching and anodising, of titanium and its alloys for laboratory and clinical work, inevitably leave some contamination consisting essentially of carbon compounds and small or trace amounts of N, Ca, S, P, Si. These contaminations are especially disadvantageous in that they can accumulate in the outermost volume of the surface oxide.

When inserted, an implant device will interact with tissue and its surface properties will have an enormous effect on the rate, the extent, and the mechanism of adsorption of tissue fluid components and in particular of proteins (see review by Brash and Horbett, in Proteins at Interfaces II, Horbett and Brash eds., ACS Symp. 602, Amer. Chem. Soc. Washington 1995, pp. 1-23).

Thus, even if pre-clinical data of surface modifications, such as a rougher surface and a modified chemistry, show a positive effect on factors involved in the formation of bone tissue there is however no evidence for a clinical effect of a modified surface on the functional success of an implant, including all the methods used today to modify an implant surface from the original machined surface. On the contrary, a typical success rate of a functional dental implant is for most indications and major implant systems reaching over 95% and the failures are mainly a question of patient selection, performance of the clinician including overloading of the prosthesis, Glauser et al.

Some manufactures claim that their surface shorten the healing time. Prof Brånemark recently developed the "Same-day-teeth" concept, where the original machined surface is carrying a functional load within hours after placement and where no chemical bonding is providing any kind of functional contribution at this early stage. This indicates that the surface contribution for shortened healing time should not be related to the surface in the proportion proposed by the manufacturers. Another example is the approval and use of machined Brånemark System implants for immediate function.

In this context the "gold standard" or reference to an implant surface structure, must still be the original machined surface from Brånemark System due to its long term clinical success and that no modified surface has yet shown any clinical improvement in terms of success and increased indications.

It follows from these considerations that the problems of surface modifications in terms of production of implant devices, in order to obtain beneficial interactions between the surfaces of the implant devices and the bone, have not been addressed properly and that there is still a need for implant devices which exhibit good osseointegration based on results showing long term clinical success and at the same time incorporating a modified rougher structure without jeopardising the long term clinical results when implanted into bone.

International Patent Application No. WO97/13477 describes a holder of a biocompatible material for implantation in bone tissue.

The holder is provided with retention elements (6) which impart good initial anchoring and stability to the holder, and are specifically designed to enable the holder to be mounted in a prepared hole without the holder being screwed. The specific retention elements described are grooves, although it is described that other types of retention element could include an embossed surface. However these are not described as a controlled embossment and therefore it can be anticipated that, similar to the blasting process mentioned in WO '477, the embossment of the prior art would be of an uncontrolled, irregular and/or scattered arrangement.

It can be seen that the grooves are the same size as conventional thread profiles, i.e. are macrointerlocking, therefore retention elements if created by an embossing process, would be expected to have similar orders of magnitude, that is several tenths of millimetres or more.

Considerable resources are being expended on research and development aimed at producing implants which can improve the process of incorporation of the implant in bone and tissue structures, for example in the jawbone.

The present invention is based on the recognition that the implant surface structure,

within a certain range of roughness, has a decisive influence for improving implantation and incorporation processes. In the prior art there is proposed a large number of vastly different surfaces in terms of production, morphology and chemistry but there is no good collective grasp of the actual creation of well defined surfaces especially in relation to positive results on the long term clinical effect. This is at least in part due to the attitude of making conclusions from pre-clinical data, on the long term predictability of the implant performance and the lack of appropriate and cost effective manufacturing methods. Thus, one aim of the present invention is primarily to overcome or mitigate these problems.

Thus according to a first aspect of the invention we provide an implant for use in connection with a bone or tissue structure, comprising surface deformations characterised in that the deformations comprise a plastically controlled pattern of deformations.

By the term plastically controlled we mean the permanent deformation of a solid, without fracture, by the temporary application of force.

The plastically controlled deformations, hereinafter referred to simply as, the deformations, described in the implant of the invention may preferentially be in a form which appears to be an embankment.

Thus, each of the deformations or embankments may form a substantially circular surround or a longitudinal surround, or a surround of a variety of shapes and sizes. In particular, each of the ridges or embankments may substantially encircle a hollow in the surface of the implant.

Alternatively, each of the ridges or embankments may form a border to one or more grooves in the surface of the implant surface. In a further embodiment, the surface may comprise a plurality of ridge bordered grooves and a plurality of substantially circular ridges.

In a yet further alternative embodiment, the substantially circular ridge or embankment may be in the form of a dome. Any combination of substantially circular ridges, ridged grooves and domes may be utilised in the surface of the implant of the invention.

In the implant of the invention the pattern may have a function of mainly mechanical interlocking of the structure. The intrusion of the pattern may have a roughness height (Rt) of from 0.1 to 100 μm, preferably of from 0.1 to 10 μm. When, for example, the implant is a dental implant, then it is preferred that the pattern will waive an R_t value of from 0.1 to 10μm. However, when, for example, the implant is an orthopaedic implant then the deformations have a mixture of R_t values, e.g. deformations with a R_t value of from 0.1 to 100μm, which may be especially suited to mechanical interlocking of the implant, and deformations with an R_t value of from 0.1 to 10μm, which may be more suited to the growth, and may, e.g., have a bone growth factor or cellular structures incorporated into the deformation.

The protrusions and ridges have a height H' from the surface of the implant and the intrusions and grooves a depth of H'' with reference from the original implant surface. Such that: $R_t = H' + H''$. D is the inner diameter at its widest point or width of the pits or grooves.

The altered part of the pattern, intrusions and protrusions, can cover from 5% of the total projected surface area of the implant surface to 100%, but where an coverage of 40-90% or values preferably being towards the upper limit of the range is the most desirable. If high coverage the machined area can function as a more shallow groove during insertion with the functions of a groove but after a healing process it will still behave as the original machined surface.

The intrusion of the pattern may have a cross section (A) of from 0.01μm ^{2} to 10,000μm^2 preferably, from 0.01μm^2 to 100μm2.

The volume per unit area of the deformations may be estimated by multiplying the coverage per unit times Rt. Thus the volume V may be from 5 x 10^{-3} to 100 $\mu m^3/\mu m^2$, preferably from 4 x 10^{-2} to 5 $\mu m^3/\mu m^2$. For a dental implant, 5 x 10^{-3} $\mu m^3/\mu m^2$ is equivalent of a total volume of approximately 1 x 10^{-6} cm^3.

The surface of the implant may, optionally prior to embossing, be subject to a surface treatment which may be selected from one or more of anodising, etching, HA, PVD, CVD, additional blasting, passivation, thread rolling and mixes thereof.

The implant of the invention may have a variety of utilities. Thus the implant may be an orthopaedic or a spinal implant. Alternatively, and preferentially, the implant may be a dental implant; for example, it may consist of a screw implant for application in the jawbone.

The macrogeometry of the implant may vary according to, *inter alia*, the nature of the implant. The most preferred macrogeometry is that described in our co-pending UK application 0123804.7. This macrogeometry is especially preferred when the implant is a dental implant.

In connection with application of implants in bone and tissue structures, it is important for the pattern to be able to have a structure which eliminates or to a large extent counteracts mechanical stress concentrations in implants inserted in the bone or equivalent, cf. the built-in stresses which can occur in connection with etched surfaces. Further demands and requirements are that the process of incorporation of the implant in the bone or tissue can be improved. The invention solves this problem too.

The contamination in the outermost volume of the surface oxide is commonly present following most customary surface preparations, such as etching and anodising, of

titanium and its alloys for laboratory and clinical work. The invention solves this problem too.

In connection with the implant, it is possible in some cases (i. e. in one embodiment) to use bonegrowth-initiating and bone-growth-stimulating agents and substances, for example those belonging to the superfamily TGF-P. It is important to be able to apply the agent or the substance to or on the implant in a technically simple and economically advantageous manner. The invention also solves this problem and proposes, through the possibility to create well defined novel pattern structures suitable as depot functions which can be used in long-term and optimal bone growth situations and incorporation functions for the implant in the bone or equivalent.

When producing patterns it is important to be able to offer technically reliable and also economically advantageous methods. The present invention also proposes methods satisfying the conditions for production of patterns of the type in question. The method is based on the recognition that the metal forming technique used, such as the embossing, can be of decisive importance and one additional problem that the invention solves is the blunting of cutting edges due to the surface treatments used of today. The roughness, in other terms than Rt, may vary depending upon, *inter alia*, the nature of the implant. The roughness may be in the range of from 0.01 to 100μm. Alternatively, for example, for an orthopaedic implant the roughness may be in the range of from 0.01 to 10μm and 10 to 100μm.

The feature which can principally be regarded as characterising a pattern according to the invention is that it is created by metal deformation after machining with the forming of intrusion patterns which gives the surface an increase in surface area, and in that the intrusions are neighbouring protrusions.

In a preferred embodiment, the controlled pattern of deformations may be created by embossing the surface and an appropriate way to do that is by rolling where the

negative of the pattern is created on the rolling surface by the way of for example laser or etching.

In another preferred embodiment the embossed pattern may only partially covering the surface thus the original surface may still exists on some areas. Most preferably the density of the deformations is greater around the threaded portion of the implant of the invention, that is, the screw threaded portion.

According to a further aspect of the invention we provide a method of manufacturing an implant as hereinbefore described. A variety of methods may be used, including, *inter alia*, embossing.

In a particularly preferred method of the invention the method incorporates a second treatment in the form of rolling. This aspect of the method of the invention is especially advantageous in that it can create undercuts in the ridges or embankments.

The position of such undercut regions is novel *per se* and is especially useful when the implant is an orthopaedic implant. Thus according to a further new aspect of the invention we provide an implant.

For use in connection with a bone or tissue structure, comprising surface deformations characterised in that the surface deformations comprise a plastically controlled pattern of deformations and at least a portion of the deformations comprise ridges which are provided with an undercut region.

In terms of embossing, the pattern can have many different geometries and it is mainly the technique to transform the pattern to the rolling device that sets the limit. In general the pattern may comprise of pits, peaks, grooves, ridges and network of grooves or ridges, or mixes thereof. One possibility in the method of the invention is to take a picture of an existing pattern and than by transformation by a computer

expose the pattern on the rolling surface, or just create the whole pattern in the computer prior to exposure.

The pattern can be established before an additional surface treatment as an undulating or uneven surface present on the implant from the start and having a high roughness value (for example 0.01 to 10μm for the microinterlocking or 10 to 100μm for the macrointerlocking) for the purpose of increasing the surface volume after surface treatment.

In addition to a first pattern forming, a second treatment of rolling on the surface can be performed where a previous pattern is compressed to form undercuts.

In one embodiment, the pattern may also be arranged with a mouth arrangement towards the bone or tissue structure, permitting increased release of bone growth substances as is described in the prior art of International Patent Application No. WO 00/.7-2778.

The pattern can vary in geometry and size along the implant body to adjust for differences in bone tissue structure and in release of bone growth substances.

The pattern can have preferred values in respect of the surface area sizes of the network, the total channel or volume in the pattern, the surface roughness is as hereinbefore described.

An implant according to the invention can principally be regarded as being characterised by the fact that *inter alia* a pattern, or each pattern, present on the implant is created by metal deformation after machining by the formation of intrusion patterns. Furthermore, the intrusions, in a controlled manner, are neighbouring protrusions, which gives the surface an increase in surface area.

In a preferred embodiment, the implant is subjected to embossing to create the pattern and an appropriate way to do that is by rolling where the pattern is created on the rolling surface by the way of for example laser or etching.

In one embodiment, the implant can consist of a screw implant for application in bone, for example dentine. In looking at the pattern and the function thereof during insertion of an implant, the pattern can be created in a way that it performs micro cutting of bone chip for enhance bone formation to a large or minor extent.

In a further embodiment, the implant can incorporate a pattern that can form a depot for applied bone-growth-initiating or bone-growth-stimulating agent or substance. The agent or the substance can migrate from the depot to the bone or tissue structure by means of concentration diffusion, which can be optimised by means of the deep intrusion.

In a further alternative embodiment, the implant as hereinbefore described may be provided with a pattern which is suitable to be used as a depot and that the depot is used for applied bone-growth-initiating or bone growth-stimulating agent or substance.

In a preferred embodiment, the implant and its pattern consists of or comprises a natural titanium oxide on the titanium bulk material or alloys thereof.

In a further embodiment, the implant can be, but shall not be limited to a dental implant, or an orthopaedic implant, a spinal implant. One characteristic feature is that the forming of a pattern according to the invention will not necessarily decrease the cutting efficiency by blunting, thus the cutting edges on the above implants can remain sharp.

In a few cases it might be advantageous to use the embossed surface according to the invention as pre-treatment or roughening treatment prior to etch, anodising or other existing method.

The surface chemistry of the implant can be monitored, and/or modified by doping the pattern, through the procedure of embossing.

A method according to the invention starts out from embossing an implant surface. The method can principally be characterised by the fact that a pattern is formed on a rolling tool and that this tool then is used to emboss the surface of an implant. In addition the embossing would normally take place in the same machine set up as for all the other metal forming or cutting procedures on that individual implant leading to major cost savings.

A further characteristic feature of the method is that contamination of the implant by the embossing may be minimised or avoided by either treating the tool surface chemically or by the way of a thin film hard coating which also can have the effect of decreasing the friction coefficient of the tool. Yet another method is to chemically remove the contamination from the embossing at the implant surface by for example an etching procedure.

In a preferred embodiment of the method, is that the pressure of the embossing can vary in order to create different patterns or depths of patterns as well as being zero and not producing any pattern on chosen areas of the implant where thus the original machined surface will be present.

By means of what has been proposed above, an improved implantation is obtained through a well defined surface pattern and micro bone chip cutting for enhance bone formation together with a novel manufacturing process, using the proposed embossing technique, the invention goes against the ideas which have hitherto been accepted in the technical field, thus opening up new avenues within the art and

making it possible to relay on a clinically long term proven machined surface but with the benefits of a modified surface and the avoidance of artefacts like blunting of cutting edges and chemical contamination.

The concentration diffusion in conjunction with the use of bone-growth-initiating and bone-growth stimulating substances can be considerably facilitated by the proposed intrusions of the pattern.

The implant can be made commercially available with a finished pattern having the stated properties, and the novel method meets by far the conditions for economically advantageous pattern production and implant production compared to any other surface modification present on the implant systems today.

The chemical state of the implants can be carefully monitored and altered for additional improvements in implantation and enhanced bone formation during phases in the healing process.

The invention will now be described by way of example only and with reference to the accompanying drawings, in which Figure 1 shows, an illustrative embodiment of two patterns produced on an implant body;
Figure 2 shows a side view of implants with different patterns; and
Figure 3 shows a side view of equipment for embossing the implant

In Figure 1a-b, reference number (1) indicates parts of an implant body. As will be described below, the implant body has after machining been treated by rolling, resulting in an embossed pattern (2) having been formed on its outer surface with an intrusion (3) and surrounding ridges (4). Between the protrusions the original machined surface (5) can be present with the characteristic machined grooves (5a). The pattern can be built up by discrete and multiple pits like in Figure 1 or by networks (6) of ridges (7) and grooves (8). The protrusion (4) can in a second rolling procedure be dented in order to form undercuts, not shown, over the intrusion 3 or

the machined surface 5. Undercuts or not the pattern can provide the function of micro cutting edges were small chips of bone is cut by the protrusions and collected in and between the grooves or pits where the small bone chips act as bone initiation spots.

The pattern 2 can have a considerable volume and it is dependent on the coverage and cross section A Rt x D of the chosen pattern. A total volume V for the channel network according to Figure 1a-b can be chosen in a range as hereinbefore described.

To achieve the desired pattern properties, one starts, for example, from a mechanically worked surface which can be turned, milled, polished or rolled. Cast and pressed implants or implant parts can also be used as well as cleaned or lubricant covered implants.

The implant can thus consist of or comprise titanium material, which means that the pattern 2 consists of deformed titanium or alloys thereof and in some preferred embodiments the pattern is covered wholly Fig 2b or partially Fig 2a by a second surface treatment such as anodising, etching, HA, PVD, CVD, additional blasting, passivation, and mixes thereof. The screw or the thread of the implant is indicated in Figure 2, but reference may also be made to the already disclosed prior art and to known implants. The corresponding thread in the bone, for example jawbone, is not shown either, but here again reference may be made to the prior art.

It will be appreciated that such a pattern can constitute a depot for substance which stimulates and/or initiates bone growth, and this has been symbolised by. A substance thus introduced into the intrusions can, by means of concentration diffusion, migrate out into the bone or tissue structure. Correspondingly, bone or tissue organisms can pass into the system in conjunction with the said diffusion. It will be appreciated that the intrusions can be given different sizes and can create conditions for bone growth with a specific penetration function in the intrusion

arrangement, contributing to the degree of incorporation of the implant in the structure.

The way in which the desired patterns are produced is described in more detail below. Examples are also given of how the process parameters affect various properties of the patterns.

The implant or the implant part is subjected to a pressure on the surface, which is high enough to exceed the elastic properties of the implant surface material and consequently introduce a lasting deformation in various forms, preferably by embossing. The embossing normally takes place as a step in the ordinary machining stage and would not need a second set up or remounting of the implant. The embossing is performed by rolling a die over the surface, where the die can be incorporated into the machine by conventional methods. The difference with conventional rolling techniques is that rolling according to the invention is not used to form the whole threads but are mainly embossing a pattern into the implant surface, which than needs considerably lower forces than thread forming by rolling. The tool, i.e. rolling die, has a the geometry of a thread profile or parts of it for the optimum embossing properties. With regards to the forming of the negative pattern it is appropriate to refer to existing methods of laser and etching the embossing tool.

After the formation of the pattern the manufacturing follows conventional procedures including cleaning in a suitable manner, for example by ultrasound cleaning in organic solvents in order to remove impurities from previous production stages.

The invention is not limited to the embodiment described above by way of example, but can be modified within the scope of the attached patent claims and the inventive concept.

As mentioned in the introduction, it should be understood that the present invention only has been illustrated by means of dental implants and that the method according

to the invention of course is applicable to all kinds of bone implants having a surface to be implanted made of titanium or titanium alloys or other implantable materials or alloys.

CLAIMS

1. An implant for use in connection with a bone or tissue structure, comprising surface deformations characterised in that the deformations comprise a plastically controlled pattern of deformations.

2. An implant according to claim 1 characterised in that the implant is provided with a screw thread.

3. An implant according to claim 2 characterised in that the density of deformations is greater on the threaded position than on the remainder of the implant.

4. An implant according to claim 1 characterised in that the a substantial portion of the deformations are circular.

5. An implant according to claim 1 characterised in that a substantial portion of the deformations comprise longitudinal grooves bordered by ridges.

6. An implant according to claim 1 characterised in that the controlled pattern of ridge domes.

7. An implant according to claim 6 characterised in that the implant deformations is a plurality of surfaces comprises a combination of domes, and/or substantially circular deformations.

8. An implant according to claim 6 characterised in that the implant comprises a plurality of ridge bordered grooves and a plurality of domes.

9. An implant according to claim 1 characterised in that the intrusion of the pattern has a height (H) of from 0.1 to 10μm.

10. An implant according to claim 9 characterised in that the intrusion of the pattern is controlled and has a function of mainly mechanical interlocking of the structure on the upper range of the height (H) and wherein the pattern has a function of mainly bone generating interlocking of the structure on the lower range of the height (H).

11. An implant according to claim 1 characterised in that the implant is a dental implant and the pattern has a volume per unit area (V) of from 0.005 to 10 $\mu m^3/\mu m^2$.

12. An implant according to claim 1 characterised in that the pattern has a surface roughness in the range of 0.2 to 5.0μm.

13. An implant according to claim 1 characterised in that the intrusion of the pattern has a height (Rt) of from 0.1 to 10μm and/or 10μm to 100μm.

14. An implant according to claim 1 characterised in that the controlled pattern has a function of mainly mechanical interlocking of the structure on the upper range of the height (Rt) and wherein the pattern has a function of mainly bone generating interlocking of the structure on the lower range of the height (Rt).

15. An implant according to claim 14 characterised in that the pattern has a surface roughness in the range of 0.2 to 5.0μm and/or 5.0 to 50 μm.

16. An implant according to claim 14 characterised in that the implant is an orthopaedic implant and in that the pattern has a function of mainly bone generating interlocking of the structure and wherein the intrusion of the pattern has a volume per unit area (V) of from 0.005 to 90 $\mu m^3/\mu m^2$.

17. An implant according to claim 1 characterised in that the pattern permits increased bone growth penetration into the pattern.

18. An implant according to claim 1 characterised in that the pattern is covered wholly or partially by a surface treatment.

19. An implant according to claim 18 characterised in that the surface treatment is selected from one or more of anodising, etching, HA, PVD, CVD, additional blasting, passivation, thread rolling and mixes thereof.

20. An implant according to claim 1 characterised in that the ridges are adapted to act like micro cutting edges cutting small bone chips for enhanced bone formation.

21. An implant according to claim 1 characterised in that the pattern exhibits an altered chemical status, enabling enhanced bone formation.

22. An implant according to claim 1 characterised in that the pattern comprises of a titanium oxide pattern.

23. An implant according to claim 1 characterised in that it is an orthopaedic implant.

24. An implant according to claim 1 characterised in that it is a dental implant.

25. An implant according to claim 24 characterised in that the implant consists of a screw implant for application in the jawbone.

26. An implant according to claim 1 characterised in that the pattern forms a depot for applied bone-growth-initiating or bonegrowth-stimulating agent or substance.

27. An implant according to claim 1 characterised in that the pattern does not decrease cutting efficiency.

28. An implant according to claim 26 characterised in that the agent or the substance migrates from the depot to the bone or tissue structure (5) by means of concentration diffusion.

29. An implant according to claim 1 characterised in that the implant is provided with means for micro cutting bone chip in order to enhance bone formation.

30. A method of manufacturing an implant according to claim 1 characterised in that the pattern (2) is produced by embossing.

31. A method of manufacturing an implant for use in connection with a bone or tissue structure, comprising surface deformations characterised in that the surface deformations comprise a plastically controlled pattern of deformations and at least a portion of the deformations comprise ridges which are undercut wherein the pattern (2) is produced incorporating a second treatment in form of rolling in order to create undercuts.

32. A method of manufacturing an implant according to claim 30 characterised in that the original machined surface is present in areas between the pattern or is surrounded by the pattern.

33. A method of manufacturing an implant according to claim 30 characterised in that the embossing does not contaminate the implant and/or any contamination of the implant is subsequently removed.

34. A method of manufacturing an implant according to claim 33 characterised in that an embossing tool is surface treated in order to not contaminate the implant.

35. A method of manufacturing an implant according to claim 34 characterised in that the surface of the embossing tool is chemically altered in order to avoid contamination of the implant.

36. A method of manufacturing an implant according to claim 35 characterised in that the surface of the embossing tool is chemically altered in order to dope the implant surface.

37. A method of manufacturing an implant according to claim 35 characterised in that the embossing tool surface is treated by the way of a thin film hard coating or any other coating technique in order to not contaminate the implant and/or decreasing the friction coefficient.

38. A method of manufacturing an implant according to claim 35 characterised in that the implant surface at a first moment is contaminated but then after a chemical treatment is freed from contamination.

39. A method of using the implant pattern according to claim 1 characterised in that the pattern is used as a depot and that the depot is used for applied bone-growth-initiating or bonegrowth-stimulating agent or substance.

40. An implant for use in connection with a bone or tissue structure, comprising surface deformations characterised in that the surface deformations comprise a plastically controlled pattern of deformations and at least a portion of the deformations comprise ridges which are characterised in that at least a portion of the ridges is provided with an undercut region.

41. An implant or a method substantially as described with reference to the accompanying description and drawings.

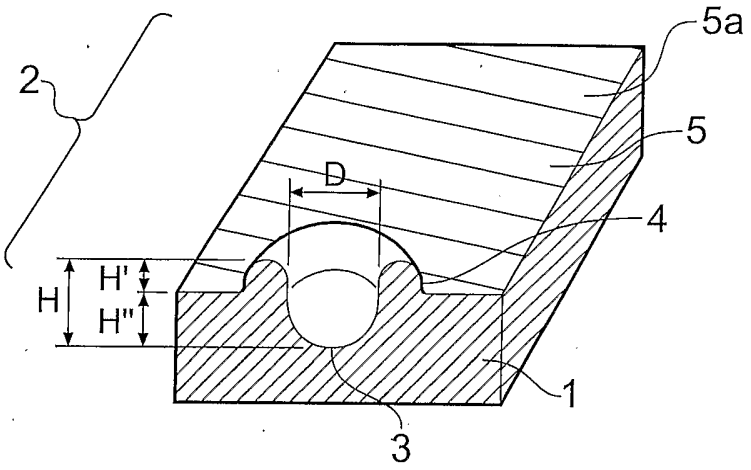

Fig. 1a

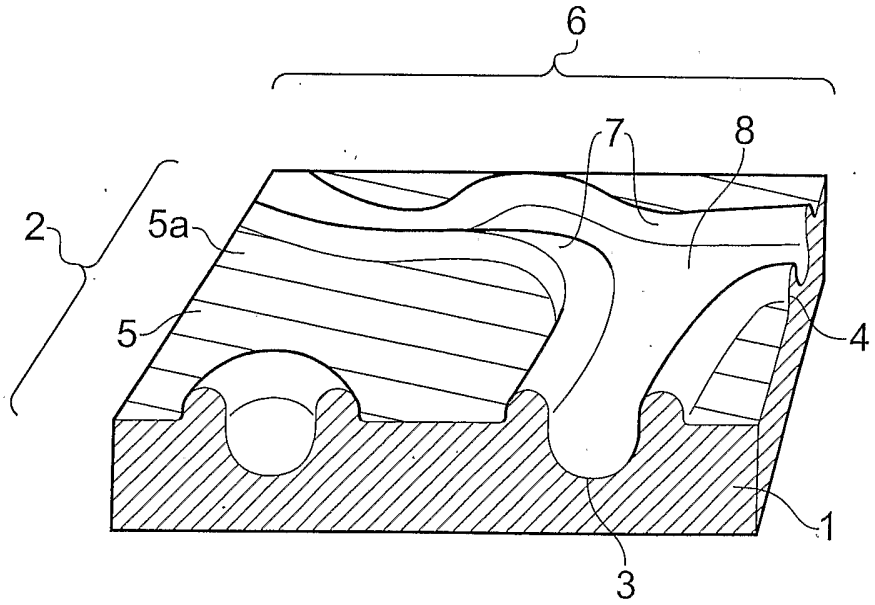

Fig. 1b

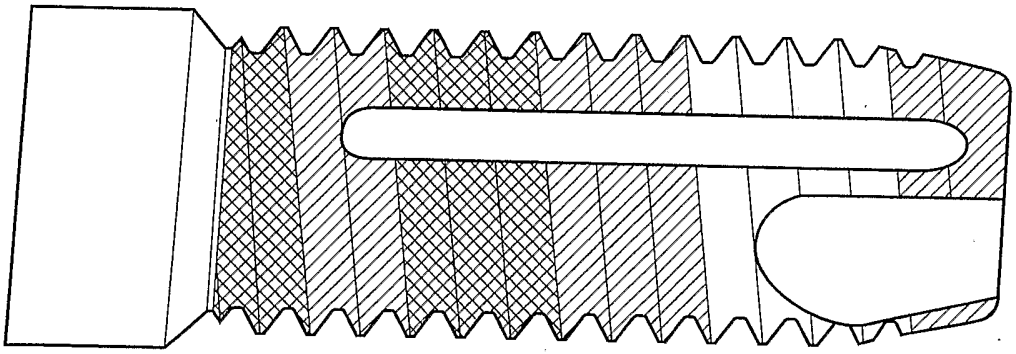

Fig. 2a

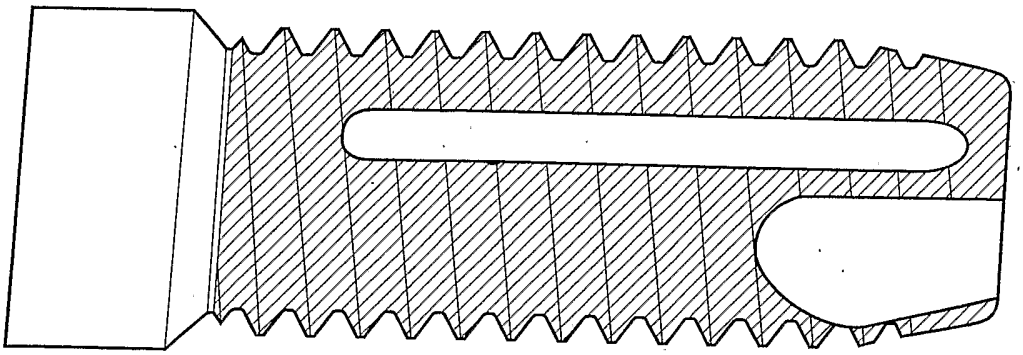

Fig. 2b

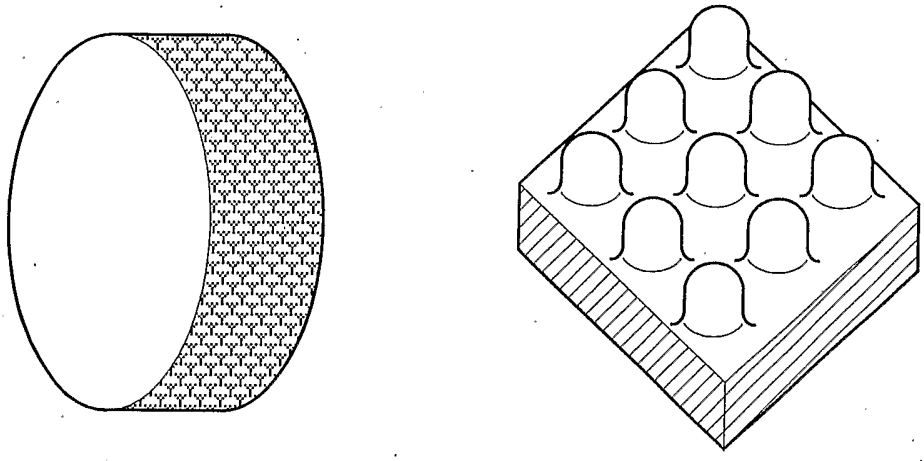

Fig. 3a

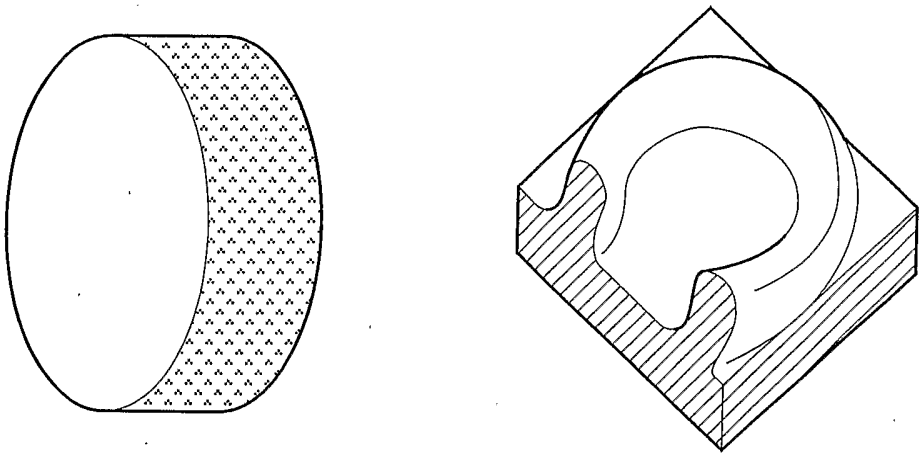

Fig. 3b

INTERNATIONAL SEARCH REPORT

PCT/GB 02/04699

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/30

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 A61F A61C A61B B22D

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, PAJ, 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	WO 00 06043 A (SUTTER FRANZ) 10 February 2000 (2000-02-10) page 4, line 3 - line 5 page 6, line 29 -page 23, line 25 figures 1-5,11-14,17 ---	1-3,5, 14,17, 20, 23-25,29
X	US 5 222 983 A (HEROLD WOLF D ET AL) 29 June 1993 (1993-06-29) column 3, line 5 -column 4, line 47; figures 1-3 --- -/--	1,2,4, 9-12,14, 16,17, 20,24, 25,29,40

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

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"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	Date of mailing of the international search report
20 February 2003	06/03/2003

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	Lickel, A

Form PCT/ISA/210 (second sheet) (July 1992)

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
X	WO 01 35871 A (WENNERBERG ANN ;ROSEN BENGT GOERAN (SE)) 25 May 2001 (2001-05-25) the whole document	1,2,4,9, 10,12, 14,17, 30,32,33
A	EP 0 875 594 A (EROTHITAN TITANIMPLANTATE AG I ;UNIV VIGO (ES); EURO TRS (ES); IMP) 4 November 1998 (1998-11-04) claim 1	38
X	US 6 231 612 B1 (BALAY BRUNO ET AL) 15 May 2001 (2001-05-15)	1,14,17, 18,21, 23,29,40
Y	column 2, line 7 -column 5, line 35; figures 2,3	19
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X	US 5 766 010 A (UEMURA YUJI) 16 June 1998 (1998-06-16) abstract column 5, line 57 - line 61; figure 4	1,4,14, 22,24
X	US 5 645 593 A (COOPER DEREK REDVERS ET AL) 8 July 1997 (1997-07-08) column 1, line 46 -column 2, line 64; figures 2,3	1,4,14, 17,26
A	US 6 066 407 A (GETZ ROLAND A) 23 May 2000 (2000-05-23) abstract	34,37

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.2

Claims Nos.: 6-8, 27, 28, 35, 36, 41

The wording of claim 6 is linguistically not comprehensible as it appears that some words are missing. Thus, the subject-matter of claim 6 and the on claim 6 depending claims 7 and 8 can not be searched.

Claim 27 is so unclear that no meaningful search can be performed. What decreases cutting efficiency is subjective, cutting efficiency per se is not uniquely definable and the claim relates to the result to be achieved without defining any technical features necessary to achieve this result.

As for claim 28, the agent or substance does not form part of the claimed implant. Hence the definition of the action that it performs ("..migrates") renders this claim so unclear that no meaningful search can be carried out.

Claims 35 and 36 are so unclear that no meaningful search is possible. The applicant refers to an embossing tool for manufacturing an implant according to claim 1, whereby the surface of the tool is chemically altered. However, the starting composition, which then is chemically altered, is not defined. Mere chemical alteration of the surface neither avoids contamination of the implant nor dopes it.

Claim 41 is not searched in agreement with Rule 6.2(a), as it contains references to figures and the description.

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The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

INTERNATIONAL SEARCH REPORT

PCT/GB 02/04699

Box I Observations where certain claims were found unsearchable (Continuation of item 1 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. [X] Claims Nos.: 39
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [X] Claims Nos.: 6-8, 27, 28, 35, 36, 41
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:

see FURTHER INFORMATION sheet PCT/ISA/210

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 II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

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 fee, this Authority did not invite payment of any additional fee.

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.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

PCT/GB 02/04699

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WO 0006043 A	10-02-2000	WO 0006043 A1	10-02-2000
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