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(54) **ONE-PIECE DENTAL DEVICE AND METHOD TO MANUFACTURE THE SAME**

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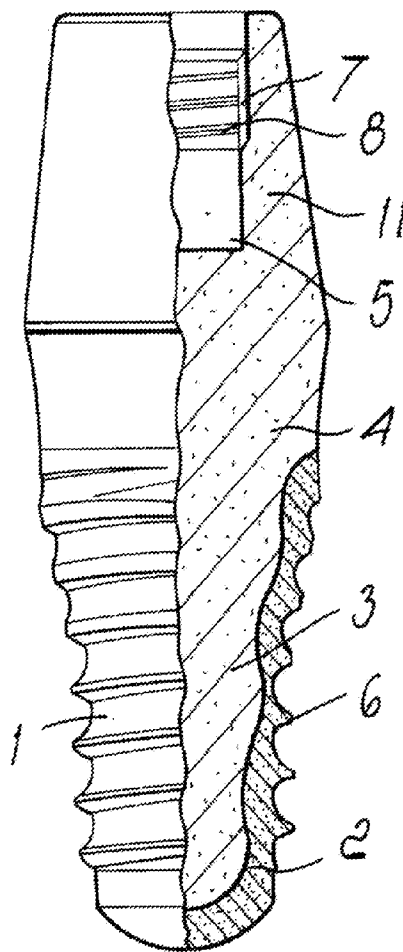
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(57) **ABSTRACT**

A dental device, in particular a one-piece dental implant, comprising an outer body made of metal; and an inner body made of plastic or composite, wherein the inner body comprises a core perfectly fitting into a cavity of the outer body, and a method for manufacturing a dental device, in particular a one-piece dental implant, comprising the following steps in any order: manufacturing an outer body of metal; and manufacturing an inner body of plastic or composite material; wherein the inner body comprises a core manufactured within a cavity of the outer body.



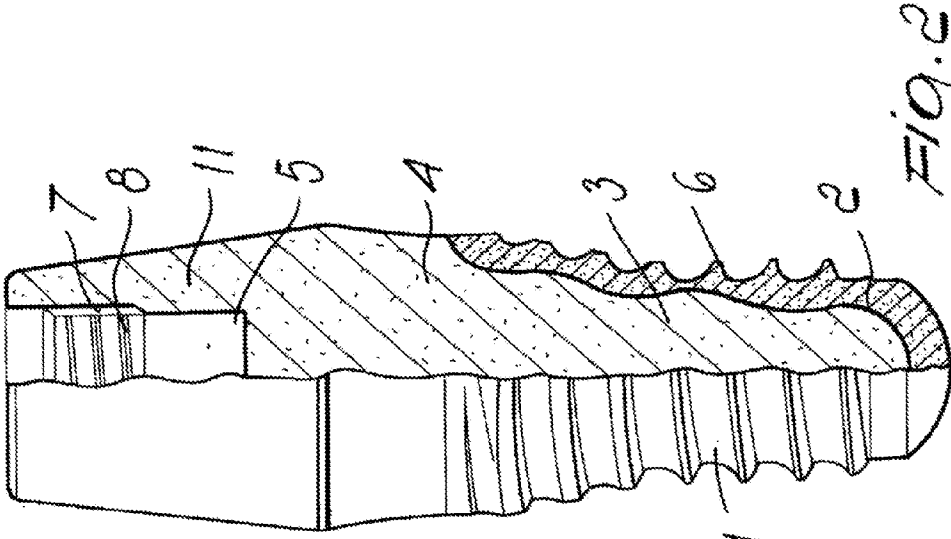


Fig. 2

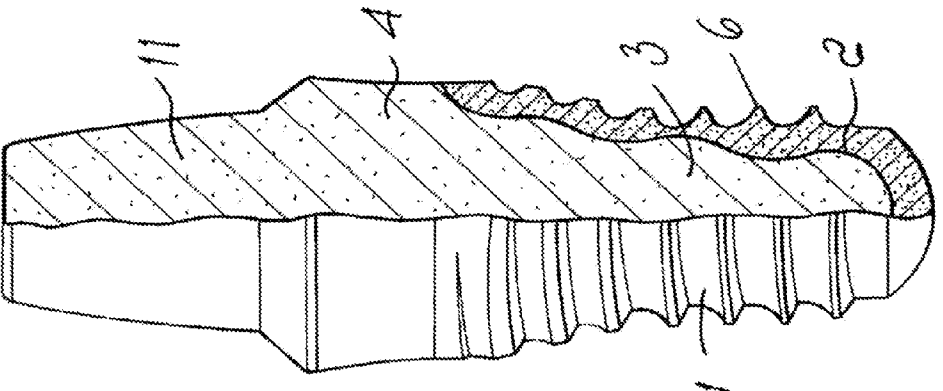


Fig. 1

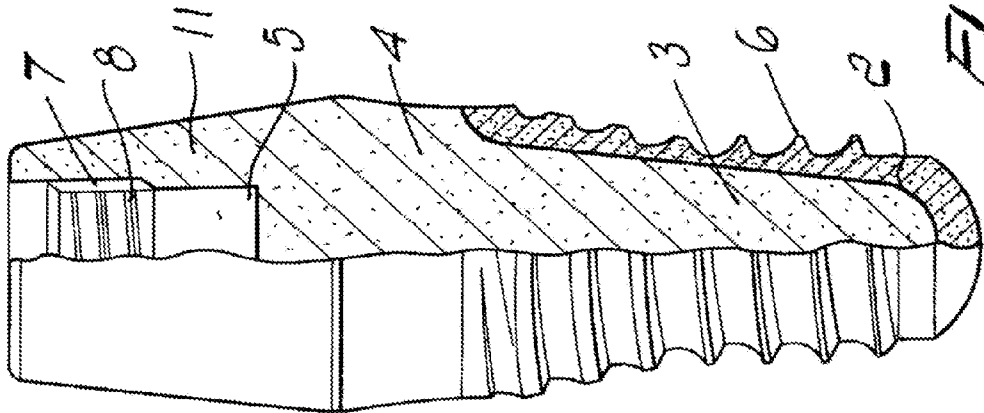


FIG. 4

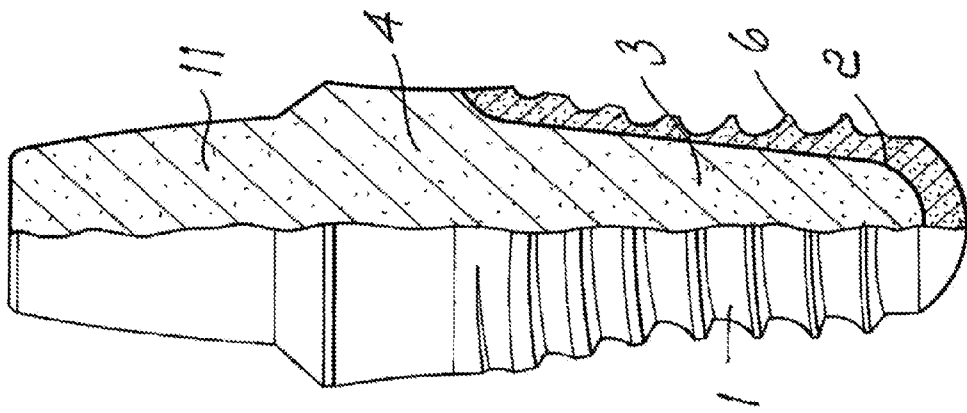


FIG. 3

## ONE-PIECE DENTAL DEVICE AND METHOD TO MANUFACTURE THE SAME

**[0001]** The invention relates in general to a one-piece dental device and to a method to manufacture the same, and in particular to a one-piece dental implant and to a method to manufacture the same.

### BACKGROUND OF THE INVENTION

**[0002]** Dental devices in general and dental implants in particular are made basically of two classes of materials: metals and ceramics.

**[0003]** With regard to metal, several metals are used for forming implants. Each metal has its own characteristic which renders the metal a possible suitable choice for the dental implants. For example, Ti (titanium) or titanium alloy are generally used. Titanium dental implants are relatively light, have high strength, and they have excellent corrosion resistance and bio-compatibility.

**[0004]** Ceramic materials such as zirconia-based, alumina-based and/or sapphire-based ceramics have also been used for manufacturing dental implants or dental devices.

**[0005]** Dental devices, in general, and dental implants, in particular, formed from ceramic materials have the disadvantage that the material is more brittle as shown by a low value for the notched bar impact test. Ceramic materials are also susceptible to uncontrolled internal and external micro-cracks, and therefore they are prone to fail catastrophically. Moreover, artificial ceramic dental devices are rather expensive. However, the ceramic dental devices in general and the visible section of dental implants in particular, have a better aesthetic impact with respect to the metal implant and therefore enjoy a higher acceptance with the dental device bearer.

**[0006]** Furthermore, in some instances, a dental implant which is made of metal only may come into contact with an abutment/crown which is also made of a metal like for instance titanium, titanium alloy, gold or a gold alloy. Alternatively the abutment/crown is made of ceramic such as zirconia-based, alumina-based (for instance in-ceram®) and/or sapphire-based ceramics, or a ceramic glass composite. In the first metal to metal case, saliva or tissue fluid, acting as an electrolyte, may cause a galvanic electric current to flow which in extreme cases may have unpleasant effects for the dental prosthesis bearer. Also the metal, in particular if metals other than titanium are used in contact with a titanium implant, may cause inflammation and irritation of the soft tissue which it contacts.

**[0007]** In view of the above, there is the need for a dental device, in particular a one-piece dental-device, that combines the advantages of metal made dental devices with those of ceramic made dental devices and which, at the same time, is not subject to the above shortcomings entailed by ceramic materials.

**[0008]** Furthermore, in view of the foregoing, there is the particular need for a dental implant, in particular a one-piece dental implant, that combines the advantages of metal made dental implants with those of ceramic made dental implants, which avoids the use of ceramic material.

### SUMMARY OF THE INVENTION

**[0009]** The object of the present invention is to provide dental devices such as a one-piece dental implant, a dental

prosthesis and the like that are easy to manufacture and have good bio-compatibility, high strength and a good aesthetic impact.

**[0010]** In one preferred embodiment thereof the present invention is directed to a dental device, in particular a dental implant, which comprises an outer body made of metal and an inner body made of a plastic material, wherein the outer metal body is manufactured preferably by metal injection molding (MIM) or Ti Plasma spraying or by lathe processing or the like and the inner body is preferably manufactured from a plastic material by molding, for instance plastic injection molding (PIM), or composite material produced for instance with composite flow molding (CFM) process.

**[0011]** Preferably the metal according to the present invention is titanium, titanium alloy or any other comparable materials. Preferably the plastic material is chosen from a group comprising PEEK (Polyetheretherketon), PPSU (Polyphenylensulfon), PES (Polyethersulfon) or combination or one of the above polymers and a fiber for instance  $Al_2O_3$  or  $SiO_2$  or  $ZrO_2$ .

**[0012]** In the case that the present invention is embodied as a one-piece endosseous dental implant it may be comprised of a metal implant part which is to be implanted in a bone tissue, that implant part having a portion defining a metal outer body or a sheath thereof; and a plastic or composite inner body. Both bodies are manufactured by metal injection molding and by plastic injection molding, respectively. Furthermore, the plastic or composite inner body may comprise a core, a collar and a hollow. The inner plastic or composite body extending at the coronal side of the implant preferably forms an abutment. Again, preferably the metal is titanium or a titanium alloy or the like and the plastics is chosen from a group comprising PEEK (Polyetheretherketon), PPSU (Polyphenylensulfon), PES (Polyethersulfon) or combination or one of the above polymers and a fiber for instance zirconia-based, alumina-based and/or sapphire-based ceramic.

**[0013]** Additionally the one-piece endosseous dental implant may be provided with an inner metal sleeve which provides means for fixing to a cap, crown or the like, wherein the inner metal sleeve is located in the hollow of the inner plastic or composite body. Also the inner metal sleeve may be chosen among titanium or a titanium alloy.

**[0014]** Preferably, if the metal outer body is manufactured by metal injection molding it has a rounded inner profile of its cavity which is believed to decrease tension between the inner and the outer bodies. If the outer metal body is lathe processed it is preferred that the inner profile of the cavity of the outer metal body is conically shaped in order to facilitate its manufacturing.

**[0015]** The present invention also provides for a method for manufacturing dental devices, in particular one-piece endosseous dental implants comprising the steps of: manufacturing an outer body of a metal material; and manufacturing an inner plastic body inside the outer metal body.

**[0016]** The metal outer body may be manufactured by metal injection molding or mechanically processed by lathe processing milling, drilling or the like. The inner plastic or composite body is formed within a cavity of the metal outer body preferably by plastic injection molding within the cavity.

### BRIEF DESCRIPTION OF THE DRAWINGS

**[0017]** The foregoing and other objects, features, and advantages of the invention, as well as presently preferred

embodiments thereof, will become more apparent from a reading of the following description, in connection with the accompanying drawings in which:

**[0018]** FIG. 1 is a perspective partially cut away view which shows a first embodiment of the invention devised as a one-piece dental device, wherein the outer body is manufactured by metal injection molding and the inner plastic or composite body is manufactured from a plastic material;

**[0019]** FIG. 2 is a perspective partially cut away view which shows a variation of the one-piece dental device of FIG. 1, wherein the inner plastic or composite body of the dental implant is provided with an inner sleeve;

**[0020]** FIG. 3 is a perspective partially cut away view which shows a second embodiment of the invention devised as a one-piece dental device, wherein the outer body is manufactured by lathe processing and the inner body is manufactured from a plastic or composite material; and

**[0021]** FIG. 4 is a perspective partially cut away view which shows a variation of the one-piece dental device of FIG. 3, wherein the plastic or composite inner body of the dental implant is provided with an inner sleeve.

#### DESCRIPTION OF THE PREFERRED EMBODIMENTS

**[0022]** Metal injection molding (MIM), plastic injection molding (PIM) and composite flow molding (CFM) are well known technologies in the art of molding. In particular, in the process of plastic injection molding, a plastic material is injected at high temperature and pressure in a mold where it is allowed to cool down and become hardened. Similar to plastic injection molding, a molten polymer (called binder) along with metal powder paste are injected into a mold in the course of metal injection molding. The volume of the part is restricted to small components. The binder material is removed by either solvent extraction or controlled heating to above the volatilization temperatures and the so called green body is sintered.

**[0023]** Metal injection molding consists essentially of the following steps:

**[0024]** powder manufacture;

**[0025]** mixing or blending;

**[0026]** injection molding; and

**[0027]** preferably sintering.

**[0028]** According to the knowledge of the present inventors, the above described two technologies have never been utilized together in order to form dental implants, in particular one-piece dental implants.

**[0029]** The present invention will be exemplified disclosing an endosseous one-piece dental implant which is envisaged as the currently preferred embodiment thereof. However, it should be understood that the basic principles of the present invention (which includes the combination of metal injection molding and molding techniques for a plastic material) may be applied to other medical/dental devices like for instance dental prosthesis or to prosthetic parts in general. Also, it is believed that the basic principles of the invention are applicable to other non-medical devices.

**[0030]** The endosseous one-piece dental implant of the present invention, as shown in a schematic representation of FIG. 1, comprises a metal outer body 1 which is to be implanted in bone tissue and an inner plastic body 2 comprising a core 3 forming at a coronal section thereof a collar 4. Coronally of the collar 4 the inner plastic body 2 may comprise an abutment 11. The one-piece dental device of FIG. 2 is

formed in a similar manner to the implant of FIG. 1 including in addition an inner sleeve 7, the inner sleeve 7 being located in a hollow 5 defined at the abutment 11 of the inner body 2. Preferably, the inner sleeve 7 is made of a metal like for instance titanium.

**[0031]** As well known in the relevant art, the metal outer body 1 may be preferably provided with an external thread structure 6. Furthermore, the section of the outer body 1 in contact with the bone tissue may be treated to give it a special surface morphology or chemical properties preferably by sandblasting and/or acid-etching (for instance by the SLA—Sand-blasted, Large grit, Acid-etched—surface treatment method). Also titanium plasma spraying thereof is intended to be within the scope of the invention. Preferably sandblasting is performed with glass beads or Al<sub>2</sub>O<sub>3</sub> grits or TiO<sub>2</sub> grits. The surface of the implant in contact with the gingival tissue may be advantageously smooth, but other surface treatments to improve soft tissue attachment are possible. In addition, surface modification at the soft tissue and/or bone tissue apposition surface can be done by growth factor adsorption, and/or peptide adsorption, and/or protein adsorption, and/or amino acid adsorption. The SLA-interface may be designed advantageously to follow the outline of the tissue and is not necessarily identical to the interface between the inner body 2 and the outer body 1.

**[0032]** The inner shape/profile of a cavity defined within the metal outer body 1 is complementary to the outer profile of the inner body 2.

**[0033]** Preferably, according to the invention, the inner profile of the cavity of the outer body 1 is a rounded profile to decrease tension between the inner and the outer bodies. This complementary rounded profile is particularly advantageous when the present inner and outer bodies are manufactured by means of plastic injection molding and metal injection molding, respectively.

**[0034]** The metal outer body 1 is made preferably of titanium or a titanium alloy or any other comparable materials. The plastic or composite inner body 2 is preferably a plastic or composite material chosen from a group including PEEK (Polyetheretherketon), PPSU (Polyphenylsulfon), PES (Polyethersulfon) or combination or one of the above polymers and a fiber for instance Al<sub>2</sub>O<sub>3</sub> or SiO<sub>2</sub> or ZrO<sub>2</sub>.

**[0035]** The plastic or composite inner body 2 comprises the core 3 which lies inside the outer body 1. The outer profile of the core 2 has, as explained, a rounded profile which is complementary to the inner profile of the cavity of the metal outer body 1, such that the rounded profile alleviates the tension between the outer body 1 and the inner body 2. The profile may also advantageously be adapted for locking against relative rotation of the two bodies. Thus, the profile includes an anti-rotation feature.

**[0036]** The collar 4 is, in the implanted state of the dental implant, basically in contact with the soft tissue, such that to avoid direct contact of the metal outer body 1 with the soft tissue.

**[0037]** As shown in FIG. 2 the dental implant may optionally be provided with the inner sleeve 7 which provides for a fixing to a cap, crown etc. (not shown), wherein the inner sleeve 7 is located in the hollow 5 defined at the collar 4 of the inner body 2.

**[0038]** Preferably, the inner sleeve 7 of the FIG. 2 is provided in a known manner with a thread 8 and anti-rotation means (for instance of polygonal, octagonal or any other suitable shape) for fixing the cap, crown etc (not shown). The

inner sleeve 7 may be coupled to the inner body 2 by snap coupling, press fitting, adhesive coupling, lock engagement, warm shrinking etc. Also it is conceivable according to the present invention to provide combinations of two or more of snap coupling, press fitting, adhesive coupling, lock engagement and warm shrinking between the sleeve 7 and the inner body 2. Furthermore, the sleeve 7 may also be provided by means of a metal injection molding process if it is made of metal or by an ceramic injection molding (CIM) process if ceramics are used therefore. The vertical length of the hollow 5 may vary according to the length of the thread 8 of the sleeve 7 and the anti-rotation means may be omitted.

[0039] The one-piece dental implant of FIGS. 3 and 4 is the same as that of FIGS. 1 and 2, respectively, except for the rounded inner profile of the cavity of the metal outer body 1 being replaced by a conical one. Such conical profile of the cavity may result if the inner profile of the cavity of the metal outer body 1 is manufactured by lathe processing, milling, drilling or the like.

[0040] The dental implants or dental devices of the present invention, as shown in FIGS. 1 through 4, may be manufactured by means of a method providing for the injection of the plastic material of the plastic inner body 2 into the inner cavity of the metal outer body 1. In this method the inner cavity of the metal outer body 1 is used as a mold and may be advantageously provided at the apical tip thereof with venting orifices. Thus, the inner cavity of the outer metal body 1 functions as a mold for molding the core 3 therein. The collar 4 and the abutment 11, if any, may be molded in a separate cavity (not shown) defining along with the inner cavity of the outer body 1, which may be held as an insert in a molding device, a closed molding chamber.

[0041] The metal outer body 1 is preferably molded according to the invention using MIM or mechanically processed by lathe processing, milling, drilling and the like, as already explained.

[0042] As the plastic or composite inner body 2 is always molded or provided into the inner cavity of the metal outer body, the two bodies are perfectly shaped and fit perfectly. The preferred method for producing the plastic inner body is plastic injection molding (PIM) while the preferred method for producing the composite inner body is composite flow molding (CFM).

[0043] The embodiments described are chosen to provide an illustration of principles of the invention and its practical application to enable thereby the person of ordinary skill in the art to utilize the invention in various embodiments and with various modifications as are suited to the particular use contemplated. In particular, the plastic or composite inner body 2 may be provided by other molding methods, like for instance press molding, extrusion, injection pressing or expanding. Also alternative methods for providing the outer metal body can be implemented. Therefore, the foregoing description is to be considered exemplary, rather than limiting, and the true scope and spirit of the invention is that described in the appended claims.

[0044] The disclosures in EPA 04011868.9 from which this application claims priority are incorporated herein by reference.

1. A dental device, in particular a one-piece dental implant, comprising an outer body made of metal; and an inner body made of plastic or composite material, wherein the inner body comprises a core perfectly fitting into a cavity of the outer body.

2. The dental device of claim 1, wherein the inner body further comprises a collar coronally of the core and an abutment coronally of the collar.

3. The dental implant of claim 1, further comprising a metal or ceramic inner sleeve fixed to a hollow portion of the inner body, the inner sleeve being adapted for providing fixing means to a cap, a crown or the like.

4. The dental implant of claim 3, further comprising one or more of the following means: snap coupling, press fitting, adhesive coupling means, lock engagement and warm shrinking for fixing the inner sleeve to the hollow portion of the inner body.

5. The dental implant of claim 3, wherein the inner sleeve is provided by means of metal injection molding.

6. The dental device of claim 1, wherein the outer body is provided by means of metal injection molding and the inner body is provided by means of plastic injection molding or by means of composite flow molding.

7. The dental device claim 1, wherein the outer body is provided by means of lathe processing, milling or drilling, and the inner body is provided by means of plastic injection molding or by means of composite flow molding.

8. The dental implant of claim 1, wherein the metal is chosen among titanium or a titanium alloy, wherein the plastic material is chosen from a group including PEEK (Polyetheretherketone), PPSU (Polyphenylsulfone), PES (Polyethersulfone) or combinations thereof; or wherein the composite material is chosen from one of said polymers and a fiber including Al<sub>2</sub>O<sub>3</sub> or SiO<sub>2</sub> or ZrO<sub>2</sub>.

9. The dental implant of claim 1, wherein the implant surface is topographically or chemically modified by sand-blasting, acid-etching or combination thereof, and/or plasma spraying, and/or growth factor adsorption, and/or peptide adsorption and/or protein adsorption, and/or amino acid adsorption, and wherein the modification of the implant surface is carried out at a soft tissue and/or bone tissue apposition surface.

10. The dental implant of claim 6, wherein the inner profile of the cavity of the outer body is complementary to the outer profile of the inner body, and wherein the respective profiles are rounded, such as to decrease tension between the inner and the outer bodies and/or such that to provide for an anti-rotation lock between the two bodies.

11. The dental implant of claim 6, wherein the inner profile of the cavity outer body is complementary to the outer profile of the inner body, and wherein the respective profiles are conically shaped.

12. The dental implant of claim 1, wherein the apical section of the outer body is provided with at least one venting orifice.

13. A dental device, in particular a one-piece dental implant, comprising an outer body made of metal; and an inner body made of plastic or composite material, wherein the inner body comprises a core perfectly fitting into a cavity of the outer body, wherein the inner profile of the cavity of the outer body is complementary to the outer profile of the inner body, and wherein the respective profiles are rounded, such as to decrease tension between the inner and the outer bodies and/or such that to provide for an anti-rotation lock between the two bodies.

14. The dental device of claim 13, wherein the outer body is provided by means of metal injection molding and the inner body is provided by means of plastic injection molding or by means of composite flow molding.

15-27. (canceled)