

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF INDIANA**

FOUR MILE BAY LLC,)	
)	
Plaintiff,)	Case No.
)	
v.)	JURY TRIAL DEMANDED
)	
ZIMMER HOLDINGS, INC. AND)	
ZIMMER DENTAL INC.,)	
)	
Defendants.)	

COMPLAINT

Plaintiff Four Mile Bay LLC (“Four Mile Bay”), by its undersigned counsel, for its Complaint against Defendants Zimmer Holdings, Inc. (“ Zimmer Holdings”) and Zimmer Dental Inc. (“Zimmer Dental”) (together, “Zimmer”), states as follows:

I. NATURE OF THE ACTION

1. This is a patent-infringement action by Four Mile Bay against Zimmer, a manufacturer and marketer of reconstructive orthopedic implants, including dental implants. As detailed below, Four Mile Bay has been harmed by Zimmer’s unlawful use of Four Mile Bay’s patent for commercial purposes.

II. JURISDICTION AND VENUE

2. This action arises under the patent laws of the United States, 35 U.S.C. §§ 101 *et seq.* This Court therefore has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

3. This Court may exercise personal jurisdiction over Zimmer Holdings and Zimmer Dental. Zimmer Holdings’ principal place of business is located in Warsaw,

Indiana. Zimmer Holdings and Zimmer Dental conduct continuous and systematic business in Indiana and this District.

4. Venue is proper under 28 U.S.C. §§ 1391(b)(3) and 1400(b).

III. PARTIES

Plaintiff

5. Four Mile Bay is a limited liability company organized under the laws of Nevada. Four Mile Bay's principal place of business is located in Wadsworth, Ohio.

Defendants

6. Zimmer Holdings is a corporation organized under the laws of Delaware, with its principal place of business located in Warsaw, Indiana. Zimmer Holdings designs, develops, manufactures, and markets, among other things, dental implants. Zimmer Holdings fabricates Trabecular Metal Material at its facility in Parsippany, New Jersey.

7. Zimmer Dental, a division of Zimmer Holdings, is a corporation organized under the laws of Delaware, with its principal place of business in Carlsbad, California. Zimmer Dental designs, develops, manufactures, and markets, among other things, dental implants.

IV. FACTUAL BACKGROUND

8. Four Mile Bay owns United States Patent No. 8,684,734 (the "'734 patent").

9. The field of invention of the '734 patent is dental implants. Humans have for thousands of years sought solutions to the challenge of missing teeth. Remains of the ancient Chinese and Egyptians tell us this. The chief object in implant dentistry throughout history has been to firmly anchor the implant in the patient's mouth. In recent decades, dental implant artisans have found success in achieving the objective of anchoring the implant in the patient's mouth through use of the process of "osseointegration."

10. The teeth of mammals are anchored in sockets. Roots of a tooth are surrounded by bone—alveolar bone—that works to anchor the tooth in the mammal’s mouth. Artisans have observed that the alveolar bone will indeed grow on the surface of a dental implant. This process of eliciting bone growth is called osseointegration.

11. Making use of osseointegration to anchor dental implants has to date focused on the surface technologies applied to dental implants. The goal is to produce a porous surface with which the patient’s alveolar bone will bond or grow into, thus anchoring the implant.

12. This solution to the challenge of anchoring the implant is a limited one. Bone surrounding the implant can only grow into the coating itself. Bone cannot grow completely through the implant and unquestionably anchor the implant. In a word, the prior art provides a surface-level solution.

13. The ‘734 patent provides a complete solution to the challenge of firmly, unquestionably, and comfortably anchoring the implant in the patient’s mouth. The apparatuses and method of the ‘734 patent include a porous structure that extends through a significant part of the implant—allowing the patient’s alveolar bone to grow completely through the implant. Also included in this invention is an internal cavity that may house a substance that stimulates bone growth.

V. CLAIMS ALLEGED

Count I

Patent Infringement Against Zimmer Holdings

14. Four Mile Bay repeats the allegations of paragraphs 1 through 13 of this Complaint as though fully alleged herein.

15. Four Mile Bay is the exclusive owner of the '734 patent, which is attached as Exhibit 1.

16. The '734 patent is valid and enforceable.

17. Zimmer Holdings has infringed and is still infringing the '734 patent by making, selling, and using dental implants—such as the Trabecular Metal Dental Implant—that embody the patented invention.

Count II
Patent Infringement Against Zimmer Dental

18. Four Mile Bay repeats the allegations of paragraphs 1 through 17 of this Complaint as though fully alleged herein.

19. Zimmer Dental has infringed and is still infringing the '734 patent by making, selling, and using dental implants—such as the Trabecular Metal Dental Implant—that embody the patented invention.

VI. JURY DEMAND

Pursuant to Federal Rule of Civil Procedure 38(b), Four Mile Bay demands a trial by jury of all claims in this Complaint so triable.

VII. REQUEST FOR RELIEF

WHEREFORE, Four Mile Bay prays for the following relief against Zimmer Holdings and Zimmer Dental:

(A) Judgment that Zimmer Holdings and Zimmer Dental have directly infringed claims of the '734 patent;

(B) For a reasonable royalty;

(C) For pre-judgment interest and post-judgment interest at the maximum rate allowed by law; and

(D) For such other and further relief as the Court may deem just and proper.

Dated: April 15, 2014

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Exhibit 1

(12) **United States Patent**
Lyren

(10) **Patent No.:** **US 8,684,734 B1**
(45) **Date of Patent:** ***Apr. 1, 2014**

(54) **DENTAL IMPLANT WITH POROUS BODY**

(56) **References Cited**

(76) Inventor: **Philip Scott Lyren**, Bangkok (TH)

U.S. PATENT DOCUMENTS

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 18 days.

This patent is subject to a terminal disclaimer.

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7,291,012	B2 *	11/2007	Lyren	433/173
8,043,090	B1 *	10/2011	Lyren	433/173
8,297,974	B1 *	10/2012	Lyren	433/173
2008/0050699	A1	2/2008	Zhang et al.	

(21) Appl. No.: **13/571,375**

(22) Filed: **Aug. 10, 2012**

Related U.S. Application Data

FOREIGN PATENT DOCUMENTS

(63) Continuation-in-part of application No. 13/195,872, filed on Aug. 2, 2011, now Pat. No. 8,297,974, which is a continuation of application No. 11/358,375, filed on Feb. 21, 2006, now Pat. No. 8,043,090, which is a continuation of application No. 10/375,343, filed on Feb. 27, 2003, now Pat. No. 7,291,012.

WO WO 02/34155 A1 * 5/2002

* cited by examiner

Primary Examiner — Ralph Lewis

(51) **Int. Cl.**
A61C 8/00 (2006.01)

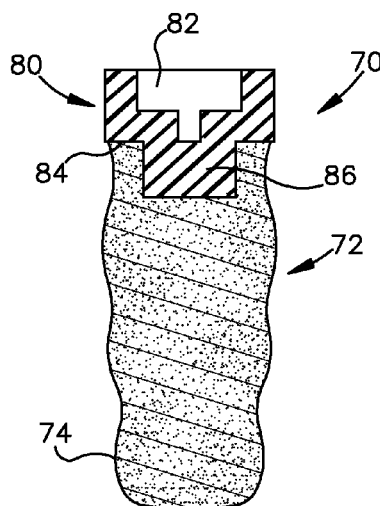
(52) **U.S. Cl.**
USPC **433/173**

(58) **Field of Classification Search**
USPC 433/173, 174, 175, 176
See application file for complete search history.

(57) **ABSTRACT**

A dental implant has a coronal body that connects to a bone fixation body. The bone fixation body has a porous structure that includes a location at which the porous structure extends throughout the bone fixation body and through a center of the bone fixation body in a cross-sectional view of the bone fixation body. The bone fixation body also includes an internal cavity with a substance to stimulate bone growth.

27 Claims, 5 Drawing Sheets



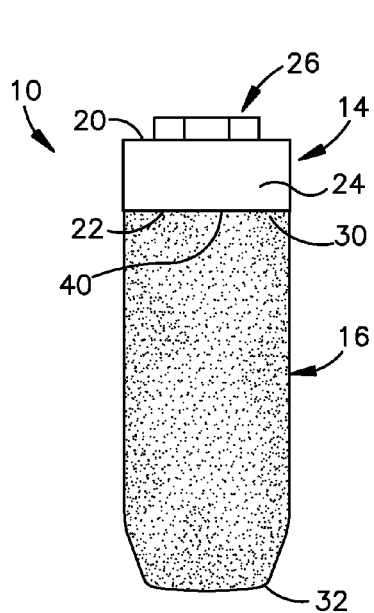


Fig. 1

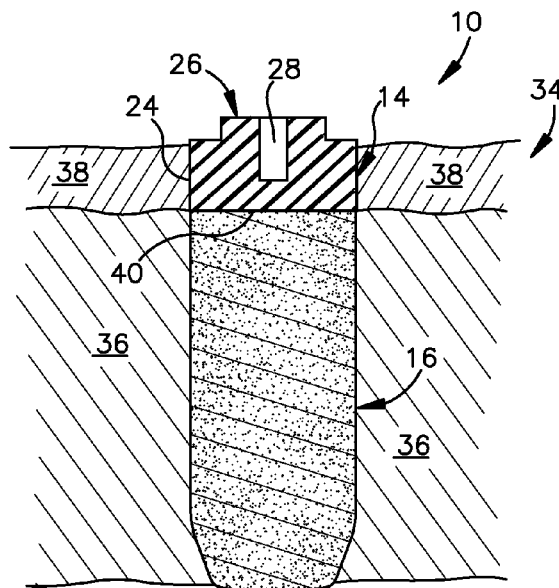


Fig. 2

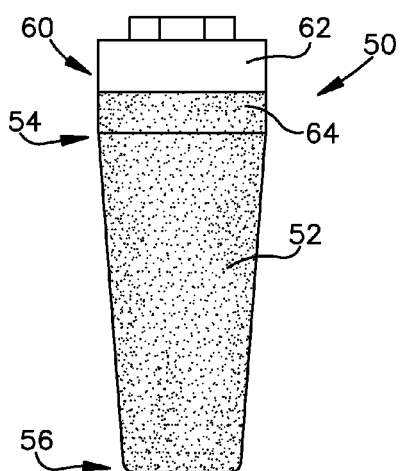


Fig. 3

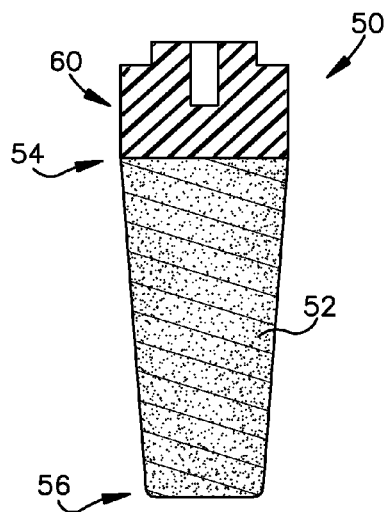


Fig. 4

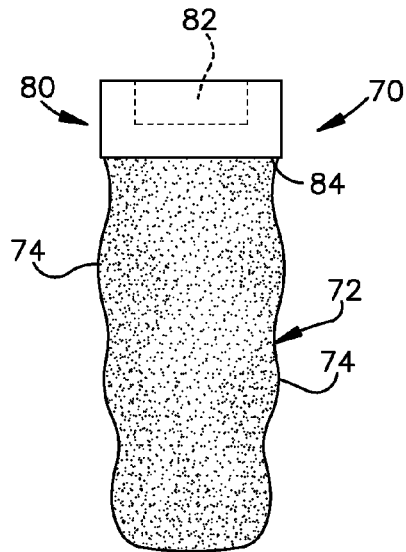


Fig. 5

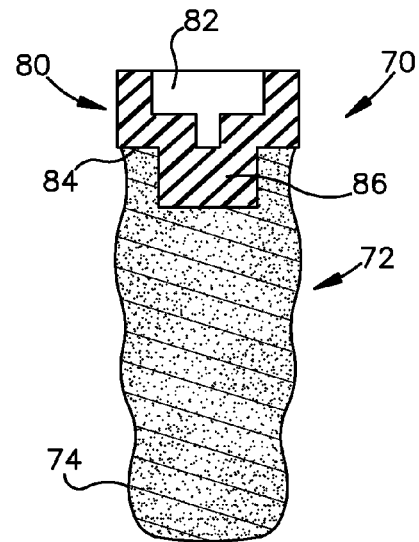


Fig. 6

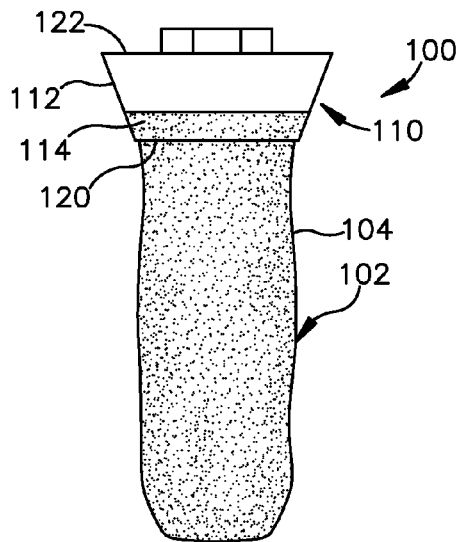


Fig. 7

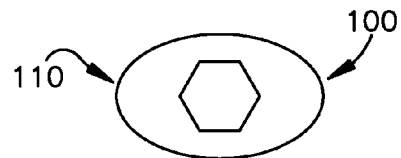


Fig. 8

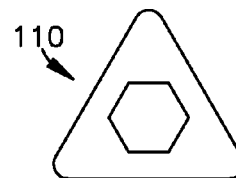
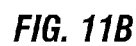
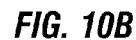
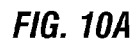


Fig. 9



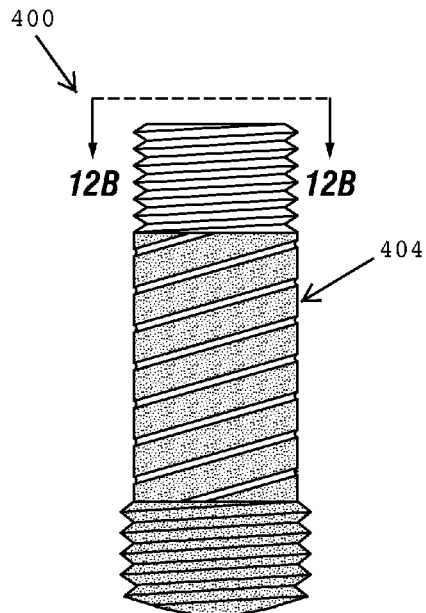


FIG. 12A

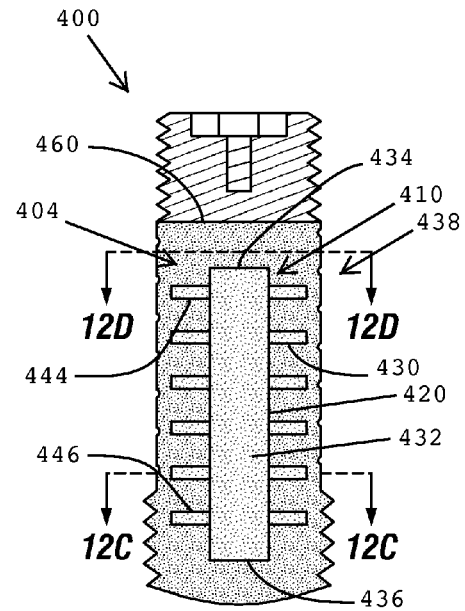


FIG. 12B

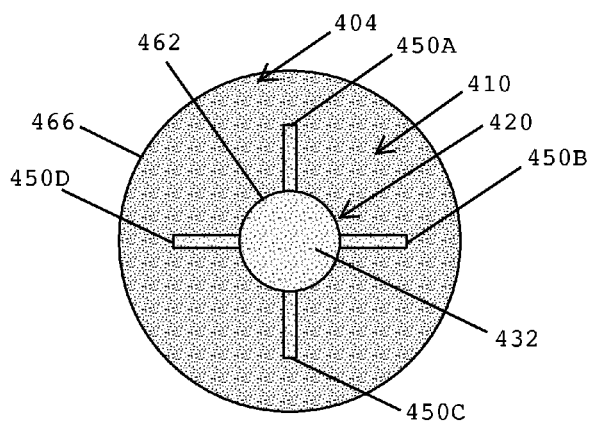


FIG. 12C

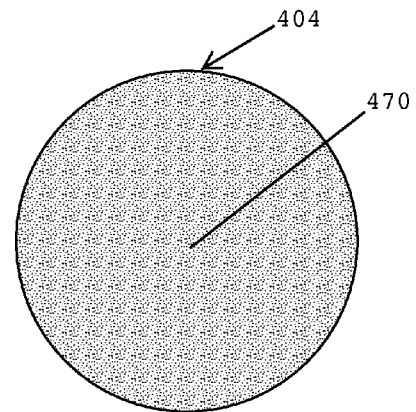


FIG. 12D

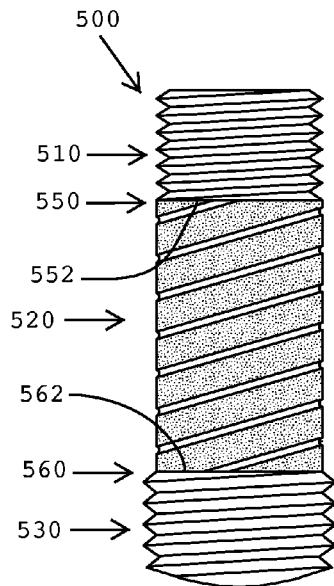


FIG. 13

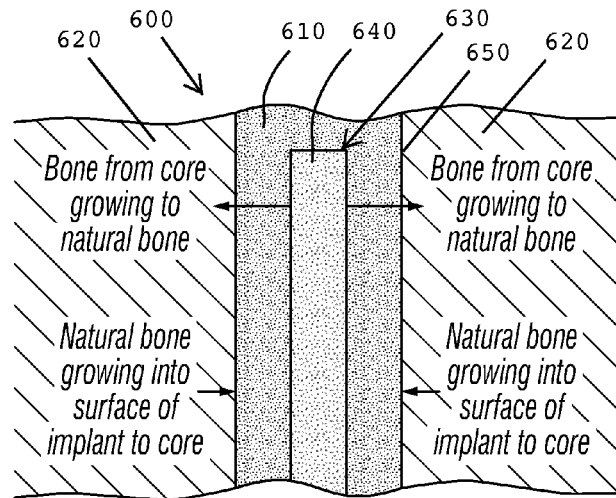


FIG. 14

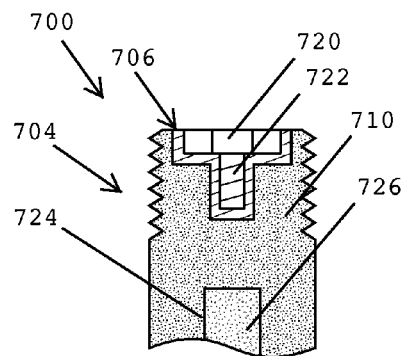


FIG. 15

US 8,684,734 B1

1

DENTAL IMPLANT WITH POROUS BODY**CROSS-REFERENCE TO RELATED APPLICATIONS**

This application is a continuation-in-part of U.S. Pat. No. 8,297,974 having Ser. No. 13/195,872 filed 2 Aug. 2011, which is a continuation of U.S. Pat. No. 8,043,090 having Ser. No. 11/358,375 filed 21 Feb. 2006, which is a continuation of U.S. Pat. No. 7,291,012 having Ser. No. 10/375,343 filed 27 Feb. 2003, which are incorporated herein by reference.

BACKGROUND OF THE INVENTION

Much effort has been directed to integrating dental implants into surrounding bone. Ideally, a dental implant would be placed into alveolar bone, and thereafter bone would readily grow into the surface of the implant. To achieve this objective, many different surface technologies have been applied to dental implants. In some instances, the surface of the implant is roughened, grit-blasted, plasma-sprayed, or microtextured. In other instances, the surface is coated with a biological agent, such as hydroxylapatite (HA). In all of these instances, the goal is the same: Produce a surface on the dental implant into which surrounding bone will grow or bond.

Porous coatings have also been applied to surfaces of dental implants. U.S. Pat. No. 5,989,027 entitled: "Dental Implant Having Multiple Textured Surfaces" to Wagner et al. (and expressly incorporated herein by reference) teaches a dental implant having multiple textured surfaces on the same implant. One surface includes a porous coated substrate, and another surface includes a nonporous surface adapted to encourage bone growth or bonding.

Porous coatings are advantageous since bone will indeed grow into the surface of the implant. Osseointegration, to a limited extent then, has been achieved with porous coated surfaces. These surfaces though are far from ideal in terms of accepting and encouraging bone growth into the body of the implant.

Porous surfaces are often thin coatings applied to the metallic substrate of the implant. Bone surrounding the implant can only grow into the coating itself. Bone cannot grow through the coating and into the metallic substrate. The depth of bone growth into the implant is limited to the depth of the porous coating. Bone simply cannot grow completely through the implant.

SUMMARY OF THE INVENTION

One example embodiment is a dental implant with a coronal body that connects to a bone fixation body. The bone fixation body has a porous structure and also includes an internal cavity with a substance that stimulates bone growth. The porous structure extends through a center of the bone fixation body in a cross-sectional view of the bone fixation body.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a side view of one embodiment of a dental implant.

FIG. 2 is a cross-sectional view of the implant of FIG. 1 embedded in a jawbone of a patient.

FIG. 3 is a side view of another embodiment of a dental implant.

FIG. 4 is a cross-sectional view of FIG. 3.

2

FIG. 5 is a side view of yet another embodiment of a dental implant.

FIG. 6 is a cross-sectional view of FIG. 5.

FIG. 7 is side view of another embodiment of a dental implant.

FIG. 8 is a top view of the FIG. 7.

FIG. 9 is an alternate top view of FIG. 7.

FIG. 10A is a side view of another example embodiment of a dental implant.

FIG. 10B is a cross-sectional view of FIG. 10A taken along lines 10B-10B.

FIG. 11A is a side view of another example embodiment of a dental implant.

FIG. 11B is a cross-sectional view of FIG. 11A taken along lines 11B-11B.

FIG. 12A is a side view of another example embodiment of a dental implant.

FIG. 12B is a cross-sectional view of FIG. 12A taken along lines 12B-12B.

FIG. 12C is a cross-sectional view of FIG. 12B taken along lines 12C-12C.

FIG. 12D is a cross-sectional view of FIG. 12B taken along lines 12D-12D.

FIG. 13 is a side view of another example embodiment of a dental implant.

FIG. 14 is a partial cross-sectional view of a dental implant embedded in a jawbone of a patient.

FIG. 15 is a partial cross-sectional view of a coronal end of another example embodiment of a dental implant.

DETAILED DESCRIPTION

Referring to FIGS. 1 and 2, an implant 10 is shown according to an example embodiment. Implant 10 is preferably constructed of a biocompatible material such as titanium and includes two primary components or bodies, a coronal body 14 and a bone fixation body 16.

The coronal body 14 has a short cylindrical configuration that extends from a proximal end surface 20 to a distal end surface 22. A transgingival section 24 is formed with a smooth outer surface. A dental interface 26 extends upwardly and adjacent the transgingival section. This interface (also referred to as an abutment-engaging end) is formed as a male hexagonal connector. The interface can have other embodiments, such as splines, internal and external octagons, stars, and other polygons. A threaded bore 28 extends into the coronal body and is adapted to receive a fixation screw for connecting the dental implant to a dental component, such as an abutment, prosthesis, healing collar, or the like. Preferably, the coronal body 14 is formed of a biocompatible metal, such as a solid metal piece of titanium or titanium alloy. The body can be machined to have a size and shape shown in the figures.

The bone fixation body 16 has an elongated cylindrical shape that extends from a proximal end 30 to a rounded distal end 32. Body 16 is formed from a porous metal, such as titanium. Preferably, the body has a completely porous structure that extends throughout the entire body from the proximal to distal ends. Specifically, as shown in FIG. 2, body 16 does not include a metal substrate. The distal end surface 22 of coronal body 14 connects or fuses to the proximal end 30 of the bone fixation body 16 at a junction 40.

FIG. 2 shows the implant 10 embedded in a jawbone 34 of a patient. Preferably, the length of the body 16 extends along the region where the implant contacts surrounding bone 36 once the implant is implanted into the jawbone. The transgingival section 24 extends along the gum tissue or gingival tissue 38.

US 8,684,734 B1

3

As noted, the bone fixation body **16** has a porous structure that extends from the outer surface and throughout the body. By "porous," it is meant that the material at and under the surface is permeated with interconnected interstitial pores that communicate with the surface. The porous structure can be formed by sintering titanium or titanium alloy powder, metal beads, metal wire mesh, or other suitable materials.

The porous structure of body **16** is adapted for the ingrowth of cancellous and cortical bone spicules. More particularly the size and shape of the porous structure emulates the size and shape of the porous structure of natural bone. Preferably, the average pore diameter of body **16** is about 40 μm to about 800 μm with a porosity from about 45% to 65%. Further, the interconnections between pores can have a diameter larger than 50-60 microns. In short, the geometric configuration of the porous structure should encourage natural bone to migrate and grow into and throughout the entire body **16**.

Preferably, body **16** is created with a sintering process. One skilled in the art will appreciate that many variations exist for sintering, and some of these variations may be used to fabricate example embodiments. In a preferred embodiment, the coronal body is prepared using machining techniques. Next, a ceramic mold is provided. The mold has a first cavity that is sized and shaped to match the size and shape of the bone fixation body. In this first cavity, the sintering material can be placed. The mold also has a second cavity that is adjacent and connected to the first cavity. This second cavity is sized and shaped to receive the coronal body. The coronal body is positioned in the second cavity such that the distal end surface is adjacent and continuous with the first cavity.

The sintering material is then placed into the first cavity. This material may be a titanium alloy powder, such as Ti-6Al-4V. Some of this powder will contact the distal end surface of the coronal body. The mold is then heated to perform the sintering process. During this process, as the material in the first cavity heats and sinters, the bone fixation body forms and simultaneously bonds or fuses to the distal end surface of the coronal body.

The size and shape of the pores and porous structure produced in the first cavity depend on many factors. These factors include, for example, the temperature obtained in the furnace, the sintering time, the size and shape of sintering material, the composition of the sintering material, and the type of ceramic mold used. These factors (and others) can be varied to produce a bone fixation body in accordance with an example embodiment. Further, these factors (and others) can be varied to produce a strong bond between the bone fixation body and coronal body.

Once the sintering process is finished, the distal surface of the coronal body is directly fused to the bone fixation body. These two bodies are now permanently connected together to form the dental implant.

In the aforementioned sintering process, the bone fixation body simultaneously forms and attaches to the coronal body. One skilled in the art though will appreciate that each of these bodies can be fabricated independently and subsequently connected together. If the bodies are made separately, then they may be attached or fused together using welding or brazing techniques, for example.

FIGS. **3** and **4** show another implant **50** according to another example embodiment. With some differences, implant **50** is similarly configured to the implant **10**. As one difference, the bone fixation body **52** has a gradual and continuous taper that extends from the proximal end **54** to the distal end **56**. Further, the coronal body **60** has two different and distinct regions on the outer surface. A first region **62** has a smooth outer surface. A second region **64** has a bone-

4

engaging surface that is contiguous and adjacent to the first region **62** on one side and contiguous and adjacent the porous bone fixation body **52** on the other side. The second region is non-porous and can be formed with various techniques. These techniques include, for example, coating with HA, grit-blasting, etching, micro-texturing, other non-porous surface treatments, or combinations of these techniques. This surface is provided as an intermediate zone between the porous body and the smooth first region **62**.

FIGS. **5** and **6** show another implant **70** according to another example embodiment. With some differences, implant **70** is similarly configured to the implant **10**. As one difference, implant **70** has a bone fixation body **72** with an outer surface that has a plurality of undulation **74**, such as hills and valleys. These undulations are adapted to firmly secure the implant into the jawbone after the implant is placed therein. Further, the coronal body **80** has a dental interface **82** formed as an internal connection, such as an internal hexagon or other internal polygon. Further yet, the distal end surface **84** of the coronal body has an elongated protrusion **86** extending outwardly. This protrusion extends into the bone fixation body **72** and is adapted to increase the interface between the coronal body and bone fixation body. This protrusion may have various configurations, such as non-tapering, tapering, cylindrical, square, rectangular, hexagonal, octagonal, polygonal, or other shapes. Preferably, the protrusion is formed as a cylinder or square.

FIGS. **7** and **8** show another implant **100** according to another example embodiment. With some differences, implant **100** is similarly configured to the implant **10**. As one difference, implant **100** has a bone fixation body **102** with an uneven outer surface **104**. This surface is adapted to aid in bone integration and anti-rotation between the bone fixation body and surrounding bone. Further, the coronal body **110** has two different and distinct regions on the outer surface. A first region **112** has a smooth outer surface; and a second region **114** has a bone-engaging surface. These regions are similar to the regions **62** and **64** described in connection with FIGS. **3** and **4**.

As yet another difference, the coronal body **110** has a shape and size adapted to conform to the size and shape of natural teeth. The shape of this body is used, for example, in single-stage dental implants. The shape and size of the coronal body can thus contour the gingival or gum tissue to a natural shape that surrounds teeth. The size and shape, for example, can be similar to a molar, premolar, or incisor. FIG. **8** shows a top view of the coronal body **110** to have a shape of an oval or ellipse. As shown in FIG. **7**, coronal body can taper upwardly from the distal end **120** to proximal end **122**.

FIG. **9** shows a top view of the coronal body **110** in an alternate embodiment to have a triangular shape.

The bone fixation body can be adapted to induce bone growth into and entirely through the body. The body, for example, can be doped with biologically active substances. These substances may contain pharmaceutical agents to stimulate bone growth all at once or in a timed-release manner.

FIGS. **10A** and **10B** show a dental implant **200** that includes a coronal body **202** and a bone fixation body **204**. The coronal body **202** connects the bone fixation body **204** along an interface or juncture **206**.

The coronal body **202** has a short cylindrical configuration that extends from a proximal end surface **210** to a distal end surface **212**. External threads or grooves **214** extend along an exterior surface from the proximal end surface **210** to the distal end surface **212**. A dental interface **216** extends inwardly into the coronal body **202**. This interface includes a

US 8,684,734 B1

5

female hexagonal connector **220** and a threaded bore **222**. The interface can have other embodiments, such as friction-fit connections, splines, internal polygons, and/or external polygons.

The dental interface **216** connects to another dental component, such as an abutment or a tooth-shaped prosthesis. For example, a tooth-shaped prosthesis has a distal end with a male hexagonal connector that fits into and engages with the female hexagonal connector **220**. A screw extends from the tooth-shaped prosthesis and into the threaded bore **222** to connect the tooth-shaped prosthesis to the dental implant **200**.

In one example embodiment, the coronal body **202** is formed of a biocompatible metal, such as a solid metal piece of titanium, titanium alloy, or other biocompatible metals and/or biocompatible materials. The external threads or grooves **214** are machined into the exterior surface of the coronal body **202** and include a micro-textured surface, such as a micro-textured surface created by grit-blasting with HA.

The bone fixation body **204** has an elongated cylindrical shape that extends from a proximal end **230** at the interface **206** to a distal end **232**. An external surface **234** of the bone fixation body **204** includes threads, channels, and/or grooves **240** that extend from the proximal end **230** to the distal end **232**. An internal cavity **250** is located inside the bone fixation body **204** and extends from a location adjacent the interface **206** to the distal end **232**.

The internal cavity **250** forms a circular opening **252** at the distal end **232** of the bone fixation body **204**. The internal cavity **250** has a cylindrical shape and is centrally located inside of the bone fixation body **204** such that the sides or wall **254** of the cavity are equally spaced from the external surface **234**. The wall **254** includes grooves **256** that are formed in and spiral around the wall. These grooves **256** circumferentially extend around the wall **254** and form a continuous channel that extends from the circular opening **252** to an end surface **260** of the internal cavity **250**.

While the dental implant **200** is being positioned into the jawbone of the patient, bone enters and fills the internal cavity **250**. As the implant rotates and threads into the jawbone, bone is forced into the cavity and travels upwardly along the grooves **256** toward the end surface **260**. The grooves guide and facilitate the passage of bone into the internal cavity. For example, bone travels in the grooves **256** from the opening **252** to the end surface **260** in order to fill the internal cavity **250**.

Example embodiments are not limited to the grooves **256** spiraling around the wall **254**. For example, the grooves can be straight and extend parallel to each other from the opening **252** to the end surface **260**. Such grooves facilitate the transfer of bone into the cavity **250** while the dental implant **200** is being screwed, forced, or pressed into the jawbone. Alternatively, the cavity **250** can be formed without grooves.

The distal end **232** of the bone fixation body **204** includes a self-tapping end **270**. This self-tapping end **270** includes one or more of recesses, channels, threads, and/or flutes that create cutting edges **272**. These edges cut into bone and tissue as the implant is being placed into the jawbone. The recesses between the cutting edges also create pathways for holding and transporting bone and/or tissue displaced during insertion of the dental implant. Furthermore, these recesses align and/or communicate with the grooves **240** so bone can smoothly travel and flow from the self-tapping end **270**, into grooves **240**, and toward the coronal body **202**.

Since the bone fixation body **204** is formed from a porous structure, the external grooves **240**, the internal grooves **256**, and the self-tapping end **270** are formed into the porous structure of the bone fixation body. Thus, the porous structure

6

of the bone fixation body not only provides a structure for integrating with bone but also provides a surface to tap bone and move bone fragments.

As noted, the self-tapping end **270** is formed in the porous structure of the bone fixation body **204**. For example, the self-tapping end is formed from the material of the porous structure and is integrally formed with the rest of the bone fixation body. FIG. **10B** shows the porous structure of the self-tapping end **270** as being continuous with the remainder of the bone fixation body. Alternatively, the self-tapping end can include additional or different material (i.e., material not found in the remainder of the bone fixation body) to assist the distal end **232** in functioning to tap into the bone. For example, a coating is applied to the self-tapping end to provide additional strength to the porous structure at the end of the dental implant.

The grooves **240** spiral around the external surface **234** of the dental implant **200**. These grooves **240** circumferentially extend around the external surface **234** and form a continuous channel that extends from the distal end **232** to the proximal end **230** at the interface **206**. These grooves also align and/or communicate with the grooves **214** at the coronal body **202** so bone can smoothly travel and flow from the self-tapping end **270**, into grooves **240**, and into grooves **214**. The grooves along the exterior surface of the dental implant thus facilitate the movement of bone from the distal end of the implant to the proximal end of the dental implant. Bone travels in the grooves and around the exterior surface to facilitate place of the dental implant and to assist in forming a secure mechanical attachment between the dental implant and surrounding bone and tissue.

Example embodiments are not limited to the grooves **240** spiraling around the exterior surface **234**. For example, the grooves can be straight and extend parallel to each other from the opening **252** to the interface **206**. Such grooves facilitate the transfer of bone along the exterior surface **234** while the dental implant **200** is being forced or pressed into the jawbone. Alternatively, the exterior surface **234** can be formed without grooves (for example, formed of the porous material but with a smooth exterior surface).

FIGS. **11A** and **11B** show another dental implant **300** according to an example embodiment. With some differences, the implant **300** is similarly configured to the implant **200** in FIGS. **10A** and **10B**. As one difference, the implant **300** includes an internal cavity **310** that is enclosed within the bone fixation body **312**. This cavity **310** has a cylindrical shape, extends from near or adjacent the juncture **318** at the proximal end **314** of the bone fixation body to near the distal end **316** of the bone fixation body, and is completely enclosed within the bone fixation body. In one example embodiment, the bone fixation body **312** completely surrounds the sides, the top, and the bottom of the cylindrically-shaped internal cavity **310** (i.e., the internal cavity is surrounded on all sides by the porous structure). As such, the internal cavity **310** lacks an ingress (such as a hole or a passageway) for entering the cavity or an egress for exiting the cavity (such as a hole or a passageway). Nonetheless, the open-celled configuration of the porous structure of the bone fixation body does allow bone to grow into and through the bone fixation body. Thus, the internal cavity can still communicate with the bone fixation body and with bone external to the bone fixation body through the interconnected interstitial pores to enable bone growth since the internal cavity is surrounded by and formed within an open-celled porous structure.

As shown in FIG. **11B**, the internal cavity includes a substance **320** to cause or stimulate bone growth. This substance **320** fills the internal cavity **310** from a proximal end surface

US 8,684,734 B1

7

330 of the internal cavity to an oppositely disposed distal end surface 332 of the internal cavity.

In one example embodiment, the substance 320 is trapped within the enclosed internal cavity. For example, the substance is placed in the internal cavity during manufacturing or formation of the dental implant. Alternatively, the substance is placed in the internal cavity after the dental implant is constructed. For instance, a small opening is formed through the implant, the substance is placed through the opening and into the internal cavity, and then the opening is sealed and/or closed. By way of example, an opening or hole is placed at the end of the screw cavity 336. This opening or hole provides temporary access to the internal cavity 310. After the substance is placed in the internal cavity, the opening or hole is closed. As yet another example, the substance is liquefied and forced through the interconnected interstitial pores of the bone fixation body and into the internal cavity. In this example, the substance travels from an exterior surface 338, through the bone fixation body 312, and into the internal cavity 310.

FIGS. 12A, 12B, 12C, and 12D show another dental implant 400 according to an example embodiment. With some differences, the implant 400 is similarly configured to the implant 300 in FIGS. 11A and 11B. As one difference, the implant 400 includes an internal cavity 410 that has a shape of a wheel enclosed within the bone fixation body 404. This internal cavity has a cylindrically shaped main body portion 420 with a plurality of spokes or channels 430 that extend outwardly from the main body portion 420. The main body portion and the spokes are surrounded and enclosed within the bone fixation body (for example, in a similar manner as the internal cavity is enclosed within the bone fixation body discussed in connection with FIGS. 11A and 11B).

As shown in FIGS. 12B and 12C, the internal cavity 410 includes a substance 432 to cause or stimulate bone growth. This substance 432 fills the internal cavity 410 from a proximal end surface 434 of the internal cavity to an oppositely disposed distal end surface 436 of the internal cavity. In one example embodiment, the substance 432 is trapped within the internal cavity.

FIG. 12B shows a series of sets of spokes 438 that are stacked on top of each other inside the bone fixation body 404. Six sets of spokes are vertically arranged in the bone fixation body. These sets of spokes are evenly spaced apart from each other and extend outwardly from the main body portion 420. A first set of spokes 444 is located near the proximal end 434 of the internal cavity, and a sixth set of spokes 446 is located near the distal end 436 of the internal cavity.

FIG. 12C shows that each set of spokes includes four spokes 450A, 450B, 450C, and 450D that are evenly spaced from each other and radiate outwardly from the main body portion 420. These spokes are in fluid communication with each other, with the other spokes in the other sets, and with the main body portion such that the substance 432 located inside the cavity can flow or migrate among the sets of spokes and the main body portion. As discussed herein, the substance, however, is not limited to being a fluid, but can be a solid structure, such as a scaffold, a membrane, a powder, a metal, and/or a polymer.

FIG. 12C also shows that the internal cavity 410 is centrally located in the bone fixation body 404. An exterior wall 462 of this internal cavity is equally spaced from an exterior wall 466 of the bone fixation body 404.

The sets of spokes facilitate the dispersement and growth of bone throughout the bone fixation body 404. Specifically, the sets of spokes are filled with the substance 432, and this substance causes and/or encourages bone to grow from and

8

into the sets of spokes and surrounding areas of the bone fixation body. The sets of spokes assist in dispersing the substance 432 into a larger volume or area of the bone fixation body since these spokes radiate throughout the bone fixation body.

FIG. 12D shows a cross-section of the dental implant taken adjacent the interface 460. As shown, the porous structure continuously extends through an entire cross-sectional view of the bone fixation body at this location such that the porous structure includes a center 470 of the bone fixation body in the cross-sectional view. Thus, in this view, the porous structure completely fills the cross-section of the dental implant.

FIG. 13 shows another dental implant 500 according to an example embodiment. With some differences, the exterior configuration of this implant is similar to the exterior configuration of the dental implant 200 shown in FIG. 10A. As one difference, the dental implant 500 has three separate sections that include a coronal body 510, a bone fixation body 520, and a self-tapping body 530. The bone fixation body 520 has a structure and/or is formed of a material that is different than the coronal body 510 and the self-tapping body 530. For example, the bone fixation body 520 has a porous structure, while the coronal body 510 and the self-tapping body 530 have a non-porous structure (e.g., formed of solid titanium or titanium alloy with a roughened or porous surface).

In the example embodiment of FIG. 13, the bone fixation body 520 is positioned between the coronal body 510 and the self-tapping body 530. A proximal end 550 of the bone fixation body connects to the coronal body 510 along an interface 552, and a distal end 560 connects to the self-tapping body 530 along an interface 562. At the interfaces 552 and 562, the bone fixation body has a circular cross-section with the porous structure completely filling this cross-section (for example, as shown in the circular cross-section in FIG. 12D). These circular cross-sections of the bone fixation body connect to solid metal circular cross-sections of the coronal body 510 and the self-tapping body 530.

The coronal body 510 and the self-tapping body 530 are structurally stronger than the bone fixation body 520 since they are formed to have a non-porous structure whereas the bone fixation body is formed to have a porous structure. As such, the bone fixation body is configured so that bone can grow completely through the porous structure. By contrast, the coronal body and the self-tapping body are configured so that bone can grow into an outer surface but not into and through center of the bodies since these locations are filled with solid metal. For example, the outer surfaces of coronal body and the self-tapping body are micro-textured or covered with a porous structure. These surfaces can integrate with surrounding bone after the dental implant is implanted in the jawbone.

The dental implant 500 can have different interior configurations. In one example embodiment, the dental implant 500 is configured with an internal cavity as shown in FIG. 10B (see internal cavity 250 shown in FIG. 10B). As another example embodiment, the dental implant 500 is configured with an internal cavity as shown in FIG. 11B (see internal cavity 310 in FIG. 11B). As another example embodiment, the dental implant 500 is configured with an internal cavity as shown in FIG. 12B (see internal cavity 410 in FIG. 12B).

FIG. 14 is a partial cross-sectional view of a dental implant embedded in a jawbone of a patient. For example, this cross-section can represent the proximal end of the bone fixation body 204 of implant 200 shown in FIG. 10B. As another example, this cross-section can represent the proximal end of the bone fixation body 312 of the implant 300 shown in FIG.

US 8,684,734 B1

9

11B. As yet another example, this cross-section can represent the proximal end of the bone fixation body **710** of the implant **700** shown in FIG. **15**.

As shown in FIG. **14**, the dental implant **600** includes a bone fixation body **610** that is embedded in a jawbone **620** of a patient. This bone includes cortical bone and/or cancellous bone. The bone fixation body **610** includes an internal cavity **630** that is filled with a substance **640** to cause or stimulate bone growth.

Once the dental implant **600** is implanted into the jawbone **620**, bone simultaneously begins to grow with natural bone growing inwardly toward the internal cavity **630** and bone from the substance growing outwardly from the internal cavity **630** toward the natural bone **620** that is growing inwardly. Natural bone **620** surrounding the dental implant **600** begins to grow into the outer surface **650** of the bone fixation body **610**. At the same time, bone begins to grow outwardly from the internal cavity **630** and toward the outer surface **650**. The substance causes or stimulates bone to grow outwardly from the internal cavity.

The porous structure of the bone fixation body thus supports bone growth inwardly toward the center of the implant and outwardly away from the center of the implant. Thus, bone grows from two different and separately located sources (one source being the natural bone located outside of the dental implant and a second source being the substance **640** located inside of the dental implant). This process of concurrently growing bone from two different locations (i.e., from within the implant and from outside of the implant) decreases the time required for bone to grow throughout the dental implant including the center of the dental implant where the substance is located. For example, the time required for bone to grow from one side of the bone fixation body to an oppositely disposed side of the bone fixation body is reduced since bone is concurrently growing both toward the center of the bone fixation body and outwardly from this center immediately after the dental implant is implanted into the jawbone. This process also decreases the time required for bone to completely fill the porous structure of the bone fixation body since bone grows in multiple different directions. For instance, bone simultaneously grows in directions from the internal cavity through sides of the cavity, through the top of the cavity, and through the bottom of the cavity. Additionally, bone grows through the sides and the bottom of the exterior surfaces of the bone fixation body. The dental implant is thus able to more quickly fully integrate with bone after being implanted (for example, more quickly have bone grow throughout the entire structure of the bone fixation body). Growing bone from the center of the implant thus expedites the time required to complete the bone integration process.

FIG. **15** is a partial cross-sectional view of another example embodiment of a dental implant **700**. A proximal or coronal end **704** of this dental implant includes a metal dental interface **706** that is surrounded by a bone fixation body **710** having a porous structure.

The dental interface **706** extends inwardly into the bone fixation body **710**. This interface includes a female hexagonal connector **720** and a threaded bore **722** that engages with a screw. The interface can have other embodiments, such as friction-fit connections, splines, internal polygons, and/or external polygons.

The bone fixation body **710** includes an internal cavity **724** with a substance **726** to cause or stimulate bone growth. The configuration of the bone fixation body **710** below the dental interface **706** can vary. As one example, the configuration of the bone fixation body **710** below the dental interface **706** of FIG. **15** is shown in FIGS. **10A** and **10B** with bone fixation

10

body **204**, internal cavity **250**, and other aspects shown in these figures. As another example, the configuration of the bone fixation body **710** below the dental interface **706** of FIG. **15** is shown in FIGS. **11A** and **11B** with bone fixation body **312**, internal cavity **310**, and other aspects shown in these figures. As another example, the configuration of the bone fixation body **710** below the dental interface **706** of FIG. **15** is shown in FIGS. **12A-12C** with bone fixation body **404**, internal cavity **410**, and other aspects shown in these figures.

The dental interface **706** is formed of a biocompatible metal, such as a solid metal piece of titanium, titanium alloy, or other biocompatible metals and/or materials. By contrast, the bone fixation body **710** is formed of a porous structure. This dental interface is embedded or disposed in the porous structure.

In one example embodiment, the porous structure completely surrounds the exterior surface of the dental implant from its proximal end to its distal end. Since this porous structure also surrounds the proximal or coronal end **704** of the dental implant, bone can grow into the entire exterior surface area of the dental implant at the coronal end. For example, when the dental implant includes one of the configurations of the bone fixation body **710** below the dental interface **706** discussed herein (such as shown in FIGS. **10A**, **10B**, **11A**, **11B**, **12A**, and **12B**), then bone can grow into the entire outer surface of a porous structure of the dental implant. The implant in such embodiments does not include a non-porous outer surface. The implant in such embodiments, however, would include a solid metal coronal body that is embedded into the porous structure of the bone fixation body.

In an example embodiment, the porous structure of the bone fixation body is different than the structure of the substance located in the internal cavity in the bone fixation body. The geometry and material composition of the porous structure of the bone fixation body and the substance in the internal cavity both induce bone formation throughout the internal cavity and the bone fixation body. The geometry and material composition of the porous structure of the bone fixation body, however, also provides strength to the implant since it bears loads from mastication forces on the tooth prosthesis. A majority of these loads pass along the bone fixation body and not to the substance located in the internal cavity. As such, the geometry and material composition of the substance can be for stimulating bone growth, whereas the geometry and material composition of the bone fixation body can be for stimulating bone growth and providing strength to the dental implant.

By way of example, the substance includes a porous structured scaffold that is inserted or fabricated in the internal cavity of the bone fixation body. This scaffold has a geometry and material composition to induce bone growth through the internal cavity and into the surrounding walls of the bone fixation body. This scaffold would not have to support the mastication loads since the bone fixation body surrounding the internal cavity supports these loads. Alternatively, the geometry and material composition of the substance located in the internal cavity can also be for providing strength to the dental implant.

In an example embodiment, the substance in the internal cavity is activated when the implant is placed into the jawbone of the patient. As one example, looking to FIG. **10B**, the substance is located in the internal cavity **250**. While the dental implant **200** is being placed into the jawbone, bone, tissue, blood, and other substances come in contact with the substance in the internal cavity and activate this substance to begin stimulating bone growth in the internal cavity. As another example, looking to FIG. **11B**, while the dental

US 8,684,734 B1

11

implant **300** is being placed into the jawbone, a fluid (including one or more of bone, tissue, blood, and other substances created from the implantation procedure) seeps or passes through the porous structure of the bone fixation body **312** and comes in contact with the substance **320** in the internal cavity **310**. This fluid activates this substance **320** to begin stimulating bone growth in the internal cavity **310**. Alternatively, bone growth and bone stimulation properties of the substance are activated with an agent (for example, an external agent applied to the structure and/or the substance during implantation).

FIGS. **10B**, **11B**, and **12B** show the dental implant with an internal cavity. The size and shape of this internal cavity can vary depending on, for example, the size and shape of the dental implant, the substance included in the internal cavity, the mechanical properties desired for the implant, and the material used to fabricate the porous structure. By way of example, these shapes of the internal cavity include, but are not limited to, cylinders (such as right circular cylinders having a cross-section as a circle, elliptic cylinders having a cross-section as an ellipse, hyperbolic cylinders having a cross-section as a hyperbola, parabolic cylinders having a cross-section as a parabola, oblique cylinders having top and bottom surfaces displaced from each other, and tapered cylinders), cones (such as right cones, oblique cones, truncated cones, and elliptical cones), wheels, spheres, cuboids, polyhedrons, polytopes, pyramids, linear and non-linear tunnels and pathways, symmetric and asymmetric voids and cavities, three dimensional shapes (such as shapes having curved lines, straight lines, closed configurations, and/or open configurations), and combinations of these shapes.

Additionally, the size and shape of the internal cavity can be adjusted to provide a closer biomechanical match of strength, stiffness, and architectural structure between the dental implant and the surrounding bone. The combination of pores in the porous structure and space of the internal cavity reduces the overall stiffness values of the dental implant so it can more closely resemble the stiffness values and properties of natural bone.

FIGS. **2**, **4**, **6**, **10B**, **11B**, and **12B** show that the porous structure of the bone fixation body connects to the metal coronal body at an interface that has a circular or elliptical cross-section (the particular cross-sectional shape of this interface depends on the shape of the bone fixation and coronal bodies and includes shapes other than circular or elliptical). For example, if the bone fixation body and the coronal body are both formed as right cylinders at the juncture of their interface, the interface (when viewed in a cross-section) is circular. Such an interface includes the entire volume of this circular cross-section since the circular cross-section of the bone fixation body abuts the circular cross-section of the coronal body. This abutment of two circular cross-sections (or other shaped cross-sections) provides strength to the implant at the juncture where the non-porous structure of the coronal body connects to the porous structure of the bone fixation body.

FIGS. **2**, **4**, **6**, **10B**, **11B**, **12B**, **13**, and **15** show that a bone fixation body with a porous structure connects to a coronal body with a non-porous structure (for example, the coronal body has as a solid metal structure formed of titanium or titanium alloy). The structure of the coronal body is thus stronger than the structure of the bone fixation body. The coronal body is formed of a non-porous structure to provide strength to the dental implant and structural support for the porous structured bone fixation body. This added strength is useful since mastication forces transfer from the tooth prosthesis to the dental implant at the coronal body. Alternatively,

12

the coronal body can be formed of a porous structure, but this porous structure should be strong enough to endure the mastication forces encountered at the coronal end of the dental implant.

The substance to cause or stimulate bone growth can be formed from a variety of different materials and different processes. As one example, the substance includes a mixture of one or more bone morphogenetic proteins (BMPs) and one or more carriers. For instance, this mixture includes BMP **4**, collagen, and a polymer, such as poly (lactic-co-glycolic acid) (PLGA) or poly (L-lactide) (PLLA). As another example, the substance includes one or more of natural bone and/or tissue and/or blood from the patient receiving the implant, tantalum, an acrylate based polymer, biphasic calcium phosphate (BCP), carboxymethylcellulose (CMC), hydroxypropylmethylcellulose (HPMC), hydroxyapatite (HA), tricalcium phosphate (TCP), stem cells (including human embryonic stem cells and adult stem cells), human bone-derived cells (hPBDs), biodegradable polymers (such as poly (glycolic acid) (PGA) and poly (lactic acid) (PLA)), poly(α -hydroxy acids), calcium-phosphates (CaP) (such as β -tricalcium phosphate (β -TCP) and α -tricalcium phosphate (α -TCP)), poly(D,L-lactide) (PDLLA), injectable bone (for example, injectable bone that includes calcium phosphate and/or calcium sulphate), allotransplantation (i.e., bone and/or tissue from a same species, such as allografts and autografts), xenotransplantation (i.e., bone and/or tissue from another species), rattan wood, bioactive glasses (such as a bioactive glass foam scaffold), cancellous structured titanium, resorbable porous structures, class A and class B bioactive materials, bone grafts, and other materials that cause and/or stimulate bone growth.

Furthermore, the substance can be formed with various geometric configurations, such as including one or more of a liquid, a powder, and a solid. These configurations include both porous structures and non-porous structures. By way of example, the substance is formed into a three-dimensional porous scaffold and placed in the internal cavity (for example, PGA, PLA, and/or PLGA scaffolds). The pore size and porosity of the scaffold can be optimized to induce colonization and proliferation of cells. For example, the pore sizes range from about 150 μm -700 μm , and the porosity of the scaffold ranges from about fifty percent (50%) to ninety percent (90%).

As discussed herein, the porous structure of the substance and/or the bone fixation body can be formed from a variety of different materials and different processes. As one example, the porous structure is formed from one or more of polymers, ceramics, and biocompatible metals and metal alloys. For example, the porous structure is constructed with tantalum, titanium, a titanium (Ti) alloy, such as titanium with one or more of zirconium (Zr), niobium (Nb), tin (Sn), silicon (Si), molybdenum (Mo), and tantalum (Ta)), biocompatible polymer, and/or a biocompatible metal or metal alloy.

By way of example, the porous structure is formed from one of a casting process and/or a powder metallurgy process. The casting process can include one or more of vacuum melting and annealing, hot rolling, scale removal, machining, and surface preparation. The powder metallurgy process can include one or more of a pre-alloying process (such as fabricating alloyed powder using gas atomization and melting) and a blending of metals to obtain a predetermined alloy composition. Metal powder is then cold pressed into a shaped and sintered. The porous structure can also be fabricated using one or more of sintering, casting, plasma-spraying, sputter deposition techniques, and metallic deposition techniques.

US 8,684,734 B1

13

As another example, the porous structure is formed by coating a solid skeleton or a hollow skeleton with one or more of a polymer, a metal, and/or a metal alloy. For example, a carbon skeleton is coated with tantalum using a vapor deposition process. For instance, tantalum is deposited on a vitreous carbon foam structure.

As yet another example, the porous structure is formed from a metal injection molding (MIM) process. For example, metals and/or polymers are mixed to form a feedstock that is then shaped. The polymer is then removed, and the structure is heated, machined, and coated.

Furthermore, the porous structure can include open cells (i.e., pores connected to each other through channels, voids, interstices, etc.), closed cells (i.e., pores disconnected from each other), and combinations of open and closed cells.

Additionally, the porosity of the porous structure can be constant throughout the porous structure or change within the porous structure. For instance, the porous structure can have a gradient porosity in which the porosity changes from the surface of the bone fixation body to the center of the bone fixation body (for example, the porosity near the surface of the bone fixation body is different than the porosity inside the internal cavity).

The porosity can also increase or decrease at different locations along the dental implant. For instance, the porosity of the porous structure where the bone fixation body contacts cortical bone can be different than the porosity where the bone fixation body contacts cancellous bone. The porosity of the porous structure where the dental implant contacts cortical bone can be lower than the porosity of the porous structure where the dental implant contacts cancellous bone. Looking to FIG. 15 for example, the coronal body 704 where the dental implant 700 contacts cortical bone has a different porosity than where the bone fixation body 710 contacts cancellous bone (e.g., locations along the bone fixation body below the coronal body). Thus, the bone fixation body 710 can have a first porosity at the coronal end and a second, different porosity at other locations, such as below the coronal end and/or in the internal cavity 724.

Although illustrative embodiments have been shown and described, a wide range of modifications, changes, and substitutions is contemplated in the foregoing disclosure; and some features of the embodiments may be employed without a corresponding use of other features. Accordingly, it is appropriate that the appended claims be construed broadly and in a manner consistent with the scope of the embodiments disclosed herein.

What is claimed is:

1. A dental implant, comprising:

a coronal body having a proximal end with a connection shaped as a polygon to receive a dental component, having a distal end surface with an elongated protrusion that extends outwardly therefrom, and being formed of solid metal; and

an elongated cylindrical porous body formed as a porous metal structure that is uniform and that includes a proximal end that engages the distal end surface of the coronal body at an interface,

wherein the distal end surface of the coronal body has a circular shape, the proximal end of the porous body has a circular shape, and the solid metal of the circular shape of the coronal body interfaces with the porous metal structure of the circular shape of the porous body at the interface, and

wherein the elongated protrusion of the coronal body includes a polygonal shape that extends into an opening of the porous body such that the porous metal structure

14

completely surrounds and engages an exterior surface of the elongated protrusion that extends into the porous body.

2. The dental implant of claim 1, wherein the elongated protrusion increases an engaging interface between the coronal body and the porous body since the coronal body engages the porous body at the exterior surface of the elongated protrusion that extends into the porous body and at the interface where the solid metal of the circular shape of the coronal body interfaces with the porous metal structure of the circular shape of the porous body.

3. The dental implant of claim 1, wherein the coronal body includes an exterior surface that is microtextured and an exterior surface that is smooth.

4. The dental implant of claim 1, wherein the porous body is doped with an agent to stimulate bone growth into the porous body.

5. The dental implant of claim 1, wherein the circular shape of the coronal body at the interface and the circular shape of the porous body at the interface include one of a shape of a circle and a shape of an oval.

6. The dental implant of claim 1, wherein the porous body has one of a continuous taper shape in a side view and a straight cylindrical shape in the side view.

7. The dental implant of claim 1, wherein the porous body is not a coating but is made separately from the coronal body and then attached to the coronal body at the interface.

8. A dental implant, comprising:

a coronal body formed of solid metal and including a proximal end with a connection shaped to connect with a dental component and a distal end surface with an elongated protrusion that extends outwardly from the distal end surface; and

an elongated cylindrical porous body having a proximal end engaged with the distal end surface of the coronal body at an interface and having an interconnected porous structure;

wherein the interconnected porous structure includes metal, the distal end surface of the coronal body has a circular shape, the proximal end of the porous body has a circular shape, and at the interface the circular shape of the coronal body includes the solid metal that interfaces with the circular shape of the porous body that includes the interconnected porous structure, and

wherein the porous body is made separately from the coronal body to have a uniform porosity and subsequently attached to the coronal body at the interface such that the elongated protrusion of the coronal body extends into an opening at the proximal end of the porous body such that the interconnected porous structure surrounds and engages the elongated protrusion that extends into the opening of the porous body.

9. The dental implant of claim 8, wherein the porous body has a size and shape that emulate a size and shape of natural human bone.

10. The dental implant of claim 8, wherein the circular shape of the coronal body at the interface and the circular shape of the porous body at the interface include one of a shape of a circle and a shape of an oval.

11. The dental implant of claim 8, wherein the porous body is doped with an agent to stimulate bone growth in a time-released manner into the porous body.

12. The dental implant of claim 8, wherein an exterior surface of the coronal body includes a first region with a smooth outer surface and a second region with a microtextured surface that is contiguous and adjacent the first region.

US 8,684,734 B1

15

13. The dental implant of claim 8, wherein the elongated protrusion is shaped as one of a square, a rectangle, a hexagon, and an octagon.

14. A dental implant, comprising:

a cylindrical coronal body formed of solid metal, including
a proximal end with an abutment-engaging end, and
including a distal end surface with an elongated protrusion that extends outwardly therefrom; and
an elongated cylindrical porous body having a uniform porosity and having a proximal end engaged with the
distal end surface of the coronal body at an interface and
having an interconnected porous structure that includes metal,

wherein the distal end surface of the coronal body at the interface has a circular shape that is the solid metal, the proximal end of the porous body at the interface has a circular shape that is the interconnected porous structure, and the circular shape of the coronal body engages with the circular shape of the porous body at the interface,

wherein the elongated protrusion of the coronal body includes an elongated polygon that extends into an opening of the porous body such that the interconnected porous structure surrounds and engages an exterior surface of the elongated polygon that extends into the porous body, and

wherein the elongated protrusion increases an interface between the coronal body and the porous body since the coronal body engages the porous body at the exterior surface of the elongated polygon that extends into the porous body and at the interface where the solid metal of the circular shape of the coronal body interfaces with the interconnected porous structure of the circular shape of the porous body.

15. The dental implant of claim 14, wherein the porous body has a porous structure that emulates a porous structure of natural human bone.

16. The dental implant of claim 14, wherein the porous body is doped with an agent to stimulate bone growth into the porous body.

17. The dental implant of claim 14, wherein the porous body has one of a shape of a continuous taper in a side view and a straight cylinder in the side view.

18. The dental implant of claim 14, wherein the elongated polygon of the elongated protrusion is shaped as one of a square, a rectangle, a hexagon, and an octagon.

19. The dental implant of claim 14, wherein the porous body is made separately from the coronal body and then attached to the coronal body at the interface and at the exterior surface of the elongated polygon.

20. A dental implant, comprising:

a coronal body that includes a proximal end engageable with a dental component, includes an end surface with an elongated protrusion that extends outwardly from the end surface, and is solid metal; and

an elongated cylindrical bone fixation body that includes a porous metal structure with a proximal end that engages the end surface of the coronal body at an interface,

wherein the end surface of the coronal body has a shape, the proximal end of the bone fixation body has a shape, and the solid metal of the shape of the coronal body engages with the porous metal structure of the shape of the bone fixation body at the interface,

wherein the elongated protrusion of the coronal body extends into an opening of the bone fixation body such

16

that the porous metal structure surrounds and engages an exterior surface of the elongated protrusion that extends into the bone fixation body,

wherein the bone fixation body is made separately from the coronal body to have a uniform porous metal structure and then attached to the coronal body at the interface and at the exterior surface of the elongated protrusion, and wherein the porous metal structure of the bone fixation body emulates a porous structure of natural human bone.

21. The dental implant of claim 20, wherein the porous body has a structure that emulates a structure of natural human bone.

22. The dental implant of claim 20, wherein the coronal body is fabricated independently from the bone fixation body and is subsequently fused to the bone fixation body.

23. The dental implant of claim 20, wherein the elongated protrusion has a polygonal shape and increases an interface between the coronal body and the bone fixation body.

24. The dental implant of claim 20, wherein the coronal body has an outer surface with a first region adjacent a second region in which the first region is smooth and the second region is non-porous and micro-textured.

25. A method, comprising:

machining a coronal body of a dental implant that is formed of solid metal to include a proximal end with a connection shaped to receive a dental component and a distal end surface with an elongated protrusion that extends outwardly therefrom;

fabricating, separately from the coronal body, a porous body of the dental implant having an elongated cylindrical shape with a uniform porous metal structure that extends throughout the porous body and with a central opening at a proximal end of the porous body; and

attaching, after the porous body is separately fabricated from the coronal body, the porous body to the coronal body to create the dental implant with an elongated cylindrical shape such that the elongated protrusion of the coronal body extends into the central opening of the porous body,

wherein the distal end surface of the coronal body has a circular shape, the proximal end of the porous body has a circular shape, and the solid metal of the circular shape of the coronal body interfaces with the porous metal structure of the circular shape of the porous body when the elongated protrusion of the coronal body extends into the opening of the porous body.

26. The method of claim 25 further comprising:

fusing the porous body to the coronal body after the porous body is separately fabricated from the coronal body.

27. A method, comprising:

forming a coronal body of a dental implant from solid metal with a proximal end having a connection that engages a dental component and with a distal end surface having an elongated male protrusion that extends outwardly therefrom;

forming, separately from the coronal body, a porous body of the dental implant having a uniform porous metal structure and having a non-tapering cylindrical shape with a central opening at a proximal end; and

engaging, after the coronal body and the porous body are separately formed from each other, the porous body to the coronal body to form the dental implant with an elongated cylindrical shape such that the elongated male protrusion of the coronal body extends into the central opening of the porous body and forms a core for the porous body,

US 8,684,734 B1

17

wherein the elongated male protrusion of the coronal body
has a cylindrical shape with a polygonal external surface
that extends into the central opening of the porous body
such that the porous metal structure surrounds and
engages the polygonal external surface that extends into 5
the porous body.

* * * * *

18

CIVIL COVER SHEET

USDC IN/ND case 3:14-cv-01300-JVB-JEM document 1-2 filed 04/15/14 page 1 of 2

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

I. (a) PLAINTIFFS

Four Mile Bay LLC

(b) County of Residence of First Listed Plaintiff Medina County, Ohio
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorney's (Firm Name, Address, and Telephone Number)

Wawrzyn LLC, 233 S. Wacker Drive, 84th Floor, Chicago, IL 60606
(312) 283-8332

DEFENDANTS

Zimmer Holdings, Inc.
Zimmer Dental Inc.

County of Residence of First Listed Defendant _____
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE
LAND INVOLVED.

Attorneys (If Known)

II. BASIS OF JURISDICTION

(Place an "X" in One Box Only)

- ☐ 1 U.S. Government Plaintiff
- ☒ 3 Federal Question (U.S. Government Not a Party)
- ☐ 2 U.S. Government Defendant
- ☐ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES

(Place an "X" in One Box for Plaintiff and One Box for Defendant)

- | | PTF | DEF | | PTF | DEF |
|---|----------------------------|----------------------------|--|----------------------------|----------------------------|
| Citizen of This State | <input type="checkbox"/> 1 | <input type="checkbox"/> 1 | Incorporated <i>or</i> Principal Place of Business In This State | <input type="checkbox"/> 4 | <input type="checkbox"/> 4 |
| Citizen of Another State | <input type="checkbox"/> 2 | <input type="checkbox"/> 2 | Incorporated <i>and</i> Principal Place of Business In Another State | <input type="checkbox"/> 5 | <input type="checkbox"/> 5 |
| Citizen or Subject of a Foreign Country | <input type="checkbox"/> 3 | <input type="checkbox"/> 3 | Foreign Nation | <input type="checkbox"/> 6 | <input type="checkbox"/> 6 |

IV. NATURE OF SUIT

(Place an "X" in One Box Only)

CONTRACT	TORTS	FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
<input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excl. Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	PERSONAL INJURY <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury	<input type="checkbox"/> 362 Personal Injury - Med. Malpractice <input type="checkbox"/> 365 Personal Injury - Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability PERSONAL PROPERTY <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability	<input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 PROPERTY RIGHTS <input type="checkbox"/> 820 Copyrights <input checked="" type="checkbox"/> 830 Patent <input type="checkbox"/> 840 Trademark	<input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit <input type="checkbox"/> 490 Cable/Sat TV <input type="checkbox"/> 810 Selective Service <input type="checkbox"/> 850 Securities/Commodities/Exchange <input type="checkbox"/> 875 Customer Challenge 12 USC 3410 <input type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 892 Economic Stabilization Act <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 894 Energy Allocation Act <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 900 Appeal of Fee Determination Under Equal Access to Justice <input type="checkbox"/> 950 Constitutionality of State Statutes
REAL PROPERTY <input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property	CIVIL RIGHTS <input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 444 Welfare <input type="checkbox"/> 445 Amer. w/Disabilities - Employment <input type="checkbox"/> 446 Amer. w/Disabilities - Other <input type="checkbox"/> 440 Other Civil Rights	<input type="checkbox"/> 510 Motions to Vacate Sentence Habeas Corpus: <input type="checkbox"/> 530 General <input type="checkbox"/> 535 Death Penalty <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Condition	LABOR <input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Mgmt. Relations <input type="checkbox"/> 730 Labor/Mgmt. Reporting & Disclosure Act <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Empl. Ret. Inc. Security Act IMMIGRATION <input type="checkbox"/> 462 Naturalization Application <input type="checkbox"/> 463 Habeas Corpus - Alien Detainee <input type="checkbox"/> 465 Other Immigration Actions	SOCIAL SECURITY <input type="checkbox"/> 861 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g)) FEDERAL TAX SUITS <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS—Third Party 26 USC 7609

V. ORIGIN

(Place an "X" in One Box Only)

- ☒ 1 Original Proceeding
- ☐ 2 Removed from State Court
- ☐ 3 Remanded from Appellate Court
- ☐ 4 Reinstated or Reopened
- ☐ 5 Transferred from another district (specify)
- ☐ 6 Multidistrict Litigation
- ☐ 7 Appeal to District Judge from Magistrate Judgment

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):

35 U.S.C. § 271, et seq.

Brief description of cause:

Patent Infringement

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23

DEMAND \$

CHECK YES only if demanded in complaint:

JURY DEMAND: ☒ Yes ☐ No**VIII. RELATED CASE(S) IF ANY**

(See instructions):

JUDGE

DOCKET NUMBER

DATE

SIGNATURE OF ATTORNEY OF RECORD

04/15/2014

Stephen C. Jarvis

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

USDC IN/ND case 3:14-cv-01300-JVB-JEM document 1-2 filed 04/15/14 page 2 of 2
INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I. (a) Plaintiffs-Defendants. Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) County of Residence. For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) Attorneys. Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. Jurisdiction. The basis of jurisdiction is set forth under Rule 8(a), F.R.C.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.

United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.

United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.

Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.

Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; federal question actions take precedence over diversity cases.)

III. Residence (citizenship) of Principal Parties. This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. Nature of Suit. Place an "X" in the appropriate box. If the nature of suit cannot be determined, be sure the cause of action, in Section VI below, is sufficient to enable the deputy clerk or the statistical clerks in the Administrative Office to determine the nature of suit. If the cause fits more than one nature of suit, select the most definitive.

V. Origin. Place an "X" in one of the seven boxes.

Original Proceedings. (1) Cases which originate in the United States district courts.

Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.

Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.

Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.

Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.

Multidistrict Litigation. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407. When this box is checked, do not check (5) above.

Appeal to District Judge from Magistrate Judgment. (7) Check this box for an appeal from a magistrate judge's decision.

VI. Cause of Action. Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553
 Brief Description: Unauthorized reception of cable service

VII. Requested in Complaint. Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.

Demand. In this space enter the dollar amount (in thousands of dollars) being demanded or indicate other demand such as a preliminary injunction.

Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. Related Cases. This section of the JS 44 is used to reference related pending cases if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.

UNITED STATES DISTRICT COURT

for the

Northern District of Indiana



FOUR MILE BAY LLC

Plaintiff(s)

v.

ZIMMER HOLDINGS, INC.

ZIMMER DENTAL INC.

Defendant(s)

Civil Action No. 3:14-cv-1300

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Zimmer Holdings, Inc.
C/O Corporation Service Company
2711 Centerville Rd, Ste 400
Wilmington, DE 19808

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Wawrzyn LLC
Stephen C. Jarvis
233 S. Wacker Drive, 84th Floor
Chicago, IL 60606

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

Signature of Clerk or Deputy Clerk

Civil Action No. 3:14-cv-1300

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____
was received by me on *(date)* _____.

☐ I personally served the summons on the individual at *(place)* _____
_____ on *(date)* _____; or

☐ I left the summons at the individual's residence or usual place of abode with *(name)* _____
_____, a person of suitable age and discretion who resides there,
on *(date)* _____, and mailed a copy to the individual's last known address; or

☐ I served the summons on *(name of individual)* _____, who is
designated by law to accept service of process on behalf of *(name of organization)* _____
_____ on *(date)* _____; or

☐ I returned the summons unexecuted because _____; or

☐ Other *(specify)*:

My fees are \$ _____ for travel and \$ _____ for services, for a total of \$ 0.00.

I declare under penalty of perjury that this information is true.

Date: _____

Server's signature


Printed name and title

Server's address

Additional information regarding attempted service, etc:

UNITED STATES DISTRICT COURT

for the

Northern District of Indiana 

FOUR MILE BAY LLC

Plaintiff(s)

v.

ZIMMER HOLDINGS, INC.

ZIMMER DENTAL INC.

Defendant(s)

Civil Action No. 3:14-cv-1300

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Zimmer Dental Inc.
C/O Corporation Service Company
2711 Centerville Rd, Ste 400
Wilmington, DE 19808

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Wawrzyn LLC
Stephen C. Jarvis
233 S. Wacker Drive, 84th Floor
Chicago, IL 60606

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

Signature of Clerk or Deputy Clerk

Civil Action No. 3:14-cv-1300

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____
was received by me on *(date)* _____.

☐ I personally served the summons on the individual at *(place)* _____
_____ on *(date)* _____; or

☐ I left the summons at the individual's residence or usual place of abode with *(name)* _____
_____, a person of suitable age and discretion who resides there,
on *(date)* _____, and mailed a copy to the individual's last known address; or

☐ I served the summons on *(name of individual)* _____, who is
designated by law to accept service of process on behalf of *(name of organization)* _____
_____ on *(date)* _____; or

☐ I returned the summons unexecuted because _____; or

☐ Other *(specify)*:

My fees are \$ _____ for travel and \$ _____ for services, for a total of \$ 0.00.

I declare under penalty of perjury that this information is true.

Date: _____

Server's signature

Printed name and title

Server's address

Additional information regarding attempted service, etc:

TO: Mail Stop 8 Director of the U.S. Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450	REPORT ON THE FILING OR DETERMINATION OF AN ACTION REGARDING A PATENT OR TRADEMARK
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In Compliance with 35 U.S.C. § 290 and/or 15 U.S.C. § 1116 you are hereby advised that a court action has been
 filed in the U.S. District Court _____ for the Northern District of Indiana _____ on the following

☐ Trademarks or ☒ Patents. (☐ the patent action involves 35 U.S.C. § 292.):

DOCKET NO. 3:14-cv-1300	DATE FILED 4/15/2014	U.S. DISTRICT COURT for the Northern District of Indiana
PLAINTIFF Four Mile Bay LLC		DEFENDANT Zimmer Holdings, Inc. Zimmer Dental Inc.
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1 8,684,734	4/1/2014	Four Mile Bay LLC
2		
3		
4		
5		

In the above—entitled case, the following patent(s)/ trademark(s) have been included:

DATE INCLUDED	INCLUDED BY <input type="checkbox"/> Amendment <input type="checkbox"/> Answer <input type="checkbox"/> Cross Bill <input type="checkbox"/> Other Pleading	
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1		
2		
3		
4		
5		

In the above—entitled case, the following decision has been rendered or judgement issued:

DECISION/JUDGEMENT

CLERK	(BY) DEPUTY CLERK	DATE
-------	-------------------	------

Copy 1—Upon initiation of action, mail this copy to Director Copy 3—Upon termination of action, mail this copy to Director
 Copy 2—Upon filing document adding patent(s), mail this copy to Director Copy 4—Case file copy