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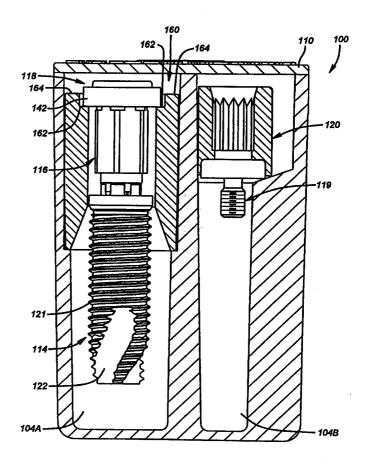
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(54) Title: DENTAL IMPLANT DELIVERY SYSTEM HAVING DRIVER MOUNT WITH REMOVABLE FLANGE

#### (57) Abstract

A dental implant delivery system comprising a vial (100) housing an implant (114) and driver mount (116) with a removable flange (142).



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#### Description

### Dental Implant Delivery System Having Driver Mount With Removable Flange

#### Technical Field

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Dental implants are typically packaged and shipped in a package or implant delivery system. The delivery system, in conjunction with outside packaging, maintains the implant in a sterile environment and is opened just before the implant is needed during the surgical procedure.

FIG. 1 illustrates an example of one such prior delivery system shown generally at 10. Delivery system 10 includes a vial 12 housing a threaded implant 14 and a driver mount 16.

The vial typically has an elongated cylindrical configuration and is used to transport the implant and driver mount. A lid, not shown, fits on top of the vial to seal and retain the implant and driver mount.

Implant 14 is shown having an external threaded section 18 and a top coronal section 20. The coronal section includes a hexagonal projection 22 for mating with different dental components. The driver mount includes a bottom portion having a hexagonal recess 24 that engages with the projections 22 on the implant. The driver mount also includes a bottom portion and a top portion having a flange 26. This flange is integrally formed with the top portion and extends outwardly to have a larger diameter than the bottom portion.

The driver mount and implant together fit within a cylindrical cavity formed within the vial. A screw 28 secures the driver mount to the implant. As shown in FIG. 1, the vial includes an internal shoulder 30 with an opening 32. The implant passes through this opening until the flange of the driver mount abuts against the shoulder. The flange and shoulder thus hold the implant and the driver mount in the vial and keep the implant from touching the sides or bottom of the vial.

In order to install implant 14 into the patient's jawbone, an implant site is prepared using conventional surgical procedures. Typically, an incision is made along the gingival tissue at the implant site, and a cylindrical bore is drilled into the alveolar bone. Once the site is fully prepared, a driving tool, such as a motorized dental hand-piece, is connected to the driver mount using an adapter. The implant and driver mount are removed from the vial. The end of the implant is fit within the bore, and the driver mount drives the implant into position. The screw and driver mount are then removed from the implant. The gingival tissue is then sutured and the implant remains within the bone for several months as osseointegration and healing occur. During a second surgical procedure, the implant is re-exposed and a dental prosthesis is affixed to the implant.

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One important disadvantage associated with prior art delivery systems is that the driver mount will not fit within some tight interdental spaces. During a single tooth restoration, for example, the implant often must be driven between two adjacent teeth. The distance between these teeth may be narrow, and the flange on the driver mount may be too wide to fit. The driver mount thus cannot be used to fully seat the implant. In such a situation, a second and narrower driver must be substituted for the driver mount having a flange.

Another disadvantage is more surgical steps are required during some implantation procedures using prior art delivery systems. Again, if the interdental space is too narrow then the flange on the driver mount may prohibit the implant from being fully and properly seated in the bone. In this case, the driver mount having an integral flange must be disengaged from the driving tool and then disengaged from the implant. Next, another narrower driver mount must be attached to the implant and then attached to the driving tool. These steps not only add time to the surgical procedure but also increase inconvenience for the surgeon. Further, the risk of contaminating the implant or dropping one of the dental components also greatly increases.

It therefore would be advantageous to employ a dental implant delivery system that could be used in instances when access to the restoration site is narrow or limited in space. Such a delivery system would be more universal and could be utilized even when the interdental space is small.

It would be advantageous to employ a dental delivery system that requires a fewer number of steps during the surgical implantation procedure. A surgical procedure requiring fewer steps ultimately would be less traumatic to the patient, more expeditiously performed, and less burdensome on the surgeon, to name a few examples. Further yet, such a delivery system would minimize the amount of handling of the system components.

The present invention solves the problems discussed with prior dental delivery systems and provides further advantages.

#### Disclosure of Invention

The present invention is directed toward a dental implant delivery system that may be used in narrow interdental spaces. The delivery system includes an implant, a driver mount, a screw connecting the driver mount to the implant, and a vial for housing the components.

The driver mount consists of a core body having a removable flange. The core body has a generally cylindrical configuration and preferably a diameter that is not substantially larger than the diameter of the implant. The flange is positioned around the core body and has a diameter larger than the core body.

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During transportation and storage of the delivery system, the implant and driver mount are suspended within the vial as the flange on the driver mount abuts against a ledge in the vial. Subsequently, during the surgical implantation procedure, the implant and accompanying driver mount are positioned at the osteotomy site. The driver mount is then used to drive and seat the implant. If the interdental space is narrow and cannot accommodate the size of the flange, a separate driver mount is not required. Rather, the flange is removed from the core body, and the driver mount is used to fully seat and position the implant.

The delivery system of the present invention is particularly advantageous because it may be used in narrow interdental spaces. Further, additional surgical steps of removing one driver mount and substituting a narrower one are not required.

The invention, accordingly, comprises the apparatus and method possessing the construction, combination of elements, and arrangement of parts which are exemplified in the following detailed description. For a fuller understanding of the nature and objects of the invention, reference should be made to the following detailed description taken in connection with the accompanying drawings.

#### 15 Brief Description of Drawings

- FIG. 1 is an exploded view of a prior dental delivery system;
- FIG. 2 is a perspective view of a vial for the dental delivery system of the present invention;
- FIG. 3 is a cross sectional view of the vial of FIG. 2 having an implant, driver mount, and healing screw;
  - FIG. 4 is an exploded view of the implant, driver mount, and removable ring;
  - FIG. 5 is a first embodiment of the ring; and
  - FIG. 6 is a second embodiment of the ring.

#### Best Mode for Carrying Out the Invention

FIG. 2 illustrates a vial 100 of the dental implant delivery system. The vial includes a body 102 having two adjacent cavities 104A and 104B, respectively. Each cavity has a generally elongated cylindrical configuration that extends downwardly toward a closed base portion 106 of body 102. The vial also includes a clip 108 and a lid 110. The clip connects to a top portion of the body and is used to attach and secure the vial. A flexible arm 112 connects the lid to the body. It will be appreciated that the vial shown in FIG. 2 is exemplary, and other vial designs and configurations known to those skilled in the art also would be applicable with the present invention.

FIG. 3 shows a cross section of the implant delivery system that includes vial 100 housing in cavity 104A an implant 114, driver mount 116, and retaining screw 118. A healing screw 119 and removable mount 120 are located in cavity 104B. Turning also to FIG. 4, the implant and driver mount are shown in more detail.

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Implant 114 may be any one of various implants known to those skilled in the art. For illustration purposes, implant 114 has outer threads 121, a cutting region 122 for self-tapping, and a coronal portion 124 having a plurality of splines 126 extending upwardly. This implant may be, for example, a TWIST implant manufactured by Sulzer Calcitek Inc. of Carlsbad, California.

Driver mount 116 has a generally elongated cylindrical configuration having two ends 130 and 132, respectively. Portions of the external surface 133 of the driver mount may be non-cylindrical, such as hexagonal. End 130 is configured to abut against the coronal end of the implant. End 130 includes a plurality of splines 134 that project downwardly to engage corresponding splines 126 of the implant. The engagement between these splines provides an anti-rotational connection between the driver mount and implant. This anti-rotational connection may be established with other configurations known to those skilled in the art, such as a mating hexagonal projection and recess.

The other end 132 of the driver mount includes a channel 136 that circumferentially extends around the body. This channel is formed between a lip 138 located at the top of end 132 and shoulder 140. Channel 136 provides a space for a removable flange or ring 142. FIG. 5 illustrates one embodiment of ring 142 in more detail.

One important advantage of the present invention is that ring 142 is removable from the driver mount. Ring 142 is secured within channel 136 between lip 138 and shoulder 140. The ring though may be removed from this position around the driver mount. The ring, for example, may be pulled over lip 138 or shoulder 140 and removed from the channel.

FIG. 6 illustrates another embodiment for the ring. Here, the ring is shaped like a thin C-clip 150. This clip fits around end 132 of the driver mount. The clip may connect, for example, with a snap-fit or frictional-fit. A small hole 152 is provided to aid in removing the clip from the driver mount. A tip of a dental instrument, such as an explorer, may be positioned in the hole and used to pull and remove the clip from the driver mount.

Use of the implant delivery system is now discussed in more detail with reference to FIGS. 3 and 4. During storage and transportation of the implant delivery system, the implant 114 and driver mount 116 remain suspended in a sterile and protected environment in vial 100. Cavity 104A includes an opening 160 forming a shoulder or ledge 162 within the cavity. The diameter through opening 160 and shoulder 162 is sufficiently large to enable the implant to pass freely into the cavity. Ring 142, affixed to the driver mount, is too large to pass through the opening. As such, the ring abuts against and rests on shoulder 162. The implant and driver mount are thus suspended within cavity 104A.

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In FIG. 3, shoulder 162 exists slightly below opening 160. This shoulder, however, may exist at various positions in cavity 104A. The shoulder, for example, may be formed on top of opening 160 such that ring 142 rests on surface 164.

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During a dental implantation procedure, lid 110 is removed from the top of vial 100 to expose the implant and driver mount. A driving tool, such as a motorized driver or ratchet wrench, and an adapter are then affixed to end 132 and the implant and driver mount are removed from the vial. The distal end of the implant is then positioned into the osteotomy site. The driving tool then imparts a driving force to the driver mount that, in turn, imparts this same force to the implant. Once the implant is fully seated and positioned, the driving tool is removed from end 132. The retaining screw 118 is then loosened, and the driver mount is removed from the implant. The implant remains in the bone, and the delivery cap 120 and healing screw 119 are then removed from cavity 104B using the noted driving tool. The cap is then placed over the coronal end of the implant until screw 119 fits within the implant. Thereafter, the cap 120 is disengaged from the screw, and the screw is left to cover the implant. Conventional procedures are then used to finish the surgical procedure and thereafter connect a prosthesis to the implant.

In some instances, the spacing available to receive the implant may be quite small. For example, the space between two adjacent teeth may be narrow. In this situation, the implant may be narrow enough to fit within this space, but the flange or ring on the driver mount may be too wide. If the flange or ring cannot safely fit within the available space, then the implant cannot be fully seated within the bone. The present invention solves this potential problem because the ring is removable from the driver mount. In such a situation, the ring would be removed from the driver mount enabling the implant to be fully and correctly positioned. Thus, a separate and narrower driver mount is not required.

Still looking to FIG. 4, the driver mount preferably has a diameter 166 equal to or less than the diameter 168 of the implant. The size of the driver mount thus does not obstruct or otherwise prohibit the placement of the implant in narrow dental spaces. The diameter 170 of the ring, however, is larger than diameter 166 of the driver mount and diameter 168 of the implant. As shown in FIG. 3, this difference in diameters enables the implant and part of the driver mount to pass through opening 160; the ring though is too large and rests on shoulders 162 to support the implant and driver mount.

The flange may be made to have any one of numerous configurations that may or may not resemble the embodiments of FIGS. 5 and 6. The term flange is defined broadly to describe a supporting feature that suspends the implant and driver mount in the vial. The flange, for example, may be formed as removable set screw or pin that protrudes through the end or side of the driver

mount or formed as a protrusion, such as a ring or bead, that adhesively bonds to the end of the driver mount. The flange also may be formed as a shoulder, an elastomeric band, an O-ring, a C-clip, a toroid, U-shaped, star shaped, a cylindrical, or the like. Further, various materials may be used to fabricate the flange. The flange may be made from a polymer, steel, titanium, or other material suitable for use in restorative dentistry. Examples of such material include silicone, santoprene, delrin, polycarbonate, or PETG

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Since certain changes may be made in the above-described apparatus and method without departing from the scope of the invention herein involved, all matter contained in the description or shown in the accompanying drawings shall be interpreted as illustrative and not in a limiting sense.

#### WHAT IS CLAIMED IS:

- 1. A dental implant delivery system, comprising:
  - a vial (100) having an opening (160) leading to an internal cavity (104A);
  - a dental implant (114) disposed within said cavity;
- 5 a driver mount (116) having a first end (130) connected to said implant and a second end (132); and

characterized by:

driver mount.

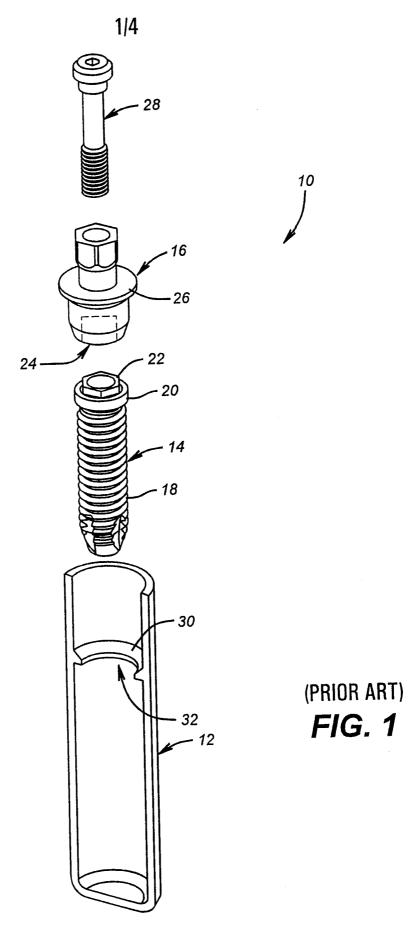
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a separate flange (142) disposed on said second end of said driver mount, said flange being removable from said driver mount and suspending said driver mount and said implant in said cavity.

2. The dental implant delivery system of claim 1 in which: said flange has a diameter (170) too large to pass completely through said cavity;

said driver mount has a diameter (166) substantially equal to or less than a diameter (168) of said implant; and

- said flange has a diameter greater than the diameters of both said implant and said driver mount.
  - 3. The dental implant delivery system of claim 1 in which: said driver mount includes a recess (136) disposed around said second end; and said flange is diposed within and removable from said recess.
- 4. The dental implant delivery system of claim 1 in which said flange is shaped as one of the following: an O-ring, a C-clip, a U-clip, a toroid, or a ring.
  - 5. The dental implant delivery system of claim 1 in which said flange is shaped as a C-clip having a hole (152) for receiving a dental tool.
- The dental implant delivery system of claim 1 in which said cavity
   further comprises a ledge (162) having a diameter smaller than a diameter (170) of said flange and larger than a maximum diameter (168) of said implant and a maximum diameter (166) of said



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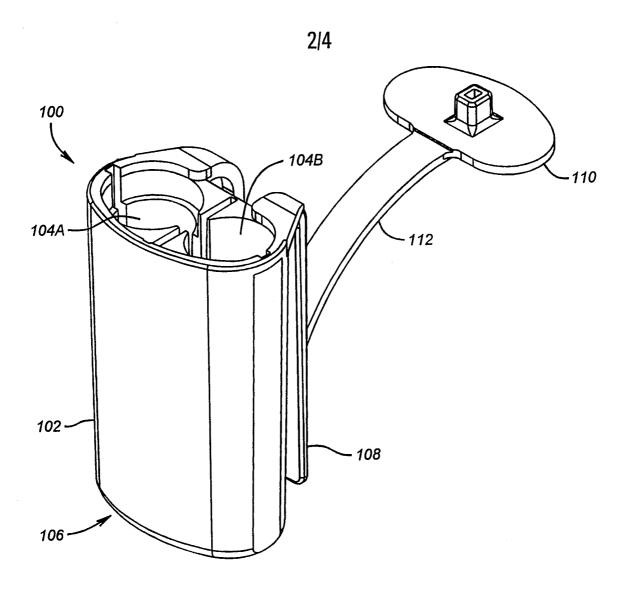
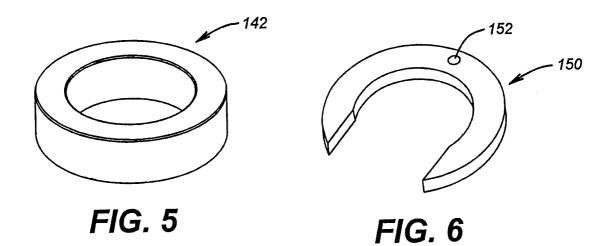


FIG. 2



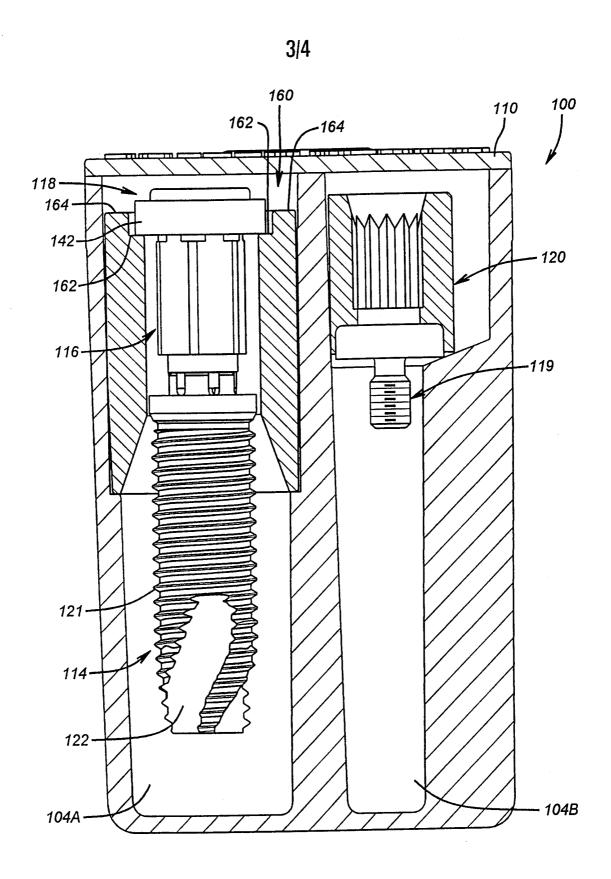


FIG. 3

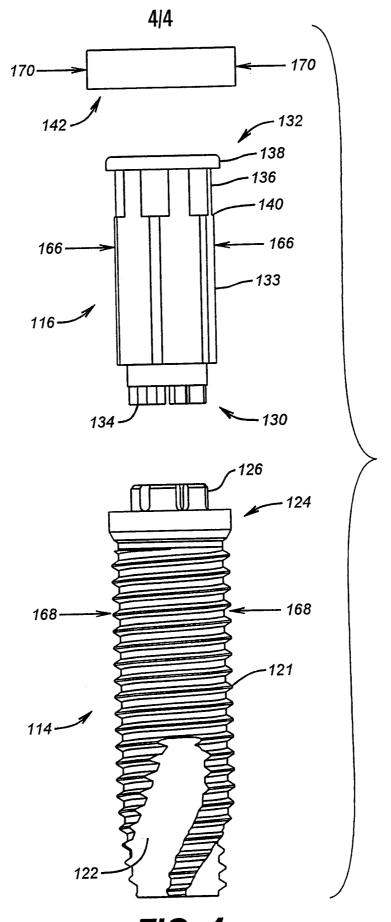


FIG. 4
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## INTERNATIONAL SEARCH REPORT

Int. tional Application No PCT/US 99/03049

A. CLASSI IPC 6	FICATION OF SUBJECT MATTER A61C8/00		
According to	o International Patent Classification (IPC) or to both national classific	eation and IPC	
B. FIELDS	SEARCHED		
Minimum do IPC 6	ocumentation searched (classification system followed by classificat $A61C$	ion symbols)	
Documentat	tion searched other than minimum documentation to the extent that	such documents are included in the fields se	arched
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C. DOCUM	ENTS CONSIDERED TO BE RELEVANT		
Category °	Citation of document, with indication, where appropriate, of the re	elevant passages	Relevant to claim No.
А	FR 2 746 629 A (PORTE MICHEL) 3 October 1997 see page 3, line 10-13 see page 3, line 33 - page 4, li see figure 1	1-6	
P,X	WO 98 44863 A (IMPLANT INNOVATIO 15 October 1998 see page 5, line 8-14 see figures 1A,1B	NS INC)	1-4
P,X	WO 98 55039 A (STRAUMANN INST AG WERNER (CH); SIMPSON JAMES PERCI 10 December 1998 see page 13, line 20 - page 14, see figures 4A-5	VAL (CH)	1
Furt	her documents are listed in the continuation of box C.	X Patent family members are listed	in annex.
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Information on patent family members

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Patent document cited in search report		Publication date	Patent family member(s)		Publication date	
FR 2746629	Α	03-10-1997	NONE			
WO 9844863	Α		AU	6956398 A	30-10-1998	
WO 9855039	Α	10-12-1998	AU	732 <b>949</b> 8 A	21-12-1998	