Instructions for Use for OsseoFuse Dental Implants

This document applies to HexaPlus™, ConicalPlus™ and Sinus™ dental implants, abutments, overdenture bars and associated surgical, restorative and dental laboratory components.

Product Description:
OsseoFuse Dental Implants are manufactured from biocompatible titanium and titanium alloy, and abutments from titanium and titanium alloy. These implants are designed for surgical implantation into the upper and/or lower jawbone for the attachment of prosthodontic appliances to replace missing teeth.

Indications for Use:
The OsseoFuse Dental Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including:
cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. This system is dedicated for one and two stage surgical procedures. This system is intended for delayed loading.

Direction for Use:
For a detailed explanation of the procedural precautions refer to the Surgical Manual. During the planning phase, it is important to determine the vertical dimension, the actual space available between the alveolar crest and the opposing dentition, in order to confirm that the available space will accommodate the proposed abutment and the final crown restoration. This information varies with each patient and abutment; therefore it should be carefully evaluated before placing any dental implant. The final prosthesis should be designed prior to the placement of the dental implant. Utilize continuous irrigation with a cool, sterile irrigating solution to avoid excessive damage to the surrounding tissue and to prevent compromising osseointegration. This is mandatory during all procedures. Avoid excessive pressure during preparation of the bone site. As the drilling speed varies based on the instrument and the surgical procedure, recommendations for speed can be found in the Surgical Manual. Only sharp instruments of the highest quality should be used for any surgical procedure involving bone. Minimizing trauma to the bone and surrounding tissue enhances the potential for successful osseointegration. In order to eliminate contaminants and other sources of infection, all nonsterile devices should be cleaned and/or sterilized prior to use.

Contraindications:
OsseoFuse Dental Implants should not be placed in patients where the remaining jaw bone is too diminished to provide adequate stability of the implant(minimum 1mm circumferential and 2mm apical). Lack of osseointegration or subsequent implant failure may occur in cases where there is insufficient surrounding bone, poor bone quality, poor oral hygiene, heavy smoking, tobacco abuse, or medical conditions such as blood disorders or uncontrolled diabetes.

Storage and Handling:
Devices should be stored at room temperature. Refer to individual product labels and the Surgical Manual for special storage or handling conditions.

Warnings:
Implant surgery and restoration involves complex dental procedures. For safe and effective use of OsseoFuse Dental Implants, proper implant surgery training is strongly recommended prior to implant use. Improper technique and patient selection may result in implant failure and/or excessive loss of supporting alveolar bone. Use of electrosurgical instruments or lasers around metallic fixtures and their abutments is not recommended due to the risk of electric shock and/or burns. Excessive mobility, bone loss, or infection may indicate the implant is failing. Any implant that appears to be failing should be treated or removed as soon as possible. If removal is necessary, remove any soft tissue from the implant site and allow site to heal as though it were an atraumatic extraction. Mishandling of small components inside the patients mouth carries a risk of aspiration and/or swallowing. Small diameter implants with angled abutments are not to be placed in the posterior region. The OsseoFuse Dental Implant System has not been evaluated for safety and compatibility in the MR environment. The OsseoFuse Dental Implant System has not been tested for heating or migration in the MR environment.

Precautions:
For safe and effective use of OsseoFuse Dental Implants, abutments and other surgical and restorative dental accessories, these products or devices should only be used by trained professionals. The surgical and restorative techniques required to properly utilize these devices are highly specialized and complex procedures. Improper technique can lead to implant failure, loss of supporting bone, restoration fracture, screw loosening and aspiration.

Sterility:
The fixture, fixture mount and cover screw have been cleaned and sterilized by gamma irradiation and are ready for use. Do not use sterile products if the packaging has been damaged or previously opened. Do not re-sterilize and autoclave except where instructions to do so are provided on the product label, in the Surgical Manual, in the Restorative Manual or in any additional marketing literature for that product. The abutment, accessories, and surgical instrumentation have not been sterilized. All nonsterile components of this system, including newly packaged surgical instruments and abutments MUST be sterilized prior to use.

- Cleaning procedure for surgical instruments and abutments before and/or after use.
  1. Place the instruments in an ultrasonic cleanser for 10 min.
  2. Remove any visible debris or bone fragments with a soft bristle brush. Rinse thoroughly.
  3. Rinse instruments with alcohol to remove any soap residue and minerals. (important to help prevent corrosion).
  4. Blot instruments dry and allow them to air dry completely.
  5. Place the instruments in an autoclave approved paper.
  6. Sterilize using one of three qualified steam sterilization cycles:
     a. Pre-vacuum Steam: 132°C (270°F) for five minutes minimum.
     b. Gravity Steam: 132°C (270°F) for thirty minutes minimum.
     c. Gravity Steam: 121°C (250°F) for fifty minutes minimum.
  7. Dry for 20 to 50 minutes as needed.
     Do not remove the instruments from the autoclave until the dry cycle is complete.

* The recommended sterilization parameters listed above have been validated to a SAL of 10-6 in accordance with a FDA-recognized standards such as ISO 17665 using Bioburden sterilization method.

*Caution: Use of hydrogen peroxide or other oxidizing agents will cause damage to the surface of the instruments. Towel or air-dry all instrumentation before sterilizing.
It is recommended that drills should be replaced when discoloration or wear is noticed to ensure cutting efficiency.
It is also recommended that proper testing, cleaning, and calibration of sterilization equipment occur frequently to assure that the units are in proper working order. Equipment operating conditions vary and it is the responsibility of each dental office to ensure that proper sterilization technique for instrumentation is followed.

Procedural Precautions, Restoration:
The healing period varies depending on the quality of the bone at the implantation site, the tissue response to the implanted device and the surgeon's evaluation of the patient's bone density at the time of the surgical procedure. Excessive force applied to the dental implant should be avoided during the healing period. Proper occlusion should be evaluated on the implant restoration to avoid excessive force.

Potential Adverse Events:
Potential adverse events associated with the use of dental implants may include:
- Failure to osseo-integrate
- Loss of osseo-integration
- Dehiscence requiring bone grafting
- Perforation of the maxillary sinus, inferior border, lingual plate, labial plate, inferior alveolar canal, gingiva
- Infection as reported by: abscess, fistula, suppuration, inflammation, radiolucency
- Persistent pain, numbness, paresthesia
- Hyperplasia
- Excessive bone loss, which might necessitate surgical intervention
- Implant fracture

OsseoFuse
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Labeling symbols:
symbols are used for products sold internationally for ease in identification

CE 0086	Symbol for "CE Mark"
STERILE R	Symbol for "STERILIZED USING IRRADIATION"
NON STERILE	Symbol for "NON-STERILE"
2	Symbol for "DO NOT RESTERILIZE"
	Symbol for "CONSULT INSTRUCTION FOR USE"
EC REP	Symbol for "AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY"
	Symbol for "USE BY"
	Symbol for "DO NOT REUSE"
	Symbol for "DO NOT USE IF PACKAGE IS DAMAGED"
	Symbol for "KEEP AWAY FROM SUNLIGHT"
	Symbol for "KEEP DRY"
	Symbol for "TEMPERATURE LIMITATION"
LOT	Symbol for "BATCH CODE"
REF	Symbol for "CATALOGUE NUMBER"
	Symbol for "MANUFACTURER"
	Symbol for "DATE OF MANUFACTURE"
	Symbol for "CAUTION"

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