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English	Instructions for Use for US: Conical Dental Implants

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ENGLISH

This document supersedes all prior revisions.

This document applies to the following BioHorizons Conical Dental Implants. Every product packaging label contains a description of the enclosed device:

Devices in Scope
BioHorizons Tapered Pro Conical Implants
BioHorizons Tapered Short Conical Implants

1.0 DESCRIPTION

BioHorizons Conical dental implants are manufactured from biocompatible titanium alloy (Ti-6AL-4V ELI) and are single use only.

Element	Composition % (mass/mass)
Nitrogen, max	0.05
Carbon, max	0.08
Hydrogen, max	0.012
Iron, max	0.25
Oxygen, max	0.13
Aluminum	5.5 – 6.50
Vanadium	3.5 – 4.5
Titanium	balance

"Peel-and-stick" labels supplied on the implant package contain important product information and should be applied to the patient's record in the event future reference is necessary.

2.0 INDICATIONS FOR USE

BioHorizons Tapered Pro Conical dental implants are intended for use in the mandible or maxilla as an artificial root structure for single tooth replacement or for fixed bridgework and dental retention. These dental implants may be restored immediately (1) with a temporary prosthesis that is not in functional occlusion or (2) when splinted together for multiple tooth replacement or when stabilized with an overdenture supported by multiple implants.

BioHorizons Tapered Short Conical dental implants are intended for use in the mandible or maxilla as an artificial root structure for single tooth replacement or for fixed bridgework and dental retention. These dental implants must be restored using delayed loading, for single tooth replacement, or may be used with a terminal or intermediate abutment for fixed or removable bridgework or for overdentures. Tapered Short Conical implants should be used only when there is not enough space for a longer implant. If the ratio of crown length to implant length is unfavorable, the biomechanical risk factors have to be considered and appropriate measures have to be taken by the dental professional.

3.0 CONTRAINDICATIONS

BioHorizons Tapered Pro Conical and Tapered Short Conical dental implants should not be used in patients who have contraindicating systemic or uncontrolled local diseases such as blood dyscrasias, diabetes, hyperthyroidism, oral infections or malignancies, renal disease, uncontrolled hypertension, liver problems, leukemia, severe vascular heart disease, hepatitis,

immunosuppressive disorder, pregnancy, collagen and bone diseases. Relative contraindications may include habits such as tobacco use, alcohol consumption, poor oral hygiene, bruxism, nail biting, pencil biting and improper tongue habits depending on severity.

4.0 DIRECTIONS FOR USE

Proper surgical procedures and techniques are the responsibility of the medical professional. Each clinician must evaluate the appropriateness of the procedure used based on personal medical training and experience as applied to the patient case at hand. BioHorizons strongly recommends completion of postgraduate dental implant education and strict adherence to the instructions and procedures for use that accompany BioHorizons dental implant products.

NOTE: A pre-operative 30-second rinse with a 0.12% Chlorhexidine Digluconate solution is recommended (The influence of 0.12% Chlorhexidine Digluconate Rinses on the Incidence of Infectious Complications and Implant Success. Lambert, Paul M., et al, J Oral Maxillofacial Surgery 55:25-30, 1997, Suppl5).

IMPORTANT! – During BioHorizons Tapered Pro Conical and Tapered Short Conical dental implant placement, the following insertion torque limits should not be exceeded:

- 117 Ncm for conical implants containing a narrow connection
- 136 Ncm for conical implants containing a regular connection

Tightening to a torque value greater than recommended may compromise the mechanical integrity of the dental implant driver.

The clinician should verify that the proper instruments are available and at hand prior to attempting placement.

5.0 WARNINGS AND PRECAUTIONS

Appropriate training in proper dental implant surgery technique is strongly recommended prior to implant use. Improper technique can result in dental implant failure and/or loss of supporting bone. Appropriate x-ray films and/or CT scans should be utilized to determine (1) if adequate bone width and depth are available at the desired implant site and (2) the location of important anatomical landmarks, such as the mandibular canal, maxillary sinuses, and adjacent teeth. Clinician judgment should be used in determining the minimum post-implantation time before placing the implants in occlusal function. An adequate number of dental implants should be used to provide support and to distribute the load to the abutments.

Clinicians should closely monitor patients for any of the following conditions: peri-implant bone loss, changes to dental implant's response to percussion, or radiographic changes in bone to dental implant contact along the dental implant's length. If the dental implant shows mobility or greater than 50% bone loss, the dental implant should be evaluated for possible removal. If the clinicians choose a short dental implant, then clinicians should consider a two-stage surgical approach, splinting the short dental implant to an additional dental implant,and placement of the widest possible fixture. Allow longer periods for osseointegration to avoid immediate loading.

Dental implants should not be used in patients with a known allergy or sensitivity to the device material.

A certain percentage of dental implants may fail to achieve or to maintain osseointegration, as demonstrated by mobility, and should be removed. Dental implants can break in function for a number of reasons including overloading due to improper occlusion, metal fatigue, and over-tightening of the implant during insertion. Small diameter dental implants with either angled or straight abutments are intended for the anterior region of the mouth and not intended for the posterior region of the mouth due to possible failure of the dental implant.

Additional technical information is available upon request from BioHorizons or may be viewed and/or downloaded at www.biohorizons.com. Contact BioHorizons Customer Care or your local representative with any questions you have regarding a specific IFU. Any serious incident that has occurred in relation to the device should be reported to the manufacturer.

6.0 COMPLICATIONS AND ADVERSE EFFECTS

The risks and complications with dental implants include, but are not limited to: (1) allergic reaction(s) to dental implant and/or abutment material; (2) breakage of the dental implant required to be explanted and/or abutment required to be removed using clinician judgement; (3) loosening of the abutment screw and/or retaining screw; (4) infection requiring revision of the dental implant; (5) nerve damage that could cause permanent weakness, numbness, or pain; (6) histologic responses possibly involving macrophages and/or fibroblasts; (7) formation of fat emboli; (8) loosening of the dental implant requiring revision surgery; (9) perforation of the maxillary sinus; (10) perforation of the labial and lingual plates; and (11) bone loss possibly resulting in revision or removal.

7.0 HANDLING AND STERILIZATION

Dental implants are supplied sterile and should be considered sterile unless the package has been opened or damaged. Using accepted sterile technique, remove from the package only after the correct size has been determined and the surgical site has been prepared. Always handle with powder-free gloves and avoid contact with hard objects that may damage the surface. Dental implants are single use only, and re-use should not be attempted. Following this guidance eliminates the risk of cross-patient contamination from secondary use of this device. BioHorizons assumes no responsibility for attempted re-use or re- sterilization.

Products to be disposed of must be treated and decontaminated as dental surgery waste in compliance with the relevant local regulations.

8.0 MAGNETIC RESONANCE (MR) SAFETY INFORMATION

MR Conditional

BioHorizons implant systems have been demonstrated through non-clinical testing to be magnetic resonance (MR) conditional. A patient with this device can be scanned safely in an MR system under the following conditions. Failure to follow these conditions may result in injury to the patient.

- Static magnetic field of 1.5-Tesla or 3-Tesla, only;
- Maximum spatial gradient magnetic field of 4,000-Gauss/cm (40-T/m);
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the Normal Operating Mode.

Under the scan conditions defined, the implant system is expected to produce a maximum temperature rise of 3.6°C after 15-minutes of continuous scanning (i.e., per pulse sequence).
In non-clinical testing, the image artifact caused by the implant system extends approximately 30-mm from this system when imaged using a gradient echo pulse sequence and a 3-Tesla MR system.

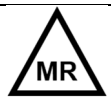
Parameter	Condition
Nominal Values of Static Magnetic Field (T)	1.5-Tesla and 3.0-Tesla
Maximum Spatial Field Gradient (T/m and gauss/cm)	40-T/m (4,000-guass/cm)
Type of RF Excitation	Circularly Polarized (CP) (i.e., Quadrature-Transmission)
Transmit RF Coil Information	There are no transmit RF coil restrictions. Accordingly, the following may be used: body transmit RF coil and all other RF coil combinations (i.e., body RF coil combined with any receive-only RF coil, transmit/receive head RF coil, transmit/receive knee RF coil, etc.)
Operating Mode of MR System	Normal Operating Mode
Maximum Whole Body Averaged SAR	2-W/kg (Normal Operating Mode)
Limits on Scan Duration	Whole body averaged SAR of 2-W/kg for 60 minutes of continuous RF exposure (i.e., per pulse sequence or back-to-back sequences/series without breaks).
MR Image Artifact	The presence of this implant system produces an imaging artifact. Therefore, carefully select pulse sequence parameters if the implant system is located in the area of interest.

To allow medical professionals to identify the specific medical devices a patient has, the MRI safety status of the medical devices, and the conditions for safe use in the MR environment for MR Conditional devices, BioHorizons recommends that clinicians provide the patient with the dental implant(s) and dental abutment(s) / bar(s) device specific peel-offs affixed to the patient card. Patient cards are available free of charge upon request from BioHorizons or for direct printing at ifu.biohorizons.com.

9.0 SYMBOLS AND DESCRIPTIONS

The symbol table below is for reference only. Refer to product packaging label for applicable symbols.

Symbol	Symbol Description
	Caution
	Electronic instructions for use
	Manufacturer
	BioHorizons products carrying the European Conformity (CE) mark fulfill the requirements of the Medical Device Directive 93/42/EEC as amended by Directive 2007/47/EC or the Medical Devices Regulation 2017/745. The CE mark is valid only if it is also printed on the product label. The four-digit number accompanying the CE mark on applicable devices corresponds to the assigned EU Notified body.
	Reference/ article number
	Lot/ batch number

Symbol	Symbol Description
	Unique Device Identifier
	Do not re-use
	Do not re-sterilize
	Use-by-date
	Sterile by gamma irradiation
	Date of manufacture
Rx Only	Caution: U.S. Federal law restricts these devices for sale, distribution and use by, or on the order of, a dentist or physician
	European Union Authorized Representative
	Do not use if package is damaged. Discard device and package.
	Medical Device
	Non-sterile
	Single sterile barrier system with protective packaging outside
	Single sterile barrier system
	Home
 MR Conditional	Magnetic resonance warning: Device is MR conditional
	United Kingdom Responsible Person