BIOHORIZONS®

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English	Instructions for use: Wide Custom Milled Abutments

BioHorizons Implant Systems Inc.
2300 Riverchase Center
Birmingham AL, 35244 USA
TOLLFREE 888.246.8338
TEL 205.967.7880
FAX 205.870.0304
www.biohorizons.com

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ENGLISH

This document supersedes all prior revisions. Original language is English.

This document applies to BioHorizons Dental Abutments listed below. Every product packaging label contains a description of the enclosed device.

Devices in Scope
BioHorizons Wide Custom Milled Abutments

DESCRIPTION

BioHorizons CAD/CAM titanium blanks are intended for the restoration of BioHorizons Tapered Internal and Internal dental implants and Zimmer® Dental ScrewVent® and Tapered ScrewVent® dental implants within the specific indications of each implant system. The label on each prosthetic package contains important product information including an indication that the prosthetic is supplied non-sterile. Refer to the following table for material(s) of implantable devices:

Implantable Devices	Material (main elements)
BioHorizons Wide Custom Milled Abutments	Ti-6AL-4V ELI (Titanium, Aluminum, Vanadium)

INDICATIONS FOR USE

BioHorizons CAD/CAM Abutments are dental abutments placed onto a dental implant to provide support for dental prosthetic restorations. The abutments include titanium abutment blanks with a pre-machined implant connection where the upper portion may be custom-milled in accordance with a patient-specific design using CAD/CAM techniques. The abutments include an abutment screw for fixation to the underlying implant. The abutments may be used for single-unit (single-tooth) or multiple-unit (bridges and bars) restorations and are compatible for use with BioHorizons Internal and Tapered Internal implant systems and Zimmer® Dental Screw-Vent® and Tapered Screw-Vent® implants with 3.5mm, 4.5mm and 5.7mm internal hex-connection mating platform diameters. All digitally designed abutments and/or copings for use with BioHorizons CAD/CAM Abutments are intended to be sent to a BioHorizons-validated milling center for manufacture. BioHorizons abutments designed using CAD/CAM techniques must fulfill the BioHorizons allowable range of design parameters.

CONTRAINDICATIONS

BioHorizons prosthetics should not be used in patients who have contraindicated 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.

DIRECTIONS FOR USE

A custom abutment design file is created by the customer using a 3Shape abutment library. The abutment design file is converted to a stereolithography (.stl) file using 3Shape software. The .stl file is converted to a numerical control(.nc) file using an appropriate software application (e.g. SUM3D). After the custom abutment design is uploaded, the milling machine software executes the necessary commands to mill the final abutment. The digitally designed file is to be sent to a registered and listed BioHorizons contract manufacturer for milling. Visit www.biohorizons.com for a list of validated milling centers. BioHorizons CAD/CAM Abutments are compatible with commercially available dental CAD/CAM systems, such as 3Shape.

Proper surgical procedures and restorative 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 dental implant courses and strict adherence to the Instructions for Use that accompany BioHorizons products. Abutment screws must be torqued to 30Ncm to prevent screw loosening. BioHorizons Wide Custom Milled Abutments contain a LIGHT BLUE abutment screw specifically designed for use in those abutments.

BioHorizons validated milling centers:

Name	Website	Location	Telephone Number	Email address
Vulcan Custom Dental	www.vulcandental.com	2300 Riverchase Center, Suite 825. Birmingham, AL, 35244	(888)484-2301 (205)484-2301	Info@VulcanDental.com

Design limitation parameters for the BioHorizons Wide Custom Milled Abutments are below:

- 0.3mm minimum wall thickness.
- 0.5mm minimum gingival margin height (from the implant-abutment junction).
- 6.0mm maximum gingival margin height (from the implant-abutment junction).
- Abutments with a post height less than 4.0 mm are intended for multi-unit restorations only.
- 30º maximum post angulation

  Note: The post height of the abutment is measured above the total gingival margin height of the final patient-matched design.

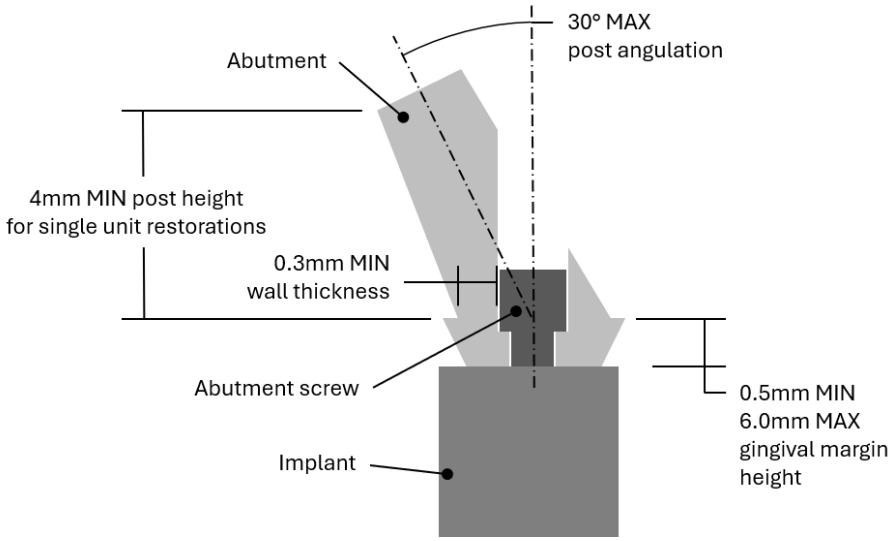


Figure 1 –Abutment design limitations for Wide Custom Milled Abutments

WARNINGS AND PRECAUTIONS

Clinician judgment, as related to individual patient presentations, must always supersede recommendations in any BioHorizons Instructions for Use (IFU). Clinicians are responsible for understanding the appropriate technical use of BioHorizons prostheticcomponents.

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. Potential causes of abutment fracture include but are not limited to: casting titanium above 2010°F (1099°C), inadequate implant support when attached to periodontically compromised teeth, non-passive fit of superstructure, overloading due to improper occlusion, incomplete seating of cemented abutments, and excessive cantilevering of pontics.

If any modifications are made to the implant/abutment interface, the abutment may not properly interface with the implant. The FDA considers the modifier of the implant/abutment interface a medical device company subject to FDA rules and regulations.

Prosthetics are single patient use only. To eliminate the risk of cross-patient contamination, re-use should not be attempted. BioHorizons assumes no responsibility for attempted re-use or re-sterilization between patients.

Devices should not be used in patients with a known allergy or sensitivity to the device material(s).

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 and competent authority of the EU Member State in which the clinician and/or patient is established.

For implantable devices, the summary of safety and clinical performance (SSCP) according to Article 32 of Regulation (EU) 2017/745 can be found in the European database for medical devices (Eudamed) at https://ec.europa.eu/tools/eudamed.

Implantable Device	Basic UDI-DI Number
BioHorizons Wide Custom Milled Abutments	08472360IIBWETABUT007J6

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 averages 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 https://ifu.biohorizons.com.

COMPLICATIONS AND ADVERSE EFFECTS

The risks and complications with prosthetic components and implants include, but are not limited to: (1) allergic reaction(s) to implant and/or abutment material; (2) breakage of the implant required to be explanted and/or abutment required to be removed using clinician judgement; (3) abutment screw and/or retaining screw loosening; (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) implant loosening requiring revision surgery; (9) maxillary sinus perforation; (10) labial or lingual plate perforation; and (11) bone loss possibly resulting in revision or removal.

HANDLING AND STERILIZATION

Always handle the device with powder-free gloves and avoid contact with hard objects that may damage the surface. After abutment preparation and before final placement in the restorative site, CAD/CAM abutments must be cleaned and sterilized. BioHorizons devices have not been validated for automated cleaning. The following cleaning protocol must be used:

1) Prepare a detergent bath in a container using a broad-spectrum cleaning agent such as Hu-Friedy's Enzymax® per the manufacturer's recommendations. Refer to the legal manufacturer's instructions for use/preparation for detergent solution.
2) Brush the device to remove visible debris using a soft bristled brush moistened with the prepared detergent solution.
3) Thoroughly rinse device under running utility tap water.
4) Place device in the sterile tube filled with the prepared detergent solution and sonicate for two (2) minutes.
5) Thoroughly rinse device under running utility tap water.
6) Spray device with 70% isopropyl alcohol (IPA).
7) Blot device dry with clean lint free cloth.

For sterilization, place final-prepped and cleaned abutment in an approved sterilization bag or wrap and run through one of the following qualified sterilization cycles:

Sterilization Cycles				
Reference:	AAMI TIR12:2020	AAMI TIR12:2020	AAMI TIR12:2020	UK HTM 01-01 Part C:2016
Type:	Gravity Steam	Gravity Steam	Prevacuum Steam	Prevacuum Steam
Exposure Time and Temperature:	30 minutes at 121 °C (250 °F)	15 minutes at 132 °C (270 °F)	4 minutes at 132 °C (270 °F)	3 minutes at 134 °C (273 °F)
Minimum Dry Time:	30 minutes	30 minutes	20 minutes	20 minutes

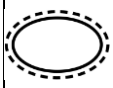
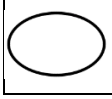
It is recommended to include a 30-minute cool-down period before removing the device from the sterilization bag or wrap.

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

SYMBOLS AND DESCRIPTIONS

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

Symbol	Symbol Description
	Caution

Symbol	Symbol Description
	Electronic instructions for use
	Manufacturer
CE	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.
REF	Reference/ article number
LOT	Lot/ batch number
UDI	Unique Device Identifier
	Do not re-use
	Do not re-sterilize
	Use-by-date
STERILE R	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
EC REP	European Union Authorized Representative
	Do not use if package is damaged. Discard device and package.
MD	Medical Device
Non-sterile	Non-sterile
	Single sterile barrier system with protective packaging outside
	Single sterile barrier system

Symbol	Symbol Description
	Home
 MR Conditional	Magnetic resonance warning: Device is MR conditional

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