BIOHORIZONS®

SCIENCE • INNOVATION • SERVICE

English	Instructions for Use: Conical Dental Prosthetics

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ENGLISH

This document supersedes all prior revisions.

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

Devices in Scope
Conical Cover Screws
Conical Healing Caps
Conical SmartShape Healers
Conical Temporary Abutments
Conical Esthetic Abutments
Conical Ti Bases
Conical CAD/CAM Ti Blanks+
Conical Multi-unit Abutments
Conical CAD/CAM Ti Base Abutment Screws
Conical Abutment Screws
Conical Angled Multi-unit Abutment Screws

1.0 DESCRIPTION

BioHorizons conical dental prosthetics are intended for the restoration of BioHorizons conical dental implants within the specific indications of each implant system. Refer to the following table for material(s) of implantable devices:

Implantable Devices	Material (main elements)
Conical Cover Screws	Ti-6AL-4V ELI (Titanium, Aluminum, Vanadium)
Conical Healing Caps	
Conical SmartShape Healers	
Conical Temporary Abutments	
Conical Esthetic Abutments	
Conical Ti Bases	
Conical CAD/CAM Ti Blanks	
Conical Multi-unit Abutments	
Conical CAD/CAM Ti Base Abutment Screws	
Conical Abutment Screws	
Conical Angled Multi-unit Abutment Screws	

The label on each prosthetic package contains important product information including whether the prosthetic is supplied sterile or non-sterile. Prosthetic connection color coding is defined as shown in the table below:

Conical Prosthetic Color Coding:	Gray	Yellow
Conical Prosthetic Size:	Narrow	Regular

2.0 INTENDED USE

BioHorizons abutments are intended for the restoration of BioHorizons dental implants in the mandible or maxilla, for single tooth replacement or for fixed bridgework and dental retention, within the specific indications of each implant system.

3.0 INDICATIONS FOR USE

BioHorizons conical dental prosthetic components connected to the endosseous dental implants are intended for use as an aid in prosthetic rehabilitations of the maxillary or mandibular arch to provide support for prosthetic restorations.

All digitally designed abutments for use with Conical CAD/CAM Ti Blanks are to be sent to a BioHorizons validated milling center for manufacture.

All digitally designed abutments for use with Conical Ti Base abutments are to be sent to a BioHorizons validated milling center for manufacture or to be designed and manufactured according to digital dentistry workflow. The workflow system integrates multiple components of the digital dentistry workflow: scan files from Intra-Oral Scanners, CAD software, CAM software, milling machine and associated tooling and accessories.

4.0 CONTRAINDICATIONS

BioHorizons conical 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.

5.0 PATIENT POPULATION

BioHorizons dental implant systems are intended for use in skeletally mature, non-pediatric edentulous or partially edentulous patients as long as the defined contraindications are nonapplicable.

6.0 INTENDED USERS

BioHorizons implant systems are only sold to licensed health care professionals, more specifically, BioHorizons implant systems are intended to be used by trained dentists, surgeons and dental technicians in a standard dental surgical setting, which may range from General Dentists' practice offices to Maxillofacial Surgical Operating Rooms, as well as laboratories for dental processes. Use of these products requires specialized knowledge and experience in implant dentistry. BioHorizons implant systems are marked and labeled as a medical device (MD) and are Rx only.

7.0 DIRECTIONS FOR USE

7.1 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 postgraduate dental implant education and strict adherence to the Instructions for Use that accompany BioHorizons products.

7.2 Conical dental prosthetic components should be torqued to the recommended torque values shown in the table below to prevent screw loosening.

Component	Recommended Torque Value (Ncm)
Conical Cover Screws	Hand Tighten (10-15 Ncm)
Conical Healing Caps	Hand Tighten (10-15 Ncm)

Conical Abutments, CAD/CAM Ti Blanks, and Ti Bases	20 Ncm

7.3 Conical CAD/CAM Ti Blanks

7.3.1 Design:

Digitally designed abutments for use with Conical CAD/CAM Ti Blanks must be designed using appropriate design software (i.e., 3Shape, exocad) with appropriate library files installed. All digitally designed files are to be sent to a BioHorizons validated milling center for manufacture.

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	(844)484-2301 (205)484-2301	Info@VulcanDental.com

7.3.2 Design limitations:

- 30° maximum post angulation.
- 0.6mm minimum wall thickness.
- 0.5mm minimum gingival margin height (from the implant-abutment junction).
- Minimum height above the screw head is 0.2mm.
- Abutments with a post height less than 4.0 mm are intended for multi-unit restorations only.

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

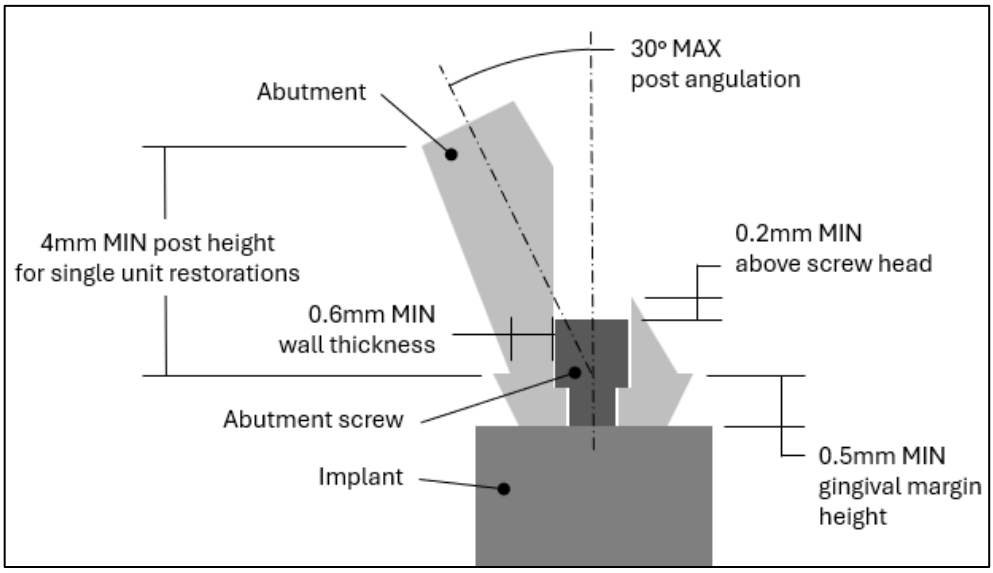

Figure 1 – CAD/CAM abutment design limitations

7.4 Conical Ti Base Abutments

Applicable for Engaging and Non-engaging Conical Ti Base abutments.

7.4.1 Design limitations:

- 20° maximum post angulation.
- 0.4mm minimum wall thickness.
- 5mm maximum gingival margin height. (refer to **Figure 2**)

  Note: The maximum gingival margin height is inclusive of the gingival height of the stock Ti Base abutment. A CAD library shall have a less-than-5mm maximum gingival margin height design limitation if measured in the software from the gingival height of the stock Ti Base abutment.
- Ti Base abutments with a post height less than 4.0 mm are intended for multi-unit restorations only. (refer to **Figure 2**)
- Screw channel:
  - Engaging Ti Base abutments:
    - 25° maximum angled screw channel for 0.8mm margin height
    - 15° maximum angled screw channel for 2.0mm margin height
  - Non-engaging Ti Base abutments: straight screw channel only.

Note: Minimal gingival margin height is established by the gingival height of the stock Ti Base abutment. The post-height of the Ti Base abutment is measured above the total gingival margin height of the final patient-matched design.

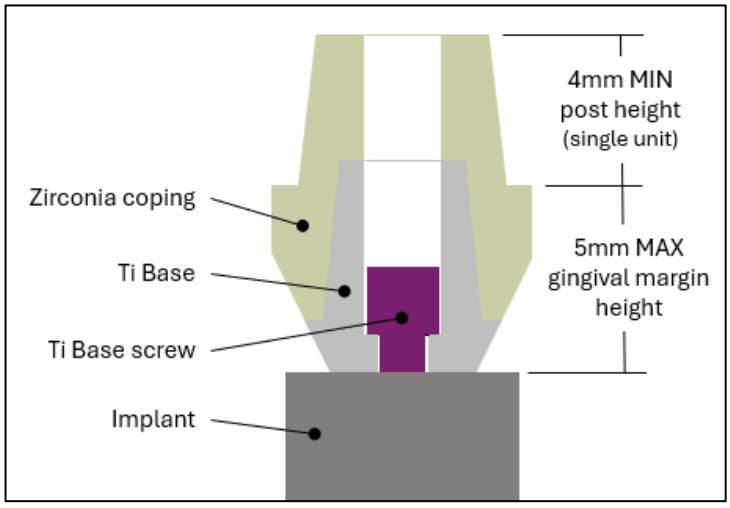

Figure 2 – Zirconia coping (superstructure) design limitations

7.4.2 Validated milling center workflow:

7.4.2.1 Design:

Digitally designed abutments for use with Conical Ti Base abutments must be designed using appropriate design software (i.e., 3Shape, exocad) with appropriate library files installed. All digitally designed files are to be sent to a BioHorizons validated milling center for manufacture.

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	(844)484-2301 (205)484-2301	Info@VulcanDental.com

7.4.2.2 Zirconia Superstructure:

It is recommended the zirconia superstructure be produced using sagemax® NexxZr zirconia (K130991) or similar and sintered according to manufacturer's instruction. The milled zirconia superstructure shall be prepared for cementation according to manufacturer's instruction. Prior to sterilization, bond the milled zirconia superstructure to the Conical Ti Base using 3M™ RelyX™ Unicem 2 Automix Self-Adhesive Resin Cement (K022476) or similar.

7.4.3 Digital dentistry workflow:

The following digital dentistry workflow has been validated by BioHorizons.

7.4.3.1 Scan:

1. For detection of the precise dental implant position during scanning, use a BioHorizons Conical Implant-level Scan Body. Ensure that the selected scan body corresponds with the dental implant's prosthetic connection size.
2. Scan the patient's anatomy and scan body using a 3Shape Trios 5 intra-oral scanner.

7.4.3.2 Computer-aided Design (CAD):

The zirconia superstructure must be designed using 3Shape Dental System with the appropriate BioHorizons library files installed.

BioHorizons library files can be downloaded from: www.vulcandental.com.

The operation manual for 3Shape Dental System can be accessed from: www.3shape.com.

BioHorizons library files have design limitations, and the user is not allowed to exceed these limitations. Refer to **Section 4.4.1** for the Conical Ti Base design limitations.

3. Import the digitized patient information from the intra oral scan to the design software.
4. Selecting the appropriate BioHorizons library for a Conical Ti Base abutment restoration that corresponds with the prosthetic connection and design needs.
5. Design the zirconia superstructure in the design software.

7.4.3.3 Computer-aided Manufacturing (CAM):

6. Send the digital design file of the zirconia superstructure using hyperDENT® Classic to an imes-icore® CORiTEC 150i Pro milling machine.
7. Manufacture the zirconia superstructure with the following tools recommended for dental zirconia according to imes-icore instructions.

- for all external steps and internal roughing step: T13/T40/T50 – Ø2.5mm, 3mm shank radius milling tool (diamond coated)
- for internal semi-finishing and finishing steps: T14/T41/T51 – Ø1.0mm, 3mm shank radius milling tool (diamond coated)
- for external small feature (e.g., occlusal surface) finishing step: T15/T42/T52 – Ø0.6mm, 3mm shank radius milling tool

7.4.3.4 Zirconia Superstructure:

It is recommended the zirconia superstructure be produced using sagemax® NexxZr zirconia (K130991) and sintered according to manufacturer's instruction. The milled zirconia superstructure shall be prepared for cementation according to manufacturer's instruction. Prior to sterilization, bond the milled zirconia superstructure to the Conical Ti Base using 3M™ RelyX™ Unicem 2 Automix Self-Adhesive Resin Cement (K022476).

8.0 WARNINGS AND PRECAUTIONS

8.1 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 prosthetic components.

8.2 Potential causes of abutment fracture include, but are not limited to: 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.

8.3 Small diameter implants are intended for the anterior region of the mouth and are not intended for the posterior region of the mouth due to possible failure of the implant.

8.4 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.

8.5 Use of abutment screws with incompatible abutments may result in abutment and/or abutment screw failure. Refer to the table below for screw compatibility.

Conical Prosthetic Component	Compatible Screw
Conical Temporary Abutments	Conical Abutment Screw (CAS)
Conical Esthetic Abutments	
Conical CAD/CAM Ti Blanks	
Conical Ti Bases	Conical CAD/CAM Ti Base Abutment Screw (CTAS)
Conical Multi-unit Angled Abutments	Conical Angled Multi-unit Abutment Screw (CMUAS)

8.6 Conical angled abutments are not recommended for use in the posterior region of the mouth.

8.7 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.

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

8.9 When an intermediate component (e.g. coping, Ti cylinder) is used with BioHorizons Conical Multi-unit Abutments, the gingival collar, angulation, and wall thickness of the intermediate component shall not be modified. When an intermediate component is

not used with BioHorizons Conical Multi-unit Abutments, a BioHorizons prosthetic screw designed for direct to Multi-unit restorations shall be used.

8.10 Use of Conical Ti Base abutments with any dental cement, ceramic or other top-half component (and/or hybrid abutment-crown component) materials, scanners, milling units and components, CAD/CAM software, templates, and tools other than those specifically identified in this labeling, may result in incorrect fit and/or damage of the dental restoration.

8.11 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.

9.0 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.

10.0 HANDLING AND STERILIZATION

Always handle the prosthetic components with powder-free gloves and avoid contact with hard objects that may damage the surface.

If the prosthetic component is supplied sterile, it should be considered sterile unless the package has been opened or damaged. Using accepted sterile techniques, remove the prosthetic component from the package only after the correct size has been determined and the surgical site has been prepared.

For non-sterile prosthetic components, remove and discard any shipping material before initial processing. Non-sterile prosthetic components must be cleaned and sterilized prior to use. The following cleaning protocol must be used:

1) Prepare a detergent bath in a sterile container using a broad-spectrum cleaning or disinfecting agent such as Hu-Friedy's Enzymax® per the manufacturer's recommendations.

2) Brush the product to remove visible debris using a soft bristled brush moistened with the prepared detergent solution.

3) Thoroughly rinse product under running utility tap water.

4) Place product in the sterile container filled with the prepared detergent solution and sonicate for two (2) minutes minimum.

5) Thoroughly rinse product under running utility tap water.

6) Spray product with 70% isopropyl alcohol (IPA).

7) Blot product dry with clean lint free cloth.

BioHorizons dental prosthetics have not been validated for automated cleaning.

For sterilization of non-sterile product, place product in an FDA cleared sterilization bag or wrap and run through one of the following qualified sterilization cycles (excluding Ti Bases):

Sterilization Cycles			
Reference:	AAMI TIR12:2020	AAMI TIR12:2020	AAMI TIR12:2020
Type:	Gravity Steam	Gravity 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)
Minimum Dry Time:	30 minutes	30 minutes	20 minutes

For sterilization of Ti Bases bonded with a zirconia superstructure, place product in an FDA cleared sterilization bag or wrap and run through the following qualified sterilization cycle:

Sterilization Cycle	
Reference:	AAMI TIR12:2020
Type:	Prevacuum Steam
Exposure Time and Temperature:	4 minutes at 132°C (270°F)
Minimum Dry Time:	20 minutes

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

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

11.0 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)

Parameter	Condition
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.

12.0 SYMBOLS AND DESCRIPTIONS

The symbols 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.
	Unique Device Identifier.
	Do not re-use.
	Do not re-sterilize.

Symbol	Symbol Description
	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.
	Home.
MR Conditional	Magnetic resonance warning: Device is MR conditional.
UK RP	United Kingdom Responsible Person.