BIOHORIZONS®
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English | Instructions for Use: BioHorizons Multi-unit Abutments for CONELOG® | 2

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ENGLISH

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 carry the CE mark and fulfill the requirements of the Medical Devices Directive 93/42/EEC
	Reference/ article number
	Lot/ batch number
	Do not re-use
	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
	EU Authorized Representative
	Do not use if package is damaged
	Medical Device
	Non-sterile

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

DESCRIPTION

BioHorizons Multi-unit Abutments for CONELOG® are intended for the restoration of CONELOG dental implants within the specific indications of each implant system. The label on each device package contains important information including whether the device is supplied sterile or non-sterile.

INDICATIONS

The BioHorizons Multi-unit Abutments for CONELOG are intended to function in the mandible or maxilla to support single and multiple-unit temporary or definitive restorations on CONELOG dental implants.

CONTRAINDICATIONS

BioHorizons Multi-unit Abutments for CONELOG 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

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 (IFU) that accompany BioHorizons devices. The BioHorizons Multi-unit straight and angled abutment screws for CONELOG are packaged with the corresponding abutments and must be torqued to 20Ncm for intended function. Prosthetic screws must be torqued to 15Ncm.

BioHorizons Multi-unit Prosthetic Component design parameters are as follows:

- Minimum post height shall be equal to or greater than 4mm.
- Reduction of wall thickness is not permitted.
- Angle correction is not permitted. Angled Multi-unit abutments shall be used for angle correction.

BioHorizons Multi-unit Prosthetic Components used with the Multi-unit Abutments for CONELOG are intended to support multiple-unit temporary or definitive restorations except for the Titanium Coping. The Titanium Coping used with the Multi-unit Abutments for CONELOG is intended to support single and multiple-unit temporary or definitive restorations.

WARNINGS AND PRECAUTIONS

Clinician judgment, as related to individual patient presentations, must always supersede recommendations in any BioHorizons IFU. Clinicians are responsible for understanding the appropriate technical use of the BioHorizons Multi-unit Abutments for CONELOG. 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 specific IFU.

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: inadequate implant support when attached to periodontically compromised teeth, non-passive fit of superstructure, overloading due to improper occlusion, incomplete seating, 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.

Small diameter implants and angled abutments are not recommended for use in the posterior region of the mouth.

BioHorizons Multi-unit Abutments for CONELOG 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.

BioHorizons Multi-unit Abutments for CONELOG require the addition of a coping or cylinder for single and multiple-unit restorations. The coping or cylinder gingival collar, angulation, and wall thickness shall not be modified. The coping or cylinder post height shall not be less than 4mm for single-unit restorations.

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) implant and/or abutment breakage; (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. The BioHorizons Multi-unit Abutments for CONELOG should be considered sterile unless the package has been opened or damaged. Using accepted sterile technique, remove product from the package only after the correct size has been determined and the surgical site has been prepared.

BioHorizons Multi-unit Prosthetic Components are provided non-sterile and must be cleaned and sterilized prior to use. The following cleaning protocol shall be used:

1. Prepare a detergent bath in a sterile container using a broad-spectrum cleaning or disinfecting agent such as HuFriedy'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 or wipe product with 70% IPA.
7. Blot product dry with clean lint free cloth.

For sterilization of the BioHorizons Multi-unit Prosthetic Components, place product in an FDA cleared sterilization bag or wrap and run through one of the following qualified sterilization cycles:

Sterilization Cycles				
Reference:	ANSI/AAMI TIR12:2010	ANSI/AAMI TIR12:2010	ANSI/AAMI TIR12:2010	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 product from the sterilization bag or wrap.

Conelog® is registered trademark of Camlog Biotechnologies GmbH.