INTRA-LOCK® DENTAL IMPLANTS

ENGLISH	Instructions for Use: CAD/CAM Bars

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This document applies to Intra-Lock CAD/CAM Bars.

DESCRIPTION

Intra-Lock CAD/CAM Bars are computer aided designed (CAD), precision computer aided milled (CAM) superstructures manufactured for individual patients. The Intra-Lock CAD/CAM Bars provide support for a fixed or removable prosthetic device.

INDICATIONS FOR USE

Intra-Lock CAD/CAM Bars are intended for use as superstructures of a multiple-unit endosseous dental implant system, attaching directly to implants or abutments, to support a prosthetic device in a partially or fully edentulous patient for the purpose of restoring chewing function. Implant-level bars are compatible with the Intra-Lock Fusion implant system. Abutment-level bars are compatible with Intra-Lock Multi-unit Abutments.

All digitally designed Intra-Lock CAD/CAM Bars are intended to be sent to a BioHorizons-validated milling center for manufacture.

CONTRAINDICATIONS

Intra-Lock CAD/CAM Bars 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 bar design file is created by a BioHorizons-validated milling center or Intra-Lock customer using commercially available dental CAD/CAM software (e.g., 3Shape). If a customer is designing the bar, the digitally designed file is to be sent to a registered and listed BioHorizons-validated milling center for milling. Visit **www.biohorizons.com** for a list of validated milling centers. Once the design is completed, dental CAD/CAM software is used to generate the CAM output for milling.

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 Intra-Lock products.

Intra-Lock CAD/CAM Bars include retaining screws specifically designed for use in those bars. Implant-level bar retaining screws must be torqued to 30 Ncm. Abutment-level bar retaining screws must be torqued to 15 Ncm.

Design parameters for the Intra-Lock CAD/CAM Bars are included in the following table.

Minimum Cylinder Wall Thickness	Max. Anterior-Posterior (AP) Spread	Maximum Implant Span	Minimum Connector Area
0.3mm	1.5	30mm	$1mm^2$

Intra-Lock CAD/CAM Bars designed using CAD/CAM techniques must fulfill the Intra-Lock allowable range of design parameters.

WARNINGS AND PRECAUTIONS

Clinician judgment, as related to individual patient presentations, must always supersede recommendations in any Intra-Lock IFU. Clinicians are responsible for understanding the appropriate technical use of Intra-Lock prosthetic components. Additional technical information is available upon request from BioHorizons or may be viewed and/or downloaded at www.intra-lock.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: 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.

Do not modify the implant/bar interface. Modifications to the implant/bar interface will result in an improper fit with the implant. The FDA considers the modifier of the implant/bar interface a medical device company subject to FDA rules and regulations.

Intra-Lock CAD/CAM Bars 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.

MAGNETIC RESONANCE (MR) SAFETY INFORMATION

MR Conditional

Intra-Lock 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 results 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 https://ifu.intra-lock.com.

COMPLICATIONS AND ADVERSE EFFECTS

The risks and complications with bars and implants include, but are not limited to: (1) allergic reaction(s) to implant and/or bar material; (2) implant and/or bar breakage; (3) 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. Prior to patient contact, Intra-Lock CAD/CAM bars must be cleaned and sterilized. Intra-Lock devices have not been validated for automated cleaning. The following cleaning protocol must be used:

1) Prepare a detergent bath in using a broad-spectrum cleaning agent such as Hu-Friedy's Enzymax® per the manufacturer's recommendations. Refer to legal manufacturer's instructions for use for preparation of the detergent solution.
2) Brush the device to remove visible debris using a soft bristled brush moistened with the prepared detergent solution.
3) Thoroughly rinse the 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 a clean lint free cloth.

For sterilization, place final-prepped and cleaned device 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.

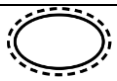
Devices to be disposed of must be treated and decontaminated as dental surgery waste in compliance with the relevant local regulations.

CAUTION: Federal law (US) restricts this device to the sale, distribution, and use by or on the order of a licensed medical professional.

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

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

Symbol	Symbol Description
	United Kingdom Responsible Person.