English

Instructions for Use: CAD/CAM Bars

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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
CE	Intra-Lock products may carry the CE mark and fulfill the requirements of the Medical Devices Directive 93/42/EEC. The CE mark is valid only if it is printed on the product label.
REF	Reference/article number
LOT	Lot/batch number
	Do not re-use
	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.
Non-sterile	Non-sterile

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

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. Intra-Lock 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 Intra-Lock or may be viewed and/or downloaded at www.intra-lock.com. Contact Intra-Lock 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.

The Intra-Lock CAD/CAM Bars have not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating, migration, or image artifact in the MR environment. The safety of Intra-Lock CAD/CAM Bars in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

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. Intra-Lock assumes no responsibility for attempted re-use or re-sterilization between patients.

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 product 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. 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 or wipe product with 70% IPA.
7) Blot product 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:	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 device from the sterilization bag or wrap.

CAUTION: FEDERAL LAW (US) RESTRICTS THIS DEVICE TO THE SALE, DISTRIBUTION, AND USE BY OR ON THE ORDER OF A LICENSED MEDICAL PROFESSIONAL.