Caution: U.S. federal law restricts this device to sale by, or on the order of, a licensed dentist or physician.

BioHorizons instruments are used for dental implant procedures such as site development, implant placement, and implant restorations within the specific indications of the implant system. The label on each instrument contains important information including whether the instrument is supplied sterile or non-sterile. Instruments and trays supplied non-sterile must be cleaned and sterilized prior to first use and each use thereafter.

INDICATIONS FOR USE

BioHorizons Zygoma instruments and surgical trays are indicated for use in site development, placement, and restoration of BioHorizons Pro Zygoma implants and associated components.

CONTRAINDICATIONS

BioHorizons instruments should not be used with patients that have allergies to the specific materials used, including stainless steel and titanium alloy.

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 pertaining to BioHorizons products.

Drills and burs: Should be replaced when wear is noticed, such as a decrease in cutting efficiency or when signs of discoloration appear. Cutting instruments should be replaced after approximately 20 to 30 osteotomy cycles, depending on bone density. For soft bone, it is recommended to use 20 cycles. For hard bones, it's recommended to use up to 30 cycles. BioHorizons recommends use of a drill usage chart to track drill use and to ensure drills are replaced as directed.

WARNINGS AND PRECAUTIONS

Clinician judgment, as related to individual patient presentations, must always supersede recommendations in any BioHorizons Instructions for Use (IFU). Refer to OSHA standard 29CFR1910.1030 prior to cleaning and sterilization. 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. BioHorizons contact information is provided at the end of this document. Prosthetic Instruments - Only use a torque wrench for final installation of prosthetic components requiring a specified installation torque. Finger-tightening of prosthetic components can

result in insufficient torque and eventual loosening of the component. Over-tightening prosthetic components could break the component or spin the mating implant.

COMPLICATIONS AND ADVERSE EFFECTS

The risks and complications with instruments, prosthetics, and implants include, but are not limited to: (1) allergic reaction(s) to instrument, implant and/or abutment material; (2) breakage of 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) orbital socket perforation (11) labial or lingual plate perforation; (12) bone loss possibly resulting in revision or removal; and (13) respiratory and/or intestinal tract damage as a result of component aspiration/ingestion.

HANDLING AND STERILIZATION

Always handle the device with powder-free gloves and avoid contact with hard objects that may damage the surface. If the device is supplied sterile, it should be considered sterile unless the package has been opened or damaged. Using accepted sterile technique, remove device from the package only after the correct size has been determined. For non-sterile devices, remove and discard any shipping material before initial processing. Non-sterile single use devices and devices intended for reuse must be cleaned and sterilized prior to use. BioHorizons devices have not been validated for automated cleaning. The following cleaning protocol must be used:

Instruments (Excluding Drills)

1) Assembled instruments (e.g., Screw-retained Implant Driver (CRIDSRP)) should be disassembled before each cleaning and sterilization cycle to avoid debris encapsulation, material discoloration and/or inappropriate drying of components.
2) Remove all the instruments from the instrumentation trays and disassemble the trays before each cleaning.
3) Prepare a detergent solution 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 of detergent solution.
4) Fully immerse the devices in the prepared detergent solution and brush them to remove visible soil.
5) Remove the devices from the detergent solution and rinse them thoroughly under running utility tap water.
6) Place devices in an ultrasonic unit filled with fresh detergent solution and sonicate for ten (10) minutes.
7) Remove the devices from the detergent solution and thoroughly rinse them under running utility tap water.
8) Wipe the devices with 70% isopropyl alcohol (IPA).
9) Blot the devices dry with clean lint free cloths and allow them to air dry completely.

Drills

1) Remove all the drills from the instrumentation trays.
2) Prepare a detergent solution 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 of detergent solutions.
3) Drills shall be brushed to remove visible debris using a soft bristled brush moistened with the prepared detergent solution.
4) Thoroughly rinse drills thoroughly under running utility tap water.
5) Drills shall be placed in a sterile tube filled with fresh detergent solution and sonicated for ten (10) minutes.
6) Thoroughly rinse drills under running utility tap water.
7) Spray the drills with 70% IPA.
8) Blot the drills dry with clean lint free cloths.

Instruments that are unable to be cleaned, are discolored, do not properly interface with mating components, and/or do not articulate as designed should be disposed of. If applicable, return the instruments to the appropriate locations in the instrumentation tray. For sterilization, place the cleaned device in an approved sterilization bag or wrap and run through one of the following qualified sterilization cycles:

Sterilization

1. Dry all instruments before the steam sterilization cycle.
2. Use packaging that is compatible with the steam sterilization process.
3. Steam sterilizes in cycles of 121°C at 1 ATM pressure for 30 minutes or 134°C at 2 ATM pressure for 20 minutes. Leave to dry for 30 minutes.
4. Always place the case in the autoclave on a flat surface away from the walls of the appliance.
5. Never overlap objects or other cases.

Attention! Improper cleaning may lead to inadequate sterilization. Failure to completely dry instruments during autoclaving may leave moisture and cause discoloration and oxidation. The use of hydrogen peroxide or other oxidizing agents will damage the surface of the instruments. Periodic testing, cleaning, and calibration of the autoclave equipment is recommended to ensure the unit remains in proper working order. 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	Title of Symbol (Reference Number)
	Caution
	Eletronic instructions for use

	Manufacturer
CE	BioHorizons products carrying the European Conformity (CE) mark fulfill the requirements of the Medical Device Directive 93/94/EEC as amended by Directive 2007/47/EC or the Medical Devices Regulaton 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 nunber
LOT	Lot/Batch number
UDI	Unique Device Identifier
	Do not re-use
	Do not resterilize
	Use-by date
STERILE R	Sterilized 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 os physician
EU REP	European Union Authorized Representative
	Do not use if package damaged. Discard device and package.
MD	Medical Device
	Non-Sterile
	Single sterile barrier system with protective packing outside
	Single sterile barrier system
	Home
	Magnetic resonance warning: Device is MR conditional

UK RP	United Kingdom Responsible Person

MANUFACTURER
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