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

INDICATIONS FOR USE

Pro Zygoma dental implants are intended for placement in the maxillary arch to provide support for fixed or removable dental prostheses in patients with partially or fully edentulous maxillae. The Pro Zygoma dental implants may be used with single-stage or two-stage procedures and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.

DESCRIPTION

Pro Zygoma dental implants are manufactured from Titanium alloy conforming to ASTM F136 (Ti-6Al-4V ELI) and are provided with an anodized surface finish and resorbable blast texture (RBT) surface coating on the threaded portion. Pro Zygoma implants have BioHorizons Pro Conical Regular connection. Provided STERILE. Sterilized by irradiation.

DIMENSIONAL INFORMATION
Pro Zygoma Dental Implant size.

Body Ø, mm	Platform Ø,mm	Lenghts, mm
3.8	3.8	30, 32.5, 35, 37.5, 40, 42.5, 45, 47.5, 50, 52.5, 55, 57.5, 60
4.2	4.2	30, 32.5, 35, 37.5, 40, 42.5, 45, 47.5, 50, 52.5, 55, 57.5, 60

CONTRAINDICATIONS

Pro Zygoma dental implants are contraindicated in the following conditions:

- the maxillary or zygoma bone quantity and quality is insufficient to provide initial stability to the implant.
- inadequate bone volume for zygoma or conventional implants, or where adequate numbers of implants cannot be placed to achieve full functional support of a prosthesis
- when the site or systemic conditions show inadequate or poor oral hygiene
- acute or chronic periodontal infection
- chemical dependence
- occlusal parafunction
- radiation history to the implant site
- inappropriate patient for prolonged or complicated oral surgery
- inability to build a functional prosthetic construction
- rehabilitation with dental implants is also contraindicated for children, pregnant women and during breastfeeding
- in cases of immediate loading, with inappropriate primary stability of the implant

WARNINGS

The surgical technique for Pro Zygoma dental implants installation is highly specialized and the surgical procedure is complex; it is recommended that clinicians be technically qualified so that the application of the Pro Zygoma dental implants is safe and efficient. Implant treatment of irradiated patients is dependent upon the timing of implant placement in relation to the radiation therapy, the anatomic sites chosen for implant placement, the radiation dosage at the selected sites, and consequent risk of osteoradionecrosis. Product is for professional use only. Product is sterilized by gamma radiation. Sterility is ensured except in cases where the package has been violated or damaged. Do not use it if the package is damaged or after the expiration date. Single use only. Do not resterilize. The reuse or re-sterilization of this product can cause damage to health.

MRI Safety Information

MR Conditional
Non-clinical testing and in vitro electromagnetic simulations demonstrated that S.I.N. Tapered Pro Conical Zygoma Implant System devices are MR Conditional.

A patient with this device can be scanned safely in an MR system under the following conditions:

Device Name	S.I.N. Tapered Pro Conical Zygoma Implant System
Static Magnetic Field Strength (B_0)	≤ 3.0 T
Maximum Spatial Field Gradient	50 T/m (5,000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Head coil and body coil permitted. Extremity T/R coils permitted.
Operating Mode	Normal Operating Mode in the allowed imaging zone
Maximum Whole Body SAR	2.4 W/kg (15 minutes of scanning, Normal Operating Mode)
Maximum Head SAR	2.0 W/kg (15 minutes of scanning, Normal Operating Mode)
Scan Duration	15 minutes
Temperature Rise	Maximum temperature rise of 0.45 °C/(W/kg), after 15 minutes of continuous scanning in a static magnetic field of 3 T with either head type or body type coils
Artifact	When imaged using a gradient-echo sequence and a 3 T MR system, image artifact can extend up to approximately 12 mm with a body coil type, and up to approximately 32 mm with a head coil type

PRECAUTIONS

Before implant installation, to obtain a predictable long-term outcome, the clinician must submit the patient to a detailed and careful medical history, examination, radiographs, laboratory tests, and study models for appropriate planning. Before surgery, a clinical, physical and radiological

examination must be performed to determine adequate bone dimensions, anatomical landmarks, occlusal conditions, and periodontal health. The patient must have clinically symptom-free sinuses and no pathology in surrounding bone or soft tissue. It is recommended that a CT scan and or CBCT analysis be performed as part of the planning process for the following reasons:

- to detect the presence of any pathology in the maxillary sinuses.
- to evaluate the bone volume and bone condition.
- to assess the relationship/occlusion of the mandible and maxilla.

Pro Zygoma dental implants are recommended for the posterior (premolar/molar) region, with one zygoma implant on each side and at least two standard dental implants in the anterior region to support fixed restoration. Where there is insufficient bone for good stability of anterior implants, a quad Zygoma protocol is indicated. This involves placing a total of four Zygoma implants (two per side) with one of these implants per side angled to emerge in the anterior region and one per side to emerge in the posterior region. Implant failure increases when implants are placed in irradiated bones as radiotherapy can result in progressive fibrosis of vessels and soft tissue, leading to diminished healing capacity. The use of zygoma implants in bone tissue which has been irradiated as part of cancer therapy may result in the following:

- delayed or failed osseointegration of implants due to reduced bone vascularity, clinically expressed as osteoradionecrosis.
- tissue dehiscence and osteoradionecrosis.
- implant failure and loss.

ADVERSE EFFECTS

Loss of the implant and prosthesis is possible for many reasons, including implant contamination, inappropriate surgical technique, poor bone quality, inappropriate oral hygiene, and parafunctional habits (tooth-grinding).

SURGICAL COMPLICATIONS

The implant installation surgical procedure may bring risks during and after the surgery, such as: pain, edema, hemorrhage, dehiscence, paresthesia, and infection.

SHIPMENT AND HANDLING

Pro Zygoma dental implants are sent to professionals duly packaged, sealed and sterilized. Always handle the devices with powder-free gloves and avoid contact with hard objects that may damage the surface. Devices that are supplied sterile should be considered sterile unless the packaging has been opened or damaged. Using accepted sterile techniques, remove the implant from the package only after the correct size/length has been determined and the surgical site has been prepared.

ATTENTION
Exclusive Product for Dental Use. Reprocessing is prohibited. If any incident caused by the product occurs, the professional must immediately inform the manufacturer. If you need a printed version of this instruction for use, free of charge, please request it by email at sin@sinimplantsystem.com or www.sinimplantsystem.com.br/downloads/

DIRECTIONS FOR USE

Note: During all drilling to develop the implant surgical site, avoid deflecting the drill sideways and use continuous, copious irrigation.

Transfer of the implant from the package to the surgical site shall be carried out using a Conical Implant Driver mated to a handpiece for proper insertion. Pro Zygoma dental implants were designed for a maximum torque of 80 Ncm. Higher torques may cause irreversible damage to the implant driver or implant as well as surgical complications. The tightening torque for installing Pro Conical Angled Multi-unit Abutments to Pro Zygoma dental implants is 20 Ncm. The tightening torque for BioHorizons prosthetic components to Pro Conical Angled Multi-unit Abutments is 15 Ncm.

Note: Do not install the cover screw with the ratchet or torque wrench since this may damage the implant; hand tighten it with a Manual .050 Hex Driver (HD050M).

Pro Zygoma Dental Implant Drilling Sequence

1. Based on surgeon preference, the surgical protocol may begin with the 2.0mm Marking Drill (DM20Z or DM20P) or the 3.8mm Round Bur (DBB 38-BH) to mark the osteotomy site. Either instrument should be used at a recommended speed of 1200 RPM.
2. If utilizing an extra-maxillary approach, a cylindrical bur (DCB38-BH or DCB42-BH) may be used to create a groove or channel for subsequent drilling and implant placement. Cylindrical Burs should be used at a recommended speed of 1200 RPM.
3. Prepare the surgical site with the 1.9mm Zygoma Pilot Drill (DZP19S, DZP19M, or DZP19L) taken to full depth at a recommended speed of 800 RPM.

Note: Zygoma drills are available in three lengths to accommodate patient anatomy and surgical placement. Attention should be given to the laser markings on the drills that indicate drilling depth.

4. Based on chosen implant diameter, further prepare the surgical site with the 3.8mm or 4.2mm Zygoma Soft Bone Drill (DZS38S, DZS38M, DZS38L or DZS42S, DZS42M, DZS42L) taken to full depth at a recommended speed of 800 RPM.
5. If necessary, based on bone condition, the 3.8mm or 4.2mm Zygoma Dense Bone Drill (DZD38S, DZD38M, DZD38L or DZD42S, DZD42M, DZD42L) may be utilized to further prepare the surgical site at a recommended speed of 800 RPM.
6. Check the depth of the prepared surgical site with the Zygoma Depth Probe (ZDP) to ensure that the selected implant is an appropriate length.

Pro Zygoma Dental Implant Placement

1. Remove the adhesive part of the package and the inner tray containing the dental implant. Place the inner tray over a surgical tray or organizer.
2. Remove the Tyvek label, exposing the implant.
3. With the Conical Implant Driver (CDIDHL, CRIDHP, or CRIDHS) attached to the handpiece, insert the driver into the implant until it is fully engaged.
4. With the implant retained by the driver, carry the implant to the prepared surgical site.
5. With the implant in position, start the implant installation at a low speed (20 RPM). Do not move the implant vertically or laterally as this can damage the surgical site and jeopardize implant stability.
6. If required, complete implant insertion using the Manual Driver (ZPMD) or Torque Wrench (STW80) with a compatible Conical Implant Driver (CRIDRL, CRIDRP, or CRIDRS).
7. After implant placement, remove the implant driver.
8. For delayed loading procedures, apply the Cover Screw using the Manual .050” Hex Driver (HD050M) and suture the gingiva.
9. For immediate loading, install the selected BioHorizons Pro Conical Multi-unit Abutment and BioHorizons prosthetic components.

Symbols Glossary
ANSI/AAMI/ ISO 15223-1:2016 Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements.

Symbol	Title of Symbol (Reference Number)	Meaning of Symbol
	Caution (5.4.4)	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	Keep away from sunlight (5.3.2)	Indicates a medical device that needs protection from light sources.
	Upper limit of temperature (5.3.6)	Indicates the upper limit of temperature to which the medical device can be safely exposed.
	Sterilized using irradiation (5.2.4)	Indicates a medical device that has been sterilized using irradiation.
	Keep dry (5.3.4)	Indicates a medical device that needs to be protected from moisture.
	Do not use if package damaged (5.2.8)	Indicates a medical device that should not be used if the package has been damaged or opened.
	Do not re-use (5.4.2)	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
	Do not resterilize (5.2.6)	Indicates a medical device that is not to be resterilized.
	Consult instructions for use (5.4.3)	Indicates the need for the user to consult the instructions for use.
	Use-by date (5.1.4)	Indicates the date after which the medical device is not to be used.
	Date of manufacture (5.1.3)	Indicates the date when the medical device was manufactured
	Manufacturer (5.1.1)	Indicates the medical device manufacturer.
	Catalogue number (5.1.6)	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Batch code (5.1.5)	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	MR Conditional (N/A)	Conditions under which a medical device can safely enter the MR environment

MANUFACTURER

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