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 Conical Angled Multi-unit Abutments in 45°, 52°, and 60° angulations are intended to restore dental implants in the maxillary arch by providing support for fixed or removable dental prostheses in patients with partially or fully edentulous maxillae to restore patient esthetics and chewing function.

Pro Conical Angled Multi-unit Abutments with 45°, 52°, and 60° of angulation are indicated for use only with Pro Zygoma dental implants.

When a one-stage surgical approach is applied, Pro Conical Angled Multi-unit Abutments in 45°, 52°, and 60° angulations can be installed for immediate loading when satisfactory primary stability of the corresponding Pro Zygoma implant is achieved and with appropriate occlusal loading.

DESCRIPTION

Pro Conical Angled Multi-unit Abutments (45°, 52°, and 60°) have BioHorizons Pro Conical Regular connection and have a yellow anodized color. The 45°, 52°, and 60° Pro Conical Angled Multi-unit Abutments are designed for use only with Pro Zygoma dental implants. All Pro Conical Angled Multi-unit Abutments are manufactured from Titanium alloy (Ti-6Al-4V ELI) conforming to ASTM F136. Provided STERILE. Sterilized by irradiation.

CONTRAINDICATIONS

Pro Conical Angled Multi-unit Abutments in 45°, 52°, and 60° angulations used in conjunction with Pro Zygoma dental implants are contraindicated in the following conditions:

- the maxillary bone quantity and quality is insufficient to provide initial stability to the implant
- inadequate bone volume for zygomatic 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 prosthesis
- 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 dental implant installation is highly specialized and the surgical procedure is complex. It is recommended that clinicians be technically qualified so that the application of the dental implants is safe and efficient. 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 if the package is damaged or after the expiration date. Single use only. Do not re-sterilize. 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 the 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 professional must submit the patient to a detailed and careful medical history, examination, radiographs, laboratory tests, and study models for appropriate planning.

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 Conical Angled Multi-unit Abutments 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 device from the package only after the correct size 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 https://www.sinimplantsystem.com/ifu-biohorizons/

DIRECTIONS FOR USE

Ensuring the continued sterility of both the Pro Conical Angled Multi-unit Abutment and Multi-unit Abutment Screw is crucial. These components are provided sterile and sealed within a blister pack.

After implant installation:

Pro Conical Angled Multi-unit Abutments (45,° 52°, 60°)

1. Remove the Multi-unit Abutment from its sterile packaging.
2. Carry the Multi-unit Abutment to the mouth using the attached Multi-unit Delivery Handle.
3. Insert the Multi-unit Abutment into the implant connection, ensuring full seating and proper orientation.

4. Affix the Multi-unit Abutment to the implant using the Multi-unit Abutment Screw using a .050” Hex Driver (HD050H, HD050HEL, HD050REL, or HD050R).
5. Tighten the Multi-unit Abutment Screw to a final torque of 20 Ncm.
6. Remove the Multi-unit Delivery Handle from the Multi-unit Abutment

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

MANUFACTURED FOR
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