Paragon Implant Mfg., LLC
27030 Malibu Hills Road, Calabasas, CA 91301
Direct: 855-NIZ-GEN5 (855-649-4365)
www.paragon-implant.com

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Instructions for Use

TriActive Dental Implant System

Caution: Federal law restricts the products mentioned herein for sale by or on the specific order of a dentist.

Dental Implants

Intended Use
TriActive dental implants are two-piece endosseous dental implants intended to be surgically placed in the upper or lower jawbone for anchoring or supporting tooth replacements to restore patient esthetics and chewing function.

Indications for Use
TriActive implants are two-piece implants for one- or two-stage surgical procedures. These implants are indicated for use in partially or fully edentulous upper and lower jaws in support of single- or multiple-unit restorations and terminal or intermediate abutment support for fixed bridgework.

TriActive Implants can be indicated for immediate function when initial implant stability has been achieved and with appropriate occlusal loading.

Short (<8.5mmL) TriActive Implants: Indicated for single tooth (mandibular and maxillary central and lateral incisors), multiple tooth replacements or denture stabilization.

Narrow (<3.7mmD) TriActive Implants are indicated for single tooth replacement of mandibular central and lateral incisors, and maxillary lateral incisors, or splinted to other dental implants for multi-unit fixed or removable partial prostheses, or for denture stabilization.

Compatibility
TriActive Implants are surgically compatible with NobelActive drills using the surgical protocol provided in the below pages and labeling.

All TriActive implant diameters and lengths fitted with Extender Healing Abutments are prosthetically compatible with corresponding TriActive Healing and Prosthetic Components.

Standard Length (≥8.5mmL) TriActive Implants are prosthetically compatible with DESS® (Terrats Medical SL) NobelActive Conical Connection Abutments and implant drivers (NP and RP Conical Connection Implant Drivers).

Short (<8.5mmL) TriActive Implants are not prosthetically compatible with DESS® (Terrats Medical SL) NobelActive Conical Connection Abutments and can only be restored with TriActive extender healing and restorative components. Short TriActive Implants are compatible with DESS® (Terrats Medical SL) implant drivers (NP and RP Conical Connection Implant Drivers).

TriActive implants fitted with Extender Healing Abutments are not prosthetically compatible with Paragon Implant GEN5+ extender-level Healing and Restorative Components.

Standard configuration Extender Multi-unit Abutments are compatible with Paragon Implant, GEN5 Standard MUA Copings (for M1.4 threaded connections).

Low-Profile configuration Extender Multi-unit Abutments are compatible with Paragon Implant, GEN5 Low-Profile MUA Copings (for 1-72 UNF threaded connections).

Contraindications
TriActive dental implants are contraindicated for patients**:**
- Who are medically unfit for an oral surgical procedure.
- Who have allergies or hypersensitivity to chemical ingredients in the following material: Grade 5 Titanium Alloy ELI (Ti-6Al-4V ELI) primarily composed of Titanium, Aluminum, and Vanadium.
- With inadequate bone or soft tissue volume unless an augmentation procedure can be considered.
- Where adequate sizes, numbers or desirable position of implants or abutments are not reachable to achieve safe support of functional or eventually parafunctional loads.
- Where the cantilever conditions are such that they extend >30mm in length between two adjoining implants or restorative distal cantilevers.

Warnings
- Short implants (<8.5mmL) should not be placed in patients who demonstrate untreated occlusal parafunction, such as bruxism or clenching.
- For short implants, immediate restoration or loading on a single implant has not been studied and is not recommended for a terminal molar in an arch or cantilevering more than one pontic off a single implant. Consider a two-stage surgical approach, splinting of implants, and placement of the widest possible implant.
- Because of the reduced surface area for anchorage in the bone, implants with threaded lengths shorter than 8.5mm length should be used with caution because they present greater risks to failures compared to standard implants, and are recommended for the following situations:
  - As an additional implant together with longer implants to support implant-borne reconstructions.
  - As an auxiliary implant for implant-borne bar constructions supporting full dentures in a seriously atrophied mandible.
- For short implants, clinicians should closely monitor patients for any of the following conditions:
  - Peri-implant bone loss
  - Changes to implant's response to percussion
  - Radiographic changes in bone to implant contact along the implant's length.
- If the implant shows mobility or greater than 50% bone loss, the implant should be evaluated for possible removal. If the clinician chooses a short implant, then the clinician should consider a two-stage surgical approach, splinting a short implant to an additional implant, and placement of the widest possible fixture. Allow longer periods of osseointegration and avoid immediate loading.
- Do not restore Short TriActive Implants with healing and restorative components other than those explicitly manufactured by Paragon Implant Company for TriActive Implants.
- 3.2mmD TriActive implants and angled abutments are not recommended for the posterior region of the mouth.

- Narrow (<3.7mmD) and Short (<8.5mmL) TriActive Implants are not indicated for 1mm supra-crestal positioning due to reduced surface area for anchorage in the bone.
- Do not use the device if it is contaminated.

Precautions

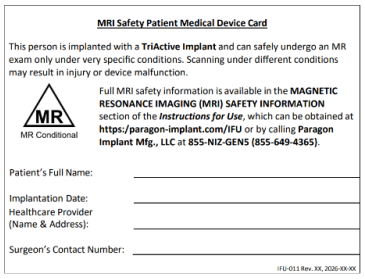
- Use appropriate ancillary components that correspond to the implant system and prosthetic being restored.
- Precautions should be taken while working with prosthetic components in clinical situations to prevent accidental ingestion and aspiration.

Undesirable side effects

The placement of a dental implant constitutes an invasive treatment that may be associated with typical side effects, such as inflammation, infection, bleeding, hematoma, pain, and swelling. Depending on the location, the placement of the implant may also lead (in rare cases) to bone fracture, perforation of neighboring structures, sinusitis, or sensory/motor disturbances. During placement of the implant the pharyngeal (gag) reflex may be triggered in patients with a sensitive gag reflex. During the submerged healing period, bone may grow over the cover screw. In some cases, cover screws may get exposed prematurely.

TriActive dental implants are the substructure of a multi-component system that replaces teeth and, as a result, the implant recipient may experience side effects like those associated with teeth, such as mucositis, calculus, peri-implantitis, fistulas, ulcers, soft tissue hyperplasia, and soft and/or hard tissue recession/loss.

MRI Safety Information:

MR Conditional	Non-clinical testing and MRI simulations demonstrated that every version of the Paragon Implant Family is MR Conditional. A patient with these devices may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.
Parameter	Condition of Use/Information
Nominal Values of Static Magnetic Field (T)	1.5-T or 3.0-T
Maximum Spatial Field Gradient (T/m and gauss/cm)	40-T/m (4,000-gauss/cm)
Type of RF Excitation	Circularly Polarized (CP) (i.e., Quadrature-Transmission, Quadrature Driven)
Transmit RF Coil	Any transmit RF coil may be used.
Receive-Only RF Coil	Any receive-only RF coil may be used.
Operating Mode of MR System	Normal Operating Mode
Maximum Whole Body Averaged SAR (W/kg)	2-W/kg (Normal Operating Mode)
Maximum Head SAR (W/kg)	3.2-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 the implant may produce an MR image artifact. Imaging protocol modifications may be necessary to compensate for the MR image artifact.
Provide MRI Patient Card to patient	 www.paragon-implant.com/IFU

TriActive Implant Sizes

Diameters	Body Diameters	Platform Diameters	Lengths
3.2mm	3.25mm	3.0mm	8.5mm, 10mm, 11.5mm, 13mm, 15mm
3.7mm	3.75mm	3.4mm	7mm, 8.5mm, 10mm, 11.5mm, 13mm, 15mm
4.3mm	4.3mm	3.4mm	7mm, 8.5mm, 10mm, 11.5mm, 13mm, 15mm
5.0mm	4.9mm	3.4mm	7mm, 8.5mm, 10mm, 11.5mm, 13mm, 15mm
5.5mm	5.5mm	3.4mm	7mm, 8.5mm, 10mm, 11.5mm, 13mm, 15mm

Surface Treatment:

Paragon's implants are made of titanium alloy (Ti-6Al-4V ELI) and blasted with MCD Apatitic Abrasive, a calcium phosphate abrasive principally composed of hydroxyapatite and tricalcium phosphate.

The coronal 2.0mm of the TriActive series of implants, traversing down the long axis of the implant is anodized either gold or rose gold. The implant platform and internal features follow the same color identification as the coronal external surface.

The implant's outer threaded surface extends from the base of the anodized coronal aspect to the most apical point of the implant and is blasted with RBM (Resorbable Blast Media), which is the MCD Apatitic Abrasive described above. The surface has a surface roughness of 1.5µm-and 2.3µm and is designed to have no residual Blast Media.

Packaging:

TriActive Implants are provided fixed to an implant carrier, held in place by a press-fit connection with tines and O-ring, and the internal threads of the implant. Once assembled, the carrier and implant engage into the slot of the inner vial which suspends the devices. The bottom section of the inner vial houses an Extender Healing Abutment, Cover Screw, and an Extender Cover Screw sealed with an inner vial plug. The Extender Healing Abutment is pre-threaded onto the Extender Cover Screw for convenient placement. The vial cap is threaded onto the outer vial which seals the devices inside the packaging and provides a sterile barrier. The cap and vial label are color-coded to the Implant's prosthetic platform. The Implant and any included components are single-use only devices and sold sterile by gamma irradiation.

TriActive Implants, Cover Screws, and Extender Healing Abutments are supplied in a gamma irradiated sterile package. The reprocessing and/or re-sterilization of these single-use devices is not permissible.

Storage and Handling:
Users are advised to visually inspect vials to ensure they are free from tampering and contents are intact and in their original packaging prior to use. Do not use the device if packaging is damaged, has a broken tamper evident ring, or illegible text on the vial label. Implants must be stored in a dry place, at room temperature, in their original packaging. Dental implants are provided in sterile vials mounted to implant carriers. Prior to removal of implant from the vial, the clinician must first confirm size and diameter relative to the prepared implant site. The implant carrier is intended to be used to transport the implant to the prepared surgical site. Do not handle implant surfaces directly.

Shelf-life:
Dental Implants, Healing Abutments, and Surgical Cover Screws are deemed sterile for 5 years from the date of manufacture and sterilization. The sterility expiration date is indicated by the hourglass symbol on the product label, followed by an expiration date.

Surgical Techniques for the Placement of Implants:

1. Pretreatment Planning

During the pre-operative stage, availability of the bone-height, the bone-width, and the planned trajectory of the implant must be determined. Appropriate radiography should be used to determine bone availability and optimal implant location while avoiding anatomically compromised structures, such as the mandibular nerve canal, maxillary sinuses and adjacent teeth with their convergent or divergent root system.

Note: Standard Length (>7mmL) and Regular (≥3.7mmD) TriActive Implants can be placed up to 1mm supra-crestal at the discretion of the clinician.

2. Surgical Site Preparation

Follow the drill sequence as shown in Table 1 and 2 for the various implant diameters and procedural steps based on the patient's bone density and volume in those respective areas. It is recommended that Figure A be used to compare the TriActive Depth requirements with the score lines on the NobelActive Surgical Drills, which are shown in Figure B.

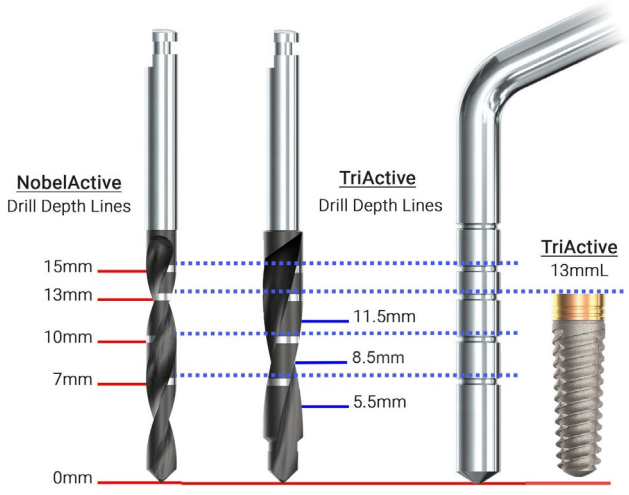


Figure A: A comparison of NobelActive Surgical Drill Depth Score Lines with depth requirements for TriActive implants.

For preparing osteotomies it is recommended that drilling proceeds at a maximum of 2000 RPM, using a steady in-and-out motion, with copious external irrigation by room temperature, sterile saline.

TriActive Dental Implants are designed with a rounded apex. When preparing an osteotomy for a specific length implant using NobelActive Drills, unless otherwise instructed, the drilling depth should be equal to the length of the implant plus an additional 0.5mm to account for the rounded apex (as noted by the 'X' in Table 1 and Table 2).

In certain cases, the surgical sequence in Table 1 and 2 instructs the clinician to drill to the "implant length -1.5mm". For TriActive implant lengths of 7mm, 8.5mm, 10mm, 11.5mm, 13mm, and 15mm, this equates to drill depths of 5.5mm, 7mm, 8.5mm, 10mm, 11.5mm, and 13.5mm, respectively.

In certain cases, the surgical sequence in Table 1 and 2 instructs the clinician to "widen cortex w/" a particular drill diameter. The proposed diameter is one of two diameters that characterizes the dimensions of the step drill. For these cases, the clinician should proceed to a depth only as far as is needed to widen the cortex with the recommended diameter of the step drill.

It is recommended that the depth of the osteotomy should be checked with a depth probe before proceeding with the next surgical drill in the sequence.

Figure B: NobelActive Twist Surgical Drills used for Drill Sequences in Table 1 and Table 2

3. Implant Placement

Once preparation of the osteotomy is finalized, to seat the various implant configurations, use the following steps.

1. Select the implant according to proposed treatment plan. Remove the peel-off label from the vial and place it next to the appropriate tooth number within the patient's information chart. The labels are supplied with information relating to the implant type, product code, length, diameter, prosthetic platform diameter and sterilization date.
2. Remove the cap from the implant vial by rotating the cap in a counterclockwise direction. Continued rotation will separate the cap from its tamper-evident ring that will remain affixed to the outer vial.
3. Gently pour the contents of the outer vial onto a sterile field. Set the outer vial aside.

4. The TriActive Implants are suspended in the sterile inner vial on a titanium alloy (Ti-6Al-4V ELI) implant carrier that is frictionally held in place with tines and O-ring. Select one of the following methods to carry the implant to the site and insert the implant into the osteotomy:
   a) With powder-free sterile gloved hands, grab hold of the colorized titanium carrier, slide it away from the inner vial and transport it to the implant to site. Initiate self-tapping by hand, rotating the assembly in a clockwise direction until resistance is felt. Gently pull the carrier straight up to separate and remove it from the implant. Seat the implant by placing an NP (2.3mm hex) or RP (2.7mm hex) conical connection driver into the implant's internal hex and rotating the implant clockwise.
   OR
   b) Connect a NP (2.3mm hex) or RP (2.7mm hex) conical connection driver into the implant carrier's internal hex and gently slide the assembly away from the inner vial. Carry the implant assembly to the osteotomy and initiate self-tapping by rotating the assembly in a clockwise direction until resistance is felt. Continue rotating the assembly clockwise until the implant is seated. Gently pull the carrier straight up to separate and remove it from the implant.

4. TriActive Implant Healing

Two-stage Healing:
Use a 1.25mmD hex driver to carry an implant Cover Screw and screw the Cover Screw into the implant using finger pressure. Suture the soft tissue over the Cover Screw.

One-stage Healing:
Use a 1.25mmD hex driver to carry the Extender Cover Screw that is connected to the Extender Healing Abutment and screw it into the Implant to 15 - 20 Ncm fully seating the Extender Healing Abutment. Suture the soft tissue around the Extender Healing Abutment.

If, after the Extender Healing Abutment is attached, restorative procedures require access to the Implant's restorative platform, the clinician must remove the friction-fit Extender Healing Abutment. To do so, remove the Extender Healing Abutment Cover Screw and insert and clockwise thread a Friction-Fit Removal Tool through the Extender Healing Abutment and into the Implant's internal threads. The tool will stop in the apex of the internal well of the Implant. Continued clockwise rotation will lift the extender off the Implant, thereby gaining access to the Implant's restorative platform.

5. Post-Operative Care

It is normally recommended that patients use a suitable, non-alcohol-based mouth wash while maintaining good oral hygiene during and post the healing phase.

6. Healing Time

Implants can heal for a period of two to four months prior to being restored. It is dependent on the bone volume and quality, as well as any type of compromising medical conditions.

Table 1: Drill Sequence for 3.7mmD x 7mmL, 4.3 x 7mmL, 5.5mmD x 7mmL Implants Only

Implant Diameter (mm)	Bone Type	Nobel Active Drill Type and Size								Paragon Implant Drill
		1.5	2.0	2.4/2.8	2.8/3.2	3.2/3.6	3.8/4.2	4.2/4.6	4.2/5.0	SD5.4M
3.7mmD	Soft	X	X	X		Widen cortex w/ 3.6mmD				
	Dense	X	X	X	Implant length -1.5mm		Widen cortex w/ 3.8mmD			
4.3mmD	Soft	X	X	X	X			Widen cortex w/ 4.2mmD		
	Dense	X	X	X	X			Widen cortex w/ 4.2mmD		
5.5mmD	Soft	X	X	X	X	X	X		Widen cortex w/ 5.0mmD	Widen cortex w/ 5.4mmD
	Dense	X	X	X	X	X	X		Widen cortex w/ 5.0mmD	Widen cortex w/ 5.4mmD

Note: X = Implant Length +0.5mm to account for rounded apex

Table 2: Drill Sequence for all Additional Implant Sizes									
Implant Diameter (mm)	**Bone Type**	**Nobel Active Drill Type and Size**							**Paragon Implant Drill**
		1.5	**2.0**	**2.4/2.8**	**2.8/3.2**	**3.2/3.6**	**3.8/4.2**	**4.2/4.6**	**4.2/5.0**	**SD5.4M**
3.2mmD	Soft	X	X	Widen cortex w/ 2.8mmD						
	Dense	X	X	Implant length -1.5mm						
3.7mmD	Soft	X	X	X	Widen cortex w/ 3.2mmD					
	Dense	X	X	X	X	Widen cortex w/ 3.6mmD				
4.3mmD	Soft	X	X	X	X		Widen cortex w/ 3.8mmD			
	Dense	X	X	X	X	Implant length -1.5mm	Widen cortex w/ 4.2mmD			
5.0mmD	Soft	X	X	X	X	X		Widen cortex w/ 4.6mmD		
	Dense	X	X	X	X	X	X	Widen cortex w/ 4.6mmD		
5.5mmD	Soft	X	X	X	X	X	X		Widen cortex w/ 5.0mmD	Widen cortex w/ 5.4mmD
	Dense	X	X	X	X	X	X	Implant Length -1.5mm		Widen cortex w/ 5.4mmD
Note: X = Implant Length +0.5mm to account for rounded apex										

Healing and Prosthetic Components

This section applies to the prosthetic components manufactured by Paragon Implant Mfg., LLC.

Paragon is a reseller of DESS products. For all DESS products, please refer to the DESS IFU at https://www.dessdental.com/en/documents/.

Caution: All DESS Ti-base abutments, Ti-blank abutments, CoCr base abutments, and CoCr blank abutments used with the subject implant bodies are not intended for any angular correction and must be straight only.

Indications for Use

TriActive Abutment System: The TriActive Abutment System is intended for use with TriActive dental implants in the maxillary and/or mandibular arches to provide support for crowns, bridges, or overdentures for edentulous or partially edentulous patients, using traditional crown & bridge techniques.

All digitally designed custom abutments for use with DESS Bases or Blanks are to be sent to a Terrats Medical SL validated milling center for manufacture. To find a validated milling center, contact DESS directly at https://www.dessdental.com/en/VMC.

The TriActive Implant bodies are indicated for compatibility with the following abutments systems:

- Ti-base Abutments manufactured by Terrats Medical SL., platform NP and RP, Straight, max 0 degrees
  - Active Hex
- Ti-blank Abutments manufactured by Terrats Medical SL., platform NP and RP, Straight, max 0 degrees
  - Active Hex
- CoCr Base Abutments manufactured by Terrats Medical SL., platform NP and RP, Straight, max 0 degrees
  - Active Hex
- CoCr Blank Abutments manufactured by Terrats Medical SL., platform NP and RP, Straight, max 0 degrees
  - Active Hex
- Angled Multi-Unit Abutments manufactured by Terrats Medical SL., platform NP and RP, Angled, max 30 degrees
  - Active Hex
- Stock Straight Abutments manufactured by Terrats Medical SL., platform NP and RP, Straight, max 0 degrees
  - Active Hex
- Locator Abutments manufactured by Terrats Medical SL., platform NP and RP, Straight, max 0 degrees
  - Active Hex

Warnings:

- These devices are contraindicated for use with cantilever configurations and multiple-units with a span of >30mm between implants.

- Angled Abutments are not recommended for the posterior region of the mouth.

Precautions:

Use appropriate abutments and ancillary components that correspond to the implant system and prosthetic platform being restored. Precautions should be taken while working with prosthetic components in clinical situations to prevent accidental ingestion and aspiration.

Undesirable side effects:

The placement of these devices is part of an invasive treatment which may be associated with typical side effects such as inflammation, infection, bleeding, hematoma, pain, or swelling. During connection or removal of this device the pharyngeal (gag) reflex may be triggered in patients with a sensitive gag reflex. During the submerged healing period, bone may grow over the cover screw. In some cases, cover screws may get exposed prematurely.

Packaging:

All abutments and accessories are cleaned and packaged in an ISO Class 7 cleanroom environment. All abutments and accessories are supplied non-sterile unless they are explicitly marked as sterile. Cleaning and Sterilization is required for all prosthetic components prior to being used intraorally.

Patient Information:

Every product packaging label contains a description of the enclosed device providing the pertinent dimensions required for the full rehabilitation of the patient to the dental specialist, restoring dentist, dental technician and other appropriately trained implant personnel. The two peel-off labels supplied on the product vial contain important product information and should be applied to the patient's record/chart in the event future reference is necessary.

Description and Insertion Procedure for Healing Components/Cover Screws:

All Cover Screws are manufactured from titanium alloy (Ti-6AL-4V ELI). The Implant level Cover Screw is placed on the implant at time of completion of the surgical process, thereby sealing the oral cavity from the inner workings of the implant. The Extender Cover Screw is placed on the Extender Healing Abutment at time of completion of the surgical process, sealing the oral cavity from the inner workings of the implant and Extender Healing Abutment. Cover Screws are provided sterile.

1. Remove the cover screw from the packaging.
2. Use a 1.25mm hex driver, insert the cover screw into the implant or Extender Healing Abutment.
3. Rotate clockwise using finger-pressure to tighten the respective mating components together.

Cover Screws are for single-use only and disposed of after osseointegration has taken place and the start of prosthetic rehabilitation.

Extender Healing Abutments:

Extender Healing Abutments are hex-engaging, implant-level components with a 2mm collar height, a 4.8mm diameter abutment platform, and 2.5mm internal hex. Extender Healing Abutments are manufactured from titanium alloy (Ti-6Al-4V ELI), anodized to match the corresponding implant/abutment interface, and sold sterile. They are intended to support soft tissue maturation and provide an interface for Extender-level Abutments.

To attach the Extender Healing Abutment packaged with a TriActive implant:

1. Use a 1.25mmD hex driver to carry the Extender Cover Screw that is connected to the Extender Healing Abutment to the implant.
2. Turn the Extender Cover Screw clockwise until the threads engage with the implant.
3. Properly index the Extender Healing Abutment with the implant.
4. Continue to turn the Extender Cover Screw clockwise and torque to 15-20 Ncm to seal implant.

To attach the Extender Healing Abutment sold separately:

1. Remove the Extender Healing Abutment from the packaging and with gloved hands and press onto implant.
2. Insert and seat an Extender Cover Screw or Restorative Extender-level Abutment onto the Extender Healing abutment.

To remove the Extender Healing Abutment:

1. Remove the Extender Healing Abutment Cover Screw or Extender Abutment.
2. Thread the Friction-Fit Removal Tool through the Extender Healing Abutment and into the implant. As the tool continues rotating, it will disengage the friction-fit connection and gently lift the Extender Healing Abutment off the implant.

Extender Healing Abutments are for single-use only and must be disposed of if no longer required for the final restoration.

Description and Insertion Procedure for TriActive Extender Restorative Components:

Extender Transfers:

Paragon's implant level transfer devices are for use in recording a direct and indirect impression which can be used as a general transfer method to record the implant position, including orientation of the implant's respective anti-rotational feature, to a master model. Transfer components are manufactured from titanium alloy (Ti-6Al-4V ELI) and anodized according to the implant's prosthetic platform. The transmucosal area maintains the tissue profile formed by the corresponding Extender Healing Abutments.

1. Remove Transfer and Transfer Fixation screws from the packaging.
2. Proceed with cleaning and sterilization instructions as detailed in section below.
3. Connect the Extender Transfer using the corresponding driver in conjunction with a fixation screw.
    a. The Open-Tray Transfer Fixation accepts a 1.25mm Hex Driver or by hand using the knurled head.
    b. The Extender Fixation Screw accepts a 1.25mm Hex Driver or UniGrip Driver.
4. Seat the transfer flush with the extender abutment interface using finger pressure.

Extender Straight Abutments:

The Extender Straight Abutments are manufactured from titanium alloy (Ti-6Al-4V ELI). Abutments are supplied with a separate fixation screw manufactured from titanium alloy (Ti-6Al-4V ELI). They are used as a terminal or intermediate abutment for cement-retained prostheses. A circumferential scalloped margin indexed to the flat of the implants internal hex, aids in profiling of the restoration to the surrounding profile of the soft tissue.

1. Remove the abutment assembly from the packaging.
2. Remove the abutment from the plastic screw mount by unscrewing the fixation screw with the corresponding driver.
3. Follow the cleaning and sterilization instructions as detailed in section below.
4. Seat the abutment using the corresponding driver in conjunction with a fixation screw.
5. Torque abutment fixation screw to 30Ncm to ensure fixation between mating components.

Warning: Modification of Straight Abutments: If modifications are required, the following must be maintained: a maximum angle of 30° from the axis of the implant, a minimum wall thickness of 0.4mm, a minimum post height of 4mm and a minimum cuff height from the interface of 0.7mm.

Caution: Modification of Abutments should be performed using copious water irrigation. Extra-oral modification of Abutments is recommended. Use a carborundum disk and carbide bur.

Extender Angled Screw Channel (ASC) Abutments and Components:

Extender ASC Abutments are used in the fabrication of a screw-retained restoration with the screw access hole placed at any angle from 0° to 25°, to permit an esthetic solution in the anterior or to improve occlusal access in the posterior. The Extender ASC Abutment coronal portion has a section of the outer wall removed during the manufacturing process. The clearance is made so the specialized ASC Driver can gain access to the fixation screw within and be used to tighten the prosthesis to the recommended torque of 30Ncm. Use of this abutment ensures that the access hole exits the restoration through the center of the occlusal table or cingulum and, in some cases in the posterior area, that the access hole can be mesially inclined for ease of access by the restoring clinician or laboratory technician. This abutment is not intended to correct angulation of the abutment, relative to the axis of the implant.

1. Remove the abutment and fixation screw from the packaging.
2. Follow the cleaning and sterilization instructions as detailed in section below.
3. Seat the abutment using a Torx 6 Driver in conjunction with a fixation screw.
4. Torque abutment fixation screw to 30Ncm to ensure fixation between mating components.

Warning: If modifications are required, the following must be maintained: a minimum wall thickness of 0.4mm, a minimum post height of 4mm and a minimum cuff height from the interface of 0.7mm.

Warning: This Abutment is not indicated for angulation correction of the restoration relative to the axis of the Implant.

Caution: Modification of Abutments should be performed using copious water irrigation. Extra-oral modification of Abutments is recommended. Use a carborundum disk and carbide bur.

Extender Multi-Unit Abutments (MUA):

Extender Multi-Unit Abutment (MUA) Screws are non-engaging, one-piece abutments manufactured from titanium alloy (Ti-6Al-4V ELI). The assembly only requires dimensional accuracy related to the internal thread of the implant. Extender Multi-Unit Abutments (MUA) are available in a Standard configuration with an external hex and M1.4 internal threads, and a Low-Profile configuration with a 1.25mm internal hex and 1-72 UNF internal threads. Both Standard and Low-Profile Extender MUA options are available in 0mm, 1mm, and 2mm long cuff heights.

1. Remove the abutment screws from the packaging.
2. Follow the cleaning and sterilization instructions as detailed in section below.
3. Use the following instructions to seat the Extender MUA depending on the Standard or Low-Profile configurations.
    a. Seat the Standard Extender MUA abutment using an abutment-specific socket tool designed to engage the coronal hex of the abutment. Torque abutment to 30Ncm to ensure fixation between mating with implant.
    b. Seat the Low-Profile Extender MUA abutment using a 1.25mmD hex driver. Torque abutment to 30Ncm to ensure fixation between mating with implant.

NOTE: Extender Multi-Unit Abutments feature a tapered cone with internal screw access for attaching various restorative components using a separate prosthesis screw. The standard configuration cone has a 23° taper and a 2.2 mm height, while the wide configuration cone has a 23° taper and a 1.0 mm height.

Extender MUAs are compatible with corresponding Standard and Low-Profile Paragon Implant, GEN5 Dental Implant System MUA Copings.

Extender NizLoc Abutment Screws

Extender NizLoc Abutment Screws are gold-anodized mono-piece Abutments possessing a prosthetic platform designed with an external profile that replicates the Locator®/GPS Attachment platform, an anchoring profile widely accepted by the dental implant industry for removable overdenture systems. The NizLoc platform is compatible with all mating DESS® components manufactured by Terrats Medical SL required for the complete restoration of Locator®/GPS type attachment system.

1. Remove the Abutment from the packaging.
2. Follow the cleaning and sterilization instructions as detailed in section below.
3. Seat the abutment using the corresponding 1.25mm driver.
4. Torque abutment fixation screw to 30Ncm to ensure fixation between mating components.

Extender Titanium Temporary Abutments:

The Extender Titanium Temporary Abutments and supplied fixation screw are manufactured from titanium alloy (Ti-6Al-4V ELI). The Extender Titanium Temporary Abutment is a hex engaging, screw retained abutment intended to be used for interim restoration and provisional support during the time a final restoration is being prepared. A maximum time limit up to 180 days applies for their use.

1. Remove the abutment and fixation screw from the packaging.
2. Follow the cleaning and sterilization instructions as detailed in section below.
3. Seat the abutment using the corresponding 1.25mm driver.
4. Torque temporary abutment fixation screw to 20Ncm to ensure fixation between mating components.

Warning: If modifications are required, the following must be maintained: a maximum angle of 30° from the axis of the implant, a minimum wall thickness of 0.4mm, a minimum post height of 4mm and a minimum cuff height from the interface of 0.7mm.

Caution: Modification of Abutments should be performed using copious water irrigation. Extra-oral modification of Abutments is recommended. Use a carborundum disk and carbide bur.

Extender Fixation Screws:

Extender Fixation Screws are designed to interface with the implant thread for attachment of two-piece Abutments or Abutment Transfers. Several screws supplied with the system have the dual-grip configuration which can receive a variety of hex or torx shaped Drivers. All of the Extender Fixation Screws are manufactured from titanium alloy (Ti-6Al-4V ELI).
Extender Fixation Screws should be torqued to 20Ncm for temporary abutments and 30Ncm for final abutments.

Post-Restorative Care:

It is recommended that patients use a suitable mouth rinse for the first 7 to 10 days following implant restoration. Subsequently, patients should perform oral hygiene and maintain regular dental prophylaxis.

Cleaning and Sterilization of Prosthetics and Single-Use Componentry:

All restorative components, inclusive of Implant- and Abutment-Level Impression Transfers, both one- and two-piece Titanium Abutments, Prosthetic Screws and accessories, are processed and packaged within a cleanroom environment. Restorative products are supplied in a non-sterile form unless otherwise indicated as sterile. Cleaning can be performed manually or in an automatic washer.

Warning: Cleaning and sterilization are required for all restorative components prior to being placed intraorally.

Warning: Always follow indications, instructions, and warnings provided by the supplier of the cleaning solution. Select only solutions intended for cleaning of medical devices made of a variety of metals and plastics.

Manual Cleaning and Drying:

Note: Enzymatic-based cleaning solutions must be diluted per the manufacturer's instructions.

Note: It is recommended that the final rinse be performed with deionized, preferably distilled water.

1. Begin cleaning by disassembling the components completely and rinsing under lukewarm, running tap water for approximately 3 minutes.
2. Scrub exterior surfaces of components with a soft-bristled, nylon brush or lint free cloth until all visible soil is removed.
3. Flush the inner surfaces, cavities, and lumina (where applicable) with 20mL of an enzyme-based cleaning solution (e.g. neodisher® MediZym) using a disposable 20mL syringe with an irrigation needle.
4. Scrub interior surfaces, lumina, and cavities (where applicable) using an appropriately sized soft-bristled, nylon brush for 20 seconds or until all visible soil is removed.
5. Rinse exterior and interior surfaces with lukewarm tap water for 10 seconds to remove cleaning solution.
6. Immerse component(s) in an ultrasonic bath containing an enzymatic-based cleaning solution (e.g. neodisher® MediZym) and sonicate/treat for 10 minutes. When cleaning multiple components, ensure components do not contact one another.
7. Remove the components from ultrasonic bath and rinse exterior and interior surfaces thoroughly under cool, running, distilled water for a minimum of 2 minutes.
8. Dry with lint-free, single-use wipes.

Automated Cleaning and Drying:

Note: Enzymatic and Alkaline cleaning solutions must be diluted per the manufacturer's instructions.

Note: Only FDA approved washer/disinfectors may be used under the following cleaning parameters.

Note: It is recommended that the final rinse be performed with deionized, preferably distilled water.

1. Begin cleaning by disassembling the components completely and soaking in lukewarm enzymatic cleaning solution (e.g. neodisher® MediZym) for approximately 5 minutes.
2. Flush the inner surfaces, cavities, and lumina (where applicable) with 20mL of the enzyme-based cleaning solution using a disposable 20mL syringe with an irrigation needle.
3. Scrub interior surfaces, lumina, and cavities (where applicable) using an appropriately sized soft-bristled, nylon brush for 20 seconds or until all visible soil is removed.
4. Scrub exterior surfaces of components with a soft-bristled, nylon brush or lint free cloth for 20 seconds until all visible soil is removed.
5. Thoroughly rinse all outer and inner surfaces, lumina, and cavities (where applicable) with cool, running, tap water for a minimum of 20 seconds.
6. Place the components in a suitable rack or load carrier within the automatic washer ensuring that the rack or load carrier is oriented in a horizontal position.
7. Perform automatic cleaning that includes:
   - A 2-minute minimum pre-cleaning with cold water.
   - A 6-minute minimum cleaning with a mildly alkaline detergent intended for automated cleaning (e.g. neodisher® Mediclean).
   - A 2-minute minimum rinsing with cold water.
   - A drying at a minimum of 50°C (122°F) for 20 minutes

Any residual moisture remaining after automatic cleaner drying cycle may be dried with lint-free, single-use wipe.

Sterilization:

Warning: Steam Sterilization operating times may vary from unit-to-unit, especially when sterilizing multiple pouches. All steam sterilizers should comply with the requirements of, and be validated, maintained, and checked in accordance with EN 285, EN 13060, ISO 17665-1, ANSI/AAMI ST79.

Caution: After cleaning and drying, perform a visual inspection of all components for unacceptable remnant soil. If necessary, repeat cleaning procedure to remove all soil before sterilization.

Caution: After cleaning and drying, perform a visual inspection of all components for unacceptable deterioration. Discard any components that fail a visual inspection.

1. Following visual inspection, insert each component into a separate, sterilizable pouch that is FDA approved or meets the ISO 11607 suitability for steam sterilization up to at least 137°C (279°F).
2. Label each sterilization pouch with information necessary to identify the device and seal.
3. Place the sealed sterilization pouch(es) into the steam sterilizer. The sterilization pouch should be oriented in a horizontal position.
4. Sterilize the device using either one of the following cycles and associated parameters:

Method	Conditions	Drying Cycle
Gravity Moist Heat Sterilization (Autoclave)	121° C (250° F) 15-20 psig 30 minutes	15 minutes
Pre-vacuum Moist Heat Sterilization (Autoclave)	132° C (270° F) 4 minutes	20 minutes

5. Use sterilized components immediately, otherwise follow the instructions for storage provided by the manufacturer of the sterilization accessories / storage containers.

Caution: If there are any signs of excess moisture or pooled water in the load at the end of the sterilization cycle, repackage and re-sterilize using a longer drying time.

Training: Implant placement and restoration involves complex procedures and should be performed by dental professionals who have received implantology training in proper techniques. Inadequate training may result in failure of the restoration and further complications. Implant prosthetics are components of a system that replaces teeth and as a result, the recipient may experience side effects similar to those associated with teeth, such as retained cement, calculus, mucositis, ulcers, soft tissue hyperplasia, soft and/or hard tissue recessions. When restoring or adapting a patient's dentition, lip biting, bruxism, and phonetic alterations may occur, and the neighboring/opposing prostheses may need adjustment or relining. Some patients may experience discoloration in the mucosal area such as graying, or wear of neighboring/opposing dentition/prostheses.

Disclaimer of Liability

Users of any products ("Products") sold by (a) Paragon Implant Company, LLC or produced by (b) Paragon Implant Mfg., LLC or (c) any company that manufactures products for Paragon Implant Mfg., LLC (collectively, (a)-(c) are referred to as "Paragon"), shall make their own determination regarding the selection of Products that are suitable for each specific application and circumstance, and shall have full responsibility over the use of any such Products. Paragon has no control over either the selection or use of its Products, which are the sole responsibility of the user.

Paragon disclaims any liability, express or implied, and shall have no responsibility for any direct, indirect, punitive, or other damage arising out of or in conjunction with any errors in professional judgment or in practice in the selection or use of Products. Users are advised and obliged to study the latest news and developments in implant dentistry, and to frequently review www.paragon-implant.com for any updates or information related to Products and/or their specifications.

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Glossary of Packaging Labeling Symbols:

The following table describes the symbols which may be printed on the packaging label. Refer to the packaging label for the applicable symbols associated with the product.

Symbol	Symbol Title	Symbol Source
	Sterilized Using Irradiation	ISO 15223-1
	Non-Sterile	ISO 15223-1
	Do Not Re-Use	ISO 15223-1
	Do Not Resterilize	ISO 15223-1
	Use-by Date (YYYY-MM-DD)	ISO 15223-1
Rx Only	Caution: U.S. federal law restricts this device to sale by or on the order of a dental professional.	21 CFR 801.109(b)(1)
	Date of Manufacture (YYYY-MM-DD)	ISO 15223-1
	Catalogue Number	ISO 15223-1
	Batch Code	ISO 15223-1
	Consult *Instructions for Use* or consult electronic *Instructions for Use* Follow the link to the eIFU: https://paragon-implant.com/IFU	ISO 15223-1
	Manufacturer	ISO 15223-1
	Do not use if package is damaged and consult Instructions for Use	ISO 15223-1
	MR Conditional: Indicates the device is safe under specific conditions in the MR environment.	ASTM F2503
	Caution	ISO 15223-1
	Keep Dry	ISO 15223-1
	Temperature Limit	ISO 15223-1
Qty:	Quantity	Paragon Implant Mfg., LLC