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Instructions for Use

GEN5™ and GEN5+™ System (3.3mmD) of Dental Implants and Prosthetics

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

Dental Implants

Indications for Use

GEN5 and GEN5+ implants are two-piece implants for one or two-stage surgical procedures. These implants are intended 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.

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

- Short (<9mmL) Implants: Indicated for single tooth (mandibular and maxillary central and lateral incisors), multiple tooth replacements or denture stabilization.
- Narrow GEN5 Implants (3.3mmD), 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.

Contraindications

GEN5 and GEN5+ dental implants are contraindicated for patients**:**

- Who are medically unfit for an oral surgical procedure
- Have allergies or hypersensitivity to chemical ingredients in the following material: Grade 5 Titanium Alloy (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
- In whom adequate sizes, numbers or desirable position of implants or abutments are not reachable to achieve safe support of functional or eventually para-functional loads
- The use of cantilever extensions exceeding 10 mm in length, or unsupported spans exceeding 30 mm between two adjoining implants.

Warnings

- 3.3mmD GEN5 and GEN5+ implants are not indicated for 1mm supracrestal placement.
- For short implants (i.e., threaded lengths shorter than 7mm), 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.
- Because of the reduced surface area for anchorage in the bone, implants with threaded lengths shorter than 7mm 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
- Short implants (i.e., threaded lengths strictly shorter than 7mm), should not be placed in patients who demonstrate untreated occlusal parafunction, such as bruxism or clenching.
- For short implants (i.e., threaded lengths shorter than 7mm), clinicians should closely monitor patients for any of the following conditions: peri-implant bone loss, changes to implant's response to percussion, or 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 (i.e., threaded lengths shorter than 7mm),, 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.
- Small diameter implants and angled abutments are not recommended for the posterior region of the mouth.

Do not use the device if it is contaminated.

Precautions

- Use appropriate ancillary components that correspond to the implant system and prosthetic being restored.
- Small diameter implants and angled abutments are not recommended for use in the posterior region of the mouth.
- 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.

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

Implant Sizes

Body Diameters	Platform Diameters	Lengths
3.3mm	3.5mm	9mm, 11mm, 12.5mm, 14mm

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 GEN5 series of implants, traversing down the long axis of the implant is anodized. 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:

GEN5 implants are provided fixed to the implant carrier, held in place by a press-fit connection between the carrier's retentive O-ring, and the straight inner walls of the implant's internal hex. Once the Implant is secured within the osteotomy, the carrier is removed. The cap and vial label are color-coded to the implant's prosthetic platform. The Implant and components included are single-use only devices and sold sterile by gamma irradiation.

GEN5⁺ Implants are provided fixed to implant carrier, held in place by a press-fit connection between the carrier's retentive tines, and the internal threads of the Extender Healing Abutment. Once the Implant is secured within the osteotomy, the carrier is removed. 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.

Caution: For **GEN5⁺** Do not attempt to drive the implant to full seat using the carrier. Thread the implant into the osteotomy until it is stable and then remove the carrier.

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

Implants are packaged with frictionally retained implant carrier. The inner vial is then inserted into the outer vial and sealed via a threaded cap.

Storage and Handling:

Users are advised to visually inspect vials to ensure seals and contents are intact and in their original packaging prior to use. Do not use if packaging is damaged, cracked vial, broken seal 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 carriers. Prior to removal of implant from the vial, the clinician must first confirm size and diameter relative to the prepared implant site. The carrier is intended to be used to transport the implant to the prepared surgical site. Sterilized surgical instruments used in the delivery and placement of the implants have a retentive feature that suspends the implant and carrier on the tip of the driver and are used to transport and place the implants. 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.

2. Surgical site preparation

Follow the drill sequence as shown in the included table for the various implant diameters and procedural steps based on the patient's bone density and volume, in those respective areas.

3. Implant Placement

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

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 as 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-proof 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 GEN5 & GEN5+ Implants are suspended in the sterile inner vial on a titanium alloy carrier that is frictionally held in place. 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.
   OR
   b) Connect a 2.5mmD hexed instrument into the carrier's hex and gently slide the assembly away from the inner vial. Carry the implant and carrier assembly to the osteotomy and initiate self-tapping rotating the assembly in a clockwise direction until resistance is felt.
5. Removal of Carrier
   - For GEN5, gently lean the carrier to the side, separating it from the implant.
   - For GEN5+, gently pull the carrier straight up to separate and remove it from the implant.
6. The implant is then seated all the way by placing a 2.5mmD hexed instrument into the implants internal 2.5mmD hex and rotating the implant clockwise.

4. Implant Healing

GEN5

Two-stage Healing:
Use a 1.25mmD hex driver to carry an implant Cover Screw (sold separately) and screw the Cover Screw into the Implant. Suture the soft tissue over the Cover Screw.

One-stage Healing:
Use a 1.25mmD hex driver to carry a Healing Abutment (sold separately) and screw the Healing Abutment into the Implant. Suture the soft tissue around the Healing Abutment.

GEN5+

One-stage Healing:
The GEN5+ Implant is designed for a one-stage surgical procedure, with the multi-functional extender primarily used as a healing component during soft and hard tissue maturation.
Use a 1.25mmD hex driver to carry an Extender Cover Screw (sold separately) and screw it into the Implant. Suture the soft tissue around the Healing Abutment.

If restorative procedures require access to the implant's restorative platform, the clinician must remove the pre-attached friction-fit Extender Healing Abutment. After removing the carrier, the clinician should insert and clockwise thread a Friction-Fit Removal Tool through the Extender 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 GEN5 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.

Implant Diameter (mm)	Bone Type	DRILL Type and Sizes					
		Pilot Drills SD1.8 or 2.0 Lindemann		2.3/ 2.0	2.8/ 2.3	3.8/ 3.4	Crestal Bone Drill
3.3	Soft	X	X	X		X Drill 1-2mm to facilitate collar	
	Dense	X	X	X	X (drill to implant length -1mm)		X (drill to depth of physical stop)

*The 3.3mmD GEN5 and GEN5+ Implants **MUST** be placed level with the crest of the alveolar ridge to increase the amount of bone to implant contact (BIC) at time of implant placement.

Healing and Prosthetic Components

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

Indications for Use

GEN5 and GEN5+ Abutment System

The GEN5 and GEN5+ Abutment System is intended for use with 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.

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. 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:
The Cover Screw is manufactured from titanium alloy (Ti-6AL-4V ELI) and is placed on the implant or factory fitted extender at time of completion of the surgical process, thereby sealing the oral cavity from the inner workings of the implant. Cover Screws are provided sterilized.

1. Remove the Cover Screw from the packaging using the corresponding 0.050" (1.25mmD) hex driver.
2. Insert into the implant and 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.

Healing Abutments:
Implant Healing Abutments are prefabricated dental implant components supplied in a variety of lengths and diameters, manufactured from titanium alloy (Ti-6Al-4V ELI). The Healing Abutments are anodized to match the specific implant/abutment and are used to support the surrounding soft tissues during the healing phase. Healing Abutments are provided sterilized.

1. Remove the Healing Abutment from the packaging using the corresponding 0.050" (1.25mmD) hex driver.
2. Insert into the implant and rotate clockwise using finger-pressure to tighten the respective mating components together.

Healing Abutments are for single-use only and disposed of after osseointegration has taken place and at the start of prosthetic rehabilitation.

Extender Healing Abutment:
Extender Healing Abutments are dental implant components with a 2mm height and a 4.8mm diameter platform manufactured from titanium alloy (Ti-6Al-4V ELI) which are friction-fitted on the GEN5 Implant during manufacturing (this makes it a GEN5+ Implant). These components are not sold separately and are anodized to match the corresponding implant/abutment interface.

1. To remove the Extender Healing Abutment from the implant, first gently pull the carrier straight up to separate and remove it from the Extender.
2. Thread the Friction-fit Removal Tool into the implant. As the tool continues rotating, it will disengage the friction-fit connection and gently lift the Extender off the implant.

Extender Healing Abutments are for single-use only and if required can be removed after osseointegration has taken place and the start of prosthetic rehabilitation.

Description and Insertion Procedure for Restorative Components
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 Healing Abutments.

1. Remove Transfer from Packaging: All Transfers packaged in vials are mounted on a plastic screw mount or contained loose within the vial.
2. Proceed with disinfection and sterilization instructions as detailed in section below.
3. Transfers are initially seated using 0.050" (1.25mmD) driver in conjunction with a fixation screw and seated flush with the implant or abutment interface.

Description and Insertion Procedure for Abutments
Straight and Angled Contoured Abutments:
The Straight and Angled Contoured Abutments are manufactured from titanium alloy (Ti-6Al-4V ELI) offered in straight at 0° or angled at 15° relative to the long axis of the implant. 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.

Insertion Procedures for Abutments:

1. Remove the abutment assembly from the outer vial.
2. Remove the abutment from the plastic screw mount by unscrewing the fixation screw with the corresponding driver.
3. Follow sterilization procedures below.
4. Abutments are initially seated using the corresponding driver in conjunction with a fixation screw. Abutments should then be torqued to 30Ncm to ensure fixation between mating components

Warning: Modification of Angled and 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.

Angled Screw Channel (ASC) Abutments and Components:
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 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.

Insertion Procedures for Abutments:

1. Remove the abutment assembly from the outer vial.
2. Remove the abutment from the plastic screw mount by unscrewing the abutment with the corresponding driver.
3. Follow sterilization procedures below.
4. Abutments are initially seated using the corresponding driver in conjunction with a fixation screw. Abutments should then be torqued 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.

Multi-Unit Abutments (MUA)

Straight Multi-Unit Abutment:

Straight Multi-unit Abutments (MUAs) are available in various cuff heights. All the abutments are manufactured from titanium alloy (Ti-6Al-4V ELI). Straight Multi-Unit Abutments are one-piece abutments and have no hex engagement upon connection to the implant. The assembly only requires dimensional accuracy related to the internal thread of the implant. The abutments come in two different profiles, and the internal thread diameters for the prosthesis attachment to the MUA base also differ.

Insertion Procedures for Abutments:

1. Remove the abutment assembly from the outer vial.
2. Follow sterilization procedures below.
3. The standard MUA abutment is torqued into place using an abutment-specific socket tool designed to engage the coronal hex of the abutment. The low-profile version, however, has a 0.050" (1.25mmD) internal hex that engages with the corresponding hex tool. The torque required to fully seat the abutment is 30Ncm.

NOTE: Multi-Unit Abutments feature a tapered cone with internal screw access for attaching various restorative components using a separate prosthesis screw. The abutment cone has a 23° taper and is 2.2 mm tall for the standard design, while the low-profile design also has a 23° taper but with a 1.0 mm tall abutment cone height.

Angled Multi-Unit Screw-Receiving Abutment:

Angled Multi-Unit Abutments feature a hex that engages the internal hex of the corresponding implant. They come in two profiles with different internal thread diameters: M1.4 and the low-profile 1-72 UNF. All the abutments are manufactured from titanium alloy (Ti-6Al-4V ELI), available in various cuff heights and 17° and 30° configurations. Abutments are supplied with a fixation screw manufactured from titanium alloy (Ti-6Al-4V ELI).
The Abutment's occlusal tapered cone, with a 23° taper, has an internal thread for attaching restorative components using a separate prosthesis screw. The cone height is 2.2 mm for the standard design and 1.0 mm for the low-profile design. Abutments are delivered using a titanium alloy (Ti-6Al-4V ELI) holder that aids in placement and orientation, also functioning as a 3D alignment Guide Pin.

Insertion Procedures for Abutments:

1. Remove the Abutment assembly from the outer vial.
2. The clinician grasps the top of the carrier, slides it with the attached abutment through the side opening of the inner vial.
3. Follow sterilization procedures below.
4. The Abutment is carried to the site using a pre-attached, color-coded holder: dark blue for the standard M1.4 and light blue for the 1-72 UNF (wide thread).
5. The holder is unscrewed from the Abutment.
6. The standard MUA Abutment is torqued into place using an abutment-specific socket tool designed to engage the coronal hex of the Abutment. The low-profile version, however, has a 0.050" (1.25mmD) internal hex that engages with the corresponding hex tool. The torque required to fully seat the abutment is 30Ncm.

NizLoc Abutments:

NizLoc Abutments 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.

Insertion Procedures for Abutments:

1. Remove the Abutment assembly from the outer vial.
2. Remove the Abutment from the plastic screw mount by unscrewing the fixation screw with the corresponding driver.
3. Follow sterilization procedures below.
4. Abutments are initially seated using the corresponding driver. Abutments should then be torqued to 30Ncm to ensure fixation within the implant.

Temporary Abutments

Titanium Temporary Abutments:

The Titanium Temporary Abutments are manufactured from titanium alloy (Ti-6Al-4V ELI) with either a hex-engaging or non-engaging configuration. Abutments are supplied with a separate fixation screw manufactured from titanium alloy (Ti-6Al-4V ELI).

Insertion Procedures for Abutments:

1. Remove the abutment assembly from the outer vial.
2. Remove the abutment from the plastic screw mount by unscrewing the fixation screw with the corresponding driver.
3. Follow sterilization procedures below.
4. Abutments are initially seated using the corresponding driver in conjunction with a fixation screw. Abutments should then be torqued to 20Ncm to ensure fixation between mating components.

Warning: Modification of Angled, Straight, and Angled Screw Channel (ASC) 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.

Plastic (PEEK) Temporary Abutments:

PEEK Plastic Temporary Abutments are used as an aid in manufacturing a prosthesis for prosthetic rehabilitation. Supplied with a hex-engaging

configuration at the apex and held in place by the respective Fixation Screw included with the Abutment. These Abutments provide support for the provisional restoration of choice. Product is supplied non-sterile so needs to be sterilized prior to placement within the patient's mouth. If a PMMA/composite restoration has been fabricated directly to the Abutment, it cannot be steam sterilized and would have to undergo cold-sterilization procedures prior to placement within the patient's mouth.

Insertion Procedures for Abutments:

1. Remove the abutment assembly from the outer vial.
2. Follow sterilization procedures below.
3. Abutments are initially seated using the corresponding driver in conjunction with a fixation screw. Abutments should then be torqued to 20Ncm to ensure fixation between mating components.

Warning: Plastic Temporary Abutments are intended for use with unloaded conditions for a period of less than 28 days.

Fixation Screw:

Fixation Screws are designed to interface with the implant thread for Angled and Straight two-piece Abutments and the Abutment thread (prosthesis fixation screws) for Copings and Abutment Transfers etc. Several screws supplied with the system have the dual-grip configuration which can receive a variety of hex or torx shaped Drivers. Other Abutment application specific screws (MUA) are shaped to fit the profile of the finished Abutment. All the Fixation Screws are manufactured from titanium alloy (Ti-6Al-4V ELI).

Instructions: Consult packaged *Instructions for Use* (IFU) notated by the symbol and other technically related sections on the website (https:/paragon-implant.com/IFU) for assistance.
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, PEEK 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 damages 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.

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
REF	Catalogue Number	ISO 15223-1
LOT	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