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INSTRUCTIONS FOR USE

NizPlant System of Implants and Componentry

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

Dental Implants

Patient target group and intended user:

The NizPlant Products are for use in fully or partially edentulous patients who do not have the conditions listed in the contraindications mentioned in this document. It is recommended that practitioners should have a sound working knowledge of dental implantology and instruction in the handling of the Products. In addition, to use the Products safely requires strict adherence to the instructions and procedures shown in this and any additional product specific *Instructions for Use* (IFU), technical brochures and catalogs.

Intended Use:

The NizPlant Implants are intended for use in the mandible and maxilla in support of and the retention of overdentures, multiple-unit, screw- or cement-retained prostheses. The implants are intended for either a delayed loading period or immediate placement and function, for the support of multiple-tooth restorations, while taking into consideration bone volume and density ensuring primary stability and appropriate occlusal load requirements.

Indications for Use:

NizPlant Implants are a one-piece implant or two-piece assembly for single-stage surgical procedures intended for surgical implantation in edentulous or partially edentulous mandibles or maxilla for attachment of complete denture prostheses, or for fixed or removable bridgework for multi-unit tooth replacement.

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

Short (<9mmL) Implants: Indicated for multiple-unit restorations of partially or fully edentulous mandibles and maxillae where vertical bone volume is limited.

The NizPlant Implants have a 2.5mmD internal hex within its most coronal portion for the insertion tool placement used in the full seating of the NizPlant Implant in the osteotomy. Implant placement, which is designed to receive multiple abutment variations, expands its restorative options allowing for the implant to be used for:

- Support of attachment-retained overdentures
- Support of screw-retained prostheses

Contraindications:

NizPlant 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: titanium alloy Ti-6Al-4V ELI (titanium, aluminum, vanadium) or DLC (Diamond Like Coating)
- 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 cantilever conditions are such that they extend past >30mm in length between two adjoining implants or restorative distal cantilevers extending past the most distal implant in excess of 1.5 times the A/P spread between the center of the most anterior implant and the distal margin of the most distally placed posterior implants.

Contraindicating systemic or uncontrolled local diseases such as: blood dyscrasias, anticoagulant therapy, diabetes mellitus, Hyperthyroidism, oral infections or malignancies, renal disease, uncontrolled hypertension, liver problems, active cancer therapy, severe vascular heart disease or recent myocardial Infarction, currently on a course of IV Bisphosphonate, uncontrolled periodontal disease, hepatitis, immunosuppressive disorder, bone or soft-tissue quality and quantity, insufficient inter-arch space, osteoporosis, collagen and other bone diseases, pregnancy.

Relative contraindications may include habits such as: tobacco use, alcohol dependency, drug abuse, poor oral hygiene, clenching of teeth, bruxism, gnawing, nail biting, pencil biting, improper tongue habit depending on severity.

Warnings:

- NizPlant 3.0mm diameter x 9.0mm length implants (NP3009) and NizPlant 3.7mm diameter x 7.0mm length implants (NP3707) are not indicated for 1mm supracrestal placement because of the reduced surface area for anchorage in the bone.
- 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
- When a short implant is the treatment of choice consider a two-stage surgical approach, splinting of implants, and placement of the widest possible implant. 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 in the 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. Allow longer periods for osseointegration.
- 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, 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, 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.

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.
- Confirm adequate inter-dental spacing and proper angulation before and during osteotomy preparation as to not damage existing dentition. If unexpected resistance or tooth contact occurs, stop the procedure and reassess positioning.
- Precautions should be taken while working with prosthetic components in clinical situations to prevent accidental ingestion and aspiration of devices.
- Surgical placement of this dental implant system shall be performed only by qualified clinicians with documented training and experience in implant dentistry. Prior to initiating the surgical procedure, the clinician must assess patient-specific anatomical conditions, bone quality, and potential risk factors. Failure to employ appropriate surgical technique may result in inadequate primary stability, injury to adjacent anatomical structures, or impaired osseointegration.

Complications and Adverse Effects:

The risks and complications with implants include, but are not limited to: (1) allergic reaction(s) to implant and restorative component materials; (2) breakage of the implant that requires it to be explanted and to be removed using clinician judgment; (3) loosening of the systems fixation screws; (4) localized peri-implantitis infection requiring revision of the dental implant and/or prosthetic; (5) nerve damage been the causative factor leading to permanent weakness, numbness, or pain; (6) histologic responses possibly involving macrophages and/or fibroblasts; (7) formation of a fat embolism; (8) loosening of the implant requiring revision surgery; (9) perforation of the maxillary sinus; (10) perforation of the labial and lingual plates; (11) bone loss possibly resulting in revision or removal; (12) Failure to Osseointegrate (FTO) and (13) the implants are conductive in nature therefore electrosurgery is contraindicated.

Product Description:

NizPlant Implants are transmucosal, single-piece implants designed with a prosthetic platform referred to as the Locator/GPS attachment platform by the dental implant industry. This attachment anchor geometry is intended to interface with various laboratory and restorative components with dimensions that have become widely accepted standard in the dental implant industry for removable denture fixation.

NizPlant Implants are supplied in a variety of lengths and diameters to solve most of the procedures for patient rehabilitation.
NizPlant Implants lengths are measured from the apex of the implant to the midpoint of the gold anodized zone, that is to the base of the abutment portion of the NizPlant Implant.

NizPlant Implant Sizes:

Body Diameters	Platform Diameters	Lengths
3.0mm	•3.9mm	9mm, 11mm, 12.5mm, 14mm
3.7mm	•3.9mm	7mm, 9mm, 11mm, 12.5mm, 14mm
4.2mm	•3.9mm	7mm, 9mm, 11mm, 12.5mm, 14mm
4.7mm	•3.9mm	7mm, 9mm, 11mm, 12.5mm, 14mm
5.2mm	•3.9mm	7mm, 9mm, 11mm, 12.5mm, 14mm
5.7mm	•3.9mm	7mm, 9mm, 11mm, 12.5mm, 14mm

NizPlant Implants have up to 5.0mmL of their coronal surface anodized a gold color (7mmL and 9mmL implants, due to its length have one less circumferential groove and is replaced with an additional external thread to increase fixation within the bone). The gold color aids aesthetically as it is the portion that extends transmucosal from bone level, through to the oral cavity by masking of the underlying color of the non-anodized standard titanium grey.

NizPlant Implants are specifically designed with a combination of 0.5mm and/or the 1mm height circumferential grooves above the blasted implant surface (7mmL and 9mmL implant does not have the additional 0.5mm circumferential score line). These visual demarcations aid the clinician by providing the option for vertical height variability during placement. For restorations where the vertical position of the surrounding bone and/or soft tissue dictate that, part of the implant's anodized portion (inclusive of the 3mm prosthetic portion) remains supra-crestal after placement.

Compatibility:

The NizPlant Implant prosthetic platform is 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 NizPlant platform is compatible with all mating components manufactured by DESS Dental required for the complete restoration of Locator®/GPS type attachment system.

Surface Treatment:

Paragon's implants are made of titanium alloy and blasted with MCD Apatitic Abrasive, a calcium phosphate abrasive, principally composed of hydroxyapatite and tricalcium phosphate.

The coronal portion of the implant, which is up to 5.0mm in length, is anodized as a gold color.

The implant's outer threaded surface extends from base of anodized coronal aspect to the most apical point of the implant and is blasted with RBM (Resorbable Blast Media), MCD Apatitic Abrasive is a calcium phosphate abrasive, principally composed of hydroxyapatite and tricalcium phosphate. during manufacturing. The surface has a surface roughness of 1.5µm-and 2.3µm and is designed to have no residual Blast Media.

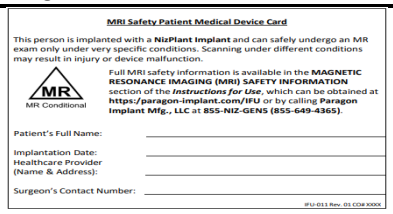
Packaging:

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.

NizPlant Implants are suspended in place by sliding the implant into the notch of the inner vial. The inner vial is then inserted into the outer vial and sealed via a threaded cap.

Cross-contamination is prevented, and the products are sealed, and gamma irradiated to ensure sterility of enclosed components.

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 an implant from the Paragon Implant Family 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

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. 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.

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 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 Procedures and Techniques for the Placement of Paragon NizPlant Implants:

1. **Pretreatment Planning**

During the pre-operative stage, availability of bone-height and bone-width, soft tissue thickness, and the planned trajectory of the implant must be determined. Appropriate radiography should be used to determine bone availability, 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. Oral palpation can be used to provide clinical feedback as to the condition of the surrounding gingiva and alveolar ridge.

2. **Surgical Procedures:**

After the planning stage is completed, the clinician will follow standard implant site preparation procedures to gain access to the underlying bone. Follow the drill sequence as shown in the included table for the various implant diameters and procedural steps to follow based on patient's bone density and volume, in those respective areas.

- Drilling procedures should be performed at 2000 RPM or less, under copious irrigation preferably with chilled saline solution. Speed used is determined by the clinician's preference and experience.
- Ensure all drills are sharp prior to the start of the surgery. In cases where multiple implant sites are planned, it is advisable to have additional narrow diameter drills sterilized in case the demand arises during surgery. (Instrumentation are not supplied sterile).
- For planned procedures that require bi-cortical stabilization of implants, the clinician is advised to drill to full depth of the final dense bone type drill sequence for the specific size of implant to be placed. This is to prevent the apex of the implant stopping at the opposing cortical plate, with its undersized osteotomy, and not being able to seat the implant to correct planned depth and consequently the stability of the implant.
- During site preparation the clinician makes the determination if the planned procedure may take place based on bone quality, quantity, and soft tissue thickness.
- The NizPlant Implants are designed for a one-stage surgical procedure having the coronal part of the implant placed transgingival. No second surgery is required to gain access to the implant.
- The NizPlant Implants are a one-piece implant with the implant prosthetic platform being placed with a variety of vertical height options relative to the surrounding hard and soft tissue, therefore vertical flexibility of implant positioning. The Drill Stops included in the Surgical Kit provide the Implantologist the guide to control to what depth they would like the implant to be seated within the bone. One set of Drill Stops seats the implant 1mmL supra-crestal while the other set guides placement so that the implant is placed at a level with the crest of the ridge, to the correct vertical height of the implant for the restorative procedures to follow.
- The NizPlant Surgical Cover Screw is supplied threaded in place within the center of the implant to prevent the ingress of detritus into the Implants internal structure.

- This Cover Screw can be removed using a 1.25mmD Hex Tool providing access for the application of screw-retained components that will be attached to the inner workings of the implant.

PARAGON IMPLANT SYSTEMS: NIZPLANT IMPLANTS											
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	3.4/ 2.8	3.8/ 3.4	4.4/ 3.8	4.8/ 4.4	5.1/ 4.8	5.4/ 5.1	Crestal Bone Drill
3.0	Soft	X	X	X								**DO NOT USE**
	Dense	X	X	X	X (drill to implant length -1mm)							**DO NOT USE**
3.7	Soft	X	X	X	X							
	Dense	X	X	X	X	X						OPTIONAL*
4.2	Soft	X	X	X	X	X						
	Dense	X	X	X	X	X	X					OPTIONAL*
4.7	Soft	X	X	X	X	X	X					
	Dense	X	X	X	X	X	X	X				OPTIONAL*
5.2	Soft	X	X	X	X	X	X	X				
	Dense	X	X	X	X	X	X	X	X			OPTIONAL*
5.7	Soft	X	X	X	X	X	X	X	X	X		
	Dense	X	X	X	X	X	X	X	X	X	X	OPTIONAL*

* Crestal Drills are used as an optional drill in cases where extremely dense bone is present at the crest of the ridge.

3. Implant Placement:

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

- 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 it relates to the Implant type, product code, length, diameter, prosthetic platform diameter and sterilization date.
- 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.
- Gently pour the contents of the outer vial onto a sterile field, set the outer vial aside.
- NizPlant Implants are suspended on the sterile inner vial by locking sideways into the slot within the inner vial.
- Within the coronal portion of the NizPlant Implant there is a 2.5mmD hex broached into the inner wall of the implant. Attach one of the retentive 2.5mmD hexed instruments into the implants hex and gently slide the assembly away from the inner vial.
- Select one of the various options to carry the implant to site and insert the implant into the osteotomy. With powder-free sterile gloved hands carry the implant to the osteotomy and initiate self-tapping by the rotation of the implant and corresponding tool in a clockwise direction until resistance is felt. Seat the implant to the desired final position by utilizing the appropriately calibrated Torque Wrench or via the latch type handpiece and motor, and the corresponding 2.5mmD hexed instrument.
- The NizPlant Implant must have a minimum of 1.5mmL-1.75mmL of its coronal portion placed supra-gingival. This requirement is to ensure that the recommended attachments (within the prosthetic) be able to depress and rotate around the coronal curvature of the NizPlant Implants.
- To remove the NizPlant Implant Cover Screw, gently insert a 0.050" (1.25mmD) Hex Tool into the mating hex of the Cover Screw which is located deep within the internal workings of the implant. The Hex Tool has a retentive feature at the tip that frictionally holds the screw as it is lifted and unthreaded in a counterclockwise direction.

4. One-Stage Healing:

- The inner portion of the implant is thoroughly cleaned just prior to the placement of the restorative components of choice. The components are attached directly to the NizPlant Implant. The parts are either press-fit, finger-tightened, or torqued (<35Ncm) into place based on the level of primary stability or osseointegration that has taken place. The soft tissue is sutured in place surrounding the supplied PEEK Comfort Cap which is seated on the coronal and majority of the transgingival portion of the NizPlant Implant.

One-Stage Healing Process Options at Time of Implant Placement:

NizPlant Cover Screw:

Remove the NizPlant Cover Screw at implant placement.

Place secondary abutment options on the implant immediately or wait for hard and soft tissue maturation before attachment.

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.

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

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

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.

Description of Restorative Components

This section applies to the restorative components for the NizPlant Implants.

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.

Cover Screws:

The Cover Screw is manufactured from titanium alloy (Ti-6AL-4V ELI) and is placed into the Implant at time of packaging within a cleanroom environment. The screw thereby seals the apical aspect of the internal workings of the implant from the oral cavity.
The clinician must use the corresponding 0.050" (1.25mmD) friction-fit hex driver in conjunction with finger-pressure to loosen, lift and remove the Cover Screw from within the NizPlant Implant.

Male Liner and Components:

The following Male Liners and sub-components are marketed/manufactured by Terrats Medical SL and are used in the restorative fabrication to retain the prosthesis to the implant.

- Metal Housing-manufactured from Titanium alloy (Ti-6Al-4V ELI), and anodized a gingival rose gold color, is encapsulated into the pink part of the patient's prosthetic. This housing stays permanently in the prosthesis and is used to house the male nylon liners of various retentions and is supplied with the black processing sleeve already inserted.
- Silicone Spacer-placed over the coronal portion of the implant or abutment snapping tightly on the neck portion of the components. This is done prior to the attachment of additional restorative components. During processing, either chairside on in the laboratory this step in the process creates a space below the attachment and above the soft tissue to provide for some vertical and rotational movement during mastication.
- Black processing sleeve manufactured from POM plastic, is used internally within the Abutment Impression Coping and within the Metal Housing internal aspect.
- Engaging and Extended Range nylon liners are housed within the Metal Housing. A selection of nylon liners is provided with the packaging giving the clinician the option to determine which to use at time of implant or abutment placement. (Nylon Male Liners are not released for sale)
  - The extended range version engages only the outer profile of the implants or abutments. The liner can accommodate up to 40° of combined internal and external rotational capabilities and of relative divergence between splinted components.
  - The engaging version of nylon liner has within the center an inverted bulbus portion which can interface and engage undercut within the NizPlant Implant. This additional retention is in combination to the retention obtained on the outer profile engagement.

Transfers:

Transfer components are manufactured from titanium alloy (Ti-6Al-4V ELI) and anodized according to the prosthetic platform. Transfer of the 3D spatial positioning of required mating features of the implant and / or abutment and relay them to the working model.

Closed-Tray Transfers are tapered titanium alloy (Ti-6Al-4V ELI) posts consisting of a series of grooves and three hex indexed flat tapering surfaces which are coronally placed to the transmucosal portion of the transfer.

1. The two-piece transfer consists of the transfer body and the fixation screw and is used to transfer the inner workings of the NizPlant Implant.
2. Remove Transfer from Packaging: All transfers packaged in vials are mounted on a plastic screw mount or carrier or contained loose within the vial.
3. Proceed with disinfection and sterilization instructions as detailed in section below.
4. 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.
5. After, the impression is made and released, remove the fixation screw and the transfer from the implant, The transfer is affixed to the corresponding Implant Analog and then the assembly is retrofitted back within the impression, and then proceed to fabrication of the working cast.

NOTE: This component does not transfer the internal workings of the NizPlant Implant, only its external profile.

Open-Tray Transfers have the coronal portion machined with two horizontal circumferential straight cut grooves and three vertical flats in the coronal aspect of the transfer to encapsulate, lock, and orient the impression component within the impression material.

1. Remove Transfer from Packaging: All transfers packaged in vials are mounted on a plastic screw mount or carrier 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.
4. The Open-tray Fixation Screw protrudes through the impression tray and is used to tighten the transfer body in. After the impression has set, unthread the long fixation screw gaining access from the outside of the impression tray.
5. The tray with encapsulated transfer body is removed.

Implant and Abutment Analogs:

Implant Analogs are a representation of the dental implant connection and its position of the outer coronal profile, internal engaging Features, and their relation to the internal threading of the implant. The Implant Analog body (not coronal aspect) is to be encapsulated by dental stone during the standard laboratory procedures used to create a stone working/master model with soft tissue moulage model.

Abutment Analogs represent the outer profile of a NizPlant Implant or NizLoc Abutment. In addition to the external profile, it also includes the internal radial profile but excluding the internal hex or the apical threads found represented in the Implant Analog. The NizLoc Abutment Analogs are provided in two different diameters to ensure the processing of the patients' prosthetic makes allowance for wider diameter NizPlant Implants and or wide diameter NizLoc Abutments. The components should not be used more than once to ensure functional integrity of a restoration.

NizPlant Implant Non-Engaging Titanium Temporary Abutments:

Titanium Temporary Abutments are non-engaging, screw retained abutments 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.

Angled Screw Channel (ASC) Abutments:

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 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: 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.

Straight Multi-Unit Abutment (MUA):

Multi-unit Abutments (MUAs) are components in dental implantology that connect dental implants to prosthetic restorations. They are used for removable prostheses, allowing for maintenance and splinting of multi-unit prostheses with a common platform, regardless of implant size or configuration. This is achieved through a screw-receiving abutment with an internal thread for a prosthesis screw. The NizPlant MUA is available in a single height and at 0° angulation. The abutment is manufactured from titanium alloy (Ti-6Al-4V ELI) and is supplied with the corresponding PEEK Comfort Cap.

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 and a full circumferential seal of the abutment on the implants. The industry-standard abutment has an M1.4 internal thread.
The abutments are available in a single cuff-height for the NizPlant Implants.

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 30 Ncm.

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.

Fixation Screw:

Fixation Screws are designed to interface with the Implants internal thread (Abutment Screws) for 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 are shaped to fit the profile of the finished abutment. All the Fixation Screws are manufactured from titanium alloy (Ti-6Al-4V ELI).

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 clean room 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 the 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 solution 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.

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 to 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

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