

TM

ARAGON

IMPLANT COMPANY

SURGICAL AND PROSTHETIC GUIDE 3.3mmD



GEN5™

GEN5+™



TABLE OF CONTENTS

Implant Design and Specifications.....	3
GEN5 & GEN5+ Implant and Dimensions.....	4-5
Surgical Drills and Drill Sequence.....	6
GEN5 Surgical Procedure.....	7-9
GEN5+ Surgical Procedure.....	10-12
Step Drill Depth Markings & Crestal Bone Drills (Optional).....	13
Prosthetic Selection Chart.....	14-15
Cover screws & Description and Insertion Procedure.....	16-17
Healing Abutments & Description and Insertion Procedure.....	18-19
Transfers & Description and Insertion Procedure.....	20-21
Contoured Abutments & Description and Insertion Procedure.....	22-23
Angled Screw Channel (ASC) Abutments & Description and Insertion Procedure.....	24-25
Straight Multi-Unit Abutments & Description and Insertion Procedure.....	26-27
Angled Multi-Unit Abutments & Description and Insertion Procedure.....	28-29
Titanium Temporary Abutments & Description and Insertion Procedure.....	30-31
Plastic (PEEK) Temporary Abutments & Description and Insertion Procedure.....	32-33
NizLoc Abutments & Description and Insertion Procedure.....	34-35
Fixation Screws.....	36-37
Tooling.....	38-39
Cleaning and Sterilization.....	40-43

About This Guide

This manual demonstrates the protocol for implantation of the GEN5 and GEN5+ 3.3mmD dental implant system. The GEN5 and GEN5+ dental implant system is recommended for use by trained clinicians with prior training and experience placing dental implants. For additional information, please refer to the GEN5 and GEN5+ Instructions for Use at paragon-implant.com/IFU.

IMPLANT DESIGN AND SPECIFICATIONS

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.

GEN5 and GEN5+ 3.3mmD implants are two-piece implants for one-stage 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 support for fixed bridgework. Implants can be indicated for immediate function when initial implant stability has been achieved and with appropriate occlusal loading.

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

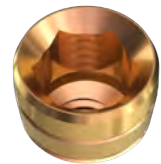
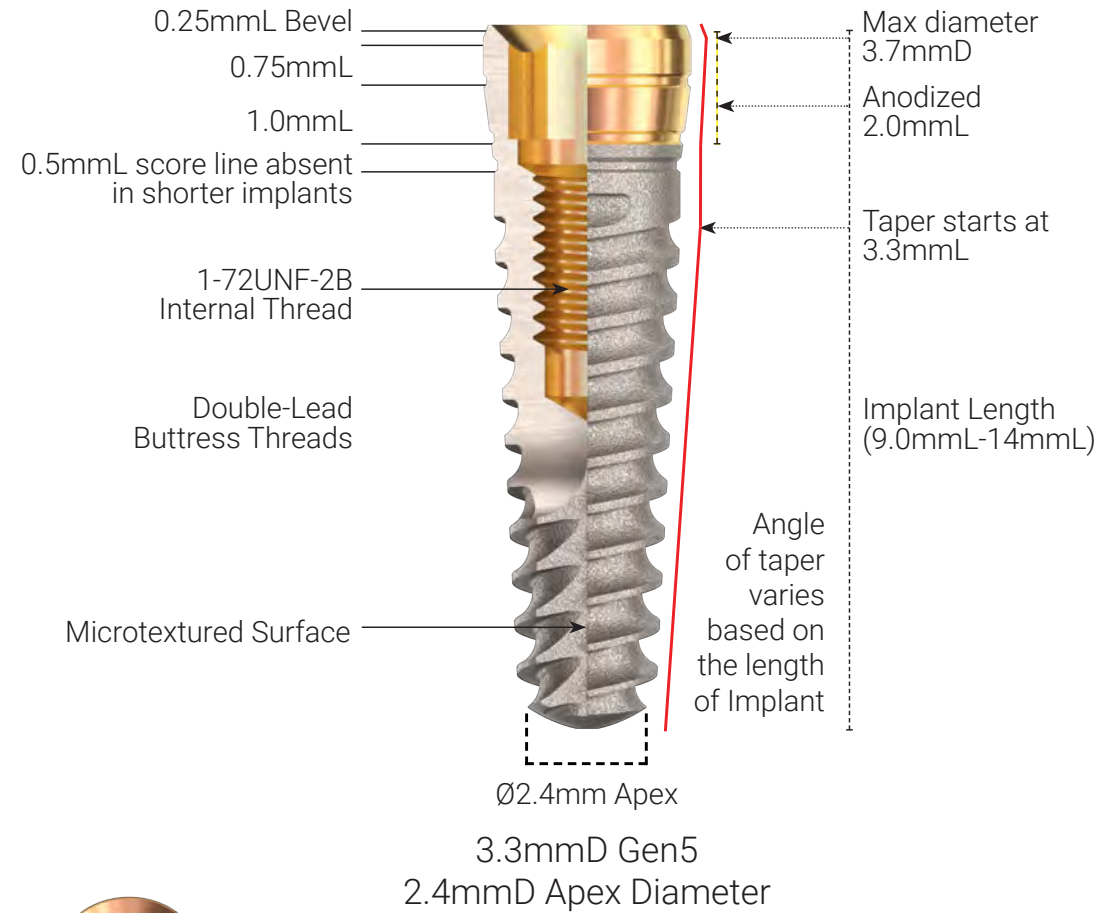
GEN5 Packaging



GEN5+ Packaging



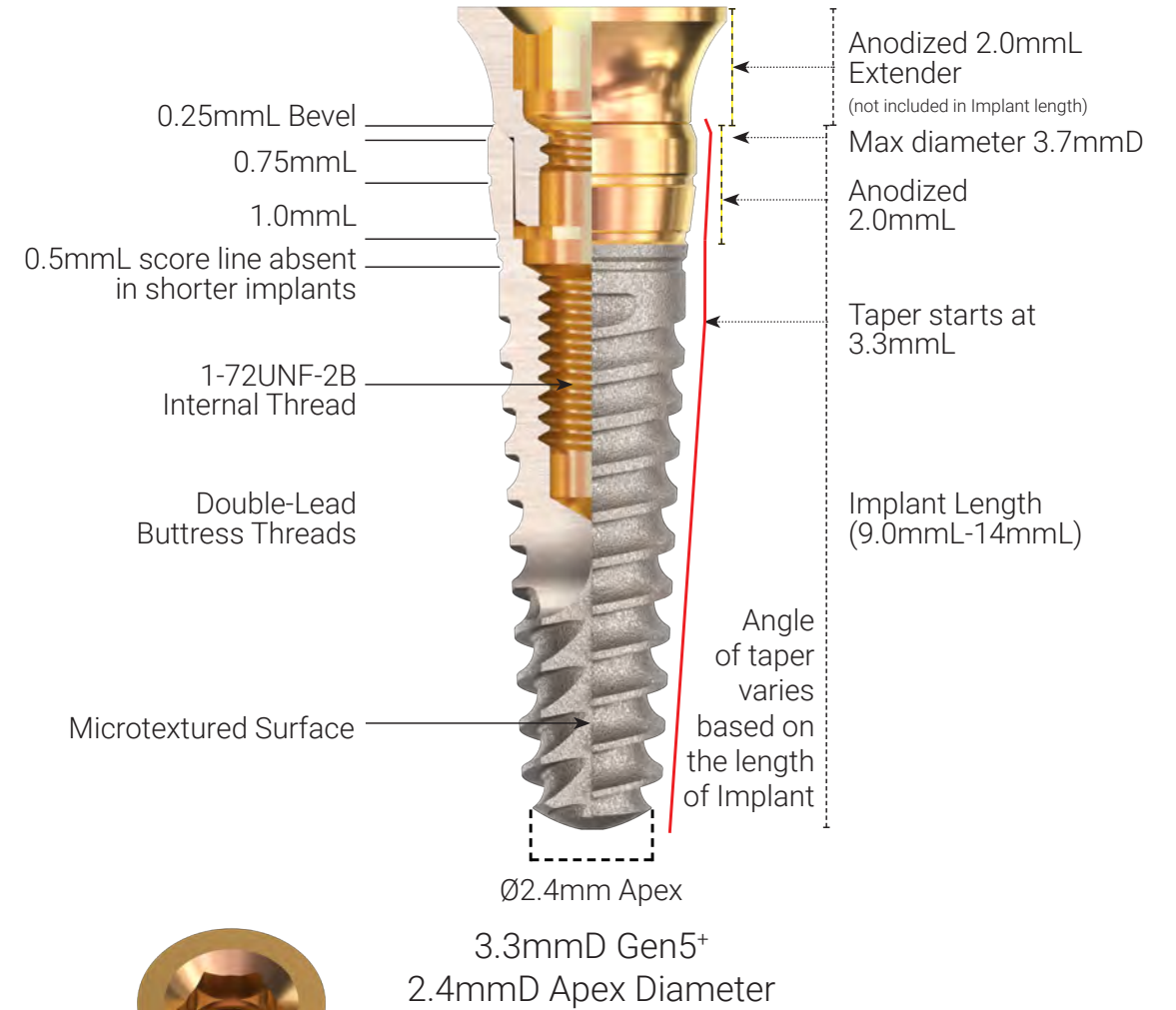
GEN5™ DIMENSIONS



Ø3.5mm Implant Platform
Ø3.3mmD Body

3.5mmD Prosthetic Platform incorporates a standard 2.5mmD Internal Hex configuration having a depth of 1.9mmL from top of Implant Platform.

GEN5+™ DIMENSIONS



Ø4.8mm Prosthetic Platform
Ø3.5mm Implant Platform
Ø3.3mmD Implant Body

Ø4.8mm Prosthetic Platform incorporates a 2.5mmD Internal Hex configuration to aid in implant placement and indexing of prosthetic components.

- GEN5 & GEN5+ IMPLANT AND DRILL DIMENSIONS
- SURGICAL DRILLS AND DRILL SEQUENCE
- GEN5 SURGICAL PROCEDURE
- GEN5+ SURGICAL PROCEDURE
- STEP DRILL DEPTH MARKINGS & BONE DRILL SEQUENCE
- PROSTHETIC SELECTION CHART
- COVER SCREWS
- HEALING ABUTMENTS & TRANSFERS
- CONTIGURED ABUTMENTS
- ASC & MUA ABUTMENTS
- TEMPORARY ABUTMENTS
- NIZLOC ABUTMENTS
- FIXATION SCREWS & TOOLING
- CLEANING AND STERILIZATION

SURGICAL DRILLS & DRILL SEQUENCE

Soft Bone Drills



SD1.8 SD2.3 SD3.8

Code

SD1.8
SD2.3
SD3.8

Description

Pilot Drill, Ø1.8mm, 7mmL
Step Drill 2.3/2.0, 7-14mmL, Long
Step Drill 3.8/3.4, 7-14mmL, Long

Dense Bone Drills



SD1.8 SD2.3 SD3.8 CD3.3

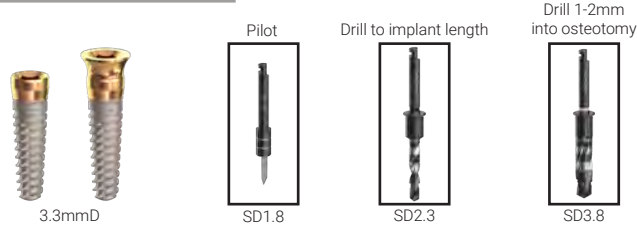
Code

SD1.8
SD2.3
SD3.8
CD3.3

Description

Pilot Drill, Ø1.8mm, 7mmL
Step Drill 2.3/2.0, 7-14mmL, Long
Step Drill 3.8/3.4, 7-14mmL, Long
Crestal Drill, Ø3.3mm

3.3mmD Implant Soft Bone



3.3mmD

SD1.8

SD2.3

SD3.8

3.3mmD Implant Dense Bone



3.3mmD

SD1.8

SD2.3

SD2.8

CD3.3

*Note: 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.

GEN5 SURGICAL PROCEDURE

Prepare Osteotomy



Prepare surgical site with sequential step drills

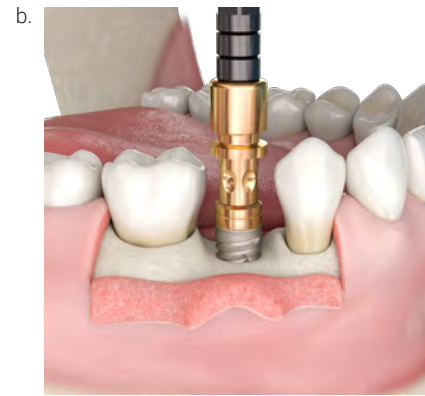
Implant Removal from Packaging

- All Paragon Implants are supplied in gamma irradiated, sterile packaging
- Each label has two tear-off labels for patient records
- Color coded labels on top of the cap identify the diameter of the platform
- Drop implant assembly out of vial onto a sterile surface

Implant Placement



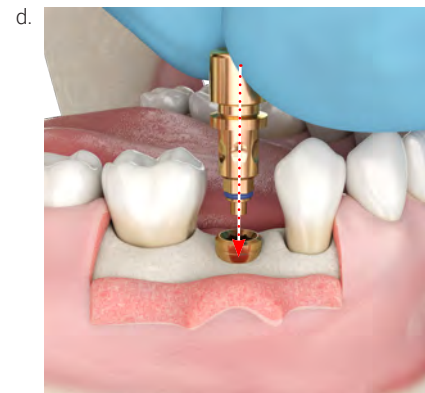
a. Engage internal hex feature of carrier with a hand or motor driven 2.5mmD driver



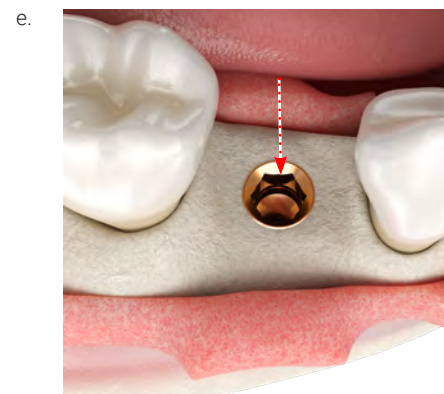
b. Align implant/carrier assembly with osteotomy for insertion



c. External dimples on the carrier are indexed to the carrier's hex driver

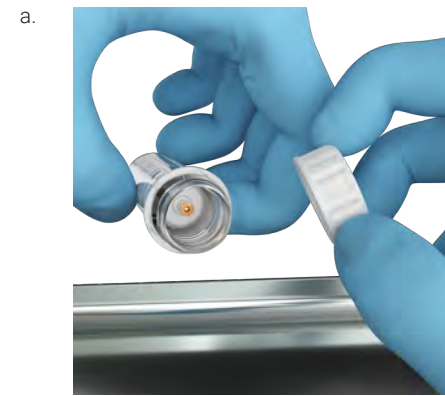


d. Insert implant level with crest

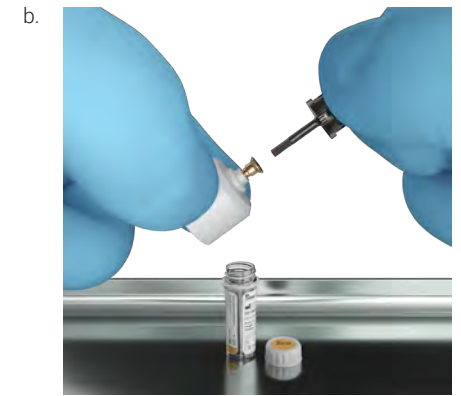


e. The internal hex of the implant should be indexed with a flat on the labial/lingual

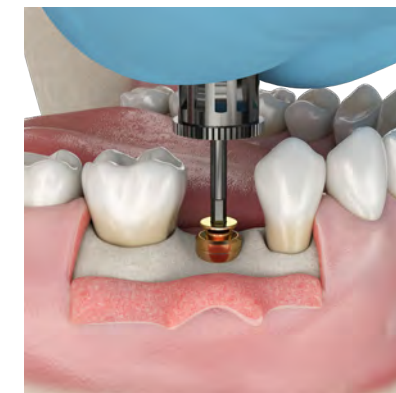
Implant Closure



a. Select cover screw, healing collar, temporary or final abutment

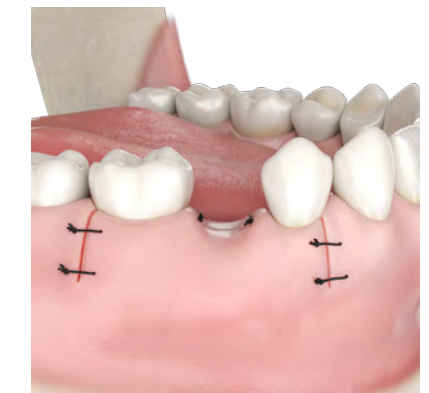


b. Use friction-fit 1.25mmD hex tool to remove the Cover Screw or Healing Collar

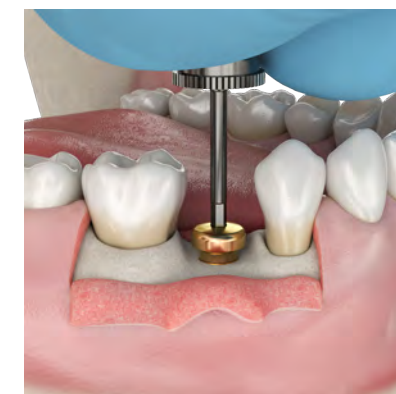


1. Attach the Cover Screw to implant

Two-stage Healing



2. For a 2-stage surgical procedure, suture soft tissue over the Cover Screw



1. Attach the Healing Abutment to implant

One-stage Healing



2. For a 1-stage surgical procedure, suture soft tissue around the Healing Abutment

GEN5+ SURGICAL PROCEDURE

Prepare Osteotomy

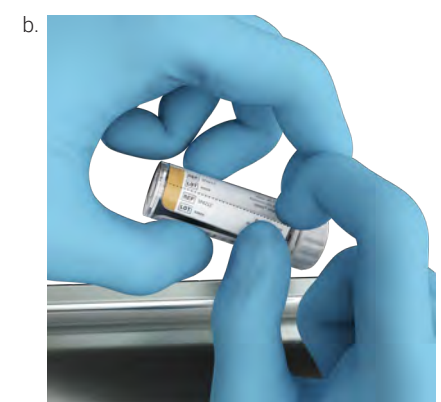


Prepare surgical site with sequential step drills

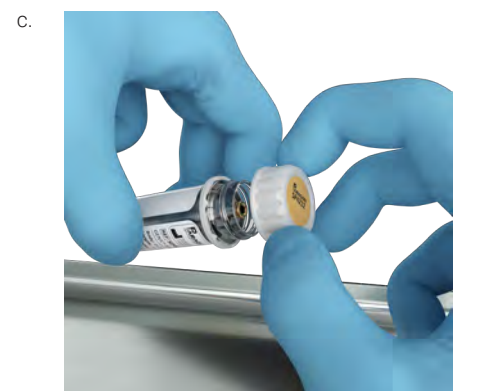
Implant Removal from Packaging



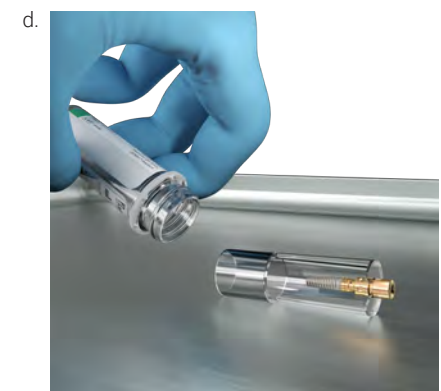
All Paragon Implants are supplied in gamma irradiated, sterile packaging



Each label has two tear-off labels for patient records



Color coded labels on top of the cap identify the diameter of the platform



Drop implant assembly out of vial onto a sterile surface

Implant Placement

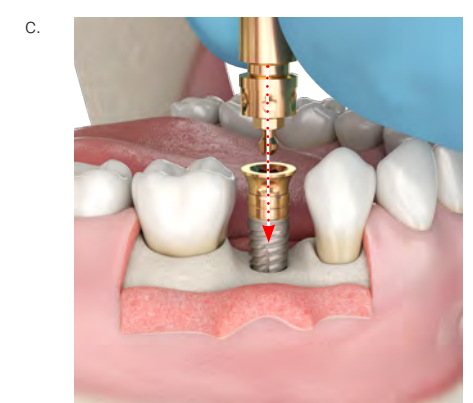


Carrier is held inside Torque Wrench Insert with a friction-fit 2.5mmD Ruby Hex Tool

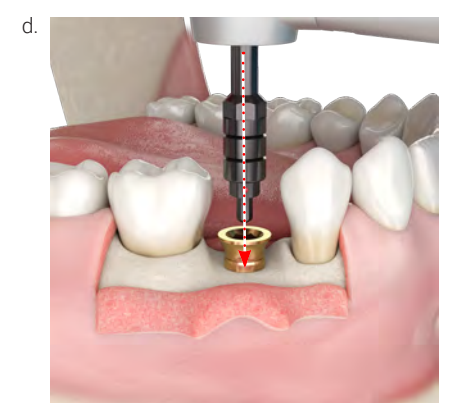
The carrier, together with the pre-attached implant, is removed from the inner vial



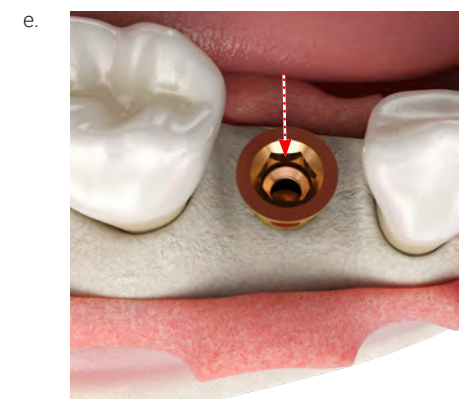
Align implant/carrier assembly with osteotomy for insertion



Stabilize implant within the osteotomy. Remove carrier from Extender

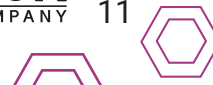


The flats of the 2.5mmD Hex Tool aid in the alignment of the Extender and Implant



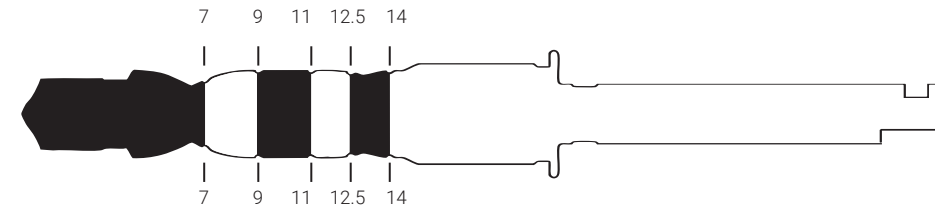
The internal hex of the implant should be indexed with a flat on the labial/lingual

GEN5+ SURGICAL PROCEDURE
 DIMENSIONS
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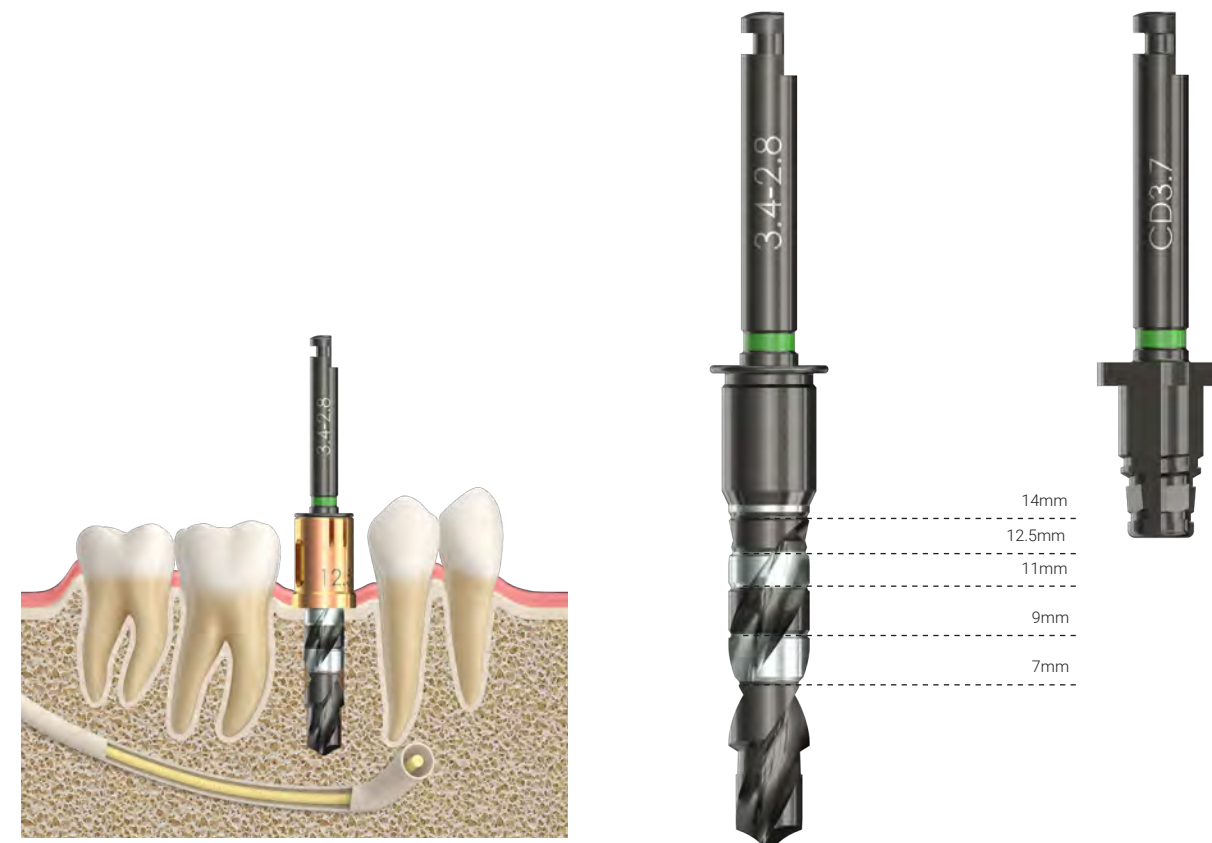


STEP DRILL DEPTH MARKINGS & CRESTAL BONE DRILLS (OPTIONAL)

You can easily verify the depth marking line on DLC drills by aligning the point of the drill with the ruler on the surgical kit.

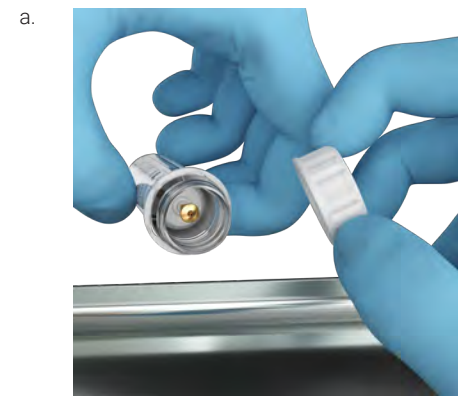


Use constant and profuse irrigation. During drilling, use an in-and-out motion. Move the drill up without stopping handpiece motor which allows the irrigation to flush away bone debris.

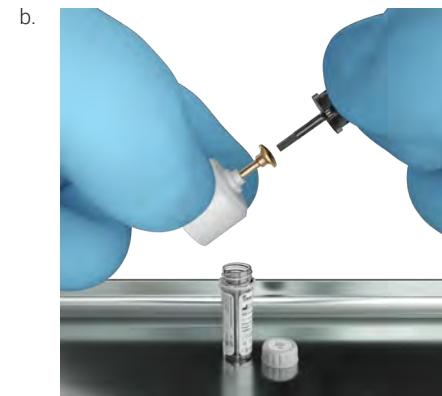


The Drill Stops provide the Implantologist control of what depth they prepare the osteotomy to, by providing a physical stop that fits over each drill.

Implant Healing



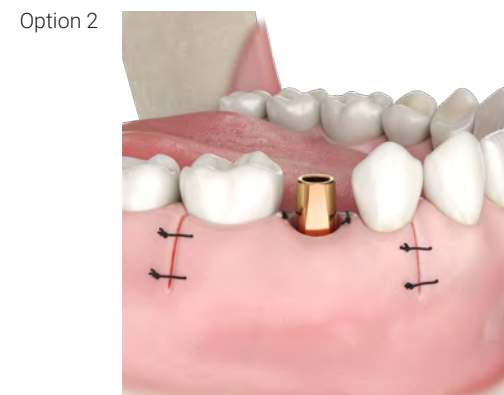
Select appropriate height cover screw for tissue level and drop on surgical tray



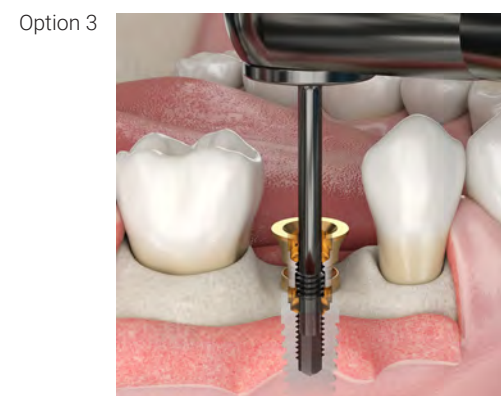
Remove the Cover Screw from the mount using the friction-fit 1.25mmD hex tool



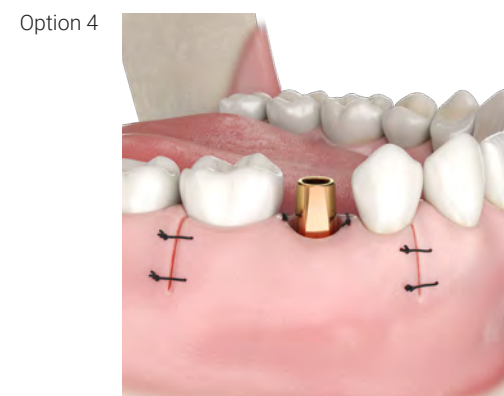
For a 1-stage surgical procedure, suture around the cover screw



Attach straight abutment for cemented restoration

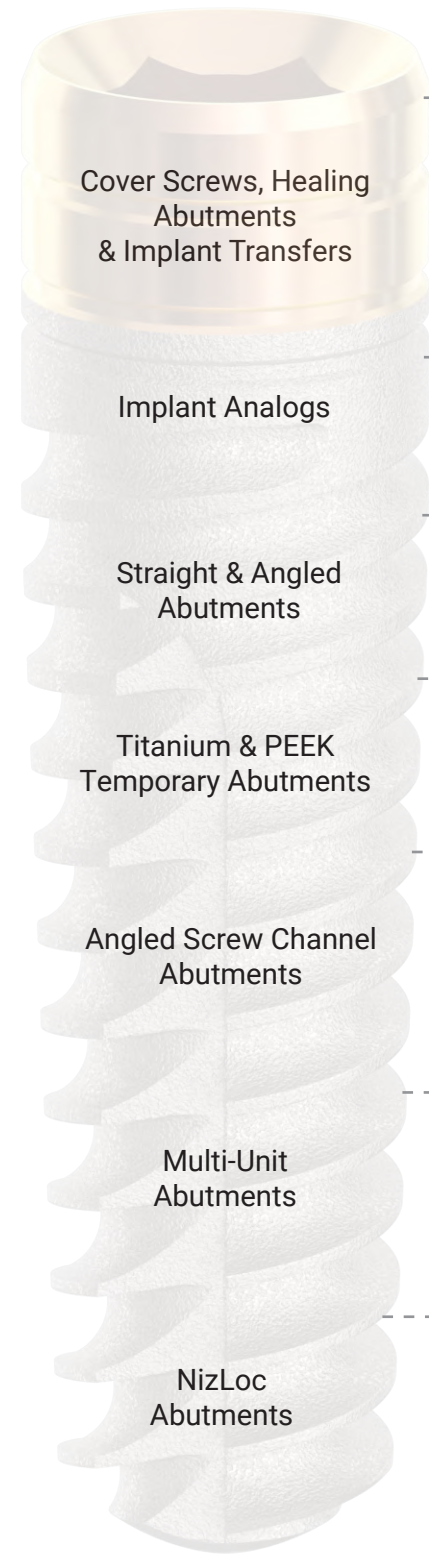


Remove the extender using the retrieval tool



Attach straight abutment to implant for cemented restoration

SELECTION CHART



GEN5™ 3.5mmD Connection






Gen5+™



GEN5 & GEN5+ IMPLANT AND DIMENSIONS
 SURGICAL DRILLS AND DRILL SEQUENCE
 GEN5 SURGICAL PROCEDURE
 GEN5+ SURGICAL PROCEDURE
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COVER SCREWS

Cover Screws	Code	Platform
 CS35	CS35	3.5mmP

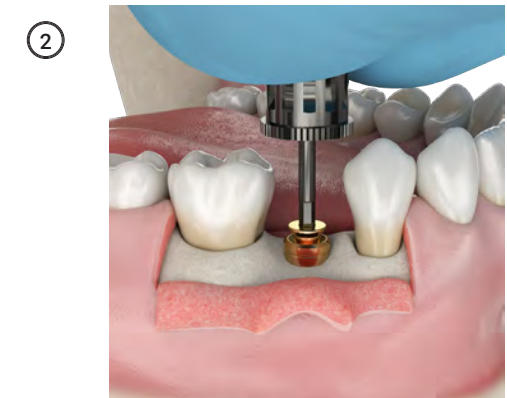
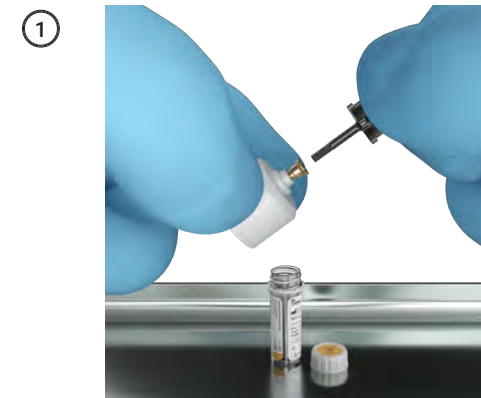
Extender Cover Screws	Code	Platform	Length
	XTCS1	4.8mmP	1.0mmL
	XTCS2	4.8mmP	2.0mmL
	XTCS3	4.8mmP	3.0mmL

DESCRIPTION AND INSERTION PROCEDURE







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


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.

The product is for single-use only and disposed of after osseointegration has taken place and the start of prosthetic rehabilitation.



HEALING ABUTMENTS

Healing Abutments 3.5			Code	Platform	Diameter	Length
			HA35-3N	3.5mmP	3.7mmD	3.0mmL
			HA35-5N	3.5mmP	3.7mmD	5.0mmL
			HA35-3R	3.5mmP	4.7mmD	3.0mmL
			HA35-5R	3.5mmP	4.7mmD	5.0mmL
			HA35-3W	3.5mmP	5.7mmD	3.0mmL
			HA35-5W	3.5mmP	5.7mmD	5.0mmL
						

Extender Healing Abutments			Code	Platform	Diameter	Length
			XTHA35	3.5mmP	4.8mmD	2.0mmL

DESCRIPTION AND INSERTION PROCEDURE

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

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.

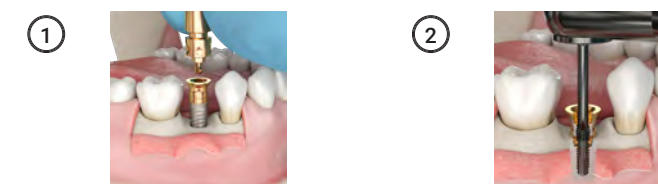
The product is for single-use only and disposed of after osseointegration has taken place and at the start of prosthetic rehabilitation.



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

1. To remove the Extender Healing Abutment from the implant, unthread the Extender Carrier Screw and remove it from the abutment body with the aid of the 1.25mmD Hex Tool.
2. Thread the Friction-fit Removal Tool through the implant carrier and into the implant. As the tool continues rotating, it will disengage the friction-fit connection and gently lift the Extender off the implant.

The product is for single-use only and if required can be removed after osseointegration has taken place and the start of prosthetic rehabilitation.



TRANSFERS

Engaging Closed-Tray Transfers (incl. UFS Screw)



Code	Platform	Diameter
CT35-EN	3.5mmP	3.7mmD
CT35-ER	3.5mmP	4.7mmD
CT35-EW	3.5mmP	5.7mmD

Additional Screws:
UFS (x2)
CTES

Engaging Open-Tray Transfers (incl. UFSL Screw)



Code	Platform	Diameter
OT35-EN	3.5mmP	3.7mmD
OT35-ER	3.5mmP	4.7mmD
OT35-EW	3.5mmP	5.7mmD

Additional Screws:
UFSL

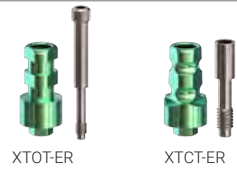
Non-Engaging Open-Tray Transfers (incl. UFSL Screw)



Code	Platform	Diameter
OT35-NN	3.5mmP	3.7mmD
OT35-NR	3.5mmP	4.7mmD
OT35-NW	3.5mmP	5.7mmD

Additional Screws:
UFSL

Extender Transfers (incl. XTFSL or XTFS Screw)



Code	Platform	Diameter
XTOT-ER	4.8mmP	4.7mmD
XTCT-ER	4.8mmP	4.7mmD

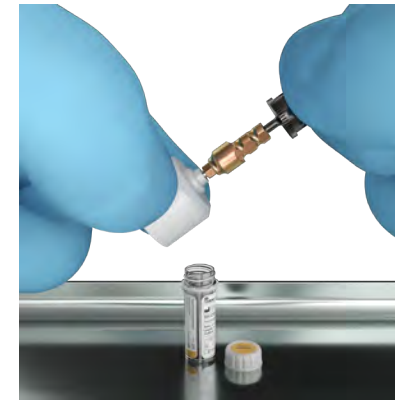
Additional Screws:
XTFSL (Open Tray)
XTFS (Closed Tray) (x2)

DESCRIPTION AND INSERTION PROCEDURE

Paragon's implant level transfer devices are for use in recording a direct & 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 carrier or contained loose within the vial.
2. Proceed with disinfection and sterilization instructions on pages 40-43.
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.

①



②



③



STRAIGHT AND ANGLED CONTOURED ABUTMENTS

Straight Contour Abutments
(incl. UFS Screw)



Code	Platform	Diameter	Length
SA35-1N	3.5mmP	3.7mmD	1.0mmL
SA35-2N	3.5mmP	3.7mmD	2.0mmL
SA35-1R	3.5mmP	4.7mmD	1.0mmL
SA35-2R	3.5mmP	4.7mmD	2.0mmL

Additional Screws:
UFS (x2)
UFSS (x2)

15° Angled Abutments
(incl. UFSXS Screw)



Code	Platform	Diameter	Length
AA35-51	3.5mmP	4.7mmD	0.75mmL
AA35-52	3.5mmP	4.7mmD	2.0mmL

Additional Screws:
UFSXS (x2)

Extender Straight & Angled Abutments
(incl. XTFS Screw of XTFSXS Screw)



Code	Platform	Diameter	Length
XTSA-1R	4.8mmP	4.7mmD	0.5mmL
XTAA-51	4.8mmP	4.7mmD	1.0mmL

Additional Screws:
XTFS (x2)
XTFSS (x2)
XTFSXS (x2)

DESCRIPTION AND INSERTION PROCEDURE

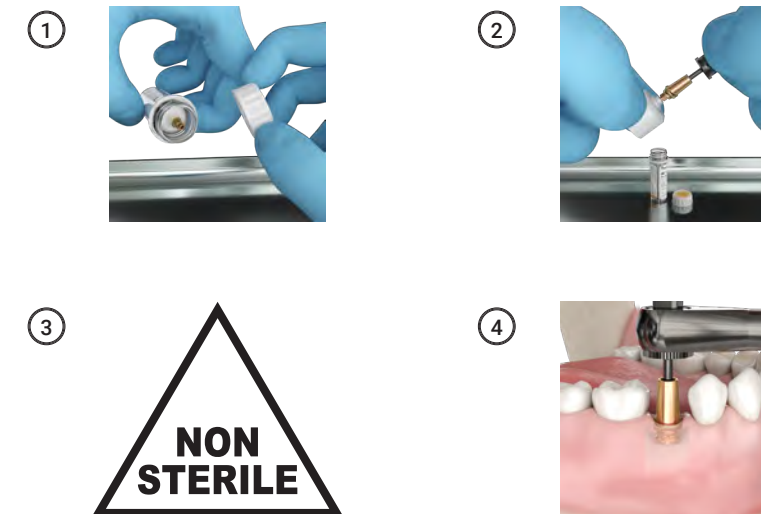
The Straight and Angled Contoured Abutments are manufactured from titanium alloy (Ti-6Al-4V ELI) offered in straight at 0° or angled at 15° relative to the long axis of the implant. Abutments are supplied with a separate fixation screw manufactured from titanium alloy (Ti-6Al-4V ELI). They are used as 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 on pages 40-43.
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 or 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 ABUTMENTS

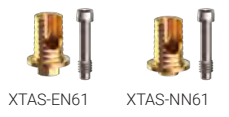
ASC Abutments 3.5
(incl. ASFXS or ASFSS Screw)



Code	Platform	Diameter	Length
AS35-EN61	3.5mmP	3.7mmD	0.5mmL
AS35-EN62	3.5mmP	3.7mmD	2.0mmL
AS35-NN61	3.5mmP	3.7mmD	0.5mmL
AS35-NN62	3.5mmP	3.7mmD	2.0mmL
AS35-ER61	3.5mmP	4.7mmD	0.5mmL
AS35-ER62	3.5mmP	4.7mmD	2.0mmL
AS35-NR61	3.5mmP	4.7mmD	0.5mmL
AS35-NR62	3.5mmP	4.7mmD	2.0mmL
AS35-EW61	3.5mmP	5.7mmD	0.5mmL
AS35-EW62	3.5mmP	5.7mmD	2.0mmL
AS35-NW61	3.5mmP	5.7mmD	0.5mmL
AS35-NW62	3.5mmP	5.7mmD	2.0mmL

Additional Screws:
ASFSXS (x2)
ASFSS (x2)

Extender ASC Abutments
(incl. XTAFS Screw)



Code	Platform	Diameter	Length
XTAS-EN61	4.7mmP	5.2mmD	0.5mmL
XTAS-NN61	4.7mmP	5.2mmD	0.5mmL

Additional Screws:
XTAFS (x2)

DESCRIPTION AND INSERTION PROCEDURE

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.

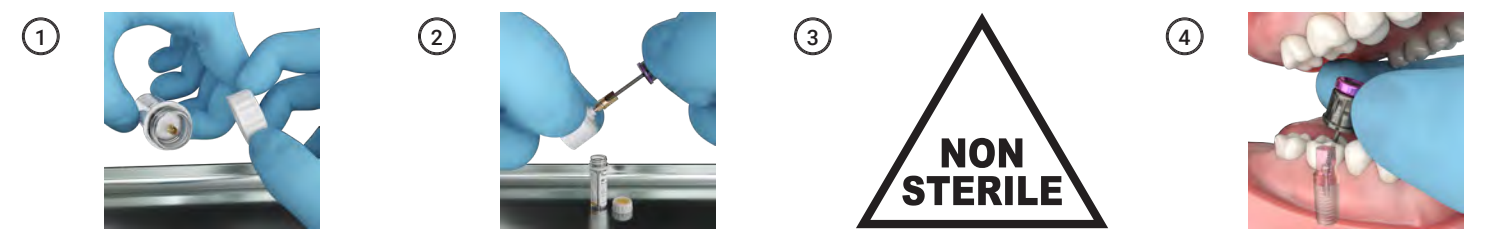
Insertion Procedures for Abutments:

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 on pages 40-43.
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.



GEN5 & GEN5+ IMPLANT AND DIMENSIONS
 SURGICAL DRILLS AND DRILL SEQUENCE
 GEN5 SURGICAL PROCEDURE
 GEN5+ SURGICAL PROCEDURE
 STEP DRILL DEPTH MARKINGS & BONE DRILL SEQUENCE
 PROSTHETIC SELECTION CHART
 COVER SCREWS
 HEALING ABUTMENTS & TRANSFERS
 CONTOURED ABUTMENTS
 ASC & MUA ABUTMENTS
 TEMPORARY ABUTMENTS
 INTRALOC ABUTMENTS
 FIXATION SCREWS & TOOLING
 CLEANING AND STERILIZATION

STRAIGHT MULTI-UNIT ABUTMENTS

Multi-Unit Abutments 3.5

(*Incl. Comfort Cap)



Code	Platform	Diameter	Length
MA35-11	3.5mmP	4.8mmD	1.0mmL
MA35-12	3.5mmP	4.8mmD	2.0mmL
MA35-13	3.5mmP	4.8mmD	3.0mmL
MA35-14	3.5mmP	4.8mmD	4.0mmL
MA35-15	3.5mmP	4.8mmD	5.0mmL

Extender Multi-Unit Abutments

(*Incl. Comfort Cap)



Code	Platform	Diameter	Length
XTMA-60-4 (x4)	4.8mmP	4.8mmD	0mmL
XTMA-61-4 (x4)	4.8mmP	4.8mmD	1.0mmL
XTMA-62-4 (x4)	4.8mmP	4.8mmD	2.0mmL

Low Profile With 1.72mmD Screw



Code	Platform	Diameter	Length
XTMAW-60-4 (x4)	4.8mmP	4.8mmD	0mmL
XTMAW-61-4 (x4)	4.8mmP	4.8mmD	1.0mmL
XTMAW-62-4 (x4)	4.8mmP	4.8mmD	2.0mmL

DESCRIPTION AND INSERTION PROCEDURE

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 abutment comes 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 on pages 40-43.
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, while the low-profile design also has a 23° taper but with a 1.0 mm tall abutment cone height.



ANGLED MULTI-UNIT ABUTMENTS

Multi-Unit Angled Abutments 3.5

(*Incl. MAFSXS Screw)



MA35-1-17 MA35-2-17 MA35-1-30 MA35-2-30

Code	Platform	Diameter	Length	Price
MA35-1-17	3.5mmP	4.8mmD	1.0/2.5mmL	
MA35-2-17	3.5mmP	4.8mmD	2.0/3.5mmL	
MA35-1-30	3.5mmP	4.8mmD	1.0/3.5mmL	
MA35-2-30	3.5mmP	4.8mmD	2.0/4.5mmL	

Additional Screws:
MAFSXS (x2)

Extender Multi-Unit Abutments

(*Incl. MAFSXS Screw)



XTMA-17 XTMA-30

Code	Platform	Diameter	Length
XTMA-17	4.8mmP	5.5mmD	4.5mmL
XTMA-30	4.8mmP	7.0mmD	4.1mmL

Additional Screws:
XTMAFSXS (x2)

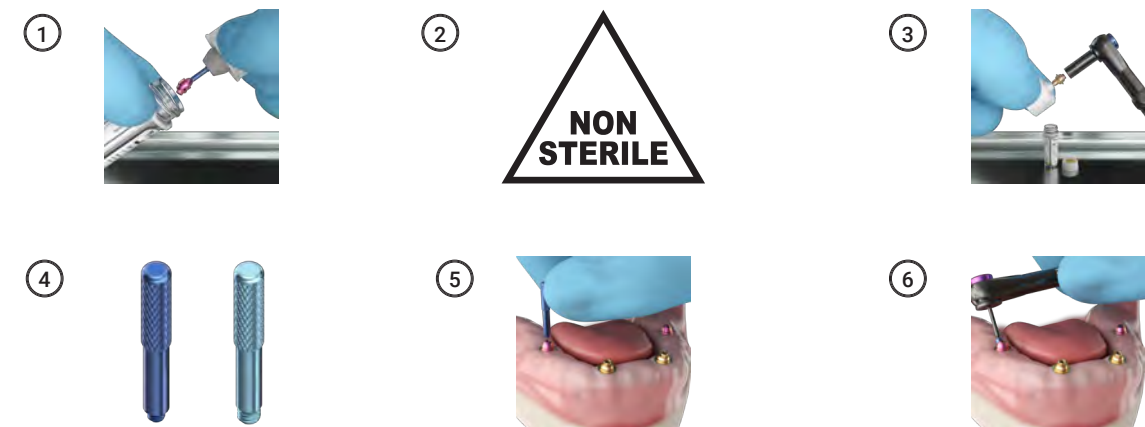
DESCRIPTION AND INSERTION PROCEDURE

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. They are secured to the implant with a pre-assembled titanium alloy (Ti-6Al-4V ELI) fixation screw that remains attached during delivery and gets tightened when the desired angle correction is made. 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) tool that aids in placement and orientation, also functioning as a 3D alignment guide pin.

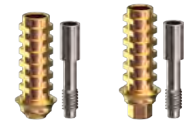
Insertion Procedures for Abutments:

1. Remove the abutment assembly from the outer vial.
2. Follow sterilization procedures on pages 40-43.
3. They are carried to the site using pre-attached, color-coded plastic carriers: dark blue for the standard 1.4UNM and light blue for the 1-72 UNF (wide thread).
4. The clinician grasps the top of the carrier, slides it with the attached abutment through the side opening of the inner vial, and carries it to the site to initiate threading of the abutment into the implant.
5. The plastic carrier is detached 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 30 Ncm.



TITANIUM TEMPORARY ABUTMENTS

Titanium Temporary Abutments (incl. UFS Screw)



TT35-NR TT35-ER

Code	Platform	Diameter
TT35-NR	3.5mmP	4.7mmD
TT35-ER	3.5mmP	4.7mmD

Additional Screws:
UFS (x2)
UFSS (x2)

Extender Temporary Abutments (incl. UFS Screw)



XTTF-EN

Code	Platform	Diameter
XTTF-EN	4.8mmP	4.8mmD

Additional Screws:
XTFS (x2)

DESCRIPTION AND INSERTION PROCEDURE

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).

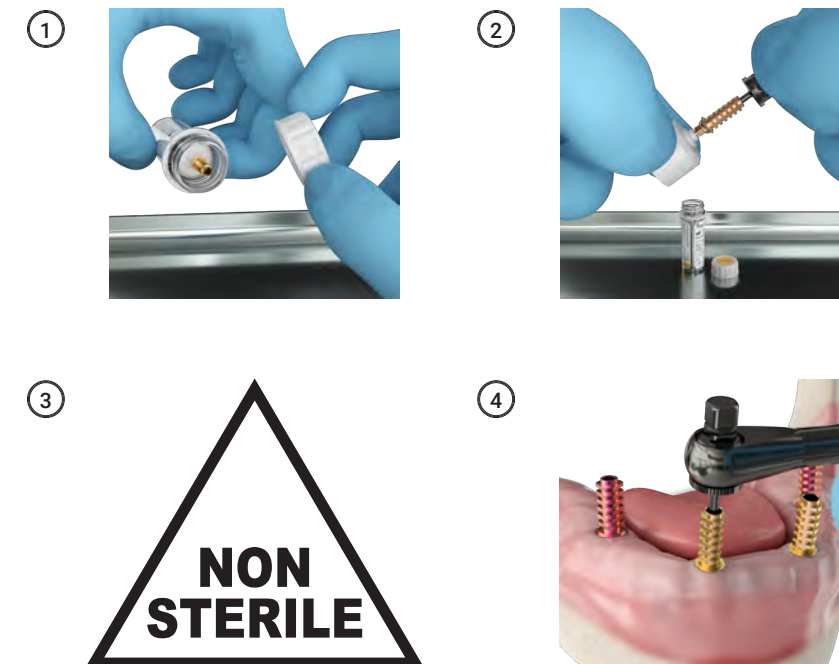
Insertion Procedures for Abutments:

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 on pages 40-43.
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.



PEEK TEMPORARY ABUTMENTS

PEEK Temporary Abutments (incl. UFS Screw)



PA35-ER PA45-ER

Code	Platform	Diameter
PA35-ER	3.5mmP	4.7mmD
PA45-ER	4.5mmP	5.7mmD

Additional Screws:
UFS (x2)
UFSS (x2)
UFSL

Extender PEEK Temporary Abutment (incl. XTFS Screw)



XTPA-ER

Code	Platform	Diameter
XTPA-ER	4.8mmP	4.8mmD

Additional Screws:
XTFS (x2)
XTFSS (x2)
XTFSL

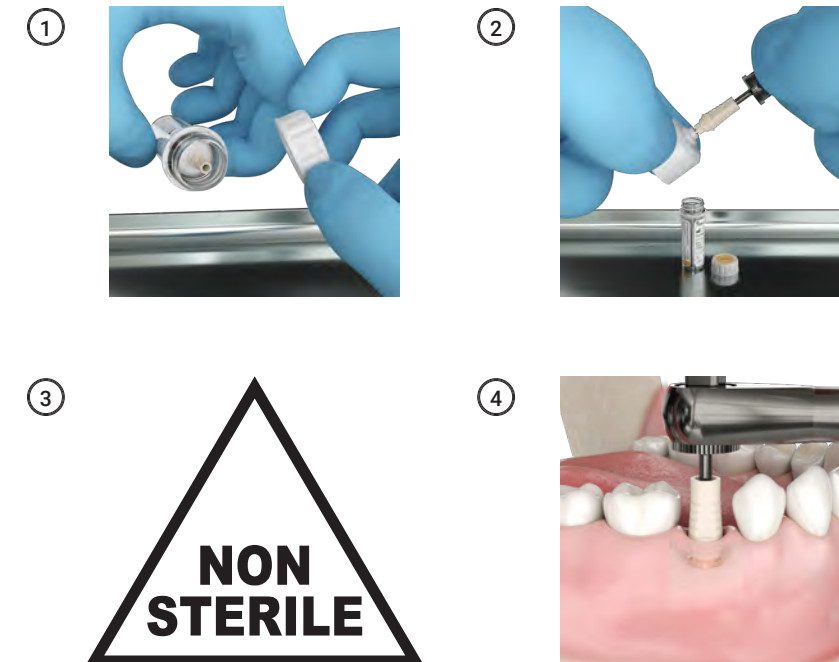
DESCRIPTION AND INSERTION PROCEDURE

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 on pages 40-43.
3. Abutments are initially seated using the corresponding driver in conjunction with a fixation screw. Abutments should then be torqued to 20 Ncm 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.



NIZLOC ABUTMENTS

NizLoc Abutments 3.5



Code	Platform	Length
NL35-11	3.5mmP	1.0mmL
NL35-12	3.5mmP	2.0mmL
NL35-13	3.5mmP	3.0mmL
NL35-14	3.5mmP	4.0mmL
NL35-15	3.5mmP	5.0mmL

Extender NizLoc Abutments



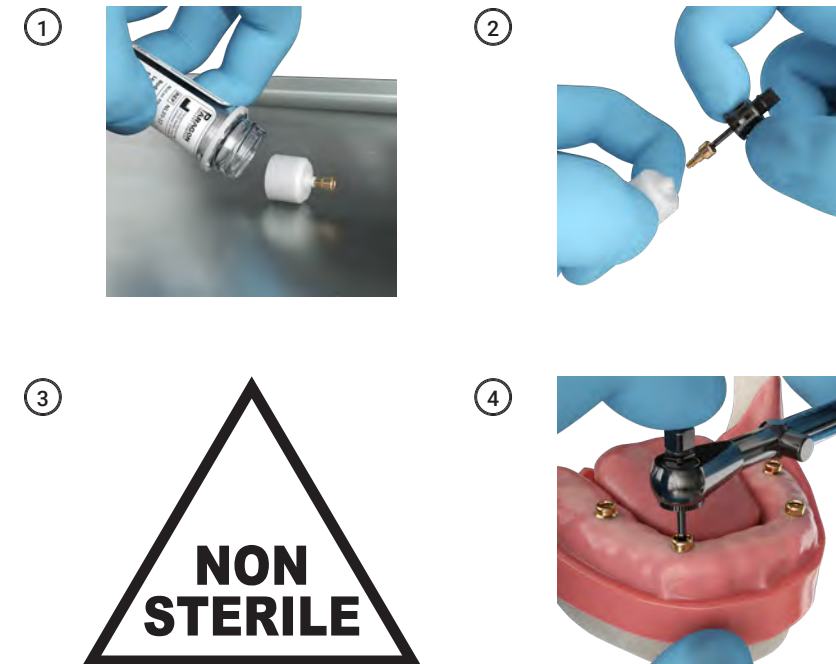
Code	Platform	Length
XTNL-0	4.8mmP	0.25mmL
XTNL-1	4.8mmP	1.25mmL
XTNL-2	4.8mmP	2.25mmL

DESCRIPTION AND INSERTION PROCEDURE

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 components manufactured by DESS Dental 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 on pages 30-33.
4. Abutments are initially seated using the corresponding driver. Abutments should then be torqued to 30Ncm to ensure fixation within the implant.



FIXATIONS SCREWS

Universal Fixation Screws



Code

- UFSXS (x2)
- UFSS (x2)
- UFS (x2)
- UFSL
- UFSXL
- XTFSXS (x2)
- XTFS (x2)
- XTFSL

Description

- Universal Fixation Screw, X-Short
- Universal Fixation Screw, Short
- Universal Fixation Screw
- Universal Fixation Screw Long
- Universal Fixation Screw X-Long
- Extender Universal Fixation Screw, X-Short
- Extender Universal Fixation Screw, Short
- Extender Universal Fixation Screw
- Extender Universal Fixation Screw, Long

Multi-Unit Angled Abutment Fixation Screw



Code

- MAFSXS (x2)
- XTMAFSXS (x2)

Description

- MUA Angled Fixation. Screw, X-Short
- Extender MUA Angled Screw, X-Short

ASC Abutment Fixation Screw



Code

- ASFSXS (x2)
- ASFSS (x2)

Description

- ASC Fixation Screw, X-Short
- ASC Fixation Screw, Short

DESCRIPTION AND INSERTION PROCEDURE

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.

TOOLING

ASC Tools



Code

ASCWD-S
 ASCWD-L
 ASCWD-XL
 ASCMD-S
 ASCMD-L
 ASCMD-XL
 ASCLD-S
 ASCLD-L
 ASCLD-XL

Description

ASC Wrench Driver, Short 24mmL
 ASC Wrench Driver, Long 29mmL
 ASC Wrench Driver, X-Long 34mmL
 ASC Manual Driver, Short 20mmL
 ASC Manual Driver, Long 25mmL
 ASC Manual Driver, X-Long 30mmL
 ASC Latch Driver, Short 27mmL
 ASC Latch Driver, Long 32mmL
 ASC Latch Driver, X-Long 37mmL

MUA Tools



Code

MAMD-S
 MAMD-L
 MAWD-S
 MAWD-L
 MAWD-XL
 MALD-S
 MALD-L

Description

MUA Manual Driver, Short 22mmL
 MUA Manual Driver, Long 26mmL
 MUA Wrench Driver, Short 22mmL
 MUA Wrench Driver, Long 26mmL
 MUA Wrench Driver, X-Long 30mmL
 MUA Latch Driver, Short 20mmL
 MUA Latch Driver, Long 24mmL

PROSTHETIC TRAY



Tools for Prosthetic Tray (optional)

Code	Description
PKE	Prosthetic Kit Empty
TW-35	Variable Setting Torque Wrench, 35Ncm
HRT1.25-S	1.25mmD Ruby Hex Tool, Short
HRT1.25-L	1.25mmD Ruby Hex Tool, Long
HRT1.25-XL	1.25mmD Ruby Hex Tool, X-Long
ASCWD-S	ASC Wrench Driver, Short 24mmL
ASCWD-L	ASC Wrench Driver, Long 29mmL
ASCWD-XL	ASC Wrench Driver, X-Long 34mmL
ASCMD-S	ASC Manual Driver, Short 20mmL
ASCMD-L	ASC Manual Driver, Long 25mmL
ASCMD-XL	ASC Manual Driver, X-Long 30mmL
MAMD-S	MUA Manual Driver, Short 22mmL
MAMD-L	MUA Manual Driver, Long 26mmL
MAWD-S	MUA Wrench Driver, Short 22mmL
MAWD-L	MUA Wrench Driver, Long 26mmL
MAWD-XL	MUA Wrench Driver, X-Long 30mmL

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.

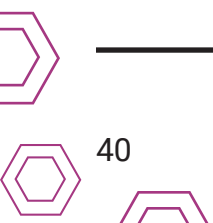
Warning: Always follow the indications, instructions and warnings provided by the supplier of the cleaning solution. Select only solutions intended for cleaning of medical devices made of a variety of metals and plastics.

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.



Paragon-implant.com

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