

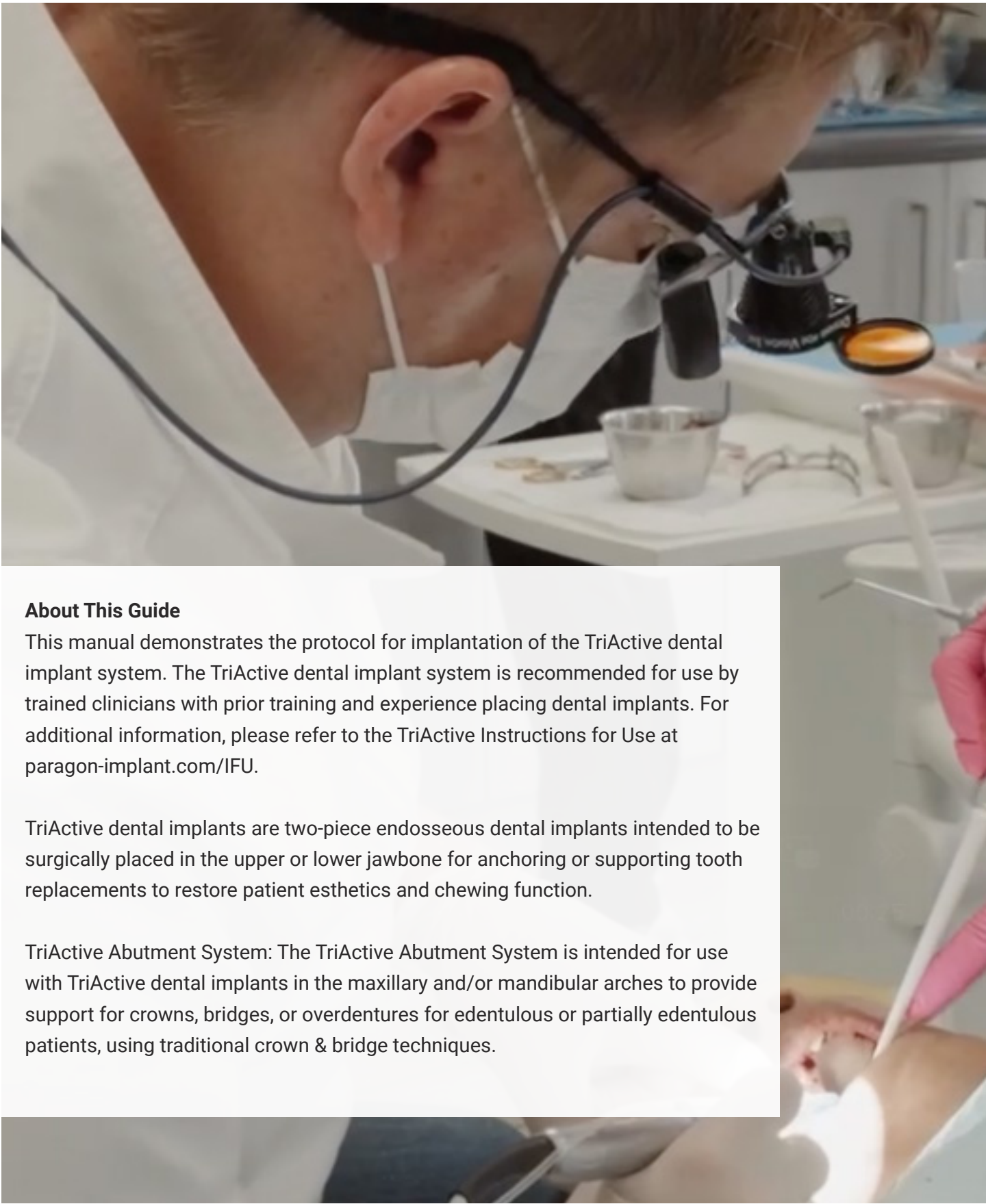
PARAGONTM

IMPLANT COMPANY

SURGICAL & PROSTHETIC GUIDE



TRIACTIVETM



About This Guide

This manual demonstrates the protocol for implantation of the TriActive dental implant system. The TriActive 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 TriActive Instructions for Use at paragon-implant.com/IFU.

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

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

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IMPLANT DESIGN AND SPECIFICATIONS

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

TriActive Implant Sizes:

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

⬡ All-On-1 Packaging includes Cover Screw and two-piece Healing Collar

⬡ Bi-directional cutting grooves for self-tapping and full seating

⬡ Depth gauge lines on neck for vertical flexibility



3.0mm Platform



3.4mm Platform



3.4mm Platform



3.4mm Platform



3.4mm Platform



3.2mmD Implant



3.7mmD Implant



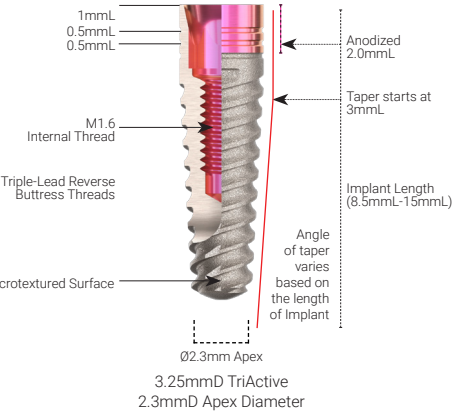
4.3mmD Implant



5.0mmD Implant



5.5mmD Implant



Ø3.0mm Implant Platform
Narrow Platform (NP)
Ø3.25mmD Body

3.0mmD Prosthetic Platform incorporates a standard 2.3mmD Internal Hex configuration (NP) having a depth of 2.4mmL from top of Implant Platform.



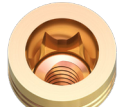
Ø3.4mm Implant Platform
Regular Platform (RP)
Ø3.75mmD Body

3.4mmD Prosthetic Platform incorporates a standard 2.65mmD Internal Hex configuration having a depth of 2.5mmL from top of Implant Platform.

3.4mmD Prosthetic Platform incorporates a standard 2.65mmD Internal Hex configuration (RP) having a depth of 2.67mmL from top of Implant Platform.



Ø3.4mm Implant Platform
Regular Platform (RP)
Ø4.3mmD Body

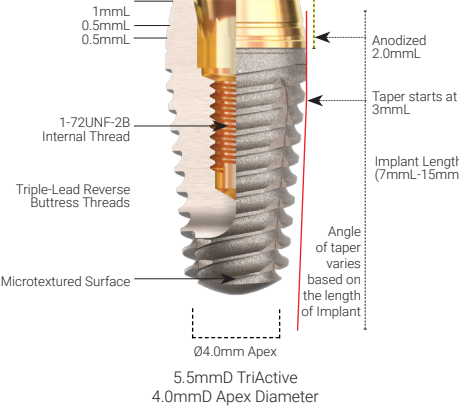
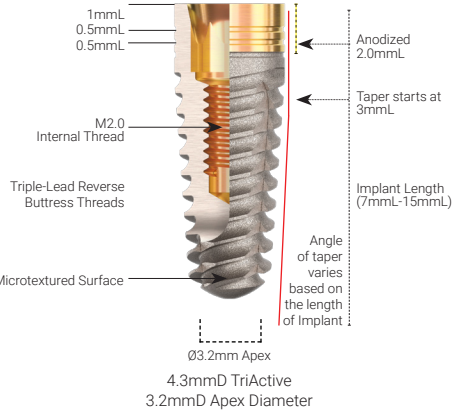


Ø3.4mm Implant Platform
Regular Platform (RP)
Ø4.9mmD Body

3.4mmD Prosthetic Platform incorporates a standard 2.65mmD Internal Hex configuration having a depth of 2.67mmL from top of Implant Platform.



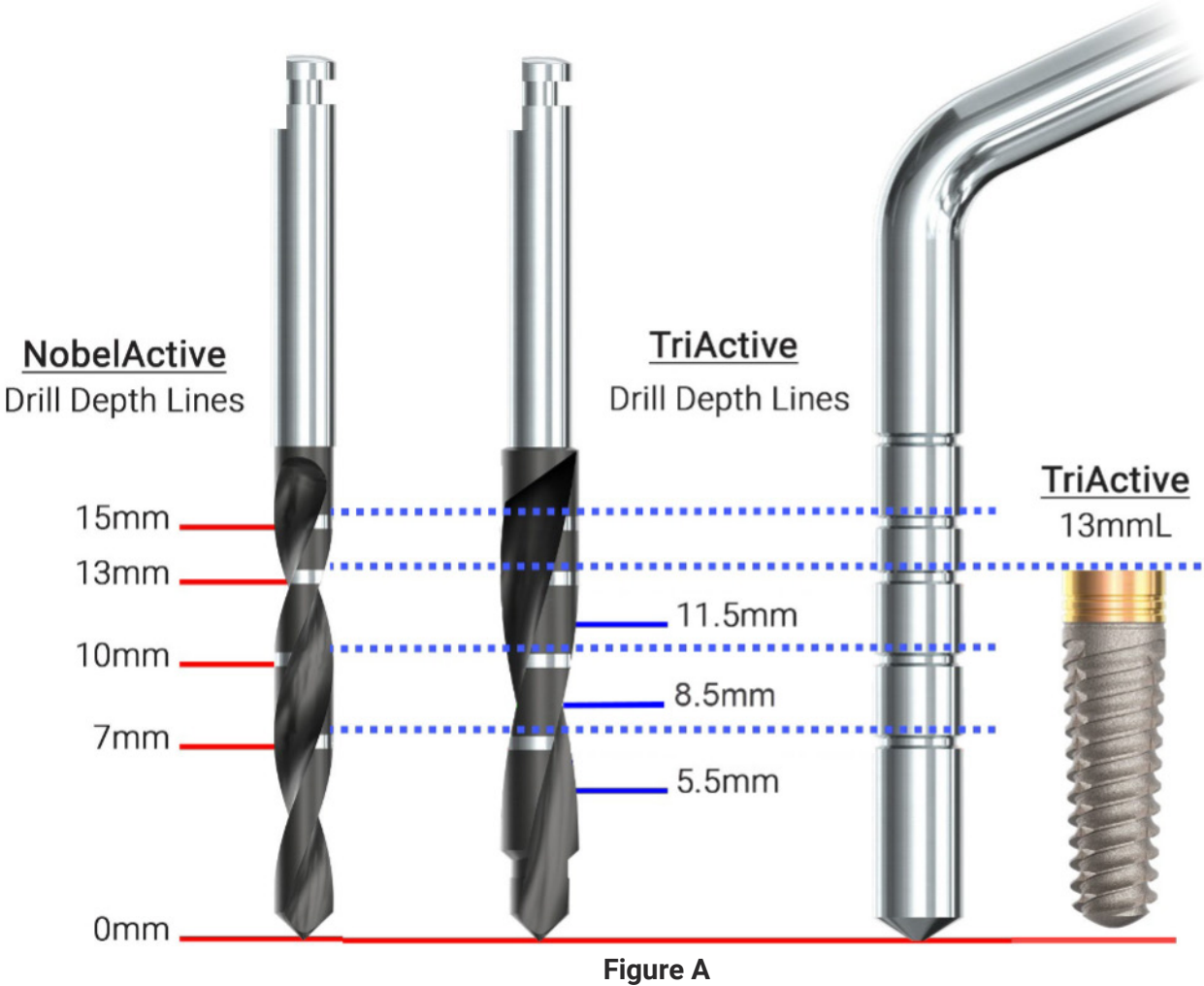
Ø3.4mm Implant Platform
Regular Platform (RP)
Ø5.5mm Body



SURGICAL DRILLS & DRILL SEQUENCE

Compatibility

TriActive Implants are surgically compatible with NobelActive drills using the surgical protocol provided herein. It is recommended that Figure A be used to compare the TriActive Depth requirements with the score lines on the NobelActive Surgical Drills, which are shown in Figure B.



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

Surgical Site Preparation

Follow the drill sequence as shown in the tables on the next page for the various implant diameters and procedural steps based on the patient's bone density and volume in those respective areas. Figure A is intended to compare the TriActive depth requirements with the NobelActive Surgical Drills, which are shown in Figure B.

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

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

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

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

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



Figure B



For 3.7mmD x 7mmL, 4.3 x 7mmL, 5.5mmD x 7mmL Implants Only										
Implant Diameter (mm)	Bone Type	Nobel Active Drill Type and Size								Paragon Implant Drill
		1.5	2.0	2.4/2.8	2.8/3.2	3.2/3.6	3.8/4.2	4.2/4.6	4.2/5.0	SD5.4M
3.7mmD	Soft	X	X	X		Widen cortex w/ 3.6mmD				
	Dense	X	X	X	Implant length -1.5mm		Widen cortex w/ 3.8mmD			
4.3mmD	Soft	X	X	X	X			Widen cortex w/ 4.2mmD		
	Dense	X	X	X	X			Widen cortex w/ 4.2mmD		
5.5mmD	Soft	X	X	X	X	X	X		Widen cortex w/ 5.0mmD	Widen cortex w/ 5.4mmD
	Dense	X	X	X	X	X	X		Widen cortex w/ 5.0mmD	Widen cortex w/ 5.4mmD

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

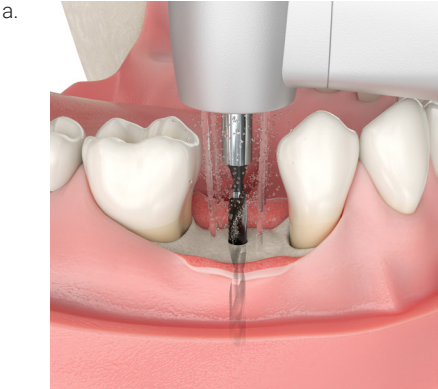
For all Additional Implant Sizes										
Implant Diameter (mm)	Bone Type	Nobel Active Drill Type and Size								Paragon Implant Drill
		1.5	2.0	2.4/2.8	2.8/3.2	3.2/3.6	3.8/4.2	4.2/4.6	4.2/5.0	SD5.4M
3.2mmD	Soft	X	X	Widen cortex w/ 2.8mmD						
	Dense	X	X	Implant length -1.5mm						
3.7mmD	Soft	X	X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

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



TRIACTIVE SURGICAL PROCEDURE

Prepare Osteotomy



Begin preparation of the osteotomy with a pilot drill to a depth equal to the implant length plus 0.5mm



Continue preparation with the next consecutive drill size to a depth equal to the implant length plus 0.5mm.



Confirm depth before proceeding to next consecutive drill size.



When required, proceed with preparation using the next consecutive drill size, in this case to, a depth equal to the length of the implant minus 1.5mm. Note the position of the scoreline relative to the crest.

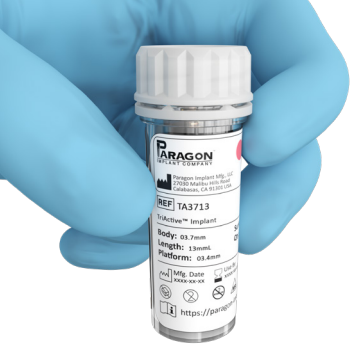
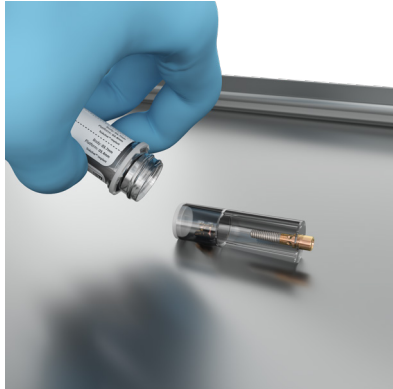


For cases where bone consists of a dense cortical plate (cortex), one of the two surgical diameters may be used to widen the cortex. Note the that the first diameter of the step drill only proceeds as deep as the thickness of the cortex.

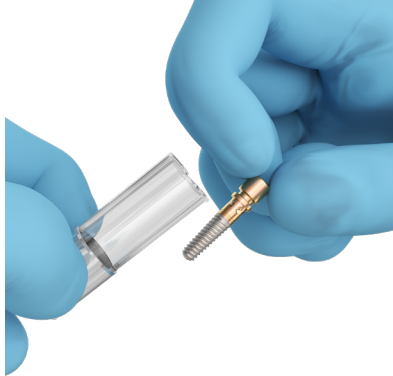
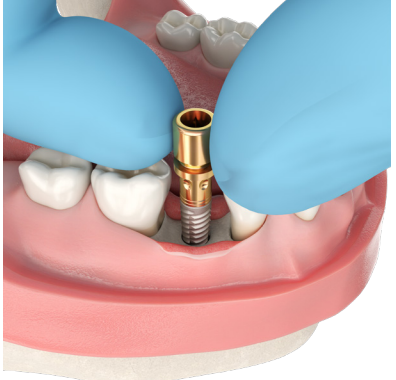
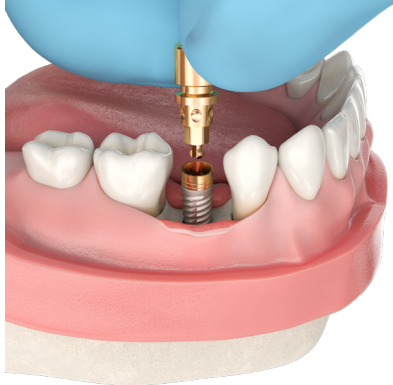
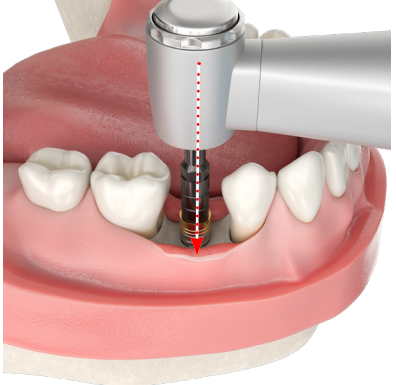


For cases where bone consists of a dense cortical plate (cortex), one of the two surgical diameters may be used to widen the cortex. Note the that the second diameter of the step drill only proceeds as deep as the thickness of the cortex.

Implant Removal from Packaging

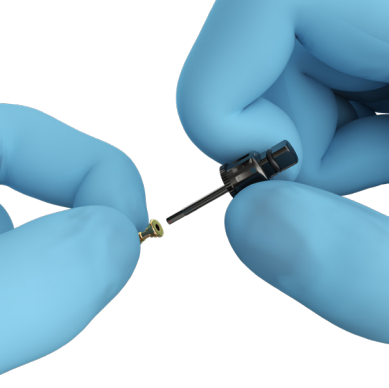
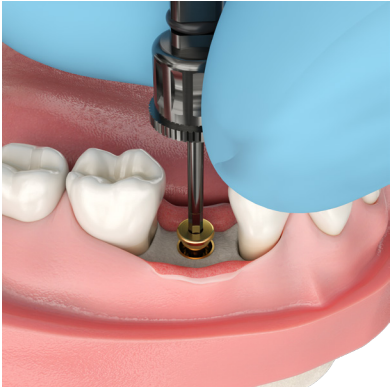
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- All Paragon Implants are supplied in gamma irradiated, sterile packaging.
- Each label has two tear-off labels for patient records.
- Color coded labels on top of the cap identify the diameter of the platform.
- Drop implant assembly out of vial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

Implant Placement

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- Remove carrier with implant from the inner vial by hand.
- Align implant/carrier assembly with osteotomy for insertion. Initiate self-tapping by hand, rotating the assembly in a clockwise direction until resistance is felt.
- Gently pull the carrier straight up to separate and remove it from the implant.
- Engage internal hex feature of implant with a 2.3mmD (3.2mmD implants) or 2.7mmD hand or motor driver. Insert implant level with crest.
- The internal hex of the implant should be indexed with a flat on the labial/lingual.

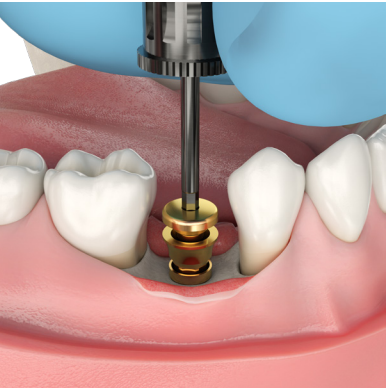
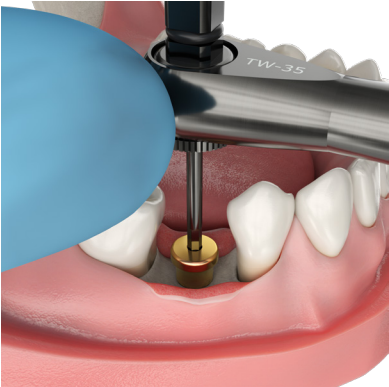
Implant Closure - Without Extender Healing Abutment

Two-stage Healing

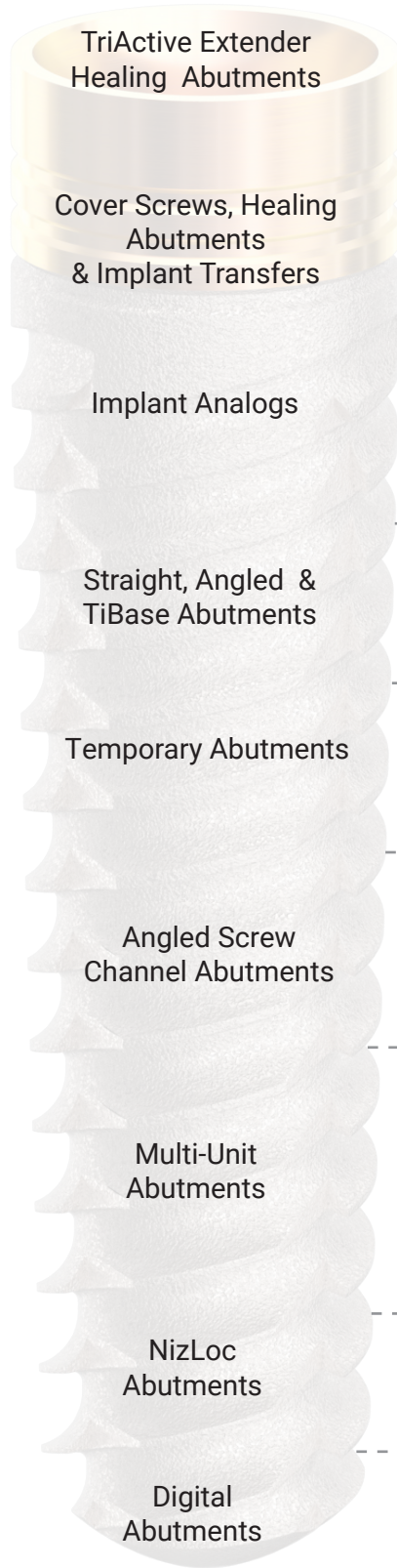
-  Select cover screw, healing abutment, temporary or final abutment.
-  Use friction-fit 1.25mmD hex tool to remove the Cover Screw.
-  Attach the Cover Screw to implant.
-  Suture soft tissue over the Cover Screw.
-  Remove Cover Screw.
-  Attach selected prosthetic component to implant for cemented restoration.

Implant Healing - Extender Healing Abutment

One-stage Healing

-  Remove friction-fit Extender Healing Abutment packaged with implant.
-  Place Extender Healing Abutment on fully seated implant.
-  Using the friction-fit 1.25mmD hex tool, tighten Extender Healing Abutment screw 15-20Ncm to fully seat on implant.
-  Suture around the Extender Healing Abutment.
-  Remove Extender Healing Abutment Cover Screw.
-  Attach selected prosthetic component to Extender for cemented restoration.

PROSTHETIC SELECTION CHART



TriActive Extender Healing Abutment Connection 4.8mmP - Paragon*	TriActive Connection 3.0mmP (NP) - Paragon	TriActive Connection 3.4mmP (RP) - Paragon	TriActive Connection 3.0mmP (NP) - DESS**	TriActive Connection 3.4mmP (RP) - DESS**
Use with TXHA32 Use with TXHA37, TXHA43, and TXHA50	TXHA32	TXHA37 TXHA43 TXHA50		
TXCS-1N TXCS-3N TXCS-1R TXCS-3R TXFEN TXFER	TCS30	TCS34	17.044 20.039/3 20.039/4 20.039/5 20.047/3 20.047/4 20.047/5	17.045 20.040/3 20.040/4 20.040/5 20.048/3 20.048/4 20.048/5
TXAN TXAR			14.041	14.042
TXSA-EN TXSA-ER			15.441 16.441 58.041 59.041 58.041/3 59.041/3	15.042 15.342 16.042 58.042 59.042 15.042/2 16.042/2 58.042/3 59.042/3
TXTF-EN TXTF-ER			24.041 25.041	24.042 25.042
TXAS-EN TXAS-ER			36.041 37.041	36.042 37.042
TXMA-60N TXMA-61N TXMA-62N TXMA-60R TXMA-61R TXMA-62R TXMAW-60N TXMAW-61N TXMAW-62N TXMAW-60R TXMAW-61R TXMAW-62R			40.007/1 40.007/2 40.007/3 41.404/2 41.404/3 43.404/3 43.404/4	40.008/1 40.008/2 40.008/3 40.008/4 41.405/2 41.405/3 43.405/3 43.405/4
TXNL-0N TXNL-1N TXNL-2N TXNL-0R TXNL-1R TXNL-2R			88.039/1 88.039/2 88.039/3 88.039/4	88.040/1 88.040/2 88.040/3 88.040/4
			52.041 14.041/D	52.042 14.042/D

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

** Not compatible with Short (<8.5mmL) TriActive Implants and cannot be used with TriActive Extender Healing Abutments.

TRIACTIVE™ PROSTHETICS

Implant Level Prosthetics Compatibility

Standard Length (≥8.5mmL) TriActive Implants are prosthetically compatible with DESS® (Terrats Medical SL) NobelActive Conical Connection Abutments and implant drivers (NP and RP Conical Connection Implant Drivers). For all DESS products, please refer to the DESS IFU at <https://www.dessdental.com/en/documents/>.

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

All TriActive implant diameters and lengths fitted with Extender Healing Abutments are prosthetically compatible with corresponding TriActive Healing and Prosthetic Components. DESS Abutments are not compatible with the TriActive Extender Healing Abutments

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

Standard configuration Extender Multi-unit Abutments are compatible with Paragon Implant, GEN5 Standard MUA Copings (for M1.4 threaded connections). Low-Profile configuration Extender Multi-unit Abutments are compatible with Paragon Implant, GEN5 Low-Profile MUA Copings (for 1-72 UNF threaded connections).

COVER SCREWS

Cover Screws	Code	Platform
	TCS30	3.0mmP
	TCS34	3.4mmP

Extender Cover Screws	Code	Platform	Length
	TXCS-1N	3.0mmP	1.0mmL
	TXCS-3N	3.0mmP	3.0mmL
	TXCS-1R	3.4mmP	1.0mmL
	TXCS-3R	3.4mmP	3.0mmL

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

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

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

EXTENDER HEALING ABUTMENTS

Extender Healing Abutments	Code	Diameter
	TXHA32	3.2mmD
	TXHA37	3.7mmD
	TXHA43	4.3mmD
	TXHA50	5.0mmD

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

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

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

To attach the Extender Healing Abutment sold separately:

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

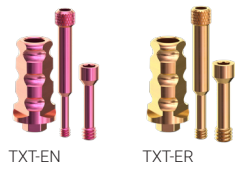
To remove the Extender Healing Abutment:

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

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

EXTENDER TRANSFERS

Extender Transfers
(incl. TXOTFS1.6 & TXFS1.6 or TXOTFS2.0 & TXFS2.0 Screws)



Code	Platform
TXT-EN	3.0mmP
TXT-ER	3.4mmP
Additional Screws:	
TXOTFS1.6 (x2)	
TXOTFS2.0 (x2)	
TXFS1.6(x2)	
TXFS2.0(x2)	

Paragon’s extender 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.

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

EXTENDER STRAIGHT ABUTMENTS

Extender Straight Abutments
(incl. TXFS1.6 or TXFS2.0 Screw)



Code	Platform	Diameter
TXSA-EN	3.0mmP	4.8mmD
TXSA-ER	3.4mmP	4.8mmD
Additional Screws:		
TXFS1.6 (x2)		
TXFS2.0 (x2)		

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

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

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

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

EXTENDER ANGLED SCREW CHANNEL ABUTMENTS

Extender ASC Abutments
(incl. TASXFS1.6 or TASXFS2.0 Screw)



TXAS-EN TXAS-ER

Code	Thread	Platform
TXAS-EN	M1.6	4.8mmP
TXAS-ER	M2.0	4.8mmP

Additional Screws:
TASXFS1.6 (x2)
TASXFS2.0 (x2)

Extender Angled Screw Channel (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.

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

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

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

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

EXTENDER MULTI-UNIT ABUTMENTS

Extender MUA Abutments	Code	Thread	Platform	Length
	TXMA-60N (x4)	M1.6	4.8mmP	0mmL
	TXMA-61N (x4)	M1.6	4.8mmP	1mmL
	TXMA-62N (x4)	M1.6	4.8mmP	2mmL
	TXMA-60R (x4)	M2.0	4.8mmP	0mmL
	TXMA-61R (x4)	M2.0	4.8mmP	1mmL
	TXMA-62R (x4)	M2.0	4.8mmP	2mmL

Extender MUA Abutments Low Profile	Code	Thread	Platform	Length
	TXMAW-60N (x4)	M1.6	4.8mmP	0mmL
	TXMAW-61N (x4)	M1.6	4.8mmP	1mmL
	TXMAW-62N (x4)	M1.6	4.8mmP	2mmL
	TXMAW-60R (x4)	M2.0	4.8mmP	0mmL
	TXMAW-61R (x4)	M2.0	4.8mmP	1mmL
	TXMAW-62R (x4)	M2.0	4.8mmP	2mmL

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

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

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

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

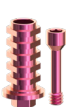
EXTENDER NIZLOC ABUTMENT SCREWS

Extender NizLoc Abutments			Code	Thread	Platform	Length
			TXNL-0N	M1.6	4.8mmP	0.25mmL
			TXNL-1N	M1.6	4.8mmP	1.25mmL
			TXNL-2N	M1.6	4.8mmP	2.25mmL
			TXNL-0R	M2.0	4.8mmP	0.25mmL
			TXNL-1R	M2.0	4.8mmP	1.25mmL
			TXNL-2R	M2.0	4.8mmP	2.25mmL

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

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

EXTENDER TITANIUM TEMPORARY ABUTMENTS

Extender Titanium Temporary Abutments (incl. TXFS1.6 or TXFS2.0 Screw)		Code	Platform	Diameter
		TXTT-EN	3.0mmP	4.8mmD
		TXTT-ER	3.4mmP	4.8mmD
TXTT-EN		Additional Screws:		
TXTT-ER		TXFS1.6 (x2)		
		TXFS2.0 (x2)		

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

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

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

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

DESS ACTIVE HEX™ PROSTHETICS

1. INTRODUCTION

DESS Dental Smart Solutions offers a variety of abutment designs compatible with TRIACTIVE dental implant connections. Each abutment design supports a specific type of restoration. This prosthetic manual contains general prosthetic procedures for each abutment design.

This procedure manual alone is not sufficient for use of DESS Dental Smart Solutions abutments. Clinicians choosing to use DESS Dental Smart Solutions abutments require specialized training in placing and restoring endosseous dental implants.

Paragon is a reseller of DESS products. For all DESS products, please refer to the DESS IFU at <https://www.dessdental.com/en/documents/>. To find a validated milling center, contact DESS directly at <https://www.dessdental.com/en/VMC>.

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

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

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

2. HEALING ABUTMENTS

The healing abutment is used as an auxiliary transmucosal abutment. It is placed on the implant fixture before prosthetic restoration to facilitate the formation of a soft tissue sulcus. Choose the correct height to ensure its correct function and prevent the transmission of chewing forces. Before placing, ensure that implant platform stays free from any tissue residues. Use gentle manual torque when installing to avoid additional implant rotation.



3. TRANSFER FOR IMPRESSION TAKING

Transfer is used for closed and open tray technique, for the transfer of implant position from the intraoral situation to the model in dental laboratory. Before being used, ensure that the connection seat for the implant position from the intraoral situation to the model in dental laboratory. Before being used, ensure that the connection seat for the implant is clean. Any traces of dirt could affect subsequent alignment of the prosthesis. Check compatibility with the implant model to which it will be connected. Remove abutment, clean the connection with spray water/air and dry. Prepare transfer adequate to implant connection and platform size. Place it on implant and check correct position. Put the screw and fix manually.

For closed tray technique choose the short screw. After tightening block the hex of the screw with wax. Use hydrocolloid, polyethylene or soft silicone. After hardening place the transfer in its grove and check the stability before sending to the laboratory.

For open tray technique choose the long screw. After tightening place the impression tray to ensure full access to transfer screws from outside. Before impression taking the transfers can be splinted with acrylic resin placed over dental floss between consecutive implants. After hardening release all screws and take out the impression tray.

4. MULTI-UNIT ABUTMENTS

Multi-Unit Abutments are intended for multi-unit restorations only. We strongly recommend a radiograph to verify final abutment seating. Place appropriate Multi Unit abutment in terms of height, platform and angulation. There are two angulations to choose with 17 degrees and 30 degrees. Use the holder to facilitate the insertion. Tighten the screw of the abutment to 30 Ncm using the specific DESS screw driver for Multi-unit and a manual torque wrench. Take an impression using standard techniques and provisionalize the patient. If a temporary prosthesis is not necessary place healing caps.

5. ANALOGUES

The analogues are for simulation of dental implant connection and position on a stone master model. Before any laboratory manipulation ensure that the anti-rotation and anti-removal parts on the analogue are securely affixed.

Check that the analogue and the prosthetic element connections match in size and type before tightening. A sealed and passive connection is needed. Do not re-use an analogue, because such a connection may be impossible to achieve with a product that may no longer be within specifications.



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6. TEMPORARY ABUTMENTS

The Temporary Abutment is used for prosthetic restorations prepared by the dentist chairside, and works as support for provisional screw-retained crowns, bridges and prostheses. Make sure that the engaging parts of the abutment are correctly aligned with the implant retention parts. We strongly recommend a radiograph to verify correct seating after tightening.

Warning: Any modifications (e.g., grinding) should be performed outside the mouth. If this is not possible, adequate suction must be used. Position the patient so that debris is not inhaled or swallowed.

Use carbide burs and carborundum discs with water cooling. Do not modify the Temporary Abutment to correct for angulation. A minimum post height of 4 mm is clinically recommended for single-unit loading.

Before placing the temporary restoration check the torque according to implant connection and size.

For cement-retained restorations it is important to seal the access hole with Teflon tape or gutta-percha and composite. Any material excess near implant platform should be removed, as it can provoke peri-implantitis and can lead to implant loss. After cementation remember to check static and dynamic occlusion avoiding excessive loading forces which may prolong or prevent the proper osseointegration, especially in cases of immediate loading. Temporary abutments are indicated for a maximum of 180 days intraorally.

7. DESSLOC ABUTMENTS

DESSLoc is a resilient implant attachment used for removable denture restoration prepared by dental technicians in a dental laboratory or by a dentist chairside.

Procedure: Measure the tissue thickness from the implant platform to the highest side of the gingival crest near the implant. Choose the corresponding abutment height or 1.5 mm higher (the attachment should not be submerged) and place it with 20 Ncm torque. The retention male portion of the denture can be mounted with self-curing resin in the dental clinic or in a dental laboratory.



8. STRAIGHT ABUTMENTS

Straight Abutments are used for prosthetic restorations prepared by dental technicians in the dental laboratory or by dentists at chairside in the dental clinic. Straight abutments form the support for prosthetic crowns and bridges. Make sure that the engaging parts of the abutment are correctly aligned with the implant retention parts and that they are in the correct place and position for all secondary parts. We strongly recommend a radiograph to verify correct seating after tightening.

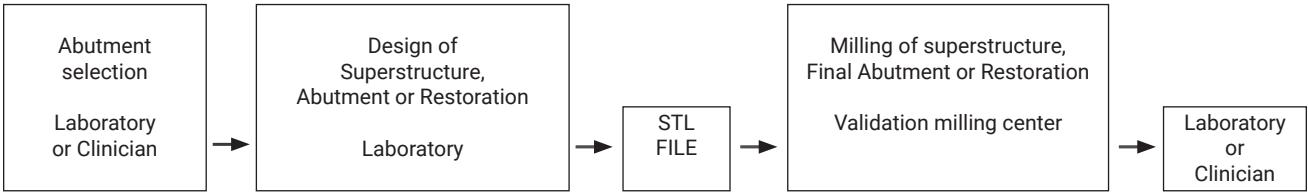
Caution: If modification is needed, do not grind the wall to less than 0.5 mm thick.

Warning: Any grinding should be performed outside the mouth. If this is not possible, adequate suction must be used. Position the patient so that debris is not inhaled or swallowed. Do not modify the Straight Abutment to correct for angulation. A minimum post height of 4 mm is clinically recommended for single-unit loading. Use carbide burs and carborundum discs with water cooling. Before cementing the final restoration, check the torque according to implant connection and size. When cementing use definitive luting cement or use temporary cement after sealing of access hole with Teflon tape or gutta-percha. Remove cement excess from edge of the crown to avoid peri-implantitis which can lead to implant loss. After cementation remember to check static and dynamic occlusion using conventional protocol.



9. WORKFLOW FOR TI BASES AND PREMILLED BLANKS

All milling of superstructures for Ti Base Interface, DESS Aurum Base, ElliptiBase, CoCr Base and milling of abutments from Pre-Milled Blank must be performed at Terrats Medical Validated Milling Centers. The following is a simplified workflow pointing out that, though selection of the Ti Base or Premilled Blank and design of the superstructure, final abutment or restoration may be performed by a dental laboratory, milling of the final device must be performed at a Terrats Medical Validated Milling Center. The following is the current list of Validated Milling Center as of the date of this Prosthetic Manual. **To see the current list of Terrats Medical Validated Milling Centers please see <https://www.dessdental.com/en/VMC>.**



Name	Location	Telephone Number	Email address
Burbank Dental Laboratory	Burbank, CA	1-800-336-3053x101	tony@burbankdental.com
Dental Crafters	Marshfield, WI	1-715-898-1434	DarrellB@dentalcrafters.net
IKON Dental	Sandy, UT	1-801-671-4624	kondental@gmail.com
Pittman Dental Laboratory	Gainesville, GA	1-770-534-4457	brett@pittmandental.com
Peterson Dental Laboratory, Inc.	Delray Beach, FL	1-561-272-6662x130	Jenny@PetersonDentalLab.com
Aurora Digital Technology Center	Wappinger Falls, NY	1-866-228-7672	enrico@auroradtc.com
Osteon Medical	Mulgrave Victoria, Australia	+61 3 9264 0111	andrea@osteonmedical.com

10. TIBASE (INTERFACE), TIBASE (DESS AURUM) AND COCR BASE

Bases are used for support of prosthetic restorations prepared by dental technicians in a dental laboratory. The Bases can be used to support a direct crown, and each Base is provided with a POM (polyoxymethylene) sleeve that can be burned-out when fabricating a direct crown. The POM burn-out sleeve is indicated for PFM (porcelain fused to metal) restorations using precious (noble alloy) or non-precious (CoCr) casting metal. TiBase Abutments are not intended for angulation correction when used with a POM burn-out sleeve. A minimum post height of 4 mm is clinically recommended for single-unit loading.

The TiBase also can be used to support a zirconia superstructure plus crown. All digitally designed zirconia superstructure components for use with TiBase are to be sent to a Terrats Medical validated milling center for manufacture.

The TiBase also can be used to support a zirconia superstructure plus crown. All digitally designed zirconia superstructure components for use with TiBase are to be sent to a Terrats Medical validated milling center for manufacture.

The design parameters for the CAD/CAM zirconia superstructures are:

- Minimum wall thickness – 0.4 mm
- Minimum post height for single-unit loading
- TiBase (Interface) – 4.2 mm
- TiBase (DESS Aurum) – 4 mm
- CoCr Base – 4.5 mm
- Maximum gingival height – 6.0 mm
- All zirconia superstructures are for straight abutments only.

TiBase and corresponding zirconia superstructure are provided to the clinician either with the superstructure cemented to the abutment by the milling center or the dental laboratory, or separately for the clinician to bond together chairside using the cement recommended in the labeling (Multi-Link cement by Ivoclar Vivadent). To aid in cement adhesion we recommend that the TiBase be thoroughly cleaned before cementation. The ceramic surface of superstructure in the cementing zone should be sandblasted and cleaned. For secure grip the diameter of TiBase and its height should not be reduced (e.g. by grinding).

Contraindications: do not use the TiBase for restorations with cantilever on a single implant, with patients who brux, with insufficient space, with direct metal-to-interface casting.

11. PRE-MILLED BLANK

Pre-milled Blank is used for fabrication of a patient specific abutment using CAD/CAM technology. All patient specific abutments are fabricated according to a prescription from the clinician.

All digitally designed abutments for use with Pre-milled Blanks are to be sent to a Terrats Medical validated milling center for manufacture.



11. PRE-MILLED BLANK (CONTINUED)

The design parameters for the CAD/CAM Pre-milled Blank custom abutments are:

- Minimum wall thickness – 0.45 mm
- Minimum post height – 4.0 mm
- Maximum gingival height – 6.0 mm
- Minimum gingival height – 0.3 mm
- All Pre-milled Blank abutments are for straight abutments only.

Implants with diameters of 3.7 mm or below with angled abutments are recommended for incisors region only. Small diameter implants and angled abutments are not recommended for the posterior region.

Once the patient specific abutment has been milled, it is sent to a dental laboratory for fabrication of a final restoration.

Parameter	Min (mm)	Max (mm)
Total Height	4.3	19
Post Height for Single-Unit Restoration	4.0	19
Wall Thickness	0.45	N/A
Diameter	Based on minimum wall thickness	
		14

12. SCREWS

The abutment screw is for attachment of the abutment to the implant. The prosthetic screw is for attachment of the prosthesis to the abutment. The laboratory screw is for fixation of the abutment to the analog during laboratory procedures. Make sure to secure the parts with corresponding screw and observe specified torque value placed on the label.

For best results, the following conditions must be met:

- Position the patient to avoid aspiration in case the screw falls during screwing/unscrewing.
- Check compatibility of the screw with the implant model to which it will be connected.
- Make sure the correct model of screw is used for each case.
- When transferring to the patient, do not use the same screw that was used in the laboratory.
- Use the suitable model key and size for tightening and unscrewing. If in doubt, check that the next size key does not fit into the seat. The driver should be placed in the longitudinal axis of the prosthesis/implant assembly. A new screw must be used when assembling a prosthesis for the first time and for every check thereafter.
- For immediate load temporary prostheses, finger tighten the screw avoiding excessive torque, and prevent the implant from turning while screwing.

Some screw models are available with DLC coating (Diamond-Like Carbon) to provide a low friction surface. Screws are provided with each abutment for the corresponding implant line. Also, screws are provided separately.



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TRIACTIVE™ CLEANING AND STERILIZATION OF PROSTHETICS AND SINGLE-USE COMPONENTRY

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

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

Warning: Always follow 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.

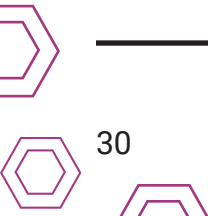
Note: For all DESS products, please refer to the DESS IFU at <https://www.dessdental.com/en/documents/>.

TRIACTIVE™ 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 enzymat-ic-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.



TRIACTIVE™ 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.

TRIACTIVE™ 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.



Manufacturing

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