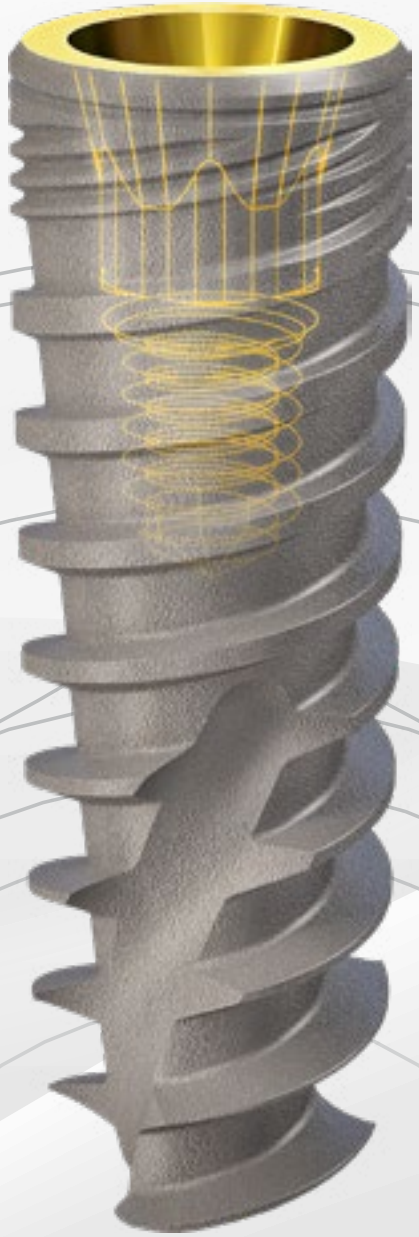
NORIS Medical®

Surgical Manual for Conical Platform Dental Implants

TUFF UNICON



INTRODUCTION

The scope of this manual is to provide a detailed overview of the

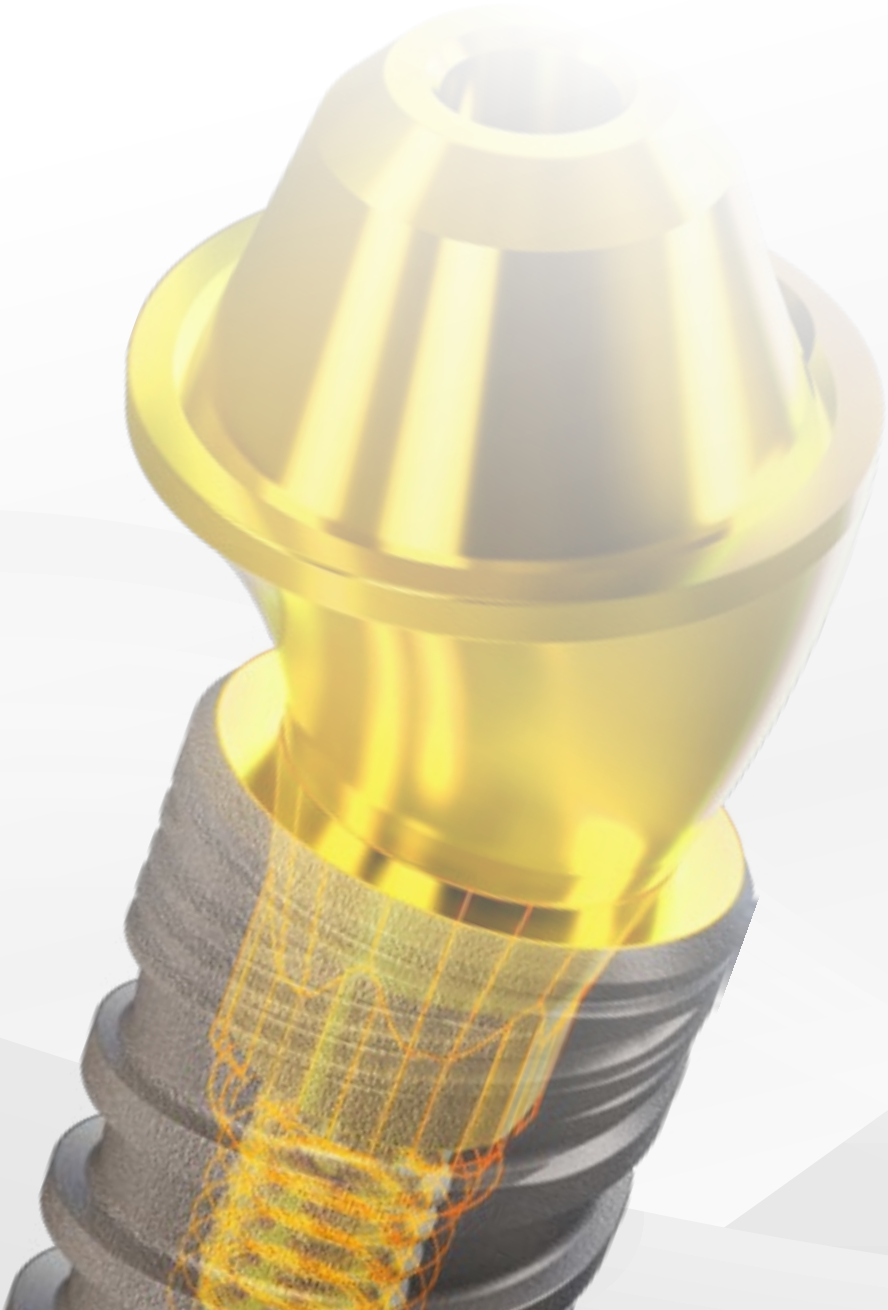
Conical Platform Dental Implant Surgical Procedures Manual

for the placement of the Tuff Unicon implants and related products needed.

This manual is designed to assist dental professionals in performing a successful and efficient implantation procedure using the conical platform dental implants and instruments.

This manual outlines the surgical steps, providing detailed instructions for site preparation, osteotomy implant bed preparation, implant insertion techniques and optional sequence.

Please review the Instructions For Use (IFU), including the indications for use, contraindications, warning and cautions before using the products in a surgical procedure.



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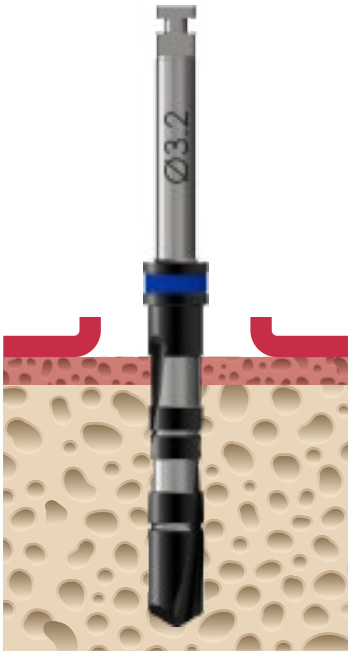
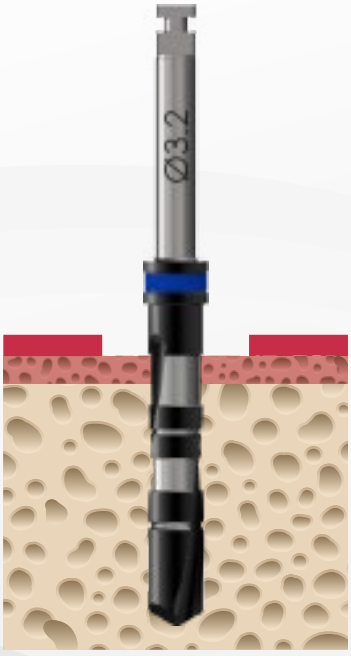
QUICK GUIDE

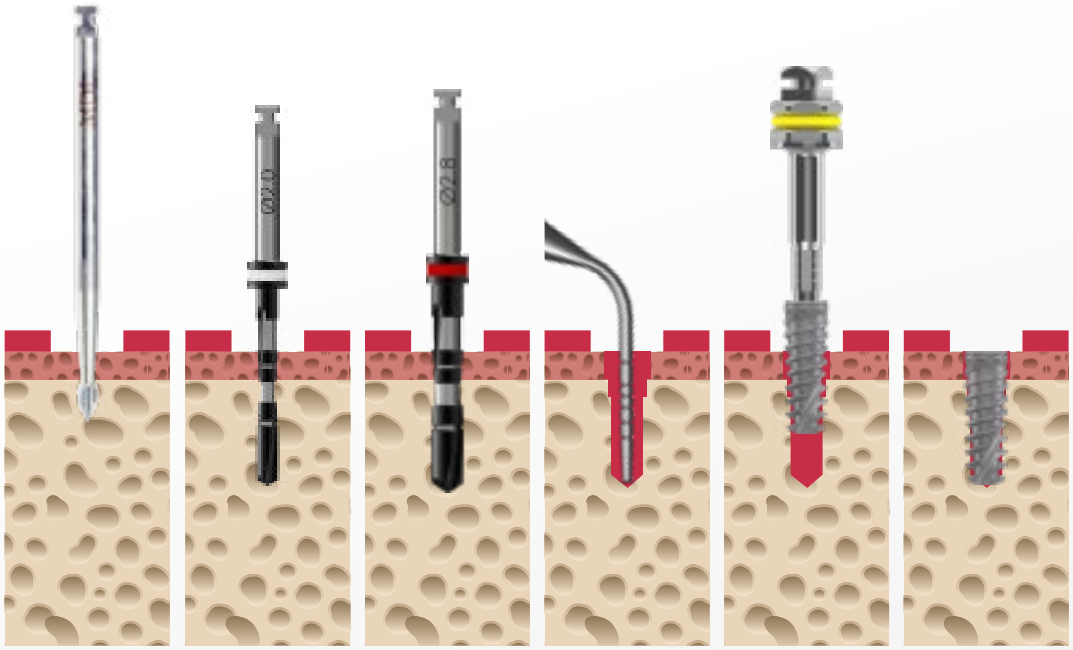
The following diagram represents the possible options for the surgical procedures and the following rehabilitation steps.



Standard Flap Procedure



Flapless Procedure



Drilling Protocol

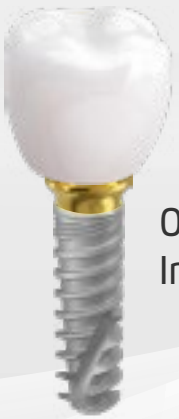
Cover Screw

Two Stage
Delayed Function

Healing Cap

One Stage
Early/Delayed Function

Temporary Prosthetic
Component

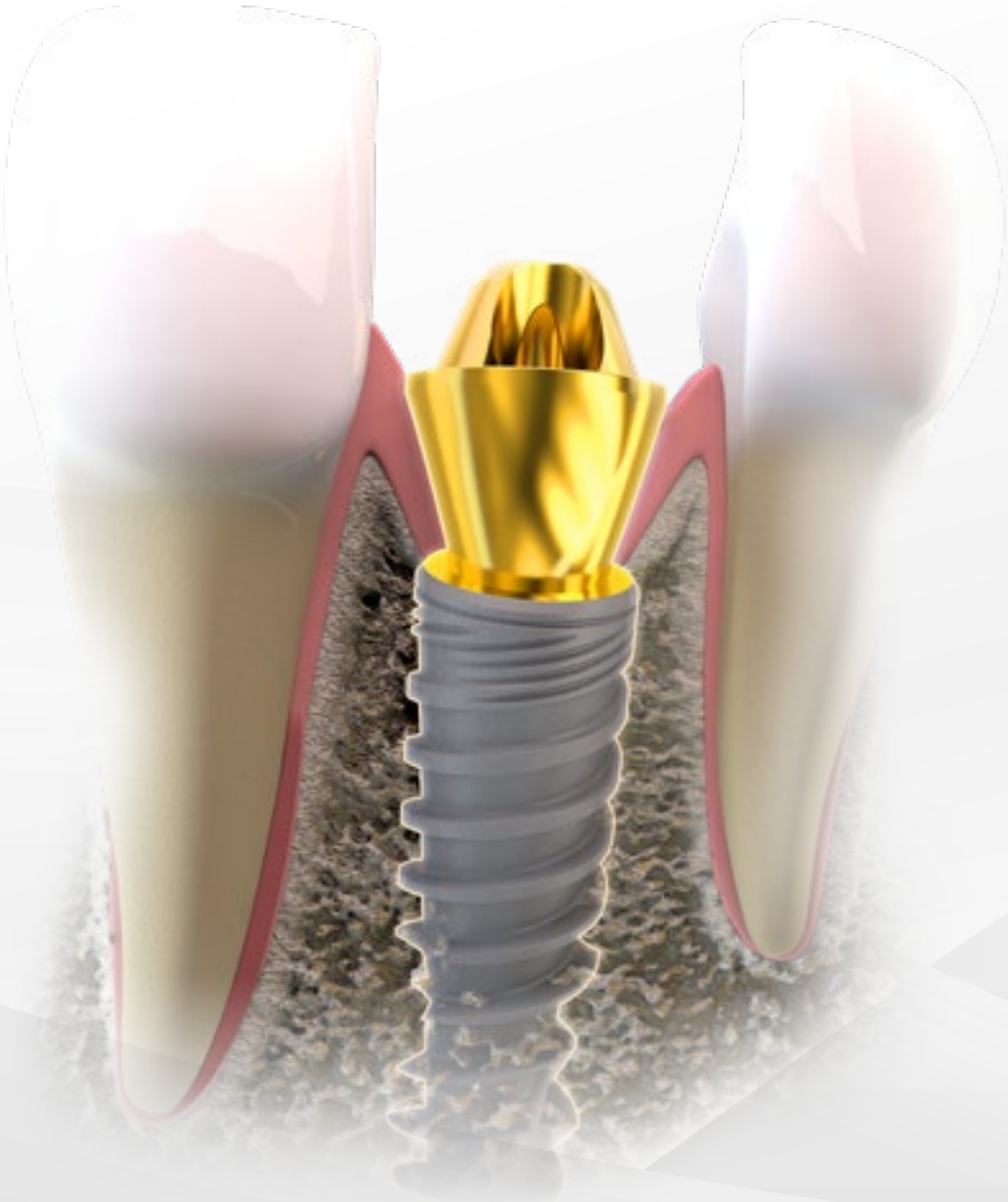


One Stage
Immediate Function

IMPORTANT CONSIDERATION AND CAUTIONS

Implant Placement

- The unique thread design of TUFF Unicon implants makes the implant active. This means that the implant has drilling ability.
- Attention is needed not to exceed the final osteotomy depth and not to change the planned direction while placing the implant.
- The maximum insertion tightening torque for the Tuff implant is 50 Ncm.
- Overtightening of the implant may lead to damage of the implant head, fracture or necrosis of the bone site.
- Overtightening of the abutment screw may lead to screw fracture.



SURGICAL PROCEDURE

Site Preparation

The surgery starts with site preparation with two options to proceed:
Standard flap procedure or flapless procedure.

STANDARD FLAP PROCEDURE

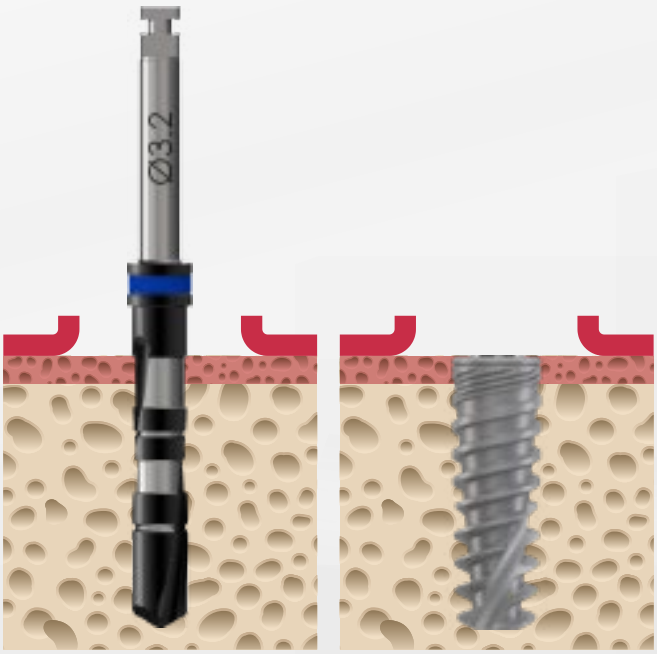
Creation of standard flap and exposure of jawbone.

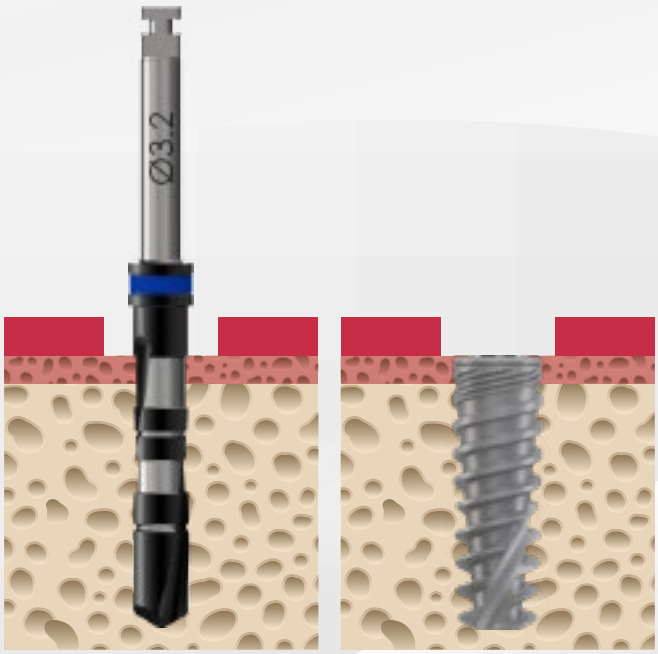
- Use surgical tools to cut and raise a flap according to desired technique per the site anatomy.
- It is recommended to raise a flap in cases that bone augmentation, sinus lift or soft tissue implantation is needed.
- Expose the bone to reveal the exact implant placement location.
- Use the recommended drilling protocol according to the implant dimension and bone type.

FLAPLESS PROCEDURE

Creation of working channel through the gum soft tissue and exposure of jawbone.

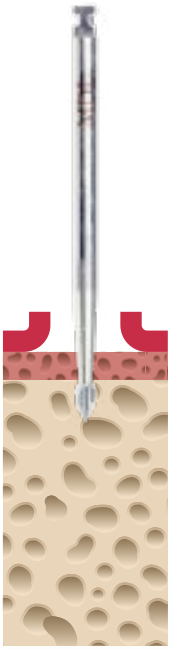
- Use surgical tools to punch/cut cylindrical shape in the gum.
- Remove the gum cylinder and expose the working channel through the gum soft tissue.
- Consider the gum height while drilling the osteotomy in the following step.
- Use the recommended drilling protocol according to the implant dimension and bone type.





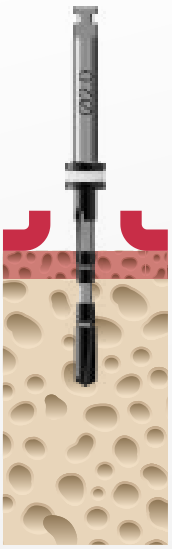
OSTEOTOMY IMPLANT BED PREPARATION - DRILLING SEQUENCE

Standard Flap Procedure



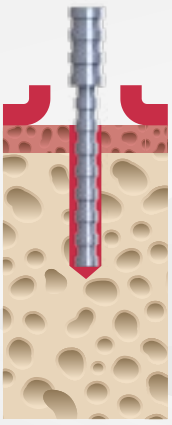
Mark the implant placement site

Use marking drill to drill/penetrate the crestal bone and mark the site.



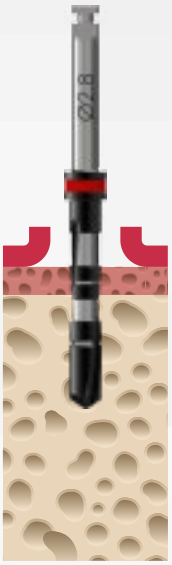
Pilot drill

Use Pilot drill to drill according to the implant length and desired depth.



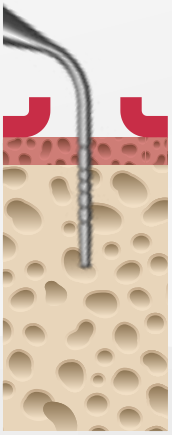
Guiding pin

In case needed, use the guiding pin for direction assessment.



Final osteotomy implant bed preparation

Use increasing drill/drills diameter/s as needed and drill according to implant size (diameter and length), bone type and desired depth. Use the recommended drill protocol.

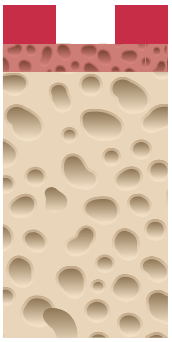


Check the osteotomy created

Using depth probe, probe and verify the desired osteotomy was created. Increase the osteotomy as desired/needed.

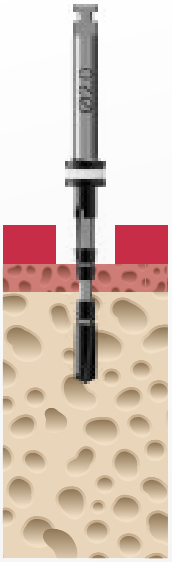
OSTEOTOMY IMPLANT BED PREPARATION - DRILLING SEQUENCE

Flapless procedure



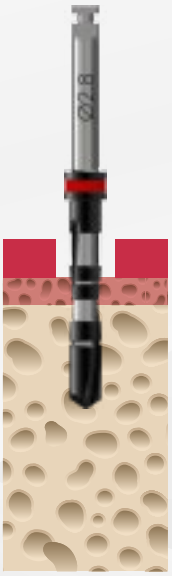
Estimation of gum height

Using depth probe, probe and verify the gum height.



Add gum height to the drilling depth

Consider the gum height while drilling the osteotomy and make sure to add it to in the drilling depth.



Continue according to flap technique drilling sequence while adding gum height as required.

OSTEOTOMY IMPLANT BED PREPARATION - DRILLING SEQUENCE

General recommendation

- To reduce heat buildup in the osteotomy site, maintain constant irrigation throughout the drilling process.
- Stop drilling in case irrigation stops.
- In all bone situations, drill with continuous in and out motion without stopping the handpiece motor. This allows the irrigation to flush away debris.
- Drilling must proceed at the recommended speed between 1500-400 RPM (according to drill diameter) under constant and profuse irrigation by sterile saline.
- In situations where adjacent natural teeth interfere with the contra-angle head and prevent the drill from reaching the desired depth, a drill extension shaft may be used.
- Remember to replace the wear drills to new drills according to the manufacture recommendations. Especially the pilot drill that wears out more often.

Recommended drilling tips based on bone quality

- During drilling procedures, bone quality should be considered in order to prevent excessive pressure on the bone in cases of hard bone, or to achieve the recommended primary stability in cases of soft bone.
- Widen the cortex in case needed.
- You may use the drill to the full depth and in cases of hard bone you may add 1mm (in case the marking lengths on the drills you are using are measured from the tip).
- It is recommended to start with soft bone protocol and in case needed/desired increase the drilling.

RECOMMENDED DRILL PROTOCOL

Straight and Step Drills

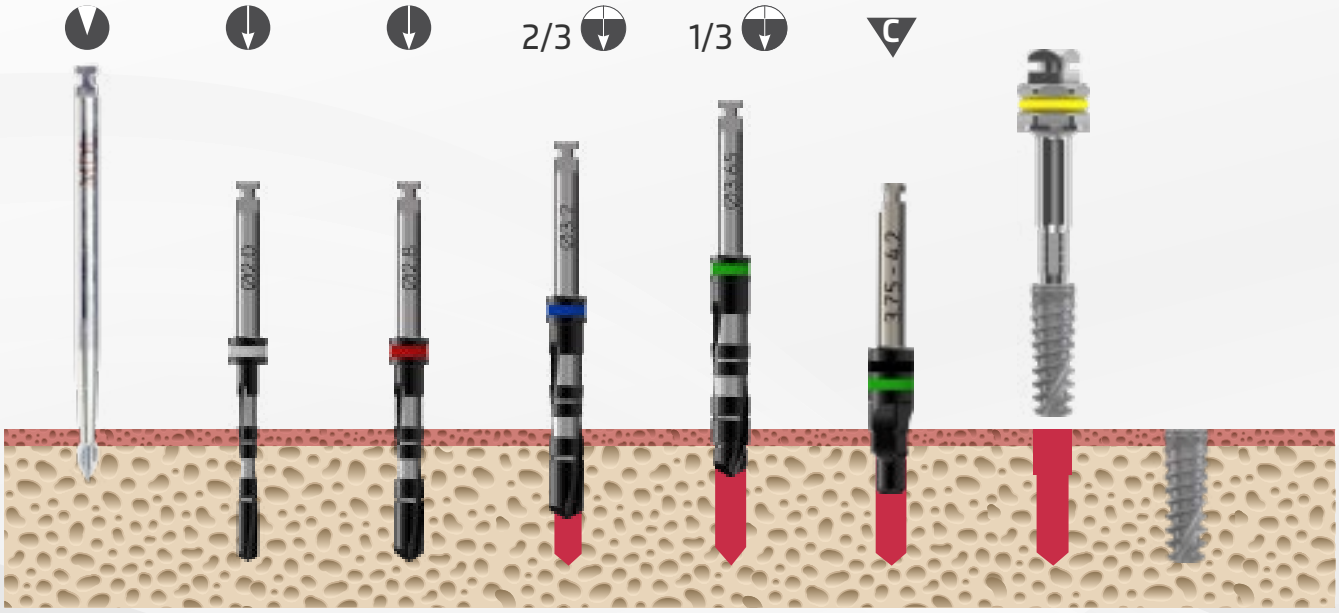
IMPLANT DIAMETER		Drill Diameter [mm]	Ø1.9	Ø1.5	Ø2.0	Ø2.8	Ø3.2	Ø3.65	Ø4.2	Ø5.2	ØCS 5-6
		Drill Speed [RPM]	1200-1500	900-1200	900-1200	800-1000	500-700	400-700	400-600	400-600	400-600
Ø3.25	Soft Bone		●	●	▼						
	Hard Bone		●	●	●	1/3 ⊕					
Ø3.5	Soft Bone		●		●						
	Hard Bone		●		●	2/3 ⊕					
Ø3.75	Soft Bone		●		●		●				
	Hard Bone		●		●		●	2/3 ⊕			
Ø4.2	Soft Bone		●		●		●	2/3 ⊕			
	Hard Bone		●		●		●		1/3 ⊕		
Ø5.0	Soft Bone		●		●		●			1/3 ⊕	
	Hard Bone		●		●		●			1/3 ⊕	Ø5 ▼
Ø5.5	Soft Bone		●		●		●			2/3 ⊕	1/3 ⊕
	Hard Bone		●		●		●			●	1/2 ⊕

●	Drill to mark osteotomy site
⊕	Drill osteotomy to implant
⊕	Drill osteotomy partially according to implant
▼	Drill through crestal bone only

▲ The recommended drill protocol procedure should not replace the dentist's/surgeon's judgment.

▲ The implants may be loaded for immediate function when good primary stability (above 35 Ncm) has been achieved and with appropriate occlusal loading.

DRILLING PROTOCOL LEGEND



●	Drill to mark osteotomy site
⊕	Drill osteotomy to implant
⊕	Drill osteotomy partially according to implant
▼	Drill through crestal bone only or with countersink to prepare the crest

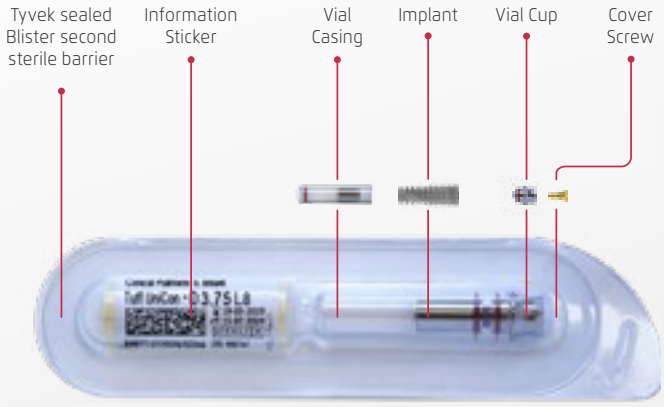
IMPLANT PACKAGE

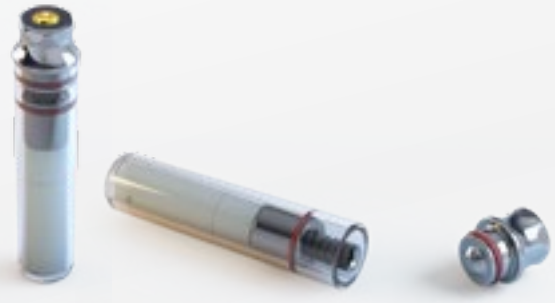
General recommendation

- The Conical Platform Tuff Unicon implant is supplied in a sterile carrier-free package.
- A sterile blister package is enclosed within the outer cardboard box.
- The blister package houses a sealed vial containing the implant, secured with a vial cup.
- Placed in the blister is a comprehensive implant label detailing crucial product information, including the reference number (REF), implant type, description, and dimensions.
- The implant label bears additional information such as the LOT number and other pertinent data to facilitate product identification and manufacturing traceability.
- For optimal record-keeping, it is recommended that the implant label be attached to the patient's medical record within the healthcare provider's clinical documentation system.

Sterile implant PACKAGE

CARRIER FREE IMPLANT PACKAGING





Implant Label

	Caution
	Keep away from sunlight
	Keep dry
-18°C +55°C	Store at temperature -18°C to +55°C
	Do not re-use
	Do not resterilize
	Sterile package unless opened or damaged
	MR conditional
Rx Only	Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner
MD	Medical device
STERILE R	Sterilized using irradiation
	Consult accompanying documents
	Use by date
	Date of Manufacture

IMPLANT INSERTION INSTRUMENTS

- Depending on the clinical situation and accessibility, choose the desired insertion instrument.
- The insertion instruments are connected to the various implant drivers that in turn are connected to the implant internal connection.

Recommended Insertion Instruments (Torque controlled)

Utilize the following instruments for controlled moment torque delivery for implant insertion:

Torque Ratchet Wrench

Use the desired torque shown on torque ratchet wrench.

Contra-Angle Handpiece

Set the desired torque on the physiodispenser (drilling unit) to the controlled torque ratchet wrench.

▲ Make sure to set the physiodispenser to low speed (under 25 RPM).

The recommended torque to insert the Conical Platform implant is up to 50 Ncm.
Warning – Never exceed 70 Ncm!

Additional Insertion Instruments (Torque uncontrolled)

Utilize the following instruments for moment torque delivery for implant insertion:

Manual Screwdriver

In the anterior region it is recommended to use the manual screwdriver to facilitate good control during insertion and angulation changes.

The manual screwdriver should be used while grasped with fingertips only to avoid excessive insertion torque.

Ratchet Wrench

Avoid excessive insertion torque.

IMPLANT INSERTION INSTRUMENTS

Implant Drivers

Utilize the following implant drivers for the torque delivery for implant insertion:

Ratchet Wrench Implant Drivers

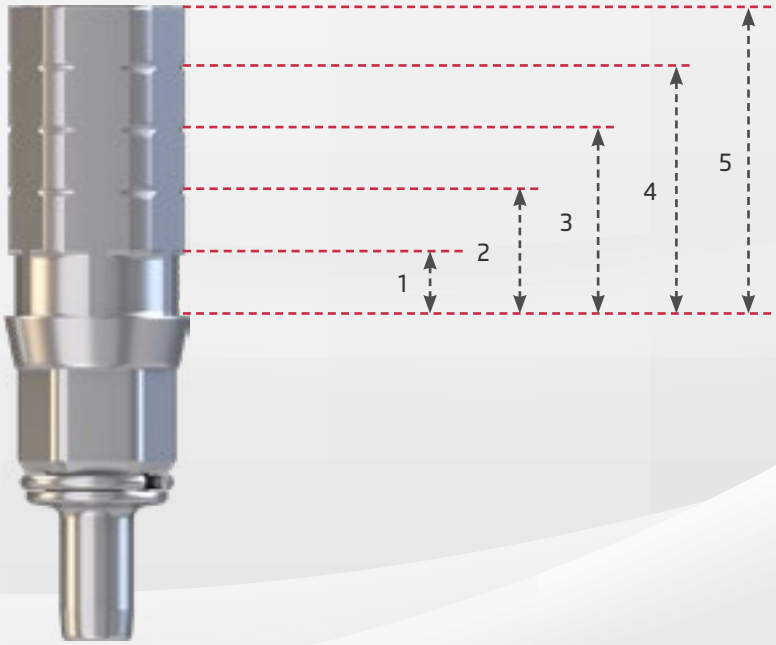
The implant driver is connected to the insertion instrument via it's external hexagon.

▲ Visually verify firm connection to the insertion instrument.

Contra-angle Implant Drivers

Avoid excessive insertion torque.

The implant driver has long external hexagon with flat faces (that are perfectly aligned with the implant internal hexagon) and height markings 1 mm a part up to 5 mm.

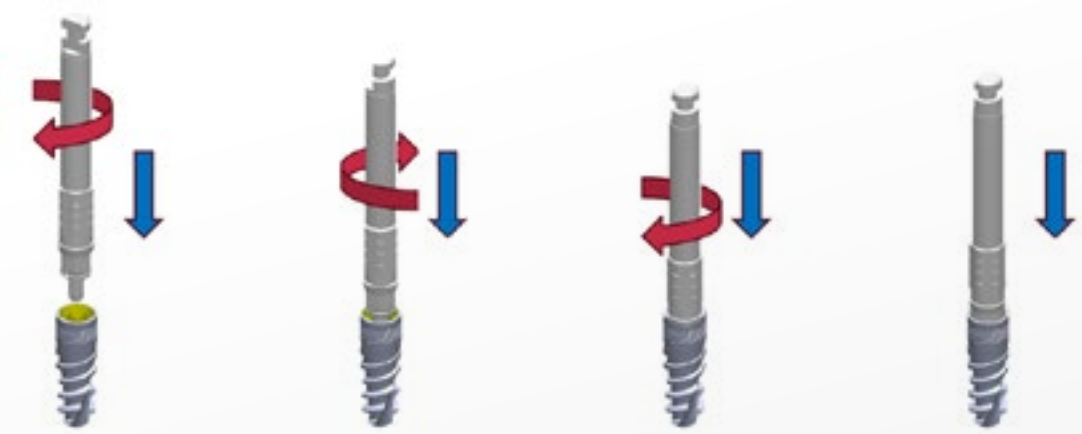


IMPLANT EXTRACTION FROM PACKAGE

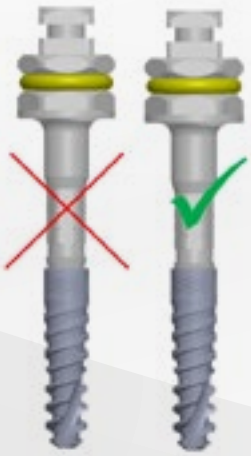
Implant extraction from package:

- Unpack the implant package
- Open the cardboard box.
- Extract the sterile double carrier-free package.
- Peel off the sealed blister lid and drop the vial in a sterile tray.
- Hold the sterile vial and remove the vial cup.
- Implant pickup from sterile vial
- Use the implant driver that connected to the insertion tool.
- Insert the driver hexagon to the implant internal connection while rotating clockwise and apply light pressure on the implant driver until driver is firmly connected to the implant.

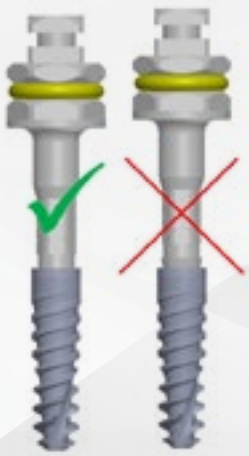
▲ Verify firm connection and that the driver is fully seated.



For
ø3.25
Implant



For
ø3.5, ø3.75, ø4.2, ø5.0, ø5.5
Implants



IMPLANT PLACEMENT

- Carefully – without touching unsterile location - lead the implant to the osteotomy entrance.
- Insert the implant into the osteotomy and engage the implant with the bone.
- Using the insertion instrument apply torque in clockwise direction and insert the implant to engage and thread to the bone.

- Continue to thread gradually and tighten the implant to the final desired position.

  ▲ Warning – Never exceed 70 Ncm!

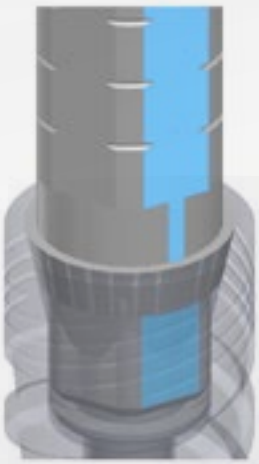
- In case the torque is too high carefully extract the implant. Increase the osteotomy by additional drilling as required.

  ▲ Warning – Avoid excessive compression of the bone and possible deformation of the internal hexagon.

- Continue to thread and tighten the implant to the final desired position.
- The recommended torque to insert the Conical Platform implant is up to 50 Ncm.

  ▲ Warning – Never exceed 70 Ncm!

- It is recommended to align the implant driver long external hexagon flat faces parallel/tangent to the jaw buccal wall.
  Thus, ensuring that the implant internal hexagon is parallel/tangent to the jaw buccal wall as well and therefore ensuring the future prosthetic abutment correct orientation.



- Gently extract the driver from the implant.

FINISH PROCEDURE

The final procedure ends according to the dentist'/surgeon's decision how to finalize the procedure.

There are generally three options:

- Two-stage delayed function
- Early/Delayed function
- One-stage immediate function

Two Stage Delayed Function

The implant is closed with implant cover screw and the gum soft tissue is sutured on top of it.

One Stage Early/Delayed Function

The implant is closed with healing cap and the gum soft tissue is sutured around the healing cap.

One Stage Immediate Function

The prosthetic component utilizing temporary crown, bridge or overdenture is installed on the implant/implants according to the dentist'/surgeon's decision.

▲ The implant should be placed with a final torque of at least 40 Ncm to ensure adequate primary stability.

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