Trefoil[™] Procedure manual





This procedure manual does not replace attending a complete training program

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Contents

Introduction	Surgical quick guide	4
	Prosthetic quick guide	5
Surgical procedure	Implant considerations	6
	Anatomical considerations	8
	Prosthetic considerations	9
Product information	Implant specifications	10
	Surgical components	11
	Drill sequence	15
	Guided components	16
	Drills and screw taps	18
	Implants	20
	Implant insertion	21
	Trefoil Bar – Fixation mechanism	22
Pre-surgical preparation		23
Clinical procedure	Clincal procedure	24
	Preparation of central implant site	26
	Implant insertion	30
	Preparation of distal implant sites	33
	Implant insertion	37
	Verification and indexing	39
	Trefoil Bar	40
	The A-P (Anteroposterior) measurement	41
Prosthetic procedure	Laboratory procedure	42
	Restorative procedure	45
	Laboratory procedure	46
Revision surgery		48
Product information	Trefoil PureSet	52
	Trefoil PureSet components	53
	Surgical components	54
	Prosthetic components	55
Appendices	Cleaning and sterilization	56
	Customer service worldwide	59

Surgical quick guide

1. Preparation of the bony platform.



3. Preparation of the implant positions with the Evaluation Template.



5. Placement of the central implant with the Positioning Template and Template for Implant.



7. Placement of the distal implant with the V-Template and Template for Implant.



9. Fabrication of the verification index with the Transfer Abutments and a Temporary Abutment CC RP.



2. Identification and marking of the implant sites with the Guide Template.



4. Preparation of the central implant site with the Positioning Template and Template for Drill.



6. Preparation of the distal implant site with the V-Template and Template for Drill.



8. Verification of the implant position with the Try-in Bar Trefoil.



10. Fixation of the abutments with acrylic to a verification index.



Introduction

Appendices

Prosthetic quick guide

1. Verification index with the implant replicas to fabricate a master working model.



3. Fixation of the mechanism with acrylic or the laser welding technique.

2. Adjustment of the fixation mechanism using a Manual Torque Wrench Prosthetic.



4. Bite registration and fixation in the articulator.





6. Preparation for investing in a flask followed by acrylic processing.



8. Delivery of the definitive prosthesis.





7. Polishing of definitive prosthesis.

5. Final tooth setup in wax.



Important considerations for implant placement

Description

The Trefoil system is used to restore chewing function in fully edentulous mandibles.

The Trefoil Implants CC RP are a part of the Trefoil system. With the aid of different standardized templates, three implants are placed in a predetermined position (between the mental foramina), corresponding to the pre-designed prosthetic bar that is used. The implants are threaded endosseous implants made of commercially pure grade 4 titanium with a TiUnite surface on the implant body. The implant body diameter is 5.0 mm. The implants are available in lengths of 11.5 mm and 13 mm with either 4.5 mm or 6.0 mm transmucosal collar. The collar has a smooth machined surface without threads.

Indication

The Trefoil system is used to restore chewing function in fully edentulous mandibles.

The three implants of the Trefoil system are placed between the mental foramen in fully edentulous mandibles in a one-stage surgical technique combined with an Immediate Function loading protocol, provided sufficient primary stability for the selected technique is achieved. In cases where sufficient primary stability of one or more implants is not reached, the implants along with the bar may also be used with an early or delayed loading protocol.

The following prerequisites must be fulfilled:

- Adequate quantity of bone (minimum height of 13 mm for 11.5 mm implant and 14.5 mm for 13 mm implant, minimum width of 7 mm).
- Adequate mouth opening (minimum 40 mm) to accommodate the guided surgery instruments.
- Implant-supported prosthesis seated directly on dedicated implants.

Contraindications

- It is contraindicated to use the Trefoil system in:
- patients who are medically unfit for an oral surgical procedure
- patients who have inadequate volume of residual bone for placing three implants to support the anticipated loads to which the patient will subject the implants (augmentation procedures can be considered).
- patients in whom adequate sizes, numbers or desirable positions of implants are not reachable to achieve safe support of functional or eventually parafunctional loads.
- patients who are allergic or hypersensitive to titanium alloy grade 5 - Ti6Al4V (titanium, vanadium, aluminum) or Diamond Like Carbon coating (DLC).
- cases of single-unit, fixed partial dentures and any types of removable restorations.
- cases of partially edentulous mandible at time of implant insertion.





- cases of maxillary treatments.

- patients with high expected loading conditions on the framework, e.g. severe bruxism.

Warning: All implants supporting the Trefoil Bar must have the same tissue collar height of either 4.5 mm or 6.0 mm. Mixing different collar heights will affect drill depth, implant height position and primary stability.

Failure to recognize actual lengths of drills relative to radiographic measurements can result in permanent injury to nerves or other vital structures. Drilling beyond the depth intended for lower jaw surgery may potentially result in permanent numbness to the lower lip and chin or lead to a hemorrhage in the floor of the mouth.

Besides the mandatory precautions for any surgery such as asepsis, during drilling in the jaw bone, one must avoid damage to nerves and vessels by referring to anatomical knowledge and preoperative radiographs.

A passive and precise fit of the Trefoil Bar is essential to the success of the implants. A forced fit can result in stress concentration on one or more implants potentially leading to implant failure, problematic screw loosening or bone loss.

Use of a non-sterile device may lead to infection of tissues or infectionous diseases.

Appropriate skeletal anatomy

In any full-arch implant rehabilitation, the patient's skeletal jaw relationship can influence the final occlusion and may affect the goal of achieving an optimal class I occlusion. Preoperative assessment of the skeletal relationship is important to address biomechanical and prosthetic limitations of more severe class II and class III conditions. In certain situations, a custom framework or combined orthognathic surgery may rather be indicated.

Imaging study to confirm bony morphology

Optimally, pre-surgical imaging studies should include 3D cone beam axial, cross-sectional, and panoramic views of the mandible. The mandibular anatomy should accommodate implants of 5.0 mm diameters and 11.5-13.0 mm lengths in the inter-foraminal region. A bucco-lingual width of 7.0 mm in the proposed area of surgery is required. Virtual implant placement may assist in this assessment. An axial view 2-3 mm above the level of the mental foramina will allow evaluation if the shape of the anterior mandible conforms to the "U"-shape requirements of the Trefoil system. Overlaying of a radiographic template or the surgical Guide Template can facilitate this assessment. Cross-sectional views provide an estimate of the extent of vertical bone reduction required to achieve the 7.0 mm bucco-lingual width.



Class I







Class III





Anatomical considerations

Important prerequisites:

- A Minimum distance 13 mm.
- B Sufficient distance from mental foramen.
- C Minimum bony platform width of 7 mm.

Adequate mouth opening of minimum 40 mm is required to accommodate the guided surgery.

Caution: It is important to identify the mental foramen and existing inferior dental nerve. The final position of the implants should be a sufficient distance from the mental foramen, avoiding the nerve loop.

Extended alveolar crest adjustment: Crest adjustment needs to be prepared with a bone bur distally to the first molar region on both sides to have sufficient space for the Trefoil Bar and the acrylic.

For a correct positioning of the Trefoil Bar and an esthetic outcome, the following factors are important:

Bony platform (c)

- The bony platform (c) should be level and parallel to the maxillary occlusal plane (a).
- The preparation should extend to the first molar region.
- Assess the adequacy of the vertical bone reduction guide, anatomic references, or measurements of the preoperative vertical dimension.

Trefoil Bar (b)

 The position of the Trefoil Bar is dependent on the implant position (d). The Trefoil Bar needs to be positioned parallel to the maxillary occlusal plane (a).







Prosthetic considerations

Appendices

Total vertical height minimum 22 mm Bar thickness 5.5 mm

Occlusion Guide Trefoil

Consider a total height of 22 mm for the Trefoil prosthesis when the 4.5 mm collar is used and 23.5 mm when a 6 mm collar implant is used.

The Occlusion Guide Trefoil can only be used in combination with the 4.5 mm collar implant.

After using the 2.0 mm Twist Drill in combination with the Evaluation Template to create the first osteotomy, check that there is sufficient space for the definitive prosthesis. Create a platform on the palatal part of the maxillary incisors to have a central stop for the Occlusion Guide Trefoil. Next, use the Occlusion Guide Trefoil to verify the minimum vertical distance between the levelled bone and the maxillary occlusal plane.

Warning: When using the Occlusion Guide Trefoil in the first osteotomy, make sure that the shank is fully seated in the osteotomy and that the base of the head rests on the bony platform. Wrong positioning may lead to misinterpretation of the vertical dimension of occlusion.

Note: The total height of the Trefoil Bar including implant collar of 4.5 mm is 14.1 mm and 15.6 mm including the 6.0 mm collar. The dimension needs to be taken into account when evaluating the vertical occlusion of dimension.

Warning: Do not use the Occlusion Guide as a depth indicator. The holding pattern along the main body does not represent a depth indication or marker.





Implant specifications

Trefoil Implant CC RP (Tissue collar)

Implant diameter: Implant lengths: Collar heights: Implant connection: 5.0 mm 11.5 and 13.0 mm 4.5 and 6.0 mm RP conical connection







Diameters / lengths: Collar heights:

Ρ

5.0 x 11.5 mm 5.0 x 13 mm 4.5 mm 4.5 mm

5.0 x 11.5 mm 5. 6.0 mm 6.

nm 5.0 x 13 mm 6.0 mm

		Α	В	С	D	E	F	G	н	I
latform		Collar height	Major diameter	Minor diameter	Thread pitch	Threaded length	Overall length	Tip diameter	Abutment interface	Collar diameter
RP 5.0	5.0 x 11.5 + 6 mm	6.0	4.9	4.1	0.8	11.5	17.5	3.8	3.4	4.5
	5.0 x 13 + 6 mm	6.0	4.9	4.1	0.8	13.0	19.0	3.8	3.4	4.5
	5.0 x 11.5 + 4.5 mm	4.5	4.9	4.1	0.8	11.5	16.0	3.8	3.4	4.5
	5.0 x 13 + 4.5 mm	4.5	4.9	4.1	0.8	13.0	17.5	3.8	3.4	4.5

All measurements in mm. Sectional measurements do not necessarily add up to total length





Surgical components

Guide Template

The Guide Template has three small holes that are used when marking the starting points for the three implants with the Guide Drill.

Evaluation Template

The Evaluation Template is used to evaluate the correct direction, angulation and parallelism of the osteotomy when drilling the Ø 2 mm preparation with the Twist Drill.

Positioning Template

The Positioning Template is used with a Template for Drill and Template for Implant for the exact positioning and installation of the central implant.

V-Template

The V-Template is used with a Template for Drill and Template for Implant for the exact positioning and installation of the two distal implants.

The V-Template is stabilized with one Temporary Screw Implant and two Stabilizing Screws for V-Template into the bone.









Guide Pin

The Guide Pin is used after the \emptyset 2 mm Twist Drill preparation. It is used to stabilize the Evaluation Templates, the Positioning Template and the V-Template.

Temporary Screw Implant

The Temporary Screw Implant is used for the temporary connection of the V-Template to the central implant.

The screw has a hexagonal connection that fits the adapter for the Torque Wrench Surgical and the Connection to Handpiece.

Stabilizing Screw for V-Template

The Stabilizing Screw for V-Template is used for the temporary connection of the V-Template to the alveolar ridge with two screws.

The screw has a hexagonal connection that fits the adapter for the Torque Wrench Surgical and the Connection to Handpiece.





Implant Mount

The Implant Mount Ø 5 mm needs to be attached to the Trefoil Implant CC RP for implant insertion using the UniGrip Screwdriver.

Connection to Handpiece

The Connection to Handpiece is used to pick up the mounted implant with the Implant Mount and used for the Temporary Screw Implant and Stabilizing Screw for V-Template.

Combined Open-end Wrench

Combined Open-end Wrench is used with the Implant Mount to unscrew the mount with the UniGrip Screwdriver.



Occlusion Guide Trefoil

After bone levelling, the Occlusion Guide Trefoil is used to verify the minimum vertical distance between the levelled bone and the maxillary occlusal plane to ensure there is sufficient space for the definitive prosthesis.



Try-in Bar Trefoil

The Try-in Bar Trefoil is screwed to the implants during surgery after implant placement allowing verification if the three implants are aligned and placed within the compensation range to seat the final pre-manufactured bar/prosthesis to the implants.

It also allows verification of the correct position of the bar in relation to the mandible and opposing dentition. The components cannot be disassembled from the bar.

Trefoil Bar

The Trefoil Bar is a titanium alloy milled framework, screwretained to three endosseous dental implants. The pre-manufactured, definitive bar contains a fixation mechanism with adaptive joints that adjust to compensate for horizontal, vertical and angular deviations from the planned implant placement.

Transfer Abutment

The Transfer Abutments are used intraorally to fabricate a verification index. They are shaped with a horizontal arm (top and bottom) to connect the two transfer abutments to the central non-engaging temporary abutment to record the position of the implants in relation to each other using a cold or light curing resin.

Depth Gauge

The Depth Gauge Ø 2/4.2 mm is a two-sided instrument that measures drill depths after Ø 2 mm or Ø 4.2 mm respectively. The depths are measured in relation to the upper surface of the Template for Drill.

The instrument has three depth marks corresponding to the implant to be placed in lengths and collar height.

Y-Template

The Y-Template accommodates the replacement of the central implant if the implant is lost or has to be removed. The Y-Template Trefoil is temporarily connected to the distal implants. The device is used with the Template for Drill and Template for Implant for the exact positioning and installation of the central implant.











Drill sequence

Drill protocols according to bone quality

Bone quality should be considered during the drilling procedure. Recommended drill sequences are based on bone quality to ensure optimal primary stability when applying Immediate Function.

Drill sequence

Accurate drilling with standardized drill templates enables precise implant positioning and placement for passive fit of the prosthesis.

Drills

The drills are used together with the corresponding Template for Drills for the preparation of the implant sites. Correct drill depth is achieved when the upper flange or depth mark of the drill is aligned with the upper surface of the template. Drills are marked with corresponding diameters and lengths.

Trefoil CC RP 5.0 mm drill sequences

Platform	Implant Ø	Soft bone (Type IV)	Medium bone (Type II & III)	Dense bone (Type I)
RP	5 mm	2.0 mm	2.0 mm	2.0 mm
		3.0 mm	3.0 mm	3.0 mm
			3.8 mm	3.8 mm
				4.2 mm
				4.4 mm
				[Screw Tap 5.0 mm]

Recommended drill sequences based on bone quality. Drill data are stated in mm and the drill diameters lined within [brackets] denoted as optional.

Drilling must proceed at high speed (maximum 2000 rpm for drills) under constant and profuse irrigation by sterile saline at room temperature. In dense bone situation drill with continuous back and forth motion.

If a screw tap is used place the screw tap into prepared implant site using low speed 25 rpm/min. and tap to appropriate depth. Switch the drill device with handpiece to reverse mode and remove the screw tap.

Introduction

Guided components

Template for Drill and Template for Implant

The Templates for Drill (2.0, 3.0, 3.8, 4.2 and 4.4 mm) are used with the Positioning Template and the V-Template for drilling.

The Template for Implant (5.0 mm) is used for tapping and implant insertion with the Positioning Template and the V-Template.

Corresponding drills, screw taps and the implant mount are used to achieve optimized preparation and implant placement in direction, angulation and depth.

Twist Drills



Templates for Drill





mm:



5.0

Template for Implant





Appendices

Guide Template, Evaluation Template, Positioning Template, V-Template, Y-Template, Template for Drill, Template for Implant, Implant Mount, Temporary Screw Implant, Stabilizing Screw for V-Template, Depth Gauge, Occlusion Guide and Try-in Bar are made of stainless steel.

Try-in Bar Trefoil, Occlusion Guide Trefoil Implant Mount Screw are made of titanium alloy grade 5.

Note: When using the Twist Drills, use copious irrigation and an "in-and-out" drilling motion with emphasis on bringing the tip of the drill out of the template when preparing the site to avoid overheating.

Drills and screw taps

The Twist Drills Trefoil and the Screw Tap Trefoil are made of stainless steel with a diamond-like carbon (DLC) coating, which gives them their black color and shall be used only in conjunction with the Trefoil Implants and the templates. They are used with external irrigation.

Caution: The drills and the screw tap are for single use only and must not be reprocessed. Reprocessing could cause loss of mechanical, chemical and/or biological characteristics. Reuse could cause cross contamination.

Caution: Twist drills extend up to 1 mm from the implant when seated. Allow for this additional length when drilling near vital anatomical structures.

Drilling must proceed at high speed (maximum 2000 rpm for drills) under constant and profuse irrigation by sterile saline at room temperature. In a dense bone situation, drill with continuous back and forth motion.

Start drilling with the Positioning Template or the V-Template with the Template for Drill in place.

Start tapping with the Positioning Template or the V-Template with the Template for Implant in place.

If a screw tap is used, a low speed of 25 rpm/min. is recommended.

Twist Drill and Screw Tap depth mark rational with the Evaluation Template and the Positioning Template Placement of the central implant with the Positioning Template and Template for Drill



- Depending on preferred implant length, drill to the first depth mark for a 11.5 mm implant or to the second line for a 13 mm implant.
- The drill depth is achieved when the depth mark is flush with the Template for Drill.
- The depth gauge has the same depth mark rational as the drills and the screw tap.



Pre-surgical preparation

Clinical procedure

Prosthetic procedure

Revision surgery

Twist Drill and Screw Tap depth mark rational with the V-Template

Placement of the two distal implants with the V-Template and Template for Drill



- Depending on preferred implant length and collar height one of the three depth marks has to be used.
- The drill depth is achieved when the depth mark is flush with the Template for Drill.
- The depth gauge has the same depth mark rational as the drills and screw taps.

Implants

Trefoil Implants CC RP

The implants are threaded endosseous implants made of commercially pure grade 4 (CP4) titanium with a TiUnite surface (porous titanium oxide surface) on the implant body.

For Immediate Function, the implant should be able to withstand a final torque between 35-45 Ncm.

Caution: Stop implant insertion when the Implant Mount is in light contact with the Template for Implant for placement of 4.5 mm tissue collar implants.

Caution: Never exceed insertion torque of 45 Ncm for the Trefoil implants. Overtightening the implant may lead to damage of the implant, fracture or necrosis of the bone site. If a Manual Torque Wrench Surgical is used to insert the implant, special care needs to be taken to avoid overtightening.

If the implant gets stuck during implant installation or 45 Ncm of insertion torque is achieved before fully seated, rotate the implant counter clockwise using Drilling Device (reverse mode) or Manual Torque Wrench Surgical and remove the implant from the site. Replace the implant back into inner casing before proceeding further. Reference Table 1 to consider medium or dense bone protocol before proceeding with implant insertion.

Caution: Final installation torque can only be measured after the Implant Mount and the Guide Template for Implant has been removed.

Caution: In case one or more of the three implants do not reach an insertion torque of minimum 35 Ncm, the implants cannot be immediately loaded. A two-stage delayed function is recommended.

Caution: Please note that the minimum primary stability of 35 Ncm might not always be achieved in soft bone (Type IV).

Warning: All implants supporting the Trefoil Bar must have the same tissue collar height of either 4.5 mm or 6.0 mm. Mixing different collar heights will affect drill depth, implant height position and primary stability.

Implant insertion



Implant insertion with the Positioning Template and the Template for Implant

- For placement of implant with collar height 4.5 mm, insert implant until Implant Mount is in light contact with the Template for Drill.
- For placement of implant with collar height 6.0 mm, insert implant until depth mark is flush with Template for Drill.

- For placement of implant with collar height 4.5 mm and 6.0 mm, insert implant until Implant Mount is in light contact

with the Template for Drill.

Implant insertion with the V-Template and the Template for Implant



Implant collar height 4.5 and 6.0 mm

Trefoil™ Bar – Fixation mechanism

The Trefoil system allows compensation for inherent deviations from the ideal implant position.

The pre-manufactured bar, anatomically designed for the natural arch of the mandible, contains adaptive joints that adjust to horizontal, vertical and angular deviations from the planned implant placement. This mechanism is specifically designed to work on only three implants and enables the definitive prosthesis to be passively seated.





Angular deviation ±4.0°

Horizontal deviation ±0.4 mm

Vertical deviation ±0.5 mm

Pre-surgical preparation

Product overview

Appendices

Jaw relation records

The opposing maxillary arch (dentition, denture, or implant prosthesis) should exhibit a proper occlusal plane while satisfying esthetics, speech, and restorative needs. Optimal stability of a removable prosthesis is recommended. Jaw relation records are obtained by establishing the proper vertical dimension and a centric bite registration. A face bow may

be considered to transfer jaw relationship to an articulator.

Vertical dimension occlusion (VDO)



Jaw relation records (alternatively a face bow)

Transfer of occlusal relationship to articulator

After the transfer of the occlusal relationship to the articulator, an approximate preparation of the bony platform needs to be prepared followed by the mandible tooth setup in wax.

Keep the mandible tooth setup in relation to the maxilla using a silicone index. This will allow the transfer of the tooth setup to the working model with the Trefoil Bar later in the workflow (page 46, Laboratory procedure step 6).



Approximate preparation of bony platform (see dotted line)



Mandible tooth setup

Note: The mandible tooth setup depends on opposing dentition (denture, natural dentition) and needs to be designed as a typical implant-supported construction with occlusion from first molar to first molar.



Centric relation records (CR)

Silicone index to register the occlusal relationship of the maxillary to the lower jaw

Clinical procedure

The following illustrations show the drill sequences for Trefoil Implant CC RP 5.0 x 13 + 4.5 mm in medium and dense bone.

1 Preparation of the bony platform

- Make a crestal incision followed by a disto-buccal releasing incisions in the second molar regions.
- Elevate the flap and identify mental foramina.
- Prepare the bony platform with a bone bur under profuse irrigation until the alveolar crest platform has a minimum width of 7 mm and a minimum ridge height of 13 mm.
- The preparation should extend to the first molar region.



2 Identification and marking of the implant sites

- Identify and mark the implant sites with the Guide Template and the Guide Drill.



Drill speed: Maximum 2000 rpm.

Caution: It is important to identify the mental foramen and existing inferior dental nerve.

The final position of the implants should be in front of the foramen, avoiding the nerve loop.

For more information regarding the anatomical considerations, please refer to page 8.

Product overview

3 Verification of bone reduction and implant position – **Mandible:** Position the Evaluation Template over guide drill

- markings created with the Guide Template Over guide and implant position with the 2.0 mm Twist Drill and the Evaluation Template to position the Occlusion Guide Trefoil.
- Maxilla: Create an occlusal plane lingually of the maxillary incisors (blue line) to have a central stop (platform) for the Occlusion Guide Trefoil.

Note:

When using the Twist Drills, use copious irrigation and an "inand-out" drilling motion with emphasis on bringing the tip of the drill out of the template when preparing the site to avoid overheating.





The Occlusion Guide Trefoil allows the verification of:

- The minimum vertical height of 22 mm for the definitive prosthesis.
- Bone reduction in relation to the maxillary occlusal space.
- The correct position and angulation of the central implant, which is to be placed first.

Warning: Do not use the Occlusion Guide as a depth indicator. The holding pattern along the main body does not represent a depth indication or marker.

Warning: Wrong positioning may lead to misinterpretation of the vertical dimension of occlusion.

Caution: Do not apply any force to the Occlusion Guide Trefoil when seated in the osteotomy. The Occlusion Guide Trefoil is used to check the vertical dimension of occlusion. A bite force or pressure applied to the device may lead to incorrect positioning or damage the upper teeth with which the Occlusion Guide Trefoil makes contact. **Caution:** When using the Occlusion Guide Trefoil in the first osteotomy, make sure that the shank is fully seated in the osteotomy and that the base of the head rests on the bony platform.

Caution: When using the 6 mm collar implant, the Occlusion Guide Trefoil does not represent the total prosthetic height. When using an implant with a 6.0 mm collar the vertical height is increasing by 1.5 mm compared to an implant with a 4.5 mm collar.

For more information regarding the prerequisites, please refer to page 9.

Preparation of central implant site

4 Drilling of central and distal implant positions

- Drill the central implant position through the Evaluation Template with the 2.0 mm Twist Drill to appropriate depth.

Warning: Ensure the Evaluation Template is kept stable and in the correct position by avoiding movements of the lever arm. Movement may lead to incorrect osteotomy direction during preparation.

- Fixate the template with Guide Pins.
- Drill the distal implant positions through the Evaluation
- Template with the 2.0 mm Twist Drill to appropriate depth. - Remove all Guide Pins

Note: Verify a smooth insertion of the Guide Pins in the distal



Drill speed: Maximum 2000 rpm.

Note: When using the Twist Drills, use copious irrigation and an "in-and-out" drilling motion with emphasis on bringing the tip of the drill out of the template when preparing the site to avoid overheating.

For more information regarding the drill depth rational, please refer to page 18.

5 Fixation of Positioning Template

The Positioning Template is used to place the central implant only.

 Place the Guide Pins into the two distal osteotomies for stabilization of the template.



6 Preparation of central implant site with the Positioning Template

- Prepare the central implant site through the Template for Drill and the Positioning Template according to the drill protocol to appropriate depth.
- The drill sequence is dependent on the bone density and implant diameter.
- Drill with an "in-and-out" motion under profuse irrigation.
- The drill depth is achieved when the depth mark is flush with the Template for Drill.

Warning: Ensure the Positioning Template is kept stable and in the correct position by avoiding movement of the lever arm. The "feet" on the bottom of either side of the Positioning Template Trefoil need to be in contact with the bony platform. Movement may lead to incorrect osteotomy direction during preparation.





Dense bone type I drill sequence2.0 mm3.0 mm3.8 mm4.2 mm4.4 mmDepth Gauge

Medium bone type II and III drill sequence

2.0 mm 3.0 mm 3.8 mm Depth Gauge

The drill depth is achieved when the depth mark is flush with the Template for Drill.

Drill speed: Maximum 2000 rpm.

Note: When using the Twist Drills, use copious irrigation and an "in-and-out" drilling motion with emphasis on bringing the tip of the drill out of the template when preparing the site to avoid overheating.

For more information regarding the drill sequence, please refer to pages 15-18.

Product overview

Appendices

7 Tapping of central implant site with the Positioning Template

- Place the Screw Tap Trefoil through the Template for Implant (\emptyset 5.0) and the Positioning Template to tap the prepared implant site. The depth is achieved when the depth mark is flush with the Template for Implant.
- Switch the drill unit to reverse mode and back the screw tap out.



Dense bone type I drill sequence

Screw Tap Trefoil 5.0 mm (optional)

Medium bone type II and III drill sequence

Screw Tap Trefoil 5.0 not required

The depth is achieved when the depth mark is flush with the Template for Implant.

Tapping: Low speed 25 rpm.

For more information regarding the drill protocol, please refer to page 18.

Implant insertion

8 Unpack implant

Each implant is packaged in a double sterile vial system. The outer package has a printed label with product data including diameter and length. The cap is color-coded to identify the implant diameter. The inner casing is also marked with implant diameter and length.

- Pull the red tab to disengage the plastic shrink-wrap film and unscrew the color-coded lid.
- Take out the sterile inner casing and lift off the plastic cap to gain access to the implant.
- Record the implant size and LOT number on the patient's chart with the two peel-off labels from the outer vial.

Note: A cover screw is not included with the implant.

9 Choose insertion instrument

Depending on the clinical situation and accessibility, there are two different options to insert the implant:

- A. With a drilling unit device and contra-angle
- B. With a Manual Torque Wrench Surgical

Caution: Never exceed insertion torque of 45 Ncm for implants used with the Trefoil system. Overtightening the implant may lead to damage of the implant, fracture or necrosis of the bone site. If a Manual Torque Wrench Surgical is used to insert the implant, special care needs to be taken to avoid overtightening. Final installation torque must be measured after the Implant Mount and the Template for Implant has been removed.

10 Pick up implant

- Connect the Implant Mount Ø 5.0 mm to the implant by using a UniGrip Screwdriver and the Combined Open-end Wrench.
- Check thoroughly that the implant mount is correctly seated over the implant before tightening the mount screw firmly.
- Pick up the implant from the inner casing using the Connection to Handpiece.





Appendices

11 Placement of the central implant with the Positioning Template

Place the implant through the Template for Implant (\emptyset 5.0) and the Positioning Template. Insert the implant until the built-in stop of the Implant Mount is in contact with the Template.

 Ensure that the Implant Mount is only in light contact with the Template for Implant.

Caution: Avoid further tightening of the implant as it might affect the correct position of the Evaluation Template.

Implant insertion: Low speed 25 rpm. Maximum torque 45 Ncm.

Note: If the Implant Mount is difficult to remove, gently pull it free with small back and forth motions using the Combined Open-end Wrench or forceps.

For more information regarding the implant insertion, please refer to page 21.





For placement of implant with collar height 4.5 mm, insert implant until Implant Mount is in light contact with the Template for Drill.

Note: Excessive torque while inserting the implant must be avoided. It can cause deformation of the implant or connection and may result in excessive compression of the bone. If strong resistance (maximum 45 Ncm) is encountered at any point during insertion, remove the implant and place it back into the inner casing (please refer to step 10). Widen the implant site according to the drill protocol or use a screw tap matching the diameter of the implant.

Caution: Never exceed insertion torque of 45 Ncm for the Trefoil implants.



Overtightening the implant may lead to damage of the implant, fracture or necrosis of the bone site. If a Manual Torque Wrench Surgical is used to insert the implant, special care needs to be taken to avoid overtightening.

If the implant gets stuck during implant installation or 45 Ncm of insertion torque is achieved before fully seated, rotate the implant counter clockwise using Drilling Device (reverse mode) or Manual Torque Wrench Surgical and remove implant from site. Replace the implant back into inner casing before proceeding further. Reference Table 1 to consider medium or dense bone protocol before proceeding with implant insertion

12 Removal of Implant Mount and Template for Implant

 Unscrew the Implant Mount using the UniGrip Screwdriver and the Combined Open-end Wrench to prevent the implant from rotating when unscrewing the mount (please refer to step 20).

Note: If the Implant Mount is difficult to remove, gently pull it free with small back and forth motions using the Combined Open-end Wrench or forceps.

- Remove the Template for Implant.

13 Verification of insertion torque

Note: Verification of the insertion torque with the Template for Implant in place might affect the real torque value. Remove the Implant Mount and the Template for Implant and using the Implant Driver CC RP for final verification together with the Manual Torque Wrench Surgical or the drilling unit device and contra-angle.

 Verify the insertion torque with Manual Torque Wrench Surgical and Implant Driver CC RP.

Note: For Immediate Function, the implant should withstand a final insertion torque of at least 35 Ncm. Do not exceed 45 Ncm.

In cases where sufficient primary stability of one or more implants is not reached, the implants along with the bar may also be used with an early or delayed loading protocol.

14 Removal of Positioning Template

- Remove the two Guide Pins and the Positioning Template.



Preparation of distal implant sites

Product overview

Pre-surgical preparation

Introduction

15 Fixation of V-Template

The V-Template is used to place the two distal implants. It has a 'top side' and a 'bottom side'. The bottom side must be seated to the central implant.

Placement of the Temporary Screw Implant

- Fix the V-Template to the central implant with the Temporary Screw Implant and the Connection to Handpiece.
- Ensure that the Temporary Screw Implant is only in light contact with the V-Template.

Caution: Verify that there is no bone contact with the V-Template in the distal areas. Bone contact may lead to improper seating/positioning of the V-Template.



Top side (flat surface)

Bottom side (to be seated to the central implant)





Temporary Screw Implant: Low speed 25 rpm using the Connection to Handpiece or the Manual Torque Wrench Surgical to maximum 15 Ncm.

Caution: Do not exceed 15 Ncm to avoid rotation of the V-Template, and to be able to remove the screw from the implant after implant placement.

Placement of the Stabilizing Screw V-Template

- Place the Template for Drill to the V-Template and engage the two Guide Pins in the distal positions of the 2.0 mm osteotomy for the correct alignment of the V-Template.







 Fix the V-Template with stabilizing screws into the bone by drilling through the V-Template (hole with the inner thread) with a 2.0 mm Twist Drill.





Drilling speed with 2.0 mm Twist Drill: Maximum 2000 rpm.

 Thumb thread the stabilizing screws through the inner threaded holes of the template.



 Continue with the Connection to Handpiece or the Manual Torque Wrench.

Caution: ensure that the stabilizing screws are only in light contact with the V-Template.



Placement of the Stabilizing Screw for V-Template: Low speed 25 rpm using the Connection to Handpiece or the Manual Torque Wrench Surgical.





Product overview

V-Template – Remove the Guide Pins – Prepare the distal sites through the Template for Drill and

 Prepare the distal sites through the Template for Drill and the V-Template according to the drill protocol to appropriate depth with regards to the implant length and collar height (please see Twist Drill depth mark rational for the V-Template below).

16 Preparation of the two distal implant sites with the

- The drill sequence is dependent on the bone density and implant diameter.
- The drill depth is achieved when the depth mark is flush with the Template for Drill.
- Drill with an in-and-out motion under profuse irrigation.





Dense bone type I drill sequence2.0 mm3.0 mm3.0 mm3.8 mm4.2 mm4.4 mmDepth Gauge



Warning: Implants must have the same collar height as the central implant. Mixing different collar heights will affect drill depth, implant position and primary stability.

- The drill depth is achieved when the depth mark is flush with the Template for Drill.

Warning: All implants supporting the Trefoil Bar must have the same tissue collar height of either 4.5 mm or 6.0 mm. Mixing different collar heights will affect drill depth, implant height position and primary stability.

Drill speed: Maximum 2000 rpm

Depth Gauge

Note: When using the Twist Drills, use copious irrigation and an "in-and-out" drilling motion with emphasis on bringing the tip of the drill out of the template when preparing the site to avoid overheating.

For more information regarding the drill protocol, please refer to pages 15-19.

17 Tapping of distal implant sites with the V-Template

- Place the Screw Tap Trefoil through the Template for Implant (\emptyset 5.0) and the V-Template to appropriate depth with regards to the implant length and collar height.
- The depth is achieved when the depth mark is flush with the Template for Implant.
- Switch the drill unit to reverse mode and back the screw tap out.







Dense bone type I drill sequence

Screw Tap Trefoil 5.0 mm (optional)

Medium bone type II and III drill sequence

Screw Tap Trefoil 5.0 not required

The depth is achieved when the depth mark is flush with the Template for Implant.

Tapping: Low speed 25 rpm.

For more information regarding the drill protocol, please refer to page 19.

Implant insertion

18 Unpack implant, choose insertion instrument, pick up implant (please refer to steps 8 to 10)



19 Placement of the distal implants with the V-Template

- Place the implant through the Template for Implant (Ø 5.0) and the V-Template. Insert the implant until the built-in stop of the Implant Mount is in light contact with the Template (please see implant insertion with the V-Template below).
 Ensure that the Implant Mount is only in light contact with
- Ensure that the Implant Mount is only in light contact with the Template for Implant.



Implant collar height 4.5 mm

The Implant Mount must always be in light contact with the Template for Implant.

Implant insertion: Low speed 25 rpm. Maximum torque 45 Ncm.

Note: If the Implant Mount is difficult to remove, gently pull it free with small back and forth motions using the Combined Open-end Wrench or forceps.

For more information regarding the implant insertion, please refer to page 21.

For placement of implant with collar height 4.5 mm, insert implant until Implant Mount is in light contact with the Template for Drill.

Caution: Never exceed insertion torque of 45 Ncm for the Trefoil[™] implants.

Overtightening of implant may lead to damage of the implant, fracture or necrosis of the bone site. If a Manual Torque Wrench Surgical is used to insert the implant, special care needs to be taken to avoid overtightening.

If the implant gets stuck during implant installation or 45 Ncm of insertion torque is achieved before fully seated, rotate the implant counter clockwise using Drilling Device (reverse mode) or Manual Torque Wrench Surgical and remove implant from site. Replace the implant back into inner casing before proceeding further. Reference Table 1 to consider medium or dense bone protocol before proceeding with implant insertion.

20 Removal of Implant Mount and Template for Implant

 Unscrew the Implant Mounts with the UniGrip Screwdriver holding the mount with the Combined Open-end Wrench to prevent the implant from rotating when unscrewing the mount.

Note: If the Implant Mount is difficult to remove, gently pull it free with small back and forth motions using the Combined Open-end Wrench or forceps.

- Remove the Template for Implant.

21 Verification of insertion torque

Note: Verification of the insertion torque with the Template for Implant in place might affect the real torque value.

- Remove the Implant Mount and the Template for Implant and use the Implant Driver CC RP for final verification together with the Manual Torque Wrench Surgical or the drilling unit device and contra-angle.
- Verify the insertion torque with Manual Torque Wrench Surgical and Implant Driver CC RP.

Note: For Immediate Function, the implant should withstand a final insertion torque of at least 35 Ncm. Do not exceed 45 Ncm.

In cases where sufficient primary stability of one or more implants is not reached, the implants along with the bar may also be used with an early or delayed loading protocol.

Note: If the Implant Mount is difficult to remove, gently pull it free with small back and forth motions using the Combined Open-end Wrench or forceps.



22 Removal of V-Template

- Unscrew the Temporary Screw Implant using the Connection to Handpiece.
- Switch the drill unit to reverse mode and back the screws out. – Unscrew the Stabilizing Screws for V-Template using the Connection to Handpiece.

Switch the drill unit to reverse mode and back the screws out. – Remove the V-Template.

Temporary Screw Implant and Stabilizing Screw for V-Template: Reverse mode with low speed or using the Connection to Handpiece or the Manual Torque Wrench Surgical.

Verification and indexing

23 Verification of implant positions

- The Try-in Bar Trefoil allows verification if the three implants are aligned and placed within the compensation range, and if the bar is in the correct position in relation to the mandible and the opposing dentition.

Caution: If the Try-In Bar Trefoil is screwed to the implants, all three screws need to be inserted without any resistance. If force needs to be applied, and the round abutments are not fully seated to the implant platform, one or more implants could be outside of the compensation range.

In such a case, the misaligned implant needs to be removed and repositioned following the drill protocol. Alternatively, a NobelProcera Implant Bar may be considered as a solution.



Caution: Tightening the Try-in Bar Trefoil when implants are placed outside the compensation range might cause damage to the Try-in Bar Trefoil and may require the Try-in Bar Trefoil to be replaced for future use.

24 Fabrication of the verification index

Fabricate the verification index with two Transfer Abutments Trefoil on the distal implants and a Temporary Abutment Nonengaging CC RP on the central implant. Connect the abutments with resin.





Temporary Abutment

Transfer Abutments

- Isolate the surgical site using a rubber dam.

- Attach the Transfer Abutments to the distal implants and orient the arms towards the Temporary Abutment on the center implant. Hand-tighten the abutments to the implants with a UniGrip Screwdriver.
- Use a cold or light-curing resin to splint the abutments.
- Remove the verification index.

Note: Maintain a small space between the horizontal arms of the Transfer Abutments and the Temporary Abutment to allow for the placement of acrylic to achieve a stable verification index.

25 Soft tissue closure

- Depending on the surgical protocol of choice, place and hand tighten three cover screws or healing abutments CC RP using a UniGrip Screwdriver.
- Suture the soft tissue flap.





Product information

Trefoil™ Bar

The Trefoil Bar with its fixation mechanism is delivered pre-assembled and held in place with the Try-in Screw Trefoil. In addition, three Lab Screws Trefoil and three Clinical Screws Trefoil are included.

Trefoil Bar consists of the following components:



- A. **Try-in Screw Trefoil:** Not for clinical use. It is used in the dental lab to fasten the Trefoil Bar to the Round Abutment Trefoil, passing through the Screw Disc Trefoil and the Bar Discs Trefoil.
- **B.** Screw Disc Trefoil: Used as a compensation component for angulations. It has a spherical bearing surface in contact with the Bar Disc Trefoil and a flat surface to support the head of the Clinical and Try-In Screw Trefoil.
- **C/D. Bar Disc Trefoil:** Has one flat bearing surface and one spherical bearing surface. The spherical bearing surface is in contact either with the Screw Disc Trefoil (above the Trefoil Bar) or with the Round Abutment Trefoil (below the Trefoil Bar). The flat bearing surface is in contact with the Trefoil Bar.
- E. Trefoil Bar: Horseshoe shaped titanium framework.
- F. Round Abutment Trefoil: Has a flat surface with a conical connection to engage with the implant and a spherical bearing surface in contact with the Bar Disc Trefoil.
- **G.** Lab Screw Trefoil: Not for clinical use. It has a 10 mm long head, used to fasten the Trefoil Bar to the implant replica passing through the Screw Disc Trefoil, Bar Discs Trefoil and the Round Abutment Trefoil.
- H. Clinical Screw Trefoil: Screw with a diamond-like carbon (DLC) coating to fasten the Trefoil Bar to the implants, passing through the Screw Disc Trefoil, Bar Discs Trefoil and the Round Abutment Trefoil.

The A-P (Anteroposterior) measurement

The A-P (Anterior-Posterior) measurement

The mandible tooth setup depends on multiple factors including patient age, gender and opposing dentition. Whether the patient has dentures or natural dentition also plays a role in deciding the acceptable length of the cantilever for the specific patient situation.



The A-P spread is a guideline used in edentulous cases to measure the maximum cantilever length and set up the teeth in the posterior accordingly.

The A-P spread is the distance measured from the center of most anterior implants to the distal aspect of the two most posterior implants.

The implant spread (in mm) can be multiplied by 1.5 (to 2.5) to give a guideline of the acceptable length of a distal cantilever*.

For the Trefoil system, the "implant spread" is 8.7 mm and the "bar spread" 14.5 mm, with a factor of 1.67.

The mandible tooth setup for Trefoil is therefore designed as a typical implant-supported construction with occlusion from first molar to first molar. Depending on the multiple factors mentioned above, the tooth setup can be individually adjusted/shortened by removing one of the premolars on both sites.



Laboratory procedure

1 Master working model

- Use the verification index to prepare a master working model.
 Screw Implant Replicas Trefoil CC RP to the verification index using a UniGrip Screwdriver.
- Fabricate a master working model.
- When the stone is set, unscrew the verification index.

An additional verification index can be taken to confirm the accuracy of the master working model.

2 Adjustment of the fixation mechanism

The Trefoil Bar with its prosthetic components are delivered preassembled with the Try-in Screw Trefoil.

Caution: All pre-assembled components are movable. In case the components have been dismantled accidentally, please please refer to the list of fixation mechanism components on page 40.

Option 1: Using the Try-in Screw Trefoil

Note: When tightening the try-in screws to the implant replicas, the screw will fixate the fixation mechanism only. The screws are not engaged into the implant replica. The Trefoil Bar is removable.

- When tightening the try-in screws with the UniGrip Screwdriver, support the bar position with your fingers.
- Verify passive fit using magnification.
- When tightening the try-in screws to a maximum 15 Ncm with the UniGrip Screwdriver Machine and the Manual Torque Wrench Prosthetic, continue to support the bar position with your fingers.

Confirm passive and accurate fit again using magnification.

Warning: A passive and precise fit of the Trefoil Bar is essential to the success of the implants. A forced fit can result in stress concentration on one or more implants, potentially leading to implant failure, problematic screw loosening or bone loss.

Important: Support the bar position with your fingers to achieve a passive fit.

Verify the passive fit using magnification.

Caution: After tightening of all try-in screws, under no circumstances disassemble the screws or remove them from the bar. In this situation, the fixation mechanism is fixed by the try-in screw.

Do not exceed 15 Ncm to be able to remove the screws from the implant replicas after the fixation of the retention mechanism with resin.







Product overview

Option 2: Using the Lab Screw Trefoil

Note: Attaching the Lab Screws Trefoil to the implant replicas allows the self-alignment of the fixation mechanism. The screws are engaged to the implant replicas. The Trefoil Bar is not removable.

 Replace the Try-in Screws Trefoil with the Lab Screws Trefoil using the UniGrip Screwdriver.

Caution: All pre-assembled components are movable. In case the components have been dismantled accidentally, please follow the instructions for re-assembly on page 40.

- Place the Trefoil Bar with the Try-in Screws Trefoil to the master working model.
- Unscrew one of the try-in screws only, and replace it with a Lab Screw Trefoil.
- Continue with the next screws.
- Tighten all Lab Screws Trefoil to a maximum of 15 Ncm using the UniGrip Screwdriver Machine and the Manual Torque Wrench Prosthetic.

Warning: A passive and precise fit of the Trefoil Bar is essential to the success of the implants. A forced fit can result in stress concentration on one or more implants, potentially leading to implant failure, problematic screw loosening or bone loss.

Caution: Do not exceed 15 Ncm to be able to remove the screws from the implant replicas after the fixation of the retention mechanism with resin.



3 Setting of the fixation mechanism

 Sandblasting of the fixation mechanism and the framework with aluminum oxide followed by an appropriate bonding material is recommended.

Note: To protect the seating surface of the round abutment during sandblasting use implant replicas or sandblast the framework on the master working model.

Fixation of the mechanism using: Light-curing composite Self-curing resin Laser welding technique

 Apply opaquer and resin to the fixation mechanism components: Screw Disc Trefoil, Bar Discs Trefoil and Round Abutment Trefoil.

Important: Avoid covering the implant collar with resin.

 The lab screws or try-in screws can now be removed using the Manual Torque Wrench Prosthetic (reverse).



Restorative procedure

4 Bite registration for occlusal relationship

Use the lab screws and add a wax rim of about 16 mm height (from the bottom of the framework) to the Trefoil Bar.

A Intraoral bite registration

- Remove the three healing abutments.
- Secure the Trefoil Bar with the wax rim to the center implant using clinical screws.
- Confirm vertical dimension.
- Obtain centric bite registration
- Verify passive fit of the Trefoil Bar.

Optional: Put impression material underneath the Trefoil Bar. This will allow the dental technician to design the definitive prosthesis in regards to the contour of the ridge (see the image on the right).

Caution: If the Trefoil Bar is screwed to the implants, all three screws need to be inserted without any resistance. If force needs to be applied, and the round abutments are not fully seated to the implant platform, the fixation mechanism needs to be repositioned.

 Remove the Trefoil Bar and put the three healing abutments back in place.

Optional: If an impression of the ridge has been taken, fixate implant replicas to the Trefoil Bar using lab screws and fabricate a new master stone model (see the image on the right).





Introduction

Laboratory procedure

5 Fixation in the articulator

- Secure the Trefoil Bar with the wax rim back to the master working model using the lab screws.
- Fix the opposing maxillary model to the wax rim and mount the models on the articulator.

6 Tooth setup

- Proceed with the previously indexed tooth setup to the maxillary dentition and attach the wax-up to the Trefoil Bar for a clinical try-in (page 23, Pre-surgical preparation).
- If no impression of the mandibular alveolar ridge has been taken, then the final wax-up should have at least 2 mm of convex-shaped wax wrap-around underneath the bar and around the retention mechanisms.
- Finish wax-up with full characterization for a clinical try-in (optional).

Note: The mandible tooth setup depends on opposing dentition (denture, natural dentition) and needs to be designed as a classical implant-supported construction with occlusion from first molar to first molar.

7 Acrylic processing

- Take the master working model with the final tooth setup and prepare for investing with stone into the flask.
- Boil out the wax.
- Remove the Trefoil Bar from the master working model using the UniGrip Screwdriver.
- Sandblasting of the framework with aluminum oxide followed by an appropriate bonding material is recommended.
- Apply pink opaquer.
- Place the Trefoil Bar back onto the master working model and tighten all Lab Screws Trefoil to a **maximum of 30 Ncm** for a stable fixation mechanism during the acrylic processing using the UniGrip Screwdriver Machine and the Manual Torque Wrench Prosthetic.
- Start acrylic processing.









Product overview

8 Final polishing

- When acrylic processing is completed, remove the master working model.
- Remove the Lab Screws Trefoil using the UniGrip Screwdriver Machine and the Manual Torque Wrench Prosthetic (reverse).
- Finish the denture work.
- Maintain at least 2 mm of convex-shaped acrylic underneath the Trefoil Bar if no impression of the mandibular alveolar ridge has been taken.

Note: Screw Implant Replicas CC RP to the Round Abutments to protect the seating surface during grinding and polishing.

B Delivery of final prosthesis

- Remove the healing abutments from the implants.
- Fix the definitive prosthesis to the implants. Use clinical screws and tighten manually.
- Carefully evaluate contact areas underneath the Trefoil Bar. Relieve areas (acrylic) if necessary, and polish any modified areas.
- Verify and adjust occlusion if required.
- Tighten all clinical screws to a maximum 35 Ncm using the UniGrip Screwdriver Machine and the Manual Torque Wrench Prosthetic.
- Close screw access holes. Be sure to keep screw-access holes free of composite.

Caution: Never exceed the recommended maximum 35 Ncm tightening torque for the abutment. Overtightening the abutment may lead to a screw fracture.





Revision surgery

Y-Template

The Y-Temple accommodates the replacement of the central implant if it is lost or has to be removed. The Y-Template Trefoil is temporarily connected to the distal implants and stabilized with the Stabilizing Screws V-Template in the bone. The device is used in conjunction with guided sleeve templates for drills/implants for the exact positioning and installation of the central implant.

1 Fixation of the Y-Template

- Fix the Y-Template to the two distal implants with the Temporary Screw Implant and the Connection to Handpiece.
- Ensure that the Temporary Screw Implant is in light contact with the Y-Template.

Caution: Do not exceed 15 Ncm to be able to remove the screws from the implant after implant placement.

- Additionally, fix the Y-Template with stabilizing screws into the bone by first drilling through the Y-Template (with the inner threads) with a 2.0 mm Twist Drill.
- Thumb thread the stabilizing screws through the inner threaded holes of the template and continue with the Connection to Handpiece or the Manual Torque Wrench.
- Ensure that the stabilizing screws are in light contact with the Y-Template.



Drilling speed with 2.0 mm Twist Drill: Maximum 2000 rpm.

Temporary Screw Implant: Low speed 25 rpm or using the Connection to Handpiece or the Manual Torque Wrench Surgical to maximum 15 Ncm.

Placement of the Stabilizing Screw for V-Template: Low speed 25 rpm using the Connection to Handpiece or the Manual Torque Wrench Surgical.

Appendices

2 Preparation of the central implant site with the Y-Template

- Follow the same principles for drilling, tapping and implant placement as for the V-Template (please refer to step 16 of the clinical procedure).

Note: Depending on the implant to be replaced and the size of the osteotomy, follow the drill protocol according to the bone density.



Note: When using the Twist Drills, use copious irrigation and an "in-and-out" drilling motion with emphasis on bringing the tip of the drill out of the template when preparing the site to avoid overheating.

3 Tapping of the central implant site with the Y-Template

- Follow the same principles for drilling, tapping and implant placement as for the V-Template (please refer to step 17 of the clinical procedure).

Note: Depending on the implant to be replaced and the size of the osteotomy, follow the drill protocol according to the bone density.





Tapping: Low speed 25 rpm.

For more information regarding the drill protocol, please refer to page 19.



For more information regarding the drill protocol, please

refer to pages 15-19.



4 Placement of central implant with the Y-Template

 Follow the same principles for drilling, tapping and implant placement as for the V-Template (please refer to step 19 of the clinical procedure).

Note: Depending on the implant to be replaced and the size of the osteotomy follow the drill protocol according to the bone density.



Implant insertion: Low speed 25 rpm. Maximum torque 45 Ncm.

Note: If the Implant Mount is difficult to remove, gently pull it free with small back and forth motions using the Combined Open-end Wrench or forceps.

For more information regarding the implant insertion, please refer to page 21 (implant inserion with the V-Template).

Product overview

5 V-Template

In addition to implant placement, the V-Template Trefoil can also be used for the replacement of a distal implant if that implant is lost or has to be removed.

- The V-Template is temporarily connected to one of the distal implants and to the central implant with Temporary Screw Implant.
- Additionally, fix the V-Template with stabilizing screws into the bone by drilling through the V-Template with the inner thread with a 2.0 mm Twist Drill.
- Thumb thread the stabilizing screws through the inner threaded holes of the template, and continue with the Connection to Handpiece or the Manual Torque Wrench.
- Ensure that the stabilizing screws are in light contact with the V-Template.
- The V-Template is used in conjunction with the Template for Drill and Template for Implant for the exact positioning and installation of the distal implant.

Note: Depending on the implant to be replaced and the size of the osteotomy, follow the drill protocol according to the bone density.

For more information regarding the drill protocol, please refer to pages 15-19.

Please refer to steps 16, 17 and 19 of the clinical procedure.





Trefoil™ PureSet

REF300401



Trefoil™ PureSet components

REF300401 Trefoil PureSet				
PUR0100	Trefoil™ PureSet Tray			
35426	Guide Drill*			
38324	Twist Drill Trefoil™ 2 x 11.5-13 mm*			
38335	Twist Drill Trefoil™ 3 x 11.5-13 mm*			
38336	Twist Drill Trefoil™ 3.8 x 11.5-13 mm*			
38337	Twist Drill Trefoil™ 4.2 x 11.5-13 mm*			
38338	Twist Drill Trefoil™ 4.4 x 11.5-13 mm*			
38339	Screw Tap Trefoil™ 5.0 mm*			
38340	Implant Mount Ø5 mm			
38343	Temporary Screw Implant			
38344	Stabilizing Screw for V-Template			
38345	Guide Template			
38346	Evaluation Template			
38347	Guide Pin			
38348	Positioning Template			
38349	V-Template			
38350	Template for Drill 2.0			
38351	Template for Drill 3.0			
38352	Template for Drill 3.8			
38353	Template for Drill 4.2			
38354	Template for Drill 4.4			
38355	Template for Implant			
38356	Depth Gauge Ø2/4.2 mm			
300516	Occlusion Guide Trefoil™			
300087	Try-in Bar Trefoil™			
28839	Manual Torque Wrench Surgical			
29148	Screwdriver Manual Unigrip 28 mm			
29153	Screwdriver Machine Unigrip 30 mm			
33247	Combined Open-end Wrench			
33065	Connection to Handpiece			
36720	Implant Driver Conical Connection RP 28 mm			
300211	Wall Chart Trefoil™ PureSet			

Trefoil™ PureS	et Tray and Plate	
PUR0100	Trefoil™ PureSet Tray	
PUR0101	Trefoil™ PureSet Plate	

*Drills and screw taps are not included in the Trefoil PureSet **Article to be disassembled for cleaning

Surgical components

Trefoil™ Impl	ant CC RP 5.0 mm
38318	Trefoil™ Implant CC RP 5.0 x 11.5 + 6 mm
38319	Trefoil™ Implant CC RP 5.0 x 13 + 6 mm
38320	Trefoil™ Implant CC RP 5.0 x 11.5 + 4.5 mm
38321	Trefoil™ Implant CC RP 5.0 x 13 + 4.5 mm

Guide Drill, Twist Drills and Screw Tap (single-use) (not included in the Trefoil™ PureSet)			
35426	Guide Drill		
38324	Twist Drill Trefoil™ 2 x 11.5-13 mm		
38335	Twist Drill Trefoil™ 3 x 11.5-13 mm		
38336	Twist Drill Trefoil™ 3.8 x 11.5-13 mm		
38337	Twist Drill Trefoil™ 4.2 x 11.5-13 mm		
38338	Twist Drill Trefoil™ 4.4 x 11.5-13 mm		
38339	Screw Tap Trefoil™ 5.0 mm		

		_	
Templates for	Templates for Drill and Template for Implant		
38350	Template for Drill 2.0		
38351	Template for Drill 3.0		
38352	Template for Drill 3.8		
38353	Template for Drill 4.2		
38354	Template for Drill 4.4		
38355	Template for Implant 5.0		

Templates Trefoil™ and screws		
38343	Temporary Screw Implant	
38344	Stabilizing Screw for V-Template	
38347	Guide Pin	
38345	Guide Template	
38346	Evaluation Template	
38348	Positioning Template	
38349	V-Template	
300093	Y-Template	

Surgical Acce	ssoires
300516	Occlusion Guide Trefoil™
38356	Depth Gauge Ø2/4.2 mm
300087	Try-in Bar Trefoil™
38359	Transfer Abutment
33247	Combined Open-end Wrench
36662	Temporary Abutment Non-Engaging CC RP

Implant Mou	nt for Trefoil™ Implant CC RP 5.0 mm	
38340	Implant Mount Ø5 mm	













Prosthetic components

Healing abutment	
36871	Healing Abutment Bridge Ø 5 mm/ H 7 mm

Drivers and Torque Wrench		
29149	Screwdriver Manual UniGrip 28 mm	
29153	Screwdriver Machine UniGrip 30 mm	
36720	Implant Driver Conical Connection RP 28 mm	
28839	NOBELREPLACE® Manual Torque Wrench Surgical	
29165	Manual Torque Wrench Prosthetic	

Trefoil™ Bar and accessories	
300077	Trefoil™ Bar
300078	Round Abutment Trefoil™
300079	Screw Disc Trefoil™ 3/pkg
300080	Bar Disc Trefoil™ 3/pkg
300081	Clinical Screw Trefoil™ 3/pkg
300082	Trv-in Screw Trefoil™ 3/pkg

Laboratory components	
300084	Lab Screw Trefoil™ 3/pkg
38360	Implant Replica Trefoil™ CC RP
29149	Screwdriver Manual UniGrip 28 mm
29153	Screwdriver Machine UniGrip 30 mm
29165	Manual Torque Wrench Prosthetic







Introduction

Cleaning and sterilization

Sterile components

The devices delivered sterile have a "Sterile" marking on the label.

See current cleaning and sterilization guidelines for details: nobelbiocare.com/sterilization.

Implants

Implants are delivered sterile and are for single-use only. Do not use implants if the packaging has been damaged or previously opened.

Note: The implants require no preparation prior to use.

Twist Drill, Twist Step Drills and Screw Taps

Twist Drills and the Screw Tap are delivered sterile and are for single use only. Do not use drills if the packaging has been damaged or previously opened.

Non-sterile components

Care and maintenance of reusable instruments are crucial for a successful treatment. Well-maintained instruments not only safeguard your patients and staff against infection, but are also essential for the outcome of the total treatment.

See current cleaning and sterilization guidelines for details: nobelbiocare.com/sterilization.











Product overview

Guided components

Guide Template, Evaluation Template, Positioning Template, V-Template, Y-Template , Template for Drill, Template for Implant, Implant Mount, Temporary Screw Implant, Stabilizing Screw for V-Template, Depth Gauge, Occlusion Guide and Try-in Bar are for multiple use and delivered nonsterile.

Trefoil Bar and screws

The Trefoil Bar, clinical screws and lab screws are delivered non-sterile and are for single use only.



Trefoil Bar cleaning and disinfection

The Trefoil Bar is delivered non-sterile. It is recommended to sterilize the Trefoil Bar prior to placing it in the oral cavity. For sterilization, see current cleaning and sterilization guidelines: nobelbiocare.com/sterilization.

In case of any intraoral bite registration of the Trefoil Bar with an occlusion wax rim or a wax try-in of the tooth set-up use disinfection agent described below.

In the clinic:

Disinfect the bar in a high-level disinfectant, according to the manufacturer's instructions. Rinse thoroughly with sterile water and dry well.

In the laboratory:

Use water and mild detergents. Rinse thoroughly with water and dry well.

Disposal

Disposal of the device shall follow local regulations and environmental requirements, taking different contamination levels into account.

Storage and handling

The device must be stored and transported in dry conditions in the original packaging at room temperature and not exposed to direct sunlight. Incorrect storage and transportation may influence device characteristics leading to failure.

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