

Nobel Biocare Guided Surgery Tooling

Important – Disclaimer of Liability

This product is part of an overall concept and may only be used in conjunction with the associated original products according to the instructions and recommendation of Nobel Biocare. Non-recommended use of products made by third parties in conjunction with Nobel Biocare products will void any warranty or other obligation, express or implied, of Nobel Biocare. The user of Nobel Biocare products has the duty to determine whether or not any product is suitable for the particular patient and circumstances. Nobel Biocare disclaims any liability, express or implied, and shall have no responsibility for any direct, indirect, punitive or other damages, arising out of or in connection with any errors in professional judgment or practice in the use of Nobel Biocare products. The user is also obliged to study the latest developments in regard to this Nobel Biocare product and its applications regularly. In cases of doubt, the user has to contact Nobel Biocare. Since the utilization of this product is under the control of the user, they are his/her responsibility. Nobel Biocare does not assume any liability whatsoever for damage arising thereof.

Please note that some products detailed in this Instruction for Use may not be regulatory cleared, released or licensed for sale in all markets.

Description

Nobel Biocare guided surgery tooling is designed to be used with a Surgical Template in order to guide the placement of Nobel Biocare dental implants which are intended for the treatment of edentulous and partially edentulous jaws, including patients missing a single tooth.

Nobel Biocare guided surgery tooling is used for surgical access, guided implant site preparation, guided screw tapping, and guided implant insertion. The tooling enables a predictable and, if indicated, minimally-invasive endosseous implant installation procedure according to case planning performed by the clinician.

A NobelGuide® Surgical Template can be ordered from Nobel Biocare using a design file created by Nobel Biocare's DTX STUDIO™ Implant software, or the template can be produced locally using the same design file.

- Refer to Nobel Biocare Instructions for Use (IFU) IFU2001 for information regarding NobelGuide® Surgical Templates. This IFU is available for download at ifu.nobelbiocare.com.
- Refer to the DTX STUDIO™ Implant Instructions for Use (available through the software, or on the DTX Studio Go website <https://go.dtxstudio.com>) for information regarding the DTX STUDIO™ Implant Software.

Nobel Biocare guided surgery tooling includes the following components

Guided Drill Guides and Guided Drill Guides Tapered

- Guided Drill Guides and Guided Drill Guides Tapered are available in different diameters for use with various guided drills and guided sleeves. They are inserted into the guided sleeves embedded in the surgical template and are used to guide the drill during preparation of the osteotomy.

Handle for Guided Drill Guide

- The Handle for Guided Drill Guide extends the existing handle on the Guided Drill Guides for easier handling and better accessibility during surgery.

Guided Implant Mounts

- Guided Implant Mounts are used to facilitate implant placement through the surgical template sleeve. The Guided Implant Mounts have an outer diameter that matches the internal dimensions of the sleeves. For the NobelActive® and the NobelActive® TiUltra™ implant system, the mounts have an outer diameter that matches the dimensions of the implant platform of the NobelActive® and NobelActive® TiUltra™ implant and therefore will be smaller than the guided sleeve with a mandatory guided screw tap step to be used before implant insertion to address the specific needs of the guided NobelActive® and NobelActive® TiUltra™ procedure.

Guided Template Abutments

- Guided Template Abutments are used to keep the surgical template in the desired position when preparing osteotomies while placing the remaining implants. Guided Template Abutments are used on the first two implants. For all other implants, the Guided Implant Mount will be left after placing the implant until all implants are placed. If only one implant is placed, there is no need for a Guided Template Abutment. If only two implants are placed, there is no need for a Guided Template Abutment on the second implant.

Guided Tissue Punches

- Guided Tissue Punches can optionally be used during flapless guided surgery, before the drilling protocol, in order to cleanly remove the soft tissue without leaving any soft tissue "tags".

Guided Start Drills

- Guided Start Drills are guided round burs which are used to prepare the entrance point for an osteotomy.

Guided Pilot Twist Drill

- Guided Pilot Twist Drills are guided drills used to prepare the osteotomy prior to implant placement. The Guided Pilot Twist Drills are designed in different diameters and lengths and have two cutting diameters, with the smaller diameter at the tip. The implant site is widened step by step to the right diameter and depth according to the drill protocol.

Guided Drills Tapered and Guided Twist Drill Tapered

- Guided Drills Tapered and Guided Twist Drills Tapered are custom designed per implant length and diameter. The depth reference system should be from the top of the guide sleeve embedded in the surgical template. A cylindrical part at the top of the drill should give guidance through the guide sleeve or a guided drill guide. A hard stop at the drill shaft forces the drill to stop at the correct height.

Guided Twist Drills

- Guided Twist Drills are guided drills used to prepare the osteotomy prior to implant placement. The Guided Twist Drills are designed in different diameters and lengths and have one cutting diameter. The implant site is widened to the right diameter and depth according to the drill protocol.

Guided Twist Step Drills

- Guided Twist Step Drills are guided drills used to prepare the osteotomy prior to implant placement. The Guided Twist Step Drills are designed in different diameters and lengths and have two cutting diameters, with the smaller diameter at the tip. The implant site is widened step by step to the right diameter and depth according to the drill protocol.

Guided Screw Taps and Guided Screw Taps Tapered

- Guided Screw Taps and Guided Screw Taps Tapered are designed to cut threads in an osteotomy in dense bone. Guided screw tapping is required for guided placement of NobelActive® and NobelActive® TiUltra™ implants. The Guided Screw Taps NobelParallel™ CC are designed to cut threads in an osteotomy in dense bone and optionally in medium bone.

Guided Dense Bone Drills Tapered

- Guided Dense Bone Drills Tapered are used additionally to the other drills to prepare an osteotomy in dense bone situations, in order to reduce the insertion torque necessary to place an implant.

Guided Dense Bone Screw Tap

- Guided Dense Bone Screw Tap are designed to cut threads in an osteotomy in dense bone. Guided screw tapping is required for guided placement of NobelActive® and NobelActive® TiUltra™ implants.

Guided Counterbores

- Guided Counterbores are designed to remove bone from around the crest of the bone in order to reduce compression around the neck of the implant and prevent the Guided Screw Tap and Guided Implant Mount from colliding with the bone. It can be used if sub-crestal placement is desired or where specific alveolar crest anatomy would prevent full depth insertion of the guided implant mount.

Table 1 – Compatibility of the Guided Surgery Tooling

Product Name	Implant	Sleeve	Driver	Other	
Guided Drill Guide 6.0/WP Ø 6 to Ø 5 mm	N/A	Guided Sleeve 6.0/WP	N/A	Handle for Guided Drill Guide	
Guided Drill Guide 6.0/WP to Ø 2.8 mm					
Guided Drill Guide 6.0/WP to Ø 2 mm					
Guided Drill Guide 6.0/WP to Ø 3.8 mm					
Guided Drill Guide 6.0/WP to Ø 3 mm					
Guided Drill Guide 6.0/WP to Ø 4.2 mm					
Guided Drill Guide NP to Ø 2.8 mm					Guided Sleeve NP
Guided Drill Guide NP to Ø 2 mm					
Guided Drill Guide NP to Ø 3.2 mm					
Guided Drill Guide NP to Ø 3 mm					
Guided Drill Guide RP to Ø 3.2 mm		Guided Sleeve RP			
Guided Drill Guide RP to Ø 2.8 mm					
Guided Drill Guide RP to Ø 2 mm					
Guided Drill Guide RP to Ø 3.4 mm					
Guided Drill Guide RP to Ø 3.6 mm					
Guided Drill Guide RP to Ø 3 mm		Guided Sleeve 6.0/WP			
Guided Drill Guide RP to Ø 4.2 mm					
Guided Drill Guide Tapered RP to NP					
Guided Drill Guide Tapered 6.0/WP to NP					
Guided Drill Guide Tapered 6.0/WP to RP					
Guided Drill Guide WP/6.0 to Ø 3.6 mm					
Guided Drill Guide WP/6.0 to Ø 4.6 mm					
Guided Surgery Implant Mount NobelActive NP	NobelActive®/NobelActive® TiUltra™ NP	Guided Sleeve NP	Surgical Driver Screwdriver Manual/ Machine Unigrip™	Manual Torque Wrench Adapter Surgical Connection to Handpiece	
Guided Surgery Implant Mount NobelActive RP 4.3	NobelActive®/NobelActive® TiUltra™ RP 4.3	Guided Sleeve RP			
Guided Surgery Implant Mount NobelActive RP 5.0	NobelActive®/NobelActive® TiUltra™ RP 5.0	Guided Sleeve 6.0/WP			
Guided Surgery Implant Mount NobelActive WP 5.5	NobelActive®/NobelActive® TiUltra™ WP 5.5				
Guided Implant Mount Bmk Syst NP	Brånemark System® NP	Guided Sleeve NP	Surgical Driver Screwdriver Manual/ Machine Unigrip™	Brånemark System® Manual Torque Wrench Adapter Surgical Connection to handpiece	
Guided Implant Mount Bmk Syst RP	Brånemark System® RP	Guided Sleeve RP			
Guided Implant Mount Bmk Syst WP	Brånemark System® WP	Guided Sleeve 6.0/WP			
Guided Implant Mount NobRpl NP	NobelReplace® NP	Guided Sleeve NP	Surgical Driver Screwdriver Manual/ Machine Unigrip™	NobelReplace® Manual Torque Wrench Adapter Surgical Connection to handpiece	
Guided Implant Mount NobRpl RP	NobelReplace® RP	Guided Sleeve RP	Guided Sleeve RP		
Guided Implant Mount NobRpl WP	NobelReplace® WP	Guided Sleeve 6.0/WP	Guided Sleeve 6.0/WP		
Guided Implant Mount NobRpl 6.0	NobelReplace® 6.0	Guided Sleeve 6.0/WP	Guided Sleeve 6.0/WP		
Guided Implant Mount NobelReplace® Conical Connection NP 3.5	NobelReplace® CC NP	Guided Sleeve NP	Surgical Driver Screwdriver Manual/ Machine Unigrip™	NobelReplace® Manual Torque Wrench Adapter Surgical Connection to handpiece	
Guided Implant Mount NobelReplace® Conical Connection RP 4.3	NobelReplace® CC RP	Guided Sleeve RP			
Guided Implant Mount NobelReplace® Conical Connection RP 5.0	NobelReplace® CC RP 5.0	Guided Sleeve 6.0/WP			
Guided Implant Mount NobelParallel™ CC NP	NobelParallel™ CC NP	Guided Sleeve NP			
Guided Implant Mount NobelParallel™ CC RP 4.3	NobelParallel™ CC RP	Guided Sleeve RP	Surgical Driver Screwdriver Manual/ Machine Unigrip™	NobelReplace® Manual Torque Wrench Adapter Surgical Connection to handpiece	
Guided Implant Mount NobelParallel™ CC RP 5.0	NobelParallel™ CC RP 5.0	Guided Sleeve 6.0/WP			
Guided Implant Mount NobelParallel™ CC WP 5.5	NobelParallel™ CC WP	Guided Sleeve 6.0/WP			

Product Name	Implant	Sleeve	Driver	Other
Guided Template Abutm w Screw NobelActive NP	NobelActive®/NobelActive® TiUltra™ NP	Guided Sleeve NP	Screwdriver Manual/ Machine Unigrip™	N/A
Guided Template Abutm w Screw NobelActive RP 4.3	NobelActive®/NobelActive® TiUltra™ RP 4.3	Guided Sleeve RP		
Guided Template Abutm w Screw NobelActive RP 5.0	NobelActive®/NobelActive® TiUltra™ RP 5.0	Guided Sleeve 6.0/WP		
Guided Template Abutm w Screw NobRpl 6.0	NobelReplace® CC/NobelReplace® CC TiUltra™ 6.0 and Replace Select™ Tapered TiUnite® 6.0 implants			
Guided Template Abutm w Screw NobRpl NP	NobelReplace® CC/NobelReplace® CC TiUltra™ NP and Replace Select™ Tapered TiUnite® NP implants	Guided Sleeve NP		
Guided Template Abutm w Screw NobRpl RP	NobelReplace® CC/NobelReplace® CC TiUltra™ RP and Replace Select™ Tapered TiUnite® RP implants	Guided Sleeve RP		
Guided Template Abutm w Screw NobRpl WP	NobelReplace® CC/NobelReplace® CC TiUltra™ WP and Replace Select™ Tapered TiUnite® WP implants	Guided Sleeve 6.0/WP		
Guided Template Abutment CC NP	NobelActive®/NobelActive® TiUltra™ NP, NobelParallel™ CC/NobelParallel™ CC TiUltra™ NP, NobelReplace® CC/NobelReplace® CC TiUltra™, NP NobelReplace® CC PMC NP implants	Guided Sleeve NP		
Guided Template Abutment CC NP	NobelReplace® CC/NobelReplace® CC TiUltra™ & CC PMC NP implants			
Guided Template Abutment CC RP 4.3	NobelReplace® CC/NobelReplace® CC TiUltra™ & CC PMC RP 4.3 implants	Guided Sleeve RP		
Guided Template Abutment CC RP 5.0	NobelReplace® CC/NobelReplace® CC TiUltra™ & CC PMC RP 5.0 implants	Guided Sleeve 6.0/WP		
Guided Template Abutment CC WP 5.5	NobelReplace® CC/NobelReplace® CC TiUltra™ & CC PMC WP 5.5 implants			
Guided Template Abutment with Screw Brånemark System NP	Brånemark System® MK III NP and NobelSpeedy® Groovy NP implants			
Guided Template Abutment with Screw Brånemark System RP	Brånemark System® MK III RP and NobelSpeedy® Groovy RP implants	Guided Sleeve RP		
Guided Template Abutment with Screw Brånemark System WP	Brånemark System® MK III WP and NobelSpeedy® Groovy WP implants	Guided Sleeve 6.0/WP		
Guided Template Abutment with Screw NobelActive WP 5.5	NobelActive®/NobelActive® TiUltra™ WP 5.5			
Handle for Guided Drill Guide	N/A	N/A	N/A	Guided Drill Guides

Table 2 – Compatibility of the Guided Surgery Rotary Instruments

Product Name	Hand Piece Connections	Product Name	Hand Piece Connections
Guided Start Drill/Counterb Bmk Syst NP	EN ISO 1797	Guided Twist Drill Tapered 2 x (10+) 8-16 mm	EN ISO 1797
Guided Start Drill/Counterbore NobRpl NP		Guided Start Drill	
Guided Start Drill/Counterb Bmk Syst RP		Guided Counterbore NobelReplace® 3.5	
Guided Start Drill/Counterbore NobRpl RP		Guided Counterbore NobelReplace® 4.3	
Guided Start Drill/Counterb BmkSyst WP Ø 5		Guided Counterbore NobelReplace® 5.0	
Guided Start Drill/Counterbore NobRpl WP		Guided Counterbore NobelReplace® 6.0	
Guided Start Drill/Counterb BmkSyst WP Ø 6		Guided ScrewTap Tapered NP	
Guided Start Drill/Counterb NobRpl 6.0		Guided Pilot Twist Drill 1.5 x (10+) 10-15 mm	
Guided Twist Drill 2 x (10+) 7-18 mm		Guided Twist Step Drill 4.2/5.0 (10+) 7-13 mm	
Guided Twist Drill 2.8 x (10+) 7-18 mm		Guided Twist Step Drill 4.2/5.0 (10+) 7-18 mm	
Guided Twist Drill 3 x (10+) 7-18 mm		Guided Screw Tap NobelActive® WP 5.5 7-8.5 mm	
Guided Twist Drill 3.2 x (10+) 7-18 mm		Guided Screw Tap NobelActive® WP 5.5 10-15 mm	
Guided Twist Drill 3.4 x (10+) 7-18 mm		Guided Twist Step Drill Ø4.2/4.6 x (10+) 7-18 mm	
Guided Twist Drill 3.8 x (10+) 7-18 mm		Guided Screw Tap NobelParallel™ CC 3.75 7-10 mm	
Guided Twist Drill 4.2 x (10+) 7-18 mm		Guided Screw Tap NobelParallel™ CC 3.75 11.5-13 mm	
Guided Twist Drill 5 x (10+) 7-18 mm		Guided Screw Tap NobelParallel™ CC 3.75 15-18 mm	
Guided Dense Bone Drill Taper NP 3.5 x 13 mm		Guided Screw Tap NobelParallel™ CC 4.3 7-10 mm	
Guided Dense Bone Drill Taper NP 3.5 x 16 mm		Guided Screw Tap NobelParallel™ CC 4.3 11.5-13 mm	
Guided Dense Bone Drill Taper RP 4.3 x 13 mm		Guided Screw Tap NobelParallel™ CC 4.3 15-18 mm	
Guided Dense Bone Drill Taper RP 4.3 x 16 mm		Guided Screw Tap NobelParallel™ CC 5.0 7-10 mm	
Guided Dense Bone Drill Taper WP 5 x 13 mm		Guided Screw Tap NobelParallel™ CC 5.0 11.5-13 mm	
Guided Dense Bone Drill Taper WP 5 x 16 mm		Guided Screw Tap NobelParallel™ CC 5.0 15-18 mm	
Guided Dense Bone Drill Taper 6.0 6 x 13 mm		Guided Screw Tap NobelParallel™ CC 5.5 7-10 mm	
Guided Dense Bone Drill Taper 6.0 6 x 16 mm		Guided Screw Tap NobelParallel™ CC 5.5 11.5-13 mm	
Guided Screw Tap NP 10-13 mm		Guided Screw Tap NobelParallel™ CC 5.5 11.5-15 mm	
Guided Screw Tap RP Ø 3.75 7-13 mm		Guided Tissue Punch NP-sleeve (3.75)	
Guided Screw Tap Tapered RP		Guided Tissue Punch WP-sleeve (5.5)	
Guided Screw Tap WP Ø 5 7-13 mm		Guided Counterbore NobelParallel™ CC 3.75	
Guided Screw Tap Tapered WP		Guided Counterbore NobelParallel™ CC 4.3	
Guided Screw Tap 6.0/WP Ø 6 7-13 mm		Guided Counterbore NobelParallel™ CC 5.0	
Guided Screw Tap Tapered 6.0		Guided Counterbore NobelParallel™ CC 5.5	
Guided StartDrill/Countb former MkIII RP		Guided Dense Bone Screw Tap NobelActive® NP 8.5-18 mm	
Guided Screw Tap RP Ø 4 7-13 mm		Guided Dense Bone Screw Tap NobelActive® RP 4.3 8.5-18 mm	
Guided Twist Drill 3.2 x (10+) 7-13 mm		Guided Dense Bone Screw Tap NobelActive® RP 5.0 8.5-18 mm	
Guided Twist Drill 3.4 x (10+) 7-13 mm		Guided Dense Bone Screw Tap NobelActive® WP 5.5 7-8.5 mm	
Guided Twist Drill 3.8 x (10+) 7-13 mm		Guided Dense Bone Screw Tap NobelActive® WP 5.5 10-15 mm	
Guided Twist Drill 4.2 x (10+) 7-13 mm		Guided Drill Tapered NP	
Guided Twist Drill 5 x (10+) 7-13 mm		Guided Drill Tapered RP	
Guided Twist Step Drill Ø 2.4/2.8 (10+) 7-13 mm		Guided Drill Tapered WP	
Guided Twist Step Drill Ø 2.8/3.2 (10+) 7-13 mm		Guided Drill Tapered 6.0	
Guided Twist Step Drill Ø 3.2/3.6 (10+) 7-13 mm			
Guided Twist Step Drill Ø 3.8/4.2 (10+) 7-13 mm			
Guided Twist Step Drill Ø 4.2/4.6 (10+) 7-13 mm			
Guided Twist Step Drill Ø 2.4/2.8 (10+) 7-18 mm			
Guided Twist Step Drill Ø 2.8/3.2 (10+) 7-18 mm			
Guided Twist Step Drill Ø 3.2/3.6 (10+) 7-18 mm			
Guided Twist Step Drill Ø 3.8/4.2 (10+) 7-18 mm			
Guided Screw Tap NobelActive® NP 8.5-10 mm			
Guided Screw Tap NobelActive® RP 4.3 8.5-10 mm			
Guided Screw Tap NobelActive® RP 5.0 8.5-10 mm			

The following components are used in guided surgical procedures but are used for other applications and are therefore described in separate IFU. Refer to the referenced IFU for further information regarding these components.

- The Unigrip™ Screwdriver is used to manually tighten and loosen screws with a Unigrip™ interface, which are used to fix dental restorations onto Nobel Biocare dental implants. Refer to Nobel Biocare IFU1085 for more information regarding the Unigrip™ screwdriver.
- Guided Anchor Pins are thin rods of stainless steel positioned close to horizontally into the jawbone in order to secure the template in its defined position during surgery. Refer to Nobel Biocare IFU2001 for more information regarding Guided Anchor Pins.
- Manual Torque Wrench Surgical is used to insert and tighten Nobel Biocare implants as an alternative to machine tightening. Refer to Nobel Biocare IFU1098 for more information regarding the Manual Torque Wrench Surgical.
- Manual Torque Wrench Prosthetic is used to insert and tighten Nobel Biocare abutments and abutment screws as an alternative to machine tightening. Refer to Nobel Biocare IFU1098 for more information regarding the Manual Torque Wrench Prosthetic.
- The Torque Wrench Prosthetic Adapter is used to connect the Screwdriver Machine Unigrip™ and Omnigrip™ Screwdriver to the Manual Torque Wrench Prosthetic. Refer to Nobel Biocare IFU1098 for more information regarding the Torque Wrench Prosthetic Adapter.
- The Connection to Handpiece is used to connect the implant mount/implant assembly to the handpiece. Refer to Nobel Biocare IFU1090 for more information regarding the Connection to Handpiece.

* Class I device; see applicable CE Mark (CE 2797) after the Manufacturer and Distributor Information.

** Class IIa device; see applicable CE Mark (CE 2797) after the Manufacturer and Distributor Information.

Guided surgery tooling is available in Instrument bundles (as well as separate instruments) for use with the following Nobel Biocare implant platforms:

- NobelParallel™ CC Guided PureSet for the placement of NobelParallel™ CC and NobelParallel™ CC TiUltra™ implants.
- NobelActive® Guided PureSet for the placement of NobelActive® and NobelActive® TiUltra™ implants.
- NobelReplace® CC Guided PureSet for the placement of NobelReplace® CC and NobelReplace® CC TiUltra™ implants.

Guided surgery tooling for use with the following Nobel Biocare implant platforms is available as separate instruments; refer to the respective Surgical Procedure in this IFU for the list of tooling compatible with each implant platform:

- NobelReplace® Tapered.
- Replace Select™ Tapered.
- Brånemark System® (Brånemark System® Mk III Groovy and Brånemark System® Mk III TiUnite® RP).
- NobelSpeedy® Groovy.

Intended Use/Intended Purpose

Guided Drill Guides, Guided Drill Guides Tapered, and the Handle for Guided Drill Guide

Intended for use to guide drilling instruments during preparation of an osteotomy.

Guided Implant Mounts

Intended for use to insert or remove dental implants during dental implant surgery.

Guided Template Abutments

Intended for use during dental implant surgery to secure a surgical template or guide in its specified position.

Guided Tissue Punches

Intended for use during guided dental implant surgery to remove a circular area of soft tissue prior to preparation of an osteotomy.

Guided Start Drills/Counterbores, Guided Pilot Twist Drill, Guided Twist Drills, Guided Twist Step Drills, the Guided Twist Drill Tapered, Guided Drills Tapered, Guided Dense Bone Drills Tapered, Guided Screw Taps, Guided Screw Taps Tapered, Guided Dense Bone Screw Taps, and Guided Counterbores

Intended for use to prepare or support the preparation of an osteotomy for placement of an endosseous dental implant.

Indications

Nobel Biocare Guided Surgery Tooling indicated for use to support guided preparation of an osteotomy, to facilitate placement of endosseous dental implants and implant system components intended to restore chewing function.

The following patient prerequisites must be fulfilled:

- Adequate amount and quality of jaw bone.
- Adequate mouth opening (minimum 40 mm) to accommodate guided surgery tooling.

Guided Drill Guides and Guided Drill Guides Tapered

Guided Drill Guides and Guided Drill Guides Tapered are indicated to be inserted into the Guided Sleeves embedded in a dental surgical template to facilitate the preparation of an osteotomy in the maxilla or mandible during guided dental implant surgery, according to the position, direction and the height/depth defined according to the surgical plan.

Handle for Guided Drill Guide

The Handle for Guided Drill Guide is indicated for use to extend the existing handle on Guided Drill Guides to facilitate handling of the drill guides during guided dental implant surgery.

Guided Implant Mounts

Guided Implant Mounts are indicated for use during guided dental implant surgery to facilitate the insertion of the implant through the Guided Sleeves embedded in the surgical template and into the osteotomy.

Guided Template Abutments

Guided Template Abutments are indicated for use during guided dental implant surgery in the maxilla or mandible, in partially edentulous and edentulous situations, as a replacement for the Guided Implant Mount, to fix the surgical template in the correct

position when preparing and placing the remaining implants, and to facilitate removal of the surgical template after surgery.

Guided Tissue Punches

Guided Tissue Punches are indicated for use during flapless guided dental implant surgery in the maxilla or mandible to cleanly remove soft tissue from the surgical site prior to preparing an osteotomy.

Guided Start Drills

Guided Start Drills are indicated for use during guided dental implant surgery in the maxilla or mandible, prior to using the 1.5 mm Guided Pilot Twist Drill or the 2 mm Guided Twist Drill to prepare the entrance point for an osteotomy in uneven bone or in pointed bone, including "knife-edge ridge" and fresh extraction alveolas.

Guided Twist Drills, Guided Pilot Twist Drills, Guided Twist Step Drills, Guided Twist Drill Tapered, and Guided Drills Tapered

Guided Twist Drills, Guided Pilot Twist Drills, Guided Twist Step Drills, Guided Twist Drill Tapered, and Guided Drills Tapered are indicated for use during guided dental implant surgery in the maxilla or mandible to prepare an osteotomy for the placement of an endosseous dental implant.

Guided Dense Bone Drills Tapered

Guided Dense Bone Drills Tapered are indicated for use during guided dental implant surgery in the maxilla or mandible in to prepare an osteotomy in dense bone for the placement of an endosseous dental implant.

Guided Screw Taps, Guided Screw Taps Tapered, and Guided Dense Bone Screw Taps

Guided Screw Taps, Guided Screw Taps Tapered, and Guided Dense Bone Screw Taps are indicated for use during guided dental implant surgery in the maxilla or mandible to cut threads in an osteotomy in order to reduce the insertion torque necessary to place an endosseous dental implant in dense bone.

Guided Counterbores

Guided Counterbores are indicated for use to remove bone from around the crest of the bone in order to reduce compression around the neck of the implant and prevent the Guided Screw Tap and Guided Implant Mount from colliding with the bone.

Guided Start Drills/Counterbores

Guided Start Drills/Counterbores are indicated for use to remove bone from around the crest of the bone in order to reduce compression around the neck of the implant and prevent the Guided Screw Tap and Guided Implant Mount from colliding with the bone.

Contraindications

It is contraindicated to use Nobel Biocare Guided Surgery Tooling in:

- Patients who are medically unfit for an oral surgical procedure.
- Patients in whom adequate sizes, numbers or desirable position of implants are not achieved to provide safe support of functional or eventually parafunctional loads.
- Patients with inadequate bone volume unless an augmentation procedure can be performed.
- Patients with inadequate mouth opening (minimum 40 mm) to accommodate guided surgery tooling.
- Patients allergic or hypersensitive to titanium alloy Ti-6Al-4V (90% titanium, 6% aluminum, 4% vanadium), stainless steel, silicone, DLC (Diamond Like Carbon) coating, or surgical template material acrylate-based photopolymer.

Materials

- Guided Counterbore Brånemark System®, NobelReplace®, NobelParallel™, Guided Start Drill
 - Stainless steel 1.4197/AISI420F Mod according to ASTM F899 or stainless steel 1.4542/AISI 630 according to ASTM F899 and DLC (Diamond Like Carbon) coating.
- Guided Counterbore NobelReplace® 3.5
 - Stainless steel 1.4542/AISI 630 according to ASTM F899, silicone GE 50S5289 50 Duro, and DLC (Diamond Like Carbon) coating.
- Guided Counterbore NobelReplace® 4.3
 - Stainless steel 1.4542/AISI 630 according to ASTM F899, silicone GE 50S5288 50 Duro, and DLC (Diamond Like Carbon) coating.
- Guided Counterbore NobelReplace® 5.0
 - Stainless steel 1.4542/AISI 630 according to ASTM F899, silicone GE 50S5286 50 Duro, and DLC (Diamond Like Carbon) coating.
- Guided Counterbore NobelReplace® 6.0
 - Stainless steel 1.4542/AISI 630 according to ASTM F899, silicone GE 50S5285 50 Duro, and DLC (Diamond Like Carbon) coating.
- Guided Counterbore NobelParallel® CC
 - Stainless steel 1.4197/AISI420F Mod according to ASTM F899 and DLC (Diamond Like Carbon) coating.
- Guided Twist Drills
 - Stainless steel 1.4197/AISI420F Mod according to ASTM F899 with DLC (Diamond Like Carbon) coating.
- Guided Template Abutments Body
 - Stainless steel 1.4197/AISI420F Mod according to ASTM F899
- Guided Template Abutments Screw
 - Stainless steel 1.4197/AISI420F Mod according to ASTM F899
- Handle for Guided Drill Guide
 - Stainless steel 1.4301/AISI 304 austenitic steel according to ASTM F899.
- Guided Drill Guides
 - Stainless steel 1.4441 LA according to ASTM F138 and stainless steel 1.4301/AISI 304 austenitic steel according to ASTM F899.
- Guided Dense Bone Drills Tapered NP
 - Stainless steel 1.4542/AISI 630 according to ASTM F899, silicone GE 50S5289 50 Duro, and DLC (Diamond Like Carbon) coating or stainless steel 1.4542/AISI 630 according to ASTM F899
- Guided Dense Bone Drills Tapered RP
 - Stainless steel 1.4542/AISI 630 according to ASTM F899, silicone GE 50S5288 50 Duro, and DLC (Diamond Like Carbon) coating.
- Guided Dense Bone Drills Tapered WP
 - Stainless steel 1.4542/AISI 630 according to ASTM F899, silicone GE 50S5286 50 Duro, and DLC (Diamond Like Carbon) coating.

- Guided Dense Bone Drills Tapered 6.0
 - Stainless steel 1.4542/AISI 630 according to ASTM F899, silicone GE 50S5285 50 Duro, and DLC (Diamond Like Carbon) coating.
- Guided Screw Tap
 - Stainless Steel 1.4197/420F Mod according to ASTM A895/ ASTM F899 or stainless steel 1.4543 GG according to ASTM F899 with DLC (Diamond Like Carbon) coating.
- Guided Implant Mounts Body
 - Titanium alloy Ti-6Al-4V (90% titanium, 6% aluminum, 4% vanadium) according to ASTM F136 and ISO 5832-3.
- Guided Implant Mounts Screw
 - Titanium alloy Ti-6Al-4V (90% titanium, 6% aluminum, 4% vanadium) according to ASTM F136 and ISO 5832-3.
- Guided Drill Guide Tapered
 - Stainless steel 1.4301/AISI 304 austenitic steel according to ASTM F899 and stainless steel 1.4441 LA according to ASTM F138.
- Guided Twist Drill Ø 1.5 x 20 mm
 - Stainless Steel 1.4197/420F Mod according to ASTM A895/ASTM F899.
- Guided Twist Drills
 - Stainless Steel 1.4197/420F Mod according to ASTM A895/ASTM F899 with DLC (Diamond Like Carbon) coating.
- Guided Twist Step Drills
 - Stainless Steel 1.4197/420F Mod according to ASTM A895/ASTM F899 with DLC (Diamond Like Carbon) coating.
- Guided Drill Tapered
 - Stainless Steel 1.4197/AISI420F Mod according to ASTM F899 and DLC (Diamond Like Carbon) coating.
- Guided Implant Mounts Body NobelActive® and NobelParallel®
 - Stainless Steel according to ASTM F899.
- Guided Implant Mounts Screw
 - Titanium alloy Ti-6Al-4V (90% titanium, 6% aluminum, 4% vanadium) according to ASTM F136 and ISO 5832-3.
- Guided Tissue Punch
 - Stainless steel 1.4542/AISI 630 according to ASTM F899.
- Guided Pilot Twist Drills
 - Stainless steel 1.4197/AISI420F Mod according to ASTM F899 and DLC (Diamond Like Carbon) coating.
- Guided Screw Tap
 - Stainless steel 1.4197/AISI420F Mod according to ASTM F899 and DLC (Diamond Like Carbon) coating.
- Guided Dense Bone Screw Tap
 - Stainless steel 1.4197/AISI420F Mod according to ASTM F899 and DLC (Diamond Like Carbon) coating.
- Guided Drill Tapered NP
 - Stainless steel 1.4542/AISI 630 according to ASTM F899, silicone GE 50S5289 50 Duro, and DLC (Diamond Like Carbon) coating.
- Guided Drill Tapered RP
 - Stainless steel 1.4542/AISI 630 according to ASTM F899, silicone GE 50S5288 50 Duro, and DLC (Diamond Like Carbon) coating.
- Guided Drill Tapered WP

- Stainless steel 1.4542/AISI 630 according to ASTM F899, silicone GE 50S5286 50 Duro, and DLC (Diamond Like Carbon) coating.

- Guided Drill Tapered 6.0
 - Stainless steel 1.4542/AISI 630 according to ASTM F899, silicone GE 50S5285 50 Duro, and DLC (Diamond Like Carbon) coating.

Warnings

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.

Cautions

General Cautions

One hundred percent implant success cannot be guaranteed. In particular, non-observance of the product's indications for use and the surgical/handling procedure(s) may result in failure.

Treatment by means of implants may lead to loss of bone, biologic or mechanical failures including fatigue fracture of implants.

Close cooperation between surgeon, restorative dentist and dental laboratory technician is essential for a successful implant treatment.

Nobel Biocare Guided Surgery Tooling must only be used with compatible Nobel Biocare instruments and/or components and/or prosthetic components. Use of instruments and/or components and/or prosthetic components that are not intended to be used in combination with Nobel Biocare Guided Surgery Tooling can lead to product failure, damage to tissue, or unsatisfactory esthetic results.

When using a new device/treatment method for the first time, working with a colleague who is experienced with the new device/treatment method may help avoid possible complications. Nobel Biocare has a global network of mentors available for this purpose.

It is especially important to achieve proper stress distribution through adaptation and fitting of the crown or bridge, by adjusting the occlusion to the opposing jaw. In addition, avoid excessive transverse loading forces, particularly in immediate loading cases.

Before Surgery

Careful psychological and physiological evaluation, followed by clinical and radiological examination must be performed on the patient prior to surgery to determine the suitability of the patient for treatment.

Special attention must be given to patients who have local or systemic factors that could interfere with the healing process of either bone or soft tissue or the osseointegration process (e.g. cigarette smoking, poor oral hygiene, uncontrolled diabetes, orofacial radiotherapy, steroid therapy, infections in the neighboring bone). Special caution is advised in patients who receive bisphosphonate therapy.

In general, implant placement and prosthetic design must accommodate individual patient conditions. In case of bruxism, other parafunctional habits or unfavorable jaw relationships, reappraisal of the treatment option may be considered.

The devices have not been evaluated in pediatric/adolescent patients and are not recommended for use in children. Routine treatment is not recommended until the end of the juvenile jaw bone growth phase has been properly documented.

Pre-operative hard tissue or soft tissue deficits may yield a compromised esthetic result or unfavorable implant angulations.

All components, instruments and tooling used during the clinical and/or laboratory procedure must be maintained in good condition and care must be taken that instrumentation does not damage implants or other components.

Before performing guided surgery, the surgical template must be carefully inspected and cleared by the clinician performing the surgery. Optimal fit on stone model or in patient's mouth needs to be verified. If in doubt, please contact Nobel Biocare technical support.

At Surgery

Particular caution should be used when placing narrow platform implants in the posterior region due to risk of prosthetic overload.

Care and maintenance of sterile instruments are crucial for a successful treatment. Sterilized instruments not only safeguard your patients and staff against infection but are also essential for the outcome of the total treatment.

Because of the small sizes of the devices, care must be taken that they are not swallowed or aspirated by the patient. It is appropriate to use specific supporting tools to prevent aspiration of loose parts (e.g. gauze, dental dam, or throat shield).

After the implant placement, the surgeon's evaluation of bone quality and primary stability will determine when implants may be loaded. Lack of adequate quantity and/or quality of remaining bone, infection and generalized diseases may be potential causes for failure of osseointegration both immediately after surgery, or after osseointegration is initially achieved.

If modifying the restoration, use copious irrigation and appropriate protection equipment. Avoid inhalation of dust.

After Surgery

To help ensure a successful long term-treatment outcome, it is advised to provide comprehensive regular patient follow up after implant treatment and to inform the patient about appropriate oral hygiene.

Intended Users and Patient Groups

- Nobel Biocare Guided Surgery Tooling is to be used by dental health care professionals.
- Nobel Biocare Guided Surgery Tooling is to be used in patients subject to dental implant treatment.

Clinical Benefits and Undesirable Side Effects

Clinical Benefits Associated with Nobel Biocare Guided Surgery Tooling

Nobel Biocare guided surgery tooling is a component of treatment with a dental implant system and/or dental crowns and bridges.

As a clinical benefit of treatment, patients can expect to have their missing teeth replaced and/or crowns restored.

Undesirable Side Effects Associated with Nobel Biocare Guided Surgery Tooling

The use of Nobel Biocare guided surgery tooling is part of an invasive treatment which may be associated with typical side effects such as bone necrosis, inflammation, infection, bleeding, hematoma, pain, swelling. Depending on its location of use it may, in rare cases, lead to fenestration or fracture of bone, damage/perforation of neighboring structures/restorations, sinusitis, or sensory/motor disturbances. During use of these devices, the pharyngeal (gag) reflex may be triggered in patients with a sensitive gag reflex.

Notice regarding serious incidents

For a patient/user/third party in the European Union and in countries with an identical regulatory regime (Regulation 2017/745/EU on Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and to your national authority. The contact information for the manufacturer of this device to report a serious incident is as follows:

Nobel Biocare AB
www.nobelbiocare.com/complaint-form

Surgical Procedure and Handling Procedures

NobelParallel™ CC Guided Surgery Tooling

1. If applicable, anchor the surgical template using an adequate number of anchor pins placed with strategic positioning and orientation to secure the surgical template in the correct position. During surgery maximum attention must be paid to secure the surgical template is in the correct position in the patient's mouth and that it does not move in any direction from the correct position when being manipulated with instruments (e.g. lateral shift through inadequate handling of twist drills in "knife-edge ridge" situations or shift/deformation of surgical template due to excessive vertical force application during implant installation). In situations where two or more neighboring implants are placed, regardless if it is a free-end situation or a situation with one or more distal teeth for support of the surgical template, it is recommended to use at least one anchor pin in this area. If necessary, place implants in a staggered approach.
2. If a flapless procedure is chosen, it is recommended to use the Guided Soft Tissue Punch before any other instruments are used to generate a clean cut. The surgical template can be temporarily detached after punching to carefully remove the punched soft tissue. The surgical template is carefully repositioned and the anchor pins replaced into the existing anchorage holes in the bone. If a (mini) flap procedure is chosen, it is recommended that the surgical template is first positioned and the anchor pins placed prior to any manipulations of the soft tissue. Remove the anchor pins and surgical template, perform the incision, respecting the position of the implants and elevate the flap. If required, carefully modify the surgical template by relieving as much material as required to accommodate the flap, rinsing with sterile saline solution prior to carefully repositioning.
3. During drilling procedures bone quality should be considered. (See Table 3 for recommended drill sequences based on bone quality to ensure optimal primary stability when applying Immediate Function). Use the Guided Start Drill prior to the Guided Twist Drill 2 mm (with the appropriate Guided Drill Guide to Ø 2 mm) to create a start point for

the following drill. Then select the appropriate Guided Drill Guide based on the sleeve size and the Guided Twist/Step Drill. The Handle for Guided Drill Guide can be used for easier handling of the Guided Drill Guide. Drilling must proceed at high speed (maximum 800 rpm for Guided Twist/Step Drills) under constant and profuse external irrigation with sterile saline solution. An in-and-out drilling motion, over the complete extent of the osteotomy is needed when preparing the site to avoid overheating. The Drill Extension Shaft can be used if required for easier access.

Table 3 – Recommended Drill Sequence for NobelParallel™ CC Implants Based on Bone Quality*

Implant Diameter	Soft Bone (Type IV)	Medium Bone (Type II-III)	Dense Bone (Type I)
Ø 3.75	2.0 #2 (2.4/2.8) (#3)	2.0 #2 2.4/2.8 #3 Guided Counterbore 3.75 C (Guided Screw Tap 3.75) (S)	2.0 #2 2.4/2.8 #3 2.8/3.2 #4 Guided Counterbore 3.75 C Guided Screw Tap 3.75 S
Ø 4.3	2.0 #2 2.4/2.8 #3 (3.2/3.6) (#5)	2.0 #2 2.4/2.8 #3 3.2/3.6 #5 Guided Counterbore 4.3 C (Guided Screw Tap 4.3) (S)	2.0 #2 2.4/2.8 #3 3.2/3.6 #5 Guided Counterbore 4.3 C Guided Screw Tap 4.3 S
Ø 5.0	2.0 #2 2.4/2.8 #3 3.2/3.6 #5 (3.8/4.2) (#6)	2.0 #2 2.4/2.8 #3 3.2/3.6 #5 3.8/4.2 #6 Guided Counterbore 5.0 C (Guided Screw Tap 5.0) (S)	2.0 #2 2.4/2.8 #3 3.2/3.6 #5 3.8/4.2 #6 Guided Counterbore 5.0 C Guided Screw Tap 5.0 S
Ø 5.5	2.0 #2 2.4/2.8 #3 3.2/3.6 #5 4.2/4.6 #7 (4.2/5.0) (#8)	2.0 #2 2.4/2.8 #3 3.2/3.6 #5 4.2/5.0 #8 Guided Counterbore 5.5 C (Guided Screw Tap 5.5) (S)	2.0 #2 2.4/2.8 #3 3.2/3.6 #5 4.2/5.0 #8 Guided Counterbore 5.5 C Guided Screw Tap 5.5 S

*Drill data are presented in mm. Drill diameters listed within parentheses (-) denote widening of cortex only.

Caution Guided Twist/Step Drills are identified by the (10+) designation on the shaft. This indicates the drills are 10 mm longer than the “freehand” Twist/Step Drills to compensate for the height of the surgical template and the Guided Drill Guide. The depth marks on the Guided Twist/Step Drills correspond to 7, 10, and 13 mm implants for 7–13 mm drills and 7, 10, 13, 15 and 18 mm for 7–18 mm drills (Figure A). The level should be measured with the Guided Drill Guide in place. Drills extend 1 mm longer than the implant when seated. Allow for this additional length when drilling near vital anatomical structures.

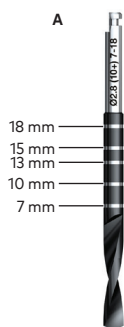
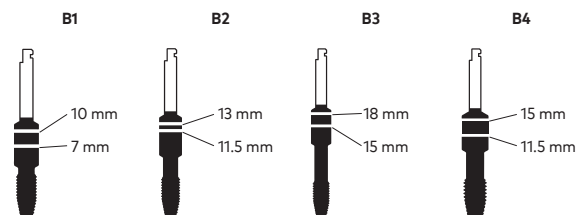


Figure A – Depth Marks on the Guided Twist/Step Drills

- Prepare implant site.
- Medium and dense bone protocol: to be used when implant will not be fully seated.
 - Select the Guided Counterbore matching the diameter of the implant. Place the Guided Counterbore directly in the guided sleeve of the surgical template and drill to the built-in drill stop at maximum speed of 800 rpm with copious irrigation.
 - For dense bone situations (and optionally for medium bone), select the Guided Screw Tap matching the diameter and length of the implant. To select an appropriate Guided Screw Tap, place into prepared implant site using low speed (25 rpm), applying firm pressure. When the threads engage, allow Guided Screw Tap to feed without pressure to appropriate depth. Figure B1 shows depth markings which correspond to full depth tapping of 7 mm and 10 mm for Ø 3.75, Ø 4.3, Ø 5.0 and Ø 5.5 implants. Figure B2 shows depth markings which correspond to full depth tapping of 11.5 mm and 13 mm for Ø 3.75, Ø 4.3, Ø 5.0 and Ø 5.5 implants. Figure B3 shows depth markings which correspond to full depth tapping of 15 mm and 18 mm for Ø 3.75, Ø 4.3 and Ø 5.0 implants only and Figure B4 shows depth markings which correspond to full depth tapping of 11.5 mm and 15 mm for Ø 5.5 implants only.
 - Switch the drill device to reverse mode and remove the Guided Screw Tap.



Figures B1 – B4 – Depth Marks on Guided Screw Taps

- Open the implant package. Connect the Guided Implant Mount NobelParallel™ CC to the implant using the Unigrip™ Screwdriver. Insert the Connection to Handpiece in the drilling unit handpiece and pick up the mounted implant. NobelParallel™ CC implants are ideally installed with low speed, maximum 25 rpm, using the drilling device. Place and tighten the implant using maximum 45 Ncm installation torque. Stop tightening the implant when the Guided Implant Mount touches the surgical template. The Guided Implant Mount NobelParallel™ CC includes a vertical stop. Ensure that the Guided Implant Mount is kept in the center of the guided sleeve during the entire insertion process.

Caution Never exceed insertion torque of 45 Ncm for NobelParallel™ CC Implants. Over tightening an implant may lead to damage of the implant, fracture or necrosis of the bone site.

- If the implant gets stuck during implant installation or 45 Ncm is achieved before fully seated, rotate the implant counterclockwise using the drilling device (reverse mode) or the Manual Torque Wrench and remove from the site. Replace the implant in the inner casing before proceeding further (refer to the Medium and dense bone protocol section). Without removing the surgical template, continue with implant installation until desired position is achieved. For Immediate Function, the implant should be able to withstand a final torque of 35–45 Ncm.
- In partially edentulous and edentulous situations it is recommended to use Guided Template Abutments implants instead of Guided Implant Mounts on the first 1 or 2 implant sites. Release the Guided Implant Mount using the Unigrip™ Screwdriver and remove the implant mount. Anchor the surgical template using the Guided Template Abutment, tightening manually using the Unigrip™

Screwdriver. Ensure the surgical template maintains its initial correct position for the next implant site preparation.

9. Prepare and install the remaining implant sites.
10. Once all implants are installed, remove Guided Implant Mounts and Guided Template Abutments using the Unigrip™ Screwdriver. Remove anchor pins, if applicable and remove the surgical template.
11. Final implant installation torque can be measured following surgical template removed using the Torque Wrench Surgical.
12. Depending on the surgical protocol of choice, place a cover screw using the Unigrip™ Screwdriver or an abutment using the Torque Wrench Prosthetic Adapter and suture. Refer to the applicable Nobel Biocare IFU for more information regarding abutments and cover screws.

For additional information on the NobelParallel™ CC implant refer to Nobel Biocare IFU1002.

Surgical Procedure: NobelActive® Guided Surgery Tooling

1. If applicable, anchor the surgical template using an adequate number of anchor pins placed with strategic positioning and orientation to secure the surgical template in the correct position. During surgery maximum attention must be paid to secure the surgical template is in the correct position in the patient's mouth and that it does not move in any direction from the correct position when being manipulated with instruments (e.g. lateral shift through inadequate handling of twist drills in "knife-edge ridge" situations or shift/deformation of surgical template due to excessive vertical force application during implant installation). In situations where two or more neighboring implants are placed, regardless if it is a free-end situation or a situation with one or more distal teeth for support of the surgical template, it is recommended to use at least one anchor pin in this area. If necessary, place implants in a staggered approach.
2. If a flapless procedure is chosen, it is recommended to use the Guided Soft Tissue Punch before any other instruments are used to generate a clean cut. The surgical template can be temporarily detached after punching to carefully remove the punched soft tissue. The surgical template is carefully repositioned, and the anchor pins replaced into the existing anchorage holes in the bone. If a (mini-) flap procedure is chosen, it is recommended that the surgical template is first positioned, and the anchor pins placed prior to any manipulations of the soft tissue. Remove the anchor pins and surgical template, perform the incision, respecting the position of the implants and elevate the flap. If required, carefully modify the surgical template by relieving as much material as required to accommodate the flap, rinsing with sterile saline solution prior to carefully repositioning.
3. During drilling procedures bone quality should be considered. (See Table 4 for recommended drill sequences based on bone quality to ensure optimal primary stability when applying Immediate Function). Use the Guided Start Drill prior to the Guided Twist Drill 2 mm (with the appropriate Guided Drill Guide to Ø 2 mm) to create a start point for the following drill. Then select the appropriate Guided Drill Guide based on the sleeve size and the Guided Twist/Step Drill. The Handle for Guided Drill Guide can be used for easier handling of the Guided Drill Guide. Drilling must proceed at high speed (maximum 800 rpm for Guided Twist/Step Drills) under constant and profuse external irrigation with sterile saline solution. An in-and- out drilling motion, over the complete extent of the osteotomy is needed when preparing the site to avoid overheating. The Drill Extension Shaft can be used if required for easier access.

Note Screw tapping is a mandatory step for guided implant insertion.

Table 4 – Recommended Drill Sequence for NobelActive® Implants Based on Bone Quality*

Implant Diameter	Soft Bone (Type IV)	Medium Bone (Type II-III)	Dense Bone (Type I)
Ø 3.5	2.0 #2 (2.4/2.8) (#3) Guided Screw Tap 3.5 S	2.0 #2 2.4/2.8 #3 (2.8/3.2) #4 Guided Screw Tap 3.5 S	2.0 #2 2.4/2.8 #3 2.8/3.2 #4 Guided Dense Bone Screw Tap 3.5 S
Ø 4.3	2.0 #2 2.4/2.8 #3 (2.8/3.2) (#4) Guided Screw Tap 4.3 S	2.0 #2 2.4/2.8 #3 3.2/3.6 #5 Guided Screw Tap 4.3 S	2.0 #2 2.4/2.8 #3 3.2/3.6 #5 (3.8/4.2) (#6) Guided Dense Bone Screw Tap 4.3 S
Ø 5.0	2.0 #2 2.4/2.8 #3 3.2/3.6 #5 Guided Screw Tap 5.0 S	2.0 #2 2.4/2.8 #3 3.2/3.6 #5 3.8/4.2 #6 Guided Screw Tap 5.0 S	2.0 #2 2.4/2.8 #3 3.2/3.6 #5 3.8/4.2 #6 (4.2/4.6) (#7) Guided Dense Bone Screw Tap 5.0 S
Ø 5.5	2.0 #2 2.4/2.8 #3 3.2/3.6 #5 (3.8/4.2) #6 Guided Screw Tap 5.5 S	2.0 #2 2.4/2.8 #3 3.2/3.6 #5 3.8/4.2 #6 4.2/4.6 #7 (4.2/5.0) (#8) Guided Screw Tap 5.5 S	2.0 #2 2.4/2.8 #3 3.2/3.6 #5 3.8/4.2 #6 4.2/5.0 #8 Guided Screw Tap 5.5 S

* Drill data are presented in mm. Drill diameters listed within parentheses (-) denote widening of cortex only.

Caution Guided Twist/Step Drills are identified by the (10+) designation on the shaft. This indicates the drills are 10 mm longer than the "freehand" Twist/Step Drills to compensate for the height of the surgical template and the Guided Drill Guide. The depth marks on the Guided Twist/Step Drills correspond to 7, 10, and 13 mm implants for 7-13 mm drills and 7, 10, 13, 15, and 18 mm for 7-18 mm drills (Figure C). The level should be measured with the Guided Drill Guide in place. Drills extend 1 mm longer than the implant when seated (Figure D). Allow for this additional length when drilling near vital anatomical structures.

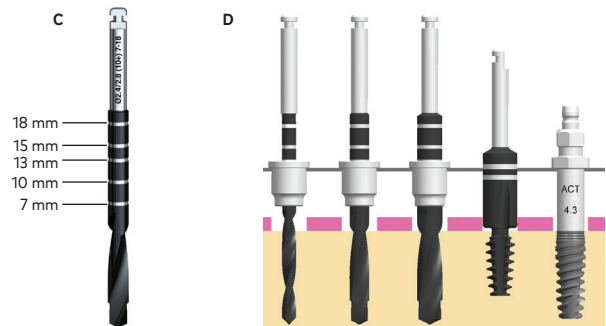


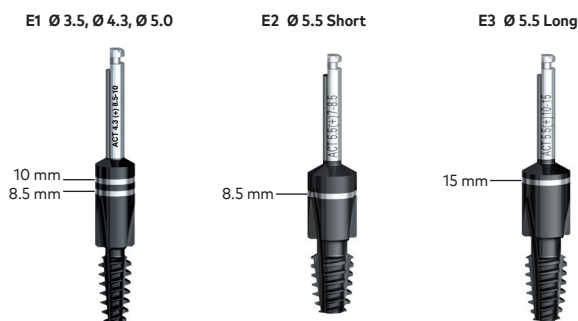
Figure C – Depth marks on drills

Figure D – Drill extension

4. Prepare implant site as previously indicated.
5. Following preparation of the osteotomy using the Guided Twist/Step Drills, it is mandatory to use the Guided Screw Tap.

Soft and medium bone -use the Guided Screw Tap (see Table 4 for recommended screw taps). Select the Guided Screw Tap NobelActive® matching the diameter of the implant. To select an appropriate Guided Screw Tap, place into prepared implant site using low speed (25 rpm), applying firm pressure. When the threads engage, allow Guided Screw Tap to feed without pressure to appropriate depth. Figure E1 shows Guided Screw Tap depth markings which correspond to full depth tapping of 8.5 mm and 10 mm for Ø 3.5, Ø 4.3 and Ø 5.0 implants. Figure E2 shows

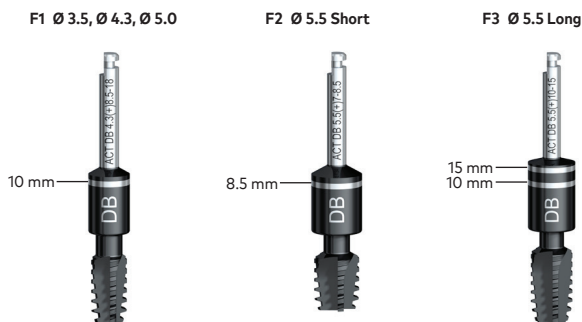
Guided Screw Tap depth markings which correspond to full depth tapping of 8.5 mm for Ø 5.5 implants. Figure E3 shows Guided Screw Tap depth markings which correspond to full depth tapping of 15 mm for Ø 5.5 implants.



Figures E1 – E3 – Depth Markings of Guided Screw Taps

Dense bone – use the Guided Dense Bone Screw Tap (see Table 4 for recommended screw taps), which are labeled with “DB” on the guiding cylinder. Select the Guided Dense Bone Screw Tap NobelActive® matching the diameter of the implant. To select an appropriate Guided Dense Bone Screw Tap, place into prepared implant site using low speed (25 rpm), applying firm pressure. When the threads engage, allow Guided Dense Bone Screw Tap to feed without pressure to appropriate depth. Figure F1 shows Guided Dense Bone Screw Tap depth markings which correspond to full depth tapping of 10 mm for Ø 3.5, Ø 4.3, and Ø 5.0 implants. Figure F2 shows Guided Dense Bone Screw Tap depth markings which correspond to full depth tapping of 8.5 mm for Ø 5.5 implants. Figure F3 shows Guided Dense Bone Screw Tap depth markings which correspond to full depth tapping of 10 mm and 15 mm for Ø 5.5 implants.

Note Depth of tapping using the Guided Screw Tap or Guided Dense Bone Screw Tap will depend on the bone quality. Tapping of just two to three threads (height of cortical bone) may be sufficient. Always consider tapping to full depth may not be possible due to anatomical constraints.



Figures F1 – F3 – Depth Markings of Guided Dense Bone Screw Taps

Warning Avoid early bone contact (Figure G). Before using the screw tap, the shape of the crest should be checked to avoid early collision between the upper half of the screw tap (with the largest diameter) and the bone. This might block the screw tap and jeopardize site preparation. Remove the bone to allow insertion of the screw tap.

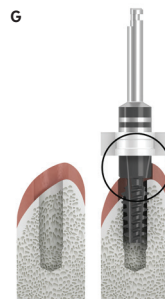
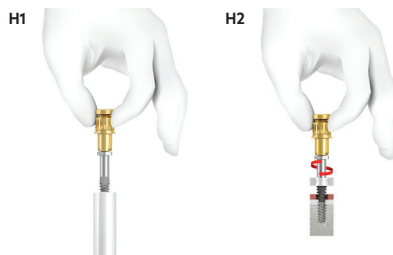


Figure G – Avoid Early Bone Contact with Screw Tap

- Open the implant package. Connect the Guided Implant Mount NobelActive® to the implant using the Unigrip™ Screwdriver. Pick up the mounted implant using the surgical Adapter from the Manual Torque Wrench Surgical (Figure H1). Perform the first turns of the insertion by hand. Start with a gentle left turn until you can feel the implant falling into the pre-tapped thread. Then turn right into the pre-tapped path. This technique makes it easier to find the correct pre-tapped path and optimize the accuracy of the implant placement (Figure H2).

Secure visually that the Guided Implant Mount is kept in the center of the guided sleeve during the entire insertion process.



Figures H1 and H2 – Using Surgical Adapter and Manual Torque Wrench Surgical to Start Placing Implant

- Remove the surgical adapter and continue with implant insertion using the Connection to Handpiece and drilling unit. NobelActive® implants must be installed with low speed, maximum 25 rpm using the drilling unit. For final implant insertion, use the Manual Torque Wrench to avoid implant over-tightening. The maximum insertion torque for the implant is 70 Ncm for NobelActive® Ø 3.5, Ø 4.3, Ø 5.0, and Ø 5.5 implants and may be measured with the NobelActive® Manual Torque Wrench Surgical. Stop tightening the implant when the Guided Implant Mount touches the surgical template.

Caution Never exceed insertion torque of 70 Ncm for NobelActive® Ø 3.5, Ø 4.3, Ø 5.0, and Ø 5.5 implants. Over tightening an implant may lead to damage of the implant, fracture or necrosis of the bone site.

Note The Guided Implant Mount NobelActive® includes a vertical stop. The implant mount body has the same outer diameter as the implant platform and therefore is smaller than that of the guided sleeve in the template sleeve (see Table 5 and Figure I). This makes it possible to plan and place the implants sub-crestally without the removal of additional bone on the neighboring crest only to allow for the implant mount diameter to pass. Additionally, this allows for measuring real clinical torque values between implant and bone.

Table 5 – Diameter References for NobelActive® CC Guided Components

Component	NP	RP 4.3	RP 5.0	WP 5.5
Guided Sleeve (A)	Ø 4.11	Ø 5.02	Ø 6.22	Ø 6.22
Implant Mount (B)	Ø 3.52	Ø 3.9	Ø 3.9	Ø 5.08
Diameter Difference	0.59	1.12	2.32	1.14

Diameters and Diameter Differences presented in mm.

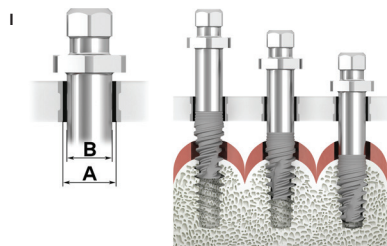


Figure 1 – Implant Mount is Smaller than Guided Sleeve

8. If the implant gets stuck during implant installation or 70 Ncm for NobelActive® Ø 3.5, Ø 4.3, Ø 5.0, and Ø 5.5 implants is achieved before fully seated, rotate the implant counter clockwise approximately ½ turn enabling use of self-tapping capacity of implant or back out implant, replace in inner casing before proceeding further and widening the site. Without removing the surgical template, continue with implant installation until desired position is achieved. For Immediate Function, the implant should be able to withstand a final torque of 35-70 Ncm.
9. In partially edentulous and fully edentulous situations the Guided Implant Mount can be replaced by the Guided Template Abutment on the first 1-2 implants. Release the Guided Implant Mount using the Unigrip™ Screwdriver and remove the implant mount. Anchor the surgical template using the Guided Template Abutment, tightening manually using the Unigrip™ Screwdriver. Ensure the surgical template maintains its initial correct position for the next implant site preparation.
10. Prepare and install the remaining implant sites.
11. Once all implants are installed, remove Guided Implant Mounts and Guided Template Abutments using the Unigrip™ Screwdriver. Remove anchor pins, if applicable and remove the surgical template.
12. Depending on the loading protocol of choice, place a cover screw using the Unigrip™ Screwdriver or an abutment using the Torque Wrench Prosthetic Adapter and suture.

For additional information on the NobelActive® implant please refer to the NobelActive® and NobelActive® TiUltra™ Instructions for use (IFU1001).

Surgical Procedure: Brånemark System® Mk III Groovy, Brånemark System® Mk III TiUnite® (RP only) and NobelSpeedy® Groovy Guided Surgery Tooling

Table 6 presents a summary of the Nobel Biocare guided surgery tooling which is compatible with the Brånemark System®:

Table 6 – Guided Surgery Tooling for Brånemark System®

Article Number	Description
29081	Connection to Handpiece
29149	Screwdriver Manual Unigrip™ 28 mm
29151	Screwdriver Machine Unigrip™ 20 mm
29167	Manual Torque Wrench Adapter Prosthetic
30909	Guided Anchor Pin Ø 1.5 mm

32110	Brånemark System Manual Torque Wrench Surgical
32797	Guided Drill Guide Kit Box
32802	Guided Template Abutment w. Screw Brånemark System NP
32804	Guided Template Abutment with Screw Brånemark System RP
32807	Guided Template Abutment w. Screw Brånemark System WP
32813	Handle for Guided Drill Guide
32814	Guided Drill Guide NP to Ø 2 mm
32815	Guided Drill Guide RP to Ø 2 mm
32816	Guided Drill Guide 6.0/WP to Ø 2 mm
32817	Guided Drill Guide NP to Ø 2.8 mm
32818	Guided Drill Guide RP to Ø 2.8 mm
32819	Guided Drill Guide NP to Ø 3 mm
32820	Guided Drill Guide RP to Ø 3 mm
32821	Guided Drill Guide 6.0/WP to Ø 3 mm
32822	Guided Drill Guide RP to Ø 3.2 mm
32823	Guided Drill Guide RP to Ø 3.4 mm
32824	Guided Drill Guide 6.0/WP to Ø 3.8 mm
32825	Guided Drill Guide 6.0/WP to Ø 4.2 mm
32863	Guided Implant Mount Brånemark System NP
32865	Guided Implant Mount Brånemark System RP
32868	Guided Implant Mount Brånemark System WP

Table 7 presents a summary of the Nobel Biocare guided surgery tooling which is compatible with the NobelSpeedy® Groovy implant platform:

Table 7 – Guided Surgery Tooling for NobelSpeedy® Groovy Implant Platform

Article Number	Description
29081	Connection to Handpiece
29149	Screwdriver Manual Unigrip™ 28 mm
29151	Screwdriver Machine Unigrip™ 20 mm
29167	Manual Torque Wrench Adapter Prosthetic
30909	Guided Anchor Pin Ø 1.5 mm
32110	Brånemark System® Manual Torque Wrench Surgical
32797	Guided Drill Guide Kit Box
32802	Guided Template Abutment w. Screw Brånemark System® NP
32804	Guided Template Abutment with Screw Brånemark System® RP
32807	Guided Template Abutment w. Screw Brånemark System® WP
32813	Handle for Guided Drill Guide
32814	Guided Drill Guide NP to Ø 2 mm
32815	Guided Drill Guide RP to Ø 2 mm
32816	Guided Drill Guide 6.0/WP to Ø 2 mm
32817	Guided Drill Guide NP to Ø 2.8 mm
32818	Guided Drill Guide RP to Ø 2.8 mm
32819	Guided Drill Guide NP to Ø 3 mm
32820	Guided Drill Guide RP to Ø 3 mm
32821	Guided Drill Guide 6.0/WP to Ø 3 mm
32822	Guided Drill Guide RP to Ø 3.2 mm
32823	Guided Drill Guide RP to Ø 3.4 mm
32824	Guided Drill Guide 6.0/WP to Ø 3.8 mm
32825	Guided Drill Guide 6.0/WP to Ø 4.2 mm
32863	Guided Implant Mount Brånemark System® NP
32865	Guided Implant Mount Brånemark System® RP
32868	Guided Implant Mount Brånemark System® WP

32816	Guided Drill Guide 6.0/WP to Ø 2 mm
32821	Guided Drill Guide 6.0/WP to Ø 3 mm
32824	Guided Drill Guide 6.0/WP to Ø 3.8 mm
32825	Guided Drill Guide 6.0/WP to Ø 4.2 mm
32826	Guided Drill Guide 6.0/WP to Ø 6 to Ø 5 mm
32868	Guided Implant Mount Brånemark System® WP
32807	Guided Template Abutment w Screw Brånemark System® WP

1. If applicable, anchor the surgical template using an adequate number of anchor pins placed with strategic positioning and orientation to secure the surgical template in the correct position. During surgery maximum attention must be paid to secure the surgical template is in the correct position in the patient's mouth and that it does not move in any direction from the correct position when being manipulated with instruments (e.g. lateral shift through inadequate handling of twist drills in "knife-edge ridge" situations or shift/deformation of surgical template due to excessive vertical force application during implant installation). In situations where two or more neighboring implants are placed, regardless if it is a free-end situation or a situation with one or more distal teeth for support of the surgical template, it is recommended to use at least one anchor pin in this area. If necessary, place implants in a staggered approach.
2. If a flapless procedure is chosen, it is recommended to use the Guided Soft Tissue Punch before any other instruments are used to generate a clean cut. The surgical template can be temporarily detached after punching to carefully remove the punched soft tissue. The surgical template is carefully repositioned and the anchor pins replaced into the existing anchorage holes in the bone. If a (mini) flap procedure is chosen, it is recommended that the surgical template is first repositioned and the anchor pins placed prior to any manipulations of the soft tissue. Remove the anchor pins and surgical template, perform the incision, respecting the position of the implants and elevate the flap. If required, carefully modify the surgical template by relieving as much material as required to accommodate the flap, rinsing with sterile saline solution prior to carefully repositioning.
3. During drilling procedures bone quality should be considered. (See Table 8 and Table 9 for recommended drill sequences based on bone quality to ensure optimal primary stability when applying Immediate Function). Use the Guided Start Drill prior to the Guided Twist Drill 2 mm (with the appropriate Guided Drill Guide to Ø 2 mm) to create a start point for the following drill. Then select the appropriate Guided Drill Guide based on the sleeve size and the Guided Twist Drill. The Handle for Guided Drill Guide can be used for easier handling of the Guided Drill Guide. Drilling must proceed at high speed (maximum 800 rpm for Guided Twist Drills) under constant and profuse external irrigation with sterile saline solution. An in-and-out drilling motion, over the complete extent of the osteotomy is needed when preparing the site to avoid overheating. The Drill Extension Shaft can be used if required for easier access.

Table 8 – Recommended Drill Sequence for Brånemark System® Implants Based on Bone Quality*

Platform	Implant Diameter	Soft Bone (Type IV)	Medium Bone (Type II-III)	Dense Bone** (Type I)
NP	Ø 3.3	2.0	2.0	2.0 2.8
RP***	Ø 3.75	2.0 (2.8)	2.0 3.0	2.0 3.2
RP***	Ø 4.0	2.0 (2.8)	2.0 3.2	2.0 2.8 3.4
WP	Ø 5.0	2.0 3.0	2.0 3.0 3.8	2.0 3.0 3.8 4.2

* Drill data are presented in mm. Drill diameters listed within parentheses (-) denote widening of cortex only.

** Screw taps are available and are recommended for use if the insertion torque exceeds 45 Ncm.

*** For Brånemark System® Mk III TiUnite® RP implants use Guided Start Drill Counterbore former Mk III RP (Art. No. 33113).

Table 9 – Recommended Drill Sequence for NobelSpeedy® Groovy Implants Based on Bone Quality*

Platform	Implant Diameter	Soft Bone (Type IV)	Medium Bone (Type II-III)	Dense Bone** (Type I)
NP	Ø 3.3	2.0	2.0	2.0 2.8
RP	Ø 4.0	2.0 (2.8)	2.0 3.2	2.0 2.8 3.4
WP	Ø 5.0	2.0 3.0	2.0 3.0 3.8	2.0 3.0 3.8 4.2
6.0	Ø 6.0	2.0 3.0 3.8	2.0 3.0 3.8 4.2	2.0 3.0 3.8 4.2 5.0

* Drill data are presented in mm. Drill diameters listed within parentheses (-) denote widening of cortex only.

** Screw taps are available and are recommended for use if the insertion torque exceeds 45 Ncm.

Caution Guided Twist Drills are identified by the (10+) designation on the shaft. This indicates the drills are 10 mm longer than the "freehand" Twist Drills to compensate for the height of the surgical template and the Guided Drill Guide. The depth marks on the Guided Twist Drills correspond to 7, 10, and 13 mm implants for 7–13 mm drills and 7, 10, 13, 15 and 18 mm for 7–18 mm drills (Figure J). The level should be measured with the Guided Drill Guide in place. Drills extend 1 mm longer than the implant when seated. Allow for this additional length when drilling near vital anatomical structures.

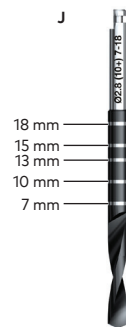
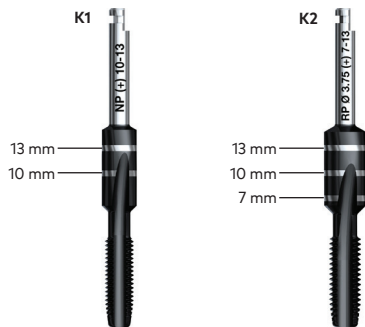


Figure J – Depth Marks on Guided Twist Drills

4. Prepare implant site.
5. Dense bone protocol: to be used if insertion torque exceeds 45 Ncm and the implant will not be fully seated.
 - Select the Guided Screw Tap matching the diameter and length of the implant. To select an appropriate Guided Screw Tap, place into prepared implant site using low speed (25 rpm), applying firm pressure. When the threads engage, allow Guided Screw Tap to feed without pressure to appropriate depth. Figure K1 shows depth markings which correspond to full depth tapping of 10 mm and 13 mm for Ø 3.3 mm implants. Figure K2 shows depth markings which shows depth markings which correspond to full depth tapping of 7 mm, 10 mm and 13 mm for Ø 3.75, Ø 4.0, Ø 5.0 and Ø 6.0 implants.
 - Switch the drill device to reverse mode and remove the Guided Screw Tap.



Figures K1 and K2 – Depth Marks on Guided Screw Taps

- If the implant shoulder was planned below the bone crest, use the Guided Start Drill/Counterbore to generate adequate access for the Guided Implant Mount. Select the Guided Start Drill/Counterbore matching the diameter of the implant.

Note A specific Guided Start Drill/Counterbore is available for Brånemark System® Mk III TiUnite® RP.

- Drill to the built-in stop at high speed (maximum 800 rpm for Guided Twist Drills) under constant and profuse external irrigation with sterile saline solution.
- Open the implant package. Connect the Guided Implant Mount to the implant using the Unigrip™ Screwdriver. Insert the Connection to Handpiece in the drilling unit handpiece and pick up the mounted implant. Brånemark System® NobelSpeedy® Groovy implants are ideally installed with low speed, maximum 25 rpm, using the drilling device. Place and tighten the implant using maximum 45 Ncm installation torque. Stop tightening the implant when the Guided Implant Mount touches the surgical template. The Guided Implant Mount includes a vertical stop. Secure that the Guided Implant Mount is kept in the center of the guided sleeve during the entire insertion process.

Caution Never exceed insertion torque of 45 Ncm for Brånemark System® and NobelSpeedy® Groovy Implants. Over tightening an implant may lead to damage of the implant, fracture or necrosis of the bone site.

- If the implant gets stuck during implant installation or 45 Ncm is achieved before fully seated, rotate the implant counter clockwise using the drilling device (reverse mode) or the Manual Torque Wrench and remove from the site. Replace the implant in the inner casing before proceeding further (refer to the Dense bone protocol section). Without removing the surgical template, continue with implant installation until desired position is achieved. For Immediate Function, the implant should be able to withstand a final torque of 35–45 Ncm.
- In partially edentulous and edentulous situations the Guided Implant Mount can be replaced by the Guided Template Abutment on the first 1–2 implants. Release the Guided Implant Mount using the Unigrip™ Screwdriver and remove the implant mount. Anchor the surgical template using the Guided Template Abutment, tightening manually using the Unigrip™ Screwdriver.
- Final implant installation torque can be measured following surgical template removed using the Torque Wrench Surgical.

- Depending on the surgical protocol of choice, place a cover screw using the Unigrip™ Screwdriver or an abutment using the Torque Wrench Prosthetic Adapter and suture.

For additional information regarding Brånemark System® please refer to the Nobel Biocare Instructions for Use (IFU) for the implant (IFU1007).

For additional information regarding NobelSpeedy® Groovy implants please refer to the Nobel Biocare Instructions for Use (IFU) for the implant (IFU1007).

Surgical Procedure: NobelReplace® Tapered and Replace Select™ Tapered Guided Surgery Tooling

- If applicable, anchor the surgical template using an adequate number of anchor pins placed with strategic positioning and orientation to secure the surgical template in the correct position. During surgery maximum attention must be paid to secure the surgical template is in the correct position in the patient's mouth and that it does not move in any direction from the correct position when being manipulated with instruments (e.g. lateral shift through inadequate handling of twist drills in "knife-edge ridge" situations or shift/deformation of surgical template due to excessive vertical force application during implant installation). In situations where two or more neighboring implants are placed, regardless if it is a free-end situation or a situation with one or more distal teeth for support of the surgical template, it is recommended to use at least one anchor pin in this area. If necessary, place implants in a staggered approach.
- If a flapless procedure is chosen, it is recommended to use the Guided Soft Tissue Punch before any other instruments are used to generate a clean cut. The surgical template can be temporarily detached after punching to carefully remove the punched soft tissue. The surgical template is carefully repositioned, and the anchor pins replaced into the existing anchorage holes in the bone. If a (mini) flap procedure is chosen, it is recommended that the surgical template is first repositioned, and the anchor pins placed prior to any manipulations of the soft tissue. Remove the anchor pins and surgical template, perform the incision, respecting the position of the implants and elevate the flap. If required, carefully modify the surgical template by relieving as much material as required to accommodate the flap, rinsing with sterile saline solution prior to carefully repositioning.
- During drilling procedures bone quality should be considered. (See Figure L for recommended drill sequences based on bone quality to ensure optimal primary stability when applying Immediate Function). Use the Guided Start Drill prior to the Guided Twist Drill 2 mm (with the appropriate Guided Drill Guide to Ø 2 mm) to create a start point for the following drill. Then select the appropriate Guided Drill Guide based on the sleeve size and the Guided Twist/Step Drill. The Handle for Guided Drill Guide can be used for easier handling of the Guided Drill Guide. Drilling must proceed at high speed (maximum 800 rpm for Guided Twist/Step Drills) under constant and profuse external irrigation with sterile saline solution. An in-and-out drilling motion, over the complete extent of the osteotomy is needed when preparing the site to avoid overheating. The Drill Extension Shaft can be used if required for easier access.

Caution Guided Tapered Drills extend up to 1 mm longer than the implant when seated. Allow for this additional length when drilling near vital anatomical structures (the yellow safety zone in the DTX Studio Implant Software includes the extended drill lengths).

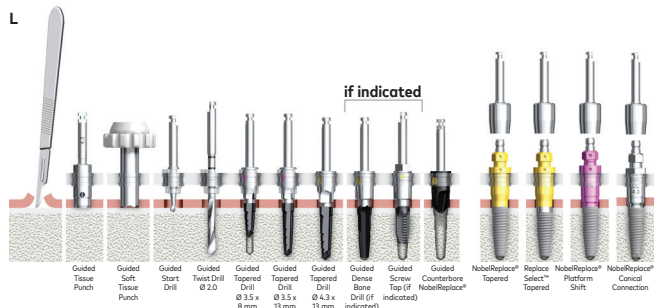


Figure L – Example Complete Drilling Sequence for the Ø 4.3 RP 13 mm Implant

Note For Replace Select™ Tapered PMC use the as drill protocol as for Replace Select™ Tapered and for NobelReplace® Conical Connection PMC use the same drill protocol as for NobelReplace® Conical Connection.

4. Prepare implant site. Start with the Guided Start Drill with the appropriate Guided Drill Guide Ø 2 mm to create a start point for the following drill. The Handle for Guided Drill Guide can be used for easier handling of the Guided Drill Guide. Drill to the full depth as defined by the in-built drill stop at high speed (maximum 800 rpm) under constant and profuse irrigation. The Guided Start Drill (round bur) allows for the exact preparation of the entry point of the Guided Twist Drill Tapered Ø 2 mm.
5. Drill using the Guided Twist Drill Tapered Ø 2 mm using the same Guided Drill Guide to the intended depth based on the implant to be placed. Drilling must proceed at high speed (maximum 800 rpm for Guided Twist Drills) under constant and profuse external irrigation with sterile saline solution. An in-and-out drilling motion, over the complete extent of the osteotomy is needed when preparing the site to avoid overheating. The Drill Extension Shaft can be used if required for easier access.

Caution The Guided Twist Drill Tapered Ø 2 mm is identified by the (10+) designation on the shaft. This indicates the drill is 10 mm longer to compensate for the height of the surgical template and Guided Drill Guide (Figure M). The level should be measured with the Guided Drill Guide 2 mm in place.

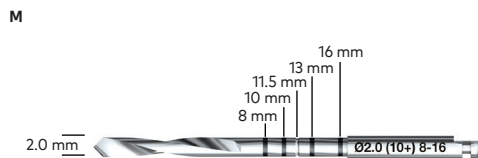


Figure M – Guided Twist Drill Tapered

6. Following the 2 mm Guided Twist Drill, the Guided Tapered Drill NP 8 mm must be used for all implants. Drilling must proceed at high speed (maximum 800 rpm) under constant and profuse irrigation by sterile saline at room temperature. An in-and-out motion, over the complete extent of the osteotomy, is needed when preparing the site to avoid overheating. This drill is guided by the template sleeve before engaging the bone and provides guidance for the longer NP Guided Drills (if an implant longer or wider than NP 8 mm is placed).

Caution For reasons of drilling precision, the step using the Guided Tapered Drill NP 8 mm is mandatory and must not be omitted.

Caution The Guided Tapered Drills are identified by the (+) designation on the shaft. The inbuilt depth stops on the Guided Tapered Drills correspond to the 8, 10, 11.5, 13, and, 16 mm implants. This indicates the tapered drills are 9 mm longer than the non-guided instruments to compensate for the height of the surgical template's inbuilt guided sleeve (Figure N). Drills extend

up to 1 mm longer than the implant when seated. Allow for this additional length when drilling near vital anatomical structures.

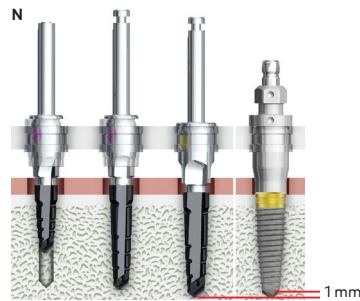


Figure N – Lengths of Guided Tapered Drills

7. Continue with the respective Guided Tapered Drills depending on the implant to be installed, length and platform. For example, in the event that a 16 mm implant is planned, first use the Guided Tapered Drill NP 8 mm, followed by the Guided Tapered Drill NP 13 mm and then Guided Tapered Drill NP 16 mm.
8. Following the last Guided Tapered Drill, the Guided Counterbore NobelReplace® must be used at max. 800 rpm to allow adequate access for the Guided Implant Mount when placing the implant. Drill to the inbuilt drill stop using profuse and constant irrigation.
9. Open the implant package. Connect the Guided Implant Mount to the implant using the Unigrip™ Screwdriver. Insert the Connection to Handpiece in the drilling device and pick up the mounted implant. NobelReplace® Tapered Groovy, Replace Select™ Tapered TiUnite®, Replace Select™ Tapered Partially Machined Collar (PMC), NobelReplace® Conical Connection, NobelReplace® Conical Connection Partially Machined Collar (PMC) and NobelReplace® Platform Shift implants are ideally installed with low speed, maximum 25 rpm, using the drilling device. Place and tighten the implant using maximum 45 Ncm installation torque.

Stop tightening the implant when the Guided Implant Mount touches the surgical template. The Guided Implant Mount includes a vertical stop. Avoid further tightening of the implant as this may affect the correct position of the surgical template. Secure that the Guided Implant Mount is kept in the center of the guided sleeve during the entire insertion process.

10. To ensure ideal prosthetic abutment orientation for internal tri-channel implants, position one of the tri-channel lobes in the buccal/facial position. The dots on the Guided Implant Mount indicate the position of the tri-channel lobes (Figure O).

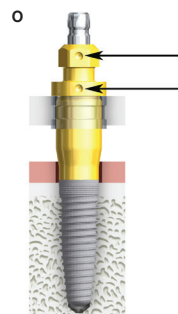


Figure O – Indication marks on the Guided Implant Mount

11. To ensure ideal prosthetic abutment orientation for internal conical connection implants, position one of the internal hexagon flat surfaces in the implant towards buccal/facial. The flat surfaces of the hexagon of the inbuilt drill stop on the Guided Implant Mount indicate the position of the internal hexagon (Figure P).

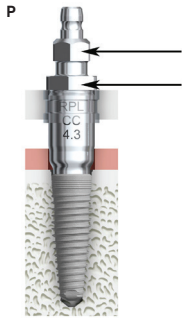


Figure P – The flat surfaces of the hexagon of the inbuilt drill stop on the Guided Implant Mount indicate the position of the internal hexagon

Caution Never exceed insertion torque of 45 Ncm. Over tightening an implant may lead to damage of the implant, fracture or necrosis of the bone site.

Caution Guided Implant Mount Conical Connection is developed for NobelReplace® Tapered Conical Connection implants only and must not be used for NobelActive® implants.

12. If the implant gets stuck during implant installation or 45 Ncm is achieved before fully seated the "dense bone protocol" may be required. Rotate the implant counterclockwise using the drilling device (reverse mode) or Manual Torque Wrench and remove implant from site. Replace the implant in the inner casing before proceeding further (refer to the dense bone protocol section). Without removing the surgical template, continue with implant installation until desired position is achieved. For Immediate Function, the implant should be able to withstand a final torque of 35-45 Ncm.
13. Dense bone protocol: The Dense Bone Drill in conjunction with the Guided Screw Tap should be used in hard bone situations when the implant cannot be fully seated.
 - The Guided Dense Bone Drill Tapered is only needed for 13 mm and 16 mm implants. If shorter implants are used, go directly to step c. Select the Guided Dense Bone Drill Tapered matching the diameter and length (13 or 16 mm) of the final Guided Tapered Drill used.
 - Drill one pass into the prepared site with high speed (800 rpm) using the Guided Dense Bone Drill Tapered under constant and profuse external irrigation with sterile saline solution to the inbuilt drill stop.
 - Select the Screw Tap matching the diameter of the implant. For product reference line Guided Screw Tap versus implant length see (Figure Q). Place the Screw Tap into the prepared site using low speed (25 rpm).
 - Apply firm, axial pressure and begin rotating the Guided Screw Tap slowly and keep centered while inserting through the guided sleeve. When the threads engage, allow Guided Screw Tap to feed without pressure to the appropriate depth.
 - Switch the handpiece into reverse mode and back the Screw Tap out.
14. Continue with implant installation until desired position is achieved using max 45 Ncm installation torque.

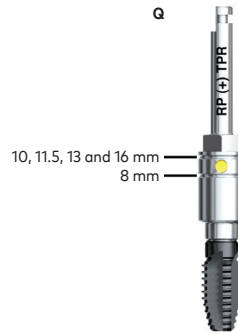


Figure Q – Product reference line Guided Screw Tap versus implant length

15. In partially edentulous and fully edentulous situations the Guided Implant Mount can be replaced by the Guided Template Abutment on the first 1–2 implants. Release the Guided Implant Mount using the Unigrip™ Screwdriver and remove the implant mount. Anchor the surgical template using the Guided Template Abutment, tightening manually using the Unigrip™ Screwdriver. Ensure the surgical template maintains its initial correct position for the next implant site preparation.
16. Prepare and install the remaining implant sites.
17. Once all implants are installed, remove Guided Implant Mounts and Guided Template Abutments using the Unigrip™ Screwdriver. Remove anchor pins, if applicable and remove the surgical template.
18. Final implant installation torque can be measured following surgical template removed using the Torque Wrench Surgical. Do not change depth of implant through torque measurement.
19. Depending on the surgical protocol of choice, place a Cover Screw using the Unigrip™ Screwdriver or an abutment using the Torque Wrench Prosthetic Adapter and suture.

For additional information regarding the NobelReplace® Tapered and Replace Select™ Tapered implants, refer to the Nobel Biocare Instructions for Use (IFU) for the implants (IFU1010 and IFU1008 respectively).

Sterility and Reusability Information

Guided Start Drills/Counterbores, Guided Counterbores, Guided Twist Drills, Guided Screw Taps, Guided Twist/Step Drills, Guided Pilot Twist Drill, Guided Dense Bone Screw Taps have been sterilized using irradiation and are intended for single use only. Do not use after the labeled expiration date.

Warning Do not use device if the packaging has been damaged or previously opened as the device sterility and/or integrity may be compromised.

Caution Guided Start Drills/Counterbores, Guided Counterbores, Guided Twist Drills, Guided Screw Taps, Guided Twist/Step Drills, Guided Pilot Twist Drill, Guided Dense Bone Screw Taps are single use devices and must not be reprocessed. Reprocessing could cause loss of mechanical, chemical and/or biological characteristics. Reuse could cause local or systemic infection.

The Guided Template Abutments, Handle for Guided Drill Guide, Guided Drill Tapered, Guided Dense Bone Drill Tapered, Guided Screw Taps Tapered, Guided Implant Mounts, Guided Drill Guided Tapered, Guided Tissue Punches are delivered non-sterile and are intended for reuse. Prior to use clean and sterilize the product following the manual or automated procedure in the Cleaning and Sterilization Instructions.

Warning Use of non-sterile device may lead to infection of tissues or infectious diseases.

The Guided Template Abutments, Handle for Guided Drill Guide, Guided Drill Tapered, Guided Dense Bone Drill Tapered, Guided Screw Taps Tapered, Guided Implant Mounts, Guided Drill Guided Tapered, Guided Tissue Punches are reusable components which shall be inspected before each reuse to ensure that the integrity and performance continues to be maintained. The devices shall be discarded if any wear, abrasion of the anodization, deformations or corrosion is visible on the component.

For information regarding the Guided Anchor Pins refer to the Nobel Biocare Instructions for Use (IFU) IFU2001.

The Guided Implant Mount shall be discarded if any wear, abrasion of the coating, deformations or corrosion is visible on the component. Before each use the coated hex of the implant mount body shall be inspected for any visible deformation and if any form of deformation is detectable the shall be discarded.

The Guided Drill Guides must specifically be inspected before each use, to ensure that no deep scratches, dents, flakes, chippings are visible on the guiding surface or any surface corrosion is visible; if any deep scratches, dents, flakes, chippings on the guiding surface or any surface corrosion is visible, the Guided Drill Guide shall be disposed.

The Guided Template Abutments must specifically be inspected before each use, to check if any plastic deformation and/or corrosion is visible. In particular, the Guided Template Abutment shall slide inside the sleeve without applying any force. If plastic deformation and/or corrosion is visible or force needs to be applied, the Guided Template Abutments shall be disposed.

Nobel Biocare recommends that the Guided Screw Taps Tapered, Guided Drills Tapered and Guided Dense Bone Drills Tapered are replaced after 20 uses, or when cutting efficiency declines.

Caution Worn-out and damaged drills need to be discarded and replaced with new sharp drills. The over-extended use may cause bone overheating and lead to implant failure.

Note Guided Drill Guides, Handle for the Guided Drill Guide, Guided Implant Mounts, Guided Template Abutments, Guided Tissue Punches, Guided Anchor Pins, Guided Screw Taps Tapered, Guided Drills Tapered and Guided Dense Bone Drills Tapered can be processed as individual devices as described in the Cleaning and Sterilization Instructions below, or together with other devices in a PureSet tray following the cleaning and sterilization instructions in Nobel Biocare Instructions for Use (IFU) IFU1067. This IFU is available on ifu.nobelbiocare.com.

Note The Guided Anchor Pins, Unigrip™ Screwdriver, Manual Torque Wrenches Surgical and Prosthetic, Torque Wrench Prosthetic Adapter, and Connection to Handpiece are reusable instruments which are delivered non-sterile and must be cleaned and sterilized prior to use and reuse. Prior to reuse, the instruments should also be inspected to ensure that the integrity and performance continues to be maintained. Refer to the following Nobel Biocare IFU for information regarding the cleaning and sterilization procedures and reusability criteria for these instruments.

Table 10 – Guided Surgery Tooling for Brånemark System®

Component	IFU Number
Unigrip™ Screwdriver	IFU1085
Manual Torque Wrenches Surgical and Prosthetic Torque Wrench Prosthetic Adapter	IFU1098
Connection to Handpiece	IFU1090
Guided Anchor Pins	IFU2001

Note Nobel Biocare guided surgery tooling can be processed as individual devices as described in the Cleaning and Sterilization

Instructions below, or together with other devices in a PureSet tray following the cleaning and sterilization instructions in Nobel Biocare Instructions for Use (IFU) IFU1067. This IFU is available on ifu.nobelbiocare.com.

Cleaning and Sterilization Instructions

The Guided Template Abutments, Handle for Guided Drill Guide, Guided Drill Tapered, Guided Dense Bone Drill Tapered, Guided Screw Taps Tapered, Guided Implant Mounts, Guided Drill Guided Tapered, Guided Tissue Punches are delivered non-sterile by Nobel Biocare and are intended for reuse. Prior to each use, the devices must be cleaned and sterilized by the user.

The devices can be cleaned manually, or in an automatic washer. Each device must then be individually sealed in a sterilization pouch and sterilized.

The following cleaning and sterilization processes have been validated according to international standards and guidelines as applicable:

- Manual and Automated Cleaning: AAMI TIR 12.
- Sterilization: AAMI ST79 and ISO 17665-1.

According to EN ISO 17664, it is the responsibility of the user/processor to ensure that the processing/reprocessing is performed using equipment, materials and personnel which are suitable to ensure the effectiveness of the processes. Any deviation from the following instructions should be validated by the user/processor to ensure the effectiveness of the process.

Note The manufacturer's instructions for use for any detergent/cleaning solution and/or equipment and accessories used to clean and/or dry the device(s) must be strictly followed where applicable.

Note Nobel Biocare guided surgery tooling has been validated to withstand these cleaning and sterilization procedures.

Caution Do not deviate from the following reprocessing instructions.

Initial Treatment at Point of Use Prior to Reprocessing

1. Discard single-use instruments and worn reusable instruments immediately after use.
2. Remove excess soil and debris from reusable devices to be reprocessed using absorbent paper wipes. Use a dental probe to remove soil and debris from cavities, where applicable.
3. Rinse the devices with cold running tap water.

Containment and Transportation/Shipping to Reprocessing Area

1. After removal of excess soil and debris, store the devices in a container which is suitable to protect the devices during transportation and to avoid any contamination of personnel or the environment.
2. Transport the devices to the reprocessing area as soon as practical. If transfer to the processing area is likely to be delayed, consider covering the devices with a damp cloth or store it in a closed container to avoid drying of soil and/or debris.

Note Reusable devices should be reprocessed by initiating the prescribed automated or manual cleaning and drying procedures within 1 hour of use, to ensure the efficacy of the reprocessing.

- If the devices are shipped to an outside facility for reprocessing, they must be contained in a transportation or shipping container which is suitable to protect the devices during transportation and to prevent contamination of personnel or the environment.

Automated Cleaning and Drying (Including Pre-cleaning)

Pre-cleaning

- Disassemble the Handle for the Guided Drill Guide prior to cleaning by unthreading the two parts.
- Immerse the device in 0.5% lukewarm enzymatic cleaning agent (e.g. Neodisher Medizym) for a minimum of 5 minutes.
- Fill lumina (where applicable) with 0.5% lukewarm enzymatic cleaning agent (e.g. Neodisher Medizym) using a 20 ml syringe.
- Brush the outer surfaces with a soft bristled nylon brush (e.g. Medsafe MED-100.33) for a minimum of 20 seconds until all visible soil is removed.
- Brush the inner surfaces, lumina and cavities (where applicable) with an appropriately sized bottle brush (e.g. 1.2 mm/2.0 mm/5.0 mm diameter) for a minimum of 20 seconds until all visible soil is removed.
- Thoroughly rinse all outer and inner surfaces, lumina and cavities (where applicable) with cold running tap water for a minimum of 10 seconds to remove all cleaning solution.
- Rinse lumina (where applicable) with 20 ml tap water using a 20 ml syringe.

Automated Cleaning and Drying

The following washer was used in the Nobel Biocare validation: Miele G7836 CD with the Vario TD program/ MMM GmbH Uniclean PL-II 15-2 EL.

Note It is recommended to perform the automated cleaning and drying with a maximum load of 11 individual devices.

- Place the devices in a suitable rack or load carrier (e.g. metal sieve basket).
- Load the devices into the washer. Ensure the rack or load carrier is oriented in a horizontal position.
- Perform automatic cleaning. The following parameters are based on the Vario TD program on the Miele G7836 CD washer:
 - Minimum 2 minutes pre-cleaning with cold tap water.
 - Draining.
 - Minimum 5 minutes cleaning with minimum 55°C tap water and 0.5% mildly alkaline detergent (e.g. Neodisher Mediclean).
 - Draining.
 - Minimum 3 minutes neutralization with cold desalinated water.
 - Draining.
 - Minimum 2 minutes rinsing with cold desalinated water.
 - Draining.
- Run drying cycle at minimum 50°C (122.0°F) for a minimum of 10 minutes.
- Dry with compressed air or clean and lint-free single use wipes, if any residual moisture remains after the drying cycle.

Visual Inspection

After cleaning and drying, inspect the device for unacceptable deterioration such as corrosion, discoloration, pitting, or cracked seals and properly discard any devices that fail the inspection.

Manual Cleaning and Drying

- Disassemble the Handle for the Guided Drill Guide prior to cleaning by unthreading the two parts.
- Immerse device for a minimum of 5 minutes in a sterile 0.9% NaCl solution.
- Scrub the outer surfaces of the device with soft-bristled nylon brush for a minimum of 20 seconds until all visible soil is removed.
- Flush the inner surfaces, lumina and cavities (where applicable) with 20 ml lukewarm enzymatic cleaning solution (e.g. Cidezyme ASP/Neodisher Medizym) using an irrigation needle connected to a 20 ml syringe.
- Brush the inner surfaces, lumina and cavities (where applicable) with appropriately sized bottle brush (e.g. 1.2 mm/2.0 mm/5.0 mm diameter) for a minimum of 10 seconds until all visible soil is removed.
- Thoroughly rinse the outer surfaces and lumina of the device with cold running tap water for a minimum of 10 seconds to remove all cleaning solution.
- Immerse the device in an ultrasonic bath (e.g. Bandelin; frequency 35 kHz; effective ultrasonic power 300 W_{eff}) containing 0.5% enzymatic cleaning agent (e.g. Cidezyme ASP/Neodisher Medizym) and treat for a minimum of 5 minutes at minimum 40°C (104°F)/maximum 45°C (113°F).
- Flush the inner surfaces, lumina and cavities (where applicable) with 20 ml lukewarm tap water using an irrigation needle connected to a 20 ml syringe.
- Thoroughly rinse the outer surfaces of the device with purified or sterile water for a minimum of 10 seconds to remove all cleaning agent.
- Dry with compressed air or clean and lint-free single use wipes.

Visual Inspection

After cleaning and drying, inspect the device for unacceptable deterioration such as corrosion, discoloration, pitting, cracked seals and properly discard any devices that fail the inspection.

Sterilization

The following steam sterilizers were used in the Nobel Biocare validation: Systec HX-320/Selectomat PL/666-1 CL (pre-vacuum cycle); Amsco Century Sterilizer/Selectomat PL/666-1 CL (gravity cycle).

Note When using Systec HX- 320, Amsco Century Sterilizer, it is recommended to perform sterilization with a maximum load of 11 devices individually sealed in sterilization pouches. When using Selectomat PL/669-1 CL, it is recommended to perform sterilization with a maximum load of 1 container with 8.6 kg metal and 2 packages of linen.

- Seal each device in a suitable sterilization. The sterilization pouch should fulfill the following requirements:
 - EN ISO 11607 and/or DIN 58953-7.
 - Suitable for steam sterilization (temperature resistance up to at least 137°C (279°F), sufficient steam permeability).

- Sufficient protection of the instruments as well as of the sterilization packaging to mechanical damage.

Table 11 presents examples of suitable sterilization pouches.

Table 11 – Recommended Sterilization Pouches

Method	Recommended Sterilization Pouch
Gravity Cycle	SPSmedical Self-Seal sterilization pouch Steriking, Wipak
Pre-vacuum Cycle	SteriCLIN® pouch Steriking, Wipak

2. Label the sterilization pouch with information necessary to identify the device (for example, the product name with article number and lot/batch number (if applicable)).
3. Place the sealed sterilization pouch into the autoclave/sterilizer. Ensure that the sterilization pouch is oriented in a horizontal position.
4. Sterilize the device. Both the gravity displacement cycle and pre-vacuum (top dynamic air removal) cycle can be applied, using the following recommended parameters (Table 12):

Table 12 – Recommended Sterilization Cycles

Cycle	Minimum Temperature	Minimum Sterilization Time	Minimum Drying Time (In Chamber)	Minimum Pressure
Gravity cycle ¹	132°C (270°F)	15 minutes	20 minutes	≥2868.2 mbar ⁴
Pre-vacuum cycle ¹	132°C (270°F)	4 minutes	20 minutes	≥2868.2 mbar ⁴
Pre-vacuum cycle ²	134°C (273°F)	3 minutes	20 minutes	≥3042 mbar ⁵
Pre-vacuum cycle ³	134°C (273°F)	18 minutes	20 minutes	≥3042 mbar ⁵

1. Validated sterilization processes to achieve a Sterility Assurance Level (SAL) of 10⁻⁶ in accordance to EN ISO 17665-1.
2. Recommendation of the Welsh Health Technical Memorandum (WHTM) 01-01 Part C.
3. Recommendation of the World Health Organization (WHO) for steam sterilization of instruments with potential TSE/CJD contamination. Ensure that the packaging and monitoring systems (chemical/biological indicators) used for this cycle are validated for these conditions.
4. Saturated steam pressure at 132°C as per required by EN ISO 17665-2.
5. Saturated steam pressure at 134°C as per required by EN ISO 17665-2.

Note Autoclave/sterilizer design and performance can affect the efficacy of the sterilization process. Healthcare facilities should therefore validate the processes that they use, employing the actual equipment and operators that routinely process the devices. All autoclaves/sterilizers should comply with the requirements of, and be validated, maintained and checked in accordance to SN EN 13060, EN 285, EN ISO 17665-1, and/or AAMI ST79, or to the applicable national standard. The autoclave/sterilizer manufacturer's instructions for use must be strictly followed.

Note Autoclave/sterilizer design and performance can affect the efficacy of the sterilization process. Healthcare facilities should therefore validate the processes that they use, employing the actual equipment and operators that routinely process the devices. All autoclaves/sterilizers should comply with the requirements of, and be validated, maintained and checked in accordance to EN 13060, EN 285, EN ISO 17665-1, and/or AAMI ST79, or to the applicable national standard. The autoclave/sterilizer manufacturer's instructions for use must be strictly followed.

Storage and Maintenance

After sterilization, place the labeled and sealed sterilization pouch in a dry and dark place. Follow the instructions provided by the manufacturer of the sterilization pouch regarding the storage conditions and expiration date of the sterilized device.

Containment and Transportation/ Shipping to Point of Use

The container and/or outer packaging used to transport or ship the processed/reprocessed device back to the point of use must be suitable to protect and safeguard the sterility of the devices during transportation, taking the device packaging and the required transportation or shipping process (intrafacility transportation or shipping to an external site) into account.

Performance Requirements and Limitations

To achieve the desired performance, Nobel Biocare Guided Surgery Tooling must only be used with the products described in this Instructions for Use and/or in the Instructions for Use for other compatible Nobel Biocare products, and in accordance with the Intended Use for each product. To confirm the compatibility of products which are intended to be used in conjunction with Nobel Biocare Guided Surgery Tooling, check the color coding, dimensions, lengths, connection type and/or any direct marking as applicable on the products or product labeling.

Facilities and Training

It is strongly recommended that new and experienced users of Nobel Biocare products always go through special training before using a new product for the first time. Nobel Biocare offers a wide range of courses for various levels of knowledge and experience. For more information please visit www.nobelbiocare.com.

Storage, Handling and Transportation






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.

Disposal

Safely discard potentially contaminated or no longer usable medical devices as healthcare (clinical) waste in accordance with local healthcare guidelines, country and government legislation or policy.

Separation, recycling or disposal of packaging material shall follow local country and government legislation on packaging and packaging waste, where applicable.

Manufacturer and Distributor Information

Manufacturer 	Nobel Biocare AB PO Box 5190, 402 26 Västra Hamngatan 1 Göteborg 411 17 Sweden www.nobelbiocare.com
UK Responsible Person <div style="border: 1px solid black; display: inline-block; padding: 2px;">UK</div> <div style="border: 1px solid black; display: inline-block; padding: 2px; margin-left: 10px;">RP</div>	Nobel Biocare UK Ltd 4 Longwalk Road Stockley Park Uxbridge UB11 1FE United Kingdom
Distributed in Turkey by	EOT Dental Sağlık Ürünleri ve Dış Ticaret A.Ş Nispetiye Mah. Aytar Cad. Metro İş Merkezi No: 10/7 Beşiktaş İSTANBUL Phone: +90 2123614901, Fax: +90 2123614904
Distributed in Australia by	Nobel Biocare Australia Pty Ltd Level 4, 7 Eden Park Drive Macquarie Park, NSW 2113 Australia Phone: +61 1800 804 597
Distributed in New Zealand by	Nobel Biocare New Zealand Ltd 33 Spartan Road Takanini, Auckland, 2105 New Zealand Phone: +64 0800 441 657
CE Mark for Class I Devices	
CE Mark for Class II/IIa Devices	
UKCA Mark for Class I Devices	
UKCA Mark for Class IIa Devices	

Note Refer to the product label to determine the applicable conformity marking for each device.

Basic UDI-DI Information

Product	Basic UDI-DI Number
Guided Drill Guides, Guided Drill Guides Tapered, and Handle for Guided Drill Guide	733274700000015578
Guided Implant Mounts	73327470000001577C
Guided Template Abutments	73327470000001346Y
Guided Tissue Punches	73327470000001877M
Guided Start Drills/Counterbores, Guided Start Drills, Guided Pilot Twist Drill, Guided Twist Drills, Guided Twist Step Drills, Guided Twist Drill Tapered, Guided Screw Taps, Guided Dense Bone Screw Taps, and Guided Counterbores	733274700000014473
Guided Drill Tapered, Guided Dense Bone Drill Tapered, Guided Screw Taps Tapered	733274700000014677

Legal Statements

EN All rights reserved.

Nobel Biocare, the Nobel Biocare logotype and all other trademarks used in this document are, if nothing else is stated or is evident from the context in a certain case, trademarks of Nobel Biocare. Product images in this folder are not necessarily to scale. All product images are for illustration purposes only and may not be an exact representation of the product.

Symbols Glossary

The following symbols may be present on the device labeling or in information accompanying the device. Refer to the device labeling or accompanying information for the applicable symbols.



Authorized Representative in the European Community/ European Union



UK Responsible Person



Authorised Representative in Switzerland



Sterilized using Ethylene Oxide



Sterilized using irradiation



Sterilized using steam or dry heat



Batch code



Catalogue number



Unique Device Identifier



Serial number



Medical device



Magnetic resonance safe



Caution



Magnetic resonance conditional



Non-sterile



Contains hazardous substances



Contains or presence of DEHP phthalate



Contains or presence of natural rubber latex



Contains or presence of phthalate



Contains biological material of animal origin



CE mark



CE mark with Notified Body number



UKCA mark



UKCA mark with Approved Body number



Consult instructions for use



For prescription use only



symbol.glossary.nobelbiocare.com
ifu.nobelbiocare.com

Link to Online Symbols Glossary and IFU Portal



Date of manufacture



Manufacturer



Use-by date



Upper limit of temperature



Temperature limit



Do not resterilize



Do not re-use



Non-pyrogenic



Date



Tooth number



Patient number



Patient identification



Health care centre or doctor



Patient information website



EU Importer



Swiss Importer



Double sterile barrier system



Single sterile barrier system



Single sterile barrier system with protective packaging inside



Single sterile barrier system with protective packaging outside



Do not use if package is damaged and consult instructions for use



Keep away from sunlight



Keep dry