

Assistant Handbook



2. Assistant Handbook

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2.1 Surgical Assistant Handbook

The Neoss® Implant System is available in 7 implant diameters $\varnothing 3.5$, $\varnothing 4.0$, $\varnothing 4.5$, $\varnothing 5.0$, $\varnothing 5.5$, $\varnothing 6.0$ and $\varnothing 6.5$, all with the prosthetic Standard Platform (SP), and in addition there is a narrow Neoss $\varnothing 3.25$ mm implant with the prosthetic Narrow Platform (NP). The implants are generally available in lengths from 7–17 mm, please refer to product catalog for detailed information about available implant types, diameters and lengths. The packaging for Neoss implants and instruments used for a specific implant diameter (countersinks and screwtaps) have the following color coding:

Ø3.25 mm Royal Blue
 Ø4.0 mm Yellow
 Ø5.0 mm Peach
 Ø5.5 mm Lilac

The Neoss implants have a universal self-cutting design making them suitible for all bone qualities.

The implant is 'picked up' from a sterile glass vial with an Implant Inserter. The surgical drills are for single use and delivered in sterile condition for immediate use. There is only one screwdriver connection in the standard assortment, the Neo screwdriver, and this is used for all components including cover screws, healing abutment screws, and final abutment screws.

Neoss implants kits includes a cover screw, two healing abutments (only 5 mm with $\emptyset 3.25$ mm implant) and a healing screw. This complete delivery method enables the clinician to undertake either one or two stage surgery at time of placement without the need to have pre-ordered individual components. There are also two stickers provided in the implant kit to assist in recording information on the patient's chart. The ProActive Edge implants are also available with a cover screw only.

The following information is a guide as requirements may vary on an individual basis.

2.1.1 General Features

The Neoss Implant System provides a simple, easy to use means of anchorage for a single crown, bridge or denture thereby satisfying a wide range of aesthetic and functional requirements. Simple implant installation and flexibility in prosthetic solutions provides optimal aesthetic restorations for a wide range of clinical situations. This handbook serve as a clinical reference for surgical and restorative assistant procedures.

The Neoss Implant System

The Neoss Implants are based on extensive research and development, the outcome of which is a state-of-the-art system, rationalized by design. The implants have patented design and geometry which imparts specific features and benefits to the system.

Neoss implants may be used as a one or two-stage implant and are manufactured from Commercially Pure Titanium Grade IV with a surface that has been subjected to a multistage blasting, etching, cleaning and chemical treatment. The system fulfills all clinical indications with a compact and rational range of implant components and instruments.

The Neoss implant to abutment connection

Unique to the Neoss Implant System is the ONE prosthetic platform, across three implant ranges. The same prosthetic components fit every standard implant. All standard Neoss implants, \emptyset 3.5 and larger, have the same standard platform (SP) with the implant to abutment connection design called NeoLoc*. For \emptyset 3.25 mm implants the implant connection has a smaller narrow platform (NP).

2.1.2 Treatment Options

The Neoss implants may be placed using a Single/One Stage Surgical Protocol (which may involve immediate loading/function) or a Two Stage surgical protocol.

Either surgical protocol may be used to construct a single tooth, bridge or overdenture. Factors which may influence the choice of one protocol over the other are detailed in the Neoss Implant System Surgical Handbook.

- Single/One Stage Surgery this procedure involves placing a healing abutment, a provisional abutment or prosthesis at time of implant placement.
- Two Stage Surgery this procedure involves placing a cover screw at the time of implant placement, then after a designated healing time a second surgical procedure to uncover the implant and place a healing/provisional or other form of abutment.

Prior to the actual procedure, treatment objectives and goals should have been discussed with the patient and careful planning in relation to the number and diameter of implants have been determined.

2.2 Surgical Procedure and Drilling Protocol ____

2.2.1 Surgery Set-up

Either an operating theatre or a well prepared dental surgery may be used for the procedure.

Suggested surgical items/instruments - GENERAL:

- · caps, gloves, gowns and masks
- · drapes for patient
- · additional drapes for bench tops, stands etc.
- suction equipment
- · irrigation equipment
- antiseptic solution/clamp and swabs for patient preparation
- surgical instruments: scalpels, mirror, bowl, cheek retractors, elevators, scissors dissecting/suture, forceps, artery forceps
- · gauze, gauze swabs etc.
- tubing covers
- · anaesthetic/syringe
- drilling equipment, handpiece and motor

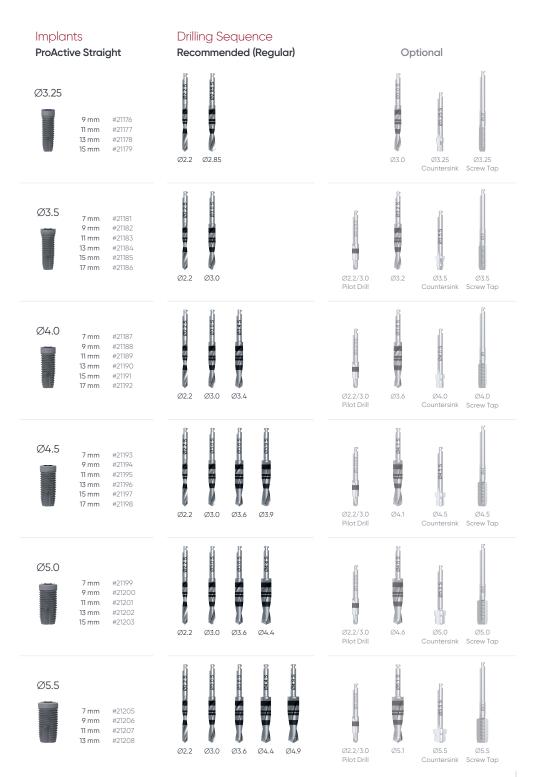
Suggested surgical items/instruments – NEOSS SYSTEM (please refer to flowchart on the following pages):

- · drill kit, optional drills, countersink, screw tap
- · implants
- pre-sterilized surgical and prosthetic tray
- Neoss System surgical instruments: drill extender, inserters 17/22/32 mm (NP 24/32 mm), Wrench Adapter, Neo screwdrivers 22/32 mm, 15 mm manual Neo screwdriver, manual handle, ratchet, direction depth gauges, Depth Gauge Probe, Insertion Handle – Large
- Neoss ProActive Implant System Box (fits the surgical and proshtetic trays used for sterilizing and storing instruments)

Handling of hazardous material according to established procedures at the hospital/clinic.







Instruments

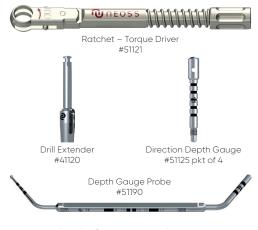
Implant Inserters and Wrench Adapter SP 17 mm SP 22 mm #51137 Ø3.25 Wrench Adapter SP 22 mm #51118 SP 32 mm #51119 NP 24 mm #51145 NP 32 mm #51142 #51144

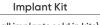








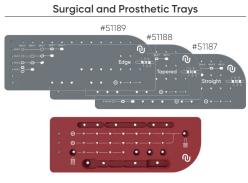




Bone Remover Cover Screw

SP #41240 NP #41241







2.2.2 Surgical Procedure

The surgical procedure may entail a range of procedures including minimally invasive surgery and raising a full thickness flap and exposing the bone in the proposed site. A series of increasing diameter drills are used to enlarge the osteotomy for implant placement - this may involve the use of countersinks and screw taps depending on individual preference and/or the quality of bone.

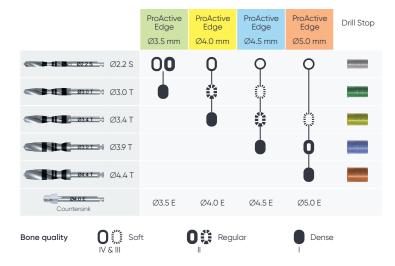
- · If the procedure is to be carried out in a hospital environment then the preparation of the theatre and surgical staff should conform to the established protocols of each individual hospital.
- · It is desirable to have both a sterile and non-sterile assistant throughout the procedure. Ensure sterile handling during preparation and surgery.
- All bone preparation drilling is carried out under profuse irrigation using either saline or sterile water to avoid overheating of the bone.
- · If a surgical guide/stent is to be used for implant placement then follow the manufacturer's recommendation for the sterilization procedure.
- The drilling sequence for bone preparation is outlined in the Neoss System Drilling Protocols (following pages) however individual preferences or bone quality may require a deviation from these protocols. It is therefore recommended that additional/optional components only be opened when indicated by the surgeon.

Note: Please refer to the Neoss Implant System Surgical Handbook for detailed information in relation to:

- Machine implant insertion
- · Manual implant insertion
- Single stage surgical procedure
- · Two stage surgical procedure
- · Post operative care

2.2.3 Drilling Protocols

ProActive Edge Implants



Guidelines

- · Start at the top of the column with the Ø2.2 mm twist drill.
- Move down to the next marking for the chosen bone quality and prepare the site with the drill <u>corresponding</u> to that marking. Dashed markings are non-mandatory unless it is the last preparation step.
- Keep moving down the column until the final preparation is performed at the chosen bone quality marking.

Example: The drill sequence for a \emptyset 4.0 implant in dense bone starts with the \emptyset 2.2 mm twist drill followed by the final preparation step (\emptyset 3.4 T). The dashed \emptyset 3.0 T drill step can be omitted.

Use of a countersink is not required in situations where under-preparation of the cortical bone is desirable, as for soft bone, in order to increase cortical anchorage.

Note: The guiding portion of the Countersink Edge is designed to match the drill for regular bone. If a narrower osteotomy for soft bone needs countersinking it might be required to widen the cortical part of the osteotomy first with the regular bone drill to seat the countersink properly.

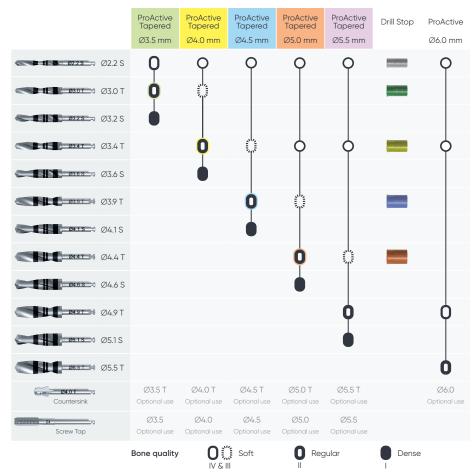
Additional notes

The Edge implant allows for further under-preparation in Soft bone.

In presence of dense bone, additional care is taken during insertion. The thread cutting and forming design of the implant acts as a screw tap. Use reverse torqueing 1/2–1 turn before continuing.

Neoss screw taps are <u>not</u> compatible with the ProActive Edge implant. The drills are the same bone cutting instruments as used for ProActive Tapered.

ProActive Tapered Implants



Guidelines

- · Start at the top of the column with the Ø2.2 mm twist drill.
- · Move down to the next marking for the chosen bone quality and prepare the site with the drill corresponding to that marking.

Drill step for Soft bone not intended for Regular and Dense bone (indicated with dash style).

Drill step for Regular bone required before drill step for Dense bone.

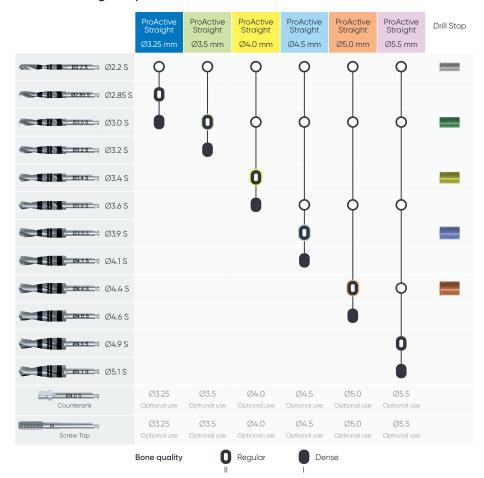
Drill step for **Dense bone** does not require drilling to full depth.

Additional notes

The Tapered implant allows for further under-preparation in Soft bone. Screw taps available but not required.

In presence of dense bone, additional care is taken during insertion. The thread cutting and forming design of the implant acts as a screw tap. Use reverse torqueing 1/2-1 turn before continuing. Twist drill Ø2.2, Dense bone drills and screw taps in the ProActive Tapered implant drill protocol are the same bone cutting instruments as used for ProActive Straight implant drill protocol.

ProActive Straight implants



Guidelines

- Start at the top of the column with the Ø2.2 mm twist drill.
- Move down to the next marking for the chosen bone quality and prepare the site with the drill corresponding to that marking.
- Keep moving down the column until the final preparation is performed at the chosen bone quality marking.

Drill step for Regular bone recommended before drill step for **Dense bone**.

Additional notes

The Neoss drill assortment allows for individualized drill protocol in **Soft bone**. Screw taps available but not required.

In presence of dense bone, additional care is taken during insertion. The thread cutting and forming design of the implant acts as a screw tap. Use reverse torqueing 1/2–1 turn before continuing.

2.2.4 Surgical Drills

The Neoss Implant System is available in 7 diameters Ø3.5, Ø4.0, Ø4.5, Ø5.0, Ø5.5, Ø6.0 and Ø6.5, all with the prosthetic Standard Platform (SP), and in addition there is a narrow Neoss \varnothing 3.25 mm implant with the prosthetic Narrow Platform (NP). Neoss Implant System Drill Kits contain the recommended drills for the placement of Neoss Edge, Tapered and Straight implants. All for regular bone Drills, Countersinks and Screw Taps are available separately. Neoss offers drills for single use (single patient only) which are delivered in a sterile condition for immediate use. If the sterile barrier is broken the drills can be re-sterilized, described in section 2.4.

Neoss also offers drills for multiple use.

Art. No.	Items Included						
41177	Drill Kit, Edge Implants Ø3.5–5.0						
41192	Drill Kit, Tapered Implants Ø3.5–5.0						
41193	Drill Kit, Straight Implants Ø3.5–5.0						
51189	Neoss Surgical and Prosthetic Tray – ProActive® Edge						
51188	Neoss Surgical and Prosthetic Tray – ProActive® Tapered						
51187	Neoss Surgical and Prosthetic Tray – ProActive® Straight						

Note: Specific lasermarkings on shafts for identification: E for Edge, T for Tapered, S for Straight.

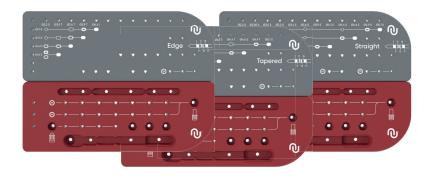
Surgical and Prosthetic Trays

The Neoss Surgical and Prosthetic Trays are designed as two interlocking parts for surgery, instruments and layout. These can be used in combination or individually. Made of highly durable silicone they are easily cleaned and sterilized (100 cycles and up to 1 year).

The grey surgical part of the tray offers clear markings for drill selection and depth on one side and storage for instruments during sterilization on the other.

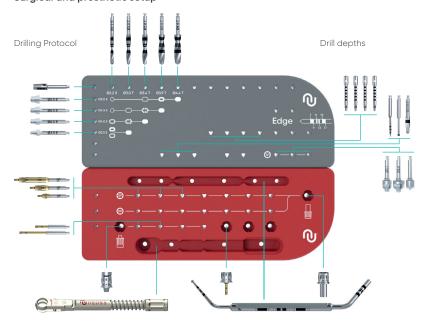
Note: The red part offers markings for instruments needed during installation of implants and abutments. The surgical and prosthetic trays are marked with 'Edge', 'Tapered' or 'Straight' respectively.

Note: It is possible to combine the drill set-up sections for ProActive Edge, ProActive Tapered and ProActive Straight implants.



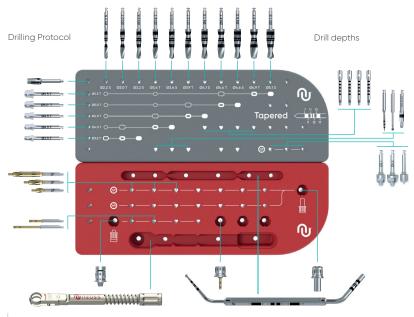
ProActive Edge Implants

Surgical and prosthetic setup



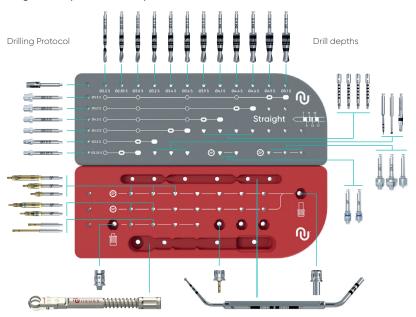
ProActive Tapered Implants

Surgical and prosthetic setup



ProActive Straight Implants

Surgical and prosthetic setup



Neoss Drill Stops

Neoss drill stop solution satisfies all clinical needs and provides improved safety, control and efficiency. The Drill Stops enable precise depth control during preparation of implant sites for the placement of Neoss System implants. Neoss Drill Stops are compatible with Neoss drills with corresponding diameters including Neoss Tapered drills.

The assortment consists of a separate kit for implant lengths 7-15 mm. Each kit includes five Drill Stops of different diameters which correspond to final recommended drill diameters in regular bone. These are delivered sterile and are color coded: clear \emptyset 2.2, green \emptyset 3.0, yellow \emptyset 3.4, blue \emptyset 3.9 and peach \emptyset 4.4.

Clinical Procedure

The Drill Stop is mounted on the corresponding drill and secured by a light push. Ensure that the mounted Drill Stop is correctly chosen and seated to the right depth by checking the corresponding depth marking on the drill. After use, the drill stop is removed by a light pull and discarded. The Drill Stops are single use only.

Note: The drill stop must be mounted with the flange and marking directions as shown.

Note: Neoss Short Drills (7 – 13 mm) are NOT compatible with Neoss Drill Stops.

Contraindications

Neoss Drill Stops are not indicated in extraction sites as it may be difficult to accurately judge the depth of the stop.

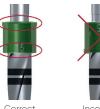
In cases with uneven bone, the drill stops have to be removed for complete or partly submerged implant placement.

Example

Preparing an implant site for a 4×11 mm implant requires use of Ø2.2, 3.0 and 3.4 mm drill stops from Neoss Drill Stop 11 mm.



Drill stop marking



Correct Incorrect mounting mounting



Depth guide

2.3 Restorative Assistant Handbook

The Neoss Implant System is available in 7 diameters $\varnothing 3.5$, $\varnothing 4.0$, $\varnothing 4.5$, $\varnothing 5.0$, $\varnothing 5.5$, $\varnothing 6.0$ and $\varnothing 6.5$, all with the prosthetic Standard Platform (SP), and in addition there is a narrow Neoss $\varnothing 3.25$ mm implant with the prosthetic Narrow Platform (NP).

Neoss engaging abutments have deformation lugs which minimise rotational movements and secures a distinct seating.

There is only one screwdriver connection in the assortment, the Neo screwdriver, and this is used for all components including cover screws, healing abutment screws, and final abutment screws.

Neo Abutment Screw is a high performance screw which enables a high clamping force between the abutment and the implant.

Generally the patient will present to the restorative surgery with a healing abutment in place. In the majority of cases the impression will be taken at 'Implant Level', however some abutments allow for their preparation intraorally – similar to that of a natural tooth – in these cases a conventional crown and bridge impression protocol would be followed.

The Neoss System offers one universal Implant Level Impression Coping for both 'Open' and 'Closed' Tray impression techniques and one Impression Coping for 'Open Tray' impression only.

The Neoss Implant System offers patients a broad range of aesthetic and functional solutions.

These are available as cemented or screw-retained options, overdenture and CAD/CAM designed prostheses.

Note: Please refer to the information in this manual for procedures and information in relation to:

- · Esthetiline Solution
- · Provisional Abutments
- Impression Techniques
- NeoLink® Gold/Titanium
- Single Unit and Multiple Unit Construction
- Titanium Prepable Abutments
- · Zirconia Abutments
- Access Abutments
- Overdenture Solutions

2.3.1 Prosthetic Tray and Instrument Kit

The tray holds the Neoss ratchet, manual handle and Neo screwdrivers and includes spare slots for additional components. The lid is easy to remove, and the base design allows for easy access to instruments.

Made of a highly durable silicone and with no grommets, the tray is easily cleaned and sterilized (100 cycles and up to 1 year).



2.4 Cleaning, Disinfection, Sterilization, Storage and Lifetime _____

Regarding instructions for cleaning, disinfecting, sterilization and storage of Neoss Reusable Products and all prosthetic products for invasive use, please refer to Guideline for cleaning & maintenance Neoss reusable products (14077).

All prosthetic products and dental instruments that are delivered non-sterile must after removal of the protective transport packaging be cleaned and if required sterilized before use. This also applies for adjusted abutments coming from lab.

Storage

Sterilized bags are stored in dry environment at room temperature.

Lifetime of reusable products

Please refer to Guideline for cleaning & maintenance Neoss reusable products (14077) to find guidelines how to decide when a reusable product is outworn and needs to be exchanged.

2.5 Oral Hygiene and Patient Care_

As with natural dentition, dental implants/prosthesis are susceptible to plaque build-up which may have a detrimental affect on the long term success of the prosthesis. It is therefore of vital importance that the patient is carefully instructed on the importance of regular check-ups and 'home care'. Following insertion of the final prosthesis the patient should be instructed in the routine for home care. When instructing patients how to maintain their implant supported prosthesis it should be remembered that some patients may not have had natural teeth for some time. Therefore individualized and thorough instruction on 'how to clean' should be developed for each patient. This may include the recommendation of certain toothbrushes, mouth rinses, dental floss or interdental cleaning aids.

Titanium is a soft metal and therefore the use of abrasive toothpastes or instruments which may scratch the abutment should be avoided.

In addition to 'home care' it is recommended that the patient be checked regularly in the first 12 months after prosthesis insertion. The dentist would include in the check-up the stability of the prosthesis, the occlusion, surrounding soft tissues and the patient's ability to maintain a high level of 'at home' oral hygiene.

2.6 General Packaging Symbols _____

*Single use devices should not be reused due to risks of product contamination, patient/user infection and/or failure of the device to perform as intended.

USE BY/EXPIRY DATE		CATALOGUE NUMBER		LOT/BATCH NUMBER		DO NOT RE-USE (Single use only)*		TEMPERATURE LIMIT
		REF		LOT		2		x Y
KEEP AWAY FROM SUNLIGHT		MANUFACTURER		DATE OF MANUFACTURE		STERILIZED USING ETHYLENE OXIDE		STERILE BY IRRADIATION (Contents of inner package sterile)
						STERILE	EO	STERILE R
NON-STERILE		NOT USE IF E IS DAMAGED	MEDICAL [DEVICE	CONSULT INSTRUC		CAUTION: Federal (USA) law restricts the sale of this device to or on the order	
NON STERILE		(Section 2)	MD				of a licensed physician or dentist Rx only	

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Caution:

Federal (USA) law restricts this device to sale by or on the order of a licensed dentist or physician.



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The Neoss implant assortment has FDA clearance for immediate placement and function recognizing sufficient bone stability and appropriate occlusal loading to restore chewing function.