Assistant Guidelines
# 2. Assistant Guidelines

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2.1 Surgical Assistant Guidelines

The Neoss® Implant System comprises implants and abutments offering a logical and simplified approach for all treatment protocols including immediate and early loading, immediate placement and one or two stage placement. The Neoss Implant System is available in 6 diameters Ø3.5, Ø4.0, Ø4.5, Ø5.0, Ø5.5 and Ø6.0 and in addition there is a narrow Neoss Ø3.25 mm implant. The implants are available in lengths from 7-17 mm with some deviations, 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
- Ø3.5 mm Green
- Ø4.0 mm Yellow
- Ø4.5 mm Blue
- Ø5.0 mm Peach
- Ø5.5 mm Lilac

The Neoss implants are a universal design for all bone qualities. The implants have both Thread Cutting and Thread Forming as the geometry of the implants ‘forms’ the site in poorer bone qualities optimizing compression. They are self tapping implants with the primary cutting face designed to cut a precise thread profile and a secondary cutting face to control compression in dense bone.

The Neoss ProActive® implants are commercially pure titanium implants with an altered surface. This surface has been subjected to a multistage blasting, etching, cleaning and chemical treatment.

The Neoss implants have an internal connection. 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 and this is used for all components including cover screws, healing abutment screws, and final abutment screws.

All Neoss implants, except Ø3.25, have the same implant to abutment connection as there is a single platform for all standard implant diameters.

Neoss implants are provided in kits which include a cover screw, two healing abutments (only 5 mm with Ø3.25 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 following information is a guide as requirements may vary on an individual basis.

2.1.1 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 Guidelines.

- 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 clinical organizer
- Neoss System surgical instruments: drill extender, inserters 17/22/32 mm (Ø3.25 mm 24/32 mm), Wrench Adapter, Neoss screwdrivers 22/32 mm, 15 mm manual screwdriver, manual handle, ratchet, direction depth gauges
- Neoss System Tray (fits the clinical organizer. Used for sterilizing and storing instruments)

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

### Implant Inserters and Wrench Adapter

- 17 mm #51137
- 22 mm #51118
- 32 mm #51119

- Ø3.25
  - 24 mm #51145
  - 32 mm #51142

- Wrench Adapter #51144

## Implant Kit

(all implants sold in kits)

Contents of Kit: Implant, Cover Screw, Healing Abutment with Screw

## Screwdrivers and Manual Handle

- Screwdriver 22 mm #51139
- Screwdriver 32 mm #51140
- Manual 15 mm #51141
- Manual Handle #51126

## Esthetic Healing Abutments

- #31360
- #31361
- #31362
- #31363
- #31364

## Titanium Healing Abutments

- 2 mm #31159
- 4 mm #31160
- 6 mm #31161
- 8 mm #31162
- 10 mm #31163

## Clinical Organizers

- Bone Mill #41138
- Drill Extender #41120
- Ratchet – Torque Driver #51121
- Direction Depth Gauge #51125 pkt of 4

# Neoss Implant System Assistant Guidelines
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 Guidelines 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 Straight implants

<table>
<thead>
<tr>
<th>Drill stop</th>
<th>Ø3.25 mm</th>
<th>Ø3.5 mm</th>
<th>Ø4.0 mm</th>
<th>Ø4.5 mm</th>
<th>Ø5.0 mm</th>
<th>Ø5.5 mm</th>
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<tbody>
<tr>
<td>countersink Optional use</td>
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<td>Optional use</td>
<td>Optional use</td>
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<td>screw tap  Optional use</td>
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</table>

**Bone quality**

- Regular
- Dense

### Guidelines

*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.
### ProActive Tapered Implants

<table>
<thead>
<tr>
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<th>Ø3.0 T</th>
<th>Ø3.2</th>
<th>Ø3.4 T</th>
<th>Ø3.6</th>
<th>Ø3.9 T</th>
<th>Ø4.1</th>
<th>Ø4.4 T</th>
<th>Ø4.6</th>
<th>Ø4.9 T</th>
<th>Ø5.1</th>
<th>Ø5.5 T</th>
<th>Ø6.0</th>
<th>Countersink</th>
<th>Screw Tap</th>
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<td>Optional use</td>
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<tr>
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<td>Ø4.0 T</td>
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<td>Ø5.0 T</td>
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#### Guidelines

- **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.
2.2.4 Surgical Drills

The Neoss Implant System is available in 6 diameters Ø3.5, Ø4.0, Ø4.5, Ø5.0, Ø5.5 and Ø6.0 and in addition there is a narrow Neoss Ø3.25 mm implant. Neoss Implant System Drill Kits contain the recommended drills for the placement of Neoss Straight and Tapered implants. All Drills, Countersinks and Screw Taps are available separately. Neoss drills are for single use (single patient only) and 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.

<table>
<thead>
<tr>
<th>Art. No.</th>
<th>Items Included</th>
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<tr>
<td>41167</td>
<td>Drill Kit, Straight Implants Ø3.5–4.5</td>
</tr>
<tr>
<td>41168</td>
<td>Supplementary Drill Kit – supplement to 41167, inc. Twist Drills 2.85, 3.2, 4.1, 4.4, 4.6, 4.9 &amp; 5.1 mm</td>
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<tr>
<td>41199</td>
<td>Drill Kit, Tapered Implants Ø3.5–5.5</td>
</tr>
<tr>
<td>51150</td>
<td>Neoss Clinical Organizer, Straight</td>
</tr>
<tr>
<td>51151</td>
<td>Neoss Clinical Organizer, Tapered</td>
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</tbody>
</table>

Note: Tapered drills and countersinks are laser marked with a ‘T’ on the shaft for identification.

Clinical Organizers

The Neoss Clinical Organizers are designed as three 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 layout section on the left provides wells for implant storage, cover and abutment screws on one side and prosthetic components crowns and bridges on the other.

The mid section may be used in combination with the other parts or alone for prosthodontics.

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

Note: The ProActive Tapered implant organizer is marked ‘Tapered’ to distinguish it from the ProActive Straight implant organizer.

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

Surgical setup

Drilling Protocol

Drill depths

Prosthetic setup

Storage and sterilization
ProActive Tapered Implants

Surgical setup

Drilling Protocol

Drill depths

Prosthetic setup

Storage and sterilization
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 Ø2.2, green Ø3.0, yellow Ø3.4, blue Ø3.9 and peach Ø4.4.

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 x 11 mm implant requires use of Ø2.2, 3.0 and 3.4 mm drill stops from Neoss Drill Stop 11 mm.
2.3 Restorative Assistant Guidelines

All Neoss implants, except Ø3.25, have the same implant to abutment connection as there is a single platform for implant diameters Ø3.5 - Ø6.0. The prosthetic platform measures Ø4.0 with six internal rotational positions.

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

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

Neoss 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® – the Concept
- Single Unit and Multiple Unit Construction
- Titanium Prepable Abutments
- Zirconia Abutments
- Express Abutments
- Access Abutments
- Overdenture Solutions

2.3.1 Prosthetic Tray and Instrument Kit

The tray holds the Neoss ratchet, manual handle and 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).
Cleaning and Disinfection

- **Pre-cleaning and disinfection** Instruments (instruments consisting of several parts should be dismantled) drills, countersinks, screw taps and the Clinical Organizer are pre-cleaned immediately after surgery with a brush under running water and/or washer/disinfector and suitable detergent (cleaning and disinfectant solution). They are then rinsed clean (a dishwasher may be used – please follow manufacturer’s recommendations). If not cleaned immediately, soak the components in suitable disinfectant and follow manufacturer’s instructions.

- **Cleaning, disinfection and drying** The instruments are placed into a glass beaker with a suitable surgical detergent (cleaning and disinfectant solution) and are cleaned in an ultrasonic bath for minimum of five minutes. The Drill/Instrument Organizer may be placed directly into the ultrasonic bath. After ultrasonic cleaning all components are rinsed under running water then dried immediately.

*Note: Abutments are processed in the same way after laboratory preparation.*

*Note: During entire handling the components are placed in an appropriate manner to avoid damage. Components are checked for damage after each procedure and damaged components are removed.*

Packaging and Sterilization

- Surgical instruments specific for the Neoss System are packaged with the Clinical Organizer in the Neoss System Tray.
- Before clinical use non-sterile parts are recommended to be sterilized. The following heat sterilization method and process parameters are validated in accordance with EN ISO 17665 and recommended by Neoss Ltd. The components are packaged in a sterilization bag and autoclaved in a prevacuum cycle at 134°C/273°F, exposure time of minimum 3 min. and up to 18 min. (US specific: 135°C/275°F, exposure time 3 min.)

  According to EN ISO 17664, it is the user’s and processor’s responsibility to ensure that the recommended process parameters above are validated and controlled.

  Neoss products can withstand temperatures up to 150°C unless otherwise stated.

*Note: Never store instruments while they are still moist or wet. Check all instruments visually. Damaged or blunt instruments should not be used. Multiple use bone cutting instruments are disposed after 10 sterilization cycles.*

*Note: For parts that cannot be autoclaved such as instruments with plastic handles, plastic retention means for overdenture and ScanPegs are disinfected.*

Storage

Sterilized bags are stored in dry environment at room temperature.
Neoss Ratchet – Instructions For Use

1. Applications

The torque ratchet is designed for the controlled manual insertion of implants and tightening abutment screws under a defined torque. The appropriate instrument (i.e. Manual Handle, Wrench Adapter or Manual Screwdriver) is inserted and carried by the ratchet head. The removal of the instrument becomes easier if the pin (5) is drawn away from the instrument.

2. Settings

- Prosthetic Torque function: the desired torque can be adjusted continuously with the adjusting nut (4) via the spring (3). The setting is readable on the scale (6) of the scale capsule (2).
- Surgery – locked function: Turn adjusting nut (4) to the graduation ∞. Do not screw in too tightly.

3. Torque Adjustment

- The preset torque is set using the adjusting nut (4).
- Torque may only be applied to the head of adjusting nut (4).
- In use when the preset torque is reached the ratchet will ‘break’ at the joint with an audible click as shown below.
- Do not apply additional torque after the ‘break’ as the ratchet could be damaged.

4. Care of the Torque Ratchet

In addition to the cleaning, disinfection, sterilization and storage instructions described in Neoss Implant System Guidelines (10501).

- After use and in preparation for pre-cleaning, dismantle the ratchet – this does not require any tools.
- After cleaning and rinsing, all components are dried immediately.
- Prior sterilization marked areas should be slightly moistened with handpiece maintenance oil.
- Reassemble the ratchet together in a relaxed position (setting about 10 Ncm). The labelling IN on the ratchet head (1) and scale (6) face the same direction.
- The lifetime of the ratchet is primarily dependent on care and not the number of sterilization cycles.
- If after extensive usage there are signs of wear or inappropriate care, the ratchet may also require calibration of the transmitted torque. Contact your local Neoss representative for more information about this service.
- The ratchet shall be disposed of if, for example, the parts are not moving smoothly, are difficult to dismantle or show signs of discoloration.

Note: the ratchet should always be stored in a relaxed position.
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.

Available in heights 2, 4, 6, 8 & 10 mm, they have a diameter of 4.0 mm and are sold separately in a sterile pack. They are used in conjunction with the screwdriver and are tightened to a maximum of 10 Ncm.

2.6 Packaging Symbols

<table>
<thead>
<tr>
<th>USE BY/EXPIRY DATE</th>
<th>STERILIZED USING ETHYLENE OXIDE</th>
<th>NON-STERILE</th>
<th>DO NOT RE-USE (Single use only)*</th>
<th>TEMPERATURE LIMIT</th>
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<td><img src="image" alt="Non-sterile" /></td>
<td><img src="image" alt="Do not re-use" /></td>
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<table>
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<tr>
<th>KEEP AWAY FROM SUNLIGHT</th>
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<th>DATE OF MANUFACTURE</th>
<th>CATALOGUE NUMBER</th>
<th>LOT/BATCH NUMBER</th>
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<tbody>
<tr>
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<td><img src="image" alt="Catalogue number" /></td>
<td><img src="image" alt="Lot/batch number" /></td>
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</table>

<table>
<thead>
<tr>
<th>STERILE BY IRRADIATION (Contents of inner package sterile)</th>
<th>CONSULT INSTRUCTIONS FOR USE (Also available on <a href="http://www.neoss.com/IFU">www.neoss.com/IFU</a>)</th>
<th>CAUTION: Federal (USA) law restricts the sale of this device to or on the order of a licensed physician or dentist</th>
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<tbody>
<tr>
<td><img src="image" alt="Sterile by irradiation" /></td>
<td><img src="image" alt="Consult instructions for use" /></td>
<td><img src="image" alt="Caution" /></td>
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</tbody>
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*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.
Disclaimer of Liability

Neoss products may only be used according to the manufacturers’ instructions and recommendations. The user of Neoss products should determine their suitability for particular patients and indications. Neoss Limited disclaims any liability, expressed 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 judgement or practice in the use or placement of the Neoss products.

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

The Neoss Implant System has not been evaluated for safety and compatibility in the Magnetic Resonance environment. The Neoss Implant System has not been tested for heating or migration in the Magnetic Resonance environment.

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