Neoss® Guide Kit

Description
Neoss Limited manufactures a dental implant system and associated surgical instruments including a surgical Guide Kit.

Indications
The Neoss® Guide Kit provides means for dental planning systems and tooth, bone or mucosa supported surgical guides from selected manufacturers to be compatible with Neoss bone cutting instruments to secure proper surgical preparation in relation to Neoss implant designs placed in totally and partially edentulous jaws, as well as in single unit cases.

Contraindications
For the Neoss® Guide concept, one contraindication is limited mouth opening which could impair the accurate and intended seating as planned. Surgically, there are no contraindications as such for the separate instruments and accessories other than for the implant treatment as a whole. Please refer to the IFU 10538 for the implants. Treatment is contraindicated where the patient has a preexisting allergy to the used parts.

Use of drills and instruments with other than Neoss products is contraindicated. Please note the short multiple use drills and the Pilot drill are NOT compatible with Neoss® Guide Kit.

Procedures
This Instructions For Use (IFU) for Neoss® Guide Kit includes adaption to selected existing surgical planning and guide systems. For detailed information on other specific Neoss Implant System products or general clinical procedures utilized, please consult the manual, Neoss Implant System Guidelines (10501) and translated versions.

Concept features and benefits
The Neoss® Guide Kit solution is designed to achieve the following:

1. Integration with original surgical drills and countersinks from Neoss.
2. Safe and accurate drilling protocol with “drill to hub” and “countersink to hub”. Together with “implant insertion to hub”, it provides a fully guided implant placement of Neoss Ø3.5 – Ø6.0 mm implants.
3. Minimize complexity compared to currently available guided systems with large assortments and complex procedures.
4. Versatility to allow for use with selected available surgical guides.
5. Provide a uniquely versatile method that allows Sleeve position to be at various heights to cater for a wide spread of clinical applications ranging from deeply submerged implants to cases with limited occlusal height.

The Neoss® Guide Kit solution does not;

1. Replace the need for careful diagnosis and treatment planning.
2. Replace the need for good surgical skills.
3. Allow for fabrication of a final prosthesis prior to the placement of implants.
Concept steps

General flowchart – Planning and Design of Guide (please refer to the specific software and guide system that you are using):

• Patient examination and treatment evaluation
• Confirm Neoss Implant and Neoss® Guide Kit compatibility with software and guide
• Prepare Radiographic Guide – optional
• CT scan
• Planning in software and design of guide
• Order surgical guide (guide Sleeve inner diameter Ø5.0 mm or Ø6.0 mm with top surface of Sleeve at 9 mm above implant)
• Order or fabricate Stone model and Surgical Index

Clinical flowchart (please refer to the specific guide system that you are using):

• Positioning of guide
• Selection of Neoss Drill–Hubs
• Preparation of site (using Neoss drills, countersinks and Neoss® Guide Kit)
• Implant placement (using Neoss® Guide Kit)
• Prosthetic procedure (using Neoss conventional impression and prosthetic components)

Requirements on Surgical Planning Software and Surgical Guides

Neoss Implants and the Neoss® Guide Kit are only included and compatible with certain surgical planning softwares, see list below. In addition, the surgical placement using the Neoss® Guide Kit requires a Ø5.0 mm Guide Sleeve (Neoss Implants Ø3.5, Ø4.0 and Ø4.5 mm of 7-15 mm lengths) or a dedicated Neoss Ø6.0 mm Guide Sleeve (Neoss Implants Ø5.0, Ø5.5 and Ø6.0 mm of 7-15 mm lengths where applicable). The Neoss provided Ø5.0 mm Guide Sleeve is recommended while the Neoss Ø6.0 mm Guide Sleeve is required due to its compatibility with the Guide Key Adaptor.

For Fully Guided, which provides fully guided implant preparation and placement with stops, so called Hubs, for all process steps, the guide sleeve position must be set at 9 mm (S9).

The following software systems and guides are compatible and currently validated with Neoss® Guide Kit:

<table>
<thead>
<tr>
<th>Software Company</th>
<th>Planning Software</th>
<th>Guide</th>
<th>Ø3.5–4.5 Implants</th>
<th>Ø5.0–6.0 Implants</th>
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<tr>
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<td>3Diagnosys</td>
<td>RealGUIDE</td>
<td>✔</td>
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<tr>
<td>Anatomage</td>
<td>Invivio 5</td>
<td>Anatomage Guide</td>
<td>✔</td>
<td>In progress</td>
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<tr>
<td>Materialise</td>
<td>Simplant</td>
<td>Simplant SAFE guide (use NobelGuide*)</td>
<td>✔</td>
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<td>Sirona SiCAT</td>
<td>GALILEOS Implant</td>
<td>SICAT surgical guides</td>
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<td>Maven Pro</td>
<td>NSequence Surgical Guide</td>
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<td>coDiagnostiX</td>
<td>coDiagnostiX Guide</td>
<td>✔</td>
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<td>Implant Studio</td>
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<td>NobelClinician Software*</td>
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<td>360dps</td>
<td>360ips</td>
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<td>SMOP</td>
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<tr>
<td>Digital Dental Service</td>
<td>DPS-pro</td>
<td>DPS-pro</td>
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</table>

* Use Replace RP 4.3 as reference implant and consider dimensional differences.

Detailed description of Procedure – Fully guided

Fully guided means that all process steps include placement to hub; drilling to hub, countersinking to hub and implant placement to hub. This option can only be used in conjunction with sleeve position of 9 mm (S9).
Positioning of guide

- A guide is produced with the Sleeve position at 9 mm (S9) above the decided implant connection.
- Position the guide according to the guide manufacturer’s recommendation.

Hint: If sufficient mobility of the jaw is present, the jaw can gently be moved sideways for better access. Another method to improve access is to create a big enough vertical slot in the guide and sleeve to receive the drill sideways, thus minimizing the vertical space needed by 9 mm for a Fully guided case.

Selection of Neoss Drill-Hubs

Select the correct Drill-Hub based on the implant length according to Neoss Guide Tray.

Note: Same Drill-Hub is used for all drill steps per specific preparation site.

Example – Drilling: For preparation of an 11 mm Implant use Drill-Hub III, white.

Preparation of site

- Push the Neoss standard drill (following the drill protocol for the chosen implant diameter) into the selected Drill-Hub. Ensure the drill is fully engaged.
- Guide Key, corresponding to the drill diameter, is positioned into the Guide Sleeve. For placement of Ø5.0 - Ø6.0 implants utilizing the Ø6.0 Guide Sleeve, the Guide Keys for drill diameters Ø2.2 - Ø4.1 mm require the Guide Key Adapter to be pre-mounted on the Guide Keys as illustrated to the right.

Note: The Guide Key Adapter is anodized in yellow for better visibility. The metal top surface indicates correct mounting direction. Use the Holder to store the Guide Key Adapters in the kit.

- Drill to Hub.
- Remove Guide Key.

Neoss Guide Keys:

There are 6 double-sided guide keys (drill diameters; Ø2.2/2.85, Ø3.0/3.2, Ø3.4/3.6, Ø3.9/4.1, Ø4.4/4.6, Ø4.9/5.1) and 1 single-ended (Ø5.5).
Preparation of site, optional
• If applicable, finalize site preparation by mounting Countersink Conduit on countersink shaft, choose Drill-Hub IV (green).
• Countersink to Hub.
Note: The direction of the Conduit – flange to contact the Drill Hub.
Note: The Countersink Conduit Ø5.0 is white and Countersink Conduit Ø6.0 natural for easy identification.

Implant placement
• Implant Mount, Ø5.0/S9 for Ø3.5, Ø4.0 and Ø4.5 Implants and Implant Mount Ø6.0/S9 for Ø5.0, Ø5.5 and Ø6.0 Implants is attached with the pre-assembled screw to the implant, while the implant remains in the vial.
• Pick-up the Implant Mount with an Implant Inserter and place the implant through the guide to hub.
• Disengage the inserter.

Removal of guide
• Once all implants are inserted, unscrew all Implant Mounts before removing the guide.
• Optionally, final implant seating can be verified using the torque ratchet.
• Choose appropriate healing, provisional and final restorative solution according to Neoss Guidelines.

Multiple Use Instruments and Handling during surgery
The instruments are intended to be re-used. They can be placed in sterile solution (saline) during surgery. Ensure sterile handling during preparation and surgery. Please note instruments that are re-sterilized may not perform as intended by the manufacturer. It is the users’ responsibility to ensure that instruments have not become damaged or worn resulting in decreased performance during cleaning, re-sterilization and handling.

General Precautions
Surgical products used to achieve and maintain osseointegration should be utilized by persons trained in this method. Such training is offered at a number of centers. Please contact the manufacturer for information. Pre-operative hard tissue or soft tissue deficits may result in a compromised esthetic outcome or unfavorable implant angulation. Pre-operative patient evaluation and close cooperation between surgeon, restorative dentist and dental laboratory technician is essential for success.

During planning and guide design, secure sufficient distal/mesial space and vertical height for the instrumentation access through the surgical guide.
All preparation of the bone tissue is carried out under profuse irrigation with saline and using an intermittent drilling technique. This prevents overheating bone and creates a pumping effect for efficient removal of bone debris. Recommended speed for drills is 800–2000 rpm using lower speed for larger drills and 800 rpm for countersinks.
Handling of hazardous material according to established procedures at the hospital/clinic.
Procedural Precautions
Because of the small size of prosthetic components, care must be taken that they are not swallowed or aspirated by the patient.

Adverse Effects
Implant techniques have normal contraindications and risks. These are extensively documented in the dental literature. Incorrect clinical placement or loading resulting in loss of implant anchorage or loss of the prosthesis are possible events after surgery. Lack of bone quantity or quality, infections, poor patient hygiene or cooperation, and general diseases are some potential causes for loss of anchorage and function.

Sterility
The Neoss® Guide Kit is supplied non-sterile. The Neoss® Guide Kit must be sterilized prior each use. Furthermore, the locally applicable legal regulations and the hygiene standards applicable for a dental practice must be observed. Use only the validated sterilization procedures specified below. For autoclaving, the components should be packaged in a sterilization bag and autoclaved in a prevacuum cycle at 134°C/273°F, exposure time 4–18 min. (US specific: 135°C/275°F, exposure time 3 min.) Sterilization methods must be validated in compliance with EN ISO 17665. The responsibility for the sterility of the Neoss Guide Kit lies with the user. It must be ensured that only suitable devices, materials and product- specifically validated methods are used to perform sterilization. It must be ensured that the methods used have been validated. The equipment and devices must be properly maintained and serviced at regular intervals. For cleaning and disinfection please refer to Neoss System Guidelines (10501).

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