

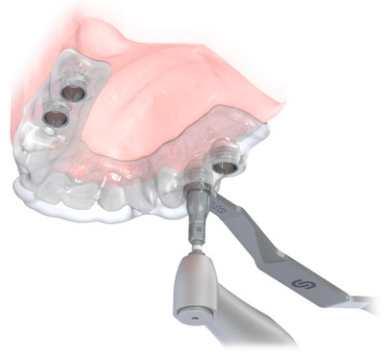
## Neoss® Guide Kit

### Description

Neoss 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 manufactures 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.

Please note use of the ProActive Edge Implant for fully guided implant placement, i.e. utilizing the Neoss Guide Implant Mount for placement with a stop through a guide, is contraindicated. Guided preparation of the site, i.e. utilizing the drills and the Drills-Hubs for preparation through a guide, is not contraindicated.

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. The surgical guide can be produced by a third party manufacturer while adhering to the instructions here within. 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 Straight and Tapered  $\varnothing 3.5 - \varnothing 6.0$  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 software, 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.

*Fully Guided:* Guide Sleeve position required to be 9 mm (S9) Fully guided with stops for all process steps. Chart required choosing correct Drill-Hub for drilling. For countersinking always use Drill-Hub IV (green).

*Partially Guided:* Full freedom of Guide Sleeve position: 7 (S7), 9 (S9), 11 (S11) or 13 (S13) mm. Drill and countersinking to hub but Implant placement to marking. Charts required choosing correct Drill-Hub for drilling and Countersink-Hub for countersinking.

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

| Software Company       | Planning Software        | Guide                                 | Fully Guided | Partially Guided | Ø3.5 – 4.5 Implants | Ø5.0 – 6.0 Implants |
|------------------------|--------------------------|---------------------------------------|--------------|------------------|---------------------|---------------------|
| 360imaging             | 360dps                   | 360ips                                | ☑            | ☑                | ☑                   | ☑                   |
| 3DDX                   | Osseoview                | 3DDX Surgical Guide                   | ☑            | ☑                | ☑                   | ☑                   |
| 3DIEMME                | 3Diagnosys               | RealGUIDE                             | ☑            | ☑                | ☑                   | ☑                   |
| 3Shape                 | Implant Studio           | Implant Studio                        | ☑            | –                | ☑                   | ☑                   |
| Anatomage              | Invivio 5                | Anatomage Guide                       | ☑            | ☑                | ☑                   | In progress         |
| Dental Wings           | coDiagnostiX             | coDiagnostiX Guide                    | ☑            | ☑                | ☑                   | ☑                   |
| Dentsply Sirona        | Simplant                 | Simplant SAFE guide (use NobelGuide*) | ☑            | –                | ☑                   | N/A                 |
| Digital Dental Service | DPS-pro                  | DPS-pro                               | ☑            | ☑                | ☑                   | ☑                   |
| Exocad                 | Exoplan                  | Exoplan                               | In progress  |                  |                     |                     |
| iCAT                   | LANDmarker               | Landmark Guide                        | ☑            | ☑                | ☑                   | ☑                   |
| Media Lab              | Implant 3D               | GuideDesign                           | ☑            | –                | ☑                   | ☑                   |
| Nobel Biocare          | NobelClinician Software* | NobelGuide*                           | ☑            | –                | ☑                   | N/A                 |
| NSequence              | 3Diagnosys               | RealGUIDE                             | ☑            | ☑                | ☑                   | ☑                   |
|                        | Maven Pro                | NSequence Surgical Guide              | ☑            | ☑                | ☑                   | –                   |
| Planmeca               | Planmeca Romexis         | 3DDX Surgical Guide                   | ☑            | ☑                | ☑                   | ☑                   |
| SICAT                  | Galileos Implant         | SICAT surgical guides                 | ☑            | ☑                | ☑                   | ☑                   |
|                        | SICAT Implant            |                                       | ☑            | ☑                | ☑                   | ☑                   |
| Swissmeda              | SMOP                     | SMOP                                  | ☑            | ☑                | ☑                   | ☑                   |

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

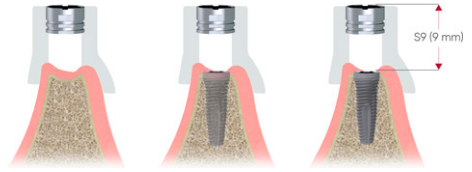
## Detailed description of Procedure – Fully guided

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.*

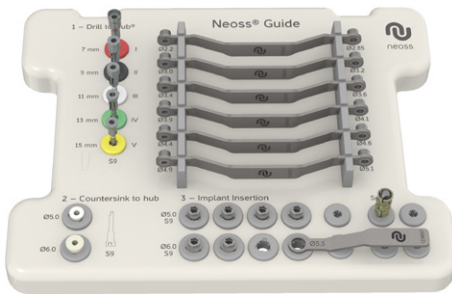


### Selection of Neoss Drill-Hubs

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.



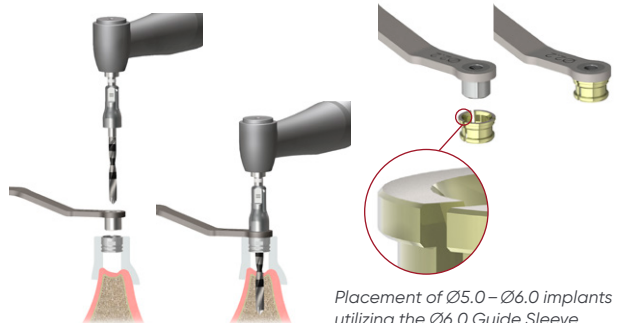
### Preparation of site

- 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.



*Placement of Ø5.0 – Ø6.0 implants utilizing the Ø6.0 Guide Sleeve*

## 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.*

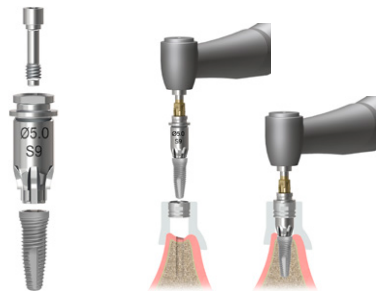


### Implant placement

- Implant Mount SP Ø5.0/S9 for Ø3.5, Ø4.0 and Ø4.5 Implants and Implant Mount SP 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 SP 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.



## Detailed description of Procedure – Partially guided

Guided with variable sleeve positions meaning all process steps includes drilling to hub, countersinking to hub and implant placement to marking. Any sleeve position – S7, S9, S11 or S13 – can be chosen for this option, but it is recommended to use one common sleeve position per guide to minimize the risk of drilling too deep.

### Positioning of guide

- A guide is produced with the Sleeve position at 7, 9, 11 or 13 mm (S7, S9, S11 or S13) 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 and sleeve position according to table.

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

*Example – Drilling:* For preparation of an 9 mm Implant and the Sleeve positioned at 11 mm (S11) use Drill-Hub III (white).

|                |       | Sleeve position |     |     |     |
|----------------|-------|-----------------|-----|-----|-----|
|                |       | S7              | S9  | S11 | S13 |
| Implant length | 7 mm  |                 | I   | II  | III |
|                | 9 mm  | I               | II  | III | IV  |
|                | 11 mm | II              | III | IV  | V   |
|                | 13 mm | III             | IV  | V   |     |
|                | 15 mm | IV              | V   |     |     |

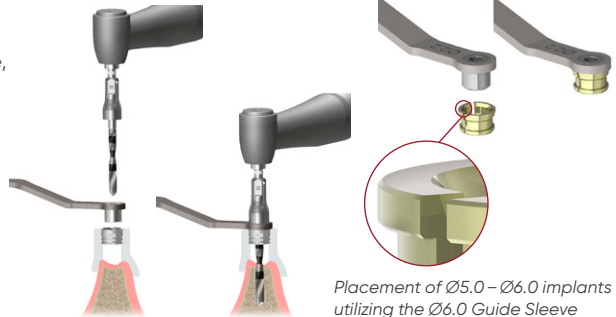


### Preparation of site

- 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.



Placement of Ø5.0 – Ø6.0 implants utilizing the Ø6.0 Guide Sleeve

## Neoss Guide Keys:

There are 6 double-sided guide keys (drill diameters;  $\varnothing 2.2/2.85$ ,  $\varnothing 3.0/3.2$ ,  $\varnothing 3.4/3.6$ ,  $\varnothing 3.9/4.1$ ,  $\varnothing 4.4/4.6$ ,  $\varnothing 4.9/5.1$ ) and 1 single-ended ( $\varnothing 5.5$ ).



## Preparation of site, optional

- If applicable, finalize site preparation by mounting Countersink Conduit on countersink shaft, choose the correct Drill-Hub based on the Sleeve position according to table.
- Countersink to Hub.

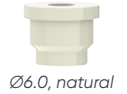
*Note: The direction of the Conduit – flange to contact the Drill Hub.*

*Note: The Countersink Conduit  $\varnothing 5.0$  is white and Countersink Conduit  $\varnothing 6.0$  natural for easy identification.*

*Note: Countersink to hub not supported if Sleeve is positioned at 13 mm.*

### Sleeve position

|     |    |     |
|-----|----|-----|
| S7  | S9 | S11 |
| III | IV | V   |

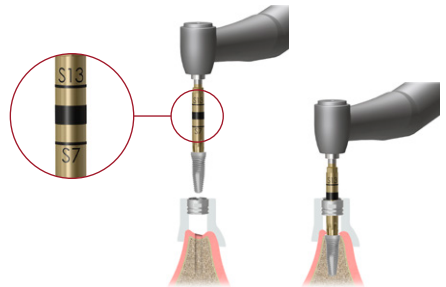


## Implant placement

- Pick-up the implant with the Neoss Guide Implant Inserter SP and place the implant through the guide to the depth of the Sleeve position as indicated on the implant Inserter.

## Removal of guide

- Once all implants are inserted, remove the guide and finalize the implant placement by choosing 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. In the event of malfunction of the device or changes in its performance of the device, the patient should contact the dentist for assessment.

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.

For cleaning and disinfection please refer to IFU Cleaning and Maintenance of Neoss Reusable Products (14077).

The instruments and accessories are reusable devices that can be reused as long as the integrity and performance of the device are maintained. The devices must be inspected before each use for visible signs of damage, deformation, wear or corrosion. Devices showing any signs of visible damage or loss of functional compatibility (for example fit of instrument with mating components, lifting function etc) shall be discarded.















### Storage

Sterilized bags and unused components must be stored in dry environment, at room temperature and out of direct sunlight. Unused components must be stored in their original packaging.

### Caution

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

## General packaging symbols

|  |   |  |  |   |
|--|---|--|--|---|
| USE BY/EXPIRY DATE<br>       | CATALOGUE NUMBER<br>                 | LOT/BATCH NUMBER<br>    | DO NOT RE-USE<br>(Single use only)<br>   | TEMPERATURE LIMIT<br>   |
| KEEP AWAY FROM SUNLIGHT<br> | MANUFACTURER<br>                     | DATE OF MANUFACTURE<br> | STERILIZED USING ETHYLENE OXIDE<br>   | STERILE BY IRRADIATION<br>(Contents of inner package sterile)<br> |
| NON-STERILE<br>              | DO NOT USE IF PACKAGE IS DAMAGED<br> | MEDICAL DEVICE<br>      | CONSULT INSTRUCTIONS FOR USE<br>(Also available on <a href="http://www.neoss.com/IFU">www.neoss.com/IFU</a> )<br> | CAUTION: Federal (USA) law restricts the sale of this device to or on the order of a licensed physician or dentist<br><b>Rx only</b>                  |

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