# Neoss Individual Prosthetics

This Instructions for use (IFU) covers specific points relevant to Neoss Individual Prosthetics. For information on general instructions for use and detailed information on other specific Neoss Implant System products, please consult Neoss Implant System Clinical Handbook (10501).

## Description

Neoss Individual Prosthetics are endosseous dental implant components i.e., abutments, bridges, and bars, used to support single tooth restorations or multi-unit prosthetic restorations. The prosthetics is retained to the implant with the aid of an abutment screw.

Neoss Individual Abutments are patient specific and are manufactured from Abutment Blanks. Abutment Blanks are hollow metal cylinders available in Ti alloy and Ti grade 4. The blank has a precision milled prefabricated Neoss® implant connection (NeoLoc®).

Neoss Individual Bridges are patient specific and are manufactured from bulk material in titanium. The posts that attach to Neoss Implants, Neoss Access Abutments or Neoss Multi-Unit Abutments have a pre-defined interface to assure compatibility.

Neoss Individual Bars are patient specific and are manufactured from bulk material in titanium. The posts that attach to Neoss Implants, Neoss Access Abutments or Neoss Multi-Unit Abutments have a pre-defined interface to assure compatibility. The bars can be made with pre-defined design features making them compatible with precision attachments that are commercially available (PRECI-VERTIX®, PRECI-HORIX®, Equator and Dolder systems. For both Neoss Individual Bars and Neoss Individual Bridges, the minimum span is 0 – 30mm.

Neoss Individual Prosthetics features the option to customize the angulation of the screw access channel (angulated screw channel, ASC). ASC requires the use of the Neoss iGO Abutment Screw and iGO Screwdriver. Neoss Individual Prosthetics with non-angulated screw channels (straight screw channel, SSC) can optionally be used with the Neo Abutment screw and Neo Screwdriver.

## Indications for use

Neoss Individual Prosthetics are connected to the Neoss Implants, Neoss Access Abutments or Neoss Multi-Unit Abutments and used as the base onto which a fixed or removable prosthetic restoration is applied for permanent patient rehabilitation.

All digitally designed CAD/CAM customizations for the Neoss Individual Abutments are only intended to be sent to and manufactured by a FDA registered and Neoss approved milling facility. Digital designs for Individual Bars/Bridges are sent to Neoss.

The Neoss implant system is intended to be used for treatment for edentulism by the replacement for one or more missing or failing teeth.

Implants and abutments are intended for single use for a single patient.

## Patient target group

Adult population. Patients that have reached skeletal maturity and their jawbone is fully developed.

## Intended user and clinical setting

A licensed dental practitioner or physician will perform the treatment using standardized, well-established surgical or prosthetic procedures in a hospital/clinic setting.

## Expected clinical benefits

The device is expected to fulfil its intended use in the specified indications, in its patient target group, during its expected lifetime.

## Expected lifetime of the product in function

The patient can, if not belonging to any groups with contraindications and if device is used as intended and for correct indications, expect the dental implant treatment to restore and maintain aesthetics and/or function for a time period comparable to natural teeth.

## Contraindications

Insufficient number of or size of implants to support biomechanical loads or undesirable positioning of implants can lead to mechanical failures including fatigue fracture of implant fixtures, prosthetics or abutment screws. Such an example is narrow diameter implants in combination with angulated abutments like angulated Access Abutments or Neoss Multi-Unit Abutments in the posterior region. Narrow diameter implants in combination with angulated abutments are only recommended for the incisor region.

Implant placement and prosthetic design must accommodate individual patient conditions such as oral hygiene, bruxism or unfavorable jaw relationships to reduce the risk of overload or fatigue failure, and treatment is contraindicated if adequate accommodation cannot be accomplished.

Please consult appropriate surgical and restorative manuals and textbooks for information on treatment planning and medical evaluation.

The design and construction of the abutment and prosthesis by the technician should incorporate appropriate retentive features for the prosthesis and should optimize the angulation between the implant fixtures and prosthesis such that an angulation correction of more than 30° to the implant axis should be avoided, since failure to do so can lead to excessive bending force and fatigue failure of the implant or abutment components. The Neoss Implant System has specific design characteristics for mating implants, abutments and prosthetic components.

## Material

Neoss Individual Prosthetics are made from commercially pure Titanium (ASTM F67) or Titanium alloy (ASTM F136).

Neoss Abutment Screws are made from Titanium alloy ASTM F136.

## Sterility at delivery

Neoss Individual Prosthetics are delivered in non-sterile condition.

## Damaged packaging

If the packaging is damaged make sure to inspect visually and ensure that device itself is not damaged.

## Preparations before use

See sections “Procedure” and section “Cleaning, disinfection and sterilization”.

## Cleaning, disinfection, and sterilisation

Abutments, bridges and bars must be carefully cleaned before sterilization. Cleaning must be performed by a trained person (manual and/or machine cleaning, ultrasonic treatment, etc.). Complete adherence to equipment manufacturer’s user instructions and recommendations for chemical detergents is required.

The individual prosthetics must be sterilized prior to insertion. Furthermore, the locally applicable legal regulations and the hygiene standards applicable for a dental practice must be observed. The following heat sterilization method and process parameters are validated in accordance with EN ISO 17665 and recommended by Neoss.

Place the cleaned components in a FDA-cleared pouch that is compatible for use with your autoclave system in order to maintain sterility for the intended sterilization cycle. Autoclave in a prevacuum cycle at 135°C/275°F, exposure time 3 min, drying cycle 60 min at pressure 30 PSI (206 kPa).

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.

The fabricator (dental technician) of the individual abutment must inform the dentist of the need to sterilize the abutment before inserting it in the patient's mouth and any limitations given the restorative materials applied to the abutment, bridge or bar by the dental technician.

## 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.

## Procedure

### Surgical planning and implant placement

Please refer to Neoss Implant System Clinical Handbook (10501) for surgical procedure including implant placement, healing and subsequent clinical steps prior to Impression taking and prosthetic design.

### Impression techniques

Impression taking could be done by conventional impression technique or by intraoral scanning.

### Conventional impression:

1. Obtain conventional impression of patient teeth setup with Neoss impression copings.
2. Based on the impression make a model with Neoss replicas.
3. Scan Bodies placed in the replicas are scanned together with the adjacent teeth and/or soft tissue, either by the dental laboratory or the Neoss approved milling facility. This can be performed with or without wax-up.

### Intraoral scanning:

Scan Bodies placed in the Neoss Implants, Neoss Access Abutments or Neoss Multi-Unit Abutments are scanned intraorally together with the adjacent teeth and/or soft tissue.

### Design & production

The scan files are transferred to an FDA cleared software for the design of the individual prosthetics.

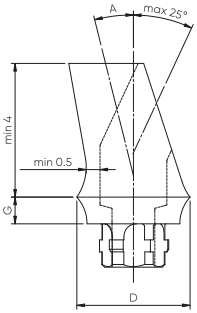
### Design

- Individual Abutments: The design is performed by a licensed clinician or dental technician and then verified for compliance with the below design limits by Neoss or a Neoss approved milling facility.
- Individual Bar/Bridge: The design is performed by a licensed clinician or dental technician and then verified for compliance with the below design limits by Neoss.

### CAD/CAM production

- Individual Abutments: CAD/CAM processing and production of the individual prosthetics are conducted by Neoss or a Neoss approved milling facility.
- Individual Bar/Bridge: CAD/CAM processing and production of the individual prosthetics are conducted by Neoss.

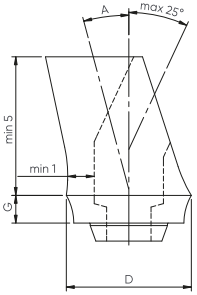
## Abutment design limits

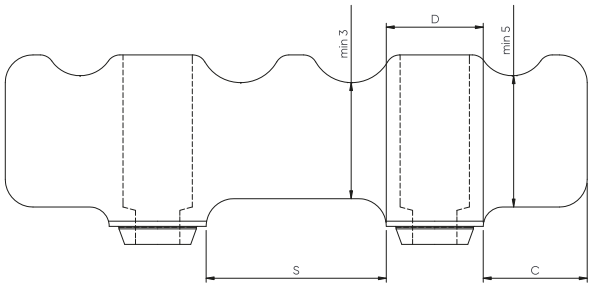



| Implant Platform | Minimum abutment diameter | Gingival height | Minimum post height | Maximum Implant to Abutment angulation | Maximum angulation of screw access channel | Minimum material thickness adjacent to screw holes |
|---|---|---|---|---|---|---|
| SP | D: Ø4.0 mm | G: 0.5 – 4 mm | 4 mm | A ≤ 30° | 25° | 0.5 mm |
| NP | D: Ø3.5 mm | G: 0.5 – 4 mm | 4 mm | A ≤ 30° | 25° | 0.5 mm |

*Note! Exceeding specified safety limits of the design of the abutment produced from a blank can result in the mechanical failure of the construction, abutment or implant. The design limitation must not be exceeded. Observe the safety limits during the design work.*

## Bridge design limits



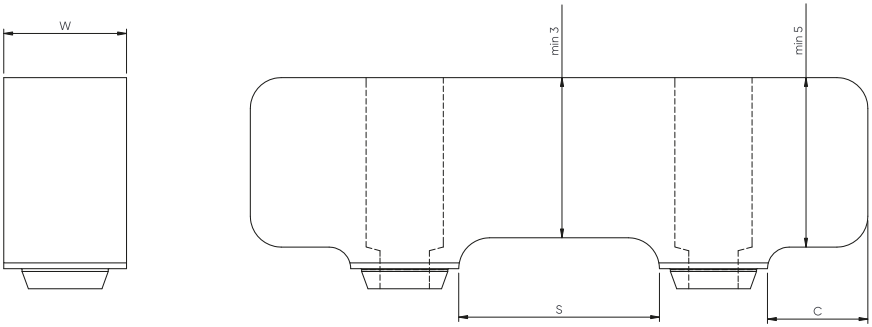




| Platform | Min. post diameter | Max. divergence between platforms | Max. implant to post angulation | Min. post height | Max. number of implants | Span between platforms (min/max) | Max. angulation of screw access channel | Min. material thickness adjacent to screw holes | Bridge cross section dimensions between posts | Min. cross section dimensions of cantilever | Max. length of cantilever |
|---|---|---|---|---|---|---|---|---|---|---|---|
| SP | D: Ø4.0 mm | 40° | A ≤ 20° | 5.0 mm | 10 | S = 0 – 30 mm | 25° | 1.0 mm | H ≥ 3 mm W ≥ 2 mm | H ≥ 5 mm W ≥ 3 mm | Full arch: 15 mm Partial: 6 mm |
| NP | D: Ø3.5 mm | | | | | | | | | | |
| Access | D: Ø4.0 mm | | | | | | | | | | |
| Multi-Unit | D: Ø4.5 mm | | | | | | | | | | |

Maximum total height of restoration is 20 mm.

*Note! Exceeding specified safety limits of the design of the bridge can result in the mechanical failure of the construction, bridge, or implant. The design limitations must not be exceeded. Observe the safety limits during design.*

## Bar design limits




| Platform | Min. cylinder diameter | Max. divergence between cylinders | Max. implant to cylinder angulation | Total number of implants/ cylinders (min/max) | Bar span between platforms (min/max) | Bar cross section dimensions | Bar cross section dimensions of cantilever | Max. length of cantilever | Cylinder height (min/max) |
|---|---|---|---|---|---|---|---|---|---|
| SP | D: Ø4.0 mm | 40° | 20° | 2/10 | S = 0 – 30 mm | Height 3 mm Width 2 mm | Height 5 mm Width 3 mm | Full arch: 15 mm Partial: 6 mm | 5/10 mm |
| NP | D: Ø3.5 mm | | | | | | | | |
| Access | D: Ø4.0 mm | | | | | | | | |
| Multi-Unit | D: Ø4.5 mm | | | | | | | | |

Maximum total height of restoration is 20 mm.

*Note! Exceeding specified safety limits of the design of the bar can result in the mechanical failure of the construction, bar or implant. The design limitations must not be exceeded. Observe the safety limits during the design work.*

### Procedure – finalizing the prosthetic restoration

The individual abutment, bridge or bar is screw retained to the Replica(s) or Analog(s) with the laboratory screws provided. The fit is checked.

Any final design adjustments are made to the individual prosthetics using either a tungsten carbide or diamond bur considering the design limitations above.

After the desired shape has been achieved, either a temporary or permanent crown/bridge is produced in the material and method of choice using conventional dental laboratory procedures.

The prosthesis is returned to the dentist for the clinical application.

### Procedure – clinical preparation and placement

After cleaning and sterilization as per section 12, the prosthesis is screwed into the patient's mouth using the compatible abutment screws and screwdriver in conjunction with the manual handle.

Once the fit has been verified, it is tightened to the recommended torque for the specific screw.

| Platform | Neo Screw | ASC (iGO Screw) |
|---|---|---|
| SP (Ø3.5 – 6.5) | 32 Ncm | 32 Ncm |
| NP (Ø3.25) | | |
| Access | 20 Ncm | 20 Ncm |
| Multi-Unit | | |

If applying a cemented solution, the crown (or bridge) is then seated on the prosthetics and checked for fit, occlusion, color etc. The prosthesis is permanently cemented using conventional crown and bridge techniques.

The occlusion and retention are checked and verified.

**Procedure – general**

The manufacturing of dental prosthetic products and the use of dental CAD/CAM systems must be carried out by qualified personnel only.

Neoss will not be held responsible for incorrectly designed or milled prosthetics as this is the responsibility of the designer and milling facility.

## Warnings

- The Neoss implant system should only be used by a licensed dental practitioner or physician who have had the appropriate education and training.
- Implement proper radiographic examination and planning to avoid vital anatomical structures (i.e. nerves, blood vessels, teeth or other sensitive structures) during implant site preparation and implant insertion.
- Because of the small size of the device components, care must be taken that they are not swallowed or aspirated by the patient.

## Precautions

- Neoss implant system components should only be used together with original components and instruments.
- Routine implant treatment is not recommended in pediatric patients with uncompleted maxillary and mandibular growth.
- Neoss implants, cover screws, abutments and abutment screws must be used solely on one patient. 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.
- All multiple use components must be maintained in good condition and inspected before use to avoid harm to patient and damage to components. See Document 14077 (Cleaning and maintenance of Neoss Reusable Products) for inspection guidelines.
- Careful clinical and radiographic examination to assess the overall medical status of the patient before treatment. Examples of risk factors for dental implant treatment are (but not limited to):
    - Insufficient bone quantity or quality
    - Local or systemic infections or inflammation
    - Compromised general and local health
    - Poor oral hygiene
    - Smoking
    - Alcohol or drug abuse
    - Disorders, medications or therapies affecting bone and wound healing (i.e. diabetes, chemotherapy, bisphosphonates)
    - History of or ongoing therapeutic radiation in the area
    - Uncontrolled bleeding disorders
    - Uncontrolled parafunctional habits or unfavorable jaw relationships
    - Poor patient compliance
- Biomechanical principles should be recognized when choosing loading protocol as well as for the design and construction of the abutment and prosthesis to minimize unfavorable forces.
- When possible, modifications to prosthetic reconstructions should take place extraorally.

- Waste materials should be handled according to the established procedures for hazardous material at the hospital/clinic/laboratory.
- In the event of malfunction of the device or changes in its performance of the device, the patient should contact the dentist for assessment.

## Adverse effects

Adverse effects related to dental implant treatment includes but are not limited to:

- Intervention related trauma
- Damage to adjacent teeth
- Fracture of the jawbone
- Temporary or permanent nerve injury (dysesthesia or paresthesia)
- Unintended sinus membrane perforation
- Post-operative bleeding
- Hematoma
- Aspirated or swallowed components
- Allergic reaction
- Malpositioned implant
- Postoperative discomfort/swelling/pain
- Bone necrosis
- Infections
- Inflammatory reactions
- Pain
- Implant loss/failure/fracture
- Prosthetic component failure/fracture
- Excessive bone loss
- Excessive gingival pressure/tension
- Peri-implantitis
- Phonetic difficulties
- Esthetic problems

## Magnetic resonance imaging (MRI)

This device has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of this device in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

## For the USA only

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

## Additional information

### Safe disposal of the device

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

The disposal of the device shall be performed in an environmentally sustainable manner according to local regulations. If the device is contaminated with human blood, tissue resides or other human secretions the device shall be disposed in appropriate containers for this.

## General packaging symbols

| | | | | | |
|---|---|---|---|---|---|
| USE BY/EXPIRY DATE  | DO NOT RE-USE (Single use only)  | STERILIZED USING ETHYLENE OXIDE   | NON-STERILE   | UNIQUE DEVICE IDENTIFIER   | LOT/BATCH NUMBER   |
| MANUFACTURER  | DATE OF MANUFACTURE  | STERILIZED USING IRRADIATION   | TEMPERATURE LIMIT   | MEDICAL DEVICE   | CATALOGUE NUMBER   |
| DO NOT USE IF PACKAGE IS DAMAGED  | KEEP AWAY FROM SUNLIGHT  | CONSULT INSTRUCTIONS FOR USE  | CAUTION: Federal (USA) law restricts the sale of this device to or on the order of a licensed physician or dentist **Rx only** | | |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