Neoss Blanks for Individual Prosthetics

Description

The Neoss implant system is a complete system of endosseous dental implants with corresponding instruments, prosthetic products and accessories.

For additional information on the specific Neoss Implant System product you are using please consult the Neoss Implant System Clinical Handbook (10501).

Neoss Individual Abutments are endosseous dental implant components used to support single tooth restorations or multi-unit prosthetic restorations. The abutment 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®).

Indications for use

Neoss Individual Prosthetics are connected to the Neoss implants 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.

Patient target group

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

For all abutments, patients treated with Neoss dental implants.

Intended user and clinical setting

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

The fabrication of the restoration is performed in a dental laboratory setting by a licensed dental technician.

Seating of abutments and restorations in the patient's mouth take place in a dental office or in an environment of a comparable clinical standard by a licensed dental practitioner or physician.

Expected clinical benefits

The product 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

Permanent abutments, permanent abutment/prosthetic screws: The patient can, if not belonging to any groups with contraindications and if product 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

- Patients who are medically unfit for the medical procedure.
- Placement of implants in insufficient numbers or sizes to support biomechanical loads or undesirable positioning is contraindicated. Influencing factors might be narrow diameter implants, angulated abutments, posterior region, insufficient bone quality and quantity. Narrow diameter implants in combination with angulated abutments are only recommended for the incisor region.
- Treatment is contraindicated where the patient has a pre-existing allergy to products used for the treatment.

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.

Material

Abutments Blanks are made of commercially pure titanium grade 4 or titanium alloy (Ti6Al4V).

Abutment screws are made of titanium alloy (Ti6Al4V) with a pure gold deposition.

Sterility at delivery

Abutment Blanks and screws are provided non-sterile.

Damaged packaging

If the packaging of a non-sterile product is damaged, make sure to inspect the product visually and ensure that the product itself isn't damaged.

Preparations before use

See sections "Procedure" and section "Cleaning, disinfection and sterilization".

Cleaning, disinfection, and sterilisation

Prosthetic products delivered non-sterile must be unpacked, cleaned and sterilized before use.

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 an 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 by the dental technician.

Storage

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

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 intra oral scanning.

Conventional impression:

1. Obtain conventional impression of patient teeth setup with Neoss impression copings.
2. Based on the impression the laboratory makes 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 are scanned intraorally together with the adjacent teeth and/or soft tissue, by the clinician.

Design & production

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

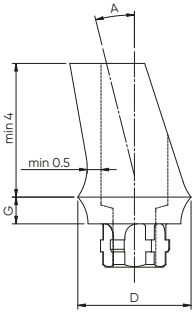
Design

The design is performed by a licensed clinician or dental technician and then verified for compliance with design limits by a Neoss approved milling facility.

CAD/CAM production

CAD/CAM processing and production of the individual prosthetics are conducted by a Neoss approved milling facility.

Abutment design limits



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

Finalizing the prosthetic restoration

The individual abutment is screw retained to the Replica or Analog with the laboratory screw 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.

Clinical preparation and placement

After cleaning and sterilization, 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 Abutment Screw
SP (Ø3.5 – 6.5)	32 Ncm
NP (Ø3.25)	32 Ncm

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 products, care must be taken that they are not swallowed or aspirated by the patient.

Precautions

- Neoss implant system products should only be used together with original products 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 products should not be reused due to risks of product contamination, patient/user infection and/or failure of the product to perform as intended.
- All multiple use products must be maintained in good condition and inspected before use to avoid harm to patient and damage to products. 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 is performed 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

- Assess vertical and horizontal intraoral space prior to treatment to assure unobstructed use of all components and instruments.
- 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. Failure to do so can lead to excessive bending force and fatigue failure of the implant or abutment components.
- 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 product or changes in its performance of the product, 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 jaw bone
- Temporary or permanent nerve injury (dysesthesia or paresthesia)
- Unintended sinus membrane perforation
- Post-operative bleeding
- Hematoma
- Aspirated or swallowed products
- Allergic reaction
- Malpositioned implant
- Postoperative discomfort/swelling/pain
- Bone necrosis
- Infections
- Inflammatory reactions
- Pain
- Implant loss/failure/fracture
- Prosthetic product failure/fracture
- Excessive bone loss
- Excessive gingival pressure/tension
- Peri-implantitis
- Phonetic difficulties
- Esthetic problems

Magnetic resonance imaging (MRI)

Neoss dental implants and implantable restorative products have not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating, migration, or image artifact in the MR environment. The safety of these products in the MR environment is unknown. Scanning a patient who has these products may result in patient injury.

For the USA only

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

Additional information

Serious incidents

If any serious incident occurs in relation to the product, the user and/or patient should report to the manufacturer (https://www.neoss.com) and the competent authority of the state in which the user and/or patient is established.

Safe disposal of the product

Handling of hazardous material according to established procedures at the hospital/clinic. The disposal of the product shall be performed in an environmentally sustainable manner according to local regulations. If the product is contaminated with human blood, tissue resides or other human secretions the product shall be disposed in appropriate containers for this.

List of Neoss approved milling facilities:

Listed at Neoss website https://www.neoss.com

General packaging symbols

USE BY/EXPIRY DATE 	DO NOT RE-USE (Single use only) 	STERILIZED USING ETHYLENE OXIDE 	NON-STERILE 	KEEP DRY 	UNIQUE DEVICE IDENTIFIER	LOT/BATCH NUMBER 
MANUFACTURER 	DATE OF MANUFACTURE 	STERILIZED USING IRRADIATION 	NARROW PLATFORM 	STANDARD PLATFORM 	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**		NOTIFIED BODY SYMBOL AND NEOSS CERTIFICATE NUMBER  MD 75473	
SINGLE STERILE BARRIER SYSTEM 	SINGLE STERILE BARRIER SYSTEM with protective packaging outside 		SINGLE STERILE BARRIER SYSTEM with protective packaging inside 		CE MARK AND NOTIFIED BODY NUMBER  2797	

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