NeoBase™ Abutments

This Instructions For Use (IFU) covers specific points relevant to Neoss NeoBase™ abutments. For information on general instructions for use and detailed information on other specific Neoss Implant System products, please consult Instructions For Use Neoss Implant System (10538), Neoss Implant System Guidelines (10501), Instruction For Use iGO Screws and iGO Screwdrivers (12040) and Instructions For Use Neoss Intra-Oral Scan Bodies (11609).

Intended use
The NeoBase™ abutments are connected to the Neoss implants and used as the base onto which the prosthetic restoration is fitted for patient rehabilitation.

Description
The NeoBase™ provides metal support for predominantly ceramic restorations whereby the NeoBase™ is cemented into the restoration before the clinical placement or subsequent to the clinical placement. NeoBase™ abutments are based on the original NeoLink® concept (10501) with an increased range covering additional post heights for increased retention and different gingival margin heights for all Neoss implants Ø3.25 mm and larger. Most importantly, all the NeoBase™ abutments require the use of the iGO screw which provides the option to angulate the screw channel up to 25°. The NeoBase™ abutments enable design and production of ceramic restorations by dental laboratory equipped with conventional design softwares and milling machines as per recommendations by Neoss.

Components and materials

<table>
<thead>
<tr>
<th>Art. No.</th>
<th>Description</th>
<th>Material</th>
<th>Implant Diameter</th>
<th>Tightening torque</th>
</tr>
</thead>
<tbody>
<tr>
<td>31367</td>
<td>NeoBase™ Mono G0.3 mm - H3.6 mm</td>
<td>Titanium grade 5</td>
<td>Ø3.5-6.5 mm</td>
<td>32 Ncm</td>
</tr>
<tr>
<td>31368</td>
<td>NeoBase™ Mono G1.5 mm - H3.6 mm</td>
<td>Titanium grade 5</td>
<td>Ø3.5-6.5 mm</td>
<td>32 Ncm</td>
</tr>
<tr>
<td>31369</td>
<td>NeoBase™ Mono G0.3 mm - H5.6 mm</td>
<td>Titanium grade 5</td>
<td>Ø3.5-6.5 mm</td>
<td>32 Ncm</td>
</tr>
<tr>
<td>31370</td>
<td>NeoBase™ Mono G1.5 mm - H5.6 mm</td>
<td>Titanium grade 5</td>
<td>Ø3.5-6.5 mm</td>
<td>32 Ncm</td>
</tr>
<tr>
<td>31371</td>
<td>NeoBase™ Multi G0.3 mm - H3.6 mm</td>
<td>Titanium grade 5</td>
<td>Ø3.25 mm</td>
<td>20 Ncm</td>
</tr>
<tr>
<td>31372</td>
<td>NeoBase™ Mono G0.3 mm - H3.6 mm Ø3.25</td>
<td>Titanium grade 5</td>
<td>Ø3.25 mm</td>
<td>20 Ncm</td>
</tr>
<tr>
<td>31373</td>
<td>NeoBase™ Mono G0.3 mm - H5.6 mm Ø3.25</td>
<td>Titanium grade 5</td>
<td>Ø3.25 mm</td>
<td>20 Ncm</td>
</tr>
<tr>
<td>31374</td>
<td>NeoBase™ Multi G0.3 mm - H3.6 mm Ø3.25</td>
<td>Titanium grade 5</td>
<td>Ø3.25 mm</td>
<td>20 Ncm</td>
</tr>
</tbody>
</table>

All components might not be available on all markets.

Contraindications
Insufficient number of or size of abutments to support biomechanical loads or undesirable positioning of implants can lead to mechanical failures including fatigue fracture of implant fixtures, abutments or abutment screws. Such an example is narrow diameter implants in combination with large angulated abutments such as angulated Access Abutments in the posterior 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.

**General Precautions**

Surgical and restorative 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 patient evaluation and close cooperation between surgeon, restorative dentist and dental laboratory technician is essential for success. Neoss implants, 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. Because of the small size of prosthetic components, care must be taken that they are not swallowed or aspirated by the patient.

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

**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.

**Procedure - design**

Neoss provides design libraries for 3Shape and Exocad software which include NeoBase™ abutments to enable creation of digital prosthetic design for Neoss with straight or angulated screw channels. A range of products supporting the digital process are incorporated into libraries such as Scan Bodies (11609) for digital impressions and Model Analogs (11619) for use with printed or milled models from external sources. Neoss Libraries together with the installation guidelines are available for download on [www.neoss-cadcam.de](http://www.neoss-cadcam.de).

Digital impression of the implant/-s position and orientation is recorded by either intra-oral scanning or desktop scanning of the master model. Design the prosthetic restoration by using relevant design software and the NeoBase™ Kit. Each NeoBase™ Kit, one for each abutment type, defines; mating geometry of the restoration, cement gap options, maximum screw channel angulation, maximum restoration height, orientation of the NeoBase™ type (engaging/non-engaging) in relation to the implant and orientation freedom of the screw access hole in relation to the implant. Final prosthetic restoration is designed and processed according to the material manufacturer’s instructions for use.

The following versions and higher of the Neoss Brand Library are compatible with NeoBase™ abutments and straight and angulated screw channels:

- 3shape: Neoss Brand Library 1.1.0
- Exocad: Neoss Brand Library 1.1.0

Exceeding specified safety limits of device 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;

| Minimum wall thickness of the ceramic material | 0.5 mm or higher. Please consult the specific material data |
| Screw channel angulation | 0-25° Screw channel angulation between 20 and 25° requires a larger screw channel than the pre-set dimension in the libraries and/or that the screw channel exits at 8 mm or lower in vertical height. |
| Maximum angulation of “chimney” portion | 30° |
| Maximum coping height | 18 mm |
| Minimum abutment height from the implant interface | 4 mm |
| Maximum gingival height | 4 mm |
Screw and screwdriver compatibility
NeoBase™ abutments are only compatible with iGO abutment screws (31347, 31349, 31350, 31352) and iGO screwdrivers (51183, 51184) and which are used for both straight and angulated screw channels.

Note: iGO screws and standard screws are visually differentiated by conically shaped and partially coated screw head.

Note: iGO abutment and laboratory screws are visually differentiated by coating and by number of threads.

Procedure - processing the NeoBase™ and the restoration
The NeoBase™ shall not be reduced e.g. by grinding when digital design is applied. Pretreatment such as blasting of the post prior the bonding can be done but only according to the specific bonding material used. The restoration is processed according to the material manufacturer’s instructions. For protection of the NeoLoc® connection of the NeoBase™ and easy handling, it is recommended that the NeoBase™ is screwed into an implant replica or the protection replica. Neoss recommend “PANAVIA® F 2.0” (www.kuraray-dental.de) as an adhesive (cement) to connect the NeoBase™ and the ceramic structure extra-orally.

1. Prepare the bonding material according to the manufacturer’s instructions and apply it to the NeoBase™.
2. Place the ceramic structure over the NeoBase™, align non-rotational planes of the NeoBase™ and the internal preparation of the ceramic structure before pushing the parts together to achieve a firm seating.
3. Immediately remove any excess cement externally and internally.
4. Remove residue with a rubber polisher after hardening.

Note: In cases of angulated screw channel, the NeoBase™ Multi and milled structures also have non-rotational features in order to align the NeoBase™ with the angulated screw channel.

Caution
The NeoLoc® implant–abutment connection is essential to the mechanical stability of the dental implant system. The abutment connection is not to be modified. Any change to this connection will characterize your facility as a medical device manufacturer subject to FDA registration, fees, regulation and restrictions. Use the protection replica to protect the connection during processing of the ceramic structure.

Clinical preparation and placement
1. The restoration assembly with the NeoBase™ is screwed onto the implant using the Neoss iGO abutment screw and iGO screwdriver.
2. Once the fit has been verified it is tightened to 32 Ncm for restorations on Neoss implants Ø3.5-6.0 and 20 Ncm for restorations on Neoss implant Ø3.25.

When screw retaining a crown direct to the implant the screw access hole should be filled with a small amount of removable material then overfilled with a permanent material (e.g. composite resin).
Note: The iGO screw connection has a carry function, but during retrieval with large angulation of the screw channel this function will be lost.

Sterilization and disinfecting
For re-sterilization of non-sterile or sterile instruments and accessories please refer to the Neoss Implant System Guidelines (10501).

Description of sterilization
The individual abutments i.e. NeoBase™ with cemented copings, 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 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.

The fabricator (dental technician) of the NeoBase™ and the ceramic structure must inform the dentist of the need to sterilize the abutment before inserting it in the patient’s mouth.

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.

Magnetic Resonance Imaging (MRI)
The Neoss products are MRI safe. Based on evaluating MR data it can be concluded that dental implants and abutments within the Neoss Dental Implant System will unlikely interfere with patient safety under the MRI conditions up to 7T. Image artefacts still needs to be considered at image analysis.

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General 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>
</tr>
</thead>
<tbody>
<tr>
<td>KEEP AWAY FROM SUNLIGHT</td>
<td>MANUFACTURER</td>
<td>DATE OF MANUFACTURE</td>
<td>CATALOGUE NUMBER</td>
<td>LOT/BATCH NUMBER</td>
</tr>
<tr>
<td>STERILE BY IRRADIATION (Contents of inner package sterile)</td>
<td>DO NOT USE IF PACKAGE IS DAMAGED</td>
<td>CONSULT INSTRUCTIONS FOR USE (Also available on <a href="http://www.neoss.com/IFU">www.neoss.com/IFU</a>)</td>
<td>CAUTION: Federal (USA) law restricts the sale of this device to or on the order of a licensed physician or dentist</td>
<td>Rx only</td>
</tr>
</tbody>
</table>

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