Neoss® TiBase Abutments and ScanPost

Introduction
The Neoss TiBase abutments and ScanPost are designed to be compatible with the TiBase solution and the inLab designs SW 4.x software within Sirona Dental CAD/CAM-System provided by Sirona Dental Solutions GmbH and selected scanners.

Indications for use Neoss TiBase
Neoss Abutments are designed to be connected to the Neoss Implants and intended for use as an aid in prosthetic rehabilitation. The Neoss TiBase is compatible with the Sirona Dental System inCoris ZI meso L. All digitally designed copings and/or crowns for use with the Neoss TiBase Abutments are to be designed and milled using the Sirona Dental CAD/CAM-System.

Indications for use Neoss ScanPost
ScanPost is used only for digital acquisition of the implant position in relation to the remaining teeth and soft tissue using a scanbody. ScanPost can be used intra-orally and extra-orally.

Product description Neoss TiBase
The Neoss implant diameters Ø3.5–6.0 mm includes TiBase abutments of two sizes, N and W, to account for different emergence profiles, a Crystaloc® abutment screw and a dedicated titanium screw as laboratory screw. The offer for the Neoss implant diameter Ø3.25 includes a TiBase abutment, an abutment screw and a laboratory screw. The articles are delivered non-sterile and intended for single use only. TiBase abutments are used in combination with taking optical impressions to record implant position in relation to topographical characteristics of neighboring teeth and soft tissue.

Individually manufactured final or provisional restorations can be cemented onto the TiBase, before being fastened to the Neoss implants with the abutment screw in the mouth. Scanbodies provided by Sirona GmbH are compatible with the TiBase for design in inLab SW 4.x software.

Product description Neoss ScanPost
ScanPost is an impression post to digitally capture the position of the implant in relation to the remaining teeth and the soft tissue. There are two ScanPosts, one is compatible for implant diameters Ø3.5–6.0 mm and one for implant diameter Ø3.25. The ScanPost is attached to the implant only for the purpose of optical detection. The ScanPost and fixing screw are sterilizable and can be used up to 50 times.

Note: The ScanPost must not be used for the final implant treatment.

Digital capture of the implant position with ScanPost is possible only in connection with one of three software products, i.e. CEREC SW 4.2, CEREC Connect SW 4.2 or inLab SW 4.2 (or higher).

Components and materials

<table>
<thead>
<tr>
<th>Art. No.</th>
<th>Description</th>
<th>Material</th>
<th>Scan body</th>
<th>Implant Diameter</th>
<th>Compatible with grinding blocks</th>
</tr>
</thead>
<tbody>
<tr>
<td>31329</td>
<td>Neoss TiBase N (NB B 3.4 L)</td>
<td>Titanium grade 5</td>
<td>L</td>
<td>Ø3.5–6.0 mm</td>
<td>Sirona inCoris ZI meso, size L, Ivoclar Vivadent: IPS e.max CAD, size L</td>
</tr>
<tr>
<td>31330</td>
<td>Neoss TiBase W (NB B 4.1 L)</td>
<td>Titanium grade 5</td>
<td>L</td>
<td>Ø3.5–6.0 mm</td>
<td>-</td>
</tr>
<tr>
<td>31331</td>
<td>Neoss ScanPost L (TiBase)</td>
<td>Stainless steel</td>
<td>L</td>
<td>Ø3.5–6.0 mm</td>
<td>-</td>
</tr>
<tr>
<td>31345</td>
<td>Neoss TiBase Ø3.25 (FX 3.4 S)</td>
<td>Titanium grade 5</td>
<td>S</td>
<td>Ø3.25 mm</td>
<td>Sirona inCoris ZI meso, size S, Ivoclar Vivadent: IPS e.max CAD, size S</td>
</tr>
<tr>
<td>31346</td>
<td>Neoss ScanPost S (Ø3.25 TiBase)</td>
<td>Stainless steel</td>
<td>S</td>
<td>Ø3.25 mm</td>
<td>-</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 20° to the implant axis, or restorations whose length exceeds a ratio of 1.25 in comparison to the length of the implant, 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. 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.

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 only 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 hints ScanPost – Scanning
Check the screw and the post for damage before reusing them. Sterilize all components of the ScanPost prior to use and re-use as per below, section Description of sterilization.
1. Attach an aspiration protection thread to the ScanPost and scanbody.
2. Prepare the patient for the intraoral scan with CEREC AC. Make sure that the correct scanbody type was selected in the software.
3. Insert the ScanPost and fix it with the fixing screw. Tightening torque: 10–20 Ncm. Check the ScanPost for proper seating in the implant.
4. Mount the scanbody on top of the post. Make sure that the scanbody is pushed onto the post completely and that the markings on the scanbody and the post line up, as per fig 1.
5. CEREC AC Omnicam – only the gray scanbodies for the Omnicam should be used with CEREC AC Omnicam. CEREC AC Bluecam – users should use only the white scanbodies for the Bluecam.
6. CEREC AC with Bluecam only: Use CEREC Optispray. It is not necessary to coat the scanbody. It is advantageous to apply a thin coating of CEREC Optispray to the scanbody. Avoid coating until a blue coloration results.
7. Take the scan. Make sure that the upper side of the scanbody was captured well and completely. The sides of the scanbody do not have to be scanned.
8. Pull off the scanbody and dispose of it.
9. Loosen the fixing screw and remove the post.
10. CEREC AC with Bluecam only, if necessary, use CEREC Optispray once again to take scans of the gingiva.

Procedure hints TiBase – Scanning and designing
1. Attach the TiBase on the implant/replica in the master model and tighten it using the supplied laboratory screw and Neoss screw driver. Assure proper seating to the implant/replica.
2. Chose scanbody:

<table>
<thead>
<tr>
<th>TiBase</th>
<th>CEREC Omnicam</th>
<th>CEREC Bluecam</th>
</tr>
</thead>
<tbody>
<tr>
<td>31329, 31330</td>
<td>L 64 31 329 (gray)</td>
<td>L 64 31 303 (white)</td>
</tr>
<tr>
<td>31345</td>
<td>S 64 31 371 (gray)</td>
<td>S 64 31 295 (white)</td>
</tr>
</tbody>
</table>

3. Align the guide groove inside the selected scanbody and mount it onto the TiBase and confirm that the seating is flush with no gaps, fig 1. The scanbody is scannable without powder or scan spray.
4. Make sure that the correct scanbody type (see table above) and TiBase was selected in the software (NB B 3.4 L for Neoss TiBase N, NB B 4.1 L for Neoss TiBase W and TiBase FX 3.45 for Neoss TiBase Ø3.25).
5. Take the scan with inEos Blue, inEos, CEREC 3 or CEREC AC. Make sure that the upper side of the scanbody was captured well and completely. The sides of the scanbody do not have to be scanned.
6. Dispose the scanbody after removing it from the model.
7. Use the inLab SW 4.0 (or higher) to design the individual shape of the restoration and mill the shape from an inCoris ZI block (see inLab 4.x User Manual). Be sure to observe the information on design, post processing and sintering of zirconia provided in the Operating Instructions for inCoris ZI blocks or other compatible blocks.

Caution
Exceeding specified safety limits of device results in the construction of a misbranded device which may lead to premature abutment fracture. The design limitation must not be exceeded.
Observe the safety limits during the design work:

| Minimum wall thickness of the inCoris ZI meso material | 0.5 mm |
| Maximum angle                                      | 20°    |
| Minimum abutment height from the implant interface | 4 mm   |
| Maximum gingival height                            | 4 mm   |

Procedure hints – Processing the TiBase
Nor diameter nor length of the TiBase shall be reduced e.g. by grinding, and the contact surfaces of the TiBase to the implant should not be sand-blasted or otherwise processed. Only the surfaces of the TiBase intended for cementation with a reconstruction must be sandblasted (50 µm aluminum oxide, max. 2.0 bar) and subsequently cleaned (with alcohol or steam). For protection of the connection of the TiBase and easy handling, it is recommended that the TiBase is screwed into an implant replica or the adjustment handle. Use “PANAVIA™ F 2.0” (www.kuraray-dental.de) as an adhesive (cement) extraorally to connect the TiBase and the sintered inCoris ZI mesostructure.
1. Protect the head of the abutment screw with wax or similar for retrievability.
2. Mix the cement according to the manufacturer’s instructions and apply it to the TiBase.
3. Place the sintered inCoris ZI restoration over the TiBase, confirm that it catches into the rotation stop before pushing it as far as it will go to achieve a firm seating on the TiBase.
4. Immediately remove any excess cement.
5. Preferably apply the Airblocker (“Oxyguard”) to the seam where the ceramic and titanium surfaces meet and to the screw channel for final hardening.
6. Remove residue with a rubber polisher after hardening.

Caution
The fixture to the 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 mesostructure.

Clinical preparation and placement
1. The restoration is screwed onto the implant using the Neoss abutment screw and screwdriver in conjunction with the manual handle.
2. Once the fit has been verified it is tightened to 32 Ncm. 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).

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. TiBase with cemented Copings, must be sterilized prior to insertion, the ScanPost before each use. 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 TiBase and the mesostructure must inform the dentist of the need to sterilize the abutment before inserting it in the patient’s mouth!

Disinfection of scanbody

Disinfect the scanbody with a commonly used disinfectant, e.g. “Dentavon® Liquid” from Schülke & Mayr, before using it on the patient.

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.

References

Sirona Dental Systems GmbH:
- Operating Instructions TiBase Information for the dentist
- Operating Instructions ScanPost
- Zirconium oxide ceramic blocks for inLab: Processing instructions: Manufacturing mesostructures

Sirona, CEREC and inCoris are trademarks of Sirona Dental Systems GmbH. Ivoclar Vivadent and IPS e.max are trademarks of Ivoclar Vivadent AG.

General packaging symbols

<table>
<thead>
<tr>
<th>USE BY/EXPIRY DATE</th>
<th>CATALOGUE NUMBER</th>
<th>LOT/BATCH NUMBER</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>REF</td>
<td>LOT</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MANUFACTURER</td>
<td>DATE OF MANUFACTURE</td>
<td>STERILIZED USING ETHYLENE OXIDE</td>
<td>STERILE BY IRRADIATION (Contents of inner package sterile)</td>
<td></td>
</tr>
<tr>
<td>NON-Sterile</td>
<td>DO NOT USE IF PACKAGE IS DAMAGED</td>
<td>MEDICAL DEVICE</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>
</tr>
</tbody>
</table>

Rx only

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