English Instructions for use: Straumann® Variobase® for CEREC®
1. Product description
Abutments
Abutments are placed into dental implants to provide support for prosthetic reconstructions such as crowns and bridges.

Basal screws
Basal screws are used for the fixation of the abutment to the dental implant.

2. Intended use
Straumann® Variobase® Abutments are intended to be placed into Straumann dental implants to provide support for prosthetic reconstructions such as crowns.

3. Indications
The Straumann® Variobase® for CEREC® are titanium alloy abutments placed onto Straumann dental implants to provide support for customized prosthetic restorations. Straumann® Variobase® for CEREC® abutments are indicated for screw-retained single-tooth or cement-retained single-tooth and bridge restorations.

All digitally designed copings and/or crowns for use with the Straumann® Variobase® for CEREC® abutments are to be designed using Sirona inLab software (Version 3.65 or higher) or Sirona CEREConline Software (Version 4.2 or higher) and manufactured using a Sirona CEREC® MC X or inLab MC XL or inLab MC X5 milling unit.

4. Contraindications
Contraindicated in cases with known allergies or hypersensitivity to chemical ingredients of the following materials used: titanium (Ti), titanium alloy (TiAlNb (titanium-aluminum-niobium or TAN)).

5. Side effects, interactions and precautions; complications with Straumann implants
Information related to side effects, interactions and precautions; complications with Straumann implants should be provided to the patient.

6. Warnings
- Dental cement or any other material used for the attachment of prosthetic components should be processed as specified by the manufacturer. An implant is only to be restored with the corresponding original abutment compatible with that specific implant.
- The WN Variobase® for CEREC® is not compatible with the Sirona Galileos Software. The use of the WN Variobase® for CEREC® in the guided surgery workflow may lead to a restoration which does not fit occlusally.

7. Caution/Precautions
- Straumann prosthetic devices must be secured to prevent aspiration during intraoral use.
- Failure to follow the procedures outlined in these instructions may lead to any of the following complications:
  - Aspiration or swallowing of components
  - Infection
  - Damage to the implant, abutment, components or tooling
  - Loosening of the abutment or other components
  - Improper final restoration or malfunction of the crown, bridge or other final prosthetics
  - Impairment of the patient’s chewing function
  - Failure of the implant
  - Removal of the implant
- The Straumann® Variobase® for CEREC® is a single-use device.
- Always place temporary restorations out of occlusion. Use temporary cement for the attachment of temporary prosthetic restorations. Dental cement or any other material used for the attachment of prosthetic components should be processed as specified by the manufacturer.
- Place implant-borne restorations only in occlusion when the implant is completely osseointegrated.
- The Straumann® Variobase® for CEREC® devices 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 the Straumann® Variobase® for CEREC® devices in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

8. Compatibility information
Straumann implants and the prosthetic components are available in a variety of configurations to meet your clinical needs. The label on each product uses abbreviations to help you identify whether a particular abutment or coping is compatible with the implant that you are restoring. The implant as well as the prosthetic component contains an identifier for the connection type, summarized in the table below.

<table>
<thead>
<tr>
<th>Implant connection type</th>
<th>Compatible parts</th>
</tr>
</thead>
<tbody>
<tr>
<td>NC (Narrow CrossFit®)</td>
<td>parts labeled NC</td>
</tr>
<tr>
<td>RC (Regular CrossFit®)</td>
<td>parts labeled RC</td>
</tr>
<tr>
<td>RN (Regular Neck)</td>
<td>parts labeled RN</td>
</tr>
<tr>
<td>WN (Wide Neck)</td>
<td>parts labeled WN</td>
</tr>
</tbody>
</table>

9. Cleaning and disinfection
Straumann® Variobase® for CEREC® and components are non-sterile when delivered. Before placing the restoration in the patient’s mouth, the product must be cleaned, disinfected and sterilized. Straumann recommends the following procedure for cleaning, disinfection and sterilization of abutments prior to use:
1. Clean the abutment rinsing it under running water while brushing the outer and inner side with adequate brushes.
2. The pre-treated product is to be cleaned/disinfected in an automated washer disinfector. Select the appropriate program according the manufacturer’s instructions.

Consult the brochure Guideline for Cleaning, Disinfection and Sterilization for Straumann® Implant-borne Prosthetic Components, 152.802 for detailed information.

10. Sterilization
The finished restoration consisting of the Variobase® for CEREC® abutment with the milled restoration bonded in place may be sterilized unwrapped or can be placed in an accessory cassette and packaged twice in common sterilization wraps (paper/film/bags). Steam sterilize according to the following parameters.

<table>
<thead>
<tr>
<th>Material</th>
<th>Method</th>
<th>Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Variobase® for CEREC®, TAN</td>
<td>Autoclave (moist heat)</td>
<td>North America: 121°C (250°F) 3 min</td>
</tr>
<tr>
<td>Screw, TAN</td>
<td>Displacement: gravity or fractionated vacuum</td>
<td>Europe: 134°C (273°F) 5 min</td>
</tr>
</tbody>
</table>
Please note:
- User should ensure the use of the appropriate biological indicator for the sterilizer and parameters used.
- The user should consult the coping/restoration material manufacturer’s recommendations regarding sterilization.

Caution: Use devices immediately after sterilization. Do not store sterilized devices.

Consult the brochure **Guideline for Cleaning, Disinfection and Sterilization for Straumann® Implant-borne Prosthetic Components**, 152.802 for detailed information.

11. Procedure

Please note: A temporary restoration can be used prior to the insertion of the final components to maintain, stabilize and form the soft tissue during the healing phase.

Please note: In order to provide a dimensionally accurate original Straumann WN implant-abutment connection, the WN Variobase® for CEREC® is not compatible with the Sirona Gaillileo software. The use of the WN Variobase® for CEREC® in the guided surgery workflow may lead to a restoration which does not fit occlusally.

Use and compatibility of the Straumann® Variobase® for CEREC®:
- The Straumann® Variobase® for CEREC® can be used for screw- and cement-retained restorations.
- When using a digital workflow the standard procedure according to the system provider instructions apply.
- Select the appropriate Straumann-compatible Sirona Ti-base (e.g., for an NC Variobase® select the SBL 3.3 Ti-base in the InLab Software) from the implant library of the CADCAM system to design the restoration.
- The Straumann® Variobase® for CEREC® requires the use of Sirona inLab software (Version 3.65 or higher) or Sirona CEREC® Software (Version 4.2 or higher) and a Sirona CEREC® MC X or MC XL or inLab MC XS milling unit.
- The Straumann® Variobase® for CEREC® is compatible with the accessory components used in the Sirona CEREC® or inLab system (e.g., scanbodies, mill cutters).
- The abutment’s coronal design is compatible with material milling blocks having a pre-machined screw hole (e.g., IPS e.max CAD, inCoris ZI meso).

a.) Fabricate the prosthetic restoration

Please note:
- The instructions for use of the material manufacturer shall be followed.
- The diameter or height of the Straumann® Variobase® for CEREC® must not be reduced, e.g. by grinding.

1. Fix the abutment either intraorally to the implant or extraorally to the implant analog on the master cast by tightening the basal screw hand-tight.
2. Insert the scan-body to the Straumann® Variobase® for CEREC®.
3. Proceed with an intraoral scan or scan the master cast to create a digital working model.
4. Select a comparable third party Ti-base from the implant library of the CADCAM system to design the restoration.
5. Process and finalize the prosthetic restoration according to the material manufacturer’s instructions for use. Always finalize the crown or coping prior to bonding to the Straumann® Variobase® for CEREC®.

b.) Bonding the prosthetic restoration onto the abutment

Please note:
- Only the surfaces of the Straumann® Variobase® for CEREC® intended for gluing with a mesostructure or anatomic reduced crown must be sandblasted (50μm aluminium oxide, max. 2 bar).
- Prior to bonding a fit test should be performed either on a model or intraorally.

1. Clean the abutment with alcohol or steam.
2. Fix the abutment to the implant analog or coping prior to bonding to the Straumann® Variobase® for CEREC®.
3. Seal the screw channel with wax.
4. Apply self-adhesive dental cement on the Straumann® Variobase® prosthetic components. Only suitable self-adhesive cementation systems for the material shall be used. Follow the instructions for use of both the dental material and bonding material manufacturer. (Straumann recommends Panavia™ F2.0 by Kuraray).
5. Bond the prosthetic restoration to the Straumann® Variobase® prosthetic components.
6. Immediately remove excess cement from the Straumann® Variobase® prosthetic components.
7. Optional for cement-retained restorations: Make a crown following the standard procedure according to the material manufacturer’s instructions and finalize it.
8. Clean the restoration prior to further processing.

9. Close the screw channels with cotton and a sealing compound (e.g. gutta-percha or composite restorative material). This allows a later removal of the Straumann® Variobase® prosthetic components in case a crown replacement is necessary.

Optional for cement-retained restorations:
10. Apply self-adhesive dental cement on the Straumann® Variobase® prosthetic components. Only suitable self-adhesive cementation systems for the material shall be used. Follow the instructions for use of both the prosthetic material and bonding material manufacturer (Straumann recommends Panavia™ F2.0 by Kuraray).
11. Bond the prosthetic restoration to the Straumann® Variobase® prosthetic components.

---

### Device type

<table>
<thead>
<tr>
<th>Device type</th>
<th>Tightening torque</th>
<th>Special considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abutments (permanent)</td>
<td>35 Ncm</td>
<td>n/a</td>
</tr>
<tr>
<td>Temporary abutments</td>
<td>15 – 35 Ncm</td>
<td>Tighten only to 35 Ncm if the implant is fully osseointegrated</td>
</tr>
<tr>
<td>Components on implant analog</td>
<td>Hand-tight</td>
<td>n/a</td>
</tr>
</tbody>
</table>

---

**Controlled by: V7.27.20-064, Rev. 106, 11.05.2020**
12) Immediately remove excess cement from the Straumann® Variobase® prosthetic components and polish the lower margin of the prosthetic restoration after the cement has set.

**Warning:** Torque values greater than 35 Ncm may result in failure of the abutment and/or implant. Torque values less than the recommended values may result in loosening of the abutment, which may lead to abutment and/or implant failure.

**Please note:** Once the Straumann abutment has been secured to the implant using the indicated torque, it should not be removed, except where a crown replacement is necessary. Never re-use a Basal Screw after it has been tightened.

**12. Further information**
For additional information about the use of Straumann products, please contact your local Straumann sales representative. Additional information on Straumann products is available on the Straumann website (www.straumann.com). The following brochures provide additional guidance on the use of the Straumann prosthetic components and instruments:

- *Guideline for Cleaning, Disinfection and Sterilization for Straumann® Implant-borne Prosthetic Components*, 152.802

**13. Please note**
Practitioners must have knowledge of dental implantology and instruction in the handling of the Straumann product described herein (“Straumann Product”) for using the Straumann Product safely and properly in accordance with these instructions for use.

The Straumann Product must be used in accordance with the instructions for use provided by the manufacturer. It is the practitioner’s responsibility to use the device in accordance with these instructions for use and to determine, if the device fits to the individual patient situation.

The Straumann Products are part of an overall concept and must be used only in conjunction with the corresponding original components and instruments distributed by Institut Straumann AG, its ultimate parent company and all affiliates or subsidiaries of such parent company (“Straumann”), except if stated otherwise in these instructions for use. If use of products made by third parties is not recommended by Straumann in these instructions for use, any such use will void any warranty or other obligation, express or implied, of Straumann.

**14. Validity**
Upon publication of these instructions for use, all previous versions are superseded.