Instructions for use: Straumann® Variobase® for crown

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

Prosthetic components directly connected to the endosseous dental implant are intended for use as an aid in prosthetic rehabilitations.

3. Indications

The Straumann® Variobase® for crown is a titanium base placed onto Straumann dental implants to provide support for customized prosthetic restorations. Straumann® Variobase® for crown is 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 crown are intended to be sent to Straumann for manufacture at a validated milling center.

4. Contraindications

Allergies or hypersensitivity to materials used, which are indicated in the following table:

<table>
<thead>
<tr>
<th>Device</th>
<th>Material</th>
</tr>
</thead>
<tbody>
<tr>
<td>Straumann Variobase® for crown, Screws</td>
<td>Titanium alloy, Ti-6Al-Nb (Titanium-aluminum-niobium or TAN)</td>
</tr>
</tbody>
</table>

5. Warnings and Precaution

Our products must be secured against aspiration when used intraorally. Failure to follow the procedures outlined in these instructions may lead to any or all of the following complications:
- Aspiration or swallowing of a component
- Breakage
- Infection
- Under the scan conditions defined above, the metallic components of the Straumann® Dental Implant System are expected to produce a maximum temperature rise of less than 5.9 °C after 15 minutes of continuous scanning.
- Under 1.5 T scan conditions, the metallic components of the Straumann® Dental Implant System are expected to produce a maximum temperature rise of less than 5.2 °C after 15 minutes of continuous scanning.
- In non-clinical testing, the image artifact caused by the device extends approximately 26 mm from the metallic components of the Straumann® Dental Implant System when imaged with a gradient echo pulse sequence (13 mm with a spin echo pulse sequence) in a 3.0 T MRI system.

6. MRI Safety Information

Non-clinical testing has demonstrated that metallic components (titanium, TAN [Ti-Al-Nb alloy], TAV [Ti-Al-V alloy], Roxolid [Ti-Zr alloy], gold alloys) of the Straumann® Dental Implant System are MR Conditional. A patient with any metallic devices can be safely scanned in an MR system meeting the following conditions:
- Static magnetic field of 3.0 T.
- Maximum spatial field gradient of 3000 gauss/cm (0.3 T/m).
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode).
- Optional: Under the scan conditions defined above, the worst case Straumann device construct exhibited displacement forces of less than 0.1 N (less than the force of gravity).

7. 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 prostheses</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>NNC (Narrow Neck CrossFit®)</td>
<td>parts labeled NNC</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>

8. Cleaning and Disinfection

Straumann® Variobase® for crown 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 rinsing under flowing water while brushing 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 to the manufacturer’s instructions.

9. Sterilization

The restoration 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 parameters below:

<table>
<thead>
<tr>
<th>Material</th>
<th>Method</th>
<th>Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Varibase® for crown, TAN</td>
<td>Autoclave (moist heat)</td>
<td>134°C (273°F) 5 minutes</td>
</tr>
<tr>
<td>Screw, TAN</td>
<td>Displacement: gravity or</td>
<td></td>
</tr>
<tr>
<td></td>
<td>fractional vacuum</td>
<td></td>
</tr>
<tr>
<td>Varibase® for crown/TAN</td>
<td>Autoclave (moist heat)</td>
<td>121°C (250°F) 20 minutes</td>
</tr>
<tr>
<td>Screw, TAN</td>
<td>Displacement: gravity or</td>
<td></td>
</tr>
<tr>
<td></td>
<td>fractional vacuum</td>
<td></td>
</tr>
</tbody>
</table>

Please note: User should ensure the use of the appropriate biological indicator for the sterilizer and parameters used.

Please note: User should consult the coping/restoration material manufacturer’s recommendations regarding sterilization.

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

10. Procedure
Use and handling of the Straumann® Varibase® for crown for the Dental Technician

Restoration design
Make a coping or crown following standard procedure according to the material manufacturer’s instructions. When using pressing or casting techniques via wax-up, use the burn-out coping for Varibase® for crown which supports a clean and sharp-edged finish of the screw channel and a good fit to the Straumann® Varibase® for crown. When using a digital workflow, use the Straumann Varibase Implant Kit with any software platform, to facilitate the precise design of the interface between the Straumann® Varibase® for crown and the coping. The kit consists of an STL file containing the required milling template for the inner coping geometry. Once the coping is designed using the CAD software, send to Straumann for milling.

The Straumann® Varibase® for crown can be processed with the digital and conventional workflow.

A modified Straumann® Varibase® for crown can only be processed with the conventional workflow.

Please note: For in-lab casting, Straumann recommends using materials Type 4 dental metals (ISO 22674). The Rp0.2 must be ≥360 MPa and have a minimum of 2% elongation after fracture. The manufacturing of the coping and/or crown must follow the standard procedure according to the material manufacturer’s instructions for use. The design specifications of the coping and/or crown must follow the design specifications according to the material manufacturer’s instructions for use with the following exceptions:

- the recommended minimum wall thickness is 0.5 mm
- the recommended minimum angulation is 0°
- the recommended maximum angulation is 30°

Please note: For in-lab pressing, Straumann recommends using the IPS e.max® Press Abutment Solutions ceramic material according to the material manufacturer’s instructions for use. The design specifications of the coping and/or crown must follow the design specifications according to the material manufacturer’s instructions for use with the following exceptions:

- the recommended minimum wall thickness is 0.9 mm
- the recommended minimum angulation is 0°
- the recommended maximum angulation is 30°

Please note: For milling, the following framework guidelines must be followed when designing in CAD software:

<table>
<thead>
<tr>
<th>Minimum Wall Thickness</th>
<th>zeron®</th>
<th>IPS e.max®</th>
<th>coron®</th>
<th>polycon® ae</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.4 mm</td>
<td>0.9 mm</td>
<td>0.3 mm</td>
<td>0.5 mm</td>
<td></td>
</tr>
</tbody>
</table>

| Minimum Angulation     | 0°     | 0°         | 0°     | 0°          |
| Maximum Angulation     | 30°    | 30°        | 30°    | 30°         |

Please note: The milled restorations may be manufactured using polycon® ae (for temporary restorations), zeron®, IPS e.max®, CAD, or coron®. The design of the coping and/or crown must follow the standard procedure according to the material manufacturer’s instructions for use.

Processing
Process the manufactured coping or crown following standard procedure according to the material manufacturer’s instructions. Always finalize the crown or coping prior to bonding to the Straumann® Varibase® for crown.

Bonding
Please note: It is not necessary to sandblast the Straumann® Varibase® for crown.
1. Fix the abutment to the implant analog with a screw (hand-tight).
2. Seal the screw channel with wax.
3. Apply self-adhesive dental cement on the abutment. Only suitable self-adhesive cementation systems for the material used shall be used. Follow the instructions for use of both the dental material and cement/bonding material manufacturer. (Straumann® recommends Panavia F2.0 resin cement by Kuraray)
4. Bond the coping to the abutment.
5. Immediately remove excess cement from the abutment and polish the lower margin of the coping after the cement is set.
6. Optional: For cement-retained restorations: Make a crown following standard procedure according to the material manufacturer’s instructions and finalize it.
7. Clean the restoration prior to sending it to the dentist.
8. Include this instruction for use when sending the restoration to the dentist.

Use and handling of the Straumann® Varibase® for crown for the Dentist

Remove the restoration from the master cast or the analog.
Clean, disinfect and sterilize the device as described in sections 7 and 8 of this Instructions for Use document.

Placing the restoration
a) Remove the healing cap or temporary restoration.
b) Clean and dry the interior of the implant and the abutment thoroughly.
c) Place the sterilized restoration into the patient’s mouth.
d) Make sure that the retentive elements of the implant abutment connection are properly aligned.
e) Use the screw delivered with the abutment to screw the abutment into the dental implant.

Please note: Always ensure that the surfaces of threads and screw heads are clean and that a new screw is used for the restoration.

f) Straumann® abutments are fixed to the implant using the Straumann® SCS screwdriver, ratchet and torque control device. Use the respective torque according to the table below:

<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 analogs</td>
<td>Hand-tight</td>
<td>n/a</td>
</tr>
</tbody>
</table>

For cement-retained restorations (optional):

- g) Close the screw channel with cotton and sealing compound (i.e., gutta-percha)
- h) Apply self-adhesive dental cement on the two-piece abutment. Only suitable self-adhesive cementation systems for the used materials shall be used. Follow the instructions for use
of the cement/bonding material manufacturer (Straumann recommends Panavia™ F2.0 resin cement by Kuraray).

i) Bond the crown to the two-piece abutment.

j) Immediately remove excess cement from the two-piece abutment.

**Warning**

Torques 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.

11. **Further Information**

For additional information about the use of Straumann products, call Straumann’s customer service department or visit www.straumann.com.

For additional information, consult: Basic information on the Straumann® Variobase® for crown

12. **Please note**

Practitioners must have appropriate knowledge 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 Product is 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.

13. **Validity**

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

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Some items of the Straumann® Dental Implant System are not available in all countries.