Basic information on the surgical and prosthetic procedures

Straumann® PURE Ceramic Implant
About this guide

This surgical and prosthetic procedure describes the steps required for implantation and restoration of the Straumann® PURE Ceramic Implant. The Straumann® PURE Ceramic Implant System is recommended for use only by clinicians with advanced surgical skills. It is assumed that the user is familiar with placing dental implants. Not all detailed information will be found in this guide. Reference to existing Straumann procedure manuals will be made throughout this document.
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1. Straumann® PURE Ceramic Implant

1.1 Introduction to the Straumann® PURE Ceramic Implant Monotype

The Straumann® PURE Ceramic Implant Monotype consists of an implant and abutment made from zirconium-dioxide ceramic. The new implant is a monotype design based on features of the Straumann® Soft Tissue Level Standard Plus and Straumann® Bone Level Implants. All Straumann® PURE Ceramic Implants can be placed with the existing Straumann® Surgical Cassette while using a very similar surgical procedure as the Bone Level surgical protocol.

The Straumann® PURE Ceramic Implant is available in two endosteal diameters, Ø 3.3 mm and Ø 4.1 mm, and each comes with two abutment heights, 4 mm and 5.5 mm. The Straumann® PURE Ceramic Implant System uses the same unified color code of instruments and implants that is used with Straumann titanium implants.

The Straumann® PURE Ceramic Implant is a one-piece monotype implant and therefore does not have an internal connection. A nomenclature, similar to Straumann® titanium implants, is used for identification of Straumann® PURE Ceramic Implant auxiliaries. All these components can be identified with the ND (Narrow Diameter) and RD (Regular Diameter) code which corresponds to a shoulder diameter of Ø 3.5 mm and Ø 4.8 mm respectively.

<table>
<thead>
<tr>
<th>Color coding</th>
<th>Endosteal implant diameter</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yellow</td>
<td>3.3 mm</td>
</tr>
<tr>
<td>Red</td>
<td>4.1 mm</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Implant overview</th>
<th>Straumann® PURE Ceramic Implant Ø 3.3 ND</th>
<th>Straumann® PURE Ceramic Implant Ø 4.1 RD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Connection</td>
<td>ND</td>
<td>ND</td>
</tr>
<tr>
<td>Ahutment height</td>
<td>AH 4 mm</td>
<td>AH 5.5 mm</td>
</tr>
<tr>
<td>Shoulder diameter</td>
<td>Ø 3.5 mm</td>
<td>Ø 3.5 mm</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Endosteal diameter</th>
<th>Length</th>
<th>8 mm</th>
<th>10 mm</th>
<th>12 mm</th>
<th>14 mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ø 3.3 mm</td>
<td>031.001S</td>
<td>031.002S</td>
<td>031.003S</td>
<td>031.004S</td>
<td></td>
</tr>
<tr>
<td>Ø 3.3 mm</td>
<td>031.011S</td>
<td>031.012S</td>
<td>031.013S</td>
<td>031.014S</td>
<td></td>
</tr>
<tr>
<td>Ø 4.1 mm</td>
<td>031.021S</td>
<td>031.022S</td>
<td>031.023S</td>
<td>031.024S</td>
<td></td>
</tr>
<tr>
<td>Ø 4.1 mm</td>
<td>031.031S</td>
<td>031.032S</td>
<td>031.033S</td>
<td>031.034S</td>
<td></td>
</tr>
</tbody>
</table>
1.2 Overview of the Straumann® PURE Ceramic Implant portfolio

The Straumann® PURE Ceramic Implant System consists of only a few components.

<table>
<thead>
<tr>
<th>Surgical components</th>
<th>Prosthetic components</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Implant</td>
<td>• Analog</td>
</tr>
<tr>
<td>• Position indicator</td>
<td>• Impression Cap</td>
</tr>
<tr>
<td></td>
<td>• Protective Cap</td>
</tr>
<tr>
<td></td>
<td>• Temporary Coping</td>
</tr>
</tbody>
</table>

2. Implant features and benefits

2.1 Design features

- Abutment design for cementable restorations
- Ivory color for natural esthetics
- 1.8 mm machined neck
- Conical thread in coronal region known from Bone Level Implants
- ZLA® surface topography comparable to Straumann® SLA®
- Thread pitch 0.8 mm from Straumann® Bone Level
- Apical tip known from Bone Level/Tapered Effect Implants
2.2 Surface

The Straumann® ZLA® surface features a topography characterized by macro- and micro-roughness similar to an SLA® surface. This surface is designed to offer a structure for cell attachment. Animal studies have shown osseointegration equivalent to Ti-SLA® regarding peri-implant bone density and BIC ratio¹.

![ZLA surface](image1) ![SLA surface](image2)

2.3 Material

The Straumann® PURE Ceramic Implant is made from yttrium-stabilized zirconium dioxide (Y-TZP). This material has been used for a long time in orthopedics with successful results.

<table>
<thead>
<tr>
<th>Property</th>
<th>Unit</th>
<th>Titanium grade 4</th>
<th>Y-TZP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Density</td>
<td>g/cm³</td>
<td>4.5</td>
<td>6.05</td>
</tr>
<tr>
<td>Hardness</td>
<td>HV</td>
<td>250</td>
<td>1100 – 1500</td>
</tr>
<tr>
<td>Strength</td>
<td>MPa</td>
<td>680 (tensile)</td>
<td>≥ 1200 (4-point bending strength)</td>
</tr>
<tr>
<td>Mod. of elasticity</td>
<td>GPa</td>
<td>110</td>
<td>200 – 220</td>
</tr>
</tbody>
</table>

⚠️ Warning

No grinding of any part of the implant or implant abutment is allowed. Grinding can lead to micro-cracks in the material which may result in a significant reduction of the implant strength.

3. Indications and contraindications

3.1 Intended use

The Straumann® PURE Ceramic Implant Monotype is suitable for oral endosteal implantation in the upper and lower jaw and for the functional and esthetic oral rehabilitation of edentulous and partially edentulous patients (unless specific indications and limitations are specified, as stated below).

3.2 Indications

The prosthetic restorations used are single crowns, fixed partial or full dentures, which are connected to the implants through the corresponding components. Reduced diameter implants are recommended for central and lateral incisors only. For details about the necessary bone volume, spacing between implants and distance from adjacent teeth, see the Instructions for Use, www.ifu.straumann.com.

3.3 Contraindications

Non-completed maxillary and mandibular growth, drug or alcohol abuse, allergies or hypersensitivity to chemical ingredients of the zirconium dioxide material: zirconium dioxide (ZrO₂), yttrium oxide (Y₂O₃), hafnium dioxide (HfO₂), aluminum oxide (Al₂O₃), all conditions that would be normally contraindicated for oral surgery.

<table>
<thead>
<tr>
<th>Implant type</th>
<th>Indications and distinctive features</th>
<th>Minimal ridge width</th>
<th>Minimal gap width</th>
</tr>
</thead>
<tbody>
<tr>
<td>Straumann® PURE Ceramic Implant</td>
<td>• Small-diameter implant for narrow interdental spaces and ridges</td>
<td>5.5 mm</td>
<td>5.5 mm</td>
</tr>
<tr>
<td>∅ 3.3 mm ND</td>
<td>• For central and lateral incisors</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Caution:</strong> Placement in the premolar and molar region is not recommended.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Straumann® PURE Ceramic Implant</td>
<td>• For oral endosteal implant indications in the maxilla and mandible, for functional and esthetic</td>
<td>6 mm</td>
<td>7 mm</td>
</tr>
<tr>
<td>∅ 4.1 mm RD</td>
<td>rehabilitation of edentulous and partially edentulous patients</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Minimal ridge width: Minimal orofacial ridge width, rounded off to 0.5 mm
** Minimal gap width: Minimal mesial-distal gap width for a single-tooth restoration, between adjacent teeth, rounded off to 0.5 mm
4. Surgical procedure for Straumann® PURE Ceramic Implant Monotype

The workflow for the surgical procedure for the Straumann® PURE Ceramic Implant Monotype includes 4 steps: Preoperative planning, basic implant bed preparation, fine implant bed preparation and implant insertion.

4.1 Preoperative planning

The monotype design of the Straumann® PURE Ceramic Implant Monotype requires the planning of the implant placing to be very thorough and detailed. A prosthetic-driven planning is recommended and also particularly important as a perfect axis for implant insertion during implant bed preparation is crucial.

For the preoperative planning, the implant position and the planning aids will provide all information required to determine the most suitable position for the implant and its prosthetic reconstruction.

4.1.1 Implant position

To plan implant positioning, the following three basic rules must be followed (see also Basic Information on the Surgical Procedures – Straumann® Dental Implant System), 152.754/en.

**Rule 1**
Distance to adjacent tooth at bone level: The required minimal distance from the implant shoulder to the adjacent tooth at bone level (mesial and distal) is 1.5 mm.

**Rule 2**
Distance to adjacent implants at bone level: The recommended minimal distance between two adjacent implant shoulders (mesiodistal) is 3 mm.

\[ \geq 1.5 \text{ mm} \]

\[ \geq 3 \text{ mm} \]
Rule 3
Special attention should be paid in order to achieve an optimal orofacial positioning of the implant, as the abutments must not be modified.

<table>
<thead>
<tr>
<th>Shoulder Diameter</th>
<th>Gap Width $a_{\text{min}}$ [mm]</th>
<th>Distance between teeth at bone level $b_{\text{min}}$ [mm]</th>
</tr>
</thead>
<tbody>
<tr>
<td>$\phi 3.5$ (ND)</td>
<td>5.5</td>
<td>6.5</td>
</tr>
<tr>
<td>$\phi 4.8$ (RD)</td>
<td>7</td>
<td>8</td>
</tr>
<tr>
<td>Rule</td>
<td>$D + 2$ mm</td>
<td>$D + 3$ mm</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Shoulder Diameter $D_1$ [mm]</th>
<th>Shoulder Diameter $D_2$ [mm]</th>
<th>$a_{\text{min}}$ [mm]</th>
<th>$b_{\text{min}}$ [mm]</th>
<th>$c_{\text{min}}$ [mm]</th>
<th>$L_{\text{min}}$ [mm]</th>
</tr>
</thead>
<tbody>
<tr>
<td>$\phi 3.5$ (ND)</td>
<td>$\phi 3.5$ (ND)</td>
<td>3</td>
<td>6.5</td>
<td>3</td>
<td>12.5</td>
</tr>
<tr>
<td>$\phi 3.5$ (ND)</td>
<td>$\phi 4.8$ (RD)</td>
<td>3</td>
<td>7</td>
<td>4</td>
<td>14</td>
</tr>
<tr>
<td>$\phi 4.8$ (RD)</td>
<td>$\phi 4.8$ (RD)</td>
<td>4</td>
<td>8</td>
<td>4</td>
<td>16</td>
</tr>
</tbody>
</table>
4.1.2 Planning aids

For diagnostics and pre-planning purposes, use the Straumann® Diagnostic T and the Straumann® Implant Distance Indicator using the NN & RN symbol as a reference for ND and RD implants respectively. (For specific information, please review the Basic Information on the Surgical Procedures – Straumann® Dental Implant System)

Additionally the Straumann® X-ray template (150.21S) is used for comparison.

The X-ray template also assists the user in selecting the suitable length. Similar to the distortions that occur in X-rays, the implant dimensions are shown on the individual templates with the corresponding distortion factors (1:1 to 1.7:1). Determining each magnification factor or scale is facilitated by showing the X-ray reference sphere on the template (next to the scale reference).

Note

Use only the X-ray template specific to the implant type. To calculate the effective bone availability use the following formula:

\[
\text{Effective bone availability} = \frac{\text{X-ray reference sphere } 5 \text{ mm} \times \text{ bone availability } (X\text{-ray})}{\text{Reference sphere diameter on the X-ray}}
\]
There is also the possibility of a digital planning with coDiagnostiX®

This 3D diagnostics and implant planning software is designed for the image-guided surgical planning of dental implants, including Straumann® PURECeramic Implants, which are included in the digital library of the system. Working with the software is based on a patient’s medical image data such as a CT (Computed Tomography) and DVT (Digital Volume Tomography) that is processed by coDiagnostiX®.

Planning is performed by the calculation of several views (such as virtual OPG or a 3-dimensional reconstruction of the image dataset) and the analysis of the image data and the placement of implants, abutments and drilling sleeves.

codiagnostix® software is designed for use by persons who have appropriate knowledge in implantology and surgical dentistry. For further information, please refer to the coDiagnostiX® Manual.
4.2 Basic implant bed preparation

For preparing the implant bed the Straumann® Surgical Cassette is used. For the Straumann® PURE Ceramic Implant Monotype a specific new instrument is introduced in the procedure, and it is used only during the basic implant bed preparation.

4.2.1 Position indicator

4.2.1.1 Intended use

The Straumann® PURE Ceramic Implant position indicators are instruments used to ensure correct positioning of the implant during implant bed preparation. The Straumann® PURE Ceramic Implant position indicators are made of titanium. They are delivered non-sterile and must be sterilized prior to use.

4.2.1.2 Characteristics

Handling feature

- Allows for easy removal from implant bed by use of perio probe or if dental floss is inserted through hole prior to insertion
- Can also be used to secure against aspiration

Product identification

- Laser marked platform and endosteal diameter identification

<table>
<thead>
<tr>
<th>Position Indicator for Straumann® PURE Ceramic Implant Ø 3.3 ND</th>
<th>Straumann® PURE Ceramic Implant Ø 4.1 RD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abutment height</td>
<td>AH 4 mm</td>
</tr>
<tr>
<td>Ø 2.2</td>
<td>031.102</td>
</tr>
<tr>
<td>Ø 2.8</td>
<td>031.103</td>
</tr>
<tr>
<td>Ø 3.5</td>
<td>–</td>
</tr>
</tbody>
</table>

Note

Position Indicators can be cleaned, disinfected and sterilized like all other Straumann instruments. Detailed instructions are provided in the brochure Care and Maintenance of Surgical and Prosthetic Instruments, 152.008/en.
4.2.2 Preparing the implant bed

After opening the gingiva, the basic implant bed preparation begins with preparing the alveolar ridge (Step 1) and marking the implantation site with a round bur (Step 2). After that follows the implant bed preparation with pilot and twist drills (Step 3 – 5), according to the endosteal implant diameter.

**Step 1 – Prepare the alveolar ridge**

Carefully reduce and smooth a narrow tapering ridge with a large round bur. This will provide a flat bone surface and a sufficiently wide area of bone. For scalloped situations, ensure there is sufficient space for the flaring neck.

**Step 2 – Mark the implantation site**

Using the Ø 1.4 mm round bur, mark the implantation site determined during the implant position planning. The implant distance indicator can be used for that purpose. Widen and correct the position of the mark with the Ø 2.3 mm or the Ø 3.1 mm round bur, if necessary.

**Step 3 – Mark the implant axis**

and prepare the implant bed to Ø 2.2 mm

With the Ø 2.2 mm pilot drill, mark the implant axis by drilling to a depth of about 6 mm. Insert the short side of the depth gauge with the distance indicator to check the depth.

Pre-drill the implant bed to the final preparation depth with the Ø 2.2 mm pilot drill. Use the Ø 2.2 mm alignment pin to check the preparation depth.
After depth check with the alignment pin, insert the Ø 2.2 mm monotype implant Position Indicator to check the implant position, angulation and restorability.

Depending on the implant that is placed, choose the correct position indicator, which visualizes the implant shoulder diameter of 3.5 mm (ND) or 4.8 mm (RD) and shows the future position of the implant shoulder and abutment. The hole in the abutment of the position indicator can be used for easy removal from implant bed and securing with a dental floss against inhaling/swallowing.

**Step 4 – Widen the implant bed to Ø 2.8 mm**
Continue with the implant bed preparation. If necessary, correct the implant position with the Ø 2.8 mm pilot drill. Use the Ø 2.8 mm depth gauge to check the preparation depth.

After depth check, if a Ø 3.3 Straumann® PURE Ceramic Implant will be placed, insert the Ø 2.8 mm monotype implant Position Indicator to check the implant position, angulation and restorability. Basic implant-bed preparation for a Ø 3.3 Straumann® PURE Ceramic Implant ends here, continue with the fine implant-bed preparation.

**Step 5 – Widen the implant bed to Ø 3.5 mm**
Continue with the Ø 3.5 mm Straumann® Twist Drill PRO and check the final preparation depth with the Ø 3.5 mm depth gauge.

After depth check with the depth gauge pin insert the Ø 3.5 mm monotype implant position indicator for check of implant position, angulation and restorability.

For an implant with an endosteal diameter of 4.1 mm, basic preparation ends here.
4.3 Fine implant bed preparation

The fine implant bed preparation encompasses profile drilling and subsequent tapping.

Step 1 – Profile drill

The profile drill prepares the implant bed for the Straumann® PURE Ceramic Implant and must be used to ensure that no excessive force is applied to the implant or implant bed during insertion.

For the Straumann® PURE Ceramic Implant Monotype, a Straumann® Bone Level profile drill is to be used. Insert the profile drill up to the planned insertion depth of the implant.

Step 2 – Tapping the thread in dense bone

Tapping prepares the implant bed for a specific thread type, in the case of the Straumann® PURE Ceramic Implant it is the same tap that is used for Bone Level implants. It is an optional step that gives the surgeon the flexibility to adjust the surgical protocol to the bone class to help achieve optimal primary stability.

For further information, please refer to the Basic Information on the Surgical Procedures – Straumann® Dental Implant System, 152.754/en.
4.4 Implant insertion

4.4.1 Opening the implant package

Step 1 – Opening of the blister and removal of the implant carrier

Note: The blister ensures the sterility of the implant. Do not open the blister until immediately before implant placement.

Step 2 – Opening of the implant carrier

Hold the base of the implant carrier with two fingers in the middle. Using the other hand, lift off the lid. The implant is held by a ceramic pin.

Note: The transfer piece is not pre-mounted. The transfer piece is an instrument used specifically with the Straumann® PURE Ceramic Implant System. It is made from medical grade stainless steel with a hard non-metallic coating.

Features

Pre-defined breaking point
- Pre-defined breaking point to ensure excess torque is not applied to the implant

Marking dots
- For ideal prosthetic abutment orientation
- A quarter turn to the next drilled holes corresponds to a vertical displacement of 0.2 mm
- Dots indicate distance to implant shoulder and are 1,2,3 mm away from it
- During positioning of the transfer piece on implant, the dots are aligned with the flat sides of the implant abutment

Retentive ring
- TAN ring to ensure secure retention to handpiece or ratchet

Hard coating
- To reduce visible wear marks of the insertion tool on the ceramic abutment

Snap feature
- To ensure secure retention of the implant
The Straumann® PURE Ceramic Implant can be placed either (a) with the aid of the handpiece or (b) manually with the ratchet.

**Step 3a – Attach the adapter to the handpiece**
Connect the transfer piece to an appropriate length adapter for the handpiece. Before pushing down the adapter on the transfer piece, assure correct alignment of the octagon. A click is heard when the adapter is attached correctly. Remove the transfer piece by pulling it to the side.

**Step 4a – Attach the transfer piece to the implant**
Push the transfer piece onto the implant abutment (snap on). A click is heard when the transfer piece is attached correctly.

**Step 5a – Remove the implant from the carrier**
**Note:** By turning counterclockwise the implant can be removed from the ceramic pin.

**Step 3b – Attach the adapter to the ratchet**
Connect the transfer piece to an appropriate length adapter for ratchet. Before pushing down the adapter on the transfer piece, assure correct alignment of the octagon. A click is heard when the adapter is attached correctly. Remove the transfer piece by pulling it to the side.

**Step 4b – Attach the transfer piece to the implant**
Push the transfer piece onto the implant abutment (snap on). A click is heard when the transfer piece is attached correctly.

**Step 5b – Remove the implant from the carrier**
**Note:** By turning counterclockwise the implant can be removed from the ceramic pin.
4.4.2 Placing the implant

Step 1 – Insert the implant
Always insert the implant to the correct depth. The implant is designed to have the implant shoulder sit 1.8 mm above the crestal bone. When using the handpiece, turn it clockwise with the recommended speed of 15 rpm.

Step 2 – Correct implant orientation
While approaching the final implant position, ensure the dots on the transfer piece are positioned buccally/lingually. This will place the abutment walls parallel with neighboring teeth or implants which will reduce the chance of complications (lack of interdental space) during the restorative phase.

⚠️ Caution: Avoid vertical position corrections using reverse rotations (counterclockwise). Reverse rotations may lead to a decrease in primary stability.

Step 3 – Removal of the transfer piece
3a – Remove the handpiece vertically and disassemble the transfer piece from the adapter for the handpiece.

3b – Remove the ratchet from the adapter. Remove the adapter vertically from the implant and disassemble the transfer piece from the adapter.
5. Prosthetic procedure for Straumann® PURE Ceramic Implant Monotype

The workflow for the prosthetic procedure for the Straumann® PURE Ceramic implant includes 4 steps: Protection during healing phase, impression taking, temporization and final restoration.

5.1 Protection during the healing phase

5.1.1 Healing phase

A healing period of at least 6 weeks is recommended for conditions where there is good bone quality and adequate bone quantity. For cancellous bone quality, at least 12 weeks are recommended. For all other conditions, such as bone augmentation or incomplete contact with the bone, a longer healing period is recommended.

Due to the design of the one-piece implant the implant abutment needs to be protected against chewing, cheek and tongue pressure with a protective device when there is low primary stability. When a good primary stability is achieved, a provisional out of occlusion can be placed immediately.

<table>
<thead>
<tr>
<th>Situation</th>
<th>Healing phase</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Good bone quality and adequate bone quantity</td>
<td>At least 6 weeks</td>
</tr>
<tr>
<td>• Implants with a diameter of 4.1 mm</td>
<td></td>
</tr>
<tr>
<td>• Cancellous bone quality</td>
<td>At least 12 weeks</td>
</tr>
<tr>
<td>• Implants with a diameter of 3.3 mm</td>
<td></td>
</tr>
<tr>
<td>• Straumann® ZLA® surface is not completely in contact with the bone</td>
<td>Healing phase corresponding to the situation</td>
</tr>
<tr>
<td>• Bone augmentation measures are necessary</td>
<td></td>
</tr>
</tbody>
</table>

Note: Micro-movements disturb osseointegration and can lead to loss of implants.
5.1.1.1 Protective cap

Intended use

The Straumann® PURE Ceramic Implant Protective Cap is intended to serve as protection for the implant abutment during the healing phase after implant placement.

Characteristics

- Snap-on mechanism to the abutment allows proper and secure seating
- Conical shape allows sufficient space for a load-free temporization
- Soft tissue management: Supports the generation of the emergence profile and keeps the implant shoulder free of gingival tissue; it thus provides ideal conditions for the impression taking.
- Smooth outer surface to minimize plaque retention

Note

- The device must be secured against aspiration during intraoral handling.
- The devices are provided non-sterile and are for single use only.
- Do not use longer than 6 months.
- The device can be steam-sterilized at 121°C (250°F) for 20 min or at 134°C (273°F) for 5 minutes.

<table>
<thead>
<tr>
<th>Protective Cap</th>
<th>AH 4 mm</th>
<th>AH 5.5 mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>For ø 3.3 (ND)</td>
<td>031 320</td>
<td>031 321</td>
</tr>
<tr>
<td>For ø 4.1 (RD)</td>
<td>031 330</td>
<td>031 331</td>
</tr>
</tbody>
</table>
5.1.1.2 Protection of the Straumann® PURE Ceramic Implant

Step 1 – Preparation
Clean and dry the implant abutment.
Ensure the implant shoulder and the upper part of the implant neck is free of blood and gingival tissue.

Step 2 – Placing of the protective cap
Snap the Straumann® Protective cap for ceramic implants onto the Straumann® PURE Ceramic Implant Monotype. Hearing a click indicates that the protective cap is correctly seated.

Note: Due to its high-enough retention to the implant shoulder, a cementation of the protective cap with temporary cement is not mandatory.

Step 3 – Fabrication of the protective device (optional, e.g. in case of low primary stability)
Use a standard technique to fabricate a protective device onto the protective cap during the healing phase (thermoplastic clasp denture, protective splint etc.).

Keep a space of 1.5 – 2.0 mm between protective device and the protective cap in order to ensure a load-free healing of the implant.
5.2 Impression taking

5.2.1 Closed-tray impression

Intended use
Closed-tray impression technique

Characteristics

**Simple:** Color-coded components corresponding to abutment height. No additional preparation (i.e. perforation) of tray required.

**Reliable:** High precision impression components give an exact replica of the intraoral situation. Clear-cut tactile response from the prosthetic connection verifies proper seating of components.

**Note**

- Impression posts are intended for single use only to ensure optimal fit and precise impression taking for each patient.
- Do not sterilize the impression posts. In order to prevent any damage (loss of elasticity or embrittlement), they must be protected from strong light or heat irradiation.
- The parts can be disinfected as required using standard commercial disinfection agents for plastic products (refer to the manufacturer’s instructions).

<table>
<thead>
<tr>
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</table>
5.2.2 Closed-tray impression – Dentist procedure

Step 1 – Preparation
Remove the Straumann® PURE Ceramic Implant Protective cap. Clean the abutment, the implant shoulder and the upper part of the implant neck thoroughly and make sure the area is free from blood, tissue etc. before the impression procedure. In case temporary cement was used to cement the protective cap, ensure all remnants are carefully removed. Be aware that the sulcus may collapse rapidly once the protective cap has been removed.

Step 2 – Positioning the impression cap
Select the right impression cap with the help of the color coding (black for 4 mm abutment height, and white for 5.5 mm abutment height). Snap the impression cap onto the Straumann® PURE Ceramic Implant abutment. Hearing a click indicates that the impression cap is correctly positioned to the implant. To ensure accuracy of the impression procedure, do not damage the inner aspect of the impression cap.

Step 3 – Impression taking
Take the impression using an elastomeric precision impression material. Once the material is cured, carefully remove the tray. The impression cap remains in the impression material.

Note
Due to its low tensile strength, hydrocolloid is not suitable for this application.

5.2.3 Closed-tray impression – Lab procedure

Step 1 – Analog fixation
Select the right analog. The analog with the white ring is intended for the white impression cap, and the analog with the black ring for the black impression cap. Snap the corresponding analog in the impression. Hearing a click indicates that the impression cap is correctly positioned to the analog.

Step 2 – Fabricating the master cast
Fabricate the master cast using standard methods and type-4 dental stone (ISO 6873). A gingival mask should always be used to ensure that the emergence profile of the crown is optimally contoured.
5.3 Temporization

5.3.1 Straumann® PURE Ceramic Implant Temporary Coping

Intended use
Serves as basis for temporary restorations for Straumann® PURE Ceramic Implants.

Two types of temporary copings are available:
Crown provisional (engaging)
Bridge provisional (non-engaging)

Features
Optimal surface roughness
Neck part of coping is very smooth which reduces plaque adhesion
Retentive surface is rough for better bonding with veneering material
Clear-cut tactile response from the prosthetic connection verifies proper seating of components

Note
• Do not use longer than 30 days.
• Place temporary restoration out of occlusion.
• The devices are provided non-sterile and are for single use only.
• The device must be secured against aspiration during intraoral handling.
• Do not sterilize in order to prevent any damage (loss of elasticity or embrittlement), they must be protected from strong light or heat irradiation.
• The parts can be disinfected as required using standard commercial disinfection agents for plastic products (refer to the manufacturer’s instructions).

<table>
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<tr>
<th>Temporary Copings</th>
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<td>For Ø 4.1 (RD)</td>
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</table>
5.3.2 Chairside temporization with the Straumann® PURE Ceramic Implant
Temporary Coping

Step 1 – Preparation
Snap the temporary coping onto the Straumann® PURE Ceramic Implant abutment in the patient’s mouth. Mark the appropriate height according to the individual situation and shorten the coping as necessary.

Note
The temporary coping must be secured against aspiration.

Step 2 – Fabricate the provisional restoration
Use a standard procedure to fabricate the provisional. The retention rings ensure proper mechanical bonding of the veneering material to the coping. The plateau of the coping helps to prevent the veneering material from flowing under the implant shoulder.

Step 3 – Finalize fabrication of the provisional restoration
After polymerization, take the provisional out of the mouth. Grind down and polish the emergence profile to achieve an even profile. To avoid tissue irritation the interface needs to be smooth and flush with the restoration.

Step 4 – Inserting the provisional
Remove the lip of the snap-on mechanism from the temporary coping to allow proper extrusion of excess cement. Use a scalpel, knife or handpiece/rubber wheel. Apply temporary cement to the inner part of the coping and cement it onto the abutment.

Note
• Do not use the Straumann® Reamer for 45° shoulders (046.243) as this will damage the internal connection of the temporary coping.
• Keep the temporary restoration out of occlusion.
• Temporary copings must not be kept in the mouth for longer than 30 days.
5.4 Creation and cementation of the final restoration

5.4.1 Lab procedure
Straumann® PURE Ceramic Implant should be restored with all-ceramic restorations. Use a conventional or digital procedure to fabricate the ceramic coping (or full-contour restoration).

5.4.1.1 Conventional
Step 1 – Wax-up
For optimal planning, design a full anatomical wax-up. Use a silicone key to check the critical distances (occlusally, laterally, emergence profile) for the intended restoration. Do not modify the shape of the analog.

Note
Straumann® PURE Ceramic Implant abutments must not be mechanically finished under any circumstances: e.g. ground, sandblasted, or polished as this might cause the product to fail. Mesial and/or distal extension of the restoration is not permissible under any circumstances (Cantilevered pontic).

Step 2 – Fabricating the suprastructure
Use the press technique to fabricate the suprastructure conventionally.

5.4.1.2 Digital
Step 1 – Data digitization
a. The patient situation can be scanned with a Straumann approved intra-oral scanner. The data is then imported in the Straumann approved software
b. The patient situation can also be taken with a conventional impression tray. The dental laboratory scans the fabricated model with a Straumann approved desktop scanner.

Note
Scan spray might be applied to the master model.
Step 2 – Design of the Straumann® CARES® coping or full-contour crown
The restoration is designed with the (Straumann approved) software.
Additional information on the different Straumann® CARES® prosthetic restorations are available in the brochure “Basic Information on Straumann® CARES® Tooth Prosthetic Procedures”, available on the Straumann website: www.straumann.com.

Note
If a scan spray was used for the data digitization, the default parameters of the “Die parameters” should be slightly adapted when designing the Straumann® CARES® prosthetic restoration with the Straumann® CARES® Visual software 7.x and higher (slightly reduce the software default parameters “Cement Gap” and “Horizontal Spacer” to compensate for the scan spray layer).

Step 3 – Finalization of the Straumann® CARES® coping or full-contour crown
Depending on the final material and processing technique selected, the delivered Straumann® CARES® coping and full-contour crown can be directly seated or finalized in different steps (e.g. layering).

5.4.2 Dentist procedure
The final restoration is placed on the master cast when delivered to the doctor’s office.

Final insertion:
• Remove the temporary restoration
• Clean the abutment thoroughly and remove all remaining temporary cement.
• Prepare the surface of the Straumann® Ceramic Implant abutment, and of the superstructure according to the instructions given by the corresponding cement manufacturer.
• Cement the superstructure onto the abutment.
• Carefully remove any excess cement.

Note
• Ensure that the restoration is seated stress-free.
• Keep static, occlusal contacts low compared to neighboring teeth and avoid dynamic occlusal contacts.
• Incomplete removal of excess cement may cause increased biofilm formation resulting in inflammation and infection.
6. Aftercare and cleaning of Straumann® PURE Ceramic Implants

Regular prosthetic aftercare of the Straumann® PURE Ceramic Implants is necessary, as in all implant systems. Since individual factors such as oral hygiene of the patient, cooperation, etc. are of great importance in determining regular prosthetic aftercare, the aftercare should be adapted to each patient individually.

Zirconia has very low affinity to plaque. However, regular and adequate prophylaxis is recommended. For cleaning Straumann® PURE Ceramic Implants, use teflon-based hand scalers and curettes only.

Rinsing solutions of chlorhexidine and/or alcohol basis can be used temporarily without reservation. These solutions are not recommended for continuous use due to possible discoloration of the tooth hard substance as well as of cement gaps.

Do not use any ultrasound-operated, metallic cleaning aids for cleaning Straumann® PURE Ceramic Implants. Avoid application of ultrasound through metallic transmitters onto Straumann® PURE Ceramic Implants. The surface can be damaged permanently by incorrect use and application of ultrasound. When metallic cleaning aids are used (ultrasound-operated scalers or hand curettes or scalers) metallic abrasion might occur on the surface of the implant.

7. Troubleshooting

7.1 Implant removal

Non-osseointegrated implant (spinner)
The Straumann® PURE Ceramic Implant transfer piece can be used to help remove a non-osseointegrated implant.

⚠️ Warning
Osseointegrated implant: Bone preservation is considered to be a core competence required by the clinician in the case of implant removal. The clinician should use a technique suitable to the implant and patient situation.

7.2 Fracture of the abutment

If part of the abutment fractures, the clinician needs to determine if another restoration can be placed or the implant must be explanted. When determining if there is enough minimum support and retentive area, use the same parameters that apply for a natural tooth stump.

Chipping or cracking of crown
In the event of a chipped or cracked crown, where the crown needs to be removed, care should be taken to avoid damaging the implant shoulder or abutment.
8. Product reference list

<table>
<thead>
<tr>
<th>Art. No.</th>
<th>Article</th>
<th>Dimension</th>
<th>Material</th>
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9. Important guidelines

Please note
Practitioners must have appropriate knowledge and instruction in the handling of the Straumann CADCAM products or other Straumann products ("Straumann Products") for using the Straumann Products safely and properly in accordance with the 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 this document or in the instructions for use for the respective Straumann Product. If use of products made by third parties is not recommended by Straumann in this document or in the respective instructions for use, any such use will void any warranty or other obligation, express or implied, of Straumann.

Availability
Some of the Straumann Products listed in this document may not be available in all countries.

Caution
In addition to the caution notes in this document, our products must be secured against aspiration when used intraorally.

Validity
Upon publication of this document, all previous versions are superseded.

Documentation
For detailed instructions on the Straumann Products contact your Straumann representative.

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Explanation of the symbols on labels and instruction leaflets

- **LOT** Batch code
- **REF** Catalogue number
- **STERILE EO** Sterilized using Ethylene Oxide
- Lower limit of temperature
- Upper limit of temperature
- Temperature limitation
- Rx only Caution: Federal law restricts this device to sale by or on the order of a dental professional.
- Do not re-use
- Non-sterile
- Caution, consult accompanying documents
- Use by
- Keep away from sunlight