

BASIC INFORMATION

Straumann® PURE Ceramic Implant System



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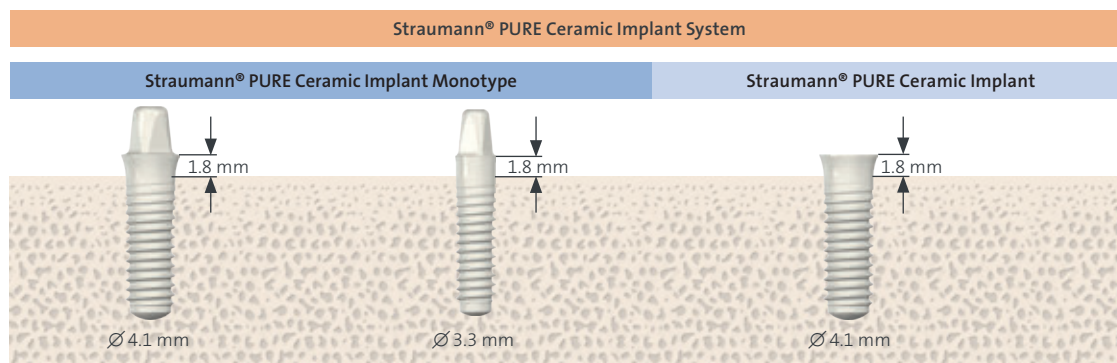
ABOUT THIS GUIDE

This surgical and prosthetic procedure describes the steps required for implantation and restoration of the Straumann® PURE Ceramic Implant System. 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 SYSTEM

The Straumann® PURE Ceramic Implant System is available as Tissue Level monotype design in the endosteal diameters of 4.1 mm and 3.3 mm and as Tissue Level two-piece design in the endosteal diameter of 4.1 mm.



A unified color code simplifies identification of instruments and implants.

Color coding	
● Yellow	Endosteal implant diameter 3.3 mm
● Red	Endosteal implant diameter 4.1 mm

2. IMPLANT FEATURES AND BENEFITS

2.1 MATERIAL

The Straumann® PURE Ceramic Implant System is made from 100 % yttria-stabilized zirconia (Y-TZP). This material has been used for a long time in orthopedics with successful results.

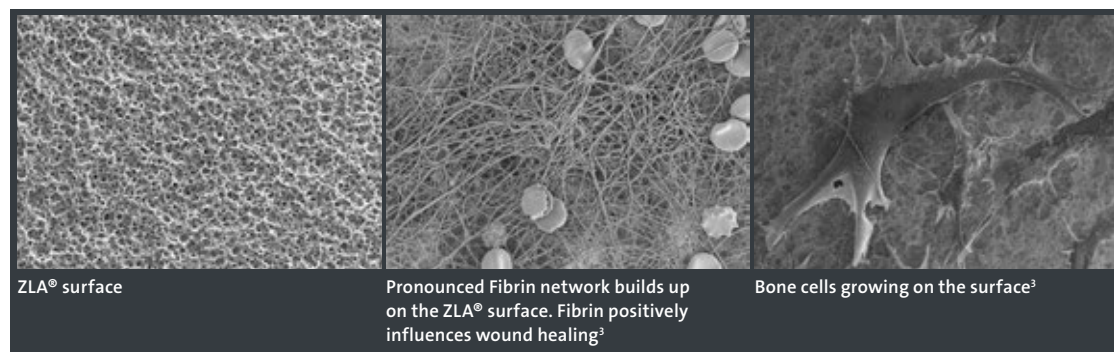
Property	Unit	Titanium grade 4	Y-TZP
Density	g/cm ³	4.5	6.05
Hardness	HV	250	1100–1500
Strength	MPa	680 (tensile)	≥ 1200 (4-point bending strength)
Mod. of elasticity	GPa	110	200–220

Warning

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

2.2 SURFACE

The Straumann® ZLA® surface features a topography characterized by macro- and micro-roughness to offer a structure for cell attachment. In preclinical studies, the ZLA® surface demonstrated similar healing patterns, healing times and osseointegration in terms of peri-implant bone density and bone-to-implant contact (BIC) as seen for the SLA® surface^{1,2}.



¹Gahlert M, Roehling S, Sprecher CM, Kniha H, Milz S, Bormann K (2012). Clin Oral Implants Res 23(3):281-286.

²Gahlert M, Rohling S, Wieland M, Eichhorn S, Kuchenhoff H, Kniha H (2010). Clin Implant Dent Relat Res 12(4):297-305.

³M. Rottmar et al., manuscript in preparation.




3. INDICATIONS AND CONTRAINDICATIONS

3.1 APPLICATION

The Straumann® PURE Ceramic Implant System is suitable for the treatment of 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). For more information visit e-ifu.straumann.com.

3.2 CONTRAINDICATIONS

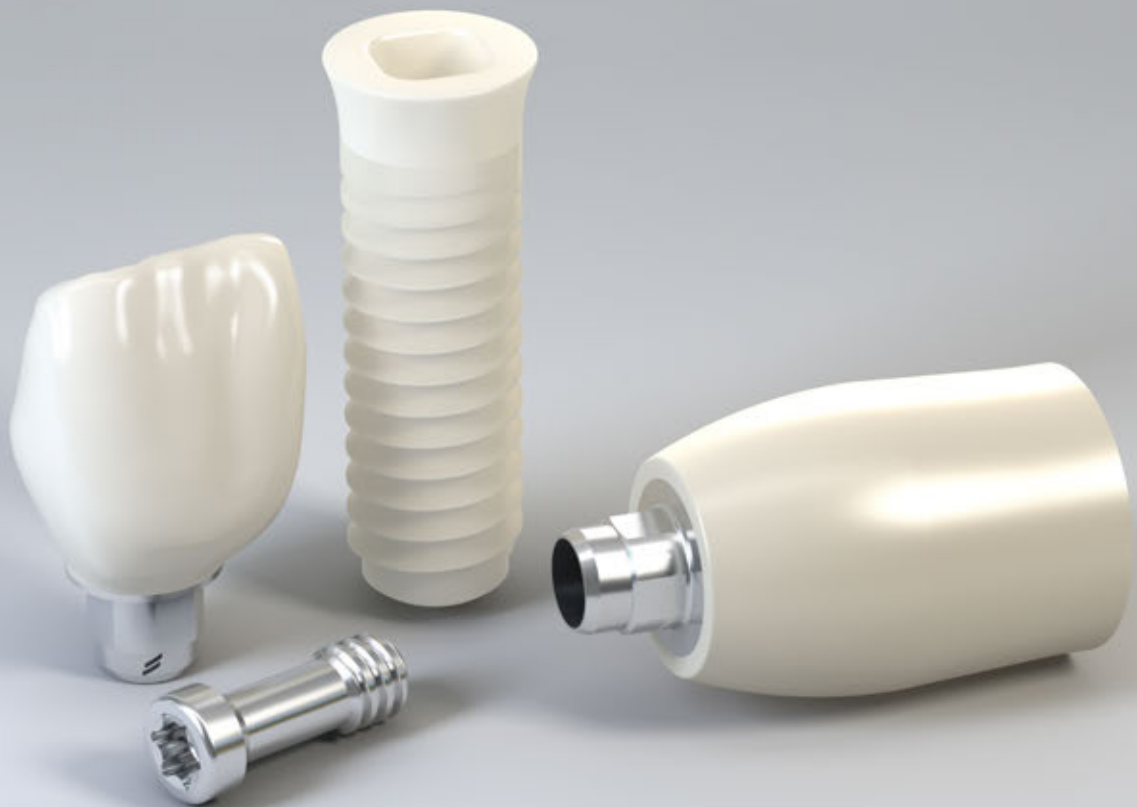
Non-completed maxillary and mandibular growth, drug or alcohol abuse, allergies or hypersensitivity to chemical ingredients of the zirconium dioxide material: zirconium dioxide (ZrO₂), yttrium oxide (Y₂O₃), hafnium dioxide (HfO₂), aluminum oxide (Al₂O₃), all conditions that would be normally contraindicated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

Specific indications for Straumann® PURE Ceramic Implant System				
Implant type		Indications and distinctive features	Minimal ridge width*	Minimal gap width**
Straumann® PURE Ceramic Implant Ø 4.1 mm RD		<ul style="list-style-type: none"> For oral endosteal implant indications in the maxilla and mandible, for functional and esthetic rehabilitation of edentulous and partially edentulous patients 	6 mm	7 mm
Straumann® PURE Ceramic Implant Monotype Ø 3.3 mm ND		<ul style="list-style-type: none"> Small-diameter implant for narrow interdental spaces and ridges For central and lateral incisors Caution: Placement in the premolar and molar region is not recommended. 	5.5 mm	5.5 mm
Straumann® PURE Ceramic Implant Monotype Ø 4.1 mm RD		<ul style="list-style-type: none"> For oral endosteal implant indications in the maxilla and mandible, for functional and esthetic rehabilitation of edentulous and partially edentulous patients 	6 mm	7 mm

* 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. STRAUMANN® PURE CERAMIC IMPLANT



The Straumann® PURE Ceramic Implant has a two-piece design based on features of the Straumann® Tissue Level Standard Plus and Straumann® Bone Level Implants.

The Straumann® PURE Ceramic Implant is available in the endosteal diameter Ø 4.1 mm. It has a 1.8 mm high machined neck and an internal connection. The internal connection is equipped with a rotational lock and an inner thread, the latter is for fixation of the temporary components and final abutments.



Color coding	
● Red	Endosteal implant diameter 4.1 mm

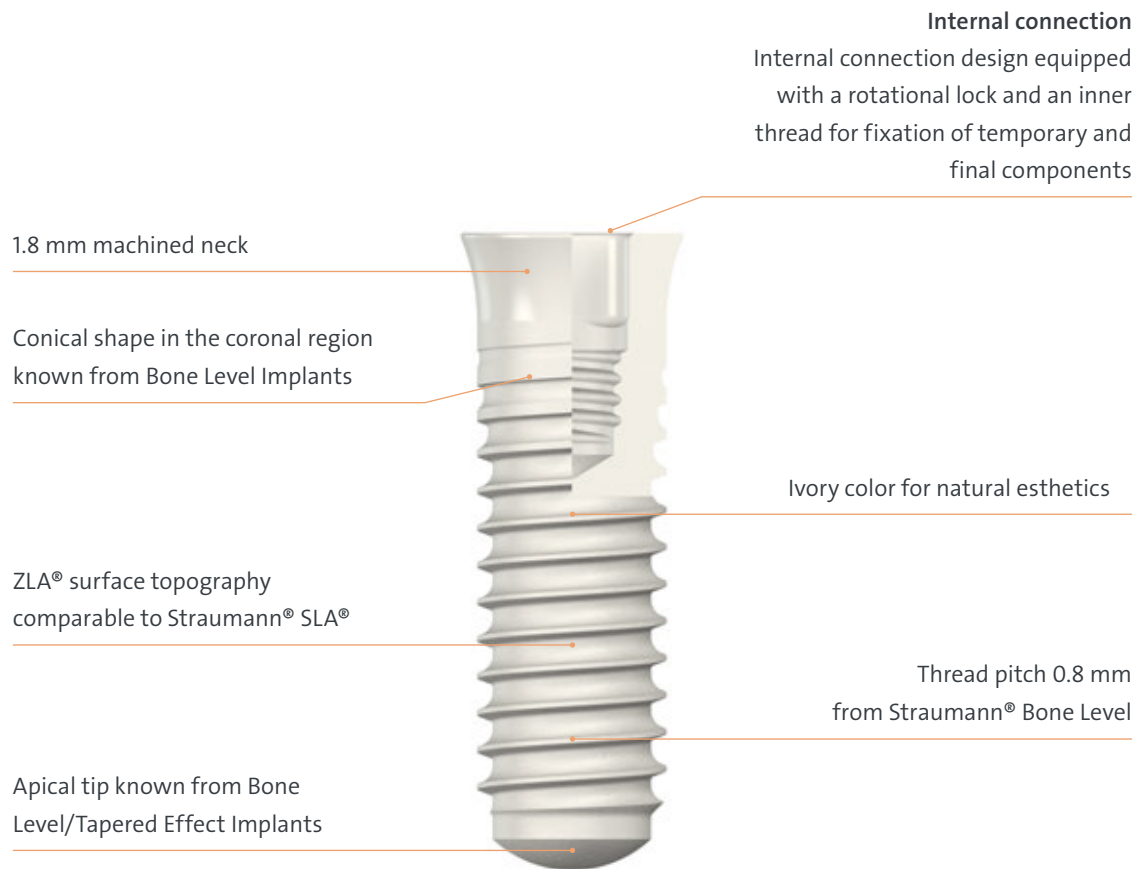
The Straumann® PURE Ceramic Implant uses the same unified color code of instruments and implants that is used with Straumann® Tissue Level titanium implants.

The Straumann® PURE Ceramic Implant auxiliaries can be identified with the RD (Regular Diameter) code which corresponds to a shoulder diameter of Ø 4.8 mm.



Implant overview			Straumann® PURE Ceramic Implant	
Connection			RD	
Shoulder diameter			Ø 4.8 mm	
<ul style="list-style-type: none"> Conical design in coronal region Thread pitch known from Straumann® Bone Level: 0.8 mm tread pitch 				
Endosteal diameter			Ø 4.1 mm	
ZrO ₂	ZLA®	8 mm	032.000S	
		10 mm	032.001S	
		12 mm	032.002S	
		14 mm	032.003S	








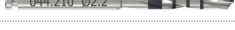







4.1 DESIGN

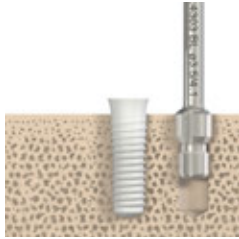





5. SURGICAL PROCEDURE FOR STRAUMANN® PURE CERAMIC IMPLANT

The Straumann® PURE Ceramic Implant can be placed with the existing Straumann® Surgical Cassette. The surgical procedure is similar to the Straumann® Bone Level surgical protocol and includes 4 steps: Preoperative planning, basic implant bed preparation, fine implant bed preparation and implant insertion.

The following table summarizes the use of instruments for the basic implant bed preparation. All drills are available in a short and a long version and as multi-use as well as single-patient drills. The table lists in an exemplary way the short multi-use drills only.

Instrumentation for basic implant bed preparation					Endosteal Ø (mm)	
Step	Art. No.	Product	max. rpm		Ø 4.1	
1 Ridge preparation	044.004	Round Bur, Ø 3.1 mm	800			
2 Mark implant position	026.0054	Needle drill, Ø 1.6 mm	800			
	044.022	Round Bur, Ø 1.4 mm				
	044.003	Round Bur, Ø 2.3 mm				
	044.004	Round Bur, Ø 3.1 mm				
3 Mark implant axis	044.210	Pilot Drill 1, short, Ø 2.2 mm	800			
	046.455	Depth Gauge, with Implant Distance Indicator, Ø 2.2/2.8 mm				
4 Prepare implant bed to Ø 2.2 mm	044.210	Pilot Drill 1, short, Ø 2.2 mm	800			
	046.703	Alignment Pin, Ø 2.2 mm, straight				
	031.123 031.143	RD Position Indicator Ø 2.2 mm, abutment height 4.0 or 5.5 mm				
5 Prepare implant bed to Ø 2.8 mm	044.214	Pilot Drill 2, short, Ø 2.8 mm	600			
	046.455	Depth Gauge, with Implant Distance Indicator, Ø 2.2/2.8 mm				
6 Prepare implant bed to Ø 3.5 mm	044.250	Twist Drill PRO, short, Ø 3.5 mm	500			
	046.450	Depth Gauge Ø 3.5 mm				
	031.125 031.145	RD PURE Position Indicator Ø 3.5 mm, abutment height 4.0 or 5.5 mm				

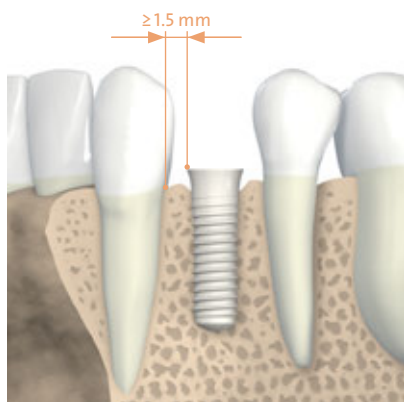
Instrumentation for fine implant bed preparation					Endosteal Ø (mm)
Step	Art. No.	Product	max. rpm		Ø 4.1
1 Profiling	026.4303	BL Profile Drill Ø 4.1 mm	300		
2 Tapping	026.4310	BL Tap for Adapter Ø 4.1 mm	300		

5.1 PREOPERATIVE PLANNING

A prosthetic-driven planning is recommended.

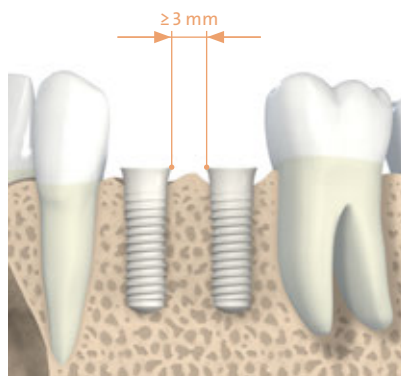
5.1.1 Implant position

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



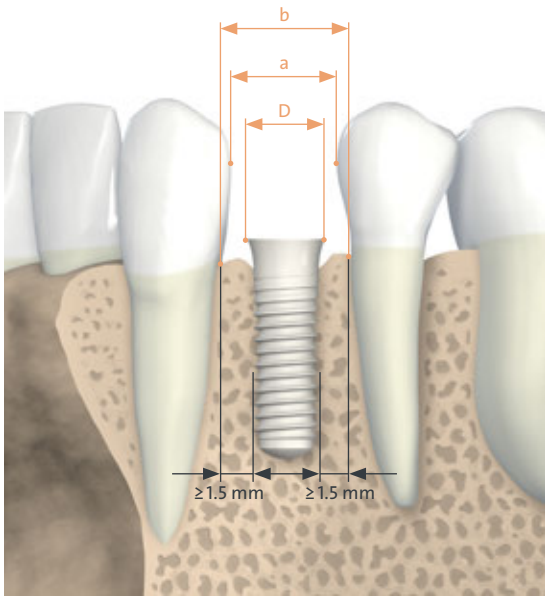
Rule 1

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.

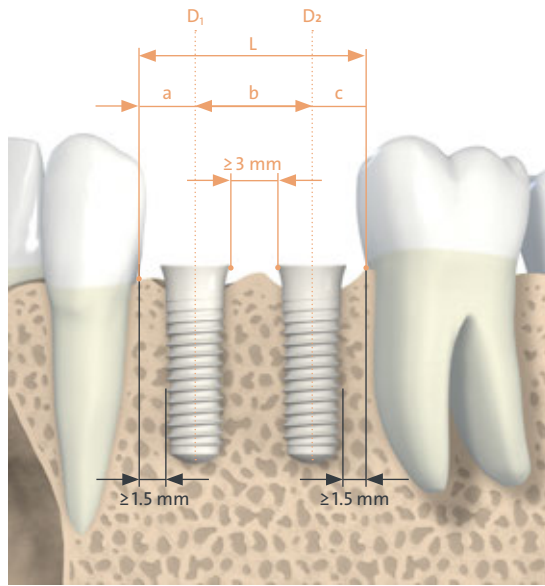


Rule 2

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



Shoulder Diameter D [mm]	Gap Width a_{min} [mm]	Distance between teeth at bone level b_{min} [mm]
Ø 3.5 (ND)	5.5	6.5
Ø 4.8 (RD)	7	8
Rule	D + 2 mm	D + 3 mm



Shoulder Diameter D_1 [mm]	Shoulder Diameter D_2 [mm]	a_{min} [mm]	b_{min} [mm]	c_{min} [mm]	L_{min} [mm]
Ø 3.5 (ND)	Ø 3.5 (ND)	3	6.5	3	12.5
Ø 3.5 (ND)	Ø 4.8 (RD)	3	7	4	14
Ø 4.8 (RD)	Ø 4.8 (RD)	4	8	4	16



Rule 3

Special attention should be paid to the Straumann® PURE Ceramic Implant in order to achieve an optimal orofacial positioning of the implant.

5.1.2 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 *Straumann® Dental Implant System, Basic Information (152.754/en)*.



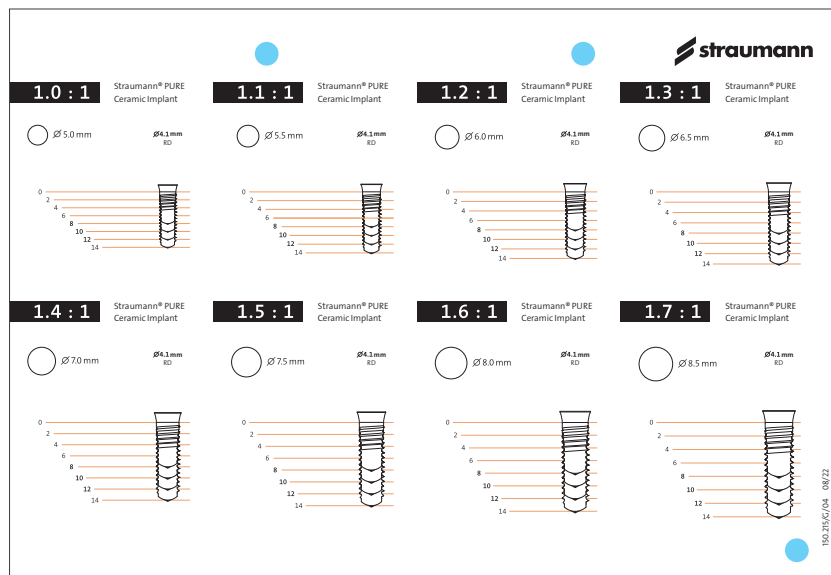
Straumann® Diagnostic T



Straumann® Implant Distance Indicator

Additionally the Straumann® X-ray template (150.215) 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:

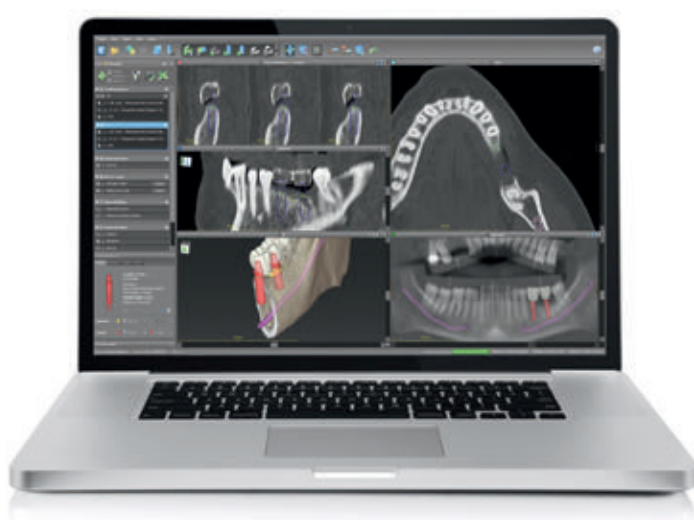
$$\frac{\text{X-ray reference sphere } 5 \text{ mm} \times \text{bone availability (X-ray}^2\text{)}}{\text{Reference sphere diameter on the X-ray}} = \text{effective bone availability}$$

Digital planning with coDiagnostiX®

This 3D diagnostics and implant planning software is designed for the image-guided surgical planning of dental implants, including the Straumann® PURE Ceramic Implant, 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 virtual replacement of implants, abutments and drilling sleeves.

Digital planning, guided surgery and guided implant placement with the SP Guided Adapter is available.



For further information, please refer to the coDiagnostiX® Manual.

DWOS Synergy workflow

DWOS Synergy provides real-time communication between the implant planning software (coDiagnostiX®) and the lab software (i.e. Straumann®CARES®Visual) and improves implant planning by allowing the visualization of the relationship between the proposed implant position and the proposed restoration.

5.2 BASIC IMPLANT BED PREPARATION

For preparing the implant bed the Straumann® Bone Level Surgical Cassette is used.

5.2.1 Position indicator

The Straumann® PURE Ceramic Implant position indicators were originally developed for the Straumann® PURE Ceramic Implant Monotype but can also be used for the Straumann® PURE Ceramic Implant to ensure correct positioning of the implant during implant bed preparation. The Straumann® PURE Ceramic Implant position indicators are made of titanium. The devices are provided non-sterile and must be processed **prior** to use according to the relevant Instructions for use (IFU).

5.2.1.1 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.





Abutment representation

Abutment height identification

- Colored marking.
black = AH 4 mm
white = AH 5.5 mm

1.8 mm neck

- Replica of implant.

Position Indicators for		
Straumann® PURE Ceramic Implant Ø 4.1 RD		
Abutment height	AH 4 mm	AH 5.5 mm
		
Endosteal diameter	Ø 2.2	031.123
	Ø 2.8	—
	Ø 3.5	031.125
		031.143
		—
		031.145

Note

Position Indicators can be cleaned, disinfected and sterilized like all other Straumann instruments. Refer to relevant instructions for use (IFU) for product specific cleaning, disinfection or sterilization requirements.

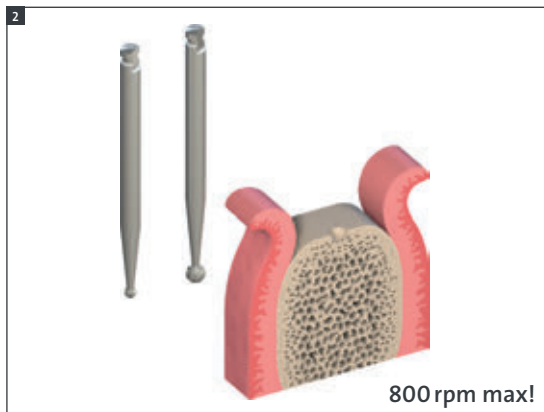
5.2.2 Preparing the implant bed

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.



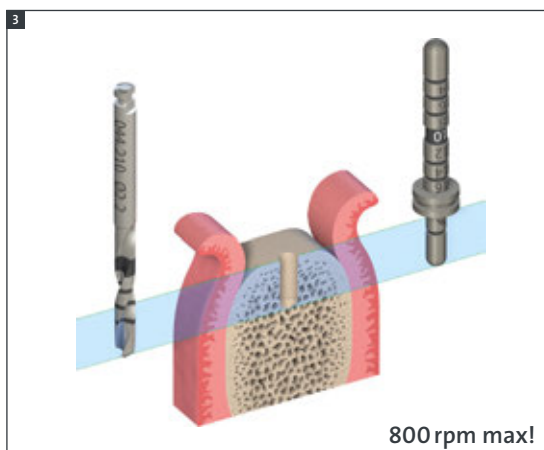
Step 1 – Prepare the alveolar ridge

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.



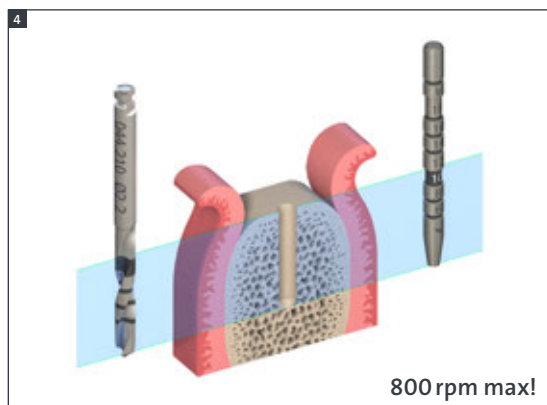
Step 2 – Mark the implantation site

Using the $\varnothing 1.4$ 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 $\varnothing 2.3$ mm or the $\varnothing 3.1$ mm round bur, if necessary.



Step 3 – Mark the implant axis

With the $\varnothing 2.2$ 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 for correct implant axis orientation. If necessary correct unsatisfactory implant axis orientation in the following step.



Step 4 – Prepare the implant bed to Ø 2.2 mm

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 implant axis and preparation depth.

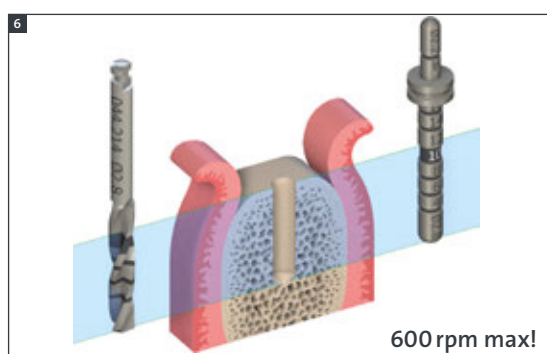
Caution: At this point take an X-ray, particularly with vertically reduced bone availability. The Alignment Pin is inserted into the drilled area, which allows a comparative visualization of the drill hole in relation to the anatomical structures.



Step 5 – Check implant position

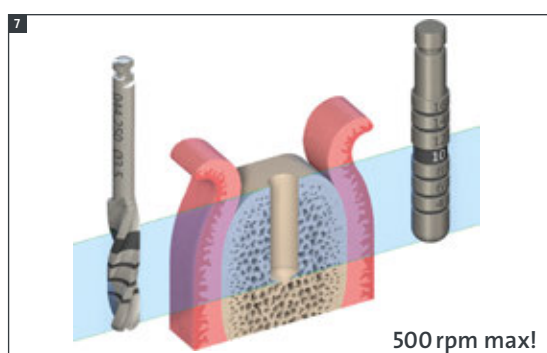
After depth check with the Alignment Pin, insert the Ø 2.2 mm PURE Ceramic Implant Position Indicator to check the implant position, angulation and restorability.

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 6 – Prepare 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.



Step 7 – 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.



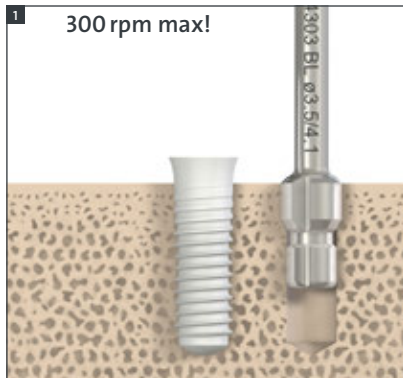
Step 8 – Check implant position

After depth check with the alignment pin, insert the Ø 3.5 mm PURE Ceramic 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.

5.3 FINE IMPLANT BED PREPARATION

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

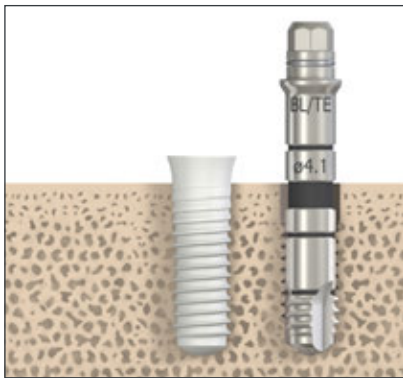


Step 1 – Bone Level Profile Drill

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

Depending on the respective bone situation at implant site, a Straumann® Tissue Level RN Standard Plus profile drill might be used afterwards.

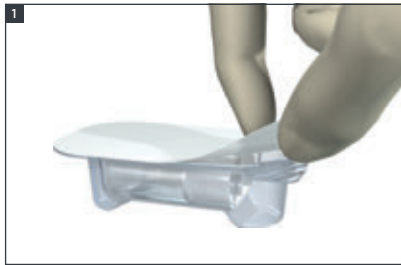


Step 2 – Tapping the thread in dense bone

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 *Straumann® Dental Implant System, Basic Information* (152.754/en).

5.4 IMPLANT INSERTION



5.4.1 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.

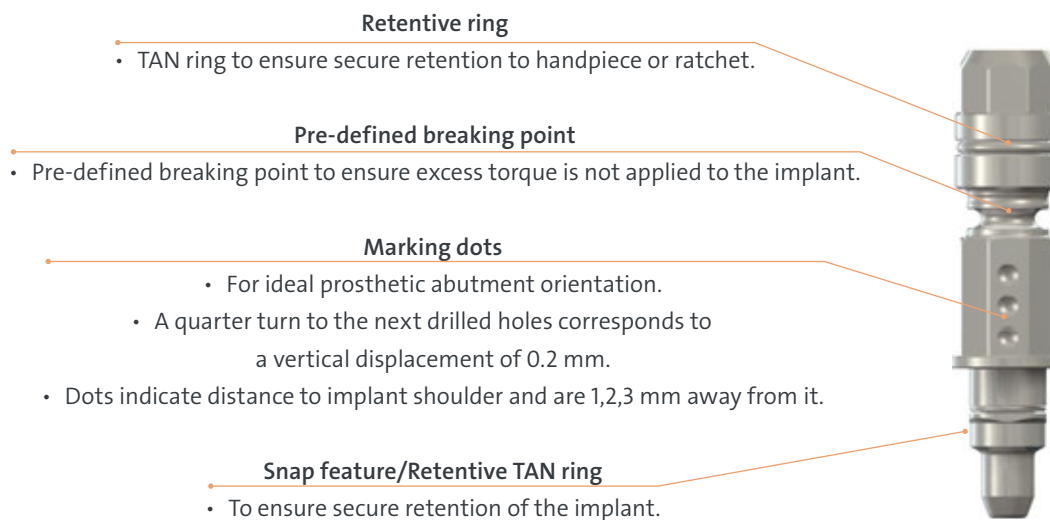


Step 2 – Opening of the implant carrier

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.

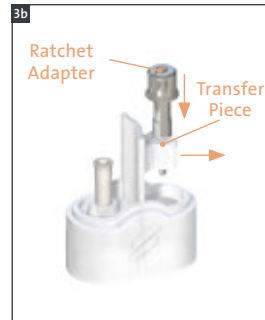
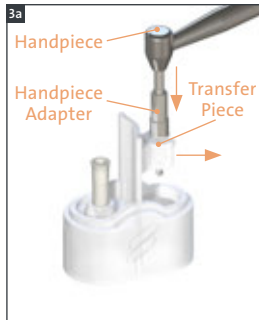
 **Note:** The transfer piece is not pre-mounted. The transfer piece is an instrument used specifically with the Straumann® PURE Ceramic Implant. It is made from medical grade stainless steel.

Transfer Piece for PURE Ceramic Implant



The Straumann® PURE Ceramic Implant can be placed either (a) with the aid of the handpiece or (b) manually with the ratchet.

5.4.2 Remove the implant from the carrier



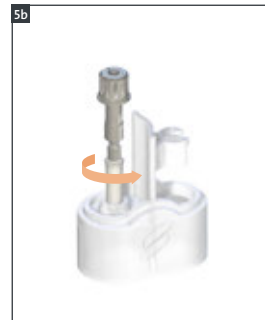
Step 3 – Attach the adapter to the transfer piece

Connect the transfer piece to an appropriate length handpiece/ratchet adapter. 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 4 – Attach the transfer piece to the implant

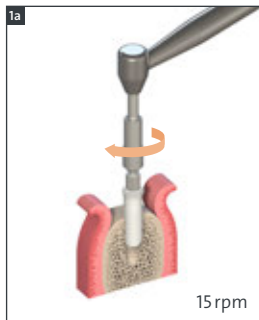
Slide the transfer piece into the implant. A click is heard when the transfer piece is attached correctly.



Step 5 – Remove the implant from the carrier

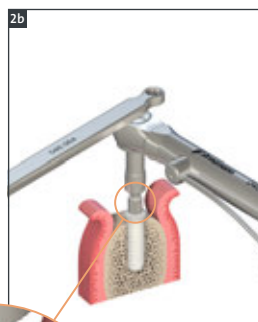
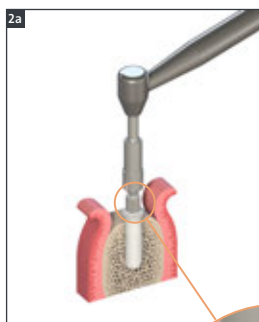
By turning counterclockwise the implant can be removed from the ceramic pin.

5.4.3 Placing the implant



Step 1 – Place implant into the implant bed

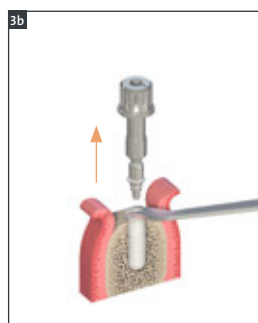
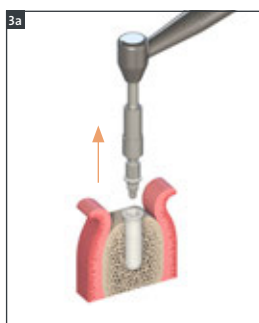
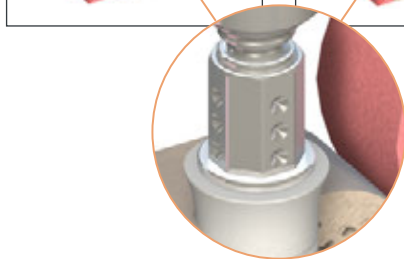
Always insert the implant clockwise to the correct depth. The implant is designed to have the implant shoulder sit 1.8 mm above the crestal bone. When using the handpiece, turn it clockwise with the recommended speed of 15 rpm. An insertion torque of 35 Ncm is recommended. If 35 Ncm are achieved before the implant has reached its final position, make sure the implant bed preparation is correct to avoid bone overcompression.



Step 2 – Correct implant orientation

While approaching the final implant position, ensure the dots on the transfer piece are positioned buccally/labially. 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

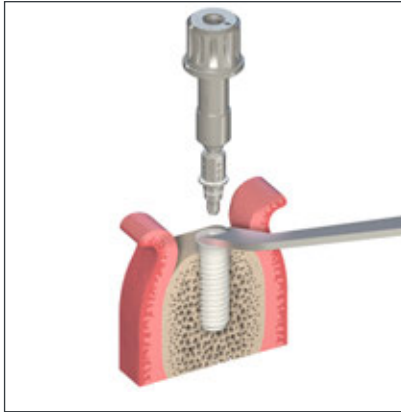
3a – Pull out the handpiece vertically and disassemble the transfer piece from the handpiece adapter.

3b – Remove the holding key from the ratchet. Pull-out the ratchet adapter vertically from the implant and disassemble the transfer piece from the ratchet adapter.

Note: In case the transfer piece can not be disassembled easily from the implant, carefully do a 1/8 turn (not more) in reverse (counterclockwise) direction.

Note: The transfer piece can be used as position control after implant placement.

5.4.4 Additional information for Straumann® PURE Ceramic Implant with the transfer piece



Release aid for the transfer piece

For situations in which any removal force is to be avoided, a release aid for the transfer piece can be used. Place the release aid onto the implant shoulder and hold it in place while detaching the Adapter with the transfer piece.

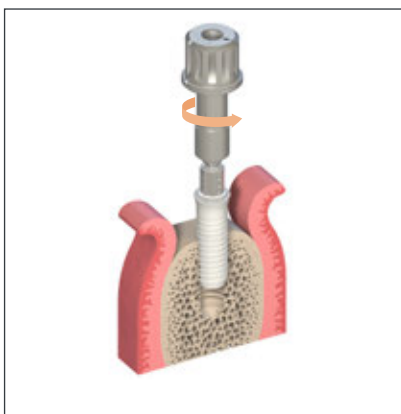
Warning: In case the implant has to be removed after implant placement, the retention of the transfer piece in the implant may be reduced. Always secure the implant against aspiration when removing the implant.



Removal of a fractured transfer piece

The transfer piece is provided with a pre-determined breaking point to prevent the implant's inner configuration from damage, thus ensuring the integrity of the interface to mount the prosthesis. If the transfer piece breaks during implant insertion, one part remains in the adapter and the other part in the implant. Both parts can be removed with tweezers.

To extract the implant after the pre-determined breaking point broke, simply take out the broken part from the adapter and re-insert the adapter on the transfer piece part remaining in the implant. Counterclockwise turns will remove the implant.



The part of the transfer piece below the pre-determined breaking point is not secured in the adapter and, additionally, need to be secured against aspiration when taking out the implant.

Warning: In case the implant has to be removed after implant placement, the retention of the transfer piece in the implant may be reduced. Always secure the implant against aspiration when removing the implant.

Caution: The broken parts of the transfer piece no longer protect against high torque. Therefore, it is not to be used to advance the placement of the implant.

6. PROSTHETIC PROCEDURE FOR STRAUMANN® PURE CERAMIC IMPLANT

6.1 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.






When a good primary stability is achieved, a provisional out of occlusion can be placed immediately.

Situation	Healing phase
<ul style="list-style-type: none"> • Good bone quality and adequate bone quantity • Implants with a diameter of 4.1 mm 	At least 6 weeks
<ul style="list-style-type: none"> • Cancellous bone quality 	At least 12 weeks
<ul style="list-style-type: none"> • Straumann® ZLA® surface is not completely in contact with the bone • Bone augmentation measures are necessary 	Healing phase corresponding to the situation

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

6.2 HEALING COMPONENTS

Choose between a submucosal and transmucosal healing. Both options are possible using a set of secondary healing components such as Closure Caps and Healing Caps. Both, Closure Caps and Healing Caps are delivered sterile.

Healing components					
	Closure Cap	Healing Caps*			
					
Material	Ti	Ti	ZrO2/Ti	ZrO2/Ti	ZrO2/Ti
0 mm	032.030S				
2 mm		032.032S	032.055S*		
3 mm		032.033S		032.056S*	
4.5 mm					032.057S*

*availability depending on registration status

6.3 SUBMUCOSAL HEALING WITH CLOSURE CAPS

For submucosal healing (healing under closed mucoperiosteal flap), Ti Closure Caps are used to close the implant.



Step 1 – Picking up the Closure Cap

Open the blister and pick up the Closure Cap with the SCS Screwdriver. The friction fit will secure the Closure Cap to the instrument during insertion and will allow a safe handling.



Step 2 – Inserting the Closure Cap after implant placement

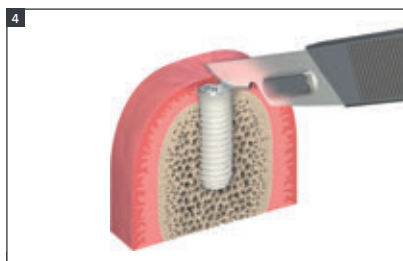
Ensure that the internal configuration of the implant is clean and bloodless. Hand-tighten the Closure Cap.



Step 3 – Wound closure

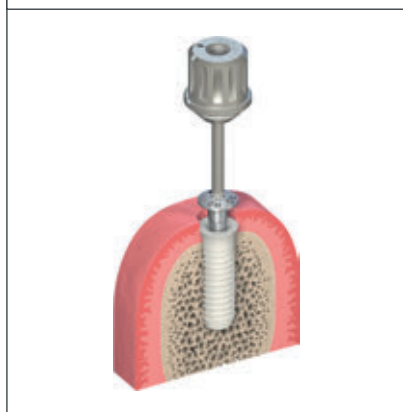
Adapt the mucoperiosteal flaps carefully and suture according to standard procedure.

Make sure a tight seal is formed over the implant whilst avoiding excessive tissue compression.



Step 4 – Reopening and removal: second surgery

Locate the implant. Make a small crestal incision down to the closure screw.



Spread the flap slightly and remove the Closure Cap with the SCS Screwdriver.

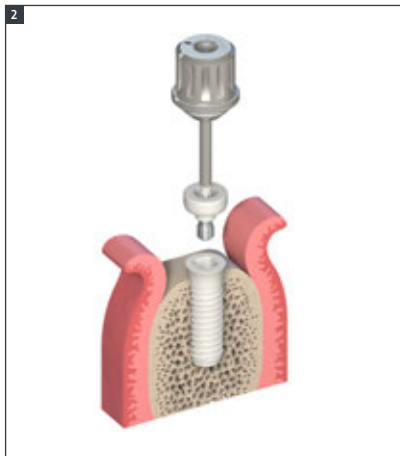
6.4 TRANSMUCOSAL HEALING WITH HEALING CAPS

Transmucosal healing can be performed with Healing Caps. Healing Caps allow shaping the soft tissue during healing. A range of Healing Caps is available. After soft tissue healing, these Healing Caps will be replaced by the appropriate temporary or final restoration.



Step 1 – Picking up the Healing Cap

Open the blister and pick up the Healing Cap with the SCS Screwdriver. The friction fit will secure the Healing Cap to the instrument during insertion and will allow a safe handling.



Step 2 – Inserting the Healing Cap after implant placement

Ensure that the internal configuration of the implant is clean and bloodless. Insert the Healing Cap with the SCS Screwdriver. The friction fit secures the components to the instrument during insertion and ensures a safe handling.

Hand-tighten the Healing Cap.



Step 3 – Wound closure

Adapt the soft tissue and suture it tightly around the abutment whilst avoiding excessive tissue compression.



Step 4 – Removal

Remove the Healing Cap with the SCS Screwdriver.

6.5 IMPRESSION TAKING

6.5.1 Open-tray impression for the Straumann® PURE Ceramic Implant

Characteristics

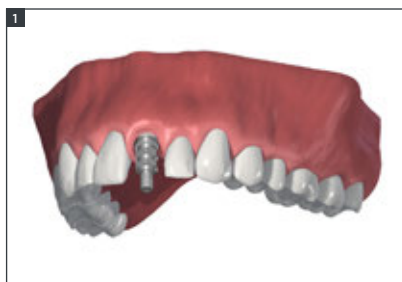
- *Simple:* Guide screw can be tightened either by hand or with the SCS Screwdriver.
- *Reliable:* High-precision impression components give an exact replica of the intraoral situation.

Note

- Open-tray impression procedure requires a custom-made tray with individual perforations for the guide screw.
- Impression posts are intended for single use only to ensure optimal fit and precise impression taking for each patient.

Impression Post	Repositionable Implant Analog with Sleeve	Repositional Implant Analog (for 3D printed models)
		
032.129	032.027	032.018

6.5.2 Open-tray impression – Dentist procedure



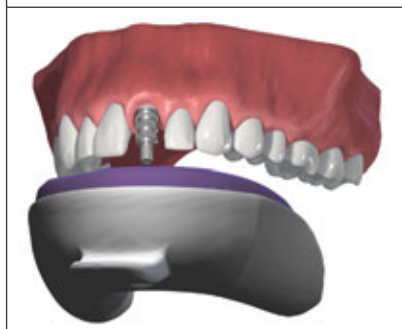
Step 1 – Positioning the Impression Post

- Ensure sufficient access to the implant site in order to avoid pinching the gingival tissue. Be aware that the sulcus may collapse rapidly once the healing components have been removed.
- Clean the internal configuration of the implant thoroughly from blood, tissue, etc. prior to the impression procedure.
- Place the Impression Post accurately into the implant and hand-tighten the guide screw.

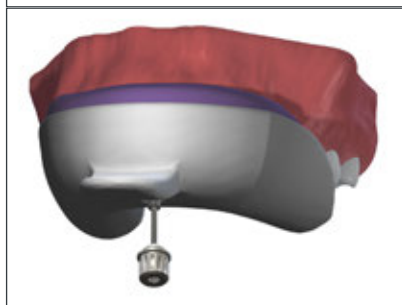


Step 2 – Impression taking

- Make perforations in the custom-made impression tray (light cured resin) according to the individual situation so that the guide screw of the Impression Post sticks out.

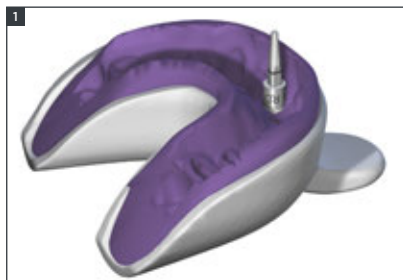


- Take the impression using an elastomeric precision impression material (VPS or Polyether materials should be used)
- Uncover the screw before the material is cured.



- Once the material is cured, loosen the guide screw and remove the tray.

6.5.3 Open tray impression – Lab procedure



Step 1 – Repositioning and fixing of CI RD Repositionable Implant Analog

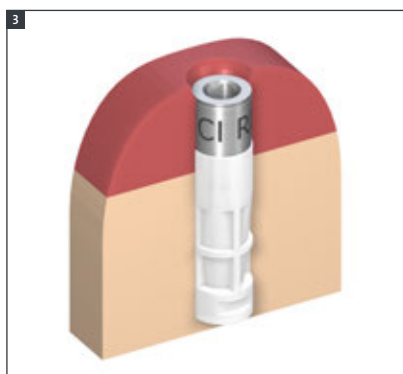
Assemble the corresponding Repositionable Implant Analog in the impression.

Fix the Repositionable Implant Analog in the impression using the guide screw.



Step 2 – Applying Sleeve

Mount the Sleeve onto the Repositionable Implant Analog. The Sleeve ensures proper fit of the Repositionable Implant Analog and controls occlusion height in the master cast. Only use new, undamaged and original Straumann® Implant Analogs.



Step 3 – Fabricating the master cast

Fabricate the master cast using standard methods and type-4 dental stone (ISO 6873). Embed Sleeve with the CI RD Repositionable Implant Analog in the stone. The CI RD Repositionable Implant Analog must not move in the master cast. A gingival mask should always be used to ensure that the emergence profile of the crown/coping is optimally contoured. Preferably use scannable material for the gingival mask.

For more information on the Straumann® PUREbase, please refer to the brochure *CI RD Straumann® PUREbase, Basic information* (702078/en).

6.6 STRAUMANN® TEMPORARY ABUTMENT VITA CAD-TEMP®

Application

- Individual soft tissue management for esthetic cases.
- Screw- or cement-retained temporary crowns.
- Cement-retained temporary bridges.

Characteristics

Simple

- Polymer material allows for easy and quick chair-side modification.
- Easy-to-achieve esthetics due to tooth-colored and modifiable polymer material.

Reliable

- Precise fit and high stability due to reinforcement with titanium alloy inlay.

Note

- Do not use for longer than 180 days.
- Place temporary restoration out of occlusion.
- The devices are provided non-sterile and are for single use only.
- Refer to relevant instructions for use (IFU) for product specific cleaning, disinfection or sterilization requirements.



6.6.1 Prosthetic procedure for Straumann® Temporary Abutment VITA CAD-Temp®



Option A: Screw-retained temporary crown

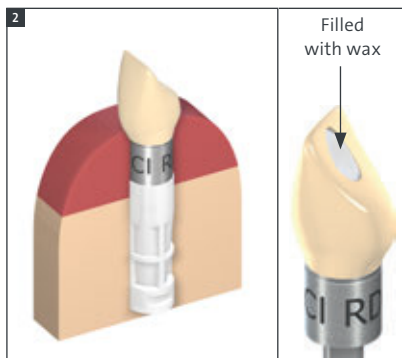
Step 1 – Customizing

Individualize the temporary abutment on an implant analog according to the mouth situation. Fine-cut tungsten carbide tools are recommended.

Guidelines for modifications:

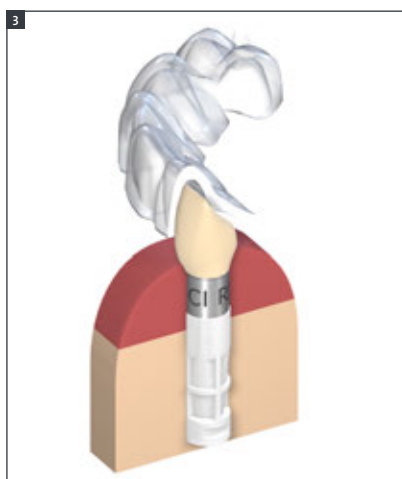
- Height reduction at most to the metal margin of the core.
- Width reduction not further than the lower metal margins.

Maximum reduction of the temporary abutment according to guidelines mentioned above.



Step 2 – Insertion

Hand-tighten the temporary abutment in the implant/Implant Analog with the SCS Screwdriver and temporarily seal the screw channel (e.g. with wax).



Step 3 – Fabrication

Use a standard technique to fabricate the temporary restoration, e.g. direct veneering or vacuum stents.

Note

- Before adding up any material or performing corrections with veneering material e.g. VITA VM® LC materials, refer to the manufacturer's instructions), the surface of the temporary restorations must be cleaned and wetted with modeling liquid.
- Clean abutment with a steam jet.



Step 4 – Finishing

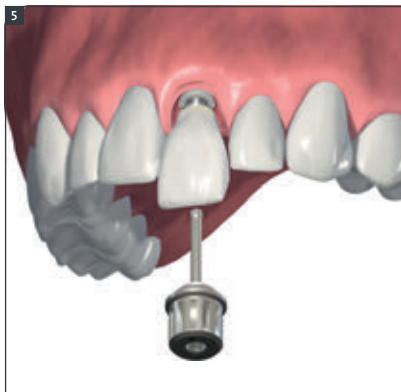
Remove excess acrylic, reopen the screw channel and finish the temporary restoration.

Note

- Restorations made from VITA CAD-Temp® can be pre-polished with a suitable silicone polisher and a small goat hair brush. Standard acrylic polishing agents that are also suitable for intra-oral use are used for high luster polishing.
- Avoid creating excessive heat.

Important

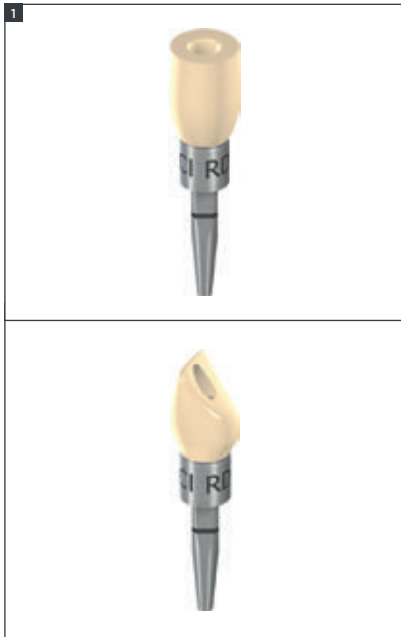
- Careful polishing is absolutely necessary to achieve an optimal result and related negative effects on the shade.
- Use a polishing aid or implant analog to protect the implant configuration while polishing the temporary restoration.



Step 5 – Insertion of the temporary restoration

Clean and sterilize the polished temporary restoration (refer to the relevant instruction of use (IFU) for specific cleaning, disinfection or sterilization requirements).

Place the temporary restoration on the implant and tighten the screw between 15 Ncm and 35 Ncm (depending on implant stability) using the SCS Screwdriver along with the Ratchet and the Torque Control Device.



Option B: Cement-retained temporary crown

Step 1 – Customizing

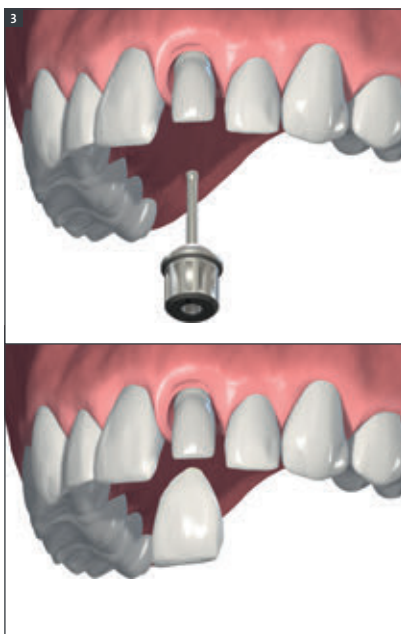
Individualize the temporary abutment on an implant analog according to the mouth situation. Fine-cut tungsten carbide tools are recommended

For modification guidelines, please see Option A *Screw-retained temporary crown* on page 35.



Step 2 – Fabrication

Use a standard procedure to fabricate the temporary restoration.



Step 3 – Insertion

Clean and sterilize the polished temporary abutment.

Place the customized temporary abutment on the implant and tighten the screw between 15 Ncm and 35 Ncm (depending on implant stability) using the SCS Screwdriver along with the Ratchet and the Torque Control Device.

Cover the screw head with absorbent cotton or gutta-percha and close the screw channel temporarily (e.g. with absorbent cotton).

Step 4 – Cementation

Coat the internal configuration of the crown with temporary cement and cement it on the temporary abutment.






6.7 CREATION AND FIXATION OF THE FINAL RESTORATION

Digital Workflow (CAD/CAM)

Straumann® PUREbase

The Straumann® PUREbase prosthetic components for Straumann® PURE Ceramic Implants provide dental laboratories with the flexibility to create customized prosthetic restorations with their chosen in-lab workflow.

For more information on the Straumann® PUREbase, please refer to the brochure *CI RD Straumann® PUREbase, Basic information* (702078/en).

Art. No.		Article	Dimension	Material
032.023		CI RD Straumann® PUREbase Abutment	AH3.5	TAN
032.024		CI RD Straumann® PUREbase Abutment	AH5.5	TAN
032.040		Bonding Aid for CI RD Straumann® PUREbase	-	TAN
032.123		CI RD Straumann® PUREbase AS	AH3.5	TAN
032.124		CI RD Straumann® PUREbase AS	AH5.5	TAN

Design

The CI RD Straumann® PUREbase (Fig. 1) differs from the Straumann Variobase family (Fig. 2): its narrower esthetic design and unique inner connection allows the Straumann® PUREbase to act as a stable inner core, while the crown/coping sits directly on the implant shoulder, forming the outer shell for the surrounding soft tissue.

Straumann® PURE
Ceramic Implant RD with
CI RD Straumann® PUREbase

vs.

Straumann® Standard
Plus RN with Straumann® RN
Variobase®

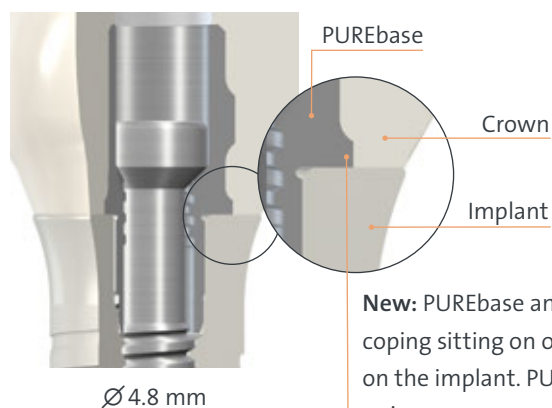


Fig. 1

New: PUREbase and crown/coping sitting on one level on the implant. PUREbase as inner core, crown/coping are forming the outer shell to the soft tissue.

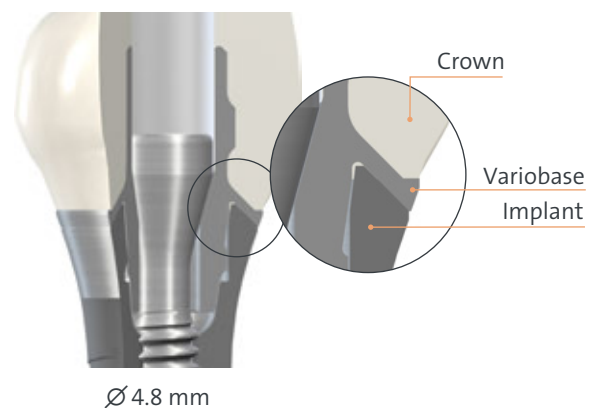
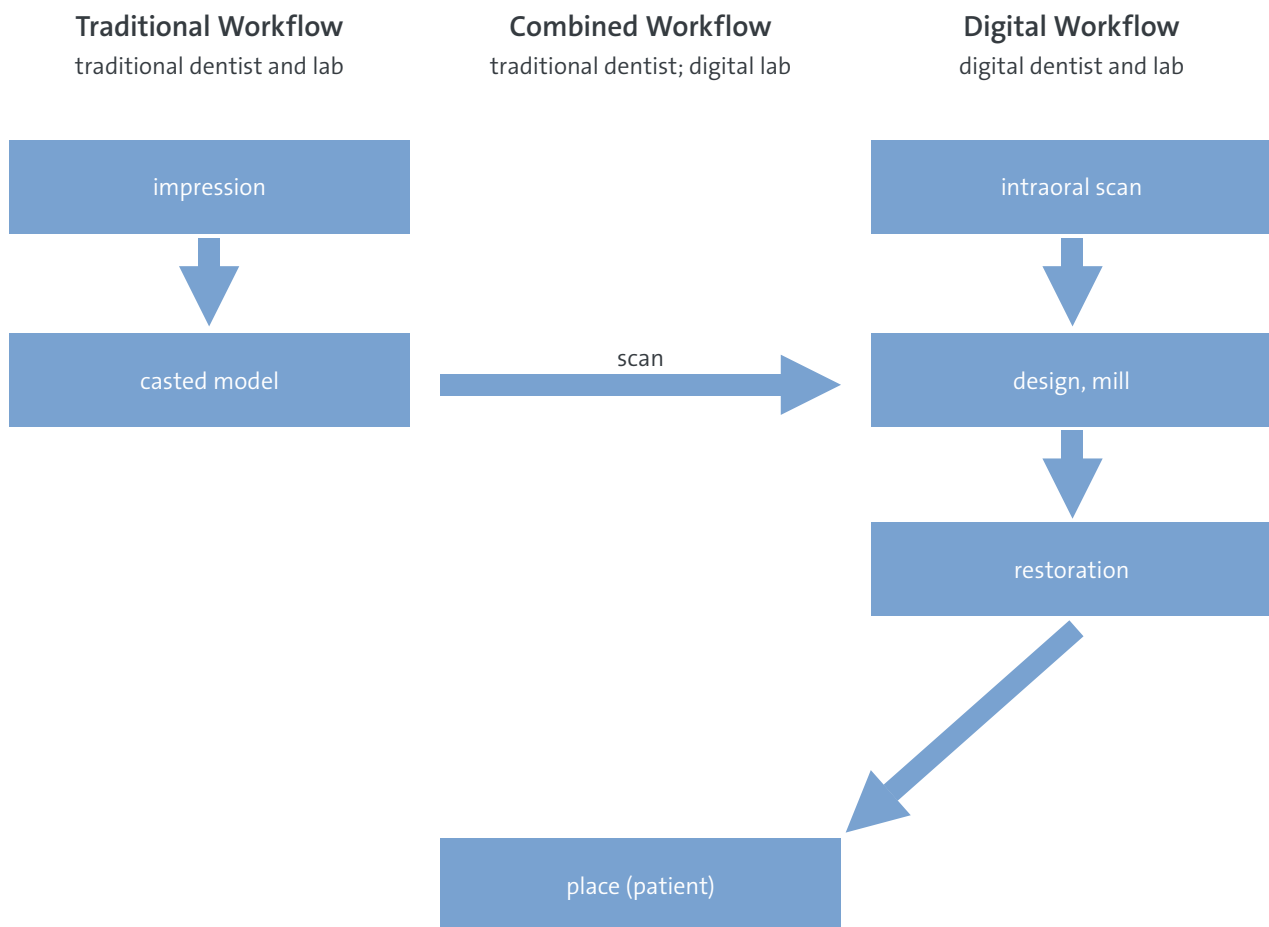


Fig. 2

6.8 DIGITAL WORKFLOW (CAD/CAM)

Digitally produced restorations of Straumann® PUREbase prosthetic components are accessible via three options*:

- Access the desired Straumann® PUREbase prosthetic components with the CARES® System and CARES® X-Stream.
- Connect your existing CAD software and mill the restoration on a Straumann® PURE prosthetic component via Straumann® centralized milling facilities or with your in-house milling equipment.
- Access the digital offering with the CARES® Scan & Shape Service.



PURE prosthetics requires digital planning. Traditional restoration in-lab, e.g. with burn-out copings are not supported.

* **Note:** Some services may not be available in your country. Please contact your country sales representative for details.

For more information on the Straumann® PUREbase, please refer to the brochure *CI RD Straumann® PUREbase, Basic information* (702078/en).

6.9 INSERTION (DENTAL PRACTICE)

Fix the final restoration on the master cast before delivery to the dentist. Check tight fit of restoration in master model or analog. **Deliver only when there is no visible microgap between restoration and implant analog.**

Step 1 – Preparation

- Remove the healing cap or temporary restoration.
- Remove the restoration from the master cast and unscrew the PUREbase prosthetic components from the CI RD Repositionable Implant Analog.
- Thoroughly clean and dry the interior of the implant and the abutment.

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



Step 2 – Final insertion

Option A: Screw-retained final restoration

Position the sterilized PUREbase prosthetic restoration in the implant. Tighten the screw to 35 Ncm using the SCS Screwdriver together with the Ratchet and the Torque Control Device. Close the SCS screw channel with cotton and sealing compound (i.e. gutta-percha). This allows for subsequent removal of the PUREbase in case a crown/coping or overdenture replacement should be required.



Option B: Cement-retained final restoration

Position the sterilized PUREbase in the implant. Tighten the screw to 35 Ncm using the SCS Screwdriver together with the Ratchet and the Torque Control Device. Close the screw channel with cotton and sealing compound (e.g. gutta-percha). This allows for subsequent removal of the PUREbase in case a crown/coping replacement should be required. Cement the superstructure to the abutment. Remove excess cement. Check the horizontal implant-abutment connection for possible gaps.

7. AFTERCARE AND CLEANING OF STRAUMANN® PURE CERAMIC IMPLANT

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 non-metallic 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.

Do not use any abrasive prophylactic pastes for cleaning Straumann® PURE Ceramic Implants. Powder/water jet cleaners are not suitable for cleaning Straumann® PURE Ceramic Implants.

8. TROUBLESHOOTING

8.1 IMPLANT REMOVAL

Non-osseointegrated implant (spinner)

The 48h Explantation Device for Straumann® PURE Ceramic Implant System can be used to help remove a non-osseointegrated implant.

Note

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. Please refer to the brochure *Guidance for Implant Removal, Basic Information* (152.806/en).

9. STRAUMANN® PURE CERAMIC IMPLANT MONOTYPE



The Straumann® PURE Ceramic Implant Monotype has a one-piece monotype design based on features of the Straumann® Tissue Level Standard Plus and Straumann® Bone Level Implants.

The Straumann® PURE Ceramic Implant Monotype 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.

Color coding	
● Yellow	Endosteal implant diameter 3.3 mm
● Red	Endosteal implant diameter 4.1 mm

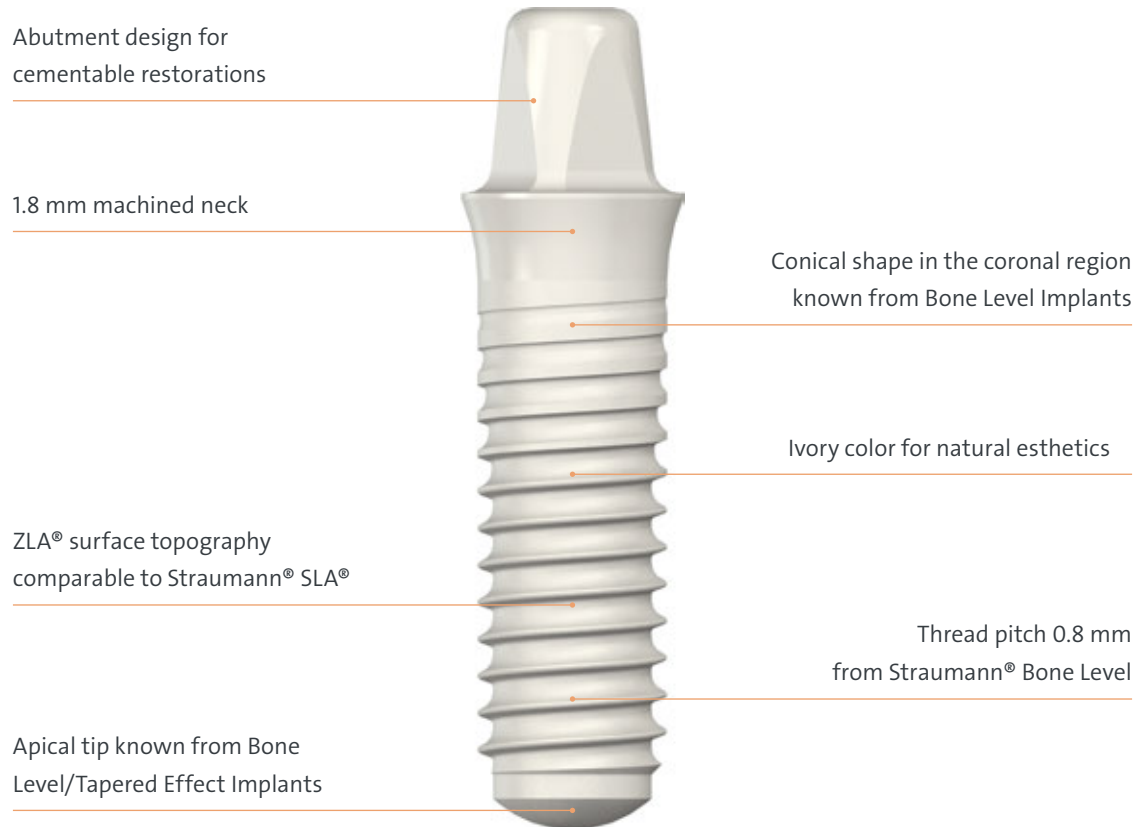


A nomenclature, similar to Straumann® Tissue Level titanium implants, is used for identification of Straumann® PURE Ceramic Implant Monotype auxiliaries. All these components can be identified with the ND (Narrow Diameter) and RD (Regular Diameter) code which corresponds to a shoulder diameter of Ø 3.5 mm and Ø 4.8 mm respectively.



Implant overview			Straumann® PURE Ceramic Implant Monotype Ø 3.3 ND		Straumann® PURE Ceramic Implant Monotype Ø 4.1 RD	
Connection			ND	ND	RD	RD
Abutment height			AH 4 mm	AH 5.5 mm	AH 4 mm	AH 5.5 mm
Shoulder diameter			Ø 3.5 mm	Ø 3.5 mm	Ø 4.8 mm	Ø 4.8 mm
<ul style="list-style-type: none"> Conical design in coronal region Thread pitch known from Straumann® Bone Level: 0.8 mm tread pitch 						
Endosteal diameter			Ø 3.3 mm	Ø 3.3 mm	Ø 4.1 mm	Ø 4.1 mm
ZrO ₂	ZLA®	8 mm	031.001S	031.011S	031.021S	031.031S
		10 mm	031.002S	031.012S	031.022S	031.032S
		12 mm	031.003S	031.013S	031.023S	031.033S
		14 mm	031.004S	031.014S	031.024S	031.034S








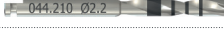











9.1 DESIGN



10. SURGICAL PROCEDURE FOR STRAUMANN® PURE CERAMIC IMPLANT MONOTYPE

The Straumann® PURE Ceramic Implant Monotype can be placed with the existing Straumann® Surgical Cassette while using a very similar surgical procedure as the Straumann® Bone Level surgical protocol. The surgical procedure includes 4 steps: Preoperative planning, basic implant bed preparation, fine implant bed preparation and implant insertion.

The following table summarizes the use of instruments for the basic implant bed preparation according to the endosteal implant diameter.

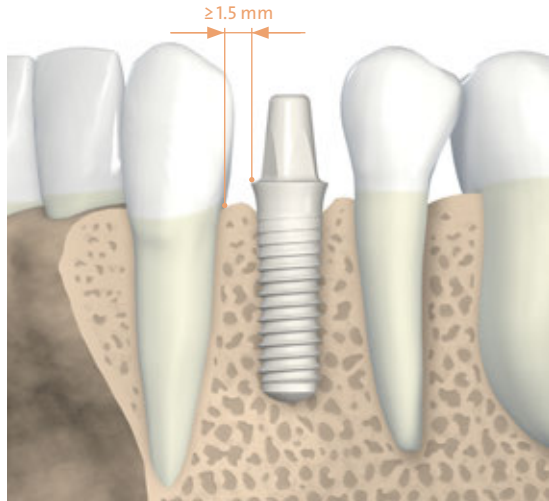
Instrumentation for basic implant bed preparation					Endosteal Ø (mm)	
Step	Art. No.	Product	max. rpm		Ø 3.3	Ø 4.1
1 Ridge preparation	044.004	Round Bur, Ø 3.1 mm	800			
2 Mark implant position	026.0054	Needle drill, Ø 1.6 mm	800			
	044.022	Round Bur, Ø 1.4 mm				
	044.003	Round Bur, Ø 2.3 mm				
	044.004	Round Bur, Ø 3.1 mm				
3 Mark implant axis	044.210	Pilot Drill 1, short, Ø 2.2 mm	800			
	046.455	Depth Gauge, with Implant Distance Indicator, Ø 2.2/2.8 mm				
4 Prepare implant bed to Ø 2.2 mm	044.210	Pilot Drill 1, short, Ø 2.2 mm	800			
	046.703	Alignment Pin, Ø 2.2 mm, straight				
	031.123	RD Position Indicator Ø 2.2 mm, abutment height 4.0 or 5.5 mm				
	031.143					
5 Prepare implant bed to Ø 2.8 mm	044.214	Pilot Drill 2, short, Ø 2.8 mm	600			
	046.455	Depth Gauge, with Implant Distance Indicator, Ø 2.2/2.8 mm				
	031.103	ND PURE Position Indicator Ø 2.8 mm, abutment height 4.0 or 5.5 mm				
	031.113					
6 Prepare implant bed to Ø 3.5 mm	044.250	Twist Drill PRO, short, Ø 3.5 mm	500			
	046.450	Depth Gauge Ø 3.5 mm				
	031.125	RD PURE Position Indicator Ø 3.5 mm, abutment height 4.0 or 5.5 mm				
	031.145					

10.1 PREOPERATIVE PLANNING

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. The 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 for the Straumann® PURE Ceramic Implant Monotype as a perfect axis for implant insertion during implant bed preparation is crucial.

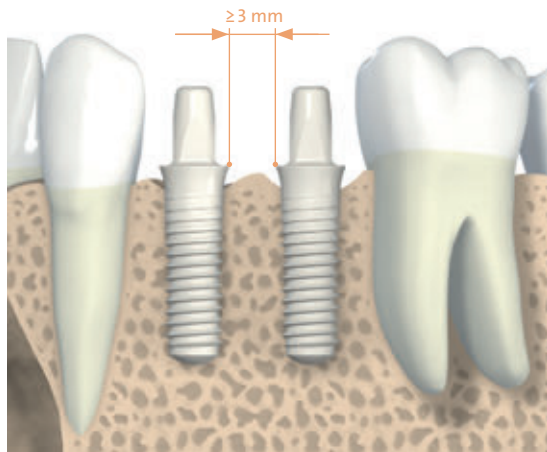
10.1.1 Implant position

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



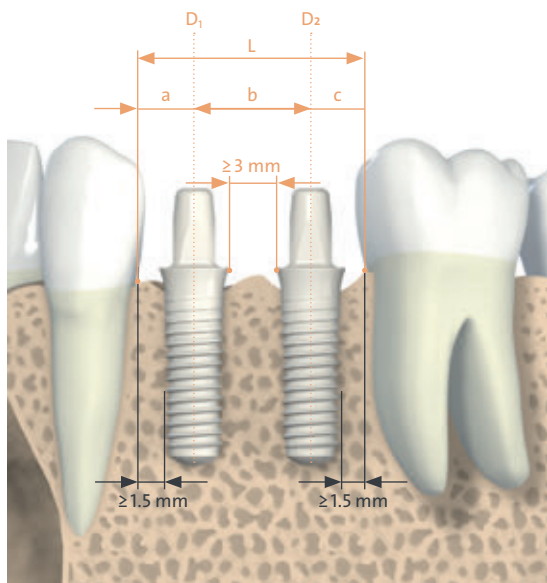
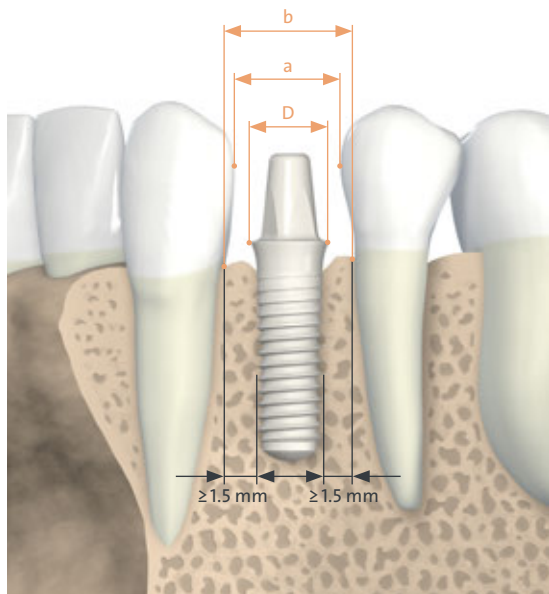
Rule 1

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.



Shoulder Diameter D [mm]	Gap Width a_{min} [mm]	Distance between teeth at bone level b_{min} [mm]
Ø 3.5 (ND)	5.5	6.5
Ø 4.8 (RD)	7	8
Rule	D + 2 mm	D + 3 mm

Shoulder Diameter D ₁ [mm]	Shoulder Diameter D ₂ [mm]	a_{min} [mm]	b_{min} [mm]	c_{min} [mm]	L_{min} [mm]
Ø 3.5 (ND)	Ø 3.5 (ND)	3	6.5	3	12.5
Ø 3.5 (ND)	Ø 4.8 (RD)	3	7	4	14
Ø 4.8 (RD)	Ø 4.8 (RD)	4	8	4	16



Rule 3

Special attention should be paid to the Straumann® PURE Ceramic Implant Monotype in order to achieve an optimal orofacial positioning of the implant, as the abutments must not be modified.

10.1.2 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 *Straumann® Dental Implant System, Basic Information* (152.754/en).



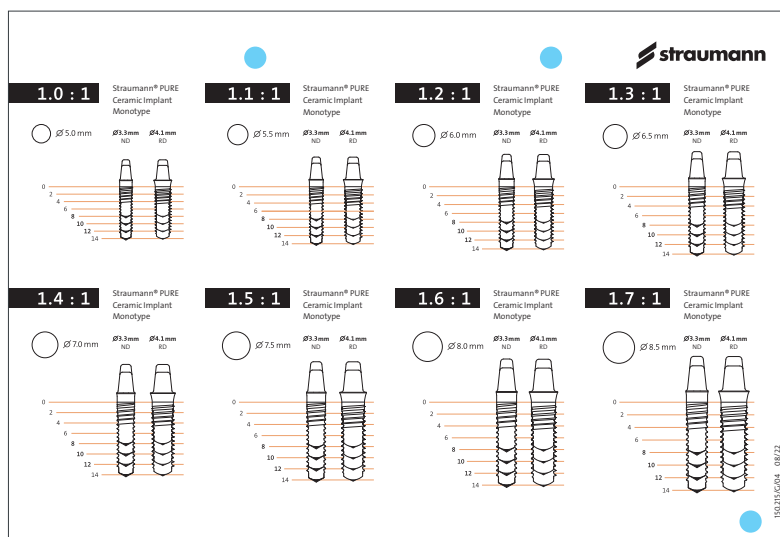
Straumann® Diagnostic T



Straumann® Implant Distance Indicator

Additionally the Straumann® X-ray template (150.215) 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:

$$\frac{\text{X-ray reference sphere } 5 \text{ mm} \times \text{bone availability (X-ray}^2\text{)}}{\text{Reference sphere diameter on the X-ray}} = \text{effective bone availability}$$

Digital planning with coDiagnostiX®

This 3D diagnostics and implant planning software is designed for the image-guided surgical planning of dental implants, including the Straumann® PURE Ceramic Implant System, 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 virtual replacement of implants, abutments and drilling sleeves. Digital planning and guided surgery is available.



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.

DWOS Synergy workflow

DWOS Synergy provides real-time communication between the implant planning software (coDiagnostiX®) and the lab software (i.e. Straumann®CARES®Visual) and improves implant planning by allowing the visualization of the relationship between the proposed implant position and the proposed restoration. Of special interest in regard to the Straumann® PURE Ceramic Implant Monotype, is that one can design the restoration and ensure that the planned position will not require modification for restorative materials.

10.2 BASIC IMPLANT BED PREPARATION

For preparing the implant bed the Straumann® Bone Level Surgical Cassette is used.

10.2.1 Position indicator

The Straumann® PURE Ceramic Implant Monotype position indicators are instruments used to ensure correct positioning of the implant during implant bed preparation. The Straumann® PURE Ceramic Implant Monotype position indicators are made of titanium. The devices are provided non-sterile and must be processed **prior** to use according to the relevant Instructions for use (IFU).

10.2.1.1 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.







Exact abutment representation

Abutment height identification

- Colored marking.
black = AH 4 mm
white = AH 5.5 mm

1.8 mm neck

- Replica of implant.

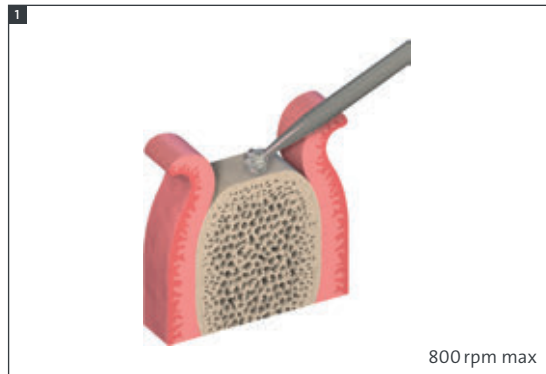
Position Indicator for					
		Straumann® PURE Ceramic Implant Monotype Ø 3.3 ND		Straumann® PURE Ceramic Implant Monotype Ø 4.1 RD	
Abutment height		AH 4 mm	AH 5.5 mm	AH 4 mm	AH 5.5 mm
					
Endosteal diameter	Ø 2.2	031.102	031.112	031.123	031.143
	Ø 2.8	031.103	031.113	—	—
	Ø 3.5	—	—	031.125	031.145

Note

Position Indicators can be cleaned, disinfected and sterilized like all other Straumann instruments. Refer to relevant instructions for use (IFU) for product specific cleaning, disinfection or sterilization requirements.

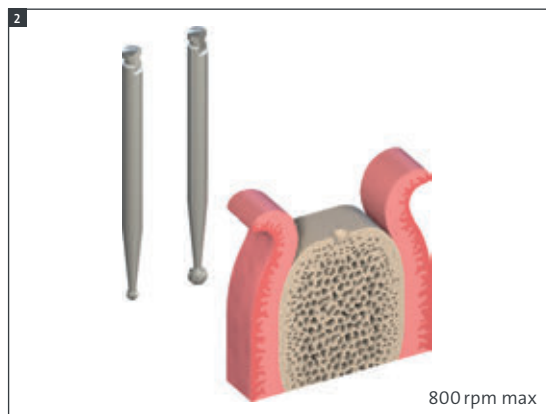
10.2.2 Preparing the implant bed

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.



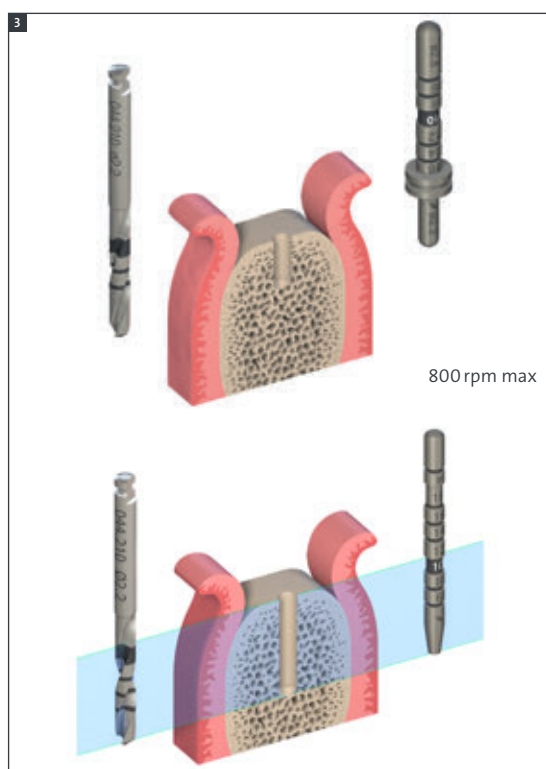
Step 1 – Prepare the alveolar ridge

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 Ø1.4 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 Ø2.3 mm or the Ø3.1 mm round bur, if necessary.



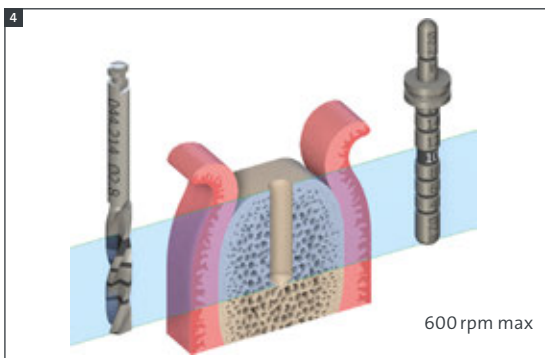
Step 3 – Mark the implant axis

With the Ø2.2 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 for correct implant axis orientation. If necessary, correct unsatisfactory implant axis orientation in the following step.



After depth check with the alignment pin, insert the Ø 2.2 mm PURE Ceramic 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.

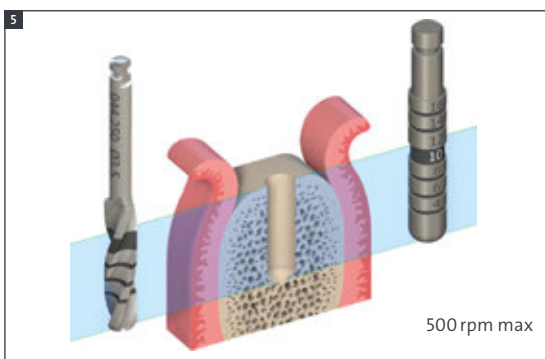


Step 4 – Widen the implant bed to Ø 2.8 mm

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.

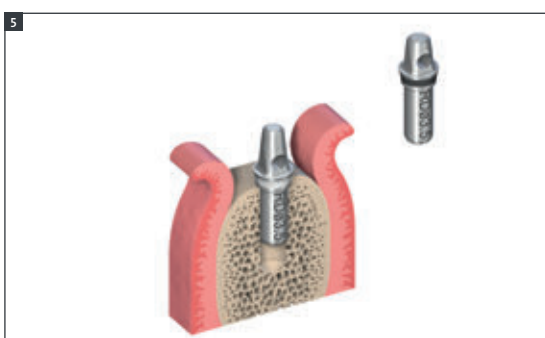


After depth check, if a Ø 3.3 Straumann® PURE Ceramic Implant will be placed, insert the Ø 2.8 mm monotype implant Position Indicator to check the implant position, angulation and restorability. Basic implant-bed preparation for a Ø 3.3 Straumann® PURE Ceramic Implant Monotype ends here, continue with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

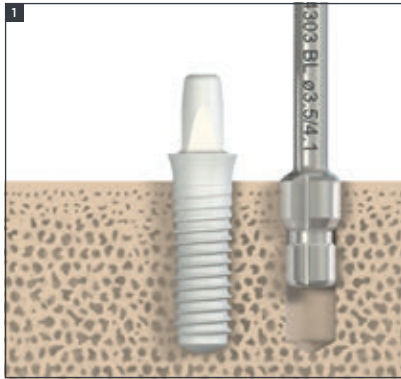


After depth check with the alignment pin, insert the Ø 3.5 mm monotype implant position indicator for check of implant position, angulation and restorability.

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

10.3 FINE IMPLANT BED PREPARATION

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

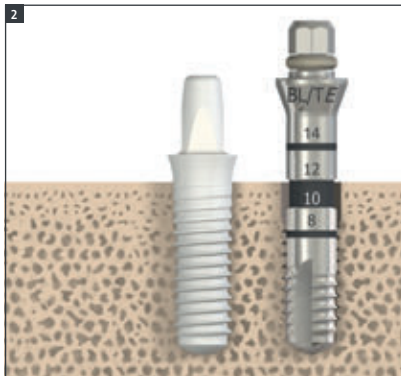


Step 1 – Profile drill

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

Depending on the respective bone situation at implant site, a Straumann Tissue Level RN Standard Plus profile drill might be used afterwards.

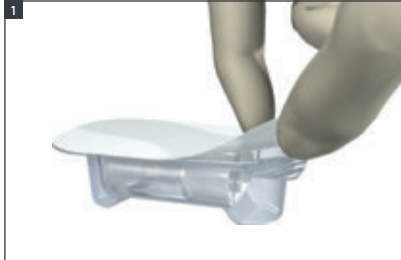


Step 2 – Tapping the thread in dense bone

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 *Straumann® Dental Implant System, Basic Information* (152.754/en).

10.4 IMPLANT INSERTION



10.4.1 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.

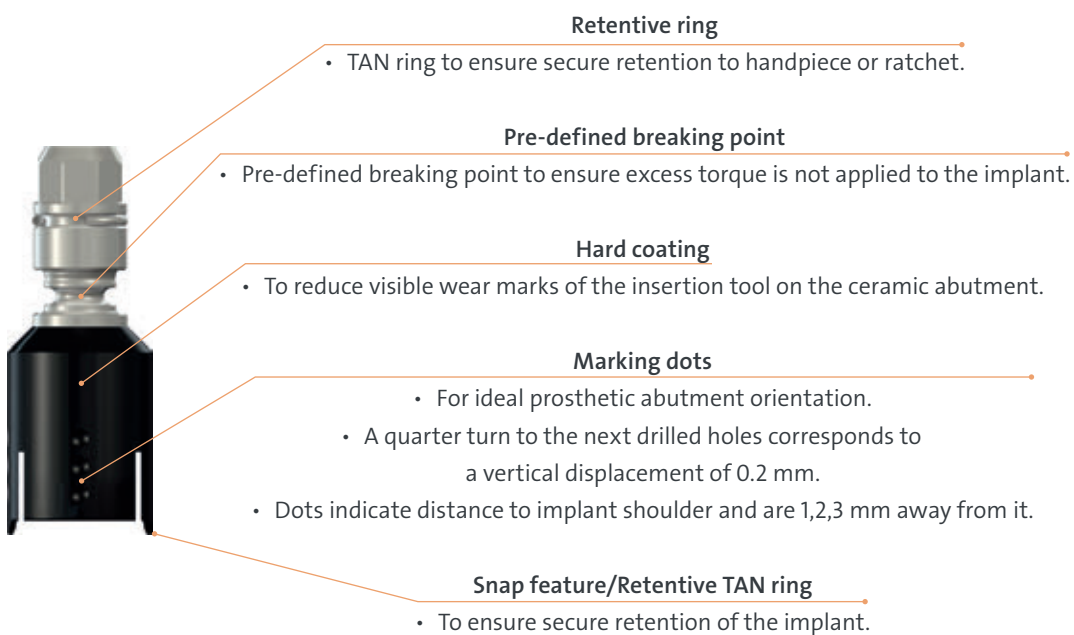


Step 2 – Opening of the implant carrier

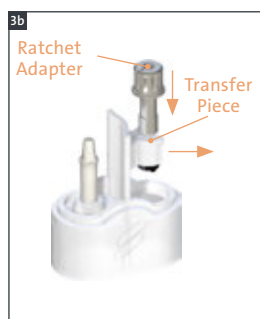
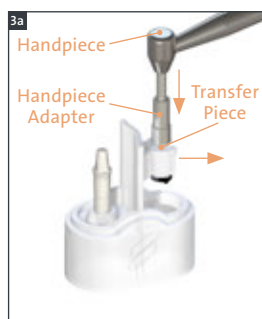
Hold the base of the implant carrier with two fingers in the middle. Using the other hand, lift off the lid. The implant is held by a ceramic pin.

 **Note:** The transfer piece is not pre-mounted. The transfer piece is an instrument used specifically with the Straumann® PURE Ceramic Implant Monotype. It is made from medical grade stainless steel.

Transfer Piece for PURE Ceramic Implant Monotype



The Straumann® PURE Ceramic Implant Monotype can be placed either (a) with the aid of the handpiece or (b) manually with the ratchet.



Step 3 – Attach the adapter to the transfer piece

Connect the transfer piece to an appropriate length handpiece/ratchet implant adapter. 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 4 – Attach the transfer piece to the implant

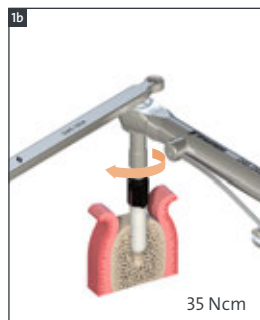
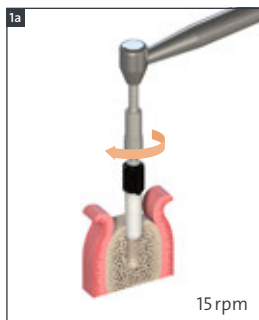
Push the transfer piece onto the implant (snap on). A click is heard when the transfer piece is attached correctly.



Step 5 – Remove the implant from the carrier

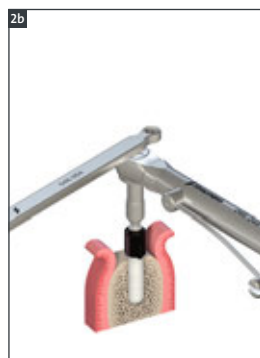
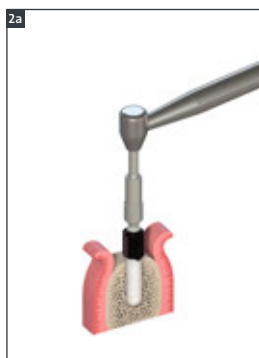
By turning counterclockwise the implant can be removed from the ceramic pin.

10.4.1 Placing the implant



Step 1 – Place implant into the implant bed

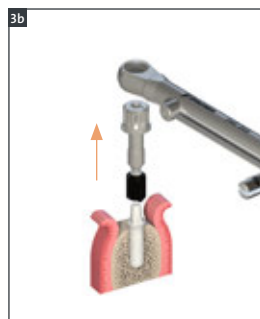
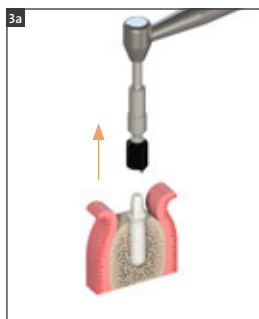
Always insert the implant clockwise to the correct depth. The implant is designed to have the implant shoulder sit 1.8 mm above the crestal bone. When using the handpiece, turn it clockwise with the recommended speed of 15 rpm.



Step 2 – Correct implant orientation

While approaching the final implant position, ensure the dots on the transfer piece are positioned buccally/labially. 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 – Pull out the handpiece vertically and disassemble the transfer piece from the handpiece adapter.

3b – Remove the holding key from the ratchet. Pull-out the ratchet adapter vertically from the implant and disassemble the transfer piece from the ratchet adapter.

Note: In case the transfer piece can not be disassembled easily from the implant, carefully do a 1/8 turn (not more) in reverse (counterclockwise) direction.

Note: The transfer piece can be used as position control after implant placement.

11. PROSTHETIC PROCEDURE FOR STRAUMANN® PURE CERAMIC IMPLANT MONOTYPE

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

11.1 PROTECTION DURING THE HEALING PHASE

11.1.1 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.

Situation	Healing phase
<ul style="list-style-type: none">• Good bone quality and adequate bone quantity.• Implants with a diameter of 4.1 mm.	At least 6 weeks
<ul style="list-style-type: none">• Cancellous bone quality.• Implants with a diameter of 3.3 mm.	At least 12 weeks
<ul style="list-style-type: none">• Straumann® ZLA® surface is not completely in contact with the bone.• Bone augmentation measures are necessary.	Healing phase corresponding to the situation

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

11.1.1.1 Protective cap (optional step)

Intended use

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

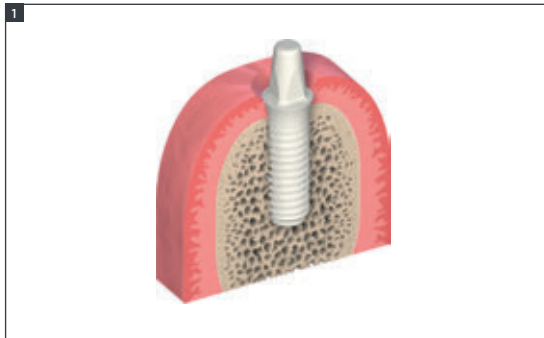
Characteristics

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

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 180 days.
- The Duration of use for the PMMA temporary copings is 30days in China and Singapore.
- Refer to relevant instructions for use (IFU) for product specific cleaning, disinfection or sterilization requirements.

Protective Cap		
	AH 4 mm	AH 5.5 mm
		
For Ø 3.3 (ND)	031.320	031.321
For Ø 4.1 (RD)	031.330	031.331

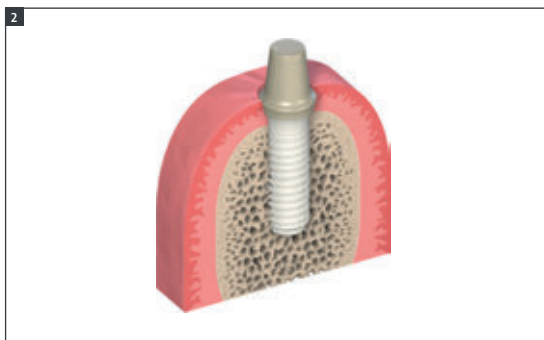


11.1.1.2 Protection of the Straumann® PURE Ceramic Implant Monotype

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.

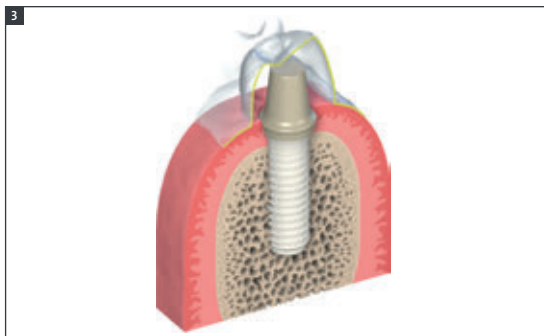


Step 2 – Placing of the protective cap

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.

11.2 IMPRESSION TAKING

11.2.1 Closed-tray impression

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.

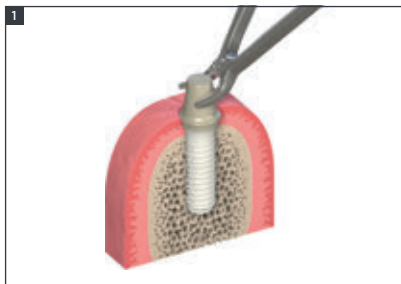
Note

- 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.
- Refer to the relevant instruction of use (IFU) for specific disinfection requirements.

Impression Caps		
	AH 4 mm	AH 5.5 mm
		
For Ø 3.3 (ND)	031.250	031.251
For Ø 4.1 (RD)	031.260	031.261

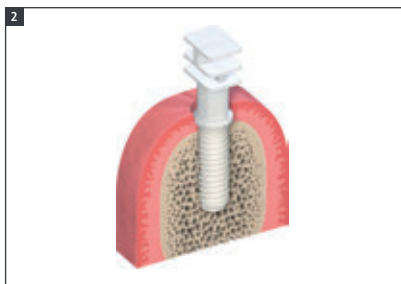
Implant Analogs		
	AH 4 mm	AH 5.5 mm
		
For Ø 3.3 (ND)	031.200	031.201
For Ø 4.1 (RD)	031.210	031.211

11.2.2 Closed-tray impression – Dentist procedure



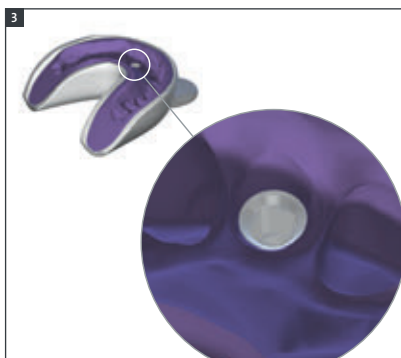
Step 1 – Preparation

Remove the Straumann® PURE Ceramic Implant Monotype 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 Monotype 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

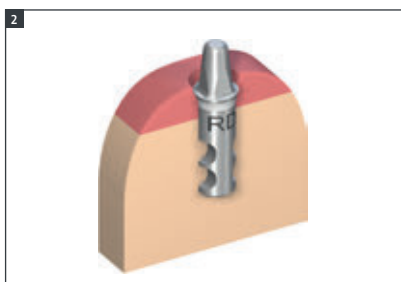
Due to its low tensile strength, hydrocolloid is not suitable for this application.

11.2.3 Closed-tray impression – Lab procedure



Step 1 – Implant analog fixation

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

11.3 TEMPORIZATION

11.3.1 Straumann® PURE Ceramic Implant Monotype Temporary Coping

Application

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

Two types of temporary copings are available:

Crown provisional (engaging)

Bridge provisional (non-engaging)

Characteristics

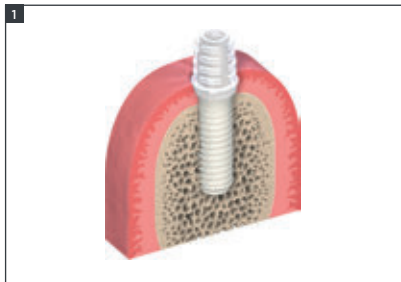
- Optimal surface roughness.
- Neck part of coping is very smooth.
- Coping has retention features for better bonding with veneering material.
- Clear-cut tactile response from the prosthetic connection verifies proper seating of components.

Note

- Do not use longer than 180 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.
- Refer to relevant instructions for use (IFU) for product disinfection requirements.

Temporary Copings		
	For crowns	For bridges
		
For Ø 3.3 (ND)	031.300	031.301
For Ø 4.1 (RD)	031.310	031.311

11.3.2 Chairside temporization with the Straumann® PURE Ceramic Implant Monotype Temporary Coping

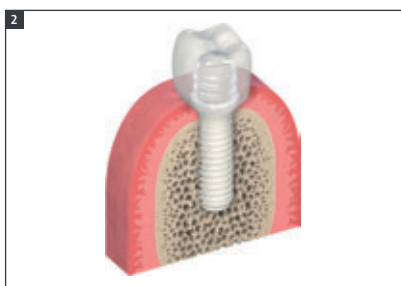


Step 1– Preparation

Snap the temporary coping onto the Straumann® PURE Ceramic Implant Monotype 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.

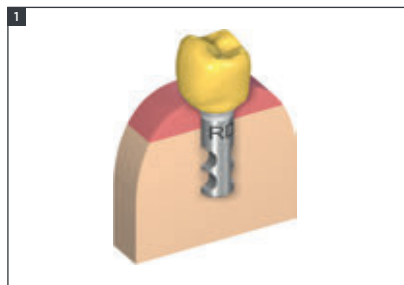
Note

- 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 180 days.
- The Duration of use for the PMMA temporary copings is 30days in China and Singapore.

11.4 CREATION AND CEMENTATION OF THE FINAL RESTORATION

11.4.1 Lab procedure

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



11.4.1.1 Conventional

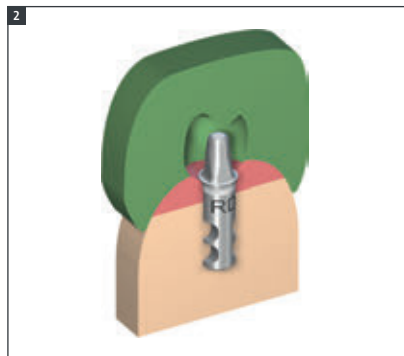
Step 1 – Wax-up

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 implant analog.

Note

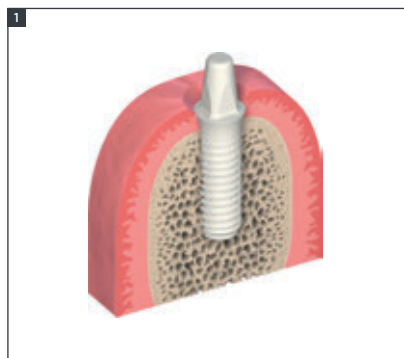
Straumann® PURE Ceramic Implant Monotype abutments must not be mechanically finished under any circumstances: e.g. ground, sandblasted, or polished as this might cause the product to fail.

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.



11.4.1.2 Digital

Step 1 – Data digitization

- The patient situation can be scanned with a Straumann approved intra-oral scanner. The data is then imported in the Straumann approved software
- 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 *Straumann® CARES® tooth prosthetic procedures, Basic Information* (152.821/en), available on the Straumann website: www.straumann.com.

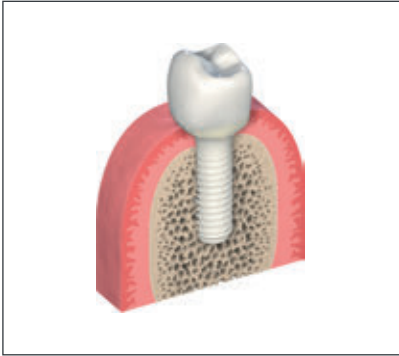
Note

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).



11.4.2 Dentist procedure

The final restoration is placed on the master cast when delivered to the doctor's office.

Final insertion:

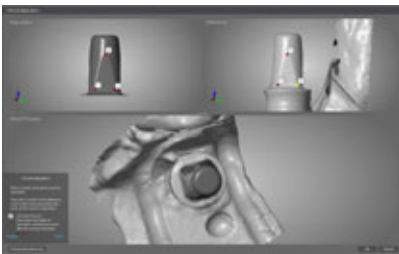
- Remove the temporary restoration.
- Clean the abutment thoroughly and remove all remaining temporary cement.
- Prepare the surface of the Straumann® PURE Ceramic Implant Monotype abutment, and of the superstructure according to the instructions given by the corresponding cement manufacturer.
- Cement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

Cement:

- Use a cement that is approved for bonding the chosen restorative material to the Straumann(r) Pure Ceramic Monotype Implant (Straumann recommends Panavia V5).
- Always use the components within a cement system. Do not mix components with different trademarks.
- Always follow the cement manufacturer's instructions throughout the cementation procedure.
- Always use the appropriate primer if one is stated in the restorative material or cement manufacturer's instructions for use.

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 bio-film formation resulting in inflammation and infection.



11.4.3 Software Workflow

- The Straumann® PURE Ceramic Implant Monotype doesn't have a Scan body to scan intra-orally or from a stone Model. The Implant or Analog is scanned and the software will reconstruct the implant using the 3-Point matching method.
- CIM Analogs should be treated with scan spray to achieve the best matching results.

12. AFTERCARE AND CLEANING OF STRAUMANN® PURE CERAMIC IMPLANT MONOTYPE

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 non-metallic 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.

Do not use any abrasive prophylactic pastes for cleaning Straumann® PURE Ceramic Implants. Powder/water jet cleaners are not suitable for cleaning Straumann® PURE Ceramic Implants.

13. TROUBLESHOOTING

13.1 IMPLANT REMOVAL

Non-osseointegrated implant (spinner)

The 48h Explantation Device for Straumann® PURE Ceramic Implant System can be used to help remove a non-osseointegrated implant.

Note

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. Please refer to the brochure *Guidance for Implant Removal, Basic Information* (152.806/en).

13.2 FRACTURE OF THE ABUTMENT (STRAUMANN® PURE CERAMIC IMPLANT MONOTYPE)

If part of the PURE Ceramic Implant Monotype 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.


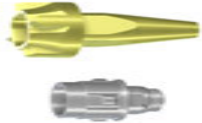








14. PRODUCT REFERENCE LIST

14.1 STRAUMANN® PURE CERAMIC IMPLANT

14.1.1 Implants

Art. No.		Article	Dimension	Material
032.000S		Straumann® PURE Ceramic Implant, Ø 4.1 mm RD	ZLA® L 8 mm	ZrO ₂
032.001S			ZLA® L 10 mm	
032.002S			ZLA® L 12 mm	
032.003S			ZLA® L 14 mm	





14.1.2 Auxiliaries

Art. No.		Article	Dimension	Material
032.023		CI RD Straumann® PUREbase, incl. Bonding Aid and screw	AH 3.5 mm	TAN
032.024		CI RD Straumann® PUREbase, incl. Bonding Aid and screw	AH 5.5 mm	TAN
032.028		CI Basal Screw	for CI RD Temporary and PUREbase Abutment	Ti
032.123		CI RD Straumann® PUREbase AS, incl. Bonding Aid and screw	AH 3.5 mm	TAN
032.124		CI RD Straumann® PUREbase AS, incl. Bonding Aid and screw	AH 5.5 mm	TAN
032.040		Bonding Aid for CI RD Straumann® PUREbase	-	TAN
032.128		CI RD Basal Screw	for CI RD PUREbase AS	TAN
032.018		Repositionable Implant Analog CI RD	—	stainless steel
032.027		CI RD Repositionable Implant Analog, incl. Sleeve	—	—
032.129		CI RD Impression Post, implant level	—	Ti/POM













Art. No.		Article	Dimension	Material
032.0305		CI RD Closure Cap	H 0.5 mm	Ti
032.0325		CI RD Healing Cap	H 2 mm	Ti
032.0335		CI RD Healing Cap	H 3 mm	Ti
032.0555		CI RD Healing Cap	Ø 5.2 mm, H 2 mm	ZrO2/Ti
032.0565		CI RD Healing Cap	Ø 5.2 mm, H 3 mm	ZrO2/Ti
032.0575		CI RD Healing Cap	Ø 5.2 mm, H 4.5 mm	ZrO2/Ti
032.036		CI RD Temporary Abutment Vita CAD-Temp®	—	PMMA/ TAN
032.041		CI RD CARES® Mono Scanbody Ø 4.1 mm	—	—
031.123		RD Position Indicator	Ø 2.2 mm, AH 4 mm, L 8 mm	Ti
031.143		RD Position Indicator	Ø 2.2 mm, AH 5.5 mm, L 8 mm	Ti
031.125		RD Position Indicator	Ø 3.5 mm, AH 4 mm, L 8 mm	Ti
031.145		RD Position Indicator	Ø 3.5 mm, AH 5.5 mm, L 8 mm	Ti
032.089		CI RD Straumann® PUREloc	Straight, angle 0°, height 1 mm	ZrO2/Ti
032.090			Straight, angle 0°, height 2 mm	
032.091			Straight, angle 0°, height 3 mm	
032.092			Straight, angle 0°, height 4 mm	
032.093			Straight, angle 0°, height 5 mm	
032.094			Straight, angle 0°, height 6 mm	
032.095V4		CI RD Straumann® PUREloc Plan Abutment	Height 1-6 mm	POM
032.054		CI RD SCS Guiding Cylinder	Ø 4.2 mm, L 10.5 mm,	Stainless steel
032.053		CI RD 48h Explantation Device	L 26.2 mm	Stainless steel

14.2 STRAUMANN® PURE CERAMIC IMPLANT MONOTYPE

14.2.1 Implants

Art. No.		Article	Dimension	Material
031.001S		Straumann® PURE Ceramic Implant Monotype, Ø 3.3 mm ND	ZLA® L 8 mm, AH 4 mm	ZrO ₂
031.002S			ZLA® L 10 mm, AH 4 mm	
031.003S			ZLA® L 12 mm, AH 4 mm	
031.004S			ZLA® L 14 mm, AH 4 mm	
031.011S		Straumann® PURE Ceramic Implant Monotype, Ø 3.3 mm ND	ZLA® L 8 mm, AH 5.5 mm	ZrO ₂
031.012S			ZLA® L 10 mm, AH 5.5 mm	
031.013S			ZLA® L 12 mm, AH 5.5 mm	
031.014S			ZLA® L 14 mm, AH 5.5 mm	
031.021S		Straumann® PURE Ceramic Implant Monotype, Ø 4.1 mm RD	ZLA® L 8 mm, AH 4 mm	ZrO ₂
031.022S			ZLA® L 10 mm, AH 4 mm	
031.023S			ZLA® L 12 mm, AH 4 mm	
031.024S			ZLA® L 14 mm, AH 4 mm	
031.031S		Straumann® PURE Ceramic Implant Monotype, Ø 4.1 mm RD	ZLA® L 8 mm, AH 5.5 mm	ZrO ₂
031.032S			ZLA® L 10 mm, AH 5.5 mm	
031.033S			ZLA® L 12 mm, AH 5.5 mm	
031.034S			ZLA® L 14 mm, AH 5.5 mm	

14.2.2 Auxiliaries

Art. No.		Article	Dimension	Material
031.102		ND Position Indicator	Ø 2.2 mm, AH 4 mm, L 8 mm	Ti
031.123		RD Position Indicator	Ø 2.2 mm, AH 4 mm, L 8 mm	Ti
031.103		ND Position Indicator	Ø 2.8 mm, AH 4 mm, L 8 mm	Ti
031.125		RD Position Indicator	Ø 3.5 mm, AH 4 mm, L 8 mm	Ti
031.112		ND Position Indicator	Ø 2.2 mm, AH 5.5 mm, L 8 mm	Ti
031.143		RD Position Indicator	Ø 2.2 mm, AH 5.5 mm, L 8 mm	Ti
031.113		ND Position Indicator	Ø 2.8 mm, AH 5.5 mm, L 8 mm	Ti
031.145		RD Position Indicator	Ø 3.5 mm, AH 5.5 mm, L 8 mm	Ti
031.200		ND Implant Analog	AH 4 mm	TAN
031.210		RD Implant Analog	AH 4 mm	TAN
031.201		ND Implant Analog	AH 5.5 mm	TAN
031.211		RD Implant Analog	AH 5.5 mm	TAN

Art. No.		Article	Dimension	Material
031.250		ND Impression Cap	AH 4 mm	POM
031.260		RD Impression Cap	AH 4 mm	POM
031.251		ND Impression Cap	AH 5.5 mm	POM
031.261		RD Impression Cap	AH 5.5 mm	POM
031.300		ND Temporary Coping	For crown	PMMA
031.310		RD Temporary Coping	For crown	PMMA
031.301		ND Temporary Coping	For bridge	PMMA
031.311		RD Temporary Coping	For bridge	PMMA
031.320		ND Protective Cap	AH 4 mm	PEEK
031.330		RD Protective Cap	AH 4 mm	PEEK
031.321		ND Protective Cap	AH 5.5 mm	PEEK
031.331		RD Protective Cap	AH 5.5 mm	PEEK
031.081		48h Explantation Device for ND Straumann® PURE Ceramic Implant (Monotype)	Length 19.8 mm	Stainless steel
031.080		48h Explantation Device for RD Straumann® PURE Ceramic Implant (Monotype)	Length 19.7 mm	Stainless steel

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