SSO – Instruction Manual

09.2-series – compatible with *Straumann SynOcta®* implants

Titanium bonding base for individual implantprosthetic construction

CE 0297

1. Product description

The titanium abutment is delivered non-sterile with an abutment screw and is intended for use with the Straumann SynOcta® Implant System.

2. Indications

The titanium base is used for customized implant-prosthetic titanium abutment manufacturing. The titanium abutment, after cementing with a CAD/CAM milled assembly, is the connecting component to the implant.

⚠ WARNING **Specific indication for small diameter (NN):** follow the note of warning from Straumann® AG concerning the reduced mechanical stability and the restricted indication of the diameter-reduced implants. (See Straumann "basic information on the surgical procedures", point 2.1.1)

3. Contraindications

The titanium abutment of the **09.2-series** can **only be combined** with the **Straumann SynOcta® implants**. They cannot be combined with implants of a different implant type or manufacturer. The diameter of the titanium abutment must correspond in size to the used implant.

The titanium abutments and abutment screws are indicated for single use only.

For fixation of the abutment on the implant, the **correct torque force of 35 Ncm**, recommended by the implant manufacturer, has to be considered carefully.

Allergies or sensitivities in connection with the titanium alloy Ti6Al4V (titanium, aluminum, vanadium) can not be ruled out in very rare cases.

4. Composition

Titanium base: Ti6Al4V ELI (Titan Grade 5 ELI / 3.7165) / ISO 5832-3 / ASTM F136
Abutment screw: Ti6Al7Nb (9.9367) / ISO 5832-11 / ASTM F1295

5. Item numbers of products

The product consists of 2 components – a retaining screw (abutment screw) and the titanium abutment itself. The accessories (scan abutment, lab analogue) for the recording of the correct implant position must be ordered separately (view item-no. in tables below).

09.2-series is compatible with **Straumann SynOcta® implants**

Identification	Ø RN	Ø WN
Titanium abutment incl. retaining screw	**09.2-12**	**09.2-13**
Titanium abutment	**09.2-12-10**	**09.2-13-10**
Abutment screw (retaining screw)	**09.2-xx-11**	**09.2-xx-11**
Scan abutment	**09.2-12-32**	**09.2-13-32**
Lab analogue	**09.2-12-33**	**09.2-13-33**

Item numbers (order numbers) SSO-series

6. Application of the titanium abutment

6.1. Time of prosthetic restoration

A temporary prosthetic restoration may only be considered as far as it can be ensured that no mechanical irritation acts the implant respectively the sutures. If a temporary restoration is done it must be observed that the dental implants are not loaded during the healing phase. The permanent prosthetic restoration of the implant may only be done after the soft tissue has healed without irritations. After a healing phase of 6-12 weeks and before the prosthetic rehabilitation is done an x-ray control is required.

6.2 Selection and position of components

For the impression of the local intraoral situation (optional closed or open tray technique) after successful osseointegration of the implant silicone or polyether impression materials are suitable. For the selection of the titanium abutment the diameter of the implant is important (see 3. Contraindications). A favourable load distribution should be chosen. A passive fit of the prosthetic restoration on the titanium abutments and a correct occlusion should be ensured. It is required to only use materials that are designated for the creation of the prosthetic restoration. Among other things the minimum wall thickness of porcelain restorations must be observed. Referral must be made to the user information of the respective manufacturer.

6.3 Processing of the titanium abutment

The contact surfaces of titanium abutment to implant must neither be blasted nor be processed mechanically! The diameter and the length of the titanium abutment must not be reduced e.g. by cutting. The areas of the titanium abutment that will be bonded must be blasted and steam cleaned. To protect the contact area during blasting of this area we recommend using a same diameter lab analogue. The ceramic copings must not be primarily interlocked.

6.4 Placement of the bonded components on the implant

Before the bonded components are placed on the integrated implant the temporary abutment must be removed and the internal areas of the implant must be cleaned. The titanium/ceramic restoration must be seated precisely on the implant. It is recommended to take a control x-ray to check the correct seating of the restoration on the implant. Soft tissue may not be jammed and there should be no gap. By using the abutment screw the titanium/ceramic restoration is permanently screwed on the implant. The permanent screw retention with the implant must be done with a **torque of 35 Ncm**. To achieve a maximum screw preload the screw should be re-tightened with the same torque after 5 minutes.

7. Application of the scan abutment

For the CAD/CAM scanning of the model, the scan abutment is used to indicate the position of the implant. The size of the scan abutment shall be corresponding to the original implant system, implant diameter and titanium abutment series. The chamfer of the scan abutment prevents the rotation of the ceramic abutment. The scan abutment is fixed on the lab analogue with the abutment screw. After correct positioning and fixing, there is no gap visible between implant and scan abutment. Rotation of the scan body is impossible.

Subsequently the scan-technical, 3-dimensional localisation (optical) of the position of the lab analogue on the work model is performed including the determination of the axis inclination and the orientation of the surfaces.

8. Processing instructions titanium base and abutment

8.1 Handling method

Ceramic abutment:

Milling with CAD/CAM machines, e.g. of zirconium oxide ceramics, according to the anatomic form of a crown or coping. The ceramic copings or crowns shall be milled or polished with diamond instruments, and with minimal pressure and water-cooling. The minimal thickness shall be 0.5 mm. Sharpe edges must be avoided.

Veneering:

Copings shall be veneered with appropriate ceramics before cementing onto the titanium abutment. The instructions for use of the ceramic manufacturers have to be considered.

Treatment of the titanium base and the ceramic abutment before cementing:

Sandblasting of the contact surfaces with Al_2O_3, 50 µm, 2 bar and intensive cleaning of dust and grease. It is recommended to protect the connection part of the titanium basis with a lab analogue during handling.

Cementing:

It is recommended to cement the ceramic abutment onto the titanium base with Panavia® F2.0 (Kuraray) or other equivalent cements. The instructions for use of the cements shall be followed carefully.

The titanium abutment shall be fixed onto a lab analogue with the abutment screw. The head of the retaining screw has to be covered with wax or resin. The mixed cement is applied onto the contact part of the titanium abutment. The abutment is pressed onto the titanium base. The final position is evaluated by slight rotation. The gap between abutment and base must be as small as possible. Remaining cement shall be removed immediately.

Polishing:

After hardening, the remaining cement shall be removed with rotating silicon instruments. The cement inside the screw channel has to be removed carefully.

8.2 Processing of ceramic coping

- **Scan** (see above)
- **Designing** of the individual ceramic coping
- **Milling** – the individual ceramic coping is milled according to the instructions of the manufacturer of the CAD/CAM system in use
- **Sintering** – the individual ceramic coping is sintered according to the instructions of the manufacturer of the CAD/CAM system in use
- **Veneering** (see above)
- **Ceramic coping** prepare for **bonding** (see above)
- **Bonding** (see above)
- **Polishing** (see above)

9. General safety information and cautionary warnings for base systems

9.1 General information

Improper surgical and prosthetic protocols may lead to damage of the implant or to bone loss. The implant system should only be used by medical and dental practitioners and surgeons who are trained and familiar with the system. The application of the implant system requires special knowledge and proficiency in dental implantology.

Each patient must be thoroughly examined and evaluated regarding his/her x-ray, psychic and physical history, including teeth and hard and soft tissue deficiencies which might influence the final result. The close cooperation of surgeon dentist and dental technician is essential for successful oral rehabilitations. The implant system and the respective protocols have been developed by experts and have been clinically tested.

The safe application requires special knowledge. Therefore our products are only supplied to medical/dental practitioners and dental technological laboratories or on their behalf. Not all products are available in all countries.

The use of non-system components and instruments may interfere with the function and the safety of the implant system. CADstar does not undertake any warrantee or replacement liabilities if non-system components are used.

Drills, instruments and system components are designated for specific implant series and implant diameters. The application in other series or different diameters may lead to mechanical failure, tissue damage or unsatisfactory aesthetic results.

Due to the small size it may come to the swallowing or aspiration of the product. Aspiration may lead to shortage of breath and in severe cases to suffocation. This is the reason why products in case of intraoral application should generally be secured against swallowing and aspiration through the use of dental dam respectively dental floss.

Secondary effects:

Allergies to the alloy, or contents of it, or electrochemically based reactions may very rarely occur.

Reactions:

In case of occlusal or approximal contact of different alloys, electrochemically based reactions may very rarely occur.

9.2 Safety hint

⚠ WARNING	**Metal dust is harmful to your health.** When milling and sandblasting, use a suction extraction system and a breathing mask.

10. Warranty

10 years on the mechanical stability of the titanium abutment, if it was processed according to the instructions for use (IFU).

11. Cleaning

The prosthetic components of the CADstar product series are delivered non-sterile in a suitable packaging. The titanium abutment and the abutment screw may only be used once in one patient. Before and after application in the patient the prosthetic components must be cleaned according to the generally valid hygiene regulations for dental technological laboratories and dental offices.

12. Transport damages – packaging

If the packaging has been damaged during transport the product must be send back to the manufacturer!

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13. Additional documents

On our homepage https://www.cadstar.dental/de/service/downloads/ the technical data sheets for all used material and IFU for all series can be downloaded.

14. Explanation of symbols

The symbols comply with DIN EN 980. They are on the label of the product packaging and are also explained in the Quick Reference Guide (IFU).

Explanation of symbols:

	Instruction manual – read carefully!
	Contents non sterile!
	Do not reuse!
LOT	Lot number
REF	Item number
	Manufacturer
Rx only	Caution: Federal law (USA) restricts this product to sale by or on the order of a dentist or physician!
CE	Medical product according to directive 93/42/EWG
0297	Identification number of the nominated point