SDS SWISS DENTAL SOLUTIONS

NON STERILE CE 0483

Instructions for the use of SDS2.2 standard implant posts and -screws

Caution: U.S Federal law restricts this device to sale by or on the order of a dental professional

Article number/application: *SDS2.2_AP-Sxxx / SDS2.2_SS-X*

Materials:
- SDS2.2 standard implant post: TZP-A zirconium dioxide ceramics
- SDS2.2 standard PEEK screw: PEEK

⚠ All above mentioned products are provided non-sterile. They are disposable and must **not** be reused!

Indications for use: SDS2.2 standard implant posts and SDS2.2 standard screws are industrially manufactured prosthetic components. They are connected to the SDS2.2 dental implant and enable the fixation of prosthetic restorations.

Application:

Installation of SDS2.2 implant post after healing:
- Detach SDS2.2 cover screw (*SDS2.2_VS-P*).
- Thoroughly clean inner geometry of SDS2.2 implant with alcohol and dry.
- Choose one of the SDS2.2 standard implant posts (*SDS2.2_AP-Sxxx)* and try-in to verify size and optimal positioning.
- Mark this identified position in order to retrieve during screw retaining/ cementation of implant post.
- Attach the accessory screwdriver (*SDS-SD-ST/SDS-SD_short-ST*) to the SDS2.2 standard screw (*SDS2.2_SS-X*) to insert the screw into implant post.
- Thoroughly clean lower part of standard implant post with alcohol and dry. No additional treatment for surface conditioning may be used.
- Thoroughly dry the inner geometry of SDS2.2 implant and apply cement to inner geometry.
- SDS recommends cementation with *Ketac™Cem Automix* (observe IFU and user manual of the manufacturer).
- Insert SDS2.2 standard implant post and hand tighten (max. 5 Ncm) SDS2.2 standard screw to ensure implant post is fixed at final position during cementation.
- Remove SDS2.2 standard screw before cement is completely cured.
- Remove excess cement after hardening.
- Close screw channel with e.g. composite.

Additional information for the use of SDS2.2 standard implant posts and SDS2.2 standard screws:
- SDS2.2 dental implant system is particularly suitable for patients with an intolerance to metal and associated chronic diseases.
- SDS2.2 standard implant posts are attached to SDS2.2 implants by cementation to enable the cementation of prosthetic restorations.
- SDS2.2 straight standard implant posts may be used in standard situations to fix single crowns or bridges by cementation.
- SDS2.2 angulated standard implant posts may be used in situations with implant axis divergence to fix single crowns or bridges by cementation.
- SDS2.2 standard PEEK screw is the standard device for mandatory fixation of SDS2.2 implant posts during cementation.

Contraindications:
- The lower part of the standard implant post which fits into the inner geometry of SDS2.2 implants must not be manipulated /prepared/ sandblasted/ etched.
- SDS2.2 standard implant posts must not be grinded.

⚠ **Warnings:** SDS2.2 standard implant posts and SDS2.2 standard screws must be secured against aspiration in intraoral use.

MRI safety information: SDS 2.2 standard implant posts and -standard screws have not been evaluated for safety and compatibility in the Magnetic Resonance (MR) environment. They have not been tested for heating, migration, or image artifact in the MR environment. The safety of the SDS2.2 dental implant system in the MR environment is unknown. Scanning a patient who has this device may result in injury.

Storage and handling: The products are provided non-sterile. They must be stored in their original packaging in clean environment under conditions stated on the label. They must be protected against external influences like impact, shock and falling when transported in the facility.

Cleaning/ disinfection/ sterilization: SDS 2.2 standard implant posts and -standard screws are provided non-sterile and are intended for single use; they must not be reused! Before use they must be cleaned, disinfected and sterilized.

As part of your responsibility for the sterility of the products in application, please observe the following:
- in general, use only adequately validated methods specific to the equipment and product for cleaning/ disinfection and sterilization
- use only thermal disinfection that requires no disinfecting agent. There is a risk of disinfectant residues on the products when chemical disinfection is used
- regularly check and service the equipment used (thermal disinfector, sterilizer)
- observe the validated parameters in each cycle

SDS recommend according to the recommendation of the Robert-Koch Institut the mechanical cleaning and disinfection by a standard automatic cleaning program in a washer/-disinfector with proven efficacy (CE marking, compliant with ISO 15883-1 und ISO 15883-2 in Europe or ANSI/ AAMI ST 15883-1/ AAMI TIR30 in the U.S.) using a proven program for thermal disinfection (A_0 value > 3.000 or – for older devices – at least 5 minutes at 90 °C/ 194 °F) which is suitable for the prosthetic components and includes sufficient rinsing cycles with deionized water with a low bacterial- (max. 10 bacteria/ ml) and low endotoxin count (max. 0.25 endotoxin units/ ml).

Mechanical cleaning and disinfection
1. Place products in the washer/ disinfector using a small parts basket in such a way that the products are directly hit by the spray jet and don´t come in contact to each other.
2. Put chemical detergent into the washer/ disinfector, following the instructions of the manufacturer of the washer/ disinfector.
3. Start the automatic cleaning program including thermal disinfection. (see **general note** below for details of the program used for validation).
4. After program end remove products from the washer/ disinfector and dry if necessary (preferably with filtered compressed air as recommended by the RKI).
5. Visual examination to ensure that the products are clean, undamaged and not corroded. In case of residual contamination after mechanical reprocessing, repeat the cleaning and disinfecting process until no visible contamination is left. In case of damage or corrosion, remove products from use.

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Sterilization in the autoclave: All non-sterile packed products must not be sterilized in the original packaging!

Packaging:

1. Pack products which have been cleaned, disinfected and inspected promptly for sterilization.
2. Use prefabricated sterile barrier system according to the requirements of ISO 11607-1/ ANSI/ AAMI ISO 11607-1 (disposable sterilization packaging with CE marking in Europe or FDA clearance in the U.S)
3. Ensure that the sterilization packaging is suitable for steam sterilization (constant temperature of at least 141°C/ 286°F, sufficient vapor permeability) and that the products are adequately protected against mechanical damage.
4. When sealing the products in the foil, make sure that the packaging is large enough to ensure that there is no pressure on the seal.

Sterilization:

For this procedure, the following instructions have to be observed: Steam sterilization using validated fractionated vacuum processes according to ISO 17665-1/ ANSI/ AAMI ISO 17665-1/ ANSI/ AAMI/ ST79 in a device that complies with the provisions of DIN EN 13060 or EN 285 in Europe or have FDA clearance in the U.S.

- Fractionated pre-vacuum (type B)
- Sterilization temperature: EU: 134 °C (273 °F) / U.S.: 132 °C (270 °F)
- Hold time: at least 4 minutes (full cycle)
- Drying time: at least 20 minutes

In order to prevent staining and corrosion, the steam must be free of particles. The recommended limits for particle contents in feed water and condensed steam are defined by the standard DIN EN 13060. Make sure not to exceed the maximum capacity of the sterilizer when sterilizing several products.

Follow the instructions of the device manufacturer. The products have to be checked for superficial damages after sterilization.

The operator of medical products is responsible for making sure that cleaning, disinfection and sterilization processes are carried out by qualified personnel, using the appropriate materials and suited equipment.

For the U.S: the validated procedures require the use of FDA-cleared sterilizers, sterilization trays, sterilization wraps, biological indicators, chemical indicators and other sterilization accessories labeled for the sterilization cycle recommended. The health care facility should monitor the sterilizer according to an FDA recognized sterility assurance standard such as ANSI/ AAMI ST79:2017. Products must be sterilized.

General note: The proof of general suitability for effective mechanical cleaning and disinfection and sterilization was provided by an independent accredited testing laboratory taking into account the above-described procedure.

In detail, the validated cleaning and disinfecting process uses the thermal disinfector (cleaning and disinfecting device) G 7835 CD (Miele & Cie. GmbH & Co., Gütersloh) and neodisher® MediClean forte (0.5 %) as the cleaning agent (Dr. Weigert GmbH & Co. KG, Hamburg) with parameters described below:

- 60 seconds pre-rinse (cold water of potable quality)
- 180 seconds pre-rinse (cold water of potable quality)
- 600 seconds clean (55 °C/ 131 °F water of potable quality and cleaner neodisher® MediClean forte (0.5%) (Dr. Weigert GmbH & Co. KG, Hamburg)
- 180 seconds rinse (cold deionized water)
- 300 seconds thermal disinfection (A_0 value > 3.000 or minimum 90 °C/ 194 °F)
- 30 minutes drying (min. 100 °C/ 212 °F)

The validated sterilization process refers to the universal program of the Tuttnauer company in the autoclave Tuttnauer EHS 3870 (fractionated vacuum process with 3 pre-vacuum phases, half-cycle hold time (132 °C/ 270 °F), drying time at least 20 minutes). The procedure described above was taken into account.

Disposal: Adhere to the general requirements for the disposal of medical devices when disposing of SDS products or packaging material.

Warranty: The SDS product may only be used according to the manufacturer's instructions. The operator is responsible for ensuring that the product is used for its intended purpose and must also assess whether the product is suited to the patient's particular situation. The products may only be used together with SDS products. The SDS warranty is invalidated by the use of third-party products that are not approved by SDS.
Liability will not be accepted for products that have been modified, misused or fitted incorrectly.

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ICONS:

REF	CATALOG NUMBER
LOT	BATCH CODE
	CONSULT INSTRUCTIONS FOR USE
	CAUTION, CONSULT ACCOMPANYING DOCUMENTS
	DO NOT REUSE
	NON-STERILE

	KEEP AWAY FROM SUNLIGHT
	KEEP DRY
Rx only	CAUTION: U.S FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A DENTAL PROFESSIONAL
CE 0483	EUROPEAN CONFORMITY
	MANUFACTURER
	DATE OF MANUFACTURE

For technical support and further information please contact:

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