SDS SWISS DENTAL SOLUTIONS

NON STERILE CE 0483

Instructions for the use of SDS 1.2 healing caps/ -temporary caps/ -standard screws

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

Article number/application: SDS1.2_HC-disc-xxx/ SDS1.2_PC_x.x-P/ SDS1.2_SS-T

Materials:

- SDS1.2 healing cap-disc xxx: TZP-A zirconium dioxide ceramics
- SDS1.2 x.x mm temporary cap: PEEK
- SDS1.2 standard titanium screw: Titanium

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

Indications for use: SDS1.2 healing caps-disc, SDS1.2 temporary caps and SDS1.2 standard screws are industrially manufactured prosthetic components. They are connected to the SDS1.2 dental implant and enable the production/ fixation of long-term temporary restorations or protect the implant during the healing phase for up to 180 days.

Application:

- Clean and dry abutment and internal thread of SDS1.2 implant before installing SDS1.2 healing cap-disc or SDS1.2 temporary cap.
- Try-in SDS1.2 healing cap-disc or SDS1.2 temporary cap.
- Fix SDS1.2 healing caps-disc by screw retaining with SDS1.2 standard titanium screw (*SDS1.2_SS-T*) using the accessory screwdriver (*SDS-SD-ST/SDS-SD_short-ST*) and accessory SDS torque ratchet (*SDSStwHAD*).
- Fix SDS1.2 temporary caps by cementing or clicking on the implant or by screw retaining with SDS1.2 standard titanium screw (*SDS1.2_SS-T*) using the accessory screwdriver (*SDS-SD-ST/SDS-SD_short-ST*) and accessory SDS torque ratchet (*SDSStwHAD*).
- Max. torque of 10 Ncm is recommended for SDS1.2 standard screw.

Additional information for the use of SDS1.2 healing caps-disc, SDS1.2 temporary caps and SDS1.2 standard screws:

- SDS1.2 dental implant system is particularly suitable for patients with an intolerance to metal and associated chronic diseases.
- SDS1.2 healing caps-disc may be used to protect dental implant during the healing phase for up to 180 days if interdental gap provides sufficient space.
- SDS1.2 temporary caps may be used as basis for production of a temporary prosthetic restorations for up to 180 days. They allow perfect fit of temporary restoration to implant abutment and screw retaining.
- SDS1.2 standard screw is the standard device for screw retaining of SDS1.2 healing caps-disc/ optional device for screw retaining of SDS1.2 temporary caps.

Contraindications:

- SDS1.2 healing caps-disc and SDS1.2 temporary caps may not be used after grinding of SDS1.2 dental implant shoulder.

⚠ **Warnings:**

- SDS1.2 healing cap-disc, SDS1.2 temporary cap and SDS1.2 standard screw must be secured against aspiration in intraoral use.

⚠ **Caution:**

- SDS 1.2 healing caps-disc/ -temporary caps and -standard screws have not been evaluated for safety and compatibility in the Magnetic Resonance (MR) environment. They have not been tested for heating or migration in the MR environment.

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: 1.2 healing caps-disc/ -temporary caps 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 EN ISO 15883-2 in Europe or AAMI TIR30:2011 (R) 2016 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 Vario TD 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 (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.

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 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.

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Sterilization:

For this procedure, the following instructions have to be observed: Steam sterilization using validated fractionated vacuum processes according to ISO 17665 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. Maximum sterilization temperature may not exceed 138°C (280°F); plus tolerance according to DIN EN ISO 17665.

- 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/ AAMI TIR12:2010. 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 implants, the packaging material and any accessories.

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.

ICONS:

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

For technical support and further information please contact:

SDS SWISS DENTAL SOLUTIONS AG • Konstanzerstrasse 11 • CH-8280 Kreuzlingen