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!

Intended use:

- SDS1.2 healing caps-disc can be used to protect the implant during the healing phase up to 180 days.
- SDS1.2 temporary caps can be used as basis for production of a temporary prosthetic restoration and are allowed to stay for a maximum of 180 days in situ. They support the connection between the implant and provisional prosthetic reconstructions.
- SDS1.2 standard screws can be used for screw-retaining of SDS1.2 healing caps-disc or SDS1.2 temporary caps to the SDS1.2 implants.

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.

Indications:

- 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 if interdental gap provides sufficient space.
- SDS1.2 temporary caps may be used as basis for temporary restorations to 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 and an 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 2.2 implant posts/ healing caps-disc/ 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:**

SDS 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 sterilised according to the following instructions:

⚠ 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 acc. ISO 15883-2.

Mechanical cleaning and disinfection

1. Place products in the washer/ disinfector in such a way that the products are directly hit by the spray jet.
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. Thermal disinfection takes place allowing for the A_0 value and observing national provisions (EN ISO 15883).
4. On completion of the cycle remove products from the washer/ disinfector and dry (preferably with compressed air as recommended by the Robert-Koch Institute).
5. Visual examination to ensure that the products are clean and undamaged. In case of residual contamination after mechanical reprocessing, repeat the cleaning and disinfecting process until no visible contamination is left.

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Manual cleaning and disinfection (alternative)

1. Place the products into the ultrasonic bath filled with detergent/ disinfectant (closed lid).
2. During chemical disinfection in the ultrasonic bath, observe the instruction of the manufacturer regarding concentration and immersion time. Be sure to observe the full correct immersion time which does not start until the last product has been placed into the bath.
3. On completion of the immersion time, rinse products thoroughly with suitable water (preferably with demineralised water).
4. Dry products (preferably with compressed air as recommended by the Robert-Koch Institute).
5. Visual examination to ensure that the products are clean and undamaged. In case of residual contamination, repeat the cleaning and disinfecting process until no visible contamination is left.

Sterilisation in the autoclave

All products are suitable for sterilisation. 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. The system components can be steam sterilised using a vacuum process at 134°C in a device according to DIN EN 13060. For this procedure, the following instructions have to be observed: Steam sterilisation using a vacuum process at 134°C in a device that complies with the provisions of DIN EN 13060; with validated processes. Maximum sterilization temperature may not exceed 138°C (280°F); plus tolerance according to DIN EN ISO 17665.

- Fractionated pre-vacuum (type B)
- Sterilisation temperature: EU: 134°C (273°F) / US: 132°C (270°F)
- Hold time: at least 5 minutes (full cycle)
- Drying time: at least 10 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 sterilisation.

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.

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:

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