



Instructions for the use of SDS 2.2 implant posts/ healing caps-disc/ standard 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_HC-disc-xxx/ SDS2.2_SS-X*

Materials:

- SDS2.2 standard implant post: TZP-A zirconium dioxide ceramics
- SDS2.2 healing cap-disc xxx: TZP-A zirconium dioxide ceramics
- SDS2.2 standard titanium screw: Titanium
- SDS2.2 standard PEEK screw: PEEK



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

Intended use:

- SDS2.2 standard implant posts are attached to SDS2.2 implants by cementation to enable the cementation of prosthetic restorations.
- SDS2.2 healing cap-discs can be used optionally to protect the implant during the healing phase up to 180 days.
- SDS2.2 standard screws are used for screw-retaining of SDS2.2 standard implant posts to ensure implant post is fixed at final position during cementation.
- SDS2.2 standard titanium screw is used for screw-retaining of healing cap-disc to the SDS2.2 implants without additional cementation and for screw-retaining of SDS2.2 standard implant posts to ensure implant post is fixed at final position during cementation.

Application:

Optional use of SDS2.2 healing cap-disc after surgery:

- Clean inner geometry of SDS2.2 implant.
- Choose SDS2.2 healing cap-disc (*SDS2.2_HC-disc-xxx*) and try-in to verify size and optimal positioning.
- For fixation of healing cap-disc use accessory screwdriver (*SDS-SD-ST/SDS-SD_short-ST*) to screw-in SDS2.2 standard titanium screw (*SDS2.2_SS-T*).
- Use accessory torque ratchet (*SDSStwHAD*) to apply a max. torque of 10 Ncm to SDS2.2 standard titanium screw.

Installation of SDS2.2 implant post after healing:

- Detach SDS2.2 cover screw (*SDS2.2_VS-P*) or optionally used SDS2.2 healing cap-disc.
- Thoroughly clean inner geometry of SDS2.2 implant with alcohol and dry.
- Choose one of the three 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.
- Choose one of the two SDS2.2 standard screws (*SDS2.2_SS-X*) and use the accessory screwdriver (*SDS-SD-ST/SDS-SD_short-ST*) to insert 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 *Panavia™ F 2.0*, *RelyX™ Luting Plus Automix* or *Ketac™ Cem Automix* (observe IFU and user manuals of the respective manufacturer).
- Insert SDS2.2 standard implant post and hand tighten SDS2.2 standard screw to ensure implant post is fixed at final position during cementation.
- Remove excess cement after hardening.
- Cover SDS2.2 standard screw head with some wax or gutta-percha and close screw channel with e.g. composite.
- Hand-tightening is recommended for SDS2.2 PEEK standard screws.
- Use accessory torque ratchet (*SDSStwHAD*) to apply a max. torque of 10 Ncm to SDS2.2 standard titanium screw.

Indications:

- 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_AB-S* standard implant post may be used in standard situations to fix single crowns or bridges by cementation.
- *SDS2.2_AB-S+1.5* standard implant post may be used in situations with larger gap to antagonists to fix single crowns or bridges by cementation.
- *SDS2.2_AB-S15°* standard implant post may be used in situations with implant axis divergence to fix single crowns or bridges by cementation.
- SDS2.2 healing caps-disc may be used optionally to protect dental implant if interdental gap provides sufficient space.
- SDS2.2 standard titanium- or PEEK screw is the standard device for mandatory fixation of SDS2.2 implant posts during cementation.
- For screw-retaining of SDS2.2 healing caps-disc the SDS2.2 standard titanium screw must be used.

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.
- SDS2.2 healing caps-disc must not be used after grinding of SDS2.2 dental implant shoulder.
- SDS2.2 healing caps-disc must not be cemented or used as basis for prosthetic restoration.
- SDS2.2 PEEK standard screw must not be used with SDS2.2 healing cap-disc.



Warnings:

- SDS2.2 standard implant posts, SDS2.2 healing cap-disc and SDS2.2 standard screws 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 standard implant posts, healing caps-disc 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 according to the following instructions:

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 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 A₀ 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.

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:

	CATALOG NUMBER
	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

For technical support and further information please contact:

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