SDS SWISS DENTAL SOLUTIONS

STERILE R CE 0483

Instructions for the use of SDS2.2 dental implants

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

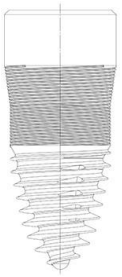
Article number/application: *SDS2.2_38xx-xx – SDS2.2_46xx-xx – SDS2.2_54xx-xx*

Scope of delivery/materials: Disposable set in sterile packaging, comprising
- SDS2.2 dental implant/TZP-A zirconium dioxide ceramics
- SDS insertion tool/surgical stainless steel
- SDS2.2 cover screw/PEEK

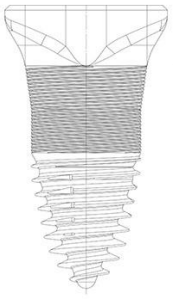
⚠ All products contained in this set are disposable and must **not** be reused!

Product description: SDS2.2 dental implants are an implant system to fit a synthetic root replacement into the human jaw for the fixation of prosthetic restorations. SDS2.2 implants are made of TZP-A (tetragonal zirconia poly-crystal) zirconium dioxide ceramics in accordance with ISO 13356 and are suitable for patients with an intolerance to metal. When delivered, the implants are mounted with the disposable SDS2.2_ITscrewST_single-use insertion tool which allows to remove the SDS2.2 dental implant from the sterile packaging without touching it and then insert it into the prepared drill hole.
The SDS2.2 dental implant system consists of the implant that is inserted into the jaw, a PEEK cover screw (*SDS2.2_VS-P*) to protect the implant-interface during healing and various zirconia standard implant posts (*SDS2.2_AP-Sxxx*) and PEEK- or titanium standard screws (*SDS2.2_SS-X*) to fix the standard implant posts during cementation or optionally used healing caps. After attachment, SDS2.2 standard implant posts enable cementation of prosthetic restorations.
The implants have a self-tapping Dynamic Thread® in the lower section of the implant for good primary stability. Its bone-condensing section has a 2.5x thread depth. The upper section of the implant has a micro-thread. The outer surface of the SDS2.2 implants is abrasive blasted for good osseointegration, the implant shoulder is machined. The implant - implant post - interface is fitted with an internal rounded hexagon as anti-rotation protection.
Drill holes are prepared by using accessory *SDS Instrument set implantology* following SDS drilling protocols (see separate IFU for *SDS instrument set implantology* and SDS2.2 drilling protocols).
The SDS2.2 implant interface can be protected during the healing phase up to 180 days by the delivered cover screw or alternatively by the SDS2.2 healing cap-disc (*SDS2.2_HC-disc-xxx*). Healing caps-disc can be fixed by screw retaining with SDS2.2 titanium standard screw (*SDS2.2_SS-T*).
SDS2.2 implants heal without any temporary restoration transgingivally or submerged. The healing phase should be 3 months in good and 6 months in cancellous bone quality.

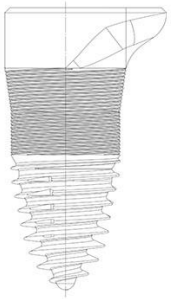
SDS2.2 implants are available with 3 different implant shoulder designs:



SDS2.2_xxxx
(standard shoulder)



SDS2.2_xxxx-ov
(oval shoulder)



SDS2.2_xxxx-ba
(balcony shoulder)

These different designs allow for insertion in interdental gaps of different dimensions. SDS2.2_xxxx-ba implants with balcony shoulder are particularly suitable for situations when the drill hole is not situated centrally between 2 neighboring teeth/implants. The final position of the balcony allows to improve the emergence profile of prosthetic restorations with cemented crowns and bridges. The same surgical technique is used for the 3 different implant shoulder designs.

Indications for use: SDS2.2 dental implants are intended as artificial replacements to be placed in the human upper or lower jaw to provide anchor points for the prosthetic restoration. They are indicated for transgingival healing.

Preparation: Intensive diagnostics of the oral cavity must be performed ahead of every implant procedure. It is necessary to take and assess appropriate X-rays (OPG/DVT/CT) to clarify anatomical structures. Expected physiological chewing forces and any parafunctional habits must be considered in selecting the implant.

Application: Use the attached disposable insertion tool to remove the SDS2.2 dental implants from the sterile packaging without touching them and then insert them into the prepared drill holes. They are inserted manually into the jaw bones, using the accessory torque ratchet (*SDSStwHAD*) or mechanically, using the accessory insertion adapter tool, ISO attachment (*SDS_ITISO-ST*). Do not apply more than 35 Ncm torque.
Remove the disposable insertion tool. Insert and hand-tighten the SDS2.2 cover screw by using the accessory SDS2.2 screw driver (*SDS-SD-ST/SDS-SD_short-ST*) or optionally attach SDS2.2 healing cap-disc with SDS2.2 titanium standard screw by using the SDS2.2 screw driver.
Remove cover screw or optional healing cap-disc after healing and attach SDS2.2 standard implant post (*SDS2.2_AB-X*) by cementation.
Screw retaining of SDS2.2 standard implant post during the cementation process with SDS2.2 standard PEEK- or -titanium screw (*SDS2.2_SS-X*) is mandatory.
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). See separate IFU for SDS2.2 standard implant posts/standard screws and user manual for cementation procedure.
After installation, SDS2.2 standard implant posts enable cementation of prosthetic restorations.
Standard surgical procedures must be applied. Incorrect surgical techniques can lead to functional failure of the implant and bone loss in the supporting bone structure or other side effects.

The product is intended for use by qualified dentists who have received extensive theoretical and practical instruction in the product and its application from SDS Swiss Dental Solutions. SDS products cannot be purchased without proof of the mandatory product training.

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The products may only be used in dental clinics and surgeries and therefore in appropriately clean and sterile environments.
The operator is responsible for selecting the implant after thorough diagnosis of the oral cavity and study of any X-ray images for the assessment of osseous structures (OPG/DVT/CT). Expected physiological chewing forces and any parafunctional habits must be taken into consideration when selecting the implant.

Combination with other products: The products are intended for exclusive use within the SDS system; combination with other implant systems is not indicated unless explicitly approved by SDS.

Additional information for the use of SDS2.2 dental implants:

- **Indicated for situations where implants are connected by interlocking or bridge restoration.**
- **SDS2.2 4.6 / 5.4 mm ∅ implants** are permitted as single-tooth implant for incisivi, cuspids, premolars and molars and as bridge post
- **SDS2.2 implants** must be inserted at tissue-level

Contraindications SDS2.2 implants: Existing medical conditions or poor general health can limit the possibility to insert dental implants surgically. Bruxism and insufficient bone quality/quantity requires specific measures to ensure treatment success. SDS implants are not suitable for applications in which the risk of excessive bending moments exists (e.g. extended crowns, extension bridges, bridges with more than one pontic unit).

- **SDS2.2 implants may not be used in bone-level position**
- **SDS2.2 3.8 mm ∅ implant may not be used in bridge restorations**
- **Implant diameter smaller than 4.6 mm for upper central incisors, cuspids, molar region and/or bridge restoration**
- Distance to neighboring tooth/implant too small to allow insertion of rotationally asymmetrical SDS2.2 balcony- of oval implant
- Bone not completely healed (residual ostitis/NICO)
- Serious and systemic health problems in patient
- Bruxism
- Untreated periodontitis, poor oral hygiene, untreated abscess or bone infection
- Crown-length greater than the osseointegrated threaded segment
- Cantilever bridges (mesial or distal)
- Pontic width between two bridge abutments bigger than one pre-molar width
- Connection of tooth with implant

The patient must be informed of risks, side-effects and complications, as well as of necessary precautions in connection with SDS2.2 dental implants. Anatomical and general health conditions can have a negative impact on dental implants.

Known risk factors:

- Poor bone quality
- Poor oral hygiene
- Diseases like blood disorders or untreated hormonal disorders
- Alcohol or drug abuse
- Stress during the healing phase

Side effects/possible adverse reactions:

- Pain, swelling, infection of soft- and hard tissue
- Dysaesthesia/paraesthesia
- No osseointegration
- Loss of osseointegration
- Bone defects necessitating bone grafting
- Perforation of the sinus, mandibular base, floor of the mouth or lower alveolar ducts
- Damage to neighbouring teeth/tooth roots
- Excessive bone loss, which might necessitate surgical intervention
- Aesthetic problems
- Fracture of the implant

⚠ **Warnings:**

- The operator is responsible for checking the package and implant for damage before use, as well as for the materially and technically correct handling of the implants. Do not use products if the primary packaging or packaging seal is damaged!
- It is prohibited to use products beyond their use-by date!
- If the implant is exposed to pressure beyond its capacity, excessive bone loss or fracture of the implant can occur.
- Our products must always be secured to prevent aspiration in case of intraoral use.
- Observe the operating instructions of the device manufacturer for laser applications.
- Appropriate hygienic measures must be observed when handling the implants. Contact with objects which could damage the implants must be avoided.

⚠ **Caution:**

- The SDS2.2 dental implant system has not been evaluated for safety and compatibility in the Magnetic Resonance (MR) environment. It has not been tested for heating or migration in the MR environment.

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Storage and handling: SDS implants are provided in sterile packaging and must be stored in original packaging under conditions stated on the label.
They must be protected against external influences like impact, shock and falling when transported in the facility. Do not use the implants if the inner package is moist, damaged or partially/fully open.

⚠ **Cleaning and disinfection:** SDS implants are provided in sterile packaging and are intended for single use; they must not be reused! For hygienic, technical and quality reasons, SDS implants must not be sterilised or disinfected either.

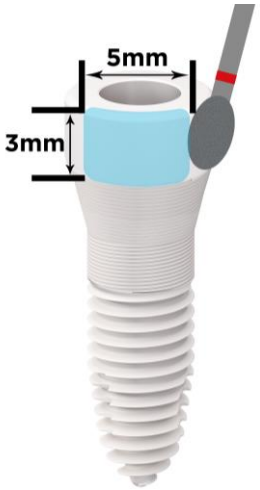
Disposal: Adhere to the general requirements for the disposal of medical devices when disposing of SDS implants, the packaging material and any accessories.

Additional information for grinding SDS2.2 implants:

- **Do not grind SDS2.2 3.8 mm ∅ implants**
- Only prepare SDS2.2 4.6 / 5.4 mm ∅ implants in the visible/aesthetic area of the implant shoulder to adjust them to the contours of the gingiva. In this regard, remove at most 0.5 mm material thickness and no more than 3 mm below the implant shoulder. Circumference of prepared area must not exceed 5 mm.

Adhere to the following preparation rules:

- Fine-grain diamond bur, granulation 46 µm (red-ring)
- Spray-jet cooling not less than 50 ml/min
- Observe the operation instructions of the diamond bur manufacturer for maximum speed (NB: pay attention to the transmission of your angle piece)
- Application pressure on the rotating instrument must not exceed 20 N.



⚠ **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. SDS implants may only be used together with SDS products or products which are authorized by SDS. 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
STERILE R	STERILISED USING IRRADIATION
	DO NOT REUSE
	CAUTION, CONSULT ACCOMPANYING DOCUMENTS
	KEEP DRY

Rx only	CAUTION: U.S FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A DENTAL PROFESSIONAL
	USE-BY DATE
59 °F/ 15 °C – 86 °F/ 30 °C	TEMPERATURE LIMITATION
CE 0483	EUROPEAN CONFORMITY
	KEEP AWAY FROM SUNLIGHT
	MANUFACTURER

For technical support and further information please contact:

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