SDS SWISS DENTAL SOLUTIONS

STERILE R CE 0483

Instructions for the use of SDS 1.2 dental implants

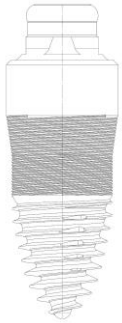
Article number/application: SDS1.2_33xx – SDS1.2_38xx-xx – SDS1.2_46xx-xx – SDS1.2_54xx-xx

Scope of delivery/materials: Disposable set in sterile packaging, comprising
- SDS1.2 dental implant/TZP-A zirconium dioxide ceramics
- SDS insertion tool/surgical stainless steel

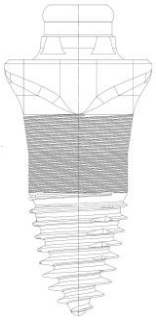
⚠ All of the products contained in this set are disposable and must **not** be reused!

Product description: SDS1.2 dental implants are an implant system to fit a synthetic root replacement into the human jaw; they consist of the implant that is inserted into the jaw. The implants are made of TZP-A (tetragonal zirconia poly-crystal) zirconium dioxide ceramics, in accordance with ISO 13356. The SDS1.2 dental implants are used to fix the prosthetic restoration and are suitable for patients with an intolerance to metal.
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 SDS1.2 implants is abrasive blasted for good osseointegration, the implant shoulder is machined. Drill holes are prepared by using SDS surgical instruments following SDS drilling protocols (see separate IFU for SDS surgical instruments and SDS1.2 drilling protocols).
Healing caps (SDS1.2_HC-disc-xxx) can be used to protect the implant during the healing phase up to 180 days. They can be fixed by screw retaining with SDS1.2 standard screw (SDS1.2_SS-T). SDS1.2 healing caps may not be used in combination with temporary caps.
SDS1.2 implants can heal without any temporary restoration or can be restored with a temporary restoration immediately, if achieved primary stability is adequate for appropriate functional loading. Temporary restorations can be produced either individually or by using a prefabricated temporary cap (SDS1.2_PC_x.x-P) as basis. The temporary cap can be fixed either by snap-on mechanism, temporary cementing or screw-retaining with SDS1.2 standard screw (SDS1.2_SS-T). Temporary caps are allowed to stay for a maximum period of 180 days in situ.
The healing phase should be 3 months in good and 6 months in cancellous bone quality.

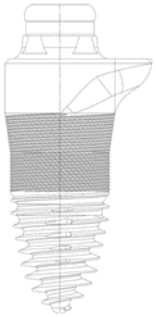
SDS1.2 implants are available with 3 different implant shoulder designs:



SDS1.2_xxxx
(standard shoulder)



SDS1.2_xxxx-ov
(oval shoulder)



SDS1.2_xxxx-ba
(balcony shoulder)

These different designs allow for insertion in interdental gaps of different dimensions or in asymmetrical implant positions and improve the emergence profile of prosthetic restorations with cemented crowns or bridges.

Intended use: SDS1.2 dental implant products are designed as artificial replacements for tooth roots in the human jaw; they are used as anchor points for the prosthetic restoration. They are suitable for oral endosseous implantation to rehabilitate edentulous or partially edentulous patients. They are inserted into artificially created drill holes in the maxillary or mandibular bone. SDS1.2 implants are suitable for one- and two stage surgical procedures and are indicated for transgingival healing. When delivered, the implants are mounted with the disposable SDS1.2_ITscrewST_single-use insertion tool which allows to remove the SDS1.2 dental implant from the sterile packaging without touching it and then insert it into the prepared drill hole.

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 SDS1.2 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 torque ratchet (SDSStwHAD) or mechanically using the insertion adapter tool, ISO attachment (SDS_ITISO-ST). Do not apply more than 35 Ncm torque. The implants osseointegrate transgingivally into the jaw bone.
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.
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.

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Service life: The product life is defined as 15 years. The product life is dependent on correct insertion of the implants, the implant setting and patient compliance.

Indications SDS1.2: SDS1.2 dental implants are particularly suitable for patients with an intolerance to metal and associated chronic diseases.

- **Indicated for situations where implants are connected by interlocking or bridge restoration, or with implant-supported full- or partial dentures**
- **SDS1.2 3.3 mm ∅ implant** is permitted exclusively as single-tooth implant for upper lateral- and lower incisivi for fixed prosthetic restorations
- **SDS1.2 3.8 mm ∅ implant** is permitted as **single-tooth implant** for upper lateral- and lower incisivi, as well as for premolars and interlocked implants
- **SDS1.2 4.6 / 5.4 mm ∅ implants** are permitted as **single-tooth implant** for incisivi, cuspids, premolars and molars and as bridge post

Contraindications SDS1.2 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).

1. **SDS1.2 3.3 mm ∅ implant may not be used for upper central incisivi, cuspids, premolars, molars and removable dentures**
2. **SDS1.2 3.3 mm ∅ and 3.8 mm ∅ implant may not be used in bridge restorations**
3. **SDS1.2 3.8 mm ∅ implant may not be used for upper central incisivi, cuspids and molars**
4. **Implant diameter smaller than 4.6 mm for upper central incisivi, cuspids, molar region and/or bridge restoration**
5. Bone not completely healed (residual ostitis/NICO)
6. Serious and systemic health problems in patient
7. Bruxism
8. Untreated periodontitis, untreated abscess or bone infection
9. Crown-length greater than the osseointegrated threaded segment
10. Cantilever bridges/extension crowns (mesial or distal)
11. Pontic width between two bridge abutments bigger than one pre-molar width
12. Connection of tooth with implant
13. Fewer than 4 implants per jaw for restorations with removable dentures
14. No reliable precautionary measures possible or patient fails to comply

The patient must be informed of risks, side-effects and complications, as well as of necessary precautions in connection with SDS1.2 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.

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.

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⚠ **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.

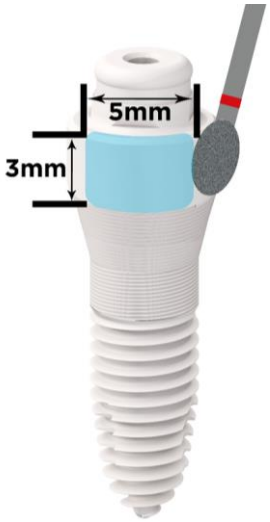
Disposal: Adhere to the general requirements for the disposal of medical devices when disposing of SDS implants, the packaging material and any accessories.

Additional information for grinding SDS1.2 implants:

- **Do not grind SDS1.2 3.3 mm ∅ implants**
- Only prepare SDS1.2 3.8/4.6/5.4 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	ORDER NUMBER
LOT	BATCH CODE
	ADHERE TO THE INSTRUCTIONS FOR USE
STERILE R	STERILISED BY RADIATION
	DO NOT REUSE
	ADHERE TO THE INSTRUCTIONS
	KEEP IN A DRY PLACE

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	STORAGE TEMPERATURE
CE 0483	CE MARK NB NUMBER 0483
	KEEP OUT OF DIRECT SUNLIGHT
	MANUFACTURER

For technical support and further information please contact:

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