Instructions for the use of SDS1.2 dental implants

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

Article number/application: 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/ T Zap-A zirconium dioxide ceramics
- SDS insertion tool/surgical stainless steel

⚠️ All products contained in this set are single use 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 T Zap-A (tetragonal zirconia poly-crystal) zirconium dioxide ceramic material that conforms with ISO 13356, Implants for surgery — Ceramic materials based on yttria-stabilized tetragonal zirconia (Y-TZP). The SDS1.2 dental implants are used to fix the prosthetic restoration and are suitable for patients with an intolerance to metal.

When delivered, the implants are mounted with the disposable SDS1.2 iTscrewST single-use insertion tool which allows removal of the SDS1.2 dental implant from the sterile packaging without touching it and then for insertion into the prepared drilled hole.

The implants have a self-tapping Dynamic Thread in the lower section of the implant for good primary stability. Its bone-contacting 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 have undergone surface roughening using abrasive blasting in order to insure good osseointegration, while the implant shoulder has been machined.

Drill holes are prepared by using accessory SDS Instrument set implantology following SDS drilling protocols (see separate IFU for SDS instrument set implantology and SDS1.2 drilling protocols). Please note that the Ø3.3 implant body measures at Ø3.25.

Healing caps-disc (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 retention with an SDS1.2 standard screw (SDS1.2_SS-T). SDS1.2 healing caps-disc 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-F) as a base. The temporary cap can be fixed by screw-retaining with SDS1.2 standard screw (SDS1.2_SS-T). Temporary caps can stay for a maximum period of 180 days in situ.

The healing phase should be 3 months in good bone quality and 6 months in cancellous bone quality.

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

- SDS1.2_xxxx (standard shoulder)
- SDS1.2_xxxx-ov (oval shoulder)

These different designs allow for insertion in interdental gaps of different dimensions. The same surgical technique is used for the 2 different implant shoulder designs.

Indications for use: SDS1.2 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. The implants are indicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading. SDS1.2_33xx implants are recommended as single-tooth implant for upper lateral and lower incisors for fixed prosthetic restorations only.

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 (SDStw) or mechanically using the insertion adapter tool, ISO attachment (SDS_ITISO-ST). Do not apply more than 35 N-cm 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.

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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 SDS1.2 dental implants:

- Indicated for situations where implants are connected by interlocking or bridge restoration
- SDS1.2_33xx is permitted exclusively as single-tooth implant for upper lateral and lower incisors for fixed prosthetic restorations
- SDS1.2_38xx is permitted as single-tooth implant for upper lateral and lower incisors, as well as for premolars and interlocked implants
- SDS1.2_4.6xx / SDS1.2_54xx are permitted as single-tooth implant for incisors, cuspsids, 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_33xx may not be used for upper central incisors, cuspsids, premolars, molars
2. SDS1.2_33xx / SDS1.2_3.8xx may not be used in bridge restorations
3. SDS1.2_38xx may not be used for upper central incisors, cuspsids and molars
4. Implant diameter smaller than 4.6 mm for upper central incisors, cuspsids, 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 abscesses 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. 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
- Dyaesthesia/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 neighboring 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.
- SDS 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.

MRI safety information:

- The SDS1.2 dental implant system has not been evaluated for safety and compatibility in the Magnetic Resonance (MR) environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the SDS1.2 dental implant system in the MR environment is unknown. Scanning a patient who has this device may result in injury.

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 sterilized 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:

- The SDS1.2 abutment must not be prepared before insertion of the implant.
- SDS recommends preparation of the SDS1.2 abutment if necessary, after final osseointegration of the implant before the impression taking procedure or after the implant has been inserted and the wound has been closed.
- Do not grind SDS1.2_33xx implants.
- Only prepare SDS1.2_38xx/ SDS1.2_46xx/ SDS1.2_54xx in the visible/ aesthetic area of the implant shoulder to adjust them to the contours of the gingiva. The outer diameter of the implant shoulder may be reduced by a maximum of 0.5 mm. The reduced circle segment must not exceed 5 mm and the reduction of the implant shoulder must not exceed 3 mm.

Adhere to the following preparation rules:

- Use single-use, sterile 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.

Fig.: maximum expansion of preparable area

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.

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For technical support and further information please contact:
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SDS1.2 Implant Removal Procedure

Attention: SDS1.2 sterile implant shall be removed immediately prior to implant placement. The sterile implant must be placed immediately after opening the blister and must not be placed or stored in the sterile field / surgical tray or elsewhere before implantation. Do not touch the implant. If the implant is touched it is non-sterile and must be discarded.

Fig. 1: non-sterile dental assistant opens SDS1.2 implant packaging in non-sterile area and removes the blister, clinician double-checks label to identify implant type.

Fig. 2: non-sterile dental assistant opens the sealed blister-lid without touching the sterile inner surface of blister or sealing edge.

Fig. 3: non-sterile dental assistant presents opened blister to the clinician without touching the sterile inner surface of blister or sealing edge.

Fig. 4: clinician (sterile) grips the sterile blister inlay (with the mounted implant) with thumb and index finger without touching the outer surface of the blister.

Fig. 5: clinician removes the blister inlay from the blister by first lifting the front part with the insertion tool and implant.

Fig. 6: clinician turns the side with the implant up.
**SDS1.2 sterile packaging and sterile implant removal**

**Attention:** SDS1.2 sterile implant shall be removed immediately prior to implant placement. The sterile implant must be placed immediately after opening the blister and must not be placed or stored in the sterile field / surgical tray or elsewhere before implantation. Do not touch the implant. If the implant is touched it is non-sterile and must be discarded.

![Fig. 7: clinician grips the insertion tool SDS1.2 single use with thumb and index finger of the other hand.](image1)

![Fig. 8: clinician removes the insertion tool SDS1.2 single use (with the assembled implant) from the inlay by simply rotating the implant downwards and thus removing it from the attachment clip without touching the inlay with the implant.](image2)

![Fig. 9: clinician removes the insertion tool SDS1.2 single use (with the assembled implant) from the inlay by simply rotating the implant downwards and thus removing it from the attachment clip without touching the inlay with the implant.](image3)

![Fig. 10: insertion tool SDS1.2 single use with assembled SDS1.2 implant ready for insertion into the drill-hole; SDS1.2 implant may not be modified by grinding before insertion into the drill hole and appropriate wound closure; adhere to SDS preparation rules.](image4)