EN

SDS SWISS DENTAL SOLUTIONS

STERILE R CE 0483

Instructions for use for SDS1.2 dental implants

Scope: Art.Nr. SDS1.2_33xx – SDS1.2_38xx(-xx) – SDS1.2_46xx(-xx)(_6x8) – SDS1.2_54xx(-xx)

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

Package content/materials:
Disposable set in sterile packaging containing
SDS1.2 dental implant/TZP-A zirconium oxid ceramics
SDS1.2 insertion tool/stainless steel

All product contained in this set are disposable and must not be reused!

Intended use:
SDS dental implants are designed to artificially replace the tooth root in the human jaw. They serve as an attachment point for prosthetic dentures. They are implantable products for permanent use. They are not suitable for reuse after a single application.
SDS Insertion Tools single-use are sterile single-use instruments delivered with the SDS Dental Implant for inserting the SDS Dental Implants into the jawbone. They can be operated manually or with the surgical contra-angle handpiece and are not suitable for reuse after single use.

Product description:
SDS1.2 dental implants are an implant system for providing the human jaw with artificial tooth root replacements. The implants are made of TZP-A (Tetragonal Zirconia Polycrystal) zirconia ceramic according to ISO 13356. The SDS1.2 dental implants serve as an attachment point for the prosthetic restoration and are also suitable for patients with metal intolerance.
The insertion tool single use SDS1.2_ITscrewST_single-use is already mounted on the implants. This enables both contact-free removal of the SDS1.2 dental implant from the sterile packaging and insertion into the prepared drill tunnel. Drill galleries are prepared with the SDS Implantology instrument set according to the SDS drill protocols (see separate instructions for use for SDS Implantology instrument set and SDS1.2 drill protocols). Please note, the real diameter of the Ø3.3 implant is 3.25 mm.
During the healing phase, SDS Healing Cap-disc (SDS1.2_HC-disc-xxx) can be used for up to 180 days to protect the implant. They are fixed by screwing with an SDS1.2 standard screw (SDS1.2_ SS-T). SDS1.2 Healing Cap-disc must not be used in conjunction with temporaries.
SDS1.2 implants can either heal without a temporary restoration or, if the primary stability achieved is adequate for the corresponding functional loading, be immediately restored with a temporary restoration. Temporary restorations can be fabricated either individually or using a prefabricated temporary cap (SDS1.2_PC_x.x-P) as a temporary base. Provisional Caps are fixed by screwing with an SDS1.2 standard screw (SDS1.2_SS-T) and may remain in situ for a maximum of 180 days. If the bone quality is good, a healing period of 3 months is recommended. If the bone quality is cancellous, a healing period of 6 months is recommended.

For products that are not included in the above scope of packaging, please refer to the separate instructions for use.

Product variants:
SDS1.2 implants are available with different implant shoulder designs. These different designs allow for insertion in interdental gaps of different dimensions. The same surgical technique is used for the different implant shoulder designs.

SDS1.2_xxxx standard shoulder

SDS1.2_xxxx-ov oval shoulder

SDS1.2_xxxx-ba balcony shoulder (*Not available in the US)

Indications for use:
SDS1.2 dental implants are intended as artificial replacements to be placed in the human upper and 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. The SDS1.2_33xx implants are recommended as single-tooth implant for upper lateral and lower incisors for fixed prosthetic restorations only.

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 as single-tooth implant for upper lateral and lower incisors for fixed prosthetic restorations only
- 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_46xx/ SDS1.2_54xx are permitted as single-tooth implant for incisors, cuspids, premolars and molars and for bridge restoration

Contraindications:
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).
- SDS1.2_33xx may not be used for upper central incisors, cuspids, premolars and molars
- SDS1.2_38xx may not be used for upper central incisors, cuspids and molars
- SDS1.2_33xx/ SDS1.2_38xx may not be used in bridge restorations
- Bone not completely healed (residual ostitis/ NICO)
- Serious and systemic health problems in patient
- Bruxism
- Untreated periodontitis, untreated abscess or bone infection
- Crown-length greater than the osseointegrated threaded segment
- Cantilever bridges/ extension crowns (mesial or distal)
- Pontic width between two bridge abutments bigger than one premolar width
- Connection of tooth with implant
- No reliable precautionary measures possible or patient fails to comply

The patient must be informed of risks, side-effects and possible complications as well as of necessary precautions in connection with SDS1.2 dental implants. Anatomical and general health conditions can have 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
- Nicotinabus
- 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 sinus, mandibular base, floor of the mouth or lower alveolar canal
- Damage to neighboring teeth/ tooth roots
- Excessive bone loss which might necessitate surgical intervention
- Aesthetic problems
- Fracture of implant

Serious incidents related to the product must be reported immediately to the manufacturer as well as to the competent national authority.

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 insertion tool single use 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_ITI- SO-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.

Intended users:
The products are 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.

Warnings:
- The operator is responsible for checking the sterile 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/ingestion 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.

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 5mm 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 (redring)
- 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 20N

Warranty:
The SDS product may only be used according to the manufacturers 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 patients particular situation. SDS implants may only be used in combination 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.

Symbols

REF	order number
LOT	LOT number
MD	medical device
	observe instructions for use
STERILE R	radiation sterilization
	single sterile barrier system
	not reusable
	do not re-sterilize
	do not use if package is damaged
	attention
	dry storage
Rx only	sale by or on the order of a dental professional only
	use-by date
	date of manufacture
	storage temperature
CE 0483	CE mark with number of notified body
	protect against sunlight
	manufacturer
EC REP	representative in the EC

Until the EUDAMED modules are fully available, the Summary of Safety and Clinical Performance report is available for viewing at www.swissdentalsolutions.com (subject to approval by the notified body).

Packaging removal of SDS1.2 dental implant:
SDS1.2 sterile dental implant shall be removed immediately prior to implant placement. The sterile dental 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 dental implant is touched it is non sterile and must be discarded.

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

Fig. 2: non-sterile dental assistant opens 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 dental 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 up the side with the implant

Fig. 7: clinician grips the insertion tool with thumb and index finger of the other hand

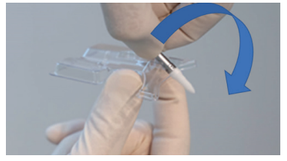

Fig. 8: clinician removes the insertion tool with the assembled dental implant from the inlay by simply rotating the implant downwards and thus removing it from the attachment clip without touching the inlay with the implant

Fig. 9: clinician removes the insertion tool with the assembled dental 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

Fig. 10: insertion tool with assembled dental implant ready for insertion into the drill-hole; SDS1.2 dental implant may not be modified by grinding before insertion into the drill hole and appropriate wound closure, adhere to SDS preparation rules

After inserting the dental implant, the SDS insertion tool remover is available to assist in detaching the insertion tool from the dental implant (see separate instructions for use „SDS insertion tool remover").

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