

MD Instructions for use for SDS Insertion tool reusable / Adapter insertion tool ISO attachment / screwdriver

Applies to: Item no. SDS1.2_ITscrew-ST/ SDS1.2_ITshort-screw-ST/ SDS2.2_ITscrew-ST/ SDS2.2_ITshort-screw-ST/ SDS ITISO-ST/ SDS-SD-ST/ SDS-SD short-ST

Contents of the package / material:

The products are supplied individually packed and are made of stainless steel.

The products are supplied in non-sterile condition. They must be cleaned, disinfected and sterilized before first use and each subsequent use. The SDS products must be secured against aspiration/swallowing when used intraorally.

Intended use:

SDS Insertion tools reusable are used to insert SDS dental implants and can be operated manually or with the surgical angle piece. They are intended for short-term use in the oral cavity and are reusable.

SDS Adapter insertion tool ISO attachments are used to connect SDS Insertion tools and SDS screwdrivers and can be operated with a surgical angle piece. They are intended for short-term use in the oral cavity and are reusable.

SDS screwdrivers are used to screw and unscrew SDS standard and cover screws, and can be operated manually or with the surgical angle piece. They are intended for short-term use in the oral cavity and are reusable.

Product versions:

see area of application

Indications for use:

SDS Insertion tools reusable and SDS Adapter insertion tool ISO attachments are used to insert SDS dental implants into the jawbone.

SDS screwdrivers are used to screw and unscrew SDS standard and cover screws.

Contraindications for use:

Patients must be informed of the risks, side effects, and complications, as well as necessary precautions associated with the use of these instruments.

Known risk factors:

- Danger to anatomical structures in the area of the intended procedure
- Overheating of the prepared bone
- Instrument breakage due to excessive force/mishandling by the user
- Aspiration or swallowing of the instrument

Side effects / possible adverse reactions

- Pain, swelling, infection of soft and hard tissue
- Dysesthesia / paresthesia
- No osseointegration
- Bone defects necessitating bone reconstruction
- Perforation of maxillary sinus, base of mandible, lingual shield, inferior alveolar canal
- Injury to adjacent teeth / roots of teeth
- Excessive bone loss requiring intervention
- Aesthetic problems

Preparation:

The instruments are supplied non-sterile and must be cleaned, disinfected and sterilized before first use and each subsequent use.



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First disinfection after use:

Immediately after use, the instruments must be immersed in a combined cleaning and disinfecting agent. This ensures user safety and prevents contaminants (blood, secretions, tissue residue) from drying on it.

The instruments must be disinfected with disinfectants and cleaning agents with a proven disinfecting effect (e.g., VAH/DGHM listed, CE marking and FDA-compliant), which are suitable for cleaning and disinfecting dental instruments and are compatible with the product materials.

The manufacturer's instructions for using the cleaning/disinfecting agents must be followed.

Pre-treatment after initial disinfection:

- SDS Insertion tools reusable must be dismantled before processing by unscrewing the fastening screw anti-clockwise.
- Use a brush with non-metallic bristles to remove any visible contamination under running water.
- Rinse all instruments completely for at least 1 minute with deionized water with a low germ count (max. 10 bacteria/ml) and a low endotoxin content (max. 25 endotoxin units/ml).
- The inner lumen of the SDS Insertion tools reusable must also be flushed through at least five times with deionized water using a syringe (at least 10 ml) in accordance with the above requirements.

Cleaning / disinfection / sterilization:

- It is important to use only cleaning/disinfection and sterilization methods that have been adequately tested for the device and product in question.
- Use thermal disinfection only, which requires no disinfectant.
- Regularly check and maintain the devices used.
- Observe the specified parameters for each processing cycle.

SDS recommends machine cleaning and disinfection with an automatic cleaning program in a CE-marked washer-disinfector.

Machine cleaning and disinfection:

- Place the products inside a basket for small parts in the washer-disinfector such that the products are directly in the path of the water spray and do not come into contact with each other.
- Put a chemical detergent into the washer-disinfector and follow the device manufacturer's instructions.
- Start the automatic cleaning program with thermal disinfection.
- Once the program has ended, remove the products from the washer-disinfector and dry them, if necessary with filtered compressed air.
- Perform a visual check to ensure that the products are clean and intact. If there is any residual dirt, the cleaning and disinfection process must be repeated until no visible contamination can be detected.
 Damaged products must not be used.

riangle The products to be sterilized must not be sterilized in the original packaging.

Packaging:

Package the products immediately after cleaning, disinfection and visual checking for sterilization.

Use CE-marked single-use sterilization packaging.

Make sure that the sterilization packaging is suitable for steam sterilization and that the products are adequately protected against mechanical damage.

When sealing the products in the foil, make sure that the packaging is large enough to prevent any pressure on the seal.



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Sterilization:

Steam sterilization should be done using the fractionated vacuum method in line with ISO 17665-1, in a DIN EN 13060-compliant or EN 285-compliant device.

- Fractionated pre-vacuum (type B)
- Sterilization temperature: 134°C
- Dwell time: at least 4 minutes (full cycle)
- Drying time: at least 20 minutes

To prevent discoloration, the steam must be free from particles. Make sure that the maximum capacity of the sterilizer is not exceeded when sterilizing multiple products.

Follow the device manufacturer's instructions.

After sterilization, the products must be checked for visible damage.

The user of the medical device is responsible for ensuring that cleaning, disinfection and sterilization processes are performed by qualified personnel with appropriate materials and suitable equipment.

Validated treatment process:

Cleaning:

"G 7835 CD" washer-disinfector (Miele & Cie. GmbH & Co., Gütersloh) neodisher® MediClean forte (0.5%) detergent (Dr. Weigert GmbH & Co. KG, Hamburg)

- Pre-rinse for 60 seconds (cold water of drinking water quality)
- Pre-rinse for 180 seconds (cold water of drinking water quality)
- Clean for 600 seconds (55°C/131°F, water of drinking water quality and the above detergent)
- Rinse for 180 seconds (cold, deionized water)
- Thermal disinfection for 300 seconds (A₀ > 3000 or at least 90°C/194°F)
- Dry for 30 minutes (at least 100°C/212°F)

Sterilization:

Tuttnauer EHS 3870 autoclave (Tuttnauer, Breda)

Universal program: Fractionated vacuum process with 3 pre-vacuum phases, half-cycle dwell time (132°C/270°F), minimum drying time 20 minutes

For United States: The validated procedures require the use of sterilizers, sterilization trays, sterilization wrap, biological indicators, chemical indicators, and other sterilization accessories that are FDA cleared for the recommended sterilization cycle. The user should monitor the sterilizer according to an FDA-recognized standard for sterilization assurance such as ANSI/AAMI ST79:2017. The instruments must be sterilized.

Use:

General instructions for different surgical techniques are described in the specialist literature. Before the surgical procedure, patients must be informed about the dos and don'ts and precautionary measures.

SDS Insertion tools reusable are fastened hand-tight to the implant using the fastening screw and the torque of the SDS Torque ratchet is transferred to the implant when the implant is inserted manually. The torque must not exceed 35 Ncm. SDS Insertion tools reusable can be detached from the implant after loosening the fastening screw. The insertion tool remover can be used to assist in loosening the fastening screw.

Adapter insertion tool ISO attachment can be attached to the SDS insertion tool to insert implants using a surgical angle piece. The torque must not exceed 35 Ncm, the screw insertion speed must not exceed 15 revolutions/minute.

SDS screwdrivers are used to screw and unscrew SDS2.2 Cover screws or SDS standard screws by hand or Torque ratchet. The torque for PEEK screws must not exceed 5 Ncm, for titanium screws 10 Ncm.

Please also note the information in the separate IFUs for SDS1.2/2.2 dental implants, SDS Torque ratchet, SDS standard and cover screw and the surgical angle piece used!



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Standard surgical procedures must be followed. Incorrect operation techniques can cause implant failure, loss of the supporting bone or other side effects.

Service life:

The service life of the products is significantly influenced by the intended and proper use and preparing the products. The instruments must be checked for damage and wear after each use and replaced, if necessary. Do not exceed the limit of 50 use-cycles.

Intended users:

The intended users are specialist personnel with dental training and who have received the necessary product and usage training from SDS Swiss Dental Solutions. SDS products cannot be obtained without proof of the necessary product training.

The products must only be used in dental clinics and practices under the stipulated environmental cleanliness and sterility conditions.

It is the user's responsibility to select the implant following an intensive examination of the oral cavity and an analysis of appropriate X-ray images to assess the bone structures (OPG/CBCT/CT). When selecting the implant, consideration must be given to both the expected physiological chewing force and any existing parafunctional habits.

Combination with other products:

The products are intended for use in the SDS system only. They are not intended for use with other implant systems, unless those systems are explicitly approved by SDS.



- It is the responsibility of the user to check that the products are not damaged before use and to ensure that they are used and handled correctly and competently. Worn or damaged instruments must be disposed of immediately and replaced with new instruments.
- If the instruments are subjected to a load greater than their functional capacity, this can lead to excessive bone loss or cause the instruments to break.
- If used intraorally, SDS products must always be secured against aspiration.
- For laser applications, the physician must follow the device manufacturer's instructions.
- When handling the instruments, the relevant aseptic regulations must be observed. The products must not come into contact with objects that could damage them.
- The instructions for use and handling contained in these instructions for use must be observed. The instruments may only be used for the specified purpose. Disregarding the application instructions can lead to injuries.
- The user is obligated to independently check the products for their suitability and usability for the intended application before using them. Damage due to contributory negligence on the part of the user leads to a reduction or exclusion of SDS's liability. This is particularly the case if the instructions for use or the safety instructions were not followed or if the user misuses the device.

Storage / handling:

Before first processing and use, the instruments should be stored in their original packaging in a clean, dry and dust-free environment at room temperature.

Processed products are preferably stored in the SDS surgical tray, otherwise in the sterile packaging according to the manufacturer's instructions. The instruments must be protected against external forces such as knocks, impacts and falling off while transporting within the facility.

Disposal:

For the disposal of the instruments and the packaging material, the general requirements for the disposal of medical devices must be observed.



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Warranty:

SDS products may only be used in accordance with the instructions provided by the manufacturer. The user is responsible for ensuring that the product is used as intended and must also verify whether the product is suitable for the situation of the individual patient. SDS implants must only be used with SDS products or products approved by SDS. Using products from third-party providers that are not approved by SDS will void the SDS guarantee. No liability is accepted for products that have been modified from their original form, misused or improperly handled or inserted.

Graphical symbols:

REF	Item number
LOT	Batch number
$\widehat{\mathbf{I}}$	Follow the instructions for use
NON STERILE	Non-sterile product
\triangle	Note
<u> </u>	Store in a dry place

茶	Protect from sunlight
Rx only	To be issued to authorized persons only
C € 0483	CE marking with number of notified body
\sim	Manufacturing date
	Manufacturer
EC REP	Authorized representative in the European Community

Technical support and additional product information can be obtained from:



SDS Swiss Dental Solutions AG Konstanzerstr. 11 CH-8280 Kreuzlingen info@swissdentalsolutions.com



SDS Deutschland GmbH Bücklestr. 5a D-78467 Konstanz