

  **Instructions for use for SDS2.1 Insertion tool**

Applies to: Art.Nr. SDS2.1 IT-ST

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**Contents of the package/material:**

SDS2.1 Insertion tool/ Rust-free stainless steel

SDS2.1 O-rings/ Silicon



SDS2.1 Insertion tools are reusable and are delivered in a non-sterile state. They must be cleaned, disinfected and sterilized before first use and each subsequent use.

SDS2.1 O-rings are consumables to be used with the SDS2.1 insertion tools, which cannot be reused after using once. They are supplied non-sterile and must be cleaned, disinfected and sterilized prior to their one-time use.

The SDS products must be secured against aspiration/swallowing when used intraorally.

**Intended use:**

SDS2.1 insertion tools are used to insert SDS2.1 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.

**Product description:**

SDS2.1 Insertion tools are instruments for the SDS2.1 dental implant system. They are used to insert the SDS2.1 dental implants into the prepared drill hole.

The SDS2.1 O-ring is required for the SDS2.1 insertion tool. The reusable SDS2.1 insertion tool must be fitted with a new O-ring before each use; the O-ring must be removed and disposed of after a single use.

**Indications for the use of the SDS2.1 dental implant system:**

SDS2.1 dental implants are used to anchor the prosthetic restoration. They are suitable for transgingival healing and can be fitted immediately if primary stability is good and the occlusal load is appropriate.

- Indicated for implants connected by a bridge or splint
- SDS2.1\_38xx is approved only as a single tooth implant for upper lateral and lower incisors, premolars and splinted implants
- SDS2.1\_46xx is approved as a single tooth implant for anterior teeth, canines, premolars and molars and for bridge fittings
- SDS2.1 dental implants must be inserted at the tissue level

**Contraindications to the use of the SDS2.1 dental implant system:**

Pre-existing conditions or poor general condition can limit the ability to insert implants surgically. Bruxism and insufficient bone quality/quantity require special measures to ensure treatment success. SDS dental implants are not suitable for indications where there is a risk of excessive flexural moment (bridges with more than one pontic, crowns/bridges with cantilevers).

- Implants with a small diameter and angled standard implant posts are not recommended for the posterior region
- SDS2.1 dental implants are not approved for bone-level positioning
- SDS2.1\_38xx are not approved for bridge fittings
- SDS2.1\_38xx are not approved for upper central incisors, canines, molars
- Bone not fully healed (residual osteitis/NICO)
- Severe general health conditions in the patient
- Bruxism
- Untreated periodontitis, untreated abscess or bone foci
- Crown length longer than osseointegrated thread section
- Cantilever bridges/crowns (mesial or distal)
- Pontic width between two abutments greater than the width of a premolar
- Connecting a natural tooth with an implant
- Safe protective measures not possible or lack of patient compliance

The patient must be informed of the risks, side effects and complications and the necessary precautions associated with SDS2.1 dental implants. Anatomic and general medical conditions can have a negative effect on the performance of dental implants.

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### Known risk factors:

- Poor bone quality
- Poor oral hygiene
- Diseases such as blood diseases or uncontrolled hormonal disorders
- Alcohol or drug abuse
- Loading during the healing phase

### Side effects/possible adverse reactions when using the SDS2.1 dental implant system:

- Pain, swelling, infection of soft and hard tissue
- Dysesthesia/paresthesia
- No osseointegration
- Loss of osseointegration
- Bone defects necessitating bone reconstruction
- Perforation of the sinus, base of the lower jaw, base of the mouth or inferior alveolar nerve
- Damage to adjoining teeth/dental roots
- Excessive bone loss that may require surgical intervention
- Esthetic problems
- Implant breakage

Any severe incidents associated with the product must be reported immediately to the manufacturer and the competent national authority.

### Preparation for use:

SDS2.1 insertion tools and SDS2.1 O-rings are delivered non-sterile and not pre-assembled and must be cleaned, disinfected and sterilized before assembly (see section "Cleaning/Disinfection/Sterilization").



After each use, the O-ring must be removed from the SDS2.1 insertion tool and disposed of. The SDS2.1 insertion tool must be subjected to the validated reprocessing procedure without the O-ring installed.

### First disinfection after use:

Immediately after use, the instrument 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:

After initial disinfection, the O-ring must be removed from the SDS2.1 insertion tool and disposed of. The instrument must be held under running water to remove contaminants if necessary with the help of a brush with metal-free bristles. Finally, the instruments must be rinsed for at least 1 minute with deionized water that is low in germs and endotoxins (max. 10 bacteria/ml / max. 0.25 endotoxin units/ml).

If there is still visible dirt, repeat the process.

### Cleaning/disinfection/sterilization:

- It is important to use only cleaning/disinfection and sterilization methods that have been adequately tested for the specific device and product.
- Use thermal disinfection only, which does not require a disinfectant.
- Regularly check and maintain the devices used.
- Observe the specified parameters for each treatment cycle.



SDS recommends mechanical cleaning and disinfection using an automatic cleaning program in an RDG (cleaner/disinfector) with CE marking/FDA conformity.

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**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.
- Feed a chemical detergent into the washer-disinfector and follow the device manufacturer's instructions.
- Start the automatic cleaning program, including 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.



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.

**Sterilization:**

Steam sterilization should be done using the fractionated vacuum method in line with ISO 17665-1, in a DIN EN 13060 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%) cleaning agent (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 cleaning agent)
- Rinse for 180 seconds (cold, deionized water)
- Thermal disinfection for 300 seconds ( $A_0 > 3000$  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

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### 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.

Once the preparation has been completed, the O-ring must be placed on the insertion tool in the recess provided (see fig.). SDS2.1 dental implants are inserted into the prepared drill hole using the SDS 2.1 insertion tool. The O-ring provides the necessary grip for the insertion tool in the dental implant when inserting it into the drill hole.

The SDS2.1 dental implant is inserted manually using the torque ratchet (SDStw) or using the adapter insertion tool ISO attachment (SDS\_ITISO-ST), with a maximum torque of 35 Ncm. The implants heal transgingivally in the jawbone.

Once the implant has been successfully inserted into the drill hole, remove the insertion tool by simply pulling it out.

### Fitting the O-ring on the SDS2.1 insertion tool:

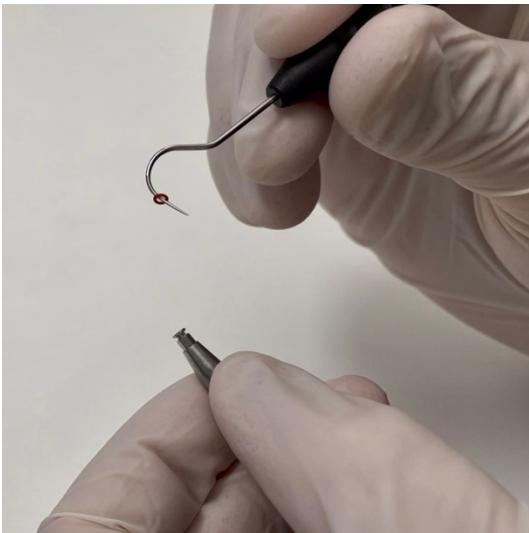


Fig. 1: Pick up the O-ring with a probe

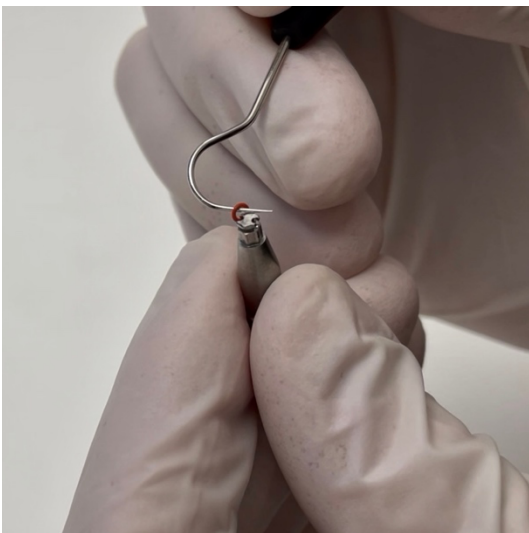


Fig. 2: Place the O-ring on the end of the insertion tool

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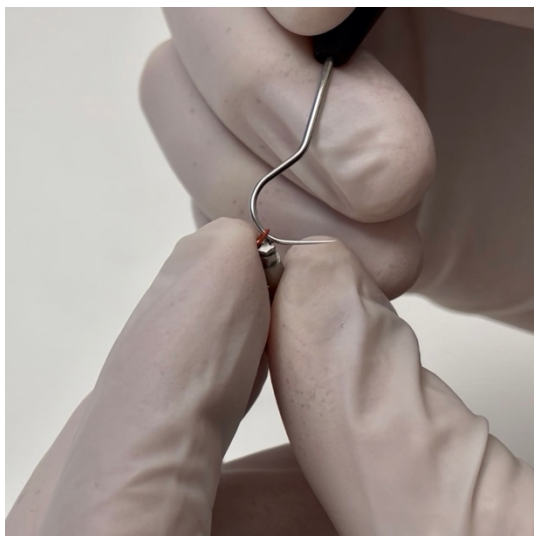


Fig. 3: Fix the O-ring using fingers

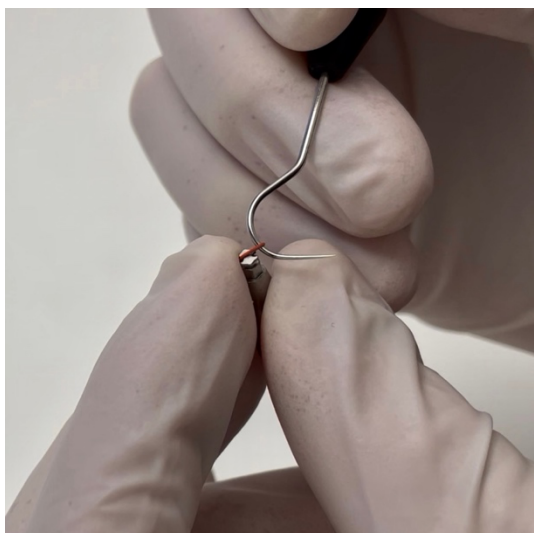


Fig. 4: Pulling the fixed O-ring onto the insertion tool

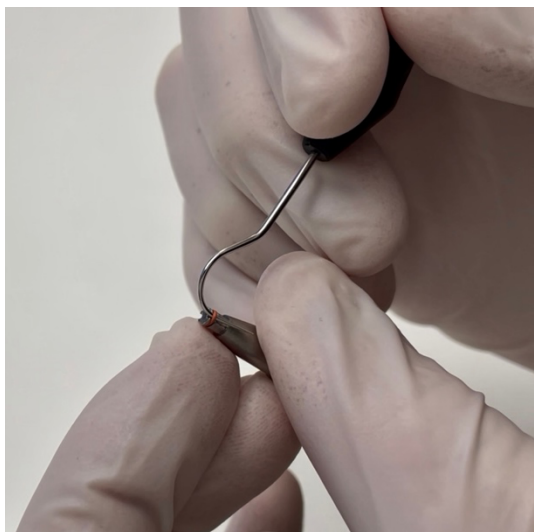


Fig. 5: Insert the O-ring in the final position in the recess provided on the insertion tool using the probe

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Fig. 6: Insertion tool with O-ring mounted

### Service life:

The service life of the SDS2.1 insertion tools is significantly influenced by the intended and proper use and preparation of the products. The SDS2.1 insertion tools must be checked for damage and wear after each use and replaced if necessary. Do not exceed the limit of 50 use-cycles.

The O-rings are consumables meant for one-time use only and must not be reused.

### Intended users:

The intended users are dental professionals who have received comprehensive theoretical and practical 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.

### Combination with other products:

The products are intended for use in the SDS2.1 dental implant system only. They are not intended for use with other implant systems unless those systems are explicitly approved by SDS.



### Warnings:

- 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.
- Products that are damaged must not be used! Worn or damaged instruments or system components must be disposed of immediately and replaced with new ones.
- The instructions for use must be observed. The instruments or system components must be used only for the specified purpose. Disregarding the safety instructions can result in injuries.
- The user is obligated to independently check the products for their suitability and usability for the intended purpose before using them. Damage due to contributory negligence on the part of the user leads to a reduction or complete exclusion of SDS's liability. This is particularly the case if the instructions for use or warnings were not followed or if the user accidentally misuses the device.
- If used intraorally, SDS products should generally be secured against aspiration.
- When using the products, the relevant aseptic regulations must be observed.

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### Storage/handling:

Before the first preparation, the products must be stored in a clean, dry and dust-free environment at room temperature.

Sterilized instruments must be stored according to the sterile packaging manufacturer's instructions, preferably in the SDS surgical box. While transporting internally, the instruments must be protected against external forces such as knocks, impacts and falling off.

### Disposal:

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







### 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.

SDS products may only be used only with products from SDS 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:

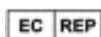
	Article number
	Batch number
	Follow the instructions for use
	Non-sterile product
	Note
	Store in a dry place

Rx only	To be supplied to authorized persons only
	Manufacturing date
CE 0483	CE marking with number of notified body
	Protect from sunlight
	Manufacturer
	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