

CE



# SDS Insertion tool remover — Instructions for use

Applies to: Item. No. SDS ITR

### Contents of the package / material:

SDS Insertion tool remover / stainless steel

The SDS Insertion tool remover is reusable and is delivered unsterilized. It 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:

The SDS Insertion tool remover is an aid for removing the insertion tool for SDS dental implants. It is intended for temporary use in the patient's oral cavity and is suitable for reuse.

### Product description:

The SDS Insertion tool remover is a means for loosening the screw connection of the SDS Insertion tool from the SDS dental implant after insertion into the patient's jaw.

SDS insertion tools are pre-assembled on the SDS dental implant with a torque of 10 Ncm and can be manually released. If necessary, the SDS Insertion tool remover can be used to loosen the screw connection.

## Indications for use:

The indications for the SDS Insertion tool remover are the same as those for the SDS dental implant system.

#### Contraindications for use:

The SDS Insertion tool remover must not be used if there is an intolerance to metal (surgical stainless steel).

#### Known risk factors:

The SDS Insertion tool remover must be secured against aspiration and swallowing during use.

### Side effects / possible adverse reactions:

None known

SDS Insertion tool removers are supplied non-sterile and must be cleaned, disinfected and sterilized before use.

#### 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.



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

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



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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%) 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 (A<sub>0</sub> > 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

### Use:

After the SDS dental implant has been inserted, the torque ratchet is set to the "IN" function on the insertion tool to fix it and prevent the dental implant from being unscrewed.

The SDS Insertion tool remover is then positioned on the hexagon of the socket screw and loosened by turning it to the left. The insertion tool can then be removed from the SDS dental implant with the socket screw loosened.

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Fig. 1: Attaching the torque ratchet with "IN" function



Fig. 2: Attaching the SDS Insertion tool remover



Fig. 3: Loosening the socket screw by turning it to the left



Fig. 4: Removing the insertion tool



Please also note the separate instructions for use for SDS1.2/ SDS2.2 dental implants!

#### 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.



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### 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.



# Warnings:

- It is the user's responsibility to ensure that the packaging and SDS Insertion tool remover are undamaged before use and are used and handled appropriately and correctly.
- If used intraorally, SDS products should generally be secured against aspiration.

#### Storage/handling:

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

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

#### Disposal:

For the disposal of the SDS Insertion tool remover and the packaging material, the general requirements for the 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 and must also verify whether the product is suitable for the situation of the individual patient. 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	Article number
LOT	Batch number
$\widehat{\mathbf{i}}$	Follow the instructions for use
NON	Non-sterile product
$\triangle$	Note
*	Store in a dry place

Rx only	To be issued to authorized persons only
~~ <b>\</b>	Manufacturing date
<b>C €</b> 0483	CE marking with number of notified body
类	Protect from sunlight
	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