



Applies to: Item no. BISS\_OPXX-i; BISS\_SS; BISS\_CSX; BISS\_TSX; BISS\_UMS; BISS\_CMS; BISS\_CD; BISS\_CDS; BISS\_PD; BISS\_HD; BISS\_SD(X); BISS\_USD(S); BISS\_TP; BISS\_HAM; BISS\_OST\_X; BISS\_ST(-X); BISS\_TT; BISS\_UCD

#### Material:

- Titanium alloy, titanium grade 23 acc. to ISO 5832-3
- Stainless steel acc. to DIN EN ISO 7153-1
- Aluminum
- PPSU
- PP

## Intended use:

The products in the BISS bone implant system are intended for stabilizing and fixing dental implants in the SDS dental implant system, and for fixing fractures in the cranio-maxillofacial area in the context of osteosynthesis. These are implantable products for long-term use.

## **Product description:**

The products in the BISS bone implant system are osteotome cages and bone screws for stabilizing and fixing SDS dental implants directly after they have been inserted in the jaw, and for fixing fractures in the cranio-maxillofacial area in the context of osteosynthesis, and also include the relevant accessories for the application.

The dimensions and materials of the products in the BISS bone implant system are designed to work with one another, which means that the products must not be used with components from other systems.

Osteotome cages and screws are intended for single use; they must not be reused after they have been inserted once. The accessories for the application can be reused within their specified service life (see "Service life"). The products are marketed in a non-sterile condition and the user must clean, disinfect and sterilize them prior to using them.

## Indications for use:

The products in the BISS bone implant system are intended for stabilizing and fixing two-part dental implants in the SDS dental implant system, and for fixing fractures in the cranio-maxillofacial area in the context of osteosynthesis. Using the products requires strict attention to be paid to the anatomical and biomechanical conditions, and known and standard surgical techniques to be adhered to precisely. The user must provide the patient with information on the loading limits before surgery and must determine a postoperative approach that is appropriate for the surgery in question.

## Contraindications for use:

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

### **Known risk factors:**

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

## Side effects/possible adverse reactions:

- Pain, swelling, infection of soft and hard tissue
- Dysesthesia/paresthesia
- Bone defects necessitating bone reconstruction
- · Perforation of the maxillary sinus, basis mandibulae, lower alveolar canal
- Injury to adjoining teeth/dental roots
- Excessive bone loss requiring intervention
- Esthetic problems





Applies to: Item no. BISS\_OPXX-i; BISS\_SS; BISS\_CSX; BISS\_TSX; BISS\_UMS; BISS\_CMS; BISS\_CD; BISS\_CDS; BISS\_PD; BISS\_HD; BISS\_SD(X); BISS\_USD(S); BISS\_TP; BISS\_HAM; BISS\_OST\_X; BISS\_ST(-X); BISS\_TT; BISS\_UCD

Implant breakage

All products in the BISS bone implant system are supplied non-sterile. Before being used for the first time, they must undergo initial processing as specified below (see "Cleaning/disinfection/sterilization").

After initial processing, the BISS components are placed in the specified positions on the BISS tray. Once the BISS tray has been used in surgery, <u>all</u> the components must be removed from the tray and undergo reprocessing. Reusable products that have already been used must undergo manual **pre-cleaning** before cleaning and disinfection:

- 1. The instruments must be disinfected with disinfectants and cleaning agents with a proven disinfecting effect (e.g., VAH/DGHM listed, with CE marking for the EU), which are suitable for cleaning and disinfecting dental instruments and are compatible with the product materials to be cleaned and disinfected. The manufacturer instructions for using these disinfectants and cleaning agents (such as the concentrations, exposure times and rinsing instructions) must be adhered to.
- 2. Any contaminants on the instruments/tray must be removed by using a brush with metal-free bristles while holding the instruments under running water.
- 3. The instruments/tray must be fully rinsed for at least 1 minute with deionized water that is low in germs (max. 10 bacteria/ml) and endotoxins (max. 0.25 endotoxin units/ml).

All the products on the tray must be cleaned, disinfected and sterilized, regardless of how they have been used.

## 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. Before cleaning/disinfection, the products must be removed from the packaging/storage tray. Suitable filter baskets can be used if necessary. Observe the device manufacturer's specifications.

## 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. SDS recommends using the relevant storage tray to sterilize the BISS products. Otherwise, the products must be packaged individually in single-use sterilization packages. In cases where the storage tray is being used, the BISS products are placed in the specified positions and the storage tray is packaged in single-use sterilization foil packaging. 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.





Applies to: Item no. BISS\_OPXX-i; BISS\_SS; BISS\_CSX; BISS\_TSX; BISS\_UMS; BISS\_CMS; BISS\_CD; BISS\_CDS; BISS\_PD; BISS\_HD; BISS\_SD(X); BISS\_USD(S); BISS\_TP; BISS\_HAM;

BISS\_OST\_X; BISS\_ST(-X); BISS\_TT; BISS\_UCD

### 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. The maximum temperature must not exceed 138°C.

- 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 (limit values according to DIN EN 13060). 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. Damaged products must not be used as they are at increased risk of breakage.

The user of the medical devices 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/disinfection:

"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

**For the USA:** The validated processes require the use of sterilizers, sterilization trays, sterilization packaging, biological indicators, chemical indicators and other sterilization accessories with FDA approval for the recommended sterilization cycle. The user should monitor the sterilizer in accordance with an FDA-recognized standard for sterilization safety, such as ANSI/AAMI ST79:2017. The instruments must be sterilized.

### Use:

The bone implants can be used when inserting SDS dental implants in order to stabilize and fix the dental implants in the specified positions.

For this purpose, an osteotome cage is placed on the implant collar and connected to the implant using a standard screw. Once the osteotome cage has been adjusted by bending its "arms", it is screwed onto the jawbone using the cortical screws. Osteotome cages remain in the patient's mouth until the dental implants have fully healed and must be removed before prosthetic fittings are installed.

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 defined as 180 days in situ. The service life depends on the implants being used correctly, the prevailing implantological conditions and the patient's compliance.

The manufacturer has defined the service life of the accessories as 10 reprocessing cycles. The number of reprocessing cycles has been validated on the basis of the specified processing procedure (see "Cleaning/disinfection/sterilization").





Applies to: Item no. BISS\_OPXX-i; BISS\_SS; BISS\_CSX; BISS\_TSX; BISS\_UMS; BISS\_CMS; BISS\_CD; BISS\_CDS; BISS\_PD; BISS\_HD; BISS\_SD(X); BISS\_USD(S); BISS\_TP; BISS\_HAM; BISS\_OST\_X; BISS\_ST(-X); BISS\_TT; BISS\_UCD

The user must check the product before each use and assess whether it can be reused. Damaged instruments must be removed from use and disposed of. Maintaining ideal storage conditions may extend the service life.

#### 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 product following an intensive examination of the oral cavity and an analysis of appropriate X-ray images to assess the bone structures (OPG/CBCT/CT).

# Combination with other products:

The BISS bone implant system contains various osteotome cages and screws, plus reusable instruments and storage trays as accessories. Components labeled "BISS" can be combined with one another; see the product description in each case for information on the combination process.

The products are intended for use in the SDS system only. They are not indicated 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 packaging is not damaged before initial processing and to ensure that it is used and handled correctly and competently.
- If used intraorally, SDS products should generally be secured against aspiration and swallowing.
- When handling the bone implants, the appropriate aseptic specifications must be observed. The bone
  implants must not be brought into contact with objects that could damage them.

### Storage/handling:

SDS AG recommends storing all BISS products in the BISS trays provided. The storage trays must be stored under the conditions specified on the label.

If storage in the BISS tray is not possible, the products must be stored in their original packaging according to the conditions specified on the label.

When transported internally, they must be protected against external influences such as shocks, impacts or falls.

### Disposal:

For the disposal of BISS 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 and must also verify whether the product is suitable for the situation of the individual patient. The BISS bone implant system may 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 Swiss Dental Solutions AG 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
$\bigcap_{\mathbf{i}}$	Follow the instructions for use

Rx only	To be issued to authorized persons only
Ω	Use by
<b>C</b> € 0483	CE marking with number of notified body





Applies to: Item no. BISS\_OPXX-i; BISS\_SS; BISS\_CSX; BISS\_TSX; BISS\_UMS; BISS\_CMS; BISS\_CD; BISS\_CDS; BISS\_PD; BISS\_HD; BISS\_SD(X); BISS\_USD(S); BISS\_TP; BISS\_HAM; BISS\_OST\_X; BISS\_ST(-X); BISS\_TT; BISS\_UCD

$\triangle$	Note
$\bigcirc$	Store in a dry place
59°F7 30°C	Temperature limit for storage
NON	Non-sterile product
8	Do not reuse

茶	Protect from sunlight
	Manufacturer
EC REP	Authorized representative in the European Community
MD	Medical device
$\sim$	Manufacturing date

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