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Instructions for Use

Shark Screw® coupling

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NON STERILE

CE 0483

Basic UDI-DI:	9120125220014E
Trade name:	Shark Screw® coupling
Part number:	C-08.00
Classification:	Class Ir
UMDNS:	13-517
EMDN:	L091001

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GENERAL INSTRUCTIONS
Knowledge of the contents of these Instructions for Use is required for proper and safe use of the Shark Screw® coupling. Users of the Shark Screw® coupling must have read and understood all points of these c.

Note:
surgebright GmbH expressly assumes no liability for damage or malfunctions resulting from failure to comply with the Instructions for Use

WARNING AND SAFETY INSTRUCTIONS
- Read these Instructions for Use carefully before use. Keep the Instructions for Use accessible to all users as well as the facility staff for the reprocessing unit for medical devices.
- The product is supplied in non-sterile form. Prepare the product **before each use** according to the information in the Instructions for Use.
- Perform a functional check before and after each use according to the information in the Instructions for Use.
- The instrument is designed only for use in combination with grafts and instruments provided by surgebright GmbH and its official distribution partners.
- The instrument is not designed for use in combination with active medical devices (e.g. drills).
- Store the product in a dry and clean place.
- Do not store the product next to hazardous substances.
- Screw in the screw in one go. Do not interrupt the screwing process.
- Do not continue to screw in the Shark Screw® allograft if resistance increases. Observe the depth marking on the instrument.
- Insert the Shark Screw® coupling completely onto the head of the Shark Screw® allograft.

Serious incidents in connection with the Shark Screw® coupling must be reported to surgebright GmbH, the local distributor and the local competent authority!

INTENDED USE
The Shark Screw® coupling is used in orthopedics and traumatology and is used to screw in Shark Screw® allografts with a claw coupling head. The product allows the allografts to be screwed in without complications.

COMBINATION WITH OTHER PRODUCTS
The medical device Shark Screw® coupling may only be used in combination with the handle with an AO coupling defined by surgebright GmbH and the Shark Screw® allograft with claw coupling head.

The **operating and technical information** enclosed with the Shark Screw® allograft must also be observed.

THE SHARK SCREW® COUPLING MUST NOT BE COMBINED WITH ACTIVE PRODUCTS.

INDICATIONS
The Shark Screw® coupling is intended for use in all clinically indicated applications of the Shark Screw® allograft with claw coupling head.

CONTRAINDICATIONS
The contraindications of the Shark Screw® coupling are the same as for the Shark Screw® allograft:

- Insufficient bone substance to anchor the Shark Screw® allograft.
- Use in a necrotic host site is contraindicated
- Insufficient bone quality or quantity
- When used in a poorly perfused or infected host site because of the poorer healing rate
- Circulatory disorders that slow down the healing process
- Acute or chronic infections
- Circumstances that prevent the patient from appropriately limiting their activities or following the doctor's instructions during the healing phase.
- Patients with bone diseases and bone formation disorders (e.g. osteoporosis) may not be suitable for the Shark Screw® allograft. Bone quality must be checked by the physician prior to surgery.

INTENDED PATIENT GROUP
The product may be used in all patients (female and male) except premature infants and babies.

INTENDED USER GROUP
The product may only be prepared by the surgical assistant or the operating physician.
It may only be used on humans by physicians with relevant training in orthopedics or traumatology.

USAGE ENVIRONMENT
The Shark Screw® coupling may only be used in designated premises (room of application group 2 – operating room) in a professional environment.

CONTACT WITH USER
Sterile clothing and gloves must be worn when handling the product. All handling steps must be carried out in the operating field or on the instrumentation table.

USE ON HUMANS
The product is intended for use on humans. The product is not to be used on the central circulatory system as well as on the central nervous system!

APPLICATION STEPS
The physician performing the surgery is responsible for the correct execution of the steps listed below:
1) Insert the instrument into the handle (observe the markings on the instruments).
2) Placement of the Shark Screw® allograft
3) Check that the Shark Screw® allograft is firmly tightened
4) Screw in the Shark Screw® allograft without stopping
5) Strict axial removal of the Shark Screw® coupling
6) Release the Shark Screw® coupling from the handle

SERVICE LIFE
The Shark Screw® coupling is a reusable surgical instrument. Its service life is limited by careless handling and material wear. Reprocessing has no influence on the service life. The service life of the product is unlimited as long as it is functional.

FUNCTIONAL CHECK
The instrument must be checked for any damage and for functionality immediately upon receipt and, as a rule, before use as well as during processing:

- **Damage or corrosion on the surface**
- **Bent or damaged shaft or claws**
- **Damage to the AO coupling**
- **Illegible labeling**

If any of the above defects occur, the instrument must be discarded.

DECOMMISSIONING AND DISPOSAL
The instrument can be sent to surgebright GmbH for disposal in sterile condition or disposed of by the user in compliance with the applicable disposal regulations. A message must be sent to surgebright for direct disposal.

RECOMMENDATIONS FOR HANDLING

Problem	Solution
Insertion depth must be determined under fluoroscopy and the Shark Screw® allograft cannot be inserted without interruption.	Use the depth marker on the instrument to determine the insertion depth during the insertion procedure.
Claw is broken off during insertion	Use the spare Shark Screw® coupling and report the incident to your local distributor.
Claw broke off during insertion because the resistance to insertion was too high.	Pre-drill the thread for the Shark Screw® allograft twice and then thoroughly flush the drill channel

REPROCESSING INSTRUCTIONS
General instructions

After receiving the product, check its identity and integrity before submitting it for processing. It is essential that all prerequisites and special information described in these instructions are met or taken into account. Otherwise, the product must not be used for clinical applications. Read the reprocessing instructions carefully. The operator is responsible for proper reprocessing without exception.

WARNINGS AND PRECAUTIONS
Keep the reprocessing instructions accessible to all personnel. The general warnings must be observed. The instrument must undergo a functional check before each processing. If the Shark Screw® coupling has been used on a patient with Creutzfeldt-Jakob disease (CJD) (confirmed CJD or suspected CJD), the instrument must not be reused and must be destroyed. Special care must be taken when handling a surgical instrument. Take special care during cleaning and sterilization. Only use tools which do not damage the instrument for manual cleaning. The operator must ensure that the Shark Screw® coupling is adequately cleaned and disinfected prior to steam sterilization. Inadequate cleaning/disinfection can lead to residual contamination.

INSTRUMENT PROCESSING
The Shark Screw® coupling must be cleaned, disinfected and sterilized prior to each use; this also applies to the initial use after delivery of the claw coupling. Effective cleaning and disinfection is an essential requirement for efficient sterilization. Please ensure already during use that you collect soiled instruments separately and do not place them back in the instrument tray, to avoid greater contamination of the loaded instrument tray. Clean/disinfect the reusable soiled claw coupling, then sort it back into the instrument tray and then sterilize the fully loaded and previously cleaned/disinfected instrument tray/packaged claw coupling. Please ensure that only device-specific and product-specific validated procedures are used for cleaning/disinfection and sterilization, that the devices used (WD, sterilizer) are regularly maintained and checked, and that the validated parameters are adhered to for each cycle. In addition, please observe the applicable legal regulations in your country as well as the hygiene regulations of the hospital. This especially applies to the different specifications regarding effective prion inactivation.

CLEANING AND DISINFECTION
A mechanical process using a washer-disinfector (WD) that meets the requirements of EN ISO 15883 should be used for cleaning and disinfecting the instrument.

PRETREATMENT
Coarse impurities must be removed from the Shark Screw® coupling immediately after use.
For this purpose, use running water or a disinfectant solution; the disinfectant should be aldehyde-free (to prevent the adhesion of blood contaminants), have a tested efficacy (CE marking), be suitable for instrument disinfection and be compatible with the Shark Screw® coupling (see chapter "Material durability").
Only use a soft brush or a clean soft cloth to manually remove contamination, but do not use metal brushes or steel wool. Check the claws to ensure that all residues have been removed.

WASHER-DISINFECTORS (WD)
When selecting the WD, make sure,
- that it has been tested for effectiveness (for example, in accordance with EN ISO 15883),
- that a tested program for thermal disinfection (at least 10 min at 93 °C or A0 value > 3000) is used (with chemical disinfection, there is a risk of disinfectant residues on the instruments),
- that the program used is suitable for the instruments,
- that suitable water is used for rinsing, and that the air used for drying is filtered and thus does not compromise the hygiene status at this point, and
- that the WD is regularly maintained and checked.

When selecting the cleaning agent system to be used, make sure
- that it is suitable for cleaning the Shark Screw® coupling,
- that – if thermal disinfection is not used – a suitable disinfectant with tested effectiveness (e.g. VAH/DGHM or FDA approval or CE marking) is also used and that this is compatible with the cleaning agent used and
- that the chemicals used are compatible with the Shark Screw® coupling (see material durability).

The concentrations of the cleaning agent and, if applicable, disinfectant specified by the manufacturer must be strictly adhered to.

1. Insert the Shark Screw® coupling into the WD. Make sure that the instruments do not come into contact with each other.
2. Start the program. (Pre-rinse: two minutes, clean: at 55°C for five minutes,

rinse: 3 minutes, disinfect: at 90°C for five minutes).

3. Remove the instrument from the WD at the end of the program.
4. Check and pack the Shark Screw® coupling as soon as possible after removal (see chapter "Functional check" and "Packaging", if necessary after additional drying in a clean place).

FUNCTIONAL CHECK

After cleaning or cleaning/disinfecting, inspect the Shark Screw® coupling for corrosion, damage, and contamination and replace any damaged Shark Screw® coupling. A Shark Screw® coupling that still has contamination must be cleaned and disinfected again.

PACKAGING

Sort the cleaned and disinfected Shark Screw® coupling into the sterilization tray provided by surgebright GmbH or use other suitable packaging that meets the following requirements:

- EN ISO 11607 and EN 868-2 to -10
- suitable for steam sterilization (temperature resistance up to at least 137 °C (279 °F), sufficient steam permeability)
- sufficient protection of the instruments or sterilization packaging against mechanical damage

STERILIZATION

Only the sterilization methods listed below may be used for sterilization; no other sterilization methods are permitted.

Steam sterilization:

- Fractionated vacuum process / pre-vacuum process or gravitation process (with sufficient product drying).
- steam sterilizer in accordance with EN 13060 or EN 285
- validated according to ISO 17665-1:2006
- maximum sterilization temperature 134 °C (plus tolerance in accordance with ISO 17665-1:2006)
- sterilization time (exposure time at sterilization temperature) min. 3 min at 134 °C

STORAGE

After sterilization, the instruments must be stored dry and dust-free in suitable packaging, such as the sterilization tray provided.

MATERIAL DURABILITY

When selecting cleaning and disinfecting agents, make sure that the following components are not included:

- organic, mineral and oxidizing acids
- strong alkalis (pH > 11 not permitted, mild alkaline cleaners recommended)
- organic solvents (alcohols, acetone, etc.), benzines
- halogenated hydrocarbons, chlorine, iodine
- ammonia

REUSABILITY

With proper care, and provided it is undamaged and fully functional, the Shark Screw® coupling can be processed and reused. Service life is limited by damage and normal wear. A damaged Shark Screw® coupling must be discarded after reprocessing.

RETURNS

Products may only be returned to surgebright GmbH after they have been disinfected/sterilized (STERILIZATION CERTIFICATE) and this is clearly visible. If no proof of cleaning/sterilization is enclosed, the instruments will be sent back.

CONFIRMATION

The above instructions for reprocessing in accordance with the ISO 17664 standard have been deemed suitable by an accredited inspection body. The product complies with the applicable European Union requirements in force. Where applicable, this is monitored by a notified body.

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