



Instructions for Use

Insertion Instruments



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Basic UDI-DI: 9120125220014E
 Trade name: Shark Screw® coupling
 Shark Screw® driver cut
 Shark Screw® driver acI
 Shark Screw® driver ht

All the products mentioned form a generic product group and are further summarized under *insertion instruments*.

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GENERAL INSTRUCTIONS

Knowledge of the contents of these Instructions for Use is required for proper and safe use of the *insertion instruments*. Users of the *insertion instruments* must have read and understood all points of these instructions.

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.
- *Insertion instruments* are supplied in non-sterile form. Prepare the devices **before each use** according to the information in the Instructions for Use. Always remove the packaging material before initial processing.
- Perform a functional check before and after each use according to the information in the Instructions for Use.
- The instruments are designed only for use in combination with grafts and instruments provided by surgebright GmbH and its official distribution partners.
- The instruments are not designed for use in combination with active medical devices (e.g. drills).

- Store the instruments in a dry and clean place.
- Do not store the instruments 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. If available, observe the depth marking on the instrument.
- Insert the head of the Shark Screw® allograft completely onto the *insertion instrument*.
- The use of a k-wire (max. diameter 1.2 mm) is recommended by surgebright GmbH as a guide for the insertion instrument Shark Screw® driver acI. This also minimizes the risk of the cannulation becoming blocked.

Serious incidents in connection with the *insertion instruments* must be reported to surgebright GmbH, the local distributor and the local competent authority!

INTENDED USE

Insertion instruments are used in orthopedics and traumatology and are used to screw in Shark Screw® allografts. The product allows the allografts to be screwed in without complications.

COMBINATION WITH OTHER PRODUCTS

If intended, *Insertion instruments* must be combined with a handle. Only the handle with AO coupling defined by surgebright GmbH may be used. Only Shark Screw® allografts may be screwed in with the *insertion instruments*.

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

INSERTION INSTRUMENTS MUST NOT BE COMBINED WITH ACTIVE PRODUCTS.

INDICATIONS

Insertion instruments are intended for use in all clinically indicated applications of the Shark Screw® allograft.

CONTRAINDICATIONS

The contraindications of the *insertion instruments* are the same as for the Shark Screw® allograft:

- 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.
- The placement of the Shark Screw® allograft must not interfere with the growth plate.

INTENDED PATIENT GROUP

Insertion instruments may be used in all patients (female and male) except premature infants and babies.

INTENDED USER GROUP

Insertion instruments may only be prepared by the surgical assistant or the operating physician. They may only be used on humans by physicians with relevant training in orthopedics or traumatology.

USAGE ENVIRONMENT

Insertion instruments 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 instruments. All handling steps must be carried out in the operating field or on the instrumentation table.

USE ON HUMANS

Insertion instruments are intended for use on humans. The instruments are 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) If intended, insert the instrument into the handle with AO coupling (observe the markings on the instruments).
- 2) Placement of the Shark Screw® allograft
- 3) Check that the Shark Screw® allograft is firmly tightened
- 4) If intended, placement of the insertion instrument on the previously placed K-wire (max. Ø 1.2 mm)
- 5) Screw in the Shark Screw® allograft without stopping
- 6) Strict axial removal of the insertion instrument
- 7) If applicable, release the insertion instrument from the handle with AO coupling

SERVICE LIFE

Insertion instruments are reusable surgical instruments. The service life is limited by careless handling and material wear. Reprocessing has no influence on the service life. The service life of the instruments is unlimited as long as it is functional.

FUNCTIONAL CHECK

Insertion instruments 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, if applicable**
- **Illegible labeling**

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

DECOMMISSIONING AND DISPOSAL

Insertion instruments can be sent to surgebright GmbH for disposal in sterile or

disinfected 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 (if available) on the instrument to determine the insertion depth during the insertion procedure.
Claw is broken off from the <i>insertion instrument</i> Shark Screw® coupling during insertion	Use the spare Shark Screw® coupling and report the incident to your local distributor.
<i>Insertion instrument</i> 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.
The <i>insertion instrument</i> Shark Screw® driver acI is used without a guide and is therefore more difficult to use.	The insertion instrument Shark Screw® driver acI should always be applied under the guidance of a correctly placed K-wire. This may have a maximum diameter of 1.2 mm.
The cannulation of the <i>insertion instrument</i> Shark Screw® driver acI is blocked. This is noted in the reprocessing unit for medical devices.	If a blockage is detected during preparation in the reprocessing unit for medical devices, it must be carefully removed using a thin rod of the appropriate length. If this is not possible, the instrument must be rejected.
An <i>insertion instrument</i> Shark Screw® driver acI which has a blocked cannulation after reprocessing has been provided to the operating theatre	The instrument must not be used due to the risk of infection or cross-contamination. The further recommended procedure is the same as if the product breaks off during use.

REPROCESSING INSTRUCTIONS

General instructions

After receiving the *insertion instruments*, check their identity and integrity before submitting them for processing. It is essential that all prerequisites and special information described in these instructions are met or taken into account. Otherwise, the products 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 *insertion instruments* must undergo a functional check before each processing. If the *insertion instruments* have been used on a patient with Creutzfeldt-Jakob disease (CJD) (confirmed CJD or suspected CJD), the instruments 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 instruments for manual cleaning. The operator must ensure that the *insertion instruments* are adequately cleaned and disinfected prior to steam sterilization. Inadequate cleaning/disinfection can lead to residual contamination.

INSTRUMENT PROCESSING

Insertion instruments must be cleaned, disinfected and sterilized prior to each use; this also applies to the initial use after delivery of the *insertion instruments*. 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 *insertion instruments*, then sort it back into the instrument tray and then sterilize the fully loaded and previously cleaned/disinfected instrument tray or the packaged *insertion instruments*. 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 *insertion instruments*.

PRETREATMENT

Coarse impurities must be removed from the *insertion instruments* 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 *insertion instruments* (see chapter "Material durability").
 Dr. Weigert neodisher Mediclean was used for validation.
 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 narrow points of the *insertion instruments* (e.g. gaps or cannulations) 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 *insertion instruments*,
- 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 *insertion instruments* (see material durability).

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

1. Insert the *insertion instrument* into the WD. Make sure that the instruments do not touch with each other. A washer-disinfector tray for minimally invasive procedures was used for the validation.
2. Start the program.
 - a. **Pre-rinsing:** With cold water (< 30 °C / < 86 °F) for at least 2 minutes
 - b. **Drain**
 - c. **Cleaning:** With a suitable cleaning agent (alkaline, concentration according to manufacturer's instructions, e.g., Dr. Weigert Neodisher MediClean 0.2%-1%, depending on the degree of contamination) at 55 °C/131 °F for at least 10 minutes
 - d. **Drain**
 - e. **Neutralization/rinsing:** two rinsing steps of one minute each with deionized water
 - f. **Disinfecting:** At 90 °C for five minutes (A₀ value > 3000)
 - g. **Drying:** At least 20 minutes at 100 °C

3. Remove the instrument from the WD at the end of the program.
4. If indicated, dry the *insertion instruments* manually using medical compressed air or lint-free swabs.
5. Check and pack the *insertion instruments* as soon as possible after removal (see section "Functional check" and "Packaging").

CHECKING

Check the *insertion instruments* after cleaning or cleaning/disinfection according to the section "Functional check".

PACKAGING

Sort the cleaned and disinfected *insertion instruments* 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 steam sterilization may be used for sterilization; other sterilization methods are not permitted.

The steam sterilizer used must comply with EN 13060/ANSI/AAMI ST55 or EN 285 and the steam sterilization must be validated in accordance with ISO 17665-1. Other national requirements must be complied with (e.g., ANSI/AAMI ST79).

Use a fractionated vacuum process/pre-vacuum process (at least 4-cycles) in compliance with the following parameters:

Holding time	At least 3 minutes
Temperature	134°C
Drying time	At least 10 minutes

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 they are undamaged and fully functional, *insertion instruments* can be processed and reused. Service life is limited by damage and normal wear. A damaged *insertion instrument* must be discarded after reprocessing.

RETURNS

Products may only be returned to surgebright GmbH after they have been disinfected/sterilized (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. *Insertion instruments* comply with the applicable European Union requirements in force. Where applicable, this is monitored by a notified body.

	Medical device
	Part number
	LOT/batch number
	Date of manufacture
	Manufacturer
	Follow the instructions for use
	Attention
	Non-sterile
	Unique Device Identifier
	Prescription only
	Quantity of device
	Product complies with the applicable requirements laid down in EU harmonization legislation and is monitored by a notified body