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Instructions for Use

Insertion Instruments

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US Federal Law restricts this device to sale by or on the order of a physician.

Trade name: Shark Screw® coupling
Shark Screw® driver acl
Shark Screw® driver cut

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GENERAL INSTRUCTIONS
Knowledge of the contents of these Instructions for Use is required for proper and safe use of *insertion instruments*. Use of *insertion instruments* without adherence to these instructions for use can lead to serious injury to patient. Users of *insertion instruments* must have read and understood all points of these instructions for use.

Note:
surgebright GmbH expressly assumes no liability for damage or malfunctions resulting from failure to comply with the instructions for use. *Insertion instruments* are **delivered non-sterile**. Prior to each use the instruments must be cleaned and sterilized.

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 staff in the reprocessing unit for medical devices.
- *Insertion instruments* are delivered in non-sterile packaging. Prepare the device 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 only designed for use in combination with grafts and instruments provided by surgebright and its official distribution partners.
- The instruments are not designed for use in combination with active medical devices
- 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 inserting process.
- Do not continue to screw in the Shark Screw® allograft if resistance increases. If available, use the depth mark on the instrument as a guide.
- Insert the *insertion instrument* completely onto the head of the Shark Screw® allograft.
- The use of a k-wire (max. diameter 1.2 mm) is recommended by surgebright as a guide for the insertion instrument Shark Screw® driver acl. This also minimizes the risk of the cannulation becoming blocked.

Any adverse event or suspected malfunction in connection with *insertion instruments* must be reported immediately to your surgebright sales representatives and surgebright!

INTENDED USE
Insertion instruments are used in orthopedics and traumatology and are used to implant Shark Screw® allografts. The products allow the allografts to be transplanted without complications.

COMBINATION WITH OTHER PRODUCTS
Insertion instruments may only be used in combination with the handle with an AO coupling and Shark Screw® allografts.

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

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

CONTRAINDICATIONS
The contraindications of *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 newborns (neonates) and infants from birth to 1 year of age.

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.

Before opening the sterile packaging in preparation for use of the device, inspect the packaging to ensure that the sterile barrier (sterilization wrap) is not torn or perforated and does not show signs of moisture or appear to be tampered with. If any of these conditions are present, the contents must be considered non-sterile. In this case, repeat the entire cleaning and sterilization process according to this IFU prior to using the device.

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
2) Insert the *insertion instrument* completely onto the head of the Shark Screw® allograft.
3) If intended, placement of the *insertion instrument* on the previously placed K-wire (max. Ø 1.2 mm)
4) Screw in the Shark Screw® allograft without stopping
5) Strict axial removal of the *insertion instrument*
6) Release the *insertion instrument* from the handle

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

FUNCTION CHECK
The instruments must be checked for any damage and for functionality immediately upon receipt and, as a rule, before use as well as during processing. The following points should be checked during each procedure:

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

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 report 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.	For guidance, use the instrument's depth mark, if available, to estimate the insertion depth during the insertion procedure.
Claw is broken off from the *insertion instrument* Shark Screw® coupling during insertion	Use the spare Shark Screw® coupling and report the suspected malfunction to your local distributor and surgebright GmbH
Insertion instrument broke off during insertion because the resistance to insertion was too high.	Tap twice and then thoroughly flush the drill channel
The *insertion instrument* Shark Screw® driver acl is used without a guide and is therefore more difficult to use.	The *insertion instrument* Shark Screw® driver acl 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 *insertion instrument* Shark Screw® driver acl 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 *insertion instrument* Shark Screw® driver acl 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 instrument*, 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 device must not be used for clinical applications. Read the reprocessing instructions carefully. The user is responsible for proper reprocessing in accordance with these instructions. It is the responsibility of the user to ensure reprocessing is performed using appropriate equipment, materials and trained personnel to achieve the desired result. This requires routine monitoring and validation of the process. Any deviation from the instructions provided must be validated by the user.

WARNINGS AND PRECAUTIONS
Keep the reprocessing instructions accessible to all personnel. The general warnings must be observed. If the instrument has been used on a patient with Creutzfeldt-Jakob disease (CJD) (confirmed CJD or suspected CJD), it must not be reused and must be destroyed. Follow the cleaning and sterilization instructions with care.

INSTRUMENT PROCESSING
Insertion instruments must always be cleaned and sterilized in accordance with the validated reprocessing procedure included in these instructions for use prior to each use, including before initial use of the device after delivery. Thorough cleaning is an essential requirement for effective sterilization of the device.

The washer/disinfector and sterilizer must be regularly maintained and checked, and it must be ensured that the validated parameters are adhered to for each cycle. In addition, observe the applicable legal regulations in your country as well as the regulations for infection prevention and control in force at your hospital. This applies especially to any specifications regarding effective prion inactivation.

CLEANING AND DISINFECTION
Use the automated cleaning and optional disinfection process described below to clean and optionally disinfect *the insertion instruments*. Any alternative cleaning procedure, including any manual cleaning procedure with or without ultrasonic treatment, must be validated by the user in accordance with all applicable regulations and standards.

POINT-OF-USE
During the clinical procedure, maintain soiled instruments separate from clean instruments. Do not place soiled instruments back in the instrument tray to avoid contamination of the unused contents of the tray.

Keep soiled instruments moist to avoid drying of contaminants prior to the cleaning process

PRECLEANING
Coarse impurities must be removed from *insertion instruments* immediately after use. For this purpose, use running water (< 86°F) or a disinfectant solution; the selected media should be aldehyde-free (to prevent the adhesion of blood contaminants), have a tested efficacy (CE marking / EPA approved), be suitable for instrument disinfection and be compatible with *insertion instruments* (see chapter "Material durability").
Dr. Weigert neodisher MediClean forte was used as part of the 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),
- The validated program described below is used to clean and disinfect *insertion instruments*, including all indications with regard to water quality,
- 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.

The cleaning agent you choose,

- Must be suitable for *cleaning insertion instruments* (e.g. Neodisher MediClean forte by Dr. Weigert) Strictly adhere to the instructions provided by the manufacturer of your cleaning agent regarding solution concentration, water quality and temperature and soaking/rinsing times).

The thermal disinfection step included in the automated cleaning procedure below is optional and intended for protection of hospital personnel only. After cleaning and optional disinfection, *insertion instruments* must always be sterilized per the instructions in this IFU prior to use.

Never subject the device to chemical disinfection after automated cleaning due to the risk of disinfectant residues remaining on the instrument surface.

1. Insert *insertion instruments* into the WD. Make sure that the instruments do not come into contact with each other. A washer-disinfector tray for minimally invasive procedures was used for the validation.
2. Start the program.
   a. **Pre-rinse**: With cold water (< 86 °F) for 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 131 °F for 10 minutes
   d. **Drain**
   e. **Neutralization/rinsing:** two rinsing steps of one minute each with deionized water
   f. **Disinfect:** At 194 °F for five minutes (A_0 value > 3000)
   g. **Drying:** 20 minutes at 212 °F
3. Remove the instruments from the WD at the end of the program.
4. If indicated, dry *insertion instruments* manually using medical compressed air or lint-free swabs.
5. Check and pack *insertion instruments* as soon as possible after removal (see chapter "Function check" and "Packaging", if necessary, after additional drying in a clean place).

FUNCTIONAL CHECK

After cleaning, thoroughly inspect *insertion instruments* for residual contamination. If contamination is found, repeat the cleaning process.

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

PACKAGING

Sort the cleaned and disinfected *insertion instruments* in a clean instrument tray. Double-wrap the tray using single use sterilization wrap cleared by FDA for double-wrapping and the sterilization parameters below.

STERILIZATION

Strictly adhere to the sterilization method and parameters recommended below, including drying time.

Sterilization of *insertion instruments* has been validated using a fractionated vacuum process / pre-vacuum process (with 4 cycles).

Place the wrapped instrument tray into the sterilizer and sterilize using the following sterilization cycle parameters:

Holding time	4 minutes
Temperature	269.6 °F
Drying time	20 minutes

Never attempt to sterilize *insertion instruments* using an alternative sterilization process, including but not limited to flash sterilization, heat sterilization, radiation sterilization, formaldehyde or ethylene oxide sterilization or plasma sterilization.

STORAGE

After sterilization, the wrapped instrument tray must be stored in a designated clean, dry and dust-free area, making sure that the sterile packaging cannot be damaged or compromised in any way.

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

In addition, contact between *insertion instruments* and H_2O_2 (hydrogen peroxide), disinfectants, and cleaning agents containing chlorine and oxalic acid should be avoided to prevent pitting and corrosion.

LIMITATIONS ON PROCESSING AND SERVICE LIFETIME

With proper care, and provided they are undamaged and fully functional, *insertion instruments* can be reprocessed and reused. End of life is typically determined by normal wear and/or damage due to improper use or care. Damaged *insertion instruments* must be sorted out after use or during reprocessing.

RETURNS

Products may only be returned to surgebright or your local sales rep 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.

GLOSSARY OF SYMBOLS

MD	Medical device
REF	Part number
LOT	LOT/batch number
	Date of manufacture
	Manufacturer
	Follow the instructions for use
	Attention
NON STERILE	Non-sterile
UDI	Unique Device Identifier
QTY	Package Size
Rx only	Prescription only