



Instructions for Use

Surgical 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® drill
 Shark Screw® tap

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

GENERAL INSTRUCTIONS

Knowledge of the contents of these instructions for use is required for proper and safe use of the *surgical instruments* manufactured for surgebright GmbH. Use of *surgical instruments* without adherence to these instructions for use can lead to serious injury to patient. Users of the *surgical 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. *Surgical 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.
- *Surgical 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 these instructions for use.
- The instruments are only designed for use in conjunction with allografts provided by surgebright, and its official distribution partners and active or non-active insertion medical devices with AO coupling (e.g., handle or power tool).
- Before use, check that the *surgical instrument* is firmly connected to the selected insertion device using the AO coupling
- Cool the *surgical instrument* during use with a suitable coolant (e.g., sterile water)
- Select the appropriate diameters of the *surgical instruments* according to the diameter of the selected Shark Screw® allograft (match the color coding)
- The use of a k-wire is recommended by surgebright as a guide for the *surgical instruments*. This also minimizes the risk of the cannula becoming blocked.
- Always proceed with caution when using *surgical instruments*
- Always have an alternative system to hand when using *surgical instruments*
- Select a suitable contact pressure
- Select a suitable power when choosing an active power tool.
- Use the correct direction of rotation when selecting an active insertion device
- Store *surgical instruments* in a dry and clean place.
- Do not store *surgical instruments* next to hazardous substances.

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

INTENDED USE

Surgical instruments are used in orthopedics and traumatology in the context of Shark Screw® allograft transplantations. The instrument allows Shark Screw® allografts to be transplanted safely and without complications.

COMBINATION WITH OTHER DEVICES

Surgical instruments may only be used in combination with active or non-active insertion medical devices (e.g., handle or power tool) in the context of Shark Screw® allograft transplantations.

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

INDICATIONS

Surgical instruments are intended for use in all clinically indicated applications of Shark Screw® allografts.

CONTRAINDICATIONS

The contraindications of the *surgical 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

Surgical 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

The device 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.

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) Select the appropriate diameter of the *surgical instruments* for the Shark Screw® allograft: Color coding of the packaging of the Shark Screw® used must match the color coding of the *surgical instrument* used; e.g., red packaging of the allograft (= Ø 4.5 mm) in combination with surgical instruments with red color coding

Ø Shark Screw®	Color coding of instruments
3.5 mm	Blue
4.0 mm	Yellow
4.5 mm	Red
5.0 mm	Black

- 2) Attachment of the surgical instrument to the (possibly active) insertion device
- 3) Checking the connection between the surgical instrument and the (possibly active) insertion device is tight
- 4) Placement of the surgical instrument on the previously correctly placed K-wire

(for instruments coded in black: max. Ø 1.8 mm*, for all other instruments: max. Ø 1.2 mm)

- 5) When using an active insertion device: select the direction of rotation and contact pressure accordingly. **The instrument must be cooled, for example, with sterile water, during utilization!**
- 6) Processing of the tissue (linear guidance by K-wire), taking into account the desired depth using the depth marking. Direction of rotation for feed: Clockwise
- 7) Direction of rotation for removal: Counterclockwise
- 8) Removal of the *surgical instrument* from the surgical field
- 9) from the insertion device
- 10) Repeat steps 1-9 for further *surgical instruments*

SERVICE LIFE

Surgical instruments are reusable. 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.

FUNCTION CHECK

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

- **Damage or corrosion on the surface**
- **Broken off parts**
- **Bent or damaged shaft**
- **Damage to the AO coupling**
- **Illegible labeling**
- **Residual contamination**
- **Blocked cannula**

If any of the stated defects occur, the device must be discarded.

DECOMMISSIONING AND DISPOSAL

The instrument can be sent to surgebright or your local sales rep for disposal **in sterile condition** or disposed of by the user in compliance with the internally applicable disposal regulations. In the case of direct disposal, appropriate protective measures must be taken to prevent or minimize the risk of injury to third parties from the sharp/pointed parts of the instruments. In addition, a report must be sent to surgebright or your local sales rep if you dispose of the instruments directly.

RECOMMENDATIONS FOR HANDLING

Problem	Solution
Actual processing depth is determined and monitored under fluoroscopy (increased radiation exposure)	Use the depth marking on the instrument to determine the processing depth during application

A lot of heat is generated during use of the <i>surgical instrument</i> .	Always cool the drill channel with a suitable coolant during use; the contact pressure and power of the insertion device should be selected according to experience and bone quality.
The <i>surgical instrument</i> breaks off during application.	The surgeon must consider whether it is still possible to use the Shark Screw® allograft, e.g., using a larger diameter allograft stored at the facility. If this is not possible, an alternative system must be used for patient care.
The <i>surgical instrument</i> is used without a guide and is therefore more difficult to use.	<i>Surgical instruments</i> should always be applied under the guidance of a correctly placed k-wire (for instruments coded in black: max. Ø 1.8 mm*, for all other instruments: max. Ø 1.2 mm).
A <i>surgical instrument</i> diameter has been selected, which is not compatible with the selected Shark Screw® allografts.	The diameter of the <i>surgical instruments</i> must be selected in accordance with the color coding on the packaging of the Shark Screw® allograft. If the Shark Screw® packaging is marked red, for example, <i>surgical instruments</i> with red rings must be used.
The cannula of the instrument 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 instrument which has a blocked cannula after reprocessing has been provided to the operating theatre	The product 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 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 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

Surgical 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 *surgical 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 the *surgical instruments* immediately after use.

Use running water (< 86 °F) or a suitable cleaning agent or disinfectant; the selected media should be aldehyde-free and alkaline (to prevent the adhesion of blood contaminants), have a tested efficacy (CE marking/EPA approved), be suitable for instrument disinfection, and be compatible with the *surgical instruments* (see Material durability). Dr. Weigert Neodisher MediClean cleaning agent 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. Care must be taken to ensure that contamination is removed without leaving any residue, especially in the case of thin cannulas. If necessary, water guns with pulsed water jets (at least 10 seconds) can be used.

WASHER-DISINFECTORS (WD)

- When selecting the WD, make sure,
- It has been tested for effectiveness (for example, in accordance with ISO 15883),
 - The validated program described below is used to clean and disinfect *surgical instruments*, including all indications with regard to water quality,
 - That suitable water (deionized) 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 *surgical instruments* (e.g. Neodisher MediClean 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, *surgical 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 the *surgical 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-rinsing:** 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:** With deionized water for 2 minutes
 - f. **Disinfecting:** At 194 °F for five minutes (A₀ value > 3000)
 - g. **Drying:** 20 minutes at 212 °F
- 3) Remove the instrument from the WD at the end of the program.
- 4) If indicated, dry the *surgical instruments* manually using medical compressed air or lint-free swabs.
- 5) Check and pack the *surgical instruments* as soon as possible after removal (see section "Functional check" and "Packaging").

INSPECTION

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

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

PACKAGING

Sort the cleaned and disinfected *surgical 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 *surgical 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	3 minutes
Temperature	273.2 °F
Drying time	10 minutes

Never attempt to sterilize *surgical 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 agents and disinfectants, ensure that they are corrosion-resistant and can be used for cleaning and disinfecting the instrument family of *surgical instruments* according to the manufacturer. In addition, contact between the *surgical instruments* and H₂O₂ (hydrogen peroxide), disinfectants, and cleaning agents containing chlorine and oxalic acid should be avoided in order to prevent pitting and corrosion

LIMITATIONS ON REPROCESSING AND SERVICE LIFETIME

With proper care, and provided they are undamaged and fully functional, *surgical 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 *surgical instruments* must be sorted out after use or during reprocessing.











RETURNS

Surgical instruments 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 devices 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

	Medical device
	Part number
	LOT/batch number
	Date of manufacture
	Manufacturer
	Follow the instructions for use
	Attention
	Non-sterile
	Unique Device Identifier
	Prescription only

* Applies to black-coded instruments from the date of manufacture 29.01.2026; prior to this date, the maximum k-wire diameter is 1.2 mm for all product variants.