



Instructions for Use

Surgical instruments



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Basic UDI-DI:

9120125220034J

Trade name:

Shark Screw® drill

Shark Screw® tap

All the products mentioned form a generic product group and are further summarized under *surgical 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 *surgical instruments*. Users of the *surgical instruments* must have read and understood all points of these operating 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 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 GmbH 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 recommended by surgebright GmbH 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.

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

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 premature infants and babies.

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.

USAGE ENVIRONMENT

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

USE ON HUMANS

Surgical instruments are intended for use on humans. They are not to be used on the central circulatory system or on the central nervous system.

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.

FUNCTIONAL 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**
- **Blunt product cutting edge**

If any of the stated defects occur, the device 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 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 GmbH 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 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 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. Special care must be taken when handling a *surgical instrument*. Take special care during cleaning and sterilization. For manual cleaning, only use tools that do not damage the *surgical instruments*. The operator must ensure that the *surgical instruments* are adequately cleaned and disinfected prior to steam sterilization. Inadequate cleaning/disinfection can lead to residual contamination. Observe the notes and instructions for use provided by the manufacturer of the Washer-Disinfector, the autoclave, and the cleaning agents and disinfectants used.

PREPARATION OF THE INSTRUMENTS

Effective cleaning and disinfection is an essential requirement for efficient sterilization. Please ensure during use that you collect soiled *surgical instruments* separately and do not place them back in the sterilization tray; this is to avoid greater contamination of the loaded sterilization tray. 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 *surgical instruments* immediately after use.

Use running water (< 30 °C/< 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/FDA registration), 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,

- that it has been tested for effectiveness (for example, in accordance with EN ISO 15883),

- that a tested program for thermal disinfection (at least 5 min. at 90 °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 *surgical instruments*,
- 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.

When selecting the cleaning agent system to be used, make sure

- that it is suitable for cleaning the *surgical instruments*,
- that the chemicals used are compatible with the *surgical instruments* (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 *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.

- Pre-rinsing:** With cold water (< 30 °C / < 86 °F) for at least 2 minutes
- Drain**
- 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
- Drain**
- Neutralization/rinsing:** two rinsing steps of one minute each with deionized water
- Disinfecting:** At 90 °C for five minutes (A₀ value > 3000)
- 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 *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").

CHECKING

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

PACKAGING

Sort the cleaned and disinfected *surgical 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. 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 *surgical instruments* must be stored dry and dust-free.

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

REUSABILITY













With proper care, and provided they are undamaged and fully functional, *surgical instruments* can be reprocessed and reused. Service life is limited by damage and normal wear. Damaged *surgical instruments* must be sorted out after use or during reprocessing.

RETURNS

Surgical instruments 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 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. The device complies 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

* 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.