



Instructions for Use

Shark Screw® Driver



Manufactured for:
surgebright GmbH
Gewerbezeile 7
A-4040 Lichtenberg bei Linz
Email: info@surgebright.com
Phone: +43 720 371 355
www.surgebright.com

Distributed by:
Surgebright Inc.
4949 S Syracuse St, Ste 550
Denver, CO 80237
Email: usdistribution@surgebright.com

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

Trade name: Shark Screw® driver

GENERAL INSTRUCTIONS

Knowledge of the contents of this instruction for use is required for proper and safe use of the *Shark Screw® driver* manufactured for surgebright GmbH. Use of the *Shark Screw® driver* without adherence to this instruction for use can lead to serious injury to patient. Users of the *Shark Screw® driver* must have read and understood all points of this instruction for use.

Note:
surgebright GmbH expressly assumes no liability for damage or malfunctions resulting from failure to comply with the instructions for use. The *Shark Screw® driver* is **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.
- The *Shark Screw® driver* is 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

- Before use, check that the *Shark Screw® driver* is firmly connected to the selected insertion device using the AO coupling
- Always have an alternative system to hand when using the *Shark Screw® driver*
- Use the correct direction of rotation when selecting an active insertion device
- Store the *Shark Screw® driver* in a dry and clean place.
- Do not store the *Shark Screw® driver* next to hazardous substances.

Any adverse event or suspected malfunction in connection with the *Shark Screw® driver* must be reported immediately to your surgebright sales representatives and surgebright.

INTENDED USE

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

COMBINATION WITH OTHER DEVICES

The *Shark Screw® driver* 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

The *Shark Screw® driver* is intended for use in all clinically indicated applications of Shark Screw® allografts.

CONTRAINDICATIONS

The contraindications of the *Shark Screw® driver* 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

The *Shark Screw® driver* 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) Connect the *Shark Screw® driver* with the selected insertion device
- 2) Connect the *Shark Screw® driver* with the hex head of the Shark Screw® allograft. Keep in mind that only Shark Screw® cut allografts can be implanted with *Shark Screw® driver*.
- 3) Implant the Shark Screw® allograft by using clockwise rotation.
- 4) Check position of the Shark Screw® allograft in the patient's bone
- 5) Removal of the *Shark Screw® driver* from the surgical field
- 6) Removal of the *Shark Screw® driver* from the insertion device (e.g. Shark Screw® handle)

SERVICE LIFE

The *Shark Screw® driver* is 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

The *Shark Screw® driver* 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**

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

DECOMMISSIONING AND DISPOSAL

The *Shark Screw® driver* 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. A report must be sent to surgebright or your local

sales rep if you dispose of the *Shark Screw® driver* directly.

REPROCESSING INSTRUCTIONS

GENERAL INSTRUCTIONS

After receiving the *Shark Screw® driver*, check its identity and integrity before submitting it for processing. It is essential that all prerequisites and special information described in these instructions for use 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 *Shark Screw® driver* 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

Shark Screw® driver 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/disinfectant 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 *Shark Screw® driver*. 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 *Shark Screw® driver* 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 *Shark Screw® driver* (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.

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 *Shark Screw® driver*, 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 the *Shark Screw® driver* (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, the *Shark Screw® driver* 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.

Rx _{only}	Prescription only
---------------------------	-------------------

- 1) Insert the *Shark Screw® driver* into the WD. Make sure that the instruments do not come into contact with each other.
- 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 *Shark Screw® driver* manually using medical compressed air or lint-free swabs.
- 5) Check and pack the *Shark Screw® driver* as soon as possible after removal (see section "Functional check" and "Packaging").

INSPECTION

After cleaning, thoroughly inspect the *Shark Screw® driver* for residual contamination. If contamination is found, repeat the cleaning process.

Check the *Shark Screw® driver* after cleaning or cleaning/disinfection according to the section "Functional check".

PACKAGING

Sort the cleaned and disinfected *Shark Screw® driver* 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 *Shark Screw® driver* 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 the *Shark Screw® driver* 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 of *Shark Screw® driver* according to the manufacturer. In addition, contact between the *Shark Screw® driver* 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 if the *Shark Screw® driver* is undamaged and fully functional, *Shark Screw® driver* can be reprocessed and reused. End of life is typically determined by normal wear and/or damage due to improper use or care. A damaged *Shark Screw® driver* must be sorted out after use or during reprocessing.










RETURNS

The *Shark Screw® driver* 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