



Instructions for Use

Shark Screw® wires



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® Pin
Shark Screw® Guidewire

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GENERAL INSTRUCTIONS

Knowledge of the contents of these Instructions for Use is required for proper and safe use of the Shark Screw® wire. Use of Shark Screw® wire without adherence to these instructions for use can lead to serious injury to patient. Users of the Shark Screw® wire 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. Shark Screw® wire is **delivered non-sterile**. Prior to each use the product must be cleaned and sterilized. Shark Screw® wire is a **single-use** product and is **not intended for implantation**.

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.
- Shark Screw® wire 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 use according to the information in the Instructions for Use.
- The product is only designed for use in combination with grafts and instruments

- provided by surgebright and its official distribution partners.
- Store the product in a dry and clean place.
 - Do not store the product next to hazardous substances.

The use of surgebright products in combination with products from other manufacturers is not recommended due to the mismatched designs, materials, mechanics and constructions. surgebright assumes no liability for any complications arising from the combination of components or the use of third-party medical products in combination.

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

INTENDED USE

The Shark Screw® wire is used in orthopedics and traumatology and is used to generate intraoperative and temporary compression between two bone fragments before inserting a Shark Screw® allograft. **The Shark Screw® wire is not intended to be implanted.**

COMBINATION WITH OTHER PRODUCTS

The medical device Shark Screw® wire may only be used in combination with active insertion medical devices (e.g., power tool) in the context of Shark Screw® allograft transplantations.

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

INDICATIONS

The Shark Screw® wire is intended for use in all clinically indicated applications of the Shark Screw® allograft.

CONTRAINDICATIONS

The contraindications of the Shark Screw® wire 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.

Additionally there are more product specific contraindications:

- Any accompanying conditions that could jeopardize or compromise the fixation or success of the procedure

INTENDED PATIENT GROUP

Shark Screw® wire may be used in all patients (female and male).

INTENDED USER GROUP

The product 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® wire with the proper insertion device
2. Align the two bone parts to be fixed together as desired.
3. Insert the Shark Screw® wire to temporarily fixate and compress the bone fragments in the desired position. If necessary, another Shark Screw® wire can be inserted.
4. Check position of the two compressed bone fragments
5. Implant the Shark Screw® allograft while compromising the bone fragments with the Shark Screw® wire.
6. Remove the Shark Screw® wire from the bone – the compression will be held by Shark Screw® allograft.

Keep the products protected from contamination in the surgical area (e.g., by covering them with a sterile cloth).

The products should always be inserted with the greatest possible care and as little force as necessary for correct positioning.

The products must be handled with the care required when handling medical devices

SERVICE LIFE

The Shark Screw® wire is a **single-use** product.

FUNCTION CHECK

Before use, the product must be inspected by the user for visible damage such as cracks, breaks, or damaged tips. Damaged products must not be used.

DECOMMISSIONING AND DISPOSAL

The packaging of the product can be disposed of via the applicable disposal system for plastics and paper or cardboard. Used products must be disposed of as medical hazardous waste (biohazardous waste) in accordance with the applicable standard of the medical facility.

RISKS ARISING FROM INTENDED USE

Risk	Solution
Injury to surrounding tissue, nerves, or vessels Puncture/injury caused by the product during insertion/positioning	Comply with the respective treatment principles
Mechanical deformation or fracture of the product	Avoid excessive force during insertion. Once feeling a resistance, back up and use another Shark Screw® wire.

PROCESSING 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 processing instructions carefully. The user is responsible for proper processing in accordance with these instructions. It is the responsibility of the user to ensure processing 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 processing instructions accessible to all personnel. The general warnings must be observed. Follow the cleaning and sterilization instructions with care.

PRODUCT PROCESSING

Shark Screw® wire must be cleaned and sterilized in accordance with the validated processing procedure included in these instructions for use prior to use. Thorough cleaning is an essential requirement for effective sterilization of the device. 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.

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.

MECHANICAL CLEANING SEQUENCE

The cleaning agent you choose, must be suitable for cleaning Shark Screw® wire (Dr. Weigert neodisher MediClean forte was used as part of the validation). 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, Shark Screw® wire must 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 product surface.

1. Insert the Shark Screw® wire into the WD. Make sure that the products do not come into contact with each other. A washer-disinfectant 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 (A0 value > 3000)
 - g. Drying: 20 minutes at 212 °F
3. Remove the product from the WD at the end of the program.
4. If indicated, dry the Shark Screw® wire manually using medical compressed air or lint-free swabs.
5. Check and pack the Shark Screw® wire as soon as possible after removal (see chapter "Function check" and "Packaging", if necessary, after additional drying in a clean place).

VISUAL INSPECTION

After cleaning, the products must be visually checked for cleanliness and integrity. Products that are not clean must be cleaned again, and damaged products must be sorted out and disposed of.

PACKAGING

The products must be packaged for sterilization in suitable sterilization packaging compatible with moist heat sterilization in accordance with EN ISO 11607-1. Care must be taken to ensure that the packaging has sufficient temperature resistance (min. 278,6°F) and is sufficiently dimensioned so that the seal is not under tension when the product is wrapped. The

validated sterilization procedure refers to double foil pouches.

STERILIZATION

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

Sterilization of Shark Screw® wire 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 Shark Screw® wire 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

Reprocessed products must be stored clean and dry at room temperature, protected from recontamination, moisture and direct sunlight.













The conditions of the storage shall be:

Temperature	Min. 5°C/ Max. 25°C
Humidity	Min. 25% rH/ Max. 75% rH
Protect from humidity	
Protect from direct sunlight	

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
	Single-use product
	Unique Device Identifier
	Package Size
	Prescription only