



Instructions for use

Shark Screw® knob



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Basic UDI-DI: 9120125220024G
Trade name: Shark Screw® knob
Part number: R-PL-00
Classification: Class I
UMDNS: 11-704
EMDN: H900399

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GENERAL INSTRUCTIONS

Knowledge of the contents of these instructions for use is required for safe use of the Shark Screw® knob. Users of the Shark Screw® knob 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.

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 facility's staff in the reprocessing unit for medical devices.
- The device is supplied in non-sterile form. Prepare the device **before each use** according to the information in the instructions for use.
- Perform a functional check before and after each use according to the information in the instructions for use.
- The device is designed only for use in combination with allografts and instruments provided by surgebright GmbH and its official distribution partners.
- Store the device in a dry and clean place.
- Do not store the device next to hazardous substances.

Serious incidents in connection with the Shark Screw® knob must be reported to surgebright GmbH, the distributor and the competent authority.

INTENDED USE

The Shark Screw® knob is used in orthopedics and traumatology to fix and couple sutures in operations involving Shark Screw® suture anchors.

BENEFITS

The clinical performance of the device lies in enabling a complication-free insertion procedure of Shark Screw® suture anchors.

COMBINATION WITH OTHER DEVICES

The medical device Shark Screw® knob may only be used in combination with the handle with an AO coupling defined by surgebright GmbH, the Shark Screw® coupling insertion device, and the Shark Screw® suture anchors.

The choice of sutures is generally the responsibility of the practicing physician, provided that the suture thickness does not exceed the diameter of the eyelets of the Shark Screw® suture anchors. In addition, tapes must not be used, as they cannot achieve the desired suture tension.

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

INDICATIONS

The Shark Screw® knob is intended for use in all clinically indicated applications of the Shark Screw® suture anchors.

CONTRAINDICATIONS

The contraindications of the Shark Screw® knob are the same as for the Shark Screw® suture anchors:

- Insufficient bone substance to anchor the Shark Screw® suture anchor
- Use in a necrotic host site is contraindicated
- Insufficient bone quality or quantity
- Use 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® suture anchors.
- Bone quality must be checked by the physician prior to surgery.

INTENDED PATIENT GROUP

The device 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

The Shark Screw® knob 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 the device. All handling steps must be carried out in the operating field or on the instrument table.

USE ON HUMANS

The device is intended for use in operations involving Shark Screw® suture anchors. The device is non-invasive.

APPLICATION STEPS

The physician performing the surgery is responsible for the correct execution of the steps listed below:

1. Pull the suture(s) into the cross hole(s) of the Shark Screw® suture anchor
2. Pull the suture(s) in through one of the two side eyelets of the Shark Screw® knob and lead them out through the top opening of the Shark Screw® knob (Fig. 1)
3. Pull the complementary suture end/s in through the opposite eyelet and lead them out through the top opening of the Shark Screw® knob (Fig. 1)
4. Place the Shark Screw® suture anchor on the Shark Screw® coupling (Fig. 1)
5. Pull the sutures into the milled groove of the Shark Screw® suture anchor
6. Insert the Shark Screw® knob into the top opening of the handle with AO coupling while maintaining maximum suture tension and applying central pressure as far as possible (Fig. 2)
7. Check for tight fit of the Shark Screw® suture anchor and for suture tension (Fig. 3)
8. Screw in the Shark Screw® suture anchor according to the suture anchor's instructions for use
9. Release the Shark Screw® knob from the handle with AO coupling after the suture anchor has been screwed in by pulling the Shark Screw® knob
10. Release the suture(s) from the eyelets of the Shark Screw® knob

SERVICE LIFE

With proper care, and provided it is undamaged and fully functional, the Shark Screw® knob can be reprocessed and reused. Service life is limited by damage and normal wear. A damaged Shark Screw® knob must be discarded after reprocessing.

DEVICE CHECK

The device must be checked for any damage and for functionality immediately upon receipt and, as a rule, before use as well as during processing.

- **Damage or corrosion on the surface**
- **Damaged or cracked eyelets**
- **Faulty insertion into the handle with AO coupling possible**
- **Deformation of the device**
- **Incorrect fit of the metal sleeve in the device**

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

DECOMMISSIONING AND DISPOSAL

The device can be sent to surgebright GmbH for disposal **after sterilization has**

taken place or disposed of by the user in compliance with the applicable disposal regulations. A message must be sent to surgebright GmbH for direct disposal.

REPROCESSING INSTRUCTIONS

GENERAL INSTRUCTIONS

After receiving the device, 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 without exception.

WARNINGS AND PRECAUTIONS

Keep the reprocessing instructions accessible to all personnel. The general warnings must be observed. The device must undergo functional testing before each reprocessing. If the Shark Screw® knob has been used on a patient with Creutzfeldt-Jakob disease (CJD) (confirmed CJD or suspected CJD), the device must not be reused and must be destroyed. Special care must be taken when handling a medical device. Take special care during cleaning and sterilization. For manual cleaning, only use tools that do not damage the device. The user must ensure that the Shark Screw® knob is adequately cleaned and disinfected prior to steam sterilization. Inadequate cleaning/disinfection can lead to residual contamination.

PREPARATION OF THE DEVICE

The Shark Screw® knob must be cleaned, disinfected and sterilized prior to each use; this also applies to the initial use after delivery. Effective cleaning and disinfection is an essential requirement for efficient sterilization. Please ensure already during use that you collect soiled devices separately and do not place them back in the sterilization tray, to avoid greater contamination of the loaded sterilization tray. Clean/disinfect the Shark Screw® knob, then sort it back into the sterilization tray provided or equivalent packaging, and then sterilize the previously cleaned device. 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 prior 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 device.

PRETREATMENT

If the user has contaminated the Shark Screw® knob (e.g., due to bloody gloves), this contamination must be removed from the device immediately after use.

Use running water or a disinfectant solution for this purpose. The disinfectant should be aldehyde-free (to prevent the adhesion of blood contaminants), have a tested efficacy (CE marking), be suitable for device disinfection, and be compatible with the Shark Screw® knob (see section "Material durability").

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 eyelets of the device 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),
- that a tested program for thermal disinfection (at least 10 min at 93 °C or A0 value >3000) is used (with chemical disinfection, there is a risk of disinfectant residues on the devices),
- that the program used is suitable for the devices and contains sufficient rinse cycles,
- 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.

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

- that it is generally suitable for cleaning of the Shark Screw® knob,
- that – if thermal disinfection is not used – a suitable disinfectant with tested effectiveness (e.g., VAH/DGHM or FDA approval or CE marking) is also used and that this is compatible with the cleaning agent used, and
- that the chemicals used are compatible with the Shark Screw® knob (see section "Material durability").

The concentrations of the cleaning agent and, if applicable, disinfectant specified by the manufacturer must be strictly adhered to.

1. Insert the Shark Screw® knob into the WD. Make sure that the devices do not come into contact with each other.
2. Start the program. (Pre-rinse: two minutes, clean: at 55 °C for five minutes, rinse: 3 minutes, disinfect: at 90 °C for five minutes).
3. Remove the device from the WD at the end of the program.
4. Check and pack the Shark Screw® knob as soon as possible after removal (see sections "Functional check" and

"Packaging", if necessary after additional drying in a clean place).

FUNCTIONAL CHECK

Check the Shark Screw® knob after cleaning or cleaning/disinfection according to the section "Device check".

PACKAGING

Sort the cleaned and disinfected Shark Screw® knob 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 devices or sterilization packaging against mechanical damage

STERILIZATION

Only the sterilization methods listed below may be used for sterilization; no other sterilization methods are permitted.

Steam sterilization:

- Fractionated vacuum process / pre-vacuum process or gravitation process (with sufficient device drying).
- steam sterilizer in accordance with EN 13060 or EN 285
- validated according to ISO 17665-1:2006
- maximum sterilization temperature 134 °C (plus tolerance in accordance with ISO 17665-1:2006)
- Sterilization time (exposure time at sterilization temperature) at least 3 min at 134 °C

STORAGE

After sterilization, the devices must be stored dry and dust-free in suitable packaging, such as the sterilization tray provided.

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

The material used to manufacture the Shark Screw® knob is heat-resistant up to +200 °C. The material is suitable for steam sterilization at 134 °C.

REUSABILITY

The reusability of the Shark Screw® knob can be found in the section "Service life".

RETURNS

Devices 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.

FIGURES

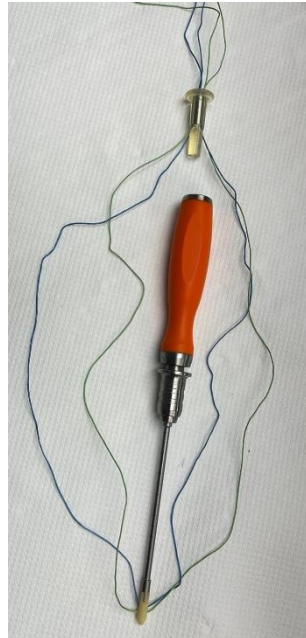


Figure 1: Pulling in the sutures



Figure 2: Tensioning of the sutures by applying central pressure



Figure 3: Shark Screw® knob holds the suture tension – Shark Screw® suture anchor can be screwed in