surgebright
brighter ways for surgery

Instructions for Use

Shark Screw® handle

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

GENERAL INSTRUCTIONS
Instructions for Use (hereafter "IFU") for the Shark Screw® handle manufactured for surgebright GmbH. Use of the Shark Screw® handle without adherence to this IFU can lead to serious injury to patient. The surgeon must read and understand this IFU prior to use of the Shark Screw® handle.

Note:
surgebright GmbH expressly assumes no liability for damage or malfunctions resulting from failure to comply with these instructions for use. The Shark Screw® handle is **delivered non-sterile**. Prior to each use the Shark Screw® handle must be cleaned and sterilized.

WARNINGS AND SAFETY INSTRUCTIONS
- The user must read this IFU in its entirety prior to first use of the Shark Screw® handle.
- The Shark Screw® handle is supplied in non-sterile form. Process the Shark Screw® handle **before each use** according to the instructions provided in this IFU.
- The IFU must be kept available for all staff members using and/or reprocessing the Shark Screw® handle.
- Defective or damaged Shark Screw® handles must be taken out of service immediately and not be used in any way.
- Please contact one of our highly trained sales representatives to address any problems. Our staff will assist you in resolving any issues.
- Properly discard the Shark Screw® handle immediately if it has been used on a patient diagnosed with or suspected of being infected with Creutzfeldt-Jakob Disease (CJD) as there is an extreme risk of cross-contamination. Sterilization of the device cannot eliminate the risk.
- The Shark Screw® handle is to be used only by qualified and trained personnel.
- The user of the product is responsible for proper use of the Shark Screw® handle. Surgebright is not responsible in any way for damages that may occur due to improper use and/or care of the Shark Screw® handle.

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

INTENDED USE
The Shark Screw® handle is used in orthopedics and traumatology in combination with dedicated drivers with AO connection to screw Shark Screw® allografts into place. The permissible operating temperature of the Shark Screw® handle is 50° F-104° F.

COMBINATION WITH OTHER PRODUCTS
The Shark Screw® handle may only be used in combination with surgebright drivers with AO connection.

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

CONTRAINDICATIONS
The contraindications of the Shark Screw® handle are the same as for the Shark Screw® allograft:

- Insufficient bone substance to anchor the Shark Screw® allograft
- Use in a necrotic host site
- Insufficient bone quality or quantity
- Use in a poorly perfused or infected host site because of the poorer healing rate
- Circulatory disorders that may 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.

INTENDED PATIENT GROUP
The Shark Screw® handle 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 Shark Screw® handle may only be prepared for use by the surgical assistant or the operating physician.

The Shark Screw® handle may only be used 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.

FUNCTION CHECK
Before use, inspect the Shark Screw® handle to assure that it is in full working order. Do not use defective product.

- Visually inspect the handle for damage.
- Pull and release the sliding ring several times to ensure that it moves smoothly.
- If damage is found or the sliding ring does not return easily into the locking position, a clean and sterile replacement Shark Screw® handle must be used.
- Place the defective handle aside for repeat reprocessing, lubrication and inspection.

ASSEMBLY STEPS
Pull and hold the sliding ring on the AO coupling (A) to open the lock and insert the driver (B). Next, release the sliding ring (C) and ensure that the driver is locked in place tightly and securely. To remove the driver, the sliding ring must be pulled again.

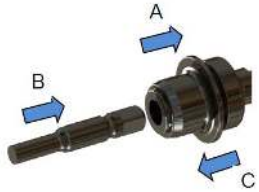

Figure 1: Assembling the Handle and Driver

REPROCESSING INSTRUCTIONS
General instructions

After receiving the Shark Screw® handle, check its identity and integrity before reprocessing. It is essential that all conditions and special instructions included in this IFU are met or taken into account. If this is not possible for any reason, the product 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® handle has been used on a patient with (confirmed or suspected) Creutzfeldt-Jakob disease (CJD), the product must not be reused and must be destroyed. Follow the cleaning and sterilization instructions with care.

INSTRUMENT PROCESSING
The Shark Screw® handle 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 the Shark Screw® handle. 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 devices moist to avoid drying of contaminants prior to the cleaning process.

PRECLEANING
Immediately after use (within a maximum of 2 hours), any visible soil needs to be removed from the Shark Screw® handle.

To manually clean the device, never use metal brushes, steel wool or any other tool that could damage the device surface.

1. Under cold running water at <104°F (<40°C), gently remove visible contamination using a soft brush or a clean soft cloth dedicated exclusively to this purpose.
2. Check cavities and lumens to ensure complete removal of all visible residues.
3. Optionally, the device may additionally be disinfected for protection of hospital personnel. The disinfectant must be aldehyde-free (to avoid the fixation of blood impurities), of proven efficacy (e.g. EPA-approved or CE-marked), intended for disinfection of surgical devices, and compatible with the Shark Screw® handle (see section "Material Durability").

MAIN CLEANING

When selecting a washer-disinfector (WD) make sure that
- It has been tested for effectiveness
- The validated program described below is used to clean and disinfect the Shark Screw® handle, including all indications with regard to water quality,
- The air used for drying is filtered and thus cannot contaminate the product, and
- The WD is regularly maintained and monitored.

The cleaning agent you choose
- Must be an alkaline detergent with a pH of 10.2-10.5 (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® handle 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. Place the Shark Screw® handle into the WD. Make sure that it does not touch any other devices.
2. Start the cleaning program. The following minimum parameters are recommended:
   - 2 minutes precleaning with cold tap water at <104°F (<40°C)
   - Drain
   - 5 minutes main cleaning with tap water at 131°F (55°C) and a 0.5% cleaning agent
   - Drain
   - 3 minutes rinse with cold demineralized water at <104°F (<40°C).
   - Drain
   - 2 minutes final rinse with cold demineralized water at <104°F (<40°C)
   - Optional: 5 minutes thermal disinfection with demineralized water at 199.4°F (93°C)
   - Hot air-dry with filtered air for 15-30 minutes at 230°F (110°C). Drying time is shown as a range because it depends on the size of the load placed in the WD.

3. Remove the instrument from the WD at the end of the program.
4. If the Shark Screw® handle is not completely dry, set it in a clean place to air-dry completely.
5. Inspect and package the Shark Screw® handle in accordance with the instructions below as soon as possible after cleaning.

INSPECTION AND LUBRICATION
After cleaning, thoroughly inspect the Shark Screw® handle for residual contamination. If contamination is found, repeat the cleaning process.

Visually inspect the Shark Screw® handle for wear, corrosion, deformation, porosity, damaged surfaces, chips or impurities. Discard damaged devices.

Pull and release the sliding ring several times to ensure that it moves smoothly.

If the sliding ring does not move smoothly or sticks, lubricate it as sparingly as possible with biocompatible medical grade white oil that is compatible with steam sterilization (steam permeable). Follow the lubricant manufacturer's instructions for dilution, shelf life and application method. Do not lubricate the remaining surfaces of the device.

After successfully inspecting the Shark Screw® handle, immediately proceed to packaging for sterilization.

PACKAGING
Place the clean Shark Screw® handle 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
Stricly adhere to the sterilization method and parameters recommended below, including drying time.

Sterilization of the Shark Screw® handle has been validated using a fractionated vacuum process / pre-vacuum process (with at least 3 cycles).

Place the wrapped instrument tray into the sterilizer and sterilize using the following sterilization cycle parameters.

Exposure time	5 minutes
Temperature	273.5°F (134° C)
Drying time	20 minutes

Never attempt to sterilize the Shark Screw® handle 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 and disinfecting agents, make sure that they do not contain the following substances:
- 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

LIMITATIONS ON REPROCESSING AND PRODUCT LIFETIME
Repeated reprocessing in accordance with these instructions for use has minimal effect on the Shark Screw® handle if instructions are followed with care and the device is not damaged or contaminated. End of life is typically determined by normal wear and/or damage due to improper use or care. A damaged Shark Screw® handle must be discarded after reprocessing.

RETURNS
Products must be cleaned and sterilized prior to being returned to surgebright or your local sales representative. Always include a clearly visible STERILIZATION CERTIFICATE with your return. If no proof of cleaning and sterilization is enclosed, the package will not be opened and the products will be sent back.

CONFIRMATION
The above instructions for reprocessing conform to the ISO 17664 standard and have been deemed suitable by an accredited inspection body.

GLOSSARY OF SYMBOLS

MD	Medical Device
REF	Catalog Number
LOT	Lot Number Batch Code
	Date of Manufacture
	Manufacturer
	Consult Instructions for Use
	Caution
NON STERILE	Non-Sterile
UDI	Unique Device Identifier
Rx only	US Federal Law restricts this device to sale by or on the order of a physician.