



Instructions for Use

Shark Screw® tray



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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® tray manufactured for surgebright GmbH. Use of the Shark Screw® tray without adherence to this IFU can lead to serious injury to patient or medical staff.

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

WARNINGS AND SAFETY INSTRUCTIONS

- The IFU must be kept available for all staff members using and/or reprocessing the Shark Screw® tray.
- 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® tray 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.
- Shark Screw® tray should be reprocessed as soon as possible following use. Instruments must be cleaned separately from the Shark Screw® tray.

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

INTENDED USE

The Shark Screw® tray is utilized to secure surgical instruments, provided by surgebright, during transport, storage and sterilization processing.

COMBINATION WITH OTHER PRODUCTS

The Shark Screw® tray may only be utilized with surgical instruments provided by surgebright.

INDICATIONS

The Shark Screw® tray is intended for use in healthcare facilities to organize, enclose, sterilize, transport, and store instrumentation, provided by surgebright, between surgical and other medical uses. Shark Screw® tray not intended on its own to maintain sterility; It is intended to be used in conjunction with a legally marketed, validated, FDA-cleared sterilization wrap. Sterilization validation is based on worst-case instrumentation (See section Sterilization)

CONTRAINDICATIONS

Utilization with instruments, which are not provided by surgebright.

DEVICE DESCRIPTION

The Shark Screw® tray is manufactured using stainless steel, anodized aluminum and medical grade silicone material. Shark Screw® tray is supplied NON-STERILE and must be inspected, cleaned and sterilized before use. The Shark Screw® tray has no direct contact with patients. The Shark Screw® tray is not implantable.

INTENDED USER PROFILE

Hospital and surgical staff having adequate training and familiarity with the handling of instruments including but not limited to, the loading and unloading of, transport, storage, and sterilization of instruments in a tray system prior to and following surgical procedures.

ASSEMBLY STEPS

Surgical instruments, provided by surgebright, can be placed in the defined brackets. Each instrument has a defined location within the Shark Screw® tray (e.g. location "Drill 3.5" is defined for Shark Screw® drill for Shark Screw® Allograft with a diameter of 3.5 mm).

REPROCESSING INSTRUCTIONS

General instructions

After receiving the Shark Screw® tray, 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® tray 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.

MANUAL CLEANING

1) After each use, wash the Shark Screw® tray with a soft sponge and an aluminum safe, neutral pH detergent. A neutral pH detergent is required to avoid faded surface colors and deterioration of the anodized surface. The detergent must be of proven efficacy (e.g. EPA-approved or CE-marked)

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

2) Thoroughly rinse the Shark Screw® tray with warm tap water for 1 minute and dry with a soft, absorbent cloth.

PACKAGING

To maintain sterility, the Shark Screw® tray must be wrapped in an approved wrap using the AAMI double wrap method prior to sterilization. The user should consult ANSI/AAMI ST79 for additional information on steam sterilization.

STERILIZATION

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

The following sterilization parameters are required for steam sterilization of loaded worst-case instrumentation provided by surgebright.

Sterilization has been validated using a fractionated vacuum process / pre-vacuum process (with at least 3 cycles).

Place the double wrapped Shark Screw® 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 sterilization using an alternative sterilization process, including but not limited to flash sterilization, heat sterilization, radiation sterilization,

formaldehyde or ethylene oxide sterilization or plasma sterilization.

Any deviations from this sterilization instruction need to be re-validated.

Water droplets and visible signs of moisture on sterile packaging or the tape used to secure it, may compromise sterility of processed loads or be indicative of a sterilization process failure. Visually check outside wrapper for dryness. If there are water droplets or visible moisture on the exterior of the package or on the tape used to secure it, the Shark Screw® tray is considered unacceptable. Repackage and re-sterilize sterilization packages with visible signs of moisture.

STORAGE

After sterilization, the wrapped Shark Screw® 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. Care should be taken when handling devices to avoid damaging the sterile barrier.

LIMITATIONS ON REPROCESSING AND PRODUCT LIFETIME

Repeated reprocessing in accordance with these instructions for use has minimal effect on the Shark Screw® tray 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® tray 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

	Medical Device
	Catalog Number
	Lot Number Batch Code
	Manufacturer
	Consult Instructions for Use
	Caution

	Non-Sterile
	Unique Device Identifier
	US Federal Law restricts this device to sale by or on the order of a physician.