Swiss LithoClast® Trilogy Max Lithotripter

Prescriptive Information

Refer to the device user manual for complete instructions on device use.

INTENDED USE/INDICATION FOR USE

The product is intended for the fragmentation and removal of urinary tract calculi in the kidney, ureter, and bladder.

OPERATING MODE

The product can deliver ultrasound and ballistic energies through a single probe simultaneously, or separately to fragment stones. The product can extract stone fragments through the probe while delivering energy or without delivering energy. The product is able to collect the stone fragments for analysis.

CONTRAINDICATIONS

Use of the product is contraindicated in patients with any of the following conditions:

- Active bleeding disorders,
- Solitary functioning kidney,
- Creatinine greater than or equal to 3 mg/dL,
- During pregnancy,
- Stricture and obstruction problems,
- An implanted electrical stimulator (e.g. pacemaker),
- Under the age of 18.

POTENTIAL ADVERSE EVENTS

Potential complications associated with fragmentation of urinary tract calculi by ballistic and/or ultrasound energy include:

- Perforation,
- Hemorrhage,
- Lesion,
- Stone migration,
- Pain/colic,
- Macroscopic hematuria,
- Infection,
- Ureteral obstruction

WARNINGS

- Before using this product, please carefully read, understand, and follow the recommendations in the instruction manual. Failure to observe the operating instructions may result in the patient or user suffering serious injury or the product being damaged. This product may only be applied for its intended use by qualified personnel and for the indications described in this manual. If the product is used in combination with other instruments, please refer to their instruction manual.

- Do not use this product in the presence of flammable anesthetics or oxidizing gases (such as nitrous oxide (N2O) and oxygen) or in close proximity to volatile solvents (such as ether or alcohol), as explosion may occur.
- Before using the product, inspect for any damage. Do not use if the product is damaged. Use original EMS spare parts and accessories only.
- Do not modify or repair the product yourself. Please contact your local Boston Scientific sales representatives.
- To avoid injury or damage, make sure that the fragmentation energy is supplied only upon contact of the probe with the stone.
- When the mains power switch is in the "0" position, the product is disconnected from the supply network.
- Make sure that the handpiece, handpiece cleaning rod, probe cleaning rod and re-usable wrenches are cleaned and sterilized according to the instructions in chapter "7. Cleaning, Disinfecting, and Sterilizing", p.25 before proceeding with installation.
    - Disinfection must be performed no later than 1 hour after the cleaning phase.
    - Sterilization must be performed after disinfection.
- To avoid the risk of electric shock, this product must only be connected to a mains power supply with protective earth. No modification shall be made on this product. The mains power switch of the product must be accessible at any time.
- The lowest effective settings should be used when attempting to break a stone to reduce the possibility of:
    1) damage to the kidney or ureteral wall; or
    2) propelling a stone fragment into the surrounding tissue
- For sterilization, the handpiece must have its internal lumen positioned vertically in the sterilizer.
- Before proceeding to the disconnection of the stone catcher, proceed with the purge explained in chapter "6. Post-Treatment Procedure", p.21.
- For single use components: risk of contamination. Contents are supplied STERILE using an ethylene orxide (EO) process. Do not use if sterile barrier is damaged.
- For single use components: risk of contamination. Do not use after the expiration date on the package label.
- For sterile products: risk of contamination. To ensure sterility before use, inspect the package and product for any damage. Do not use if the package seal appears to have been broken, or if the package or product is damaged.
- Do not use the product in surgery after a product update without first performing functional tests.
- Do not touch the probe during activation. The vibrations of the probe may cause heat and instant burns.
- If a probe breaks distally, use sterile grasping forceps to remove probe pieces from the urinary tract.
- Throughout the entire treatment, keep the probe tips under endoscopic vision.
- The probe tip should be extended 10mm - 20 mm beyond the endoscope tip.
- An excessively high suction level can impair the endoscopic vision, collapse an organ, or damage the mucosa.

- Safe storage and transportation to the reprocessing area shall be applied to avoid any damage to the instrument and contamination to the environment and the people involved in the reprocessing process.
- Check all wearing parts regularly for wear, and replace if necessary.
- Fragments blocked in the lumen of the probe and the handpiece may lead to loss of suction and heating of the probe. If blockage occurs, stop lithotripsy. Use the handpiece cleaning rod or probe cleaning rod to remove fragments from the probe and from the handpiece lumen before continuing.
- Make sure that the handpiece connector is dry before connecting it to the console.
- The housing of the console is not waterproof. Do not spray or spill any liquids on the console.
- Before shipping any used Swiss LithoClast® Trilogy Max components, follow the instructions provided in chapter "7. Cleaning, Disinfecting, and Sterilizing", p.25.
- Danger of urothelial and mucosal perforation! During the entire treatment, the user must keep the probe tip under proper endoscopic view.
- Make sure that aspiration is always operational when using the probe. Uninterrupted aspiration during lithotripsy is required to evacuate fragments and liquids as well as to ensure the cooling of the probe and the handpiece.
- To avoid damage to the endoscope, the probe should not be activated with its tip still inside the working channel of the endoscope.
- Please be aware of potential discomfort due to heating of the frontal area during long uses. Make sure to hold the handpiece as per recommended handling areas in chapter "5.5. Starting Treatment", p.20, "Figure 40".

Swiss LithoClast® Trilogy Max Lithotripter is manufactured by E.M.S. Electro Medical Systems S.A. and distributed by Boston Scientific Corporation.

CAUTION: U.S. Federal law restricts this device to sale by or on the order of a physician.