Endostik

ENDOSCOPIC DISSECTORS

by fabco®

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Endoscopic Dissectors

(Please Read Prior to Use)

DESCRIPTION

Endostik® endoscopic dissectors are made of an absorbent material with an embedded x-ray detectable marker that is then affixed to a 5mm shaft. Endostik® endoscopic dissectors are designed for introduction and use through all appropriately-sized trocars or a trocar with convertors. The device is for use in swabbing small amounts of fluid or for blunt tissue dissection of soft tissue(s) and structures.

INSTRUCTIONS FOR USE

Step 1. Verify count and integrity of dissector sponges when package is opened.

Step 2. Insert device through any appropriately-sized trocar.

Step 3. Use under direct visualization from an endoscope or similar method.

Step 4. Use the device for swabbing and blunt dissection of soft tissue(s) or structures, as needed.

Step 5. Verify count of sponges and dissector integrity after withdrawal from the trocar/patient.

PRECAUTIONS AND WARNINGS

- Endoscopic procedures should be performed only by physicians having adequate training and familiarity with endoscopic techniques. A thorough understanding of operating principles, risks versus benefits, and the hazards involved in utilizing endoscopic techniques is essential to avoid the potential for injury to the patient and/or user.
- Do not use if individual packaging is damaged or open. As long as the individual package is not opened or damaged and is within the expiration date shown, the product is sterile. Use proper aseptic technique in all phases of handling.
- This product is for single use only; do not re-sterilize. Re-use can result in microbial contamination causing subsequent health deterioration of patient. Devices contain absorbent materials that cannot be cleaned. FABCO will not be responsible for any product that has been re-sterilized and/or reused.
- Tissue contact of individual devices should be limited to <1 hour.
- Count all devices before and after the procedure prior to surgical closure. In the event a device cannot be located, an x-ray can be used to locate the devices. Failure to perform count and dissector-integrity verification may result in additional procedures and/or extended surgery.
- Used Dissectors should be considered as bio waste and be disposed of in accordance with local regulations
- Sponges may be obscured from x-ray when behind bone or in morbidly obese individuals. It is recommended that at least three views, using the optimal parameters for the imaging (x-ray) equipment, at a variety of angles (e.g., 45 degrees, 22.5 degrees, and 0 degree angles) for anterior and posterior, or the appropriate plane, be taken and examined for a missing device. If there are concerns regarding visualization, consult with your local imaging expert to establish the optimal radiographic parameters (e.g., kVp, mAs) for visualization with the imaging equipment.

Phthalate Warning

The X-ray detectable material in this device contains phthalates, specifically Diisononyl phthalate (DINP). The results of certain animal experiments have shown phthalates to be potentially toxic to reproduction. Proceeding from the present state of scientific knowledge, risks for male premature infants cannot be excluded in the case of long-term exposure or application. Medical products containing phthalates should be used only temporarily with pregnant women, nursing mothers, babies and infants.

REF	LOT	Rx only	STERILE EO			PHT
Reorder number	Lot number		Sterilized by Ethylene Oxide	Read Instructions	Expiration date	DINP