



Reddick®-Saye Screw Retractor Kit

Instructions for Use – English

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(Model Number e2504-01)

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IMPORTANT INFORMATION, Please Read Before Use

STERILE EO

Indications for Use

The Reddick®-Saye Screw Retractor Kit is specifically designed for use during laparoscopic cholecystectomy procedures.

Description

The Reddick®-Saye Screw Retractor is 30 cm in length and 5 mm in diameter with allows insertion through standard trocars. The cork screw tip grasps the diseased gallbladder for manipulation. The Reddick-Saye needle set is designed to puncture the gallbladder and allow easy removal of the bile.

Directions for Use

The Reddick-Saye Retractor is utilized to grasp the fundus of the acute or chronically inflamed gallbladder. The gallbladder wall is thickened in these diseased processes, making it difficult or impossible to hold the fundus with standard laparoscopic forceps. The Reddick-Saye needle and sheath are inserted percutaneously into the fundus of the gallbladder. The needle is removed leaving the sheath inside the gallbladder. The bile is drained with syringe aspiration. The sheath is removed from the abdomen. The Reddick-Saye Retractor is introduced through the lateral laparoscopic portal and aimed toward the fundus of the gallbladder. The tip of the Reddick-Saye Retractor is introduced into the thickened gallbladder wall and the Reddick-Saye Retractor turned clockwise two revolutions. After adequate anchoring into the wall, the push rod is advanced superiorly to push the gallbladder and liver toward the diaphragm. A second Reddick-Saye Retractor can be placed in the Hartmann's pouch if it is also thickened. The Reddick-Saye Retractor is introduced through the midclavicular port. The Reddick-Saye Retractor is turned clockwise two revolutions. Once anchoring has occurred, the push rod is pulled inferiorly and laterally to expose the cystic duct and artery. At the conclusion of the procedure, both Reddick-Saye Retractors are turned two revolutions counter clockwise and removed through the laparoscopic ports. The gallbladder is removed through the umbilical portal with either a standard grasper or a Reddick-Saye Retractor.

WARNING

DO NOT INSERT THE REDDICK-SAYE RETRACTOR MORE THAN TWO REVOLUTIONS AS THE SHARP TIP MAY DAMAGE SURROUNDING TISSUE.

WARNING

DRAIN THE BILE BEFORE INSERTING THE REDDICK-SAYE RETRACTOR TO REMOVE THE GALLBLADDER.

Cautions

1. The Reddick-Saye Retractor is for temporary use only
2. The Reddick-Saye Retractor is for single use only.
3. The Reddick-Saye Retractor is supplied sterile and non-pyrogenic in a peel-open package.
4. Inspect each package and do not use if there is any evidence that the package has been opened or damaged.
5. Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.

Contraindications / Possible Adverse Effects

This device is single-use only. Do not attempt to clean or re-sterilize this product. After use, this product may be a potential biohazard. The cleanliness and sterility of the re-processed device cannot be assured. Reuse of the device may lead to cross contamination, infection, or patient death. The performance characteristics of the device may be compromised due to reprocessing or re-sterilization since the device was only designed and tested for single use. The shelf life of the device is based on single use only. While a device may appear undamaged, previous stress may have created imperfections that would reduce the service life of the device. Do not treat patients with devices that have momentarily come in contact with a different patient.

Notices: Limited Product Warranty; Limitation of Remedies

Symmetry Surgical® warrants that this medical device is free from defects in both materials and workmanship. Any other expressed or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed. Suitability for use of this medical device for any particular surgical procedure should be determined by the user in conformance with the manufacturer's instructions for use. There are no warranties that extend beyond the description on the face hereof.

Symbol Legend

Lot Number	Reference Number	Distributed By	Quantity	Outer Diameter	Usable Length	Caution: Federal USA law restricts this device to sale by or on the order of a physician.	Do Not Use if Package is Opened or Damaged	Consult instructions for use: www.symmetrysurgical.com/IFU

Do Not Reuse	Date of Manufacture	Manufacturer	Sterilization by Ethylene Oxide	Use by Date	Do Not Resterilize



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