symmetry surgical®

Reddick® Cholangiogram Catheter

Instructions for Use - English

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(Model Numbers e2401-50, e2401-51, e2401-52, e2401-53, e2400-50, e2400-51, e2400-52, e2400-53)

IMPORTANT INFORMATION, Please Read Before Use

Indications for Use

The Reddick® Scoop Tip Cholangiogram Catheter (model # e2401-50, -51, -52, -53) and the Reddick Cystic Duct catheter (model # e2400-50, -51, -52, -53) have been specifically designed for the Laparoscopic Cholecystectomy procedure.

Description (Reddick® Scoop Tip Cholangiogram Catheter)

The Reddick® Scoop Tip Cholangiogram Catheter is a bilumen balloon catheter with distal irrigation capabilities. Two stopcocks are bonded to the proximal arms of the catheter. The white stopcock indicates the lumen for balloon inflation, and the blue stopcock indicates the lumen for irrigation and dye injection. Recommended accessories to the catheter are included in the packaging and listed in the contents section below.

A non-radiopaque body prevents the catheter from creating a shadow on the cholangiogram, while a radiopaque marker at the tip makes the balloon position easily identifiable. Depth markings of 2 and 3 cm on the catheter aid the physician in positioning the balloon in the cystic duct, and the balloon holds it securely in place after inflation.

Specifications	
Maximum Liquid Capacity	0.2 mL
Maximum Gas Capacity	0.4 mL
Useable Length	50 cm

Contents			
e2401-50	e2401-51	e2401-52	e2401-53
1 catheter	1 catheter	1 catheter	1 catheter
1 syringe, 3 mL	1 syringe, 3 mL	1 syringe, 3 mL	1 syringe, 3 mL
1 Introducer Sheath	1 Introducer Sheath	1 Reddick Needle Introducer Set	1 Reddick Needle Introducer Set
		1 Introducer Sheath	1 Introducer Sheath

Description (Reddick® Cystic Duct Cholangiogram Catheter)

The Reddick Cystic Duct catheter is a bilumen balloon catheter with distal irrigation capabilities. However, the design modifications improve the functionality of the Reddick Cystic Duct catheter during the Laparoscopic Cholecystectomy procedure. The taut catheter improves the maneuverability. The balloon design firmly anchors the catheter in the Cystic Duct without clamping. The depth marks of 2 and 3 cm aid the physician in visualization of the balloon position in the Cystic Duct. The non-radiopaque body prevents the catheter from creating a shadow on the cholangiogram. The catheter is positioned through the Reddick Introducer Sheath into the cystic duct. The balloon is inflated in the cystic duct to hold the catheter in place.

Specifications	
Maximum Liquid Capacity	0.2 mL
Maximum Gas Capacity	0.4 mL
Useable Length	50 cm

Contents			
e2400-50	e2400-51	e2400-52	e2400-53
1 catheter	1 catheter	1 catheter	1 catheter
1 syringe, 3 mL	1 syringe, 3 mL	1 syringe, 3 mL	1 syringe, 3 mL
1 Introducer Sheath	1 Introducer Sheath	1 Reddick Needle Introducer Set	1 Reddick Needle Introducer Set
		1 Introducer Sheath	1 Introducer Sheath

Directions for Use

The catheter is positioned through either the Reddick Introducer Sheath or Needle Introducer into the cystic duct. The distally curved Reddick Introducer Sheath and its scooped tip are designed for easier catheter insertion into the cystic duct incision.

Contraindications

1. The catheter is not to be used as a dilation catheter.
2. The catheter is not to be used for the introduction of drugs other than saline, heparin, and contrast media.
3. The catheter is a temporary device and cannot be implanted.

Precautions

1. The catheter is recommended for single use only.
2. Inspect the product and package prior to use and do not use the catheter if there is any evidence that the package has been punctured or that the catheter has been damaged.
3. Pretest the catheter before use, using either Test a or b.
   a. Inflate the balloon to the recommended capacity with air and immerse the balloon in sterile water. If there is any evidence of air escaping around the balloon or if the balloon will not remain inflated, do not use the product. Maximum air capacity is 0.4mL.
   b. Or check the balloon integrity by inflating and deflating with sterile saline for injection before use. If the balloon does not appear to function normally, do not use the product. Maximum liquid inflation is 0.2 mL.
4. Air should not be used to inflate the balloon if there is a possibility of embolization with balloon rupture.
5. Make secure connections between all syringes and stopcock hubs to avoid the introduction of air.
6. To avoid damage to the fragile latex, do not grasp the balloon with instruments at any time.
7. Do not inflate the balloon to any greater volume than is necessary. DO NOT EXCEED the recommended maximum inflation capacity. See chart for specific catheter inflation limits.
8. Deflate the balloon prior to withdrawing the catheter.
9. The possibility of balloon rupture must be taken into account when considering the risk involved in a balloon catheterization procedure.

Storage/Shelf Life

The shelf life is indicated by the use by date on the package label. Since natural rubber latex is acted on by environmental conditions, proper storage procedures must be practiced to achieve optimum shelf life. The product should be stored in a cool dark

area away from fluorescent lights, sunlight and chemical fumes to prevent premature deterioration of the rubber balloon. Proper stock rotation should be practiced. Symmetry Surgical, Inc. products are supplied sterile and non-pyrogenic in sealed easy to open containers. This device is packaged in a non-sterile outer pouch and a sterile inner peel-open package. The sterility of the inner package is assured as long as it is unopened and undamaged. Since the shelf life of the product is dictated by the natural life of the latex, resterilization will not extend the shelf life of the product. Symmetry Surgical, Inc. cannot reprocess or replace outdated product.

Description (Reddick® Needle Introducer)

This two-piece needle set includes a tapered end outer cannula and a solid, sharp, 8-inch-long, 13-gauge needle with a two-facet point. A hemostasis valve is bonded to the proximal end of the cannula to provide a friction fit to the catheter introduction to prevent leakage of CO_2 gas during Laparoscopic Cholecystectomy procedures.

Directions for Use

The two-piece needle is inserted through the body cavity. The stylet is withdrawn permitting introduction of the cholangiography catheter or other instrument. The hemostasis valve provides a friction fit to the catheter or other instrument preventing the escape of gas during Laparoscopic Cholecystectomy procedures.

Precautions

1. The device is recommended for single use only.
2. The device is a temporary device and cannot be implanted.
3. Inspect the product and package prior to use. Do not use the trocar set if there is any evidence that the package has been punctured or the product damaged. The top of the Needle is extremely delicate and may be damaged if dropped or otherwise mishandled.
4. Extreme care should be used during placement and insertion to avoid unintentional puncture of any internal organs.
5. Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.
6. Remove protective tip cover before use.

Instructions

1. Remove protective tip cover.
2. Inspect tip for damage.
3. Make a small incision just below the ribs and lateral to the upper 5 mm trocar. Pulling Hartmans Pouch inferior and lateral will help obtain a better angle for insertion.
4. Insert the two-piece needle set through the body cavity.
5. Remove the stylet and insert catheter through the hemostasis valve of the cannula and into the cystic duct.

Specification

Inner Diameter	Length	Material
0.080 inches (2mm)	17 cm usable length	Nylon

WARNING

THIS PRODUCT IS STERILIZED UTILIZING ETHYLENE OXIDE. THESE PRODUCTS CAN EXPOSE YOU TO CHEMICALS INCLUDING ETHYLENE OXIDE (EtO), WHICH IS KNOWN TO THE STATE OF CALIFORNIA TO CAUSE CANCER AND/OR BIRTH DEFECTS OR OTHER REPRODUCTIVE HARM. FOR MORE INFORMATION GO TO www.P65Warnings.ca.gov

Contraindications / Possible Adverse Effects

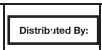
This device is single use only. Do not reuse, reprocess, or re-sterilize. The cleanliness and sterility of the re-processed device cannot be assured. Reuse of the device may lead to cross contamination, infection, or patient death. The performance characteristics of the device may be compromised due 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.

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	No Dropping Peel Pouch into Sterile Field	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 Overinflate Balloon. Do Not Use if Balloon is Folded.

						
Do Not Reuse	CAUTION: This product contains natural rubber latex which may cause allergic reactions.	After use, this product may be a potential biohazard. Handle and dispose of this product in accordance with acceptable medical practice and applicable laws and regulations	Manufacturer	Sterilization by Ethylene Oxide	Use by Date	Do Not Resterilize

	
Warning	Contains or Presence of Phthalates

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