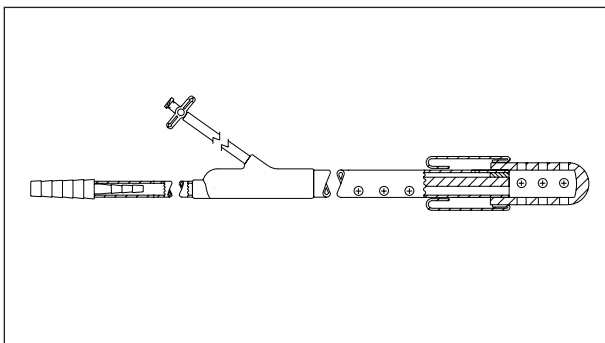


LAP-BAND® System Calibration Tube

DIRECTIONS FOR USE (DFU)



Rx Only

 apollo
endosurgery

LAP-BAND® System Calibration Tube

The LAP-BAND® System Calibration Tube is a flexible gastric tube designed to be used in gastric and bariatric surgical procedures including gastrectomy, fundoplication, gastric banding, vertical banded gastroplasty and gastric bypass. The catheter provides visible and tactile delineation of the antrum of the stomach along with the ability to decompress the stomach, drain and remove gastric fluid and size a gastric pouch.

DESCRIPTION

LAP-BAND® System Calibration Tube
(Reference No. A-2017)

The dual lumen LAP-BAND® System Calibration Tube (Figure 1) utilizes one lumen for drainage, suction and irrigation (A) and the second lumen to inflate/deflate the fixation/balloon (B). The catheter is attached to a 36-inch suction tubing and a 6-inch tubing with a stopcock for filling the balloon.

INDICATIONS

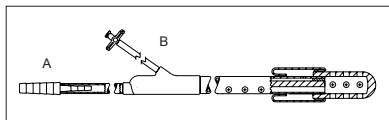


Figure 1 Calibration Tube

The LAP-BAND® System Calibration Tube is indicated for use in gastric and bariatric surgical procedures to decompress the stomach, drain and remove gastric fluid and size the gastric pouch.

CONTRAINDICATIONS

The LAP-BAND® System Calibration Tube is contraindicated when general or bariatric surgical procedures are contraindicated.

COMPLICATIONS

Complications which may result from the use of this product include the risks associated with the medications and methods utilized in the surgical procedure, the risks associated with any surgical procedure and the patient's degree of intolerance to a gastric tube.

SURGICAL PROCEDURE

Decompression

The LAP-BAND® System Calibration Tube is inserted into the esophageal passage and advanced into the stomach. Once in the stomach, the distal end of the tube is connected to standard low vacuum suction and the stomach is decompressed, removing air and/or gastric fluid.

Pouch Calibration

After decompression is completed and all air and fluids removed, the balloon attached to the tube is inflated with 15-25 cc of air or saline and drawn up to the cardia. Do not overinflate the balloon as this could rupture and cause damage to surrounding tissues. The bulge created by the balloon can be seen and a visible boundary is established for gastric dissection, band placement or staple resection.

After gastric dissection, band placement or staple resection, the balloon is deflated and the catheter is removed. The surgical procedure is then completed using standard techniques.

HOW SUPPLIED

The LAP-BAND® System Calibration Tube is supplied non-sterile and for single use only.

Note: Do not autoclave the LAP-BAND® System Calibration Tube as this will damage the device.

RISKS OF RE-USE

The Calibration Tube is a non-sterile product for single use only. Do not use a calibration tube that appears damaged (cut, torn, etc.) in any way. The Calibration Tube is not intended to be sterilized or re-used. Cleaning and autoclaving processes may cause damage to the components resulting in incomplete inflation, distortion or leakage, and improper function. Re-use of the device can cause infection to the patient.

RETURNED GOODS POLICY

Authorization must be received from your Apollo Endosurgery Account Manager prior to return of the merchandise. Merchandise returned must have all the manufacturer's seals intact to be eligible for credit or replacement. Products returned may be subject to restocking charges.

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**AUTHORIZED TRAINING PROGRAM AND
PRODUCT INFORMATION**









LAP-BAND® System placement is an advanced laparoscopic procedure. Surgeons planning LAP-BAND® System placement must participate in a LAP-BAND® System training program authorized by Apollo Endosurgery, Inc. or an authorized Apollo distributor. This required training program is specific to the Apollo LAP-BAND® System and does not qualify for use with other gastric bands.

For additional information, please contact:

Manufacturer

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CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

	Non-sterile
	Caution. See instructions for use.
	Lot Number
	Date of Manufacture - Year, Month & Date
	Reference Number
Rx Only	CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.
	Do not use if package is damaged.
	Product contains no latex.
	Single use only. Do not re-use.



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