The RapidPort® EZ Tubing Kit

DIRECTIONS FOR USE (DFU)
The RapidPort® EZ Tubing Kit (English)

Ref. No. A-20331 LAP-BAND AP® System RapidPort®
EZ Tubing Kit

INTRODUCTION
The LAP-BAND AP® Adjustable Gastric Banding System is designed to induce weight loss in severely obese patients by limiting food consumption. With this system, no cutting or stapling of the stomach is required and there is no bypassing of portions of the stomach or intestines.

The RapidPort® EZ Tubing Kit is a replacement part for the LAP-BAND AP® Adjustable Gastric Banding System. Deflation of the band may occur due to damage to the Silicone Tubing. If such complications should arise, the individual component can be replaced with the RapidPort® EZ Tubing Kit.

RAPIDPORT® EZ TUBING KIT DESCRIPTION
The RapidPort® EZ Tubing Kit contains the following components:
• 1 each Silicone Tubing, 61.12 cm (24.5 inch) (sterile)
• 1 each End Plug (sterile)
• 1 each Band blunt flushing needle, 16 gauge, 40.5 mm (1.6 inch) (sterile).

INDICATIONS
Indications for Silicone Tubing replacement are:
• Repositioning or relocating of the RapidPort® EZ Access Port
• A tubing leak

CONTRAINDICATIONS
The LAP-BAND® System Tubing Kits are contraindicated in patients where the LAP-BAND® System is contraindicated, and:
1. Patients who have an infection anywhere in the body or where the possibility of contamination prior to or during the surgery exists.
2. Patients who are known to have, or are suspected to have, an allergic reaction to materials contained in the system or who have exhibited a pain intolerance to implanted devices.

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 any foreign object implanted in the body. Infection can occur in the immediate postoperative period or years after insertion of the device. In the presence of infection or contamination, removal of the device may be indicated. Deflation of the band may occur due to leakage from the band, the port, or the connecting tubing.

The material in this device has been shown in biocompatibility studies to cause slight irritation in intermuscular implantation in animal models.

HOW SUPPLIED
The RapidPort® EZ Tubing Kit components are sterile and for single use only.

The RapidPort® EZ Tubing Kit components are provided sterile in double packaging with a protective outer container. If the package has been opened outside the sterile field, the product must be considered non-sterile.

RISKS ASSOCIATED WITH RE-USE
The RapidPort® EZ Tubing Kit is not intended to be re-sterilized or re-used. Cleaning and autoclaving processes can cause damage to the components resulting in improper function and possible failure of connectors. Such failures would lead to band deflation and would require re-entry in order to resolve. Reuse of the device can cause risk of infection to the patient.

PREPARATION OF ACCESS PORT OR LAP-BAND® SYSTEM
Depending on the area or location of the repair, it is possible that the RapidPort® EZ Access Port and/or the LAP-BAND® System will need to be flushed with sterile saline to remove trapped air prior to placement. Refer to the LAP-BAND® System Directions for Use (DFU) for additional information.

RETURNED GOODS POLICY
Authorization must be received from your distributor 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 maybe subject to restocking charges.

LIMITED WARRANTY, LIMITATION OF LIABILITY AND DISCLAIMER OF OTHER WARRANTIES
There is no express or implied warranty, including without limitation any implied warranty of merchantability or fitness for a particular purpose, on the Apollo Endosurgery, Inc. product(s) described in this publication. To the fullest extent permitted by applicable law, Apollo Endosurgery, Inc. disclaims all liability for any indirect, special, incidental, or consequential damages, regardless of whether such liability is based on contract, tort, negligence, strict liability, products liability or otherwise. The sole and entire maximum liability of Apollo Endosurgery, Inc., for any reason, and buyer’s sole and exclusive remedy for any cause whatsoever, shall be limited to the amount paid by the customer for the particular items purchased. No person has the authority to bind Apollo Endosurgery, Inc. to any representation or warranty except as specifically set forth herein. Descriptions or specifications in Apollo Endosurgery, Inc. printed matter, including this publication, are meant solely to generally describe the product at the time of manufacture and do not constitute any express warranties or recommendations for use of the product in specific circumstances. Apollo Endosurgery, Inc. expressly disclaims any and all liability, including all liability for any direct, indirect, special, incidental, or consequential damages, resulting from reuse of the product.
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 Endosurgery, Inc. distributor. This required training program is specific to the Apollo Endosurgery, Inc. LAP-BAND® System and does not qualify for use with other gastric bands.

For additional information please contact:

Manufacturer
Apollo Endosurgery, Inc.
Austin, TX 78746 USA
Tel: (512) 279-5100
Fax: (512) 279-5105

CAUTION: This device restricted to sale by or on the order of a physician.

Not made with natural rubber latex.

Patented. See: www.apolloendo.com/patents
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