

The RapidPort® EZ Tubing Kit

DIRECTIONS FOR USE (DFU)

Rx Only



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

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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 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
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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

	Sterilized using steam or dry heat.
	Caution. See Instructions for Use.
	Single Use Only. Do Not Re-use.
 YYYY-MM-DD	Use By Year, Month, & Day
	Manufacturer
	Serial Number
	Reference Number
	Do not use if package is damaged
Rx Only	Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.



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Assembled in Costa Rica

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GRF-00295-00R02

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