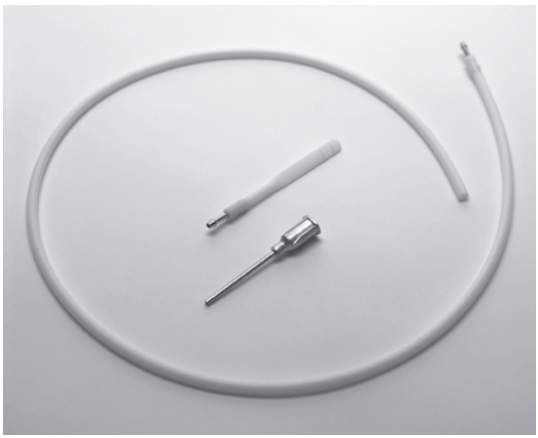
LAP-BAND® SYSTEM

LAP-BAND® System Tubing Kit

DIRECTIONS FOR USE (DFU)



Rx Only

apollo endosurgery

LAP-BAND® System Tubing Kit

INTRODUCTION

The LAP-BAND® 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 LAP-BAND® System Tubing Kit is a replacement part for the LAP-BAND® Adjustable Gastric Banding System. Deflation of the band may occur due to leakage at the Stainless Steel Connector transition or the connecting Silicone Tubing. If such complications should arise, the individual component can be replaced with the LAP-BAND® System Tubing Kit.

LAP-BAND® System Tubing Kit (Ref. No. A-20401)

DESCRIPTION

The LAP-BAND® System Tubing Kit contains the following components:

- 1 each Silicone Tubing, 50.8 cm (sterile)
- 2 each Stainless Steel Connectors (sterile)
- 1 each End Plug (sterile)
- 1 each Band Priming Needle, 40.5 mm (sterile)

INDICATIONS

Indications for Silicone Tubing or Stainless Steel Connector replacement are:

- Repositioning or relocating of the Access Port
- A tubing leak at or near the Stainless Steel Connector

CONTRAINDICATIONS

The LAP-BAND® System Tubing Kit is 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 biocompatability studies to cause slight irritation in intermuscular implantation in animal models.

RISK ASSOCIATED WITH RE-USE

The LAP-BAND® Tubing Kit is not intended to be re-sterilized or re-used. Cleaning and autoclaving processes may cause damage to tubing and/or components resulting in improper function and possible failure. Reuse of the tubing and/or components can cause infection to the patient.

HOW SUPPLIED

The LAP-BAND® System Tubing Kit components are sterile and for single use only.

The LAP-BAND® System 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.

PREPARATION OF ACCESS PORT OR LAP-BAND® SYSTEM

Depending on the area or location of the repair, it is possible that the 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 Surgical Procedures for additional information if necessary.

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. Returned products are subject to restocking charges. No credit will be issued on marked or damaged boxes with stickers.

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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 or an authorized Apollo Endosurgery distributor. This required training program is specific to the Apollo Endosurgery 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 U.S.A.
Tel: (512) 279-5100
Fax: (512) 279-5105

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

The LAP-BAND® Adjustable Gastric Banding System contains no latex or natural rubber materials.

Patented. See www.apolloendo.com/patents.

	Sterilized using steam or dry heat
	Caution. See instructions for use.
	Single Use Only. Do Not Reuse.
 YYYY-MM-DD	Use By Year, Month, & Day
	Manufacturer
SN	Serial Number
REF	Reference Number
	Do not use if package is damaged
	Product contains no latex
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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