RapidPort® EZ Access Port Kit

DIRECTIONS FOR USE (DFU)

Rx Only

apollo endosurgery

The RapidPort® EZ Access Port Kit

INTRODUCTION

The RapidPort® EZ Access Port Kit is connected to the LAP-BAND AP® Adjustable Gastric Banding System with silicone tubing. The RapidPort® EZ Access Port Kit is for percutaneous adjustment of the stoma diameter and is self-sealing when penetrated by the Access Port Needle. The access port is provided as part of the LAP-BAND AP® Adjustable Gastric Banding System and is available as a replacement port.

The RapidPort® EZ Access Port has two variations that are distinguishable via x-ray. The chart below indicates visible differences, fill volumes, and which LAP-BAND® Systems with RapidPort® EZ they are used for.

ACCESS PORT VARIATIONS		
LAP-BAND® System:	# Radiopaque Markers	Fill Volume
AP® Standard	1	0-10 cc
AP® Large	2	0-14 cc

DESCRIPTION

The RapidPort® EZ Access Port Kit contains the following components:

- RapidPort® EZ Access Port (sterile), one each
- Band blunt flushing needle, 16 gauge, 40.5 mm (1.6 inch) (sterile), one each
- Access Port blunt flushing needle, 22 gauge, 57 mm (2.25 inch) (sterile), one each
- Silicone Tubing, 61.12 cm (24.5 inch) (sterile), one each
- Strain Relief (sterile), one each
- End Plug (sterile), one each

ACCESS PORT FEATURES:

The access port is for percutaneous adjustment of the stoma diameter and is self-sealing when penetrated by the Access Port Needle.

FEATURES INCLUDE:

1. High-compression septum; tested to over 200 punctures with a 20 gauge non-coring needle.
2. Titanium Alloy reservoir; positive tactile feedback when the Access Port Needle makes contact with the titanium reservoir, designed for long-term durability and reservoir integrity.
3. Stainless Steel anchors; method of access port fixation, taking the place of suturing.

Warning: the RapidPort® EZ Access Port's Stainless Steel anchors contain Nickel which is a known allergen.

4. Radiopaque and compatible with diagnostic imaging; including MRI (3T or lower MRI scans) and CT scanning. (Please refer to MRISafety.com for more information.)
5. Contoured plastic housing; light-weight smooth and rounded.

INDICATIONS FOR RAPIDPORT® EZ ACCESS PORT KIT REPLACEMENT ARE:

1. A leaking port (the LAP-BAND® System will not maintain its adjustment).
2. Removal of an access port from an infected site.
3. Contamination of an access port.

CONTRAINDICATIONS

The RapidPort® EZ Access Port Kit is contraindicated in the 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 suspected to have, an allergic reaction to materials contained in the system or who have exhibited a pain intolerance to implanted devices.

WARNINGS AND PRECAUTIONS

Patients should be advised not to consider their implants lifetime devices; explant and replacement surgery may be indicated at any time. Medical management of adverse reactions may include explantation. Revision surgery for explantation and replacement may also be indicated to achieve patient satisfaction.

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 post-operative period or years after insertion of the device. In the presence of infection or contamination, removal of the device is indicated.

Deflation of the band may occur due to leakage from the band, or the port, or the connecting tubing.

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

HOW SUPPLIED

The RapidPort® EZ Access Port Kit and components are for single use only.

The RapidPort® EZ Access Port Kit and 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.

RAPIDPORT® EZ ACCESS PORT PREPARATION

1. Remove the access port and the 22 gauge blunt flushing needle from the sterile container.
2. Attach a 5cc saline-filled syringe to the blunt flushing needle.
3. Hold the access port in an upright position with the port on the bottom and the access port's outlet barb facing up.
4. Inject sterile saline into the access port's outlet barb to irrigate the access port. As the access port fills with sterile saline, air and excess fluid will be forced out of the access port past the blunt flushing needle.
5. The access port is now full of saline, mostly free of air, and ready to be attached to the implanted band tubing. Keep the access port upright until it is attached to the band fill tubing.

Access Port Placement and Closure: The band tubing is brought outside the abdomen. The tubing may be shortened to tailor the position of the access port to the patient while avoiding tension between the port and the band. Lengthen the tubing by using a section of the silicone tubing and a connector (provided). The Strain Relief is threaded over the LAP-BAND® System tubing with the locking mechanism end of the Strain Relief pointing toward the end of the tubing; allow 2 cm of tubing to extend beyond the Strain Relief (Figure 1).

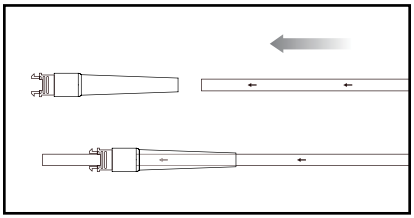

Figure 1. Strain Relief and end of tubing alignment

The tubing is then pushed onto the Access Port's outlet barb until the tubing is flush against the Access Port (Figure 2).

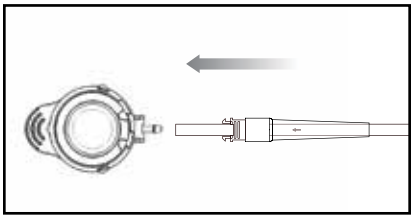

Figure 2. Tubing alignment with Access Port's outlet barb

The Strain Relief is then locked into the Access Port's port housing (Figure 3).

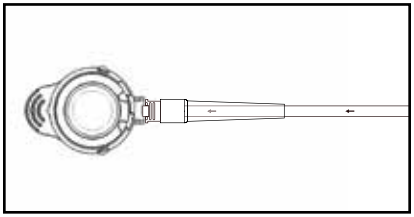

Figure 3. Strain Relief locked into the Access Port's port housing

The RapidPort® EZ Access Port's safety cover (black cover) is then removed and discarded and the access port is placed on, or in the rectus muscle or in an accessible subcutaneous site. The access port is sutured in place utilizing the three suture holes in the port base or secured in place by use of the RapidPort® EZ Port Applier (B-20390). Refer to the RapidPort® EZ Port Applier Directions for Use for detailed information on the RapidPort® EZ fixation feature.

The trocar holes are then closed.

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 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 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 U.S.A.
Tel: (512) 279-5100
Fax: (512) 279-5105

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

The LAP-BAND® System Access Port II Kit 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 Re-use.
	Use By Year, Month, & Day
	Manufacturer
	Serial Number
	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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Manufacturer
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Assembled in Costa Rica

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