RapidPort® EZ Access Port Kit

DIRECTIONS FOR USE (DFU)

Rx Only

apollo endosurgery

RapidPort® EZ Access Port Kit

Ref. No. C-2304 Standard RapidPort® EZ Access Port Kit
Ref. No. C-2306 Large RapidPort® EZ Access Port Kit

INTRODUCTION

The RapidPort® EZ Access Port is connected to the LAP-BAND AP® Adjustable Gastric Banding System with silicone tubing. The RapidPort® EZ Access Port 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 with which LAP-BAND® systems they are used.

ACCESS PORT VARIATIONS			
RapidPort® EZ Access Port Kit Ref. No.	**LAP-BAND® system:**	**# Radiopaque Markers**	**Fill Volume**
C-2304	AP Standard	1	0-10 cc
C-2306	AP Large	2	0-14 cc

RAPIDPORT® EZ ACCESS PORT KIT DESCRIPTION

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

- RapidPort® EZ Access Port with stainless steel connector (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, 127 mm (5 inch) (sterile), one each
- Access Port Needle, 20 gauge, 89 mm (3.5 inch) (sterile), one each
- Silicone tubing, 495 mm (19.5 inch) (sterile), one each
- Stainless steel connector (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. Stainless steel anchors for alternate access port fixation, taking the place of suturing or other fixation method.
3. Radiopaque and compatible with diagnostic imaging; including MRI (3T or lower MRI scans) and CT scanning, although a minimal “halo” effect has been reported due to the stainless steel tubing connector. Please refer to MRISafety.com for more information.
4. Contoured plastic housing; light-weight smooth and rounded.
5. Strain relief; tested to ensure tubing remains intact after 2 million cycles of flexing.
6. Needle guard; tested to ensure tubing does not leak after 30 needle punctures.

INDICATIONS

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 that the LAP-BAND® System is a long-term implant. Medical management of adverse reactions may include explantation. Revision surgery for explantation and replacement may also be indicated to achieve patient satisfaction.

The RapidPort® EZ Access Port’s stainless steel anchors contain nickel, which is a known allergen.

ADVERSE EVENTS

Adverse events that may result from the use of this product include:

1. The risks associated with the medications and methods utilized in the surgical procedure,
2. The risks associated with any surgical procedure and the patient’s degree of intolerance to any foreign object implanted in the body.
3. 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 is indicated.
4. Deflation of the band may occur due to leakage from the band, the port, or the connecting tubing.
5. The material in this device has been shown in biocompatibility studies to cause slight irritation in intramuscular implantation in animal models.

Please refer to the LAP-BAND® System DFU for additional adverse event information.

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.

INSTRUCTIONS FOR USE

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 tubing facing up.
4. Inject sterile saline into the access port tubing to irrigate. 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

6. After the band is placed, 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. Remove the end plug from the band tubing. Then, push the access port tubing with stainless steel connector onto the band tubing until it is flush against the band tubing (**Figure 1**).

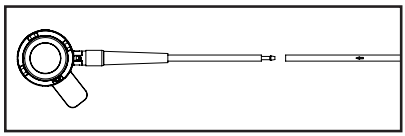

Figure 1. Band tubing and port tubing connection

7. Pull the black safety cover off the bottom of the access port and discard it.
8. Place the access port on or in the rectus muscle or in an accessible subcutaneous site. The access port is secured in place by sutures utilizing the three suture holes in the port base, stainless steel anchors using the RapidPort® EZ Port Applier (C-20390), or other fixation methods. Refer to the RapidPort® EZ Port Applier Directions for Use for detailed information on the RapidPort® EZ fixation feature.

CAUTION: Failure to create a stable, smooth path for the access port tubing, without sharp turns or bends, can result in tubing breaks and leakage. In order to avoid incorrect placement, the access port should be placed lateral to the trocar opening. A pocket must be created for the access port so it is placed far enough from the trocar path to avoid abrupt kinking of the tubing. The tubing path should point in the direction of the RapidPort® EZ Access Port connector. (**Figure 2**)

9. Once the access port is placed, the trocar holes are then closed.

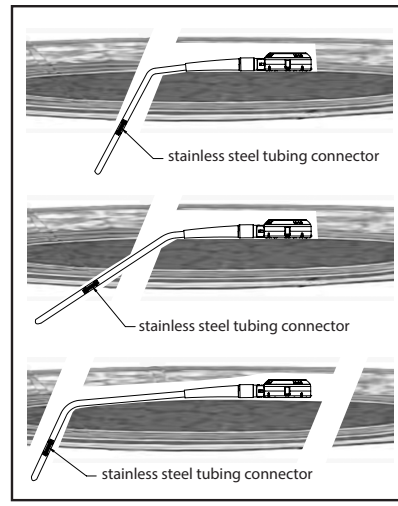

Figure 2. Port Placement Options

MEDICAL IMAGING

The LAP-BAND® System has been proven to be MRI safe per testing conducted by Apollo Endosurgery, Inc. when exposed to 3T or lower MRI scans. (Please refer to MRISafety.com for more information.)

MRI Safety Information

MR
MR Conditional

Non-clinical testing demonstrated that the LAP-BAND AP® System RapidPort EZ Access Port Kit (B-2304, B-2306) is MR Conditional. A patient with this device can be scanned safely in an MR system immediately after placement under the following conditions:

- Static magnetic field of 1.5T-Tesla and 3-Tesla, only
- Maximum spatial gradient magnetic field of 3000 Gauss/cm or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning

Under the scan conditions defined, the LAP-BAND AP® System RapidPort EZ Access Port Kit (B-2304, B-2306) is expected to produce a maximum temperature rise of 1.7°C after 15-minutes of continuous monitoring.

In non-clinical testing, the image artifact caused by the RapidPort EZ Access Port extends approximately 20 mm from this implant when imaged using a gradient echo pulse sequence and a 3-Tesla MR system.

RETURNED GOODS POLICY

Authorization must be received from your Apollo Endosurgery, Inc. 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, 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.

Not made with natural rubber latex.

Patented. See: www.apollendo.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
Rx Only	Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.
	MR Conditional

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Assembled in Costa Rica

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