

LAP-BAND® System Access Port I Kit

DIRECTIONS FOR USE (DFU)



Access Port Needle



Access Port Priming Needle



Access Port I



End Plug



Band Priming Needle



Stainless Steel Connectors



Tubing

Rx Only

Ref. No. B-2101 LAP-BAND® Access Port Kit, Access Port, Tapered Connector

Ref. No. B-2104 LAP-BAND® Access Port Kit, Access Port, VG

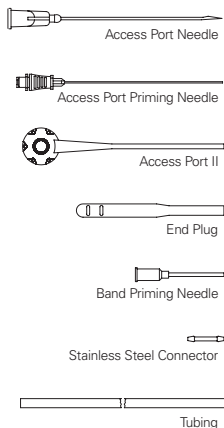
Ref. No. B-2107 LAP-BAND® Access Port Kit, Access Port

INTRODUCTION

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

Description

The Access Port I Kit contains the following components:



ACCESS PORT FEATURES:

- High-compression septum; tested to over 200 punctures with a 20 gauge noncoring needle.
- Titanium reservoir; positive tactile feedback designed for long-term durability when the Access Port needle makes contact; resists gouging from repeated needle contact for long-term reservoir integrity.
- Radiopaque and compatible with diagnostic imaging including MRI and CT scanning (the small stainless steel connector attached to the Access Port I tubing has been reported to interfere minimally with MRI scanning).
- Contoured polysulfone housing: lightweight, smooth and rounded.
- A stainless steel connector used with ligatures to join the tubing of the band to the Access Port I.

The Access Port I Kit is available in three variations.

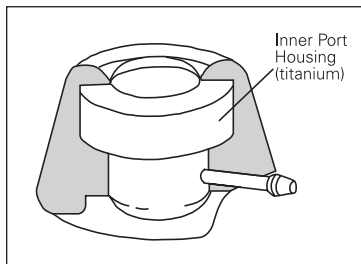


Figure 1. Cross-section view of the Access Port I. This large, round titanium area holds the self-healing septum. The smaller portion is the fluid chamber

They are distinguishable, via x-ray, by the number of radiopaque markers embedded in the septum (see Figures 2-4). Use the chart below to ensure you are using the correct Access Port for the particular LAP-BAND® System implanted in your patient. To aid the Doctor and/or staff during adjustments, the number of radiopaque markers embedded in the Access Port septum indicate which Access Port is implanted and what the corresponding fill volume range is.

LAP-BAND® System Access Port I Usage			
LAP-BAND® System	Fill Volume Range	Access Port I Kit Cat. #	# of Radiopaque Markers
9.75	0-4 cc	B-2101	0
10.0	0-4 cc	B-2101	0
VG	0-10 cc	B-2104	1
AP Standard	0-10 cc	B-2104	1
AP Large	0-14 cc	B-2107	2

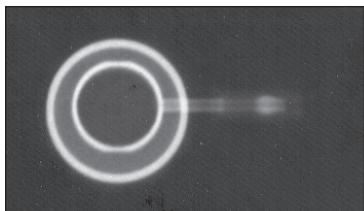


Figure 2. Top or bottom X-ray view of the B-2101 Access Port I

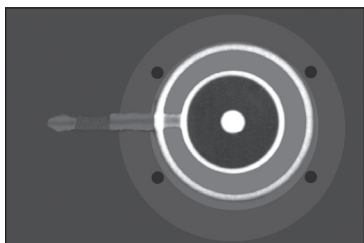


Figure 3. Top or bottom X-ray view of the B-2104 Access Port I

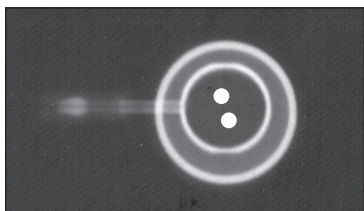


Figure 4. Top or bottom X-ray view of the B-2107 Access Port I

INDICATIONS

Indications for Standard Access Port replacement are:

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

CONTRAINDICATIONS

The Access Port I is contraindicated in patients where the LAP-BAND® System is contraindicated, and:

1. Patients who have an infection anywhere in the body or 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. 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.

CAUTION: Failure to create a stable, smooth path for the Access Port I tubing, without sharp turns or bends, can result in tubing breaks and leakage. In order to avoid incorrect placement, the Access Port I should be placed lateral to the trocar opening.

A pocket must be created for the Access Port I, 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 Access Port I connector so the tubing will form a straight line with a gentle arching transition into the abdomen.

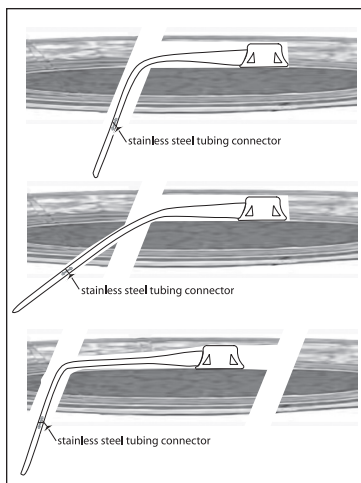


Figure 5. Port Placement Options

COMPLICATIONS

Complications that 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, the port or the connecting tubing.

HOW SUPPLIED

The Access Port I and components are for single use only.

The Access Port I and components are provided sterile in double packaging with a protective outer container. The Access Port I needle is provided sterile in separate packaging. If the package has been opened outside the sterile field, the product must be considered non-sterile.

ACCESS PORT I PREPARATION

The Access Port I is flushed with sterile saline to remove air prior to placement. The flushing of the Access Port I is accomplished by using a 3 or 5 cc syringe filled with sterile saline and a 22-gauge (127 mm) blunt needle (provided with system) which fits loosely inside the fill tubing of the port. The following technique is recommended for flushing the Access Port I:

1. Hold the Access Port I with the fill tubing upright.
2. Attach a 3 or 5 cc saline-filled syringe to the 22-gauge blunt flushing needle.
3. Inject sterile saline to irrigate the Access Port I. As it fills, all air and excess fluid will be forced out of the tubing past the blunt needle.
4. Keep the Access Port I tubing upright until it is attached to the band fill tubing.

The Access Port I and tubing are now full of saline, free of air, and ready to be attached to the implanted band tubing.

MRI Safety Information



Non-clinical testing demonstrated that the LAP-BAND AP[®] System Access Port I Kit (B-2101, B-2104, B-2107) 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 Access Port I Kit (B-2101, B-2104, B-2107) 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 worst case Apollo Endosurgery access port extends approximately 20 mm from the 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 Account Manager prior to return of the merchandise. Returned merchandise must have all the manufacturer's seals intact to be eligible for credit or replacement. Products returned may be 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 ORDERING 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 distributor. This required training program is specific to the Apollo 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.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.



MR Conditional



Manufacturer
Apollo Endosurgery, Inc.
Austin, TX 78746 U.S.A.

Assembled in Costa Rica

Tel: (512) 279-5100
Fax: (512) 279-5105

www.apolloendo.com

GRF-00297-00R03

All rights reserved.

© 2014 Apollo Endosurgery, Inc., Austin, TX

Apollo Endosurgery and LAP-BAND
are worldwide trademarks or registered
trademarks of Apollo Endosurgery, Inc.