LAP-BAND® System
Access Port II Kit

DIRECTIONS FOR USE (DFU)

Access Port Needle

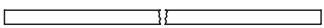
Access Port Priming Needle

Access Port II

End Plug

Band Priming Needle

Stainless Steel Connector



Tubing

Rx Only

apollo endosurgery

LAP-BAND® System Access Port II Kit

INTRODUCTION

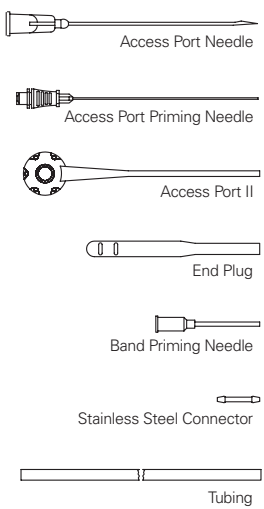
The LAP-BAND® System Access Port II is connected to the LAP-BAND® Adjustable Gastric Banding System with silicone tubing. The Access Port II is for percutaneous adjustment of the stoma diameter and is self-sealing when penetrated by the Access Port needle. The Access Port II is part of the LAP-BAND®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

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

ACCESS PORT II VARIATIONS			
LAP-BAND® System	Septum	#Radi-opaque Markers	Fill Volume
9.75 /10.0	white	0	0-4 cc
VG AP® Standard	clear	1	0-10 cc
AP® Large	clear	2	0-14 cc

DESCRIPTION

The Access Port II Kit contains the following components:

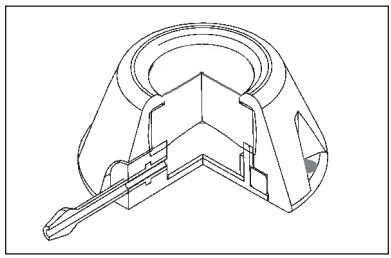


ACCESS PORT FEATURES:

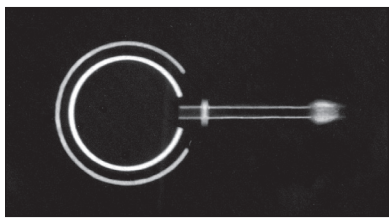
Access Port II Kit (9.75/10.0)
Access Port II Kit (VG, AP® Standard)
Access Port II Kit (AP® Large)

Features Include:

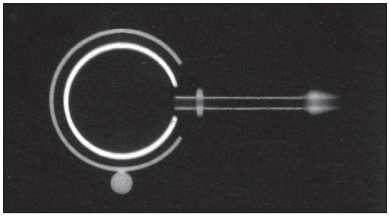
- High-compression septum; tested to over 200 punctures with a 20 gauge non-coring needle.
- Titanium protective base plate; positive tactile feedback, designed for long-term durability when the access port needle makes contact, resists gouging from repeated needle contact for long-term reservoir integrity.
- Radiopaque and compatible with diagnostic imaging; including MRI and CT scanning (the small stainless steel connector attached to the access port tubing has been reported to interfere minimally with MRI scanning).
- Contoured acetal copolymer housing; light-weight, smooth and round
- A stainless steel connector which is used with ligatures to join the tubing of the band to the Access Port II.



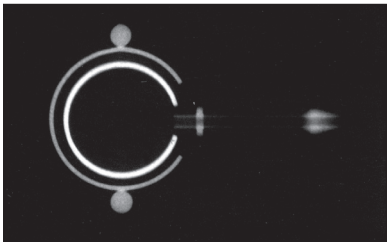
Cross-section view of the Access Port II



Radiographic top or bottom view of the Access Port II for the LAP-BAND® System 9.75 and 10.0



Radiographic top or bottom view of the Access Port II for the LAP-BAND® VG System, and the LAP-BAND AP® System Standard. Note the single radiopaque marker.



Radiographic top or bottom view of the Access Port II for the LAP-BAND AP® System Large. Note the two radiopaque markers.

INDICATIONS

Indications for Access Port II replacement are:

1. A leaking port (the LAP-BAND® System will not maintain its adjustment).
2. Due to removal of an Access Port II from an infected site.
3. Contamination of the Access Port II.

CONTRAINDICATIONS

The Access Port II 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, 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 Access Port II and components are for single use only.

The Access Port II and components are provided sterile in double packaging with a protective outer container. The Access Port 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 II PREPARATION

1. Remove Access Port along with the 22 gauge blunt flushing needle from the sterile container
2. The blunt flushing needle fits loosely inside the fill tubing of the Access Port. Do not attempt to insert it into the port.
3. Hold the Access Port with the fill tubing in an upright position with the port on the bottom.
4. Attach a 5cc saline-filled syringe to the blunt flushing needle.
5. Inject sterile saline to irrigate the Access Port. As it fills, all air and excess fluid will be forced out of the tubing past the blunt flushing needle.
6. Keep the port tubing upright until it is attached to the band fill tubing.
7. The Access Port and tubing are now full of saline, mostly 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 II Kit (B-2105, B-2106) 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 II Kit (B-2105, B-2106) 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 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 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.

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.
	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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