LAP-BAND® SYSTEM

LAP-BAND® System Adjustment Kit

DIRECTIONS FOR USE (DFU)

Rx Only

apollo endosurgery

INTRODUCTION

The B-20310-10 LAP-BAND® System Adjustment Kit consists of single-use items used to perform standard adjustments to the LAP-BAND® System and to provide additional information for the patient. The kit contains the following items:

1) Sterile non-pyrogenic, isotonic 0.9% saline in a pre-filled 10 cc syringe
2) Sterile Access Port Needle (Huber-type, straight, non-coring 20-gauge x 2" needle)
3) Sterile One-Way Stopcock w/swivel Luer Lock
4) Sterile Alcohol pad
5) Sterile adhesive bandage
6) Sterile medium exam gloves (latex-free)
7) Patient Materials

Description of Access Port Needle

The Access Port Needle is a non-coring deflected tip ("Huber tip") needle for use with the LAP-BAND® Adjustable Gastric Banding System. The needle is used to penetrate the septum of the LAP-BAND® System Access Port during adjustment of the LAP-BAND® Adjustable Gastric Banding System.

Indications and Contraindications

Please refer to the DFU (Directions For Use) provided with the LAP-BAND® Adjustable Gastric Banding System for indications, contraindications, warnings, precautions, instructions for use and other important information regarding the use of the LAP-BAND® Adjustable Gastric Banding System and the Access Port Needle.

How Supplied

The contents of the pre-filled syringe, needle, stopcock, adhesive bandage, alcohol pad and exam gloves are supplied STERILE. If the package has been damaged or opened prior to use, the sterile components must be considered non-sterile and should not be used on a patient. The contents are for single use only. CAUTION: Do not attempt to clean, re-sterilize or re-use the Access Port Needle or any other component of the Kit.

Instructions for Use: Band Adjustment

Postoperatively, the surgeon may adjust the stoma size percutaneously by injecting or aspirating saline with the Access Port needle via the self-sealing Access Port.

The following are general guidelines for LAP-BAND® System adjustments:

1. The first postoperative adjustment should occur after six weeks. Usually 1-2 cc of normal saline would be added for the 9.75 and 10.0 cm LAP-BAND® Systems and between 1-3 cc of normal saline would be added for the LAP-BAND® VG System.
2. The patient should be reviewed regularly (every 4-6 weeks, depending on need), and weight and clinical status measured. If the weight loss has averaged less than 1 lb per week over the period, and the patient indicates there is not excessive restriction to eating, a further increment of fluid should be added.
3. Where the average weight loss between visits has been greater than 2 lbs per week, normally no additional fluid would be added.
4. If the weight loss averaged between 1 and 2 lbs per week, additional fluid would be indicated if the patient felt he/she could eat too freely or found difficulty in complying with the dietary rules.
5. Fluid would be removed from the system if there were symptoms of excessive restriction or obstruction, including excessive sense of fullness, heartburn, regurgitation and vomiting. If symptoms are not relieved by removal of the fluid, a barium meal should be used to evaluate the anatomy.

Prior to doing an adjustment to decrease the stoma, review the patient's chart for total band volume and recent adjustments. If recent adjustments have not been effective in increasing restriction and the patient has been compliant with nutritional guidelines, the patient may have a leaking band system, or may have pouch enlargement or esophageal dilatation due to stomal obstruction, band slippage or over-restriction.

Band system patency can be confirmed by injecting saline into the band system, then immediately withdrawing it. An absence or decrease in fluid volume indicates a leak in the system may exist. The band may be evaluated for a leak using a radiopaque solution, such as Hypaque or Conray-43, flushing it from the band system after the evaluation. If pouch enlargement or band/stomach slippage is suspected, a limited upper GI with a small amount of barium or gastrografin can be used to evaluate the size of the pouch, the gastric stoma and the position of the band.

CAUTION: Insufficient weight loss may be a symptom of inadequate restriction (band too loose). Or, it may be a symptom of pouch or esophageal enlargement and may be accompanied by other symptoms such as heartburn, regurgitation or vomiting. If this is the case, inflation of the band would not be appropriate.

Excessive restriction may result in a closed stoma. Because of the possible complications that can occur with excessive restriction, a doctor familiar with the adjustment procedure must be available for several days post-adjustment to adjust the stoma in case of an emergency.

Deflation (an increase in stoma size) is considered if the patient experiences frequent episodes of vomiting, is unable to swallow liquids or appropriate foods, or if there are medical indications for increasing nutrient intake. Elective deflation of the band is advisable in the following situations:

- Pregnancy
- Significant concurrent illness
- General anesthesia
- Remote Travel
- Travel to areas where food or water contamination is endemic

CAUTION: Esophageal distension or dilatation has been reported and may be associated with stoma obstruction because of incorrect band placement or over-restriction due to excessive band inflation. Patients should not expect to lose weight as fast as gastric bypass patients, and band inflation should

proceed in small increments. Deflation of the band is recommended if esophageal dilatation develops.

If esophageal dilatation is present, then steps should be taken to identify and resolve the cause(s). Deflation of the band may resolve dilatation that is entirely due to over-restriction. Dietary evaluation and appropriate nutritional counseling regarding correct eating behavior should follow band deflation and precede subsequent gradual re-inflations. Re-inflation of the band should be conducted gradually in small increments over several months. Dietary counseling should be ongoing, and repeat upper GI exams should be done at each band inflation to evaluate the esophagus.

Band deflation may not resolve the dilatation if the stoma obstruction is due to a significant gastric slippage or if the band is incorrectly placed around the esophagus. Band repositioning or removal may be necessary if band deflation does not resolve the dilatation.

Locating the Access Port with X-ray

B-2210 & B-2220 Access Port Radiographic Profile: The Access Port's white plastic housing is not radiopaque. Only the internal titanium portal housing is visible on x-ray. An ideal overhead view (0°) of the Access Port shows two concentric rings for the 9.75 cm and 10.0 cm LAP-BAND® Systems. (Figure 1).

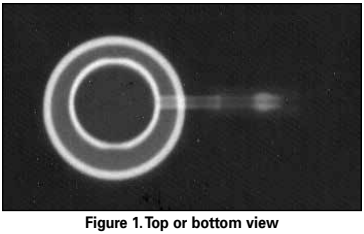

Figure 1. Top or bottom view x-ray image of the Access Port

The LAP-BAND® VG System's (B-2250) Access Port includes a single radiopaque dot (Figure 2) in the port to distinguish it from the ports used with the 9.75 and 10.0 cm LAP-BAND® Systems.

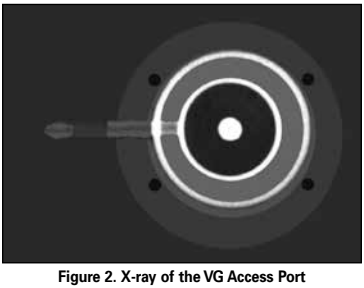

Figure 2. X-ray of the VG Access Port with "free floating" radiopaque dot in center

Be aware that an upside down (180°) port shows the same image. The largest diameter portion of the titanium portal housing is at the top of the Access Port (Figure 3).

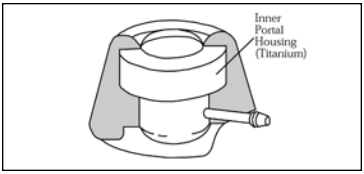

Figure 3. Cross-section view of the Access Port

This large round titanium area holds the self-sealing septum. The smaller portion is the fluid chamber. Access Ports have been reported to be "flipped" or inverted based on an oblique or side view of the port being misinterpreted. If you initially see an oblique (Figure 4) or side view (Figure 5) on x-ray, then either reposition the patient or the x-ray equipment until you obtain a perpendicular, overhead (0°) view. Targeting the port for needle penetration can be difficult if this orientation is not controlled.

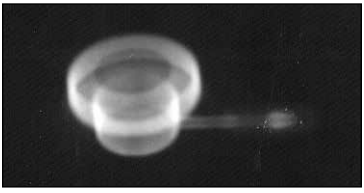

Figure 4. Access Port, oblique view

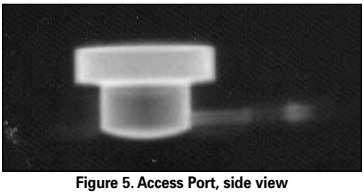

Figure 5. Access Port, side view

Steps for Performing an Adjustment

1. Shield the reproductive organs of all patients.
2. Wash your hands with a germicidal solution. Sterile gloves are advised. Always penetrate the Access Port using aseptic technique.
3. Complete a skin prep with an antiseptic solution.
4. Locate the Access Port radiologically: place a small metal object (coin, washer, or use an Access Port needle as a pointer) on the abdomen and move it as necessary to position it exactly over the center of the port. Make a circle around the object to mark the injection site.
5. Local anesthesia may be used to eliminate pain during injection.
6. Position the needle perpendicularly to the septum of the Access Port (Figure 6).

CAUTION: When adjusting band volume, the needle must be inserted perpendicular to the Access Port septum. Failure to do so may cause damage to the port and result in leaks.

CAUTION: Use of an inappropriate needle may cause Access Port leakage and require reoperation to replace the port. Do not use standard hypodermic

needles as these may cause leaks. Use only LAP-BAND® System Access Port Needles.

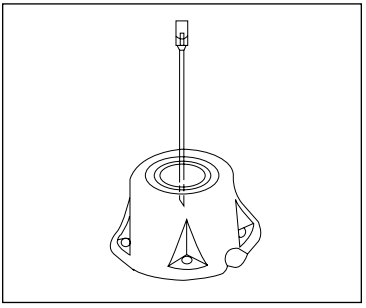

Figure 6. Needle and Access Port

CAUTION: Take care to ensure that the radiographic screen is perpendicular to the needle shaft (the needle will appear as a dot on the screen). This will facilitate adjustment of needle position as needed while moving through the tissue to the port.

7. When the Access Port is felt, and just prior to penetrating it, confirm radiographically that the needle is properly positioned. Attach a syringe to the needle before penetrating the port. A one-way stopcock can be connected to the needle to prevent fluid loss.

CAUTION: Never enter the Access Port with a "syringeless" needle. The fluid in the device is under pressure and will be released through the needle.

8. Penetrate the Access Port. The port must be penetrated until the needle is stopped by the bottom of the portal chamber. Withdraw some saline to confirm that the bevel of the needle is within the port. If, after penetration, the saline solution cannot be withdrawn or injected, the bevel of the needle may be occluded by the port septum. Try to advance the needle farther into the port to the bottom of the portal chamber. If you cannot advance, then re-enter the port with another sterile needle.

CAUTION: Once the septum is punctured, do not tilt or rock the needle, as this may cause fluid leakage or damage to the septum.

9. To increase stoma size: taking into account any fluid withdrawn to confirm port penetration, remove fluid to deflate the band and increase the stoma size. Take care to remove only enough fluid to deflate the band; avoid creating a vacuum.

10. To decrease stoma size: taking into account any fluid withdrawn to confirm port penetration, inject additional saline to further inflate the band and decrease the stoma size.

CAUTION: Important: if fluid has been added to decrease the stoma size, it is important to establish, before discharge, that the stoma is not too small. Check the adjustment by having the patient drink water. If the patient is unable to swallow, remove some fluid from the port, then recheck. A physician familiar with the adjustment procedure must be available for several days post-adjustment to deflate the band in case of an obstruction.

Adjustment Following Significant Weight Loss

Once significant weight has been lost, it may become possible to palpate and locate the Access Port without x-ray. If this is the case, complete all the other steps, skin prep, aseptic technique, etc. An evaluation of the stoma and pouch size is recommended via a gastrografin or limited barium swallow prior to and following adjustments. This is important to avoid inadvertent overinflation of the band and possible stoma obstruction.

Returned Goods Policy

Authorization must be received from your Apollo Account Manager prior to return of the merchandise. Merchandise returned must have all the manufacturer's seals intact and its packaging undamaged 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 or an authorized Apollo distributor. This required training program is specific to the Apollo LAP-BAND® System and does not qualifiy for use with other gastric bands.

The LAP-BAND® Adjustable Gastric Banding System and the LAP-BAND® System Adjustment Kit contain no latex or natural rubber materials.

Patented. See www.apolloendo.com/patents

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	Caution. See instructions for use.
	Single Use Only. Do Not Re-use.
LOT	Lot Number
 YYYY-MM-DD	Use By Year, Month, & Day
REF	Reference Number
Rx Only	CAUTION: Federal law (U.S.A) restricts this device to sale by or on the order of a physician.

Manufacturer

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010-07
[L010 Rev.07] 06/2014
GRF-00255-00R01