The RapidPort® EZ Port Applier

DIRECTIONS FOR USE (DFU)

Rx Only

apollo endosurgery

The RapidPort® EZ Port Applier

Ref. No. B-20390

INDICATIONS FOR USE

The RapidPort® EZ Port Applier is an optional accessory for the LAP-BAND AP® Adjustable Gastric Banding System and is designed to be used only with LAP-BAND AP® Systems that include the RapidPort® EZ Access Port. It is designed as an alternative method of Access Port fixation, taking the place of suturing.

The RapidPort® EZ Port Applier enables the surgeon to anchor the RapidPort® EZ Access Port to the patient's abdominal muscle fascia in less time than manually suturing an access port. Qualified LAP-BAND® System surgeons should be familiar with the LAP-BAND® System procedure prior to the use of the RapidPort® EZ Port Applier.

Surgeons planning laparoscopic placement must have extensive advanced laparoscopic experience, i.e., fundoplications as well as previous experience in treating obese patients, and have the staff and commitment to comply with the long-term follow-up requirements of obesity procedures. They should comply with the American Society of Bariatric Surgeons (ASBS) and the Society of American Gastrointestinal Endoscopic Surgeons (SAGES) joint "Guidelines for Surgical Treatment of Morbid Obesity" and the SAGES "Guidelines for Framework for Post-Residency Surgical Education and Training". Surgeon participation in a training program authorized by Apollo or by an authorized Apollo distributor is required prior to use of the LAP-BAND® System. Please see the last page for directions on obtaining additional information.

CONTRAINDICATIONS

In addition to the following contraindications, the RapidPort® EZ Port Applier has the same contraindications that are listed in the LAP-BAND AP® System Directions for Use (DFU):

1. The RapidPort® EZ Port Applier is contraindicated if the surgeon is unable to place, for any reason, the Access Port flat against the abdominal muscle fascia.
2. The RapidPort® EZ Port Applier is contraindicated if fat on the abdominal anterior muscle sheath fascia cannot be adequately cleared for proper fixation of the Access Port.
3. The RapidPort® EZ Port Applier is contraindicated for patients who are known to have, or are 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 stainless steel anchors on the Access Port are sharp and may penetrate surgical gloves if not handled appropriately. Care must be taken by the surgical team while handling and attaching the Access Port onto the RapidPort® EZ Port Applier. Always keep the black safety cover on the Access Port until the Access Port is loaded onto the RapidPort® EZ Port Applier and the Access Port is about to be placed in the patient.

CAUTION: The Access Port's black safety cover is not to be implanted. The Access Port must be securely fastened to the patient's rectus fascia with all four of the stainless steel anchors firmly embedded in the patient's fascia.

If this is not achieved, the Access Port may become loose and inaccessible for post-operative adjustments, thus requiring revisional surgery.

ADVERSE REACTIONS AND COMPLICATIONS

Complications which 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 post-operative period or years after insertion of the device. In the presence of infection or contamination, removal of the device is indicated. Please refer to the LAP-BAND AP® System DFU for additional adverse reactions and complications.

HOW SUPPLIED

The RapidPort® EZ Port Applier is provided sterile for single use only.

The RapidPort® EZ Port Applier should be stored in a clean, dry location (standard hospital supply storage).

INSTRUCTIONS FOR USE

1. Prime the Access Port as described in the LAP-BAND AP® system DFU.
2. The Strain Relief is threaded over the LAP-BAND AP® 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**).

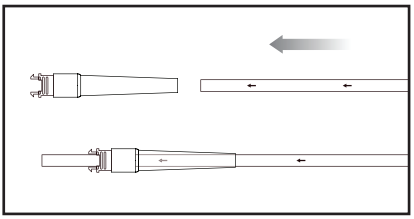

Figure 1. Strain Relief and end of tubing alignment

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

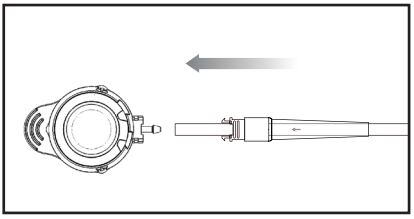

Figure 2. Tubing alignment with Access Port's outlet barb

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

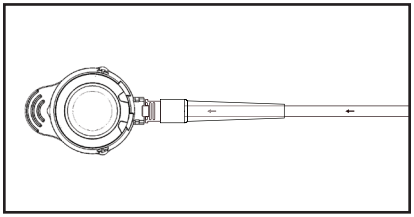

Figure 3. Strain Relief locked into the Access Port's port housing

5. Hold the RapidPort® EZ Port Applier as shown (**Figure 4**). Ensure that the RapidPort® EZ Port Applier trigger is in the fully opened position (**Figure 5**).

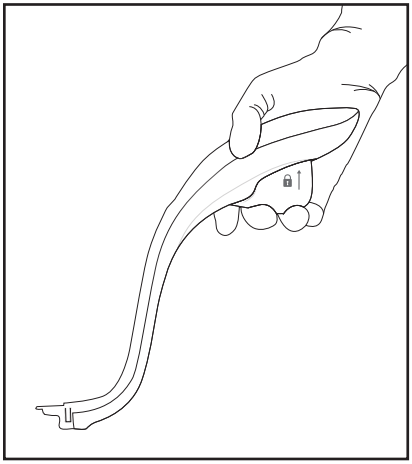

Figure 4. Proper hand positioning when holding the Port Applier

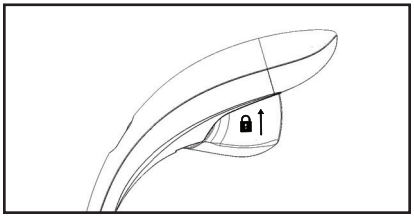

Figure 5. Port Applier trigger in the open position

6. Insert the Access Port into the RapidPort® Port Applier deployment head. Ensure the attached black safety cover is facing opposite the Port Applier. The port will snap into place (**Figure 6**).

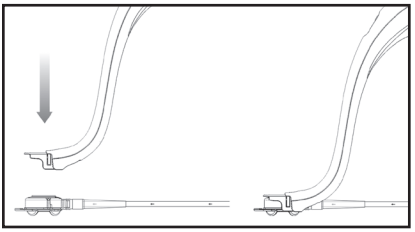

Figure 6. Loading the Access Port into the Port Applier deployment head

7. Pull the black safety cover off the bottom of the Access Port. Discard the safety cover.

CAUTION: Do not squeeze or attempt to depress the handle to the RapidPort® EZ Port Applier. Doing so will deploy the fasteners prematurely.

8. Place the tubing coming from the LAP-BAND AP® System into the abdomen. 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 and a pocket must be created for the Access Port, so that 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 connector so that the tubing will form a straight line with a gentle arching transition into the abdomen. The tubing should be perpendicular to the midline of the patient.

9. Verify that the fat has been fully cleared and fascia is visible in the selected area. Ensure an adequate incision size to accept the RapidPort® EZ deployment head. Introduction of the deployment head from an angled position may facilitate insertion. Pocket dissection must be adequate to allow for a smooth transition of the tapered connector into the abdomen. Incision length can be minimized by temporarily removing the retractors until the instrument's deployment head is positioned correctly in the abdomen. Position the RapidPort® EZ deployment head flat against the patient's rectus muscle fascia to ensure that all four stainless steel fasteners will fully engage the fascia and/or muscle tissue.

Note: Tubing must be placed in the abdomen to ensure the Access Port is flat. Exposed tubing may cause a tilting of the Access Port and prevent the ability of all fasteners to engage in the fascia.

CAUTION: When using retractors, take care not to apply undue force to the RapidPort® EZ deployment head.

10. Once the deployment head is properly positioned in the dissected pocket, apply pressure to the deployment head by pushing down on the applier handle to ensure the Access Port is flat against the fascia and the instrument is steadied for firing. Firmly squeeze the RapidPort® EZ Port Applier trigger until the trigger is fully depressed (**Figure 7**) and the stainless steel anchors are deployed into the underlying fascia. At this point, the port will release from the tool. The instrument's trigger will lock in the depressed position. Do not release the trigger.

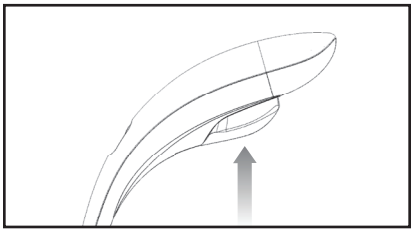

Figure 7. Port Applier trigger fully depressed

11. To disengage the Port Applier, keep the trigger fully depressed and gently slide the deployment head back a few millimeters in the direction of the tubing. Once the head has cleared the port you may remove your hand from the trigger. Finally, remove the applier from the incision site. Angling the instrument, once it is detached from the Access Port, can aid in the removal of the instrument.
12. Ensure that the Access Port's stainless steel anchors are fully engaged into fascia by running a finger around the base of the Access Port.

WARNING: In order for the Access Port to be properly affixed, all four stainless steel fasteners must be well within the patient's fascia and/or underlying muscle. Otherwise, the Access Port can become detached and subsequent removal and/or replacement may become necessary.

UNLOCKING ACCESS PORT AND REPOSITIONING

To ensure durable fixation of the Access Port, the stainless steel anchors are locked into place. In the event the Access Port needs to be repositioned, re-engage the Access Port with the tool in the locked position. Although your fingers may rest on the trigger, do not depress the trigger at any time. Follow the tubing with the deployment head. Once the head is over the port it will engage the port. Once engaged, press the unlock button on the top of the instrument (button has unlock symbol). This will retract the anchors.

MEDICAL IMAGING

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

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 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 qualify for use with other gastric bands.

The RapidPort® EZ Port Applier contains no latex or natural rubber materials.

Patented. See www.apolloendo.com/patents

FOR ADDITIONAL INFORMATION PLEASE CONTACT:

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

	Sterilized using irradiation
	Caution. See instructions for use.
	Reference Number
	Product contains no latex.
Rx Only	CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.
 YYYY-MM-DD	Use by Year, Month, & Day
	Single use only. Do not reuse.
	Do not use if package is damaged.
	Lot Number

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Assembled in U.S.A.

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