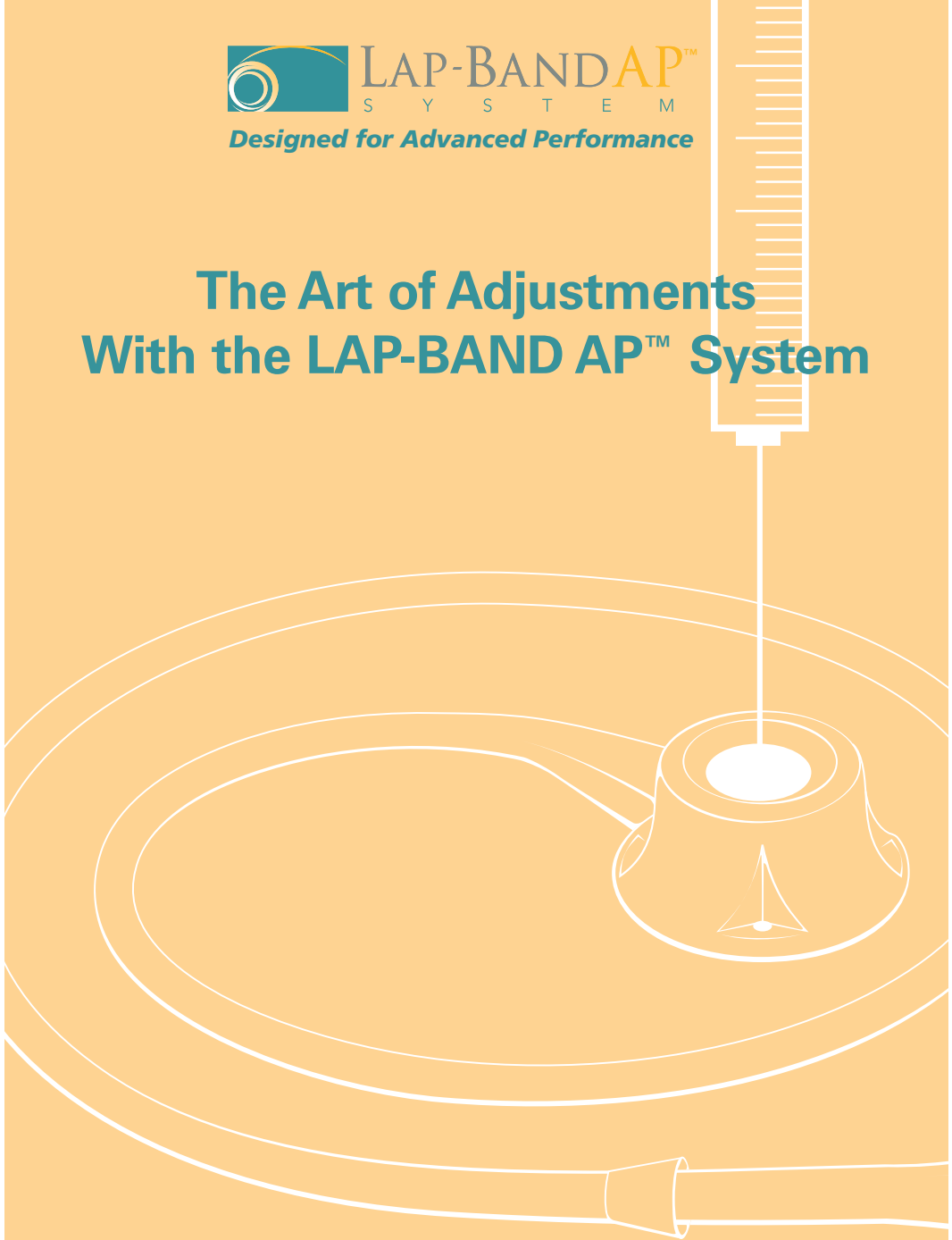




LAP-BAND AP™  
S Y S T E M

*Designed for Advanced Performance*

# The Art of Adjustments With the LAP-BAND AP™ System



For use with the LAP-BAND AP™ Adjustable Gastric Banding System

<u>TOPIC</u>	<u>PAGE</u>
OPTIMIZING OUTCOMES WITH THE GREEN ZONE .....	1
STEPS TO EFFECTIVE ADJUSTMENTS .....	4
Step 1: Determine the Fill Amount .....	4
Step 2: Prepare the Syringe .....	6
Step 3: Prepare the Patient .....	6
Step 4: Place Needle With Syringe in the Access Port.....	7
Step 5: Remove All Saline From the LAP-BAND AP™ System ..	7
Step 6: Add Saline to the LAP-BAND AP™ System .....	8
Step 7: Check the Adjustment .....	8
Step 8: Patient Instructions .....	8
ADJUSTMENT FOLLOWING INSUFFICIENT WEIGHT LOSS .....	9
NOTES .....	10

## OPTIMIZING OUTCOMES WITH THE GREEN ZONE

The LAP-BAND AP™ Adjustable Gastric Banding System journey is different for each patient. However, each patient is striving to achieve a common goal: reaching a point of prolonged satiety and satisfactory weight loss or weight maintenance. The key to good clinical results with the LAP-BAND AP™ System is to find the ideal fill volume that helps the patient achieve these goals. This only comes through patient consultation and ongoing adjustments to help get the patient into an ideal fill volume for optimal weight loss.

The ideal volume is intended to achieve 2 effects—satiety and satiation. The effectiveness of the band will vary depending on how close we are to the optimal adjustment. Whether the patient feels a sense of satiety (ie, not hungry) and satiation (ie, satisfied after eating) indicates if you need to add more fluid at each visit or whether you are close to the optimal adjustment.

### **Satiety**

The first effect of adding fluid is that the patient will feel less hungry. With the LAP-BAND AP™ System, patients rapidly achieve satiety—meaning they do not feel hungry or have an appetite for food. This is the principal reason behind why the band works so well. For many of your patients, it will be the first time in their life they can remember not feeling hungry. They will not think about food. They will not be looking to eat and they will be able to go for many hours without eating because they simply won't have any interest in food.

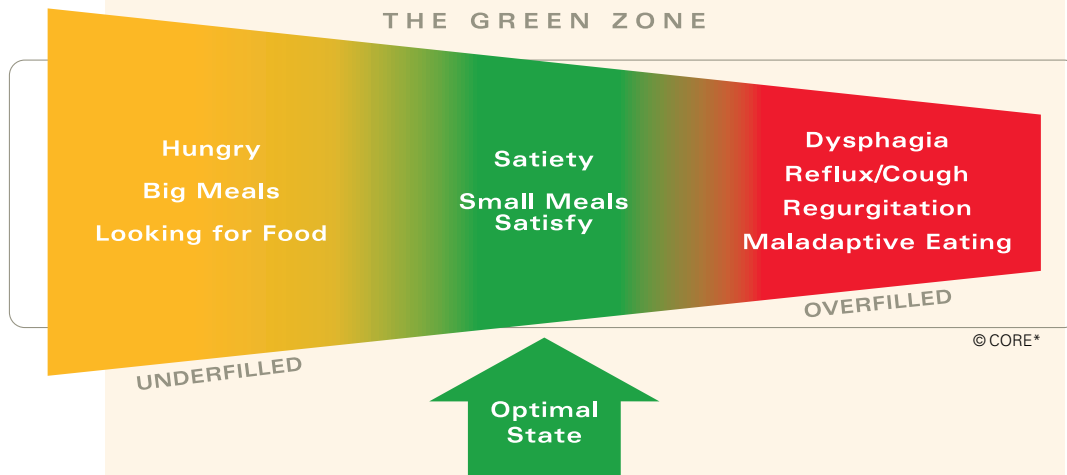
This feeling of satiety will enable the patient to stick to the rule of not having more than 3 meals per day. If, after an adjustment, the patient is still looking for a snack between meals or even feeling hungry, you may need to add more fluid to the band.

### **Satiation**

The second effect of adjustments is to give the patient a feeling of satisfaction after eating only a small amount of food. This is called satiation, a sense of being satisfied by the amount of food one has eaten. If the amount of fluid added is optimal, the patient will be comfortable or satisfied with only a small amount of food. The goal is to have the patient eat just enough to take away any feeling of hunger and then stop.

To achieve satiation, the patient has to learn to do the following:

- Eat slowly and eat only a small amount of food
- Recognize the sense of satiation. Using a small plate with a small amount of food on it for meals can help with this
- Never eat everything on the plate. If the patient is not leaving some food on the plate, an adjustment may be needed
- Take 15 to 20 minutes to eat each meal
- Chew each bite well. The 2 worst eating practices the patient has to overcome are eating too quickly and eating too much. These habits will stretch the new “mini” stomach. Eventually this could lead to band slippage or symmetrical enlargement and a reoperation may become necessary



The Centre for Obesity Research and Education (CORE), Monash Medical School, Melbourne, Australia, effectively describes this optimal adjustment state as the “Green Zone,” or the point at which the LAP-BAND AP™ System is most effective for a particular patient.

To set the framework for achieving this optimal zone through adjustments, CORE defined patient symptoms as key factors to determine which zone the patient is in and if a LAP-BAND AP™ System adjustment is needed.

\*Centre for Obesity Research and Education.

**The Yellow Zone:** If the LAP-BAND AP™ System is too loose, the patient is hungry, meals are bigger, small meals do not satisfy, and weight loss is poor. Fluid needs to be added to the band to increase the restriction.

**The Red Zone:** If the LAP-BAND AP™ System is too tight, the patient will have difficulty eating, swallowing may be difficult and painful, and food may regurgitate into the esophagus or the mouth. The band may cause obstruction such that fluids will not be able to pass through or solid food may sit in the small gastric pouch or lower esophagus. When the patient lies down, food may regurgitate or reflux into the mouth and respiratory tract, which may lead to sleep disturbance, wheezing, or night cough. In an attempt to remedy these difficulties and allow food to pass, the patient may seek foods that “slip past” the band. These foods include chocolates, ice cream, milk drinks, pureed foods, yogurt, and snack foods that crumble (such as potato chips). This eating pattern is referred to as maladaptive eating. If any of these problems occur, some fluid will need to be removed from the band to reduce restriction. If symptoms do not resolve, a barium upper GI series is necessary to rule out a complication such as slippage.

**The Green Zone** is achieved by successive incremental adjustments and by:

- Monitoring the patient’s weight loss
- Listening to the patient’s hunger symptoms
- Observing any signs of overfilling of the LAP-BAND AP™ System

At the optimal adjustment point, the LAP-BAND AP™ System is adjusted so that small meals provide early satisfaction (satiety) and a prolonged reduction in hunger (satiety) so that energy intake can be substantially reduced. At this point, episodes of obstruction or regurgitation will be rare and occur mainly when food is ingested quickly, or inadequately chewed, or when improper food choices are made. Patients need to remember that the LAP-BAND AP™ System is a tool to help them lose weight, but they will have to stay committed to get the results they want. Try not to let the patient talk you into adding too much fluid because that will not necessarily mean more weight loss.

By using the “zone” framework, physicians learn to think less about the volume of saline in the LAP-BAND AP™ System and more about how the patient feels. The goal is to create the right physiological response so that patients are generally not hungry and are satisfied by small meals. The Green Zone, or optimal adjustment range, is best achieved by small incremental adjustments and by listening carefully to the patient.

The following are examples of questions that will assist you in determining how much (or how little) to adjust the patient's LAP-BAND AP™ System:

- How much are you eating?
- What are you eating?
- How often are you eating?
- How is your appetite?
- Do you get hungry?
- Have you learned when to stop eating with the LAP-BAND AP™ System?
- How fast are you eating?
- How long do you spend eating?
- Do you think you are still eating too much?

The first adjustment is usually made 4 to 6 weeks after surgery, once the patient can comfortably eat solid foods. For the first year, the patient's progress and overall health should be monitored regularly (every 4 to 6 weeks). Weight loss for most patients averages about 1 to 2 pounds per week.

It's important to confirm the total fill volume in the patient's band before making an adjustment. If adjustments where fluid was added to the band have not been effective in increasing restriction, the band may have a leak. Alternatively, the patient may have an enlarged pouch or dilated esophagus due to obstruction, band slippage, or overrestriction.

## STEPS TO EFFECTIVE ADJUSTMENTS

This section will take you through 8 basic steps to effectively perform adjustments with the LAP-BAND AP™ System. For additional information, please refer to the LAP-BAND AP™ System Directions For Use (DFU), which can be found in the product package, or visit [www.lapbandcentral.com/dfu](http://www.lapbandcentral.com/dfu).

### STEP 1: Determine the Fill Amount

If the LAP-BAND AP™ System was prepared as described in "LAP-BAND AP™ System Preparation in the Operating Room," the inflation area of the band will be full of saline (ie, no air) at the time of the first adjustment.

Use the "Green Zone" to decide how much saline should be added or removed from the LAP-BAND AP™ System. Both the "Green Zone" and the adjustment algorithm on the following page are designed to provide general guidelines for making adjustments to the LAP-BAND AP™ System. The degree of adjustment will vary from patient to patient.

## ADJUSTMENT ALGORITHM FOR THE LAP-BAND AP™ SYSTEM

	APS BAND	APL BAND
Total volume	10 cc	14 cc
Volume at surgery	3 cc approx	4 cc approx
Suggested first fill	1 cc	2 cc
Subsequent fills	± 0.5 cc	± 0.5 cc

- After the APS band has been filled to a total volume of approximately 7 cc, subsequent increases may need to be reduced by ± 0.5 cc
- After the APL band has been filled to a total volume of approximately 9 cc, subsequent increases may need to be reduced by ± 0.5 cc
- Saline should be added to the band if the patient is still hungry after meals or adequate weight loss is not being achieved. Saline should be removed from the band if the patient is having difficulty eating, the patient regurgitates after meals or vomits, or the stoma is obstructed
- Smaller incremental volumes will be needed as the patient approaches the Green Zone
- 3-4 visits will be necessary (on average) before the Green Zone is achieved

### STEP 2: Prepare the Syringe

After consulting with the patient, prepare a 10 cc syringe (APS) or a 15 cc syringe (APL) with the amount of saline you wish to add to the LAP-BAND AP™ System band. Doing so will allow you to withdraw into the syringe all saline from the patient's band before adding the desired incremental amount.

### STEP 3: Prepare the Patient

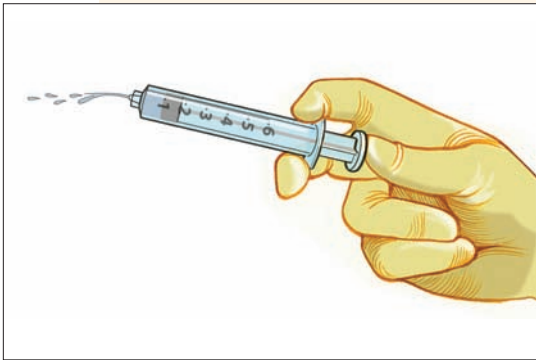
Prepare the patient's skin using a standard aseptic skin preparation technique. Place the patient supine with his or her hands behind

the head or crossed over the chest to facilitate tightening of the abdominal muscles. This will assist you in locating the Access Port. Placing a small pillow under the patient's lower back can also help make the Access Port more accessible. Locate the Access Port radiographically or by manual palpation. If locating radiographically, shield the reproductive organs of all patients. Local anesthesia may be used to eliminate pain during injection.

Connect the supplied needle to the syringe. Use of an inappropriate needle may cause Access Port leakage and require reoperation to replace the Access Port. Do not use standard hypodermic needles as these may cause leaks. Use only LAP-BAND AP™ System Access Port Needles.

When the Access Port is felt, and just prior to penetrating it, you may

want to confirm that the needle is properly positioned radiographically. Attach a syringe to the needle before penetrating the Access Port. A one-way stopcock can be connected to the needle to prevent fluid loss. Never enter the Access Port with a needle that is not attached to a syringe. The fluid in the device is under pressure and could be released through the needle.



PREPARE THE SYRINGE



PATIENT SUPINE, FLEXING ABDOMINAL MUSCLES

### STEP 4: Place Needle With Syringe in the Access Port

Position the needle perpendicular to the septum of the Access Port. Penetrate the Access Port.

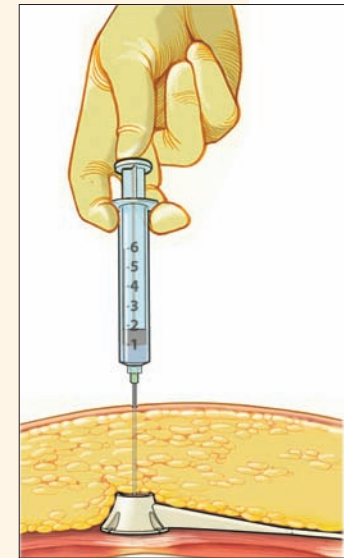
The Port must be penetrated until the needle is stopped by the bottom of the portal chamber. Withdraw some saline to confirm that the bevel of the needle is within the Access Port. If the saline solution cannot be withdrawn or injected after penetration, the bevel of the needle may be occluded by the port septum. Try to advance the needle further into the port to the bottom of the portal chamber. If you cannot advance, then reenter the port with another sterile needle. Once the septum is punctured, do not tilt or rock the needle, as this may cause fluid leakage or damage to the septum.

### STEP 5: Remove All Saline From the LAP-BAND AP™ System

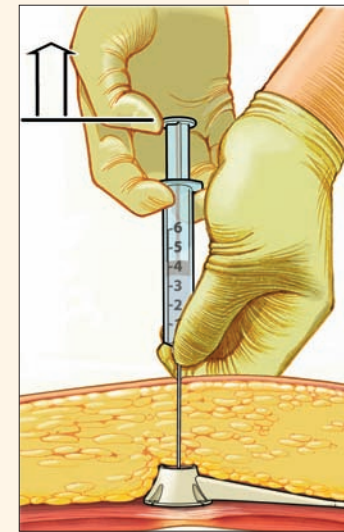
Withdraw all saline from the patient's LAP-BAND AP™ System into the syringe and record the amount withdrawn.

Pull on the piston to ensure all saline has been removed. With the LAP-BAND AP™ System, you will have to manually remove all saline from the band. Be sure to hold on to the needle hub and not the syringe when removing saline. Holding on to just the syringe could dislodge the needle from the syringe.

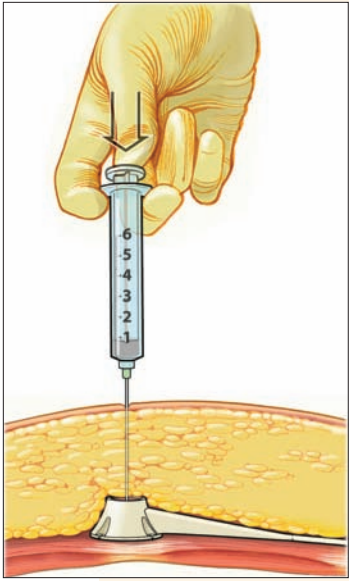
It is important to remember that the LAP-BAND AP™ System is an optimal pressure system (nearly a zero pressure system). The inflation area will generate enough positive pressure to push the plunger of a syringe only at higher volumes (greater than 6 cc or more). Therefore, it is not possible to accurately measure the volume using the traditional "bounce" technique of withdrawing all the fluid and then allowing the plunger of the syringe to recoil back to a steady state position.



PLACE NEEDLE WITH SYRINGE IN THE ACCESS PORT



REMOVE ALL SALINE FROM THE LAP-BAND AP™ SYSTEM



ADD SALINE TO THE LAP-BAND AP™ SYSTEM

It is recommended to use the “extractable volume” method for measuring how much fluid is in the band. To measure the volume, as much fluid as possible should be withdrawn into the syringe, the plunger being pulled on with a force that is just short of the pressure needed to draw air bubbles into the syringe from around the hub of the needle. This volume should be considered as the total volume in the LAP-BAND AP™ System.

**STEP 6: Add Saline to the LAP-BAND AP™ System**

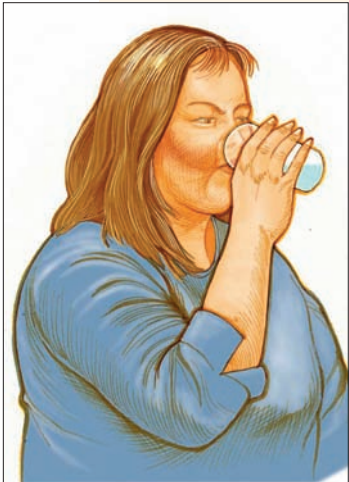
Inject the amount of saline that you have determined to add to the patient’s LAP-BAND AP™ System along with all saline that was removed from the band. Record this amount in the patient’s chart.

**STEP 7: Check the Adjustment**

Before discharging the patient, it is important to establish that the stoma is not too narrow. Check the adjustment by having the patient drink water. If the patient is unable to swallow, remove some fluid from the Access Port, then recheck. Trained individuals with a special interest in obesity that are familiar with the LAP-BAND AP™ System adjustment procedure must be available for several days postadjustment to deflate the band in case of an obstruction.

**STEP 8: Patient Instructions**

Explain to the patient what he or she will experience immediately after an adjustment. Typically, LAP-BAND AP™ System patients feel a heightened feeling of restriction after an adjustment. During this period, keeping the patient on liquids and/or soft foods is recommended. This heightened feeling of restriction should go away after about 1 or 2 days. Advising patients to eat soft foods after an adjustment should help them feel more comfortable.



PATIENT DRINKING WATER TO CHECK THE ADJUSTMENT

**ADJUSTMENT FOLLOWING INSUFFICIENT WEIGHT LOSS**

**CAUTION:** Insufficient weight loss may be a symptom of inadequate restriction (when the LAP-BAND AP™ System is too loose). It may also 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 LAP-BAND AP™ System 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 postadjustment to adjust the stoma in case of an emergency.

Deflation (or 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 patient’s band is advisable in the following circumstances:

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

Possible risks and complications with the LAP-BAND® System include but are not limited to infection, nausea, vomiting, band slippage and obstruction, and in rare cases, gastric perforation and reoperation. More detailed risk information is available at [www.lapbandcentral.com](http://www.lapbandcentral.com) or 1-800-624-4261.

Allergan would like to thank the Centre for Obesity Research and Education, Monash Medical School, Melbourne, Australia, for their assistance in creating this information.





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The LAP-BAND AP™ Adjustable Gastric Banding System contains no latex or natural rubber materials.  
Caution: The LAP-BAND AP™ System and accessories are restricted to sale by or on the order of a physician.  
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