

Preparing for surgery

with the ReShape Lap-Band® 2.0 FLEX

These checklists are meant to help each member of the surgical team with the placement of the ReShape Lap-Band® 2.0 FLEX.



Band Preparation

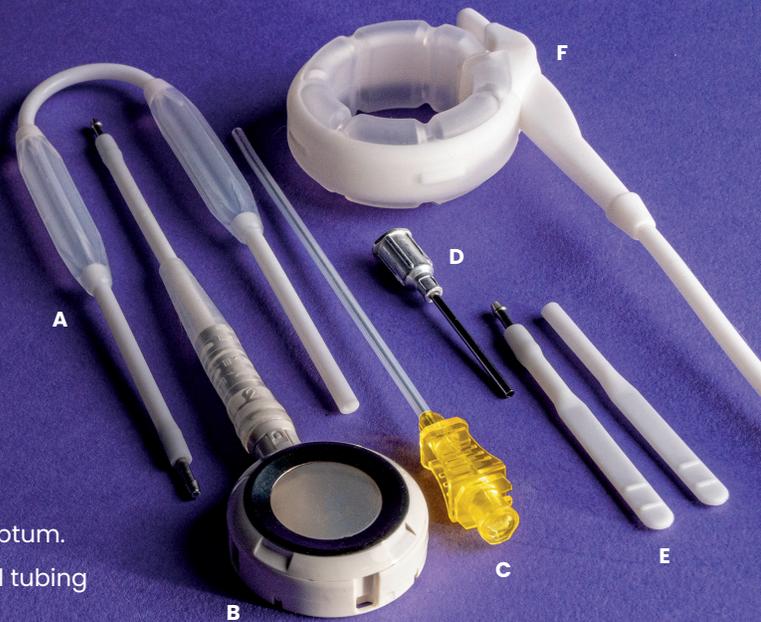
For the Circulator:

1. Give Scrub Tech/RN 15 cc of sterile, nonpyrogenic isotonic 0.9% NaCl saline solution and a 10 cc syringe (w/o needle).
2. Prior to opening the box, confirm the size and type of the ReShape Lap-Band 2.0 FLEX System with the surgeon.
3. Do not open or throw away the sterile Access Port Needle unless it is requested by the surgeon. If the needle is not used, label with patient's name and give to the surgeon for future ReShape Lap-Band 2.0 FLEX System adjustments.
4. If requested by the surgeon, give anesthesiologist the Calibration Tube (packaged/sold separately).

Access Port Preparation:

1. Remove the Access Port and 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 septum.
3. Hold the Access Port with the port side facing up. Keep the fill tubing in an upright position with the port on the bottom.
4. Attach a 5 cc, 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 and past the Blunt Flushing Needle.
6. Keep the port tubing upright until it is attached to the FLEX 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.

ReShape
lap·band 2.0
FLEX



- A. FLEX Tubing with Connector
- B. RapidPort EZ Access Port with Connector
- C. Access Port Needle, 20 Gauge (89mm/3.5in)
- D. Blunt Flushing Needle 16 Gauge (40.5mm/1.6 in)
- E. End Plug with Connector
- F. Lap-Band

FLEX



Band Preparation

For the Anesthesiologist:

1. The Calibration Tube is an oral suction tube which requires a lubricant and 30 cc syringe for inflation.
2. Surgeon will instruct anesthesiologist to remove patient's N/G tube (if one has been inserted). Insert the Calibration Tube orally until it passes below the gastro-esophageal (GE) junction.
3. Surgeon will ask anesthesiologist to inflate balloon with 25 cc of air (or saline) and to pull back on tube until resistance is met – this determines precisely where the GE junction is located. Do not over inflate the balloon as this could cause balloon rupture and injury to surrounding tissues.
4. Once the junction is clearly marked, the surgeon will then instruct anesthesiologist to deflate the Calibration Tube and either retract it into the esophagus or remove it entirely.
5. Discard the Calibration Tube after use only when surgeon has completed surgery. During insertion of the calibration balloon, care must be taken to prevent perforation of the esophagus or stomach.
4. Fill a syringe(s) with at least 15 cc of saline and connect to the priming needle. Flush the band and inflatable shell several times, each time drawing out air and replacing it with saline. A residual amount of saline will stay in the band.
5. View the inflatable portion of the band for leaks or uneven inflation.
6. Inject about 5 cc saline and disconnect the syringe. The excess saline will flow out of the band, leaving about 4 cc of saline in the ReShape Lap-Band 2.0 FLEX System Standard and 5 cc in the ReShape Lap-Band 2.0 FLEX System Large.

Note: Keep the syringe and priming needle available to prime the FLEX Tubing System after the band has been placed around the stomach.

7. At this point, you have replaced most of the air in the band with saline.
8. Insert the end plug into the tubing end until the stainless-steel tubing connector disappears into the open end of the band fill tube – this will facilitate pulling the tube around the stomach. The tubing can be slippery. Using 4x4 gauze sponges will help grasp the tubing.
9. Place the band in a saline bowl or set aside until ready for insertion – it is now ready for implantation.
10. If your patient's anatomy requires a larger initial circumference, the band's perimeter can be made larger by removing saline from the band via the Access Port. It is important to remove any additional saline via the Access Port so no air will enter the band, compromising later adjustments.

For The Scrub Tech/RN:

1. After the Circulator opens the outer ReShape Lap-Band 2.0 FLEX System package, pick up inner sterile container by the tab and put on back table in a secure location.
2. Peel lid from inner tray and remove the band and priming needle.
3. Connect priming needle to the ReShape Lap-Band 2.0 FLEX System tubing end.

MAXIMUM FILL CAPACITY VOLUMES

Ref. No D-3360	ReShape Lap-Band 2.0 FLEX, Standard	13 cc Max. Volume
Ref. No D-3365	ReShape Lap-Band 2.0 FLEX, Large	20 cc Max. Volume

Rx Only. 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 re-operation. For more detailed risk information, please scan this QR code or visit: lapband.com/product-info

