STANDARD BARIATRICS® STANDARD BOUGIE™

Standard Bougie™

Product Code: SB18
Supplied: Clean, Non Sterile
Length: Approx. 95 cm
Diameter: 18 Fr (Approx. 6 mm)
Packaging: PET/LDPE and Tyvek
Shelf Life: 1 year
Material: Thermoplastic Elastomer
This product is not made with natural rubber latex

	Federal law restricts the device to sale by or on the order of a physician.		Read instructions carefully.
	Manufacturer		Lot number
	Catalog number		Do not re-use
	Use By Date		Non-sterile
	Do not use if package is damaged		

INDICATIONS FOR USE
The Standard Bougie™ is indicated for use in conjunction with the Standard Clamp® in vertical sleeve gastrectomy procedures for the application of suction, stomach decompression, drainage of gastric fluids, irrigation and to serve as a sizing guide.

CONTRADICATIONS
- The Standard Bougie™ is not intended for use in Roux-en-Y Gastric Bypass (RYGBP) procedures.
- Esophageal stricture that does not allow passage of Standard Bougie™
- Conditions which would preclude gastric or bariatric surgical procedures.

DEVICE DESCRIPTION
The Standard Bougie™ is a non-sterile, single patient use device. The device comprises a tube with a closed, rounded tip, and a balloon at the distal end. The proximal end of the Standard Bougie™ includes a standard Luer lock valve for balloon inflation/deflation and a 7.5mm inner diameter straight tube for connection to operating room suction or tapered Tumi syringe for injection of fluid.

WARNINGS & PRECAUTIONS
1. Federal law restricts this device to sale by or on the order of a physician or licensed practitioner. Use of this device should only be performed by persons having adequate training and familiarity with minimally invasive surgical techniques, and with the use of this device. Consult medical literature relative to techniques, complications, and hazards prior to use of this device.
2. Please read these instructions carefully.
3. Correctly sizing the stomach is a clinical decision made based upon an assessment of the patient, training, clinical literature, experience, etc. It is the responsibility of the clinician to correctly size the stomach. If the Standard Bougie™ is not of a size deemed suitable by the clinician, it should not be used as a sizing guide.
4. Do not use this product in patients presenting with Zenker's diverticulum unless certain that entry into the diverticulum can be avoided.
5. Use of this product in patients presenting with esophageal varices may result in increased bleeding risk.
6. Do not staple or sew the Standard Bougie™ to the stomach. Before firing any staple loads in the stomach, always confirm placement of the Standard Bougie™ by either visual or tactile cues. Laparoscopic stapling techniques rely upon visual and tactile feedback to preclude stapling across devices (including the Standard Bougie™). Use of a powered stapler may affect normal tactile feel making it possible to staple across items such as a weighted bougie or the Standard Bougie™. Ensure Standard Bougie™ is freely mobile within the stomach prior to activating stapler to avoid stapling the Standard Bougie™**.**
7. Any instrument passed blindly through the esophagus presents the risk of esophageal perforation. The Standard Bougie™ is designed to be flexible, with a blunt tip to limit this risk. If at any point undue resistance is felt, do not continue to advance the Standard Bougie™.
8. Stapling indwelling tubes is a risk when performing a sleeve gastrectomy. To limit this risk, The Standard Bougie™ is designed and indicated for stomach decompression, negating the need of an OG/NG tube for initial decompression of the gastric space.
9. Stapling indwelling temperature probes is a risk when performing a sleeve gastrectomy. If temperature monitoring is warranted for these shorter, elective procedures, consider the use of a forehead probe rather than an indwelling temperature probe. If an indwelling temperature probe is required, note the depth of placement, and externally tape the probe in place. Before any staple loads are fired, ensure the placement of the probe has not changed.
10. The Standard Bougie™ is not indicated for the removal of solid materials such as food. Do not use the Standard Bougie™ if solid materials such as food are present in the stomach.
11. Do not attempt to move the Standard Bougie™ while suction is applied. Make sure the suction has been turned off or disconnected from the Standard Bougie™ before moving inside of the patient.
12. The syringe must be removed after the desired balloon diameter is achieved. If the syringe is not removed, fluid will return to the syringe and the balloon diameter will decrease in size.

STANDARD BARIATRICS®

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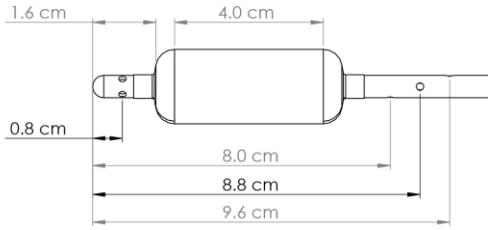
SYSTEM COMPONENTS & SPECIFICATIONS

Tubing	The tubing is approximately 95 cm long. Model SB18 has a tube diameter of 18 French.
Holes	The Standard Bougie™ includes 2.5 mm diameter apertures that extend to a distance of no more than 10 cm from the distal end.
Balloon	The balloon is located 1.6 cm from the distal end and is 4cm long.



18Fr Standard Bougie™
BALLOON INFLATION TABLE

	Balloon Diameter	Fill Volume
Minimum	1.5cm	6ml
Nominal	2.0cm	10ml
Maximum	2.5cm	16ml

DIRECTIONS FOR USE

Prior to use, inspect the package to ensure that the integrity has not been compromised.

Step 1 – Remove Standard Bougie™ from packaging - Remove the non-sterile Standard Bougie™ from packaging, by peeling the two layers of the Tyvek peel-pouch apart.

Step 2 – Lubricate distal tip of catheter - Apply surgical lubricant onto the tip, balloon and entire working length of the Standard Bougie™ before inserting into patient.

Step 3 – Insertion - Carefully insert the Standard Bougie™ into patient through blind orogastric insertion into the stomach, the same way an OG tube is placed. The tip of the catheter is intended to be placed into the antrum of the stomach. Once inserted into the stomach the tip can be visualized under laparoscopy.

Step 4 – If needed, evacuate stomach contents - To remove fluid, use a standard 5-in-1 adapter (not included) to connect OR suction tubing to the 7.5 mm inner diameter straight tube on the proximal end of the Standard Bougie™ and apply no more than 150 mmHg suction.

Step 5 – Inflate balloon - For sizing, connect a 20ml Luer lock syringe to the Luer lock connector on the inflation lumen and slowly inject enough fluid to achieve desired diameter. Reference the balloon inflation table above or label attached to the Standard Bougie™. The syringe must be removed after the desired balloon diameter is achieved. If the syringe is not removed, fluid will return to the syringe and the balloon diameter will decrease in size.

Step 6 – Adjust the balloon location such that the larger diameter of the balloon is retracted until it is positioned at the incisura angularis and held in place by the anesthesia provider.

Step 7 – Place the Standard Clamp® lateral to the Standard Bougie™, reference Figure 1. The Standard Clamp® 1 cm width acts as a spacer, which once placed, does not allow the Standard Bougie™ to migrate into the path of the stapler. Use of the 18Fr Standard Bougie™ with the Standard Clamp®results in a 40Fr sleeve diameter. Once the Standard Clamp®is placed, ensure the Standard Bougie™ is freely mobile within the stomach.

Step 8 – If needed, check for staple-line leak by attaching a 60ml Tumi syringe and depressing the plunger to eject air into the stomach.

Step 9 –Deflate balloon by re-connecting a 20ml Luer lock syringe to the inflation lumen and slowly remove all fluid from the balloon.

Step 10 –Carefully remove device from patient. Do not apply suction when moving or removing the Standard Bougie™ .

NOTE: The distal end of the Standard Bougie™ may adhere to the lumen of the stomach when suction is applied. Do not move the device when suction is applied.

NOTE: When using the Standard Bougie™ in the sleeve gastrectomy, or similar procedure, prior to stapling, such as when creating the pouch, make sure that the exact location of the Standard Bougie™ is known and that it is not in the path of the stapler. Ensure Standard Bougie™ is not included in the stapler prior to firing the stapler

INSPECTION AND HANDLING

Standard Bougie™ devices are carefully inspected before shipment. Standard Bougie™ and packaging should be inspected upon receipt as packaging may become damaged in transit. The Standard Bougie™ should be handled and operated by personnel completely familiar with their use. Handle the Standard Bougie™ with care at all times.

HOW SUPPLIED

The Standard Bougie™ is provided clean and non-sterile and intended for single patient use. Dispose of device per local ordinances. Do not sterilize, reprocess or reuse the Standard Bougie™ .

PACKAGING AND STORAGE

The Standard Bougie™ is provided in non-sterile packing and should be stored at room temperature. Avoid prolonged exposure to elevated temperatures. The Standard Bougie™ should always be handled with great care in transportation and storage.

QUESTIONS

For questions related to this product please contact Standard Bariatrics® customer service: 513-620-7751

Standard Bariatrics®
4362 Glendale Milford Road
Cincinnati, OH 45242 USA
Phone: 513-620-7751

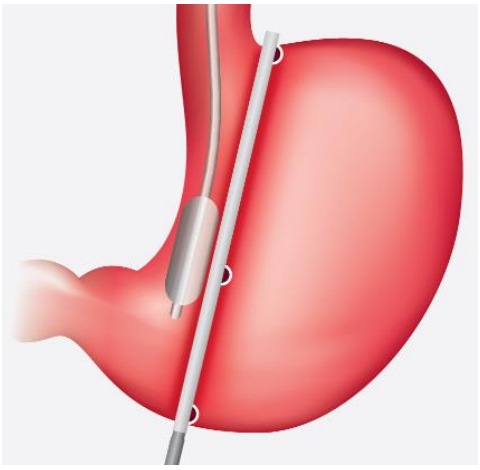


Figure 1. Standard Clamp® placed lateral to Standard Bougie™

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