










# STANDARD BOUGIE™, 38FR (SB38) – INSTRUCTIONS FOR USE

## STANDARD BARIATRICS® STANDARD BOUGIE™ SB38

**Product Code:** SB38  
**Length:** Approx. 95 cm  
**Catheter Diameter:** 38 Fr (Approx. 12.7 mm)  
**Balloon Diameter:** 2.0 cm – 3.0 cm  
 This product is not made with natural rubber latex

Symbol	Definition	Reference Standard/ Requirement
	CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician	21 CFR 801, Reference # 109
	Catalogue Number	ISO 15223-1, Reference # 5.1.6
	Lot Number	ISO 15223-1, Reference # 5.1.5
	Consult Instructions for Use	ISO 15223-1, Reference # 5.4.3
	Manufactured For	ISO 15223-1, Reference # 5.1.1
	Use by Date	ISO 15223-1, Reference # 5.1.4
	Non- Sterile	ISO 15223-1, Reference # 5.2.7
	Do not re-use	ISO 15223-1, Reference # 5.4.2
	Do not use if the package is damaged	ISO 15223-1, Reference # 5.2.8
<b>Standards:</b> 21 CFR 801 Title 21, Code of Federal Regulations, Part 801 - Labeling ISO 15223-1 Medical Devices – Symbols To Be Used with Medical Device Labels, Labeling, and Information to be Supplied		

### INDICATIONS FOR USE

The Standard Bougie™ SB38 is indicated for use in conjunction with the Titan SGS™ stapler in vertical sleeve gastrectomy pouch creation for the application of suction, stomach decompression, drainage of gastric fluids, irrigation and insufflation, and to serve as a sizing guide.

### CONTRADICTIONS

- The Standard Bougie™ SB38 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™ SB38 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™ SB38 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 tip syringe for injection of fluid.

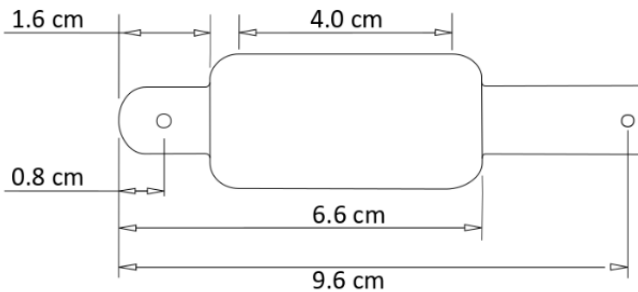
### WARNINGS & PRECAUTIONS

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. Maintain visualization of the Standard Bougie™ SB38 within the sleeve pouch throughout the procedure.
4. 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™ SB38 is not of a size deemed suitable by the clinician, it should not be used as a sizing guide.
5. Do not use this product in patients presenting with Zenker's diverticulum unless certain that entry into the diverticulum can be avoided.
6. Use of this product in patients presenting with esophageal varices may result in increased bleeding risk.
7. Do not staple or sew the Standard Bougie™ SB38 to the stomach. Before firing any staple loads in the stomach, always confirm placement of the Standard Bougie™ SB38 by either visual or tactile cues. Laparoscopic stapling techniques rely upon visual and tactile feedback to preclude stapling across devices (including the Standard Bougie™ SB38). 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™ SB38. Ensure Standard Bougie™ SB38 is freely mobile within the stomach prior to activating stapler to avoid stapling the Standard Bougie™ SB38.
8. Any instrument passed blindly through the esophagus presents the risk of esophageal perforation. The Standard Bougie™ SB38 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™ SB38.
9. Do not inject air into the balloon. Only water or saline should be injected into the balloon. Do not fill the balloon with more than 22ml of water or saline.
10. Stapling indwelling tubes is a risk when performing a sleeve gastrectomy. To limit this risk, The Standard Bougie™ SB38 is designed and indicated for stomach decompression, negating the need of an OG/NG tube for initial decompression of the gastric space.
11. 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.
12. The Standard Bougie™ SB38 is not indicated for the removal of solid materials such as food. Do not use the Standard Bougie™ SB38 if solid materials such as food are present in the stomach.
13. Do not attempt to move the Standard Bougie™ SB38 while suction is applied. The distal end of the Standard Bougie™ SB38 may adhere to the lumen of the stomach when suction is applied. Make sure suction has been turned off or disconnected from the Standard Bougie™ SB38 before moving inside of the patient or removing from patient.
14. 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.
15. Do not attempt to remove the Standard Bougie™ SB38 from the patient without removing all residual fluid from the balloon.

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## SYSTEM COMPONENTS & SPECIFICATIONS

<b>Tubing</b>	The catheter tubing is approximately 95 cm long and has a diameter of 38 French (12.7mm)
<b>Holes</b>	The Standard Bougie™ SB38 includes 2.7 mm diameter apertures that extend to a distance of no more than 10 cm from the distal tip of the catheter.
<b>Balloon</b>	The balloon is located 1.6 cm from the distal end and is 4cm long.



**38Fr Standard Bougie™**  
**BALLOON INFLATION TABLE**

	Balloon Diameter	Fill Volume
<b>Minimum</b>	2.0cm	8ml
<b>Nominal</b>	2.5cm	14ml
<b>Maximum</b>	3.0cm	22ml

*Additional fluid required to prime catheter*

## HOW SUPPLIED

The Standard Bougie™ SB38 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™.

## DIRECTIONS FOR USE

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

**Step 1** – Remove the non-sterile Standard Bougie™ SB38 from packaging.

**Step 2** – Prime the balloon inflation line by injecting approximately 5ml of fluid (water or saline only) into the device. Then lift the syringe above the balloon and remove air and excess fluid from the inflation line.

**Step 3** –Apply surgical lubricant onto the tip, balloon and entire working length of the Standard Bougie™ SB38 before inserting into patient.

**Step 4** –Carefully insert the Standard Bougie™ SB38 through blind orogastric insertion into the patient’s stomach, the same way an OG tube is placed. The distal 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 5** – If needed, evacuate stomach contents by connecting suction tubing directly to the straight tube on the proximal end of the Standard Bougie™ SB38 and apply no more than 150 mmHg suction. A standard 5-in-1 adapter (not included) may be used to connect suction tubing.

**Step 6** – Inflate balloon by connecting a Luer lock syringe to the Luer lock connector on the inflation lumen. Slowly inject enough fluid to achieve desired diameter. Reference the balloon inflation table above or label attached to the Standard Bougie™ SB38. 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 7** – 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. Suction may be applied to further aid in stabilizing the position of the Standard Bougie™ SB38.

**Step 8** – Place the Titan SGS™ stapler lateral to the Standard Bougie™ SB38, reference Figure 1. Ensure the Standard Bougie™ SB38 remains in the desired position while the surgical stapler is placed. Use of the Standard Bougie™ SB38 with the Titan SGS™ stapler results in a 40Fr sleeve diameter. Once the Titan SGS™ stapler is placed, ensure the Standard Bougie™ SB38 is freely mobile within the stomach.

**Step 9** – If needed, check for staple-line leak by attaching a tapered tip syringe to the straight tube on the proximal end of the Standard Bougie™ SB38 and depress the plunger to eject air or fluid into the stomach.

**Step 10** –Deflate balloon by re-connecting Luer lock syringe to the inflation lumen and slowly remove all fluid from the balloon.

**Step 11** –Carefully remove device from patient. Do not apply suction when moving or removing the Standard Bougie™ SB38. Ensure all fluid has been removed from balloon prior to removing the Standard Bougie™ SB38.

## INSPECTION AND HANDLING


Standard Bougie™ SB38 devices are carefully inspected before shipment. Standard Bougie™ SB38 and packaging should be inspected upon receipt as product or packaging may become damaged in transit or storage. The Standard Bougie™ SB38 should be handled and operated by personnel completely familiar with their use. Handle the Standard Bougie™ SB38 with care at all times.

## PACKAGING AND STORAGE

The Standard Bougie™ SB38 is provided in non-sterile packing and should be stored at room temperature. Avoid prolonged exposure to elevated temperatures. The Standard Bougie™ SB38 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®  
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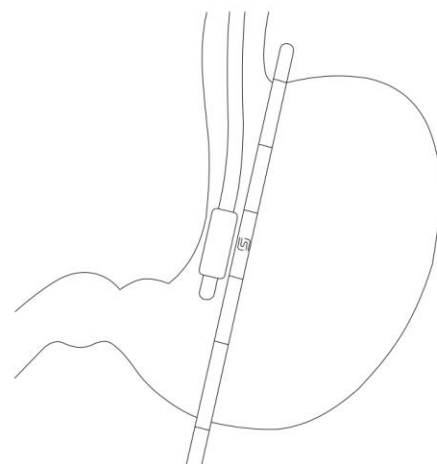


Figure 1. Titan SGS™ stapler placed lateral to Standard Bougie™ SB38