

STANDARD TAPERED BOUGIE, 38Fr (STB38) INSTRUCTIONS FOR USE (IFU)

STANDARD BARIATRICS® STANDARD TAPERED BOUGIE, 38Fr (STB38)

Product Code: STB38

Length: Approx. 95 cm

Catheter Diameter: 38 Fr (Approx. 12.7 mm)

Balloon Diameter: 28mm (± 2.0mm) tapered to 38 Fr (Approx. 12.7mm)

Nonsterile syringe: 60mL/ CC

Optional Standard Bougie Hand Pump Product Code: SBHP (provided separately)

The STB38 and SBHP are not made with natural rubber latex

INDICATIONS FOR USE

The Standard Tapered Bougie, 38Fr (STB38) 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.

CONTRAINDICATIONS

- The Standard Tapered Bougie, 38Fr (STB38) is not intended for use:
 - In Roux-en-Y Gastric Bypass (RYGBP) procedures
 - Where esophageal stricture does not allow passage of Standard Tapered Bougie, 38Fr (STB38)
 - In conditions which would preclude gastric or bariatric surgical procedures.

DEVICE DESCRIPTION

The Standard Tapered Bougie, 38Fr (STB38) is a non-sterile, single patient use device. The device comprises a tube with a rounded tip featuring drainage holes, and tapered balloon at the distal end. The proximal end of the Standard Tapered Bougie, 38Fr (STB38) includes a standard Luer lock valve for balloon inflation/deflation using the 60mL/ CC syringe (provided) and a straight tube for connection to operating room suction, Standard Bougie Hand Pump (SBHP) or tapered tip syringe.

The optional Standard Bougie Hand Pump (SBHP) is a non-sterile, single patient use device. The device comprises a 3oz hand pump, pressure relief valve, tubing and two connection points. The two connection points allow for connection to Operating Room (OR) Suction via the Drain T-Valve and connection to the Standard Tapered Bougie, 38Fr (STB38) via the suction adapter. The pressure relief valve activates at approximately 40mmHg to prevent over-inflation.

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 Tapered Bougie, 38Fr (STB38) 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 Tapered Bougie, 38Fr (STB38) is not of a size deemed suitable by the clinician, it should not be used as a sizing guide.

WARNINGS & PRECAUTIONS CONTINUED

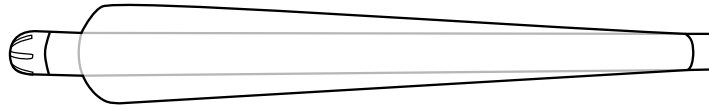
5. Do not use this product in patients presenting with Zenker's diverticulum unless certain that entry into the diverticulum can be avoided.
6. Use of this product in patients presenting with esophageal varices may result in increased bleeding risk.
7. Do not staple or sew the Standard Tapered Bougie, 38Fr (STB38) to the stomach. Before firing any staple loads in the stomach, always confirm placement of the Standard Tapered Bougie, 38Fr (STB38) by either visual or tactile cues. Laparoscopic stapling techniques rely upon visual and tactile feedback to preclude stapling across devices (including the Standard Tapered Bougie, 38Fr (STB38)). 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 Tapered Bougie, 38Fr (STB38). Ensure Standard Tapered Bougie, 38Fr (STB38) is freely mobile within the stomach prior to activating stapler to avoid stapling the Standard Tapered Bougie, 38Fr (STB38).
8. Any instrument passed blindly through the esophagus presents the risk of esophageal perforation. The Standard Tapered Bougie, 38Fr (STB38) 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 Tapered Bougie, 38Fr (STB38).
9. Do not inject water or saline into the balloon. Only air should be injected into the balloon. Do not fill the balloon with more than 60 CC of air.
10. Stapling indwelling tubes is a risk when performing a sleeve gastrectomy. To limit this risk, The Standard Tapered Bougie, 38Fr (STB38) 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 Tapered Bougie, 38Fr (STB38) is not indicated for the removal of solid materials such as food. Do not use the Standard Tapered Bougie STB38 if solid materials such as food are present in the stomach.
13. Do not attempt to move the Standard Tapered Bougie, 38Fr (STB38) while suction is applied. The distal end of the Standard Tapered Bougie, 38Fr (STB38) may adhere to the lumen of the stomach when suction is applied. Make sure suction has been turned off or disconnected from the Standard Tapered Bougie, 38Fr (STB38) 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, air will return to the syringe and the balloon diameter will decrease in size.
15. Do not attempt to remove the Standard Tapered Bougie, 38Fr (STB38) from the patient without removing all residual air from the balloon.

STANDARD TAPERED BOUGIE, 38Fr (STB38) INSTRUCTIONS FOR USE (IFU)

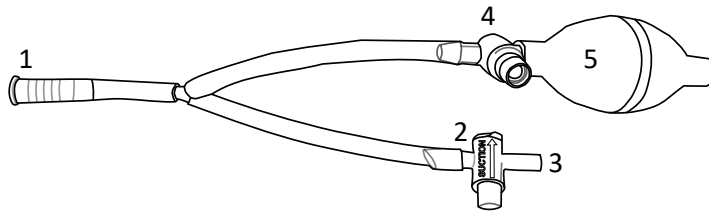
SYSTEM COMPONENTS & SPECIFICATIONS

STB38:

Tubing	The catheter tubing is approximately 95 cm long and has a diameter of 38 French (12.7mm)
Drainage Holes	The Standard Tapered Bougie, 38Fr (STB38) includes apertures at the tip of the catheter.
Balloon	The balloon is located 1.9 cm from the distal end and is 16.6 cm long.
Syringe	60mL/ CC syringe provided for the purpose of inflating the balloon with air



SBHP:



Item Number	Component
1	STB38 Connection Point (Suction Adapter)
2	Drain T- Valve (Pictured in closed position)
3	OR Suction Connection Point
4	Pressure Relief Valve
5	Hand Pump

HOW SUPPLIED

The Standard Tapered Bougie, 38Fr (STB38) and Standard Bougie Hand Pump (SBHP) are 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 Tapered Bougie, 38Fr (STB38) or Standard Bougie Hand Pump (SBHP).

DIRECTIONS FOR USE

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

Step 1 – Remove the non-sterile Standard Tapered Bougie, 38Fr (STB38) from packaging.

Step 2 – Apply surgical lubricant onto the tip, balloon and entire working length of the Standard Tapered Bougie, 38Fr (STB38) before inserting into patient.

Step 3 – Carefully insert the Standard Tapered Bougie, 38Fr (STB38) 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 4 – If needed, evacuate stomach contents by connecting suction tubing directly to the straight tube on the proximal end of the Standard Tapered Bougie, 38Fr (STB38) and apply no more than 150 mmHg suction. A standard 5-in-1 adapter (not included) may be used to connect suction tubing.

Step 5 – Inflate balloon by connecting a Luer lock syringe to the Luer lock connector on the inflation lumen. Slowly inject 60mL/ CC air to achieve desired diameter. The syringe must be removed after the balloon diameter is achieved. If the syringe is not removed, air will return to the syringe and the balloon diameter will decrease in size.

Step 6 – Adjust the balloon location such that the tip of the catheter is in contact with the antrum and held in place by the anesthesia provider. Suction may be applied to further aid in stabilizing the position of the Standard Tapered Bougie, 38Fr (STB38).

Step 7 – Place the Titan SGS® stapler lateral to the Standard Tapered Bougie, 38Fr (STB38), reference Figure 1.

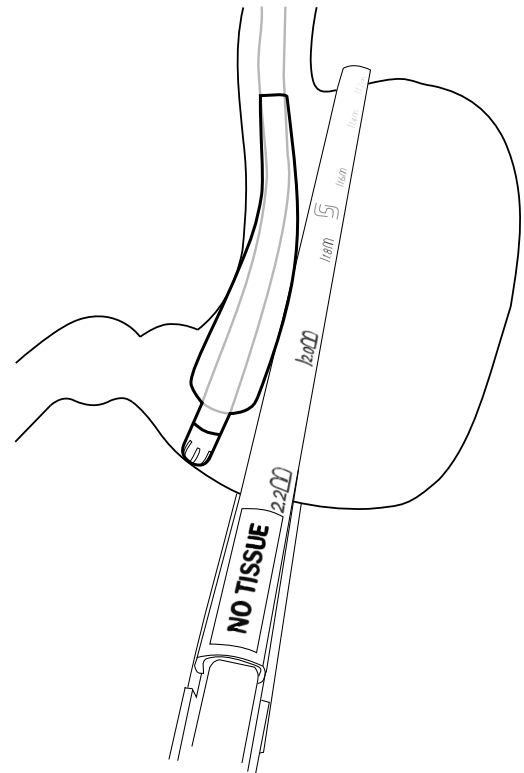


Figure 1: TITAN SGS® placed lateral to Standard Tapered Bougie STB38

Step 7a – To use the optional Standard Bougie Hand Pump (SBHP), turn off and remove OR suction from the Standard Tapered Bougie, 38Fr (STB38). Insert the white straight tube of the Standard Tapered Bougie, 38Fr (STB38) directly into the blue Suction Adapter of the Standard Bougie Hand Pump (SBHP). Connect OR Suction to the Standard Bougie Hand Pump Drain T- valve; verify Drain T- valve is in the closed position (as depicted in Figure 2).

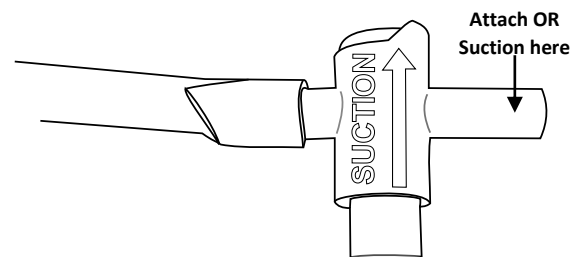


Figure 2: Drain T- Valve in Closed Position

STANDARD TAPERED BOUGIE, 38Fr (STB38) INSTRUCTIONS FOR USE (IFU)

Step 7b – To adjust the gastric folds/rugae of the stomach, connect the bulb to the valve and squeeze to achieve the desired effect. Use the Standard Bougie Hand Pump (SBHP) only when the stomach can be directly visualized. Do not occlude the Pressure Relief Valve during inflation.

Step 7c – Ensure the Standard Tapered Bougie, 38Fr (STB38) remains in the desired position while the surgical stapler is placed.

Step 7d – Switch the Drain T- valve to the open position by pressing the white actuator up (open is depicted in Figure 3). Remove air from the stomach by applying no more than 150 mmHg suction. Maintain visualization of the stomach during deflation.

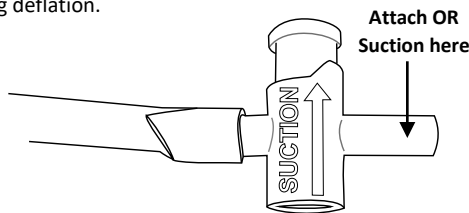


Figure 3: Drain T- Valve in Open Position

Step 7e – Confirm placement of Standard Tapered Bougie, 38Fr (STB38) and TITAN SGS®. Use of the 38Fr Standard Tapered Bougie, 38Fr (STB38) with the Titan SGS® stapler results in an approximate 40Fr sleeve diameter. Once the Titan SGS® stapler is placed, ensure the Standard Tapered Bougie STB38 is freely mobile within the stomach. For Titan SGS® use instructions, reference the Titan SGS® Instructions for Use (IFU).

Step 8 – If needed, check the staple-line for leaks by using one of the methods described in Steps 8a and 8b.

Step 8a – (if optional Standard Bougie Hand Pump (SBHP) is not used) Attach a tapered tip syringe directly to the straight tube on the proximal end of the Standard Tapered Bougie. Depress the plunger to inject air into the stomach.

Step 8b – (if optional Standard Bougie Hand Pump (SBHP) is used) Inflate the stomach by squeezing the hand pump of the Standard Bougie Hand Pump. Use the Standard Bougie Hand Pump (SBHP) only when the stomach can be directly visualized. Do not occlude the Pressure Relief Valve during inflation.

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

Step 10 –Carefully remove device from patient. Do not apply suction when moving or removing the Standard Tapered Bougie, 38Fr (STB38). Ensure all air has been removed from balloon prior to removing the Standard Tapered Bougie, 38Fr (STB38).

INSPECTION AND HANDLING

Standard Tapered Bougie, 38Fr (STB38) and Standard Bougie Hand Pump (SBHP) devices are carefully inspected before shipment. The product packaging should be inspected upon receipt as product or packaging may become damaged in transit or storage. The Standard Tapered Bougie, 38Fr (STB38) and Standard Bougie Hand Pump (SBHP) should be handled and operated by personnel completely familiar with their use. Always handle the Standard Tapered Bougie, 38Fr (STB38) and Standard Bougie Hand Pump (SBHP) with care.

PACKAGING AND STORAGE

The Standard Tapered Bougie, 38Fr (STB38) and Standard Bougie Hand Pump (SBHP) are provided in non-sterile packing and should be stored at room temperature. Avoid prolonged exposure to elevated temperatures. The Standard Tapered Bougie, 38Fr (STB38) and Standard Bougie Hand Pump (SBHP) should always be handled with great care in transportation and storage.

DISPOSAL

The Standard Tapered Bougie, 38Fr (STB38) and Standard Bougie Hand Pump (SBHP) should be disposed of per hospital guidelines following use or removal from packaging.

SYMBOLOLOGY

Symbol	Definition	Reference Standard/ Requirement
Rx ONLY	CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician	21 CFR 801.109
MD	Medical Device	ISO 15223-1, Reference # 5.7.7
REF	Catalogue Number	ISO 15223-1, Reference # 5.1.6 21 CFR 820.120
LOT	Batch Code	ISO 15223-1, Reference # 5.1.5 21 CFR 820.65
	Consult Instructions for Use	ISO 15223-1, Reference # 5.4.3
	Date of Manufacture	ISO 15223-1, Reference # 5.1.3
	Manufacturer	ISO 15223-1, Reference # 5.1.1
	Distributor	ISO 15223-1, Reference # 5.1.9
	Use- by Date	ISO 15223-1, Reference # 5.1.4 21 CFR 801.18
	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
	Not made with natural rubber latex	N/A
Standards: Code of Federal Regulations (CFR) Title 21, Part 801 – Labeling Code of Federal Regulations (CFR) Title 21, Part 820 – Quality System Regulation ISO 15223-1 Medical Devices – Symbols To Be Used with Medical Device Labels, Labeling, and Information to be Supplied		

QUESTIONS

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

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