# STANDARD BOUGIE® 38Fr (SB38) INSTRUCTIONS FOR USE (IFU)

## STANDARD BARIATRICS® STANDARD BOUGIE®

**Product Code:** SB38
**Length:** Approx. 95 cm
**Catheter Diameter:** 38 Fr (Approx. 12.7 mm)
**Balloon Diameter:** 2.0 cm – 3.0 cm

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

The SB38 and SBHP are not made with natural rubber latex

**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.**

**CONTRADICATIONS**
- 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® SB38
- 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 straight tube for connection to operating room suction or tapered tip syringe for injection of fluid.

The optional Standard Bougie Hand Pump 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 Bougie® via the suction adaptor. 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 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.

**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 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.

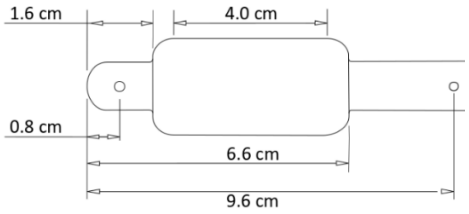
14. The syringe must be removed after the desired balloon diameter is achieved. If the syringe is not removed, fluid will return to the syringe and the balloon diameter will decrease in size.

15. Do not attempt to remove the Standard Bougie® SB38 from the patient without removing all residual fluid from the balloon.

# STANDARD BOUGIE® 38Fr (SB38) INSTRUCTIONS FOR USE (IFU)

**SYSTEM COMPONENTS & SPECIFICATIONS**
**SB38:**

| | |
|---|---|
| **Tubing** | The catheter tubing is approximately 95 cm long and has a diameter of 38 French (12.7mm) |
| **Holes** | 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. |
| **Balloon** | The balloon is located 1.6 cm from the distal end and is 4cm long. |

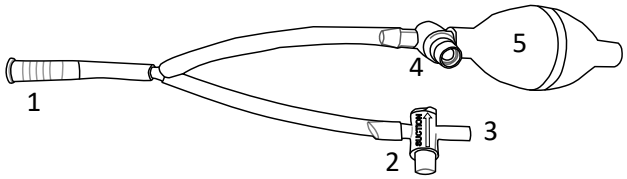



**38Fr Standard Bougie®**
**BALLOON INFLATION TABLE**

| | Balloon Diameter | Fill Volume |
|---|---|---|
| **Minimum** | 2.0cm | 8ml |
| **Nominal** | 2.5cm | 14ml |
| **Maximum** | 3.0cm | 22ml |

*Additional fluid required to prime catheter*

**SBHP:**




| Item Number | Component |
|---|---|
| 1 | SB38 Connection Point (Suction Adaptor) |
| 2 | Drain T- Valve (Pictured in closed position) |
| 3 | OR Suction Connection Point |
| 4 | Pressure Relief Valve |
| 5 | Hand Pump |

**HOW SUPPLIED**
The Standard Bougie® SB38 and Standard Bougie Hand Pump 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 Bougie® SB38 or Standard Bougie Hand Pump.

**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 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.

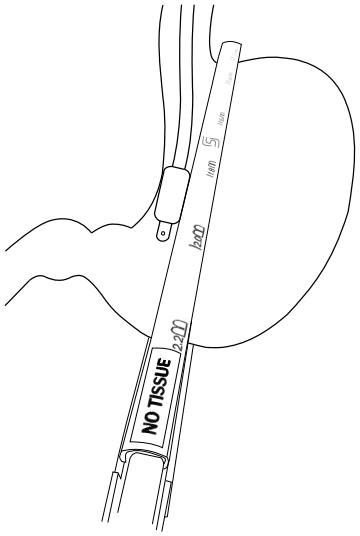



*Figure 1: TITAN SGS® placed lateral to Standard Bougie® SB38*

**Step 8a –** To use the optional Standard Bougie Hand Pump, turn off and remove OR suction from the Standard Bougie® SB38. Insert the white stepped adaptor of the Standard Bougie Hand Pump directly into the straight tube on the proximal end of the Standard Bougie® SB38. 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).

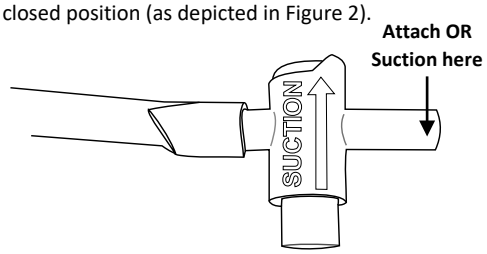



*Figure 2: Drain T- Valve in Closed Position*

# STANDARD BOUGIE® 38Fr (SB38) INSTRUCTIONS FOR USE (IFU)

**Step 8b –** To adjust the gastric folds/rugae of the stomach, connect the bulb to the valve and squeeze to achieve the desired effect. Use SBHP only when the stomach can be directly visualized. Do not occlude the Pressure Relief Valve during inflation.

**Step 8c** – Ensure the Standard Bougie® SB38 remains in the desired position while the surgical stapler is placed.

**Step 8d –** 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.

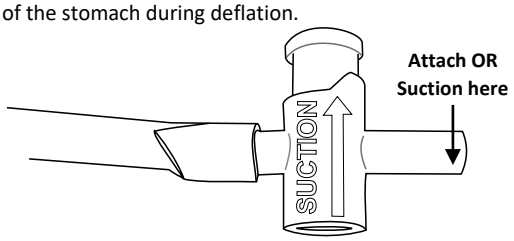



*Figure 3: Drain T- Valve in Open Position*

**Step 8e** – Confirm placement of Standard Bougie® SB38 and TITAN SGS®. Use of the 38Fr 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 the staple-line for leaks by using one of the methods described in Steps 9a and 9b.

**Step 9a** – (if optional Standard Bougie Hand Pump is not used) Attach a tapered tip syringe directly to the straight tube on the proximal end of the Standard Bougie®**.** Depress the plunger to inject air into the stomach.

**Step 9b –** (if optional Standard Bougie Hand Pump is used) Inflate the stomach by squeezing the hand pump of the Standard Bougie Hand Pump. Use SBHP only when the stomach can be directly visualized. Do not occlude the Pressure Relief Valve during inflation.

**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 and Standard Bougie Hand Pump 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 Bougie® SB38 and Standard Bougie Hand Pump should be handled and operated by personnel completely familiar with their use. Always handle the Standard Bougie® SB38 and Standard Bougie Hand Pump with care.

**PACKAGING AND STORAGE**

The Standard Bougie® SB38 and Standard Bougie Hand Pump are provided in non-sterile packing and should be stored at room temperature. Avoid prolonged exposure to elevated temperatures. The Standard Bougie® SB38 and Standard Bougie Hand Pump should always be handled with great care in transportation and storage.

**DISPOSAL**

The Standard Bougie® SB38 and Standard Bougie Hand Pump should be disposed of per hospital guidelines following use or removal from packaging.

**SYMBOLOGY**

| 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<br>21 CFR 820.120 |
| LOT | Batch Code | ISO 15223-1, Reference # 5.1.5<br>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<br>21 CFR 801.18 |
| NON STERILE | 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 |
| LATEX | 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

Manufactured For:
Standard Bariatrics®
4300 Glendale Milford Rd.
Cincinnati, OH 45242 USA
Phone: 513-620-7751

Distributed By:
Teleflex Medical, Inc.
3015 Carrington Mill Blvd.
Morrisville, NC 27560 USA



STANDARD BARIATRICS | Teleflex®