





# 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.

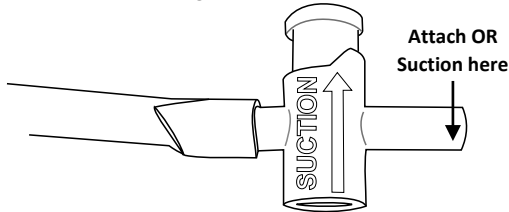


Figure 3: Drain T- Valve in Open Position

**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.

## SYMBOLOLOGY

Symbol	Definition	Reference Standard/ Requirement
	CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician	21 CFR 801.109
	Medical Device	ISO 15223-1, Reference # 5.7.7
	Catalogue Number	ISO 15223-1, Reference # 5.1.6 21 CFR 820.120
	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
<b>Standards:</b> 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