

STANDARD BOUGIE® 38FR

Achieve precise anatomical alignment and protect the incisura angularis during sleeve pouch creation using the Standard Bougie 38FR with the Titan SGS® stapler and the bladeless technology of the Standard Trocar®.



- **Standard Luer valve**
- **Standard suction connection** to evacuate stomach contents and check for staple line leaks
- **Graduated markings** every 5cm to aid in accurate placement
- **38FR catheter** made with custom-blended thermoplastic polyurethane designed for optimal manipulability and flexibility
- **Angularis protecting balloon** assists the surgeon in achieving precise anatomical alignment and protect the incisura angularis during sleeve gastrectomy procedures
- **Atraumatic tip** aids with safe and easy insertion

Figure 1
The Titan SGS placed lateral to the Standard Bougie 38FR

THE RIGHT LINE EVERY TIME

Designed for use with the Standard Bougie 38FR and Standard Trocar, the Titan SGS stapler offers you an elegant alternative for performing sleeve gastrectomy. The device is designed to help you achieve more consistent and symmetrical sleeve pouch anatomy, setting your patients up for the best possible outcomes.



DIRECTIONS FOR USE STANDARD BOUGIE® 38FR

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.

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 below 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. Confirm placement of the Standard Bougie SB38 with Titan SGS. 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 inject air into the stomach.

Step 10 — Deflate balloon by reconnecting 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.

38FR SYSTEM COMPONENTS & SPECIFICATIONS

Model	SB38
Description	Non-sterile, single use device with a balloon at the distal tip
Qty/Bx	6
Tubing	The catheter tubing is approximately 95cm long and has a diameter of 38 French (12.7mm)
Holes	The Standard Bougie SB38 includes 2.7mm diameter apertures that extend to a distance of no more than 10cm from the distal tip of the catheter
Balloon	The balloon is located 1.6cm from the distal end and is 4cm long

38FR INFLATION TABLE

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

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