

## Standard Precision Bougie<sup>™</sup> Device

## **Indications For Use**

The Standard Precision Bougie<sup>™</sup> Device is indicated for use in conjunction with the Titan SGS<sup>™</sup> Stapler in longitudinal 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, discard and replace the device.

**Step 1** — Remove the non-sterile Standard Precision Bougie<sup>™</sup> Device from packaging.

**Step 2** — Apply surgical lubricant onto the tip, balloon and entire working length of the Standard Precision Bougie $^{\text{TM}}$  Device before inserting into patient.

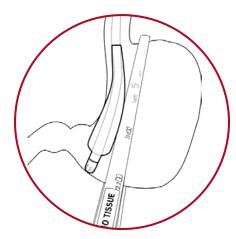
Step 3 — Carefully insert the Standard Precision Bougie™
Device through blind orogastric insertion into the patient's stomach the same way an OG tube is placed. The distal tip of the catheter is intended to be placed into the antrum of the stomach. Once inserted into the stomach the tip can be visualized 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 Precision Bougie™ Device 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 Precision Bougie™ Device.

Figure 1
The Titan SGS™ Stapler placed lateral to the Standard Precision
Bougie™ Device.



**Step 7** — Place the Titan SGS™ Stapler lateral to the Standard Precision Bougie™ Device, reference Figure 1.

**Step 8** — If needed, check the staple-line for leaks by attaching a tapered tip syringe directly to the straight tube on the proximal end of the Standard Precision Bougie™ Device. Depress the plunger to inject air into the stomach.

**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 Precision Bougie™ Device. Ensure all air has been removed from balloon prior to removing the Standard Precision Bougie™ Device.

| Standard Precision Bougie™ Device |   |
|-----------------------------------|---|
| Model                             | STB38   |
| Description                       | Non-sterile, single patient use device with a tapered balloon at the distal end         |
| Qty/Bx                            | 6   |
| Tubing                            | The catheter tubing is approximately 95cm long and has a diameter of 38 French (12.7mm) |
| Drainage Holes                    | The Standard Precision Bougie™ Device includes apertures at the tip of the catheter     |
| Balloon                           | The balloon is located 1.9cm from the distal end and is 16.6cm long                     |
| Syringe                           | 60mL/CC syringe provided for the purpose of inflating the balloon with air              |

Refer to the Instructions for Use for a complete listing of the indications, contraindications, warnings, precautions and adverse reactions.

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