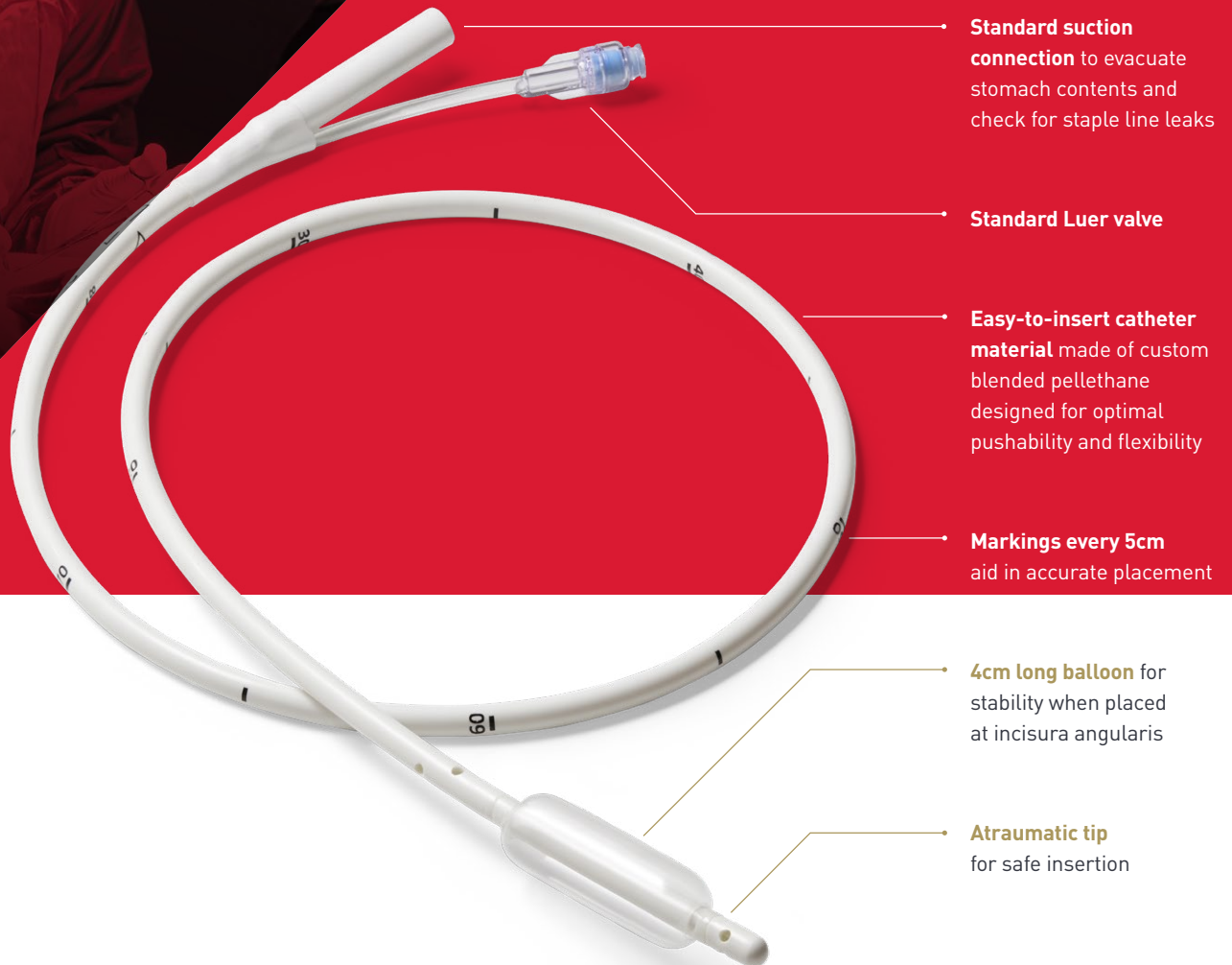


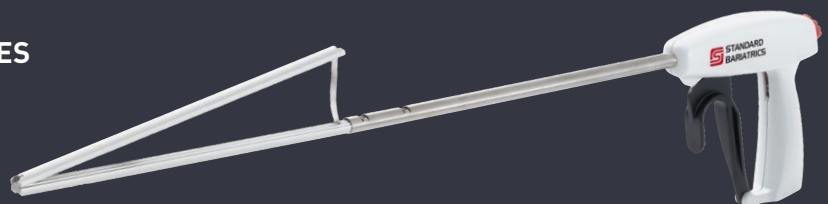
## 18FR STANDARD BOUGIE™

Achieve precise anatomical alignment and protect the incisura angularis during sleeve gastrectomy procedures performed using the Standard Clamp®.



### OPTIMAL ANATOMY = OPTIMAL OUTCOMES

Holding the line with the Standard Clamp® and the Standard Bougie for better, more consistent anatomy and results.\*



\*The Standard Bougie is to be used with the Standard Clamp.

# DIRECTIONS FOR USE 18FR STANDARD BOUGIE™

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

**Step 1** — Remove Standard Bougie from packaging. Remove the nonsterile Standard Bougie from packaging, by peeling the two layers of the Tyvek peel-pouch apart.

**Step 2** — Lubricate distal tip of catheter. Apply surgical lubricant onto the tip, balloon and entire working length of the Standard Bougie before inserting into patient.

**Step 3** — Insertion. Carefully insert the Standard Bougie into patient through blind orogastric insertion into the stomach, the same way an OG tube is placed. The 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.

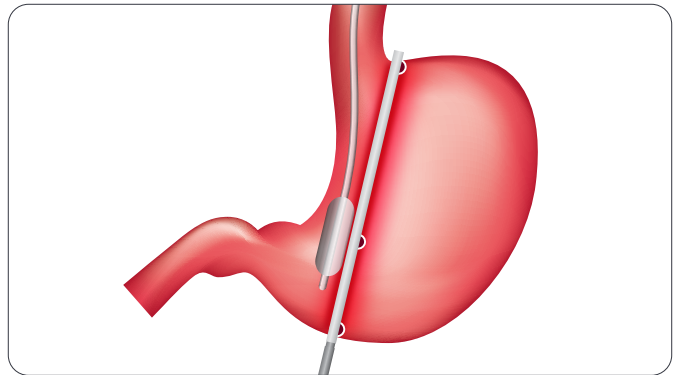
**Step 4** — If needed, evacuate stomach contents. To remove fluid, use a standard 5-in-1 adapter (not included) to connect OR suction tubing to the 7.5mm inner diameter straight tube on the proximal end of the Standard Bougie and apply no more than 150mm Hg suction.

**Step 5** — Inflate balloon. For sizing, connect a 20ml luer lock syringe to the luer lock connector on the inflation lumen and slowly inject enough fluid to achieve desired diameter. Reference the balloon inflation table below or label attached to the Standard Bougie. 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 6** — 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.

**Step 7** — Place the Standard Clamp® lateral to the Standard Bougie, reference Figure 1. The Standard Clamp's 1cm width acts as a spacer, which once placed, does not allow the Standard Bougie to migrate into the path of the stapler. Use of the 18FR Standard Bougie with the Standard Clamp results in a 40FR sleeve diameter. Once the Standard Clamp is placed, ensure the Standard Bougie is freely mobile within the stomach.

**Step 8** — If needed, check for staple-line leak by attaching a 60ml Tumi syringe and depressing the plunger to eject air into the stomach.



**Figure 1**

The Standard Clamp placed lateral to the Standard Bougie.

**Step 9** — Deflate balloon by re-connecting a 20ml luer lock syringe to the inflation lumen and slowly remove all fluid from the balloon.

**Step 10** — Carefully remove device from patient. Do not apply suction when moving or removing the Standard Bougie.

**NOTE:** The distal end of the Standard Bougie may adhere to the lumen of the stomach when suction is applied. Do not move the device when suction is applied.

**NOTE:** When using the Standard Bougie in the sleeve gastrectomy, or similar procedure, prior to stapling, such as when creating the pouch, make sure that the exact location of the Standard Bougie is known and that it is not in the path of the stapler. Ensure Standard Bougie is not included in the stapler prior to firing the stapler.

## 18FR STANDARD BOUGIE SPECIFICATIONS

<b>Model</b>	SB18-8
<b>Description</b>	Non-sterile, single use device with a balloon at the distal tip
<b>Qty/Bx</b>	8

For more information or to place an order:  
[orders@standardbariatrics.com](mailto:orders@standardbariatrics.com)

18FR INFLATION TABLE		
	Balloon Diameter	Fill Volume
<b>Minimum</b>	1.5cm	6ml
<b>Nominal</b>	2.0cm	10ml
<b>Maximum</b>	2.5cm	16ml



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4362 Glendale Milford Road, Cincinnati, OH 45242

1-513-620-7751 | [standardbariatrics.com](http://standardbariatrics.com)