

# GASTRIC CALIBRATION TUBE

## Instruction for Use–Type II

### 1. Product Information

**Product Name:** Gastric Calibration Tube

**Model & Specification:**

**Type II:** 32 Fr, 34 Fr, 36 Fr, 38 Fr, 40 Fr

**Note:** Type II is used for calibration and fixation (includes a balloon).

Code	Specification	OD (mm)	Length (mm)	Color	Scale (cm)	Balloon volume (mL)	Balloon diameter (mm)
SY02-04	32Fr	10.70	745±20	Blue	20-100	30±5	40±5
SY02-00	34Fr	11.30	745±20	Blue	20-100	30±5	40±5
SY02-01	36Fr	12.00	745±20	Blue	20-100	30±5	40±5
SY02-02	38Fr	12.40	745±20	Blue	20-100	30±5	40±5
SY02-03	40Fr	13.20	745±20	Blue	20-100	30±5	40±5

The product is sterile (sterilized by ethylene oxide) and intended for single use.



### 2. Structural Composition

**Type II:** This model includes a balloon for calibration and fixation. It consists of a tube, inner cone connector, silicone tip, universal connector, check valve, development line, and balloon. It is supplied sterile, sterilized by ethylene oxide, and intended for single use.

### 3. Intended Purpose

The Gastric Calibration Tube (Type II) is indicated for use in **Longitudinal Sleeve Gastrectomy (LSG)** procedures to drain and remove gastric fluid and to provide a calibration of the gastric pouch.

### 4. Usage Method

#### Step 1: Model Selection

**a.** Select the appropriate model of the Gastric Calibration Tube based on the patient's height, body habitus, and surgical requirements (including suitable diameter and length).

**b.** Verify the external packaging, production batch number, and expiration date (valid for 2 years) to ensure the product is within its valid period.

#### Step 2: Unpacking and Sterile Check

**a.** Inspect the packaging for any damage, moisture, or contamination. If any abnormality is found, do not use.

**b.** In a sterile environment, open the outer packaging as instructed and remove the product.

**c.** Double-check the label, production batch number, and expiration date. Confirm that the balloon port, inner cone connector, one-way valve, and universal connector are intact and free of foreign matter.



#### Step 3: Balloon Orientation Calibr

**a.** Identify the balloon's expansion direction using the **blue marking line** on the Gastric Calibration Tube (the side with the blue marking line indicates the balloon expansion direction).

**b.** Use the graduations on the tube to determine the insertion depth for **accurate positioning**.



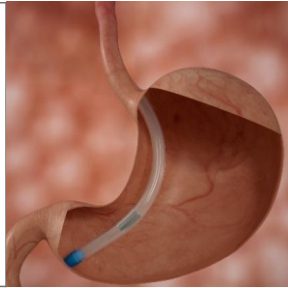
#### Step 4: Esophageal Insertion

**a.** Lubrication: Before insertion, apply a suitable lubricant to the tube's distal end to reduce friction and minimize patient discomfort.

**b.** Insertion: Gently introduce the Gastric Calibration Tube through the patient's mouth into the esophagus. Avoid excessive force or angulation to reduce the risk of mucosal injury.

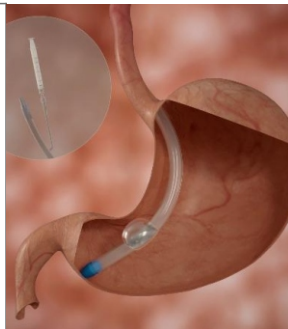
**Step 5: Laparoscopic Positioning Verification**

- a. Under laparoscopic visualization, confirm that the tube's distal tip has entered the stomach.
- b. **Fine Adjustment:** Gently pull back or advance the tube to ensure it lies along the lesser curvature. Compare with external gradation marks or endoscopic landmarks to verify **proper insertion depth**.



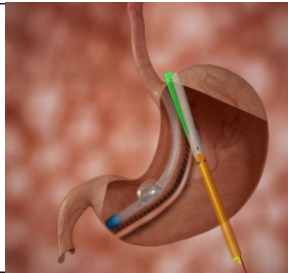
**Step 6: Balloon Inflation and Fixation**

- a. **Balloon Inflation:** Once correct placement is confirmed, attach a syringe to the check valve (or dedicated balloon port). Slowly inject approximately 30 mL of normal saline to inflate the balloon.
- **WARNING: Do not inflate** the balloon before the tube is fully inserted into the stomach to avoid potential esophageal injury.
- b. **Position Check:** After inflation, gently pull the tube so that the balloon rests firmly against the gastric wall near the pylorus. If the balloon position is suboptimal, deflate it, reposition the tube, and re-inflate.



**Step 7: Gastric Calibration and Resection**

- a. **Calibration:** With the balloon serving as a "stop" near the pylorus, use the **non-inflated portion** of the tube along the lesser curvature as a guide for the resection pathway.
- b. **Resection:** Perform the sleeve gastrectomy (stapling or cutting) close to the tube. Maintain consistent spacing from the tube to achieve the desired gastric pouch size.



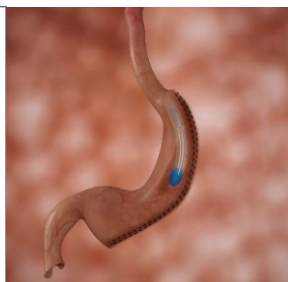
**Step 8: Post-Suturing Leak Test (Methylene Blue Injection)**

- a. **Connection:** After resection and suturing, connect a syringe containing methylene blue solution (or an approved dye per hospital protocol) to the tube via the inner cone connector or universal connector.
- b. **Injection:** Slowly inject dye into the newly formed gastric pouch.
- c. **Leak Check:** Under laparoscopic visualization, inspect the staple line or sutured areas for any sign of dye leakage.



**Step 9: Test Completion and Drainage**

- a. **Drainage:** Withdraw the methylene blue solution or any residual fluid through the Gastric Calibration Tube.
- b. **Deflation:** Before removal, ensure the balloon is fully deflated by aspirating all the saline back into the syringe.
- c. **Removal:** Gently remove the Gastric Calibration Tube from the esophagus.
- d. **Disposal:** Dispose of the used tube and its accessories as medical waste according to local regulations.



**5. Warnings**

- **This product is suitable for gastric operations to empty, clean, and inject the stomach.**
- **Do not use** if the product is contaminated, has foreign bodies, or is defective or ruptured.
- To prevent cross-infection, use for **one person only**.
- This product is disposable; **do not reuse**. Must be used under the guidance of medical personnel.
- Check the package integrity before use. If the package is damaged, do not use.
- Confirm the packaging label, production date, and validity period before use; use within the valid period.
- The stomach tube is made of silicone rubber. In special cases, follow the doctor's advice.
- Any serious incident related to this device must be reported to the manufacturer and the competent authority of the EU Member State where the user/patient is located.

**6. Intended Patient Population**

Adults over 18 years of age.

**7. Intended User**

Healthcare professionals.

**8. Intended Environment**

Medical institutions.

**9. Performance Characteristics**

- a. **Balloon Performance:** The balloon withstands a burst volume of no less than 60mL.
- b. **Tensile Strength:** The tube withstands a static tension of at least 15 N without breaking or separating.
- c. **Leakage Prevention:** Each connection is tested at 30 kPa water pressure for 2minutes to ensure no leakage.
- d. **Appearance:** The product is translucent with a smooth outer surface, free from defects such as depressions, shrinkage, bubbles, impurities, or fiber foreign bodies. Graduations are clear, uniform, and legible.

**10. Clinical Benefits**

**Enhanced Surgical Efficiency**

- Fewer adjustments, reduced operating time, and decreased anesthesia exposure.

**Improved Safety**

- Accurate placement reduces risks such as esophageal perforation and postoperative pain, enhancing patient recovery.

**Effective Weight Management**

- Consistent long-term weight loss outcomes, critical for successful bariatric surgery.

**11. Contraindications**

- Zenker's diverticulum
- Esophageal varices
- Esophageal stricture
- Upside-down stomach

**12. Additional Information**

a. **Production Batch Number and Production Date:** Refer to the product label.

b. **Validity:** 2 years from the production date.

c. **Storage Conditions:** Store in a cool, ventilated, and dry area.

d. **Transportation Conditions:** Protect against dampness, compression, and rain. Avoid collisions, friction, or scratches with hard objects.

e. **Latest Date:** 2025.02.28

f. **Latest Version:** 04

**Illustrated Explanation: Symbols according to ISO 15223-1:2021.**

Graphics and symbols	Explain	Graphics and symbols	Explain
	CE Marking		Do not use if the package is damaged
	Authorized representative in the European Community/ European Union		Medical Device
	Refer to the instructions		Sterile by EO
	No secondary use		Limit of stacking layers
	Keep dry		Batch code
	Vertically upward		Use-by date
	Date of manufacture		Single sterile barrier system with protective packaging inside
	Keep away from sunlight		Unique device identifier
	Manufacturer		Caution