SHENYUN

INSTRUCTIONS FOR USE

Sterile Single Use Gastric Calibration Tube



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CE 1639

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1. PRODUCT INFORMATION

Product name: Sterile Single Use Gastric Calibration Tube · Type I and Type II, 32–40 Fr. Sterile (ethylene oxide), single use.



Type I · length 1,200 ± 20 mm · clear tube, blue tip and markings · scale 30–90 cm

Code	Size	OD (mm)	ID (mm)
SY01-04	32 Fr	10.70	6.7 ± 0.3
SY01-00	34 Fr	11.30	7.1 ± 0.3
SY01-01	36 Fr	12.00	8.0 ± 0.3
SY01-02	38 Fr	12.40	8.4 ± 0.3
SY01-03	40 Fr	13.20	8.2 ± 0.3

Type II · length 745 ± 20 mm · clear tube, blue tip and markings · scale 2–10 cm (1 cm intervals, 52–60 cm from the tip) · balloon volume 30 ± 5 mL · balloon diameter 40 ± 5 mm

Code	Size	OD (mm)
SY02-04	32 Fr	10.70
SY02-00	34 Fr	11.30
SY02-01	36 Fr	12.00
SY02-02	38 Fr	12.40
SY02-03	40 Fr	13.20

2. STRUCTURAL COMPOSITION

- **Type I**: tube, inner cone connector, silicone tip, universal connector, check valve and development line. Used for calibration and fixation.
- **Type II**: tube, inner cone connector, silicone tip, universal connector, check valve, development line and balloon. Used for calibration and fixation (with balloon).
- Supplied sterile, sterilized by ethylene oxide, for single use.

3. INTENDED PURPOSE

- **Type I** is indicated for use in gastric bypass (mini) and longitudinal sleeve gastrectomy (LSG) procedures to provide visible and tactile delineation of the stomach and with the ability to decompress the stomach, drain and remove gastric fluid.
- **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. INTENDED PATIENTS, USERS AND ENVIRONMENT

- Intended patient population: adults over 18 years of age.
- Intended user: healthcare professionals.
- Intended environment: medical institutions.

5. CONTRAINDICATIONS

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

6. WARNINGS AND PRECAUTIONS

> ! Do not inflate the Type II balloon before the tube is fully inserted into the stomach, to avoid potential esophageal injury.

- Strictly control the positive pressure (≤ 50 kPa) and negative pressure (≤ 40 kPa) during operation to prevent damage to the gastric wall.
- All procedures must be performed in a qualified medical institution by professional healthcare personnel; use under the guidance of medical personnel.
- Check the package integrity before use. Do not use if the package is damaged, or if the product is contaminated, contains foreign matter, or is defective or ruptured.
- Confirm the packaging label, production date and validity period before use; use within the valid period.
- This product is intended for single use only, for one patient; do not reuse, to prevent cross-infection.
- During injection or aspiration, closely monitor the fluid flow within the tube to ensure proper functioning of the calibration tube and the flow stopper clip.
- The tube is made of silicone rubber. In special cases, follow the doctor’s advice.

7. INSTRUCTIONS FOR USE

Type I

1. **Preparation**: check that the packaging is intact and undamaged, confirming that the device is sterile and within its expiration date; verify the packaging labels, manufacturing date, expiry date and batch number. If necessary, apply a water-soluble lubricant to the tube and the guide section to facilitate smooth insertion.
2. **Insertion**: insert the tube orally, guide tip first, until the predetermined intragastric positioning site is reached. Confirm correct placement in the stomach using the scale on the tube.
3. **Leak test and flow control**: once the gastric pouch (or stomach segment) is constructed, connect a syringe via the universal connector and slowly instill air or fluid into the stomach segment. Engage the flow stopper clip to occlude the tube, preventing backflow or leakage and keeping the pressure within a safe range. After instillation, disengage the clip and aspirate the instilled fluid through the lateral drainage ports while observing for any leakage.
4. **Completion and removal**: after the leak test and all procedures are completed, gently and carefully remove the tube from the patient, avoiding additional discomfort or injury.

Type II

1. **Model selection**: select the appropriate model according to the patient's height, body habitus and surgical requirements (diameter and length). Verify the outer packaging, production batch number and expiration date (valid for 2 years).
2. **Unpacking and sterile check**: inspect the packaging for damage, moisture or contamination; do not use if any abnormality is found. Open the outer packaging in a sterile environment and remove the product. Confirm that the balloon port, inner cone connector, one-way valve and universal connector are intact and free of foreign matter.
3. **Balloon orientation**: the side with the blue marking line indicates the balloon expansion direction. Use the graduations on the tube to determine the insertion depth.
4. **Esophageal insertion**: apply a suitable lubricant to the distal end. Gently introduce the tube through the mouth into the esophagus, avoiding excessive force or angulation.
5. **Laparoscopic positioning**: under laparoscopic visualization, confirm that the distal tip has entered the stomach. Pull back or advance gently so that the tube lies along the lesser curvature; verify the insertion depth with the graduations or endoscopic landmarks.
6. **Balloon inflation and fixation**: once placement is confirmed, attach a syringe to the check valve (or balloon port) and slowly inject approximately 30 mL of normal saline. Gently pull the tube so that the balloon rests against the gastric wall near the pylorus. If the position is suboptimal, deflate, reposition and re-inflate.
7. **Gastric calibration and resection**: with the balloon 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. Perform the sleeve gastrectomy close to the tube, keeping consistent spacing.
8. **Leak test (methylene blue)**: after resection and suturing, connect a syringe with methylene blue solution (or an approved dye per hospital protocol) via the inner cone or universal connector, inject slowly and inspect the staple line under laparoscopic visualization for leakage.
9. **Completion**: withdraw the dye and residual fluid through the tube. Fully deflate the balloon by aspirating all the saline, then gently remove the tube.

8. PERFORMANCE CHARACTERISTICS (TYPE II)

- Balloon burst volume not less than 60 mL.
- The tube withstands a static tension of at least 15 N without breaking or separating.
- Each connection is tested at 30 kPa water pressure for 2 minutes without leakage.
- Translucent with a smooth outer surface, free from depressions, shrinkage, bubbles, impurities or fibres; graduations clear, uniform and legible.

9. 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.

10. STORAGE, TRANSPORT AND SHELF LIFE

- Batch number and production date: see the product label.
- Shelf life: 2 years from the production date.
- Storage: store in a cool, ventilated and dry area.
- Transport: protect against dampness, compression and rain; avoid collisions, friction or scratches with hard objects.

11. DISPOSAL

Dispose of the used tube and its accessories as medical waste according to local regulations.

12. INCIDENT REPORTING

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 and/or patient is located.

13. SYMBOLS

CE 1639	CE marking		Do not use if the package is damaged	EC REP	Authorized representative in the European Community / European Union
MD	Medical device		Refer to the instructions	STERILE EO	Sterile by EO
	No secondary use		Limit of stacking layers		Keep dry
LOT	Batch code		Vertically upward		Use-by date
	Date of manufacture		Single sterile barrier system with protective packaging inside		Keep away from sunlight
UDI	Unique device identifier		Manufacturer		Caution

Symbols according to ISO 15223-1:2021.

MANUFACTURER

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