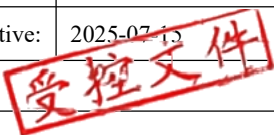


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Single Use Sterile BARILUX OG Calibration Tube

Instructions for Use

[Product Name]

Single Use Sterile BARILUX OG Calibration Tube

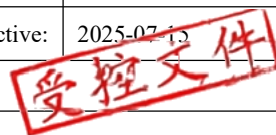
[Product Model]

34 Fr, 36 Fr, 38 Fr, 40 Fr

[Specification]

Specification	Model			
	34FR	36FR	38FR	40FR
Outer Diameter(mm)	11.3±0.3	12.0±0.3	12.4±0.3	13.2±0.3
Inner Diameter(mm)	7.1±0.3	8±0.3	8.4±0.3	8.3±0.3
Radiopaque Line Colour	Red	Blue	Green	Yellow
Tip Colour	Red	Blue	Green	Yellow
Tube length(mm)	1260±50	1260±50	1260±50	1260±50

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[Device identification and components]

The four models share the illustrated component arrangement. Red identifies 34 Fr, blue 36 Fr, green 38 Fr and yellow 40 Fr. Select the model by the labelled Fr size and the specification table above, not by colour alone. The photographs below illustrate the blue 36 Fr configuration; dimensions differ between models. Images are not to scale.

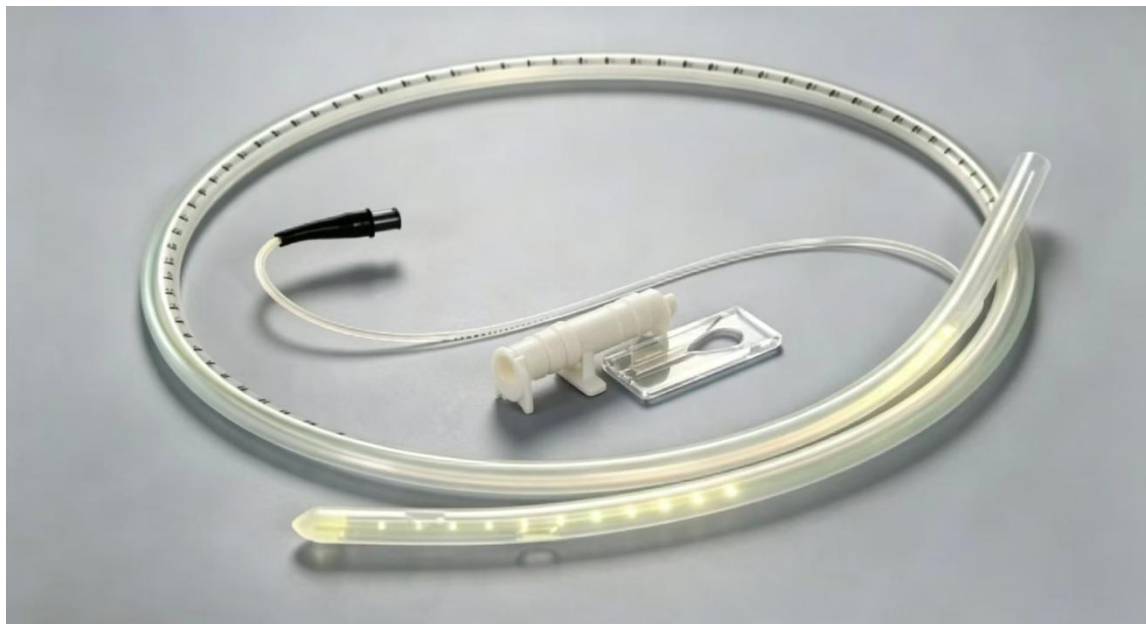


Figure 1. Complete tube with attached clear proximal adapter and flow-control clip; separate white universal connector in the centre. The blue distal tip, light guide cable, Black connector, numerical markings and longitudinal line are visible.

The tube comprises a distal tip, two lateral irrigation/aspiration holes, a longitudinal radiopaque line and numerical visual-reference markings. The markings do not provide quantitative measurement. The clip controls flow through the tubing. The supplied universal connector connects the adapter only to a compatible manually operated syringe; do not connect to powered suction equipment.

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[Component detail photographs]

Figure 2a. Distal tip and irrigation/aspiration holes.



Figure 2b. Proximal adapter.



Figure 2c. Flow-control clip.



Figure 2d. Universal connector.



Figure 2e. light guide cable



Figure2f.Blackconnector



Before use, check the labelled model, expiry date and integrity of the sterile packaging. Inspect the tube, distal openings, adapter, clip and connector for damage.

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[Intended Purpose and Indications]

The Single Use Sterile BARILUX OG Calibration Tube is intended to be used during bariatric or gastric surgical procedures, such as sleeve gastrectomy, gastric bypass and fundoplication, to:

- provide a physical template for the visual and tactile delineation and calibration of stomach size during resection or suturing;
- decompress the stomach by removing gastric contents, fluid or gas through manual aspiration using a syringe;
- enable gastric irrigation and manual aspiration using sterile 0.9% sodium chloride solution during surgery;
- support intraoperative leak testing with methylene blue solution when clinically indicated;
- provide visual orientation and positioning reference markings to assist the clinician in identifying the tube position during use.

The device is not intended for routine drug delivery or general administration of medicinal products.

[Graduation marks]

The graduation marks are visual references for orientation and positioning only. They do not provide quantitative measurements and must not be used to determine insertion depth, anatomical dimensions, resection length, gastric pouch size, dose, volume or any other quantitative clinical parameter. The device has no measuring function.

[Intended User]

The device must be used only by healthcare professionals trained and experienced in the relevant bariatric or gastric surgical procedures and in the placement and use of orogastric tubes.

[Intended Patient Population]

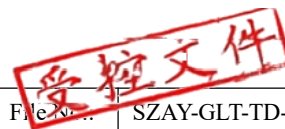
The device is intended for adults aged 18 years or older undergoing bariatric or gastric surgery in which gastric calibration, decompression, irrigation or manual aspiration is clinically required.

The device is intended for patients for whom intraoperative placement of a gastric calibration tube is considered appropriate by the responsible healthcare professional based on the patient's anatomical condition, clinical status and planned surgical procedure.

The device is not intended for neonatal or paediatric patients, or for non-surgical use.

Do not use the device in patients with the contraindications listed below. For other anatomical abnormalities, suspected perforation, gastric obstruction or recent upper

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gastrointestinal trauma, assess the risk of tube placement before use. Clinical judgement must not override the stated contraindications.

[Intended Use Environment]

The device is intended to be used in hospitals or surgical centres with appropriate facilities and qualifications for bariatric or gastric surgical procedures. The device shall be used in an operating room or equivalent controlled surgical environment by trained healthcare professionals.

[Clinical Benefits]

When used as intended, the device supports bariatric or gastric surgery by assisting gastric calibration, decompression, irrigation and manual aspiration using a syringe.

The device provides a physical reference for gastric calibration, enables removal of gastric contents, fluid or gas, and supports intraoperative leak testing where clinically indicated.

The device does not provide a therapeutic effect by itself. Its clinical benefit is supportive and procedural.

[Performance Characteristics]

The key performance characteristics of the device include:

- gastric calibration support by providing a physical template;
- gastric decompression, irrigation and manual aspiration through the tube lumen and distal openings;
- tube lumen patency during intended use;
- resistance to kinking or collapse under intended-use conditions;
- tensile and connection strength of the tube and connectors;
- connector leak tightness;
- smooth tube surface and smooth distal holes to reduce tissue irritation risk;
- radiopaque line visibility to support positioning confirmation;
- visual reference markings for orientation and positioning only;
- sterile supply by ethylene oxide sterilization;
- single-use configuration.

[Contraindications] Do not use the device in the following circumstances:

- 1) Known or suspected hypersensitivity to silicone or other materials of the device.
 - 2) Oesophageal disease, including oesophageal varices, diverticula, tumours or strictures.
- Do not attempt insertion through a stricture that prevents passage of the tube.

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3) Coagulation disorders.

4) Other clinical conditions in which placement of an orogastric tube is contraindicated following assessment by the treating healthcare professional.

[Potential Adverse Events / Undesirable Side-effects]

Potential adverse events associated with oral insertion and use of a gastric calibration tube include:

- mucosal irritation or tissue damage during insertion, positioning, use or removal;
- pharyngeal, oesophageal or gastric injury, including bleeding or perforation, particularly in patients with anatomical abnormalities, oesophageal disease, obstruction, severe stenosis, suspected perforation, recent upper gastrointestinal trauma, oesophageal varices, diverticula or tumours;
- infection or contamination;
- cross-infection or transmission of infectious disease if the device is reused, reprocessed, re-sterilized, improperly handled after use, or not disposed of correctly;
- blockage, leakage, connector loosening, tube kinking or functional failure;
- incorrect positioning or use error, which may lead to ineffective calibration, tissue injury or procedural delay.

Follow these instructions and the specified patient-selection criteria, contraindications and precautions. Do not reuse, reprocess or re-sterilize the device. Dispose of it after use as potentially contaminated medical waste in accordance with hospital procedures and applicable local regulations.

[Compatibility]

Use the supplied universal connector to connect the gastric calibration tube adapter only to a manually operated syringe with a compatible connector for irrigation, aspiration and intraoperative leak testing. Do not connect the device to a suction pump, wall suction or any other powered suction system.

Before connection, trace the gastric tube from the patient to the syringe and confirm the intended fluid route. Use only the supplied universal connector. Do not connect to intravascular, respiratory or neuraxial lines, and do not use additional conversion adapters. Check that all connections are secure and leak-free and that the lumen is patent. Do not force incompatible connectors together.

Use sterile 0.9% sodium chloride solution for irrigation. For leak testing, use methylene blue solution at 0.1%–0.2% only when clinically indicated. The responsible clinician determines the volume and suitability for the individual patient in accordance with the solution's product information. Do not use other fluids, additives or concentrations with this device.

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Do not use a diagnostic solution in a patient with a contraindication or known hypersensitivity to that solution. Use aseptic technique when preparing and connecting fluids. Do not return aspirated gastric contents or recovered test fluid to the patient.

[Instructions for Use]

- 1) Check the labelled model and expiry date. Inspect the sterile packaging and device. Do not use if the package is open, damaged or wet, or if any device component is damaged. Open the package using aseptic technique.
- 2) Connect the tube adapter to the supplied universal connector and a compatible manually operated syringe. Check that the connections are secure and leak-free and that the tube is not kinked. Do not force connections or connect to powered suction equipment.
- 3) Apply a medical lubricant suitable for mucosal contact to the distal tip to facilitate insertion.
- 4) Gently advance the tube orally towards the stomach. If resistance is encountered, stop advancement immediately. Do not force the tube. Assess the cause and tube position before any further manipulation. If obstruction or injury is suspected, stop use and assess the patient.
- 5) Confirm the gastric position of the tube by clinical assessment and radiographic imaging as appropriate to the procedure. Do not begin irrigation, aspiration or leak testing until gastric position has been established. The graduation marks do not measure insertion depth.
- 6) Use the correctly positioned tube as a physical calibration guide during gastric resection or suturing. Before each stapler firing or suture placement, check that the tube is clear of the intended staple or suture line. Do not trap, staple, suture or cut the tube.
- 7) For irrigation or aspiration, open the flow-control clip and use the connected manual syringe. Introduce fluid or aspirate gently; do not force the syringe plunger. If flow is obstructed, stop immediately. Do not increase force to overcome the obstruction. Stop aspiration and release negative pressure before assessing tube patency or position.
- 8) If malposition or injury is suspected, stop use immediately. Do not deliver further fluid or continue aspiration. Release negative pressure and obtain prompt clinical assessment. Do not advance or withdraw the tube forcefully; further manipulation or removal depends on assessment of the suspected injury.
- 9) Before repositioning or withdrawal, stop fluid delivery and aspiration, open the flow-control clip and disconnect the syringe from the universal connector to release negative pressure. Withdraw gently only after suction has ceased. If resistance is encountered, stop and assess the cause.
- 10) After removal, inspect the tube and its components for completeness. If a component is missing or damaged, assess the patient for possible retained material. Dispose of the



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device as potentially contaminated medical waste in accordance with hospital procedures and applicable local regulations.

[Scale Markings]

The scale markings on the tube are provided only as visual reference markings to assist healthcare professionals with orientation and positioning of the tube during use. They do not determine insertion depth or any other quantitative clinical parameter.

The scale markings are not intended to provide quantitative measurement results and shall not be used for diagnosis, treatment decision-making, dose determination or any other medical measurement purpose.

[Warnings and Precautions]

Warnings:

- 1) Selection of the tube size and the intended gastric calibre is the responsibility of the treating clinician, based on the patient's anatomy, planned procedure, clinical assessment and relevant training and experience.
- 2) Do not use the device in patients with oesophageal diverticula, including Zenker's diverticulum. In patients with a large hiatal hernia, assess the risk of tube placement and exercise particular caution during insertion.
- 3) Do not use in patients with oesophageal varices because tube insertion may cause bleeding.
- 4) Do not staple, suture or cut the tube, or entrap it in the gastric staple or suture line.
- 5) Stop aspiration and release negative pressure before repositioning or withdrawing the tube. Do not withdraw the tube while negative pressure is applied.
- 6) Do not use after the expiry date.
- 7) Excessive negative pressure may draw gastric mucosa into the distal openings and cause injury. Do not apply forceful aspiration. If obstruction or mucosal entrapment is suspected, stop aspiration, open the flow-control clip and disconnect the syringe to release negative pressure before assessing tube position.
- 8) The device is intended for manual syringe use only. Do not connect it to a suction pump, wall suction or any other powered suction system.
- 9) Do not use a powered syringe driver or infusion pump with the device.

Precautions:

- 1) For single use only. Do not use if the sterile packaging is damaged or has been opened.
- 2) The device is supplied sterile following ethylene oxide sterilization. Sterility is maintained while the sterile barrier remains intact and the specified storage conditions and

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expiry date are observed.

3) The shelf life is two years from the date of sterilization when stored and transported under the specified conditions. Do not use after the expiry date on the label.

4) Handle the packaged device with care during transport.

5) Store in a well-ventilated area, free from corrosive gases, at a relative humidity not exceeding 80%.

6) Check the integrity of the sterile barrier before use. Do not use if it is open, damaged or wet.

7) Do not reuse, reprocess or re-sterilize any part of the device.

8) Do not modify the device. Modification may compromise its safety and performance.

Additional warnings and precautions:

- Do not use the device if the package is opened, damaged or wet, or if the sterile barrier integrity is suspected to be compromised.
- Do not use the device after the expiry date.
- Do not reuse, reprocess or re-sterilize the device.
- Inspect the device before use. Do not use if the tube, connector, tip, scale markings, radiopaque line or packaging is damaged.
- Stop using the device if resistance, blockage, leakage, connector loosening, tube kinking, visible damage or any change in performance that may affect safety occurs. Do not continue use of the affected device; replace it with a new sterile device if continued clinical use is required.
- The device is non-active and does not generate electrical energy or emit radiation. Observe the specified storage, handling and surgical-use conditions.
- Do not staple, suture or apply a surgical clamp across the tube. Use only the supplied tube closure clip when temporary closure is required.
- Stop manual aspiration and release negative pressure before repositioning or withdrawing the tube.
- Do not use the device for routine drug delivery or general administration of medicinal products.
- Do not use with unverified medicinal products, solvents, cleaning agents or disinfectants.
- Use only a manually operated syringe with a connector compatible with the supplied universal connector. Confirm that the connection is secure and leak-free before use.

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- Potential adverse events include mucosal irritation, tissue damage, bleeding, perforation, infection, cross-infection, incorrect positioning, blockage, leakage and device functional failure.
- Reuse, reprocessing, re-sterilization or improper handling after use may cause cross-infection or transmission of infectious disease.
- After use, handle the device as potentially contaminated medical waste and dispose of it according to hospital procedures and applicable local regulations.

[Surgical Use]

1) For intraoperative leak testing, first establish gastric tube position and ensure that the tube is clear of the staple or suture line. The responsible clinician selects the diagnostic fluid and its preparation for the procedure, taking account of the patient's contraindications and the fluid's product information. Introduce the fluid, such as methylene blue solution, gently using the manual syringe. Do not force fluid against resistance. Use only the supplied flow-control clip for temporary tube closure. Reopen the clip before manual aspiration of the test fluid.

2) If aspiration is obstructed or mucosal entrapment is suspected, stop aspiration. Open the flow-control clip and disconnect the syringe from the universal connector to release negative pressure through the open proximal pathway. Do not move the tube while suction persists. Reassess patency and gastric position before further use. Do not connect to powered suction equipment.

CAUTION: Do not reposition or withdraw the tube during aspiration or irrigation. Stop fluid delivery or aspiration and release negative pressure first to reduce the risk of gastric or oesophageal injury.

3) After completion of the procedure, stop fluid delivery and aspiration, open the flow-control clip and disconnect the syringe to release negative pressure before gently withdrawing the tube. If resistance is encountered during withdrawal, stop and assess the cause; do not pull forcefully.

[Precautions]

- 1) Read all instructions before use.
- 2) Only healthcare professionals trained in the relevant surgical techniques and orogastric tube placement may use this device.

[Shelf Life]

2 years. Observe the expiry date on the label.

[Maximum Duration of Use]

Less than 6 hours during a single surgical procedure. The device is single use only and

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shall be discarded after the procedure. Do not reuse, reprocess or re-sterilize.

[Date of Manufacture]

See the product label or packaging.

[Sterilization Method]

Sterilized using ethylene oxide.

[Storage Conditions]

Store in a well-ventilated area, free from corrosive gases, at a relative humidity not exceeding 80%.

[Symbol Description]

	CE mark		Manufacturer
	Authorized representative in the European Community		Sterilized using ethylene oxide
	Use-by date		Non-pyrogenic
	Medical Device		Do not re-use
	Date of manufacture		Batch number
	Caution		Consult instructions for use
	Unique device identifier		Keep away from sunlight
	Keep dry		Do not use if package is damaged and consult instructions for use
	Single sterile barrier system with protective packaging outside		Do not re-sterilize

[Disposal]

After use, the device shall be considered potentially contaminated and shall be disposed of as medical waste in accordance with hospital procedures and applicable local regulations. Do not reuse, reprocess or re-sterilize the device after use.

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Do not reuse, reprocess or re-sterilize the device.

[Serious Incident Reporting]

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.



[Manufacturer]

Name: Suzhou Anying Medical Equipment Co.Ltd.

Address: Building 3, No. 58 Suwei Road, Weitang Town, Xiangcheng District, Suzhou City, Jiangsu Province, China



[EU Representative]

Name: Lins Service&Consulting GmbH

Address: Pranchstrasse 47, 67061 Ludwigshafen am Rhein, Germany