

Instructions for Use**[Product Name]**

Gastrointestinal Decompression Drainage Nutrient Tube

[Intended Use]

Gastrointestinal Decompression Drainage Nutrient Tube is used for gastric decompression and administration of nutrition, fluids and medication.

[Type and Specification]

Model	Specification	Outer diameter(mm)		length(mm)	
		Basic size	Limit deviation	Catheter size	Limit deviation
FY-Z	14Fr	4.7	±0.30	1400, 1500, 1600	Nominal length ±10%
	16Fr	5.3		1400, 1500, 1600	
	18Fr	6.0		1400, 1500, 1600	

[Intended User]

Professional medical staff

[Intended Patient Population]

Patients who require short-term enteral nutrition.

Gastrointestinal tube size should be determined by patient height and weight. For patients around 150cm tall or 55kg in weight, 14Fr is recommended. 16Fr is suitable for those over 160cm tall or 65kg, and 18Fr is best for those over 175cm tall or 75kg.

In addition to considering height and weight, the patient's specific situation should also be considered to determine the most suitable gastrointestinal tube model for the patient.

[Intended Use Environment]

Clinical environments such as gastroenterology departments, operating rooms, and inpatient wards in hospitals.

[Contraindications]

- 1) Nasopharyngeal stenosis or severe damage to the nasopharynx and nasal obstruction;
- 2) Severe coagulation and esophageal stenosis;
- 3) Esophageal or cardiac stenosis or obstruction corrosive gastritis;
- 4) Severe esophageal varices;
- 5) Severe dyspnea and other diseases not suitable for gastric tube insertion.

[Indication]

- 1) Used for enteral nutrient, diagnosis, treatment and monitoring of critically ill patients;
- 2) Used for gastric paralysis/gastric emptying disorder, gastric emptying disorder, pyloric stenosis;
- 3) In addition to small intestinal nutrient, it can also be used for gastric drainage, gastric pH measurement, and early diagnosis and treatment of gastric bleeding in critically ill patients.

[Use Method]**Endoscopic transnasal insertion method:**

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- 1) Select the nostril for tube placement and clean the nasal cavity.
- 2) Keep the patient's upper body upright or in a semi-recumbent position at about 45°.
- 3) Insert the gastrointestinal catheter (without hydrophilic guide wire) into the nasal cavity, and make gentle movements to the stomach while pushing it.
- 4) Insert the endoscope from the patient's mouth and introduce it into the stomach.
- 5) Use the biopsy clip of the endoscope to control the traction line of the gastrointestinal catheter through the pylorus to the jejunum.
- 6) Pull out the endoscope and keep the position of the gastrointestinal catheter unchanged.
- 7) Confirm whether the position of the gastrointestinal catheter is correct through X-ray, and the angiography of the white joint in the middle is at the position of the pyloric entrance.
- 8) According to the printed mark on the gastrointestinal catheter, determine the length of the gastrointestinal catheter entering from the nasal cavity, and fix the gastrointestinal catheter to the patient's nose with tape.

Normal intubation and placement method:

- 1) Under the perspective state, in a semi-recumbent or left anterior oblique position, the front end of the gastrointestinal catheter is facing the greater curvature of the stomach.
- 2) Turn to the right side and make the front guide of the gastrointestinal catheter face the pylorus. In this state, insert the hydrophilic guide wire into the gastrointestinal catheter along the feeding cavity, so that the hydrophilic guide wire is ahead of the front end of the guide wire, and confirm that the hydrophilic guide wire passes through the pylorus. At this time, if the hydrophilic guide wire cannot pass through the pylorus, the endoscope can be inserted through the mouth, and the hydrophilic guide wire can be introduced into the pylorus with forceps.
- 3) After the front end of the gastrointestinal catheter passes through the pylorus, the hydrophilic guide wire is withdrawn from the gastrointestinal catheter for about 5cm, and then the catheter is sent forward for 5cm. Repeat this process to insert the gastrointestinal catheter as far as possible.
- 4) After pulling out the hydrophilic guide wire, continue to send the gastrointestinal catheter into the stomach so that it is in a relaxed state in the stomach. Confirm that the side hole part of the gastrointestinal catheter has indeed entered the stomach.
- 5) Use X-ray to confirm whether the position of the gastrointestinal catheter is correct. The white angiography circle in the middle is at the entrance of the pylorus.
- 6) According to the printed mark on the gastrointestinal catheter, determine the length of the gastrointestinal catheter entering the nasal cavity, and fix the gastrointestinal catheter to the patient's nose with tape.

[Warnings and Precautions]

- 1) This product is a single-use sterile device and is prohibited from being reused to avoid the risk of cross infection.
- 2) To ensure safety, please check all parts of the product to see if they are in good condition before use. If any abnormality is found, stop using the product.
- 3) To ensure safety, you must check the expiration date of this product before use. It is strictly forbidden to use expired products.
- 4) To ensure safety, please check that the packaging of this product is intact before use. If the packaging is damaged,

the sterility will be affected, so please stop using it immediately.

- 5) To ensure safety, this product should be used immediately after opening the package. After use, be sure to follow the requirements of local medical regulations and properly dispose of medical waste. After use, the metal guide wire should be immediately placed in a sharps box that meets EU standards. When handling the metal guide wire, be sure to wear protective gloves and avoid direct contact with sharp objects to prevent punctures.
- 6) When using this product, in order to prevent insertion and connection errors, strict management and standardized operations should be performed.
- 7) When the catheter is inserted and during its indwelling period, you can confirm whether the catheter head reaches the correct position through various methods such as X-ray, gastric juice aspiration, listening to bubbles or looking at the scale position.
- 8) When connecting the end of the catheter to the nutrient bag, etc., select an appropriate interface. After starting operation, check the connection points for looseness or leakage. Ensure all interfaces are securely connected before use.
- 9) Please use it in a securely connected state.
- 10) When injecting nutrient solution, pay attention to the operating regulations of nutrient solution and other products.
- 11) When using this product to inject medicinal liquid into the body, please choose the correct medicinal liquid under the guidance of a doctor.
- 12) Before and after nutrient injection, be sure to flush the lumen of the catheter with warm water or water (the lumen of the catheter may be blocked by high-viscosity injectables or pastes).
- 13) During the indwelling process, pay attention to the status of the inner cavity and confirm that the injection is maintained smoothly.
- 14) When covering the catheter cap, wipe off the nutrient or water before proceeding (if the catheter cap is covered in a wet state, it may easily cause loose embolism or the catheter cap to fall off.)
- 15) When opening the conduit cover, hold the conduit cover gently and operate with caution (excessive force may cause the conduit cover to break).
- 16) Do not suture this product to the skin. If tape is used to fix the product, care should be taken when removing the tape to prevent the adhesive force of the tape from damaging the conduit due to excessive force.
- 17) When using this product, please do not bend or stretch it forcefully, and do not clamp it with pliers to prevent the catheter from breaking or causing the inner cavity to be blocked.
- 18) Do not expose this product to strong acids, strong alkalis and other chemicals and organic solvents during use.
- 19) When operating this product, if you feel it is difficult to insert or the patient keeps coughing, in order to avoid accidentally entering the trachea or lungs and damaging the organs, you should stop operating or pull it out first and then reinsert it.
- 20) When using X-rays on patients who are pregnant or may be pregnant, you should pay attention to the impact of X-rays on the fetus and operate with caution.
- 21) During the decompression process, the pressure regulating chamber is already open, and there is no need to inject additional air into the pressure regulating chamber.

- 22) The maximum retention time of this product shall not exceed 30 days.
- 23) 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.

[Shelf-life]

Three years

[Sterilization Method]

Ethylene oxide

[Storage and Transport Conditions]

- 1. No heavy pressure, direct sunlight, rain or snow dipping, so as not to damage the device.
- 2. Handle with care during transport and avoid violent collision.
- 3. The product should be far away fire, heat source and corrosive gas, and please pay attention to good ventilation.
- 4. Store in a cool and dry place, and ensure that the room is well ventilated, no corrosive gas, and relative humidity does not exceed 80%.
- 5. Stock rotation on first in first out basis.

[Production Date]

See on the package.

[Symbol Explanation]

	Manufacturer		Date of manufacture
	Authorized representative in the European Community		Batch code
	Consult instructions for use or consult electronic instructions for use		Use-by date
	Do not re-sterilize		Caution
	Do not use if package is damaged and consult instructions for use		Sterilized using ethylene oxide
	Do not re-use		Up
	Medical device		Unique device identifier
	CE Marking		Catalogue number
	Keep away from sunlight		Keep dry
	Fragile, handle with care		Do not contain natural rubber latex
	Single sterile barrier system with protective packaging inside		

 **[Manufacturer]**



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[EU Representative]

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