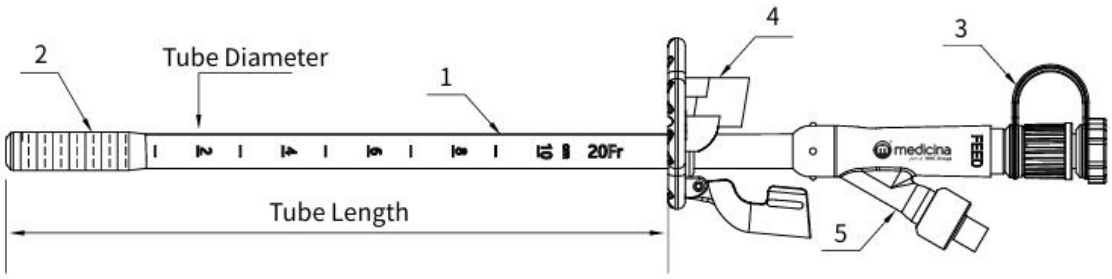
Silicone Gastrostomy Tube

1. Product model/specification and Classification description

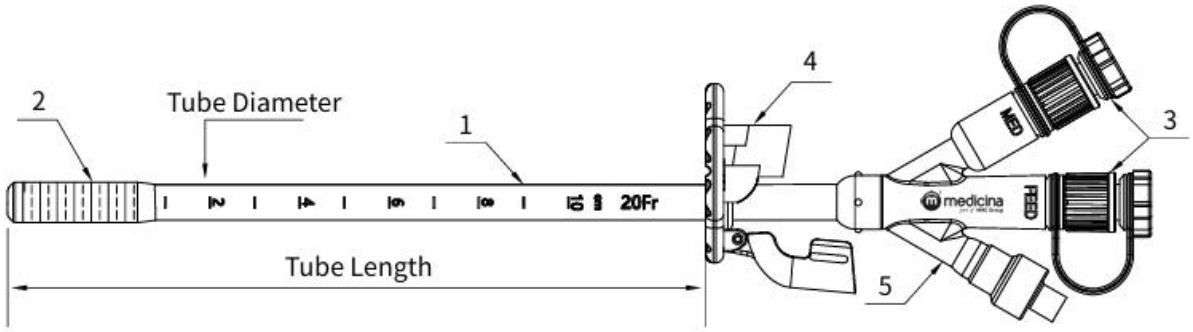
1.1 Product specifications and models

Silicone Gastrostomy Tube (hereinafter referred to as Gastrostomy tube) consists of the Tube body, Balloon, Feeding joint, Fixed ring (N type without Fixed ring), Filling joint, and other components. Product specifications are classified based on Tube body diameter, Feeding joint type, Fixed ring type, Tube body length and Accessory type. The basic structural components are shown in Figures 1 to 7,and the specifications and models are listed in Appendix A. This product is disposable, sterilized with irradiation sterilization, provided sterile, and has a shelf life of 2 years.



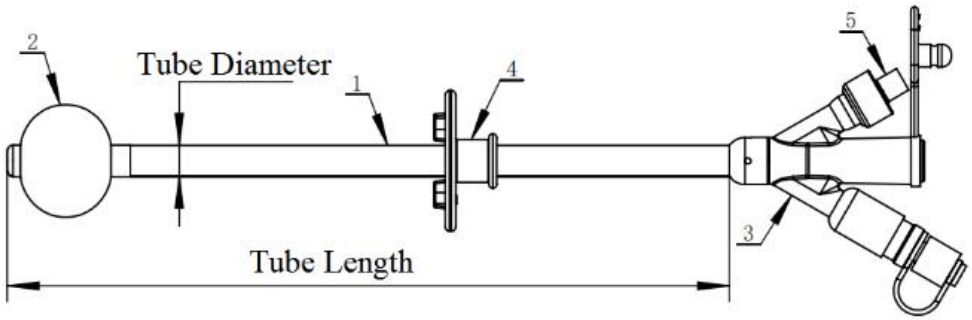
1 Tube body 2 Balloon 3 Feeding joint 4 Fixed ring 5 Filling joint

Figure 1: Schematic composition diagram of GT Series E-type (EMFit) joint (2-channels)



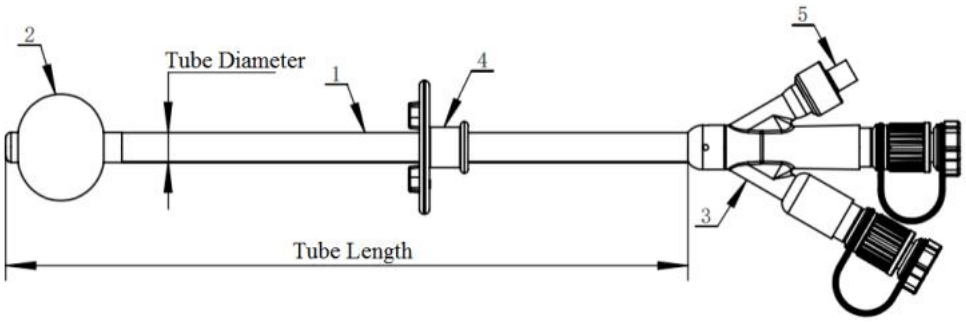
1 Tube body 2 Balloon 3 Feeding joint 4 Fixed ring 5 Filling joint

Figure 2: Schematic composition diagram of VED Series E-type (EMFit) joint (3-channels)



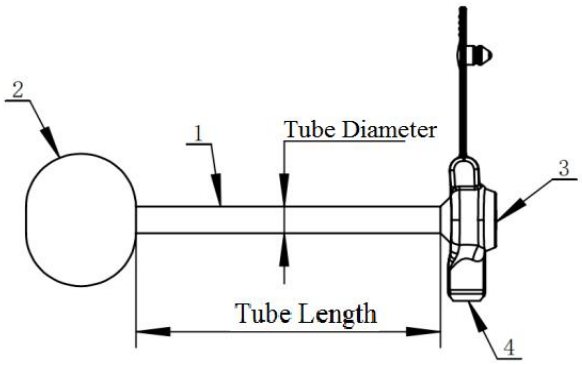
1 Tube body 2 Balloon 3 Feeding joint 4 Fixed ring 5 Filling joint

Figure 3: Schematic composition diagram of Y-type Silicone Gastrostomy Tube



1 Tube body 2 Balloon 3 Feeding joint 4 Fixed ring 5 Filling joint

Figure 4: Schematic composition diagram of E-type Silicone Gastrostomy Tube



1 Tube body 2 Balloon 3 Feeding joint 4 Filling joint

Figure 5: Schematic composition diagram of N-type Silicone Gastrostomy Tube

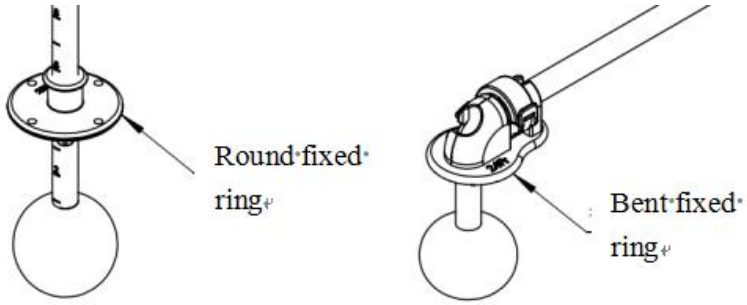


Figure 6: Schematic diagram of Fixed ring types

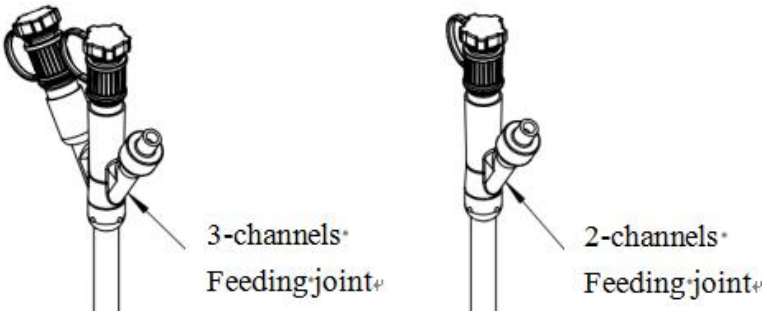


Figure 7： Schematic diagram of Feeding joint channel types

1.3 The composition of materials in contact with humans is shown in Table 1.

Table 1 Material Composition Table

Component Name	Materials
Tube body、Balloon、Fixed ring	Silicagel
Feeder	PP, Rubber
Injector	PP, Rubber
Gauze sponges	100% Cotton gauze fabric
Guide bar	PP

2. Performance indicators

2.1 Appearance

Tube body, Balloon, and Feeding joint should have smooth, uniform inner and outer walls, with no obvious spots or foreign objects.

2.2 Dimensions

The dimensions of each component should comply with the requirements of Appendix A.

2.3 Tensile Properties

The Tube body should withstand the following no impact linear tension without breaking or separating:

a) For outer diameters less than or equal to 4mm: 35N.

b) For outer diameters greater than 4mm: 75N.

2.4 Connection Strength

The Feeding joint should connect to the Feeder or Enteral nutrition catheter, and the connection should withstand a linear tensile force of 15N without impact, without breaking or separating.

2.5 Hydraulic leak resistant

The pipeline system at the connection between the Feeding joint and the connector on the Feeder or Enteral nutrition catheter should not leak under a water pressure of 50kPa for 2 minutes.

2.6 Filling joint

The Filling joint should comply with the specifications for the Female 6% (luer) conical lock fittings in ISO 80369-7:2021.

2.7 Flow rate

The flow rate of the tube body should not be less than 9mL/min.

2.8 Feeder

The specification for the Feeder is 60mL and should have a valid medical device product registration certificate.

2.9 Injector

The specification for the Injector is 5mL and should have a valid medical device product registration certificate.

2.10 Gauze sponges

The specification for the Gauze sponges is 10cm×10cm - 16 layers and should have a valid medical device product registration certificate.

2.11 Balloon

2.11.1 Balloon burst volume

The burst volume of the balloon should comply with the specifications in Table 2.

Table 2 Requirements of Balloon burst volume

Balloon rated volume	Balloon burst volume
5mL	≥10mL
10mL	≥20mL
20mL	≥40mL

2.11.2 Retention of Balloon Volume

The Balloon should be inflated without any observed leakage.

2.11.3 Balloon eccentricity

The maximum radius of the Balloon should not exceed twice the minimum radius.

2.11.4 Tube specification

Under conditions without external force insertion, the tube should pass through the corresponding French standard hole.

2.11.5 Balloon integrity

The Balloon should remain intact and not rupture.

2.11.6 Balloon integrity in simulated gastric fluid

The balloon should remain intact and without rupture in simulated gastric juice.

2.12 Tubing clamp

The Tubing clamp should have a closing function under a water pressure of 50kPa.

2.13 Fixed Ring

The retention force of the Fixed ring with the Tube body should be ≥5N.

2.14 Chemical properties

2.14.1 Reducing substances

The difference in volume of potassium permanganate solution [$c(KMnO_4)$=0.002mol/L] consumed by the test solution and the same batch blank control solution should not exceed 2.0mL.

2.14.2 Total content of heavy metals

When measured by Atomic Absorption Spectroscopy (AAS), the total content of barium, chromium, copper, lead, and tin in the test solution should not exceed 1μg/mL, and the cadmium content should not exceed 0.1μg/mL.

When measured by colorimetric method, the color presented by the test solution should not exceed the standard control solution with mass concentration ρ (Pb^{2+}) = 1μg/mL.

2.14.3 pH value

The difference in pH value between the test solution and the same batch of blank solution should not exceed 1.5.

2.14.4 Evaporation residue

The total amount of evaporation residue in the test solution should not exceed 2mg.

2.14.5 Ultraviolet absorbance

The absorbance of the test solution in the range of 250nm to 320nm should not exceed 0.1.

2.14.6 Color and lust

The test solution should be colorless and transparent.

2.14.7 Ethylene oxide residual amount

The residual amount of ethylene oxide should be ≤10μg/g.

2.15 Sterility

The product should be sterilized by an ethylene oxide process to ensure sterility.

3. Performance indicators

3.1 Appearance

Observation should be conducted using visual inspection or a 3x magnifying glass, and the results should comply with the requirements of 2.1.

3.2 Dimensions

Measurements should be taken using general or specialized measuring tools, and the results should comply with the requirements of 2.2.

3.3 Tensile Properties

Tests should be carried out in accordance with Appendix C of ISO 20695: 2020, and the results should comply with the requirements of 2.3.

3.4 Connection strength

Tests should be carried out in accordance with Appendix C of ISO 20695:2020, and the results should comply with the requirements of 2.4.

3.5 Hydraulic leak resistance

Tests should be carried out in accordance with Appendix D of ISO 20695:2020, and the results should comply with the requirements of 2.5.

3.6 Filling joint

Tests should be carried out in accordance with ISO 80369-7:2021, and the results should comply with the requirements of 2.6.

3.7 Flow rate

Tests should be carried out in accordance with ASTM F 2528 – 06 （2023） PROCEDURE A, and the results should comply with the requirements of 2.7.

3.7.1 Labelling and pictograms

Tests should be carried out in accordance with EN-ISO 15223-1:2017

3.7.2 Small diameter connectors for liquids and gases for sanitary applications

Tests should be carried out in accordance with EN ISO 80369-3:2019

3.7.3 Enteral nutrition systems. Designs and testing

Tests should be carried out in accordance with EN ISO 20695:2020

3.8 Feeder

Verification of the medical device product registration certificate from Feeder. It should comply with the requirements of 2.8.

3.9 Injector

Verification of the medical device product registration certificate from Injector. It should comply with the requirements of 2.9.

3.10 Gauze sponges

Verification of the medical device product registration certificate from Gauze sponges. It should comply with the requirements of 2.10.

3.11 Balloon

3.11.1 Balloon burst volume

Tests should be carried out in accordance with ASTM F 2528-06(2023) PROCEDURE B, and the results should comply with the requirements of 2.11.1.

3.11.2 Retainability of balloon volume

Tests should be carried out in accordance with ASTM F 2528-06(2023) PROCEDURE C, and the results should comply with the requirements of 2.11.2.

3.11.3 Balloon eccentricity

Tests should be carried out in accordance with ASTM F 2528-06(2023) PROCEDURE D, and the results should comply with the requirements of 2.11.3.

3.11.4 Tube specification

Tests should be carried out in accordance with ASTM F 2528-06(2023) PROCEDURE E, and the results should comply with the requirements of 2.11.4.

3.11.5 Balloon integrity

Tests should be carried out in accordance with ASTM F 2528-06(2023) PROCEDURE F, and the results should comply with the requirements of 2.11.5.

3.11.6 Balloon integrity in simulated gastric fluid

Tests should be carried out in accordance with ASTM F 2528-06(2023) PROCEDURE G, and the results should comply with the requirements of 2.11.6.

3.12 Tubing clamp

Inject water at a pressure of 50 kPa into the Feeding tube, close the Tubing clamp, and the results should comply with the requirements of 2.12.

3.13 Fixed ring

Fix the Fixed ring, apply an axial dynamic tension of 100 mm/min at the tube body end, and the results should comply with the requirements of 2.13.

3.14 Chemical properties

Take a sample, add 1 mL of water for every 0.2 g of the sample. Under conditions of 37°C ± 1°C, steep for 72 hours, then separate the sample from the liquid. Allow it to cool to room temperature to serve as the testing solution.Place the same volume of water in a glass container and prepare a blank control solution using the same method.

3.14.1 Reducing substances

Accurately measure 10 mL of the test solution, add it to a 250 mL iodine volumetric bottle, accurately add 1 mL of sulfuric acid solution and 10 mL of potassium permanganate solution with the concentration specified in the product standard, boil for 3 minutes, cool quickly, add 0.1 g of potassium iodide, seal tightly, and shake well. Immediately titrate with the sodium thiosulfate standard titration solution of the same concentration until it turns light yellow, add 5 drops of starch indicator solution, and continue titrating with the sodium thiosulfate standard titration solution until it is colorless.Use the same method to titrate the blank control solution.The results should comply with the requirements of 2.14.1.

3.14.2 Content of metal impurities

Accurately measure 25mL of test solution in a 25mL Nessler colourimetric tube, take another 25mL Nessler colourimetric tube, add 25mL of lead standard solution, add 2mL of acetate buffer (PH3.5) to the two tubes, and then add 2mL of thioacetamide test solution, shake well and leave it for 2mins, put it on a white background to be observed from the top, and then compare the colour shades.If the test solution is coloured, add a small amount of dilute caramel solution or other non-interfering coloured solutions to the standard control solution to make it the same colour as the test solution. Then add 2 mL of thioacetamide test solution to each of the test solution and the standard control solution, shake well, leave it for 2 min, and observe from above on a white background to compare the colour shades.The results should

comply with the requirements of 2.14.2.

3.14.3 pH value

Take the test solution and blank control solution, measure their pH values with an pH meter respectively, and use the difference between the two as the test result. The results should comply with the requirements of 2.14.3.

3.14.4 Evaporation residue

The evaporating dish was previously dried at 105℃ to constant weight. Measure 50 mL of the test solution into an evaporating dish, evaporate to dryness on a water bath and dry to constant weight in a 105°C constant temperature box. Use the same method to determine the blank control solution.

Calculate the mass of evaporative residue according to equation (1)

$$m=[(m_{12}-m_{11})-(m_{02}-m_{01})\times 1000 \quad \text{.....(1)}$$

In the above formula:

m — Mass of the evaporative residue, in milligrams (mg).

m_{11} — Mass of the evaporation dish without the test solution, in grams (g).

m_{12} — Mass of the evaporation dish with the test solution, in grams (g).

m_{01} — Mass of the evaporation dish without the blank control solution, in grams (g).

m_{02} — Mass of the evaporation dish with the blank control solution, in grams (g).

The results should comply with the requirements of 2.14.4.

3.14.5 Ultraviolet absorbance

Take the test solution, filter it with a 0.45μm microporous filter membrane if necessary, and within 5 hours, use a 1cm cuvette to measure the absorbance within the 250nm~320nm wavelength range using the blank control solution as a reference. The results should comply with the requirements of 2.14.5.

3.14.6 Color and lust

Visually inspect the test solution and the result should comply with the requirements of 2.14.6.

3.14.7 Ethylene oxide residual amount

Tests should be carried out in accordance with ISO 10993-7, and the results should comply with the requirements of 2.14.7.

3.15 Sterility

The test should be carried out by the film filtration method, the result should comply with the requirements of 2.15.

4. Terminology

The technical requirements are used in general terms, no special terms.

Appendix A

Medicina Item Number	Product Description	ZKSK(Manufacturer) code number
GF12L	Single Port ENFit Gastrostomy Tube 12fr	GT12F-E2
GF14L	Single Port ENFit Gastrostomy Tube 14fr	GT14F-E2
GF16L	Single Port ENFit Gastrostomy Tube 16fr	GT16F-E2
GF18L	Single Port ENFit Gastrostomy Tube 18fr	GT18F-E2
GF20L	Single Port ENFit Gastrostomy Tube 20fr	GT20F-E2
GF22L	Single Port ENFit Gastrostomy Tube 22fr	GT22F-E2
GF24L	Single Port ENFit Gastrostomy Tube 24fr	GT24F-E2
GF12LY	Dual Port ENFit Gastrostomy Tube 12fr	GT12F-E
GF14LY	Dual Port ENFit Gastrostomy Tube 14fr	GT14F-E
GF16LY	Dual Port ENFit Gastrostomy Tube 16fr	GT16F-E
GF18LY	Dual Port ENFit Gastrostomy Tube 18fr	GT18F-E
GF20LY	Dual Port ENFit Gastrostomy Tube	GT20F-E

	20fr	
GF22LY	**Dual Port ENFit Gastrostomy Tube 22fr**	**GT22F-E**
GF24LY	**Dual Port ENFit Gastrostomy Tube 24fr**	**GT24F-E**

Model and Component of Silicone Gastrostomy Tube

Model	Component
GT Series Y-type	Tube body, Balloon, Feeding joint, Bent fixed ring/Fixed ring, Filling joint, Guide bar
GT Series E-type	
GT Series N-type	Feeder, Injector, Gauze sponges, Guide bar, Straight feeding tube, Bent feeding tube, Feeding E joint Feeder, E-type Straight feeding tube, E-type Bent feeding tube, Tube body, Balloon, Feeding joint, Filling joint
VED Series	Tube body, Balloon, Feeding joint, Fixed ring, Filling joint