SHENYUN
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TECHNICAL DATA SHEET

Sterile Single Use Gastric Calibration Tube

1. GENERAL INFORMATION

Models	Type I standard SY01-xx · Type II with balloon SY02-xx
Intended use	Type I: mini gastric bypass and sleeve gastrectomy (LSG) – delineation of the stomach, decompression and drainage of gastric fluid · Type II: sleeve gastrectomy (LSG) – drainage of gastric fluid and gastric pouch calibration; balloon used as pyloric stop for positioning
Material	Medical-grade silicone
Construction	Tube with depth markings and X-ray detectable line, silicone tip, conical connector, universal connector, one-way valve; Type II with 30 mL balloon
Sterility	Sterile, ethylene oxide (EO)
Use	Single use
Shelf life	2 years
Silicone properties (typical)	Hardness 70 Shore A · density 1.21 g/cm³ · tensile strength ≥ 10 MPa · elongation at break ≥ 380%

2. TECHNICAL SPECIFICATIONS

Type I · length 1,200 mm

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

Type II · length 745 mm · balloon 30 mL, Ø 40 mm

Model	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

3. PACKAGING

Per carton	50 pcs (1 pc per box)
Carton	520 × 520 × 410 mm

See the Packaging Specification for packaging details, freight and customization options.

4. REGULATORY INFORMATION

Quality management system	ISO 13485:2016, certificate CN25/00005189, SGS United Kingdom Ltd, valid until 2028-07-30
EU MDR	Class IIa, EU quality assurance certificate CN25/00007163, SGS Belgium NV (NB 1639), valid until 2030-10-22 · Basic UDI-DI 6975573320097D2 · EMDN G020502 · rule 5
Saudi Arabia	SFDA MDMA-2-2024-1267, valid until 2027-06-11

5. MANUFACTURER

Manufacturer	Suzhou Shenyun Medical Equipment Co., Ltd. Building 11, No. 666 Yinzang Road, Linhu Town, Wuzhong District, Suzhou, Jiangsu, P.R. China
EU SRN	CN-MF-000026847
EU authorised representative	MedPath GmbH, Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany (SRN DE-AR-000000087)

Specifications are subject to change without notice. Contact info@symedical.com.cn for the latest version.