SHENYUN
Suzhou Shenyun Medical Equipment Co., Ltd.
info@symedical.com.cn
Tel / WhatsApp +86 151 5045 7575
www.sybariatric.com

SAFETY DATA SHEET

Sterile Single Use Gastric Calibration Tube

1. IDENTIFICATION

Product	Sterile Single Use Gastric Calibration Tube
Models	SY01-xx, SY02-xx
Recommended use	Single-use medical device for gastric pouch calibration in bariatric surgery
Supplier	Suzhou Shenyun Medical Equipment Co., Ltd. Building 11, No. 666 Yinzang Road, Linhu Town, Wuzhong District, Suzhou, Jiangsu, P.R. China
Contact	info@symedical.com.cn · +86 512 6520 9633 · +86 151 5045 7575

2. HAZARD IDENTIFICATION

This product is a finished medical device and an article in the sense of GHS and REACH. Classification for hazards under GHS / Regulation (EC) No 1272/2008 (CLP) does not apply to articles. No hazards are expected under normal conditions of use. Thermal decomposition or combustion may release carbon monoxide, carbon dioxide and silicon dioxide (silica).

3. COMPOSITION

Tube and tip	Medical-grade silicone

4. FIRST-AID MEASURES

Not applicable under normal use. After inhalation of combustion fumes, move to fresh air and seek medical advice if symptoms occur.

5. FIRE-FIGHTING MEASURES

Use water spray, foam, dry chemical or carbon dioxide. Combustion may release carbon monoxide, carbon dioxide and silicon dioxide (silica). Firefighters should wear self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Solid article; no special measures. Collect and dispose of as solid waste.

7. HANDLING AND STORAGE

Store in the original packaging in a clean, dry place away from direct sunlight and sources of ignition. Supplied sterile (ethylene oxide). Do not use if the package is opened or damaged.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

No special measures under normal use. Follow standard hospital hygiene practice.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state	Solid article
Appearance	Clear silicone tube with blue tip and markings, with fittings
Water solubility	Insoluble
Hardness	70 Shore A (typical material value)
Density	1.21 g/cm³ at 25 °C (typical material value)
Tensile strength	≥ 10 MPa (typical material value)
Elongation at break	≥ 380% (typical material value)

10. STABILITY AND REACTIVITY

Stable under recommended storage conditions. Avoid open flame and strong oxidising agents.

11. TOXICOLOGICAL INFORMATION

The device has passed biological evaluation according to the ISO 10993 series. Combustion fumes may irritate the eyes and respiratory tract.

12. ECOLOGICAL INFORMATION

Solid article, insoluble in water. Do not release into the environment.

13. DISPOSAL CONSIDERATIONS

Unused product: dispose of as solid waste according to local regulations. Used product may be contaminated: dispose of as clinical waste according to hospital and local regulations.

14. TRANSPORT INFORMATION

Not regulated as dangerous goods for road, sea or air transport (ADR / IMDG / IATA). Keep dry and protect from mechanical damage.

15. REGULATORY INFORMATION

- ISO 13485:2016 quality management system (SGS, CN25/00005189)
- EU MDR (EU) 2017/745, Class IIa, CE certificate CN25/00007163 (SGS Belgium NV, NB 1639)
- Saudi SFDA MDMA-2-2024-1267

16. OTHER INFORMATION

This safety data sheet provides information on the finished medical device for handling, storage, transport and disposal. For clinical use, refer to the Instructions for Use. Contact info@symedical.com.cn for the latest version.

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