

SHENYUN

SHENYUN

GASTRIC CALIBRATING TUBE



THE DEVELOPMENT OF SURGERY

■ INTRODUCTION TO SURGICAL DEVELOPMENT

The process of sleeve gastrectomy from its inception to gradual maturity.

GETTING STARTED

Dr. Michelle Gagner, a professor of clinical medicine at Florida International University, performed the world's first "laparoscopic sleeve gastrectomy" in 1999.

Dr. Michelle Gagner
Bariatric Surgery Specialist



PROMOTION STAGE

According to the "China Obesity Metabolic Surgery Database: 2019 Annual Report", in 2008, there were only 117 cases of weight loss metabolic surgery performed nationwide, but by 2019, it had soared to 11,700 cases, a 100-fold increase in 10 years.

Wang Cunchuan
President of Asia Pacific Region

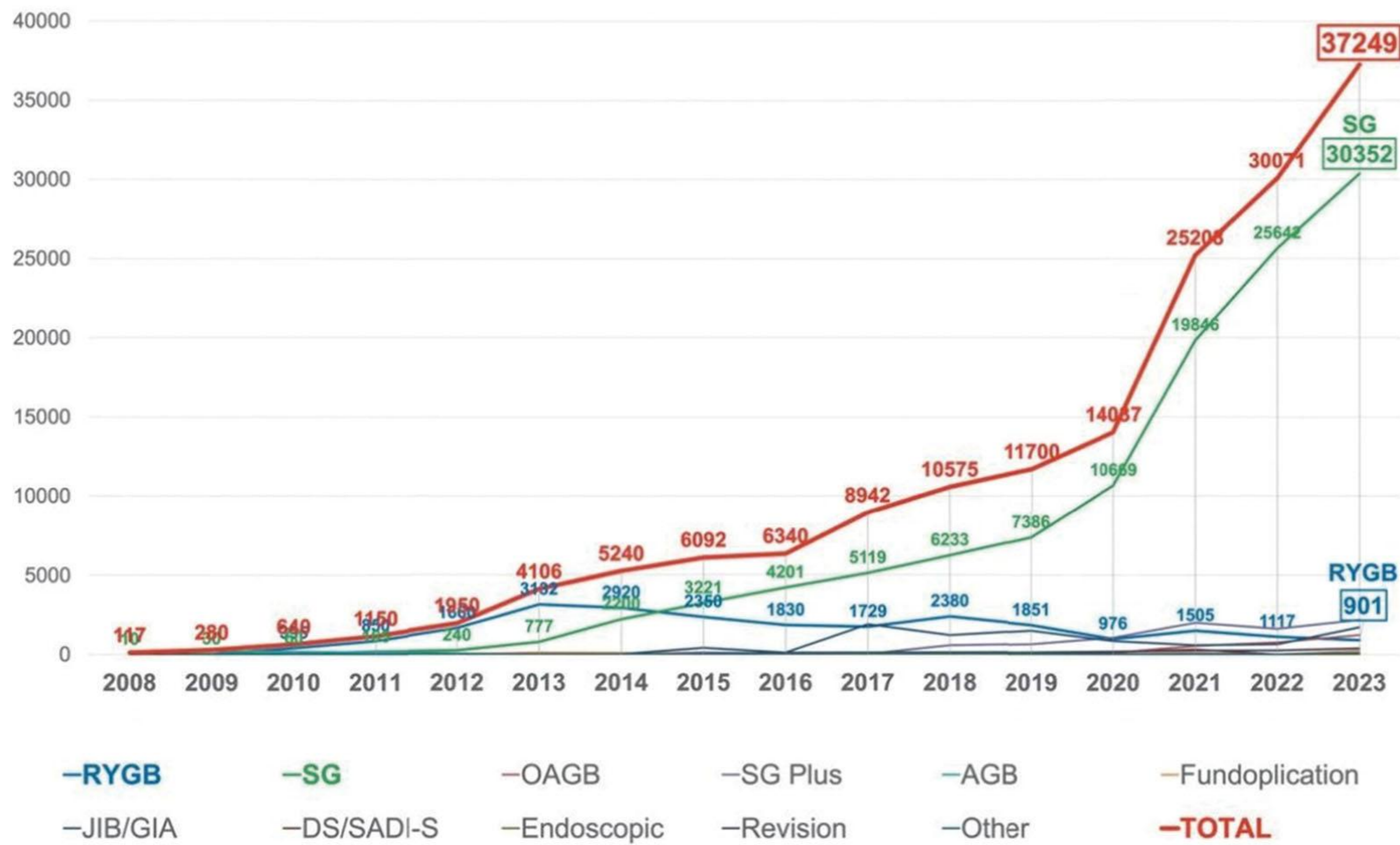


INNOVATION PHASE

The operation of gastrectomy has been gradually standardized, the instruments have been gradually targeted, and various medical institutions have formulated detailed surgical specifications and management procedures to ensure the safety and effectiveness of the operation.



■ CHINESE OBESITY METABOLIC SURGERY DATA CHART



- The 2023 annual report pointed out that the number of sleeve gastrectomies increased by 3000% in the 15 years from 2008 to 2023, and increased by 300% from 2020 to 2023.

■ IFSO DATABASE STATISTICS CHART



China currently ranks 30,071 sleeve gastrectomies, but in the next five years, China will surpass Brazil and become the only country after the United States, with a total of 178,600 sleeve gastrectomies.



PRODUCT TRADING

GASTRIC CALIBRATING TUBE

The Gastric Calibration Tube is a key device used in gastric surgery pouches, designed to assist in adjusting the size and positioning of the gastric pouch.

Gastric Surgery Assistance:

Calibrate and adjust the size and position of the gastric pouch during surgical procedures such as gastrectomy, gastric bypass or sleeve gastrectomy.

Leak Test:

Used to detect potential pouch leaks in the gastric pouch at the end of surgery.

■ FEATURES

- Made of medical grade silicone, the material is soft, safe and reliable.
- The surface is equipped with precise scales and development lines for accurate measurement.
- Multiple auxiliary holes can be used for irrigation, flushing or suction of gastric contents. Internal conical connector: can match various injection devices, perform leak testing, and the balloon can be precisely positioned.
- Provide a variety of different specifications and models to meet different surgical needs.

■ PRECAUTIONS

- **Operation specification:** The intubation operation should be performed by professional medical staff to ensure accuracy and safety.
- **Patient cooperation:** During the operation, the patient should be allowed to relax and cooperate as much as possible to reduce discomfort.
- **Monitoring of use:** Regularly check the position and function of the gastric tube to prevent slippage and blockage.
- **Timely replacement:** If the gastric tube is found to be damaged or has been used for a long time, it should be replaced in time to prevent infection.

■ GASTRIC CALIBRATION TUBE DEVELOPMENT

The innovative development of the gastric calibration tube has gone through a process from exploration to gradual maturity.



FIRST STAGE

Initially, there were no specialized instruments, and doctors used large drainage tubes as instruments for stomach calibration.



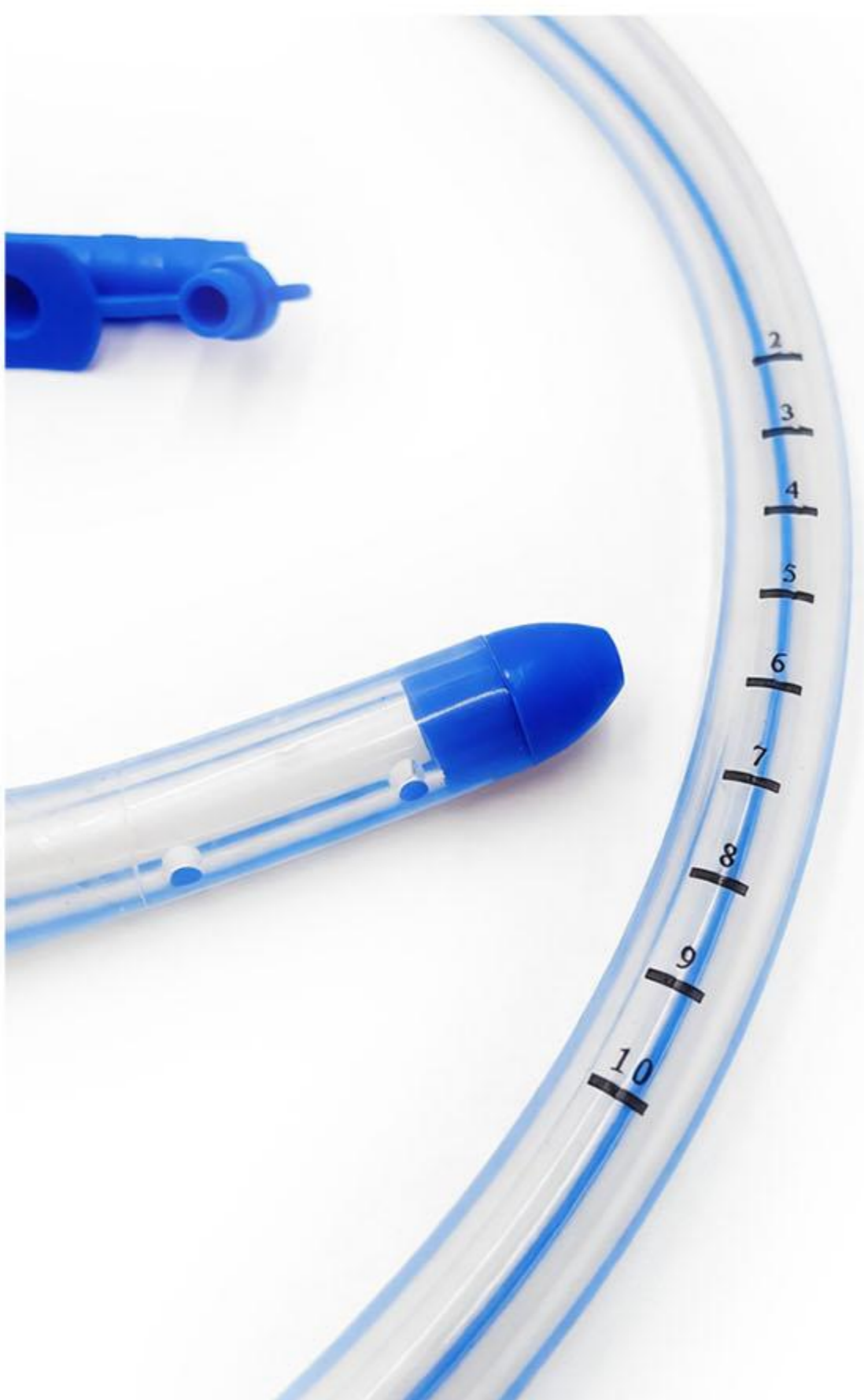
SECOND STAGE

For leak testing, a connector that can connect to a syringe is added to facilitate the injection of methylene blue test liquid. A new universal connector is added.



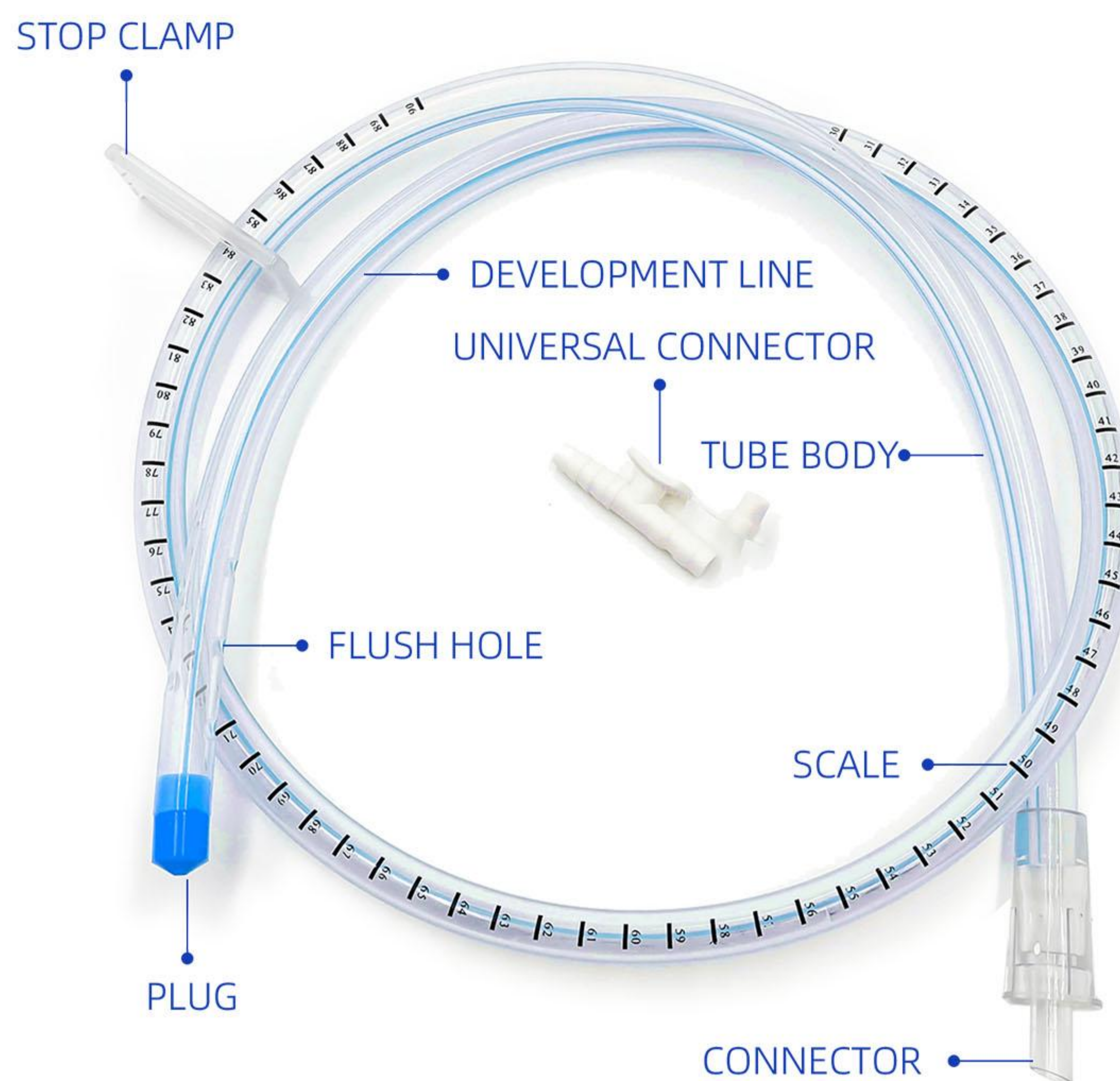
THIRD STAGE

In order to complete a sleeve gastrectomy that meets the standard size requirements, a unilateral balloon was added, which greatly improved the accuracy of gastric pouch cutting.



■ **TYPE I GASTRIC CALIBRATION TUBE**

It consists of a catheter, an inner cone joint, a silicone head, a universal joint, and an inspection clamp. This product is a sterile product, sterilized with ethylene oxide, and is disposable.



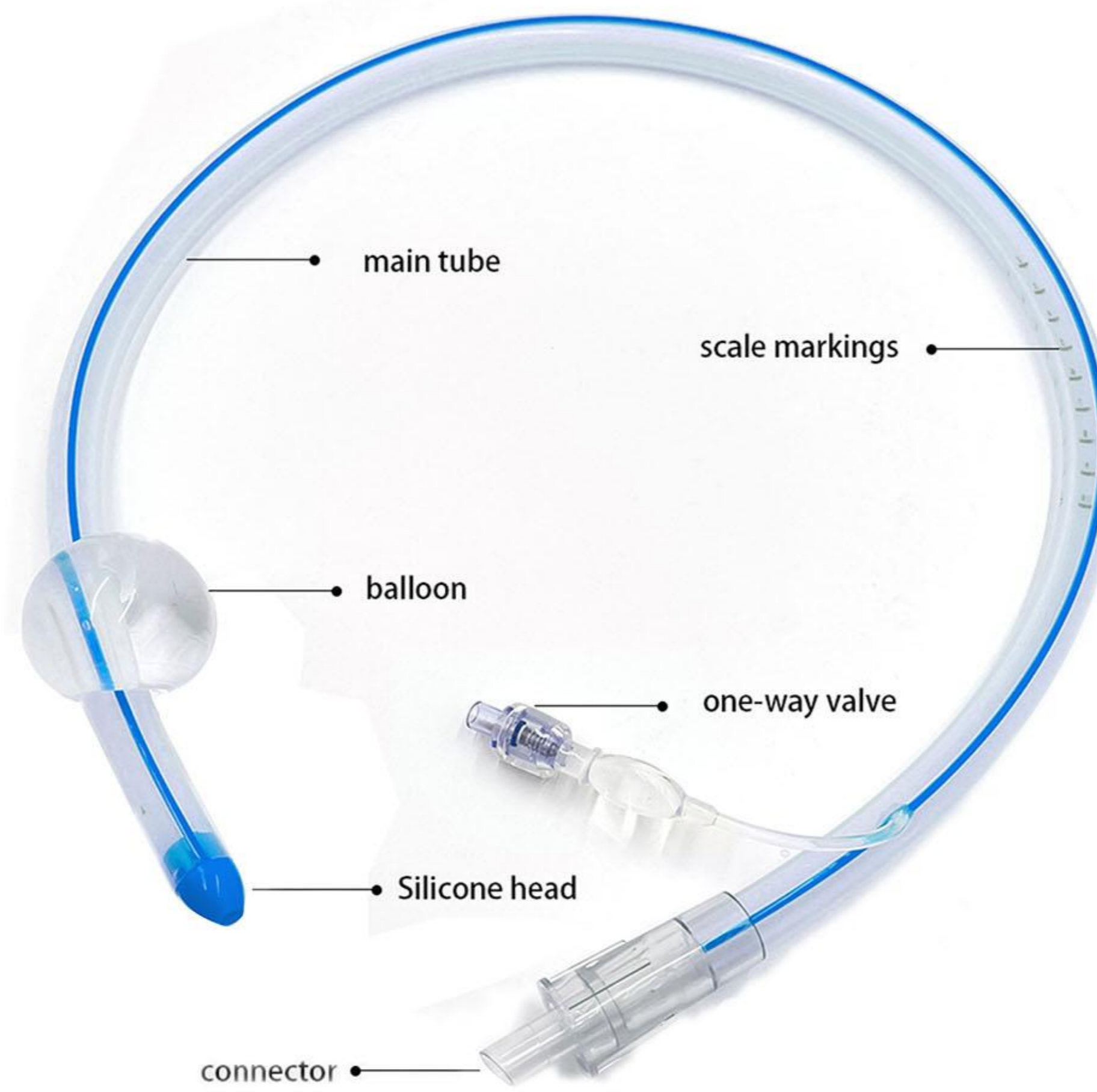
CODE	SIZE	LENGTH	OUTER DIAMETER	INNER DIAMETER	COLOR
SY01-04	32Fr	1200mm	10.7mm	6.7ml	blue
SY01-00	34Fr	1200mm	11.3mm	7.1ml	blue
SY01-01	36Fr	1200mm	12mm	8.0ml	blue
SY01-02	38Fr	1200mm	12.4mm	8.4ml	blue
SY01-03	40Fr	1200mm	13.2mm	8.2ml	blue

- Gastric calibration tubes are available in five sizes: 32Fr, 34Fr, 36Fr, 38Fr, and 40Fr. The tubes are color-coded to prevent misuse.

■ TYPE II GASTRIC CALIBRATION TUBE

It consists of a catheter, an inner cone connector, a silicone head, a universal connector, a one-way valve (with metal parts), and a balloon.

This product is provided in a sterile state, sterilized with ethylene oxide, and is for single use.



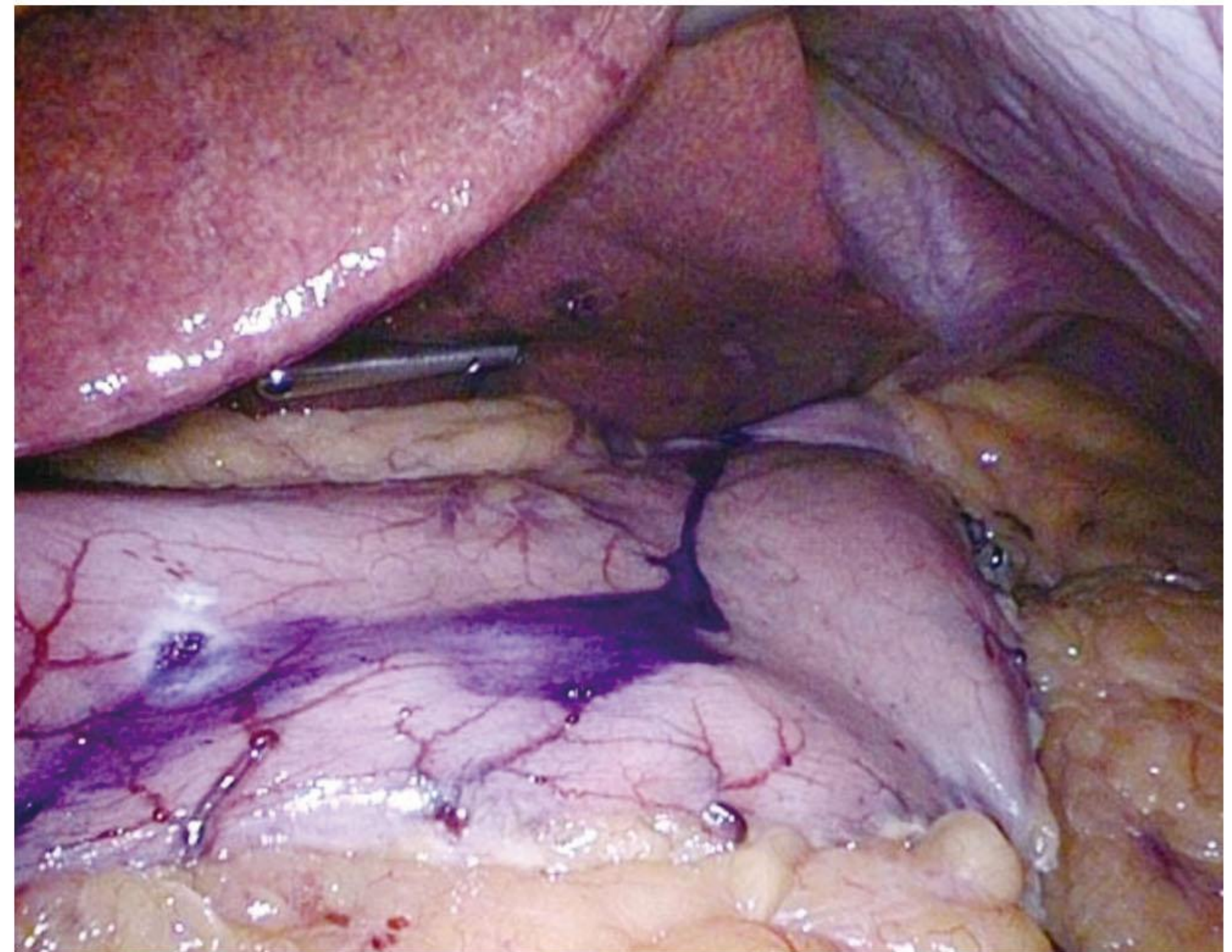
MODEL	SIZE	LENGTH	BALLOON DIAMETER	BALLOON CAPACITY	COLOR
SY02-04	32Fr=10.7mm	745mm	41mm	30ml	blue
SY02-00	34Fr=11.3mm	745mm	41mm	30ml	blue
SY02-01	36Fr=12.0mm	745mm	41mm	30ml	blue
SY02-02	38Fr=12.7mm	745mm	41mm	30ml	blue
SY02-03	40Fr=13.2mm	745mm	41mm	30ml	blue

- Gastric calibration tubes are available in five sizes: 32Fr, 34Fr, 36Fr, 38Fr, and 40Fr. The tubes are color-coded to prevent misuse.

■ **IMPORTANT FEATURES**

Postoperative Leak Test

- After surgery, methylene blue liquid is injected through the tube to check if there is a risk of leakage in the sutures.

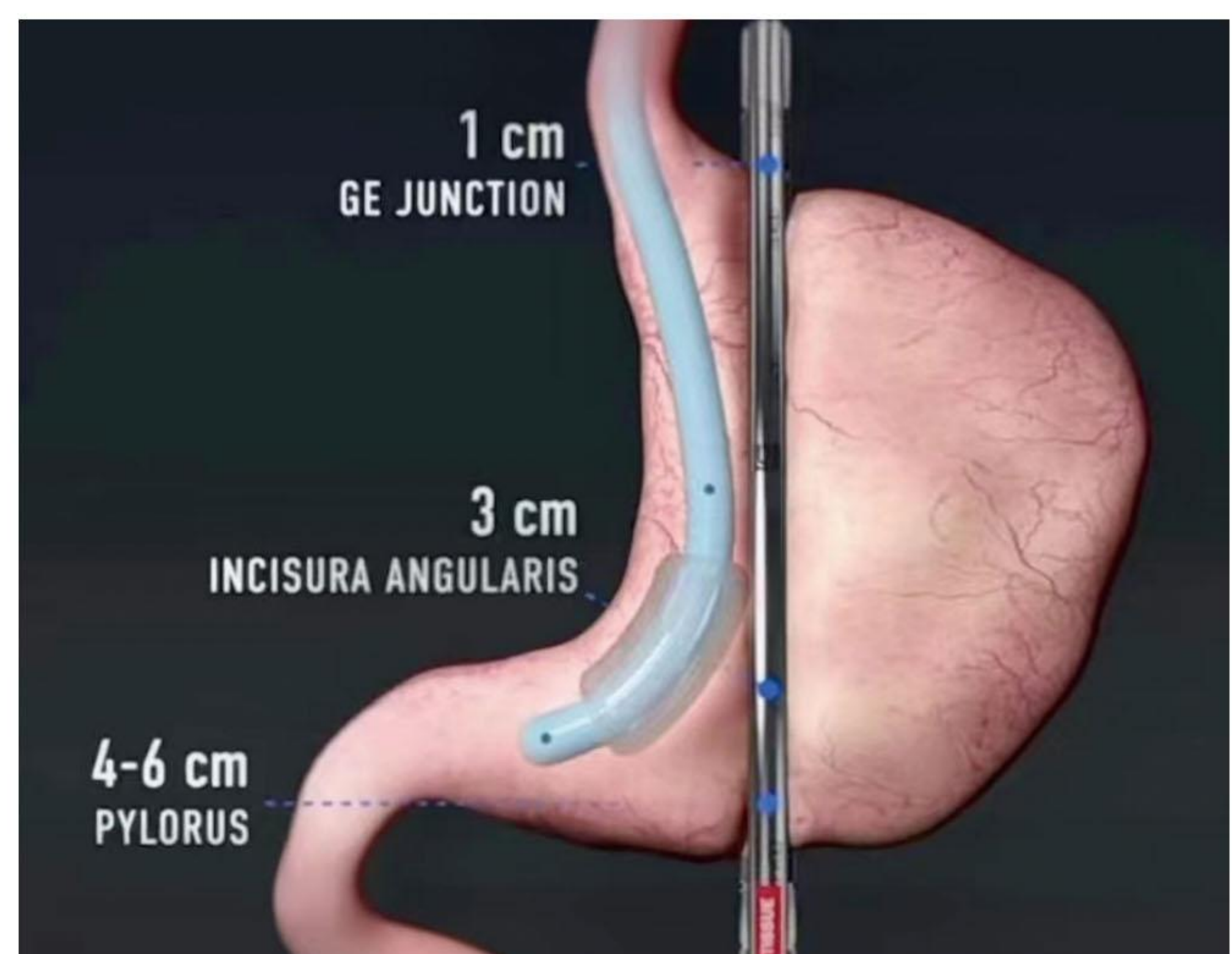


Suture leaks can be classified as acute (< 7 days), early (1-6 weeks), late (after 6 weeks), and chronic (after 12 weeks).
 The risk of leak after LSG has been reported to be 2.4%, with 89% of leaks occurring in the proximal third of the stomach near the angle of His.

■ **PRODUCT INNOVATION**

Innovation:

- The inflated balloon can ensure that the resection size reaches the standard 3CM
- The pyloric resection size reaches the standard 4-6CM



CLINICAL EFFECTS

1

The gastric calibration tube regulates the gastric capacity, controls the patient's food intake, and achieves a weight loss effect. This has been verified in many clinical trials, showing that it has a positive effect on long-term weight loss and health improvement.

2

By using a dedicated calibrated tube during surgery, the standard size and shape of the stomach is ensured to meet ideal standards, thereby reducing the risk of postoperative anastomotic leakage and bleeding.

3

The use of special calibration tubes helps surgeons to precisely control surgical operations, effectively eliminating the risk of postoperative leakage and improving the success rate of surgery.

中华人民共和国医疗器械注册证	
注册证编号:	苏械注准 20232141554
注册人名称	苏州神韵医疗器械有限公司
注册人住所	苏州市吴中区临湖镇银藏路 666 号 11 幢
生产地址	苏州市吴中区临湖镇银藏路 666 号 11 幢
代理人名称	不适用
代理人住所	不适用
产品名称	一次性使用胃管
型号、规格	32Fr、34Fr、36Fr、38Fr、40Fr。
结构及组成	一次性使用胃管由导管、内圆锥接头、硅胶头、通用连接器、单向阀（带金属件）、球囊组成，产品以无菌状态提供，经环氧乙烷灭菌，一次性使用。
适用范围	供插入胃部，排空、清洗、灌注用，不包括鼻饲用管。
附件	产品技术要求
其他内容	
备注	

江苏省药品监督管理局 批准日期: 2023 年 11 月 02 日
生效日期: 2023 年 11 月 02 日
有效期至: 2028 年 11 月 01 日

国家知识产权局	
100000 北京市北京门头沟区莲花山西路 98 号院 5 号楼 703 室-3 北京国源中科知识产权代理事务所(普通合伙) 胡勋勋(15815571812)	发文日: 2022 年 12 月 22 日
申请号: 202223513960.1	发文序号: 2022122201603280
专利通知书	
根据专利法第 28 条及其实施细则第 38 条、第 39 条的规定, 申请人提出的专利申请已由国家知识产权局受理。现将确定的申请号、申请日等信息通知如下: 申请号: 202223513960.1 申请日: 2022 年 12 月 22 日 申请人: 苏州神韵医疗器械有限公司 发明人: 刘源, 许大志 发明创造名称: 袖状胃手术使用的胃校准管经核实, 国家知识产权局确认收到文件如下: 权利要求书 1 份 2 页, 权利要求项数: 8 项 说明书 1 份 8 页 说明书附图 1 份 5 页 说明书摘要 1 份 1 页 摘要附图 1 份 1 页 专利代理委托书 1 份 2 页 实用新型专利请求书 1 份 4 页	
提示: 1. 申请人收到专利申请受理通知书之后, 认为其记载的内容与申请人所提交的相应内容不一致时, 可以向国家知识产权局请求更正。 2. 申请人收到专利申请受理通知书之后, 再向国家知识产权局办理各种手续时, 均应当准确、清晰地写明申请号。	
审查员: 自动受理 联系电话: 010-62386655	审查部门: 国家知识产权局 专利审查业务部
20001 纸质申请, 回函请寄: 100088 北京市海淀区蓟门桥西土城路 6 号 国家知识产权局专利局受理处 2022.10 电子申请, 应当通过专利业务办理系统以电子文件形式提交相关文件。除另有规定外, 以纸质等其他形式提交的 9 4 8 0 0 4 0 0 0 0	

Registration Certificate
No.: Su Xie No. 20232141554

Patent No. 2022235139601