

[Applicable population]

1. 18-65 years old, regardless of gender;
2. Those who have tried other weight loss methods in the past but are not satisfied with the effect;
3. Able to walk completely independently without any serious chronic orthopedic diseases;
4. Adult obese patients with a BMI ≥ 30 kg/m² and ≤ 40 kg/m².

[Contraindications]

1. Symptomatic congestive heart failure, cardiac arrhythmia or unstable coronary artery disease;
2. Current suffering from respiratory disease such as chronic obstructive pulmonary disease (COPD), pneumonia or cancer;
3. History of bariatric surgery;
4. Acute pancreatitis or Chronic pancreatitis within 12 months;
5. History of or current small bowel obstructions;
6. History of abdominal and/or pelvic surgery, excluding one of the following surgeries performed at least 12 months before balloon placement: Cesarean section, diagnostic laparoscopy, laparoscopic appendectomy, laparoscopic cholecystectomy. (Patients were excluded if they had 2 Cesarean sections, or a Cesarean section and laparoscopic appendectomy. Patients may be included if they have had one Cesarean section)
7. History of autoimmune connective tissue disorder (e.g. Lupus erythematosus, scleroderma) or immunocompromised;
8. Esophageal, gastric, or duodenal disease (including hiatal hernias (≥ 2 cm), paraesophageal hernias, polypus, acute erosive gastritis, cancer, varices, diverticula, gastroparesis, ulcers, stenosis, achalasia with esophagitis);
9. Insulin-dependent diabetes;
10. Severe coagulopathy, severe hepatic insufficiency or cirrhosis;
11. Long term or recent use of gastric stimulants to change gastrointestinal function or integrity, including but not limited to non-steroidal anti-inflammatory drugs and aspirin;
12. Antiplatelet drugs and other drugs that affect blood coagulation are needed;
13. Take drugs that may affect the efficacy due to delayed gastric emptying, such as anticonvulsant

and antiarrhythmic drugs;

14. Anemia: Hgb < 110g/L for females; Hgb <120g/L for male;
15. Night eating syndrome (NES) or bulimia;
16. History of or current drug abuse or excessive alcohol use;
17. H. pylori infection without cure;
18. Proton pump inhibitors could not be taken during balloon implantation;
19. Patients with inflammatory bowel disease (e.g., Crohn's disease, Ulcerative Colitis, etc.);
20. History of malignant tumor;
21. Patients with mental illness;
22. Breastfeeding or pregnant women, or intending to become pregnant within half a year;
23. History of allergy to silicone and/or gelatin;
24. Patients with a history of gastric ulcer should be fully evaluated before use;
25. Patients with contraindications to gastroscopy are prohibited from using the device;
26. Other patients deemed unsuitable by the doctor.

[Complications]

The Intra-gastric Balloon System must only be used by qualified physicians for the indicated use. Potential complications include, but are not limited to the following:

1. Pain
2. Infection
3. Bleeding
4. Adverse Tissue Reaction
5. Cardiorespiratory sequelae
6. Gastrointestinal sequelae including nausea, vomiting, organ perforation, trauma or obstruction
7. Unintended migration of implant
8. Death

[Precautions]

1. Use this product within the shelf life.

2. Store it in a cool, dry and dark place.
3. Do not use the product if the package is damaged.
4. Check whether the product is damaged before use. Reject the damaged product.
5. Do not soak the product into the disinfectant before use.
6. Do not sterilize the product with the high-pressure steam.
7. Keep the product dry before swallowing.
8. The used product is subject to concentrated disposal after the harmless treatment per hygiene and disease control provisions.
9. During the balloon implantation period, you should try to avoid eating hard, highly viscous or high-fiber foods that are difficult to digest (such as enoki mushrooms, celery, leeks, etc.). If you need to eat them, be sure to cut them into short pieces of about 1 cm;
10. When eating fish and meat, be careful to chew slowly and avoid swallowing fish bones or bones;
11. When the body has adapted to the balloon but suddenly experiences abdominal pain, vomiting, bloating, gas retention and other discomfort or symptoms, you should immediately seek medical attention.

[Warnings]

1. Do not re-use or sterilize devices except for the Infusion Pressure Bag. Discard after one procedure. Structural integrity and/or function may be impaired through reuse, cleaning, or sterilization.
2. For Infusion Pressure Bag, refer to its manufacturer's instructions for use, cleaning, and care.
3. Doctors must be trained and proficient in the use of the Intra-gastric balloon system before using this product. In addition, the prescribing doctor must have access to an endoscopy unit and personnel proficient in gastroscopy and foreign object retrieval when the devices need to be removed for any reason.
4. The use of multiple devices in sequence or in parallel has not been investigated.
5. To avoid esophageal trauma, do not fill the Balloon until the entire Capsule is confirmed to be in the stomach with X-Ray.
6. To prevent unexpected detachment of Catheter from the Balloon, do not pull back on Catheter when attaching the Proximal Connector.
7. Do not detach Balloon from Catheter until Balloon filling is completed and confirmed. Incomplete

Balloon filing may lead to intestinal obstruction.

8. Do not withdraw Catheter using high force. Movement against resistance may result in adverse events or device damage.
9. During the Balloon placement, a program of daily oral proton pump inhibitors (PPIs) is needed
10. There are reports of adverse events such as acute pancreatitis and overfilling of the balloon during use of similar products abroad. Medical staff and users are reminded to pay attention to the above adverse events during use. Currently, no such adverse events have occurred during the clinical trial of this product;
11. During each use, each person can only place one balloon, and it is forbidden to place multiple balloons;
12. After the Intra gastric Balloon is placed, artifacts may be generated during MRI examination. The impact of the Intra gastric Balloon on the MRI examination results should be considered. It is not recommended to use MRI when placing the balloon. If it must be used, please consult the attending physician and radiologist.