Intragastric Balloon System

Instructions for Use

Doc. No.:CE/TD-IBS-22-01

Version:A.01

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Beijing ZKSK Technology Co., Ltd.

WARNING:

1. Read the Instructions for use carefully before use. Strictly follow the instructions provided in the IFU.

2. This product is sterilized using Ethylene Oxide and has a sterile shelf life of 2 years.

3. Do not use if expired. The production date and expiration date are indicated on the product packaging.

4. Inspect the packaging thoroughly before use. Do not use if the primary packaging is damaged.

5. This product is for single use only. Reuse, reprocessing, and/or re-sterilization may lead to product failure and/or disease transmission.

6. The maximum placement time for the intragastric balloon is 12 months, and it must be removed by or before this time.

7. For proper filling, the delivery device and Balloon must be correctly positioned in the stomach (the delivery device must be placed below the lower esophageal sphincter). Filling the Balloon in the esophageal opening may cause severe injury.

8. During Balloon filling, avoid excessive filling speed, as high pressure may damage the Balloon valve or cause premature detachment of the Balloon from the delivery device.

9. Patients must be closely monitored throughout the treatment period to detect potential adverse events.

10. The Filling Volume of the Balloon ranges from 400 mL to 700 mL. Risks increase significantly if the Filling Volume exceeds 700 mL.

11. There have been reports of deflated (leaking) balloons migrating into the intestines, causing intestinal obstruction and requiring surgical removal. Patients with gastrointestinal motility disorders, a history of abdominal or gynecological surgery, radiation therapy, or active inflammatory bowel disease may be at higher risk of intestinal obstruction. These factors should be considered when assessing surgical risks. Intestinal obstruction may be fatal.

12. The device is contraindicated for women who are pregnant or breastfeeding. If pregnancy is confirmed at any point during treatment, the device should be removed immediately.

13.The Balloon is made of soft silicone elastomer and can be easily damaged by instruments or sharp objects. Handle the Balloon only with gloved hands and follow the handling instructions in the IFU.

14.Spontaneous overinflation of the intragastric balloon has been reported in some patients. Overinflation often requires early removal to prevent serious complications such as gastric outlet obstruction and contact ulcers.

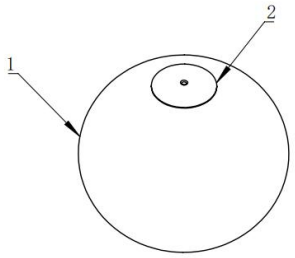
15.Patients must be closely monitored throughout the treatment period to identify potential complications. Patients should be instructed to report any symptom changes to their physician immediately. Educate patients about possible symptoms of Balloon deflation, intestinal obstruction, ulcers, and other complications, and advise them to contact their physician if such symptoms occur.

16.Any serious adverse events related to this product should be reported to the manufacturer, user, and/or the competent authority in the European Union member state where the patient is located.

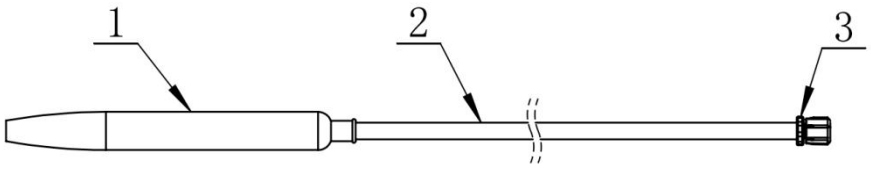
[Product Name]
Intragastric Balloon System

[Intended Use]
It is designed to assist weight loss by partially filling the stomach and inducing satiety.

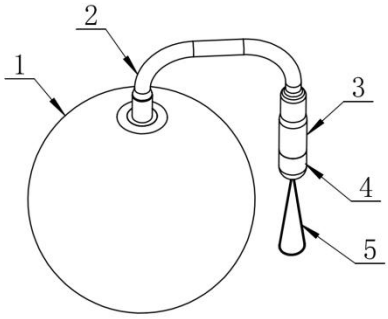
[Structure and Components]
The Intragastric Balloon System consists of a Balloon, Balloon delivery device, and Filling Device.It is classified by adjustable/ non-adjustable Filling Volume. The basic structure is illustrated in Figures 1 to 5, and the specifications are listed in Table 1. This product is for single use, sterilized with Ethylene Oxide, and provided sterile. The product has a shelf life of 2 years.



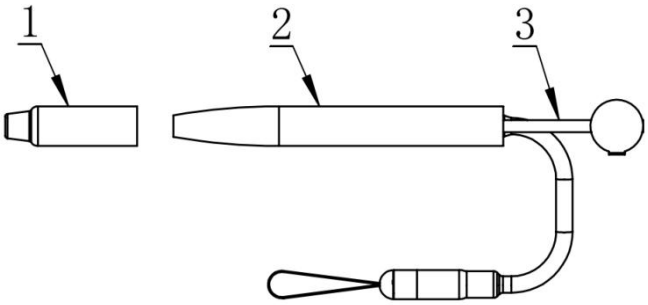
1- Balloon 2- Valve Cap
Figure1 Schematic Diagram of Balloon for Non-Adjustable Intragastric Balloon System



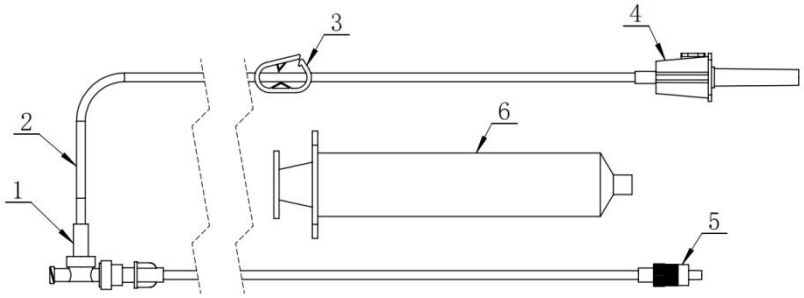
1- Balloon Sheath (non-adjustable) 2- Delivery Tube 3- Delivery Tube Connector
Figure 2 Schematic Diagram of Delivery System for Non-Adjustable Intragastric Balloon System



1- Balloon 2- Valve Stem Tube 3- Check Valve Connector
4- Connector Cap Cover 5- Pull Wire
Figure 3 Schematic Diagram of Balloon for Adjustable Intragastric Balloon System



1- Endoscopic Sheath 2- Balloon Sheath (adjustable) 3- Balloon Sheath Strap
Figure 4 Schematic Diagram of Delivery System for Adjustable Intragastric Balloon System



1- Three-way Valve 2- Filling Tube 3- Clamp
4- Puncture Needle 5- Filling Tube Connector 6- Syringe
Figure 5 Schematic Diagram of Filling System for Intragastric Balloon System

[SPECIFICATION AND MODEL]

1.Product specification and model name rule:

ZK-BALL - □
(1) (2)
(1) Product Name Code
(2) Filling Volume Type Code (01: Non-adjustable, 02: Adjustable)

2. Specifications and Models Table:

Table 1 Specification and Model of Intragastric Balloon System

No.	Specification and Model	Filling Volume Type	Balloon Rated Filling Volume
1	ZK-BALL-01	Non-adjustable	400~700mL
2	ZK-BALL-02	Adjustable	400~700mL

[Indications/Target Population]

- Pre-surgical temporary use for weight loss in morbidly obese patients (BMI 40 and above or a BMI of 35 with co-morbidities) prior to bariatric or other surgery, in order to reduce surgical risk.
- Temporary use for weight loss in overweight and obese patients (BMI > 27) who have failed to achieve and maintain weight-loss with a supervised weight control program.

[Contraindications]

- Less than 18 years.
- Treatment represents an unreasonable risk to the patient.
- Pregnancy.
- History of inflammatory disease of the gastrointestinal tract (including ulceration, any erosive gastritis, grade 3-4 esophagitis, Barrett's esophagus, or specific inflammation such as Crohn's disease or ulcerative colitis).
- Severe coagulopathy; upper gastro-intestinal bleeding conditions such as esophageal or gastric varices, congenital or acquired intestinal telangiectasia.
- Congenital or acquired anomalies of the GI tract such as atresias or stenoses.
- Emotional disorders, eating disorders, or substance abuse.
- History of a known diagnosis or pre-existing symptoms of systemic lupus erythematosus, scleroderma, or other autoimmune connective tissue disorder.
- Medical illnesses such as, but not limited to cardiopulmonary disease that would increase the risk of endoscopy or weight loss.
- Any other medical condition which could increase the risk of elective endoscopy or weight loss.
- Previous gastric, esophago-gastric, bariatric or duodenal surgery.
- CLINICALLY SIGNIFICANT HIATAL HERNIA, ESOPHAGEAL DIVERTICULUM, STENOSES, RINGS OR WEBS THAT CAN CAUSE DEVICE IMPLANTATION ABOVE THE DIAPHRAGM.
- Motility disorders of the GI tract such as gross esophageal motility disorders, gastroparesis or intractable constipation.
- Subjects who require continuous therapy with known ulcerogenic medication

(e.g., aspirin, non-steroidal antiinflammatory agents, COX-2 inhibitors), anti-coagulants or anti-platelet agents.
- Subjects unable or unwilling to participate in a medically supervised diet and behavior modification program with frequent follow up meetings.
- Allergic to Silicone.

[Potential Complications]
Possible complications of the use of the Intragastric Balloon System include, but are not limited to:
- Intestinal obstruction by the balloon. This may require abdominal surgery and/or subsequent surgery. Death due to complications related to intestinal obstruction or surgery is possible.
- Balloon deflation and subsequent replacement.
- Renal Injury.
- Esophageal obstruction. Once the balloon has been inflated in the stomach, the balloon could be pushed back into the esophagus. If this occurs, surgery or endoscopic removal could be required. Injury to the digestive tract during placement of the balloon in an improper location such as in the esophagus or duodenum. This could cause bleeding or even perforation, which could require a surgical correction for control.
- Insufficient or no weight loss.
- Injury to teeth, tissue in the oral cavity or throat and upper esophageal sphincter.
- Temporary weight-loss treatments have been shown to have poor long-term success rates (weight-loss maintenance) in severely obese patients.
- Adverse health consequences resulting from weight loss.
- Gastric discomfort, feelings of nausea and vomiting following balloon placement as the digestive system adjusts to the presence of the balloon.
- Continuing nausea and vomiting with dehydration, electrolyte abnormalities, weakness, fainting or falling episode. This could result from direct irritation of the lining of the stomach or as a result of the balloon blocking the outlet of the stomach. It is even theoretically possible that the balloon could prevent vomiting (not nausea or retching) by blocking the inlet to the stomach from the esophagus.
- A feeling of heaviness in the abdomen. Abdominal or back pain, either steady or cyclic.
- Gastroesophageal reflux.
- Pancreatitis (Including Acute).
- Influence on digestion of food. Blockage of food entering into the stomach.
- Bacterial growth in the fluid which fills the balloon. Rapid release of this fluid into the intestine could cause infection, fever, cramps and diarrhea.
- Injury to the lining of the digestive tract as a result of direct contact with the balloon, catheter, polypectomy snare, or as a result of increased acid production by the stomach - esophagitis, gastritis or duodenitis. This could lead to ulcer formation with pain, bleeding or even perforation. Surgery could be necessary to correct this condition, and could result in death.

- Catheter entrance into the duodenum causing anorexia, nausea, vomiting or abdominal pain. This could spontaneously resolve or require endoscopy to pull the catheter back into the stomach, and could become a recurring problem, which would necessitate device removal.
- Spontaneous Hyperinflation is the enlargement of the balloon with extra air that can occur spontaneously. This can lead to symptoms such as pain, nausea, vomiting, dehydration, ulceration, perforation, and could require a down adjustment or removal of the balloon.
- Foul smelling belches or burps.

[Complications of routine endoscopy include]
Adverse reaction to sedation or local anaesthetic; Abdominal cramps and discomfort from the air used to distend the stomach; Sore or irritated throat following the procedure; Aspiration of stomach contents into the lungs; Cardiac or respiratory arrest (these are extremely rare and are usually related to severe underlying medical problems); Digestive tract injury or perforation; Upper digestive tract bleeding.

[Intended Users]
Operators using this product must possess expertise in endoscopic techniques and transoral gastric intubation. The instructions for use of this product do not replace formal training in these methods, and operators must have received adequate clinical technical training.

[Clinical Benefits]
Aids in patient weight loss.

[CAUTIONS]
1.Both physicians and patients should evaluate the risks associated with endoscopy and intragastric Balloon placement (see Warnings, Precautions, and Complications sections for details), as well as the potential benefits of this temporary weight loss therapy, prior to use.
2.Temporary weight-loss treatments have been shown to have poor long-term success rates (weight-loss maintenance) in obese and morbidly obese patients.
3.Physicians have reported concomitant use of proton pump inhibitors (PPIs) and H2 receptor blockers, which reduce gastric acid production or decrease acidity. As the intragastric Balloon is made of silicone elastomer and may degrade in gastric acid, these medications help regulate gastric pH levels, potentially prolonging Balloon integrity and reducing risks of gastric ulcers and subsequent perforation. Therefore, their use is strongly recommended.
4.Deflated devices should be removed promptly. Bowel obstructions have been reported in currently marketed balloons due to deflated balloons passing into the intestines and have required surgical removal. Some obstructions have reportedly been associated with patients who have diabetes or who have had prior abdominal surgery, so this should be considered in assessing the risk of the procedure. Bowel

obstructions can result in death.
5.The risk of intestinal obstruction may be higher in patients who have had prior abdominal or gynecological surgery. The risk of intestinal obstruction may be higher in patients who have a dysmotility disorder or diabetes
6.Pregnancy or breast-feeding contraindicates use of this device. Should pregnancy be confirmed at any time during the course of treatment, it is recommended that the device be removed.
7.Patients should ensure that effective birth control is in place prior to implantation and throughout the duration of implantation, and that they tell their doctor as soon as possible if pregnancy is confirmed during treatment.
8.Precise gastric positioning is critical for Balloon filling. During filling, Balloon entrapment at the esophageal opening may cause injury and/or esophageal rupture. Physiological responses to the intragastric Balloon vary depending on the patient's general condition and activity levels.
9.Each patient must be monitored closely during the entire term of treatment in order to detect the development of possible complications. Each patient should be instructed to report to physicians immediately regarding any and all change of symptoms. Symptoms of deflation, gastrointestinal obstruction, ulceration and other complications which might occur should be reviewed with patient, and patients should be advised to contact his/her physician immediately upon the onset of such symptoms.
10.Patients with an intragastric balloon that present with severe abdominal pain that have a negative endoscopy and x-ray may additionally require a CT scan to definitively rule out a perforation.
11.Patients reporting loss of satiety, increased hunger and/or weight gain should be examined radiographically and/or endoscopically, as this is indicative of a balloon deflation. Should the loss of satiety, increased hunger and/or weight gain not be associated with balloon deflation or other physiological cause, and the balloon is below the recommended maximum (700ml) capacity, the physician may consider increasing the balloon volume. (See Balloon Volume Adjustment instructions below.)
12.If it is necessary to replace a balloon which has spontaneously deflated, the recommended initial fill volume of the replacement balloon is the same as for the first balloon or the most recent volume of the removed balloon. A greater initial fill volume in the replacement balloon may result in severe nausea, vomiting or ulcer formation.
13.This product has undergone safety testing in 3T MRI scanners. Patients with implanted devices can safely undergo 3T MRI examinations.
14.This product is composed of soft silicone elastomer and is easily damaged by instruments or sharp objects. The balloon must be handled only with gloved hands and as recommended in the Instructions for Use.

[Instructions for Non-adjustable Intragastric Balloon System]

1.Follow hospital protocols for patient sedation and endoscopy preparation.
2.Perform endoscopy to assess contraindications for device placement.
3.Remove the endoscope.
4.If no contraindications:
A. Lubricate the delivery device sheath with medical gel or equivalent.
B. Gently insert the delivery device into the esophagus and stomach.
5.Keep the delivery device in place, reinsert the endoscope, and observe the filling process. The sheath must be below the lower esophageal sphincter and fully within the gastric cavity.
6.If positioned correctly, unscrew the proximal connector and remove the guidewire.
7.Connect the Filling Tube Connector of Filling Device to the proximal connector and insert the Puncture Needle into a sterile saline bag.
8.Attach a syringe to the Three-Way Valve of Filling Device and fill the Balloon with sterile saline in 50 mL increments (total: 400–700 mL). Fill slowly (≥10 seconds per increment) to avoid high pressure.
WARNING: Rapid filling may damage the Balloon valve or cause Balloon premature detachment with Balloon Delivery System.
9.After filling, confirm Balloon deployment under endoscopy. Gently pull the delivery device to detach the Balloon while keeping it near the endoscope tip or lower esophageal sphincter.
NOTE: Patients may feel slight pressure during detachment.
10.Once the Balloon is detached from the delivery device, endoscopic examination should be performed to verify the absence of fluid leakage from the Balloon.
11.Remove the endoscope.

[Instructions for Adjustable Intragastric Balloon System]

1.Follow hospital protocols for patient sedation and endoscopy preparation.
2.Perform endoscopy to assess contraindications for device placement.
3.Remove the endoscope.
4.Unpack the Balloon and accessories.
5.Pull the Balloon Sheath Strap to remove all restraints.
6.Dry the endoscope thoroughly.

7.Place the Endoscopic Sheath over the distal end of the endoscope, rolling it over the Balloon’s edge.The tip of the Balloon should maintain approximately 3 mm distance from the endoscope's distal end.
8.Insert the Check Valve Connector into the Valve Stem Tube.
WARNING: Skipping this step may tear the Filling Tube, requiring Balloon removal.
WARNING: Do not twist the valve during this step, as it may cause kinking of the Filling Tube and prevent proper fluid injection.
9.The Filling System's Filling Tube Connector is connected to the Check Valve.Use

medical lubricating gel or equivalent product to thoroughly lubricate the entire length of the Balloon and the Check Valve Connector. With one hand, insert the endoscope and device as a single unit into the throat, advancing through the esophagus and into the stomach following standard endoscopic insertion techniques. Once the gastric antrum is reached, retroflex the endoscope to confirm proper Balloon positioning in the stomach. Connect the Filling Device to the syringe, attach the Puncture Needle to the solution bag, and inflate the Balloon with sterile saline solution.
NOTE: If resistance occurs during filling, reposition the endoscope until the filling is smooth.
10.Fill or deflate to the desired volume (initial recommendation: 450–500 mL).
NOTE: Patients may feel slight pressure during balloon detachment from the balloon sheath..
11.Withdraw the infusion device until the Check Valve Connector exits the mouth. Firmly grip the Check Valve Connector with gauze padding, then unscrew the Filling Tube Connector. Securely tighten the connector cap onto the check valve. The connector cap is packaged separately in its own pouch.
NOTE: The Check Valve Connector and cap are slippery, making it difficult to verify complete sealing. The Check Valve Connector must be thoroughly dried with tissue before capping.
12.Insert the capped check valve assembly into the posterior oropharynx.
13.Push the cap and Valve Stem Tube below the gastroesophageal junction using the endoscope tip, then remove the endoscope.

[Adjustable Balloon Volume Adjustment Method]
1.Perform endoscopy and inspect the Balloon and Check Valve Connector for leaks.
2.Use biopsy forceps to grasp the Pull Wire on the connector cap. Retract the forceps to bring the cap against the distal end of the endoscope.

3.Withdraw the endoscope while maintaining contact between the cap and endoscope tip to prevent lodging at the gastroesophageal junction. Once the endoscope tip with the attached cap exits the mouth, firmly grip the Check Valve Connector. The operator should feel the elastic recoil tension of the stretched Valve Stem Tube. A second operator may be required to assist.
4.Unscrew the connector cap from the Check Valve Connector. Connect the Check Valve Connector to the Filling Tube Connector of the Filling Device. Do not lose the connector cap.
5.Gently advance the Filling Device down the throat until the Balloon Valve Stem Tube is no longer taut.
6.Reinsert the endoscope to confirm proper Balloon positioning in the stomach.
7.Connect the large syringe and solution bag to the Filling Device and begin infusion for volume increase (400mL-700mL range);
Disconnect the Filling Tube from the Three-way Valve, connect to the large syringe, and begin aspiration for volume decrease (400mL-700mL range).
8.Never inflate/deflate without endoscopic visualization of the Valve Stem Tube. If

kinking occurs, use the endoscope tip or reposition the Filling Device to straighten the tube.
9.After adjustment, maintain the endoscope in the mid-esophagus while removing the Filling Device.
WARNING: The Check Valve Connector and cap are slippery, making it difficult to determine whether you have fully tightened the fitting cap. Dry the connector thoroughly with tissue before capping.
10.Insert the capped Check Valve Connector into the posterior oropharynx, allowing it to slide down the esophagus.
11.Confirm that the Check Valve Connector is in the esophagus. It may get stuck between the teeth and tongue in the mouth; if so, it should be released by sweeping with your finger. Push the Balloon down below the gastroesophageal junction. Remove the endoscope.

[Balloon Removal Instructions]

- Perform an endoscopic examination, use an injection needle to puncture the balloon, and the adjustable model can also be connected to the balloon check valve connector through the built-in fluid injection device. Refer to the adjustment volume method 1 to 7 steps;
- By injecting needle or using a syringe to draw out the liquid in the balloon;

Note: DEFLATION USING THE INFLATION TUBE REQUIRES ENDOSCOPIC OBSERVATION. (avoid tube kinking)

- Allow the balloon to completely empty of all the fluid.
- A grasping forceps or snare may be used to extract the balloon.
- Pull the balloon until it presses against the end of the endoscope. Then, slowly remove the balloon along with the endoscope.

[Waste Disposal]
Dispose of used products and packaging according to hospital policies or regulations to prevent environmental or human harm.

[Production Date]
See product packaging.

[Sterilization Method]
Ethylene Oxide sterilization.

[Shelf Life]
2 years.

[Transport and Storage Conditions]
Protect from heavy pressure, direct sunlight, and rain during transport. Store indoors in a clean, ventilated, dry, and non-corrosive environment.

[Labeling Instructions]

	Consult instructions for use or consult electronic instructions for use		Do not re-use
	Sterilized using ethylene oxide		Do not use if primary package is damaged
	Lot number		use-by date
	Date of manufacture		Manufacturer
	Caution		Unique device identifier
	Keep dry		Protect from heat and radioactive sources
	Medical device		Package quantity
	Authorized representative in the European Community		CE marking
	Unique device identifier		Catalogue number

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