Intragastric Balloon System

Instructions for Use (IFU)

Version: 03

2025-06-11

⚠ **Please read these instructions thoroughly before using this product.**

1 [Product Name]

Intragastric Balloon System

2 [Product Model and Specification]

PA450, balloon volume after filling: 450 mL ± 50 mL.

3 [Packing List]

Each set includes:

- 1 Intragastric Balloon System
- 1 IFU (Instructions for Use)
- 1 Implant Card
- 1 qulalification certificate

Note: A separate package contains 6 practice capsules (Model PAC450) for swallowing training. These are for practice only.

4 [Clinical Trial Overview]

A clinical trial evaluated the safety and efficacy of the Intragastric Balloon System in 190 overweight or obese subjects (aged 18–65 years, BMI ≥ 27.5 kg/m²). After 4–6 months of treatment:

- **Weight Loss Response Rate (RR)**: 65.75% (FAS analysis at 16 weeks).
- **95% CI** (normal approximation): (58.83%, 72.66%).
- Statistical significance: Lower CI limit (58.83%) > target value (35%) (*p* < 0.001).

Adverse Events:

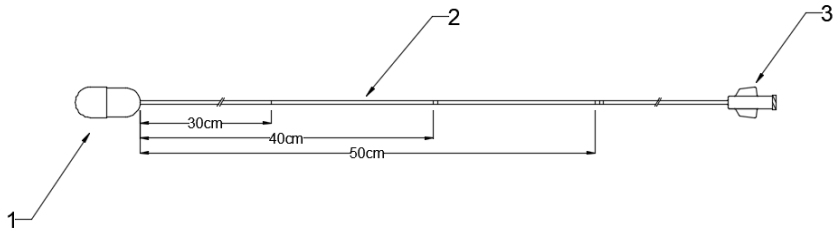
- 180 device-related adverse events occurred.
- 2 subjects withdrew due to intolerance.

- Most events involved gastrointestinal disorders (e.g., nausea, epigastric pain, flatulence, abdominal pain, vomiting, reflux gastritis, diarrhea, abdominal distension, intestinal obstruction).

5 [Product structure, composition and working mechanism]

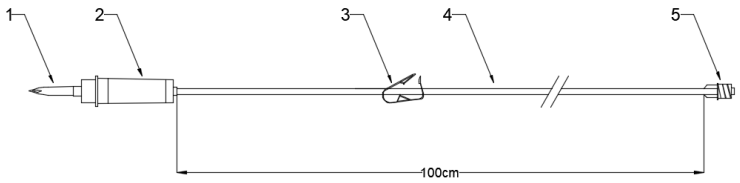
The Intragastric Balloon System is comprised of the Balloon Assembly (Figure 1) ， the Infusion Set Assembly (Figure 2)， and the Practice Capsule (Figure 4) . All instruments are provided non-sterile and for single use only.

The Intragastric Balloon System can be used in conjunction with sodium chloride injection (Figure 5) and infusion pressure bag (Figure 6) in medical institutions. Among them, the sodium chloride injection is used to fill the balloon and is for one-time use, while the infusion pressure bag is used to assist filling and can be used repeatedly.



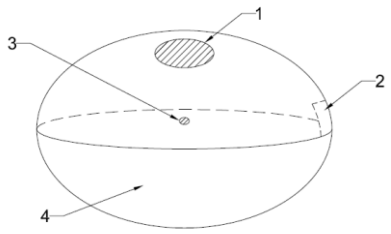
1. Capsule and Balloon 2. Catheter 3. Inner Cone Joint

Figure 1 Balloon Assembly



1. Spike 2. Flow Indicator 3. Clamp 4. Extension Hose 5. Outer Cone Joint

Figure 2 Infusion Set Assembly



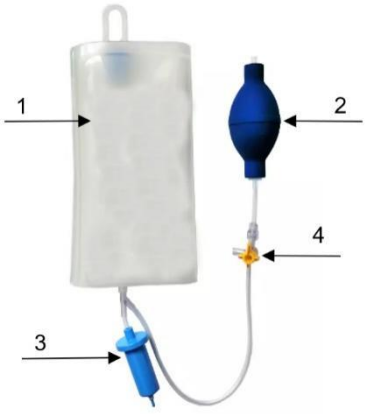
1. Biodegradable Film 2. Self Sealing Valve 3. X-ray Imaging Materials 4. Balloon body

Figure 3 Filled balloon structure

Figure 4 Practice Capsule

1. Bag 2. Sodium Chloride Injection 3. Septum Port

Figure 5 Sodium Chloride Injection



1. Pressure Infuser 2. Inflation Bulb 3. Pressure Regulator 4. Stopcock

Figure 6 Infusion Pressure Bag

As shown in Figure 1, the balloon assembly includes a balloon, a Catheter and a capsule. The balloon is connected to one end of the Catheter and is pre-compressed in the capsule. The capsule separates from the balloon within 10 minutes after being swallowed into the stomach. The proximal end of the Catheter is provided with a length marker and an inner cone joint. The length marker is used to assist in judging the position when the capsule is swallowed, and the inner cone joint is used to connect the infusion set assembly.

Under the pressure of the Infusion Pressure Bag, fill the balloon to an ellipsoid shape (Figure 3) through the Infusion Set Assembly with the sodium chloride injection.

As shown in Figure 3, the main body of the balloon is made of thin film material, coupled with a biodegradable film and an imageable material under X-ray. The self-sealing valve on the balloon is connected with the Catheter. After the infusion, the Catheter is pulled out and separated from the balloon. The balloon is expected to remain in the stomach for 4 to 6 months, but it may vary according to individual differences. When the biodegradable film on the balloon degrades, the saline is discharged from the balloon, then the ruptured balloon is excreted with the feces after the fluid is emptied.

6 [Required Devices]

The following devices are not provided by our company, but they are necessary for balloon implantation and need to be prepared separately in medical institutions:

1. 500mL sodium chloride injection;
2. 500mL infusion pressure bag;
3. 2 mL methylene blue injection
4. 50mL syringe (with needle).

7 [Intended use]

The Intragastric Balloon System is indicated for use to facilitate weight loss in adults with overweight or obesity (30≤BMI ≤40 kg/m2) who have failed to lose weight through diet and exercise. The System is to be used in conjunction with a supervised nutrition and behavior modification program.

Expected benefit : Total weight loss (%TWL) > 7%

8 [Intended users]

1. Adults aged 18–65.
2. Previous unsuccessful weight loss attempts.
3. Ambulatory without severe chronic orthopedic disease.
4. BMI ≥ 30 kg/m² and ≤ 40 kg/m².

9 [Contraindications]

Do not use in patients with:

1. Symptomatic congestive heart failure, arrhythmia, or unstable coronary artery disease.
2. Active respiratory diseases (e.g., COPD, pneumonia, cancer).
3. History of bariatric surgery.
4. Acute/chronic pancreatitis (within 12 months).
5. History or current small bowel obstruction.

6. Abdominal/pelvic surgery history *(except: 1 cesarean section, diagnostic laparoscopy, laparoscopic appendectomy/cholecystectomy performed ≥12 months prior)*.
7. Autoimmune connective tissue disorders (e.g., lupus, scleroderma) or immunosuppression.
8. Esophageal/gastric/duodenal pathology (e.g., hiatal hernia ≥2cm, polyps, ulcers, varices, gastroparesis).
9. Insulin-dependent diabetes.
10. Severe coagulopathy, hepatic insufficiency, or cirrhosis.
11. Recent/long-term use of gastric irritants (e.g., NSAIDs, aspirin).
12. Need for antiplatelet/anticoagulant therapy.
13. Use of drugs affected by delayed gastric emptying (e.g., anticonvulsants, antiarrhythmics).
14. Anemia (Hgb <110 g/L [female]; <120 g/L [male]).
15. Night eating syndrome or bulimia.
16. History/current drug/alcohol abuse.
17. Untreated *H. pylori* infection.
18. Inability to take proton pump inhibitors during implantation.
19. Inflammatory bowel disease (e.g., Crohn's, ulcerative colitis).
20. History of malignancy.
21. Psychiatric illness.
22. Pregnancy, breastfeeding, or planned pregnancy within 6 months.
23. Allergy to silicone/gelatin.
24. History of gastric ulcers (requires thorough evaluation).
25. Contraindications to gastroscopy.
26. Other physician-determined unsuitability.

10 [residual risks]

The Intragastric Balloon System must only be used by qualified physicians for the indicated use. residual risks include:

1. Nausea
2. Epigastric pain
3. Flatulence
4. Celialgia
5. Vomit

6. Reflux gastritis
7. Diarrhea
8. Abdominal bloating
9. Constipation
10. Belching
11. Abdominal discomfort
12. Ileus
13. Indigestion
14. Enteritis
15. Hypogastric pain
16. Gastroenteritis
17. Hiccup
18. Balloon intolerance

Seek immediate medical attention if any of these symptoms occur during balloon use.

11 [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,discard if damaged.
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. Used product may retain patient fluids and must be treated as infectious medical waste. Place in leak-proof biohazard bag for disposal by licensed medical waste contractor.
9. To Prevent Intestinal Obstruction (Bowel Blockage), Strictly Follow These Rules:

   Absolutely Avoid

   ❌ **Hard foods**: Nuts, seeds, popcorn, hard cheese chunks

   ❌ **High-fiber risks**: Raw carrots, celery stalks, whole grain bread with visible grains, undercooked legumes

   ❌ **Sticky/spiky items**: Salami (with connective tissue), fish/meat with bones

Safe Consumption Rules

Cutting standard: All fibrous ingredients (meat/vegetables) must be diced into **≤1cm³ pieces**

Cooking requirement: Vegetables boiled until soft; meat deboned and cartilage removed

Chewing protocol: Chew each bite **≥20 times** until pasty before swallowing

10. If you experience sudden abdominal pain, vomiting, bloating, inability to pass gas, or other discomfort—even after adjusting to the balloon—seek immediate medical attention.

12 [Warnings]

1. Single-use only (except infusion pressure bag). Reuse/resterilization compromises integrity.
2. Follow manufacturer's instructions for infusion pressure bag maintenance.
3. Physicians must be trained in system use.
4. Safety of sequential/parallel device use not studied.
5. Confirm capsule position via X-ray before inflation to avoid esophageal trauma.
6. Do not pull on the catheter when connecting the infusion set component to the female conical fitting of the catheter.
7. Do not pull catheter until filling is complete and confirmed (risk of intestinal obstruction).
8. Withdraw catheter gently; forced removal may cause injury or device damage.
9. Daily oral proton pump inhibitors (PPIs) are required during placement.
10. Monitor for acute pancreatitis/balloon overinflation (reported with similar devices).
11. There are two different types of adverse events associated with liquid-filled intragastric balloons used to treat obesity reported by FDA in 2017, as following:

    - Over-inflating with air or with more liquid (spontaneous hyperinflation)

    - Acute pancreatitis

    We recommend that health care providers:

    - Recognize that patients with implanted liquid-filled intragastric balloons may develop balloon-related symptoms or other abnormalities following balloon placement, and throughout the duration of their treatment. Consider spontaneous over-inflation and/or pancreatitis in the differential diagnosis of patients presenting with the symptoms noted in this communication. If abnormalities are found, perform any confirmatory diagnostic studies. If the device is removed, follow the manufacturer's instructions for device returns or evaluations.

    - Report any adverse events related to intragastric balloon systems to competent authority.;

12. Only one balloon per patient.
13. Balloon may interfere with MRI; Patients must inform the radiology team about the presence of an intragastric balloon. MRI is strongly discouraged during the balloon implantation period. Alternative imaging modalities (e.g., CT or ultrasound) should be prioritized. If MRI is medically necessary, please remove the balloon under gastroscopy before performing MRI examination.
14. Catheter must not be pulled during inflation

13 [Operating Instructions]

1. **Device and Patient Preparation**

1.1 Practice capsule

1) Practice Capsule swallowing shall be performed at least 1 day prior to device procedure.
2) Practice Capsule is ready for the patient to swallow after it is removed from the packaging.
3) Allow the patient to place the Practice Capsule in mouth and swallow with water as needed.

1.2 Preventive medication

The first prophylactic dose is recommended at least 2 hours before balloon insertion.

The type, dose and time of use of the drug are recommended as follows and can be adjusted according to the actual situation:

a) Proton pump inhibitors: omeprazole (20mg, twice a day), used continuously for 16 weeks;

b) Antiemetic drugs: ondansetron (8mg, 3 times a day); aprepitant (125mg/day for the first time, 80mg/day thereafter);

Please follow the doctor's advice on the specific type, dosage and time of use of the drug or adjust it according to the actual situation.

1.3 Balloon assembly

1) Confirm that the subject has been fasted for at least 8 hours and water deprivation for at least 2 hours before surgery.
2) Take the Balloon Assembly out of the package and it is ready for the patient to swallow. The balloon and Catheter are suggested to be lubricated evenly with olive oil (or other edible oil), and lubricate the Catheter to the three bar marking strips.

1.4 Infusion assembly

The operation steps are as follows:

a) Place the sodium chloride injection bag into the Infusion Pressure Bag and hang it on the infusion stand, as shown in Figure 7;

Figure 7 Sodium chloride infusion bag and Infusion Pressure Bag hanging on the infusion stand

b) Remove the sealing port on the sodium chloride injection bag, as shown in Figure 8;

Figure 8 Removal of the bag seal port of sodium chloride injection

c) Extract 50 mL sodium chloride injection from the sodium chloride injection bag with a syringe, and discard;

d) Use a syringe to inject 2 mL of methylene blue injection into the sodium chloride injection bag and shake the injection bag to mix evenly.

e) Lock the Clamp on the Infusion Set Assembly and clamp the pipeline. Insert the Spike into the sodium chloride injection bag, as shown in Figure 9.

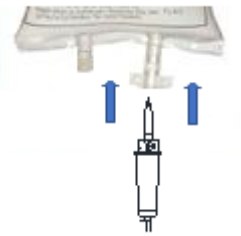


Figure 9 Sodium Chloride Injection Bag and Infusion Set Assembly

2. **Swallowing the capsule**

2.1 Put the capsule into the subject's mouth and swallow it with warm water;

2.2 Determine the position of the swallowed capsule preliminarily according to the length marker on the Catheter;

2.3 **Verify capsule position under X-ray:**

The catheter and balloon contain visualization materials visible under X-ray.

Successful gastric placement is confirmed when:

Balloon markers appear in the stomach

If capsule lodges in esophagus/LES:

Have subject continue drinking water

Monitor until X-ray confirms gastric placement

⚠ **Caution:** To avoid damage to the esophagus, do not inflate the balloon until the entire capsule has reached the stomach as indicated by X-ray.

⚠ **Caution:** Secure the Catheter after X-ray confirms balloon is in stomach.

3. **Filling the Balloon**

3.1 After the capsule reaches the stomach for 10 minutes, connect the Outer Cone Joint of the Infusion Set Assembly to the Inner Cone Joint of the Catheter;

Note: Do not fill the balloon in advance, otherwise the capsule has not been separated from the balloon, which will lead to filling failure;

Note: If the capsule has been in the stomach for more than 30 minutes, do not inflate the balloon. Pull up the Catheter to remove the balloon and recycle it; if the balloon is not observed to be withdrawn with the Catheter, use an X-ray machine to confirm that the balloon is in the body and wait for the balloon to be discharged naturally.

3.2 Turn off the switch of the Infusion Pressure Bag;

3.3 Squeeze the Inflation Bulb on the Infusion Pressure Bag until the pressure on the regulator arrives 300mmHg;

3.4 Turn on the Clamp on the Infusion Set;

3.5 Maintain a pressure of 300 mmHg until a continuous liquid flow can be seen from the Flow Indicator of the Infusion Set;

NOTE: If you see only liquid droplets in the Flow Indicator, the capsule is not fully opened and you need to pause the infusion for a few minutes and try again.

3.6 When continuous liquid flow is seen in the Flow Indicator, it means that the capsule has been fully opened and the pressure should be maintained at 300 mmHg;

⚠ **Caution:** An incompletely filled balloon has the risk of sliding completely or partially into the gastrointestinal tract and causing intestinal obstruction or pyloric obstruction, so it is necessary to control the position of the balloon in the stomach by fixing the Catheter.

3.7 If the infusion shall be stopped or the balloon shall be emptied at any stage of infusion, turn on the switch of the Infusion Pressure Bag to exhaust the air in the infusion pressure bag. Turn off the Clamp on the Infusion Set Assembly, separate the Catheter and the Infusion Set Assembly. Connect the catheter to the syringe. Aspirate the syringe to empty the balloon. If the liquid in the balloon cannot be completely drained, the balloon needs to be punctured or torn under endoscopy to drain the liquid, and the balloon passes out of the body through the gastrointestinal tract. (See 6.1 Handling of unexpected situations for details);

3.8 Close the Clamp when the sodium chloride is about to finish infusion while some remaining in the Catheter. Then confirm the position and the inflation state of the balloon with the X-ray machine. Do not separate the Catheter from the Balloon or the Infusion Set Assembly until the balloon is fully filled.

4. **Withdrawing the Catheter**

After the balloon is confirmed to be correctly filled and located in the target position with the X-ray machine:

4.1 Open the vent valve of the Infusion Pressure Bag to completely relieve its pressure;

4.2 Separate the Catheter from the Infusion Set Assembly;

4.3 Gently but quickly withdraw the Catheter from the patient's mouth, the distal end of the Catheter will separate from the self-sealing valve of the balloon;

⚠ **Caution:** Do not remove the Catheter until complete balloon inflation has been confirmed, or intestinal obstruction may occur.

⚠ **Caution:** Do not withdraw the Catheter with great force, moving the Catheter against resistance may cause adverse events or device damage.

4.4 After the Catheter is removed from the subject, visually inspect whether the Catheter is damaged.

Caution: After the balloon is implanted, if adverse events occur, please follow the following guidance:

1) Symptoms like nausea, acid reflux, vomiting, stomach pain, stomach bloating, belching, hiccups, indigestion, palpitations, chest pain, insomnia, etc. can usually be relieved after rest;
2) Symptoms like abdominal distention, diarrhea, constipation, abdominal pain, etc. can usually be relieved by taking medicine;
3) Intestinal obstruction, gastric pyloric obstruction, etc. should be treated according to the doctor's advice;
4) If intolerance occurs after the balloon is inserted, you can seek outpatient treatment and remove the balloon through endoscopy;
5) Stomach ulcer, abdominal cramps, infection and dehydration, etc. need to be hospitalized for observation.

5. **Balloon discharge**

5.1 Normally, the balloon ruptures about 4 to 6 months after implantation, which varies according to individual differences. Patients can tell the balloon has ruptured by green or blue urine.

5.2 The ruptured balloon should be excreted with feces within 2 weeks;

Caution: If empty discharged balloon cannot be observed, the subject need to go to the medical institution for inspection and treatment according to the following 6.

6. **Handling of unexpected conditions**

6.1 If the patient does not have green or blue urine or observe the balloon being excreted within 24 weeks, X-Ray imaging examination will be performed at the 24week follow-up. If X-Ray imaging shows that the balloon is still expanding in the stomach, the balloon shall be pierced or tear under the endoscope to aspirate the fluid and excreted through the gastrointestinal tract. The following steps are recommended while the specific steps are determined by the doctor accordingly:

1) Prepare the subject for endoscopy according to the SOP of the hospital;
2) Insert the endoscope into the subject’s stomach;
3) Find out the clear image of the balloon utilizing the endoscope;
4) Insert a pair of mouse tooth forceps or biopsy forceps into the working channel of the

endoscope;

5) Pierce or tear the balloon using the mouse tooth forceps or biopsy forceps to aspirate the fluid;
6) Withdraw the mouse tooth forceps or biopsy forceps from the working channel of the endoscope;
7) Aspire the fluid in the stomach and withdraw the endoscope;
8) Instruct the patient to observe the torn balloon in feces. If the balloon cannot be observed in feces within two weeks, imaging examination can be performed again. If the empty balloon still stays in the stomach, remove the balloon through the mouth according to the following steps. The specific removal steps are determined accordingly:
    a) Prepare the subject for endoscopy and endotracheal intubation according to the SOP of the hospital;
    b) Endotracheal intubation after completion of intravenous anesthesia;
    c) Insert the endoscope into the subject's stomach;
    d) Find out the clear image of the balloon utilizing the endoscope;
    e) Provide antispasmodic treatment for the esophageal muscle according to the SOP of the doctor;
    f) Use large mouse tooth forceps/alligator forceps, loop or the combination of the two to clamp the balloon, and gently pull the balloon out of the esophagus;
    g) Remove the balloon from the subject's mouth.

6.2 If the imaging shows that the balloon is in the stomach and has collapsed or emptied, the subjects shall be informed to observe their feces. If the balloon cannot be observed in feces within two weeks, imaging examination can be performed again. If it is confirmed that the balloon still stays in the stomach, the treatment shall be in accordance with 6.1.

6.3 If the imaging shows that the balloon is in the intestinal tract, the subjects shall be informed to observe their feces and pay attention to the removal of the balloon. If the balloon is not expelled within two weeks and intestinal obstruction occurs, it must be removed endoscopically.

6.4 If the subject has severe intolerance, the balloon shall be pierced or teared under the endoscope to aspirate the fluid and let it remove through the gastrointestinal tract. The specific steps are the same as 6.1.

14 [Storage and transports]

1. Storage: 15–25°C, 40–60% RH; cool, dry, dark.

2. Avoid prolonged heat exposure.

3. Transport: Protect from crushing, sunlight, rain/snow.

15 [Implantable Component Materials]

The intragastric balloon will remain in the stomach for four to six months. During use, the following materials will come into contact with the gastric mucosa: these materials are commonly used in implantable medical devices, are well-established and safe, and their levels are strictly maintained within safe threshold limits.

	Material	**Quantity**
Balloon	Silicone(PDMS)	3g
	PLLA-TMC	0.6g
	Parylene C	0.024g

16 [Notice]

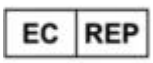
Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

17 [Term of Validity]

1. Non-sterile product.
2. Use before expiration date (labeled on product).
3. Do not use expired products.
4. Production date: See product label.
5. The URL address of SSCP in EUDAMED is: https://XXX.XXXX.XXXX**[Symbols]**

18 [Symbols]

	"Do not re-use" Indicates a medical device that is intended for one single use only		"Caution" Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences

	"Consult instructions for use or consult electronic instructions for use" Indicates the need for the user to consult the instructions for use		"Keep dry" Indicates a medical device that needs to be protected from moisture
	"Keep away from sunlight" Indicates a medical device that needs protection from light sources		"Use by date" Indicates the date after which the medical device is not to be used
	"Temperature limit" Indicates the temperature limits to which the medical device can be safely exposed is 15℃~25℃		"Do not use if package is damaged and consult instructions for use" Indicates that a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information
	"Batch code" Indicates the manufacturer's batch code so that the batch or lot can be identified		"Model number" Indicates the model number or type number of a product
	"Date of manufacture" Indicates the date when the medical device was manufactured		"Non sterile" Indicates a medical device that has not been subjected to a sterilization process
	"Manufacturer" Indicates the medical device manufacturer		"MR unsafe" Indicates the medical device may pose risks in magnetic resonance environments
	"Contains biological material of animal origin" Indicates a medical device that contains biological tissue, cells, or their derivatives, of animal origin		"Medical device" Indicates the item is a medical device
	"Authorized representative in the European Community/European Union" Indicates authorized representative in the European Community/European Union		"Unique device identifier" Indicates a carrier that contains unique device identifier information

19 [Instruction for completion of Implant Card]

The implantable card is a collapsible form, and the size after folding shall be 85.6mm×54mm.

FRONT:

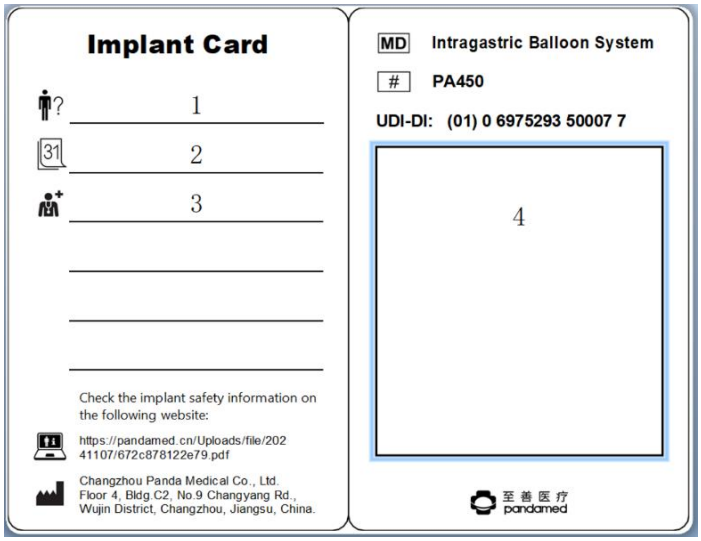
1. Name of the patient or patient ID. To be filled by the healthcare institution/provider.

2. Date of implantation. To be filled by the healthcare institution/provider.

3. Name and address of the healthcare institution/provider. To be filled by the healthcare institution/provider.

4. UDI,Lot,device type,date of manufacture and use by date.

Noted:Fields 4 will be filled with stickers.Detached the stickers and placed on the right place at the IC according to the numbers)



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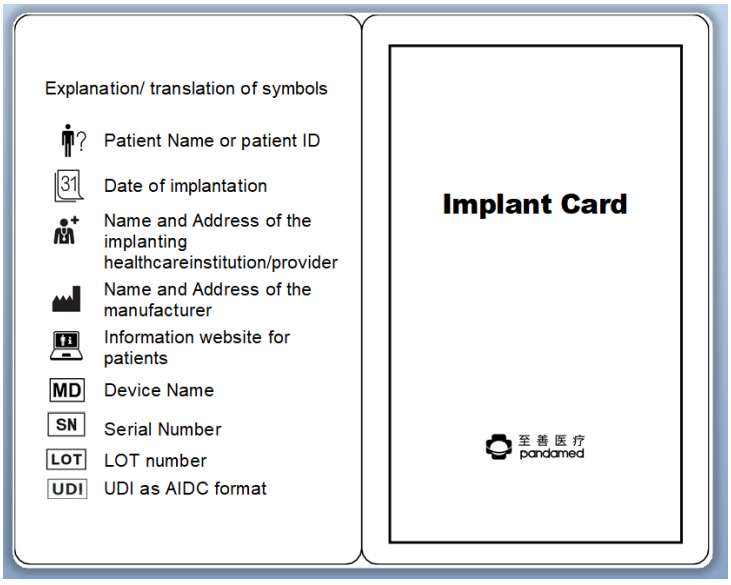
Back:



BACK(Explanation/ translation of symbols:**):**

	Patient Name or patient ID, Име на пациента, Imeno pacienta, Patientens navn, Patientenname, Имя пациента, Nombre del paciente, Patsiendi nimi, Potilaan nimi, Nom du patient, Ime i prezime bolesnika, Ime i prezvisko pacjenta, A beteg neve, Nome do paciente, Paciento vardas ir pavardė, Pacienta vārds, uzvārds, Naam patiënt, Pasientens navn, A beteg neve, Nome do doente, Nume pacient, Meno pacienta, Ime bolnika, Patientens namn
	Date of Implantation, Дата имплантационного вмешательства, Datum implantace, Implanteringsdato, Implantationsdatum, Ημερομηνία εμφύτευσης, Fecha de implantación, Implanteerimiskuupäev, Implantointipäivämäärä, Date d'implantation, Datum implantatie, Beültetés dátuma, Data dell'impianto, Implantavimo data, Implantēšanas datums, Implantačný dátum, Data wszczepienia, Data do implante, Data implantării, Datum implantácie, Datum vsaditve
	Date of Implantation, Дата имплантационного вмешательства, Datum implantace, Implanteringsdato, Implantationsdatum, Ημερομηνία εμφύτευσης, Fecha de implantación, Implanteerimiskuupäev, Implantointipäivämäärä, Date d'implantation, Datum implantatie, Beültetés dátuma, Data dell'impianto, Implantavimo data, Implantēšanas datums, Implantačný dátum, Data wszczepienia, Data do implante, Data implantării, Datum implantácie, Datum vsaditve
	Device Name, Nazwa urządzenia medycznego, Název zdravotnických prostředků, Medicinsk enhed, Name des Medizinprodukts, Nombre del dispositivo médico, Nom du dispositif médical, Orvosi eszköz neve, Namn på medicinsk enhet, Ime medicinske naprave, Nome do dispositivo médico, κατασκευαστής
	Manufacturer κλπ, Producer, Fabrikant, Produttore, Fabricante, Fabricant,, Hersteller
	Information website for patients, Webová stránka s informacemi pro pacienty, Informatiewebsite para patienten, Webseite mit Informationen für Patienten, Sitio web con información para el paciente, Site d'informations pour le patient, Információs honlap betegek számára, Sito web con le informazioni per i pazienti, Website met informatie voor patiënten, Strona internetowa z informacjami dla pacjenta
	SN Translation of serial number in required languages.
	LOT Translation of LOT number in required languages.
	UDI Explanation of unique device identifier (UDI) in required languages.

Here attached the Implant card:

Place to attach the Implant card

20 [Manufacturer & EU Representative]

Changzhou Panda Medical Co., Ltd.
Floor 4, Bldg.C2, No.9 Changyang Rd., Wujin District, Changzhou, Jiangsu, 213145, China.
+86 519 85285618
www.pandamed.cn
service@pandamed.cn

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