



# User's manual

## end-ball

Intra-gastric balloon system

Medical Device



### **ENDT110**

**BEFORE USING THE PRODUCT**  
**PLEASE READ THE INFORMATION IN THESE INSTRUCTIONS FOR USE CAREFULLY**

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Unique registration number (SRN): FR-MF-000009349 (manufacturer) and FR-PR-000009350 (assembler)



## 1. PREPARATION

Perform a control endoscopy

### Important

*Note the distance between the mouth and the cardia from the markings on the endoscope*

Balloon et accessories :



Procedure :



- Have the appropriate equipment available for removing the balloon in case of complication during installation (ENDAC03 extractor kit, Alligator clamp)
- Check the integrity of the medical device before starting the procedure
- Remove the protective tube around the balloon
- Moisten the tip of the endoscope
- Coat the balloon with surgical gel

## 2. INSERTION UNDER ENDOSCOPIC CONTROL

- The patient must be positioned in the left lateral position, the head in the axis of the spine, maintained by a pillow
- Use the finger as a guide. Only hold the system by the external sheath. Do not touch the non-return valve to avoid disconnecting the filling needle.





- Passage through esophagus with the balloon continuously under endoscopic view
- Position the balloon in the stomach, the mesial part of the introducer at least 5 cm from the cardia.



- The introducer must have sufficient space to allow the deployment of the balloon without compressing the gastric wall.
- The introducer must be visible in its entirety before beginning the inflation.
- If the introducer is not visible in its entirety, reposition the introducer correctly

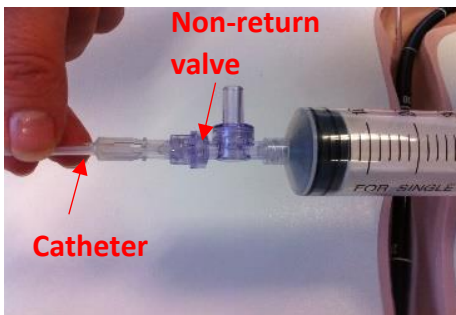
### 3. FILLING UNDER ENDOSCOPIC CONTROL



Connect the syringe to the non-return valve

Inflating with air:

- Inject at least two syringes of air for deploying the balloon



- Be careful not to pull on the non-return valve/catheter to prevent any premature disconnection of the filling needle.



Inflating with liquid:

- Use the filling kit ENDAC01 (Connection between the pouch of saline solution and the non-return valve) and inject the liquid (isotonic saline solution with methylene blue)



Total volume recommended

- 3 syringes of air + 500 ml of liquid

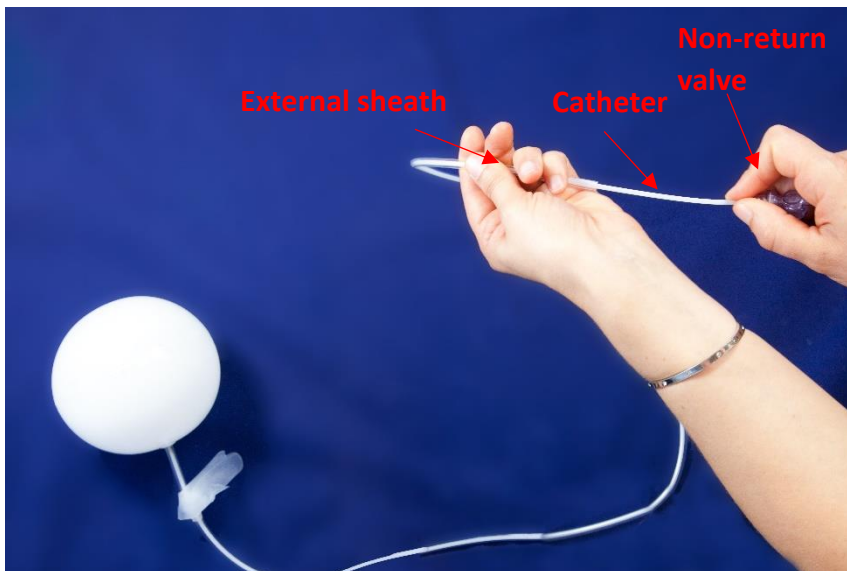
*Minimum total volume: 400 ml*

*Maximum total volume: 700 ml*

## 4. RELEASING UNDER ENDOSCOPIC CONTROL



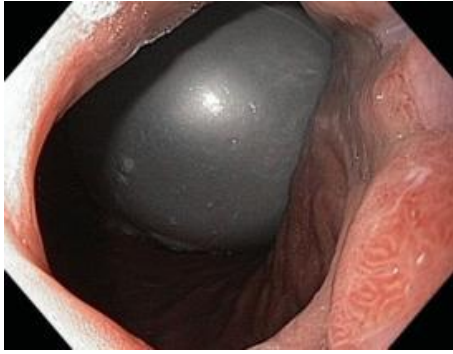
The balloon is now inflated



- Hold the external sheath and the catheter separately
- The balloon is blocked against the external sheath
- There is no need to position the balloon against the cardia for the releasing
- Pull until the balloon disconnects



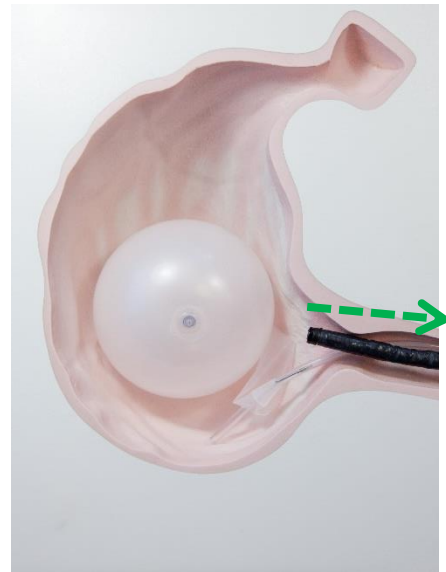
- The balloon is now released



Under endoscopic control, check the position, integrity and mobility of the balloon in the stomach.

**After releasing the balloon, under endoscopic control, check that the balloon is properly inflated (tight bag, smooth appearance, etc.), the correct positioning and freedom of movement of the balloon in the stomach and the integrity of the balloon. This ensures that the introducer needle has not remained in the balloon valve and there is no leakage from the balloon.**

- **Gently remove the system:**
  - First, remove the endoscope
  - Second, remove the catheter: check its integrity (in particular, the presence of the inflation needle)





## 5. EXTRACTION

### Universal Bi conical connector



### Accessories :

#### Extraction hooks



#### Hollow drainage needle



### Procedure :

- Bring down the endoscope in the stomach and visualize the balloon

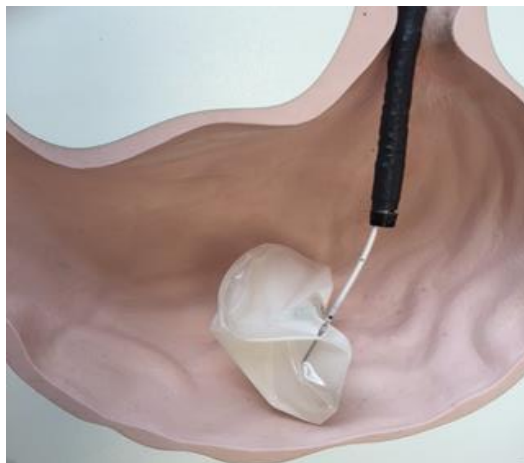


- Position the catheter needle, perpendicularly at the contact of the balloon.



- Drill the balloon by pressing a sharp blow on the handle of the needle

- Connect the catheter needle with the aspiration using the biconical connector



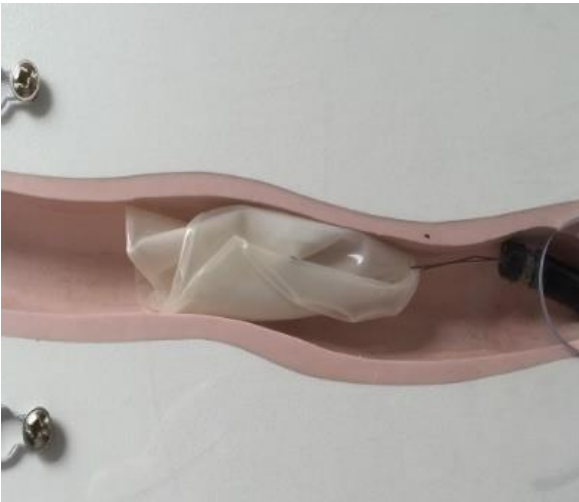
- Wait until the balloon is completely deflated
- Then remove the needle / catheter



- Bring down the forceps extraction in the working channel
- Secure the balloon with the hooks
- Keep the balloon against the end of the endoscope



- Bring slowly up the balloon through the cardia and along the esophagus.



- The emptier the balloon is, the easier is the manoeuver

### 6. ENDOSCOPIC CONTROL

- Perform endoscopic control to check if there are no affected areas after the passage of the balloon

