

ORBERA® Placement Procedure

Step-by-Step Reference Guide



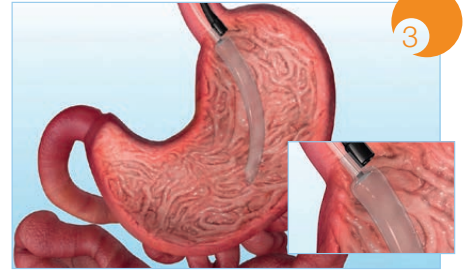
Balloon Placement



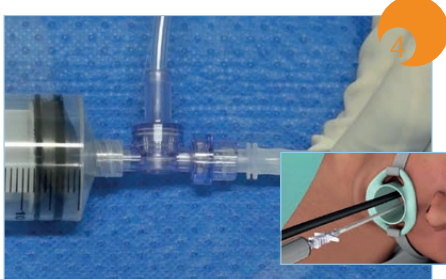
1 Perform diagnostic endoscopy and check for contraindications



2 Lubricate the ORBERA® System placement sheath and insert the ORBERA® Placement Catheter Assembly



3 Confirm balloon is below the lower oesophageal sphincter and well within the stomach cavity, then remove guide wire



4 Attach 3-way stopcock and 50 cc syringe to the Luer-Lock and insert filling kit spike into a bag of saline



5 Fill balloon with saline 50 cc at a time up to a fill volume of 400 to 700 cc



6 Disconnect Placement Catheter and gently pull the tubing out



Equipment Needed for Placement

- Endoscope
- ORBERA® System placement/fill catheter with guide wire
- ORBERA® System connecting tube with 3-way valve and saline bag spike
- Bag of saline
- 50 cc Syringe



CAUTION: During the filling process the fill tube must remain slack. If the fill tube is under tension during the intubation process, the fill tube may dislodge from the balloon, preventing further balloon deployment.

WARNINGS: Rapid fill rates will generate high pressure which can damage the OIB System valve or cause premature detachment. Proper positioning of the Placement Catheter Assembly and the ORBERA® balloon within the stomach is necessary to allow proper inflation. Lodging of the balloon in the oesophageal opening during inflation may cause injury and/or device rupture.

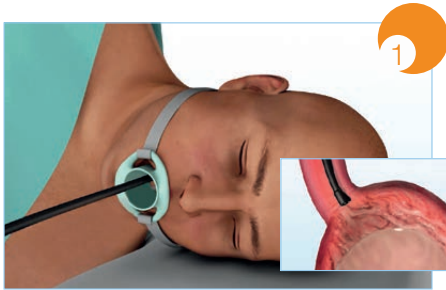
Orbera® Intragastric Balloon System Directions For Use (DFU).

ORBERA® Removal Procedure

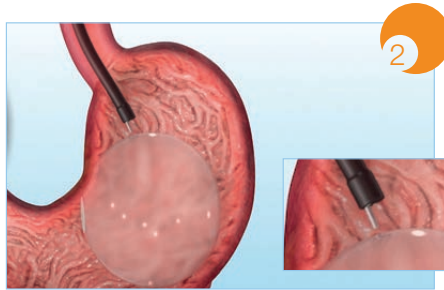
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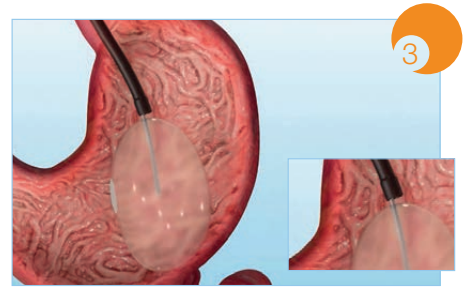
Balloon Removal



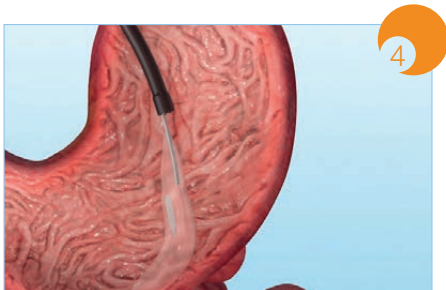
1 Prepare for removal and perform an endoscopy



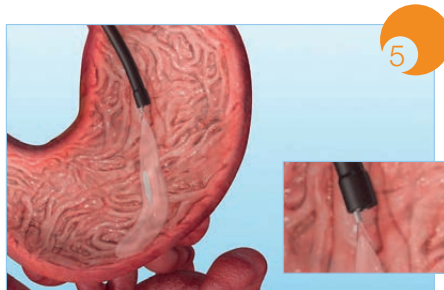
2 Insert an aspiration needle down the working channel and puncture the balloon



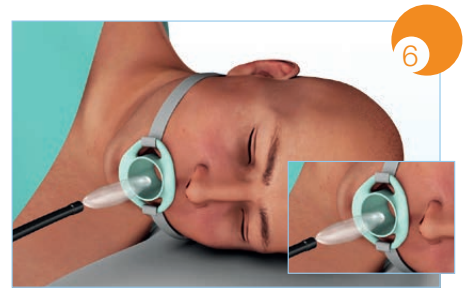
3 Insert needle 4-5 cm into the balloon and deflate the balloon using suction



4 After complete deflation, remove the aspiration needle tubing



5 Grab the balloon with the two-pronged wire grasper and pull to scope tip



6 Hold catheter firmly while extracting the balloon up the oesophagus



Equipment Needed for Removal

- Endoscope
- Needle aspirator
- Two-pronged wire grasper
- McGill's forceps (if necessary)



WARNING: Endoscopic removal of ORBERA® must be completed in the presence of an empty stomach. Patients should be NPO for a minimum of 12 hours prior to removal. If food is found in the stomach upon endoscopic examination, then measures (aspiration of stomach contents, endotracheal intubation, or delay of procedure) must be taken to protect the airway. The risk of aspiration of gastric contents into the patient's lungs represents a serious risk which can result in death.