ReShape® Integrated Dual Balloon System
Procedure Manual
**TABLE OF CONTENTS**

Introduction ......................................................................................................................................................... 3

**Product Description** ............................................................................................................................................. 3

Overview.................................................................................................................................................................. 3

Component description ............................................................................................................................................... 4

Intragastric Balloon .................................................................................................................................................. 4

Placement Catheter................................................................................................................................................... 4

Removal Catheter..................................................................................................................................................... 5

**Procedure Supplies** ............................................................................................................................................. 6

Balloon Placement Procedure .................................................................................................................................. 6

Balloon Removal Procedure .................................................................................................................................... 6

ReShape Dual Balloon Placement Procedure ....................................................................................................... 7

Step 1. Device preparation ......................................................................................................................................... 7

Step 2. Patient sedation .............................................................................................................................................. 8

Step 3. Diagnostic endoscopy and guidewire positioning .......................................................................................... 8

Step 4. ReShape Dual Balloon insertion .................................................................................................................. 9

Step 5. Balloon inflation ............................................................................................................................................. 9

Step 6. Disengaging the Balloon from the catheter ................................................................................................. 10

ReShape Dual Balloon Removal ............................................................................................................................. 12

Step 1. Procedure preparation .............................................................................................................................. 12

Step 2. Patient sedation .......................................................................................................................................... 12

Step 3. Balloon drainage .......................................................................................................................................... 13

Step 4. Capture and removal of the balloon .......................................................................................................... 14

References ............................................................................................................................................................... 15
Introduction

This procedure manual is designed to give the reader essential background information on the ReShape® Integrated Dual Balloon System. The information in this manual provides a technical description of the devices and also serves as a guide on preparation, placement and removal procedures.

Note: this manual does not replace the instructions for use (IFU), and as such should be used in combination with the IFUs supplied with the products.

Product Description

Overview
The ReShape Integrated Dual Balloon is a temporary implant designed to facilitate weight loss by occupying space in the stomach and producing a sensation of satiety. The device is constructed from medical grade silicone rubber. The balloon is introduced orally via a placement catheter under endoscopic guidance and direct visualization.

The balloon is designed to be placed in the stomach during an outpatient procedure using conscious sedation (MAC). It remains in the stomach for up to six months and is then removed.

Fig.1 - ReShape Integrated Dual Balloon
Component description
The ReShape Integrated Dual Balloon System contains (a) Intragastric Balloon / Placement Catheter Assembly, and the following accessories: (b) two Prefilled Valve Sealant Syringes, (c) Guidewire and (d) Patient ID Card.

The ReShape Integrated Dual Balloon System is not made with natural rubber latex.
The ReShape Removal Catheter is packaged separately.
# Procedure Supplies

## Balloon Placement Procedure

<table>
<thead>
<tr>
<th>Equipment/Supplies</th>
<th>Quantity per procedure</th>
<th>Brand</th>
<th>Part Number</th>
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<tr>
<td><strong>Single-use items</strong></td>
<td></td>
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<td></td>
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<tr>
<td><em>ReShape</em> Dual Balloon</td>
<td>1</td>
<td><em>ReShape Medical</em></td>
<td>RSM110</td>
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<td>Guidewire</td>
<td>1</td>
<td><em>ReShape Medical</em></td>
<td>Included with balloon</td>
</tr>
<tr>
<td><em>ReShape</em> Infiltration Pump single-spine tubing</td>
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<td><em>ReShape Medical</em></td>
<td>ITS-10-RS</td>
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<td>Clinic supply</td>
<td>Clinic supply</td>
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<td>500cc flexible saline bags (0.9% NaCl solution)</td>
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<td>Clinic supply</td>
<td>Clinic supply</td>
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<tr>
<td>Prefilled Valve Sealant syringes (USP grade)</td>
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<td><em>ReShape Medical</em></td>
<td>Included with balloon</td>
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<td>Clinic supply</td>
<td>Clinic supply</td>
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<td>Sterile graduated containers (size = min. 100 cc)</td>
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<td>Clinic supply</td>
<td>Clinic supply</td>
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<td>Olympus (or equivalent)</td>
<td>MAJ-168 (or equivalent)</td>
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<tr>
<td><strong>Reusable items</strong></td>
<td></td>
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<td><em>ReShape Medical</em></td>
<td>KIP-II-RS</td>
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<td>Diagnostic gastroscope single-channel, 2.8mm channel 8.6-11.3mm insertion tube 1400mm total length</td>
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<td>Olympus (or equivalent)</td>
<td>GIF-Q160 GIF-Q180 (or equivalent)</td>
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## Balloon Removal Procedure

<table>
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<th>Equipment/Supplies</th>
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<th>Brand</th>
<th>Part Number</th>
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<td><strong>Single-use items</strong></td>
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<td><em>ReShape</em> Removal Catheter</td>
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<td><em>ReShape Medical</em></td>
<td>RSM210</td>
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<td>Large hexagonal endoscopic snare Minimum opening size: 20mm</td>
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<td><em>Cook Medical</em> (or equivalent)</td>
<td>ASH-1-S (or equivalent)</td>
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<td>Olympus (or equivalent)</td>
<td>MAJ-168 (or equivalent)</td>
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<tr>
<td>Suction pump tubing Standard ¼ inch diameter</td>
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<td>Clinic Supply</td>
<td>Clinic supply</td>
</tr>
<tr>
<td><strong>Reusable items</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Suction pump (Removal Catheter independent from endoscope suction)</td>
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<td>Clinic Supply</td>
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<td>Olympus (or equivalent)</td>
<td>FG-49L-1 (or equivalent)</td>
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<tr>
<td>Laryngoscope and Magill forceps</td>
<td>1</td>
<td>Clinic supply</td>
<td>Clinic supply</td>
</tr>
<tr>
<td>Diagnostic gastroscope single-channel, 2.8mm channel 8.6-11.3mm insertion tube 1400mm total length</td>
<td>1</td>
<td>Olympus (or equivalent)</td>
<td>GIF-Q160 GIF-Q180 (or equivalent)</td>
</tr>
</tbody>
</table>
**ReShape Dual Balloon Placement Procedure**

While the patient is under conscious sedation (MAC), an endoscope is inserted through the mouth into the stomach and a guidewire is placed. The un-inflated balloons are advanced over the guidewire and placed in the stomach. Each balloon is inflated independently with a saline-methylene blue solution using an automated pump. The device is then released and remains in the stomach for up to six months. The balloons do not change the stomach’s anatomy; they simply occupy space to reduce the capacity for food. In the event of a complication requiring the removal of an inflated ReShape Dual Balloon, a ReShape Removal Catheter should be available at each placement procedure.

**Recommended patient diet instructions to minimize the amount of food and liquid in the stomach during the procedure:**
- **48 hours prior to procedure:** Soft foods only, no meat in any form.
- **24 hours prior to procedure:** Clear liquids only.
- **12 hours prior to procedure:** NPO - No food or liquids by mouth.

**Step 1. Device preparation**

**Materials:**
- ReShape Integrated Dual Balloon
- ReShape Guidewire
- Lubricant
- Adult-sized endoscopic bite block
- ReShape Infiltration Pump and ReShape Pump Tubing
- Two (2) prefilled valve sealant syringes
- Two (2) 500cc saline bags
- 4cc of methylene blue (10mg/mL concentration)
- Syringe and needle to transfer the methylene blue into the saline bags

1. The balloon is supplied preloaded on the placement catheter. Remove the catheter from the package and inspect for any visible damage. Do not use device if damage is noted.

2. Prepare two 500cc bags of saline solution.
   a. Inject and mix 2cc of methylene blue (10mg/mL) into each 500cc bag of saline
   b. Attach the infiltration pump tubing to the saline bag
   c. Determine the final inflation volume for each balloon. Hold the saline bag upside down and use the pump to remove any air and excess fluid from the 500cc saline bag in order to prevent over/under-inflation of the ReShape Dual Balloon. For example, if the intended balloon size is 450cc, remove all air and 50cc of solution from the saline bag such that only 450cc of fluid remains. Repeat this step for the saline bag intended for the second balloon.
      i. When emptying the saline bags into the graduated cylinder, place the pump speed between 4 – 7 to avoid splashing

**Note:** Maintain cleanliness of the saline and tubing. Do not allow the pump tubing to contact the floor. Do not handle the tubing with dirty gloves.
3. Refer to the ReShape Infiltration Pump Instructions for Use for setup and operating information for the ReShape Pump and its accessories.
   a. Set the infiltration pump flow on the back of the pump to “Momentary Flow”
   b. Increase the infiltration speed to 10 for filling the balloons
   c. Alternate manual inflation method: The manual inflation method requires (1) 20mL Luer-lock syringe, (1) 122cm IV tubing with spike, (1) 3-way valve, and (1) pressure tubing set. Assemble the inflation instruments and connect them to the saline/methylene blue solution. Verify that the instruments are connected such that the solution is pumped from the saline bag to the distal end of the pressure tubing intended for connection to the balloon catheter.

Step 2. Patient sedation
Prepare and position the patient as customary for a diagnostic endoscopy (i.e. left lateral decubitus). Administer an oral anesthetic spray as necessary. Administer conscious sedation per the institution’s protocol for monitored anesthesia care (MAC).

Step 3. Diagnostic endoscopy and guidewire positioning
1. The placement procedure requires a single-channel gastroscope with a diameter of 8.6 – 11.3mm, instrument channel diameter of 2.8mm, and a maximum working length of 140cm.

2. Position the bite block in the patient’s mouth. Ensure that the bite block is large enough for both the ReShape Dual Balloon and the endoscope to pass through in parallel.

3. Perform an esophagogastrroduodenoscopy (EGD) to identify any significant gastrointestinal pathology that would contraindicate implantation per protocol. If excessive food or liquid is present in the stomach, the procedure should be postponed.

4. Advance the guidewire through the endoscope’s instrument channel port. Place the distal portion of the guidewire into the duodenum and position the guidewire along the greater curvature of the stomach.

5. Remove the endoscope from the patient while leaving the guidewire in place. **While removing the endoscope, take note of the distance from the patient’s mouth to the gastro-esophageal junction.** This measurement will be used when introducing the Dual Balloon.
**Step 4. ReShape Dual Balloon insertion**

1. Prior to insertion, apply an ample amount of lubricant to the entire surface of the balloon.

2. Apply lubricant to the proximal segment of the guidewire and pass the guidewire through the ReShape Dual Balloon’s guidewire lumen. The main operating physician should maintain control of the guidewire and provide countertraction when necessary. Insert the placement catheter into the patient’s mouth, down the esophagus, and into the stomach. The depth markers on the placement catheter may be used as a reference for the distance between the patient’s mouth to the proximal end of the implant.
   
   a. In the event of reduction in oxygen saturation levels, anesthesia should increase the oxygen flow rate to the patient, attempt to suction the back of the throat, and hold a jaw thrust to help regain normal oxygen saturation levels.

3. Reinsert the endoscope into the stomach alongside the placement catheter. Verify that the ReShape Dual Balloon is properly positioned as described below:
   
   a. The delivery catheter detent cap of the placement catheter is distal to the GE junction.
   b. The balloon is lying along the greater curvature of the stomach.
   c. Confirm the distal balloon is at or before the angle of incisura, not extending past the pylorus.
   d. Reposition the ReShape Dual Balloon as necessary.

4. After verifying the balloon’s placement, position the endoscope superior to the proximal balloon and withdraw the guidewire from the ReShape Dual Balloon.

**Step 5. Balloon inflation**

1. Remove the Luer-caps from each fill tube and inflate the balloons sequentially.

   ![Note: Maintain cleanliness of the saline and tubing. Do not allow the pump tubing to contact the floor. Do not handle the tubing with dirty gloves.](image)

2. The proximal balloon is to be inflated first. Connect the infiltration pump tubing to the proximal balloon fill tube (catheter lanyard 1) and inflate to the desired volume. Monitor inflation under endoscopic visualization.
   
   a. Confirm that the saline/methylene blue solution bag contains only the intended inflation volume for the balloon and any air and excess fluid has been removed.
   b. Inflate the proximal balloon. Monitor its inflation through the endoscope.
i. Monitor the balloon during filling and verify that the fill tube does not disconnect.
ii. Observe and make sure the orientation and location of the balloon does not change during inflation.
iii. Upon completion of balloon inflation, endoscopically inspect the balloon and confirm:
   1. The intended inflation volume was completely transferred from the saline bag to the balloon.
   2. No leakage of fluid from balloon.
c. Once inflation is complete, attach the first valve sealant syringe to the proximal balloon fill tube (catheter lanyard 1) and inject 6cc of sealant into the proximal balloon
   i. Leave the valve sealant syringe attached to the fill tube to serve as a confirmation that this step has been completed.

3. Then, reposition the endoscope so the distal balloon can be viewed. Connect the infiltration pump tubing to the distal balloon fill tube (catheter lanyard 2) and inflate to the desired volume. Monitor inflation under endoscopic visualization.
   a. Confirm the saline/methylene blue solution bag contains only the intended inflation volume for the balloon and any air and excess fluid has been removed.
   b. Inflate the distal balloon. Monitor its inflation through the endoscope.
      i. Monitor the balloon during filling and verify that the fill tube does not disconnect.
      ii. Upon completion of balloon inflation, endoscopically inspect the balloon and confirm:
          1. The intended inflation volume was completely transferred from the saline bag to the balloon.
          2. No leakage of fluid from balloon.
   c. Once inflation is complete, attach the second valve sealant syringe to the distal balloon fill tube (catheter lanyard 2) and inject 6cc of sealant into the distal balloon.
      i. Leave the valve sealant syringe attached to the fill tube to serve as a confirmation that this step has been completed.

4. **DO NOT DISCONNECT THE PLACEMENT CATHETER FROM THE BALLOON UNTIL VALVE SEALANT HAS BEEN INJECTED INTO EACH BALLOON.**

**Step 6. Disengaging the Balloon from the catheter**

1. Position the endoscope proximal to the detent cap on the placement catheter. **It is important to keep the endoscope proximal to the detent cap during removal of the placement catheter.** If the endoscope is alongside the detent of the balloon catheter, the combined diameter of the detent cap and the endoscope may be too large to be pulled into the esophagus.
2. Hold both the Dual Balloon Catheter and the endoscope together and pull back in tandem. Take care to keep the endoscope proximal to the detent cap. Pull the inflated balloons against the GE junction; continue to pull the catheter and the endoscope with a slow and smooth constant force to release the inflated balloons from the placement catheter.
3. Once released from the Dual Balloon Catheter, continue to withdraw the placement catheter and endoscope from the patient.

4. Reinsert the endoscope to inspect the upper GI tract and the ReShape Dual Balloon.

5. Provide the patient with a Patient ID Wallet Card and instruct the patient on potential post-procedure discomfort and symptoms.
**ReShape Dual Balloon Removal**

Attention: Appropriate precautions must be taken to ensure that the patient returns for balloon removal six months after insertion.

The device is removed via endoscopy under conscious sedation (MAC). Each balloon is completely drained in a controlled manner. A snare captures the deflated dual balloon around the proximal cap and the device is removed through the mouth.

**Recommended patient diet instructions to minimize the amount of food and liquid in the stomach during the procedure:**
- **48 hours prior to procedure:** Soft foods only, no meat in any form.
- **24 hours prior to procedure:** Clear liquids only.
- **12 hours prior to procedure:** NPO - No food or liquids by mouth.

⚠️ **Note:** If the patient does not follow these instructions, consider cancelling the removal procedure as food in the stomach during removal could increase the risk of aspiration.

**Step 1. Procedure preparation**

**Equipment and Materials:**
- *ReShape* Removal Catheter
- Adult-sized endoscopic bite block
- Two (2) suction pumps or equivalent with ¼ inch tubing; one dedicated to the Removal Catheter.
- Lubricant
- Endoscopic snare
- Endoscopic rat-tooth grasping forceps
- Laryngoscope and Magill forceps

1. **Remove the *ReShape* Removal Catheter from its packaging.** Inspect the Removal Catheter for any damage.
2. **Prepare two (2) suction canisters or equivalent with empty 1-liter canisters.**
3. **Have a laryngoscope and Magill forceps on hand.** In case of difficulty while removing the drained balloons through the upper esophageal sphincter, a laryngoscope and Magill forceps may be used to retrieve the *ReShape* Dual Balloon device.

**Step 2. Patient sedation**

Prepare and position the patient as customary for a diagnostic endoscopy (i.e., left lateral). Administer conscious sedation, per the institution’s protocol for monitored anesthesia care (MAC).

⚠️ **Note:** In case of emergency or complication during removal, the patient should be intubated.
Step 3. Balloon drainage

1. The removal procedure requires a single-channel gastroscope with a diameter of 8.6 – 11.3mm, instrument channel diameter of 2.8mm, and a maximum working length of 140cm.

2. Position an adult-size endoscopic bite block into the patient’s mouth.

3. Perform an endoscopic inspection of the esophagus and stomach. If excessive food or liquid is present, the procedure should be postponed.

4. With the endoscope in the stomach, insert the Removal Catheter through the endoscope’s instrument channel.

5. The order in which the balloons are drained is at the discretion of the physician. Position the endoscope adjacent to the first balloon to be drained and orient the Removal Catheter perpendicular to the surface of the balloon.

6. Advance the Removal Catheter up to the balloon surface, apply light pressure and turn the crank handle clockwise until it stops to advance the needle and puncture the balloon.
   a. Insert the Removal Catheter into the balloon up to the second depth marking, and then fully retract the needle by turning the crank handle counter clockwise. It is important to ensure that the needle has been retracted before inserting the catheter beyond the second marking.
   b. Insert the catheter deeper into the balloon up to the third depth marking.
   c. Open the Removal Catheter’s valve and apply suction to drain the balloon.
   d. Hold the endoscope steady and ensure that the catheter remains positioned within the balloon until the balloon is completely drained.
e. After draining the balloon, withdraw the catheter from the balloon.

⚠️ Note: If necessary, temporarily leave the Removal Catheter’s valve open and disconnect the suction pump tube. This will relieve the vacuum within the deflated balloon and allow the catheter to be pulled out of the balloon.

7. Close the Removal Catheter’s valve and reconnect the suction pump tube. Reposition the Removal Catheter perpendicular to the surface of the next balloon and repeat the same steps as was done to drain the first balloon.

8. Completely withdraw the Removal Catheter from the endoscope when the second balloon has been drained.

9. Insert endoscopic rat-toothed grasping forceps to tear a hole in each of the balloons. This allows trapped fluid and air to completely drain from the balloon and reduce resistance during removal.

10. Before removing the graspers, search for the proximal cap of the balloon device. If necessary, use the graspers to reposition the balloon device such that the proximal cap is easily seen.

⚠️ Note: If the proximal cap is unreachable or sitting too far into the fundus, grasp the central shaft and push the entire balloon device distally. This will allow snaring of the proximal cap in an antegrade position. Alternatively, flip the balloon to place the proximal cap in the distal portion of the stomach where the distal cap can be snared by retroflexing the endoscope.

11. Remove the grasper and any remaining fluid from the stomach using endoscopic suction.

**Step 4. Capture and removal of the balloon**

1. Insert an endoscopic snare and prepare to capture the drained ReShape Dual Balloon.
   a. Position the endoscope as necessary in order to access the proximal cap.
   b. Capture the proximal cap with the endoscopic snare.
Note: Snaring the proximal cap provides a secure hold of the drained ReShape Dual Balloon. Do not capture the device by the balloon skin or along the shaft.

2. With the ReShape Dual Balloon proximal cap firmly grasped within the snare, remove the endoscope and the captured balloon from the patient. Make sure to hold both the snare and endoscope when pulling the balloon up the esophagus. The snared balloon should remain under direct endoscopic visualization during the entire removal.
   a. In case of difficulty during removal, use the following technique:
      i. If the balloon releases from the snare in the lower esophagus:
         1. Push the balloon with the tip of the endoscope until the balloon has been pushed from the esophagus back down into the stomach.
            Note: this should be done with light and steady pressure. Too much force could cause the scope to bend instead of pushing the balloon.
         2. Reposition the balloon device as necessary and snare the proximal cap, again.
      ii. If the balloon releases from the snare in the upper esophagus, use a laryngoscope and Magill forceps to retrieve the ReShape Dual Balloon device.

3. Reinsert the endoscope to inspect the patient’s esophagus and stomach.

References

Instructions for Use – ReShape® Integrated Dual Balloon System
Instructions for Use – ReShape® Gastroenterology Guidewire
Instructions for Use – ReShape® Removal Catheter
Instructions for Use – ReShape® Infiltration Pump