



Airless Intestinal Endoscopy
with 100% visibility:
Consistently Efficient with Less Pain

Instructions for use

Exclusively Manufactured
for and Distributed by
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Intended Use

The Vizballoons® and Daisycuffs™ are intended for use with an endoscope to facilitate ease of insertion. Daisycuffs™ may be used alone. Using Vizballoon® allows 100% visibility. It is recommended to use Daisycuffs™ with the Vizballoon®.

Notes

Do not use this device for any purpose other than the stated intended use.

If package is opened or damaged when received, do not use. Visually inspect with particular attention to kinks, bends and breaks. If an abnormality is detected that would prohibit proper working condition, do not use. Please notify Visualization Balloons, LLC for return authorization.

The Vizballoons® should only be used by or under the supervision of physicians trained in endoscopic procedures. A thorough understanding of the technical principles, clinical applications, and risks associated with these procedures is necessary before using these devices.

The Vizballoons® are designed for use with endoscopes having a minimum working channel size of 3.2 mm.

Storage

Store at controlled room temperature.

Potential Complications

Those associated with GI endoscopy and colonoscopy include, but are not limited to: perforation; hemorrhage; hematoma; septicemia/infection; general complications of the intravenous sedation.

Warnings and Precautions

1. Do not use the Vizballoons® immediately after air insufflation of unsuccessful standard colonoscopy. Reschedule patient for Vizballoons® airless colonoscopy on a separate day.
2. Consult the medical literature relative to complications, hazards, and techniques prior to the performance of any endoscopic procedure.
3. Endoscopic procedures should only be performed by persons having adequate training and familiarity with these techniques.



4. If resistance is met during the procedure, do not advance the catheter without first determining the cause of resistance and taking remedial action.
5. Do not apply excessive amount of lubricant on the shaft of the scope to avoid inadvertent slippage of the Daisycuffs™ .
6. Do not exceed the recommended Vizballoons® inflation volume.
7. Do not inflate the Vizballoons® prior to insertion into the endoscope.
8. Deflate the Vizballoons® prior to retro-flexion in the rectum or cecum.
9. Do not reuse the Vizballoons® or try to sterilize; it is for Single Use Only.

Contraindications

Contraindications include but are not limited to those specific to colonoscopy.

Indications For Use

The Vizballoons® are intended for use in any situation where one seeks to avoid intestinal and abdominal distention: A) Redundant anatomy with previous inability to reach the end of a colon; B) Tortuous and long anatomy when previous attempt took significant time and effort.

Preparation

Precaution: A thorough understanding of the technical principles, clinical applications, and risks associated with endoscopic procedures is necessary before using this product.

1. Open the package and remove the Vizballoon® from the pouch.
2. Prior to use, carefully examine the Vizballoon® and Daisycuffs™ to make sure the sterile packaging has not been damaged during shipment.

The Directions for Use that follow describe:

1. Using Daisycuffs™ by themselves.
2. Using Vizballoon® with two Daisycuffs™.



DAISYCUFFS™ DIRECTIONS FOR USE

Daisycuffs™ help to pleat the intestine onto the scope. They are most efficient when used in a relatively collapsed lumen: A) In combination with Vizballoon® ; B) water colonoscopy technique; C) when gas insufflation during the insertion is decreased to a minimum.

Step 1

Place the first Daisycuff™ onto the distal tip of the scope, having the petals face towards the distal tip of the scope.

Step 2

Once the Daisycuff™ has engaged the surface, roll it along the scope to the desired position (usually 20cm mark).



Step 3

Adjust the Daisycuff™ so it is neatly positioned with the petals facing the distal tip of the scope. The Daisycuff™ should be symmetrical and even and the petals should not be buckled.



Step 4

Repeat steps 2 and 3 for additional Daisycuff™. Place the second **Daisycuff™ at the scope's tip flush with the scope's face.** You are now ready to use the endoscope with the two Daisycuffs™.



Step 5

Use short bursts of the endoscope water jet to clear the lens and occasionally create extra space between the intestinal wall and scopes face.

Use frequent short “in and out” movements to pleat the intestine onto the endoscope.

When end of the insertion is achieved (cecum, ileum, jejunum), turn on the air or CO₂ supply to the endoscope and begin to insufflate the bowel as needed to facilitate exam and perform therapeutic maneuvers upon withdrawal.

Remove the Daisycuffs™ after completion of procedure.

After use, treat the Daisycuffs™ as potential biohazards. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.



VIZBALLOON® DIRECTIONS FOR USE

Step 1

IMPORTANT: Completely shut off the air supply (or CO₂ supply) on the processor unit of the scope.



Step 2

Connect the jet water supply to the auxiliary “jet water port” of the scope if applicable.

Step 3

Open the Vizballoon® package and carefully remove the catheter and Daisycuffs™. Examine them for any apparent damage.

Step 4

Gently pull the balloon protector off of the tip of the catheter.



Step 5

Slide the introducer up over the catheter so that it completely covers the uninflated balloon.



Step 6

Insert the introducer with a Vizballoon® into the accessory channel of the endoscope. When balloon comes out of the scope, Fill a 10 cc syringe with 5 cc of sterile normal saline and attach to the stopcock. Place stopcock in the open position.



Step 7

Point the syringe downward and draw a vacuum on the syringe before injecting saline into the balloon to evacuate residual air from within the catheter.



Step 8

Slowly inject saline (over 20-30 seconds) into Vizballoon® to slightly more than 50% of the balloon's fill volume.



Step 9

Ensure the Vizballoon® is kept below the level of the syringe and the distal tip of the balloon is pointing downward so any air bubbles will collect at the top of the balloon and be evacuated from the balloon on aspiration.

Step 10

Withdraw all the air and saline from the Vizballoon® while ensuring the balloon remains below the level of the syringe.



Step 11

Slowly inject more saline until the Vizballoon® reaches the diameter **slightly smaller than the diameter of the scope used for the procedure** (usually not more than 12 mm).

Step 12

Carefully examine the inflated balloon for leaks. If leaks are detected, or the Vizballoon® begins to deflate when gentle finger pressure is applied, remove the balloon and insert a new balloon following steps 1-13.



Step 13

Apply lubricant to the anal canal.

Step 14

Slowly introduce the endoscope/cap/balloon assembly into the rectum while visualizing anal canal.

Step 15

Advance the endoscope and Vizballoon® within the center of the bowel lumen. At points of sharp angulation, observe the segment of the most prominent “blanching out” of the submucosal vasculature. The diametrically opposite point is the direction of the open lumen. Deflect the endoscope tip toward the open lumen.



Step 16

When progressive “blanching out” is observed, withdraw the endoscope until the “blanching out” disappears. “Blanching effect” is a visual reflection of the pressure exerted by the endoscope onto the intestinal wall and vice versa (quantitatively and qualitatively).



Use frequent short “in and out” movements, with or without torque, to plect the intestine onto the scope.

Inject water when vision through the balloon is not clear.

When end of the insertion is achieved (cecum, ileum, jejunum), deflate and withdraw the Vizballoon®. Turn on air or CO2 supply to the endoscope and begin to insufflate the bowel as needed to facilitate exam and perform therapeutic maneuvers upon withdrawal.

Remove the Daisycuffs™ after completion of procedure.

After use, treat Vizballoon® and Daisycuffs™ as potential biohazards. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

Warranty

Visualization Balloons, LLC warrants that reasonable care has been used in the design and manufacture of these devices. This is in lieu of expressed or implied warranty by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness. Factors relating to the patient, diagnosis, treatment, surgical procedures, and other matters beyond Visualization Balloons, LLC's control may directly affect the instrument and the results obtained from its use. Visualization Balloons, LLC's obligation under this warranty is limited to the repair or replacement of these devices and Visualization Balloons, LLC shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of these devices. Visualization Balloons, LLC neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with these devices. Visualization Balloons, LLC assumes no liability with respect to devices reused, reprocessed or sterilized and makes no warranties, expressed or implied, including but not limited to merchantability or fitness for intended use, with respect to such devices.



