ENDORAIL SET

COMPONENT OF THE ENDORAIL MEDICAL DEVICE

INSTRUCTIONS FOR USE

DISCLAIMER

Endostart S.r.l. disclaims all liability for injuries or property damage due to improper use of this product and failure to observe the indications, warnings, instructions and precautions laid out in this user manual.

In the event of a serious incident related to the Endorail medical device, the user must notify the manufacturer and the competent authority of the country in which the event occurred.

Endostart S.r.l. cannot be held liable for any injuries or property damage resulting from failure to observe the rules or precautions listed below and generally reported in this user manual.

These instructions for use are provided in hard copy only and must always accompany the Endorail medical device.

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WARNING	To ensure proper use of the device and to prevent injuries to patients, read all information contained in these instructions for use.
WARNING	Read all the information contained in the Endorail System instruction for use.

1 GENERAL INFORMATION

1.1 INTENDED USE

The Endorail is an accessory to an endoscope and is intended to ensure positioning of a standard endoscope (i.e., an endoscope with an instrument channel that is at least 3.2 mm diameter and is used for standard endoscopic visualization) during endoscopy of the large intestine.

1.2 INTENDED POPULATION

Endorail is indicated for adults (>21 years), male and female with BMI≤30 kg/m2.

1.3 INTENDED USERS

Endorail is intended for use by digestive endoscopy specialists supported by nursing staff.

1.4 CLASSIFICATION

Classification Name:	Endoscope Channel Accessory
Regulation Name:	Endoscope and Accessories
Regulation Number:	21 CFR 876.1500
Product Code:	ODC
Regulatory Class:	Class II
Classification Panel:	Gastroenterology/Urology

1.5 DEVICE DESCRIPTION

Endorail includes two components to be used in combination called: Endorail Set and Endorail System. Endorail Set (code ESETGEN2V02A) is disposable and includes the following elements:

- Endorail Balloon Guide (EBG),
- Endorail Solution Syringe (ESS),
- Endorail Powder (EP),
- Spike.

Before the procedure, the operator prepares the syringe containing the ferromagnetic fluid using the ESS, the spike and the EP. The EBG is a balloon catheter that can be introduced as needed through the endoscope instrument channel during the colonoscopy, if the procedure becomes challenging. Endorail Set does not require to be pre-mounted and does not interfere with the normal examination process. The EBG is advanced beyond the colonoscope tip where the balloon is filled with the ferromagnetic fluid and magnetically anchored with the Endorail

Handpiece (EH) placed on the patient's abdomen. Once anchored, the colonoscope can be straightened and guided along the catheter. Afterward the EBG can be unlocked, deflated and retrieved.

1.5.1 ENDORAIL BALLOON GUIDE

EBG consists of 7 elements:

1. Endorail Valve (EV)
2. Luer Lock connector
3. Catheter
4. Balloon proximal bond
5. Balloon
6. Balloon distal bond
7. Balloon protection tube

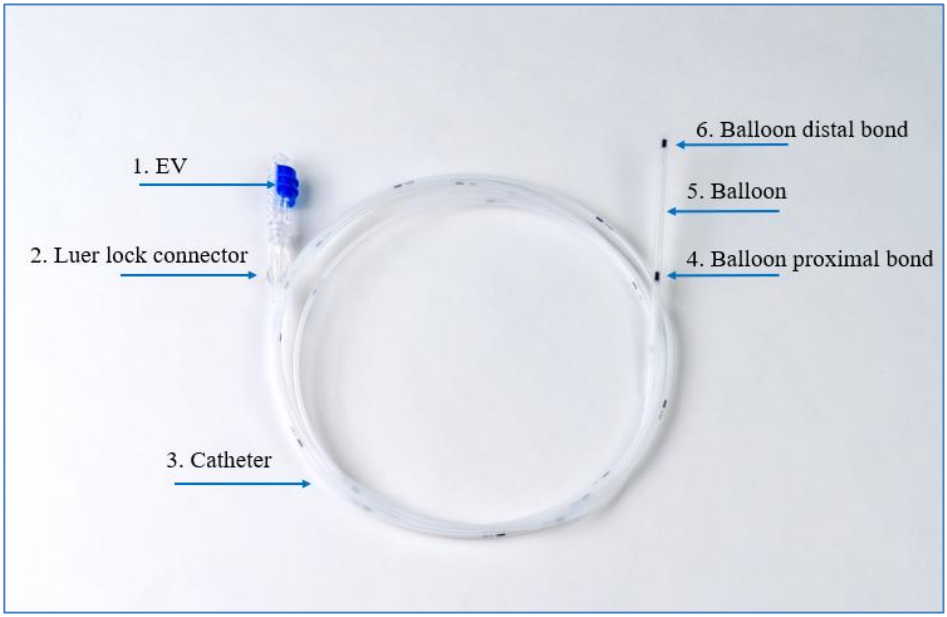

Fig. 1 EBG components

Fig. 2 Balloon protection tube

The EBG consists of a catheter whose distal portion has an elastic balloon, its proximal portion a luer lock connector hooked up to a valve that allows one to block and release flow inside the catheter.

- ENDORAIL VALVE (EV)

The Endorail Valve is a component used to enable or block the flow of the ferromagnetic fluid.

The valve has luer lock connection elements, the proximal one enabling connection with the syringe, the distal one with the balloon catheter.

With the slide switch one can control whether the flow is interrupted (OFF position) or enabled (ON position).

Fig. 1 Endorail Valve (EV)

- BALLOON

The balloon is located in the distal portion of the catheter and is delimited, both proximally and distally, by the respective black bonds. The balloon is made of an elastic material and has a nominal capacity of 19 ml; when deflated it is 60 mm long (+2mm -2mm).

- BALLOON PROTECTION TUBE

The balloon protection tube consists of a 120 mm protective plastic tube that fully fits over the balloon; it must be removed before using the device.

- CATHETER

The tube constituting the body of the catheter has centimeter markings every 10 cm, starting from 30 cm from the balloon tip. The portion of the distal tube between the two bonds has specific holes that make it possible to inflate or deflate the balloon.

1.5.2 ENDORAIL POWDER (EP)

Endorail Powder consists of a glass vial (maximum capacity: 50 ml) containing 29.10 g of carbonyl iron powder and closed with an aluminum overseal. The overseal can be opened manually to uncover the central portion where the spike can be inserted through the underlying perforable septum. Before performing the endoscopic procedure, the powder must be mixed with the saline solution contained in the ESS syringe following the procedure described in section 5.4.

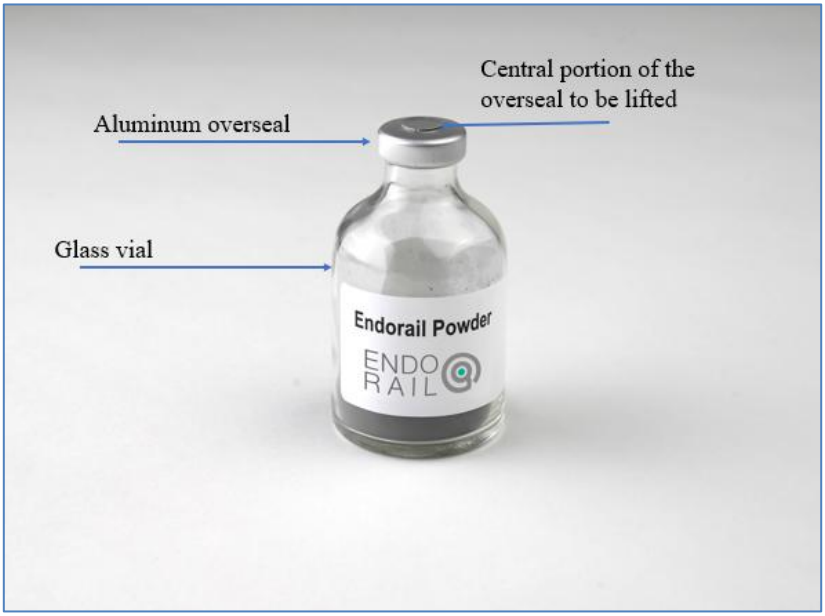

Fig. 4 Endorail Powder (EP)

1.5.3 SPIKE

The spike is a perforator fit with an air intake with membrane and self-sealing, two-way valve. The device has a coupling ring to connect and securely lock the opening of the vial of EP.

Fig. 5 Spike

1.5.4 ENDORAIL SOLUTION SYRINGE (ESS)

The ESS consists of a syringe pre-filled with 23 ml of saline solution containing the following ingredients:

- Trisodium citrate dihydrate
- Sodium Chloride
- Water for Injection (WFI).

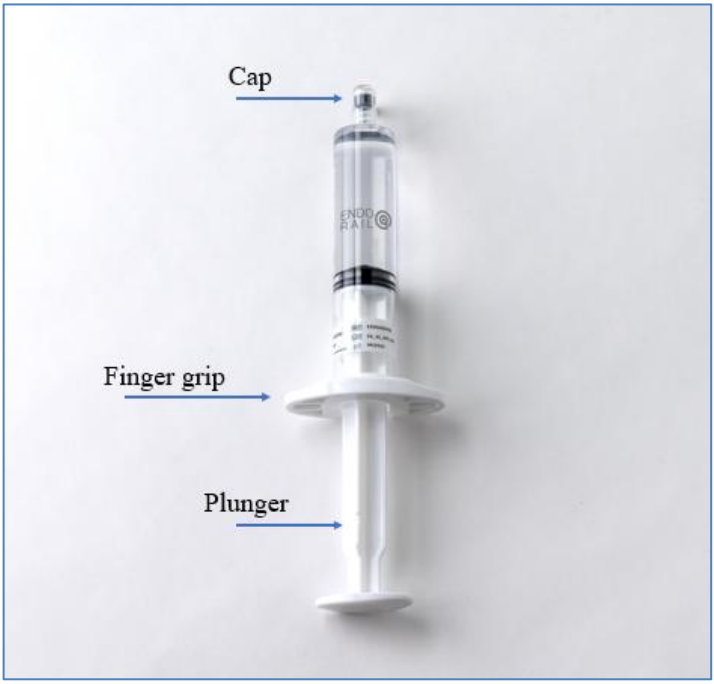

Fig. 6 Endorail Solution Syringe (ESS)

The syringe has a maximum capacity of 35 ml, a tip with luer lock connection and a cap. The Endorail Solution Syringe is used together with the Endorail Powder and Spike to reconstitute a syringe filled with about 26 ml of a ferromagnetic fluid.

2 CONTRAINDICATIONS

Do not use the device:

1. On patients with body mass index (BMI) >30 kg/m2
2. On patients ≤21 years of age
3. On patients with any contraindication to colonoscopy
4. On patients with known allergy or hypersensitivity to any of the elements of the Endorail Set (e.g.: iron)
5. On patients with permanent or semi-permanent implanted active and/or ferromagnetic/magnetic medical devices
6. On patients with dense diverticulosis
7. On patients with diverticulitis
8. On patients with ferromagnetic/magnetic foreign body
9. On patients with large abdominal hernias
10. On patients with severe thrombocytopenia
11. On patients with severe coagulopathy
12. On patients with peritonitis
13. On patients with peritoneal carcinomatosis
14. On pregnant women
15. On patients with bleeding diathesis
16. On patients with severe splenomegaly
17. On patients with gastrointestinal perforation
18. In conjunction with the use of electrosurgical units or electrocoagulation electrodes
19. In MRI rooms

3 WARNINGS

1. The device should never be used by doctors or nurses with permanent or semi-permanent implanted active and/or ferromagnetic/magnetic medical devices.
2. Do not modify any part of the device.
3. Never use the device for purposes other than those indicated in this instruction for use.
4. Do not use the device if any component shows evident signs of damage.
5. Do not reuse or reprocess. Reuse or reprocessing may compromise the structural integrity of the device or create a risk of contamination.
6. Do not use the device for more than three anchoring cycles (balloon inflation, balloon anchoring, balloon deflation) and for a maximum overall time of 1 hour.
7. Do not use if the package is opened or damaged.
8. Use on or before the expiration date printed on the Endorail Set label.
9. Do not attempt to push the balloon beyond any pathological sub-stenosis or stenosis of the colon.
10. Following the priming, never fill the balloon by more than 19 ml as it could compromise its integrity.

4 PRECAUTIONS

1. Dispose of the device if any leakage occurs from any connection at any time during the procedure.
2. If the ferromagnetic fluid/powder comes into contact with the patient/user's eyes at any time during the procedure, rinse thoroughly with water.

5 ENDORAIL SET PREPARATION

5.1 PRELIMINARY OPERATIONS

Before using the device, we recommend:

- Turning the patient into a supine position
- Uncovering the patient's abdomen and checking that the skin is intact.
- Making certain that there is sufficient space in front of the tip of the colonoscope for the balloon to emerge entirely; specifically, the black proximal bond of the balloon must be visible.
- Using the Endorail Set only if it is possible to advance the balloon under visual control.

5.2 OPENING THE PACKAGING

The Endorail Set is provided inside an outer packaging consisting of a cardboard box with Endorail logo. Each box (Endorail Set Box) contains n° 4 units of Endorail Set. Each Endorail Set is individually packed in a pouch and is provided non-sterile but with a controlled microbial count.

Open the Endorail Set pouch and withdraw:

- the tray holding the EP, ESS and Spike
- the pouch containing the EBG

Fig. 7 Endorail Set tray.

Fig. 8 Endorail Balloon Guide pouch.

Open the EBG pouch all the way and withdraw the catheter. Unroll it and check that it is intact.

Check that the EV valve is properly connected to the balloon catheter luer lock connector and that all elements are intact.

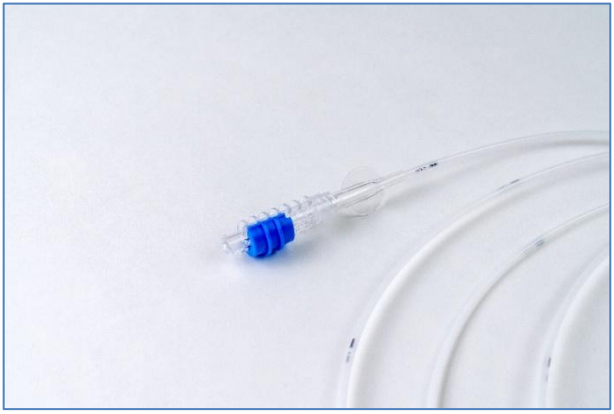

Fig. 9 Connecting the EV valve with the catheter connector

5.3 RECONSTITUTION OF THE FERROMAGNETIC FLUID

Take the EP from the tray and remove the overseal to reveal the underlying perforable septum.

Fig. 10 Removing the EP cap.

Take the spike from the tray and insert it into the perforable septum on the vial until a click is heard.

Fig. 11 Inserting the Spike into the vial's perforable septum.

CAUTION Do not turn the vial upside down during this procedure.

Remove the syringe from the tray and unscrew the cap. Connect the syringe to the spike using the luer lock connection.

Fig. 12 Connecting the syringe to the spike.

Place the base of the vial on a flat surface and slowly inject the saline solution from the syringe into the vial to mix it with the iron powder and reconstitute the ferromagnetic fluid.

Fig. 13 Injecting the saline solution from the syringe into the vial.

CAUTION Inject the saline solution in the vial in about 5 sec to prevent breaking the spike hydrophobic membrane.

Disconnect the syringe from the spike and place it on a flat surface.

Grip the vial and the spike and shake them vertically for 5 seconds.

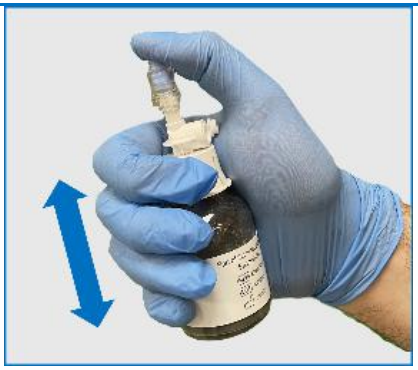

Fig. 14 Shaking vertically for 5 seconds.

Turn the components 180° so that the base of the vial is facing upwards and shake vertically for another 5 seconds.

Fig. 15 Turning the components 180° and shaking vertically for 5 seconds.

Reconnect the syringe to the spike, place the vial at the top and draw the contents by pulling the syringe plunger out until it reaches the stop.

When suction is completed, it is normal for a thin layer of powder to adhere to the inner walls of the vial.

Fig. 16 Drawing the contents of the vial into the syringe.

CAUTION	Handle the syringe with care. The finger grip is a removable component and its detachment might cause leakage.
NOTE	If there are significant deposits or accumulations of powder on the inner walls of the vial, inject the contents of the syringe back into the vial and shake for a further 5 sec.

While keeping the vial at the top, inject the excess volume of air into the vial. All the ferromagnetic fluid must be drawn out (about 26 ml).

The presence of a few millimeter-sized air bubbles is to be considered normal.

Fig. 17 Injecting the excess volume of air into the vial

Disconnect the syringe from the spike.

Connect the syringe to the EV valve.

Fig. 18 Connecting the syringe to the EV valve.

It is worth noting that, if the syringe is not shaken, the sedimentation process takes place after only few seconds. Any settling of iron powder is therefore normal and not to be considered a defect.

5.4 EBG LUBRICATION

The EBG has been designed to ensure smooth passage through the colonoscope operating channel. To improve sliding and limit friction

against the internal walls of the channel itself, the balloon must be lubricated using a water-soluble endoscope lubricating gel only.

Thus, remove the balloon protection tube. Apply a generous amount of gel to the balloon, then place the EBG on the medical-grade paper of the opened pouch.

CAUTION	Handle the EBG with care to avoid possible damage to the catheter. Do not use a catheter that has been damaged.

5.5 INSERTION OF THE EBG

Insert the EBG into the colonoscope operating channel until the tip of the catheter is clearly visible on the endoscopic images.

While holding the colonoscope in place, carefully push the balloon past the tip of the colonoscope so that it emerges entirely; specifically, the black proximal bond of the balloon must be visible.

WARNING	Never attempt to inflate the balloon before it is entirely outside the end of the colonoscope operating channel.
WARNING	To avoid kinking, advance the catheter slowly with small incremental steps (approximatively 2 cm advancement for each step), until the balloon exits the distal edge of the colonoscope.
CAUTION	Try to avoid the impact between the catheter tip and the colon mucosa.

NOTE

If the EBG cannot slide through the colonoscope operating channel and/or the balloon cannot exit the tip of the colonoscope.

- Try to insert the EBG into the operating channel after having partially straightened the colonoscope and, in particular, its tip
- Remove the balloon and verify whether it is completely deflated
- Re-lubricate the balloon and insert it into the operating channel after opening the inlet valve

6 PRIMING

Priming is a preliminary step used to prepare the device (removing air from the EBG) and check that all of its components are functioning correctly.

Verify that EV valve is set to ON and inject the entire contents of the syringe into the catheter.

To inject the liquid more easily, position your fingers as shown in figure 19.

Fig. 19 Injection.

NOTE	If, at any point during the procedure, deposits of the ferromagnetic powder are clearly seen inside the syringe, switch off the EV and shake the syringe for about 5 seconds. Then, switch on the EV and inflate the balloon.

When inflation has been completed, the balloon will be filled partly with the ferromagnetic fluid and partly with air.

With one hand grip the body of the syringe. With the other hand, pull out the plunger until it stops, thus drawing up the full contents of the EBG.

Fig. 20 Suction.

Through endoscopic visualization, verify that the balloon has been completely deflated by:

- Checking that the walls have collapsed on the balloon shaft
- Checking whether the flow is interrupted in the proximal portion of the catheter.

Fig. 21. Balloon walls after priming

Once the balloon is deflated, while holding the syringe in suction, close the EV valve by sliding the switch to OFF.

Disconnect the syringe from the EV valve and position it vertically with the tip pointing upwards.

If the maneuver is performed correctly, the syringe will contain about 19 ml of ferromagnetic fluid and at least 5 ml of air.

Remove all the air from the syringe.

Reconnect the syringe to the EV valve.

Fig. 22 Removing air from the syringe.

NOTE If the syringe is not filled with at least 5 ml of air during the priming procedure, reconnect the syringe to the EV valve and repeat the priming procedure.

7 INSTRUCTIONS FOR USE – CLINICAL PHASE

WARNING	Do not magnetically anchor the balloon over injured or damaged mucosa.
WARNING	Never attempt to push the balloon beyond any pathological sub-stenosis or stenosis of the colon

To use the EBG correctly, a series of operations must be performed as described below and collectively identifiable as the **ANCHORING - GUIDED ADVANCEMENT/STRAIGHTENING - RELEASE CYCLE (AGSR-CYCLE).** In particular, the AGSR cycle is identified with a procedure that includes the following operations: magnetic anchoring, guided advancement with possible straightening of the colonoscope, and release.

7.1 INFLATION OF THE EBG

Shake the syringe for 5 seconds. Set the EV valve to ON.

Position the syringe vertically with the tip pointing downwards. Push the syringe plunger to inject the ferromagnetic fluid under visual control and fill the balloon with the ferromagnetic fluid contained in the syringe.

Set the EV to OFF.

WARNING	Never attempt to inflate the balloon before it is entirely outside the end of the colonoscope operating channel.

7.2 ANCHORING

The handpiece must be placed on the patient's abdomen on the abdominal quadrant corresponding to the segment of the colon where the EBG balloon is located (called the anchoring quadrant). If necessary, check whether there is an area of abdominal transillumination indicating the position of the colonoscope tip and thus of the balloon.

7.2.1 VERIFICATION OF ANCHORING FORCE AND GUIDED FORWARD MOVEMENT

Once the balloon has been anchored, its stability must be checked by performing the following operations:

- Grip the proximal body of the catheter with two fingers and gently pull on the balloon to check whether it is in contact with the upper surface of the colonic mucosa.
- Once anchored adequately, proceed with traction of the catheter until the tip of the colonoscope comes to within approximately 1 cm of the balloon.

CAUTION	The balloon should not be bumped with the tip of the colonoscope.

7.3 GUIDED ADVANCEMENT/STRAIGHTENING

Should the endoscopist deem it necessary, colonoscope straightening operations may be performed following such reference methods as traction, torsion, etc. These operations should be performed gently so as to limit the risk of releasing the balloon.

NOTE	If the balloon is released during guided colonoscope forward advancement or straightening operations, the anchoring procedure should be repeated and, if necessary, consider increasing the level of the magnetic power.

7.4 DEFLATING THE BALLOON AND REMOVING THE EBG

Once the endoscopic procedure has been completed, perform balloon release and handpiece removal operations following the Endorail System instructions for use.

Set the EV valve to ON. Pull the syringe plunger until it stops to draw up the ferromagnetic fluid contained in the EBG.

Verify that the balloon has been completely emptied by:

- Checking that the walls have collapsed on the balloon shaft
- Placing the syringe in a vertical position with the tip pointing upwards and checking whether the flow is interrupted.

Once the balloon is deflated, close the EV valve by sliding the switch to OFF while holding the syringe in suction.

Remove the EBG from the colonoscope. Passage through the operating channel must be smooth and offer no resistance.	
WARNING	Never attempt to retrieve the EBG inside the colonoscope operating channel before the balloon is completely deflated.
CAUTION	If the EBG cannot be retrieved from the endoscope operating channel due to incomplete deflation, consult chapter 8 Troubleshooting.
CAUTION	If it proves necessary to perform another AGSR-CYCLE, check whether air has entered the syringe after deflating the balloon. In case there is air in the syringe, disconnect the syringe from the EBG, remove the air, and reconnect it to the EV valve.

8 TROUBLESHOOTING

Problem	Solution
The Endorail Balloon Guide cannot be withdrawn from the endoscope due to incomplete deflation.	Reinject all the ferromagnetic fluid inside the balloon and try to deflate the balloon. If, despite the above-mentioned operations, the balloon still cannot be deflated, remove balloon and colonoscope simultaneously.
Balloon rupture or perforation resulting in leakage of the ferromagnetic fluid inside the patient's colon	In case of EBG balloon rupture and ferromagnetic fluid leakage inside the patient's colon, withdraw the EBG from the colonoscope lumen and quickly wash out the colon thoroughly to remove the dispersed fluid. If necessary, and depending on the clinical situation, consider administering laxatives to accelerate expulsion of any iron residues. Dispose of the device and, if possible, complete the colonoscopy. **WARNING** In case of leakage of the ferromagnetic fluid inside the intestinal lumen, MRI should not

	be performed at any time within the next seven days.

9 DISPOSAL

Follow the hospital's internal rules for disposal of potentially contaminated plastic devices and the disposal of liquids by taking the necessary precautions considering the composition of the ferromagnetic fluid.

10 STORAGE CONDITIONS

Temperature:	+5 / +30°C
Humidity:	Dry place

11 TECHNICAL CHARACTERISTICS

Technical characteristics of the Endorail Balloon Guide	
Dimensions	• Catheter usable length: 2500±25 mm • Nominal balloon length when deflated: 60 $^{+2}_{-2}$ mm • Max Outer diameter: 2.70 mm • Catheter length markings to confirm insertion depth: every 10 cm starting from 30 cm from the balloon tip • Nominal balloon capacity: 19 ml • Nominal inflated balloon outer diameter: 23±2.5 mm
Materials	• Catheter Shaft: Polyamide • Balloon: Thermoplastic Elastomer • Proximal and distal balloon bonding material: Polyamide • Catheter luer lock connector: ABS (Acrylonitrile butadiene styrene) • Endorail valve: PC (Polycarbonate)

Technical characteristics of the Endorail Syringe

Dimensions	• Nominal capacity: 30 ml • Maximum graduated capacity: 30 ml • Maximum capacity: 35 ml
Materials	• Syringe: PC (Polycarbonate) • Saline solution: Water for Injections, Sodium Chloride and Trisodium citrate dihydrate

Technical characteristics of the Endorail Powder	
Weight	Ferromagnetic powder weight: 29.10 ± 1 g
Materials	Ferromagnetic Iron Powder

12 LIST OF SYMBOLS

	Manufacturer
	Medical device
	Caution
	Do not use if package is damaged
 Max 3 times	Single Patient, multiple use
	Keep away from sunlight
	Temperature limit for storage between +5 and +30 °C
	Consult instructions for use
	MR Unsafe
	Federal (USA) law restricts this device to sale by or on the order of a physician
	Not made with natural rubber latex
	Catalogue number
	Batch code
	Use-by date
	Unique Device Identifier