

1 ENDORAIL SET PREPARATION

1.1 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.

1.2 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

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



Fig. 18 Connecting the syringe to the EV valve.

1.4 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

1.5 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 (approximately 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

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.

2 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.