TECHNICAL DATA SHEET MIFUSEMC001 – 23.07.2025

ENDORAIL SET CE

PRODUCT CODE: ESETGEN2V02

Manufacturing company	Endostart S.r.l. Via delle Regioni 265 50052 Certaldo (FI)
Device classification	Class I - non- sterile, Rule 5 according to MDR 745/2017, Annex VIII and Chapter III.
CND classification	G0399
Italian Health Minister Repertoire number registration	2274616
Expiring Date	24 months

1. INTENDED USE

Endorail Set is a medical device intended to facilitate the endoscope positioning during endoscopy of the large and small intestine.

2. DEVICE DESCRIPTION

Endorail Set is a disposable non-sterile medical device which includes the following elements:

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

Endorail Set must be used in combination with Endorail System.

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 procedure. EBG is advanced beyond the endoscope tip where the balloon is filled with the ferromagnetic fluid and magnetically anchored with the Endorail Handpiece (part of the medical device Endorail System) placed on the patient's abdomen. Once anchored, the positioning of the endoscope can be adjusted. Afterward the EBG can be unlocked, deflated and retrieved.

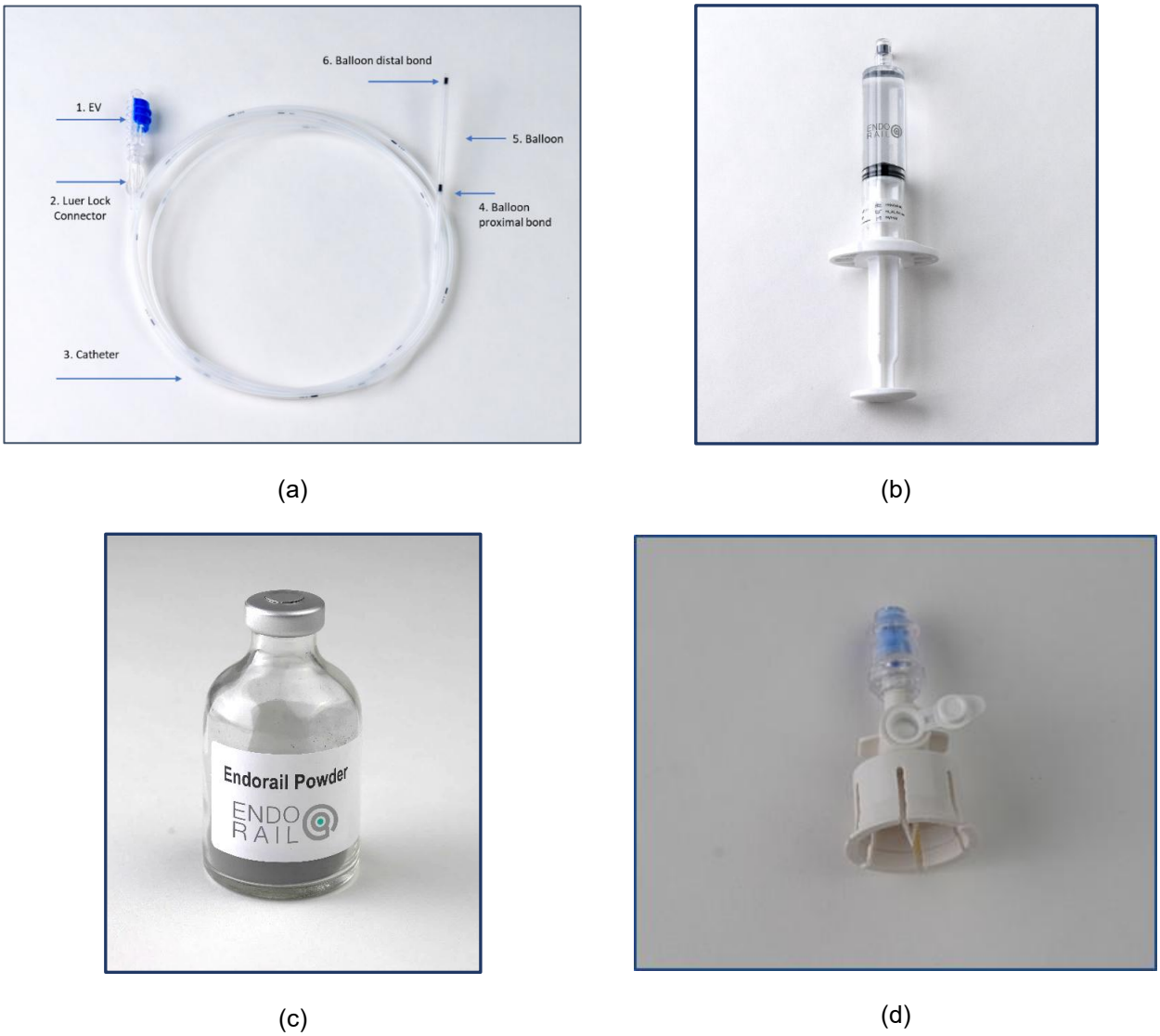

Figure 1 (a) Endorail Balloon Guide. (b) Endorail Solution Syringe. (c) Endorail Powder. (d) Spike

2. TECHNICAL FEATURES

	ENDORAIL BALLOON GUIDE
Dimensions	Catheter usable length: 2500 mm Balloon length: 60 mm Catheter and deflated balloon max Outer diameter: 2,70 mm/8,10 Fr Inflated balloon diameter: 23 mm Distance between 2 marks of the centimeter scale: 10 cm
Materials	Catheter Shaft: Polyamide Balloon: Thermoplastic Elastomer Prox and distal balloon bonding material: Polyamide Catheter luer lock connector: ABS (Acrylonitrile butadiene styrene) Endorail valve: PC (Polycarbonate)

Components	Refer to Figure 1 a. 1. Endorail Valve (EV) 2. Luer Lock Connector 3. Catheter 4. Balloon proximal bond 5. Balloon 6. Balloon distal bond
Notes	The Endorail Balloon Guide is singularly packed in a medical pouch made of medical grade paper and a PET/PP multilayer laminate.

	ENDORAIL SOLUTION 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
Notes	Syringe compliant with ISO 7886-1:2017 Sterile hypodermic syringes for single use – Part 1: Syringes for manual use

	ENDORAIL POWDER
Dimensions	Glass vial dimensions: 50H(1)
Materials	Glass vial: Type 3 clear glass Rubber Stopper: Chlorobutyl Aluminium capsule – Aluminum alloy Ferromagnetic Iron Powder
Notes	(1) Glass vial compliant with ISO 8362-4-50H

	SPIKE
Dimensions	Needle-less vented spike and self-sealing valve, biosafe, with coupling system for 20 mm diameter vials
Materials	ABS (Acrylonitrile butadiene styrene)
Notes	N.A.

3. COMPATIBILITY

Biocompatibility	Device in compliance with: • ISO 10993-1 Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process • EN ISO 10993-5 Biological evaluation of medical devices – part 5: test for In vitro cytotoxicity. • EN ISO 10993-10 • Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization. • ISO 10993-11 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity. • UNI EN ISO 10993-23 Biological evaluation of medical devices - Part 23: Tests for irritation • EP 2.2.3 – 10th edition Potentiometric determination of pH • International Pharmacopoeia - Ninth Edition, Chapter 5.1.4 (rectal use) • USP NF 2022 Issue 3 Par 151
Usability	Device in compliance with: • IEC EN 62366 -1- Year 2015 / Amd 1:2020 Medical devices – Part 1: Application of usability engineering to medical devices
Storage conditions	The device shall be stored in a dry environment. Temperature: 5 - 30°C

4. PACKAGING

The Endorail Solution Syringe, the Endorail Powder and the Spike are placed over a tray which guarantees their protection during transportation and storage, as shown in Figure 2. The tray is made of PET (Polyethylene terephthalate) and shaped to allow the correct and safe housing of the three components.

Figure 2 Endorail Set tray.

The tray, in conjunction with the Endorail Balloon Guide are packed in a pouch made of medical paper and a PET/PP multilayer laminate (see Figure 3 a). 4 Endorail Set units constitute the Endorail Set Box, code EBOXGEN2V01 (see figure 3 b).

(a) (b)

Figure 3 (a) Endorail Set packaging. (b) Endorail Set Box packaging.

The Endorail Set Box can be shipped in 2 validated configurations:

1. Shipping Unit 1 (SU1) which is a validated transport packaging consisting of a cardboard box (385x320x150mm) containing 1 unit of Endorail Set Box.
2. Shipping Unit 6 (SU6) which is a validated transport packaging consisting of a cardboard box (400x600x420mm) containing 6 units of Endorail Set Box.

TECHNICAL FEATURES PACKAGING
Device complies with: ASTM D4169 “Standard Practice for Performance Testing of Shipping Containers and Systems”
Device complies with: ASTM F1886/F1886M “Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection”
Device complies with: ASTM D4332 “Standard Practice for Conditioning Containers, Packages, Or Packaging Components for Testing”