

1. Company administrative information				
Review date: 2024-10				
1.1	Name: Delmont imaging			
1.2	Complete adress: 390 Avenue du Mistral 13600 La Ciotat, FRANCE		Tel: 09 51 51 30 30 Fax: 09 57 51 31 00 e-mail: contact@delmont-imaging.com Website: www.delmont-imaging.com	
1.3	Materialovigilance contact details: Robin GREFFEUILLE		Tel: 04 22 22 00 13 Fax: 09 57 51 31 00 e-mail: vigilance@delmont-imaging.com	
2. Device or equipment information				
2.1	Common name: Irrigation and suction pump			
2.2	Commercial name: iFlow mini			
2.3	Nomenclature code: N/A			
2.4	Medical device class: IIb Conformity: Conform to European regulation 2017/745 Notified body number: 1304 Date first marketed in the EU: 2024 Medical device manufacturer: Delmont imaging			
2.5	Device description: iFlow mini is a non invasive, active medical device designed for fluids’ management in endoscopic procedures to ensure the distension of the uterus (during hysteroscopy), the fluids’ irrigation and the suction function.			
2.6	Catalog references:			
	iFlow mini			
	Article reference	GTIN/UID-ID code	Specification	Packaging
	D110 100 012	03701217808720	Pump: (See image a.) - Dimensions: 185 x 230 x 130 mm - Weight: 2 kg - Electrical alimentation: -Grid voltage range: 100-230 V -Fuses: 2x T0.63A - 250V UL/CSA 5 x 20 mm -Operating frequency range: 50/60 Hz. - Safety: Protection class I, CF type, protection index IPX 3	1

Article reference	GTIN/IUD-ID code	Specification	Packaging
		Description: - Front side: standby button, navigation buttons, sensor housing, support for irrigation tube, display screen - Lateral right side: vacuum suction Luer lock type - Lateral left side: air outlet connected to the cuff - Back side: 1 fixing screw to a rail, 1 fixing screw to the medical stand Technical data: <u>Hysteroscopy program:</u> - Adjustable target pressure between 60 and 150 (by default) or 200 mmHg - Pressure measurement between 60-255 ±15 mmHg - Adjustable vacuum suction pressure: 30 kPa (or 225 mmHg) for the LOW function or 50 kPa (or 375 mmHg) for the HIGH function <u>Laparoscopy program:</u> - Irrigation flow rate: 1L/min (depending on the diameter of the instrument) - Adjustable vacuum suction pressure: 30 kPa for the LOW function or 50 kPa for the HIGH function	
Tubes			
Irrigation tubes			
D110 100 015	03701217808652	Single use, sterile irrigation tube: (See image b.) Dimensions: diameter: 6.8mm, total length: 4100mm Weight: 0.12kg Description: - 1 spike of 4.1mm length - 1 clamp before the spike - 1 pressure dome for connection to the pump sensor - 1 Luer lock, male type, instrument connection tip	15

Article reference	GTIN/IUD-ID code	Specification	Packaging
D110 100 016	03701217808676	Single use, sterile, double irrigation tube: (See image c.) Dimensions: diameter: 6.8mm, total length: 4200mm Weight: 0.12kg Description: - 2 spikes of 4.1mm length, linked by a «Y» connexion - 1 clamp before each spike - 1 pressure dome for connection to the pump sensor - 1 Luer lock, male type, instrument connection tip	15
Suction tube			
D110 100 022	03701217805989	Single-use, sterile suction tube: (See image d.) Dimensions: diameter: 6.8mm, total length: 4600mm Weight: 0.22kg Description: - 1 tube with a connection tip to the recovery bag, 1 clamp, length: 1005mm - 1 tube with a connexion tip to the suction stopcock of the instrument, length: 1510 mm. - 1 «Y» connexion - 1 connexion to the collection container	15
Vacuum suction tube			
D110 100 017	03701217808638	Non sterile, vacuum suction tube with filter, 30 days of use: (See image e.) Dimensions: diameter: 6.8mm, total length: 2700mm Weight: 0.08kg Description: - 1 tip for connection to the collection container - 1 female Luer lock connection tip for connection to the pump - 1 hydrophobic filter	1

Datasheet - iFlow mini -

Article reference	GTIN/IUD-ID code	Specification	Packaging
Pressure cuffs			
1L cuff			
D110 100 014	03701217808737	Dimensions: width: 160mm, height: 415mm, tube diameter: 4mm. Weight: 0.08kg Description: - 1 loop for attachment to the medical stand - 1 hook for attaching the fluid bag - 1 female connection to the pump or «Y» adapter - Reusable	1
3L cuff			
D110 100 020	03701217802698	Dimensions: width: 275mm, height: 465mm, tube diameter: 4mm. Weight: 0.14kg Description: (See image f.) - 1 loop for attachment to the medical stand - 1 hook for attaching the fluid bag - 1 female connection to the pump or «Y» adapter - Reusable	1
3L long cuff			
D110 100 013	03701217808720	Dimensions: width: 275mm, height: 535mm, tube diameter: 4mm. Weight: 0.18kg Description: - 1 loop for attachment to the medical stand - 1 hook for attaching the fluid bag - 1 female connection to the pump or «Y» adapter - Reusable	1
Y adapter			
D110 100 018	03701217805552	Dimensions: diameter: 7 mm, total length: 540 mm. Weight: 0.02 kg Description (See image g.) - 2 male connectors for pressure cuffs - 1 clamp on each arm of the adapter - 1 male connector to the pump air outlet	1

delmont imaging

Athélia V - 297, Av. du Mistral - 13 600 La Ciotat, FRANCE

Tel. : +33(0) 9 51 51 30 30 - fax : +33(0) 9 57 51 31 00

www.delmont-imaging.com - contact@delmont-imaging.com

SAS au capital de 252 400 euros - RCS Marseille 817 710 411 - N° de TVA Intracommunautaire : FR 81 817 710 411

	Article reference	GTIN/IUD-ID code	Sepecification	Packaging
	Kit : No Labeling : Refer to the appendix.			
2.7	Device and accessories composition: - Pump box materials: - PPE (Polyphenylene ether) - Pressure sensor membrane: silicone - Power cable: PVC (Polyvinyl chloride) - Irrigation tube materials: - Spike: ABS (Acrylonitrile butadiene styrene) - Tube: PVC (Polyvinyl chloride) - Pressure dome: ABS (Acrylonitrile butadiene styrene) - Connector (male luer lock) to the instrument: ABS (Acrylonitrile butadiene styrene) + PVC (Polyvinyl chloride) - Suction tube materials: - Connector (male) to the instrument: ABS (Acrylonitrile butadiene styrene) - Connector to the collection bag: PVC DEPH-Free - Connector (female luer lock) to the collection container: PVC (Polyvinyl chloride) - Tubes: PVC (Polyvinyl chloride) Free of latex, phthalate, active substances, products of animal or biological origin. Related devices and accessories: D100 100 019 Self-test tube for iFlow mini pressure sensor. (See image h.) - Vacuum suction tube materials: - Female luer lock connection tip: ABS (Acrylonitrile butadiene styrene) - Tube: PVC (Polyvinyl chloride) - Hydrophobic filter: PTFE (Polytetrafluoroethylene) - Vacuum connection tip: PVC (Polyvinyl chloride) - Cuffs materials: - Translucent film: TPU (Thermoplastic polyurethanes) - Cuff inner tube: Nylon - Tube: PVC (Polyvinyl chloride) - Connector: ABS (Acrylonitrile butadiene styrene)			
2.8	Application: Diagnostic and operative endoscopic procedures for hysteroscopy and laparoscopy. Intended use: The device is indicated for an use by healthcare professionals in diagnostic and operative endoscopic procedures for hysteroscopy and laparoscopy in a healthcare center equipped with an appropriate endoscopic setup. - Laparoscopy: Irrigation of body cavities and aspiration of fluids during diagnostic and operative procedures. - Hysteroscopy: uterine distention and dilatation maintenance through a pressure monitoring sensor and aspiration of fluid during diagnostic and operative procedures. The aspiration function is used to provide a flushing flow and siphon off secretions.			

3. Sterilization process

Medical device supplied sterile: only the following references: D110 100 015, D110 100 016, D110 100 022.
Device sterilization mode: Non-sterilizable.
Is this medical device indicated/used for newborns: No
Is this medical device indicated/used for premature newborns: No
Is this medical device indicated/used for infants: No

4. Storage conditions

Storage conditions: Room temperature: 10°C to +35°C / Relative humidity: 10% to 85%, without condensation. Avoid direct sunlight. Atmospheric pressure: 70 kPa to 106 kPa.
Expiry date: The storage time of the device is not limited, except for sterile elements, i.e. the following references: D110 100 015, D110 100 016, D110 100 022.

5. Safety in use

- 5.1 **Technical safety:** Follow the operating instructions.
 5.2 **Biological safety:** N/A

6. Directions for use

- 6.1 **Instructions for use :** Follow the operating instructions.
 6.2 **Indications:** Refer to section 2.8
 6.3 **Precautions for use :** Follow the operating instructions.
 6.4 **Contraindications :** Follow the instructions.

7. Product additional informations

N/A

8. List of appendices

- Labelling and traceability label (if applicable)
- User manual (D900 700 176)
- CE certificate

9. Images

a.		e.	
b.		f.	
c.		g.	
d.		h.	