

1. Company administrative information Review date: 2025-01			
1.1	Name: Delmont imaging		
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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: Electrosurgery generator		
2.2	Commercial name: iSpark		
2.3	Nomenclature code: N/A		
2.4	Medical device class: IIb Conformity: Conform to European regulation CE 93/42/EEC. Notified body number: 2274 Date first marketed in the EU: 2015 Medical device manufacturer: EMED SP. Z O. O. SP. K.ul. Ryzowa 69A, 05-816 Opacz Kolonia, Poland.		
2.5	Device description: iSpark+ is a high frequency alternating current generator, designed for use by qualified surgeons during surgical endoscopies only with dedicated programs for surgery, urology and gynecology.		
2.6	Catalog references:		
	Electrosurgical generators		
	Non upgradable iSpark generator 230V		
	Article reference	Characteristics	Packaging
	D100 400 050	• See bellow	1
	Non upgradable iSpark generator 110V		
Article reference	Characteristics	Packaging	
D100 400 051	• See bellow	1	

Non upgradable iSpark generators 230V or 110V characteristics:

- **Dimensions:** Width: 385 mm, Height: 141 mm, Depth: 304 mm.
- **Weight:** 7 kg.
- **Description:**
 - **Front face** (See image a.): Touch screen (TFT 7" WVGA display), 2 universal SDS outputs for instrument, 1 output for neutral electrode.
 - **Back side** (See image b.): 1 main power switch, 1 output for IEC 60320 C13 power supply, 1 USB-A output, 1 output for the footswitch, 1 sound output emitting audio signals between 40 and 88 dBA, 1 equipotential plug and 1 «service» port.
 - **Bottom face:** 4 non-slip feet.
- **Power supply:**
 - Voltage: 110-120 V or 220-240 V (depending on the model),
 - Power frequency: 50/60 Hz, power consumption: 1350 VA,
 - Fuses: 2 x T8 A / 250 V (220-240 VAC model) or 2 x T16 A / 250 V (110-120 VAC model),
 - Operating frequency: 333 kHz.
- **Safety:**
 - Automatic power regulation,
 - Instrument recognition,
 - 6 levels of neutral electrode monitoring (NEM),
 - Protection category: I, protection rating: IP 2X, type CF.
- **List of the programs installed by default:**

Functionality	Name	Description	Number of effects	Maximum power
Monopolar cutting	Mono cut	Monopolar cutting with different haemostasis effects	9	400W
	Precise cut	Precise monopolar cutting for small areas		80 W
	Mixed cut	Alternating cutting and gentle coagulation		150 W
	Uro cut	Monopolar cutting for urological procedures in a non-conductive fluid		400 W
	Hystero cut	Monopolar cutting for gynaecological procedures in a non-conductive fluid		
Monopolar coagulation	Soft coag	Low-voltage contact monopolar coagulation for large areas	9	200W
	Forced coag	High-voltage contact monopolar coagulation		
	Hybrid coag	High-voltage monopolar coagulation with or without contact		
	Uro coag	Monopolar coagulation for urological procedures in a non-conductive fluid		
	Hystero coag	Monopolar coagulation for gynaecological procedures in a non-conductive fluid		

Functionality	Name	Description	Number of effects	Maximum power
Bipolar cutting	Bi-cut	Bipolar cutting with different haemostasis effects	9	200W
	Uro Bi-cut	Bipolar cutting for urological procedures in a conductive fluid		330W
	Hystero bi-cut	Bipolar cutting for gynaecological procedures in a conductive fluid		
Bipolar coagulation	Soft bi-coag	Low-voltage contact bipolar coagulation (AutoStart/ AutoStop function)	9	120W
	Forced bi-coag	High-voltage bipolar coagulation (AutoStart/AutoStop function)		100 W
	Sciss bi-coag	Soft bipolar coagulation for work with bipolar scissors		200W
	Uro bi-coag	Bipolar coagulation for urological procedures in a conductive fluid		400W
	Hystero bi-coag	Bipolar coagulation for gynaecological procedures in a conductive fluid		
<ul style="list-style-type: none"> • Accessories supplied: 1 power cable (See image c.). 				
Kit: No Labeling: Refer to appendix.				
2.7	Device and accessories composition: <ul style="list-style-type: none"> • Housing: Aluminum coated with polyester-epoxy paint • Front face: Acrylonitrile butadiene styrene (ABS) • Socket: Polycarbonate (PC) & Acrylonitrile butadiene styrene (ABS) Latex free. Phtalates free. Active substances free. Products of animal or biological origin free.			
	Related devices and accessories: D100 400 003 Wired two-pedal footswitch (Cut & Coag). (See image d1). D100 400 004 Wired one-pedal footswitch (Coag). (See image d2). D200 190 027 Neutral silicone electrode, reusable, for adults, iSpark connection cable included. (See image e.1) D200 190 028 Neutral silicone electrode, single-use, for adults, iSpark connection cable included. (See image e.2) D200 190 029 Neutral silicone electrode, single-use, for infants, iSpark connection cable included.(See image f.) D200 190 031 2 pin-bipolar adapter for iSpark. (See image g.1) D200 190 032 3 pin-monopolar adapter for iSpark. (See image g.2) D200 190 007 iSpark bipolar resection cable - Delmont resectoscopes. (See image h.) D200 190 020 iSpark bipolar HF cable - flat square plug. (See image i.) Find all the available cables in our catalog. D100 400 005 Cart for iSpark electrosurgery unit. (See image j.)			
2.8	Application: Surgical endoscopy examinations. Intended use: The device is indicated for use by a healthcare professional in operative endoscopic procedures, in a healthcare center equipped with an appropriate setup.			

3. Sterilization process

Medical device supplied sterile: No
Device sterilization mode: Non-sterilizable but cleanable using a soft, dust-free, lint-free cloth, then disinfected using a medical product dedicated to plastic, metal and glass.
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: Yes

4. Storage and preservation 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.
Usage conditions: Room temperature: 10° to 30°C / Relative humidity: 30% to 75%, without condensation. Avoid direct sunlight. Atmospheric pressure: 70 kPa to 106 kPa.

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:** High-frequency alternating current generation for cutting and coagulation in surgical endoscopy. Follow the operating instructions for more information.

6.3 **Precautions for use:** Follow the operating instructions.

6.4 **Contraindications:** Follow the operating instructions.

7. Product additional information

N/A

8. List of appendices

- Labelling and traceability label (if applicable)
- EMED user manual (REF 900-289)
- CE certificate
- Declaration of conformity

9. Images

