

1. Company administrative information		
Review date: 2025-01		
1.1	Name: Delmont imaging	
1.2	Complete address: 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: 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, gynecology, urology, laparoscopy, arthroscopy, gastroenterology, argon and ThermoStapler®.	
2.6	Catalog references:	
Electrosurgical generators		
Upgradable iSpark+ generator 230V		
	Article reference	Characteristics
	D100 400 052	• See bellow
		Packaging
		1
Upgradable iSpark+ generator 110V		
	Article reference	Characteristics
	D100 400 053	• See bellow
		Packaging
		1

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 (including 1 with argon output), 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 argon gas socket, 1 argon probe socket, 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 V model) or 2 x T16 A / 250 V (110-120 V 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 Surgery 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
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		
	Spray coag	High-voltage non-contact monopolar coagulation	80	80W

Functionality	Name	Description	Number of effects	Maximum power
Bipolar cutting	Bi-cut	Bipolar cutting with different haemostasis effects	9	200W
Bipolar coagulation	Forced bi-coag	High-voltage bipolar coagulation (AutoStart/AutoStop function)	9	100 W
	Soft bi-coag	Low-voltage contact bipolar coagulation (AutoStart/AutoStop function)		120W
	Sciss bi-coag	Soft bipolar coagulation for work with bipolar scissors		200W
Programs available for iSpark+				
Article reference	Characteristics			Packaging
Surgery and Standard Argon programs				
D100 400 007	<ul style="list-style-type: none"> List of programs: - Surgery programs, installed by default - Standard Argon programs: Argon Cut / Argon Coag 			1
Surgery and UROGYN programs				
D100 400 028	<ul style="list-style-type: none"> List of programs: - Surgery programs, installed by default - UROGYN programs: Uro Cut / Uro Bi-Cut / Uro Coag / Uro Bi-Coag / Hystero Cut / Hystero Bi-Cut / Hystero Coag / Hystero Bi-Coag 			1
Surgery and Arthroscopy programs				
D100 400 032	<ul style="list-style-type: none"> List of programs: - Surgery programs, installed by default - Arthroscopy programs: Artro Cut / Artro Bi-Cut / Artro Coag / Artro Bi-Coag 			1
Surgery and Gastro Argon programs				
D100 400 009	<ul style="list-style-type: none"> List of programs: - Surgery programs, installed by default - Gastro programs: <ul style="list-style-type: none"> - standard: Polipo Cut / Papillo Cut / Muco Cut / Endo Spray/ Endo Coag / Endo Bi-Coag - specific to Gastro Argon: Pulse Argon / Endo Argon 			1
Surgery and ThermoStapler® programs				
D100 400 010	<ul style="list-style-type: none"> List of programs: - Surgery programs, installed by default - ThermoStapler® programs: ThermoStapler® / ThermoStapler® LAP 			1

Article reference	Characteristics	Packaging
Surgery and Gastro programs		
D100 400 011	<ul style="list-style-type: none"> • List of programs: - Surgery programs, installed by default - Gastro programs: Polipo Cut / Papillo Cut / Muco Cut / Endo Spray / Endo Coag / Endo Bi-Coag 	1
Surgery, UROGYN, Standard Argon and Gastro Argon programs		
D100 400 014	<ul style="list-style-type: none"> • List of programs: - Surgery programs, installed by default - UROGYN programs: Uro Cut / Uro Bi-Cut / Uro Coag / Uro Bi-Coag / Hystero Cut / Hystero Bi-Cut / Hystero Coag / Hystero Bi-Coag - Standard Argon programs: Argon Cut / Argon Coag -Gastro programs: <ul style="list-style-type: none"> - standard: Polipo Cut / Papillo Cut / Muco Cut /Endo Spray/ Endo Coag / Endo Bi-Coag -specific to Gastro Argon: Pulse Argon / Endo Argon 	1
Surgery, UROGYN and ThermoStapler® programs		
D100 400 033	<ul style="list-style-type: none"> • List of programs: - Surgery programs, installed by default - UROGYN programs: Uro Cut / Uro Bi-Cut / Uro Coag / Uro Bi-Coag / Hystero Cut / Hystero Bi-Cut / Hystero Coag / Hystero Bi- Coag - ThermoStapler® programs: ThermoStapler® / ThermoStapler® LAP 	1
Surgery, UROGYN and Arthroscopy programs		
D100 400 034	<ul style="list-style-type: none"> • List of programs: - Surgery programs, installed by default - UROGYN programs: Uro Cut / Uro Bi-Cut / Uro Coag / Uro Bi-Coag / Hystero Cut / Hystero Bi-Cut / Hystero Coag / Hystero Bi- Coag - Arthroscopy programs: Artro Cut / Artro Bi-Cut / Artro Coag / Artro Bi-Coag 	1
Surgery, UROGYN and Gastro programs		
D100 400 020	<ul style="list-style-type: none"> • List of programs: - Surgery programs, installed by default - UROGYN programs: Uro Cut / Uro Bi-Cut / Uro Coag / Uro Bi-Coag / Hystero Cut / Hystero Bi-Cut / Hystero Coag / Hystero Bi- Coag - Gastro programs: Polipo Cut / Papillo Cut / Muco Cut / Endo Spray / Endo Coag / Endo Bi-Coag 	1

Article reference	Characteristics	Packaging
Surgery, Standard Argon and ThermoStapler® programs		
D100 400 026	<ul style="list-style-type: none"> • List of programs: - Surgery programs, installed by default - Standard Argon programs: Argon Cut / Argon Coag - ThermoStapler® programs: ThermoStapler® / ThermoStapler® LAP 	1
Surgery, Gastro Argon, Standard Argon and ThermoStapler® programs		
D100 400 025	<ul style="list-style-type: none"> • List of programs: - Surgery programs, installed by default - Gastro programs: <ul style="list-style-type: none"> - standard: Polipo Cut / Papillo Cut / Muco Cut / Endo Spray / Endo Coag / Endo Bi-Coag - specific to Gastro Argon: Pulse Argon / Endo Argon - Standard Argon programs: Argon Cut / Argon Coag - ThermoStapler® programs: ThermoStapler® / ThermoStapler® LAP 	1
Surgery, UROGYN, Standard Argon and ThermoStapler® programs		
D100 400 016	<ul style="list-style-type: none"> • List of programs: - Surgery programs, installed by default - UROGYN programs: Uro Cut / Uro Bi-Cut / Uro Coag / Uro Bi-Coag / Hystero Cut / Hystero Bi-Cut / Hystero Coag / Hystero Bi-Coag - Standard Argon programs: Argon Cut / Argon Coag - ThermoStapler® programs: ThermoStapler® / ThermoStapler® LAP 	1
Surgery, Arthroscopy, Gastro Argon and Standard Argon programs		
D100 400 017	<ul style="list-style-type: none"> • List of programs: - Surgery programs, installed by default - Arthroscopy programs: Artro Cut / Artro Bi-Cut / Artro Coag / Artro Bi-Coag - Gastro programs: <ul style="list-style-type: none"> - standard: Polipo Cut / Papillo Cut / Muco Cut / Endo Spray / Endo Coag / Endo Bi-Coag - specific to Gastro Argon: Pulse Argon / Endo Argon - Standard Argon programs: Argon Cut / Argon Coag 	1

Article reference	Characteristics	Packaging
Surgery, UROGYN, Gastro and Arthroscopy programs		
D100 400 018	<ul style="list-style-type: none"> • List of programs: - Surgery programs, installed by default - UROGYN programs: Uro Cut / Uro Bi-Cut / Uro Coag / Uro Bi-Coag / Hystero Cut / Hystero Bi-Cut / Hystero Coag / Hystero Bi-Coag - Gastro programs: Polipo Cut / Papillo Cut / Muco Cut / Endo Spray / Endo Coag / Endo Bi-Coag - Arthroscopy programs: Artro Cut / Artro Bi-Cut / Artro Coag / Artro Bi-Coag 	1
Surgery, Gastro, Arthroscopy and ThermoStapler® programs		
D100 400 019	<ul style="list-style-type: none"> • List of programs: - Surgery programs, installed by default - Gastro programs: Polipo Cut / Papillo Cut / Muco Cut / Endo Spray / Endo Coag / Endo Bi-Coag - Arthroscopy programs: Artro Cut / Artro Bi-Cut / Artro Coag / Artro Bi-Coag - ThermoStapler® programs: ThermoStapler® / ThermoStapler® LAP 	1
Surgery, Gastro Argon and Standard Argon programs		
D100 400 021	<ul style="list-style-type: none"> • List of programs: - Surgery programs, installed by default - Gastro programs: <ul style="list-style-type: none"> - standard: Polipo Cut / Papillo Cut / Muco Cut / Endo Spray / Endo Coag / Endo Bi-Coag - specific to Gastro Argon: Pulse Argon / Endo Argon - Standard Argon programs: Argon Cut / Argon Coag 	1
Surgery, UROGYN, Arthroscopy and ThermoStapler® programs		
D100 400 022	<ul style="list-style-type: none"> • List of programs: - Surgery programs, installed by default - UROGYN programs: Uro Cut / Uro Bi-Cut / Uro Coag / Uro Bi-Coag / Hystero Cut / Hystero Bi-Cut / Hystero Coag / Hystero Bi-Coag - Arthroscopy programs: Artro Cut / Artro Bi-Cut / Artro Coag / Artro Bi-Coag - ThermoStapler® programs: ThermoStapler® / ThermoStapler® LAP 	1

Article reference	Characteristics	Packaging
Surgery, UROGYN, Gastro and ThermoStapler® programs		
D100 400 023	<ul style="list-style-type: none"> • List of programs: - Surgery programs, installed by default - UROGYN programs: Uro Cut / Uro Bi-Cut / Uro Coag / Uro Bi-Coag / Hystero Cut / Hystero Bi-Cut / Hystero Coag / Hystero Bi-Coag - Gastro programs: Polipo Cut / Papillo Cut / Muco Cut / Endo Spray / Endo Coag / Endo Bi-Coag - ThermoStapler® programs: ThermoStapler® / ThermoStapler® LAP 	1
Surgery, Arthroscopy, Gastro Argon, Standard Argon and ThermoStapler® programs		
D100 400 024	<ul style="list-style-type: none"> • List of programs: - Surgery programs, installed by default - Arthroscopy programs: Artro Cut / Artro Bi-Cut/ Artro Coag / Artro Bi-Coag - Gastro programs: <ul style="list-style-type: none"> -standard: Polipo Cut / Papillo Cut / Muco Cut /Endo Spray / Endo Coag / Endo Bi-Coag -specific to Gastro Argon: Pulse Argon / Endo Argon - Standard Argon programs: Argon Cut / Argon Coag - ThermoStapler® programs: ThermoStapler® / ThermoStapler® LAP 	1
All programs activated except ThermoStapler®		
D100 400 015	<ul style="list-style-type: none"> • List of programs: - Surgery programs, installed by default - UROGYN programs: Uro Cut / Uro Bi-Cut / Uro Coag / Uro Bi-Coag / Hystero Cut / Hystero Bi-Cut / Hystero Coag / Hystero Bi-Coag - Arthroscopy programs: Artro Cut / Artro Bi-Cut/ Artro Coag / Artro Bi-Coag - Gastro programs: <ul style="list-style-type: none"> -standard: Polipo Cut / Papillo Cut / Muco Cut /Endo Spray / Endo Coag / Endo Bi-Coag -specific to Gastro Argon: Pulse Argon / Endo Argon - Standard Argon programs: Argon Cut / Argon Coag 	1

Article reference	Characteristics	Packaging
All programs activated except Argon		
D100 400 012	<ul style="list-style-type: none"> • List of programs: - Surgery programs, installed by default - UROGYN programs: Uro Cut / Uro Bi-Cut / Uro Coag / Uro Bi-Coag / Hystero Cut / Hystero Bi-Cut / Hystero Coag / Hystero Bi-Coag - Gastro programs: Polipo Cut / Papillo Cut / Muco Cut / Endo Spray / Endo Coag / Endo Bi-Coag - Arthroscopy programs: Artro Cut / Artro Bi-Cut / Artro Coag / Artro Bi-Coag - ThermoStapler® programs: ThermoStapler® / ThermoStapler® LAP 	1
All programs activated		
D100 400 035	<ul style="list-style-type: none"> • List of programs: - Surgery programs, installed by default - UROGYN programs: Uro Cut / Uro Bi-Cut / Uro Coag / Uro Bi-Coag / Hystero Cut / Hystero Bi-Cut / Hystero Coag / Hystero Bi-Coag - Arthroscopy programs : Artro Cut / Artro Bi-Cut / Artro Coag / Artro Bi-Coag - Gastro programs: <ul style="list-style-type: none"> -standard: Polipo Cut / Papillo Cut / Muco Cut / Endo Spray / Endo Coag / Endo Bi-Coag -specific to Gastro Argon: Pulse Argon / Endo Argon - Standard Argon programs: Argon Cut / Argon Coag - ThermoStapler® programs: ThermoStapler® / ThermoStapler® LAP 	1

• Program specificities:				
Functionality	Name	Description	Number of effects	Maximum power
Monopolar cutting	Polipo cut	Alternating monopolar cutting and coagulation for polyp removal in endoscopic procedures	9	400W
	Papillo cut	Monopolar cutting used for Vater's papilla in endoscopic procedures		
	Muco cut	Monopolar cutting (pulsed current for a precise duration) for mucosectomy procedures		
	Artro cut	Monopolar cutting for arthroscopic procedures in a non-conductive fluid		
	Uro cut	Monopolar cutting for urological procedures in a non-conductive fluid		
	Hystero cut	Monopolar cutting for gynaecological procedures in a non-conductive fluid		
	Argon cut*	Argon-enhanced monopolar cutting		
Monopolar coagulation	Endo coag	Monopolar endoscopic coagulation for additional hemostasis in the event of polypectomy	9	40W
	Endo spray	Non-contact monopolar endoscopic coagulation for quick and localized homeostasis		25W
	Argon coag*	Argon-enhanced, non-contact, very superficial and gentle monopolar coagulation	80	80W
	Endo argon*	Very superficial and gentle enhanced-argon monopolar coagulation in endoscopic procedures, if risk of perforation	40	40W
	Pulse argon*	Precisely argon-pulsed monopolar coagulation in gastroenterology procedures, for thin walls		
	Artro coag	Monopolar coagulation for arthroscopy procedures in a non-conductive fluid	9	200W
	Uro coag	Monopolar coagulation for urological procedures in a non-conductive fluid		
	Hystero coag	Monopolar coagulation for gynaecological procedures in a non-conductive fluid		

*Argon programs' characteristics:
 - Argon quality: 4.8 (99,998%) or higher
 - Inlet gas pressure: 4-5 Bar
 - Gas outflow: 0.1 to 10L/min in 0,1L/min steps
 - Pressure: regulator with pressure sensor on cylinder

Functionality	Name	Description	Number of effects	Maximum power
Bipolar cutting	Uro bi-cut	Bipolar cutting for urological procedures in a conductive fluid	9	330W
	Hystero bi-cut	Bipolar cutting for gynaecological procedures in a conductive fluid		
	Artro bi-cut	Bipolar cutting for arthroscopy procedures in a conductive fluid		300W
Bipolar coagulation	Uro bi-coag	Bipolar coagulation for urological procedures in a conductive fluid	9	400W
	Hystero bi-coag	Bipolar coagulation for gynaecological procedures in a conductive fluid		
	Artro bi-coag	Bipolar coagulation for arthroscopy procedures in a conductive fluid		200W
	Endo bi-coag	Bipolar coagulation in endoscopy for gentle haemostasis		70W
ThermoStapler®	ThermoStapler®	Bipolar mode to seal large blood vessels before cutting in open surgery	9	300W
	ThermoStapler® LAP	Bipolar mode for laparoscopic procedures for optimal sealing		60W
<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) / Argon socket: Nickel-plated brass Latex free. Phtalates free. Active substances free. Products of animal or biological origin free.			
	Related devices and accessories: <ul style="list-style-type: none"> D100 400 003 Wired two-pedal footswitch (Cut & Coag). (See image d1.). D100 400 004 Wired one-pedal footswitch (Coag). (See image d2.). D200 190 028 Neutral silicone electrode, single-use, for adults, iSpark connection cable included. (See image e.1) D200 190 027 Neutral silicone electrode, reusable, 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	<p>Application: Surgical endoscopy examinations.</p> <p>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.</p>
-----	---

3. Sterilization process

	<p>Medical device supplied sterile: No</p> <p>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.</p> <p>Is this medical device indicated/used for newborns: No</p> <p>Is this medical device indicated/used for premature newborns: No</p> <p>Is this medical device indicated/used for infants: Yes</p>
--	--

4. Storage and preservation conditions

	<p>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.</p> <p>Expiry date: The storage time of the device is not limited.</p> <p>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.</p>
--	---

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

	<ul style="list-style-type: none"> - Labelling and traceability label (if applicable) - EMED user manual (REF 900-289) - CE certificate - Declaration of conformity
--	---

9. Images

