Instructions for Use
(Single-use electrosurgery electrode)

1. Product Name
: LAPALEX-P

2. Model Name

No.	Model Name	Hook Type	Remark
1	GYP-S5x350	SPATULA	Optional - Suction/Irrigation Button change type
2	GYP-S5x450	SPATULA	
3	GYP-J5x350	J-HOOK	
4	GYP-J5x450	J-HOOK	
5	GYP-L5x350	L-HOOK	
6	GYP-L5x450	L-HOOK	
7	GYP-B5x350	BASIC	
8	GYP-B5x450	BASIC	

3. Intended Purpose
: A single-use electrosurgery electrode has application in minimally invasive procedures to facilitate tissue dissection, coagulation, irrigation, and fluid evacuation through a common trocar sleeve.

3.1. Clinical Benefit
- Improvement of satisfaction as the cosmetic outcome aspect
- Reduction of post-operative pain
- Increase of safety outcome than conventional multi-port laparoscopic surgery

4. Intended User

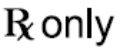
Job	Doctor
Age	Not relevant
Gender	Not relevant
Education	Professional doctor license
Knowledge	Knowledge of laparoscopic surgery
Language	User is able to read the manual in international language.
Experience	Experience of laparoscopic surgery

5. Intended Patient Population

Age	Adult
Weight	Not relevant
Gender	Not relevant
Nationality	Not relevant
Language	Not relevant
Medical condition	A patient requiring laparoscopic surgery

6. Symbol Description

No.	Symbol	Title of symbol	Description of symbol
1		Reference number	Indicates the product model.
2		Product component	Indicates the product component.
3		Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
4		Medical device	Indicates the item is a medical device
5		Unique device identifier	Indicates a carrier that contains Unique Device Identifier information
6		Date of manufacture	Indicates the date when the medical device was manufactured
7		Manufacturer	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC
8		Follow instructions for use	Indicates the need for the user to consult the instructions for use
9		Caution	To signify a general warning
9		Authorised representative in the European Community	Indicates the authorized representative in the European Community/European Union
11		CE Marking	"CE" which literally means "European Conformity"
12		Temperature Limit	Indicates the temperature limits to which the medical device can be safely exposed.
13		Humidity limitation	Indicates the range of humidity to which the medical device can be safely exposed.
14		Atmospheric pressure limitation	Indicates the range of atmospheric pressure to which the medical device can be safely exposed.
15		WEEE Marking	The product should not be discarded as unsorted waste but must be sent to separate collection facilities for recovery and recycling.
16		Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.

No.	Symbol	Title of symbol	Description of symbol
17		Sterilized using ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide.
18		Type BF applied part	Type BF applied part
19		Use-by date	Indicates the date after which the medical device is not to be used.
20		Fragile-handle with care	Indicates a medical device that can be broken or damaged if not handled carefully
21		This way up	Indicates that the packaged product has been moved to the correct vertical position.
22		Keep dry	Indicates medical devices that require protection from moisture.
23		Product specification	Indicates the product specifications
24		Do not use if package is damaged and consult instructions for use	Indicates that a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information NOTE 1 This symbol can also mean “Do not use if the product sterile barrier system or its packaging is compromised”. NOTE 2 For products that do not have instructions for use, the recommendation to consult them does not
24		Prescription Use	Indicates the prescription use in accordance with 21CFR801.15 (c)(1)(i)(F) and 21CFR801.109(b)(1)

7. Precautions and Warnings

- Disposable. Do not reuse.
- Please check the product packaging carefully before use. If the product packaging is damaged, the product can no longer be used.
- Please check the marking on the sterilization packaging box. A “red” mark means that this product has not been sterilized with ethylene oxide and cannot be used directly in hospitals, and a “blue” mark means that it has been sterilized with ethylene oxide.
- Please check the product's expiration date before use. The product's expiration date is 3 years, and products that have passed the expiration date cannot be used.
- Do not press the Suction Button and Irrigation Button at the same time.
- This product is a single-use medical device and cannot be reused or re-sterilized after use.
- Dispose of used products in accordance with relevant requirements for hospital equipment waste.
- A physician with specialized knowledge of suction pumps under the guidance of an experienced professional.
- This product should only be used by a physician with specialized knowledge of inhalers under the guidance of an experienced professional.
- The user and/or patient that any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.
- This device shall be used with an electrosurgical unit (ESU) that has been tested, and conforms with its relevant IEC 60601 series of standards including its collaterals, particulars, national deviations and differences. (e.g. IEC 60601-1, IEC 60601-2-2, etc.)
- Do not exceed the output settings specified by the electrosurgical generator manufacturer. Excessive power settings or prolonged activation may result in excessive thermal damage, patient burns, or unintended tissue injury. Always use the lowest effective power setting and minimize activation time. Refer to the instructions for use (IFU) of the electrosurgical generator for detailed guidance on output settings and activation duration.
- Improper setup or use of the electrosurgical generator or return electrode may result in patient burns or injury. For additional instructions on proper use, refer to the instructions for use (IFU) of the electrosurgical generator and return electrode.
- This device is a monopolar electrosurgical instrument. A return electrode (neutral electrode) must be used during operation to prevent patient burns or injury.
- This device is designed for single-use only. Re-using the device may pose serious risks to both patients and users due to technical factors identified by the manufacturer:
  Failure to achieve complete decontamination can lead to cross-infection between patients, potentially causing severe medical conditions such as bacteremia, pneumonia, diarrhea, abdominal pain, and spontaneous bacterial peritonitis.

7.1. Contraindication

- These instruments are not intended for contraceptive coagulation of fallopian tissue but may be used to achieve hemostasis following transection of the fallopian tube.
- These instruments are not intended for use when minimally invasive techniques are contraindicated

7.2 Limitation

1) Compatibility Device

The device can be available in all products with suction/irrigation pump and electrosurgical generator on the market.

The device connector (Electrode Cable) is designed to be compatible with standard electrosurgical generators.

The device is compatible with irrigation pumps equipped with flexible tubing connectors designed to connect to Luer-lock connectors or barbed connectors (e.g., approximately 8 mm outer diameter).

The device is also compatible with suction pumps equipped with flexible tubing connectors designed to connect to barbed connectors (e.g., approximately 8 mm outer diameter).

However, the size of the connecting tubes or connectors shall be following;

Category	Diameter	Power
Suction	Ø8	**3PIN**
Irrigation	Ø8	
Electrode	Ø5.4	

Category	Specification	
Suction Pump	Vacuum Flow	Max. -480mmHg
	Flow Range	Max. 2.2l/min.
Irrigation Pump	Pressure Range	Max. 300mmHg
	Flow Range	Max.0.1~2.2l/min.
Electrosurgical Unit	RF Power Output	Cut: Max. 200W
		Coag: Max. 80W
Trocar	Compatible Trocar Minimum/Maximum Diameter	Ø5.5~Ø6

8. Side Effect

: Complications from thermal injury

9. Device Description

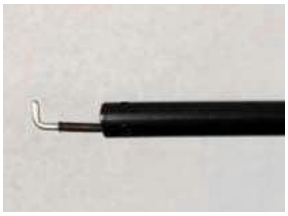
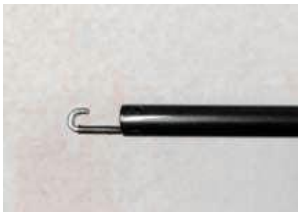
1) General Description

: When high frequency energy from electrosurgery penetrates the electrode through cables and connectors, the high frequency current from the electrode is applied to the human body.
It is used to cauterize tissues using thermally polarized methods that are applied and heat generated by biological resistance.

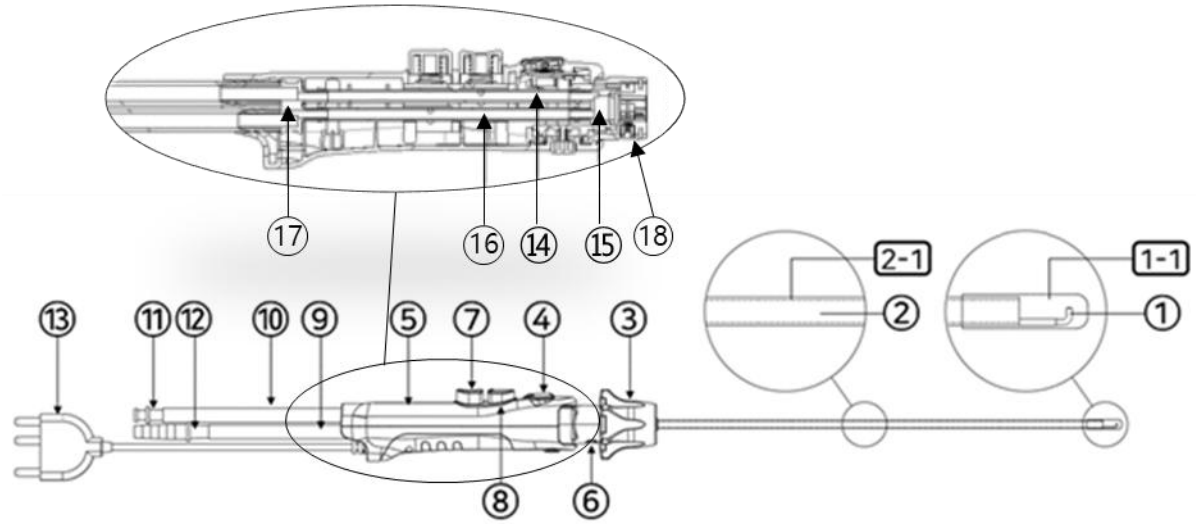
2) Device Feature

* Suction/Irrigation Button change type
: Only different with buttons location. And others function all same.

* Hook Type

Hook			
			
L-hook	J-Hook	SPATULA	BASIC

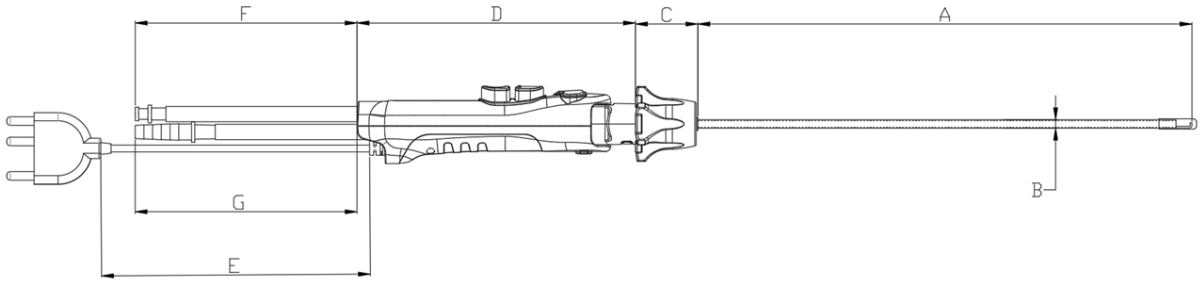
3) Part Description



No.	Name of part	Function	Remark
1	Hook	Tips for Incision and Coagulation of Tissue	L-HOOK J-HOOK SPATULA BASIC
1-1	Hook Cover	Caps protecting hooks	
2	Shaft	Pathways for Inhalation and Injection of Liquid	
2-1	Shaft Insulation Cover	Cover to protect shaft current from external exposure	
3	Rotator	Exposure control of hooks and parallel and rotational motion control of shaft	
4	Electrode Button	Buttons for manipulating incision and coagulation	
5	Handle	Handles for Using the Instrument	
6	Assembly Button	When the shaft and handle are detached. Buttons used	
7	Fluid Control Button 1	Button for controlling liquid suction or irrigation. - Basic Type: Suction Button - Suction/Irrigation Button change type: Irrigation Button	
8	Fluid Control Button 2	Button for controlling liquid suction or irrigation. - Basic Type: Irrigation Button - Suction/Irrigation Button change type: Suction Button	
9	Suction Tube	Liquid suction tube	
10	Irrigation Tube	Liquid irrigation tube	
11	Irrigation Connector	Connector to connect to irrigation pump	
12	Suction Connector	Connector to connect to suction pump	

13	Electrode Cable	Cable to Electrosurgery Machine	3 Pin type
14	Irrigation Inner Tube	Internal fluid passage of the handle	
15	Front Connector	Fix-to-internal tube connection	
16	Suction Inner Tube	Internal passage for aspirated fluid in the handle	
17	Rear Connector	The part where the suction tube and irrigation tube are connected	
18	O-ring	Seal at the fix-to-internal channel connection	

4) Dimensions



No	Model Name	Dimensions (mm)						
		A	B	C	D	E	F	G
1	GYP-S5x350	350	5.4	37	165	2830	200	200
2	GYP-S5x450	450	5.4	37	165	2830	200	200
3	GYP-J5x350	350	5.4	37	165	2830	200	200
4	GYP-J5x450	450	5.4	37	165	2830	200	200
5	GYP-L5x350	350	5.4	37	165	2830	200	200
6	GYP-L5x450	450	5.4	37	165	2830	200	200
7	GYP-B5x350	350	5.4	37	165	2830	200	200
8	GYP-B5x450	450	5.4	37	165	2830	200	200

10. How to Use

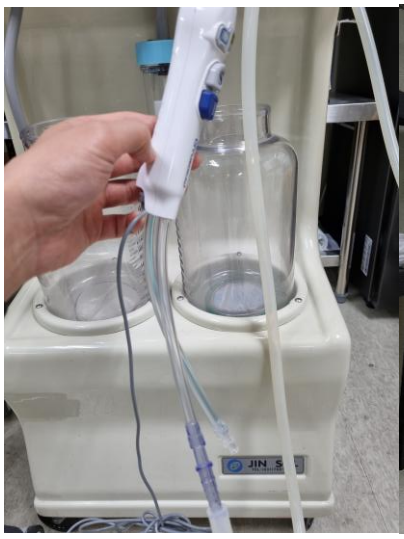
10.1. Pre-use preparation

1) Read the instructions before use
2) Check the packaging status before use
- Package damage
- Shelf-life period is valid

3) Should be used by doctor or trained specialists to ensure proper use of the instrument.

10.2. Operating method

1) Remove the handle and shaft from the package.
2) Connect the suction line and irrigation line to the liquid line connection part extending from the bottom of the handle.



3) Connect the three-prong connector at the end of the electrosurgical cable to the hand-controlled output part of the electrosurgical device.
4) Use as follows depending on the purpose.
- Electrode Tip Exposure: To adjust the exposure of the electrode tip, slide the shaft rotator handle forward and backward to advance or reverse the shaft cover.

- Electrode Tip Rotation: Turn the shaft rotor handle.

- Liquid suction/irrigation: Press suction button for liquid aspiration (S).
  Press the irrigation button to vent the liquid.(I)
- Using an electrosurgical device: To use the electrode tip, press the electrode button on the handle. Press the Cutting button when cutting tissue, and the Coag button when coagulating tissue.

5) After using the tissue cutting, coagulation, or liquid suction/irrigation function, observe the area to confirm the result.

10.3. How to archive and manage after use

1) Disconnect the product from the electrosurgical device.
2) Since it is a single-use device, dispose it after use.

10.4. Troubleshooting

: If you have a problem, contact your local dealer.

10.5. Cleaning and disinfection

: The device is single-use device. Do not re-use after cleaning and disinfection.

10.6. Disposal

: Since it is a single-use device, dispose it after use.

The device contains components that are classified as industrial waste, and caution must be exercised when disposing of this product as the disposal of certain components may result in environmental pollution. Do not dispose of this equipment as general industrial or household waste. Ensure that you comply with applicable regulations in your region when disposing of all or part of this product. For more information on waste disposal, contact GAYOUNG Medical Co., Ltd. or an official agency in your region.

11. Specifications

Item	Specification
Maximum rated accessory voltage	1,000 Vp
Single use only / Multiple use	Single use device
Sterilization	Ethylene oxide (EO) GAS Sterilization
Mode of operation	Continues operation
Suitability for use in an oxygen rich environment	No suitable
Applied part	Hook
Environmental Condition	1) Operation Environmental condition ① Ambient temperature: 10℃~40℃ ② Ambient humidity: 30 ~ 75% RH ③ Atmospheric pressure: 70kPa ~ 106kPa 2) Transport Environmental condition ① Ambient Temperature: -25℃ ~ 55℃ ② Ambient Humidity: 10% ~ 90% ③ Atmospheric Pressure: 70kPa ~ 106kPa 3) Storage Environmental condition ① Ambient Temperature: -25℃ ~ 55℃ ② Ambient Humidity: 10% ~ 90% ③ Atmospheric Pressure: 70kPa ~ 106kPa

12. Electromagnetic Compatibility (EMC)

This device is designed to be in compliance with IEC 60601-1-2, which contains electromagnetic compatibility (EMC) requirements for medical electrical equipment. The limits for emissions and immunity specified in this standard are designed to provide reasonable protection against harmful interference in a typical facility.
The system complies with the applicable essential performance requirements in IEC 60601-1 and 60601-2-2. Results of immunity testing show that the essential performance of the system is not affected under the test conditions described in the following tables.

⚠	WARNING · Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally. · Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation. · Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

- **Electromagnetic Emissions**

This device is intended for use in the electromagnetic environment specified below. The customer or the user of the system should ensure that it is used in such an environment.

Emission Test	Compliance	Electromagnetic Environment – Guidance
RF emissions CISPR 11	Group 1	This device does not use RF energy. Therefore, there are not a RF emissions and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	This device is suitable for use in all establishments other than domestic and those directly connected to a low-voltage power supply network that supplies buildings used for domestic purposes. However, heed the following warning: This device is intended for use by healthcare professionals only. This equipment may cause radio interference or may disrupt the operation of nearby equipment.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	In compliance	

- **Electromagnetic Immunity**

This device is intended for use in the electromagnetic environment specified below. The customer or the user of the system should ensure that it is used in such an environment.

Immunity Tests	IEC 60601 Test Level	Compliance	Electromagnetic Environment – Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2, 4, 8, 15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient / burst IEC 61000-4-4	±2 kV for power supply lines 100 kHz repetition frequency	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5kV, ±1 kV line(s) to line(s) ±0.5 kV, ±1 kV, ±2 kV line(s) to ground	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % U_T: 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T: 1 cycle and 70 % U_T: 25/30 cycles Single phase: at 0° 0 % U_T: 25/30 cycle	0 % U_T: 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0 % U_T: 1 cycle 70 % U_T: 25/30 cycles Single phase: at 0° 0 % U_T: 25/30 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device is powered from an uninterruptible power supplied or a battery.
Power frequency (50/60Hz) Magnetic fields IEC 61000-4-8	30 A/m, 50/60 Hz	30 A/m, 50/60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Immunity Tests	IEC 60601 Test Level	Compliance	Electromagnetic Environment – Guidance
Proximity magnetic fields in the frequency range 9 kHz to 13.56 MHz immunity IEC 61000‑4-39	8 A/m 30 kHz CW Modulation 65 A/m 134.2 kHz PM 2.1 kHz 7.5 A/m 13.56 MHz PM 50 kHz	8 A/m 30 kHz CW Modulation 65 A/m 134.2 kHz PM 2.1 kHz 7.5 A/m 13.56 MHz PM 50 kHz	Resistance to magnetic fields was tested and applied only to surfaces of enclosures or accessories accessible during intended use.
Conducted RF IEC 61000-4-6	3 Vrms 0.15 MHz to 80 MHz 6 Vrms in ISM and amateur radio bands between 0.15 MHz and 80 MHz 80% Am at 1 kHz	3 Vrms 0.15 MHz to 80 MHz 6 Vrms in ISM and amateur radio bands between 0.15 MHz and 80 MHz 80% Am at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF and Proximity fields from Rf wireless communications equipment IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz 80 % AM at 1 kHz	10 V/m 80 MHz to 2.7 GHz 80 % AM at 1 kHz	The interface between the patient physiological signal simulation, if used, and the ME Equipment or ME System shall be located within 0.1 m of the vertical plane of the uniform field area in one orientation of the ME Equipment or ME System.
	385 MHz (18 Hz Pulse Modulation)	27 V/m	
	450 MHz (FM +/ - 5 kHz deviation1 kHz sine or 18 Hz Pulse Modulation)	28 V/m	

Immunity Tests	IEC 60601 Test Level	Compliance	Electromagnetic Environment – Guidance
	710 MHz to 780 MHz (217 Hz PM)	9 V/m	
	810 MHz to 930 MHz (18 Hz PM)	8.5 V/m	
	1720 MHz to 1970 MHz, 2450 MHz (217 Hz PM)	28 V/m	
	5240 MHz to 5785 MHz (217 Hz PM)	9 V/m	

※ Note: This device is not life-supporting equipment.

※ Note: Uᴛ is the A.C. mains voltage prior to application of the test level.

※ Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

- **Recommended Separation Distances**

The system is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the system as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter (W)	Separation Distance According to Frequency of Transmitter (m)	
	150 kHz to 80 MHz d=1.2 √P	80 MHz to 2.7 GHz d=2.0 √P
0.01	0.12	0.20
0.1	0.38	0.63
1	1.2	2.0
10	3.8	6.3
100	12	20

For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by

absorption and reflection from structures, objects, and people.

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13. Website

Instruction of the safety and performance can be found on the following website

http://www.gymed.co.kr/doc_eng/sub2_2.php