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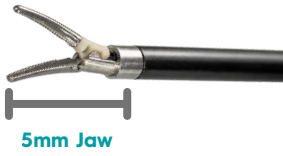
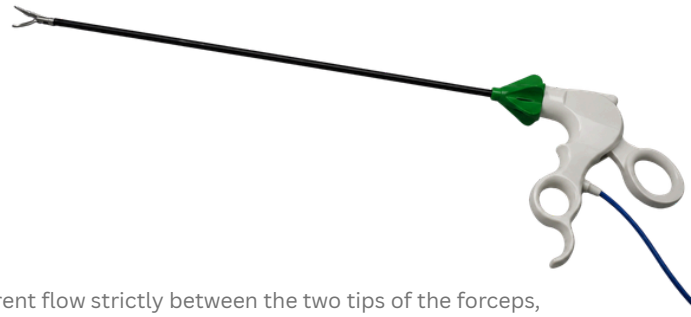
Disposable Laparoscopic Bipolar Forceps



Instructions for Use

Product Description

The Disposable Laparoscopic Bipolar Forceps are sterile, single-use electrosurgical instruments designed to conduct high-frequency (HF) current from an electrosurgical unit (ESU) to a surgical site. These devices feature integrated cables with a Valleylab-compatible plug for direct connection to bipolar ESU outputs. The shaft and handle are engineered with insulation thickness that meets IEC 60601-1 and IEC 60601-2-2 safety standards.



Clinical Benefits

- **Controlled Hemostasis:** Provides precise electrocoagulation by limiting current flow strictly between the two tips of the forceps, significantly reducing the risk of accidental burns to surrounding tissues.
- **Operative Efficiency:** Multifunctional design allows for simultaneous grasping, dissection, and coagulation, which minimizes the need for instrument changes and reduces overall operative time.
- **Lower Power Requirement:** Bipolar technology requires approximately 25% to 33% of the current used in monopolar electrosurgery, enhancing patient safety.
- **No Grounding Pad Required:** Eliminates the risk of site burns associated with patient return electrodes.
- **Healing and Recovery:** The use of bipolar electrosurgery may facilitate accelerated tissue healing and a reduction in the duration of postoperative hospital stays by minimizing lateral thermal damage.

Intended User

This device is restricted for use by qualified, specially trained doctors or surgeons who are familiar with laparoscopic techniques and electrosurgical safety.

Inspections

Before use, the following inspections must be performed; if any inspection fails, discard the device:

- **Integrity Check:** Visually inspect the instrument for damage such as cracks, breaks, or peeling in the shaft insulation.
- **Cable & Connection:** Ensure the integrated cable and plug are free of kinks or exposed wiring.
- **Surface Quality:** Confirm the tips are free of sharp edges, pits, or deep scratches that could cause unintended tissue trauma.
- **Functionality:** Test the handle and jaw mechanism to ensure smooth opening and closing before insertion into the trocar.

Patient Population

- **General:** Suitable for use in both adult and pediatric patient populations.

Contraindication

Electrosurgery is potentially hazardous for patients with active implants such as pacemakers, neurostimulators, or AICDs; consult a specialist before use.

Single-Use/ Disposable Product

- **Sterility:** Supplied sterile via Ethylene Oxide (EO) gas.
- **Single-Use Only:** Strictly for one-patient use. Do not reuse, reprocess, or re-sterilize.

Disposal

- No special decomposition or disposal required for these devices. Follow local hospital protocols to discard the device.

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Shelf Life, storage and Transportation

The Disposable Laparoscopic Bipolar Forceps have a shelf life of three years and must be stored in a clean, cool, dry area at temperatures between 5°C and 30°C. Maintain relative humidity levels between 30% and 70% while protecting the devices from direct sunlight and mechanical damage. Because they are delicate medical instruments, they should be handled with extreme care at all times.

Performance Claims

- **Reliable Insulation:** Conforms to IEC 60601 series for electrical safety, preventing alternating current paths and accidental burns.
- **Material Quality:** High-grade stainless steel construction provides the necessary rigidity for mechanical dissection and grasping.
- **Latex-Free:** Manufactured without natural rubber latex to prevent allergic reactions.
- **Safe Interaction:** Designed to prevent "never-events" by mitigating clinical hazards through bipolar energy delivery.

Adverse event

- Inform the relevant competent authority and/or manufacturer of the device in case of any adverse event during the device use.

Undesirable Side Effects

There are no known side effects associated with the device when used as intended by a professional. However, improper use may lead to unexpected tissue burns or injuries due to insulation failure or incorrect generator settings.

Precautions

Before connecting devices to an electrosurgical unit, make sure that the unit has been switched off or is in standby mode. Disregarding these instructions may lead to burns and electrical shock. Leave device in holster when not in use. Never use the devices in the presence of flammable or explosive substances. Do not touch any other metallic instruments, trocar sleeves, optics or the likes during use. Always use bipolar devices with bipolar output of the generator.

Warnings

- **Explosion Hazard:** Never use in the presence of flammable gases, liquids, or oxygen-enriched environments.
- **Voltage Limit:** Do not exceed a generator setting of 500Vp for bipolar voltage to avoid insulation breakdown.
- **Contact Safety:** Do not touch other metallic instruments (e.g., trocars, optics) while the device is activated.
- **Device Placement:** The device must not be laid directly on the patient's body when not in use.
- **Risks of Reuse:** Reusing disposable instruments may lead to material degradation, loss of insulation integrity, or cross-contamination and infection.

Preparation for Use

- **Check Packaging:** Verify the sterile barrier is intact and the "Use By" date has not passed.
- **ESU Connection:** Ensure the electrosurgical unit is switched off or in standby mode before connecting the forceps.
- **Generator Settings:** Set the generator to the lowest possible power setting required to achieve the desired clinical effect.
- **Trocar Insertion:** Insert the forceps through a compatible trocar sleeve; ensure the contact surfaces are visible before activation.
- **Activation:** Ensure the tips are firmly grasping the target tissue before pressing the footswitch to activate the HF current.

Symbols	Meaning
	Latex Free
	Single Use
	Keep Dry
	Sterile by EO
	See Instructions For Use
	Humidity Limits
	Reference Number
	Batch Number
	Keep Away From Sunlight
	Temperature Limits

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