

FAQ

Frequently Asked Questions

COMPETITIVE ANALYSIS



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The ConMed device incorporates a proximity switch that activates electrocautery current whenever the tines of the forceps are approximated. There are several problems with this type of forceps:

1. This interferes with the normal use of bipolar forceps, which are also used to pick up and move objects to and from the
2. Surgical site and dissection. Inadvertent activation could be dangerous.
3. The ConMed design incorporates the switch into the forceps requiring the surgeon to use only the forceps provided
4. by ConMed. Surgeons often have their favorite forceps with which they are comfortable and proficient.
The ConMed system is compatible with only a handful of electrocautery generators.
5. The ConMed system requires the use of a special cable which must be purchased separately.

The Valleylab™ generators incorporate an impedance testing circuit that can automatically activate bipolar forceps when the impedance is below a predefined value. Problems with this are similar to the ConMed device described above.



BiPAD[®] Bipolar Electrocautery Forceps Cord
with Integrated Hand Activation.

Make the "switch" NOW.[™]

FAQ

Frequently Asked Questions

BiPAD[®] **HAND ACTIVATED DISPOSABLE CORD** (cont'd)



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Make the "switch" NOW.[™]

Is the **BiPAD**[®] Hand Switch adjustable for the size/style of forceps?

Yes. The length and the style, straight or bayonet, of the forceps can vary. This can require a longer or shorter actuator arm for comfort. The length of the actuator arm can be adjusted by pushing/pulling the arm through the actuator housing. Hold the forceps in the usual way, then adjust the length of the arm until it is comfortable. Most surgeons adjust the length of the arm so that the tip of the actuator arm (the mitt) touches the crease between the last two phalanges of the second finger. Note that the best way to adjust the length of the forceps is to hold the main housing and the actuator assembly with one hand, applying enough pressure to keep the actuator arm from sliding off of the main housing. Hold the actuator arm with your other hand and slide inward (shortening) or outward (lengthening) as necessary.

Is the **BiPAD**[®] Hand Switch adjustable to accommodate a range of surgeon preferences?

Yes. The ergonomically-designed actuator arm can be fitted to the inner curve of the surgeon's finger or fingertip or third digit tip, allowing the surgeon to hold the forceps in their usual, preferred manner.

Does the **BiPAD**[®] Hand Switch accommodate left or right-handed surgeons?

Yes. The forceps can be attached either direction to accommodate either right or left-handed use.

What are the indications for the use of **BiPAD**[®] Hand Switch?

The Hand Activated Bipolar Electrocautery Cord should be used by surgeons only. Any use of this device for tasks other than for which it is indicated may result in damage or injury.

Will **BiPAD**[®] produce an irrigating version?

Yes.

How easy is conversion to **BiPAD**[®] Hand Switch?

Converting is as simple as replacing your existing disposable cord with **BiPAD**[®] the cord.

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BiPAD[®] HAND ACTIVATED DISPOSABLE CORD



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What is the BiPAD[®] Hand Activated Disposable Cord?

Make the "switch" NOW.[™]

BiPAD[®] (BiPolar Activation Device) is a medical device consisting of a sterile cord that connects your bipolar forceps to the existing electrocautery generator while providing a hand switch that can replace or supplement the foot pedal.

BiPAD[®] provides surgeons with the first and only practical hand-activated switch for bipolar electrocautery, thereby liberating them from the foot pedal.

Do I need a special electrocautery generator to use the BiPAD[®]?

No. BiPAD[®] works with most existing generators that employ the Valleylab composite bipolar plug, including Ethicon and Bovie bipolar generators. It also works with most Codman Malis generators. You will need to use a BiPAD[®] "Y" connector for use with Codman/Malis bipolar electrocautery units.

Contact us at support@bipadsurgical.com to determine if your generators are compatible.

Do I need a special forceps?

No. The Hand Activated Disposable Bipolar Electrocautery Cord is an electrocautery accessory designed to be universal when used with standard "two-pronged" bipolar non-irrigating two-prong connector forceps.

Can I still use the foot pedal?

Yes. BiPAD[®] is designed to accommodate surgeon preference and can be used with or without the foot pedal. However, we expect the foot pedal will go the way of the monopolar foot pedal and be eliminated.

Is the BiPAD[®] Hand Switch adjustable for the size of the hand?

Yes. A larger hand usually requires a longer actuator arm. The length of the BiPAD actuator arm can be adjusted by pushing/pulling the arm through the actuator housing. Adjust the length of the arm until it is comfortable. Most surgeons adjust the length of the arm so that the tip of the actuator arm (the mit) touches the crease between the last two phalanges (ie, the distal and the intermediate phalanges) of the second finger. Note that the best way to adjust the length of the forceps is to hold the main housing and the actuator assembly with one hand, applying enough pressure to keep the actuator arm from sliding off of the main housing. Hold the actuator arm with your other hand and slide inward (shortening) or outward (lengthening) as necessary.

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ELECTROCAUTERY BASICS (cont'd)



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What is bipolar electrocautery important?

Bipolar electrocautery is vitally important in all open surgeries (i.e., non-endoscopic surgeries) [1] because it provides a means of controlling hemorrhage without damaging surrounding tissues.

What type of surgery requires forceps electrocautery?

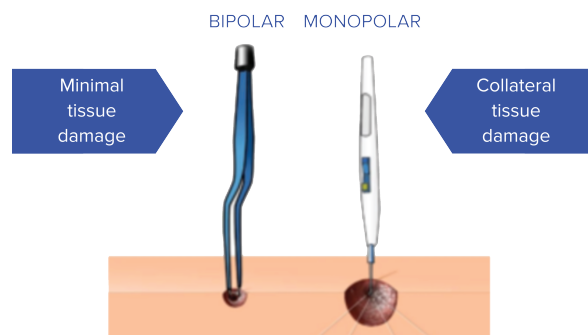
Surgeries that utilize bipolar forceps electrocautery: Almost all open surgeries require bipolar electrocautery. These are surgeries in which an incision is made to provide exposure. Most surgeries are open.

Surgeries that do not utilize bipolar forceps electrocautery: Laparoscopic and endoscopic procedures may not use bipolar forceps electrocautery.

What the current challenges of bipolar electrocautery?

Current systems rely on a foot pedal for the activation of the generator. This presents a number of challenges that may create safety issues:

- Finding the foot pedal can delay activation, which may lead to blood loss.
- Misplacement of foot pedal often requires operating room staff to crawl on the floor under the operating table to relocate the foot pedal. The area under the operating table is unsterile and dirty and exposes staff to pathogens. This also delays activation and distracts the surgeon.
- Surgeons may activate the wrong foot pedal in search of the bipolar electrocautery foot pedal.
- Prolonged surgeries and foot pedal distractions contribute to physician fatigue.



Bipolar forceps electrocautery is generally accepted as the *most accurate form of electrocautery*.

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ELECTROCAUTERY BASICS



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What is electrocautery?

- Electrocautery is the process of passing an electrical current through body tissues during surgery in order to control hemorrhage.
- Electrocautery is essential for all types of surgery.
- Electrocautery is the most commonly used surgical technique for controlling hemorrhage during surgery.
- Thermal injuries that lead to morbidity and mortality can occur.

What is bipolar versus monopolar electrocautery?

	BIPOLAR	MONOPOLAR
OVERVIEW	<p>Bipolar forceps electrocautery is used for very precise hemostasis. It is more precise because electricity does not spread in all directions from the tip to the grounding pad as in monopolar electrocautery.</p> <p>Instead, with bipolar forceps electrocautery, electrical current passes only from one tip of the forceps to the other.</p> <p>Only the tissue between the tips of the forceps is exposed to the electrocautery current. This reduces collateral damage and reduces injury to other parts of the body such as cardiac defibrillators and joint implants. These can be damaged when monopolar electrocautery current pass through them on its way to the grounding pad in the thigh.</p>	<p>Monopolar electrocautery passes current through the patient's body to cauterize at the location of surgery. The monopolar pencil contains one electrode, the other is a grounding pad usually attached the thigh of the patient.</p> <p>The surgeon touches the pencil electrode to the point of hemorrhage and presses a button on the pencil. This button activates electrosurgery current which then passes from the tip of the pencil electrode in all directions to cauterize everything in the vicinity. The current then passes through the patient's body to the grounding pad on the thigh.</p>
POINT OF CONTACT	Two contacts with current flow limited to the space between the contacts, tips of forceps.	A single point of contact with body tissues and a grounding pad with electrical current spreading out in all directions from the point of contact.
TISSUE DAMAGE	<p>More Precise.</p> <p>Less tissue damage and is therefore essential for cautery around nerves, blood vessels and vital organs like the brain, spinal cord and heart.</p>	<p>Less Precise.</p> <p>Generally the accepted form of electrosurgery for dissection. Current can spread unpredictably, damaging vital structures.</p>
CONTRA-INDICATIONS	None.	Pacemaker, metal implants
RISK OF PATIENT BURNS	Low risk.	Present.
RISK OF OR FIRE	Low risk.	Present.
DESSICATION EFFECT	Superior.	Inferior.