

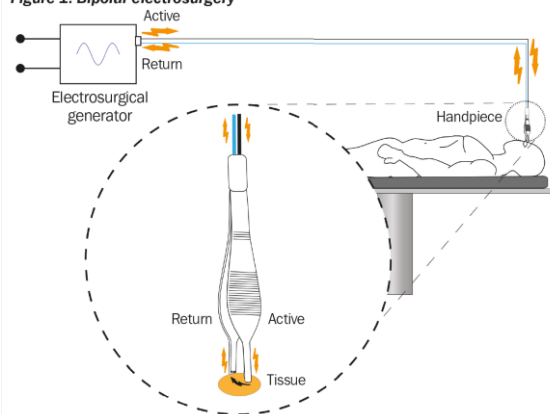
INSTRUCTIONS FOR USE OF STERILE/NON STERILE SINGLE USE BIPOLAR FORCEPS WITH & WITHOUT CABLES

PROLOGUE

An electrosurgical bipolar forceps is used in Electrosurgery to cutting and coagulating with accessories and intended to remove tissue and control bleeding by use of high/low-frequency electrical current. RB Medikal Instruments' bipolar forceps are available in a wide variety of designs both (European & American pattern), with & without cables, length and tip sizes to cover a wide range of surgical applications. They are precision crafted from the finest grade stainless steel and coated with nylon powder to provide superior control and safety.

ATTACHMENTS

Figure 1. Bipolar electrosurgery



INTENDED USE

An electrosurgical bipolar forceps is used in Electrosurgery to cutting and coagulating with accessories and intended to remove tissue and control bleeding by use of high/ low-frequency electrical current.

Note: Electrosurgical instruments should be used only by individuals who are trained and licensed to use such devices

INSPECTION OF FORCEPS

It is very important to examine carefully each Electro surgical instrument for breaks, cracks or malfunctions before use. It is especially essential to check areas such as blades, points, ends, stops and snaps as well as all movable parts. Do not use damaged instruments. Never attempt to make repairs yourself. Any repairs made by the customer may void the warranty. Service and repairs should be referred to trained qualified persons only. Refer

questions about repair to the manufacturer.

CLEANING BEFORE PACKAGING

Dip cleaning cloth in 70%IPA and 30% distilled water mix solution and clean/disinfect the instruments with it and pack product into packaging pouch.

STANDARD STERILIZATION METHOD

Every instrument must be cleaned and sterilized before it is used for the first time. The instrument was developed for sterilization and methods are;

Ethylene Oxide Sterilization:

Instruments can be sterilized using the following methods:-

100% ETO Cycles

Concentration ETO: 850 ± 50mg/l

Temperature: +30° to +60°C

Exposure time: 3-4 hours

Humidity: 55-80% RH minimum

PREPARATION FOR USE

Bipolar Forceps are designed to grasp, manipulate and coagulate selected tissue. Open the sterilized instrument from pouch & connected through a suitable bipolar cable with the bipolar output of an electrosurgical generator. Single Use Bipolar forceps are operated via foot switch. Appropriate current should be set on ESU by user prior to procedure taking place. Electrosurgical instruments and other material or equipment that will contact the surgical site must be sterilized prior to use. Use an extra piece of sterile drape material or the inside of the wrap to set instruments on when they are not in use. One of the most common errors for an inexperienced surgeon is setting instruments down on an unsterile surface.

SHELF LIFE

RB Medikal Instruments is declared 3 years shelf life for its sterile Bipolar Forceps & 2 years for its non-sterile Bipolar Forceps.

STORAGE, TRANSPORT & OPERATING CONDITIONS

Ambient temperature range: -05°C to 30°C

Relative humidity range: 35% to 68%

Atmospheric pressure range: 700 hPa to 1060 hPa

ELECTROSURGICAL CUTTING AND COAGULATION APPLICATION

When a continuous or interrupted waveform is used in contact with the tissue and the output voltage current density is too low to sustain arcing, desiccation of the tissue will occur. Some ESUs have a distinct mode for this purpose called Desiccation or contact coagulation. In noncontact coagulation, the duty cycle of an interrupted waveform and the crest factor (ratio of peak voltage to rms voltage) influence the degree of homeostasis. While a continuous waveform re-establishes the arc at essentially the same tissue location concentrating the heat there, an interrupted waveform

TABLE 81.3 Typical output characteristics of ESUs

	Output Voltage Range Open Circuit, V	output Power Range, W	Frequency, KHz	Crest Factor { I_{pk}/I_{rms} }	Duty Cycle
Bipolar Mode					
Coagulated desiccate	200-1000	1.70	300-1050	1.6-120	25-100%

Causes the arc to re-establish itself at different tissue locations. The arc seems to dance from one location to the other raising the temperature of the top tissue layer to coagulation levels. These waveforms are called fulguration or spray. Since the current inside the tissue spreads very quickly from the point where the arc strikes, the heat concentrates in the top layer, primarily desiccating tissue and causing some carbonization. During surgery, a surgeon can easily choose between cutting, coagulation, and a combination of the two by activating a switch on the grip of the active electrode or by use of a footswitch.

WARNINGS

Fire hazards are associated with use of electrosurgical devices. Do not place them in contact with or near to inflammable materials (i.e. drapes, gauze, and oxygen sources). Use a holster or quiver to hold Electrosurgery devices and similar accessories safely away from operative site.

RETURN GOODS POLICY

Products must be returned in unopened packages with manufacturer's seals intact to be accepted for replacement or credit unless returned due to a complaint of product defect. Determination of a product defect will be made by RB Medikal Instruments. Products will not be accepted for replacement if they have been used for a second time.

COMPATIBILITIES

Generators:

Valleylab, Conmed, Megadyne, boviemed, dremed and all others are similar with above mentioned brands.

Cables:

Prima-medical, Aesculap, Everest and all others are similar with above mentioned brands.

RECYCLING

When reprocessing medical devices please follow your local government Health & Safety procedures.

SYMBOLS USED ON LABELING

	Manufacturer	REF	Catalogue Number
	Lot Number		See Instruction for use
	Keep Dry		Keep away from sunlight
	Latex Free		Date of manufacture
	Expiry Date		Do not use if package is damaged
	Single Use	STERILE EO	Sterilized using Ethylene Oxide method
	Latex Free		Temperature Limitations
	Non Sterile	QTY	Quantity
	See instructions for use		Manufacturing Date
	Medical device		

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