

Distributed By:

ENCISION

DETACHABLE BIPOLAR COAGULATION FORCEPS



Important Information - Please read before use!

Caution

Please read all information contained in this insert. Incorrect handling and care as well as misuse can lead to premature wear of surgical instruments.

This instrument is designed for use with the bipolar outputs of electro-surgical generators only. Do not exceed 60 Watts in the bipolar coagulation mode of generators.

Description

The Detachable Bipolar Coagulation Forceps are intended for use in general operative and laparoscopic surgical procedures. The device is intended to be passed through a 5mm laparoscopic cannula.

Coagulation is achieved using electro-surgical energy under laparoscopic visualisation. This device is intended to be used with the outputs of compatible electro-surgical generators such as Erbe, Martin, Berchtold, Codman, Valleylab and similar generators. Do not exceed 60 Watts in the bipolar coagulation mode of generators.

Indications for Use

The Detachable Bipolar Coagulation Forceps are designed to manipulate, grasp and cut selected tissue. Bipolar Coagulation current may be selectively applied to the tissue as indicated. Suitable Cables and Adapters: Encision Catalog #: BP4200V, BP4200W

Note: Bipolar coagulation instruments should be used only by individuals who are trained and licensed to use such devices. Examples of such training and experience include:

Training through qualified residency program, surgical skills workshops, training programs offered by equipment manufacturers or preceptorship/surgical assistant training.

Contraindications

Not intended for contraceptive coagulation of the fallopian tube but may be used to achieve hemostasis following transection of the tube.

Contraindications to endoscopic procedures, not necessarily bipolar coagulation include:

As identified in the Manual of Endoscopy available from the American Association of Gynecologic Laparoscopists.

The presence of large pelvic or pelvic-abdominal masses, hypovolemic shock and severe cardiac decompensation.

Also, intestinal obstruction and marked bowel distention, increase possibility of pelvic and abdominal adhesions.

A significantly elevated diaphragm contra-indicates the use of insufflation which may be necessary for proper surgical visualisation and may increase the chance of inadvertent bowel injury.

Pelvic abscess, chronic pulmonary disease, diaphragmatic hernia, obesity, and septic peritonitis may exclude some patients from surgical consideration depending on severity of these conditions.

Caution: Please refer to the labelling and user manual for the electro-surgical generator for additional information on contraindications on electro-surgical or laparoscopic use.

Complications reported in the medical literature during laparoscopic surgical procedures include:

Haemorrhage, damage to surrounding soft tissue, leakage of bile or other secretions, infection (local and systemic), bowel perforation, damage to large blood vessels and/or neurological structures, inadvertently retained instruments and death.

Adverse events reported while using bipolar electro-surgical devices include: Inadvertent activation with resultant tissue damage at the wrong site and/or equipment damage.

Fires involving surgical drapes and other combustible materials have been reported. Alternate current pathways resulting in burns where the patient or physician or assistant is in contact with exposed metal. Explosions caused by electro-surgical sparking in a flammable gas environment (i.e. explosive anesthetic gases).

Organ perforation. Sudden massive haemorrhage.

Cautions & Warnings

US Federal Law restricts this device to sale by or on the order of a physician only.

Special safety precautions should be observed when using electro-surgical instruments.

Electro-surgical instruments can pose a significant shock, burn or explosion hazard if used improperly, incorrectly or carelessly.

Avoid touching or grounding electro-surgical instruments to non-insulated instruments, scopes, Trocar sleeves, etc. All persons using such devices should be knowledgeable in the use and handling of laparoscopic instruments, coagulation equipment, their accessories and other related equipment.

Test all instruments, accessories and equipment prior to each use.

Written Standard Operating Procedures for the cleaning, sterilization, storage, inspection and maintenance of the instruments, accessories and equipment are recommended.

Do not use electro-surgical instruments on patients with pacemakers. Do not use in presence of flammable liquids or anaesthetics.

Electro-surgical generators used with these devices are designed to cause destruction of tissue and are inherently dangerous if operated improperly. Follow all safety precautions and instructions supplied by the manufacturer of the electro-surgical generator.

The electrode tip must always be in full view before activating power.

Apply power only when electrode tip is in full contact with the tissue selected for coagulation. Electrode tip must not come in contact with the laparoscope or other metal instruments during use.

Failure to observe these cautions and contraindications may result in injury, malfunction or other unanticipated occurrences or events for the operator, staff and/or the patient.

Initial use of new instruments

Every instrument must be cleaned and sterilized before it is used for the first time.

The instrument was developed for sterilization by autoclave and has shown good results using this method.

Inspection and functional check

It is very important to carefully examine each 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. Service and repairs should be referred to trained qualified persons only. Refer questions about repair to the manufacturer or your biomedical engineering department.

Assembly and Operation

Assemble/disassemble forceps following the example assembly instructions and diagram.

Once correct assembled and connected to power, the device may be used in either the right or the left hand and any desired handle orientation to facilitate use and reduce hand discomfort and/or fatigue.

To close jaws: compress (grip) handle.

To open jaws: gently release handle compression (grip).

Forceps jaws will not retract into the tube.

Never withdraw laparoscopic or surgical devices from the surgical site without direct observation or laparoscopic view to prevent inadvertent damage to adjacent tissue.

The Detachable Bipolar Coagulation Forceps are designed to provide concentrated grasping force or to cut at the forceps jaw and will cause some degree of tissue crushing where the jaws grasp or close. Tissue that is not to be clamped, crushed, cut or coagulated should not be grasped except with extreme care to avoid damage. Coagulation forceps require the use of good surgical judgement and should not be used where crushing injury or coagulation is not acceptable. When retracting tissue with the forceps, the traction force applied to the tissue should be low enough to avoid tearing the selected tissue.

Cleaning and Maintenance

Every surgical instrument should be disinfected and thoroughly cleaned after each use. Proper cleaning, inspection and maintenance will help ensure correct function of the surgical instrument. Clean,

inspect and test each instrument carefully. Sterilize all instruments before surgery. A good cleaning and maintenance procedure will extend the useful life of the instrument. Special attention must be paid to slots, stops, ends, hollow tubes and other highly inaccessible areas. Check insulation, cables and connectors for cuts, voids, cracks, tears, abrasions, etc.

Do not use damaged instruments.

This device can be disassembled. It must be cleaned in the disassembled state.

(Note: Keep all parts together and protected from being misplaced, do not intermix with other or similar devices of other manufacture.)

Cleaning and rinsing must take place immediately after each use for best effect. Failure to clean promptly may result in adherent particles or dried secretions that may resist cleaning and complicate or resist future sterilization.

Instruments must be completely cleaned and rinsed of all foreign matter.

Use warm water and a commercially available instrument pre-soak or cleaning agent. Enzymatic cleaners (such as Enzo™) must be used to remove protein deposits. Follow the enzymatic cleaner's instructions; rinse thoroughly.

- Do not use corrosive cleaning agents (i.e. bleach). Cleaning solutions and rinses at or near a neutral pH (7.0) are best.
- Do not use abrasive cleaners.
- Only a soft bristle brush should be used.
- Immerse the entire device in detergent and clean while soaking. Use a minimum of six strokes in and six strokes out with an instrument brush for all inside channels.
- Rinse with sterile deionized water.
- Repeat this procedure
- Can be disinfected in the washing machine up to 203°F (95°C).
- Rinse thoroughly with distilled water.
- Prepare for storage and/or sterilization.

After cleaning and rinsing, dry instruments completely and carefully with compressed air (including inside channels and highly inaccessible areas).

Note: After cleaning and before sterilization, treat all instruments with a lubricant which is considered as being physiologically safe, especially their blades, ends, stops, snaps and all movable parts.

Storage and Sterilization

Instruments must be stored in a clean, dry, moisture free area.

The instruments should be stored individually in their shipping carton or in a protective tray with partitions. Protects tips with cloth, gauze or tubing if stored in drawers.

Instruments and cables are reusable and meet AAMI standards for sterilization.

We guarantee our products to withstand a minimum of twenty sterilization cycles when sterilized according to the criteria listed below. Most devices will surpass this standard if a protocol is established for the proper care and inspection of medical devices at your facility.

Use steam autoclave sterilization. Thoroughly clean instruments of all debris, tissue and foreign matter prior to sterilization.

Follow the sterilizer manufacturer's instructions for operation and loading of steam autoclaves. There must be direct steam exposure to all surfaces of the instruments being sterilized including the internal surface and tubes channels.

Allow instrument to air cool to room temperature before use.

Standard sterilization method

Sterilization of the products with fractional pre-vacuum procedure (in accordance with ISO 13060 / ISO 17665) under observation of the respective national requirements.

- 3 pre-vacuum phases with a pressure of at least 60 mbar.
- Heating up to a sterilization temperature of at least 132°C and at most 137°C
- Exposure time: at least 3 min.; at most 18 min.
- Drying time: at least 10 min.

Other time and steam temperature cycles may also be used. However, user must validate any deviation from the recommended time and temperature.

(Note: Contact the manufacturer of your steam autoclave to confirm appropriate temperatures and sterilization times.)

Caution: Autoclave temperatures should not exceed 280°F (137°C); handles, insulation or other non-metallic parts may be damaged.

References:

- Nelson Labs # 200432706-02
- MDS GmbH Testbericht 084183-10

Handling

All surgical instruments must be handled with the greatest care when being transported, cleaned, treated, sterilized and stored.

This is especially true for blades, fine points and other sensitive areas.

Surgical instruments corrode and their functions are impaired if they come into contact with aggressive materials. The instruments must not be exposed to acids or other aggressive cleaning agents.

Warranty

All Bissinger products are guaranteed to be free from defects in material and workmanship at the time of shipping.

All of our products are designed and manufactured to meet the highest quality standards. We cannot accept any liability for failure of products which have been modified in any way from their originals, for any failure due to misuse or application which is not in accordance with the designer's intentions.

GLOSSARY OF SYMBOLS		
SYMBOL	MEANING	ISO 7000 REF NO.
	Manufacturer	3082
	Lot number	2492
	Catalog number	2493
	Unsterile	2609
	Consult Instructions for Use	1641
	Attention	0434A
	Not made with natural rubber latex	ISO 15223 5.4.5 with negation symbol Annex B.2

Distributed Exclusively By:

Encision Inc.

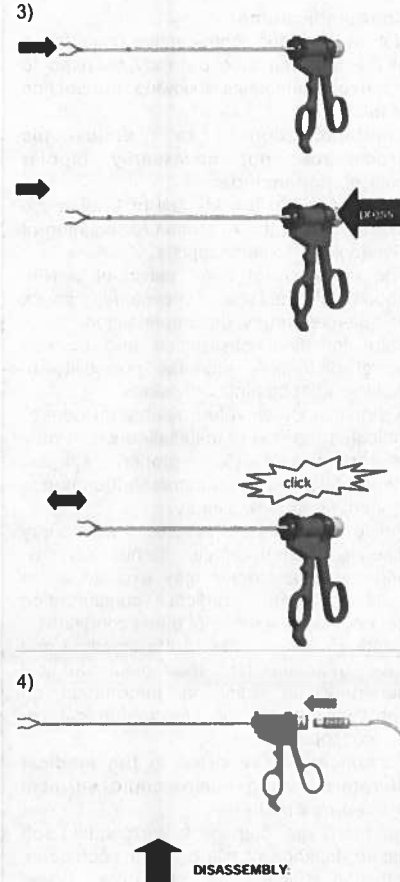
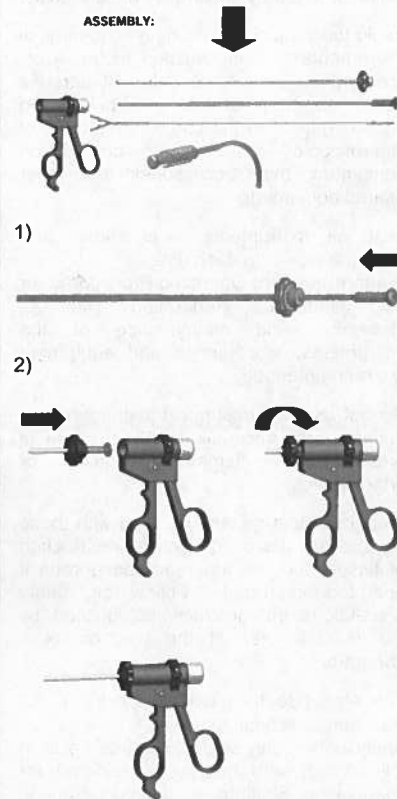
6797 Winchester Circle
Boulder, CO 80301 USA
Phone: 303.444.2600
Fax: 303.444.2693
www.encision.com

Manufactured By:
Günter Bissinger Medizintechnik GmbH
Hans-Theisen-Str. 1
79331 Tenningen
Germany
www.bissinger.com

Erstellt: 08.02.05/Bi
Geändert: 23.08.2021/DR
IFU-Encision_VE.doc

Index E

ASSEMBLY:



DISASSEMBLY: