BIPOLAR COAGULATION FORCEPS

T.00xx.xx

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.

Description
The GIMMI Bipolar Coagulation Forceps is 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 electrosurgical energy under laparoscopic visualisation. This device is intended to be used with the outputs of compatible electrosurgical 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 GIMMI Bipolar Coagulation Forceps is designed to manipulate and grasp selected tissue. Bipolar coagulation current may be selectively applied to the tissue as indicated.

Suitable Cables and Adapters:
GIMMI Art.-No. T.57XX.X

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

Contraindications
Not intended for contraceptive coagulation of the fallopian tube but may be used to achieve hemostasis following transaction 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.
- Pelvic abscess, chronic pulmonary disease, diaphragmatic hernia, obesity, and septic peritonitis may exclude some patients from surgical consideration depending on severity of these conditions.

Note: Please refer to the labelling and user manual for the electrosurgical generator for additional information on contraindications on electrosurgical or laparoscopic use.

Complications reported in the medical literature during laparoscopic surgical procedures include:
- Hemorrhage, 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 electrosurgical 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 is in contact with exposed metal.

The GIMMI Bipolar Coagulation Forceps are designed to provide concentrated grasping force 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 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. Sterilise 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.

Cleaning and maintenance procedure:
- Inspect the instrument carefully.
- Remove all坚持s and debris.
- Use warm water and a commercially available instrument pre-soak or cleaning agent. Enzymatic cleaners (such as EnzolTM) may be used to remove protein deposits. Follow the enzymatic cleaner’s instructions; rinse thoroughly.
- The electrode tip must be in full view before activating power.
- Apply pressure when the electrode tip is in full contact with the tissue selected for coagulation.

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 sterilised before it is used for the first time.

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

Check 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, steps and apaxes as well as movable parts.

Do not use damaged instruments. Never attempt to make repairs yourself. Instrument 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
Once correct 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.

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

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