



Cardiac Surgery Specialists

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

COBRA[®] Bipolar System

Instructions for Use COBRA[®] Bipolar Inserts

Catalog Number 600-15902US and 600-15902F-US

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Instructions for Use

Carefully read all instructions prior to use. Observe all contraindications, warnings and precautions noted in these directions. Failure to do so may result in patient complications. ESTECH relies on the physician to determine, assess and communicate to each patient all foreseeable risks of the procedure.

Description:

System

The ESTECH COBRA[®] Bipolar Surgical System (System) is comprised of two components, the COBRA Bipolar Inserts (Inserts) and the COBRA Bipolar Clamp (Clamp). The Clamp is designed to fit over the Inserts and engage tissue such that constant contact between Inserts and tissue to be coagulated is maintained throughout the procedure.

Inserts

The ESTECH COBRA Bipolar Inserts have a flexible distal section. It is designed to conform to the specific anatomy of the tissue area to be coagulated, according to the chosen clamp. The distal section of the Inserts has two RF electrodes spaced 2mm apart and one return electrode. The Inserts fit into the groove of each clamp jaw. Inserts are designed for single use only and are supplied sterile as long as the package is undamaged or unopened. The COBRA Bipolar Inserts are connected to the Electrosurgical Unit (ESU) by a dedicated cable (Model 659). Instructions for use of the ESU may be found in the ESU's Operator's Manual.

Clamp

The COBRA Bipolar Clamp is designed to conform to the specific anatomy of the tissue area to be coagulated. The clamps are reusable and supplied non-sterile. A channel in the clamp jaw facilitates easy insertion of the Inserts.

Indications:

The ESTECH COBRA Bipolar System is intended for the coagulation of soft tissue using radiofrequency (RF) energy during general surgery. The System may also be used to coagulate blood and soft tissue to produce hemostasis.

Sterilization Method: The sterilization process for the Inserts is EtO method and provides sterility assurance level 10^{-6} in compliance with the obligatory requirements of ISO 11135 and EN 550. The reusable clamp is sterilized with steam autoclave.

Contraindications:

- Local or systemic infection

Warnings:

Inserts

- Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found call your ESTECH representative.
- For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which in turn may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

Clamp

- The Clamp is supplied non-sterile. Sterilize prior to use.

System

- The device(s) should be used by physicians thoroughly trained in the techniques of invasive surgical procedures.
- The operator should keep the set temperature and power limit as low as possible to achieve the desired end effect. This avoids excessive thermal damage to tissue, or collateral damage to adjacent tissue not intended for coagulation.
- Care should be taken to assure that the Inserts are not in contact with tissue other than that to be coagulated to avoid inadvertent tissue damage.
- Care should be taken when using the Inserts in proximity to vascular and nerve tissue to avoid inadvertent tissue damage.
- Care should be taken to thermally isolate the tissue to be coagulated when anatomically possible to avoid damage to unintended tissues or structures.
- Following RF coagulation, visual inspection of underlying tissues should be routinely performed to rule out the presence of inadvertent tissue damage.
- Care should be taken to assure that the Insert is not in contact with other surgical instruments, staples or other objects while coagulating. Inadvertent contact with objects while coagulating could lead to conduction of RF Energy or heat and unintentional coagulation of tissues in contact with that object.
- Care should be taken when positioning Insert to prevent perforation or other damage to adjacent tissue.

Precautions:

- Before using, inspect for physical damage, including electrical insulation on the cables and the Inserts. Replace damaged equipment.
- After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.
- Do not attempt to operate the system before thoroughly reading the ESU Operator's Manual and Instructions for Use. For future reference, keep these documents in a convenient, easily accessible place.
- While the distal portion of the Inserts is designed to be flexible, to conform to the anatomy of the area to be coagulated in conjunction with a selected clamp, excessive or rough shaping of the Inserts may damage internal components of the Inserts.
- Pacemakers and implantable cardioverter/defibrillators can be adversely affected by RF signals. Refer to the manufacturer's Instructions for Use.
- The risk of igniting flammable gases or other materials is inherent in the application of RF power. Precautions must be taken to restrict flammable materials from the area where tissue coagulation is performed.
- Electromagnetic interference (EMI) produced by the ESU during the delivery of RF power may adversely affect the performance of other equipment.
- The Inserts are intended for use only with the ESU, Instrument Cables and accessories.

Storage:

- Store in a cool dry place.

Inspection Prior to Use:

Carefully inspect the package prior to use for any breach of the sterile barrier or damage to the contents. If the sterile barrier integrity is compromised or the contents damaged, contact your ESTECH representative. The Clamp should also be inspected carefully, prior to each use and during the cleaning procedure to identify any signs of unusual wear, cracking, any deformed condition or corrosion. Microscopic cracks may be detected by the appearance of rust on the clamp. Should any irregularity be noted, the clamp should not be used.

Instructions for Use

1. Sterilize clamp prior to use.
2. Inspect the Inserts and all packaging materials carefully. Open the package using sterile technique.
3. Place the angled edge tip of the Insert directly into the channel of the Clamp. Continue pushing the Inserts fully into the jaw of the Clamp. Care must be taken to avoid pinching gloved finger during advancement of Inserts.
4. Connect the proximal handle of the Inserts to the Instrument cable by plugging the cable into the port on the handle of the Inserts.
5. Insert both blue return electrode connectors into the receptacle on the face of the ESU
6. Select electrodes to be activated on the ESU.
7. Activate selected electrodes by depressing the switch on the ESU, or by using the optional footswitch.
8. Radiofrequency energy may be discontinued by depressing the switch on the ESU.
9. The Inserts are disposable and must be removed and discarded prior to cleaning and resterilizing the Clamp. Dispose of Inserts with contaminated materials.

Lesion Depth (mm) for COBRA Bipolar System at Maximum Power (40W)

Time/Set Temperature	70°C	80°C	90°C	95°C
10 Seconds	2.1	2.2	5.1	6.1
20 Seconds	1.6	8.4	6.9	6.7
30 Seconds	7.1	7.3	7.8	10.8
60 Seconds	9.2	6.4	7.8	9.0

*Note: Based on extensive testing, the parameters determined to provide the most optimal lesions are: Power 40W, Temperature: 80°C, Time 30seconds

Cleaning and Sterilization of Clamp

Please reference attached Instructions for Reprocessing of Reusable Devices.

Complications

The following potential risks or discomforts may be associated with electrosurgical procedures. The frequency and severity of these events can vary, and may necessitate additional medical intervention, including surgery. Strict adherence to the forgoing instructions before use will help reduce the incidence of complications.

Allergic reaction, Arrhythmias, Cardiac or respiratory arrest, Cardiac valve damage, Chest pain, Damage to vessel intima or cardiac ultrastructures, Death, Hematoma / ecchymosis, Hemorrhage, Infarction, Infection, Perforation, Pericardial effusion, Pericarditis / pleuritis, Pseudoaneurysm, Pulmonary edema, Sinus or AV node injury, Stroke, Tamponade, Thrombosis, Vasovagal reaction.

Warranty and Limitations

ESTECH warrants that reasonable care has been used in the design and manufacture of this instrument. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose. Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures, and other matters beyond ESTECH's control directly affect the instrument and the result obtained from its use. ESTECH's obligation under this warranty is limited to the repair or replacement of this instrument and ESTECH shall not be liable for any incidental or consequential loss, damage, or expense directly or indirectly arising from the use of this instrument. ESTECH neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. ESTECH assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instrument.

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