



Cardiac Surgery Specialists

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

COBRA Adhere™ XL Surgical System

Catalog Number 600-002US

Patent No. 6,849,075; 5,651,780; 5,769,847; 5,797,905; 5,810,802; 5,871,523; 6,030,382; 6,106,522; 6,129,724; 6,387,092; 6,447,506; 6,464,699; 6,464,700; 6,471,699; 6,500,172; 6,610,055

Directions 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 Cobra Adhere™ XL Surgical System (System) is comprised of two components, the Cobra Adhere XL Surgical Probe (Probe) with integrated Suction Stabilizer (Stabilizer) and the Cobra Adhere XL Introducer. The stabilizer is designed to engage tissue under negative pressure such that constant contact between probe and tissue to be coagulated is maintained throughout the procedure. The Introducer is designed to facilitate introduction and advancement of the Probe/Stabilizer to the desired anatomical position

Probe

The ESTECH Cobra Adhere™ XL Surgical Probe has a flexible distal section. This probe is designed to conform to the specific anatomy of the tissue area to be coagulated. The distal section of the probe can have from two to fourteen 15 mm electrodes spaced 2mm apart along the body. Any linear combination of coagulating electrodes may be used. Exiting from the proximal end of the probe handle are two clear tubes with female luer fittings. One luer will be attached to a fluid pump and the other leads to a receptacle to catch sterile saline as it exits the probe. The Cobra Adhere™ XL Surgical Probe is connected to the Electrosurgical Unit (ESU) by a dedicated cable (Model 659). Directions for use of the ESU may be found in the ESU's Operator's Manual.

Suction Stabilizer

The ESTECH Cobra Adhere™ XL Suction Stabilizer is a series of vacuum tubes. It is comprised of:

- A distal tube that mates with the proximal luer of the Introducer.
- A suction stabilizer consisting of a contoured suction bladder that fits over the Probe and vacuum tubing with a female luer and stopcock connected to the suction stabilizer
- Accessory vacuum tubing, consisting of ¼" internal diameter tubing with a male luer connector on one end and vacuum source connector on opposite end
- A three foot segment of ¼" vacuum tubing connecting a fluid canister to a vacuum source

Introducer

The ESTECH Cobra Adhere™ XL Introducer is pouched separately from the Probe/Stabilizer and can be used as needed to advance the Probe/Stabilizer to the desired anatomical position. The introducer has a curved shape that is straightened out with an inserted stainless steel stylet for initial use. After the straightened distal end of the XL Introducer is advanced to the posterior side of the target organ, the stylet is removed while the XL Introducer is advanced and the distal tip emerges from the posterior side of the target organ. The proximal barb of the XL

Introducer is then attached to the distal tubing end of the Cobra Adhere XL Probe/Stabilizer. By pulling on the Introducer the Probe is brought into alignment with the target tissue. Once in place, the Introducer is detached from the Probe and the distal Stabilizer tubing is used to reposition the Probe electrodes.

Indications:

The Estech Cobra Adhere XL Surgical System is intended for the coagulation of cardiac tissue using radiofrequency (RF) energy during cardiac surgery. The System can be used during general surgery to coagulate soft tissues. The System may also be used to coagulate blood and soft tissue to produce hemostasis.

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

Contraindications:

- Local or systemic infection
- Do not apply suction over an artery or aneurismal tissue

Warnings:

- The device(s) should be used by physicians thoroughly trained in the techniques of invasive surgical procedures and in the specific approach to be used
- 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; collateral damage to adjacent tissue not intended for coagulation
- Care should be taken to assure that the probe is not in contact with tissue other than that to be coagulated to avoid inadvertent tissue damage
- Care should be taken when using the probe 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 probe 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 the surgical probe to prevent perforation or other damage to adjacent tissue
- Turn vacuum control stopcock open to atmosphere and off to vacuum source prior to removal of attachment from tissue
- Care should be taken when positioning Suction Stabilizer to prevent perforation or other damage to adjacent tissue during the application of a vacuum
- Do not force the Introducer or Surgical probe during advancement if snagged
- Take care not to occlude vacuum lumen
- Take care not to puncture the Stabilizer
- Excessive vacuum may cause bruising and/or hematoma
- Inadvertent application of vacuum over an artery may constrict or occlude the artery resulting in infarction

Precautions:

- 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 re-sterilize. Reuse, reprocessing or re-sterilization 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 re-sterilization 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
- Before using, inspect for physical damage, including electrical insulation on the cables and the catheter shaft

- Replace damaged equipment. If damage is found call your ESTECH representative
- 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 ESU Operator's Manual and Directions for Use. For future reference, keep these documents in a convenient, easily accessible place
- While the distal portion of probe and suction stabilizer is designed to be flexible to conform to the anatomy of the area to be coagulated, excessive or rough shaping of the suction stabilizer may damage internal components of the probe
- Pacemakers and implantable cardioverter/defibrillators can be adversely affected by RF signals. Refer to the manufacturer's Directions for Use
- Dispersive Indifferent Patch (DIP) electrodes used with the ESTECH system should be applied carefully according to the manufacturer's directions. Poor or incomplete contact of the DIP electrodes may result in skin burns. The use of DIP electrodes which meet or exceed ANSI/AAMI HF-18 requirements is recommended
- The risk of igniting inflammable 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
- If fluid is seen leaking from any part of the probe, do not use. Replace with a new one

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, DO NOT USE and contact your ESTECH representative

Directions for Use

1. Inspect the Cobra Adhere™ XL Surgical System and all packaging materials carefully. Open the package using sterile technique
2. Ensure 2 DIP electrodes are in good contact, according to the manufacturer's directions
3. Connect the proximal end of the Probe to the Model # 659 Instrument cable by plugging the cable into the port on the handle of the Probe. The cable connector marked 'D' and "Distal" will allow activation of the distal 1-5 electrodes. The cable connector marked 'P' and "Proximal" will allow activation of the proximal 1-5 electrodes. These electrodes are identified as D1-D5 and P1-P5 on the suction bladder.
4. If required, attach 3-foot line from the vacuum canister to the vacuum regulator connection
5. Connect the blue connector on one end of the 12-foot vacuum line to the vacuum canister. Connect the male fitting of the 12-foot vacuum line to the three-way stopcock. Turn the stopcock to the off position with the "Off" indicator pointed in the direction of the vacuum source
6. Attach one female luer fitting to a fluid pump set at 500ml/hr flow rate. Either sterile water or normal saline can be used as a coolant. The other female luer fitting should be attached to a receptacle to catch coolant as it exits the probe. The fluid pump should be operating whenever the ESU is supplying energy
7. If using the Introducer, open the package using sterile technique, and remove the malleable stylet from its protective sheath.
8. Insert the stylet into the blue curved tubing to straighten it and provide pushability for advancement.
9. Advance the introducer to the desired anatomical location. By withdrawing the stylet the Introducer tubing will advance in a preformed curve. The tubing will curve opposite the axial white stripe.
10. Remove the stylet and couple the proximal barb fitting of the Introducer tubing to the distal tubing of Suction Stabilizer. Insure that the white stripe of the Introducer tubing and blue stripe of the Stabilizer are aligned.
11. By pulling on the Introducer the Probe is brought into alignment with the target tissue. Once in place, the Introducer is detached from the Probe and the distal Stabilizer tubing is used to reposition the Probe electrodes.
12. Turn vacuum regulator on to sufficient negative pressure to affix device to tissue using the lowest vacuum setting possible to enable positive vacuum attachment to the tissue. Turn vacuum control stopcock on to vacuum source. Push Stabilizer against tissue to complete seal. Allow pressure to build up prior to activating RF energy. Maintain manual pressure as required to ensure probe/tissue contact
13. Select the electrodes to be activated on the ESU.
14. Activate selected electrodes by depressing the switch on the ESU.

15. Radiofrequency energy may be discontinued by depressing the switch on the ESU or by releasing pressure on the footswitch
16. When the cycles are complete, turn vacuum control stopcock to off position prior to removing the Stabilizer. Remove the device in the opposite direction it was advanced.

Lesion Depth (mm) for Cobra Adhere™ XL Surgical System at Maximum Power (150W)

Time/Set Temperature	60°C	70°C	80°C	90°C
15 Seconds	2	2.75	2	3.5
30 Seconds	2.75	4	4.75	4.25
60 Seconds	3.75	4.25	4.25	4.5
90 Seconds	5.75	7.25	7.5	6.75
120 Seconds	7.75	7.25	6.5	6

***Note: Based on extensive testing, the parameters determined to provide the most optimal lesions are: Power 25W per active channel, Temperature: 60°C and Vacuum>600mmHg**

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, Embolus, air embolus, 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 expressed or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular use. 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 re-sterilized and makes no warranties, expressed or implied, including but not limited to merchantability or fitness for intended use, with respect to such instrument.

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