



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

COBRA Fusion[®] Ablation System

Catalog Numbers 700-001, 700-001MI, 700-001S, 700-002, 700-003, 700-004

Patent No. 5,651,780; 5,769,847; 6,106,522; 6,129,724; 6,387,092; 6,447,506; 6,471,699; 6,500,172; 7,115,122; 7,226,448; 7,335,196; 7,413,568; 7,837,684; 7,957,820; 8,419,729; 8,518,038; Additional Patents Pending

Instructions for Use



Sterile – Single Use Only



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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.

System Description:

The Cobra Fusion System is comprised of four main components: the COBRA Fusion 50 or 150 Ablation System, the Magnetic Retriever System, and the Pacing/Recording Adapter Cable.



Figure 1. Cobra Fusion Ablation System

Left to Right: (1) COBRA Fusion ablation probe, (2) Magnetic Introducer, (3) Magnetic Retriever, (4) Magnetic Positioner, (5) Magnetic Swivel Positioner, (6) Accessory Temporary External Pacemaker Connecting Cable

The COBRA Fusion ablation Probe includes an integrated suction stabilizer designed to engage tissue under vacuum such that constant contact between Probe electrodes and tissue to be ablated is maintained throughout the procedure. The Introducer and Retriever System are designed to facilitate introduction and advancement of the Probe to the desired anatomical position. The accessory cable allows the Probe to be connected to a temporary pacing/recording device.

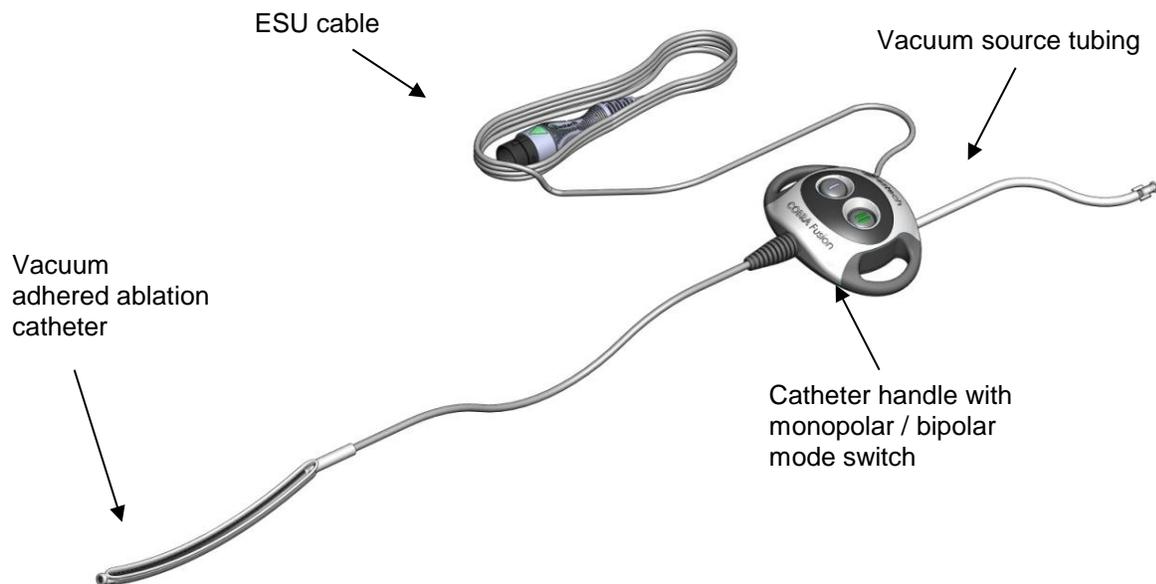
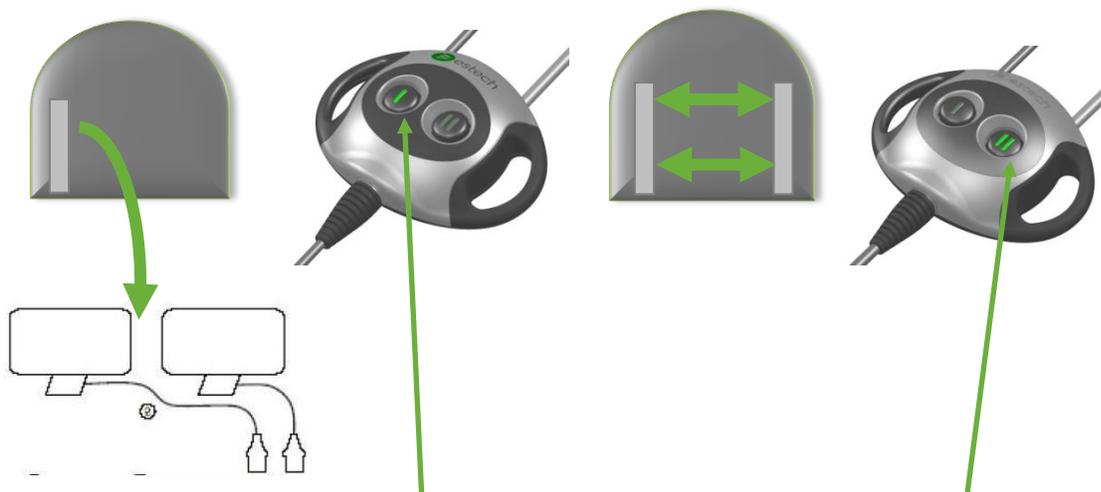


Figure 2. Features of the COBRA Fusion Ablation Probe

The Cobra Fusion comprises a flexible distal ablation Probe, designed to conform to the specific anatomy of the tissue to be ablated. The distal section of the Probe allows for one to six 25 mm electrodes to be activated corresponding to the numeric indicators on the device. Any combination of active electrodes may be used. The user can optionally direct RF energy from the active RF electrodes toward the integrated indifferent electrode (Bipolar mode) or toward the indifferent electrode pads placed on the patient's back (Monopolar mode) by selecting the corresponding mode on the handle as shown below.



Monopolar Mode: Active electrode delivers RF energy to indifferent electrode pads on patient's back when this mode is selected by depressing this button.

Bipolar Mode: Active electrode delivers RF energy to the integrated indifferent electrode when this mode is selected by depressing this button.

The Cobra Fusion is connected to the Electrosurgical Unit (ESU) by a cable permanently attached to the handle of the Probe. Directions for use of the ESU may be found in the ESU Operator's Manual.

The distal ablation Probe includes an integrated vacuum stabilizer, which is connected to a vacuum source using the included accessory tubing. Accessory tubing consists of a 3-way stopcock and tubing with a male luer connector on one end and vacuum source connector on opposite end. The stopcock/tubing attaches to the tubing that exits the Probe handle. A three foot segment of tubing for connecting a fluid canister to a vacuum source is also provided.

The Cobra Fusion comprises a magnet at its distal end which couples to the magnetic connector at the proximal end of the Introducer. This allows the user to temporarily attach the Introducer, guide the Probe to the desired anatomical position, and then decouple the Introducer. The Cobra Fusion Introducer can be used as needed to advance the Probe 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 Introducer is advanced to the desired location of the heart, the stylet is removed while the Introducer is advanced. The proximal magnetic connector of the Introducer is then attached to the distal magnetic connector of the Cobra Fusion Probe. The distal end of the introducer can be retrieved by using either the ball-tipped retriever or the flexible retriever provided in the accessory retriever kit. Once coupled, pulling on the Introducer/Retriever will bring the Probe into alignment with the target tissue. Once in place, the Introducer is detached from the ablation Probe.

When the Cobra Fusion is connected to an auxiliary temporary external pacemaker it can be used to provide transient cardiac pacing, sensing, recording, and stimulation for the assessment of electrical isolation / conduction block of ablation lesions in the surgical treatment of arrhythmias. The COBRA Fusion must be disconnected from the ESU and connected to a temporary external pacemaker using the accessory cable provided.



Indications

The ESTECH Cobra Fusion Ablation System is intended to ablate cardiac tissue during cardiac surgery using radiofrequency (RF) energy when connected directly to the Estech Electrosurgical unit (ESU).

The ESTECH Cobra Fusion Pacing/Recording Adapter Cable may be used for temporary cardiac pacing, sensing, recording, and stimulation during the evaluation of cardiac arrhythmias during surgery when connected to a temporary external cardiac pacemaker or recording device.

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

Contraindications

- Local or systemic infection
- Do not apply suction over an artery, large vein 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 (60 - 70°C) and power limit based on tissue thickness (5-7mm) as low as possible to achieve the desired end effect. This minimizes excessive thermal damage to tissue, potential for collateral damage to adjacent tissue not intended for ablation, and potential for char, thrombus, or steam pop formation or occurrence. **Recommended temperatures should not be exceeded.**
- Physicians should consider a comprehensive anti-coagulation protocol including pre-operative, intra-operative and post-operative anti-coagulation management to prevent potential thromboemboli.
- Off-Pump ablations should be performed on the beating heart, with the heart at full or near full volume and normal or near normal cardiac output, to prevent stasis of blood.
- 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 the proximity of vascular or nerve tissue to avoid inadvertent tissue damage.
- Care should be taken to thermally isolate the tissue to be ablated when anatomically possible to avoid damage to unintended tissues or structures.
- Following RF ablation, visual inspection of underlying tissues should be routinely performed to rule out the presence of inadvertent tissue damage.
- Care should be taken to ensure 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 ablation of tissues in contact with that object.
- Care should be taken when positioning the Probe to prevent perforation or other damage to adjacent tissue. Do not force the Introducer or Probe during advancement if snagged.
- When using the push button magnetic decoupling feature, ensure that the distal end of the accessory shafted device is directly facing the magnet to avoid applying the ejector rod to tissue.
- Turn vacuum control stopcock open to atmosphere and off to vacuum source prior to removal of suction 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.
- Take care not to occlude vacuum lumen or puncture the Suction Stabilizer as this may result in loss of vacuum.
- Do not exceed recommended vacuum limit. Excessive vacuum may cause bruising and/or hematoma.
- Inadvertent application of vacuum or ablation over an artery may constrict or occlude the artery resulting in infarction.

- Read auxiliary device manual and observe instructions and warnings. This device can be used with a temporary pacemaker.
- Do not connect the pacing/recording adapter cable to supply mains (line voltage) operated equipment without verifying isolation of the connected equipment to EN60601-1-1. Supply mains operated equipment may introduce dangerous leakage currents into the heart.
- Avoid the possibility of unintentional contact between the device tip electrodes or pacing lead connectors and any conductive surface contact. The pacing lead connectors should only be connected to a temporary pacemaker or to a recorder designed for safely recording biopotentials.



Precautions

- Contents supplied **STERILE** using an ethylene oxide (EtO) process. 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. Use of product with a compromised sterile barrier may lead to patient injury.
- 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. 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, patient injury, illness or death.
- Do not attempt to operate the system before thoroughly reading ESU Operator's Manual and Instructions for Use.
- Care should be taken when manipulating the device. While the distal portion of the Probe is designed to be flexible to conform to the anatomy of the area to be ablated, excessive or rough shaping of the suction stabilizer, including bending and axial torque, may damage internal components of the device. When using surgical instruments, only grasp at the distal or proximal ends, away from the electrodes. Do not grasp the electrodes or spine of the suction stabilizer with instruments.
- If using a TEE probe, care should be taken to withdraw the TEE probe prior to ablation to avoid compressing the esophagus against the left atrium during ablation.
- User should avoid twisting or extreme manipulation of the device to preclude inadvertent injury to neighboring tissue (the correct orientation of the device should be ensured).
- Many variables, including patient anatomy, pathology, and surgical techniques, may influence procedural outcomes. Patient and procedure selection is a responsibility of the medical professional.
- Avoid attaching the device or ablating over the appendages of the heart, and extremely thin, fragile, or aneurysmal tissue.
- Post-operative anti-coagulation therapy for protection against thromboemboli is inclusive of the bridging period between the end of the procedure and until effective therapeutic levels of Oral Anticoagulation (OAC) are achieved.
- Pacemakers and implantable cardioverter/defibrillators can be adversely affected by RF signals and magnetic fields. 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 ablation is performed.
- Electromagnetic interference (EMI) produced by the ESU during the delivery of RF power may adversely affect the performance of other equipment.
- Bare electrode tips and lead wire connectors constitute a direct path to the heart. Small currents (approximately 10 μ amps) may be sufficient to cause fibrillation. Only trained personnel should handle the COBRA Fusion and COBRA Fusion Pacing/Recording Adapter Cable and connecting pins.

Directions for Use (Ablation)

1. Inspect the System and all packaging materials carefully. Open the package using aseptic technique.

2. Ensure 2 DIP electrodes are in good contact, according to the manufacturer's directions.
3. Connect the ESU cable into the black receptacle on the face of the ESU.
4. If required, attach 1-meter (3-foot) line from the vacuum canister to the vacuum regulator connection.
5. Connect the blue connector on one end of the 4-meter (12-foot) vacuum line to the vacuum canister. Connect the male fitting of the three-way stopcock vacuum tube of the Probe handle. Turn the stopcock to the off position with the "Off" indicator pointed in the direction of the vacuum source.
6. If using the Introducer, insert the stylet into the grey curved tubing to straighten it and provide pushability for advancement.
7. 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 dark stripe.
8. Remove the stylet and couple the proximal magnetic fitting of the Introducer tubing to the distal magnetic fitting of the Probe. Ensure that the dark stripe of the Introducer tubing is oriented opposite the open side of the suction stabilizer.
9. If using the Magnetic Retriever, advance toward the Magnetic Introducer. Magnets at the distal end of the Introducer and Retriever will couple automatically when in close proximity.
10. By pulling on the Retriever, the Introducer and connected Probe are brought into alignment with the target tissue. Once in place, detach the Introducer from the Probe. The accessory Positioning devices can then be coupled to the distal end of the Probe to aid in Probe manipulation and placement.
11. Turn vacuum regulator on to -500 mmHg to affix device to tissue. Turn vacuum control stopcock on to vacuum source. Push stabilizer against tissue to complete seal. Allow vacuum to build up prior to activating RF energy. Maintain manual pressure as required to ensure Probe/tissue contact and seal integrity. Reduce tension on Fusion 150 around heart once suction has been applied.
12. Select the mode of ablation to enable or disable the integrated indifferent electrode. When ablating in bipolar mode, indifferent electrode pads should be disconnected from the ESU receptacles.



13. Select up to 3 electrodes to be activated simultaneously on the ESU.
14. Activate selected electrodes by depressing the RF on/off switch on the ESU.
15. Radiofrequency energy may be discontinued by depressing the RF on/off switch on the ESU.
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.
17. Upon completion of procedure, disconnect device from ESU and discard after use.

**Ablation Time (seconds) COBRA Fusion
at 50W/Electrode, -500 mmHg of vacuum**

| Tissue Thickness | 60°C | | 70°C | |
|------------------|---|---|--|---|
| |  |  |  |  |
| Mode |  |  |  |  |
| 5 mm | 60 | 30 | 60 | 30 |
| 7 mm | 120 | 120 | 120 | 90 |

Times based on mode of energy delivery selected by surgeon

Directions for Use (Pacing/Recording Mode)

1. Inspect the System and all packaging materials carefully. Open the package using aseptic technique.
2. Connect the COBRA Fusion to the temporary external pacemaker using the non-sterile accessory COBRA Fusion Pacing/Recording Adapter Cable. Connect the Cobra Fusion cable into the female

receptacle of the adaptor cable. Connect the two pins to the temporary external pacemaker or recording device.

3. If required, attach 1-meter (3-foot) line from the vacuum canister to the vacuum regulator connection.
4. Connect the blue connector on one end of the 4-meter (12-foot) vacuum line to the vacuum canister. Connect the male fitting of the 4-meter (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.
5. If using the Introducer, insert the stylet into the curved tubing to straighten it and provide pushability for advancement.
6. 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 dark stripe.
7. Remove the stylet and couple the proximal magnetic fitting of the Introducer tubing to the distal magnetic fitting of the Probe. Ensure that the dark stripe of the Introducer tubing is oriented opposite the open side of the suction stabilizer.
8. If using the Magnetic Retriever, advance toward the Introducer. Magnets at the distal end of the first and second introducers will couple when in close proximity.
9. By pulling on the Retriever, the Introducer and connected Probe are brought into alignment with the identified anatomical sites for pacing/recording. Once in place, the Introducer is detached from the Probe. The accessory positioning devices can then be coupled to the distal end of the Probe to aid in Probe placement.
10. The pacing/recording leads are located within the distal end of the suction chamber of the Probe. Turn vacuum regulator on to -500 mmHg to affix device to tissue. Turn vacuum control stopcock on to vacuum source. Push stabilizer against tissue to complete seal. Allow vacuum to build up prior to activating device. Maintain manual pressure as required to ensure Probe/tissue contact.
11. Turn on the temporary external pacemaker. Refer to its IFU for appropriate settings and procedure.
12. The device will pace, sense, record, or stimulate when the auxiliary device is on, according to its intended use.
13. Upon completion of procedure, disconnect Probe from pacing/recording adapter cable. Discard Probe after use. The pacing adapter is reusable and should be cleaned and stored in accordance with hospital procedures.

How Supplied

The Cobra Fusion System components are available in the COBRA Fusion 50 or 150 Ablation System, the Magnetic Retriever System, and the Pacing/Recording Adapter Cable. Note: The Magnetic Retriever System and Pacing Adapter Cable can be sold separately.

Contents

- One (1) COBRA Fusion Ablation System
- One (1) Instructions For Use

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, Hematoma / ecchymosis, Hemorrhage, Infarction, Infection, Perforation, Pericardial effusion, Pericarditis / pleuritis, Pseudoaneurysm, Pulmonary edema, Sinus or AV node injury, Stroke, Tamponade, Thrombosis, Vasovagal reaction.

Disposal

After use, dispose of product and packaging in accordance with hospital, administrative and/or local, state, federal and international laws and regulations.

Warranty and Limitations

Users assume responsibility for approving the acceptable condition of this product before it is used, and for ensuring that the product is only used in the manner described in these instructions for use, including, but not limited to, ensuring that the product is not re-used.

Under no circumstances will AtriCure, Inc. be responsible for any incidental, special or consequential loss, damage, or expense, which is the result of the deliberate misuse or re-use of this product, including any loss, damage, or expense which is related to personal injury or damage to property.

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Graphic Symbols for this Device Labeling

| | | | | | | | |
|---|-------------------------------|---------------------------------|-------------------|------------------------|---|---|--|
| Catalogue Number | | Caution | | Manufacturer | | Sterilized using Ethylene Oxide | |
| Batch Code | | Do Not Re-use | | Use-By date | | Do Not Use if Package is Damaged | |
| Quantity | Storage Temperature limit | Storage Humidity Limitation | Non-Pyrogenic | | Does not contain Natural Rubber Latex | | |
| Does not Contain di (2-ethylhexyl) phthalate (DEHP) | | Follow Instructions For Use | | Do Not Resterilize | | Caution: U.S. Federal law restricts this device to sale by or on the order of a physician or other licensed practitioner. Rx ONLY | |