DIAMONDTEMP™ ABLATION CATHETER
Unidirectional and Bidirectional

The DiamondTemp Ablation Catheter:
- Has a 7.5 Fr, saline-irrigated, 4.1 mm tip
- Features a 4.1 mm catheter tip segment consisting of a dual composite tip electrode, 2 ring electrodes, 6 irrigation ports, and a network of industrial diamonds
- Includes customized offerings:
  - Small and large curve configurations
  - Unidirectional and bidirectional models

Real-time Temperature Sensing:
6 thermocouples directly measure tissue surface temperature every 20 ms to enable constant feedback. RealTemp™ temperature control powers therapeutic temperature for ablation in real time.

Exclusive Diamond-enabled Tip Cooling:
Catheter tip includes industrial diamonds, enabling rapid cooling due to their high thermal diffusivity property.¹

The diamond tip enables effective cooling and reduces the necessary irrigation flow rate to 8 ml/min for all ablation powers.¹

Localized High-resolution EGM:
4.1 mm catheter tip segment consists of a dual composite tip electrode, 2 ring electrodes, and 6 irrigation ports. The split tip electrode is electrically isolated to allow for clear, high-resolution EGM sensing.¹
References

Brief Statement
DiamondTemp™ Ablation Catheter

Indications
The DiamondTemp catheter is indicated for use in cardiac electrophysiological mapping (stimulation and recording) and for treatment of drug refractory, recurrent, symptomatic paroxysmal atrial fibrillation when used in conjunction with the DiamondTemp RF generator and accessories (DiamondTemp catheter-to-RF generator cable, DiamondTemp GenConnect cable, DiamondTemp EGM cable, DiamondTemp irrigation pump, DiamondTemp irrigation tubing set) and compatible mapping system.

Contraindications
Use of the DiamondTemp catheter is contraindicated for: 1) patients with active systemic infection, 2) patients with prosthetic valves, 3) patients with intracardiac thrombus or myxoma, or interatrial baffle or patch via transseptal approach, 4) patients unable to receive heparin or an acceptable alternative to achieve adequate anticoagulation, 5) pregnant women and children <18 years of age, and 6) patients who are hemodynamically unstable.

Warnings/Precautions
Cardiac ablation procedures should be performed only by physicians trained in the techniques of RF catheter ablation in a fully equipped electrophysiology (EP) laboratory. The catheter is for single use only. Do not reprocess or resterilize. Reusing, reprocessing, or resterilizing may compromise the structural integrity of the device or lead to product failure, which may result in patient injury, illness, or death. Reuse, reprocessing, or resterilizing may also create a risk of contamination of the device. Contamination may lead to injury, illness, or death of the patient. Pacemakers, implantable cardioverter defibrillators (ICDs), and leads can be adversely affected by RF signals. ICDs should be deactivated prior to ablation, precautions should be taken when the catheter is in close proximity to leads, and complete system analysis should be performed after ablation. Long-term risks of RF ablation lesions have not been established. Ablation too close to the esophageal area can result in esophageal fistula. Ablation near the AV node can cause permanent or partial conduction block. To ensure proper operation of the tissue contact impedance measurement function, all four electrodes and six thermocouples on the catheter tip must protrude from the distal tip of the guiding sheath. Carefully monitor the tissue contact impedance before delivery of RF energy. Do not place the RF electrode in proximity to any other mapping or ablation electrodes, as this may cause inadvertent, ineffective, or unsafe tissue ablation and may increase chances of char, coagulum, or steam pops. Although a higher contact impedance value typically indicates acceptable tissue contact, and low contact impedance values typically indicate lack of tissue contact, caution should be exercised. Areas of previously ablated tissue may also display a low contact impedance value. Other parameters, such as EGM, fluoroscopic images, and intracardiac ultrasound should be monitored before deciding to apply RF. Always advance and withdraw components slowly to minimize the vacuum created and therefore minimize risk of air embolism. Stimulation of cardiac tissues caused by pacing stimulus or RF energy may lead to inadvertent induction of arrhythmias. These arrhythmias may require defibrillation that could also result in skin burns. Do not use the catheter for epicardial ablation. Using ablation parameters (such as temperature set-point, ablation duration, or irrigation flow rate) other than those recommended by Epix Therapeutics may be hazardous to patients. Exercise caution and sound medical reasoning when deciding to deviate from recommended parameters. Perform catheter advancement under fluoroscopic guidance in conjunction with internal contact, electrograms, and impedance monitoring to minimize the risk of cardiac damage, perforation, or tamponade. Tip-to-tissue contact impedance is actively monitored only before and after ablation. During ablation, use caution when the temperature drops suddenly. A drop in temperature may be associated with loss of tissue contact. In case of steam pop or automatic shut off, discontinue RF energy. Remove the catheter for visual inspection and check for coagulum, charring, or other catheter defects.

Manual prebending of the distal curve may damage the steering mechanism and may cause patient injury. Do not attempt ablation with the catheter without the use of the DiamondTemp irrigation pump and DiamondTemp generator and approved accessories.

Potential Complications
Potential complications/adverse events from cardiac catheterization and ablation include, but are not limited to, the following: Abnormal vision; Air embolism; Anaphylaxis; Anemia; Aneuryms; Angina; Arrhythmia (including new or worsening of existing condition, or requiring cardioversion); Arterial or venous thrombus; Atrial septal defect; AV fistula; Cardiac arrest; Cardiac tamponade; Catheter entrapment leading to valve or heart wall damage; Catheter insertion site hematoma; Chest pain (nonspecific); Congestive heart failure exacerbation; Component damage to ICD or pacemaker; Coronary artery dissection; Death; Dislodgement of implantable device or permanent pacing lead; Dizziness; Embolic events, including infarction of other tissues, coronary, pulmonary, and bowel structures; Endocarditis; Esophageal damage or necrosis; Exacerbation of COPD; Exacerbation of pre-existing atrial fibrillation; Fluid overload; Gastroptosis or GI event; Hemorrhage; Herniorrhrax; Hypotension; Hypoxia; Inadvertent AV block; Infection; Myocardial infarction; Neck pain, back pain, or groin pain; Palpitations; Perforation (cardiac); Pericardial effusion; Pericarditis; Peripheral venous thrombosis; Phrenic nerve damage; Pleural effusion; Pneumonia; Pneumothorax; Pseudoaneurysm; Pulmonary edema; Pulmonary vein stenosis; Radiation injury resulting in dermatitis, erythema, etc.; Renal insufficiency or failure; Respiratory failure; Sepsis; Sepsis; Skin burns; Stroke or cerebrovascular incident; Syncope; Thromboembolic event; Transient ischemic attack; Vasovagal reaction; Ventricular arrhythmia; Vessel wall or valvular damage or insufficiency.

See the appropriate product device manuals for detailed information regarding the RF ablation procedure, indications (or intended use), contraindications, warnings, precautions, and potential complications/adverse events. See the appropriate eIFUs for the DiamondTemp catheters.

For further information, call Medtronic at 1-800-238-2518 and/or consult the Medtronic website at medtronic.com.

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