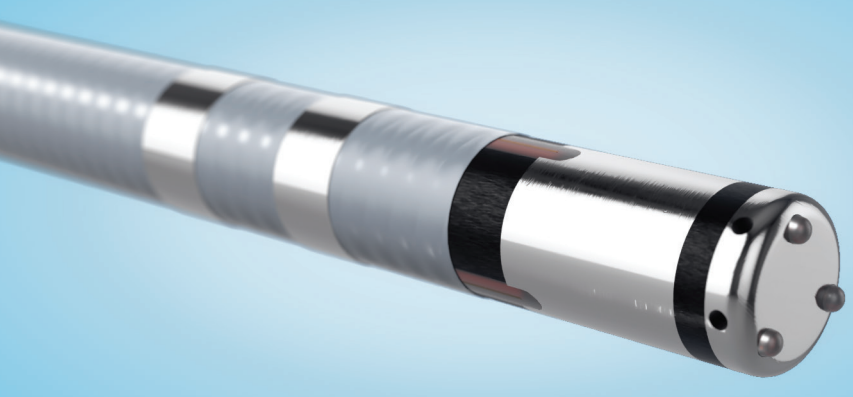
REAL-TIME, TEMPERATURE-CONTROLLED ABLATION

The DiamondTemp™
Ablation System with RealTemp™



Medtronic

THE NEXT ERA OF RF ABLATION

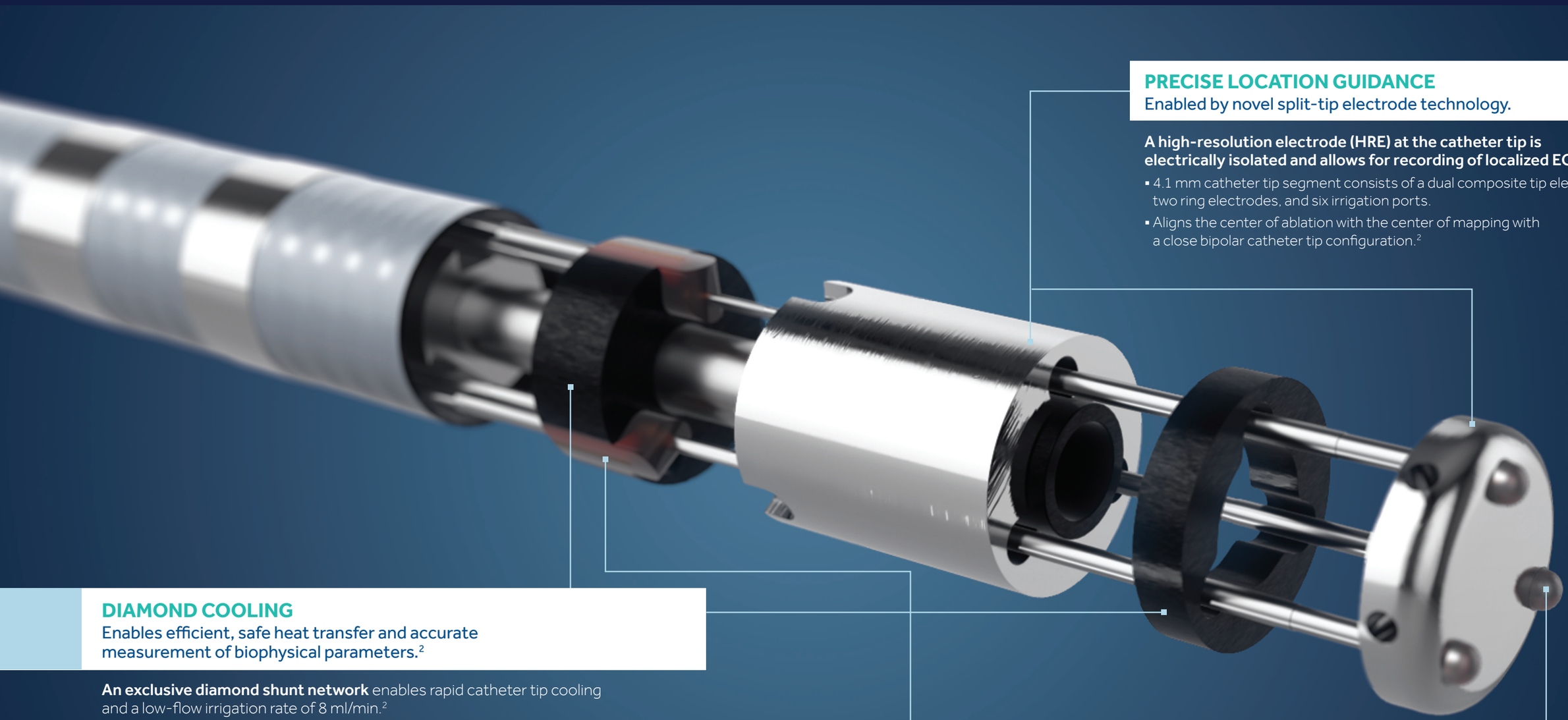
DiamondTemp™ Ablation Catheter

The only low-flow, open-irrigated, real-time temperature-controlled RF catheter that creates safe and effective cardiac lesions[1] via quick conduction of thermal energy enabled by industrial diamonds.[2]

RealTemp™ technology includes[2]:

- Real-time tissue surface temperature measurement and power modulation based on tissue temperature
- Diamond-enabled rapid catheter tip cooling
- High-resolution electrograms for precise location guidance

A DIFFERENTIATED DESIGN
WITH REALTEMP™ TECHNOLOGY



PRECISE LOCATION GUIDANCE
Enabled by novel split-tip electrode technology.

A high-resolution electrode (HRE) at the catheter tip is electrically isolated and allows for recording of localized EGMs.

- 4.1 mm catheter tip segment consists of a dual composite tip electrode, two ring electrodes, and six irrigation ports.
- Aligns the center of ablation with the center of mapping with a close bipolar catheter tip configuration.[2]

DIAMOND COOLING
Enables efficient, safe heat transfer and accurate measurement of biophysical parameters.[2]

An exclusive diamond shunt network enables rapid catheter tip cooling and a low-flow irrigation rate of 8 ml/min.[2]

- Catheter is composed of chemical vapor deposition (CVD) diamonds and platinum-iridium components.[2]
- Heat transfer is 200–400 times faster with CVD diamonds.[3,4]
- Minimal heat is retained at the catheter tip and lower irrigation flow rate is required.
- Demonstrated 57.7% reduction in saline infusion compared to CF-RF.[1]

REAL-TIME TEMPERATURE SENSING
Provides real-time temperature feedback and modulates power accordingly.

Temperature provides direct feedback on lesion creation.
Irreversible tissue damage is created at temperatures > 50 °C.[5]

- The DiamondTemp ablation system runs in temperature control mode.
- RealTemp drives six thermocouple readings by the generator 50 times per second and automatically adjusts the power to the ablation set temperature.

SAFE, EFFECTIVE, & EFFICIENT

Results from the DAF trial demonstrated that the DTA system is a safe, effective, and efficient treatment for paroxysmal AF.

DIAMOND-AF (DAF) CLINICAL TRIAL[1]

Comparing the DiamondTemp ablation system versus a contact force-sensing ablation system (CF-RF).

BACKGROUND

Tissue temperature is a well-established biophysical parameter of irreversible tissue damage. Irrigated RF was introduced to mitigate the risk of char and thrombus formation; however, thermal acuity is disrupted.

To address these limitations, the DiamondTemp ablation (DTA) system was designed to accurately measure tip-tissue temperature during energy delivery.

STUDY DESIGN

The DAF trial was an FDA-regulated, prospective, multicenter, noninferiority, randomized, controlled trial which compared the safety and effectiveness of the DTA system and a CF-RF ablation system (TactiCath™) (control).

482 paroxysmal AF patients were randomized (239 DTA system and 243 control) for PVI at 23 sites in the United States, Europe, and Canada. Patients were followed for 12 months.

STUDY POPULATION

Key Inclusion Criteria:

- Symptomatic paroxysmal AF
  - At least two self-terminating AF episodes reported in last six months
  - At least one ECG documented episode in last 12 months
- Prior Class I-IV AAD failure
- ≥ 18 years of age

Key Exclusion Criteria:

- Prior cardiac interventions
- Neurological events within six months
- Class III/IV or uncontrolled heart failure
- Left ventricular ejection fraction < 35%
- Left atrial diameter > 5.5 cm

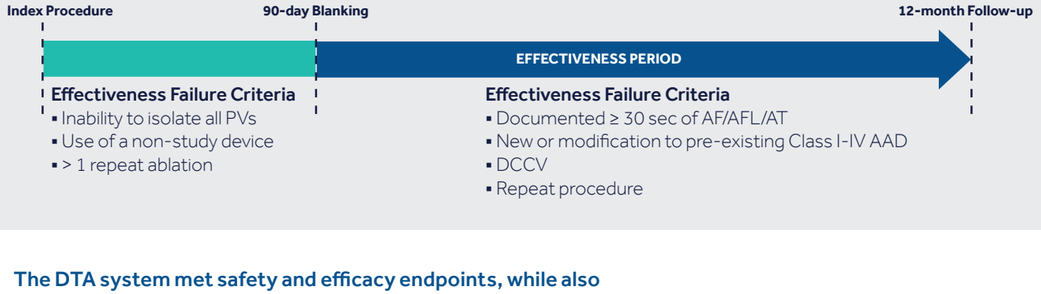
PRIMARY SAFETY AND EFFICACY ENDPOINT ACHIEVED

PRIMARY ENDPOINTS

Effectiveness:
The primary effectiveness endpoint was freedom from recurrence of an atrial arrhythmia (AF, AFL, AT) during the effectiveness period. This was a composite endpoint of seven failure criteria.

Safety:
The primary safety endpoint is defined as freedom from a composite of serious adverse events (SAE) occurring within 30 days and clinically symptomatic pulmonary vein stenosis through six months post-index ablation procedure.

Primary Effectiveness Endpoint:
Freedom from recurrence of atrial arrhythmias (AF/AFL/AT)



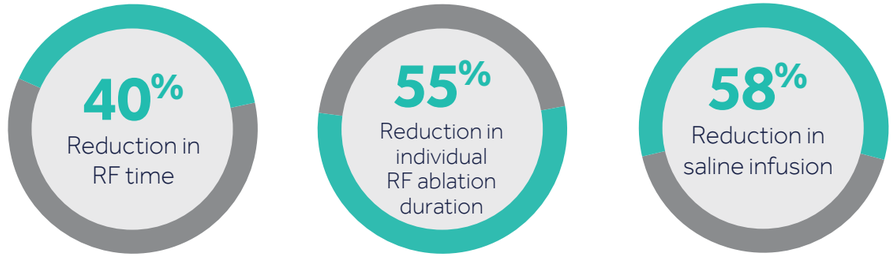
The DTA system met safety and efficacy endpoints, while also demonstrating procedural efficiencies versus CF-RF.

PRIMARY SAFETY ENDPOINT MET

3.3% Safety event rate compared with **6.6%** with contact force-sensing RF.

PRIMARY EFFECTIVENESS ENDPOINT MET

79.1% Compared with **75.7%** with contact force-sensing RF.



DTA demonstrated favorable off-drugs effectiveness compared to CF-RF (59.4% and 49.4%, p-value < 0.05).

Metric	DTA Group	Control Group	% Reduction with DTA
Total RF time	17.9 ± 8.1 min	29.8 ± 14 min	39.9%
Individual RF ablation duration	14.7 ± 5.3 s	32.6 ± -25.3 s	54.9%
Saline infusion volume	332.2 ± 120.8 ml	785.5 ± -351.5 ml	57.7%

BIOPHYSICAL FEEDBACK DURING ABLATION

ELECTROGRAM (EGM) ATTENUATION

75% to 80% reduction in the split-tip EGM amplitude occurred, followed by ablation for an additional three to five seconds.[6]

SURFACE TEMPERATURE

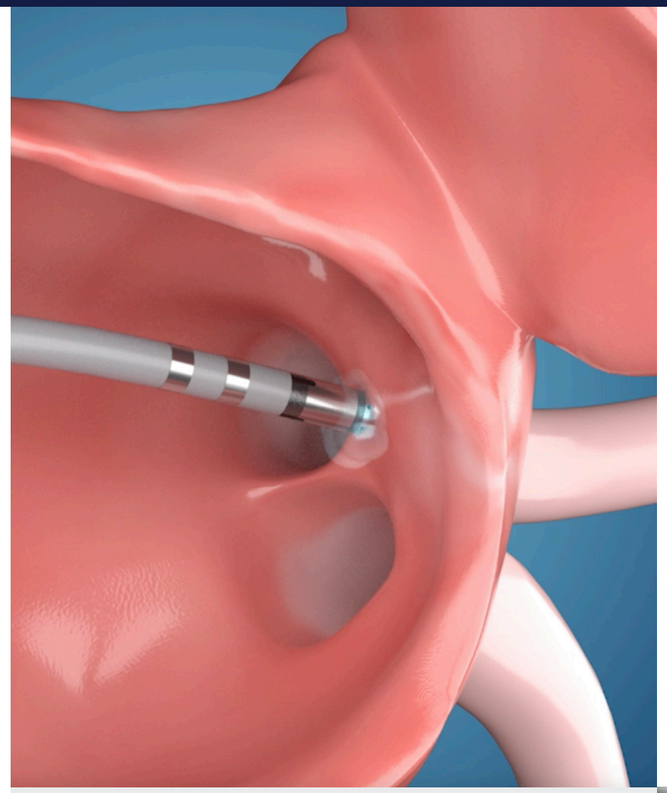
Temperature provides direct feedback of lesion creation. Irreversible tissue damage is created at temperatures > 50 °C.[5]

The best predictor of lesion size is achieved through tissue temperature; the ablation lesion closely corresponds to the zone of sufficiently heated tissue.[7]

IMPEDANCE DROP OF 5–10 Ω

Impedance changes reflect changes in tissue characteristics: impedance drop can offer an independent means of assessing the true outcome of interest — tissue heating.

Significant tissue heating is associated with a predictable fall in impedance.[8]



The level of tissue contact is reflected by the catheter temperature reading. The RFG will adjust power based on the catheter temperature (and therefore, tissue contact) to deliver therapeutic lesions.[9]

CATHETER CONTACT WITH THE DIAMONDTEMP ABLATION SYSTEM

DTA ADJUSTS POWER

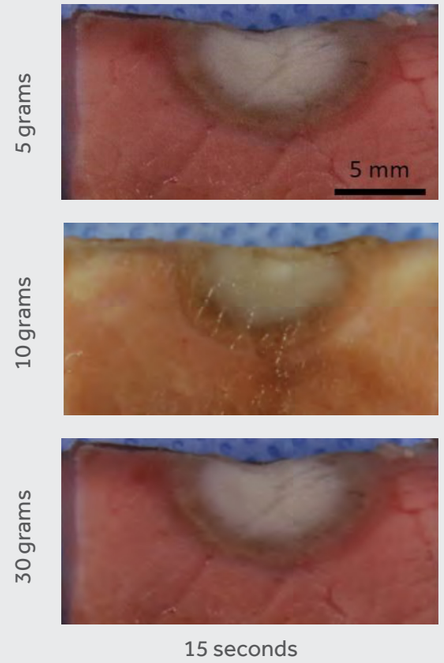
To maintain target therapeutic temperature[9]

In vivo **lesions were delivered with varying contact force and ablation duration.**

Preclinical studies indicate that contact force does not have a significant impact on lesion depth or volume.

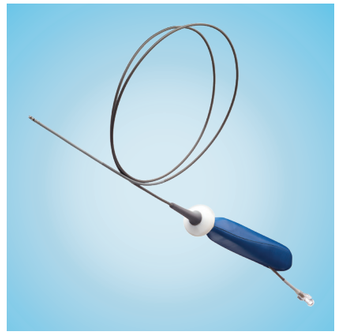
Results:

- Increasing the applied catheter force did not have a significant impact on lesion depth or volume.
- **Temperature-controlled power modulation removes the influence of applied contact force on lesion formation.**



THE DIAMONDTEMP ABLATION SYSTEM

DiamondTemp™ Ablation Catheter
The DTA is a sterile, single-use, externally irrigated catheter.
The DTA catheter:
- Has an 8.0 Fr shaft and saline-irrigated, 4.1 mm tip
- Features a tip segment consisting of a dual composite tip electrode, two ring electrodes, six irrigation ports, and a network of industrial diamonds
- Includes customized offerings:
  – Small curve (45 mm) and large curve (63 mm) configurations
  – Unidirectional and bidirectional models



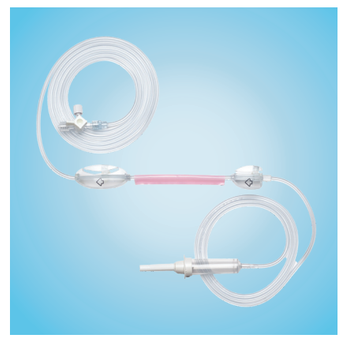
DiamondTemp™ Generator
The DTA generator operates in temperature control mode and desired catheter tip-to-tissue temperature is selected by the user. Thermocouples in the catheter tip provide temperature feedback and the generator automatically adjusts the power output to maintain the desired tip-to-tissue temperature.

DiamondTemp™ Irrigation Pump
The DiamondTemp irrigation pump delivers saline to the DiamondTemp ablation catheter when used in conjunction with the DiamondTemp tubing. The irrigation pump has a touch screen display and flow control button that controls a two-flow-rate feature for easy selection of the appropriate irrigation flow rate. The irrigation pump communicates with the DiamondTemp generator and may be operated either under control of the generator or independently. The irrigation pump is intended for use only with the DiamondTemp tubing set.

DiamondTemp™ Catheter-to-RFG Cable
The DiamondTemp catheter-to-RF generator cable provides the connection between the DiamondTemp generator and DiamondTemp catheter. The cable distal end has a 19-pin connector that connects to the DiamondTemp catheter. The cable proximal end has a 26-pin connector that connects with the RF generator.

DiamondTemp™ GenConnect Cable
The GenConnect cable is used to connect the DiamondTemp catheter to the RF generator when a GenConnect device is used. The GenConnect cable distal end has a 26-pin female connector that connects to the catheter cable and a proximal end with a 26-pin male connector that connects with the generator.

DiamondTemp™ Irrigation Tubing
The DiamondTemp irrigation tubing set is designed for use with the DiamondTemp ablation system. The tubing is an accessory to the DiamondTemp irrigation pump and is supplied separately. The tubing delivers saline (0.9%) Heparin 1 IU/mL to the catheter when used with the irrigation pump. The delivery action is based on a peristaltic mechanism employing rollers and mechanical fingers that push fluid through the tubing. The tubing is provided sterile and is for single use only.



References
[1] Kautzner J, Albenque JP, Natale A, et al. A Novel Temperature-Controlled Radiofrequency Catheter Ablation System Used to Treat Patients With Paroxysmal Atrial Fibrillation. JACC Clin Electrophysiol. March 2021;7(3):352-363.
[2] Avila C, DiamondTemp Catheter Design. Metronic data on file, January 2021.
[3] Brown A, et al. *Introduction to Heat Transfer.* 3rd ed. McGraw Hill; 1958.
[4] Eckert ERG, et al. Heat and Mass Transfer. Cited in: Holman JP. *Heat Transfer.* 9th ed. McGraw Hill; 2002.
[5] Nath S, et al. *J Cardiovasc Electrophysiol.* 1994;5:863-876.
[6] Iwasawa J, et al. *J Am Coll Cardiol.* 2017;70:542-553.
[7] Nakagawa H, et al. *Circulation.* 1995;91:2264-2273.
[8] Strickberger SA, et al. *Am Heart J.* 1995;130:1026-1030.
[9] Verma, et al. AF Symposium 2021 Abstract: AFS2021-0.

Brief Statement
DiamondTemp™ Ablation System
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. Do not attempt ablation without the use of the irrigation pump. Before attempting ablation, make sure the pump flow rate is at the minimum continuous flow and the pump is actively communicating with the generator. The potential adverse events that may be associated with ablation procedures can vary greatly in frequency and severity and may necessitate additional medical intervention, including surgery. Carefully review the specific indications, contraindications, warnings, precautions, and adverse events included with each DiamondTemp catheter, prior to use of the DiamondTemp generator or irrigation pump. The irrigation pump is designed for use only with sterile heparinized normal saline solution. Specified flow-rate accuracy may not be maintained when used with incompatible fluids or delivery devices. The air bubble detector is disabled during irrigation pump priming and purging functions. Do not prime or purge the catheter when it is inserted in the vasculature of the patient. Do not remove the irrigation tubing set from the irrigation pump while the tubing set is in-line with a catheter that is inside the patient.
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; Aneurysm; 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; Gastroparesis or GI event; Hemorrhage; Hemothorax; 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; Seizure; 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, DiamondTemp RF generator, DiamondTemp irrigation pump, DiamondTemp irrigation tubing set, DiamondTemp catheter-to-RF generator cable, DiamondTemp GenConnect cable, and EGM cable.
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.

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