Medtronic

DiamondTemp™

Ablation Catheter

Instructions for Use

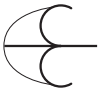
Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

Contents

1 Glossary of symbols

The following table defines symbols that are used on packaging and product labeling. Refer to the labels to determine which symbols apply to this product and for the product-specific information, such as the date of manufacture.

Symbol	Standard/Standard Title or Reference	Symbol title/Reference number	Explanatory Text
Rx only	21 CFR 801.109[a]	Prescription only	USA Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.
	ISO 15223-1[b]	Consult instructions for use (clause 5.4.3)	Consult instructions for use at this website: www.medtronic.com/manuals
	ISO 15223-1[b]	Catalog number (clause 5.1.6)	Indicates the manufacturer's catalog number so the device can be identified
	ISO 15223-1[b]	Batch code (clause 5.1.5)	Indicates the manufacturer's batch code so that the batch or lot can be identified
	ISO 15223-1[b]	Use by date (clause 5.1.4)	Indicates the date after which the device is not to be used
	ISO 15223-1[b]	Manufacturer (clause 5.1.1)	Indicates the medical device manufacturer
	N/A	Manufactured in/ manufacturing site	Indicates where the device was manufactured
	ISO 15223-1[b]	Date of manufacture (clause 5.1.3)	Indicates the date when the medical device was manufactured
	ISO 15223-1[b]	Keep Dry (clause 5.3.4)	Indicates a medical device that needs to be protected from moisture
	ISO 15223-1[b]	Do not use if package is damaged (clause 5.2.8)	Indicates a medical device that should not be used if the package has been damaged or opened
	ISO 15223-1[b]	Caution (clause 5.4.4)	Indicates there is important cautionary information for the medical device.
	ISO 15223-1[b]	Do not re-use (clause 5.4.2)	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure
	ISO 15223-1[b]	Do not resterilize (clause 5.2.6)	Indicates a medical device that is not to be resterilized
	ISO 15223-1[b]	Sterilized using ethylene oxide (clause 5.2.3)	Indicates a medical device that has been sterilized using ethylene oxide
	ISO 15223-1[b]	Non-pyrogenic (clause 5.6.3)	Indicates a medical device that is non-pyrogenic.
	ISO 15223-1[b]	Keep away from sunlight (clause 5.3.2)	Indicates a device that needs protection from light sources.
	N/A	Storage temperature limit (clause 5.3.7)	Indicates the required temperature range for storing the device
	N/A	Transit temperature limit (clause 5.3.7)	Indicates the required temperature range for transporting the device
	N/A	Package contents	Indicates the components included in the device package

Symbol	Standard/Standard Title or Reference	Symbol title/Reference number	Explanatory Text
	N/A	Unidirectional catheter	Indicates that a unidirectional catheter is included in the device package
	N/A	Bidirectional catheter	Indicates that a bidirectional catheter is included in the device package
	ISO 7000[c]	Product documentation	Indicates that product documentation is included in the device package
	N/A	Unidirectional	Indicates a catheter that operates only in one direction
	N/A	Bidirectional	Indicates a catheter that operates in two directions
	ISO 15223-1[b]	Sterile barrier	Single sterile barrier system with protective packaging inside

[a] 21 CFR 801.109: United States Code of Federal Regulations, Title 21, Food and Drugs

[b] ISO 15223-1: Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied

[c] ISO 7000: Graphical symbols for use on equipment

2 Device description

The Medtronic DiamondTemp ablation catheter is a sterile, single use, externally irrigated ablation catheter designed to deliver radiofrequency (RF) energy for cardiac ablation. It is designed to be used in conjunction with the DiamondTemp generator, DiamondTemp catheter-to-RFG cable, DiamondTemp GenConnect cable, DiamondTemp EGM cable, DiamondTemp irrigation pump, and DiamondTemp tubing set.

The DiamondTemp ablation catheter is available as unidirectional (*Figure 1*) or bidirectional (*Figure 2*) with a distal electrode segment and a proximal handle that are connected by a torquable shaft. The unidirectional catheter has an actuation piston to actuate the curve in one direction. The bidirectional catheter has a steering knob to actuate the curve in either direction and a tension knob to lock the curve. (Refer to *Table 1* for model information.) The distal tip and ring electrodes of the catheter are designed to record intracardiac electrocardiogram (ECG) signals for mapping and stimulus delivery. RF energy delivery by catheter tip-to-tissue contact is similar to other commercially available, externally irrigated catheters. Refer to the catheter package labeling for electrode spacing details.

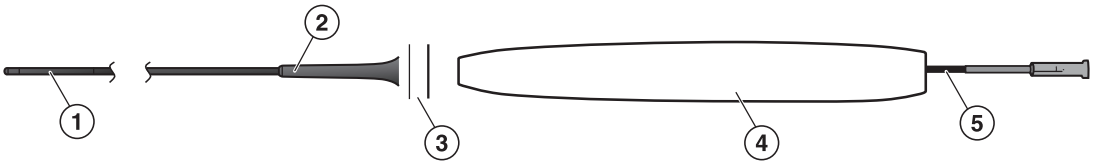
Table 1. Catheter models and specifications

Description	Specification
Catheter shaft size (outer diameter)	2.83 mm (8.5 Fr)
Catheter ablation tip size (tip electrode)	2.50 mm (7.5 Fr)
Length	110 cm (43.3 in)
Model CEDT100S	Unidirectional, small curve (45 mm)
Model CEDT200L	Unidirectional, large curve (63 mm)
Model CEDTB300S	Bidirectional, small curve (45 mm)
Model CEDTB400L	Bidirectional, large curve (63 mm)

The catheter is constructed of thermoplastic elastomer materials and noble metal electrodes. Thermocouples are incorporated at the distal and proximal end of the tip electrode for temperature sensing during RF ablation. The highest temperature from all thermocouples is displayed on the generator. The generator modulates the delivered RF energy to maintain tissue temperature at a user-defined temperature set-point.

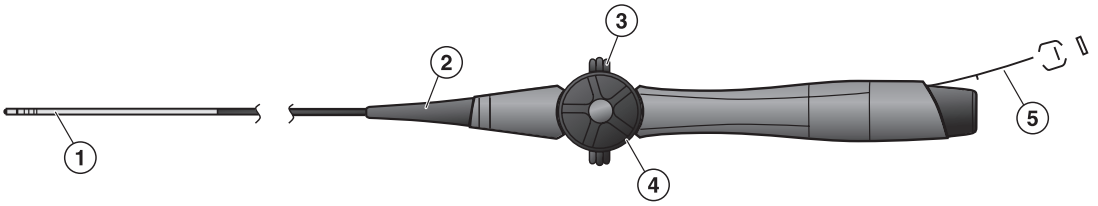
The catheter, when connected to the tubing set and irrigation pump, delivers normal saline (0.9%) with Heparin at 1 IU mL via a lumen in the catheter. Saline is delivered to the tissue and through 6 ports located on the catheter tip. The saline cools the catheter tip and tip-tissue interface. One luer connection at the proximal end of the handle connects to the tubing set, allowing the irrigation pump to generate the flow of normal saline to the catheter.

Figure 1. DiamondTemp Ablation Catheter (unidirectional)



1 Catheter shaft
2 Shaft strain relief
3 Actuation knob
4 Handle
5 Cooling lumen

Figure 2. DiamondTemp Ablation Catheter (bidirectional)



1 Catheter shaft
2 Strain relief
3 Steering knob
4 Tension knob
5 Cooling lumen

3 Indications for use

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.

4 Contraindications

- Patients with active systemic infection
- Patients with prosthetic valves
- Patients with intracardiac thrombus or myxoma, or interatrial baffle or patch via transseptal approach
- Patients unable to receive heparin or an acceptable alternative to achieve adequate anticoagulation
- Pregnant women and children <18 years of age
- Patients who are hemodynamically unstable

5 Warnings and precautions

- Before use, inspect the catheter for any foreign particles or material, defects, or physical damage, including electrical insulation of the cable. If the catheter is defective or damaged, do not use and contact a Medtronic representative. Replace damaged devices or equipment as necessary.
- Carefully read all DiamondTemp ablation system (catheter, generator, catheter-to-RFG cable, GenConnect cable, irrigation pump, tubing set) instructions before use. Observe all contraindications, warnings, and precautions noted in the directions. Failure to do so may result in patient complications.
- If the DiamondTemp system is used in conjunction with a compatible mapping system (such as the Abbott EnSite™ Velocity™ or Precision™ Mapping System), consult the respective instructions to ensure correct connectivity and usage. Construct an anatomic map of the region of interest only after all mapping catheters and electrodes, the DiamondTemp catheter, respective cables, and neutral electrodes (including the ablation return pad) are completely and properly connected. The subsequent addition of catheters or electrodes may render the anatomic map inaccurate and require remapping.
- Carefully read the instructions for all ancillary devices or products used in the procedure before use.
- 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.
- Use the catheter before the “Use by” date on the device package.
- Cardiac ablation procedures should be performed only by physicians trained in the techniques of RF catheter ablation in a fully equipped electrophysiology (EP) laboratory.
- Pacemakers and implantable cardioverter defibrillators (ICDs) can be adversely affected by RF signals and appropriate precautions should be taken before, during, and after ablation to minimize risk.
- Implantable devices such as ICDs should be deactivated or programmed to the OFF mode before ablation. Perform complete ICD system analysis on all patients after ablation.
- Use careful catheter manipulation and awareness when in close proximity to atrial or ventricular leads.
- Anticoagulation therapy is required before device introduction to prevent thrombus formation.
- Catheter ablation procedures present a risk of significant x-ray exposure, which can result in acute radiation injury as well as increased risk for somatic and genetic effects to both patients and laboratory staff. Catheter ablation

should only be performed after adequate attention has been given to the potential exposure associated with the procedure and steps taken to minimize this exposure.

- Long-term risks of RF ablation lesions have not been established.
- To avoid risk of injury, do not ablate near the phrenic nerve.
- Ablation too close to the esophageal area can result in esophageal fistula.
- Use caution when placing lesions in the proximity of the cardiac conduction system.
- Ablation near the AV node can cause permanent or partial conduction block.
- Ablation within and in close proximity to the coronary arterial vasculature has been associated with myocardial infarction and death.
- Catheter materials are not compatible with magnetic resonance imaging (MRI).
- In accordance with hospital protocol, monitor the patient's fluid balance throughout the procedure to avoid fluid overload.
- Catheter entrapment within the heart or blood vessels is a possible complication of EP procedures.
- Do not use excessive force when inserting, advancing, or removing the catheter.
- Before insertion into the patient, flush the catheter by pressing the Purge Flow button on the irrigation pump, at a flow rate of 60 mL/min, and ensure there are no air bubbles.
- To ensure proper operation of the tissue contact impedance measurement function, all 4 electrodes and 6 thermocouples on the catheter tip must protrude from the distal tip of the guiding sheath.
- Ablation over other catheter electrodes (on a diagnostic catheter, for example) has been associated with unintended EGM noise.
- 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.
- If the contact impedance reads less than 35 Ω, the generator will not allow delivery of RF energy. In such circumstances, replace the catheter. If after replacing the catheter the condition persists, replace the catheter-to-RFG cable and the GenConnect cable (if used). If the condition still persists, power down the generator and contact a Medtronic representative.
- Although a high 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 display a low contact impedance value. Other parameters, such as EGM, fluoroscopic images, and intracardiac ultrasound should be monitored before deciding to apply RF.
- Do not deliver RF energy if the catheter is outside the target site. The RF generator can deliver significant electrical energy and may cause patient injury.
- Use caution during multiple sheath and catheter exchanges through the transseptal puncture. Caution is necessary to avoid causing a residual atrial septal defect that would require repair.
- The transseptal procedure presents the potential risk for an air embolus, which may involve the coronary arteries. Aspiration and flushing of the sheath, dilator, and needle should be performed during insertion or exchange, to minimize this risk. Refer to the individual sheath, dilator, and needle instructions.
- Fibrin may accumulate in or on the sheath and catheter assembly during the procedure. Aspirate when removing the dilator or catheter. Follow the sheath instructions for maintaining sheath patency during use.
- 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 Medtronic may be hazardous to patients. Exercise caution and sound medical reasoning when deciding to deviate from recommended parameters.
- Delivery of RF energy may result in neuromuscular stimulation. Monitor patient reactions.
- The power, temperature, and impedance display of the generator should be continuously monitored during RF energy delivery.
- Irrigated ablation systems have been shown to create larger lesions than standard RF ablation catheters. Use caution when ablating near electrically vulnerable, thin-walled, or other arterial structures.
- During use of the RF generator and irrigation pump, pay attention to all messages, error codes, warnings, and tones, and exercise caution as needed.
- Perform catheter advancement under fluoroscopic guidance in conjunction with careful manipulation, 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.
- Always straighten the catheter before insertion or withdrawal from the patient.
- Always maintain irrigation flow to prevent coagulation within and around electrodes.

- If the irrigation flow is interrupted, withdraw the catheter from the patient, visually inspect the tip, and then flush the catheter before reinsertion and before resuming the procedure.
- Do not use the catheter if it appears damaged or kinked, or if there is any difficulty in deflecting the distal section to achieve the desired curve.
- Do not use if the catheter irrigation ports are blocked.
- Use fluoroscopy or information from a mapping system to confirm the position of the catheter during the procedure.
- Manual prebending of the distal curve may damage the steering mechanism and may cause patient injury.
- Do not immerse the proximal handle or cable connectors in fluid. Ensure that the cable and catheter connections remain dry throughout the procedure.
- Position connecting cables to avoid contact with the patient and other electrical leads.
- Do not attempt ablation with the catheter without the use of the DiamondTemp irrigation pump, the DiamondTemp generator, and approved accessories.
- After use, dispose of the catheter and packaging in accordance with hospital, administrative, and local government policy.
- Do not expose the catheter to organic solvents such as alcohol.

6 Potential adverse events

The following potential adverse events are associated with cardiac ablation procedures:

- 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 (non-specific)
- 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, back, 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

7 Clinical data

Study title – DIAMOND-AF: A Randomized Controlled Clinical Evaluation of the DiamondTemp Ablation System for the Treatment of Paroxysmal Atrial Fibrillation

Number of centers – 23 centers in the United States, Canada, and Europe

Number of subjects – 482 enrolled/randomized subjects globally. There were 243 enrolled/randomized subjects in the control (TactiCath) group and 239 enrolled/randomized subjects in the investigational (DiamondTemp) group.

Study purpose – The purpose of DIAMOND-AF was to provide data demonstrating the safety and effectiveness of the DiamondTemp Ablation System for the treatment of drug refractory, recurrent, symptomatic paroxysmal atrial fibrillation (PAF). The study was considered successful if the investigational device was considered non-inferior to the control device for the primary safety and effectiveness endpoints.

7.1 Study Design, Study Population, Study Visits, and Length of Follow-up Methods

The Diamond-AF Study was a prospective, single-blind, 1:1 randomized, controlled trial performed at multiple centers in the United States, Canada and Europe. The primary focus of the left atrial ablation procedure was to create a series of point-by-point RF lesions encircling the left and right PVs to achieve electrical PVI from the rest of the left atrium (LA). All subjects were followed per protocol in relation to the date of the index ablation procedure. Follow-up was required prior to hospital discharge and at 7 days, 1 month, 3 months, 6 months, and 12 months post-ablation. Subjects were provided a cardiac event monitor at the hospital pre-discharge visit to be used throughout the duration of the study. This data was transmitted to and read at an ECG core lab.

7.2 Study Endpoints

7.2.1 Primary Endpoints

7.2.1.1 Primary Effectiveness Endpoint

The primary effectiveness endpoint was defined as freedom from documented AF, atrial flutter[1] (AFL) and atrial tachycardia (AT) episodes following the blanking period (3-month follow-up post-ablation procedure) through the end of the effectiveness evaluation period (12-month follow-up post-ablation procedure).

An effectiveness failure was defined by any of the following events:

- Inability to electrically isolate all accessible targeted pulmonary veins during the ablation procedure[2].
- Documented episodes of AF, AFL or AT lasting ≥ 30 seconds in duration as evidenced by electrocardiographic data during the effectiveness evaluation period

[1] Occurrence and/or ablation of cavotricuspid isthmus (CTI)-dependent AFL, as confirmed by entrainment maneuvers during EP testing at any time during this study was not a primary effectiveness failure because it was not considered an iatrogenic arrhythmia following a left atrial ablation procedure for AF.

[2] Electrical isolation as confirmed by demonstration of exit and/or entrance conduction block.

- DC cardioversion for AF, AFL or AT during the effectiveness evaluation period
- A repeat ablation procedure to treat AF, AFL or AT during the effectiveness evaluation period
- Use of a new or modification to existing Class I-IV anti-arrhythmic drug (AAD) regimen to treat AF, AFL or AT recurrence during the effectiveness evaluation period
- Use of a non-study device for ablation of any AF targets during the index or repeat ablation procedure during the blanking period
- More than one (1) repeat ablation procedure during the blanking period.

7.2.1.2 Primary Safety Endpoint

The primary safety endpoint was defined as freedom from a composite of serious adverse events (SAE) occurring within 30 days and clinically symptomatic pulmonary vein stenosis through 6 months post-index ablation procedure, as adjudicated by an independent Clinical Events Committee (CEC) for relatedness to the procedure or device.

The primary safety device- or procedure-related SAE composite was a combined rate of the following events:

- Atrioesophageal fistula
- Bleeding complication
- Cardiac tamponade / perforation
- Death
- Extended hospitalization
- Myocardial infarction
- Pericarditis
- Phrenic nerve paralysis
- Pulmonary edema
- Pulmonary vein stenosis
- Stroke post-ablation
- Thromboembolism
- Transient ischemic attack (TIA) post-ablation
- Vagal nerve injury
- Vascular access complications

7.2.2 Secondary Endpoints

Secondary Endpoints and Results

There were seventeen (17) pre-defined secondary endpoints in the Diamond-AF Study, four (4) of which included hypothesis testing.

Secondary endpoints to characterize the performance of the DiamondTemp Ablation System, relative to the control device, include:

- Mean duration of individual RF ablations (seconds).
- Mean cumulative RF time per procedure (minutes).
- Freedom from a composite of SAE occurring within 7 days post-index ablation procedure as adjudicated by an independent CEC for relatedness to the procedure or device.
- Freedom from documented AF, AT and AFL[3] episodes following the blanking period through 12 month follow-up post-ablation procedure in the absence of class I and III anti-arrhythmic drug therapy.
- Rate of acute procedural success, defined as confirmation of electrical isolation of PVs via assessment of entrance block at least 20 minutes following the last ablation around the respective PV.
- Rate of single procedure success defined as the rate of subjects treated with one single ablation procedure during study participation and with freedom from documented AF, AT and AFL[3] at 12 months.
- Rate of single procedure success defined as the rate of subjects treated with one single ablation procedure during study participation and with freedom from ALL primary effectiveness endpoint failure criteria.
- Rate of occurrence of electrically reconnected PVs following a 20-minute waiting period assessed by entrance block at index procedure.
- Accumulated changes in Quality of Life (QOL) using the AF QOL Survey (AFEQT Questionnaire) from baseline through 6 and 12 months following ablation procedure.
- Neurological changes measured using the NIH stroke scale between baseline and post-ablation (pre-discharge visit) and at 12 months post-ablation procedure.
- Total procedure time (minutes), defined as time of first assigned ablation catheter insertion into the vasculature to time of last procedural ablation catheter removed.
- Time to achieve initial PVI at index procedure (minutes), defined as time of delivery of first RF ablation with the assigned ablation catheter until confirmation of PVI.
- Total treatment device time (minutes), defined as time of delivery of first RF ablation with the assigned ablation treatment catheter to removal of the treatment catheter.

- Total number of RF ablations per procedure.
- Total fluid infused through the assigned ablation catheter (mL).
- Total fluoroscopy time (minutes).
- Number of re-hospitalizations due to atrial fibrillation recurrence after blanking period.

7.3 Total Number of Enrolled Study Sites and Subjects, Subject Accountability, and Follow-up Rate

Investigators at 23 participating study sites in the United States, Canada, and Europe enrolled/randomized a total of 482 subjects.

Four hundred eighty five (485) subjects signed an informed consent to participate in the DIAMOND-AF clinical study. Four hundred eighty two (482) subjects were enrolled/ randomized in the Diamond-AF clinical study (Intention-to-Treat Cohort). Two hundred thirty nine (239) subjects were randomized to treatment with the investigational DiamondTemp catheter and two hundred forty three (243) subjects were randomized to treatment with the control TactiCath catheter system.

Enrolled/randomized subject accountability is summarized in *Table 2*, *Table 3*, and *Figure 3*.

- Consented subjects: All subjects who signed a consent form.
- Intention-to-Treat (ITT) analysis cohort: The ITT cohort comprised of all randomized subjects regardless of whether they received study treatment, with analyses conducted according to the randomized treatment assignment.
- Safety analysis cohort: The 476 subjects who had a study ablation catheter inserted comprise the Safety Analysis cohort.

Of the 239 subjects randomized to the DiamondTemp group, 225 completed the study with 14 (5.9%) exited prematurely. Likewise, of the 243 subjects randomized to the control group, 230 completed the study and 13 (5.3%) exited prematurely. Of the 482 subjects in ITT, 476 subjects had exposure to a study device (ablation catheter).

Table 2. Subject Disposition

Subject Disposition	Number (N)
Number of Subjects with Signed Consent	485
Number of Subjects Not Randomized	3
Documented Stroke, CVA, TIA or Suspected Neurological Event[a]	1
Enrollment Cap Met[b]	1
Regularly Prescribed Amiodarone[c]	1
Number of Subjects Enrolled/Randomized (Intention-to-Treat Analysis Cohort)	482

[a] Subject 15-021 met exclusion criterion #24

[b] Subject 15-010 met all criteria but was never randomized prior to study exit (30-Oct-2018), with a reason of "Subject's ablation was not scheduled and patient was not randomized prior to enrollment number being met"

[c] Subject 17-001 met exclusion criterion #19

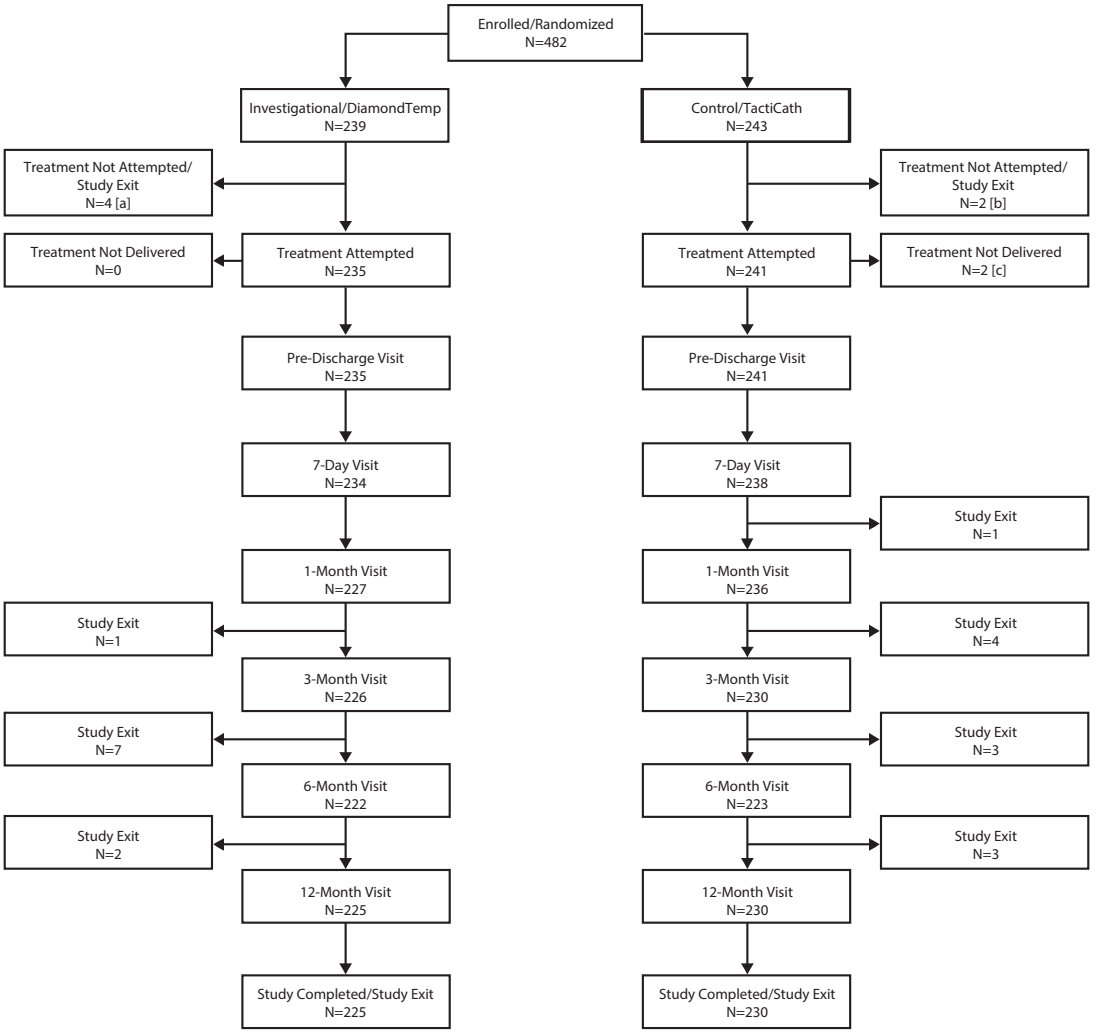
Table 3. Scheduled Visit Compliance

Visit	Control (N=243)	DiamondTemp (N=239)	All Subjects (N=482)
Enrolled/Randomized	243 (100%)	239 (100%)	482 (100%)
Ablation Procedure	241 (99.2%)	235 (98.3%)	476 (98.8%)
Pre-Discharge Visit	241 (99.2%)	235 (98.3%)	476 (98.8%)
7 Day Visit	238 (97.9%)	234 (97.9%)	472 (97.9%)
1 Month Visit	236 (97.1%)	227 (95.0%)	463 (96.1%)
3 Month Visit	230 (94.7%)	226 (94.6%)	456 (94.6%)
6 Month Visit	223 (91.8%)	222 (92.9%)	445 (92.3%)
12 Month Visit	230 (94.7%)	225 (94.1%)	455 (94.4%)
Study Completion			
Completion of Study as Planned	230 (94.7%)	225 (94.1%)	455 (94.4%)
Discontinued Prematurely	13 (5.3%)	14 (5.9%)	27 (5.6%)

Figure 3 study flowchart shows subject accountability from enrollment to 12 months follow-up/study completion.

[3] Occurrence and/or ablation of cavotricuspid isthmus (CTI)-dependent AFL, as confirmed by entrainment maneuvers during EP testing at any time during this study was not a primary effectiveness failure because it was not considered an iatrogenic arrhythmia following a left atrial ablation procedure for AF.

Figure 3. Study Flowchart of Subject Population, from Enrollment to 12 Month Visit



[a] Subject withdrew consent (06-013); Subject progressed to persistent AF (11-001); Enrollment closure (09-003, 13-015).

[b] Enrollment closure (10-004); Physician no longer believed the subject was a good candidate for the study (11-004).

[c] Treatment attempted but not delivered with TactiCath due to technical difficulties (09-001); Treatment attempted but not delivered with TactiCath due to procedure failure (22-005).

Follow-up visit compliance was 91.8% or higher for all follow-up visits, with 94.7% of control subjects and 94.1% of DiamondTemp subjects completing the study as planned through the 12 month follow-up visit.

7.4 Baseline Characteristics

Table 4 shows demographic information for subjects by treatment group in the Intention-to-Treat cohort. Demographic data was balanced with no significant differences between the treatment groups.

Table 4. Demographic Characteristics, Intention-to-Treat Cohort, Control vs DiamondTemp

Demographics	Control (N=243)	DiamondTemp (N=239)
Age, years		
Mean (SEM / SD)	63.0 (0.67 / 10.42)	62.3 (0.72 / 11.13)
Median	64.0	65.0
Min, Max	27.0, 84.0	22.0, 82.0
N (N Missing)	243 (0)	239 (0)
Sex, n (%)		
Male	143 (58.8%)	136 (56.9%)
Female	100 (41.2%)	103 (43.1%)

Table 4. Demographic Characteristics, Intention-to-Treat Cohort, Control vs DiamondTemp (continued)

Demographics	Control (N=243)	DiamondTemp (N=239)
Race, n (%)		
American Indian or Alaska Native	2 (0.8%)	3 (1.3%)
Asian	2 (0.8%)	0 (0%)
Black or African American	4 (1.6%)	4 (1.7%)
Other, specify: Caribbean	0 (0%)	1 (0.4%)
Other, specify: Ecuadorian	0 (0%)	1 (0.4%)
Prefer Not to Say	68 (28.0%)	66 (27.6%)
Unknown	6 (2.5%)	5 (2.1%)
White	161 (66.3%)	159 (66.5%)
Ethnicity, n (%)		
Hispanic or Latino	5 (2.1%)	6 (2.5%)
Not Hispanic or Latino	169 (69.5%)	167 (69.9%)
Prefer Not to Say	69 (28.4%)	66 (27.6%)

Min = Minimum, Max = Maximum; SD= Standard Deviation; SEM=Standard Error of the Mean.

Notes: N = Number of subjects in the population. n = Number of subjects in the specific category. Percentages are calculated as 100 x (n/N).

Age is derived from the date of informed consent.

Table 5 shows baseline information for subjects by treatment group in the Intention-to-Treat cohort. Baseline characteristics were well balanced with no significant differences between the treatment groups.

Table 5. Baseline Characteristics, Intention-to-Treat Cohort, Control vs DiamondTemp

Baseline Characteristics	Control (N=243)	DiamondTemp (N=239)
Height, cm		
Mean (SEM / SD)	172.7 (0.63 / 9.89)	172.9 (0.63 / 9.69)
Median	172.7	172.7
Min, Max	152.0, 196.0	147.3, 205.7
N (N Missing)	243 (0)	239 (0)
Weight, kg		
Mean (SEM / SD)	85.4 (1.03 / 16.01)	84.1 (1.17 / 18.06)
Median	85.0	83.0
Min, Max	51.0, 146.0	45.8, 131.7
N (N Missing)	243 (0)	239 (0)
BMI, kg/m^2		
Mean (SEM / SD)	28.6 (0.29 / 4.48)	28.0 (0.32 / 5.00)
Median	28.1	27.5
Min, Max	19.8, 42.9	14.2, 44.1
N (N Missing)	243 (0)	239 (0)
Serum Creatinine, mg/dL		
Mean (SEM / SD)	0.9 (0.01 / 0.22)	0.9 (0.02 / 0.23)
Median	0.9	0.9
Min, Max	0.1, 1.6	0.5, 2.2
N (N Missing)	227 (16)	223 (16)
LVEF, %		
Mean (SEM / SD)	60.1 (0.45 / 7.08)	59.8 (0.47 / 7.19)
Median	60.0	60.0
Min, Max	38.0, 80.0	44.0, 82.0
N (N Missing)	243 (0)	235 (4)
LA Diameter, cm		
Mean (SEM / SD)	4.1 (0.04 / 0.67)	4.0 (0.04 / 0.59)
Median	4.0	4.0
Min, Max	2.2, 5.5	2.5, 5.5

Table 5. Baseline Characteristics, Intention-to-Treat Cohort, Control vs DiamondTemp (continued)

Baseline Characteristics	Control (N=243)	DiamondTemp (N=239)
N (N Missing)	243 (0)	233 (6)
NYHA Functional Class, n (%)		
Class I	36 (14.8%)	32 (13.4%)
Class II	20 (8.2%)	22 (9.2%)
Class III	0 (0%)	0 (0%)
Class IV	0 (0%)	0 (0%)
NA (1)	117 (48.1%)	116 (48.5%)
Unknown (2)	70 (28.8%)	69 (28.9%)
Heart Rate, bpm		
Mean (SEM / SD)	69.3 (1.23 / 19.23)	69.0 (1.12 / 17.37)
Median	64.0	65.0
Min, Max	36.0, 169.0	35.0, 140.0
N (N Missing)	243 (0)	239 (0)
Systolic BP, mmHg		
Mean (SEM / SD)	136.3 (1.25 / 19.41)	138.1 (1.28 / 19.82)
Median	133.0	135.0
Min, Max	92.0, 206.0	77.0, 199.0
N (N Missing)	243 (0)	239 (0)
Diastolic BP, mmHg		
Mean (SEM / SD)	77.4 (0.70 / 10.94)	77.5 (0.69 / 10.73)
Median	78.0	78.0
Min, Max	46.0, 110.0	43.0, 104.0
N (N Missing)	243 (0)	239 (0)
CHA2DS2-VASc Score		
Mean (SEM / SD)	2.11 (0.10 / 1.50)	1.92 (0.09 / 1.38)
Median	2.0	2.0
Min, Max	0.0, 7.0	0.0, 6.0
N (N Missing)	243 (0)	239 (0)

BMI=Body Mass Index; BP=Blood Pressure; LA=Left Atrium; LVEF=Left Ventricular Ejection Fraction; NYHA=New York Heart Association.

Min = Minimum, Max = Maximum; SD = Standard Deviation; SEM=Standard Error of the Mean.

(1) Subjects without heart failure, will have an NYHA result that is not applicable (NA).

(2) NYHA score is missing/not available in source documents.

Table 6 shows years since first diagnosis of atrial fibrillation and history of AAD therapy for subjects by treatment group in the Intention-to-Treat cohort.

Table 6. History of Atrial Fibrillation and AAD Therapy, Intention-to-Treat Cohort, Control vs DiamondTemp

Medical History	Control (N=243)	DiamondTemp (N=239)
Years Since First Diagnosis (years)		
Mean (SEM / SD)	4.0 (0.34 / 4.85)	3.5 (0.33 / 4.68)
Median	2	2
Min, Max	0, 26	0, 28
N (N Missing)	205 (38)	207 (32)
AAD Use History		
Subjects with History of AAD Use and Failed/Not Tolerate, n(%)	243 (100.0%)	239 (100.0%)

Table 6. History of Atrial Fibrillation and AAD Therapy, Intention-to-Treat Cohort, Control vs DiamondTemp (continued)

Medical History	Control (N=243)	DiamondTemp (N=239)
Subjects with History of Class I/III AAD Use and Failed/Not Tolerate, (*), n(%)	191 (78.6%)	187 (78.2%)
Subjects with History of Class II/IV AAD Use and Failed/Not Tolerate, (*), n(%)	121 (49.8%)	117 (49.0%)

AAD=Anti-arrhythmic drugs; AF=Atrial Fibrillation; PAF=Paroxysmal Atrial Fibrillation

Min = Minimum, Max = Maximum; SD=Standard Deviation; SEM=Standard Error of the Mean.

Notes: N = Number of subjects in the population. n = Number of subjects in the specific category. Percentages are calculated as 100 x (n/N).

All other percentages are calculated as 100 x (n/N1). N1 = Number of subjects in category.

(*) Categories are not mutually exclusive and subjects may count in more than one category.

Table 7 shows medical history information for subjects by treatment group in the Intention-to-Treat cohort. Medical history was well-balanced between treatment groups with the exception of 'Non-PAF/AFL Arrhythmias or conduction disturbances'. Medical history details related to a previous left atrial ablation, receipt of a septal closure device or mitral valve surgical procedure was not collected in this study, as these were study exclusion criterion if they occurred at any time prior to enrollment.

Table 7. Medical and Smoking History, Intention-to-Treat Cohort, Control vs DiamondTemp

Medical History	Control (N=243)	DiamondTemp (N=239)
Atrial Flutter	51 (21.0%)	46 (19.2%)
Hypertension Requiring Medication	137 (56.4%)	124 (51.9%)
Hypertension Regardless of Medications Required	138 (56.8%)	125 (52.3%)
Diabetes	28 (11.5%)	20 (8.4%)
Structural Heart Disease	7 (2.9%)	7 (2.9%)
Cerebrovascular Accident/Transient Ischemic Attack	20 (8.2%)	12 (5.0%)
Thromboembolic Events	6 (2.5%)	4 (1.7%)
Coronary Artery Disease	29 (11.9%)	27 (11.3%)
Myocardial Infarction	2 (0.8%)	4 (1.7%)
Non-PAF/AFL Arrhythmias or conduction disturbances	42 (17.3%)	22 (9.2%)
Vascular Disease	20 (8.2%)	13 (5.4%)
Congestive Heart Failure	3 (1.2%)	6 (2.5%)
Previous CABG Procedure	1 (0.4%)	0 (0%)
Previous ICD/CRT/Pacemaker Implant	0 (0%)	1 (0.4%)
Gastrointestinal (GI) Disease	25 (10.3%)	28 (11.7%)
Pulmonary Disease with Different Etiologies	4 (1.6%)	6 (2.5%)
Other	159 (65.4%)	149 (62.3%)
Smoking History – Yes	75 (30.9%)	71 (29.7%)
Smoking History - Current Smoker	16 (6.6%)	17 (7.1%)
Smoking History - Previously Smoked	59 (24.3%)	54 (22.6%)

CABG=Coronary Artery Bypass Graft; CRT= Cardiac resynchronization therapy; ICD= implantable cardioverter defibrillator;

PAF= Paroxysmal Atrial Fibrillation

Notes: N = Number of subjects in the population. n = Number of subjects in the specific category. Percentages are calculated as 100 x (n/N).

Categories are not mutually exclusive and subjects may count in more than one category.

7.5 Procedural Characteristics

Table 8 shows a summary of index ablation procedure details.

There were 5 (2.1%) subjects with steam pops reported in the control group and 7 (3.0%) subjects with steam pops reported in the DiamondTemp group. No adverse events were reported as a result of a steam pop that occurred in either treatment group.

Table 8. Index Ablation Procedure Characteristics, Intention-to-Treat Cohort, Control vs DiamondTemp

Procedural Characteristics	Control (N=243)	DiamondTemp (N=239)
Total Number of AF Index Ablation Procedures[N1]	241	235
TEE for LA Thrombus Screening Performed	236 (97.9%)	234 (99.6%)
Esophageal Monitoring/Protection:		
Esophageal Deviation, n (%)	22 (9.1%)	19 (8.1%)
Use of Esophageal Temperature Probe, n (%)	191 (79.3%)	186 (79.1%)
Ablation Parameter Settings – Max Power Set Point		
Mean (SEM/SD)	33.3 (0.39/6.01)	49.7 (0.24/3.74)
Median	30.0	50.0
Min, Max	5.0, 70.0	0.0, 56.0
N (N Missing)	239 (2)	233 (2)
Ablation Parameter Settings – Max Temperature Set Point		
Mean (SEM/SD)	44.1 (0.32/4.94)	59.9 (0.10/1.60)
Median	43.0	60.0
Min, Max	30.0, 70.0	43.0, 65.0
N (N Missing)	233 (8)	234 (1)
Non-PVI Ablation Targets(*):		
Type I CTI Flutter	69 (28.6%)	74 (31.5%)
Other	5 (2.1%)	3 (1.3%)
Posterior Wall	3 (1.2%)	4 (1.7%)
Focal Triggers	2 (0.8%)	4 (1.7%)
Roof	2 (0.8%)	2 (0.9%)
SVC	3 (1.2%)	1 (0.4%)
CFAE	2 (0.8%)	1 (0.4%)
Flutter Line	2 (0.8%)	1 (0.4%)
Mitral Isthmus Line	2 (0.8%)	1 (0.4%)
AVRT/AVNRT	1 (0.4%)	1 (0.4%)
Incidence of Steam Pops, n (%)	5 (2.1%)	7 (3.0%)
Incidence of Char or Coagulum, n (%)	0 (0%)	0 (0%)

AF=Atrial Fibrillation; CTI=Cavotricuspid Isthmus; LA= Left Atrium; PV=Pulmonary Vein; TEE =Transesophageal echocardiography.

Min = Minimum, Max = Maximum; SD=Standard Deviation; SEM=Standard Error of the Mean.

Notes: N = Number of subjects in the Intention-to-Treat Population.

n = Number of subjects in the specific category. Percentages are calculated as 100 x (n/N1). N1 = Number of subjects in category.

(*) Categories are not mutually exclusive and subjects may count in more than one category.

Table 9 presents the additional intervention performed to maintain sinus rhythm during the blanking period. Comparable number of subjects between the two arms received repeat ablation or cardioversion before the evaluation period.

Table 9. Additional Treatment During the Blanking Period

Subjects with Additional Treatment during Blanking Period	Control (N=243)	DiamondTemp (N=239)	P-value[a]
Repeat ablation	11 (4.53%)	10 (4.18%)	1.00
Cardioversion	11 (4.53%)	7 (2.93%)	0.47

[a] P-value is calculated using two-sided Fisher's exact test

7.6 Rhythm Monitoring Compliance

Post-ablation rhythm monitoring included symptomatic and twice monthly symptomatic/asymptomatic event monitor transmissions during the evaluation period, ECG at 3, 6, and 12 months, and 24-hour Holter monitor at 6 and 12 months.

The rhythm monitoring compliance was similar between the two treatment groups with regard to 12-lead ECGs, 24-hour Holter monitors, and trans-telephone monitors (*Table 10* and *Table 11*).

Table 10. Rhythm Monitoring Compliance, 12-Lead ECGs and Holter from CRF Data, Intention-to-Treat Cohort, Control vs DiamondTemp

Rhythm Monitoring Method	Control (N=243) n (%)	DiamondTemp (N=239) n (%)	All Subjects (N=482) n (%)
12-Lead ECGs			
3 Month Visit 12-Lead ECG	219/237 (92.4%)	209/235 (88.9%)	428/472 (90.7%)
6 Month Visit 12-Lead ECG	206/234 (88.0%)	207/228 (90.8%)	413/462 (89.4%)
12 Month Visit 12-Lead ECG	224/231 (97.0%)	223/227 (98.2%)	447/458 (97.6%)
24-hour Holter Monitor			
6 Month Visit 24-hour Holter Monitor	202/234 (86.3%)	199/228 (87.3%)	401/462 (86.8%)
12 Month Visit 24-hour Holter Monitor	213/231 (92.2%)	204/227 (89.9%)	417/458 (91.0%)

ECG= Electrocardiogram;

Notes: N = Number of subjects in the Intention-to-Treat Population. n = Number of subjects in the specific category. For ECG and Holter, percentages for populations are calculated as 100 x (n/expected number of measurements at that visit).

Six subjects were randomized/enrolled but did not undergo index ablation procedure (06-013, 09-003, 10-004, 11-001, 11-004, 13-015).

Table 11. Rhythm Monitoring Compliance, Trans-telephonic Monitor (TTM), Intention-to- Treat Cohort, Control vs. DiamondTemp

Rhythm Monitoring - TTM	Control (N=243)	DiamondTemp (N=239)	All Subjects (N=482)
TTMs			
(Total) Transmitted TTMs	5419	4557	9976
Expected TTMs[1]	4373	4288	8661
Overall TTM Compliance (Subject) (%)[2]			
Mean (SEM/SD)	60.5 (2.02/31.01)	61.3 (2.09/32.03)	60.9 (1.45/31.49)
Median	70.0	72.2	72.2
Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0
N (N Missing)	236 (7)	235 (4)	471 (11)

TTM= Trans-telephonic Monitor.

Six subjects were randomized/enrolled but did not undergo index ablation procedure (06-013, 09-003, 10-004, 11-001, 11-004, 13-015).

[1] Subject Expected TTM is 2 if the subject's study participation in a given month is longer than 15 days, otherwise it is 1 for that month.

[2] Overall compliance is defined on a per subject basis and is based on a subject average monthly compliance rates over months 1 through 10 after the blanking period. A subject's monthly compliance rate is defined as minimum (TTM

transmitted for that month, TTM expected for that month)/TTM expected for that month, over months 1 through 10 after the blanking period.

7.7 Results

7.7.1 Safety Results

7.7.1.1 Primary Safety Endpoint

The primary safety analysis includes all randomized ITT subjects (243 Control and 239 DiamondTemp). There were 16 (6.6%) Control subjects and 8 (3.3%) DiamondTemp subjects that experienced at least one CEC-adjudicated primary safety endpoint event that contributed to the primary safety endpoint. The primary safety event freedom rate was 96.7% for the DiamondTemp group and 93.4% for the Control group. The difference (DiamondTemp – Control) in the primary safety endpoint freedom was 3.24% (95% CI: -1.32%, 7.79%), and the lower 97.5% confidence bound of -1.32% exceeded the pre-specified non-inferiority margin (NIM) of -6.5%. The primary safety endpoint was met (p < 0.0001, *Table 12*).

Table 12. Summary of CEC Adjudicated Adverse Events Contributing to the Primary Safety Endpoint, Intention-to-Treat Cohort, Control vs DiamondTemp

	Control	DiamondTemp
CEC Adjudicated Adverse Events Contributing to the Primary Safety Endpoint	**By Subject (Ns=243) n (%)**	**By Subject (Ns=239) n (%)**
Atrioesophageal Fistula	0 (0%)	0 (0%)
Bleeding Complication	0 (0%)	0 (0%)
Cardiac Tamponade/Perforation	2 (0.8%)	2 (0.8%)
Cardiovascular-Related Death Post-Ablation	0 (0%)	0 (0%)
Clinically Symptomatic Pulmonary Vein Stenosis at 6 Months Post-Index Ablation Procedure	0 (0%)	0 (0%)
Extended Hospitalization	6 (2.5%)[a]	0 (0%)
Myocardial Infarction	0 (0%)	0 (0%)
Pericarditis	1 (0.4%)	0 (0%)
Phrenic Nerve Paralysis	0 (0%)	1 (0.4%)
Pulmonary Edema	1 (0.4%)	0 (0%)
Stroke Post Ablation	1 (0.4%)	0 (0%)
Thromboembolism	0 (0%)	0 (0%)
Transient Ischemic Attack	1 (0.4%)	2 (0.8%)
Vagal Nerve Injury	0 (0%)	1 (0.4%)
Vascular Access Complication	4 (1.6%)	2 (0.8%)
Total	16 (6.6%)	8 (3.3%)

[a] Reasons for extended hospitalization include hematoma, pericardial effusion (< 1 cm), fever and chill, bladder outlet obstruction with UTI, hypotension, chest pain.

Notes: Ns = Number of subjects in the population. n = Number of subjects in the specific category.

Subject based percentages are calculated as 100 x (n/Ns).

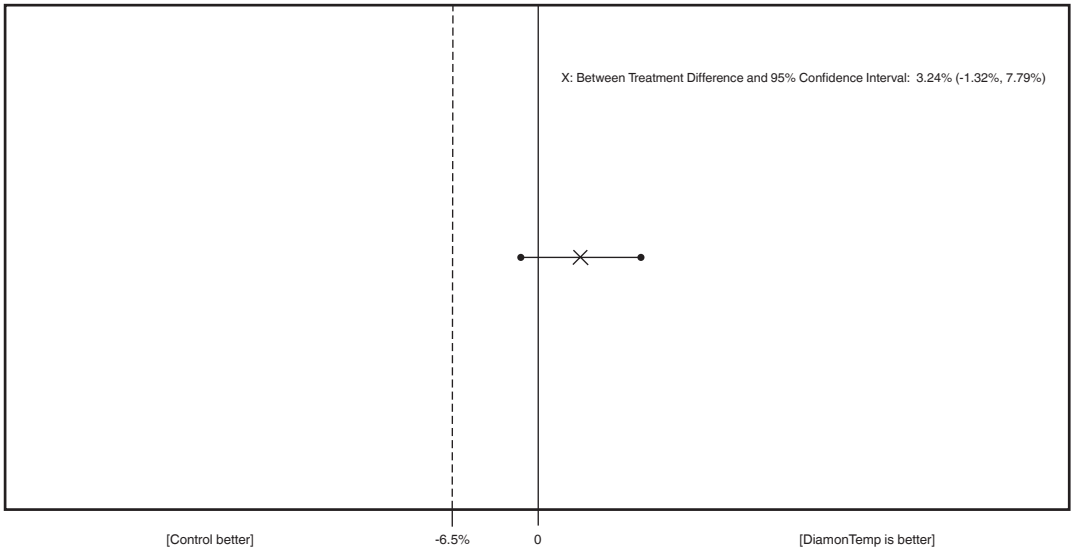
For the 'by Subject' columns, subjects reporting a particular adverse event more than once are only counted once by the event category.

Table 13 and *Figure 4* display the primary safety objective results for the ITT cohort. The primary safety event freedom rate was 96.7% for the DiamondTemp group and 93.4% for the control group. The DiamondTemp minus control group primary safety endpoint freedom rate was 3.24% with a two-sided 95% confidence interval of -1.32% to 7.79%. Since the lower two-sided 95% confidence limit of -1.32% exceeded the non-inferiority margin of -6.5%, the primary safety objective was met (p<0.0001).

Table 13. Primary Safety Result, Intention-to-Treat Cohort

Primary Safety Endpoint: Freedom from Primary Safety Event as Adjudicated by the CEC	Control (N=243) Number (%) (95% CI)	DiamondTemp (N=239) Number (%) (95% CI)	Difference (95% CI)	Farrington- Manning p-value (Non-inferiority Test)
Total, By Subject	227 (93.4%) (89.5%, 96.2%)	231 (96.7%) (93.5%, 98.5%)	3.24% (-1.32%, 7.79%)	<0.0001

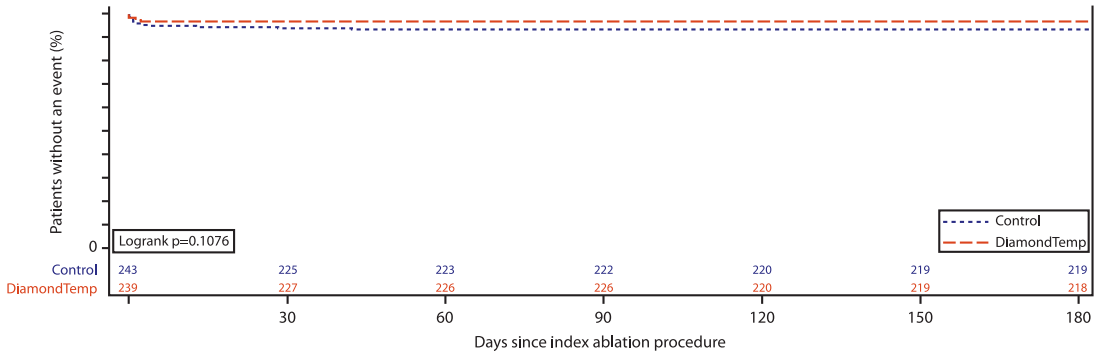
Figure 4. Primary Safety Freedom Rate: Between Treatment Difference



A Kaplan-Meier analysis was also performed to evaluate the primary safety endpoint as a sensitivity analysis. The Kaplan-Meier method allows subjects to be included in the analysis up until the time they fail the primary safety endpoint or are censored due to premature study exit.

Figure 5 displays the Kaplan-Meier estimates for the freedom from primary safety event through 6 months (180 days) post-index ablation procedure; the entire time period for which subjects were at risk for a primary safety event. Based on the Kaplan-Meier methodology the freedom from primary safety event at 6 months was 97% for the DiamondTemp group and 93% for the control group. The log-rank test indicated that there was no difference in the freedom from primary safety event between groups (p=0.11).

Figure 5. Kaplan-Meier Survival: Time to Failure of the Primary Safety Endpoint, Intention-to-Treat Cohort



Kaplan-Meier Survival: Time to Failure of the Primary Safety Endpoint, Intention-to-Treat Cohort				
		Month 1	**Month 3**	**Month 6**
Control	Number at Risk	225	222	219
	Kaplan-Meier Estimate	0.94	0.93	0.93
	Standard Error	0.0155	0.0160	0.0160
DiamondTemp	Number at Risk	227	226	218
	Kaplan-Meier Estimate	0.97	0.97	0.97
	Standard Error	0.0117	0.0117	0.0117

Month 1 (day 30), Month 3 (day 90), Month 6 (day 180)

Table 14 displays the primary safety endpoint status by treatment group and geography and indicates that the primary safety endpoint results were consistent by geography (Breslow-Day p-value = 0.54).

Table 14. Primary Safety Event Outcome: Relative Risk of Success; Overall and Stratified by Geographic Region and Treatment, Intention-to-Treat Cohort

Geographic Region	Treatment	PSE Success	PSE Failure	Total	Relative Risk of Success	Breslow Day Test p-value
Europe	DiamondTemp	124	5	129	1.02	0.5425
	Control	124	8	132		
	DiamondTemp	107	3	110	1.05	
North America	Control	103	8	111		
Overall	DiamondTemp	231	8	239	1.03	
	Control	227	16	243		
Pooled / Adjusted (CMH)[a]					1.03	

[a] CMH= Cochran-Mantel-Haenszel

The DIAMOND-AF Clinical Study met its primary safety objective (Intention-to-Treat Cohort). Primary safety endpoint success was observed in 227 (93.4%) control (TactiCath) subjects and 231 (96.7%) DiamondTemp subjects (95% CI for difference: -1.3% to 7.8%; p<0.0001 for non-inferiority). There was no evidence of heterogeneity in primary effectiveness outcome between treatment groups by geography (p=0.54). The DiamondTemp Ablation System demonstrated a reasonable assurance of safety for the treatment of drug refractory, recurrent, symptomatic PAF.

7.7.1.2 Summary of Adverse Events

Adverse events occurring during the study were continuously monitored and collected. There were no Unanticipated Adverse Device Effects or deaths reported in the DIAMOND-AF Clinical Study.

Table 15 summarizes all adverse events by seriousness and relatedness. In the ITT cohort, there were 171 adverse events reported in 98 (41.0%) of the 239 subjects randomized to the DiamondTemp group. Of these events, 21 events in 18 (7.5%) subjects were considered device or procedure related regardless of severity. There were 199 total adverse events reported in 103 (42.4%) of the 243 subjects randomized to the control group. Of these events, 35 events in 31 (12.8%) subjects were considered device or procedure related regardless of severity.

Table 15. AE Overall Summary Table, Intention-to-Treat Cohort, Control vs DiamondTemp

Adverse Event Classification	Number of Events (Number of subjects, % of Subjects)	
	Control (N=243)	DiamondTemp (N=239)
Total Adverse Events	199 (103, 42.4%)	171 (98, 41.0%)
Primary Safety Events[1]	16 (16, 6.6%)	8 (8, 3.3%)
Serious[2]		
Yes	61 (43, 17.7%)	53 (34, 14.2%)
No	138 (80, 32.9%)	118 (79, 33.1%)
Relatedness[2],[4]		
Device and/or Procedure Related[3]		
Related	35 (31, 12.8%)	21 (18, 7.5%)
Possibly Related	23 (18, 7.4%)	16 (15, 6.3%)
Unknown	2 (2, 0.8%)	0 (0, 0%)
Not Related	139 (79, 32.5%)	134 (81, 33.9%)
Device Relatedness		
Related	3 (3, 1.2%)	2 (2, 0.8%)
Possibly Related	4 (4, 1.6%)	3 (3, 1.3%)
Unknown	2 (2, 0.8%)	2 (2, 0.8%)
Not Related	190 (99, 40.7%)	164 (95, 39.7%)
Procedure Relatedness		
Related	35 (31, 12.8%)	21 (18, 7.5%)
Possibly Related	23 (18, 7.4%)	16 (15, 6.3%)
Unknown	2 (2, 0.8%)	0 (0, 0%)
Not Related	139 (79, 32.5%)	134 (81, 33.9%)

[1] Primary safety events are based on CEC adjudication.

[2] Seriousness and Relatedness are based on investigator assessment.

[3] Device and/or Procedure Relatedness- the strongest relationship with device or procedure is used in this category.

[4] A subject may count in more than one relatedness category.

7.7.2 Effectiveness Results

7.7.2.1 Primary Effectiveness Endpoint

A summary of Diamond-AF Study primary effectiveness endpoint results are noted below. The primary effectiveness endpoint analysis was performed on the Intention-to-Treat (ITT) Cohort (i.e. all enrolled/randomized subjects). The primary effectiveness endpoint was met. *Table 16*, *Table 17* and *Figure 6* below show the primary effectiveness results for subjects by treatment group in the Intention-to-Treat cohort. Of the 243 enrolled/randomized control subjects (ITT cohort), 184 (75.7%) were free of all primary effectiveness endpoint failure criteria. Of the 239 enrolled/ randomized DiamondTemp subjects (ITT cohort), 189 (79.1%) were free of all primary effectiveness endpoint failure criteria. The DiamondTemp minus control freedom rate was 3.4% with a two-sided 95% confidence interval ranging from -4.2% to 10.9%. The lower two-sided 95% confidence limit exceeded the non-inferiority margin of -12.5%, and the Farrington-Manning Score test for non-inferiority yielded a p-value of <0.0001. Therefore, the primary effectiveness objective was met.

Table 16. Primary Effectiveness Endpoint, Intention-to-Treat Cohort, Control vs DiamondTemp

	Control (N=243)		DiamondTemp (N=239)	
Criteria	**Success (No/Absent) n (%)**	**Failure (Yes/Present) n (%)**	**Success (No/Absent) n (%)**	**Failure (Yes/Present) n (%)**
Inability to electrically isolate all accessible targeted pulmonary veins during the ablation procedure.[a]	241 (99.2%)	2 (0.8%)	239 (100.0%)	0 (0%)
Documented episodes of AF, AFL or AT lasting ≥30 seconds in duration as evidenced by electrocardiographic data during the effectiveness evaluation period.	197 (81.1%)	46 (18.9%)	198 (82.8%)	41 (17.2%)
DC cardioversion for AF, AFL, or AT during the effectiveness evaluation period.	238 (97.9%)	5 (2.1%)	231 (96.7%)	8 (3.3%)
A repeat ablation procedure to treat AF, AFL or AT during the effectiveness evaluation period.	229 (94.2%)	14 (5.8%)	226 (94.6%)	13 (5.4%)
Use of a new or modification to existing Class I-IV anti-arrhythmic drug (AAD) regimen to treat AF, AFL or AT during the effectiveness evaluation period.	217 (89.3%)	26 (10.7%)	218 (91.2%)	21 (8.8%)
Use of a non- study device for ablation of any AF targets during the index or the repeat ablation procedure during the blanking period.	242 (99.6%)	1 (0.4%)	239 (100.0%)	0 (0%)
More than one (1) repeat ablation procedure during the blanking period.	243 (100.0%)	0 (0%)	239 (100.0%)	0 (0%)

[a] Electrical isolation as confirmed by demonstration of exit and/or entrance conduction block.

AAD=Anti-arrhythmic drugs; AF=Atrial Fibrillation; AFL=Atrial Flutter; AT=Atrial Tachycardia; DC=Direct Current.

Notes: N = Number of subjects in the Intent-to-Treat Population. n = Number of subjects in the specific category. Percentages are calculated as 100 x (n/N).

Subjects failing a particular criterion more than once are counted only once for that predefined category.

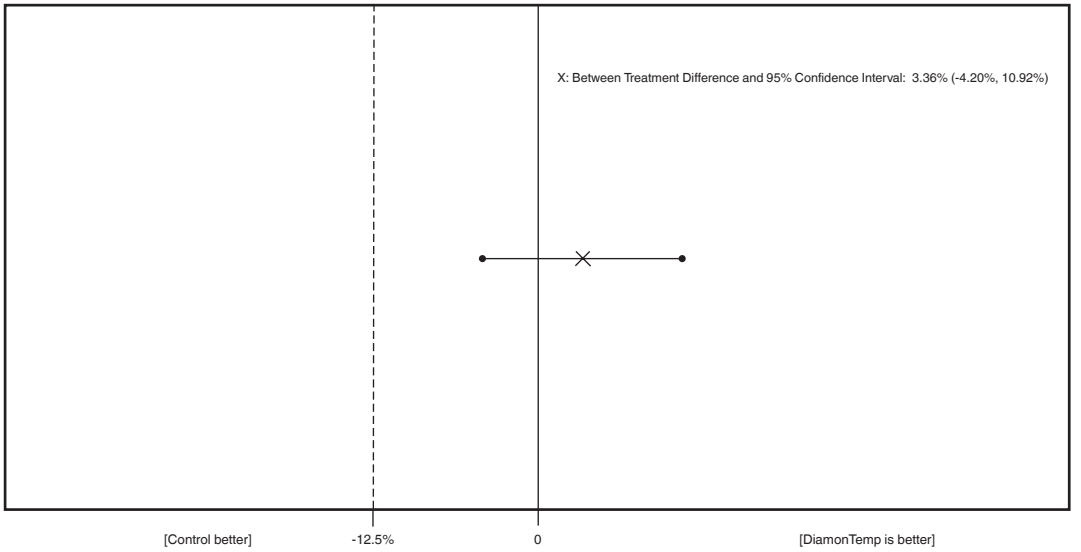
Table 17. Primary Effectiveness Result, Intention-to-Treat Cohort

Primary Effectiveness Endpoint: Freedom from AF, AFL, AT During the Effectiveness Period	**Control (N=243) Number (%) (95% CI)**	**DiamondTemp (N=239) Number (%) (95% CI)**	**Difference (95% CI)**	**Farrington- Manning p-value (Non-inferiority Test)**
Total, By Subject[1],[2]	184 (75.7%) (69.8%, 81.0%)	189 (79.1%) (73.4%, 84.1%)	3.4% (-4.2%, 10.9%)	<0.0001

[1] In the total row, success is the absence of any of the criteria, while failure is the presence of one or more of the criteria.

[2] The Farrington-Manning Score test for non-inferiority (DiamondTemp minus control) is used with a non-inferiority margin of -12.5%.

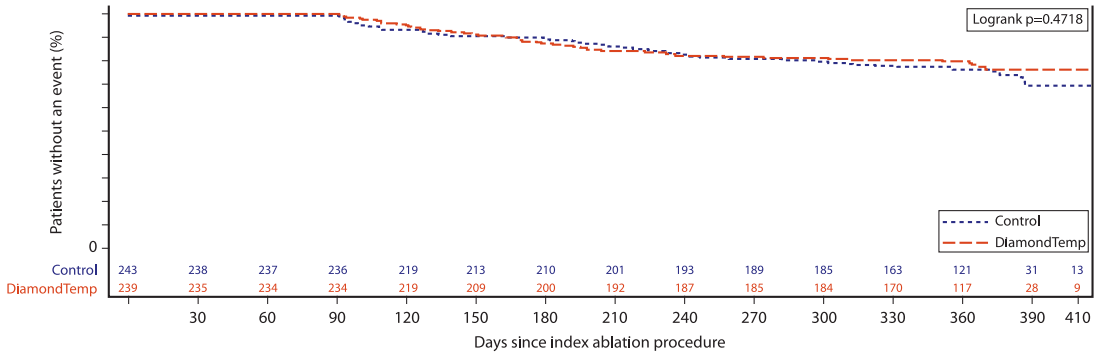
Figure 6. Primary Effectiveness: Between Treatment Difference



A Kaplan-Meier analysis was also performed to evaluate the primary effectiveness endpoint as a sensitivity analysis. The Kaplan-Meier method allows subjects to be included in the analysis up until the time they fail the primary effectiveness endpoint or are censored due to premature study exit.

Figure 7 displays the Kaplan-Meier estimates for the freedom from primary effectiveness endpoint failure through 12 months post-ablation by treatment arm. Based on the Kaplan-Meier methodology the freedom from primary effectiveness endpoint failure at the end of the primary effectiveness period (day 410) post-ablation was 76% for the DiamondTemp group and 70% for the control group. The log-rank test suggested there was no difference in the freedom rate between groups (p=0.47).

Figure 7. Kaplan-Meier Survival: Time to Failure of the Primary Effectiveness Endpoint, Intention-to-Treat Cohort



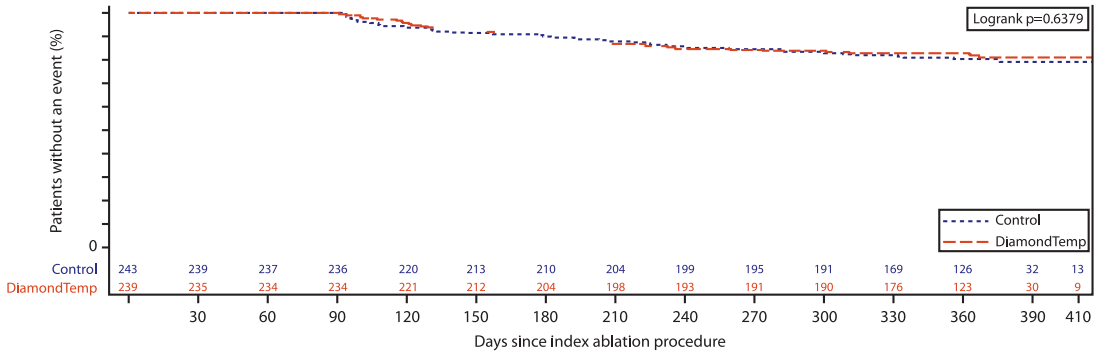
Kaplan-Meier Survival: Time to Failure of the Primary Effectiveness Endpoint, Intention-to-Treat Cohort					
		Month 3	Month 6	Month 9	Month 12
Control	Number at Risk	236	210	189	13
	Kaplan-Meier Estimate	0.99	0.89	0.81	0.70
	Standard Error	0.0058	0.0199	0.0256	0.0419
DiamondTemp	Number at Risk	234	200	185	9
	Kaplan-Meier Estimate	1.00	0.87	0.82	0.76
	Standard Error	0.0000	0.0219	0.0256	0.0309

3 Months (day 90), 6 Months (day 180), 9 Months (day 270), 12 Months (day 410)

An important component of the primary efficacy endpoint was the freedom from documented AF/AFL/AT episodes lasting 30 or more seconds following the 3-month blanking period through 12 months as identified on 24-hour Holter recordings, 12-lead ECG, or event monitor recordings (twice a month plus symptom driven). *Figure 8* displays

Kaplan-Meier estimates for the freedom from documented AF/AFL/AT episodes lasting 30 or more seconds by treatment group. At 12 months post-ablation, Kaplan-Meier estimates for the freedom from documented AF/AFL/AT was 81% for the DiamondTemp group and 79% for the control group. The log-rank test indicated that there was no difference between treatment groups in the risk for AF/AFL/AT recurrence during the effectiveness evaluation period (p=0.64).

Figure 8. Kaplan-Meier Survival: Time to Documented AF/AFL/AT ≥ 30 Seconds, Intention-to-Treat Cohort



Kaplan-Meier Survival: Time to Documented AF/AFL/AT ≥ 30 Seconds, Intention-to-Treat Cohort					
		Month 3	Month 6	Month 9	Month 12
Control	# at Risk	236	210	195	13
	Kaplan-Meier Estimate	1.00	0.90	0.85	0.79
	Standard Error	0.0000	0.0194	0.0236	0.0290
DiamondTemp	# at Risk	234	204	191	9
	Kaplan-Meier Estimate	1.00	0.89	0.84	0.81
	Standard Error	0.0000	0.0205	0.0240	0.0270

3 Months (day 90), 6 Months (day 180), 9 Months (day 270), 12 Months (day 410)

Table 18 displays the primary effectiveness endpoint outcome by treatment group and geography. The Breslow-Day test indicated that there was no evidence for heterogeneity in primary effectiveness endpoint success rate between treatment groups by geography (p=0.36).

Table 18. Primary Effectiveness Endpoint: Relative Risk of Success; Overall and Stratified by Treatment and Geographic Region, Intention-to-Treat Cohort

Geographic Region	Treatment	PEE Success	PEE Failure	Total	Relative Risk of Success	Breslow Day Test p-value
Europe	DiamondTemp	93	36	129	1.01	0.3580
	Control	94	38	132		
North America	DiamondTemp	96	14	110	1.08	
	Control	90	21	111		
Overall	DiamondTemp	189	50	239	1.04	
	Control	184	59	243		
Pooled / Adjusted (CMH)					1.04	

CMH= Cochran–Mantel–Haenszel

The DIAMOND-AF Clinical Study met its primary effectiveness objective (Intention-to-Treat Cohort). Primary effectiveness endpoint success was observed in 184 (75.7%) control (TactiCath) subjects and 189 (79.1%) DiamondTemp subjects (95% CI for difference: -4.2% to 10.9%; p<0.0001 for non-inferiority). There was no evidence of heterogeneity in primary effectiveness outcome between treatment groups by geography (p=0.36). The DiamondTemp Ablation System demonstrated a reasonable assurance of effectiveness for the treatment of drug refractory, recurrent, symptomatic PAF.

Worst Case Scenario

Sensitivity analysis was performed using a worst case scenario in the safety cohort, in which all missing DiamondTemp data (n=8) were considered as primary effectiveness failures and all missing Control data (n=8) were considered as primary effectiveness successes. The difference of primary effectiveness success rate was -0.2% (95% CI: -8.0%, 7.6%), and the 97.5% lower confidence bound of -8.0% still met the predetermined NIM of -12.5% (*Table 19*).

Table 19. Primary Effectiveness Endpoint Sensitivity Analysis

Analysis	Primary Effectiveness Endpoint Successes		95% CI for Difference	Farrington-Manning p-value (non-inferiority test)
	Control (N=241)	DiamondTemp (N=235)		
Safety Cohort	182 (75.5%)	185 (78.7%)	(-4.4%, 10.8%)	<0.0001
Worst Case Scenario[a]	182 (75.5%)	177 (75.3%)	(-8.0%, 7.6%)	0.001

[a] The worst case scenario considered all Control subjects who had not failed the primary effectiveness endpoint at the time of their pre-mature exit as successes and all DiamondTemp subjects who had not failed the primary effectiveness endpoint prior to pre-mature exit as failures.

TTM Compliance Analysis

Table 20 presents the distribution of TTM compliance and the primary effectiveness success at each quartile between the two groups.

Table 20. TTM Monitoring Compliance and Primary Effectiveness Endpoint (PEE) Success per Quartile

PEE Status			TTM Compliance		
Frequency (Percentage)	(0-25%)	(25-50%)	(50-75%)	(75-100%)	Total
DiamondTemp Success	38 (84.44%)	23 (76.67%)	36 (65.45%)	88 (83.81%)	185
DiamondTemp N	45	30	55	105	235
Control Success	41 (82.00%)	28 (73.68%)	37 (68.52%)	76 (76.77%)	182
Control N	50	38	54	99	241

7.7.3 Secondary Endpoint Results

A summary of Diamond-AF Study secondary endpoint results is noted below in *Table 21*, and the first four (4) secondary endpoints in the summary included hierarchical hypothesis testing and therefore have p-values reported if applicable.

Table 21. Secondary Endpoints, Intention-to-Treat Cohort, Control vs DiamondTemp

Secondary Endpoints Results	Control (N=243)	DiamondTemp (N=239)	p-value[1]
Mean Duration of Individual RF Ablations (Seconds)			<0.0001
Mean (SEM / SD)	32.59 (1.642/25.34)	14.67 (0.343/5.260)	
95% CI	(29.4, 35.8)	(14.0, 15.4)	
Median	26.2	14.0	
Min, Max	8.9, 193.0	7.0, 47.4	
N (N missing)	238 (5)	235 (4)	
Mean Cumulative RF Time Per Procedure (minutes)			<0.0001
Mean (SEM / SD)	29.80 (0.908/14.00)	17.93 (0.527/8.085)	
95% CI	(28.0, 31.6)	(16.9, 19.0)	
Median	25.9	16.0	
Min, Max	8.4, 83.2	2.5, 54.9	
N (N missing)	238 (5)	235 (4)	
Total Fluoroscopy Time (minutes)			0.8528
Mean (SEM / SD)	12.83 (0.611/9.439)	12.66 (0.669/10.19)	
95% CI	(11.6, 14.0)	(11.3, 14.0)	
Median	10.58	9.95	
Min, Max	0.00, 60.05	0.00, 54.90	
N (N missing)	239 (4)	232 (7)	
Total Procedure Time (minutes), Defined as Time of First Assigned Ablation Catheter Insertion Into the Vasculature to Time of Last Procedural Ablation Catheter Removed			
Mean (SEM / SD)	115.4 (3.28/50.84)	109.7 (3.01/46.18)	
95% CI	(108.9, 121.8)	(103.8, 115.6)	

Table 21. Secondary Endpoints, Intention-to-Treat Cohort, Control vs DiamondTemp (continued)

Secondary Endpoints Results	Control (N=243)	DiamondTemp (N=239)	p-value[1]
Median	100.0	97.0	
Min, Max	37, 314	48, 389	
N (N missing)	240 (3)	235 (4)	
Freedom from a composite of SAE occurring within 7-days post-index ablation procedure as adjudicated by an independent CEC for relatedness to the procedure or device	230/243 (94.7%)	231/239 (96.7%)	
Freedom from documented AF, AT and AFL episodes following the blanking period through 12 month follow-up post-ablation procedure in the absence of class I and III anti-arrhythmic drug therapy	120/243 (49.4%)	142/239 (59.4%)	
Rate of acute procedural success, defined as confirmation of electrical isolation of PVs via assessment of entrance block at least 20 minutes following the last ablation around the respective PV	228/243 (93.8%)	228/239 (95.4%)	
Rate of single procedure success defined as the rate of subjects treated with one single ablation procedure during study participation and with freedom from documented AF, AT and AFL at 12 months	185/243 (76.1%)	183/239 (76.6%)	
Rate of single procedure success defined as the rate of subjects treated with one single ablation procedure during study participation and with freedom from ALL primary effectiveness endpoint failure criteria	173/243 (71.2%)	175/239 (73.2%)	
Rate of occurrence of electrically reconnected PVs following a 20-minute waiting period assessed by entrance block at index procedure	45/243 (18.5%)	45/239 (18.8%)	
Accumulated Changes in QOL Using the AF QOL Survey (AFEQT Questionnaire) from Baseline Through 6 and 12 Months Following Ablation Procedure			
At 6 Months:			
Mean (SEM / SD)	25.54 (1.569/22.68)	27.79 (1.606/23.10)	
Median	22.2	25.0	
Min, Max	-28.7, 86.1	-26.9, 98.1	
N (N missing)	209 (34)	207 (32)	
At 12 Months:			
Mean (SEM / SD)	30.15 (1.570/23.23)	31.07 (1.599/23.44)	
Median	26.9	26.9	
Min, Max	-35.2, 86.1	-50.9, 98.1	
N (N missing)	219 (24)	215 (24)	

Table 21. Secondary Endpoints, Intention-to-Treat Cohort, Control vs DiamondTemp (continued)

Secondary Endpoints Results	Control (N=243)	DiamondTemp (N=239)	p-value[1]
Neurological Changes Measured Using the NIH Stroke Scale Between Baseline and Post-Ablation (Pre-Discharge Visit) and at 12 Months Post-Ablation Procedure			
At Discharge:			
Mean (SEM / SD)	0.0 (0.02/0.32)	0.0 (0.02/0.30)	
Median	0.0	0.0	
Min, Max	-1, 3	-2, 2	
N (N missing)	222 (21)	216 (23)	
At 12 Months:			
Mean (SEM / SD)	-0.1 (0.03/0.38)	-0.1 (0.02/0.36)	
Median	0.0	0.0	
Min, Max	-4, 1	-3, 0	
N (N missing)	212 (31)	214 (25)	
Time to Achieve Initial PVI at Index Procedure (minutes), Defined as Time of Delivery of First RF Ablation with the Assigned Ablation Catheter Until Confirmation of PVI			
Mean (SEM / SD)	69.4 (2.28/35.15)	65.7 (1.95/29.89)	
Median	56.5	56.0	
Min, Max	21, 218	24, 192	
N (N missing)	238 (5)	235 (4)	
Total Treatment Device Time (minutes), Defined as Time of Delivery of First RF Ablation with the Assigned Ablation Treatment Catheter to Removal of the Treatment Catheter			
Mean (SEM / SD)	91.4 (3.94/60.91)	83.1 (2.22/33.99)	
Median	75.0	71.0	
Min, Max	22, 802	30, 196	
N (N missing)	239 (4)	235 (4)	
Total Number of RF Ablations Per Procedure			
Mean (SEM / SD)	71.1 (2.58/39.78)	74.2 (2.16/32.95)	
Median	63.0	67.5	
Min, Max	11, 264	17, 279	
N (N missing)	238 (5)	232 (7)	
Total Fluid Infused Through the Assigned Ablation Catheter (mL)			
Mean (SEM / SD)	785.2 (22.83/351.5)	332.2 (7.88/120.8)	
Median	721.7	307.0	
Min, Max	3.8, 2095	57.0, 800.0	
N (N missing)	237 (6)	235 (4)	
Number of Re-Hospitalizations Due to Atrial Fibrillation Recurrence After Blanking Period			
Mean (SEM / SD)	0.1 (0.02/0.26)	0.1 (0.02/0.29)	
Median	0.0	0.0	
Min, Max	0.0, 2.0	0.0, 2.0	
N (N missing)	243 (0)	239 (0)	
0 Re-Hospitalization	229/243 (94.2%)	221/239 (92.5%)	
1 Re-Hospitalization	13/243 (5.3%)	17/239 (7.1%)	
2 Re-Hospitalizations	1/243 (0.4%)	1/239 (0.4%)	

AF=Atrial Fibrillation, AFL=Atrial Flutter, AT=Atrial Tachycardia, CEC=Clinical Events Committee, NIH=National Institute of Health, PV=Pulmonary Vein, PVI=Pulmonary Vein Isolation, QOL=Quality of Life, RF=Radiofrequency

Min=Minimum, Max=Maximum, SEM=Standard Error of the Mean, SD=Standard Deviation

Notes: N=Number of subjects in the Intent-to-Treat Population. n=Number of subjects in the specific category. Percentages are calculated as 100 x (n/N).

[1] The top four specific secondary endpoints were evaluated for superiority over Control using a priori hierarchical hypotheses with a two-tailed alpha of 0.05, and testing stopped when the first non-significant result was reached.

7.7.4 Blinding Assessment

The DIAMOND AF trial is a randomized, controlled, single-blind study. The success of subject blinding to treatment assignment was evaluated by asking subjects whether they know they were in which treatment group at the 12-month

follow-up visit. *Table 22* summarizes the blinding assessment results. In both treatment groups, majority of subjects did not know the treatment assignment.

Table 22. Blinding Assessment

Number of Subjects (Percentage)		**Which Treatment Group Does the Subject Believe He/She was Assigned To? (At 12-Month Follow-up Visit)**		
Actual Treatment Group Assignment	Does Not Know	Control Device	Investigational Device	Total
Control	121 (53.1%)	49 (21.5%)	58 (25.4%)	228
Investigational	120 (53.3%)	11 (4.9%)	94 (41.8%)	225
Total	241	60	152	453[a]

[a] Of all 455 subjects who completed the 12-month visit, 453 provided a response to this blinding question.

7.8 Study Strengths and Weaknesses

The following points cover the major strengths and weaknesses of the study.

Strengths:

- Randomized control trial design
- Independent adjudication of primary safety and effectiveness endpoints
- This large, prospective, global, multicenter randomized study had sufficient statistical power to test the primary safety and effectiveness hypotheses

Weaknesses:

- This study provided effectiveness and safety data limited through 12 months

7.9 Conclusion

The DIAMOND-AF Clinical Study met its primary objectives for effectiveness and safety. The DiamondTemp Ablation System demonstrated a reasonable assurance of effectiveness and safety for the treatment of drug refractory, recurrent, symptomatic PAF, with 79.1% of subjects randomized to the DiamondTemp Ablation System free from all primary effectiveness endpoint failure criteria at 12 months compared to 75.7% of subjects randomized to the control group (non-inferiority p-value <0.0001). Furthermore, 96.7% of subjects randomized to the DiamondTemp Ablation System were free from any primary safety endpoint event relative to 93.4% of subjects randomized to the control group, as adjudicated by the CEC (non-inferiority p-value <0.0001). Of the four (4) secondary endpoints with hypothesis testing, a statistically significant difference in favor of the DiamondTemp Ablation System was demonstrated with regard to lower mean duration of individual RF ablations (p-value <0.0001) and lower mean cumulative RF time per procedure (p-value <0.0001) relative to the control group ablation system.

8 Directions for use

1. Verify that the generator and irrigation pump are set up per instructions in the respective user manuals.
2. Inspect the catheter packaging before use. If the packaging is open, damaged, or expired, do not use and contact a Medtronic representative.
3. Remove the catheter from its package. Carefully inspect the catheter, including the ablation tip and electrodes, for integrity and overall condition. Activate the steering mechanism to confirm that the desired curve is achieved.
4. Do not use if the catheter is damaged.
5. Power ON the generator and irrigation pump. Refer to the generator and irrigation pump user manuals for a complete description of generator and pump set-up and communication between the devices. The recommended generator and irrigation pump settings are summarized in *Table 23*.

Table 23. Recommended Generator and Irrigation Pump Settings

GENERATOR SETTINGS	
Operational Mode	Temperature Control
Maximum Temperature Set-Point	60°C
Maximum Power Setting	50 W
Maximum Ablation Duration	45 s
IRRIGATION PUMP SETTINGS	
Irrigation flow rate during ablation	8 mL/min
Minimum continuous flow rate	2 mL/min

6. Connect an IV bag with sterile, normal (0.9%) saline heparinized at 1 unit/mL to the tubing set.
7. Connect the catheter to the luer fitting of the tubing set.

8. Flush the catheter by pressing and holding the Purge Flow button on the irrigation pump (refer to the irrigation pump user manual for complete instructions).

   Caution: Purge the tubing set and catheter of air bubbles before inserting the device into the patient.
9. Connect the catheter-to-RFG cable to the catheter. To do this, align the blue strain-relief end of the catheter-to-RFG cable connector key to the catheter receptacle key, and then push the connector into the catheter receptacle firmly until it stops. Do not force connectors or pin damage can occur. To disconnect, pull the connector body until it separates from the receptacle.
10. Connect the catheter-to-RFG cable to the generator or GenConnect cable (refer to *Chapter 9*). To do this, align the catheter-to-RFG cable green connector to the green receptacle key of the generator or GenConnect cable, and then push the connector into the receptacle firmly until it stops. Do not force the connectors or pin damage can occur. To disconnect, pull the connector body until it separates from the receptacle.
11. Connect the return pad cable to the return pad icon on the generator front panel.
12. Start minimum continuous irrigation of the catheter at a flow rate of 2 mL/min.

    Caution: To avoid occlusion of the irrigation conduits, the catheter must be continuously irrigated when within the vasculature. Irrigation should only be stopped after removing the catheter from the body.
13. Make sure the catheter tip orientation is in the neutral (straight) position before insertion. To aid in insertion, the catheter may be used with a compatible 2.83 mm (8.5 Fr) inner diameter sheath.
14. The catheter should be passed from a peripheral vessel to the desired endocardial position with the aid of fluoroscopy.
15. To adjust the curve of the distal tip on the unidirectional catheter, push or pull the actuation knob located on the handle. Do not pull on the saline luer or connector. A notch on the actuation knob provides orientation to the plane of the tip curvature. To adjust the curve of the distal tip of the bidirectional catheter, actuate the steering knob in either direction and turn the tension knob to lock the curve.
16. Set the generator to the desired temperature control set-point. The generator will automatically adjust the power output. Refer to the generator user manual for more detailed information.
17. Press the START button on the generator to begin the RF ablation. The irrigation pump will automatically increase from minimum flow rate to ablation flow rate.

    Caution: While creating a lesion, do not leave the power on for more than 45 seconds continuously.
18. Monitor the temperature, power, and impedance display on the generator during RF energy delivery.

    Caution: If a sudden rise in impedance is noted during RF delivery that does not exceed the impedance cut-off preset limit, manually discontinue the power delivery by pressing the STOP button. To assist in this regard, the generator screen displays the real-time relative impedance change in the green impedance field. When a large, positive-sign, percent increase is displayed, consider stopping RF delivery. Clinically assess the situation. If necessary, remove the catheter and inspect the tip electrode for any char or coagulum. Clean the distal tip to eliminate any coagulum, if present. Flush the catheter before reinsertion.

    Note: Temperature represents the temperature of the tissue surface in contact with the catheter.
19. The temperature set-point should not exceed 60°C. Assess intracardiac electrograms and impedance before changing the temperature set-point.

    Caution: In case of a steam pop or automatic shut off, remove the catheter for visual inspection and check for coagulum, charring, or defects. Flush the ports before reinsertion into the patient. If the catheter has defects, exchange it for a new one. Relocate the new catheter within the cardiac anatomy and attempt another RF application.

    Caution: If the pump alarms and stops the irrigation, immediately remove the catheter from the patient and inspect. Flush the catheter. At the end of each ablation period, the irrigation pump will automatically return to the minimum continuous flow rate.
20. To stop ablation, press the STOP button on the generator.

    Note: Alternatively, the foot switch may be used to initiate and stop RF energy delivery.
21. The catheter may be repositioned for additional ablation. When the procedure is finished, bring the distal tip of the catheter to a neutral position (straight) before removing the catheter from the patient.

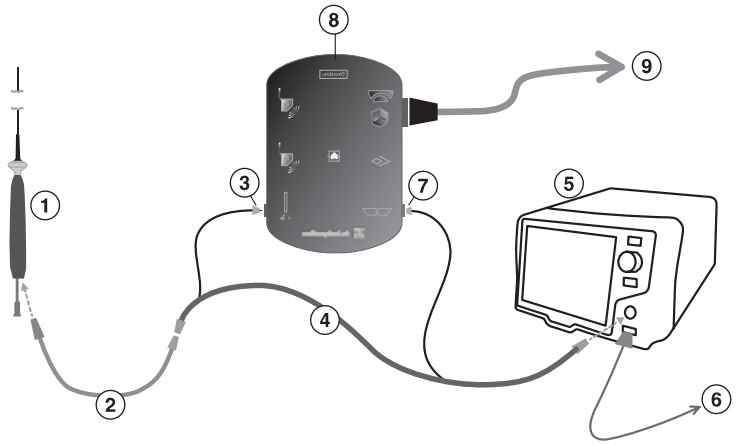
9 Connection to other equipment

The DiamondTemp ablation catheter may be connected to a commercially available EP recording system and cardiac stimulator using a connection cable with connectors in the pin configuration corresponding to the DiamondTemp catheter. The use of cables with shrouded pins is recommended and is required in some countries, such as the United States. Such equipment must have an isolated patient cable. Only EP recording systems that show proof of certified compliance with all applicable requirements of IEC 60601-1, IEC 60601-1-1, and IEC 60601-1-2 should be used, including, but not limited to, compliance with requirements for patient isolation, patient auxiliary currents, leakage currents, and EMC/EMI.

The DiamondTemp ablation system can be used with a compatible mapping system (for example, the Abbott EnSite™ Velocity™ or Precision™ Mapping System). When connecting the DiamondTemp system to the mapping system, use a GenConnect box (or similar connection box) (*Figure 9*) with the DiamondTemp GenConnect cable. Refer to the GenConnect cable instructions for additional information.

1. Connect the distal end (26-pin female receptacle) of the GenConnect cable to the catheter-to-RFG cable. To do this, align the green connector end of the catheter-to-RFG cable to the green receptacle key of the GenConnect cable, and then push the connector into the receptacle firmly until it stops. Do not force the connectors or pin damage can occur. To disconnect, pull the connector body until it separates from the receptacle.
2. Connect the proximal end (26-pin male connector) of the GenConnect cable to the generator. To do this, align the green strain-relief end of the GenConnect cable connector key to the generator receptacle key, and then push the connector into the receptacle firmly until it stops. Do not force connectors or pin damage can occur. To disconnect, pull the connector body until it separates from the receptacle.
3. Connect the GenConnect cable grey 9-pin connector to the catheter input of the GenConnect box.
4. Connect the GenConnect cable black 14-pin connector to the generator output of the GenConnect box.
5. Confirm correct connectivity with the mapping system.
6. Connect the return pad directly to the generator.

Figure 9. DiamondTemp Generator Connection to Mapping and Navigation System



1 DiamondTemp ablation catheter
2 Catheter-to-RFG cable
3 9-pin quick connector
4 GenConnect cable
5 DiamondTemp RF generator
6 Ablation return pad
7 14-pin twist connector
8 GenConnect box (oriented upside down, for purposes of illustration)
9 Amplifier

10 How supplied

The DiamondTemp ablation catheter is supplied along with the required product documentation. The contents were sterilized with ethylene oxide (EtO) and are sterile if the package is unopened and undamaged. Do not resterilize the catheter.

11 Packaging and shelf life

The DiamondTemp ablation catheter packaging is designed to protect the product from damage, minimize product exposure to the atmosphere, and provide aseptic product transfer. It is recommended that the product remain in the unopened package until time of use. Contents are sterile if the package is unopened and undamaged. Do not resterilize the catheter. Do not use the catheter if the packaging sterile barrier is open or damaged.

The product expiration date (“Use by”) is stated on the product labeling. The product must be stored in a cool and dry location, in a 15°C to 30°C (59°F to 86°F) noncondensing environment. Dispose of the product and packaging according to standard procedures for solid biohazard waste products.

12 Limited warranty

The following Limited Warranty applies to customers within the United States only:

A. This Limited Warranty provides the following assurance to the purchaser of a Medtronic catheter, hereafter referred to as Product:

(1) Should the Product fail to function within normal tolerances due to a defect in materials or workmanship on or before its “Use By” or "Use Before" date, Medtronic will at its option: (a) issue a credit to the purchaser equal to the Purchase Price, as defined in Subsection A(2), against the purchase of the replacement product or (b) provide a functionally comparable replacement product at no charge.

(2) As used herein, Purchase Price shall mean the lesser of the net invoiced price of the original, or current functionally comparable, or replacement product.

B. To qualify for this Limited Warranty, these conditions must be met:

(1) The Product must be used on or before its “Use By” or "Use Before" date.

(2) The Product must be returned to Medtronic within 60 days and shall be the property of Medtronic.

(3) The Product must not have been used for any other patient.

(4) The Product must be used in accordance with the labeling and not altered or subjected to misuse, abuse, accident, or improper handling.

C. This Limited Warranty is limited to its express terms. In particular:

(1) Except as expressly provided by this Limited Warranty, MEDTRONIC IS NOT RESPONSIBLE FOR ANY DIRECT, INCIDENTAL, OR CONSEQUENTIAL DAMAGES BASED ON ANY DEFECT,FAILURE, OR MALFUNCTION OF THE Product, WHETHER THE CLAIM IS BASED ON WARRANTY, CONTRACT, TORT, OR OTHERWISE.

(2) This Limited Warranty is made only to the purchaser of the Product. AS TO ALL OTHERS, MEDTRONIC MAKES NO WARRANTY, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY, OR FITNESS FORA PARTICULAR PURPOSE WHETHER ARISING FROM STATUTE, COMMON LAW, CUSTOM, OR OTHERWISE. NO EXPRESS OR IMPLIED WARRANTY TO THE PATIENT SHALL EXTEND BEYONDTHE PERIOD SPECIFIED IN A(1) ABOVE. THIS LIMITED WARRANTY SHALL BE THE EXCLUSIVE REMEDY AVAILABLE TO ANY PERSON.

(3) The exclusions and limitations set out above are not intended to, and should not be construed so as to, contravene mandatory provisions of applicable law. If any part or term of this Limited Warranty is held to be illegal, unenforceable, or in conflict with applicable law by a court of competent jurisdiction, the validity of the remaining portions of the Limited Warranty shall not be affected, and all rights and obligations shall be construed and enforced as if this Limited Warranty did not contain the particular part or term held to be invalid. This Limited Warranty gives the purchaser specific legal rights. The purchaser may also have other rights which vary from state to state.

(4) No person has any authority to bind Medtronic to any representation,condition, or warranty except this Limited Warranty. This Limited Warranty is provided by Medtronic, Inc., 710 Medtronic Parkway, Minneapolis, MN 55432-5604. It applies only in the United States. Areas outside the United States should contact their local Medtronic representative for exact terms of the Limited Warranty.

General warning

Medtronic catheters are used in the extremely hostile environment of the human body. Catheters may be easily damaged by improper handling or use due to their unavoidably fragile character, which is dictated by the unusual requirements of their application. Consequently, no representation or warranty is made that failure or cessation of function of the catheter will not occur, or that the body will not react adversely to the catheter, or that medical complications will not follow.

Medtronic

Medtronic, Inc.
710 Medtronic Parkway
Minneapolis, MN 55432
USA
www.medtronic.com
+1 763 514 4000

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Medtronic

DiamondTemp™

Ablation Catheter

Instructions for Use

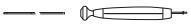
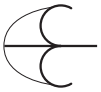
Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

Contents

1 Glossary of symbols

The following table defines symbols that are used on packaging and product labeling. Refer to the labels to determine which symbols apply to this product and for the product-specific information, such as the date of manufacture.

Symbol	Standard/Standard Title or Reference	Symbol title/Reference number	Explanatory Text
Rx only	21 CFR 801.109[a]	Prescription only	USA Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.
	ISO 15223-1[b]	Consult instructions for use (clause 5.4.3)	Consult instructions for use at this website: www.medtronic.com/manuals
	ISO 15223-1[b]	Catalog number (clause 5.1.6)	Indicates the manufacturer's catalog number so the device can be identified
	ISO 15223-1[b]	Batch code (clause 5.1.5)	Indicates the manufacturer's batch code so that the batch or lot can be identified
	ISO 15223-1[b]	Use by date (clause 5.1.4)	Indicates the date after which the device is not to be used
	ISO 15223-1[b]	Manufacturer (clause 5.1.1)	Indicates the medical device manufacturer
	N/A	Manufactured in/ manufacturing site	Indicates where the device was manufactured
	ISO 15223-1[b]	Date of manufacture (clause 5.1.3)	Indicates the date when the medical device was manufactured
	ISO 15223-1[b]	Keep Dry (clause 5.3.4)	Indicates a medical device that needs to be protected from moisture
	ISO 15223-1[b]	Do not use if package is damaged (clause 5.2.8)	Indicates a medical device that should not be used if the package has been damaged or opened
	ISO 15223-1[b]	Caution (clause 5.4.4)	Indicates there is important cautionary information for the medical device.
	ISO 15223-1[b]	Do not re-use (clause 5.4.2)	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure
	ISO 15223-1[b]	Do not resterilize (clause 5.2.6)	Indicates a medical device that is not to be resterilized
	ISO 15223-1[b]	Sterilized using ethylene oxide (clause 5.2.3)	Indicates a medical device that has been sterilized using ethylene oxide
	ISO 15223-1[b]	Non-pyrogenic (clause 5.6.3)	Indicates a medical device that is non-pyrogenic.
	ISO 15223-1[b]	Keep away from sunlight (clause 5.3.2)	Indicates a device that needs protection from light sources.
	N/A	Storage temperature limit (clause 5.3.7)	Indicates the required temperature range for storing the device
	N/A	Transit temperature limit (clause 5.3.7)	Indicates the required temperature range for transporting the device
	N/A	Package contents	Indicates the components included in the device package

Symbol	Standard/Standard Title or Reference	Symbol title/Reference number	Explanatory Text
	N/A	Unidirectional catheter	Indicates that a unidirectional catheter is included in the device package
	N/A	Bidirectional catheter	Indicates that a bidirectional catheter is included in the device package
	ISO 7000[c]	Product documentation	Indicates that product documentation is included in the device package
	N/A	Unidirectional	Indicates a catheter that operates only in one direction
	N/A	Bidirectional	Indicates a catheter that operates in two directions
	ISO 15223-1[b]	Sterile barrier	Single sterile barrier system with protective packaging inside

[a] 21 CFR 801.109: United States Code of Federal Regulations, Title 21, Food and Drugs

[b] ISO 15223-1: Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied

[c] ISO 7000: Graphical symbols for use on equipment

2 Device description

The Medtronic DiamondTemp ablation catheter is a sterile, single use, externally irrigated ablation catheter designed to deliver radiofrequency (RF) energy for cardiac ablation. It is designed to be used in conjunction with the DiamondTemp generator, DiamondTemp catheter-to-RFG cable, DiamondTemp GenConnect cable, DiamondTemp irrigation pump and DiamondTemp tubing set.

The DiamondTemp ablation catheter is available as unidirectional (*Figure 1*) or bidirectional (*Figure 2*) with a distal electrode segment and a proximal handle that are connected by a torquable shaft. The unidirectional catheter has an actuation piston to actuate the curve in one direction. The bidirectional catheter has a steering knob to actuate the curve in either direction and a tension knob to lock the curve. (Refer to *Table 1* for model information.) The distal tip and ring electrodes of the catheter are designed to record intracardiac electrocardiogram (ECG) signals for mapping and stimulus delivery. RF energy delivery by catheter tip-to-tissue contact is similar to other commercially available, externally irrigated catheters. Refer to the catheter package labeling for electrode spacing details.

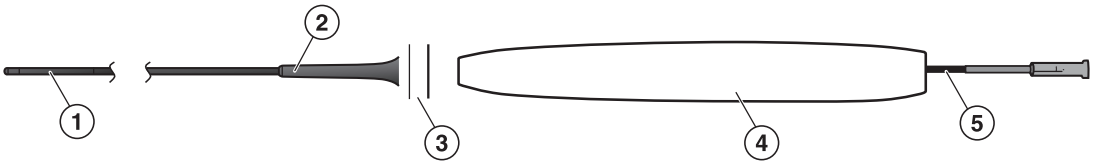
Table 1. Catheter models and specifications

Description	Specification
Catheter shaft size (outer diameter)	2.83 mm (8.5 Fr)
Catheter ablation tip size (tip electrode)	2.50 mm (7.5 Fr)
Length	110 cm (43.3 in)
Model CEDT100S	Unidirectional, small curve (45 mm)
Model CEDT200L	Unidirectional, large curve (63 mm)
Model CEDTB300S	Bidirectional, small curve (45 mm)
Model CEDTB400L	Bidirectional, large curve (63 mm)

The catheter is constructed of thermoplastic elastomer materials and noble metal electrodes. Thermocouples are incorporated at the distal and proximal end of the tip electrode for temperature sensing during RF ablation. The highest temperature from all thermocouples is displayed on the generator. The generator modulates the delivered RF energy to maintain tissue temperature at a user-defined temperature set-point.

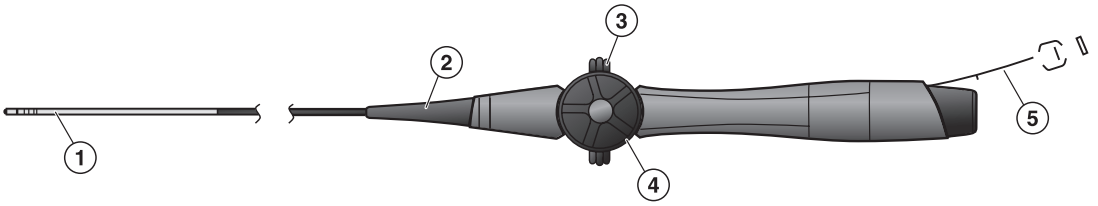
The catheter, when connected to the tubing set and irrigation pump, delivers normal saline (0.9% Heparin 1 IU mL) via a lumen in the catheter. Saline is delivered to the tissue and through 6 ports located on the catheter tip. The saline cools the catheter tip and tip-tissue interface. One luer connection at the proximal end of the handle connects to the tubing set, allowing the irrigation pump to generate the flow of normal saline to the catheter.

Figure 1. DiamondTemp Ablation Catheter (unidirectional)



1 Catheter shaft
2 Shaft strain relief
3 Actuation knob
4 Handle
5 Cooling lumen

Figure 2. DiamondTemp Ablation Catheter (bidirectional)



1 Catheter shaft
2 Strain relief
3 Steering knob
4 Tension knob
5 Cooling lumen

3 Indications for use

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.

4 Contraindications

- Patients with active systemic infection
- Patients with prosthetic valves
- Patients with intracardiac thrombus or myxoma, or interatrial baffle or patch via transseptal approach
- Patients unable to receive heparin or an acceptable alternative to achieve adequate anticoagulation
- Pregnant women and children <18 years of age
- Patients who are hemodynamically unstable

5 Warnings and precautions

- Before use, inspect the catheter for any foreign particles or material, defects, or physical damage, including electrical insulation of the cable. If the catheter is defective or damaged, do not use and contact a Medtronic representative. Replace damaged devices or equipment as necessary.
- Carefully read all DiamondTemp ablation system (catheter, generator, catheter-to-RFG cable, GenConnect cable, irrigation pump, tubing set) instructions before use. Observe all contraindications, warnings, and precautions noted in the directions. Failure to do so may result in patient complications.
- If the DiamondTemp system is used in conjunction with a compatible mapping system (such as the Abbott EnSite™ Velocity™ or Precision™ Mapping System), consult the respective instructions to ensure correct connectivity and usage. Construct an anatomic map of the region of interest only after all mapping catheters and electrodes, the DiamondTemp catheter, respective cables, and neutral electrodes (including the ablation dispersive electrode) are completely and properly connected. The subsequent addition of catheters or electrodes may render the anatomic map inaccurate and require remapping.
- Carefully read the instructions for all ancillary devices or products used in the procedure before use.
- 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.
- Use the catheter before the “Use by” date on the device package.
- Cardiac ablation procedures should be performed only by physicians trained in the techniques of RF catheter ablation in a fully equipped electrophysiology (EP) laboratory.
- Pacemakers and implantable cardioverter defibrillators (ICDs) can be adversely affected by RF signals and appropriate precautions should be taken before, during, and after ablation to minimize risk.
- Implantable devices such as ICDs should be deactivated or programmed to the OFF mode before ablation. Perform complete ICD system analysis on all patients after ablation.
- Use careful catheter manipulation and awareness when in close proximity to atrial or ventricular leads.
- Anticoagulation therapy is required before device introduction to prevent thrombus formation.
- Catheter ablation procedures present a risk of significant x-ray exposure, which can result in acute radiation injury as well as increased risk for somatic and genetic effects to both patients and laboratory staff. Catheter ablation

should only be performed after adequate attention has been given to the potential exposure associated with the procedure and steps taken to minimize this exposure.

- Long-term risks of RF ablation lesions have not been established.
- To avoid risk of injury, do not ablate near the phrenic nerve.
- Ablation too close to the esophageal area can result in esophageal fistula.
- Use caution when placing lesions in the proximity of the cardiac conduction system.
- Ablation near the AV node can cause permanent or partial conduction block.
- Ablation within and in close proximity to the coronary arterial vasculature has been associated with myocardial infarction and death.
- Catheter materials are not compatible with magnetic resonance imaging (MRI).
- In accordance with hospital protocol, monitor the patient's fluid balance throughout the procedure to avoid fluid overload.
- Catheter entrapment within the heart or blood vessels is a possible complication of EP procedures.
- Do not use excessive force when inserting, advancing, or removing the catheter.
- Before insertion into the patient, flush the catheter by pressing the Purge Flow button on the irrigation pump, at a flow rate of 60 mL/min, and ensure there are no air bubbles.
- To ensure proper operation of the tissue contact impedance measurement function, all 4 electrodes and 6 thermocouples on the catheter tip must protrude from the distal tip of the guiding sheath.
- Ablation over other catheter electrodes (on a diagnostic catheter, for example) has been associated with unintended EGM noise.
- 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.
- If the contact impedance reads less than 35 Ω, the generator will not allow delivery of RF energy. In such circumstances, replace the catheter. If after replacing the catheter the condition persists, replace the catheter-to-RFG cable and the GenConnect cable (if used). If the condition still persists, power down the generator and contact a Medtronic representative.
- Although a high 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 display a low contact impedance value. Other parameters, such as EGM, fluoroscopic images, and intracardiac ultrasound should be monitored before deciding to apply RF.
- Do not deliver RF energy if the catheter is outside the target site. The RF generator can deliver significant electrical energy and may cause patient injury.
- Use caution during multiple sheath and catheter exchanges through the transseptal puncture. Caution is necessary to avoid causing a residual atrial septal defect that would require repair.
- The transseptal procedure presents the potential risk for an air embolus, which may involve the coronary arteries. Aspiration and flushing of the sheath, dilator, and needle should be performed during insertion or exchange, to minimize this risk. Refer to the individual sheath, dilator, and needle instructions.
- Fibrin may accumulate in or on the sheath and catheter assembly during the procedure. Aspirate when removing the dilator or catheter. Follow the sheath instructions for maintaining sheath patency during use.
- 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 Medtronic may be hazardous to patients. Exercise caution and sound medical reasoning when deciding to deviate from recommended parameters.
- Delivery of RF energy may result in neuromuscular stimulation. Monitor patient reactions.
- The power, temperature, and impedance display of the generator should be continuously monitored during RF energy delivery.
- Irrigated ablation systems have been shown to create larger lesions than standard RF ablation catheters. Use caution when ablating near electrically vulnerable, thin-walled, or other arterial structures.
- During use of the RF generator and irrigation pump, pay attention to all messages, error codes, warnings, and tones, and exercise caution as needed.
- Perform catheter advancement under fluoroscopic guidance in conjunction with careful manipulation, 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.
- Always straighten the catheter before insertion or withdrawal from the patient.
- Always maintain irrigation flow to prevent coagulation within and around electrodes.

- If the irrigation flow is interrupted, withdraw the catheter from the patient, visually inspect the tip, and then flush the catheter before reinsertion and before resuming the procedure.
- Do not use the catheter if it appears damaged or kinked, or if there is any difficulty in deflecting the distal section to achieve the desired curve.
- Do not use if the catheter irrigation ports are blocked.
- Use fluoroscopy or information from a mapping system to confirm the position of the catheter during the procedure.
- Manual prebending of the distal curve may damage the steering mechanism and may cause patient injury.
- Do not immerse the proximal handle or cable connectors in fluid. Ensure that the cable and catheter connections remain dry throughout the procedure.
- Position connecting cables to avoid contact with the patient and other electrical leads.
- Do not attempt ablation with the catheter without the use of the DiamondTemp irrigation pump, the DiamondTemp generator, and approved accessories.
- After use, dispose of the catheter and packaging in accordance with hospital, administrative, and local government policy.
- Do not expose the catheter to organic solvents such as alcohol.

6 Potential adverse events

The following potential adverse events are associated with cardiac ablation procedures:

- 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 (non-specific)
- 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, back, 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

7 Clinical study

This section is intended to provide clinical study data for the DiamondTemp ablation catheters. See the associated Word document for a draft of the clinical study summary information.

8 Directions for use

1. Verify that the generator and irrigation pump are set up per instructions in the respective user manuals.
2. Inspect the catheter packaging before use. If the packaging is open, damaged, or expired, do not use and contact a Medtronic representative.
3. Remove the catheter from its package. Carefully inspect the catheter, including the ablation tip and electrodes, for integrity and overall condition. Activate the steering mechanism to confirm that the desired curve is achieved.
4. Do not use if the catheter is damaged.
5. Power ON the generator and irrigation pump. Refer to the generator and irrigation pump user manuals for a complete description of generator and pump set-up and communication between the devices. The recommended generator and irrigation pump settings are summarized in *Table 2*.

Table 2. Recommended Generator and Irrigation Pump Settings

GENERATOR SETTINGS	
Operational Mode	Temperature Control
Maximum Temperature Set-Point	60°C
Maximum Power Setting	50 W
Maximum Ablation Duration	45 s
IRRIGATION PUMP SETTINGS	
Irrigation flow rate during ablation	8 mL/min
Minimum continuous flow rate	2 mL/min

6. Connect an IV bag with sterile, normal (0.9%) saline heparinized at 1 unit/mL to the tubing set.
7. Connect the catheter to the luer fitting of the tubing set.
8. Flush the catheter by pressing and holding the Purge Flow button on the irrigation pump (refer to the irrigation pump user manual for complete instructions).

   Caution: Purge the tubing set and catheter of air bubbles before inserting the device into the patient.
9. Connect the catheter-to-RFG cable to the catheter. To do this, align the blue strain-relief end of the catheter-to-RFG cable connector key to the catheter receptacle key, and then push the connector into the catheter receptacle firmly until it stops. Do not force connectors or pin damage can occur. To disconnect, pull the connector body until it separates from the receptacle.
10. Connect the catheter-to-RFG cable to the generator or GenConnect cable (refer to *Chapter 9*). To do this, align the catheter-to-RFG cable green connector to the green receptacle key of the generator or GenConnect cable,

and then push the connector into the receptacle firmly until it stops. Do not force the connectors or pin damage can occur. To disconnect, pull the connector body until it separates from the receptacle.

11. Connect the dispersive indifferent patch (DIP) cable to the return pad icon on the generator front panel.
12. Start minimum continuous irrigation of the catheter at a flow rate of 2 mL/min.

    Caution: To avoid occlusion of the irrigation conduits, the catheter must be continuously irrigated when within the vasculature. Irrigation should only be stopped after removing the catheter from the body.
13. Make sure the catheter tip orientation is in the neutral (straight) position before insertion. To aid in insertion, the catheter may be used with a compatible 2.83 mm (8.5 Fr) inner diameter sheath.
14. The catheter should be passed from a peripheral vessel to the desired endocardial position with the aid of fluoroscopy.
15. To adjust the curve of the distal tip on the unidirectional catheter, push or pull the actuation knob located on the handle. Do not pull on the saline luer or connector. A notch on the actuation knob provides orientation to the plane of the tip curvature. To adjust the curve of the distal tip of the bidirectional catheter, actuate the steering knob in either direction and turn the tension knob to lock the curve.
16. Set the generator to the desired temperature control set-point. The generator will automatically adjust the power output. Refer to the generator user manual for more detailed information.
17. Press the START button on the generator to begin the RF ablation. The irrigation pump will automatically increase from minimum flow rate to ablation flow rate.

    Caution: While creating a lesion, do not leave the power on for more than 45 seconds continuously.
18. Monitor the temperature, power, and impedance display on the generator during RF energy delivery.

    Caution: If a sudden rise in impedance is noted during RF delivery that does not exceed the impedance cut-off preset limit, manually discontinue the power delivery by pressing the STOP button. To assist in this regard, the generator screen displays the real-time relative impedance change in the green impedance field. When a large, positive-sign, percent increase is displayed, consider stopping RF delivery. Clinically assess the situation. If necessary, remove the catheter and inspect the tip electrode for any char or coagulum. Clean the distal tip to eliminate any coagulum, if present. Flush the catheter before reinsertion.

    Note: Temperature represents the temperature of the tissue surface in contact with the catheter.
19. The temperature set-point should not exceed 60°C. Assess intracardiac electrograms and impedance before changing the temperature set-point.

    Caution: In case of a steam pop or automatic shut off, remove the catheter for visual inspection and check for coagulum, charring, or defects. Flush the ports before reinsertion into the patient. If the catheter has defects, exchange it for a new one. Relocate the new catheter within the cardiac anatomy and attempt another RF application.

    Caution: If the pump alarms and stops the irrigation, immediately remove the catheter from the patient and inspect. Flush the catheter. At the end of each ablation period, the irrigation pump will automatically return to the minimum continuous flow rate.
20. To stop ablation, press the STOP button on the generator.

    Note: Alternatively, the foot switch may be used to initiate and stop RF energy delivery.
21. The catheter may be repositioned for additional ablation. When the procedure is finished, bring the distal tip of the catheter to a neutral position (straight) before removing the catheter from the patient.

9 Connection to other equipment

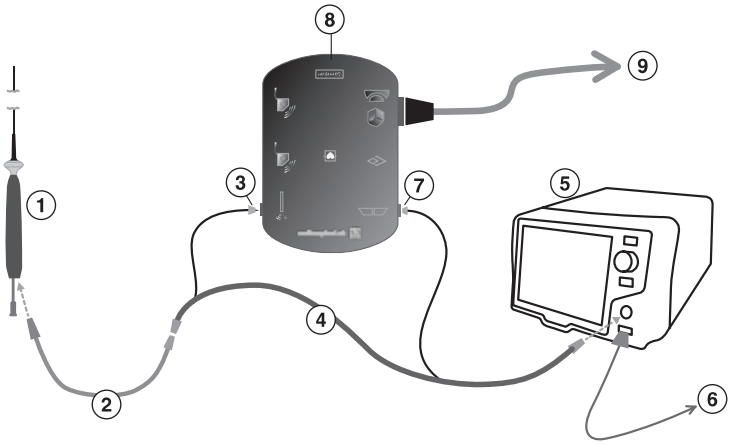
The DiamondTemp ablation catheter may be connected to a commercially available EP recording system and cardiac stimulator using a connection cable with connectors in the pin configuration corresponding to the DiamondTemp catheter. The use of cables with shrouded pins is recommended and is required in some countries, such as the United States. Such equipment must have an isolated patient cable. Only EP recording systems that show proof of certified compliance with all applicable requirements of IEC 60601-1, IEC 60601-1-1, and IEC 60601-1-2 should be used, including, but not limited to, compliance with requirements for patient isolation, patient auxiliary currents, leakage currents, and EMC/EMI.

The DiamondTemp ablation system can be used with a compatible mapping system (for example, the Abbott EnSite™ Velocity™ or Precision™ Mapping System). When connecting the DiamondTemp system to the mapping system, use a GenConnect box (or similar connection box) (*Figure 3*) with the DiamondTemp GenConnect cable. Refer to the GenConnect cable instructions for additional information.

1. Connect the distal end (26-pin female receptacle) of the GenConnect cable to the catheter-to-RFG cable. To do this, align the green connector end of the catheter-to-RFG cable to the green receptacle key of the GenConnect cable, and then push the connector into the receptacle firmly until it stops. Do not force the connectors or pin damage can occur. To disconnect, pull the connector body until it separates from the receptacle.
2. Connect the proximal end (26-pin male connector) of the GenConnect cable to the generator. To do this, align the green strain-relief end of the GenConnect cable connector key to the generator receptacle key, and then push the connector into the receptacle firmly until it stops. Do not force connectors or pin damage can occur. To disconnect, pull the connector body until it separates from the receptacle.
3. Connect the GenConnect cable grey 9-pin connector to the catheter input of the GenConnect box.

4. Connect the GenConnect cable black 14-pin connector to the generator output of the GenConnect box.
5. Confirm correct connectivity with the mapping system.
6. Connect the DIP electrode directly to the generator.

Figure 3. DiamondTemp Generator Connection to Mapping and Navigation System



1 DiamondTemp ablation catheter
2 Catheter-to-RFG cable
3 9-pin quick connector
4 GenConnect cable
5 DiamondTemp RF generator
6 Ablation DIP electrode
7 14-pin twist connector
8 GenConnect box (oriented upside down, for purposes of illustration)
9 Amplifier

10 How supplied

The DiamondTemp ablation catheter is supplied along with the required product documentation. The contents were sterilized with ethylene oxide (EtO) and are sterile if the package is unopened and undamaged. Do not resterilize the catheter.

11 Packaging and shelf life

The DiamondTemp ablation catheter packaging is designed to protect the product from damage, minimize product exposure to the atmosphere, and provide aseptic product transfer. It is recommended that the product remain in the unopened package until time of use. Contents are sterile if the package is unopened and undamaged. Do not resterilize the catheter. Do not use the catheter if the packaging sterile barrier is open or damaged.

The product expiration date (“Use by”) is stated on the product labeling. The product must be stored in a cool and dry location, in a 15°C to 30°C (59°F to 86°F) noncondensing environment. Dispose of the product and packaging according to standard procedures for solid biohazard waste products.

12 Limited warranty

The following Limited Warranty applies to customers within the United States only:

A. This Limited Warranty provides the following assurance to the purchaser of a Medtronic catheter, hereafter referred to as Product:

(1) Should the Product fail to function within normal tolerances due to a defect in materials or workmanship on or before its “Use By” or "Use Before" date, Medtronic will at its option: (a) issue a credit to the purchaser equal to the Purchase Price, as defined in Subsection A(2), against the purchase of the replacement product or (b) provide a functionally comparable replacement product at no charge.

(2) As used herein, Purchase Price shall mean the lesser of the net invoiced price of the original, or current functionally comparable, or replacement product.

B. To qualify for this Limited Warranty, these conditions must be met:

(1) The Product must be used on or before its “Use By” or "Use Before" date.

(2) The Product must be returned to Medtronic within 60 days and shall be the property of Medtronic.

(3) The Product must not have been used for any other patient.

(4) The Product must be used in accordance with the labeling and not altered or subjected to misuse, abuse, accident, or improper handling.

C. This Limited Warranty is limited to its express terms. In particular:

(1) Except as expressly provided by this Limited Warranty, MEDTRONIC IS NOT RESPONSIBLE FOR ANY DIRECT, INCIDENTAL, OR CONSEQUENTIAL DAMAGES BASED ON ANY DEFECT,FAILURE, OR MALFUNCTION OF THE Product, WHETHER THE CLAIM IS BASED ON WARRANTY, CONTRACT, TORT, OR OTHERWISE.

(2) This Limited Warranty is made only to the purchaser of the Product. AS TO ALL OTHERS, MEDTRONIC MAKES NO WARRANTY, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY, OR FITNESS FORA PARTICULAR PURPOSE WHETHER ARISING FROM STATUTE, COMMON LAW, CUSTOM, OR OTHERWISE. NO EXPRESS OR IMPLIED WARRANTY TO THE PATIENT SHALL EXTEND BEYONDTHE PERIOD SPECIFIED IN A(1) ABOVE. THIS LIMITED WARRANTY SHALL BE THE EXCLUSIVE REMEDY AVAILABLE TO ANY PERSON.

(3) The exclusions and limitations set out above are not intended to, and should not be construed so as to, contravene mandatory provisions of applicable law. If any part or term of this Limited Warranty is held to be illegal, unenforceable, or in conflict with applicable law by a court of competent jurisdiction, the validity of the remaining portions of the Limited Warranty shall not be affected, and all rights and obligations shall be construed and enforced as if this Limited Warranty did not contain the particular part or term held to be invalid. This Limited Warranty gives the purchaser specific legal rights. The purchaser may also have other rights which vary from state to state.

(4) No person has any authority to bind Medtronic to any representation,condition, or warranty except this Limited Warranty. This Limited Warranty is provided by Medtronic, Inc., 710 Medtronic Parkway, Minneapolis, MN 55432-5604. It applies only in the United States. Areas outside the United States should contact their local Medtronic representative for exact terms of the Limited Warranty.

General warning

Medtronic catheters are used in the extremely hostile environment of the human body. Catheters may be easily damaged by improper handling or use due to their unavoidably fragile character, which is dictated by the unusual requirements of their application. Consequently, no representation or warranty is made that failure or cessation of function of the catheter will not occur, or that the body will not react adversely to the catheter, or that medical complications will not follow.

Medtronic

Medtronic, Inc.
710 Medtronic Parkway
Minneapolis, MN 55432
USA
www.medtronic.com
+1 763 514 4000

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