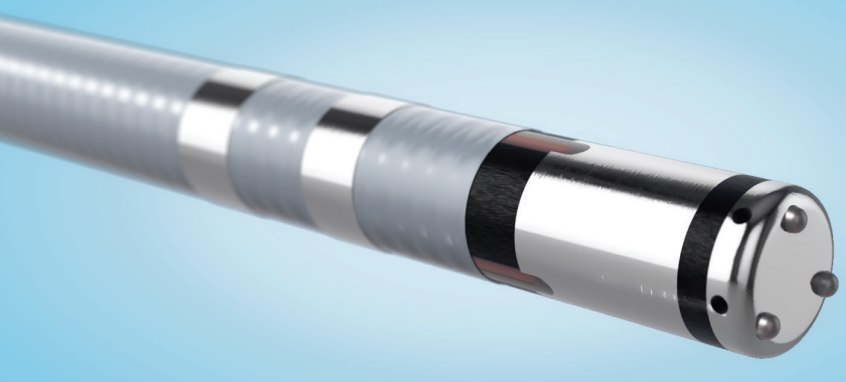
REAL-TIME, TEMPERATURE-CONTROLLED ABLATION

The DiamondTemp™
Ablation System with RealTemp™



Medtronic

THE NEXT ERA OF RF ABLATION

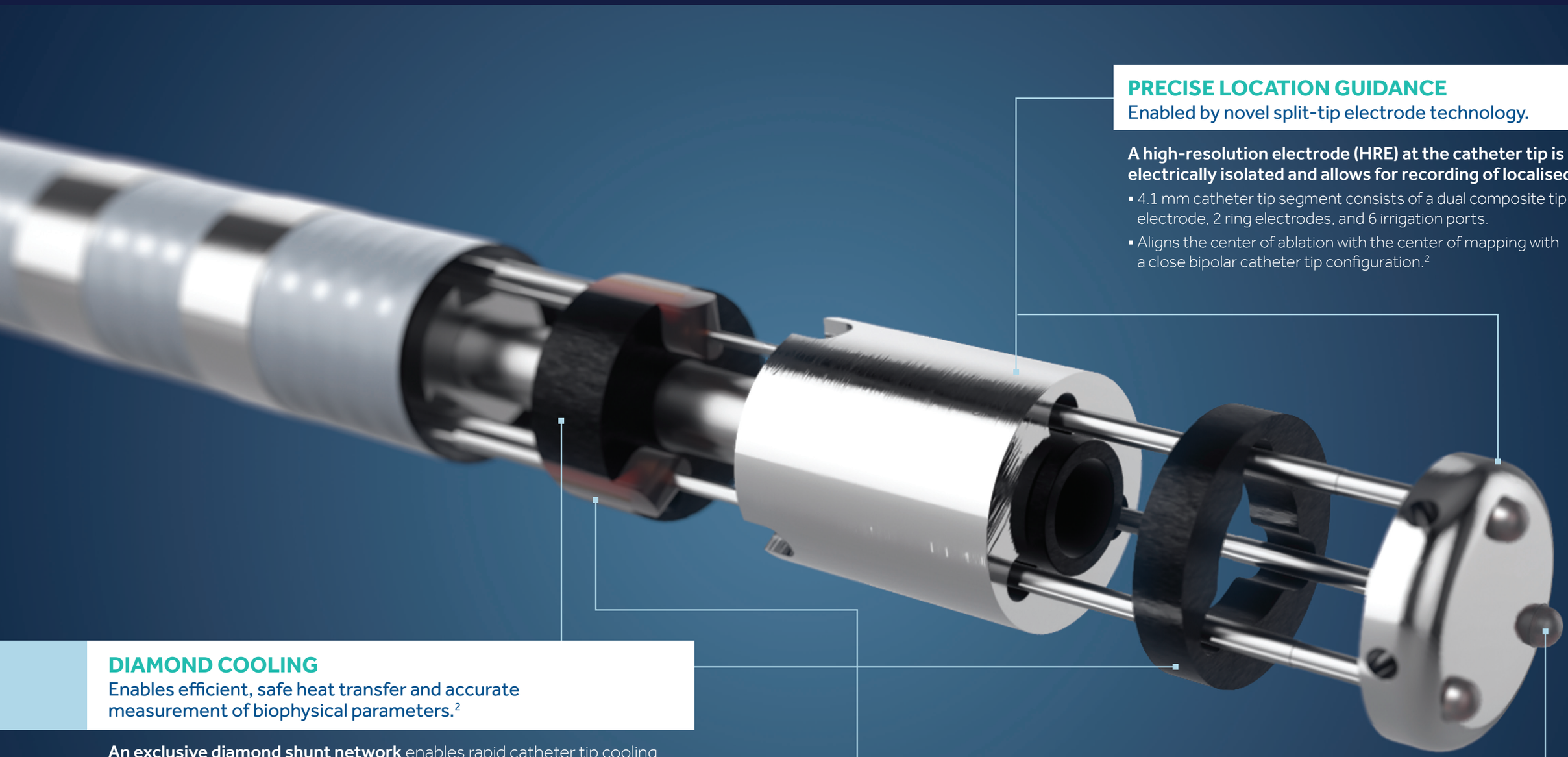
DiamondTemp™ Ablation Catheter

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

RealTemp™ technology includes[2]:

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

A DIFFERENTIATED DESIGN
WITH REALTEMP™ TECHNOLOGY



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

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

- 4.1 mm catheter tip segment consists of a dual composite tip electrode, 2 ring electrodes, and 6 irrigation ports.
- Aligns the center of ablation with the center of mapping with a close bipolar catheter tip configuration.[2]

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

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

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

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

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

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

SAFE, EFFECTIVE, & EFFICIENT

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

DIAMOND-AF (DAF) CLINICAL TRIAL[1]

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

BACKGROUND

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

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

STUDY DESIGN

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

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

STUDY POPULATION

Key Inclusion Criteria:

- Symptomatic paroxysmal AF
  - At least two self-terminating AF episodes reported in last 6 months
  - At least one ECG documented episode in last 12 months
- Prior Class I-IV AAD failure
- ≥ 18 years of age

Key Exclusion Criteria:

- Prior cardiac interventions
- Neurological events within 6 months
- Class III/IV or uncontrolled heart failure
- Left ventricular ejection fraction < 35%
- Left atrial diameter > 5.5 cm

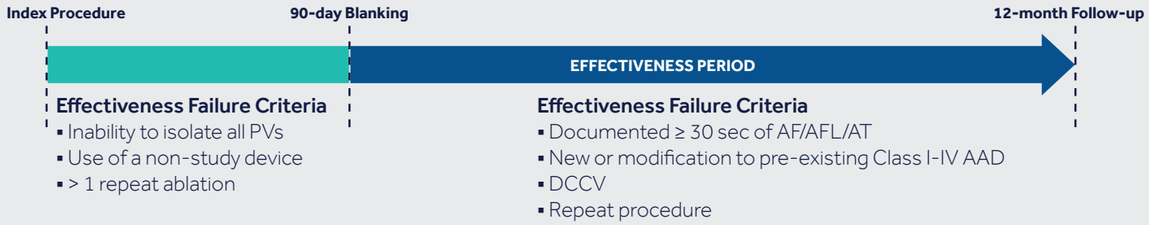
PRIMARY SAFETY AND EFFICACY ENDPOINT ACHIEVED

PRIMARY ENDPOINTS

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

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

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



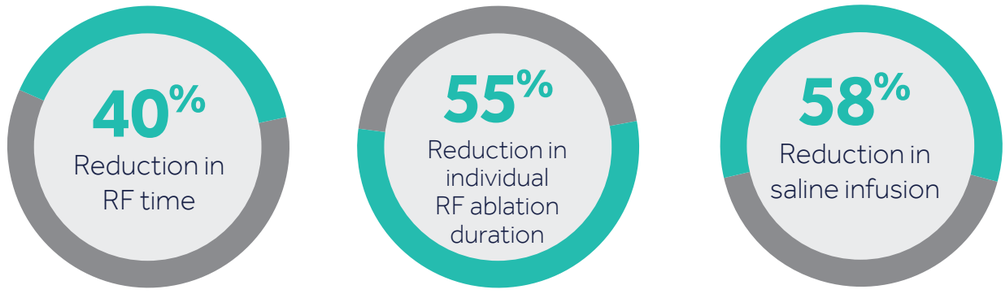
The DTA system met safety and efficacy endpoints, while also demonstrating procedural efficiencies versus CF-RF.

PRIMARY SAFETY ENDPOINT MET

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

PRIMARY EFFECTIVENESS ENDPOINT MET

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



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

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

BIOPHYSICAL FEEDBACK DURING ABLATION

ELECTROGRAM (EGM) ATTENUATION

75% to 80% reduction in the split-tip EGM amplitude occurred, followed by ablation for an additional 3 to 5 seconds.[6]

SURFACE TEMPERATURE

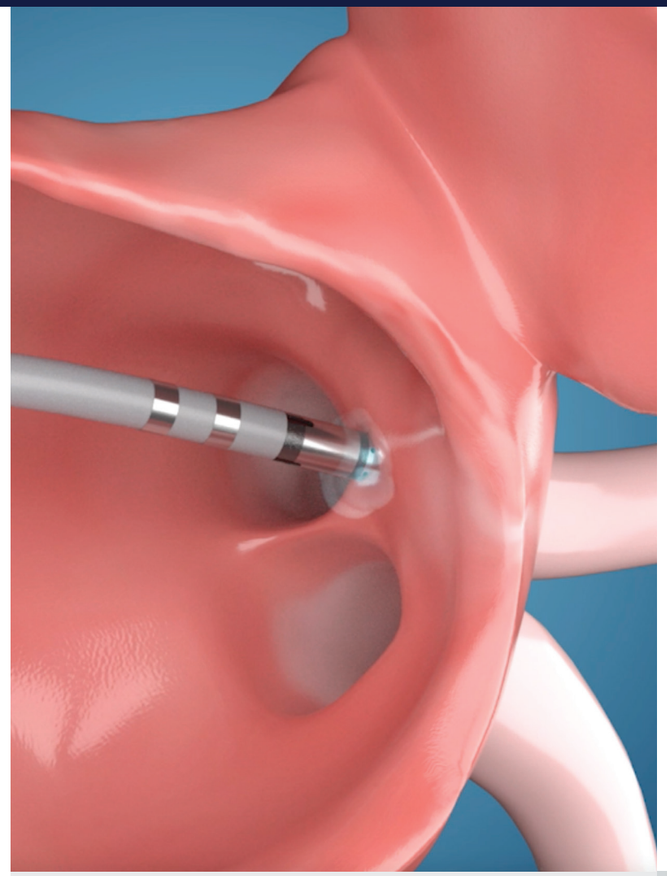
Temperature provides direct feedback of lesion creation. Irreversible tissue damage is created at temperatures > 50 °C.[5]

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

IMPEDANCE DROP OF 5–10 Ω

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

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



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

CATHETER CONTACT WITH THE DIAMONDTEMP ABLATION SYSTEM

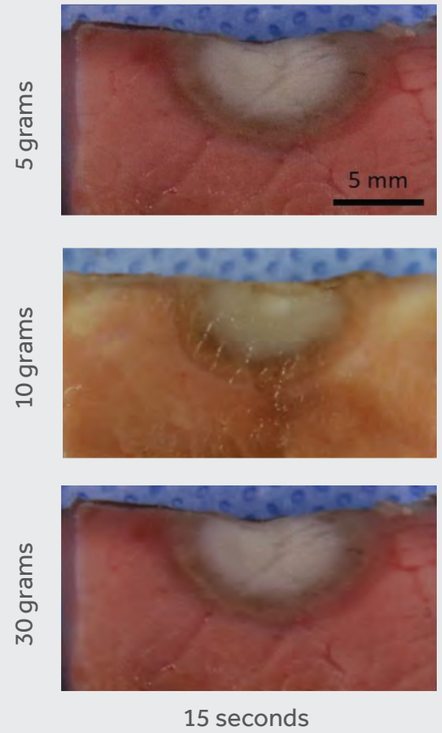
DTA ADJUSTS POWER

To maintain target therapeutic temperature[9]

In vivo **lesions were delivered with varying contact force and ablation duration.**
Preclinical studies indicate that contact force does not have a significant impact on lesion depth or volume.

Results:

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



THE DIAMONDTEMP ABLATION SYSTEM

DiamondTemp™ Ablation Catheter
The DTA is a sterile, single-use, externally irrigated catheter. The DTA catheter:
- Has an 8.5 Fr shaft and saline-irrigated, 4.1mm tip
- Features a tip segment consisting of a dual composite tip electrode, 2 ring electrodes, 6 irrigation ports, and a network of industrial diamonds
- Includes customised offerings:
  – Small curve (45 mm) and large curve (63 mm) configurations
  – Unidirectional and bidirectional models

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

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

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

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

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

References
[1] Kautzner J, et al. *J Am Coll Cardiol Clin Electrophysiol*. Published online January 27, 2021.
[2] Avila C, DiamondTemp Catheter Design. Metronic data on file, January 2021.
[3] Brown A, et al. Introduction to Heat Transfer. 3rd ed. McGraw Hill; 1958.
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[5] Nath S, et al. *J Cardiovasc Electrophysiol*. 1994;5:863-876.
[6] Iwasawa J, et al. *J Am Coll Cardiol*. 2017;70:542-553.
[7] Nakagawa H, et al. *Circulation*. 1995;91:2264-2273.
[8] Strickberger SA, et al. *Am Heart J*. 1995;130:1026-1030.
[9] Verma, et al. AF Symposium 2021 Abstract: AFS2021-07.

Brief Statement
See the device manual for detailed information regarding the instructions for use, indications, contraindications, warnings, precautions, and potential adverse events. For further information, contact your local Medtronic representative and/or consult the Medtronic website at medtronic.eu.

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