DIAMOND AF[1] CLINICAL TRIAL

The DiamondTemp™ Ablation System

A Novel Temperature-controlled Radiofrequency Catheter Ablation System Used to Treat Patients with Paroxysmal Atrial Fibrillation

The DiamondTemp™ Ablation system met safety and efficacy endpoints, demonstrating noninferiority to contact force-sensing RF. DTA also demonstrated procedural efficiencies over contact force-sensing RF. These results confirm DTA is safe, effective, and efficient for treating drug-refractory, symptomatic, paroxysmal AF.

STUDY DESIGN

The DIAMOND AF trial was an FDA-regulated, prospective, multicenter, noninferiority, randomised, controlled trial which compared safety and effectiveness of the DiamondTemp Ablation System (DTA) and a contact-force sensing ablation system (TactiCath™) (Control).

Paroxysmal AF patients were 1:1 randomised for PVI at sites in the U.S., Europe, and Canada and followed for 12 months.

PRIMARY SAFETY ENDPOINT MET

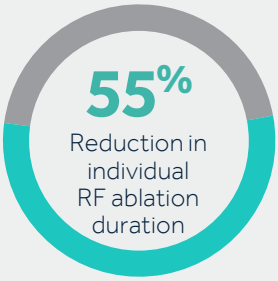
3.3% Safety event rate compared with **6.6%** with contact force-sensing RF.

PRIMARY EFFECTIVENESS ENDPOINT MET

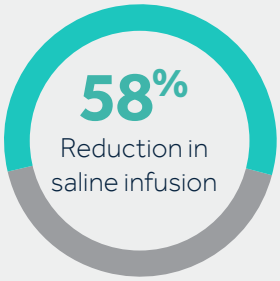
79.1% Compared to **75.7%** with contact force-sensing RF.

EFFICIENCY OUTCOMES VERSUS CF-RF

Total RF time
DTA Group: 17.9 ± 8.1 min
Control Group: 29.8 ± 14 min



Individual RF ablation duration
DTA Group: 14.7 ± 5.3 s
Control Group: 32.6 ± 25.3 s



Saline infusion volume
DTA Group: 332.2 ± 120.8 ml
Control Group: 785.5 ± -351.5 ml

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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 & Objectives	Prospective, multicenter, non-inferiority, randomised trial ▪ 23 sites across United States, Europe, and Canada Compare safety and effectiveness for the treatment of drug-refractory, recurrent, symptomatic PAF ▪ DTA system versus force-sensing RF ablation system (Tacticath) ▪ 239 patients treated with DTA ▪ 243 patients treated with Tacticath	
Patient Population	**Key Inclusion Criteria:** ▪ Symptomatic paroxysmal AF: – At least two self-terminating episodes 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 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 (7) failure criteria: ▪ During the index procedure/within the 90-day blanking period: – Inability to isolate all PVs – Use of a non-study device – > 1 repeat procedure ▪ Between blanking period (90 days) and 12-month follow-up: – Documented ≥ 30 s of AF/AFL/AT – New or modification to preexisting Class I-IV AAD – DCCV – Repeat procedure	**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 6 months post-index ablation procedure.
Secondary Endpoints	There were a total of 17 secondary endpoints, including Quality of Life, Improvement in NIH Stroke Scale, rehospitalisation, 10 procedural characteristics, and 4 primary endpoint sub-analysis.	
Conclusion	The authors concluded that "The safety and efficacy of the DTA system proved non-inferior to force-sensing RF ablation for the treatment of patients with paroxysmal AF." They go on to say, "The DTA system is efficient, procedural metrics are similar to the control system at baseline and then improve over a very short learning curve duration."	

Reference

[1] Kautzner J, McElderry T, et al. Results of the DIAMOND-AF Trial. Presented at the Asia Pacific Heart Rhythm Society Congress 2020.

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 or consult the Medtronic website at medtronic.com.

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