# The ACT Diamond Temp Catheter: Temperature controlled RF ablation for Pulmonary Vein Isolation in patients with AF

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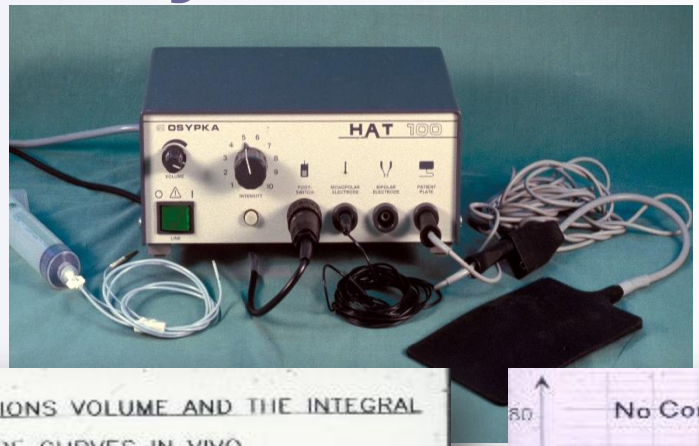
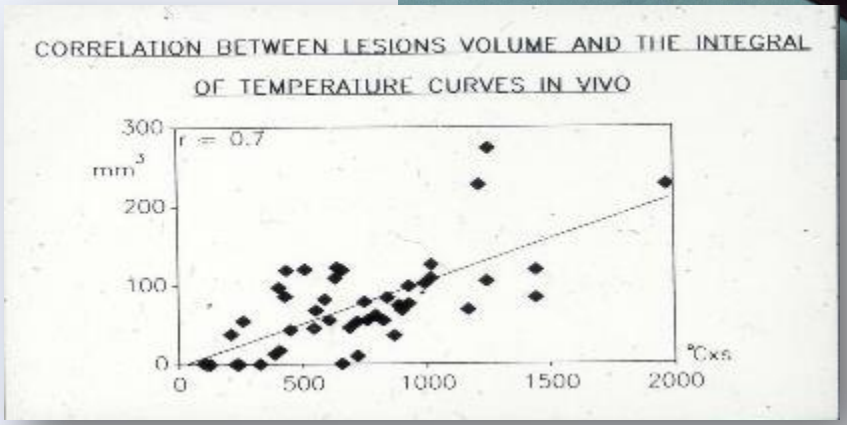
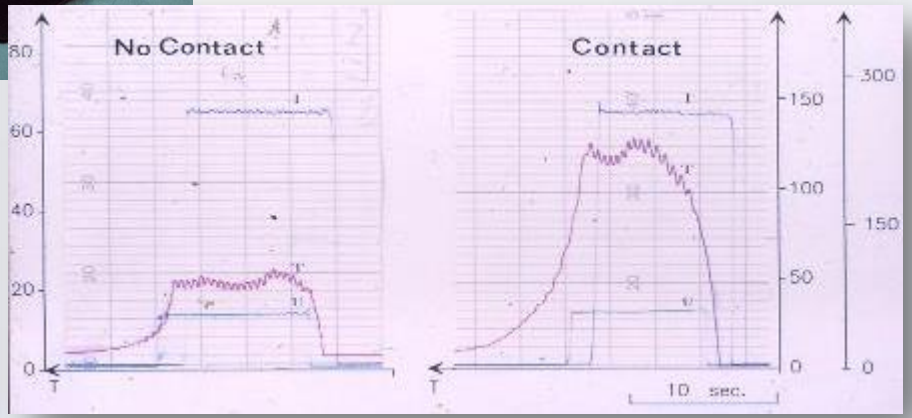
# My disclosures - 2018

- Advisory Board member
  - Bayer, Boehringer-Ingelheim, Biosense-Webster, Boston Scientific, EPIX, MicroPort (Liva Nova), Medtronic, MSD, St Jude Medical (Abbott)
- Steering Committee member
  - Daiichi Sankyo
- Clinical studies – PI
  - Biosense-Webster, Biotronik, EPIX, Medtronic, St Jude Medical (Abbott), Daiichi Sankyo
- Speaker bureau
  - Biosense-Webster, Biotronik, Boston Scientific, Medtronic, MSD, Pfizer, St Jude Medical (Abbott)

# History of catheter ablation




Courtesy M Borggreffe

# Evolution of AF Ablation

| 1st Generation | 2nd Generation | 3rd Generation | 4th Generation |
|---|---|---|---|
| **Solid tip, either temp or power control** | **Irrigated Catheters** | **Force-Sensing Irrigated Catheters** | **DiamondTemp™ Temperature Control** |
| • Effective temperature control<br>• Lack of tip irrigation resulted in char and thrombus | • Cooling avoided thrombus<br>• No way to measure tissue temperature → used power-control<br>• Could result in inadequate lesions due to lack of feedback on lesion creation | • Force sensing gives physician feedback on whether lesion will be effective at current power setting → surrogate for tissue temperature measurement | • Temperature measurement **continuous closed-loop feedback** results in effective lesion regardless of contact force through automatic power adjustment |

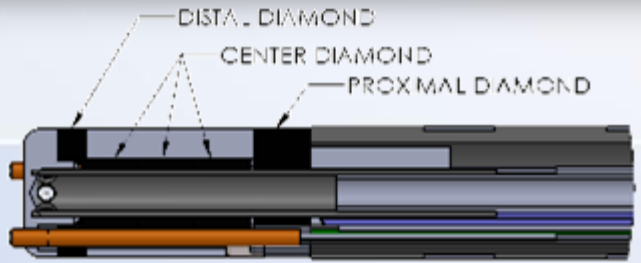
# Why diamond?

The highest thermal conductivity of any material

Used in industry as heat sink – absorbs or conducts excess heat

# DiamondTemp™ Cardiac Ablation System


- **Compatible** to existing EP Cath-lab system
- Compatible with the STJ EnSite™ Velocity™ Mapping System
- RF Generator **automatically adjusts power output** based on the temperature set-point (60º C)
- Ablation duration determined by monitoring **temperature curve and localized, high resolution EGM**




Diamond tip

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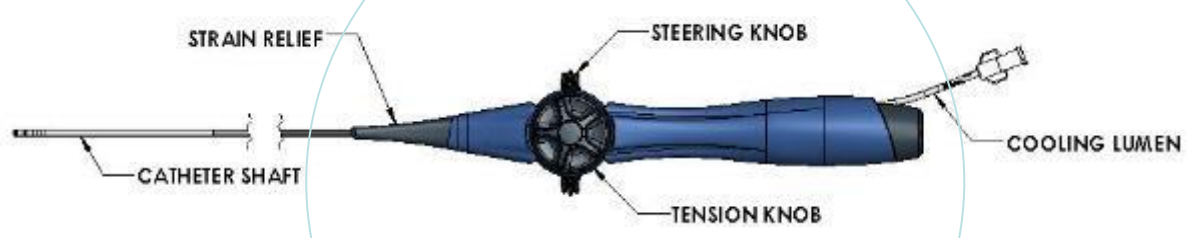
# The DiamondTemp™ Catheter

- 7.5F, 4.1 mm catheter tip
- Saline-irrigated catheter
- Small and large curve configurations

**Temperature Sensing**

- Six thermocouples for real-time temperature recording
- Temperature sensors thermally isolated from the RF electrode




- Diamond network at the distal tip provide heat shunting
- One flow rate 8 ml/min for all power levels.

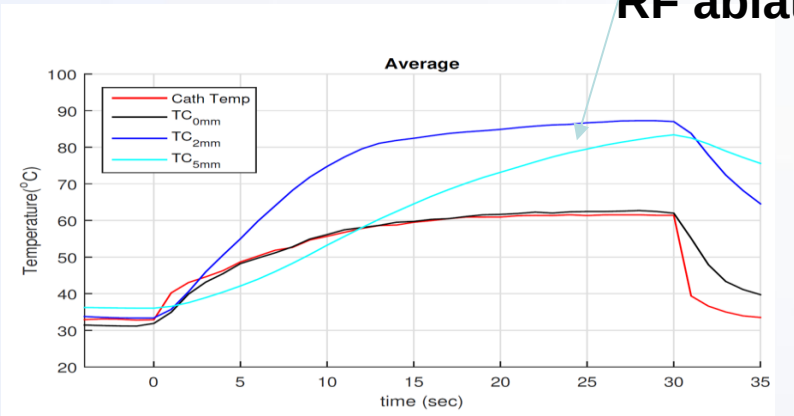
**Diamond Cooling**

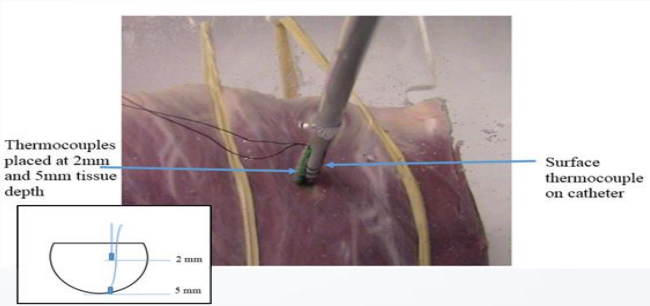
**High Resolution EGM**

- Provides precise, localized, high fidelity electrical information

# Temperature sensing

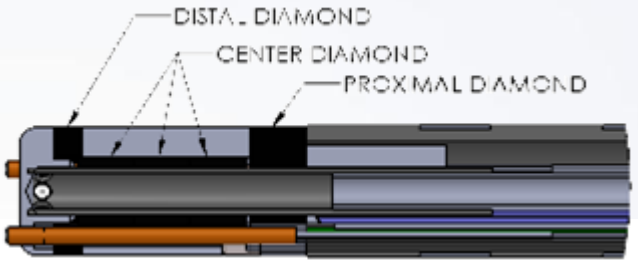
**Temperature recorded from sensor is the same as external thermocouples during RF ablation.**

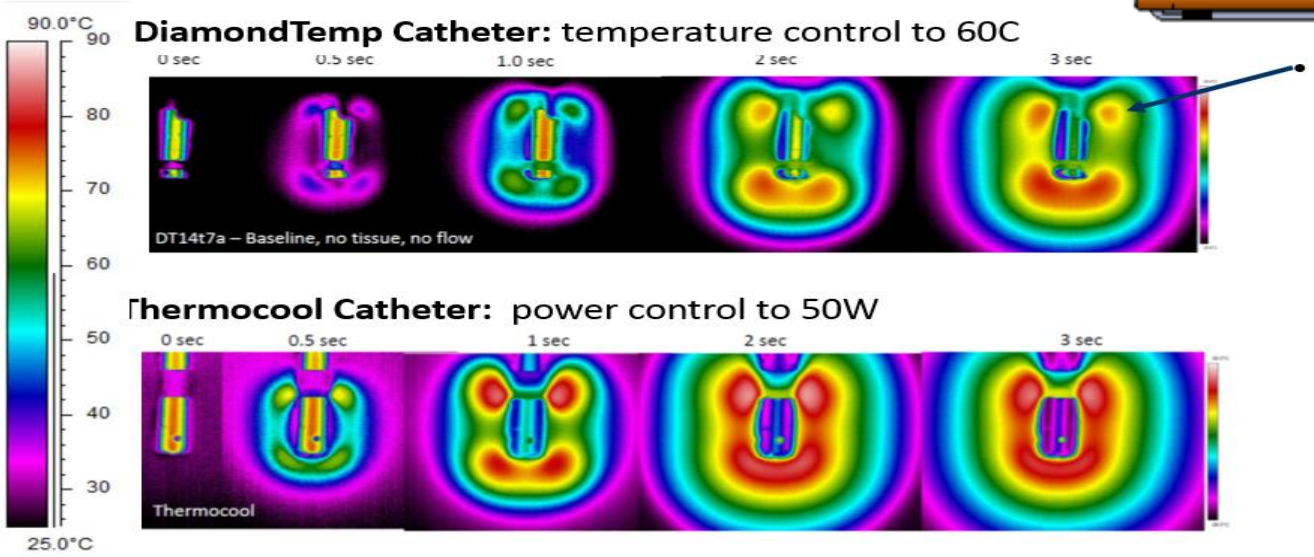



- System continuously monitors highest sensor temperature and **automatically controls the power** to that temperature
- Preset constant power 50W limited by measured temperature (50-60$^0$C)
- Constant flow of 8ml/min

# Diamond tip cooling



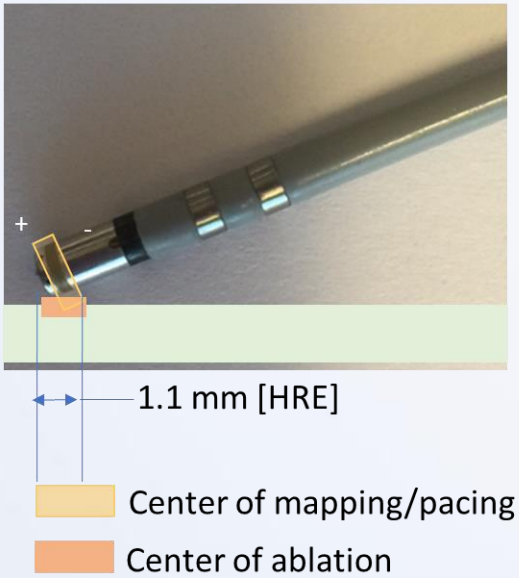



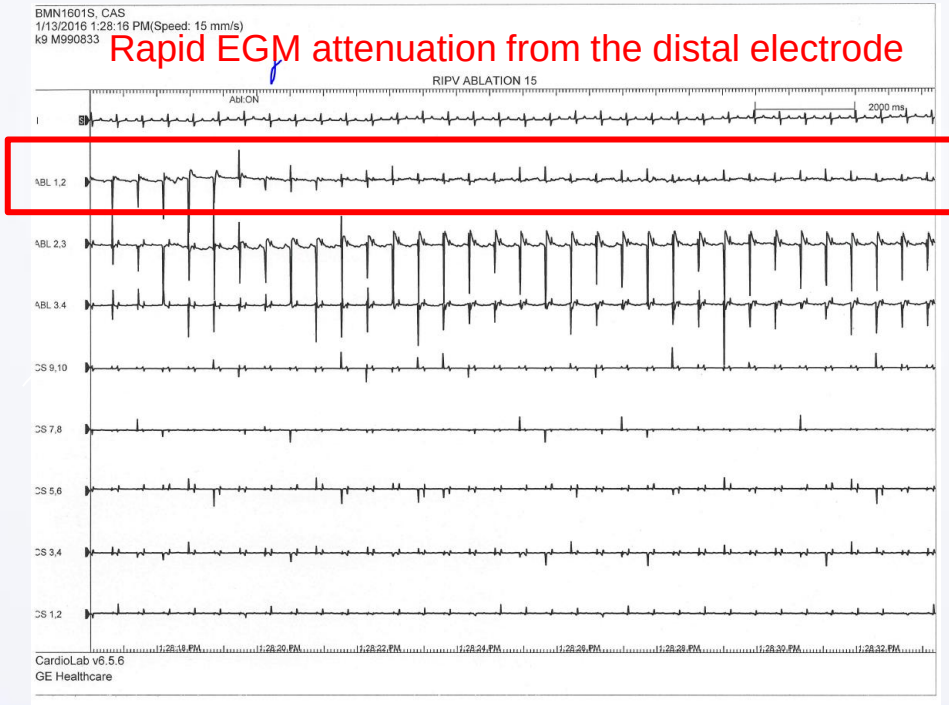

IR shows significant reduction in hot spots at the proximal edge of the tip in comparison to a conventional open-irrigated catheter due to the diamond tip.

Saline irrigation through the catheter tip to the diamond network means that very little heat is retained therefore reducing hotspots at the catheter tip.

# High Resolution EGM

DiamondTemp High-Res Electrodes
(bipolar mapping/pacing)



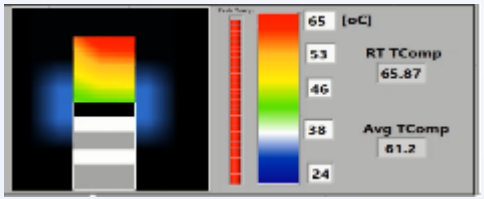




A high-resolution electrode at the catheter tip allows for the recording of highly localized signals at the center of ablation with minimal far field artifact.

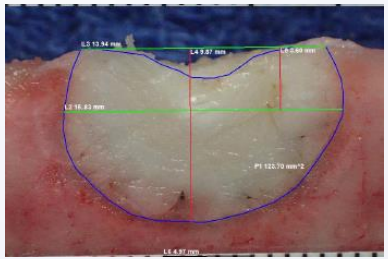
# Indicators of lesion creation

- Temperature
- EGM Attenuation
- % Impedance Drop

**Feedback from true biologic indicators can be displayed on DT RFG**

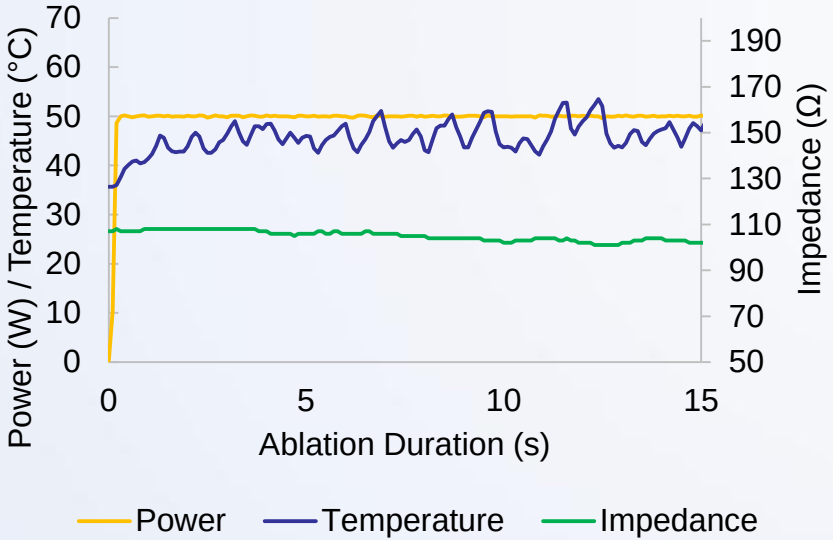



**Lesion Creation with High Confidence**

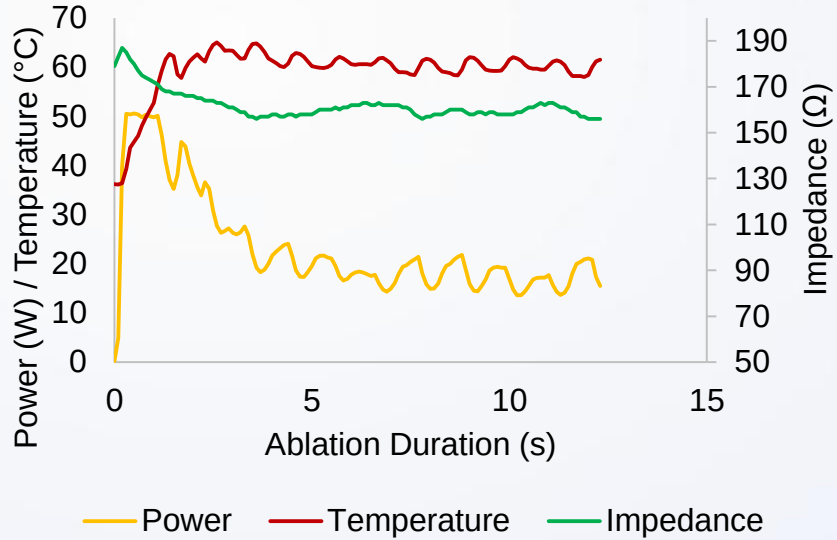


# Speed of ablation is tailored to demonstration of lesion creation

Examples of Temperature Curves for Discreet Lesions



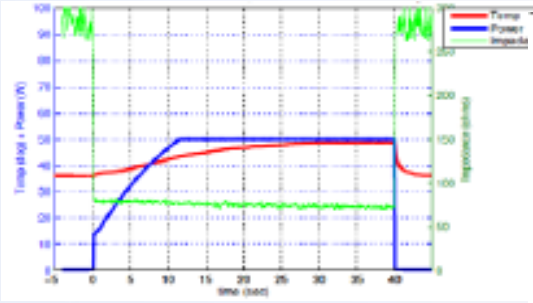

**If the temperature fails to reach and impedance does not drop substantially – *Ablate Longer or Reposition Catheter***



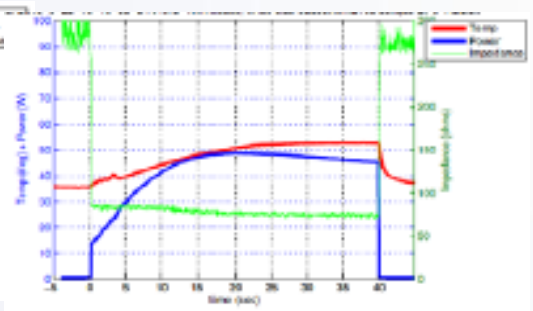

**If the temperature rises very quickly, EGM attenuation is observed, and impedance drops 10-12% – *Ablate Shorter***

# How about contact force?

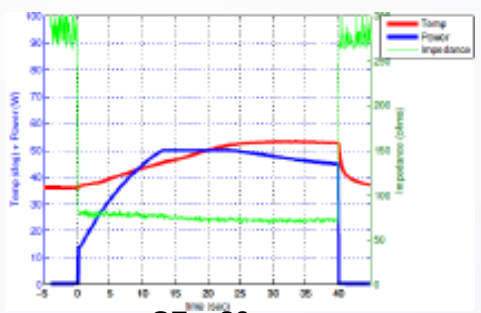
**With temp control, as contact improves, less power is needed to reach the same target temperature.**



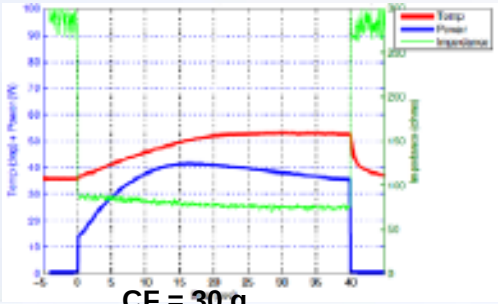
**Contact Force = 10 g**



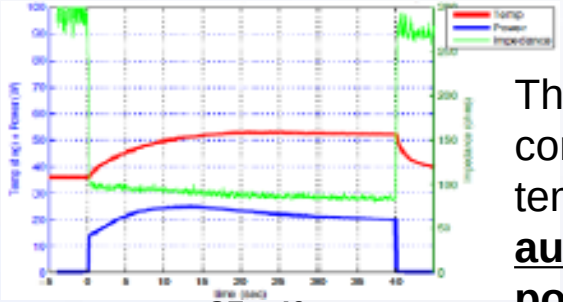
**CF = 15 g**



**CF = 20 g**



**CF = 30 g**



**CF = 40g**

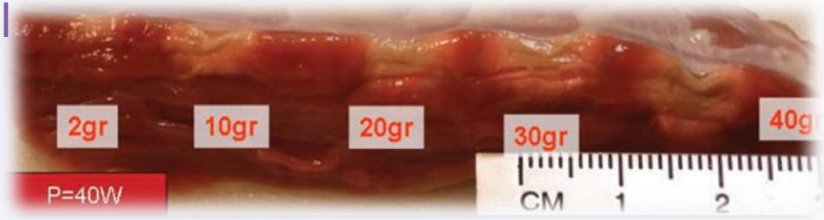
The DiamondTemp System continuously monitors highest temperature sensor and **automatically controls the power** to that temperature

# Ex vivo study of lesions (temp control)

Temperature control lesions are **similar, homogenous and therapeutic** **regardless of contact** force

## Power Control

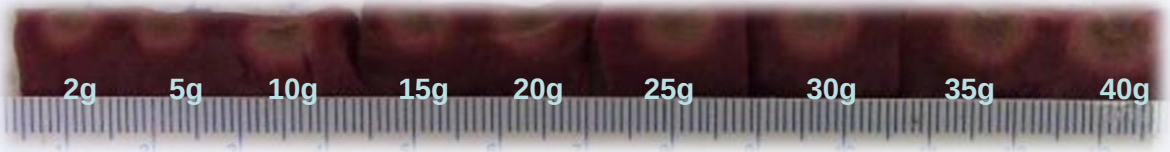
ThermoCool
40W, 60 sec




Constant power Lesions creates vastly different lesion size depending on contact force.

## Temp Control

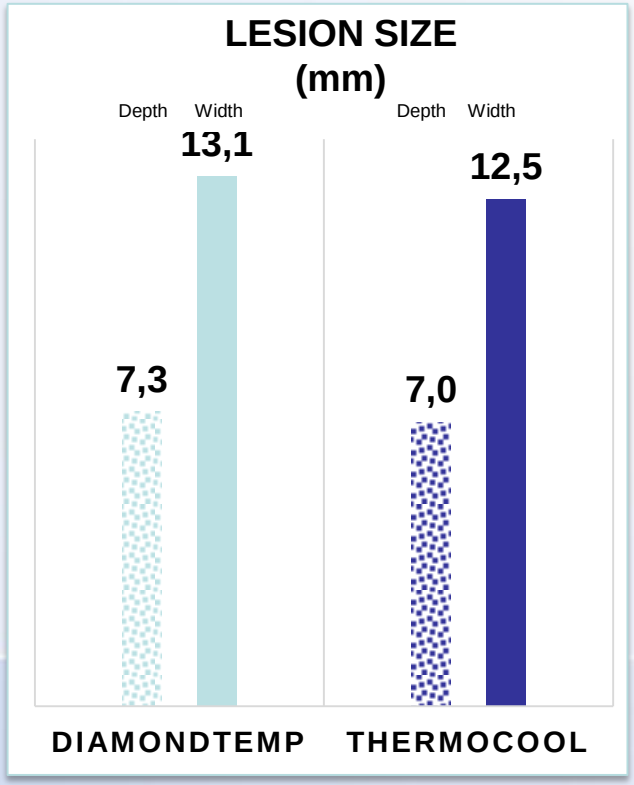
DiamondTemp
50W, 60 ° C

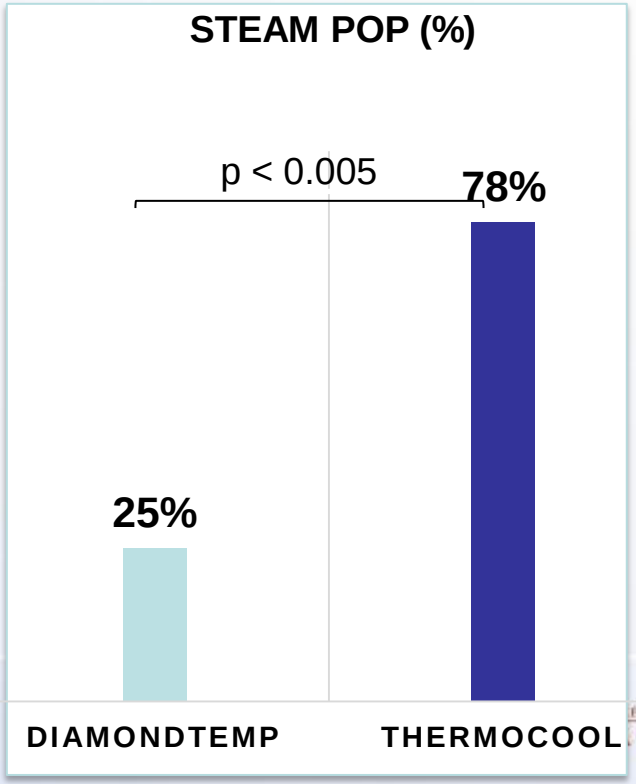


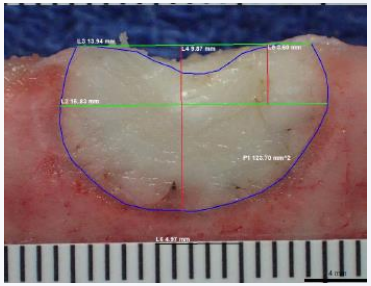

Temperature control lesions are all **similar and therapeutic** regardless of tip contact force.

# *In vivo* – Thigh Model Comparative study

**Temperature control lesions are all relatively similar and therapeutic regardless of tip contact force.**



**Test conditions**

- DT: 60˚ C, 40g, 45 secs
- TC: 50W 40g 60 secs

**Key Results**

- Equivalent lesion volume
- Significant difference in incidence of steam pop

# How the DiamondTemp System is Used Clinically?


| Recommended Settings | DiamondTemp Feature |
|---|---|
| **Temperature**<br>➢ Maximum of 60 °C | At temperature control mode, RFG delivers power to achieve max temp of 60°C |
| **Power**<br>➢ Maximum of 50 W | |
| **Flow Rate**<br>➢ 8 ml/min during ablation<br>➢ 2 ml/min during standby | Diamond network's cooling efficiency allows for 8 ml/min flow rate at all power |
| **Contact**<br>➢ Pre-ablation, use distal EGM, 3D map, ICE | High resolution EGM feature allows the recording localized signals pre-ablation<br>During ablation, contact is determined by temperatures reached |
| **Ablation Duration**<br>➢ EGM attenuation* (+ 3-5 seconds)<br>➢ Temperature (>50°C)<br>➢ Impedance drop (8-10%) | EGM attenuation + surface temperatures >50°C and impedance drops of 8-10% give high confidence that a therapeutic lesion is formed.<br>• Irreversible thermal necrosis >50°C [1] |

*Significant EGM attenuation defined as a 75-80% reduction in amplitude or after initial reduction in amplitude, amplitude remains unchanged.

[1] Nath, S. J Cardiovasc Electrophysiol. 1994 Oct;5(10):863-76

# Clinical Studies on the DiamondTemp System

Series of clinical studies to demonstrate safety and effectiveness of the system

| Clinical Study | Indication | Number of Patients | Location | Status |
|---|---|---|---|---|
| TRAC-AF FIH | PAF | 70 | EU | *Study Completed* |
| Diamond-AF IDE, Randomized, controlled | PAF | 480 | US and EU | *Completed enrollment*<br>*Follow up underway* |
| FASTR-AF Feasibility | PAF/Persistent AF | 60 | EU | *Completed enrollment*<br>*Follow up underway* |
| TRAC-VT Feasibility | VT | 50 | EU | Currently enrolling |
| Diamond-AF II IDE | Persistent AF | 300 | US and EU | Currently enrolling |

# TRAC-AF First-In-Human Study

**TABLE 2** Baseline Clinical Characteristics

| | Study Group (n = 35) | Control Group (n = 35) | p Value |
|---|---|---|---|
| Age, yrs | 60 ± 10 | 63 ± 11 | 0.312 |
| Male | 24 (69) | 28 (80) | 0.274 |
| LVEF, % | 64 ± 4 | 63 ± 12 | 0.371 |
| LA diameter, mm | 44 ± 4 | 40 ± 5 | 0.052 |
| AF duration, months | 42 | | |
| Hypertension | 27 | | |
| Heart failure | 0 | | |
| Diabetes mellitus | 6 | | |
| Stroke | 1 | | |
| CAD | 5 | | |
| Antiarrhythmic therapy | | | |
| Class I | 16 | | |
| Class II | 16 (46) | 25 (71) | 0.029 |
| Class III | 9 (26) | 14 (40) | 0.203 |
| Class IV | 3 (9) | 2 (6) | 0.500 |

Values are mean ± SD or n (%).
AF = atrial fibrillation; CAD = coronary artery disease; LA = left atrial; LVEF = left ventricular ejection fraction.

**TABLE 3** Procedural Details

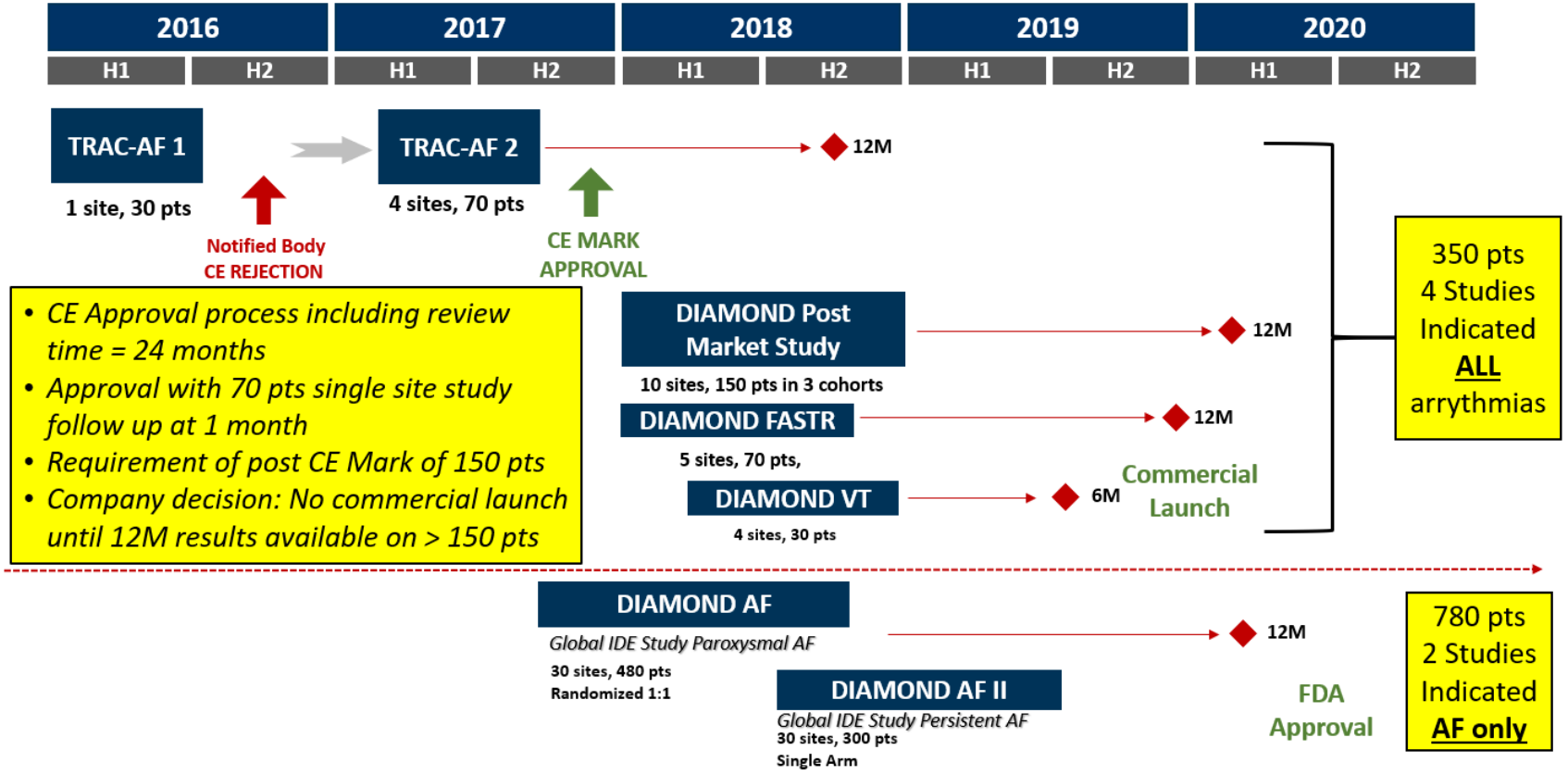
| | Study Group (n = 35) | Control Group (n = 35) | p Value |
|---|---|---|---|
| No. of ablation lesions per patient | 83.6 ± 13.2 | 151.6 ± 38.2 | <0.001 |
| Left PV lesion set | 37.9 ± 8.8 | 60.2 ± 18.2 | <0.001 |
| Right PV lesion set | 46.1 ± 9.5 | 91.3 ± 26.0 | <0.001 |
| RF application time per point, s | 18.8 ± 1.9 | 35.1 ± 4.1 | <0.001 |
| | | 1.9 | 33.8 ± 5.4 <0.001 |
| | | 2.4 | 35.8 ± 4.2 <0.001 |
| | | 5.2 | 89.2 ± 27.2 <0.001 |
| | | 3.3 | 34.4 ± 13.1 <0.001 |
| | | 3.7 | 54.8 ± 17.9 <0.001 |
| Fluoroscopy time, min | 11.2 ± 8.5 | 19.5 ± 6.8 | <0.001 |
| Average impedance drop, Ω | 13.1 ± 3.5 | 8.1 ± 2.1 | <0.001 |
| Average power, W | 36.3 ± 2.6 | 31.2 ± 2.5 | <0.001 |

Values are mean ± SD.
PV = pulmonary vein; RF = radiofrequency.

At 3 months, 23 patients underwent remapping: 39 of 46 PV pairs (84.8%) remained durably isolated in 17 of these patients (73.9%)

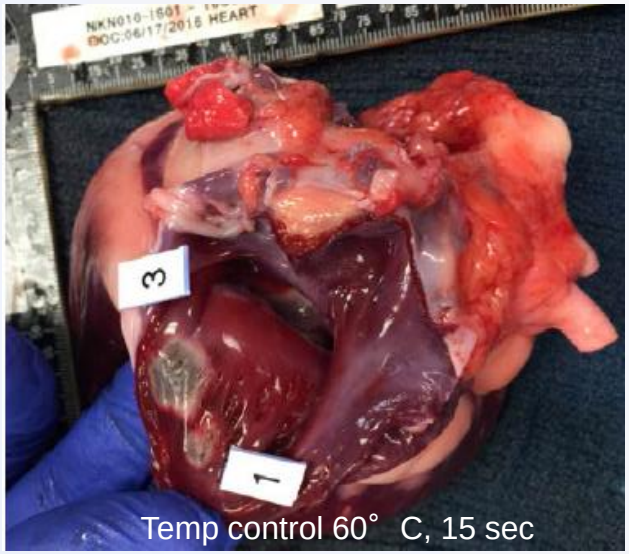
Iwasawa J, et al. JACC 2017:70;542-553

# Clinical Program and CE Approval Overview



# How does temp control ablation apply to VT?

***In vivo* studies to characterize the technology for VT underway**

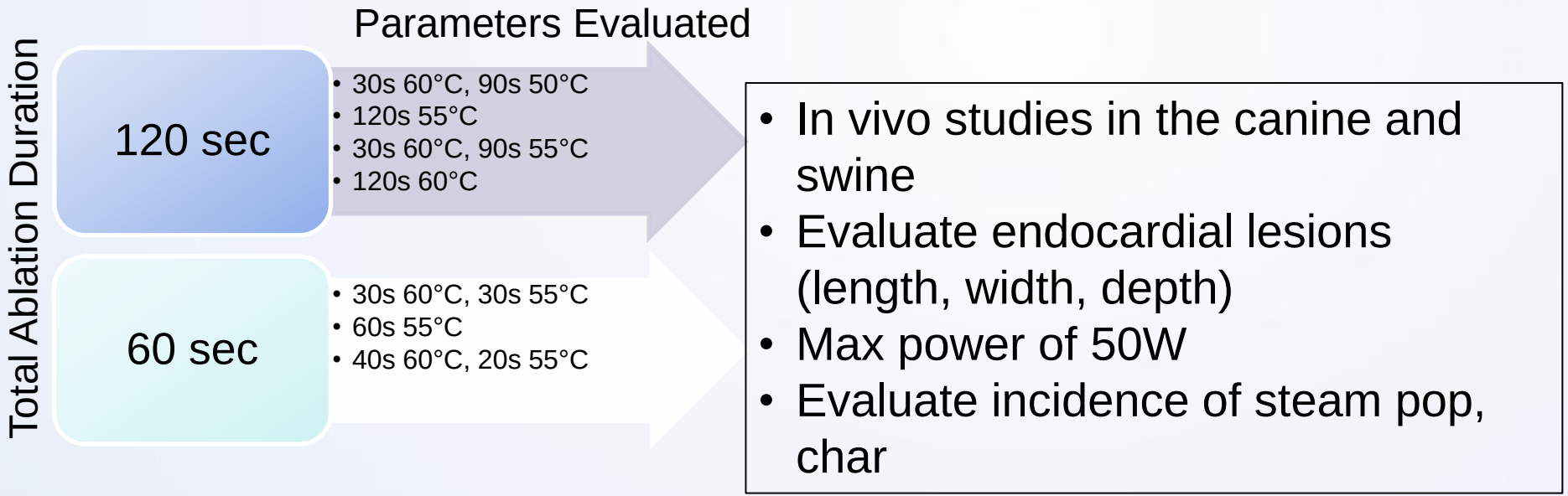


Temp control 60° C, 15 sec

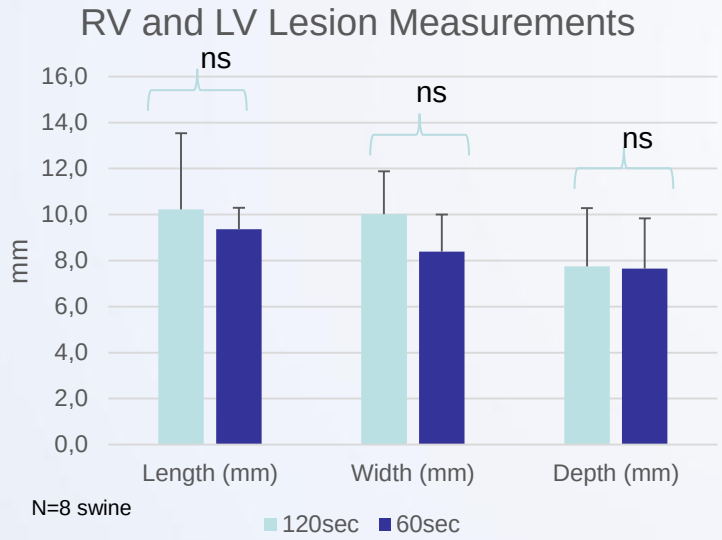
Temp control 60° C, 60 sec

**In Vivo, Canine Study:** Temp control lesions created in the right and left ventricle with no steam pop

# Preclinical Evaluation in the Ventricle



# Preclinical Study Results (Ventricle)




N=8 swine

- The lesions were nearly fully formed at the first 30s at 60° C
- Impedance reduces by 25% within the first 30s and doesn't change after
- Beyond 30 sec at 60° C , thermal growth was minimal
- No significant lesion grown at 50 ° C between 60 to 120 seconds
- No steam pop occurred in any of the RF applications.
- No char was observed on the catheter or lesions at necropsy

In the ventricle, the recommendation is to ablate at 55-60° C for 60 seconds due to comparable lesion size to a 120 sec ablation

# TRAC-VT First-In-Human Study

| | |
|---|---|
| **Indication** | Ventricular Tachycardia |
| **Study Design** | Prospective, single-arm, multi-center, non-blinded |
| **Objective** | Demonstrate safety/effectiveness of the DiamondTemp Ablation System for the treatment of ventricular tachycardia |
| **Primary Endpoint** | Safety: SAE through 30 days<br>Effectiveness: termination or non-inducible clinically-relevant VT (spontaneous or induced) |
| **Investigational Sites** | 5 Sites in Europe |
| **Total Subjects** | 50 patients |
| **Principal Investigator** | Josef Kautzner, MD, PhD (IKEM – Prague, CZ) |
| **Study Start Status/Timing** | • IKEM started May 2018. |

# Conclusions

- Novel temperature-guided, irrigated tip ablation catheter with circumferential microelectrode opens new era in RF ablations
- Rapid sensing of the tissue temperature allows adjustment of power depending on tissue contact and characteristics and surrounding cooling (and leads to shorter RF applications)
- Catheter ablation appears to be safe without detectable pops
- Ongoing trials will document safety and efficacy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