

# Medtronic

## Affera™ Mapping and Ablation System

A focal ablation catheter that toggles between radiofrequency and pulsed field energy to treat atrial fibrillation



## 12-month outcomes resulting in CE Mark

A prospective, single-arm, first-in-human clinical trial to treat AF

At the operator's discretion, lesions were placed with RF or PF energy modalities.

PF was exclusively used on the posterior wall near the esophagus.

Paroxysmal (PAF)

70

Persistent (PerAF)

108

The PF waveforms evolved during the trial. There were 54 PerAF patients treated with the PULSE3 commercially available waveform.

### Safety

## 0.6%

Primary safety endpoint



0 AE fistula



0 Coronary spasm



0 PV stenosis



0 Phrenic nerve injury

1 Hospitalization: inflammatory pericardial effusion not requiring catheter/surgical intervention

### Efficacy

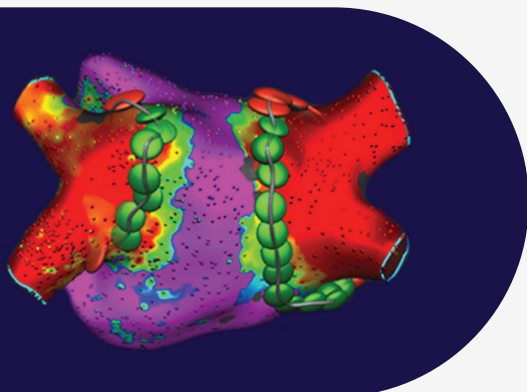
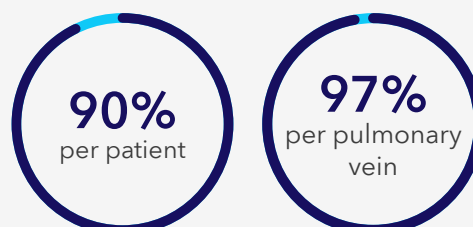
Freedom from atrial arrhythmias



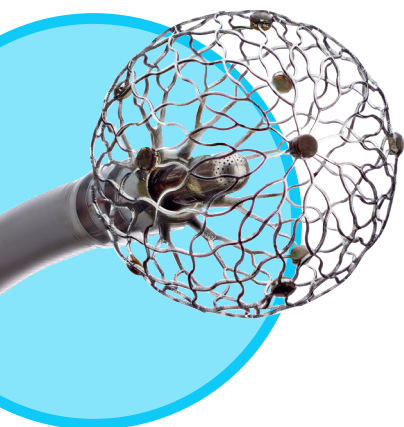
Improvement of efficacy and PV durability with PULSE3 optimized waveform

### Durability

Remapping at  $96 \pm 43$  days demonstrated PVI in:



# Affera™ Mapping and Ablation System



## Sphere-9™ Catheter

9 mm, wide-area focal lattice-tip electrode

Delivers Pulsed Field and Radiofrequency energy from entire surface area

## Tailored ablation strategy

Lesion sets delivered during trial

PV Pairs 356

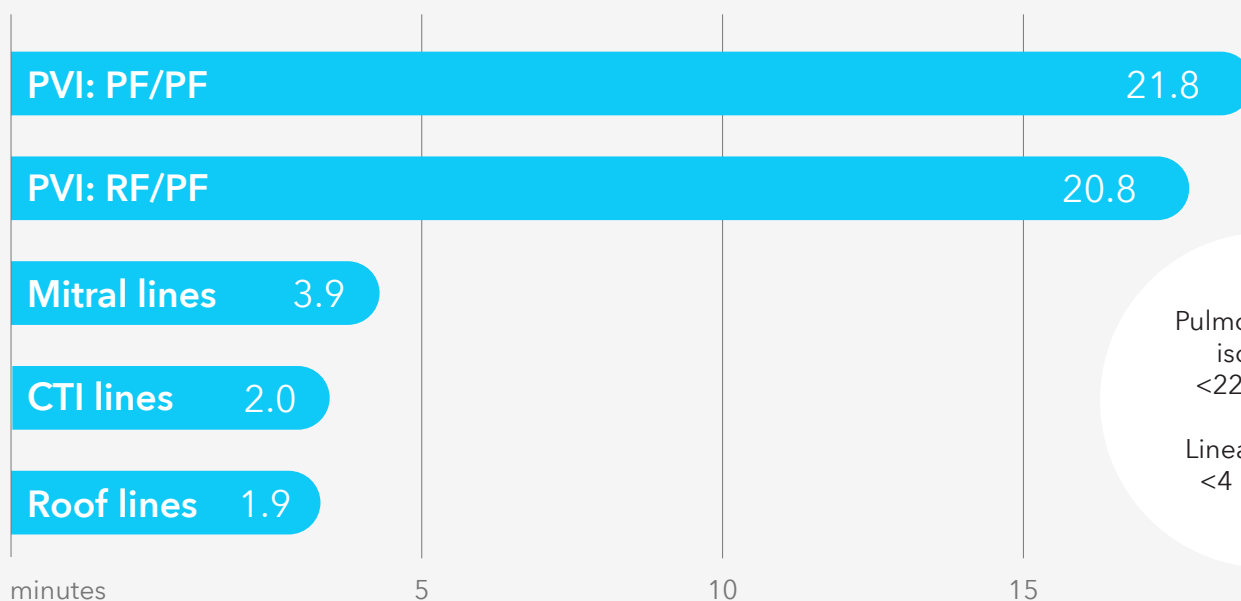
Roof lines 130

CTI lines 121

Mitral lines 78

## Transpired ablation time

From first to last energy application



Pulmonary vein isolation  
<22 minutes

Linear lesions  
<4 minutes

### Reference:

Reddy, Vivek Y., et al. "A focal ablation catheter toggling between radiofrequency and pulsed field energy to treat atrial fibrillation." *JACC: Clinical Electrophysiology* (2023): In press.

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**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.eu.

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Formal product name in IFUs may differ from what is in this document:  
Sphere-9™ Catheter = Sphere-9™ Mapping and Ablation Catheter

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