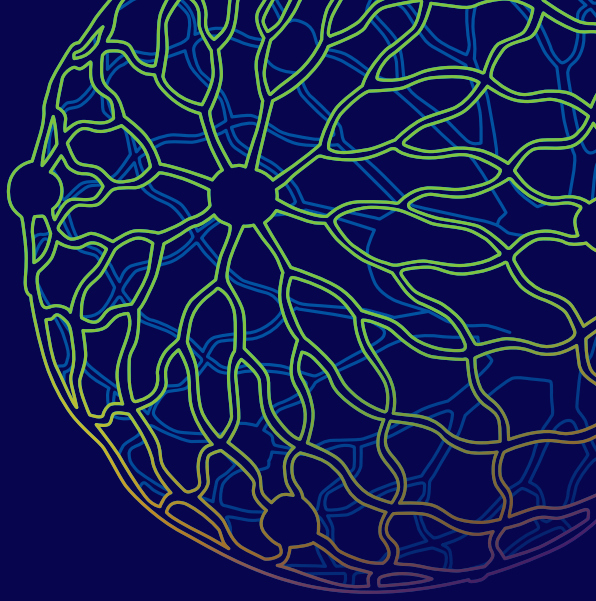
Medtronic

SPHERE Per-AF U.S. IDE study results



Source: Anter E, Mansour M, Nair DG, et al. Dual-energy lattice-tip ablation system for persistent atrial fibrillation: a randomized trial. *Nat Med.* 2024.

Randomized 1:1 Persistent AF clinical trial

Sphere-9 catheter
with Affera mapping and ablation system
n = 212

THERMOCOOL SMARTTOUCH®* SF
with CARTO®* mapping system
n = 208

Trial results at a glance

Primary safety event rate†

1.4%

Primary effectiveness‡

73.8%

Procedural characteristic superiority over STSF

25 min less Superior skin-to-skin procedural time

27 min less Superior time between first and last application

29 min less Superior energy application time

† For a full list of safety events, review the SPHERE Per-AF manuscript.
‡ Primary effectiveness endpoint definition: The primary effectiveness endpoint was acute procedure failure, repeat ablation at any time, or after three months: recurrence of AF/AFL/AT, cardioversion, or new/re-initiated/increased AAD usage.

The Sphere-9™ catheter was **noninferior in safety** and provided **quality of life improvements** for patients

1.4%
primary safety event rate vs. 1% with the STSF catheter†

0 PV stenosis

0 Phrenic nerve paralysis

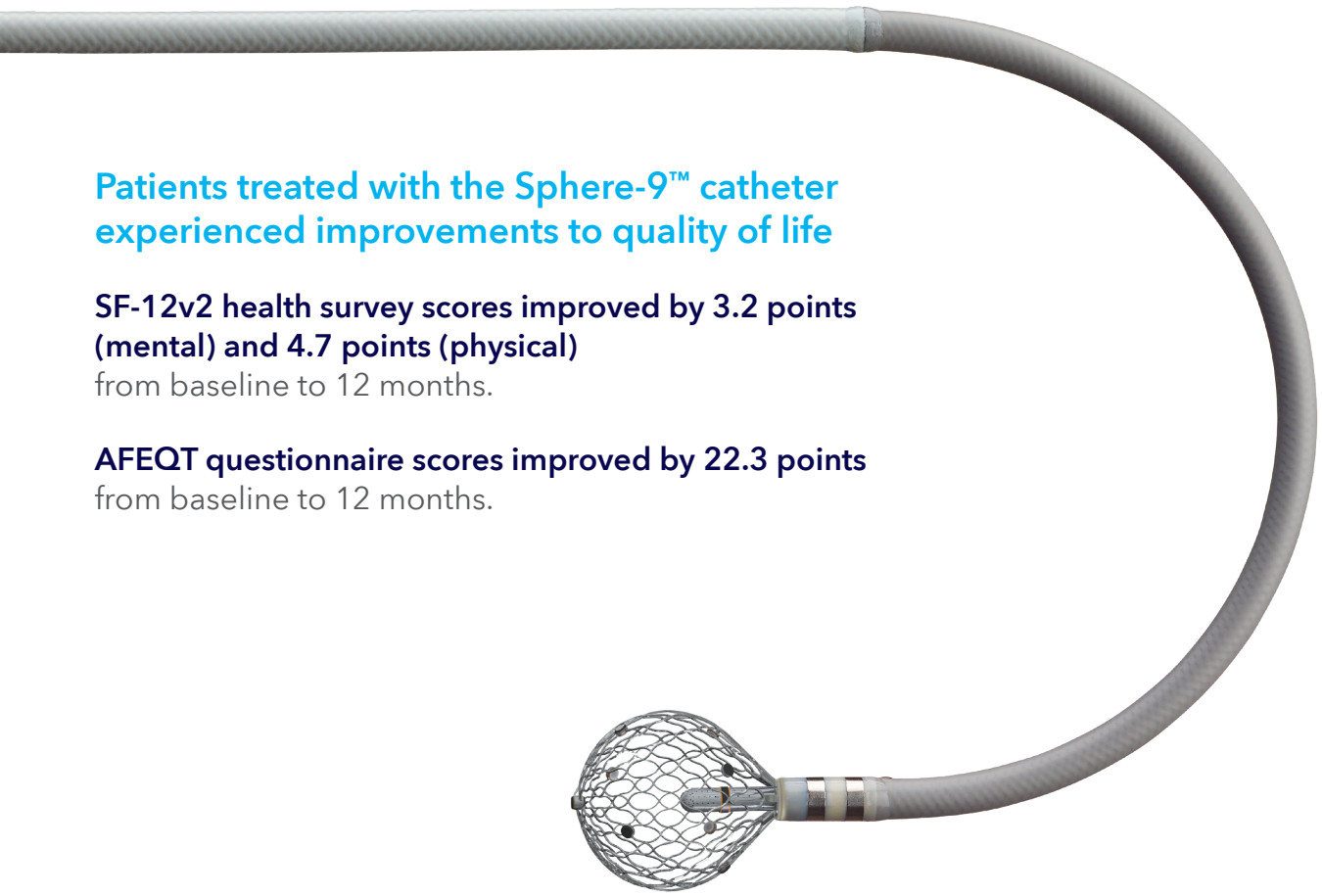
0 Major vascular access complications

0 Atrio-esophageal fistula

0 Cardiac tamponade

3/212 Hospitalizations due to cardiovascular or pulmonary AE‡

0/212 Death
0/212 Myocardial infarction
0/212 Transient ischemic attack (TIA)
0/212 Stroke/Cerebrovascular accident (CVA)
0/212 Thromboembolism
0/212 Heart block
0/212 Gastroparesis
0/212 Severe pericarditis



Patients treated with the Sphere-9™ catheter experienced improvements to quality of life

SF-12v2 health survey scores improved by 3.2 points (mental) and 4.7 points (physical)
from baseline to 12 months.

AFEQT questionnaire scores improved by 22.3 points
from baseline to 12 months.

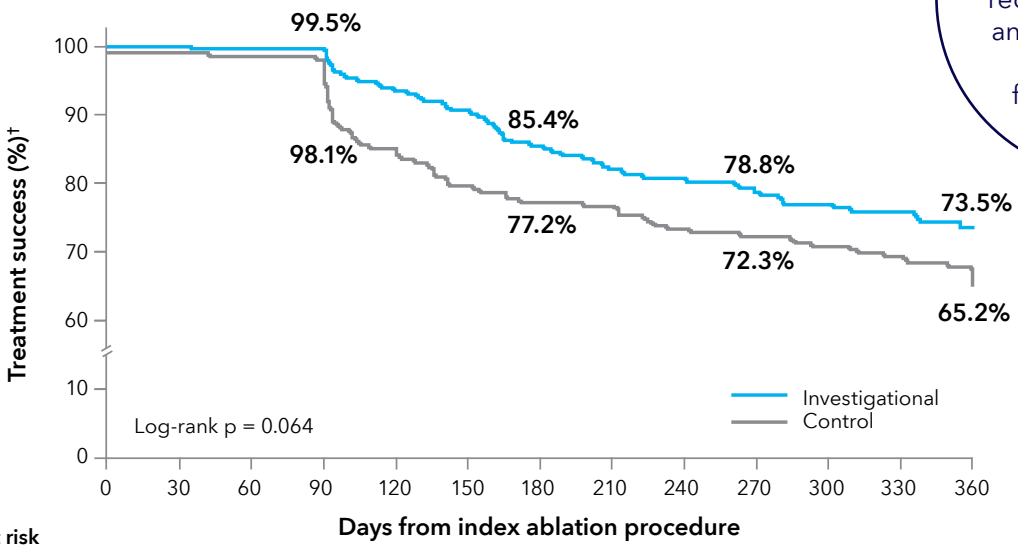
† Investigational arm – 212 patients. Control Arm – 208 patients.
‡ The 3 hospitalization events within 1 week post-procedure and were for chronic obstructive pulmonary disease exacerbation, pulmonary edema, and hemoptysis.

The Sphere-9 catheter delivered **higher effectiveness** outcomes for persistent AF patients

73.8%
Primary effectiveness at 12 months vs. 65.8% in the control arm

- Demonstrated noninferior effectiveness
- Higher treatment success compared to the control arm at 3, 6, 9, and 12 months
- 100% acute procedural success

Patients treated with Sphere-9 catheter observed less recurrence of AF, AT, and AFL throughout the entire follow-up period

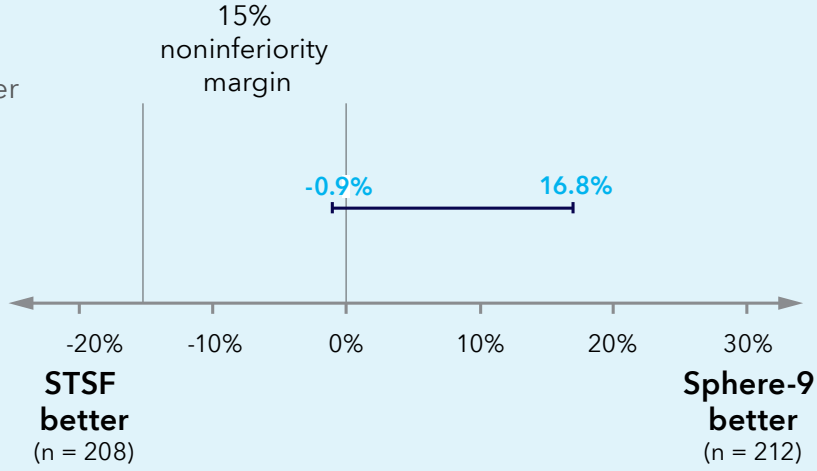


No. at risk					
Investigational	212	211	181	166	84
Control	208	202	159	148	82

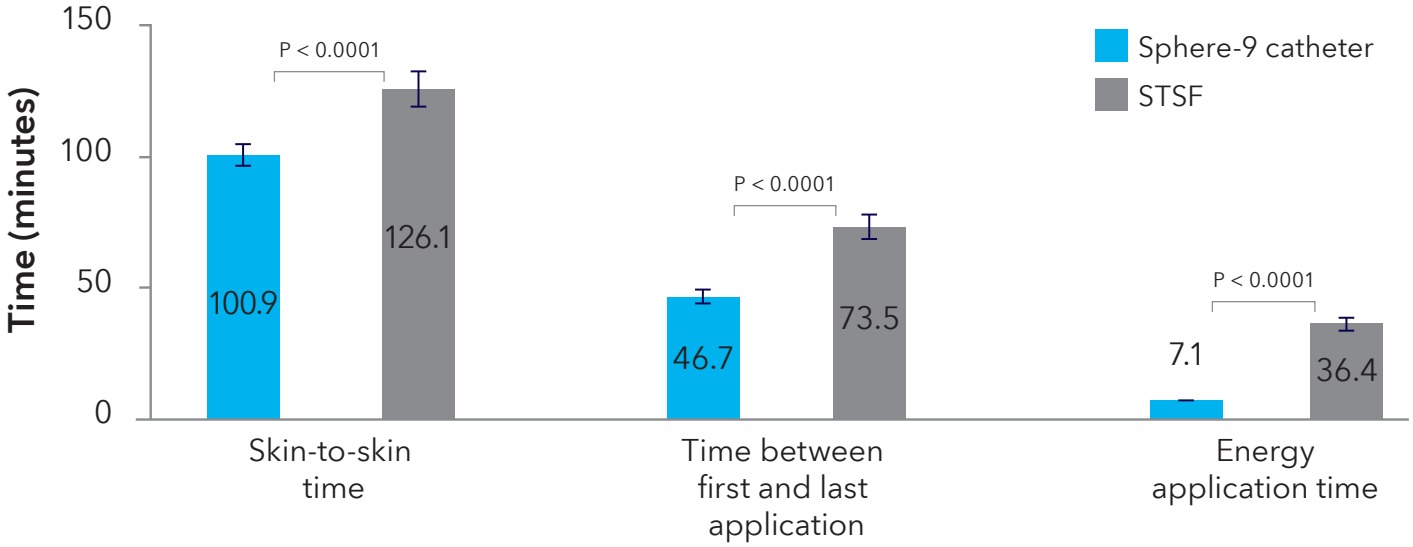
† The **Kaplan-Meier analysis** included early study exits via censoring which accounts for the slightly different effectiveness results.

Primary effectiveness testing

Difference between Sphere-9 catheter and STSF.

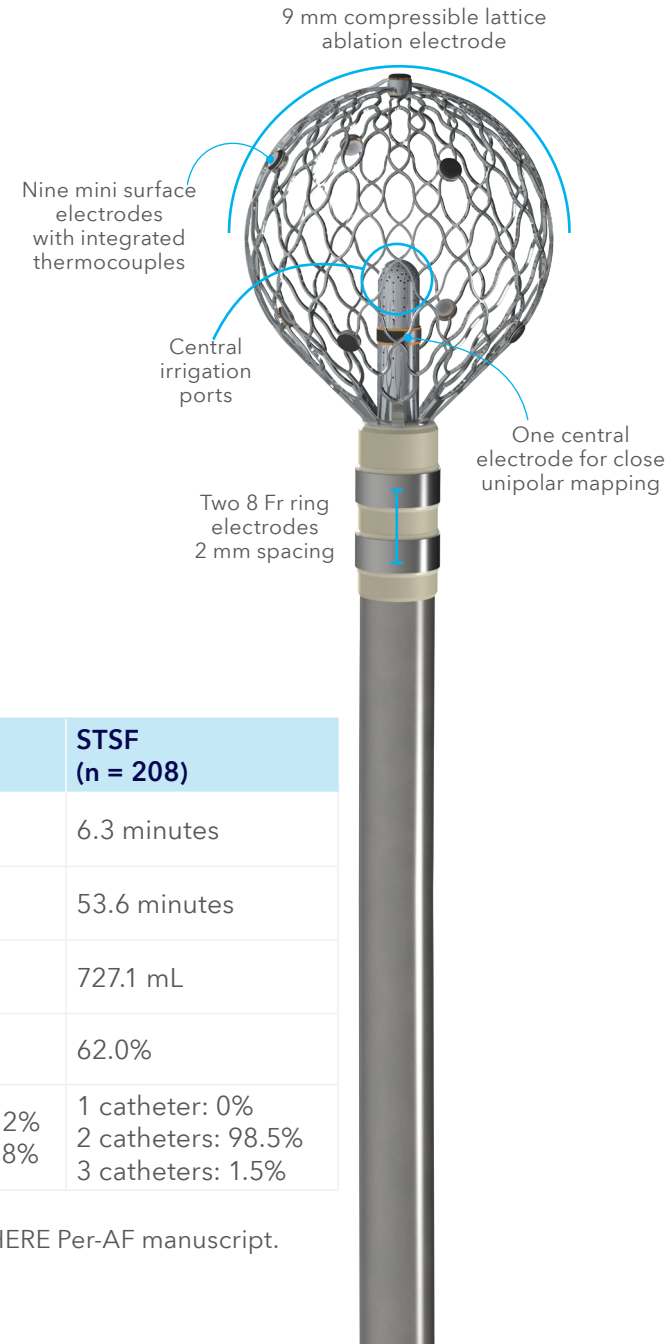


The Sphere-9 catheter with all-in-one design delivered **procedural characteristic superiority**



Dual energy wide area focal catheter

- PF lesions are delivered in four-second intervals
- RF lesions are delivered in five-second intervals



Additional procedural characteristic results†

Parameter	Sphere-9 (n = 212)	STSF (n = 208)
Fluoroscopy time†	4.9 minutes	6.3 minutes
Time between first and last application for pulmonary vein isolation	25.9 minutes	53.6 minutes
Total fluid delivered by ablation catheters	482.0 mL	727.1 mL
Procedures with single transseptal accesses	95.3%	62.0%
Number of mapping and/or ablation catheters used in LA	1 catheter: 97.2% 2 catheters: 2.8%	1 catheter: 0% 2 catheters: 98.5% 3 catheters: 1.5%

† For a full list of procedural characteristic results, review the SPHERE Per-AF manuscript.

SPHERE Per-AF trial design and study population

Randomized, controlled clinical trial comparing Sphere-9 catheter with the Affera mapping and ablation system to the THERMOCOOL SMARTTOUCH®* SF catheter with CARTO®* mapping system for the treatment of patients with persistent atrial fibrillation refractory or intolerant to drugs.

Randomized 1:1

Sphere-9 catheter with Affera mapping and ablation system

THERMOCOOL SMARTTOUCH®* SF with CARTO®* mapping system

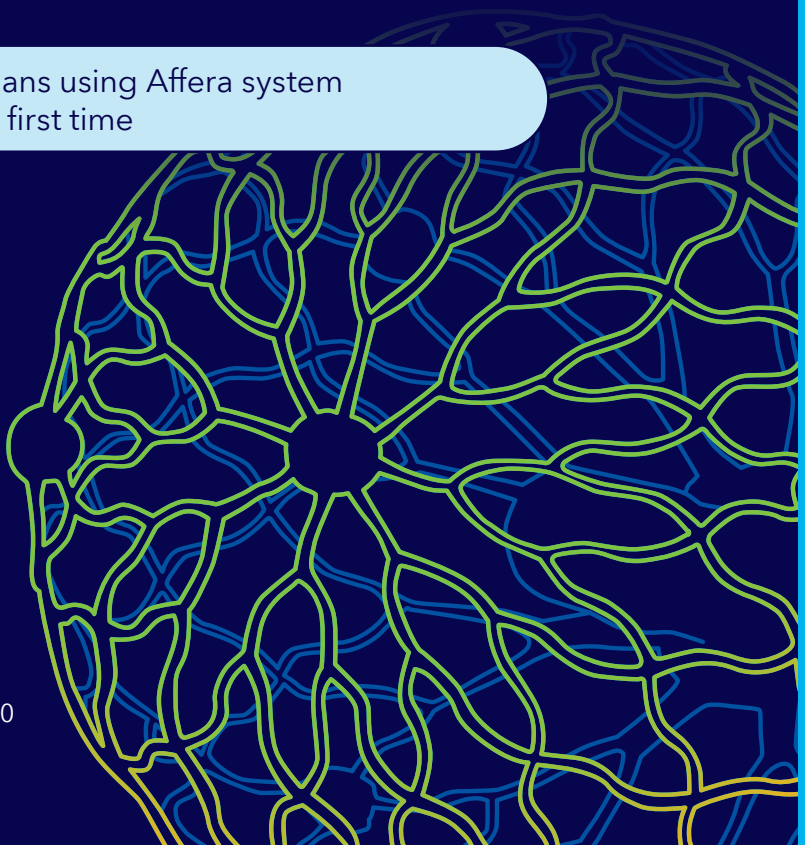
Treatment strategy

PVI plus additional lesions at physician discretion in both arms

Trial investigator† experience with Sphere-9 catheter

6 Average number of patients treated per operator in the investigational arm

87.5% Physicians using Affera system for the first time



† All operators had significant experience with the control arm device (typically > 1,000 patients treated).

By the numbers

3 countries
U.S., Israel, Czechia

23 sites
activated

> 40
operators

420 patients
treated in primary analysis

< 12 months
to complete enrollment

Brief statement
See the device manual for 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 www.medtronic.eu.

For applicable products, consult instructions for use on manuals.medtronic.com. Manuals can be viewed using a current version of any major internet browser. For best results, use Adobe Acrobat® Reader with the browser.

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