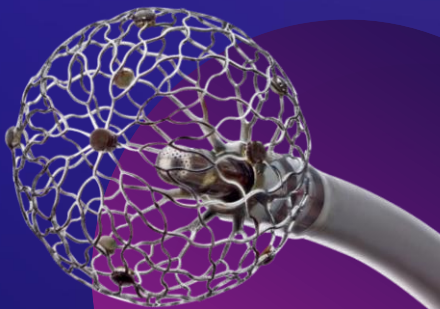


Affera™ Sphere-9™

Cost Savings in AF Ablation in the Spanish National Health System (SNS)¹

The emergence of advanced pulsed field ablation (PFA) tools offers the potential to improve procedural efficiency and outcomes in the management of atrial fibrillation (AF). In a publicly funded, resource-constrained health system such as Spain's SNS, assessing the cost-effectiveness of new technologies is essential to inform evidence-based decision-making and ensure the efficient allocation of healthcare resources.



Affera™ Sphere-9™
Dual-energy mapping
and ablation catheter

Objective:

To assess the cost-effectiveness of the dual energy Affera Sphere-9™ catheter conventional contact-force radiofrequency (CFRF) catheter for the treatment PersAF patients, from the Spanish SNS perspective.

Methods:

- A hybrid model, combining a 1-year decision tree with a Markov model, was developed to estimate total costs and quality-adjusted life years (QALYs) over a lifetime horizon (40 years).
- Model parameters were primarily derived from individual patient-level data from the SPHERE Per-AF trial (NCT05120193)², with additional inputs obtained from published literature.
- Intervention costs, complication costs, drug costs, and stroke- and heart failure-related health state-specific costs were obtained from Spanish sources.

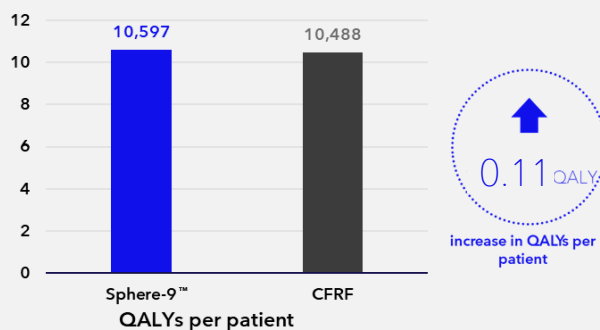
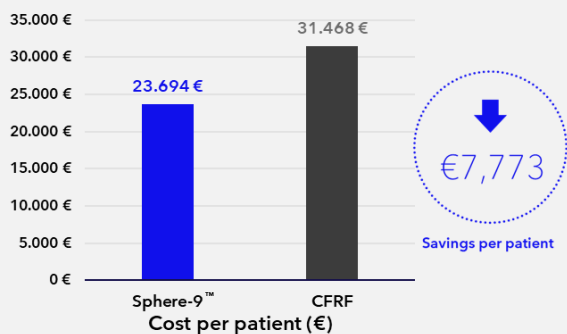
Results:

1. Cost reduction:

Estimated mean total costs per patient undergoing ablation with Sphere-9™ was €23,694, versus €31,468 for CFRF ablation. Per-patient savings: €7,773.

2. Improved quality of life and survival:

Ablation with the Sphere-9™ catheter was associated with an average of 10.597 QALYs per patient, compared to 10.488 QALYs for CFRF ablation. Increment: 0.11 QALYs per patient.

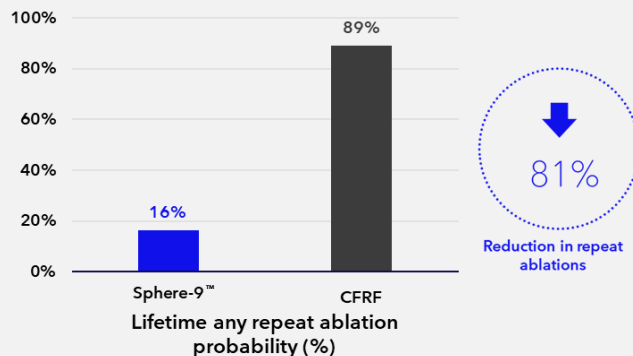
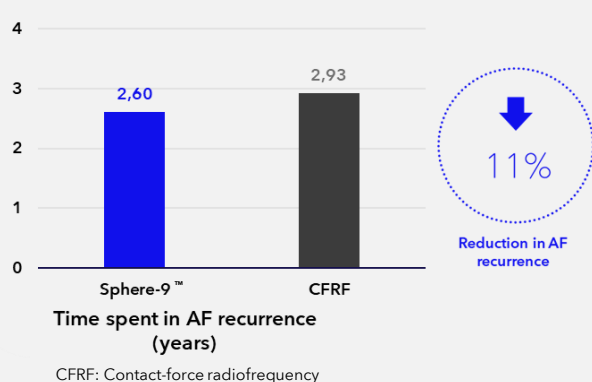


3. Recurrence reduction:

Model results suggested an 11% relative reduction in time spent in AF recurrence with Sphere-9™, corresponding to a gain of approximately 0.32 years symptom-free.

4. Significant reduction in repeat ablations:

The model estimated an 81% reduction in repeat ablations per patient with Sphere-9™.



Conclusion

The dual-energy Sphere-9™ catheter represents a more effective and cost-saving solution for the treatment of persistent AF compared with conventional RF ablation from the Spanish SNS perspective.

References:

1. Peinado R, Anter E, Reddy VY, Iskandar R, Ismyrloglou E, Mburu W, Monje J, Arias MA. Rentabilidad de un catéter de doble energía con punta de red focal grande para el tratamiento de la fibrilación auricular persistente en España. Comunicación presentada en RITMO 2026.
2. Anter E, Mansour M, Nair DG, et al. Dual-energy lattice-tip ablation system for persistent atrial fibrillation: a randomized trial. Nat Med. 2024;30(8):2303-2310.

Brief statement

This material should not be considered the exclusive source of information, it does not replace or supersede information contained in the device manual(s). Please note that the intended use of a product may vary depending on geographical approvals. See the device manual(s) for detailed information regarding the intended use, the (implant) procedure, indications, contraindications, warnings, precautions, and potential adverse events. For a MRI compatible device(s), consult the MRI information in the device manual(s) before performing a MRI. If a device is eligible for eIFU usage, instructions for use can be found at Medtronic's website 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. Medtronic products placed on European markets comply with EU and UK legislation (if applicable) on medical devices. For any further information, contact your local Medtronic representative. Medtronic medical devices marketed in Spain are in compliance with the Spanish legislation in force

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