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PRECEPT Study Results[1-3]

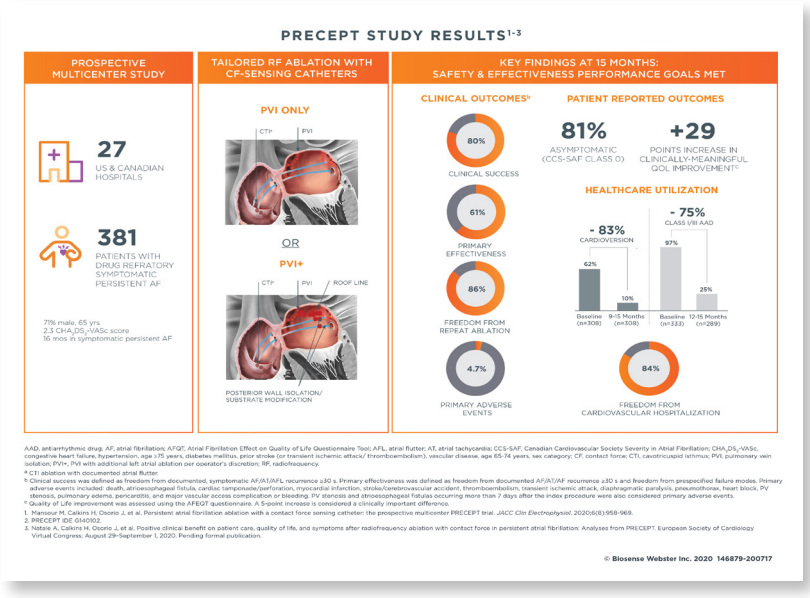
The articles in this email may consist of clinical trials and observational studies as well as economic analyses. Access to these articles and to additional clinical articles with similar results are provided through the embedded links. Membership to individual sites may be required in order to access the material.

INTRODUCTION

The PRECEPT study evaluated the safety and effectiveness of radiofrequency catheter ablation in patients with persistent atrial fibrillation (AF) using the contact-force sensing THERMOCOOL SMARTTOUCH® SF Catheter with CARTO VISITAG™ Module. This newsletter summarizes key study findings.

Click the link below to visit our website for in-depth PRECEPT study information and access to additional resources, including a graphic abstract and comprehensive peer-reviewed article summary.

LEARN MORE ABOUT PRECEPT



METHODS

STUDY DESIGN: Prospective, multicenter, nonrandomized clinical study

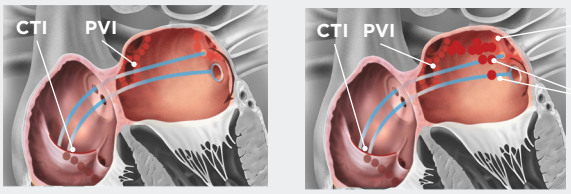
ENROLLMENT: 381 patients with documented, drug refractory persistent AF, defined as continuous AF sustained beyond 7 days but <1 year in duration

ABLATION APPROACH: Isolation of all pulmonary veins with THERMOCOOL SMARTTOUCH® SF Catheter was required for all patients (pulmonary vein isolation [PVI] only). Additional ablations were allowed (PVI+) per operator's discretion.

PRIMARY EFFECTIVENESS: Freedom from documented AF/atrial tachycardia (AT)/atrial flutter (AFL) ≥30 sec and prespecified failure modes at 15 months (40% performance goal)

CLINICAL SUCCESS: Freedom from documented symptomatic AF/AT/AFL recurrence ≥30 s evaluated at 15 months

PRIMARY ADVERSE EVENTS: Within 7 days of the initial and any repeat ablation procedures (16% performance goal)



PVI Only or PVI+

Recommended CARTO VISITAG™ Module Settings

- Location stability: 3 mm
- Minimum time: 3 s
- Force-over-time filter: <50%

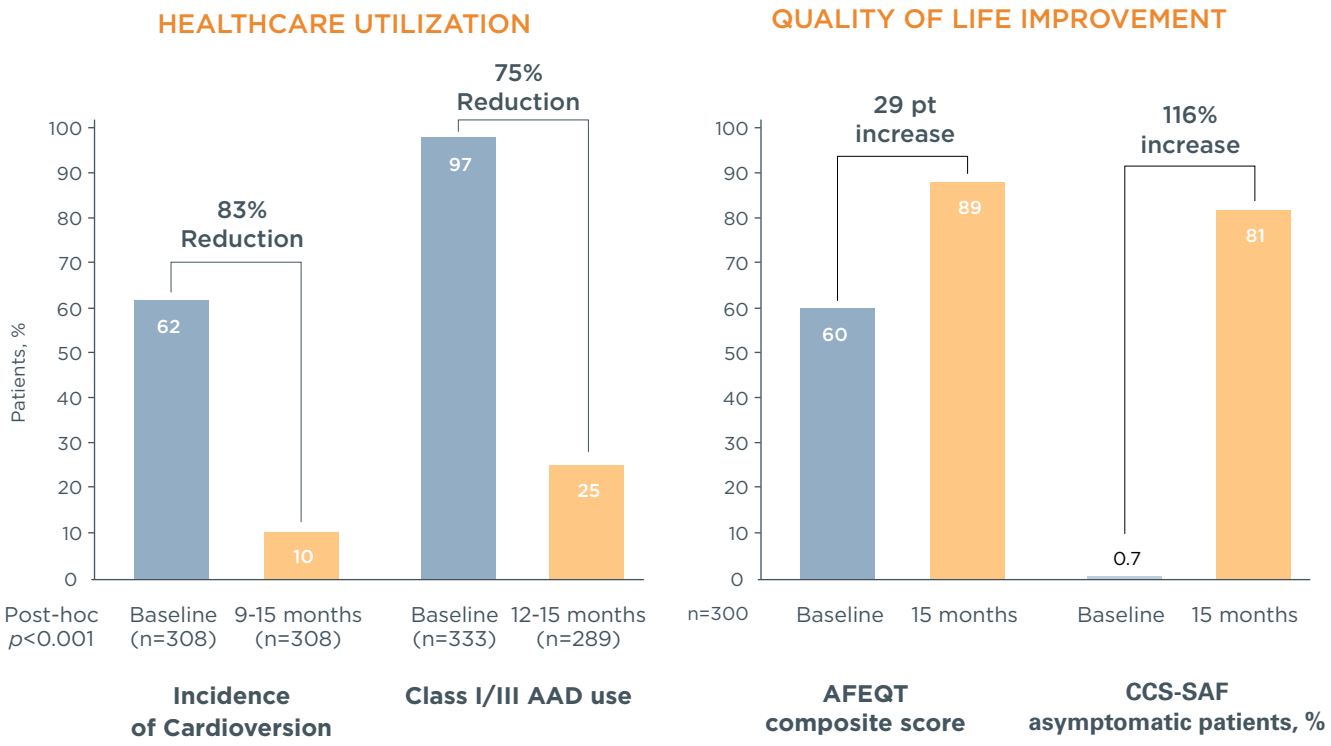
RESULTS

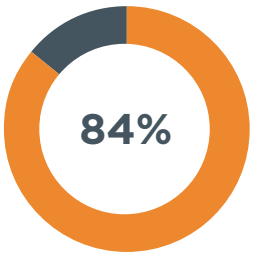
PRECEPT met prespecified 15-month effectiveness and safety performance goals.

Clinical Success | **Primary Effectiveness** | **Freedom From Repeat Ablation** | **Primary Adverse Events**

PRECEPT patients experienced improvements in quality of life and reduced healthcare utilization.

Healthcare Utilization Rates and Quality of Life 15 Months Postablation





FREEDOM FROM CARDIOVASCULAR HOSPITALIZATION

KEY TAKEAWAYS

- The **PVI only/PVI+ tailored radiofrequency ablation** approach is **safe and effective** for the treatment of **persistent atrial fibrillation.**
- Radiofrequency catheter ablation **significantly decreased** antiarrhythmic **drug use, cardioversion,** rate of **hospitalization**, and AF **symptoms** in persistent AF patients.
- The favorable efficacy/safety results and positive clinical impact of **reduced healthcare utilization and improved quality of life** may assist with shared decision making for treating patients with persistent AF.

REFERENCES

1. Mansour M, Calkins H, Osorio J, et al. Persistent atrial fibrillation ablation with a contact force sensing catheter: The prospective multicenter PRECEPT trial. *JACC Clin Electrophysiol*. 2020;6(8):958-969.
2. PRECEPT IDE G140102.
3. Natale A, Calkins H, Osorio J, et al. Positive clinical benefit on patient care, quality of life, and symptoms after radiofrequency ablation with contact force in persistent atrial fibrillation: Analyses from PRECEPT. European Society of Cardiology Virtual Congress; August 29–September 1, 2020. Pending formal publication.

ARTICLES WITH SIMILAR RESULTS

Stabile G, Di Donna P, Schillaci V, et al. Safety and efficacy of pulmonary vein isolation using a surround flow catheter with contact force measurement capabilities: A multicenter registry. *J Cardiovasc Electrophysiol.* 2017;28(7):762-767.

FORWARD TO A FRIEND

2020 EUROPEAN SOCIETY OF CARDIOLOGY GUIDELINES FOR THE DIAGNOSIS AND MANAGEMENT OF ATRIAL FIBRILLATION

The European Society of Cardiology (ESC) published new guidelines for AF diagnosis and treatment that incorporate evidence from recent clinical trials. The guidelines advocate for collaboration among multiple healthcare professionals to confirm and characterize AF ("CC") before implementing a comprehensive treatment plan based on anticoagulation/stroke, better symptom control, and comorbidities management ("ABC" treatment pathway). Key recommendations of the "CC to ABC" structured AF characterization and management approach include:

PATIENT INVOLVEMENT: Shared, informed decision-making process that values input from **patients and families/caregivers** while crafting a **holistic, individualized care plan.**

QUALITY OF CARE: Introduction of tools that measure **patient-reported metrics** to measure quality of care and identify opportunities that could **improve treatment quality and patient outcomes.**

The complete 2020 ESC guidelines are available at: https://doi.org/10.1093/eurheartj/ehaa612.

FORWARD TO A FRIEND

In the US, 4mm Catheters (NAVISTAR® Catheter, CELSIUS® Catheter, EZ STEER® Catheter (NAV and Non-NAV)) have a "General Indication" for creation of endocardial lesions in patients 4 years of age and older. This "General Indication" includes treatment of Ventricular Tachycardia.

THERMOCOOL® Navigation Catheters are indicated for the treatment of drug refractory recurrent symptomatic paroxysmal atrial fibrillation, when used with CARTO® 3 Systems (excluding NAVISTAR® RMT THERMOCOOL® Catheter).

Bertaglia E, Bella PD, Tondo C, Proclemer A, Bottoni N, De Ponti R, et al. Image integration increases efficacy of paroxysmal atrial fibrillation catheter ablation: results from the CARTOMERGE® Module Italian Registry. *Europace* 2009;11:1004-1010.

THERMOCOOL® Navigation Catheters are indicated for the treatment of recurrent drug/device refractory sustained monomorphic ventricular tachycardia (VT) due to prior myocardial infarction (MI) in adults

The NAVISTAR® THERMOCOOL® and EZ STEER® THERMOCOOL® NAV Catheters are FDA approved for the treatment of drug refractory recurrent symptomatic paroxysmal atrial fibrillation, when used with compatible three-dimensional electroanatomic mapping systems.

The THERMOCOOL SMARTOUCH® SF Catheter is indicated for drug refractory recurrent symptomatic persistent atrial fibrillation (AF) (continuous AF >7 days but <1 year), refractory or intolerant to at least 1 Class I or III AAD, when used with the CARTO® 3 System.

In the US, Biosense Webster THERMOCOOL® Non-Navigational Catheters are indicated for the treatment of Type I Atrial Flutter in patients 18 years of age or older.

Always verify catheter tip location using fluoroscopy or IC signals and consult the CARTO® 3 System User Guide regarding recommendations for fluoroscopy use. Pellegrino, P.L., Brunetti, N.D., Gravina, D., Sacchetta, D., De Sanctis, V., Panigada, S., Di Biase, L., Di Biase, M., and Mantica, M. (2013). Nonfluoroscopic mapping reduces radiation exposure in ablation of atrial fibrillation. Journal of cardiovascular medicine 14, 528-533.
Earley, M.J., Showkathali, R., Alzetani, M., Kistler, P.M., Gupta, D., Abrams, D.J., Horrocks, J.A., Harris, S.J., Sporton, S.C., and Schilling, R.J. (2006). Radiofrequency ablation of arrhythmias guided by non-fluoroscopic catheter location: a prospective randomized trial. *Eur Heart J* 27, 1223-1229

Caution: US law restricts this device to sale by or on the order of a physician.
Important information: Prior to use, refer to the instructions for use supplied with this device for indications, contraindications, side effects, warnings and precautions.

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