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# Summary

## Persistent Atrial Fibrillation Ablation With Contact Force Sensing Catheter: The Prospective Multicenter PRECEPT Trial[1,2]


1. Mansour M, Calkins H, Osorio J, Pollak SJ, Melby D, Marchlinski FE, Athill CA, Delaughter C, Patel AM, Gentlesk PJ, DeVille B, Macle L, Ellenbogen KA, Dukkipati SR, Reddy VY, Natale A. *JACC Clin Electrophysiol.* 2020;6(8):958-969.
2. PRECEPT IDE G140102.


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## STUDY QUESTION

What are the safety and effectiveness of radiofrequency ablation in patients with persistent atrial fibrillation treated with the THERMOCOOL SMARTTOUCH® SF Catheter?

## METHODOLOGY

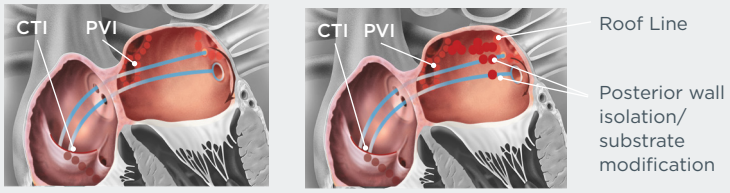
**DESIGN:**
SINGLE ARM. PROSPECTIVE, MULTICENTER, NONRANDOMIZED CLINICAL STUDY

**27**
**CENTERS**

**381**
**PATIENTS**
with documented persistent atrial fibrillation <1 year

**INTERVENTIONS**
THERMOCOOL SMARTTOUCH® SF Catheter with CARTO VISITAG™ Module

**Tailored Ablation Strategy**




**PVI Only** or **PVI+**

## OUTCOMES

**PRIMARY EFFECTIVENESS**
(Freedom from documented AF/AT/AFL and 5 failure modes[a] at 15 months)

**CLINICAL SUCCESS**
(Freedom from symptomatic AF/AT/AFL at 15 months)

**PRIMARY ADVERSE EVENTS**
(within 7 days of the initial and repeat ablation procedures[b])

## RESULTS

**TAILORED PVI-ONLY/PVI+ PERSISTENT ATRIAL FIBRILLATION ABLATION WITH THERMOCOOL SMARTTOUCH® SF CATHETER WITH CARTO VISITAG™ MODULE IS ASSOCIATED WITH**

**61%** Primary effectiveness at 15 months

**80%** Clinical success at 15 months

**4.7%** Rate of primary adverse events at 15 months

**86%** Freedom from repeat ablation at 15 months

## CONCLUSION

The PRECEPT study demonstrated the clinical safety and effectiveness of persistent atrial fibrillation ablation using contemporary contact-force sensing technologies.

AF, atrial fibrillation; AFL, atrial flutter; AT, atrial tachycardia; CTI, cavotricuspid isthmus; PV, pulmonary vein; PVI, pulmonary vein isolation. PVI+, PVI with additional non-PV target ablations allowed per operator's discretion.

[a] Failure modes included: acute procedural failure, use of nonstudy catheter, repeat procedures, use of new/higher dose antiarrhythmic drug, and surgical ablation.

[b] Primary adverse events included: death, atrioesophageal fistula, cardiac tamponade/perforation, myocardial infarction, stroke/cerebrovascular accident, thromboembolism, transient schemic attack, diaphragmatic paralysis, pneumothorax, heart block, PV stenosis, pulmonary edema, pericarditis, and major vascular access complication or bleeding. PV stenosis and atrioesophageal fistulas occurring more than 7 days after the index procedure were also considered primary adverse events.

[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.

## OBJECTIVE

To evaluate the safety and effectiveness of catheter ablation in patients with persistent atrial fibrillation using the contact-force sensing THERMOCOOL SMARTTOUCH® SF Catheter with CARTO VISITAG™ Module.

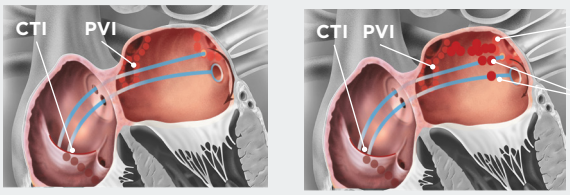
## METHODS

### Experimental Design

| | |
|---|---|
| **STUDY DESIGN** | Prospective, multicenter, nonrandomized clinical study |
| **STUDY PERIOD AND LOCATION** | • June 2016 to June 2019<br>• 27 centers in the United States and Canada |
| **SAMPLE SIZE** | • 381 patients ≥18 yrs old<br>• Documented persistent atrial fibrillation <1 yr<br>• Nonresponsive or intolerant to ≥ 1 AAD (Class I/III) |
| **PATIENT FOLLOW-UP** | Phone follow-up: 7 days<br>Clinical follow-up: 1, 3, 6, 9, 12, and 15 months |
| **PRIMARY ENDPOINT** | • Primary effectiveness<br>• Incidence of any PAEs occurring within 7 days of the initial and repeat ablation procedures[a] |
| **OTHER OUTCOMES** | • Acute procedural success (entrance block in all PVs)<br>• Clinical success |

### Tailored Ablation Approach

- Isolation of all PVs was required for all patients (PVI only). Additional ablations were allowed (PVI+) per operator's discretion.
- Right atrial cavotricuspid isthmus linear ablation was required in cases of documented typical atrial flutter.

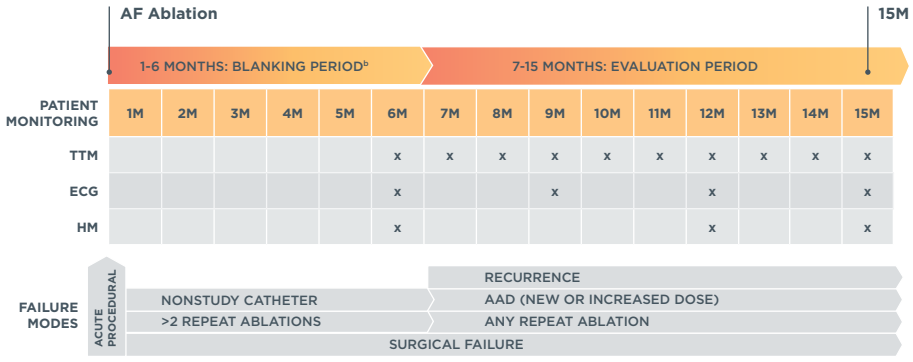



PVI Only or PVI+

**Recommended CARTO VISITAG™ Module Settings**

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

### Study Design




**Primary effectiveness**
Freedom from documented AF/AT/AFL recurrence ≥30 s and freedom from prespecified failure modes (see gray bars)

**Clinical Success**
Freedom from documented **symptomatic** AF/AT/AFL recurrence ≥30 s

AF, atrial fibrillation; AFL, atrial flutter; AT, atrial tachycardia; CTI, cavotricuspid isthmus; ECG, electrocardiogram; HM, Holter monitoring; PAEs, primary adverse events; PV, pulmonary vein; PVI, pulmonary vein isolation; PVI+, PVI with additional non-PV target ablations allowed per operator's discretion; RF, radiofrequency; TTM, transtelephonic monitoring.

[a] PAEs included: death, atrioesophageal fistula, cardiac tamponade/perforation, myocardial infarction, stroke/cerebrovascular accident, thromboembolism, transient ischemic attack, diaphragmatic paralysis, pneumothorax, heart block, PV stenosis, pulmonary edema, pericarditis, and major vascular access complication or bleeding. PV stenosis and atrioesophageal fistulas occurring more than 7 days after the index procedure were also considered PAEs.

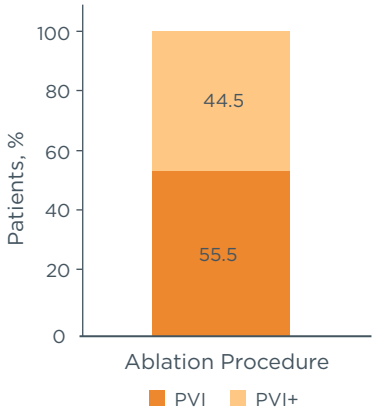
[b] The blanking period consisted of a 3-month medication adjustment period followed by a 3-month therapy consolidation period. All symptomatic cardiac episodes were recorded and transmitted via TTM at the time of the event.

## RESULTS

### Demographics and Procedural Efficiency

| PARAMETER | SAFETY POPULATION (n=348) |
|---|---|
| Age, mean (SD), y | 65.4 (8.7) |
| Male, No. (%) | 246 (70.7) |
| $CHA_2DS_2$-VASc score, mean (SD) | 2.3 (1.5) |
| Left atrial dimension, mean (SD), mm | 42.4 (5.1) |
| Left ventricular ejection fraction, mean (SD), % | 56.2 (7.2) |
| Medical history, No. (%) | |
| • Hypertension | 238 (68.4) |
| • Obstructive sleep apnea | 134 (38.5) |
| • Coronary disease | 77 (22.1) |
| • Symptomatic PsAF duration, mean (SD), month | 15.5 (30.2) |

### Procedural Characteristics (Safety Population, n=348)




**Time, mean (SD), minutes**

| | |
|---|---|
| Total procedure | 178.0 (71.0) |
| Ablation | 107.7 (48.6) |
| RF application | 55.6 (23.0) |
| Mapping | 15.3 (17.5) |
| Fluoroscopy | 15.3 (16.6) |

### Safety

The overall rate of primary adverse events was 4.7%, similar to paroxysmal atrial fibrillation studies.[3,4]

**0** — Incidence of death, atrioesophageal fistula, myocardial infarction, thromboembolism, pneumothorax, heart block, pulmonary vein stenosis, transient ischemic attack

**1** — Case each of cerebrovascular accident/stroke, diaphragmatic paralysis

**2** — Pericarditis cases

**3** — Major vascular access complication/bleeding cases

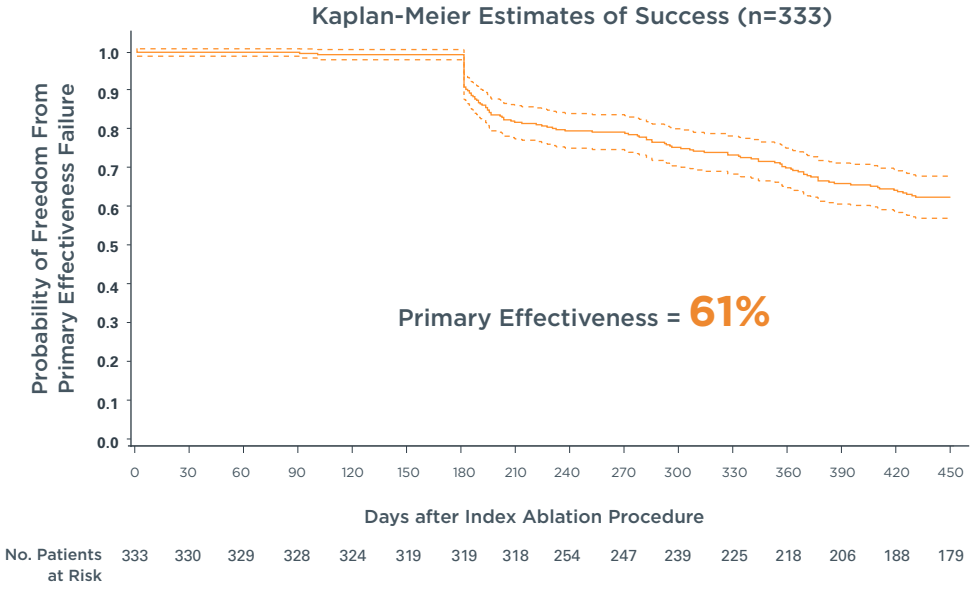
**5** — Cases each of cardiac tamponade, pulmonary edema (respiratory insuficiency)

$CHA_2DS_2$-VASc, congestive heart failure, hypertension, age ≥75 years, diabetes mellitus, prior stroke (or transient ischemic attack/ thromboembolism), vascular disease, age 65–74 years, sex category; PVI, pulmonary vein isolation; PsAF, persistent atrial fibrillation; RF, radiofrequency.

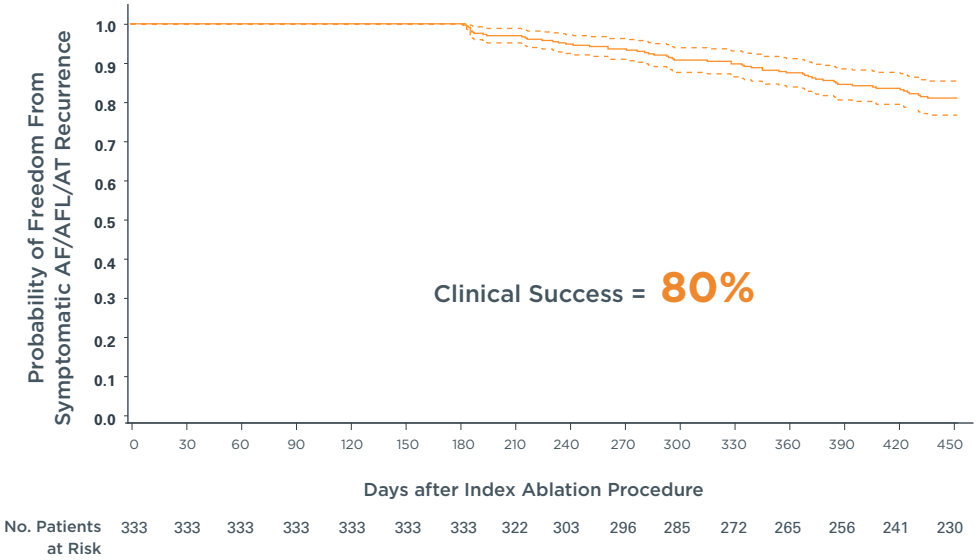
## RESULTS

### Effectiveness

Utilization of PVI only or PVI+ tailored ablation strategy results in high clinical effectiveness in a broad group of persistent atrial fibrillation patients.

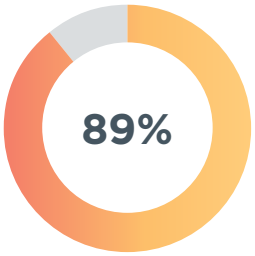



The 1-sided exact 97.5% lower confidence bound of 55.5% was higher than the predetermined performance goal of 40.0%.

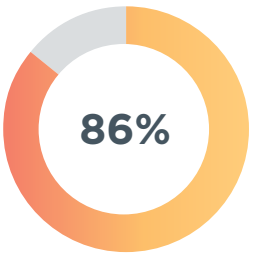



- Kaplan Meier estimates of single procedure freedom from documented AF/AT/AFL recurrence was 64% by all 3 study arrhythmia monitoring methods.

### Repeat Ablation




12-Month Freedom From Repeat Ablation




15-Month Freedom From Repeat Ablation

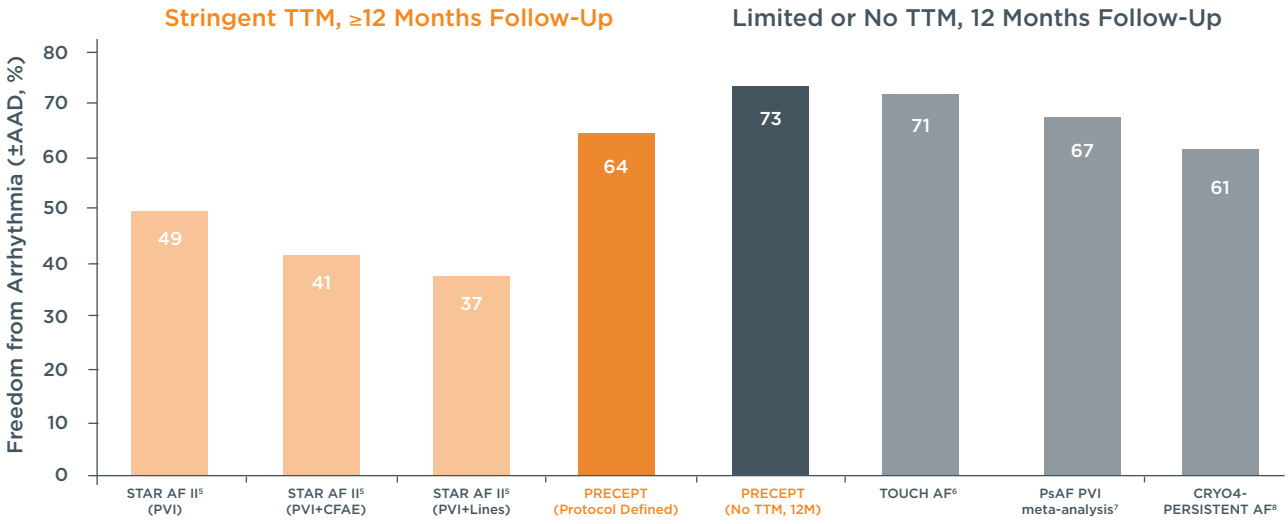
AF, atrial fibrillation; AFL, atrial flutter; AT, atrial tachychardia.

## RESULTS

### PRECEPT Compared With Other Multicenter Persistent Atrial Fibrillation Studies

PRECEPT reported higher freedom from arrhythmia rates than other contemporary clinical studies.

- The single procedure success rate reported for PRECEPT was 64%.
  - Exploratory analysis of single-procedure success rate at 12 months with ECG/Holter monitoring was estimated at 73%.




| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Ablation Technology | | Non-CF RF | | | CF RF | CF RF | CF RF | Non-CB, Non-CF or CF RF | CB2 |
| Arrhythmia Monitoring | 12-lead ECG | Yes | | | Yes | Yes | Yes | Yes | Yes |
| | Holter Monitor | 24-hr | | | 24-hr | 24-hr | 48-hr | Mostly 24-h | 48-hr |
| | TTM | Stringent | | | Stringent | None | Limited | Mostly none | None |
| Follow-Up | | 3 to 18 months | | | 6 to 15 months | 3 to 18 months | 3 to 12 months | Mostly 3 to 12 months | 3 to 12 months |
| Repeat Ablation[a] | | 14 (22%) | 67 (26%) | 83 (33%) | 26/333 (7.8%) | 31/333 (9.3%) | 21 (17%) | N/A | 17 (17%) |

## CONCLUSION

The PRECEPT study demonstrated the clinical safety and effectiveness of persistent atrial fibrillation ablation using contact-force sensing technologies. The primary adverse events rate was within the range reported in paroxysmal atrial fibrillation studies.

AAD, antiarrhythmic drug; AF, atrial fibrillation; CB, cryoballoon; CB2, second generation cryoballoon; CF, contact force; CFAE, complex fractionated atrial electrograms; ECG, electrocardiogram; PVI, pulmonary vein isolation; TTM, transtelephonic monitoring.
[a] Number of patients receiving repeat ablation after the blanking period.

## REFERENCES


1. Mansour M, Calkins H, Osorio J, et al. Persistent atrial fibrillation ablation with contact force sensing catheter: The prospective multicenter PRECEPT trial. *JACC Clin Electrophysiol*. 2020;6(8):958-969.
2. PRECEPT IDE G140102.
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5. Verma A, Jiang CY, Betts TR, et al. Approaches to catheter ablation for persistent atrial fibrillation. *N Engl J Med*. 2015;372(19):1812-1822.
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8. Boveda S, Metzner A, Nguyen DQ, et al. Single-procedure outcomes and quality-of-life improvement 12 months postcryoballoon ablation in persistent atrial fibrillation: results from the multicenter CRYO4PERSISTENT AF trial. JACC Clin *Electrophysiol*. 2018;4(11):1440-1447.


The CARTO VISITAG™ Module provides access to data collected during the application of RF energy. The data does not indicate the effectiveness of RF energy application. CARTO VISITAG™ Module settings are user defined based on the user's clinical experience and medical judgment. Biosense Webster, Inc. does not recommend any settings for the CARTO VISITAG™ Module.

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.

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


**Biosense Webster, Inc.**
31 Technology Drive
Irvine, CA 92618 USA
Tel: +1-909-839-8500
Tel: +1-800-729-9010
**www.biosensewebster.com**


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