

# SUMMARY

## Comparison of Real-world Clinical and Economic Outcomes between the THERMOCOOL<sup>®</sup> SF and THERMOCOOL<sup>®</sup> Catheters in Patients Undergoing Radiofrequency Catheter Ablation for Atrial Fibrillation

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# BACKGROUND



The **THERMOCOOL® SF Catheter** with advanced, porous tip **requires substantially less fluid** than THERMOCOOL® Catheters to maintain adequate catheter cooling.

**Reduced use of fluid** during catheter ablation is believed to be associated with **a lower risk of complications**, particularly in patients with a higher comorbidity burden.

The THERMOCOOL® SF Catheter minimizes fluid use to improve patient outcomes and reduce complications compared to conventional catheters.<sup>1-4</sup>



SHORTER PROCEDURE &  
FLUOROSCOPY TIMES

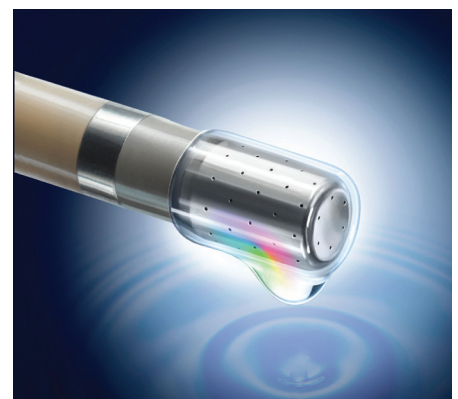


LOWER RATE OF  
RECURRENCE



FEWER  
COMPLICATIONS

This study was conducted because there was limited real-world evidence demonstrating the benefit of the THERMOCOOL® SF Catheter and the porous tip technology.

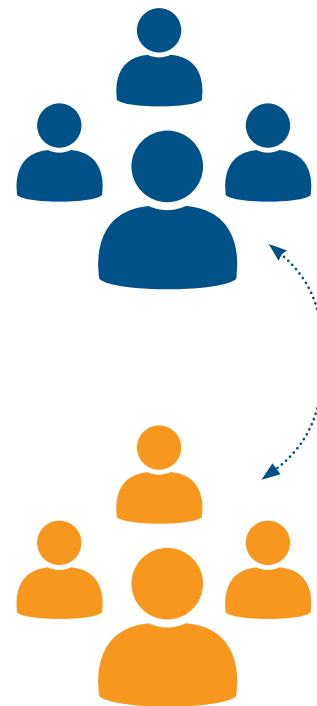


## STUDY OBJECTIVE

Assess and compare the real-world clinical and economic outcomes of THERMOCOOL® SF Catheter use with THERMOCOOL® Catheter use in AF patients undergoing RF ablation.

## STUDY DESIGN & KEY FEATURES

- Retrospective, observational database study
- Compared outcomes of patients receiving outpatient catheter ablation between 2013-2016 using a THERMOCOOL® SF Catheter or THERMOCOOL® Catheter
- Within the Premier Healthcare Database, a nationally representative database including over 700 U.S. hospitals
- Multivariable-adjusted regression analysis was used to examine primary clinical and cost outcomes
- A subgroup analysis of patients susceptible to fluid overload was performed to demonstrate the benefits of fluid reduction
- Two sensitivity analyses were conducted to reduce study bias and demonstrate study finding generalizability



# METHODS

## INCLUSION CRITERIA

- Age  $\geq 18$  years
- Providers with at least 12 months of pre-index data in Premier
- Non-zero cost at index admission
- Underwent procedure at hospital that had performed  $\geq 10$  procedures with the catheter used in the 12-month pre-index period

## EXCLUSION CRITERIA

- Ablation not using a THERMOCOOL® SF or THERMOCOOL® catheter
- Any cardiac ablation or valvular procedure, implantation of a pacemaker or ICD, or an LAA occlusion in the 12-month period before the index date.

## PRIMARY OUTCOMES



### READMISSIONS

1. All-cause readmission
2. AF related readmission
3. CV related readmission



### COST

1. Total admission cost
2. Supply cost during admissions

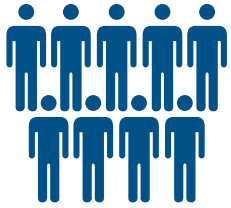


### DIRECT CURRENT CARDIOVERSIONS



### REPEAT ABLATIONS

# RESULTS



## TOTAL STUDY POPULATION: 1,477 PATIENTS

- 1,014 THERMOCOOL® SF patients
- 463 THERMOCOOL® patients



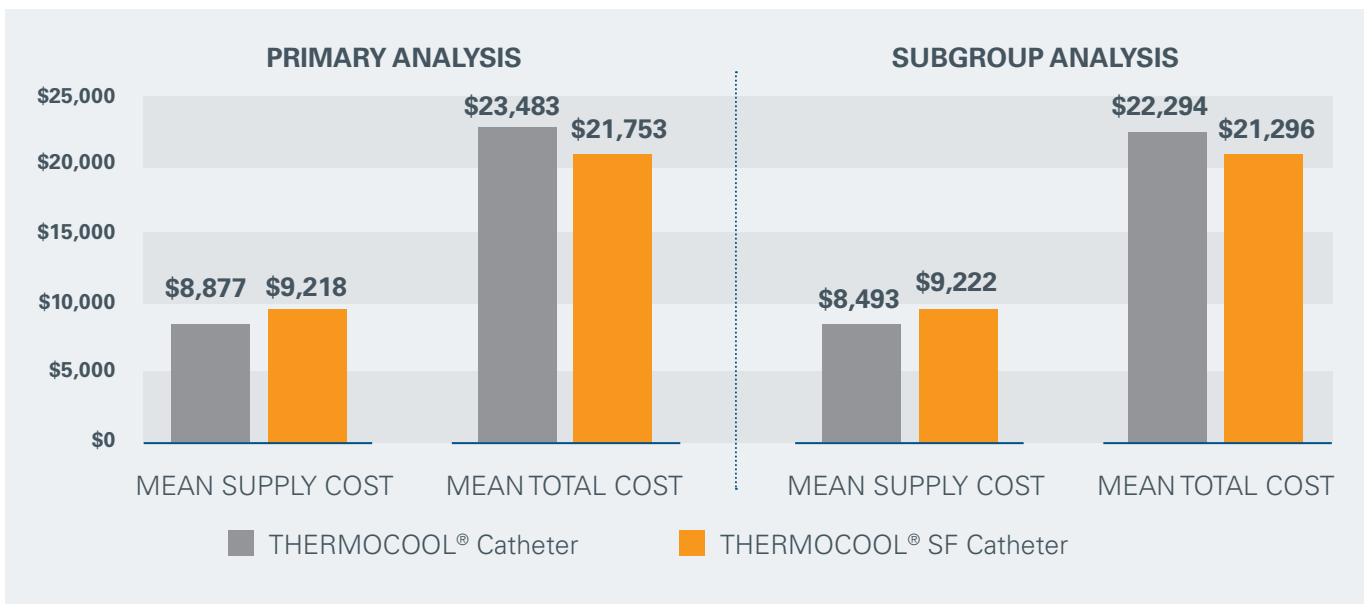
## FLUID OVERLOAD SUSCEPTIBILITY SUBGROUP\*

- 765 THERMOCOOL® SF patients
- 319 THERMOCOOL® patients



## COST OUTCOMES

In both the primary analysis and subgroup analysis, there was **no significant differences in mean total costs and mean supply costs** between the THERMOCOOL® SF and THERMOCOOL® groups despite the price premium of the THERMOCOOL® SF catheter.



\*As defined in study protocol, patients susceptible to fluid overload included those who had congestive heart failure, valvular disease, renal failure, cardiomyopathy, peripheral vascular disease, pulmonary circulation disorder, hypertension, and/or ischemic heart disease.

# RESULTS

## 12-MONTH CLINICAL OUTCOMES

In the **primary outcome analysis**, compared to the THERMOCOOL® group, the THERMOCOOL® SF group had:

ALL-CAUSE READMISSIONS	CV-RELATED READMISSIONS	AF-RELATED READMISSIONS	DIRECT CARDIOVERSIONS	REPEAT ABLATIONS
↓ 55%	↓ 55%	No sig.diff.	↓ 39%	No sig.diff.

The **subgroup analysis**, which specifically compared patients with sensitivity to fluid overload, found that compared to the THERMOCOOL® Catheter group, patients receiving THERMOCOOL® SF had:

ALL-CAUSE READMISSIONS	CV-RELATED READMISSIONS	AF-RELATED READMISSIONS	DIRECT CARDIOVERSIONS	REPEAT ABLATIONS
↓ 58%	↓ 69%	↓ 82%	↓ 48%	↓ 55%



In the propensity-score matched sensitivity analysis, patients from the THERMOCOOL® Catheter and THERMOCOOL® SF cohorts were matched based on covariates to reduce selection bias.



In the generalizability sensitivity analysis, both inpatient and outpatient ablations using the THERMOCOOL® Catheter and THERMOCOOL® SF Catheter were included in the total cohort.

In both the sensitivity analyses, similar trends were observed to the primary and subgroup analyses demonstrating that study results were not influenced by selection bias, and can be generalizable to ablation procedures in all settings.

# DISCUSSION AND CONCLUSION



**Study limitations** include possible coding errors, patient selection bias and unidentified confounding variables.

When compared with the use of the THERMOCOOL® Catheter, use of the **THERMOCOOL® SF Catheter was associated with:**

- Reduced hospital readmissions
- Lower odds of direct cardioversion
- Reduced rate of repeat ablation
- Equivalent procedure costs

This was particularly evident in patients susceptible to fluid overload, **without any significant increases in cost.**



## KEY TAKEAWAY



This study was the **first study to use real-world evidence** to show **improved clinical advantages by reducing fluid delivery.** These improved outcomes achieved by using a **porous tip catheter** may translate into improved patient outcomes as well as **economic savings for providers and payers.**

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

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**1.** Bertaglia E, Fassini G, Anselmino M, et al. Comparison of THERMOCOOL® Surround Flow catheter versus THERMOCOOL® Catheter in achieving persistent electrical isolation of pulmonary veins: a pilot study. J Cardiovasc Electrophysiol. 2013;24(3):269–273. **2.** Park CI, Lehrmann H, Keyl C, et al. Enhanced efficiency of a novel porous tip irrigated RF ablation catheter for pulmonary vein isolation. J Cardiovasc Electrophysiol. 2013;24(12):1328–1335. **3.** Scaglione M, Blandino A, Raimondo C, et al. Impact of ablation catheter irrigation design on silent cerebral embolism after radiofrequency catheter ablation of atrial fibrillation: results from a pilot study. J Cardiovasc Electrophysiol. 2012;23(8):801–805. **4.** Oza SR, Hunter TD, Biviano AB, et al. Acute safety of an open-irrigated ablation catheter with 56-hole porous tip for radiofrequency ablation of paroxysmal atrial fibrillation: analysis from 2 observational registry studies. J Cardiovasc Electrophysiol. 2014;25(8):852–858.