SUMMARY

Comparison of Real-world Clinical and Economic Outcomes between the THERMOCOOL™ SF and THERMOCOOL™ Catheters in Patients Undergoing Radiofrequency Catheter Ablation for Atrial Fibrillation

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BACKGROUND

The **THERMOCOOL™ SF Catheter** with an 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.

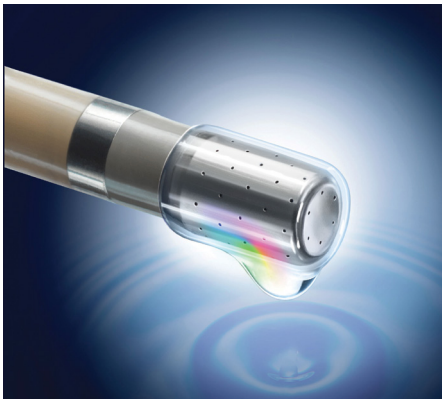
The THERMOCOOL™ SF Catheter minimizes fluid use to improve patient outcomes and reduce complications compared to conventional catheters.[1-4]

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.



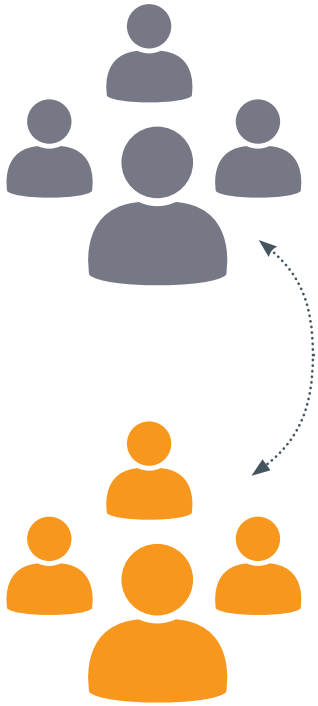
METHODS

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 ≥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 ≥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

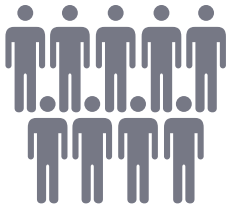
COST

1. Total admission cost
2. Supply cost during admissions

DIRECT CURRENT CARDIOVERSIONS

REPEAT ABLATIONS

RESULTS



TOTAL STUDY POPULATION: 1,477 PATIENTS

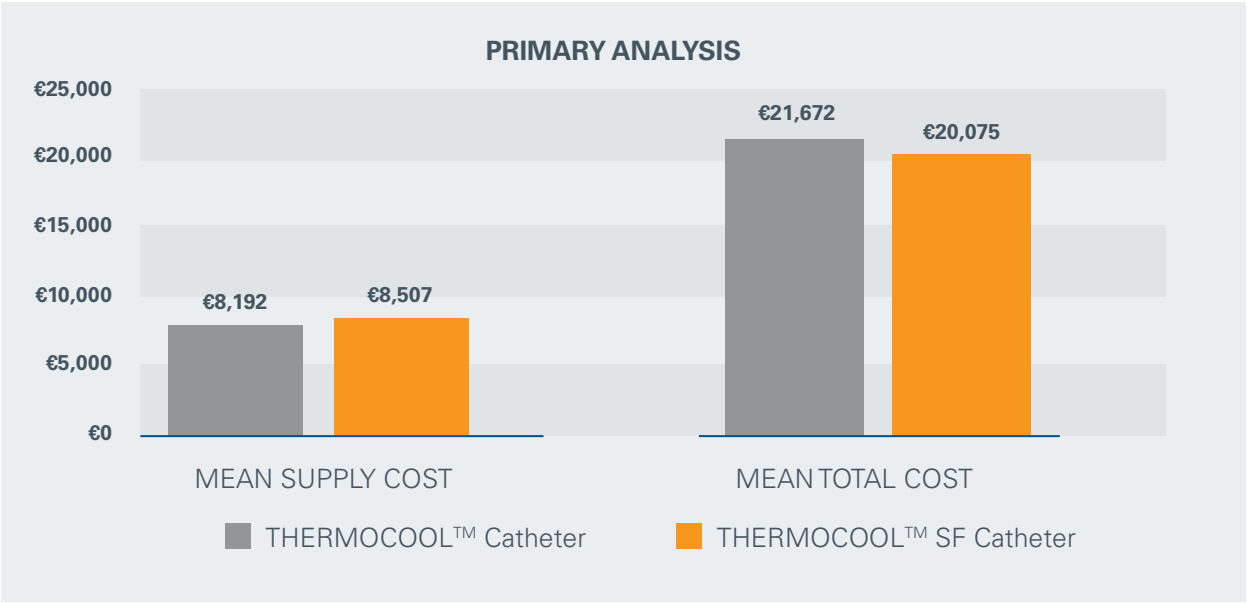
- 1,014 THERMOCOOL™ SF patients
- 463 THERMOCOOL™ patients

FLUID OVERLOAD SUSCEPTIBILITY SUBGROUP**

- 765 THERMOCOOL™ SF patients
- 319 THERMOCOOL™ patients

COST OUTCOMES

In both the primary analysis and subgroup analysis, there were **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.



*No statistically significant difference in cost, $p \geq 0.05$.

**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[A]	CV-RELATED READMISSIONS[A]	AF-RELATED READMISSIONS[A]	DIRECT CARDIOVERSIONS[A]	REPEAT ABLATIONS[A]
THERMOCOOL™	16.99	10.14	6.03	23.98	9.65
THERMOCOOL™ SF	12.73	7.08	4.20	14.29	12.09
Adjusted Difference	↓ 55%*	↓ 55%*	↓ 60%†	↓ 39%*	↓ 15%†

[A] All values represents patient means for each cohort
* Denotes a statistically significant difference where $p<0.05$
† Denotes a non-statistically significant difference where $p\geq0.05$

The **subgroup analysis**[A], 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[A]	CV-RELATED READMISSIONS[A]	AF-RELATED READMISSIONS[A]	DIRECT CARDIOVERSIONS[A]	REPEAT ABLATIONS[A]
THERMOCOOL™	18.00	10.80	6.40	26.29	2.16[B]
THERMOCOOL™ SF	12.68	6.34	3.49	14.10	3.08[B]
Adjusted Difference	↓ 58%*	↓ 69%*	↓ 82%*	↓ 48%*	↓ 55%*[B]

[A] All values represents patient means for each cohort
[B] Statistically significant 55% lower rate of repeat ablation was found at 0-3 months
* Denotes a statistically significant difference where $p<0.05$

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.

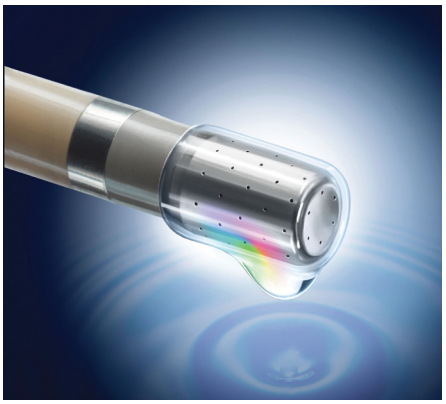
DISCUSSION AND CONCLUSION

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 at 0-3 months
- 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).
For product details such as indications, contraindications, warnings and precautions please consult the IFU.
Not all products are licensed or available in all EMEA countries.
This publication is not intended for distribution outside of the EMEA region.

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