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POLARx™

Cryoablation System

Clinical Compendium

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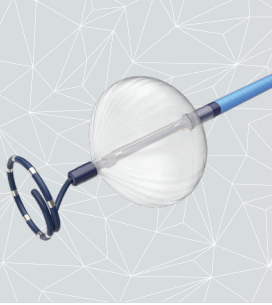


CLINICAL SUMMARIES

Clinical Summary

POLARx™ Cryoablation Catheter

SAFETY DATA AND ACUTE OUTCOME

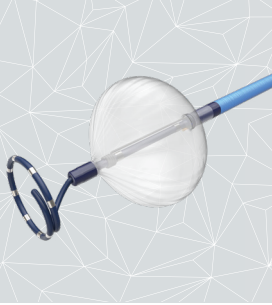
- Spera, et al., Ultra-high-resolution assessment of lesion extension after cryoballoon ablation for pulmonary vein isolation, 2022, (https://doi.org/10.3389/fcvm.2022.985182)
- Tiltz, et al., Acute Procedural Efficacy and Safety of a Novel Cryoballoon for the Treatment of Paroxysmal Atrial Fibrillation: Results from the POLAR ICE Study, 2022, (https://doi.org/10.1093/europace/euac053.079)
- Anic, et al., Acute safety, efficacy, and advantages of a novel cryoballoon ablation system for pulmonary vein isolation in patients with paroxysmal atrial fibrillation: initial clinical experience, 2021, (https://doi.org/10.1093/europace/euab018)

SAFETY DATA AND LONG-TERM OUTCOME

- Ellenbogen, et al., One-year outcomes of pulmonary vein isolation with a novel cryoballoon: primary results of the FROZEN AF trial, 2024, (https://onlinelibrary.wiley.com/doi/10.1111/jce.16220)
- Christian-H Heeger, et al. Novel cryoballoon ablation system for pulmonary vein isolation: multicenter assessment of efficacy and safety – ANTARTICA study, 2022, (https://doi.org/10.1093/europace/euac148)
- Knecht, et al., Efficacy and safety of a novel cryoballoon ablation system: multicentre comparison of 1-year outcome, 2022, (https://doi.org/10.1093/europace/euac094)
- Fassini, et al., Novel cryoballoon technology for a successful pulmonary vein isolation: acute outcome and follow up from a large multicenter Italian clinical setting, 2022, (https://doi.org/10.1093/europace/euac053.217)
- Martin, et al., Novel cryoballoon to isolate pulmonary veins in patients with paroxysmal atrial fibrillation: long-term outcomes in a multicentre clinical study, 2022, (https://doi.org/10.1007/s10840-022-01200-5)

BIOPHYSICAL PREDICTORS FOR ACUTE PVI

- Honarbakhsh, et al., POLARx Cryoballoon metrics predicting successful pulmonary vein isolation: targets for ablation of atrial fibrillation, 2022, (https://doi.org/10.1093/europace/euac100)
- Iacopino, et al., Key characteristics for effective acute pulmonary vein isolation when using a novel cryoballoon technology: insights from the CHARISMA registry, 2022, (https://doi.org/10.1007/s10840-021-01063-2)



TECHNOLOGY COMPARISON STUDIES

- Yap, et al., Comparison of the 1-year clinical outcome of a novel cryoballoon to an established cryoballoon, 2022, (https://doi.org/10.1007/s10840-022-01262-5)
- Yap, et al., Comparison of the acute outcome of two cryoballoon technologies for pulmonary vein isolation: An updated systematic review and meta-analysis, 2022, (doi:%2010.1111/jce.15182)
- Guckel, et al., Impact of pulmonary vein variant anatomy and cross-sectional orifice area on freedom from atrial fibrillation recurrence after cryothermal single-shot guided pulmonary vein isolation, 2022, (https://doi.org/10.1007/s10840-022-01279-w)
- Imnadze, et al., Two competing cryoballoon technologies for single shot pulmonary vein isolation: first experiences with the novel system, 2022, (http://doi.org/10.31083/j.rcm2304118)
- Yap, et al., Comparison of procedural efficacy, balloon nadir temperature, and incidence of phrenic nerve palsy between two cryoballoon technologies for pulmonary vein isolation: A systematic review and meta-analysis, 2021, (doi.org/10.1111/jce.15182)
- Mojica, et al., Procedural Safety and Efficacy for Pulmonary Vein Isolation with the Novel POLARx™ Cryoablation System: A Propensity Score Matched Comparison with the Arctic Front™ Cryoballoon in the Setting of Paroxysmal Atrial Fibrillation, 2021, (doi: 10.4022/jafib.20200455)
- Tilz, et al., Novel Cryoballoon Ablation System for Single Shot Pulmonary Vein Isolation – The Prospective ICE-AGE-X Study, 2021, (doi:%2010.1253/circj.CJ-21-0094)
- Creta, et al., First experience of POLARx™ versus Arctic Front Advance™: An early technology comparison, 2021, (doi:%2010.1111/jce.14951)
- Yap, et al., Comparison of procedural efficacy and biophysical parameters between two competing cryoballoon technologies for pulmonary vein isolation: Insights from an initial multicenter experience, 2021, (doi:%2010.1111/jce.14915)

Clinical Data

Safety Data and Long-Term Outcome

ONE-YEAR OUTCOMES OF PULMONARY VEIN ISOLATION WITH A NOVEL CRYOBALLOON: PRIMARY RESULTS OF THE FROZEN AF TRIAL

Ellenbogen, et al., 2024
doi: 10.1111/jce.16220

CLINICAL PERSPECTIVE

What's New

The 50 patient FIT arm is the largest study to date studying the safety and effectiveness of the 31 mm POLARx FITTM Cryoballoon System.

What's Important

The FIT extension arm 12-month freedom from documented atrial arrhythmias was 82.0%. The primary cohort had a 79.9% freedom from atrial arrhythmia recurrence. The study reports a safety event free rate of 96% in the primary cohort, and 100% in the extension arm.

There was an increase in grade 4 occlusion and single-shot success with the 31 mm CB.

OBJECTIVE

FROZEN AF is an international multicenter, open-label, prospective, single-arm study to determine the safety and performance of a

novel cryoballoon system for treatment of PAF. The studies extension arm examined the safety and performance of a novel variable size cryoballon.

METHODS

Subjects were indicated for PVI treatment of PAF and had failed or were intolerant of one or more AADs.

In total, 404 subjects were enrolled across 44 centers. Of these 385 subjects received treatment with the investigational device, 60 treatment subjects were classified as roll-In and 325 as treatment.

Additionally, as part of an extension arm, 54 patients were enrolled to examine the safety and effectiveness of the novel variable size cryoballoon POLARx FIT.

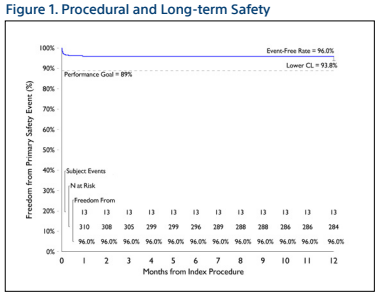
The duration and number of cryo-applications was at physician discretion. Cryo-applications were recommended based on an algorithm measuring time to isolation (TTI), with a 180 s application where TTI occurred in less than 60 s and a 240 s application where TTI occurred after 60 s or was not detected.

Follow-up was performed at discharge, 7 days, 3 months, 6 months, and 12 months post index procedure. Trans telephonic monitoring (TTM) was collected by patients two times per month (either symptomatic or asymptomatic) from 3 to 12m post procedure. Twenty-four hours Holter monitoring was provided at the 12m FU visit.

SAFETY

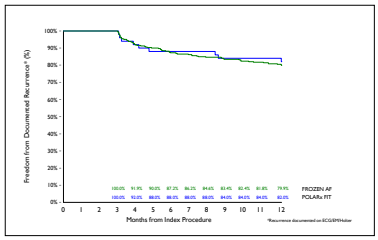
The present study reports a safety event free rate of 96% in the primary cohort, and 100% in the extension arm with no reported PV stenosis, persistent phrenic nerve palsy, or esophageal fistulas.

Figure 1. Procedural and Long-term Safety



No reported:
- PV stenosis
- Persistent phrenic nerve palsy
- Esophageal fistulas

Figure 2. Freedom from Documented Recurrence of Atrial Arrhythmias



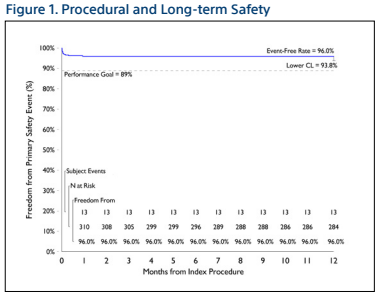
FROzEN (n = 325)
12-Month
79.9%

FIT Extension (n = 50)
12-Month
82.0%

EFFICACY

Overall freedom from recurrence of atrial arrythmia was confirmed in 79.9% of patients in the main cohort and 82.0% in the FIT Extension.

Figure 1. Procedural and Long-term Safety



No reported:
- PV stenosis
- Persistent phrenic nerve palsy
- Esophageal fistulas

DISCUSSION

The FROZEN AF study demonstrates the safety and effectiveness of the POLARx cryoballoon. The trial met effectiveness and safety endpoints in patients with drug-refractory PAF, with a high 1-year recurrence free rate or 79.9% and 0% permanent phrenic nerve impairment.

Additionally, the FIT extension arm demonstrated the promise of the variable size cryoballoon, with 84% freedom from AF recurrence and a promising safety profile.

CONCLUSIONS

The present findings showed an excellent safety and performance profile for the novel 28 mm / 31 mm cryoablation system.

Clinical Data

Safety Data and Acute Outcome

ULTRA-HIGH-RESOLUTION ASSESSMENT OF LESION EXTENSION AFTER CRYOBALLOON ABLATION FOR PULMONARY VEIN ISOLATION

Spera, et al., 2022
https://doi.org/10.3389/fcvm.2022.985182

CLINICAL PERSPECTIVE

What's New

This is the largest study to evaluate the acute lesion extension, the effect on the antral fragmented electrogram and the rate of unidentified PV signals after CB ablation by means of POLARx™ System.

What's Important

This novel cryoballoon system created wide antral lesions and eliminated antral fragmented potentials. The new system, with short tip and circular mapping catheter, failed to achieve PV isolation in only 0.9% of all PVs treated.

OBJECTIVE

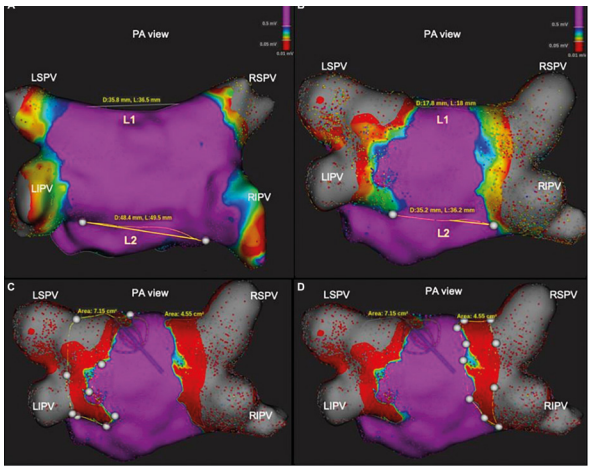
The aim of this study was to report preliminary experience of POLARx cryoablation system in a multicenter Italian registry to assess safety and effectiveness.

METHODS

29 consecutive patients from the CHARISMA registry undergoing AF ablation at four Italian centers were prospectively evaluated. The RHYTHMIA™ mapping system and the ORION™ mapping catheter were used.

Ablation procedure

- Application time for each veins was calculated as the time-to-isolation (TTI). Cryoenergy application was 180s if TTI was 60s or less. Otherwise, cryoenergy application was 240s.
- In order to avoid phrenic nerve palsy, continuous high-output pacing was performed during right-PV applications. In addition, the Diaphragm Movement Sensor, DMS (Boston Scientific) was used to check nerve capture during CB ablation.
- Acute entry block and paced exit block were verified at the end of the procedure by means of the POLARMAP™.



Mapping procedure

- Ultra-high-resolution 3-D left atrium bipolar voltage mapping was performed before and immediately after PVI.
- Electrograms differentiation:
  - –above 0.5 mV: healthy and unablated tissue;
  - –less than 0.2 mV: dense scar tissue
  - –between 0.2 and 0.5 mV: damaged but viable tissue
- The LUMIPOINT™ map analysis tool was used in both maps sequentially on each PV component in order to assess the presence of PV gaps and the change in the antral potentials after PVI.

DISCUSSION

The main findings of our study are:

1. **the lesions** created with the new CB ablation **system involve the PV antrum**, with about **50% of the PW remaining untouched**;
2. **the new system**, which uses a short-tip CB and a circular mapping catheter, **failed to achieve PVI in only 0.8% of all PVs treated**;
3. **antral fragmented potentials were completely eliminated** by CB ablation, without any residual antral potentials being identified by LUMIPOINT;
4. **the novel CB system is a safe and effective means of achieving PV occlusion and isolation**.

Outcome

After CB ablation, **complete isolation of each PV** was documented by the POLARMAP™ catheter in all patients. By contrast, confirmatory high-density mapping through the ORION™ catheter and the LUMIPOINT tool **unveiled PV signals in 1 out of 114 of the PVs** (0.9%–1 patient with PV gap: 3.5%).

CONCLUSIONS

Pulmonary vein isolation by means of this novel cryoballoon created wide antral lesions and eliminated antral fragmented potentials. The new system, with short tip and circular mapping catheter, failed to achieve PV isolation in only 0.9% of all PVs treated.

Clinical Data

Safety Data and Acute Outcome

ACUTE PROCEDURAL EFFICACY AND SAFETY OF A NOVEL CRYOBALLOON FOR THE TREATMENT OF PAROXYSMAL ATRIAL FIBRILLATION: RESULTS FROM THE POLAR ICE STUDY

Tilz, et al., 2022
https://doi.org/10.1093/europace/euac053.079

CLINICAL PERSPECTIVE

What's New

These data suggest a correlation between cryoballoon biophysical parameters and single shot success. There's a clear relationship between TTI, Occlusion Score, and Single Shot Success Rate.

What's Important

The procedure times and dwell times were short, and the serious adverse event rate was low. This study showed a success rate of 96.2% and 81.4% of PVs isolated with a single cryoablation.

OBJECTIVE

The aim of this study was to Provide real-world data on the use of the POLARx™ Cryoablation System for the treatment of atrial fibrillation.

METHODS

- 400 patients EU study across 19 centers indicated for treatment of paroxysmal AF with the POLARx cryoablation system.
- This real-world study did not mandate any specific cryodosing regimen; this was left to the operator.
- Procedural characteristics, such as time to isolation (TTI), cryoablations per pulmonary vein, balloon nadir temperature, and occlusion grade were recorded.
- PVI was confirmed via entrance block.

Timing

- 69.0±25.2 min Procedure time
- 15.8±10.0 min fluoroscopy times
- 47.3±18.8 min Left atrial dwell time

DISCUSSION

Initial experience with a novel cryoballoon (CB) with a stable low balloon pressure (POLARx, Boston Scientific) has demonstrated acute procedural safety and efficacy in de novo PVI procedures in patients with paroxysmal AF. However, to date, there is limited multicenter data on real world acute outcomes and procedural characteristics with this novel cryoballoon.

Good occlusion may drive faster freeze and lower nadir temperatures, resulting in longer thaw times with this novel cryoballoon. As longer thaw time is associated with acute effectiveness (and durability) this may result in a higher single shot rate.

The major results of this study are:

1. Complete PVI was achieved in 96.1% of PVs (1437/1496).
2. Procedure and fluoroscopy times were 69.0±25.2 min and 15.8±10.0 min, respectively.
3. Grade 3 or 4 occlusion was achieved in 98.1% of PVs reported.
4. Electrical isolation was achieved with an average TTI of 50±33.8s and in 81.4% of PVs isolation required only a single cryoablation.
5. PVI was performed on atypical anatomies (12 LCPV, 7 RMPV, & 3 RCPV) in 19 pts.
6. Serious adverse events included phrenic nerve palsy (0.5%), tamponade (0.5%), AV block (0.3%), stroke (0.3%), and transient ischemic attack (0.3%).
7. No patients suffered from Atrial Esophageal Fistula or Pulmonary Vein Stenosis.
8. These data suggest a correlation between cryoballoon biophysical parameters and single shot success.

CONCLUSIONS

Real world usage data on the novel CB suggests that this device is safe and effective, with a PV isolation success rate of 96.2% and 81.4% of PVs isolated with a single cryoablation. These data are in keeping with reports on other cryoballoon systems and have markedly shorter procedure times than have been previously reported on this cryoballoon.

Good occlusion likely drives faster freeze and lower nadir temperatures, resulting in longer thaw times with this novel cryoballoon. Future research should examine the relationship between these parameters to drive optimization of cryoablation techniques and provide guidance toward improved workflow.

Clinical Data

Safety Data and Acute Outcome

ACUTE SAFETY, EFFICACY, AND ADVANTAGES OF A NOVEL CRYOBALLOON ABLATION SYSTEM FOR PULMONARY VEIN ISOLATION IN PATIENTS WITH PAROXYSMAL ATRIAL FIBRILLATION: INITIAL CLINICAL EXPERIENCE

Anic, et al., 2021
https://doi.org/10.1093/europace/euab018

CLINICAL PERSPECTIVE

What is Known

Cryoablation outcomes are well established.

What's New

This is the first study to provide 12 months follow up after POLARx™ treatment.

What's Important

71% of the patients remained free of AF, Atrial flutter and atrial tachycardia.

OBJECTIVE

Cryoballoon pulmonary vein isolation (PVI) is a safe and effective treatment for atrial fibrillation (AF). Current limitations include incomplete vein occlusion due to balloon rigidity and inconsistent electrogram recording, which impairs identification of isolation. We aimed to evaluate the acute safety and performance of a novel cryoballoon system.

METHODS

This was a non-randomized, single arm, prospective, multicentre study. All patients consented for 1-month follow-up and a subset of subjects re-consented for 1-year follow-up. The primary performance endpoint of the study was the effectiveness at isolating PVs.

In addition, the following were evaluated across veins:

(i) occlusion grade after balloon inflation,

(ii) incidence of recording PV potentials with the cryoablation mapping catheter during freeze,

(iii) nadir temperature during freeze,

(iv) success of acute isolation.

The primary safety endpoint was procedure or device related major adverse events (MAE) at 30 days.

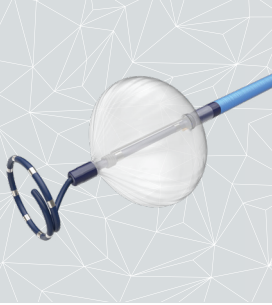
RESULTS

A total of 30 patients with paroxysmal AF underwent PVI with the cryoablation system, performed at two centres by three operators.

A Grade 4 occlusion score was achieved in 94.2% of veins and a Grade 3 or above was achieved in 100%.

All patients (30 of 30) left the procedure with all veins isolated (120 of 120). Isolation was achieved with a total of 163 cryoballoon ablations and did not require touch-up radiofrequency ablations.

A total of 74% of veins (89 of 120) were isolated with a single ablation.



DISCUSSION

This first clinical trial of an advanced cryoablation system permitted complete PV occlusion, consistently recorded PV potentials, and reached target ablation temperatures in all patients.

Isolation was achieved with a single freeze application in 74% of veins.

Mean nadir temperature of 53.1± 5.3C observed in this series is 3–8C lower than reported in current practice. Despite cooler temperatures being achieved, no persistent oesophageal cooling was noted when following the study protocol.

In this first in human pilot series, no major adverse events were observed.

Twenty-four of 30 patients consented for 1-year clinical follow-up. Of these, 17 patients (71%) remained free of AF, atrial flutter (AFL), and atrial tachycardia (AT).

CONCLUSIONS

In this first in human experience, the novel cryoballoon was safe and efficacious in isolating pulmonary veins for the treatment of paroxysmal atrial fibrillation. Specific design elements to the cryoballoon and mapping catheter aiming to resolve several current procedural challenges were successful.

Clinical Data

Safety Data and Long-term Outcome

NOVEL CRYOBALLOON ABLATION SYSTEM FOR PULMONARY VEIN ISOLATION: MULTICENTER ASSESSMENT OF EFFICACY AND SAFETY – ANTARCTICA STUDY

Christian-H Heeger, et al., 2022
https://doi.org/10.1093/europace/euac148

CLINICAL PERSPECTIVE

What's New

The current ANTARCTICA study set out to assess the procedural efficacy, mid-term outcome, safety and characteristics of the novel POLARx™ CB for PVI.

What's Important

The rate of periprocedural complications was comparable with data of the current cryoballoon system and the rate of recurrence-free survival after mean of > 6 months short-term follow-up was 86.1%.

The POLARMAP™ catheter provides a high rate of online visualization of PV signals (71%) by mainly using the ST POLARx.

OBJECTIVE

The aim of the study was to assess the incidence of periprocedural complications using the POLARx cryoballoon system.

Furthermore, this study aimed to analyse procedural efficacy and periprocedural data as indicated by acute PVI, time to isolation (TTI), lowest CB temperature during cryoenergy application, procedure duration, as well as fluoroscopy time.

METHODS

A total of 317 patients with paroxysmal or persistent AF were included and underwent POLARx CB-based PVI in 6 centres from Germany and Italy. Acute efficacy and safety were assessed in this prospective multicenter observational study.

RESULTS

In 317 patients [mean age: 64±12 years, 209 of 317 (66%) paroxysmal AF], a total of 1256 pulmonary veins (PVs) were identified, and 1252 (99.7%) PVs were successfully isolated utilizing mainly the short tip POLARx CB (82%).

- The mean minimal CB temperature was –57.9±7° and real-time PVI was registered in 72% of PVs. The procedural duration as well as fluoroscopy time were 92±41 min and 15±10 min.
- The rate of serious adverse events was 6.0% which was significantly reduced after a learning curve of 25 cases (9.3% vs. 3.0%, P=0.018).
- In a total of 230 of 317 patients (72.6%), at least 3 months follow-up was available. The rate of AF-/AT-free survival after mean follow-up duration of 226±115 days and a 90-day blanking period was 86.1% (198/230 patients).

SAFETY DATA

The rate of serious adverse events was significantly reduced after a learning curve of 25 cases.

EFFECTIVENESS DATA

86.1%

AT/AF free rate after 90-day blanking period.

CONCLUSIONS

This is the first study reporting on the acute efficacy, mid-term outcome and safety of POLARx™-based PVI in a multicentre study.

Even experienced CB users may observe significantly more complications during the initial 25 cases. After passing the learning curve, the POLARx CB showed a promising acute efficacy and safety profile.

Clinical Data

Safety Data and Long-term Outcome

EFFICACY AND SAFETY OF A NOVEL CRYOBALLOON ABLATION SYSTEM: MULTICENTRE COMPARISON OF 1-YEAR OUTCOME

Knecht, et al., 2022
https://doi.org/10.1093/europace/euac094

CLINICAL PERSPECTIVE

What's New

This is the first multicenter study to compare the efficacy and safety of the novel POLARx™ system with the currently established fourth-generation Arctic Front Advance Pro™ system (AFA-Pro, Medtronic).

What's Important

No differences were observed in the efficacy and safety of POLARx and AFA during a follow-up of 12 months.

OBJECTIVE

The aim of the study was to compare the 1-year efficacy and safety of a novel cryoballoon (NCB) ablation system (POLARx) for pulmonary vein isolation (PVI) compared with the standard cryoballoon (SCB) system (Arctic Front).

METHODS

We analyzed 40 consecutive patients treated with the NCB system (28 mm, short tip POLARx, Boston Scientific) between December 2020 and January 2021 from two centres. Forty previously treated patients using the SCB (28 mm Arctic Front Advance Pro, Medtronic, Minneapolis, MN, USA) within the prior 2 months were used as reference group resulting in a study population of 80 consecutive patients.

After obtaining PV occlusion by optimal alignment of the sheath and the catheter and confirmation by contrast injection, a freezing cycle with a standard duration of 180–240 s was started. For the SCB, a temperature of −40°C and/or a time to PV isolation (time to isolation [TTI]) within 60 s was targeted. Freezing cycles were prematurely terminated when −60°C was reached. For the NCB, no specific target temperatures were used because of limited available data at the time of the study, but reaching TTI ,60 s was attempted.

In case of AF recurrence during follow up (FU), repeat ablation procedures were performed using a 3D electroanatomical mapping (EAM) system in combination with a multipolar mapping catheter.

RESULTS

At 12 months, freedom from AF/AT was observed in 68% in the NCB group and in 70% in the SCB group.

Overall time to recurrence was 156+87 days without significant differences between the groups (NCB: 144 +68 days, SCB: 170+107 days, P=0.468). Of the 21 patients with AF/AT recurrence, one patient presented with atypical atrial flutter in the SCB group (1%). At repeat ablation, this patient presented in sinus rhythm and re-isolation of one PV was performed.

In the NCB group, one patient suffered a periprocedural stroke due to air embolism and one a transient phrenic nerve palsy. The patient made a full recovery with no residual neurological deficits and was discharged one week after the ablation.

Re-hospitalization due to cardiovascular causes after discharge was documented in 15 patients (19%), 5 of 40 (13%) in the NCB group, compared with 10 of 40 (25%) in the SCB group.

No discernable differences in PV reconnection patterns between the two ablation systems were observed. A numerically higher number of reconnections could be observed for the right PVs compared to the left PVs, but there was no difference between the NCB and the SCB.

CONCLUSIONS

In this multicentre study comparing the two currently available CB systems for ablation of AF, no differences were observed in the efficacy and safety during a follow-up of 1 year. These findings suggest comparable clinical applicability of the NCB compared to the established SCB.

Clinical Data

Safety Data and Long-term Outcome

NOVEL CRYOBALLOON TECHNOLOGY FOR A SUCCESSFUL PULMONARY VEIN ISOLATION: ACUTE OUTCOME AND FOLLOW UP FROM A LARGE MULTICENTER ITALIAN CLINICAL SETTING

Fassini, et al., 2022
https://doi.org/10.1093/europace/euac053.217

CLINICAL PERSPECTIVE

What's New

This is the first set of long-term follow-up of real-world data with POLARx™ and the AF/AT recurrence rates were low in this study.

What's Important

This study proved novel cryo-balloon system to be safe and effective and resulted in a very low rate of AF/AT recurrence during follow up. No major procedure related adverse events were reported.

OBJECTIVE

The aim of this study was to report preliminary experience of POLARx cyoablation system in a multicenter Italian registry to assess safety and effectiveness.

METHODS

- Consecutive patients (112 pts, 439 PVs) undergoing AF (n=89, 79.5% paroxysmal AF, n=23, 20.5% persistent AF) ablation from the CHARISMA registry at 6 Italian centers.
- Protocol directed cryoablation was delivered 180 sec or 240 sec according to operator's preference if PVI was achieved <60 sec or 240 sec if TTI was no available.
- Rhythm monitoring during the follow-up examinations was performed via the clinical assessment of AF recurrence, ECG and Holter monitoring, according to the clinical practice of each center.
- All patients were followed-up for at least 6 months after the procedure.
- PVI was confirmed via entrance and exit block.
- All patients were followed-up for at least 6 months.
- Arrhythmia recurrences within the first 3 months (blanking period) were classified as early recurrences and were not considered procedural failures.

DISCUSSIONS

624 cryo-applications from 112 pts (439 PVs) were analyzed. **PVI was achieved in all pts** using only cryoablation.

The mean number of **freeze** applications per pt was 5.6±2.1 (1.4±1.2 for LSPV, 1.5±1.1 for LIPV, 1.3±0.8 for RSPV and 1.3±0.8 for RIPV), with 318 (72.4%) PVs treated with a single cryoablation (92, 21% with 2 cryoablation; 29, 6.6% with more than 2 cryoablations).

Fourty-four (39.3%) pts were treated with a **single application** to each of the PVs.

Over a median of 296[245 to 382] days of follow-up, five (4.5%) patients experienced an **early recurrence of AF/AT** during the 90-day blanking period. Overall, 12 patients (10.7%) suffered an AF/AT recurrence after the 90-day blanking period (median time to recurrence 200[124 to 297] days). Specifically, 8 (7.1%) patients had AF recurrence only, 3 (2.7%) had AT recurrence only and 1 (0.9%) experienced both events.

One (0.9%) patient underwent a **repeated ablation** procedure.

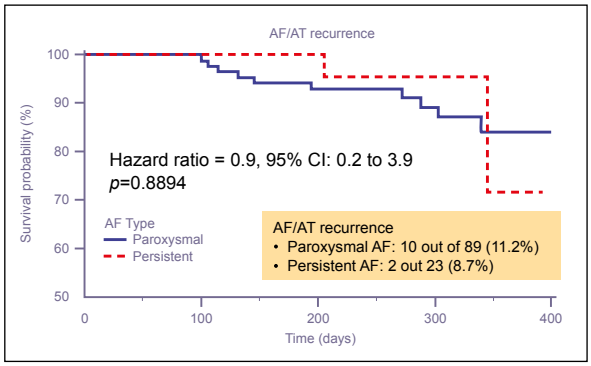
The proportion of patients exhibiting AF/AT recurrences was **similar between AF types** (10 out 89, 11.2% for paroxysmal AF vs 2 out 23, 8.7% for persistent AF, p=1.00) with a hazard ratio of 0.9 (95%CI: 0.2 to 3.9, log-rank p=0.8894).

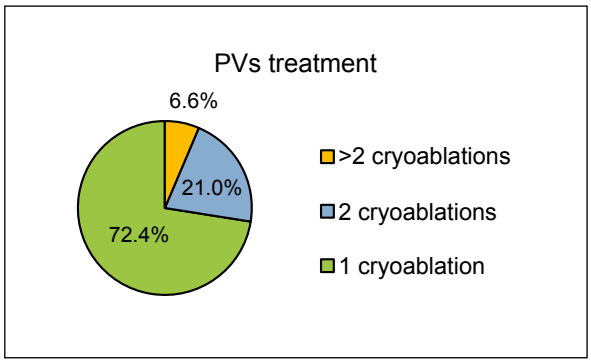
One transient phrenic nerve palsy was observed, with full recovery in the 48-h post procedure; **no major** procedure-related **adverse events** were reported.

CONCLUSIONS

In this first multicentric experience, the novel cryo-balloon system proved to be safe and effective and resulted in a very low rate of AF/AT recurrence during follow-up. No major procedure related adverse events were reported.

- 72.4% of the PVs requested a single application.
- 39.3% patients were treated with a single application to each vein.
- After the blanking period, over a median of 296 [245 to 382] days of follow-up, 11.2% (10/89) and 8.7% (2/23) of patients had an AF/AT recurrence.





Clinical Data

Safety Data and Long-term Outcome

NOVEL CRYOBALLOON TO ISOLATE PULMONARY VEINS IN PATIENTS WITH PAROXYSMAL ATRIAL FIBRILLATION: LONG-TERM OUTCOMES IN A MULTICENTRE CLINICAL STUDY

Martin, et al., 2022
https://doi.org/10.1007/s10840-022-01200-5

CLINICAL PERSPECTIVE

What's New

This study evaluates the effectiveness and safety of a novel cryoballoon ablation system, the POLARx™ Cryoablation System.

What's Important

POLARx Cryoablation System 1-year freedom from atrial arrhythmias was 77% (n=58).

OBJECTIVE

The aim of this study was to demonstrate the acute performance, characterize the lesion set achieved, and evaluate the long-term safety and efficacy in treating paroxysmal AF using the POLARx cryoballoon system.

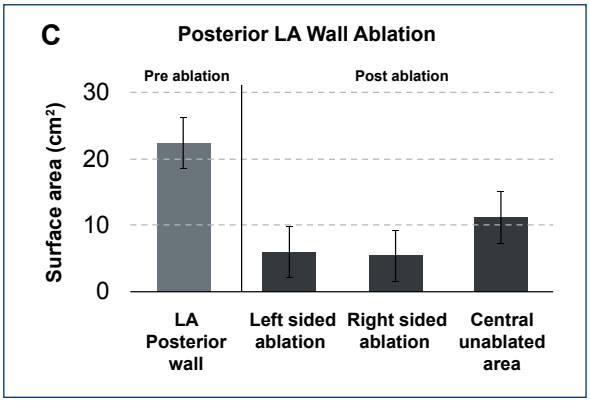
METHODS

This was a non-randomized, single arm, prospective, multicentre study. Patients were enrolled as part of the continued access protocol (NCT03723070), which includes 58 patients enrolled after the initial first-in-human cohort previously reported.

The primary safety endpoint was freedom from device- or procedure-related serious adverse events at 12-month post procedure.

The primary efficacy endpoint was acute procedural success, with PVI confirmed via exit and entrance block testing.

Secondary endpoints included all procedure and device-related adverse events, treatment success defined as the proportion of subjects free from symptomatic atrial arrhythmias at 12 months post-procedure and cryoballoon procedural characteristics.



Martin, A., Fowler, M., Breskovic, T. et al. Novel cryoballoon to isolate pulmonary veins in patients with paroxysmal atrial fibrillation: long-term outcomes in a multicentre clinical study. J Interv Card Electrophysiol 65, 609–616 (2022). https://doi.org/10.1007/s10840-022-01200-5.

RESULTS

The mean procedural time for PVI ablation was 108 min across all 58 cases. The mean fluoroscopy time was 14 min. Acutely, 231/232 (99.6%) PVs were successfully isolated, with one PV without documented exit and entrance block testing.

In total, 306 cryoablations were performed, resulting in a mean of 5.3 cryoablations per patient (1.3 cryoablations per vein). All cryoablations achieved a grade 3 (8%) or grade 4 (92%) occlusion, with similar performance across individual PVs.

Electrical isolation of the PV with a single cryoablation was achieved in 175 veins (76%), and 23 patients (40%) had successful PVI with only 4 cryoablations (1 per vein).

At 12 months, 43 (77%; 95% CI: 64–87%) out of 56 patients were free from recurrent, symptomatic atrial arrhythmias.

Treatment with this novel cryoballoon resulted in phrenic nerve injury in four patients (6.9%); for one (1.7%) patient, this persisted following the procedure but resolved within 6 months.

Our data shows that the proximal extent of cryoballoon ablation is antral within the LA, treating 50% of the posterior wall of the LA. This is similar to the extent of ablation that has been described having been created by the Arctic Front cryoballoon system.

CONCLUSIONS

Initial multicentre clinical experience with the novel cryoballoon ablation catheter has demonstrated safety and efficacy of PVI in patients with paroxysmal AF. Ablation with this catheter provides a wide and antral lesion set with significant debulking of the posterior wall of the LA.

Clinical Data

Biophysical Predictors for Acute PVI

POLARX CRYOBALLOON METRICS PREDICTING SUCCESSFUL PULMONARY VEIN ISOLATION: TARGETS FOR ABLATION OF ATRIAL FIBRILLATION

Honarbakhsh, et al., 2022
https://doi.org/10.1093/europace/euac100

CLINICAL PERSPECTIVE

What's New

This is the first multicenter study to identify cryoablation metrics that are predictive of successful pulmonary vein isolation (PVI) with the POLARx™ Cryoballoon.

What's Important

Temperature at 30 s, nadir temperature, and time to isolation were independent predictors of sustained PVI combining two of these three targets was associated with reconnection in only 2-5% of PVs w/POLARx.

OBJECTIVE

Evaluate the novel POLARx Cryoballoon in atrial fibrillation (AF) catheter ablation through a propensity-matched comparison with the Arctic Front Advance™ (AFA). The aim was also to identify cryoablation metrics that are predictive of successful pulmonary vein isolation (PVI) with the POLARx Cryoballoon.

METHODS

This prospective multi-centre study included patients that underwent cryoablation for AF. All patients underwent PVI with reconnection assessed after a 30-min waiting period and adenosine.

Safety, efficacy, and cryoablation metrics were compared between POLARx and a propensity-matched AFA cohort. Seventy patients were included with 278 veins treated.

Cryoablation was performed until PVI was achieved. Applications of the cryoballoon were standardized at 180 s for all PVs.

Therefore, all cryoablations continued until 180 s regardless of the metrics achieved during the cryoablation.

RESULTS

Safety, efficacy, and procedural metrics for the POLARx Cryoballoon were comparable to that achieved with the AFA Cryoballoon, but the cryoablation profile was different with lower nadir temperatures and PVI achieved at a lower temperature and at a quicker time.

The temperature at 30 s and time to reach −40°C were strongly predictive of initial PVI with the POLARx Cryoballoon. The temperature at 30 s, nadir temperature, and TTI were predictive of sustained PVI.

The overall rate of PV reconnection after a waiting period and with adenosine was moderate at 16.5% of PVs without consolidating cryoablation.

However, rates of acute PV reconnection were lower where TTI was ≤38 s (8.3%) and lower still when this endpoint was paired with a temperature of ≤–40°C at 30 s or a nadir temperature of ≤–54°C (4.8% and 2.6%, respectively). If both temperature targets were met, then PV reconnection remained low at 2.2% irrespective of TTI.

CONCLUSIONS

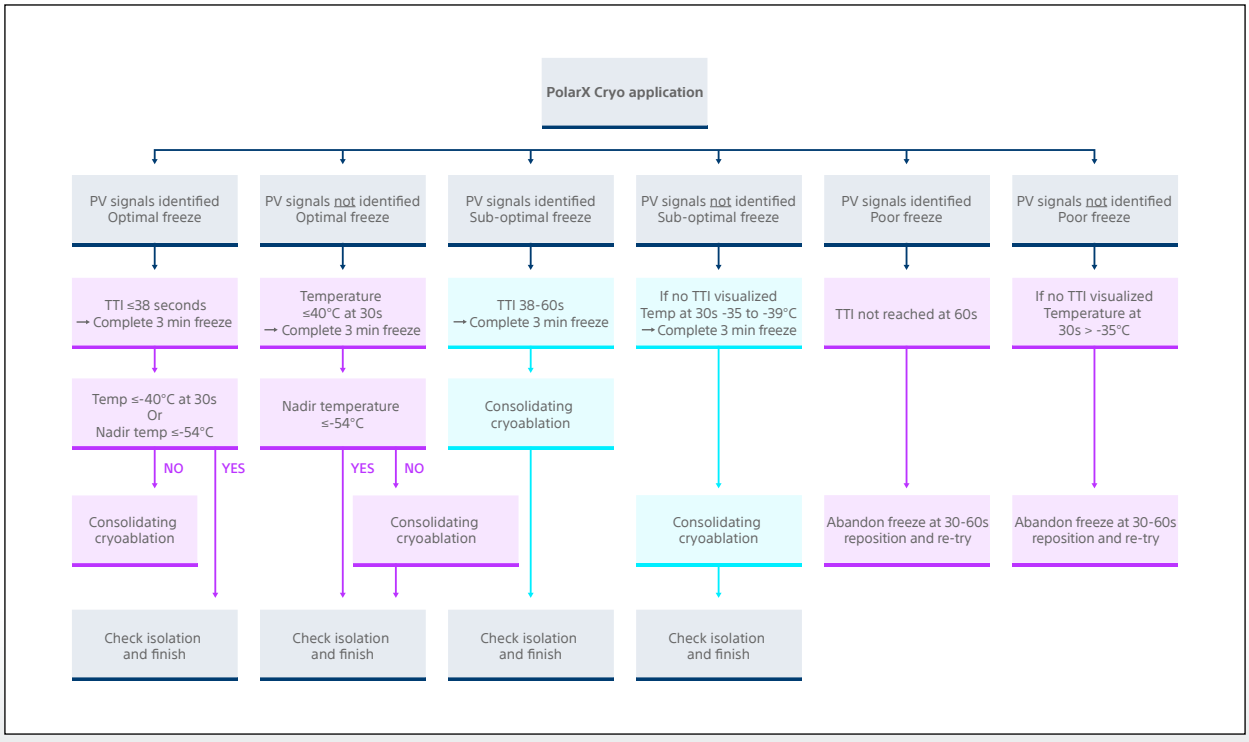
PVI using the novel POLARx™ Cryoballoon was similarly quick, safe, and effective as the AFA Cryoballoon in a prospective propensity matched comparison. However, cryoablation metrics were significantly different with the POLARx Cryoballoon with lower nadir temperatures and lower temperature at PVI.

TTI was 12 s earlier with the POLARx Cryoballoon compared with the AFA Cryoballoon.

Achieving a temperature of ≤–39°C within 30 s was predictive of initial PVI with POLARx Cryoballoon.

Achieving a temperature of ≤–40°C at 30 s, a nadir temperature of ≤–54°C and a TTI of ≤38 s were all predictive of sustained PVI with the POLARx Cryoballoon.

Combining two of these three metrics were associated with reconnection in only 2–5% of PVs.



KEY CHARACTERISTICS FOR EFFECTIVE ACUTE PULMONARY VEIN ISOLATION WHEN USING A NOVEL CRYOBALLOON TECHNOLOGY: INSIGHTS FROM THE CHARISMA REGISTRY

Iacopino, et al., 2022

https://doi.org/10.1007/s10840-021-01063-2

CLINICAL PERSPECTIVE

What's New

This is the first study that looked at the biophysical predictors of acute PVI with POLARx™.

What's Important

This study found that nadir balloon temperature, thaw time to 0°C, PV occlusion grade, and TTI were all strong biophysical predictors of acute pulmonary vein isolation with the POLARx Cryoablation System.

OBJECTIVE

The aim of this study was to evaluate procedural and biophysical parameters resulting in acute PV isolation when using this new CB.

METHODS

The CHARISMA was a prospective, single-arm, multicenter cohort study designed to describe clinical practice regarding the approach to the ablation of various arrhythmias. In this paper, we present the analysis of the first 69 consecutive patients indicated for AF ablation who underwent PV isolation by means of a novel CB system in five Italian centers.

Optimal vessel occlusion was considered to have been achieved when selective contrast injection showed the absence of contrast backflow to the atrium.

Leak(s) of contrast into the left atrium under fluoroscopic evaluation indicates incomplete occlusion. For analysis purpose, the occlusion grade was scored as follows: GR4 (complete occlusion), GR3 (incomplete occlusion with slight leakage), GR2 (poor occlusion with massive leakage), and GR1 (very poor occlusion with extensive leakage).

DISCUSSION

A total of 274 PVs were targeted in the 69 patients.

The mean number of freeze applications per patient was 5.3.

Twenty-five (36.2%) patients were treated with a single application to each of the PVs (212 PVs [77.4% of the total] were treated in a single-shot fashion). TTI information was available in 170 (62.0%).

The median grade of PV occlusion was 4 [3 to 4]. In the majority of cases, occlusion was scored as complete (n = 157, 68.6%) ranging

from 75.4% in LIPV through 71.2% in LSPV and 65.5% in RSPV to 60.8% in RIPV;

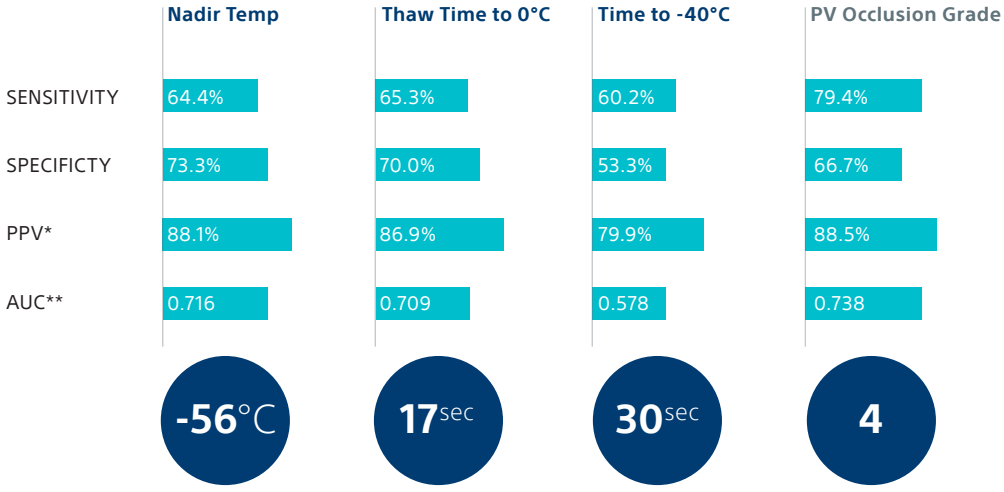
We analyzed the acute procedural outcome of PV isolation by means of a novel CB technology in patients with paroxysmal and persistent AF. Our key findings were as follows:

1. the POLARx™ appears to be effective and safe, achieving 100% PV isolation while causing only one transient phrenic palsy;
2. the temperatures required to achieve acute PV isolation were lower than those reported with the standard CB technology;
3. a nadir temperature of – 56 °C, a thaw time to 0 °C > 17 s, and complete PV occlusion were the best predictors of acute PV isolation.

CONCLUSIONS

The novel POLARx cryoballoon system is safe and effective for PVI. The temperatures required to achieve acute PV isolation are lower than those reported with the standard CB technology. In our series, a nadir temperature of – 56 °C, a thaw time to 0 °C ≥ 17 s, and the achievement of complete PV occlusion were the best predictors of acute PV isolation.

Biophysical predictors for acute PVI



*Positive Predictive Value. **Area under the ROC Curve

Clinical Data

Comparison Study

COMPARISON OF THE 1-YEAR CLINICAL OUTCOME OF A NOVEL CRYOBALLOON TO AN ESTABLISHED CRYOBALLOON

Yap, et al., 2022
https://doi.org/10.1007/s10840-022-01262-5

CLINICAL PERSPECTIVE

What's New

This is the first report comparing the 1-year freedom from atrial arrhythmias between the novel POLARx™ cryoballoon and the fourth-generation AFA-Pro™.

What's Important

The 1-year freedom from atrial arrhythmias was 82% and 87% for the POLARx and AFA-Pro group, respectively.

OBJECTIVE

The aim of the present study was to compare the 1-year clinical outcome between POLARx and AFA-Pro of our original study cohort.

METHODS

We prospectively included consecutive patients who underwent cryoballoon ablation (CBA) for the treatment of AF between May and October 2020 in 3 centers.

Time-to-isolation (TTI)-based cryodosing was employed. The primary outcome was the freedom from atrial arrhythmias between 90 and 365 days after the procedure.

RESULTS

110 patients in the study period (POLARx™: n = 57; AFA-Pro™: n = 53).

1 YEAR EFFECTIVENESS DATA

82% freedom from atrial arrhythmias for POLARx™ at 1 year follow-up.

EFFECTIVENESS & SAFETY

Freedom from redo procedures and rate of persistent PNP was similar between both cryoballon technologies.

The rate of PV isolation was similar between groups (POLARx: 99.5% of all PVs versus AFA-Pro: 100% of all PVs, P = 1.00).

The POLARx group had a longer procedure time (median 81 min versus 67 min, P < 0.001) and longer balloon in body time (median, 51 min versus 35 min, P < 0.001).

There was no difference in the magnitude of PV occlusion (grade 4 occlusion: POLARx: 81.6% versus AFA-Pro 77.3%, P = 0.21).

Balloon nadir temperatures and temperatures at TTI were lower with POLARx, but the timing of TTI was similar between groups.

During a follow-up of 1 year, there was no difference in freedom from atrial arrhythmias after a blanking period of 90 days (Fig. 1). The 1-year freedom from atrial arrhythmias was 82% and 87% for the POLARx and AFA-Pro group, respectively (log-rank P = 0.60).

CONCLUSIONS

The 1-year clinical outcome after PVI with POLARx is comparable to AFA-Pro. The lower measured balloon nadir temperatures with POLARx do not seem to be associated with a lower recurrence rate of atrial arrhythmias nor with more procedure-related complications in comparison to AFA-Pro.

Clinical Data

Comparison Study

COMPARISON OF THE ACUTE OUTCOME OF TWO CRYOBALLOON TECHNOLOGIES FOR PULMONARY VEIN ISOLATION: AN UPDATED SYSTEMATIC REVIEW AND META-ANALYSIS

Yap, et al., 2022
https://doi.org/10.1016/j.ijcha.2022.101115

CLINICAL PERSPECTIVE

What's New

This updated meta-analysis provides new safety data on minimal esophageal temperature and thromboembolic events.

What's Important

The acute outcome of POLARx™ is comparable to AFA-Pro™, despite lower balloon nadir temperatures with POLARx. There was a higher rate of TTI recording in the inferior PVs with POLARx.

OBJECTIVE

The aim of this updated comprehensive meta-analysis was to compare differences in acute outcome between POLARx and AFA-Pro in patients with AF undergoing PVI.

METHODS

A total of 8 studies, involving 1146 patients from 11 European centers were included (POLARx n = 317; AFA-Pro n = 819).

The studies included fulfilled the following criteria:

1. patients with paroxysmal and/or persistent AF undergoing PVI with a cryoballoon;
2. comparison of POLARx cryoballoon with AFA-Pro cryoballoon;
3. reported outcome data.

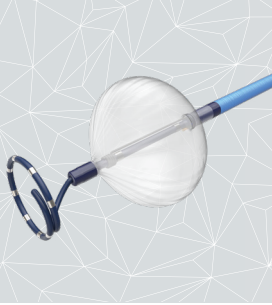
RESULTS

There were no differences in acute PV isolation, procedure time, fluoroscopy time, ablation time, minimal esophageal temperature, and risk of phrenic nerve palsy or thromboembolic events.

Balloon nadir temperatures were lower for POLARx in all PVs.

Compared with AFA-Pro, POLARx had a

- Higher rate of first freeze isolation in the left inferior PV.
- Higher likelihood of time-to-isolation (TTI) recording in LIPV and RIPV.
- In contrast, the TTI in LIPV was longer with POLARx in comparison to AFA-Pro.



CONCLUSIONS

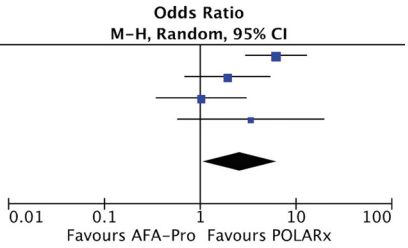
POLARx™ and AFA-Pro™ have a similar acute outcome.

Interestingly, there was a higher rate of TTI recording in the inferior PVs with POLARx. This updated metaanalysis provides new safety data on esophageal temperature and thromboembolic events.

A. First freeze isolation LIPV

Study or Subgroup	POLARx Events	POLARx Total	AFA-Pro Events	AFA-Pro Total	Weight	Odds Ratio M-H, Random, 95% CI
Guckel et al. 2022	56	65	260	519	31.9%	6.20 [3.00, 12.79]
Knecht et al. 2021	32	40	27	40	26.6%	1.93 [0.70, 5.33]
Moser et al. 2021	39	47	38	46	25.6%	1.03 [0.35, 3.01]
Tilz et al. 2021	23	25	17	22	16.0%	3.38 [0.58, 19.57]
Total (95% CI)		**177**		**627**	**100.0%**	**2.60 [1.06, 6.43]**
Total events	150		342			

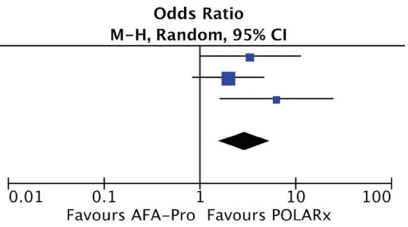
Heterogeneity: $Tau^2 = 0.53$; $Chi^2 = 8.54$, df = 3 (P = 0.04); $I^2 = 65\%$
Test for overall effect: Z = 2.08 (P = 0.04)



B. TTI recording LIPV

Study or Subgroup	POLARx Events	POLARx Total	AFA-Pro Events	AFA-Pro Total	Weight	Odds Ratio M-H, Random, 95% CI
Mojica et al. 2021	25	30	18	30	26.8%	3.33 [1.00, 11.14]
Moser et al. 2021	33	47	25	46	52.0%	1.98 [0.84, 4.65]
Tilz et al. 2021	21	25	10	22	21.2%	6.30 [1.62, 24.53]
Total (95% CI)		**102**		**98**	**100.0%**	**2.91 [1.54, 5.49]**
Total events	79		53			

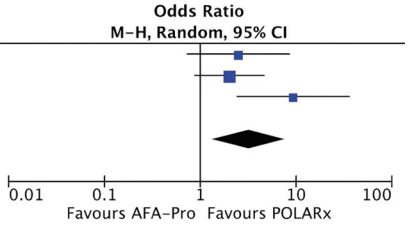
Heterogeneity: $Tau^2 = 0.01$; $Chi^2 = 2.07$, df = 2 (P = 0.35); $I^2 = 3\%$
Test for overall effect: Z = 3.30 (P = 0.0010)



C. TTI recording RIPV

Study or Subgroup	POLARx Events	POLARx Total	AFA-Pro Events	AFA-Pro Total	Weight	Odds Ratio M-H, Random, 95% CI
Mojica et al. 2021	25	30	20	30	29.8%	2.50 [0.74, 8.50]
Moser et al. 2021	22	50	14	50	43.6%	2.02 [0.88, 4.64]
Tilz et al. 2021	21	25	9	25	26.6%	9.33 [2.43, 35.84]
Total (95% CI)		**105**		**105**	**100.0%**	**3.23 [1.35, 7.74]**
Total events	68		43			

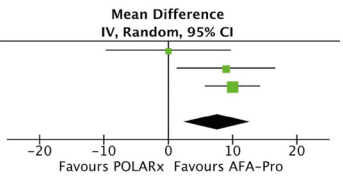
Heterogeneity: $Tau^2 = 0.27$; $Chi^2 = 3.68$, df = 2 (P = 0.16); $I^2 = 46\%$
Test for overall effect: Z = 2.64 (P = 0.008)



D. TTI LIPV

Study or Subgroup	POLARx Mean [sec]	POLARx SD [sec]	POLARx Total	AFA-Pro Mean [sec]	AFA-Pro SD [sec]	AFA-Pro Total	Weight	Mean Difference IV, Random, 95% CI
Mojica et al. 2021	26	10	25	26	19	18	21.0%	0.00 [-9.61, 9.61]
Moser et al. 2021	34	19	33	25	10	25	28.9%	9.00 [1.42, 16.58]
Tilz et al. 2021	36	8	21	26	4	10	50.1%	10.00 [5.77, 14.23]
Total (95% CI)			**79**			**53**	**100.0%**	**7.61 [2.43, 12.80]**

Heterogeneity: $Tau^2 = 9.32$; $Chi^2 = 3.50$, df = 2 (P = 0.17); $I^2 = 43\%$
Test for overall effect: Z = 2.88 (P = 0.004)



Amira Assaf, Rohit E. Bhagwandien, Tamas Szili-Torok, Sing-Chien Yap, Comparison of the acute outcome of two cryoballoon technologies for pulmonary vein isolation: An updated systematic review and meta-analysis, IJC Heart & Vasculature, Volume 42, 2022, 101115, ISSN 2352-9067, https://doi.org/10.1016/j.ijcha.2022.101115. (https://www.sciencedirect.com/science/article/pii/S2352906722001646)

Clinical Data

Comparison Study

IMPACT OF PULMONARY VEIN VARIANT ANATOMY AND CROSS-SECTIONAL ORIFICE AREA ON FREEDOM FROM ATRIAL FIBRILLATION RECURRENCE AFTER CRYOTHERMAL SINGLE-SHOT GUIDED PULMONARY VEIN ISOLATION

Guckel, et al., 2022
https://doi.org/10.1007/s10840-022-01279-w

CLINICAL PERSPECTIVE

What's New

The aim of this study was to evaluate ablation efficacy and outcome using the novel POLARx™ CB compared to the established AFA system in consideration of individual anatomical characteristics and the underlying AF pattern.

What's Important

CB-guided ablation with both single-shot systems is associated with comparable 12-month AF-free survival rates.

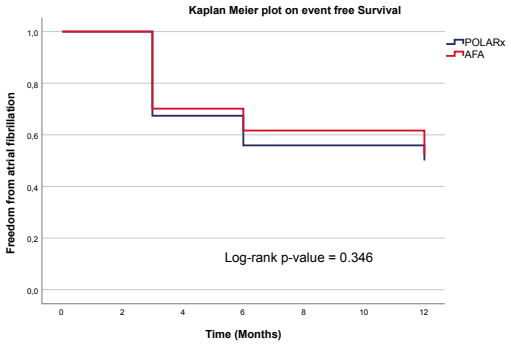
OBJECTIVE

This study aimed to evaluate ablation efficacy and outcome using the novel POLARx CB compared to the established AFA system in consideration of individual anatomical characteristics and the underlying AF pattern.

METHODS

This observational study included 687 consecutive patients undergoing index CB-guided PVI for symptomatic and drug efractory paroxysmal (PAF) and persistent AF (PERS AF).

We compared clinical characteristics and procedural outcomes of 86 patients undergoing single-shot device-guided PVI utilizing the 28-mm POLARx versus another cohort of 601 patients treated with the second-generation 28-mm AFA catheter.



Number at risk

	Baseline	3 Months FU	6 Months FU	12 Months FU
POLARx	86	58	48	43
AFA	601	398	343	318

Guckel, D., Lucas, P., Isgandarova, K. et al. Impact of pulmonary vein variant anatomy and cross-sectional orifice area on freedom from atrial fibrillation recurrence after cryothermal single-shot guided pulmonary vein isolation. J Interv Card Electrophysiol 65, 251–260 (2022). https://doi.org/10.1007/s10840-022-01279-w.

We analyzed patients with a normal PV anatomy (two left- and two right-sided PVs) to patients with a variant PV anatomy (normal vs. variant PV anatomy).

The diagnosis of PAF vs. PERS AF was made according to current guidelines. Arrhythmia recurrence was defined as an ECG documented episode of any AF/atrial tachycardia (AT) > 30 s.

RESULTS

687 consecutive patients undergoing CB-guided PVI for AF. A total of 401 patients (58%) suffered from PAF and 286 patients (42%) from PERS AF. Eighty-six patients (10%) were treated with the POLARx™ system.

Patients were further divided into POLARx patients with PAF (50 patients, 58%) and PERS AF (36 patients, 42%) and AFA patients with PAF (351 patients, 58%) and PERS AF (250 patients, 42%).

Patients with PERS AF presented with significantly higher recurrence rates compared to patients diagnosed with PAF (PERS AF: n = 204, 71% vs. PAF: n = 122, 30%, $p < 0.001$).

Kaplan–Meier analyses revealed a comparable estimated AF-free survival between POLARx and AFA treated patients including PAF and PERS AF.

No differences in terms of PV CSOA were revealed between patients with PERS AF and PAF, but CSOA was a predictor for AF recurrence in patients with PAF. Patients with PAF and AF recurrence have had significantly larger CSOA of the left-sided and the right superior PVs compared to patients without arrhythmia recurrence.

CONCLUSIONS

CB-guided ablation with both single-shot systems is associated with comparable 12-month AF-free survival rates.

Variant PV anatomy seems to be relevant for AF recurrence.

An association between CSOA and the outcome after Cb guided PVI is documented for PAF.

Clinical Data

Comparison Study

TWO COMPETING CRYOBALLOON TECHNOLOGIES FOR SINGLE SHOT PULMONARY VEIN ISOLATION: FIRST EXPERIENCES WITH THE NOVEL SYSTEM

Imnadze, et al., 2022
http://doi.org/10.31083/j.rcm2304118

CLINICAL PERSPECTIVE

What's New

The aim of this study was to analyze only comparative studies between two cryoballoon systems. To address important clinical points such as procedural parameters, learning curve etc.

What's Important

The efficacy and safety of NCB are comparable with the SCB. The learning curve seems to be short if there is already experience with the SCB.

OBJECTIVE

The aim of this study was to analyze only comparative studies between two cryoballoon systems. To address the following questions: Is the new system technically similar to the previous one? Is there a difference in terms of periprocedural parameters (procedural time, fluoroscopy time, left atrial dwell time, minimal temperature, and time to isolation effect)? Are acute success and complication rates similar? Is the learning curve different?

DISCUSSION (1)

The sheath – The sheath for the NCM system is 1 Fr larger, but due to its more gradual taper from the dilator to the sheath, it tends to more easily cross the septum. Moreover, the sheath and the balloon shaft in the NCB system are more flexible and softer.

Balloon catheter – The SCB inflation pressure is low. Following the initiation of the ablation, the pressure increases up to six times which makes the cryoballoon more rigid and slightly increases the size of the CB. Unlike the SCB, the inflation pressure of the NCB remains consistently low during the entire ablation. Therefore, the NCB does not increase in size after the initiation of the ablation. A complete occlusion is required before commencing the freeze of the NCB balloon promotes a more antral lesion which might lead to enhanced tissue ablation.

Multipolar diagnostic catheter – The mapping catheters are also similar in both systems, but it has been observed that there is a higher rate of real-time visualization utilizing the NCB mapping catheter. Time to isolation (TTI) was recorded in a higher percentage of pulmonary veins (PVs) with the NCB than with the SCB (93.1% vs. 79.6%).

DISCUSSION (2)

Console – The NCB console is generally more modern. The pedal is used to inflate/deflate the balloon and to initiate/ stop cryo-energy delivery. This option helps the operator to perform the procedure autonomically without assistance. In the upcoming version, the operator can also manage the procedure using a sterile remote control replacing the functions of the foot pedal.

Minimal temperature & TTI – The NCB achieves lower balloon nadir temperatures faster than the SCB. However, in contrast to SCB, in NCB cooling rates from –30°C or –40°C. TTI was comparable between the two systems in all studies, despite lower balloon temperatures at TTI with the NCB system.

Success and complications – All articles published to date show a comparable success rate for both groups Assaf et al. [27] demonstrated in a meta-analysis that patients undergoing the PVI procedure with NCB and SCB systems have a similar acute procedural efficacy. The long-term success rate in maintaining normal sinus rhythm is the most important outcome of these procedures.

No major learning curve was observed for both systems. Despite differences in handling, the similarity of the techniques allows relatively quick mastering of the NCB system.

CONCLUSIONS

The efficacy and safety of NCB are comparable with the SCB. The NCB results in faster cooling rates and lower balloon temperatures, but TTI is similar for both systems, which may be due to minor differences in catheter design. Furthermore, the learning curve seems to be short if there is already experience with the SCB.

Clinical Data

Comparison Study

COMPARISON OF PROCEDURAL EFFICACY, BALLOON NADIR TEMPERATURE, AND INCIDENCE OF PHRENIC NERVE PALSY BETWEEN TWO CRYOBALLOON TECHNOLOGIES FOR PULMONARY VEIN ISOLATION: A SYSTEMATIC REVIEW AND META-ANALYSIS

Yap, et al., 2021
DOI: 10.1111/jce.15182

CLINICAL PERSPECTIVE

What's New

This is the first meta-analysis to compare the differences in procedural efficacy, balloon nadir temperature, and incidence of phrenic nerve palsy (PNP) between POLARx™ and AFA-Pro™ in patients with AF undergoing PVI.

What's Important

This meta-analysis demonstrates that patients with symptomatic AF undergoing cryoballoon ablation have a similar acute procedural efficacy with either the POLARx or AFA-Pro system.

OBJECTIVE

The aim of this comprehensive meta-analysis was to compare the differences in procedural efficacy, balloon nadir temperature, and incidence of phrenic nerve palsy (PNP) between POLARx and AFA-Pro in patients with AF undergoing PVI.

METHODS

The studies included fulfilled the following criteria:

1. patients with paroxysmal and/or persistent AF undergoing PVI with a cryoballoon;
2. comparison of POLARx cryoballoon with AFA-Pro cryoballoon;
3. reported outcome data including but not limited to acute PVI success, procedure time, fluoroscopy time, ablation time, balloon nadir temperature for each pulmonary vein (PV), and PNP.

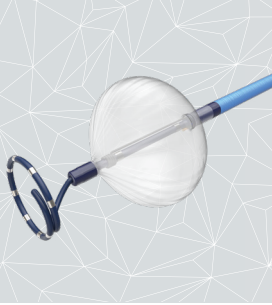
The following exclusion criteria were used: conference abstracts, case reports, review articles, editorials, and letters to the editor.

DISCUSSION

This meta-analysis demonstrates that patients with symptomatic AF undergoing cryoballoon ablation have a similar acute procedural efficacy with either the POLARx or AFA-Pro system, in terms of acute PVI success, procedure time, fluoroscopy time, and ablation time.

Despite a lower balloon nadir temperature with POLARx, the incidence of PNP is similar to AFA-Pro.

Tilz et al. demonstrated a trend toward a shorter procedure time with POLARx, potentially secondary to a combination of stable balloon size during inflation and ablation, foot pedal, slider switch, and POLARSHEATH™ according to the authors. In contrast, Yap et al. and Kochi et



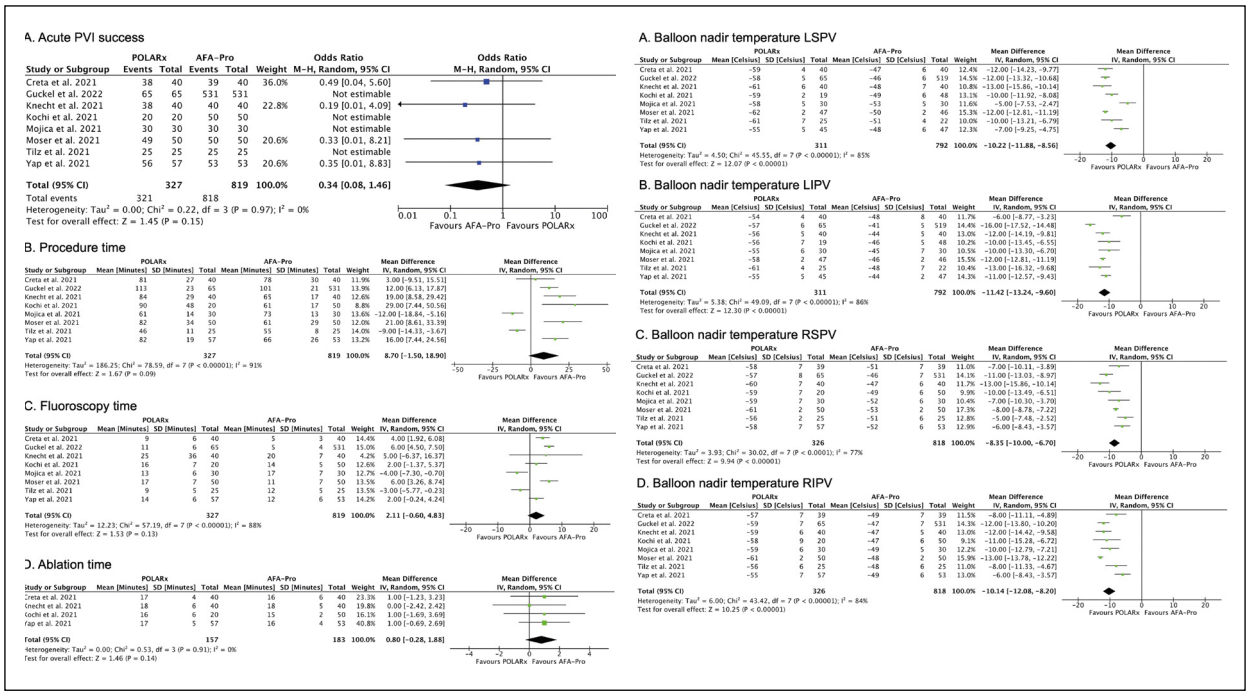
al. showed a longer procedure time with the POLARx™ system.

A learning curve effect was demonstrated by Yap et al. as the procedure times between both platforms were similar in the second half of the study cohort. It seems that the use of this novel cryoballoon is relatively straightforward in centers with experienced cryoballoon users.

Despite similarities in balloon shape and thermal energy source, the balloon nadir temperature with POLARx was significantly lower than AFA-Pro. This is important for clinicians as biophysical parameters associated with durable PVI established with AFA-Pro may potentially not be applicable for POLARx.

CONCLUSIONS

In AF patients undergoing PVI, POLARx and AFA-Pro had a similar procedural efficacy. Balloon nadir temperatures were lower with POLARx, however, the incidence of PNP was similar.



Assaf, A, Bhagwandien, R, Szili-Torok, T, Yap, S-C. Comparison of procedural efficacy, balloon nadir temperature, and incidence of phrenic nerve palsy between two cryoballoon technologies for pulmonary vein isolation: a systematic review and meta-analysis. J Cardiovasc Electrophysiol. 2021; 32: 2424- 2431. https://doi.org/10.1111/jce.15182

Clinical Data

Comparison Study

PROCEDURAL SAFETY AND EFFICACY FOR PULMONARY VEIN ISOLATION WITH THE NOVEL POLARX™ CRYOABLATION SYSTEM: A PROPENSITY SCORE MATCHED COMPARISON WITH THE ARCTIC FRONT™ CRYOBALLOON IN THE SETTING OF PAROXYSMAL ATRIAL FIBRILLATION

Mojica, et al., 2021
doi: 10.4022/jafib.20200455

CLINICAL PERSPECTIVE

What's New

To the best of our knowledge, this is the first study comparing the acute efficacy and safety outcome of POLARx cryoablation system with Arctic Front cryoablation system with a Propensity Score Matched comparison.

What's Important

This study demonstrates that POLARx can be associated with significant lower Procedure time, fluoroscopy time, and cumulative freeze duration.

OBJECTIVE

The aim of the study was to compare the new POLARx cryoablation system with the standard Arctic Front cryoballoon in terms of safety and efficacy during PV isolation for AF.

METHODS

All procedures were done by two primary operators who both performed more than1,000 Arctic Front cryoballoon each.

A total of 202 consecutive patients with paroxysmal AF underwent cryoablation and were included in our study. Thirty patients who underwent cryoablation using POLARx and 172 using Arctic Front were included in the matching process. Of that cohort, all the 30 POLARx patients were matched to 30 Arctic Front patients in a 1:1 ratio based on propensity scores which resulted in two balanced groups.

Pulmonary vein occlusion was assessed with contrast injection. Pulmonary vein electrical isolation was recorded with the ILMC positioned at the proximal site in the ostium before cryoablation of each.

A single 180-second application was delivered for each vein with TTI or temperature of less than -40 °C within one minute of cryoablation, otherwise a bonus freeze was delivered.

DISCUSSION

Acute PV isolation was achieved in all veins (100%) without the need for additional focal catheter application. No significant difference was found in total cryoballoon applications with POLARx™ and Arctic Front™.

The main findings were:

- PV isolation with either POLARx or Arctic

Front cryoablation system provided acute isolation in 100% of all PVs.

- POLARx was associated with shorter procedure and fluoroscopy time.
- In all PVs, POLARx showed slower time to reach 0°, faster time to reach -40°C, lower temperature at 60 seconds, lower nadir temperature, longer thaw time to 0 °C, shorter cumulative freeze duration, and no significant difference in time to isolation.
- There were no difference in procedure-related complications between the 2 groups.

Despite having shorter time to reach -40°C in POLARx,both groups reached -40°C within 60 seconds. This not only represents an acute indicator of PV isolation but also a significant predictor of permanency of PV isolation on the long term.

CONCLUSIONS

The novel POLARx cryoablation system showed similar efficacy in vein occlusion and isolation and safety profile when compared to Arctic Front cryoablation system. Procedure time, fluoroscopy time, and cumulative freeze duration were significantly lower with POLARx cryoablation system.

	POLARx™ (N, 30)	Arctic Front™ (N, 30)	P value
Procedure duration, minutes	60.50±14.23	73.43±13.26	0.001
Fluoroscopy duration, minutes	12.83±6.03	17.23±7.17	0.01
Contrast used, mL	62.17±7.84	60.17±8.03	0.9
Phrenic Nerve Injury	1 (3)	1 (3)	1.0

Mojica J, Lipartiti F, Al Housari M, Bala G, Kazawa S, Miraglia V, Monaco C, Overeinder I, Strazdas A, Ramak R, Paparella G, Sieira J, Capulzini L, Sorgente A, Stroker E, Brugada P, De Asmundis C, Chierchia GB. Procedural Safety and Efficacy for Pulmonary Vein Isolation with the Novel Polarx™ Cryoablation System: A Propensity Score Matched Comparison with the Arctic Front™ Cryoballoon in the Setting of Paroxysmal Atrial Fibrillation. J Atr Fibrillation. 2021 Jun 30;14(1):20200455. doi: 10.4022/jafib.20200455. PMID: 34950358; PMCID: PMC8691321.

Clinical Data

Comparison Study

NOVEL CRYOBALLOON ABLATION SYSTEM FOR SINGLE SHOT PULMONARY VEIN ISOLATION – THE PROSPECTIVE ICE-AGE-X STUDY

Tilz, et al., 2021
doi: 10.1253/circj.CJ-21-0094

CLINICAL PERSPECTIVE

What's New

This is the first study reporting on the acute efficacy and safety of POLARx™ as compared to AF-CB4™.

What's Important

This study is demonstrating an identical acute efficacy for PVI. Additionally, the POLARx showed significantly lower cryoballoon temperatures and a trend towards shorter procedure times compared to the AF-CB4.

OBJECTIVE

The aim of this study was to compare the procedural efficacy and ablation characteristics of the novel POLARx to the AF-CB4 for PVI.

METHODS

Consecutive patients with symptomatic, drug-refractory PAF or short standing PersAF (duration ≤3 months) were recruited for CB-based PVI (Figure 1).

25 consecutive patients were treated with the POLARx cryoballoon, a total of 25 consecutive previous patients treated with the AF-CB4 served as a control group. The patients were not randomized.

The procedures were performed by operators with high experience in CB procedures.

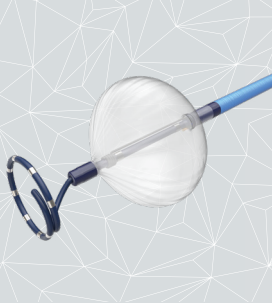
The procedure was performed in patients under deep sedation, the PVs were treated following a clockwise sequence.

A TTE-based ablation protocol was utilized for both cryoballoon systems. The standard freeze-cycle duration was 180 s. If the TTE could be visualized and was measured for <60 s, the freeze-cycle duration was 180 s and no further bonus-freeze application was performed. If TTE was measured ≥60 s, the freeze-cycle duration was 180 s and a bonus-freeze application of 180 s was performed. The procedural endpoint was disappearance of PV recordings verified via the circular mapping catheter after the freeze cycle (entrance block).

DISCUSSION

The current ICE-AGE-X study set out to compare the procedural efficacy and ablation characteristics of the novel POLARx™ to the AF-CB4™ for PVI.

A total of 50 consecutive patients underwent CB-based PVI utilizing either the AF-CB4 (1st n=25 cases) or the POLARx (2nd n=25 cases). No imbalances were apparent between the groups.



The major findings are:

1. the POLARx provides an identical rate of acute PVI as the AF-CB4;
2. the rate of real-time PV recordings as significantly higher in the POLARx group;
3. the minimal CB temperature was significantly lower in the POLARx group;
4. the trend towards shorter procedure time was observed for the POLARx;
5. no differences were observed between AF-CB4 and POLARx concerning catheter maneuverability, catheter stability and periprocedural complications.

CONCLUSIONS

To the best of our knowledge, this is the first study reporting on the acute efficacy and safety of POLARx -based PVI as compared to AF-CB4 -based PVI. While demonstrating an identical acute efficacy for PVI. Additionally, the POLARx showed significantly lower cryoballoon temperatures and a trend towards shorter procedure times compared to the AF-CB4.

PROCEDURAL DETAILS and COMPLICATIONS

Total number of isolated PVs 100 (100) POLARx 97 (100) AF-CB4	**Minimal CB temperature (°C)** -57 ± 7 POLARx -50 ± 6 AF-CB4	**Time to PVI** 48 ± 32 POLARx 41 ± 23 AF-CB4
Rate of TTI recordings 81 (81) POLARx 41 (42) AF-CB4	**Duration of total freezing time (s)** 211 ± 70 POLARx 208 ± 81 AF-CB4	**Total procedure time (min)** 45 min POLARx 55 min AF-CB4
Total fluoroscopy time 8 min POLARx 12 min AF-CB4	**Total amount of contrast** 60 mL POLARx 70 mL AF-CB4	**Major Complications** 1 (4) POLARx 1 (4) AF-CB4

Number of patients: POLARx n = 25; AF-CB4 n = 25
Number of PVs: POLARx n = 100; AF-CB4 n = 97

Clinical Data

Comparison Study

FIRST EXPERIENCE OF POLARX™ VERSUS ARCTIC FRONT ADVANCE™: AN EARLY TECHNOLOGY COMPARISON

Creta, et al., 2021
doi: 10.1111/jce.14951

CLINICAL PERSPECTIVE

What is Known

Cryoablation outcomes are well established.

What's New

This is the first UK study to compare the efficacy and safety of the to compare the procedural efficacy of POLARx system with the currently Arctic Front Advance Pro system (AFA-Pro, Medtronic).

What's Important

The novel POLARx cryoballoon appears similar in acute efficacy and has a short learning curve.

OBJECTIVE

The aim of the present study is to describe our early experience with the POLARx cryoablation system and describe procedural aspects in comparison to the incumbent Medtronic Arctic Front Advance.

METHODS

This was a non-randomized prospective single-centre study. We analysed clinical procedures from the first consecutive 40 PVI procedures performed using the POLARx in the UK. These data were compared with the 40 previous consecutive cases undergoing ablation by the same operators using the Arctic Front Advance CB (Medtronic).

We systematically collected procedural metrics including skin-to-skin time, time to PVI, left atrial dwell time, fluoroscopy time and dose, nadir and isolation balloon temperatures, as well as acute efficacy and safety outcomes.

POLARX VS. ARCTIC FRONT

Duration and fluoroscopy use were slightly higher for the POLARx cases, which also had lower indicated nadir temperatures than Arctic Front Advance cases.

Furthermore, more ablations were performed with the POLARx system, specifically for the right pulmonary veins. Times to isolation were similar overall.

Our preliminary data suggest that this technology is effective and safe, with PVI achieved in almost all patients using a workflow identical to that developed for use with Arctic Front Advance cryoablation.

The quality of the electrograms with the POLARMAP™ pulmonary vein catheter was felt to be excellent.

1. The POLARx™ system appears safe and is able to be used in a similar workflow to our prior experience with the Arctic Front Advance™ CB system.

2. Acute procedural metrics were somehow comparable to those achieved by using the incumbent device, with some differences likely due to the learning curve.
3. Reported temperatures were significantly lower for a given physiological effect i.e. PV isolation.

RESULTS

Pulmonary vein isolation was achieved for all four veins by the end of the procedure in all but two patients. The median procedure time and total freeze application time were 60 [44-160] minutes and 16 [9-28] minutes, respectively.

A median of 7 [3-162] freezing applications were required per patient to achieve isolation of all vein. Single freeze isolation was achieved for 55.0% (22/40) in the left upper pulmonary vein, 72.5% (29/40) in the left lower pulmonary vein, 48.7% (19/39) in the right lower and 53.8% (21/39) in the right upper pulmonary vein. Nadir temperatures during freezing were 59.0±4.4 degree (left upper pulmonary vein), 54.4±4.4 (left lower pulmonary vein), 56.6±7.1 (right lower pulmonary vein), and 58.4±6.9 (right upper pulmonary vein).

CONCLUSIONS

The POLARx cryoballoon is effective for pulmonary vein isolation. Measured isolation and nadir temperatures are lower compared to the predicate Arctic Front Advance catheter. The technology appears similar in acute efficacy and has a short learning curve, but formal dosing studies may be required to prove equivalence of efficacy.

Clinical Data

Comparison Study

COMPARISON OF PROCEDURAL EFFICACY AND BIOPHYSICAL PARAMETERS BETWEEN TWO COMPETING CRYOBALLOON TECHNOLOGIES FOR PULMONARY VEIN ISOLATION: INSIGHTS FROM AN INITIAL MULTICENTER EXPERIENCE

Yap, et al., 2021
DOI: 10.1111/jce.14915

CLINICAL PERSPECTIVE

What is Known

Cryo ablation outcomes are well established.

What's New

This is the first multicenter study to compare the efficacy and safety of the to compare the procedural efficacy and biophysical parameters of the novel POLARx™ system with the currently established fourth-generation Arctic Front Advance Pro™ system (AFA-Pro, Medtronic).

What's Important

The novel POLARx cryoballoon had similar efficacy and safety compared to the AFAP, and requires only a short learning curve.

OBJECTIVE

The aim of this study was to compare the procedural efficacy and biophysical parameters of the novel POLARx system (Boston Scientific) with the currently established fourth-generation Arctic Front Advance Pro system (AFA-Pro, Medtronic).

METHODS

One hundred and ten consecutive patients who underwent first-time cryoballoon ablation (POLARx: n = 57; AFA-Pro: n = 53) were included in this prospective cohort study.

All patients underwent PVI using a 28-mm cryoballoon.

AFA-Pro [8-mm tip]; or POLARx [short tip: 5-mm tip or long tip: 12-mm tip].The balloon was inserted through a steerable sheath, PV potentials were recorded using a 20-mm circular inner lumen mapping catheter with 8 electrodes.

After optimal PV occlusion was achieved, assessed by contrast injection, cryoablation was started. A time-to-isolation (TTI) guided ablation protocol was used. The freeze duration was 180 s if TTI was less than 60 s, otherwise a 240-s freeze cycle was employed. No bonus freeze was employed routinely. PVI was confirmed by entrance/exit block at the end of the procedure.

During cryoablation of the right-sided PVs Diaphragmatic excursion was assessed by palpation or, in case of the POLARx™ system, by using the Diaphragmatic Movement Sensor (DMS).

DMS percentage drops below a cutoff (65%), cryoablation was immediately terminated.

RESULTS

A total of 422 PVs was targeted (POLARx: n = 216, AFA-Pro™: n = 206). Acute isolation was achieved in 99.8% of all PVs, and was similar between groups (POLARx: 99.5% vs. AFA-Pro: 100%, p = 1.00).

Procedure time and balloon in body time were longer, and the amount of contrast agent used was higher in the POLARx group in comparison with the AFA-Pro group.

A learning curve analysis was performed with regard to procedural parameters. Analysis of the second half of the cohort showed no difference in procedure time balloon in body time, and contrast usage.

Cryoablation with POLARx was associated with a shorter time to balloon temperature –30°C and –40°C, a lower balloon nadir temperature, and a longer thawing time till 0°C. PV potentials could be recorded more often during CBA with POLARx than with AFA-Pro (96.3% vs. 88.6%, p < .001). TTI could be recorded in 93.1% of PVs using POLARx versus 79.6% using AFA-Pro (p < .001). There were no differences in TTI between systems, however, POLARx was associated with a lower balloon temperature at TTI in comparison with AFA-Pro.

With POLARx, CBAs resulting in acute PVI were associated with higher grade of PV occlusion.

CONCLUSIONS

The novel cryoballoon is comparable to AFA-Pro and requires only a short learning curve to get used to the slightly different handling. It was associated with faster cooling rates and lower balloon temperatures but TTI was similar to AFA-Pro.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Instructions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

POLARx™ FIT Cryoablation Balloon Catheter INTENDED USE The Boston Scientific Cardiac Cryoablation System is intended for cryoablation and electrical mapping of the pulmonary veins for pulmonary vein isolation (PVI) in the ablation treatment of paroxysmal atrial fibrillation. The POLARx FIT Cryoablation Balloon Catheter is a single use, flexible, over-the-wire balloon catheter intended to ablate cardiac tissue. **INDICATIONS FOR USE** The Boston Scientific Cardiac Cryoablation System using the POLARx FIT Cryoablation Balloon Catheter is indicated for the treatment of patients with drug refractory, recurrent symptomatic paroxysmal atrial fibrillation (PAF). **CONTRAINDICATIONS** Use of the POLARx FIT Catheter is contraindicated as follows: In patients with an active systemic infection as this may increase the risk for endocarditis and sepsis. In patients with a myxoma or an intracardiac thrombus as the catheter could precipitate an embolic event. In patients with a prosthetic heart valve (mechanical or tissue). In the ventricle of the heart where the device may become entrapped in a valve or chordae structures. In patients with a recent ventriculotomy or atriotomy as this may increase the risk of cardiac perforation or embolic event. In patients with pulmonary vein stents as the POLARx FIT Catheter may dislodge or damage the stent. In patients with cryoglobulinemia as the cryoablation application may lead to vascular injury. In conditions where insertion into or manipulation in the atrium is unsafe as this may increase the risk of perforation or systemic embolic event. In patients with intra-atrial septal patch or any other surgical intervention in or adjacent to the intra-atrial septum. In patients with an interatrial baffle or path as the transseptal puncture could fail to close. In patients with hypercoagulopathy or an inability to tolerate anticoagulation therapy during an electrophysiology procedure. In patients with a contraindication to an invasive electrophysiology procedure where insertion or manipulation of a catheter in the cardiac chambers is deemed unsafe. In patients previously implanted with a percutaneous Left Atrial Appendage Occlusion device. **WARNINGS** Introducing catheters and sheaths into the circulatory system increases the risk of air emboli. Always advance/ retract components slowly and use proper flushing techniques to minimize risk of air embolism. Avoid proximity to all heart valves whenever possible. Manipulation of the POLARx FIT Catheter across a heart valve structure may result in entanglement and damage to the valve. Use of N2 O as a refrigerant during the cryoablation procedure increases the risk of a gas embolism if the integrity of the POLARx FIT Catheter balloon is disrupted. Replace the POLARx FIT Catheter if there is any concern the POLARx FIT Catheter balloon has been damaged. Do not use the POLARx FIT Catheter without a POLARMAP Mapping Catheter fully inserted into the guidewire lumen, past the POLARx FIT Catheter balloon. An absent or partially inserted POLARMAP Mapping Catheter may not provide sufficient mechanical support for POLARx FIT Catheter balloon inflation and cryoablation operations and may result in POLARx FIT Catheter damage and N2 O leakage. Administer appropriate peri-procedural anticoagulation therapy per standard of care for patients undergoing cardiac cryoablation procedures. Administer anticoagulation therapy during and post-procedure according to local institution standards to minimize bleeding and thrombotic complications. Electrophysiology procedures, including ablation, may introduce arrhythmias. Always deflate the POLARx FIT Catheter and retract into the POLARSHEATH Sheath before pulling back across the septum. Crossing the septum with the POLARx FIT Catheter balloon exposed, inflated or inflating within the septum may cause endocardial damage. Do not use the POLARx FIT Catheter if it is not working properly. A POLARx FIT Catheter failing to function properly should be removed and replaced before continuing with the procedure. Do not inflate the balloon while housed in the POLARSHEATH Sheath. Always verify that the POLARx FIT Catheter balloon is outside the POLARSHEATH Sheath before inflation to prevent POLARx FIT Catheter damage. Do not inflate the balloon while the POLARx FIT Catheter is positioned inside the PV. Always inflate the POLARx FIT Catheter balloon while the POLARx FIT Catheter is positioned in the LA and then position it in the PV ostium. Inflating the POLARx FIT Catheter balloon in the PV may result in vascular injury. Always deflate and extend the POLARx FIT Catheter balloon prior to retraction of the balloon back into the POLARSHEATH Sheath. Do not use the POLARx FIT Catheter if any part of the POLARx FIT Catheter shaft appears to be kinked or damaged. If the POLARx FIT Catheter shaft appears kinked while in the body, remove the POLARx FIT Catheter and replace with a new POLARx FIT Catheter before continuing with the procedure. When using the POLARx FIT Catheter, catheter manipulation must be carefully performed in order to avoid cardiac damage, perforation, or tamponade. Do not advance the POLARx FIT Catheter with an exposed lumen; always advance the POLARx FIT Catheter over the POLARMAP Mapping Catheter, with the POLARMAP Mapping Catheter distal to the POLARx FIT Catheter balloon. Do not use excessive force to advance or withdraw the POLARx FIT Catheter when resistance is encountered. The steerability feature of the POLARx FIT Catheter is designed to operate in a single plane of motion. Attempts to deflect the distal section in other planes (e.g. perpendicular to normal steering plane, etc.) may result in damage to the steering mechanism and impaired ability to position the POLARx FIT Catheter as desired by the operator. Do not pull or move the POLARx FIT Catheter, POLARSHEATH Sheath, attached cables, or SMARTFREEZE Console while the POLARx FIT Catheter balloon is frozen as this may lead to tissue damage. Catheter ablation procedures near or in the PV may cause narrowing or stenosis. Avoid ablation in the tubular portion of the PV. Implantable pacemaker (PM) and cardioverter/defibrillator (ICDs) leads may be displaced during an EP procedure. See PM/ICD technical manual for additional instructions.5 Black (K) ΔE ≤5.0 BSC (MB eIFU Template 8.2677 x 11.6929 A4, 92524324F), eIFU, MB, POLARx FIT, US, 51594697-01A. To prevent occlusion of the refrigerant line, over-pressurization and potential POLARx FIT Catheter failure when using the POLARx FIT Catheter in combination with the POLARSHEATH Sheath, avoid applying simultaneous high torque (twisting) and tensile stress (pulling) on the POLARx FIT Catheter while the catheter is engaged in the POLARSHEATH Sheath and the POLARx FIT Catheter is deflected. Cryoablations may cause collateral injury to the esophagus and in rare instances atrio-esophageal fistulas. Temperature monitoring with a probe placed within the esophagus may mitigate this risk. Cryoablations may cause collateral phrenic nerve injury. Stop cryoablation immediately if phrenic nerve impairment is observed. Continuous phrenic nerve pacing, and diaphragm movement monitoring should be performed to mitigate this risk. The POLARx FIT Catheter contains pressurized gas during operation. Failure of the POLARx FIT Catheter balloon to operate properly may result in a release of gas into the circulatory system and potential gas emboli. Use caution when manipulating the POLARx FIT Catheter around other intracardiac devices. Entanglement may prevent removing the devices from the cardiac chamber and require surgical intervention. Significant x-ray exposure during an electrophysiology procedure may result in acute radiation injury as well as increased risk for somatic and genetic effects, to both patients and laboratory staff. Catheter ablation should only be performed after adequate attention has been given to the potential radiation exposure associated with the procedure and steps taken to minimize this exposure. **PRECAUTIONS** Use only isolated equipment (IEC 60601-1 Type CF equipment, or equivalent) with the POLARx FIT Catheter and SMARTFREEZE Console. The POLARx FIT Catheter shall only be used with the SMARTFREEZE Console. Use only the POLARMAP Mapping Catheter with the POLARx FIT Catheter. Use only the POLARSHEATH Sheath with the POLARx FIT Catheter. If necessary, use only 0.081 cm (0.032 in.) or 0.089 cm (0.035 in.) guidewires with the POLARx FIT Catheter. Use of other guidewire sizes may damage the POLARx FIT Catheter. It is the user's responsibility to ensure that the equipment used with the POLARx FIT Catheter meets all local applicable electrical safety requirements. Perform cryoablation procedures only within environmental parameters as outlined in Section 11.8, Specifications. Do not immerse the POLARx FIT Catheter handle or Cryo-Cable in fluids; electrical performance could be affected. Do not change the equipment configuration or modify the equipment or applied parts in any way. Doing so may cause the system to behave unreliably and affect the patient adversely. Always straighten the POLARx FIT Catheter prior to insertion or withdrawal from the body. Flush the guidewire lumen initially and then frequently throughout the cryoablation procedure to prevent coagulum formation. If contrast is used, flush the lumen thoroughly after each contrast injection. Do not physically scrub or twist the POLARx FIT Catheter balloon surface as damage to the POLARx FIT Catheter balloon may impact balloon shape or integrity. Do not apply excessive torque to the POLARx FIT Catheter during the procedure as it may adversely affect the cryoablation function. Do not apply excessive torque to the steering lever as doing so may damage the POLARx FIT Catheter deflection mechanism. Do not apply excessive force to the POLARx FIT Catheter extension slider switch (slider switch) during cryoablation or while the POLARx FIT Catheter balloon temperature is below freezing as doing so may damage the catheter. Properly scavenge and dispose of the N2 O with appropriate hospital systems. Do not outgas in the operating room. Dispose of the POLARx FIT Catheter per local regulatory and biohazard standards. **ADVERSE EVENTS** Potential adverse events associated with manipulation of the POLARx FIT Catheter within the left atrium and pulmonary veins may include the following conditions: Arrhythmia (new or exacerbated), Conduction pathway injury, Cardiac arrest, Cardiac trauma, for example: Cardiac perforation/tamponade/effusion, Valvular damage, Stiff left atrial syndrome. Death, Edema/heart failure/pleural effusion, GI disorders, Hypertension, Hypotension, Infection/inflammation/exposure to biohazardous material, Injury related to tissue damage and/or adjacent structures, for example: Esophageal injury, Pulmonary injury, Catheter entrapment, Physical trauma. Injury due to embolism/thromboembolism/air embolism/foreign body embolism: CVA/stroke, TIA, MI. Neurological impairment, and its symptoms, for example: Cognitive changes, Visual disturbances, Headache, Motor impairment, Sensory impairment, Speech impairment, Pulmonary embolism, Asymptomatic cerebral embolism, Nerve injury, for example: Phrenic nerve injury. Vagal nerve Injury, Pain or discomfort, for example: Angina, Chest pain, Non-cardiovascular pain7 Black (K) ΔE ≤5.0. Procedural related side effects, for example: Allergic reaction (including anaphylaxis), GU complications, Side effects related to medication or anesthesia, Radiation injury/tissue burn, Renal failure/insufficiency. Vasovagal response, PV Stenosis and its symptoms, for example: Cough, SOB, Fatigue, Hemoptysis. Respiratory distress/insufficiency/dyspnea. Surgical and access complications, for example: Hematoma/seroma, AV Fistula, Bleeding, Pseudoaneurysm, Pneumothorax, Residual atrial septal defect. Thrombus/thrombosis, Vessel Trauma, including: Perforation, Dissection, Coronary artery injury, Vasospasm, Occlusion, Hemothorax. 97085860 (Rev. A)

SMARTFREEZE™ Cryoablation System Console INTENDED USE/INDICATIONS FOR USE The Boston Scientific Cardiac Cryoablation System is intended for cryoablation and electrical mapping of the pulmonary veins for pulmonary vein isolation (PVI) in the ablation treatment of patients with drug refractory recurrent symptomatic paroxysmal atrial fibrillation (PAF). The SMARTFREEZE Console is intended to be used with POLARx Cryoablation Balloon Catheters only. **Intended Use Environment** The SMARTFREEZE Console is intended to be used in facilities equipped for interventional cardiac electrophysiology procedures. **CONTRAINDICATIONS** Use of the Boston Scientific Cardiac Cryoablation System is contraindicated as follows: In patients with an active systemic infection as this may increase the risk for endocarditis and sepsis. In patients with a myxoma or an intracardiac thrombus as the catheter could precipitate an embolic event. In the ventricle of the heart where the device may become entrapped in the valve or chordae structures. In patients with a prosthetic heart valve (mechanical or tissue). In patients with a recent ventriculotomy or atriotomy because this may increase the risk of cardiac perforation or embolic event. In patients with pulmonary vein stents as the catheter may dislodge or damage the stent. In patients with cryoglobulinemia as the application of cryogenic energy may lead to vascular injury. In conditions where insertion into or manipulation in the atria is unsafe as this may increase the risk of perforation or systemic embolic event. In patients with intra-atrial septal patch or any other surgical intervention in or adjacent to the intra-atrial septum. In patients with an interatrial baffle or patch as the transseptal puncture could fail to close. In patients with hyper-coagulopathy or an inability to tolerate anticoagulation therapy during an electrophysiology procedure. In patients with a contraindication to an invasive electrophysiology procedure where insertion or manipulation of a catheter in the cardiac chambers is deemed unsafe. In patients previously implanted with a percutaneous Left Atrial Appendage Occlusion device. **WARNINGS** To avoid the risk of electric shock, the SMARTFREEZE Console must always be connected to a supply mains with protective earth. This Console must only be used with Boston Scientific equipment and accessories listed in this manual or patient injury or death may occur. Do not modify the SMARTFREEZE Console in any way. Doing so may affect performance and/ or patient safety. The Equipotential ground provides a direct connection between the chassis of the SMARTFREEZE Console and the equalization bus of the electrical installation. It is not a protective earth connection point. The SMARTFREEZE Console must be installed by a qualified/ trained Boston Scientific representative. For assistance with installation, please contact your local Boston Scientific representative or Technical Support. There are no user serviceable parts in the SMARTFREEZE Console. Do not attempt to service the SMARTFREEZE Console while in use with a patient. Do not touch the SMARTFREEZE Console and the patient simultaneously as this may cause patient harm. Standard of care methods for evaluating phrenic nerve function and determining when intervention is needed should always be applied during right pulmonary vein ablations. The DMS is not intended as a substitute for such standard of care methods. Read and follow IFUs for POLARx Catheter, POLARx FIT Catheter, and cryoablation system components prior to use. Observe all contraindications, warnings, and precautions. Failure to do so may result in patient harm or device malfunction. **PRECAUTIONS** Electrophysiology procedures, including ablation, may introduce arrhythmias. It is the user's responsibility to ensure that the equipment used with the System meets all local applicable electrical safety standards. Perform cryoablation procedures only within environmental parameters as outlined in Section 14.1.1. Cryoablation procedures should only be performed in a fully equipped facility. Use only isolated equipment (IEC 60601-1 Type CF equipment or equivalent) with this equipment and accessories. Use of accessories, transducers and cables other than those specified or provided by Boston Scientific could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation. Do not connect any device to the Ethernet port. Only connect an external monitor that is compliant to IEC 60601-1:2012 or any local equivalent standards. Do not use a power bar or extension cord. When connecting an external monitor to the SMARTFREEZE Console, an evaluation of IEC 60601-1:2012 requirements should be performed. Use of this equipment adjacent to or stacked with other equipment should be avoided as it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally. The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio- frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30cm (12in) to any part of the SMARTFREEZE Console, including cables specified by Boston Scientific. Otherwise, degradation of the performance of this equipment could result. Only connect portable flash drives to USB ports for extraction of procedural data. Connection of a USB flash drive could result in previously unidentified risks to Patient, Operators or third parties. It is the hospital's responsibility to identify, analyze, evaluate and control these risks. IEC 80001-1:2010 provides guidance on this matter. Properly scavenge and dispose of the N2O with appropriate hospital systems. Do not outgas in the operating room. Only physicians thoroughly trained in electrophysiology procedures should operate the System. Do not use a power bar or extension cord when connecting the SMARTFREEZE Console to the hospital AC source (wall outlet). In order to maintain the device cybersecurity, firmware, and software (including off the shelf applications) of the SMARTFREEZE Console and accessories cannot be updated by the user. Contact your local Boston Scientific representative to schedule approved updates including security patches. In order to maintain the device cybersecurity, do not attempt to connect the SMARTFREEZE Console to the internet or hospital network in any way. Post installation, there are no specific security actions that the user or user facility are expected to take/implement to ensure secure use of this device. Patient data is stored on the console and should be purged prior to system decommissioning. Contact your local Boston Scientific representative to schedule this service. **ADVERSE EVENTS** Any potential clinical complications are in large part expected to be related to the accessories and/or therapeutic catheter that are used with the system, rather than the system itself. In order to identify potential adverse events, the user is instructed to read the pertinent instructions for use associated with the catheters and accessories that will be employed during the ablation procedure. As with other ablation systems, the SMARTFREEZE Console can be incidentally associated with minor or major clinical complications intrinsic to intracardiac procedures. Potential adverse events associated with the use of the system include, but are not limited to, the following: Procedural related side effects: Allergic reaction (including anaphylaxis), Genitourinary complication, Side effects related to medication and/or anesthesia, Radiation injury/tissue burn, Renal failure/insufficiency, Vasovagal response. Arrhythmia (new or exacerbated), Conduction pathway injury (Heart block, nodal injury, etc.). Nerve injury, for example: Phrenic nerve injury, Vagal nerve injury. Injury due to embolism/ thromboembolism/air embolism/gas embolism/foreign body embolism: Cerebrovascular accident (CVA)/ stroke, Transient ischemic attack (TIA), Myocardial infarction. Neurological impairment and its symptoms, for example: Cognitive changes, visual disturbances, headaches, motor impairment, sensory impairment, and speech impairment. Pulmonary embolism, Asymptomatic cerebral embolism. Electric shock, Injury related to tissue damage and/ or adjacent structures, for example: Esophageal injury, Pulmonary injury, Catheter entrapment, Physical trauma. Cardiac trauma, for example: Cardiac perforation/cardiac tamponade/pericardial effusion, Valvular damage, Stiff left atrial syndrome. 97085857 (Rev. A)

POLARSHEATH™ Steerable Sheath 12F INTENDED USE The POLARSHEATH Sheath is intended to facilitate the placement of diagnostic and/or therapeutic intracardiac devices during percutaneous catheter ablation procedures. The sheath deflection facilitates catheter positioning. **INDICATIONS FOR USE** The POLARSHEATH steerable sheath is indicated for percutaneous catheter introduction into the vasculature and into the chambers of the heart. **CONTRAINDICATIONS** Use of the POLARSHEATH Sheath is contraindicated as follows: In patients with an active systemic infection as this may increase the risk for endocarditis and sepsis. In patients where vascular access is unobtainable, or the femoral vein is known to be obstructed. In conditions where insertion into or manipulation in the atrium is unsafe as this may increase the risk of perforation or systemic embolic event. In the ventricle of the heart where the device may become entrapped in a valve or chordae structures. In patients with a prosthetic heart valve (mechanical or tissue). In patients with a recent ventriculotomy or atriotomy as this may increase the risk of cardiac perforation or embolic event. In patients with pulmonary vein stents as the POLARSHEATH Sheath may dislodge or damage the stent. In patients with an interatrial baffle or patch as the transseptal puncture could fail to close. In patients with hypercoagulopathy or an inability to tolerate anticoagulation therapy during an electrophysiology procedure. In patients with a contraindication to an invasive electrophysiology procedure where insertion or manipulation of a sheath in the cardiac chambers is deemed unsafe. **WARNINGS** Introducing catheters and sheaths into the circulatory system entails the risk of air emboli. Air embolism can occlude blood vessels resulting in serious consequences such as tissue infarction and/or end organ failure. Always advance/withdraw the POLARSHEATH Sheath slowly. Always advance/withdraw catheters slowly through the POLARSHEATH Sheath valve and minimize catheter exchanges. Administer appropriate levels of peri-procedural anticoagulation therapy for patients undergoing left-sided and transseptal cardiac procedures and for selected patients undergoing right-sided procedures. Administer anticoagulation therapy during and post-procedure according to institution standards to minimize bleeding and thrombotic complications. To minimize potential for air ingress, avoid actions that may induce strong negative pressure (vacuum) or create a leak pathway. Do not aspirate via the side port if the sheath lumen is occupied (i.e., by the dilator or components of the cryoablation catheter) as the aspiration may draw air across the sheath valve into the POLARSHEATH Sheath. Do not aspirate via the side port while the cryoablation balloon catheter is being introduced into the POLARSHEATH Sheath as this risks air ingress. Using high pressure flushing with heparinized saline, ensure that egress of heparinized saline from the hemostatic valve is observed during the introduction of the catheter. Avoid compromising the seal of the valve on the body of the cryoablation balloon catheter or holding open any portion of the valve membrane, such as by placing an introducer across the valve, as this may damage the valve and create a pathway for air to enter the POLARSHEATH Sheath.

Do not push the introducer sleeve of the POLARx through the hemostasis valve. The POLARSHEATH Sheath has undergone evaluation with Boston Scientific cryoablation balloon catheters to ensure compatibility. The use of other diagnostic and ablation catheters has not been evaluated and Boston Scientific does NOT recommend their use. The potential for blood leakage and air emboli may be increased if catheters with diameter less than 11F are used within the POLARSHEATH Sheath. Monitor the spontaneously-breathing patient for risk factors which may lead to negative left atrial pressures. Negative left atrial pressure may increase the risk of air ingress through the hemostasis valve particularly during insertion and removal of the catheter. Such risk factors may include, among others, pre-existing low left atrial pressure (e.g., noted at time of transseptal puncture), hypovolemia, airway collapse, deep breathing, snoring, or apnea, and may be more prevalent under sedation. Use additional caution when using drugs with respiratory depressive effects in such patients. Do not use the POLARSHEATH Sheath if any part of the catheter shaft appears to be kinked or damaged. If the catheter appears kinked while in the body, remove the device and replace with a new catheter. Do not navigate the POLARSHEATH Sheath through a prosthetic valve (mechanical or tissue). Avoid proximity to all valves whenever possible. Manipulation of the catheter across these structures may result in entanglement and damage to the valve. Take care to minimize damage to the femoral vein and access site upon insertion, manipulation, or withdrawal of the POLARSHEATH Sheath. Complications associated with femoral vein catheterization include hematoma and thrombosis. Regular flushing of the POLARSHEATH Sheath and dilator lumen is recommended to prevent blood stagnation, clots, emboli, and serious patient injury. Prevent any obstruction of the side port to ensure continuity of the saline flush. Rapid removal of the catheters may damage the valve membrane, resulting in blood flow and/or air ingress through the valve. Air ingress may be recognized by the visual presence of air bubbles in the side port tubing or by an audible sucking sound emanating from the hemostasis valve. Imaging modalities employed during the procedure, such as fluoroscopy or intracardiac echocardiography, may also demonstrate the presence of air. If air embolism is suspected, begin appropriate management immediately as indicated by treatment guidelines or consensus statements. Ensure there is no significant blood leakage through the hemostatic valve during the procedure. Connecting POLARSHEATH Sheath to a continuous drip provides forward flow, which can minimize back-bleeding. To minimize unintended back-bleeding through the side port, make sure the stopcock is in a closed position to the POLARSHEATH Sheath at all times unless aspirating or flushing. The POLARSHEATH Sheath and the dilator have not been tested for compatibility with transseptal needles and should not be used as the guiding catheter for a needle in a transseptal puncture procedure. Do not use the POLARSHEATH Sheath if the package is open and/or the sterile barrier is broken. Use prior to the Use By date as labeled on the POLARSHEATH Sheath package label. **PRECAUTIONS** Cardiac catheterization procedures should be performed only in a fully equipped facility. The POLARSHEATH Sheath and its accessories are to be used only by physicians, or under the supervision of physicians, trained in cardiac electrophysiology procedures in properly equipped facilities. **ADVERSE EVENTS** Potential adverse events associated with cannulation of the peripheral vasculature and intracardiac placement of the POLARSHEATH Sheath and dilator may include the following conditions: Arrhythmia (new or exacerbated), Conduction pathway injury. Cardiac arrest. Cardiac trauma, for example: Cardiac perforation/tamponade/effusion, Valvular damage, Stiff left atrial syndrome. Death, Edema/ heart failure/pleural effusion, GI disorders, Hypertension, Hypotension, Infection/inflammation/exposure to biohazardous material. Injury related to tissue damage and/or adjacent structures, for example: Esophageal injury, Pulmonary injury, Catheter entrapment, Physical trauma. Injury due to embolism/ thromboembolism/air embolism/foreign body embolism: CVA/stroke, TIA, MI. Neurological impairment and its symptoms, for example: Cognitive changes, Visual disturbances, Headache, Motor impairment, Sensory impairment. Speech impairment, Pulmonary embolism, Asymptomatic cerebral embolism. Nerve injury, for example: Phrenic nerve injury, Vagal nerve Injury. Pain or discomfort, for example: Angina, Chest pain, Non-cardiovascular pain. Procedural related side effects, for example: Allergic reaction (including anaphylaxis), GU complications, Side effects related to medication or anesthesia, Radiation injury/tissue burn, Renal failure/insufficiency, Vasovagal response. PV Stenosis and its symptoms, for example: Cough, SOB, Fatigue, Hemoptysis. Respiratory distress/insufficiency/dyspnea. Surgical and access complications, for example: Hematoma/seroma, AV Fistula, Bleeding, Pseudoaneurysm, Pneumothorax, Residual atrial septal defect. Thrombus/thrombosis. Vessel Trauma, including: Perforation, Dissection, Coronary artery injury, Vasospasm, Occlusion, Hemothorax. 97078815 (Rev. A)

POLARMAP™ Circular Mapping Catheter INTENDED USE The POLARMAP Catheter is intended to obtain electrograms and provide pacing in cardiac structures in the atrial regions of the heart. **INDICATIONS FOR USE** The POLARMAP Catheter is indicated for electrophysiological mapping (recording or stimulating only) of the cardiac structures of the heart. **CONTRAINDICATIONS** Use of the POLARMAP Catheter is contraindicated as follows: In patients with an active systemic infection as this may increase the risk for endocarditis and sepsis. In patients with a myxoma or an intracardiac thrombus as the POLARMAP Catheter could precipitate an embolic event. In patients with a prosthetic heart valve (mechanical or tissue). In the ventricle of the heart where the POLARMAP Catheter may become entrapped in a valve or chordae structures. In patients with a recent ventriculotomy or atriotomy as this may increase the risk of cardiac perforation or embolic event. In patients with pulmonary vein stents as the POLARMAP Catheter may dislodge or damage the stent. In patients with an interatrial baffle or patch as the transseptal puncture could fail to close. In patients with hypercoagulopathy or an inability to tolerate anticoagulation therapy during an electrophysiology procedure. In conditions where insertion into or manipulation in the atrium is unsafe as this may increase the risk of perforation or systemic embolic event. In patients with intra-atrial septal patch or other surgical intervention in or adjacent to the intra-atrial septum. In patients with a contraindication to an invasive electrophysiology procedure where insertion or manipulation of a catheter in the cardiac chambers is deemed unsafe. **WARNINGS** Introducing catheters into the circulatory system entails risk of air embolism. Always advance and withdraw the POLARMAP Catheter slowly. Minimize catheter exchanges and follow with proper flushing. Administer appropriate levels of peri-procedural anticoagulation therapy for patients undergoing left-sided and transseptal cardiac procedures and for selected patients undergoing right-sided procedures. Administer anticoagulation therapy during and post-procedure according to institution's standards to minimize bleeding and thrombotic complications. Catheter procedures may introduce life threatening arrhythmias. Do not use the POLARMAP Catheter if any part of the catheter shaft appears to be kinked or damaged. If the catheter appears kinked while in the body, remove the device and replace with a new catheter. POLARMAP Catheter placement and manipulation should be performed under fluoroscopy. Exercise care and attention when manipulating the POLARMAP Catheter within the heart. Do not apply excessive force or torque to the POLARMAP Catheter, especially if resistance is encountered. Always rotate the POLARMAP Catheter clockwise. Inappropriate catheter manipulation may result in cardiac injury such as perforation or tamponade or device damage. Avoid positioning the POLARMAP Catheter around the chordae tendineae as this increases the likelihood of entrapment within the heart. Do not navigate the POLARMAP Catheter through a prosthetic valve (mechanical or tissue). Avoid proximity to all valves whenever possible. Manipulation of the POLARMAP Catheter across these structures may result in entanglement and damage to the valve. Do not allow the patient to contact grounded equipment that might produce electrical current leakage during ablation or Direct Current CardioVersion (DCCV). This may result in induced arrhythmias that could result in patient death. Do not connect the POLARMAP Catheter to a radiofrequency (RF) generator or use it to deliver RF energy. This may result in patient harm or device malfunction. Use only isolated equipment (IEC 60601-1 Type CF equipment, or equivalent) with the POLARMAP Catheter, or patient injury or death may occur. Do not allow leakage current from any devices connected to the patient to exceed 10µA under any circumstances. Use caution when manipulating the POLARMAP Catheter in patients with intracardiac devices (catheters, implants, wires, etc). Entanglement with intracardiac devices may require surgical intervention. Significant x-ray exposure during an EP procedure may result in acute radiation injury, as well as increased risk for somatic and genetic effects, to both patients and laboratory staff. Take appropriate precautionary measures to minimize radiation exposure to patients and laboratory staff. **PRECAUTIONS** Do not change the equipment configuration or modify the equipment or applied parts in any way. Doing so may cause the system to behave unreliably and affect the patient adversely. It is the user's responsibility to ensure that the equipment used with the POLARMAP Catheter meets all local applicable electrical safety requirements. Disconnect the POLARMAP Catheter from the EP Electrical Cable prior to cardioversion or defibrillation. Failure to do so may result in damage to any connected EP recording system or equipment. Do not attempt to preshape the POLARMAP Catheter shaft or electrode loop. Do not scrub the catheter or electrode surface. Do not apply organic solvents such as alcohol. If using the POLARx Catheter, loosen the Tuohy valve prior to removal of the POLARMAP Catheter to prevent damage to the POLARMAP Catheter. Do not immerse the POLARMAP Catheter handle or cable connector in fluids; electrical performance could be affected. **ADVERSE EVENTS** Potential adverse events associated with manipulation of the POLARMAP Catheter within the left atrium and pulmonary veins may include the following conditions: Arrhythmia (new or exacerbated), Conduction pathway injury. Cardiac arrest. Cardiac trauma, for example: Cardiac perforation/tamponade/effusion, Valvular damage, Stiff left atrial syndrome. Death, Edema/heart failure/pleural effusion, GI disorders, Hypertension, Hypotension, Infection/inflammation/exposure to biohazardous material. Injury related to tissue damage and/or adjacent structures, for example: Esophageal injury, Pulmonary injury, Catheter entrapment, Physical trauma. Injury due to embolism/thromboembolism/air embolism/ foreign body embolism: CVA/stroke, TIA, MI. Neurological impairment and its symptoms, for example: Cognitive changes, Visual disturbances, Headache, Motor impairment, Sensory impairment, Speech impairment; Pulmonary embolism, Asymptomatic cerebral embolism. Nerve injury, for example: Phrenic nerve injury, Vagal nerve Injury. Pain or discomfort, for example: Angina, Chest pain, Non-cardiovascular pain. Procedural related side effects, for example: Allergic reaction (including anaphylaxis), GU complications, Side effects related to medication or anesthesia, Radiation injury/tissue burn, Renal failure/insufficiency, Vasovagal response. PV Stenosis and its symptoms, for example: Cough, SOB, Fatigue, Hemoptysis. Respiratory distress/insufficiency/dyspnea. Surgical and access complications, for example: Hematoma/seroma, AV Fistula, Bleeding, Pseudoaneurysm, Pneumothorax, Residual atrial septal defect. Thrombus/thrombosis, Vessel Trauma, including: Perforation, Dissection, Coronary artery injury, Vasospasm, Occlusion, Hemothorax. 97078813 (Rev A)

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