

# Initial experience of three-minute freeze cycles using the second-generation cryoballoon ablation: acute and short-term procedural outcomes

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## Abstract

**Background** The second-generation cryoballoon (CB-A) (Arctic Front Advance, Cryocath, Medtronic, MN, USA) might significantly improve procedural outcome with respect to the first-generation balloon. These technological improvements might also question the current recommendation of the need a 4-min freeze to achieve durable pulmonary vein isolation (PVI).

**Objective** The main aim of the study was to analyze the procedural efficacy of a 3-min freeze–thaw cycles with the CB-A balloon in the terms of rates of acute PVI and 6-month outcome.

**Methods** Patients having undergone CB-A for PAF or early persistent AF, with 3-min freeze–thaw cycles were consecutively included in our analysis. Acute procedural success was measured in terms of the rate of PVI. Short-term follow-up was evaluated by the means of 24-h Holters and clinical examinations at regular intervals.

**Results** Fifty-two consecutive patients (35 male (67 %); mean age, 59.8±10.5) were included. Mean procedure and fluoroscopy times were 96±15 and 13.2±8.3 min, respectively. Mean time from groin puncture to catheter extraction was

60.4±20 min. After a mean of 1.5 freeze cycles per vein of 3 min in duration, all 208 (100 %) PVs could be isolated with the CB-A. A total 192 (91 %) veins were isolated during the first freeze. At a mean of 5.7-month follow-up, 82 % of patients were free of AF.

**Conclusion** CB-A is effective in producing PVI by using 3-min-duration freeze cycles. After a mean of 1.5 freeze per vein, freedom from AF was achieved in 82 % of patients at 6-month follow-up.

**Keywords** Cryoballoon · Atrial fibrillation · Ablation · Pulmonary vein isolation · Freeze duration

## 1 Introduction

The second-generation version of the cryoballoon (CB-A) (Arctic Front Advance, Medtronic, MN, USA) has been recently launched on the market with technical modifications designed to significantly improve procedural outcome with respect to the first-generation balloon. The number of injection ports has been doubled, from four to eight, and these have been positioned more distally on the catheter shaft resulting in a larger and more uniform zone of freezing on the balloon surface if compared to the previous version. In fact, the CB might achieve significantly lower temperatures and faster isolation times in comparison to the first-generation device [1]. Furthermore, recent studies conducted on animal models concluded that the second-generation CB achieved durable pulmonary vein isolation (PVI) with significantly shorter freeze cycle duration [2, 3]. In fact, no difference was observed in terms of isolation acute PVI, histological ablation lesion depth, and in circumferential transmural lesions between 2 and 4 min of freezes in canine models. Conversely, 4-min-duration freeze

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cycles were associated to a higher degree of neointimal proliferation leading to stricture in roughly 20 % of PVs, whereas this complication was not observed following 2-min freezes. Although current recommendations tend to advise 4-min-duration applications when using the CB-A, shorter applications might also lead to permanent isolation when using this novel device. In fact, experimental studies found that the size of focal cryolesions plateaued within the 3 min of ablation [4]. Prolongation of ablation beyond this duration did not lead to further increase in lesion depth or volume. Therefore, a longer-than-needed ablation time in a thin structure such as the PV ostial wall may not only prolong procedural times but also potentially increase the risk of complications in important extracardiac structures, such as the phrenic nerve (PN) or the esophagus. Based on the abovementioned considerations, we decided to shorten the duration of freeze cycles to 3 min in our most recent series of patients. In the present study, we report on the acute procedural findings and short-term follow-up in a series of consecutive patients having undergone PVI with the second-generation CB-A delivering 3-min freeze–thaw cycles.

## 2 Methods

### 2.1 Aim of the study

The aim of the study was to analyze the procedural efficacy of 3-min freeze–thaw cycles with the CB-A balloon in the terms of rates of acute PVI and 6-month outcome.

### 2.2 Patient population

#### 2.2.1 Inclusion criteria

Patients having undergone CB-A for PAF or early persistent AF, with 3-min freeze–thaw cycles were consecutively included in our analysis.

#### 2.2.2 Exclusion criteria

The exclusion criteria in our center were any contraindication for the procedure, including the presence of an intracavitary thrombus, uncontrolled heart failure, and contraindications to general anesthesia.

### 2.3 Pre-procedural management

All patients provided written informed consent to the ablation procedure. Structural heart disease was defined as follows: coronary artery disease (CAD), impaired left ventricular ejection fraction (LVEF) <40 %, LV hypertrophy >15 mm, valvular insufficiency >grade 2/4, significant valvular stenosis,

and prior valve replacements. A transthoracic echocardiogram (TTE) was performed within 1 week prior to ablation, enabling assessment of the left ventricular ejection fraction and intracavitary dimensions. To exclude the presence of thrombi in the left atrial appendage, all patients underwent transesophageal echocardiography (TEE) the day before the procedure. Also, patients underwent a pre-procedural CT scan to assess detailed left atrial (LA) anatomy.

### 2.4 Ablation procedure

The ablation procedure was performed under general anesthesia [5]. After having obtained general anesthesia, two right-sided femoral venous accesses were obtained. Conversely to our approach in previous patients when venous accesses were performed immediately before achieving general anesthesia in order to offer anesthesiological personnel central venous access from the beginning of the procedure, and only positioning the electrophysiological catheters once the patient was asleep, we currently only achieve femoral access once the patient is fully sedated. The goal of this approach is to minimize sheath and catheter dwelling time in the patient. After having achieved venous access a 6-Fr decapolar catheter was advanced in the coronary sinus. Then a single transeptal puncture was carried out. After having achieved left atrial access, a 100-IU/kg heparin bolus was given iv. A 0.32 F Emerald exchange wire (Cordis, Johnson and Johnson, Diamond Bar, CA, USA) was advanced in the left superior PV and a steerable 15 F over-the-wire sheath (FlexCath Advance, Cryocath, Medtronic, MN, USA) was positioned in the left atrium. A 20 mm in diameter inner lumen mapping catheter (ILMC) was then advanced in each PV ostium to obtain baseline electrical information. After withdrawing the mapping catheter, a 28-mm double-walled cryoballoon (Arctic Front, Cryocath, Medtronic, MN, USA) was advanced over the wire up to the left atrium, inflated, and positioned in the PV ostium of each vein. Optimal vessel occlusion was considered to have been achieved when selective contrast injection showed total contrast retention with no backflow to the atrium. The degree of balloon occlusion obtained by injection of 50 % diluted contrast medium into the PV was evaluated using a semiquantitative grading, as described previously: grade 4=excellent (full retention of contrast medium without visible outflow) to grade 1=very poor (immediate rapid outflow from the PV) [6]. For each vein, cryoablation consisted of  $\geq 1$  applications lasting 3 min. Usually, the left superior pulmonary vein (LSPV) was treated first, followed by the left inferior (LIPV), right inferior (RIPV), and right superior (RSPV). In order to avoid phrenic nerve palsy (PNP), a complication observed during right-sided PV ablation with the cryoballoon, the decapolar catheter was inserted in the superior vena cava, and diaphragmatic stimulation was achieved by pacing the ipsilateral phrenic nerve with a 1,000-ms cycle and a 20-mA

output. The reason of pacing at such a slow rate was to prevent catheter displacement, due to diaphragmatic contraction, in the early phases of application. During the whole procedure, activated clotting time was maintained over 250 s by supplementing heparin infusion as required.

### 2.5 Assessment of electrical isolation

PV activity was recorded with the ILMC at a proximal site in the ostium prior to ablation in each vein. During ablation, if PVPs were visible during energy delivery, time to isolation was recorded when PVPs completely disappeared or were dissociated from LA activity. If PVPs were not visible during ablation due to a distal positioning of the ILMC, the latter was immediately retracted after completion of the freeze–thaw cycle to a more proximal position in which PVPs had been recorded prior to ablation. If needed, pacing from the distal or proximal CS catheter was performed in order to distinguish far-field atrial signals from PVP recorded on the mapping catheter, for left- and right-sided veins respectively. Evaluation of PVI was performed 10 min in all veins after ablation.

### 2.6 Post-ablation management

Patients were discharged the day following ablation if the clinical status was stable. After the intervention, the patients were continuously monitored with ECG telemetry for at least 18 h. Before hospital discharge, all patients underwent TTE, in order to exclude pericardial effusion, and chest X-ray. Oral anticoagulation was started the evening of ablation and continued for at least 3 months. Antiarrhythmic drug treatment (AAD) was continued for 1 month.

### 2.7 Follow-up

After discharge from the hospital, patients were scheduled for follow-up visits at 1, 3, 6, and 12 months. Twenty-four-hour Holter ECG recordings were obtained at each follow-up visit. All documented AF episodes of >30 s were considered as a recurrence.

### 2.8 Statistical analysis

Data are given as mean and standard deviation (SD) or as absolute values and percentages as appropriate. Comparisons of continuous variables were done with a Student's *t* test or Mann–Whitney *U* as appropriate, while assessment of normal distribution of values was done with Kolmogorov–Smirnov test and binomial variables with chi-square or Fisher test as appropriate. Statistical significance was considered when *p* value <0.05. Statistical analyses were conducted using SPSS software (SPSS v21, IL, USA).

## 3 Results

### 3.1 Baseline population characteristics

A total of 52 (35 male (67 %); mean age, 59.8±10.5) consecutive patients affected by drug resistant AF were included. Forty-three (82 %) individuals presented with PAF and nine (18 %) with short-standing persistent AF. Mean time of AF was 32 months. Mean LA size was 42±7 mm. All patients failed ≥1 class I or III anti-arrhythmic drug (AAD). A total 208 veins were depicted on the pre-procedural CT scan. Four distinct PV patterns were present in 94 % of patients, whereas discrete left common ostium could be observed in 6 % (three patients). Table 1 shows the baseline clinical and anatomical characteristics of the study population.

### 3.2 Procedural characteristics

All patients underwent a procedure with the large 28-mm CB-A. Mean total procedure time and fluoroscopy times were 96±15 and 13.2±8.3 min, respectively. Mean grade of PV occlusion was 3.7. In 17 (8 %) PVs (all RIPVs), a pull-down maneuver [7] was performed to reach isolation because of an

**Table 1** Baseline population characteristics

Age, years (SD)	59.8 (10.5)
Males, <i>N</i> (%)	35 (67)
Paroxysmal AF, <i>N</i> (%)	41 (82)
Duration of symptoms, months (SD)	32.0 (48.1)
BMI, kg/cm <sup>2</sup> (SD)	27 (3.6)
Hypertension, <i>N</i> (%)	17 (32)
Diabetes, <i>N</i> (%)	5 (10)
Dyslipidemia, <i>N</i> (%)	17 (32)
HF, <i>N</i> (%)	2 (4.3)
CHA2DS2VASc (SD)	1.2 (1.3)
LVEF % (SD)	58.3 (6.7)
LA dimension, mm (SD)	42.2 (7.0)
PV common ostium, <i>N</i> (%)	3 (6 %)
PV dimension, mm (SD)	
LSPV minimum	15.2 (9.3)
LSPV maximal	18.8 (3.5)
LIPV minimum	11.8 (3.2)
LIPV maximal	18 (4.1)
RSPV minimum	16.3 (2.9)
RSPV maximal	19.4 (3)
RIPV minimum	14.8 (2.6)
RIPV maximal	16.7 (2.3)

AF atrial fibrillation, BMI body mass index, HF heart failure, LVEF left ventricular ejection fraction, LA left atrium, PV pulmonary vein, LSPV left superior pulmonary vein, LIPV left inferior, RSPV right superior, RIPV right inferior

inferior leak. This maneuver led to isolation in all of these veins. Mean time from groin puncture to catheter extraction were  $60.4 \pm 20$  min. Mean number of freeze–thaw cycles was  $1.5 \pm 0.6$  in the LSPV;  $1.5 \pm 0.4$  in the LIPV;  $1.4 \pm 0.5$  in the RSPV and  $1.4 \pm 0.5$  in the RIPV. Mean minimal temperature in degrees Celsius achieved were  $-53 \pm 6$  in the LSPV;  $-49 \pm 6$  in the LIPV;  $-51 \pm 6$  in the RSPV; and  $-49 \pm 5$  in the RIPV. In case of occurrence of a common ostium, the veins were treated separately (Table 2). The last 14 patients were treated with second-generation steerable sheath (FC-A) (Flex Cath Advance, Medtronic, MN, USA) which offers a significantly higher degree of maneuverability. Interestingly, in these patients, a pull-down maneuver was only needed in one (2 %) to achieve isolation in the RIPV.

### 3.3 PV isolation

All 208 PVs (100 %) could be isolated with the 28-mm CB-A. Isolation could be achieved in 91 % (192) of veins during the first 3 min of freeze. Real-time (RT) recordings could be observed in 55 % of PVs (70 % LSPV, 40 % LIPV, 50 % RSPV, and 43 % RIPV). Mean time to isolation and temperature at isolation were  $47 \pm 30$  s and  $-37 \pm 11$  °C in the LSPV;  $30 \pm 9$  s and  $-26 \pm 10$  °C in the LIPV;  $29 \pm 17$  s and  $-28 \pm 11$  °C in the RSPV; and  $51 \pm 46$  s and  $-32 \pm 11$  °C in the RIPV.

In the first 24 (46 %) consecutive patients, a 3-min bonus freeze was performed in all veins after isolation. Isolation was achieved during the first freeze in 91 out of 96 veins. In the last 28 patients (54 %), a bonus application was not given if PVI was documented after the first freeze. During the first 3-min freeze, 101 out of 112 veins could be acutely isolated. The other 11 were isolated with an additional freeze. In four (2 %) veins, early recovery could be documented. Interestingly, time

to isolation was significantly longer ( $68$  vs  $37$  s;  $p < 0.001$ ) in veins which exhibited early LA-PV reconnection. Single application led to isolation of the latter. Mean time from groin puncture and catheter extraction from the patient, and total fluoroscopy times were significantly lower in patients not having received a systematic bonus freeze ( $52 \pm 11$  vs  $71 \pm 18$  min and  $11 \pm 4$  vs  $19 \pm 11$  min, respectively) (Table 3).

### 3.4 Complications

The most frequent complication observed was transient phrenic nerve palsy (PNP) which occurred in four (8 %) of cases. Two (50 %) occurred during the first application, the others during the second. All PNP (100 %) occurred during ablation in the RSPV. Most patients showed resumption of diaphragmatic capture before the end of the procedure, and all recovered before patient discharge. At the time of PNP, the PVs were isolated. One (2 %) pseudoaneurysm which required surgical treatment occurred. One (2 %) patient experienced hemoptysis the day after ablation. In the latter, OAC was stopped, and the patient was observed clinically. Hemoptysis completely disappeared 2 days later, and standard chest X-ray did not show any abnormality.

### 3.5 Short-term follow-up

At a mean follow-up of  $5.7 \pm 2$  months, 43 (82 %) of patients did not experience AF recurrence. Of these, three (6 %) patients did not stop AADs despite having been instructed to do so at 1 month following the procedure. Mean time to first ECG documented recurrence was  $4 \pm 2.4$  months. The only predictors of AF recurrence were a higher total number of freezes in the PVs ( $p < 0.01$ ). There were no differences in the recurrence rate between patients who underwent a systematic bonus freeze and patients not having received an additional application. Two patients initially affected by short-standing persistent AF underwent repeat ablation because of persistent AF relapse after the first 3 months following the index procedure. In both patients, all eight PVs were isolated. Roof line and CFAE ablation were performed utilizing a focal open-irrigated

**Table 2** Procedure characteristics

Groin puncture to catheter extraction time, min (SD)	60.4(20)
Total procedure time, min (SD)	96 (15)
Fluoroscopy time, min (SD)	13.2 (8.3)
Real-time recording, %	55
LSPV freezes (SD)	1.5 (0.5)
Minimal temperature, °C	-53.4 (5.8)
LIPV freezes (SD)	1.5 (0.5)
Minimal temperature, °C	-49.4 (5.8)
RSPV freezes (SD)	1.4 (0.5)
Minimal temperature, °C	-51.2 (6.2)
RIPV freezes (SD)	1.4 (0.5)
Minimal temperature, °C	-49.7 (6)
Complications (%)	
Groin pseudoaneurysm	2
Phrenic nerve palsy	8

LSPV left superior pulmonary vein, LIPV left inferior, RSPV right superior, RIPV right inferior

**Table 3** Pulmonary vein isolation characteristics

LSPV	Time to isolation, s	47 (30)
	Temperature at isolation, °C	-37 (11)
LIPV	Time to isolation, s	30 (9)
	Temperature at isolation, °C	-26 (10)
RSPV	Time to isolation, s	29 (17)
	Temperature at isolation, °C	-28 (11)
RIPV	Time to isolation, s	51 (46)
	Temperature at isolation, °C	-32 (11)

LSPV left superior pulmonary vein, LIPV left inferior, RSPV right superior, RIPV right inferior



tip RF ablation catheter guided by 3D electroanatomical mapping.

#### 4 Discussion

To the best of our knowledge, this is the first study reporting on acute procedural outcomes and short-term follow-up of CB-A ablation with 3-min-duration freeze–thaw cycles. The main findings of our study are that (1) acute PVI with the CB-A could be achieved in all veins with a 3-min-duration freeze–thaw cycle following a mean of 1.5 applications; (2) 3 min of single freeze isolation could be achieved in a high number of veins; (3) the mean time to isolation documented by RT recordings was 40 s; (4) the most frequently observed complication was transient PNP; and (4) the freedom from AF at a short-term follow-up period of 6 months was 82 %.

Recently, Andrade et al. [2] elegantly compared the effects of 2 vs 4 min of freeze cycles by using the CB-A ablation in canine models. Interestingly, the authors did not observe significant differences between both freeze durations in terms of acute PVI, histological ablation lesion depth, and in circumferential transmural lesions. On the contrary, 4-min freezes were associated with thicker neointima proliferation leading to PV stricture in 6 out of 30 veins. No stricture occurred in the veins ablated with 2 min of freeze cycles. Although conducted on canine models, these findings are important. In fact, the current recommendation of performing 4-min freezes might be obsolete in the setting of cryothermal balloon ablation with the second-generation device.

In our study, 3 min of freeze cycles proved to be effective in achieving PV isolation in all veins by using 28 mm diameter CB-A. After a mean of 1.5 freezes, all PVs could be acutely isolated considering a systematic bonus freeze in the first 24 patients. This result is comparable with the recent publication by Furnkranz et al. [1] which reported on a mean of  $1.3 \pm 0.8$  freezes per vein to achieve isolation by utilizing 4 min of cycles if the bonus freeze was not taken into consideration.

In the abovementioned article by Andrade et al., single freeze isolation occurred in roughly 90 % of veins irrespective of cycle duration (2 or 4 min). In their observation, Furnkranz et al. reported on a “single shot” success of 84 %. Similar findings were reported in a recent publication by Metzner et al [8]. Although conducted in a small cohort of patients, the rates of PVI in our study achieved with 3 min of single freeze cycles were comparable with those of the abovementioned studies. In fact, PVI following single freeze could be achieved in 91 % of veins. This slightly higher percentage in comparison to the study by Furnkranz et al. might have various explanations. First, in roughly 20 % of patients, the CB-A was utilized in conjunction with the FC-A steerable sheath which offers a significantly larger maneuverable angle. This novel tool permitted to achieve successful occlusion in a large proportion of

RIPVs. The FC-A was not used in previous studies. Furthermore, in our series, the number of LCPV was inferior. In addition, the latter were discrete permitting a selective approach in both the superior and inferior PV. Larger and longer “common portions” might have hampered complete isolation of the left-sided PVs. Finally, it should be underlined that conversely to Metzner et al. [8], we did not use a standard circular mapping catheter to confirm PVI. In fact, a recent publication by Kuhne et al. [9], describing a single-center experience conducted on patients undergoing ablation with the first-generation CB in conjunction with an ILMC, concluded that validation of PVI with a standard CMC could be confirmed in only 93 % of veins. Therefore, bearing this in mind, the rate of acute isolation after a single freeze in our study might have been overestimated.

In our observation, RT recordings could be documented in 55 % of veins. Although the time to isolation occurred in a mean few seconds faster than that in the article of Furnkranz et al. (40 vs 52 s), our findings are in line with very recent experimental data published on the CB-A [2]. Furthermore, if compared to data available with the first CB, time to isolation seems to occur in a shorter time [1]. This might be the result of the significant technological improvements in the CB-A which leads more uniform cooling around its circumference and in its distal portion. Hypothetically, shorter times to isolation might indicate faster transmural lesions of the thin PV antral wall in comparison to the first-generation CB.

Although freeze duration was reduced, PNP was the most common complication and occurred in 8 % of individuals [9–11]. When PNP occurred, PVI had been achieved in all veins. In 50 % of cases, PNP occurred during the second freeze. This might indicate a progression in the depth of the lesion during the second freeze which might question the need of a bonus application if isolation is achieved during the first cycle. In fact as mentioned above, the new CB-A might achieve transmural of the thin PV antral wall in a shorter time in comparison to its predecessor and create unnecessary damage to deeper layers of extracardiac structures. Although all PNP's reverted before discharge, this percentage remains quite high, and immediate recognition is of utmost importance to avoid irreversibility. Recently, Franceschi et al. [12, 13] described a sophisticated monitoring method that might help preempting this complication. In our study, the latter was not performed. Future studies analyzing possible predictors of PNP during CB-A ablation are warranted. In addition, esophageal damage ranging from superficial thermal lesions to ulcerations might occur in a significant amount of patients during CB-A. According to two recent articles [8, 14], endoluminal esophageal temperature seems to reliably predict the occurrence of such complications with suggested cutoff values of  $<+10$  and  $<+12$  °C, respectively. In our study, no patient experienced symptoms suggesting esophageal damage. However, as esophageal lesions in the setting of CB-A are usually

asymptomatic and no systematic endoluminal temperature measurement was adopted nor esophagoduodenoscopy (EGDS) was performed following ablation, we cannot completely rule out the occurrence of such complication. Therefore, although most esophageal lesions in the setting of CB-A have favorable prognosis following ablation, an endoluminal temperature probe during this procedure might help in preventing this collateral effect.

At 6-month follow-up, 82 % of patients were free of AF. Articles describing success rates at 6-month follow-up after first-generation device CB report on freedom from AF ranging between 60 and 86 % [6, 15–18]. However, it should be highlighted that the latter analyzed clinical outcome in patients having undergone first-generation CB ablation with two or more applications per vein and with dual balloon sizes in a large single center study in a substantial proportion of patients. Furthermore, the only study among these reporting a success rate higher than 80 % [18] with single-size CB was conducted on a very small number of patients and described an experience with both 23- and 28-mm balloons, and all patients were exclusively affected by PAF. Although, in the present study the follow-up is too short to draw any substantial conclusion, the success rate following 3-min freeze cycles certainly appears promising.

Finally, predictors of AF recurrence were an increased total number of freezes. A higher number of freezes might have indicated more challenging veins to isolate, therefore potentially more prone to later reconnect with the LA.

## 5 Limitations

Our study bares a few limitations. First, the study was conducted on a limited number of patients which might, in itself, create a limit in drawing substantial conclusions. In fact, the main aim of our study was to describe an initial experience with 3-min-duration freeze cycles. Therefore, it is obviously premature at this stage in time to recommend a reduction in freeze duration during second-generation CB ablation. Large randomized studies with longer follow-up are needed. Second, based on published data which seem to indicate that early reconnection might only occur in a very small portion of veins following CB ablation [19], we observed for LA-PV recovery for only 10 min following the last freeze–thaw cycle. Longer waiting times might have led to the detection of higher rates of LA-PV reconnection. Third, we did not use the cMAP technique to monitor PN activity. Therefore, the rate of PNP might have been lower than that observed if this promising technique would have been utilized. Fourth, the new CB-A seems to be associated to a higher rate of esophageal lesions [8, 14]. We did not perform a systematic intraprocedural endoluminal esophageal temperature monitoring nor EGDS to verify the presence of this complication. Therefore, the complication rate might

have been underestimated. Furthermore, as stated previously, the Achieve inner lumen mapping catheter might be slightly less reliable than the classical circular mapping catheter in documenting PVI. Therefore, the rate of isolated veins in our observation might have been overestimated [9]. Finally, no patient was implanted with an internal loop recorder. Therefore, asymptomatic episodes might have occurred unnoticed, and our success rate might have been overestimated.

## 6 Conclusions

CB-A is effective in producing PVI by using 3-min-duration freeze cycles. Furthermore, electrical isolation can be achieved in a significantly high number of veins after a single 3-min freeze cycle. On a short-term follow-up of 6 months, freedom from AF was achieved in 82 % of patients. Very short time to isolation and a high rate of PNP occurring during bonus applications might question the need of further cryoenergy cycles if isolation is achieved during the initial freeze with the second-generation CB-A.

**Conflict of interest** GBC, AS, and CdA receive compensation for teaching purposes from AF solutions Medtronic. GBC receives compensation for proctoring purposes from AF solutions, Medtronic. PB has received speaker fees from AF solutions.

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