

**TITLE****227F1 FREEZOR® XTRA, US, LABEL IMAGE SPECIFICATION**

Rev	Revision Description	Change Order
1A	Initial release	CO10154502

1. This label image is the combination of the FormScape template file, PDPS model data record, and a representative view of the label set die lines.
2. The lot number, use by date, manufacturing date if applicable, product number (REF) and barcode information is shown for example only. The real data will be included at the time of manufacture.
3. Use by date: Two years from date of sterile packaging.
4. This label should be printed using a 300 dpi thermal transfer printer or equivalent.
5. Spacing and text wrapping shown in image may differ slightly from actual printed label. Content of printed version must be accurate.
6. The label printed in manufacturing must be at an equal or later Model data and Template revision as shown on the following image.
7. This file is controlled by CRDM Package Engineering.
8. The two character serial identifier, represented as XX, below the data matrix code is optional for printed labels in manufacturing. The two character serial identifier will only show when it is included with the lot number.

Medtronic
Freezor® Xtra
227F1

REF 227F1
Reorder number

LOT W00000000W
Lot number

0000-00-00
YYMMDD

Use by

Package contents:
1x
Cardiac CryoAblation Catheter

Diagram showing dimensions:
Total length: 108 cm
Tip diameter: 2.5 mm
Shaft diameter: 7 Fr
Distal electrode length: 6 mm
Electrode width: 2-5.2 mm
Base diameter: 49 mm

Sterile EO
Sterilized using ethylene oxide
Do not use if package is damaged
Do not reuse
Fragile: handle with care
15°C — 30°C
59°F — 86°F
Storage temperature

Consult instructions for use
Do not sterilize
Keep dry

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

Manufacturer
Medtronic CryoCath LP
9000 Autoroute Transcanadienne
Pointe-Claire, Quebec, H9R 5Z8
Canada
www.medtronic.com
Made In Canada

Medtronic REF 227F1 Reorder number LOT W00000000W Lot number	[Barcode]
Medtronic REF 227F1 Reorder number LOT W00000000W Lot number	[Barcode]
Medtronic REF 227F1 Reorder number LOT W00000000W Lot number	[Barcode]
Medtronic REF 227F1 Reorder number LOT W00000000W Lot number	Lot to: 0000-00-00 YYMMDD
Medtronic REF 227F1 Reorder number LOT W00000000W Lot number	Lot to: 0000-00-00 YYMMDD
Medtronic REF 227F1 Reorder number LOT W00000000W Lot number	Lot to: 0000-00-00 YYMMDD

(01)00000000000000(17)00000010W0000000000W

MEDT013B002 1A-MN26ATBD001 1A

P020045/S
6-24



Carton Label

Freezor® Xtra
227F1

Freezor® Xtra
227F1

REF 227F1
Reorder number

LOT W00000000W
Lot number

0000-00-00
Use by

Package contents: 1x Cardiac CryoAblation Catheter Product documentation

STERILE EO Sterilized using ethylene oxide
Do not reuse
Consult instructions for use
Do not resterilize

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

Manufacturer
Medtronic CryoCath LP
9000 Autoroute Transcanadienne
Pointe-Claire, Quebec, H8R 5Z3
Canada
www.medtronic.com
Made in Canada

M426472B001 1A - C

Label Type LblTop



Note: Image is not to scale

Bottom Carton Label

LOT	W00000000W		85% Humidity limitation
Lot number			
	Keep dry		Fragile: handle with care
	-35°C — 58°C -31°F — 136°F Transit temperature		15°C — 30°C 59°F — 86°F Storage temperature
			
	Medtronic	REF 227F1 Reorder number	
			
(01)0000000000000000(17)000000(10)W00000000W YYMMDD			
M426013B002 1A-M426475B001 1A - B			

Label Type Lbl1End

Note: Image is not to scale

**TITLE****227F3 FREEZOR® XTRA, US, LABEL IMAGE SPECIFICATION**

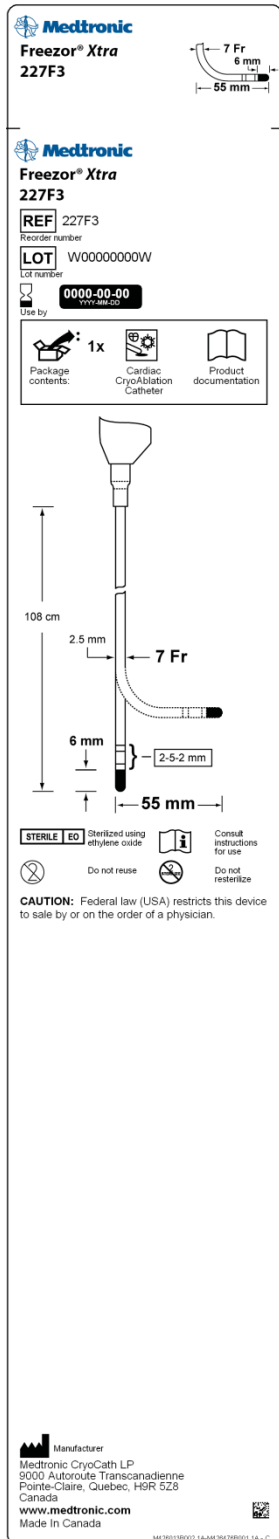
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Carton Label



Label Type LblTop

Note: Image is not to scale

Bottom Carton Label

LOT	W00000000W		Humidity limitation
Lot number			
	Keep dry		Fragile: handle with care
	-35°C — 58°C -31°F — 136°F Transit temperature		15°C — 30°C 59°F — 86°F Storage temperature
			
	Medtronic	REF 227F3	Reorder number
			
(01)00000000000000(17)000000(10)W00000000W YYMMDD			
M426013B002 1A-M426476B001 1A - B			

Label Type Lbl1End

Note: Image is not to scale

**TITLE****227F5 FREEZOR® XTRA, US, LABEL IMAGE SPECIFICATION**

Rev	Revision Description	Change Order
1A	Initial release	CO10154502

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2. The lot number, use by date, manufacturing date if applicable, product number (REF) and barcode information is shown for example only. The real data will be included at the time of manufacture.
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Carton Label

Freezor® Xtra
227F5

Freezor® Xtra
227F5

REF 227F5
Reorder number

LOT W00000000W
Lot number

0000-00-00
YYMMDD
Use by

1x
Package contents

Cardiac CryoAblation Catheter

Product documentation

STERILE EO Sterilized using ethylene oxide

Consult instructions for use

Do not reuse

Do not resterilize

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

Manufacturer
Medtronic CryoCath LP
5000 Autoroute Transcanadienne
Pointe-Claire, Quebec, H9R 5Z8
Canada
www.medtronic.com
Made in Canada

M426474B001 1A - C

Label Type LblTop

Note: Image is not to scale

Bottom Carton Label

LOT	W00000000W		Humidity limitation
Lot number			
	Keep dry		Fragile: handle with care
	-35°C — 58°C -31°F — 136°F Transit temperature		15°C — 30°C 59°F — 86°F Storage temperature
			
	Medtronic	REF 227F5	Reorder number
 (01)0000000000000000(17)000000(10)W00000000W YYMMDD M426013B002 1A-M426477B001 1A - B			

Label Type Lbl1End

Note: Image is not to scale



Medtronic

FREEZOR® XTRA
227F1, 227F3, 227F5

Cardiac CryoAblation Catheter

Technical Manual

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

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Freezor, Medtronic

Explanation of symbols

	Lot number
	Reorder number
	Use by
	Sterilized using ethylene oxide
	Do not reuse
	Do not resterilize
	Do not use if package is damaged
	Package contents
	Cardiac cryoablation catheter
	Consult instructions for use
	Fragile: handle with care
	Keep dry
	Product documentation
	Humidity limitation
	Storage temperature
	Transit temperature
	Open here
	Manufacturer

1 Description

The Freezor Xtra Cardiac CryoAblation Catheter is a flexible, steerable catheter used to ablate cardiac tissue. It is used together with the CryoConsole and related components. The tip of the Freezor Xtra catheter reaches cryoablation temperatures when refrigerant is injected from the CryoConsole to the tip of the catheter. The catheter tip has an integrated type T thermocouple for temperature reading capability. The catheter is introduced into the pericardial space by traditional minimally invasive techniques or directly during surgical cardiac procedures. The Freezor Xtra catheter is available in 3 models, as described in the following table:

Model	Curves available
227F1	49 mm
227F3	55 mm
227F5	60 mm

For details about the CryoConsole and how to use it with the catheter to perform cryoablation procedures, see the *CryoConsole Operator's Manual*.

1.1 Contents of package

The Freezor Xtra Cardiac CryoAblation Catheter is supplied sterile. The package contains the following items:

- 1 Freezor Xtra Cardiac CryoAblation Catheter
- Product documentation

2 Indications for use

The Freezor Xtra Cardiac CryoAblation Catheter, CryoConsole system, and related accessories are indicated for the cryoablation of the conducting tissues of the heart in the treatment of patients with atrioventricular nodal reentrant tachycardia (AVNRT). The Freezor Xtra catheter is also intended for minimally invasive cardiac surgery procedures, including surgical treatment of cardiac arrhythmias. The Freezor Xtra catheter freezes the target tissue and blocks the electrical conduction by creating an inflammatory response or cryonecrosis.

3 Contraindications

The Freezor Xtra Cardiac CryoAblation Catheter is contraindicated in patients with the following conditions:

- Active systemic infections
- Cryoglobulinemia
- Other conditions where the manipulation of the catheter would be unsafe (for example, intracardiac mural thrombus)

4 Warnings and precautions

Cryoadhesion – Do not pull on the catheter, sheath, umbilical cables, or console while the catheter is frozen to the tissue, as this may lead to tissue injury.

Improper connection – Do not connect the cryoablation catheter to a radio frequency (RF) generator or use it to deliver RF energy. Doing this may cause catheter malfunction or patient harm.

RF ablation – Before powering up an RF generator or applying RF energy, disconnect the cryoablation catheter from the CryoConsole to avoid an error message and unnecessary catheter replacement.

Pressurized refrigerant – The catheter contains pressurized refrigerant during operation. Release of this gas into the body or circulatory system due to equipment failure or misuse could result in gas embolism, pericardial tamponade, tissue emphysema or other patient injury.

Induced arrhythmias – Catheter procedures may mechanically induce arrhythmias.

Fluoroscopy during catheter placement – The use of fluoroscopy during ablation procedures presents the potential for significant x-ray exposure to both patients and laboratory staff. Extensive exposure can result in acute radiation injury and increased risk for somatic and genetic effects. Only perform ablation after giving adequate attention to the potential radiation exposure associated with the procedure, and taking steps to minimize this exposure. Give careful consideration before performing ablation procedures on or near pregnant women.

Endocardial catheter positioning around the chordae tendinae – Avoid positioning the catheter around the chordae tendinae, as this increases the likelihood of catheter entrapment within the heart, which may necessitate surgical intervention or repair of injured tissues.

Endocardial cryoablation near prosthetic heart valves – Do not pass the catheter through a prosthetic heart valve (mechanical or tissue). The catheter may become trapped in the valve, damaging the valve and causing valvular insufficiency or premature failure of the prosthetic valve.

Do not resterilize – Do not resterilize this catheter for purpose of reuse. Resterilization may compromise the structural integrity of the catheter or create a risk of contamination from the catheter that could result in patient injury, illness, or death.

For single use only – This catheter is intended only to be used once for a single patient. Do not reuse, reprocess, or resterilize this catheter for purpose of reuse. Reuse, reprocessing, or resterilization may compromise the structural integrity of the catheter or create a risk of contamination of the catheter that could result in patient injury, illness, or death.

Catheter handling –

- Do not use excessive force to advance or withdraw the catheter, especially if resistance is encountered.
- Use extreme care when manipulating the catheter. Lack of careful attention can result in injury such as perforation or tamponade.
- Do not use the catheter if it is kinked, damaged, or cannot be straightened.
- Straighten the cooling segment before inserting or withdrawing the catheter.
- Do not at any time preshape or bend the catheter shaft or cooling segment. Bending or kinking the catheter shaft may damage internal structures and increase the risk of catheter failure. Prebending of the distal curve can damage the catheter.
- Catheter advancement should be performed under fluoroscopic guidance.

Biohazard disposal – Discard all used catheters and sterile components in accordance with hospital procedures.

Leakage current from connected catheters – Use only isolated equipment (IEC 60601-1 Type CF equipment, or equivalent) with the CryoConsole and catheters or patient injury or death may occur.

System compatibility – Use only Medtronic cryoablation catheters, refrigerant tanks, and components with the CryoConsole. The safety and use of other catheters or components has not been tested.

Sterile package inspection – Inspect the sterile packaging and catheter prior to use. If the sterile packaging or catheter is damaged, do not use the catheter. Contact your Medtronic representative.

Catheter integrity – Do not use the catheter if it is kinked or damaged. If the catheter becomes kinked or damaged while in the patient, remove it and use a new catheter. Prior to injecting, the physician should ensure that there is no kink in the catheter.

Required use environment – Cryoablation procedures should be performed only in a fully equipped facility.

Qualified users – This equipment should be used only by or under the supervision of physicians trained in surgical or endocardial cryoablation procedures.

Fluid incursion – Do not expose the catheter handle or coaxial and electrical connectors to fluids or solvents. If these components become wet, the cryoablation system may not function properly, and connector integrity may be compromised.

Cardioversion/defibrillation during ablation procedure – Disconnect the catheter's electrical connection prior to cardioversion/defibrillation. Failure to do so may trigger system messages indicating a need for catheter exchange.

Coronary vessels – Cryoablation involving coronary vessels with liquid nitrous oxide systems has been associated with subsequent clinically significant arterial stenosis. Care should be taken to minimize unnecessary contact with coronary vessels during cryoablation.

Anticoagulation therapy – Administer appropriate levels of peri-procedural anticoagulation therapy for patients undergoing endocardial right-sided procedures. Administer anticoagulation therapy before and after the procedure according to the hospital standards.

Embolism risk – Introducing any catheter into the circulatory system entails the risk of air or gas embolism, which can occlude vessels and lead to tissue infarction with serious consequences. Always advance and withdraw components slowly to minimize the vacuum created and therefore minimize the risk of air embolism.

5 Adverse events

Potential adverse events associated with cardiac catheter cryoablation procedures include, but are not limited to, the following conditions:

- Access site complications (e.g., hematoma, infection, thrombosis, ecchymosis, AV fistula, bleeding from puncture site, hemorrhage)
- Arrhythmia (including new or worsening existing arrhythmias)
- Cardiac arrest
- Cardiac tamponade/perforation
- Catheter entrapment in cardiac structures requiring surgical intervention
- Chest discomfort, pain or pressure
- Coronary artery spasm, dissection, thrombosis
- Damage to adjacent organs/structures
- Death
- Endocarditis
- Heart block, partial or complete, potentially requiring permanent pacemaker
- Hematoma
- Hemothorax
- Infection/sepsis
- Myocardial infarction
- Pericardial effusion
- Pericarditis
- Pleural effusion
- Pneumothorax
- Pseudoaneurysm
- Pulmonary edema
- Pulmonary embolism
- Stroke/transient ischemic attack/embolism
- Thrombosis
- Valvular damage
- Vascular complication (e.g., stenosis)
- Vasovagal reaction

6 Clinical study

6.1 Study design

The Freezor Xtra Catheter, Cryoablation CryoConsole system, and related accessories were evaluated in a clinical study for the treatment of atrioventricular nodal reentrant tachycardia (AVNRT) using an endocardial approach. The study was designed as a prospective multicenter, nonrandomized, single arm, unblinded, investigational clinical study to assess the safety and effectiveness of the catheter used percutaneously in the treatment of AVNRT. There were 34 total centers (8 in Canada, 26 in the US) that enrolled subjects. Subjects with a study procedure attempt were followed for a minimum of 6 months and up to 3 years post study cryoablation procedure. Postprocedure follow-up visits included phone follow-up at 8 days, in-person visits at 1, 3, and 6 months, and annual phone follow-up visits at 1, 2, and 3 years. Unscheduled visits occurred, as needed, for the continued evaluation of the safety and effectiveness of the device in the treatment of AVNRT in enrolled subjects.

6.2 Study endpoints

The primary endpoints for the study were as follows:

Chronic safety - defined as the absence of serious complications associated with the catheter or use of the catheter during the procedure or within the six months post-ablation

Chronic efficacy - defined as the following:

- At the conclusion of the ablation procedure assessment: inability to induce more than one echo beat by the same pacing maneuvers that induced AVNRT prior to the procedure
- During the 6 months post ablation: no recurrence of clinical AVNRT

Chronic safety and effectiveness were analyzed by calculating at a one-sided 0.025 significance level to meet the following pre-specified performance goals through 6 months of follow-up:

- 7% of subjects experiencing at least one safety event
- 83% of subjects achieving chronic effectiveness success

6.3 Description of subjects

A total of 572 subjects were enrolled in the study. Of the 572 enrolled subjects, 397 met study criteria and underwent cryoablation, which comprised the cohort used for primary endpoint analyses.

Of the 175 ineligible subjects, 22 subjects exited the study prior to the EP study, 150 had an EP study but did not receive cryoablation due to not meeting post-EP inclusion or meeting post-EP exclusion criteria, 2 subjects met all inclusion and no exclusion criteria but were not treated due to an inability to induce AVNRT, and 1 subject was treated despite being ineligible for the study.

Subject description	N
Consented	572
Exited prior to EP study	22
EP study	550
Exited at conclusion of EP study (not eligible)	150
Not exited at conclusion of EP study (treated, but not eligible)	1
Intent-to-treat (ITT) could not reproduce AVNRT	1
ITT exited due to extremely long time to induce AVNRT	1
Analysis Populations	N
ITT:	399
All subjects who have signed the ICY-AVNRT consent form and have met all pre-EP and post-EP study inclusion and no exclusion criteria.	
Modified Intent-to-Treat (mITT):	397
All subjects within the ITT set who had cryoablation application(s) applied with a Freezor Xtra cardiac cryoablation catheter.	

6.4 Baseline demographics

The majority of subjects enrolled in the study were female (279/397; 70.3%) with a median age of 54 years. A large majority of subjects were of White or Caucasian Race (353/397; 88.9%).

Subject Characteristics	N (%)
Gender (N, %)	397 (100.0%)
Male	118 (29.7%)
Female	279 (70.3%)
Age (years)	

N	397 (100.0%)
Mean +/- Standard Deviation	52.6 +/- 13.9
Median	54.0
25th Percentile – 75th Percentile	44.0 - 62.0
Minimum – Maximum	18.0 - 84.0
Race/ Ethnic Origin (N, %)	
Subject/physician chose not to provide information	10 (2.5%)
Not reportable per local laws or regulations	0 (0.0%)
American Indian or Alaska Native	1 (0.3%)
Asian	10 (2.5%)
Black or African American	16 (4.0%)
Hispanic or Latino	4 (1.0%)
Native Hawaiian or Pacific Islander	0 (0.0%)
White or Caucasian	353 (88.9%)
Two or more races	1 (0.3%)
Other race	2 (0.5%)

6.5 Medical history

AVNRT:

Subjects must have had an SVT compatible with AVNRT documented by ECG, TTM, Holter, or event monitor for inclusion in the study. The average SVT cycle length was 345.2 ± 65.2 ms with QRS duration of 86.7 ± 24.0 ms.

No subject had exclusionary AV block (Atrioventricular block [1° (PR interval ≥ 220 ms), 2°, 3°] or left bundle branch block) present at baseline. Some form of bundle branch block presence was reported in 16 subjects (16/397; 4.0%), with the majority of those (10/397; 2.5%) reporting right bundle branch block. Four (4) subjects (1.0%) had electrical alternans present.

6.6 Cryoablation procedure data

Procedure time:

The average total procedure time (period of time between puncture of the skin to obtain venous access for the EP study to the final ECG performed at the end of the cryoablation procedure) was 149.1 ± 55.5 minutes (median 142.0 minutes). Fluoroscopy time for the total procedure was 11.51 ± 9.4 minutes (median 9.0 minutes).

The ablation procedure time is the time from first ablation catheter insertion to last ablation catheter removal. The portion of the procedure in which ablations were performed averaged 89.48 ± 40.3 (median 80.0 minutes). These times include a 30-minute waiting period to evaluate slow pathway recovery. Fluoroscopy time from the first cryoapplication to the last cryoapplication averaged 4.8 ± 5.9 minutes (median 3.1 minutes) in the ablated subjects.

Procedure Characteristics	Index Procedures (N = 397)
Total procedure time (Min)	
N	397 (100.0%)
Mean +/- Standard Deviation	149.1 +/- 55.49
Median	142.0
25th Percentile – 75th Percentile	109.0 - 180.0
Minimum – Maximum	52.00 - 417.0
Total fluoroscopy time (Min)	
N	394 (99.2%)
Mean +/- Standard Deviation	11.51 +/- 9.36
Median	9.00
25th Percentile – 75th Percentile	5.70 - 14.40
Minimum – Maximum	0.02 - 95.98
Total ablation procedure time (Min)	
N	397 (100.0%)
Mean +/- Standard Deviation	89.48 +/- 40.32
Median	80.00
25th Percentile – 75th Percentile	62.00 - 110.0
Minimum – Maximum	24.00 - 390.0
Total ablation fluoroscopy time (Min)	
N	367 (92.4%)
Mean +/- Standard Deviation	4.78 +/- 5.89
Median	3.10
25th Percentile – 75th Percentile	1.10 - 6.20
Minimum – Maximum	0.02 - 57.00

Energy applications:

Of 3628 energy applications, the majority reported sinus rhythm (3037, 83.7%) during the application. The average application duration was 146.5 ± 97.5 seconds and temperature was -76.2 ± 12.4 C.

Ablation locations were defined as 6 numbered zones within Koch's triangle (the area bounded by the coronary sinus orifice, tendon of Todaro, and atrioventricular node); locations and energy application percentages as follows:

- 1 – Superior (6.8%)
- 2 – Mid (45.0%)
- 3 – Inferior (34.9%)
- 4 – Below coronary sinus ostium (3.4%)
- 5 – Antrum of coronary sinus ostium (9.3%)
- 6 – Coronary sinus (0.5%)

The majority of Freezor Xtra Catheter energy applications (1634/3628, 45.0%) were at Location 2 (Mid), followed by inferior (Location 3, 1267/3628, 34.9%).

AV block assessment:

No subjects received a permanent pacemaker due to AV block as a result of the study procedure or Freezor Xtra Catheter.

There were 3 (3/397, 0.76%) adverse events of 1st degree AV block in 3 subjects, first observed at the pre-discharge visit. These events were adjudicated by the Adverse Events Adjudication Committee (AEAC) as not serious, and related to both the Freezor Xtra Catheter and the cryoablation procedure. Those 3 subjects had 1st degree AV block observed during at least one subsequent follow-up visit over the 6 month follow-up period.

Acute procedural success:

Following a postprocedure 30-minute waiting period, investigators assessed procedural success (the inability to induce more than one echo beat by the same pacing maneuvers that induced AVNRT before cryoablation).

Acute procedural success was reported in 95.2% (378/397) of cases. Of the 378 acute procedural successes, 71.7% had no remaining AV node echo beats.

Freezor Xtra Catheter Acute Procedural Success	Acute Procedural Successes (N=378)
Number of remaining AV node echo beats	
0	271 (71.7%)
1	107 (28.3%)
Freeze-thaw-freeze performed at the successful site?	
Yes	357 (94.4%)

Did the physician report that the catheter location changed between the 2 applications?

No	353 (98.9%)
Yes	4 (1.1%)

6.7 Safety Results

Cryoablation treatment was performed on 397 mITT subjects, of which 4 had a primary safety event through 6 months of follow-up.

A primary safety event is defined as the occurrence of any adverse event that meets the following criteria:

- Adjudicated by the AEAC as being serious and study ablation procedure-related and/or Freezor Xtra Catheter-related that results in death, a life-threatening illness or injury, permanent impairment of a body function or permanent damage to a body structure
- Necessitates significant intervention, such as major surgery or even intravenous medical therapy (e.g. vasopressors), to prevent permanent impairment of a body function or permanent damage to a body structure
- Requires in-patient hospitalization or a prolongation of an existing hospital stay

All 4 primary safety events were classified as serious and procedure-related. None of the 4 events was considered related to the Freezor Xtra Catheter.

1. Cardiac tamponade: adjudicated by the AEAC to be related to the EP procedure and diagnostic catheter.
2. Incision site hemorrhage: adjudicated by the AEAC to be related to the procedure and the sheath.
3. Pulmonary embolism: adjudicated by the AEAC to be related to the procedure (occurred 25 days postprocedure).
4. Device difficult to use: adjudicated by the AEAC to be related to the EP procedure and the diagnostic catheter.

The rate of primary safety events through 6 months was 1.0%, which is below the predefined performance goal of 7.0%.

Table 1. Primary safety objective

Chronic safety	Kaplan-Meier estimate at 6 months (%)	95% Two-sided confidence interval ¹	P-value for H ₀ : P _s < 0.07
Treated subjects with at least one chronic safety event through 6 months	1.0%	(0.4%, 2.7%)	<0.0001

¹ Kaplan-Meier log-log confidence interval

6.8 Effectiveness

Subjects must have met both of the following acute and chronic conditions to be considered a chronic effectiveness (treatment) success:

- Acute success: The inability to induce more than one echo beat by the same pacing maneuvers that induced AVNRT before cryoablation (with drug provocation if required for induction before cryoablation) at the conclusion of the study cryoablation procedure assessment
- Chronic success: Lack of documented recurrence of clinical AVNRT during the 6-month follow-up period after the study cryoablation procedure

Cryoablation treatment was performed on 397 mITT subjects, of which 29 had a chronic effectiveness failure through six months of follow-up. There were 19 failures due to acute failure (at the conclusion of the ablation procedure assessment, performed 30 minutes post-procedure), and 10 due to recurrence of AVNRT documented between procedure and 6 months post procedure.

Freedom from AVNRT through 6 months was 92.6%, which is above the pre-defined performance goal of 83.0%.

Table 2. Primary effectiveness objective

Chronic effectiveness	Kaplan-Meier estimate at 6 months (%)	95% Two-sided confidence interval ¹	P-value for H ₀ : P _E > 0.83
Treated subjects without acute procedural failure or AVNRT recurrence through 6 months	92.6%	(89.5%, 94.8%)	<0.0001

¹ Kaplan-Meier log-log confidence interval

7 Instructions for use

7.1 Connect the catheter

To connect the catheter, follow these steps. (For more detailed instructions, refer to the *CryoConsole Operator's Manual*.)

1. Connect the auto connection box to the CryoConsole.
2. Connect the catheter to a sterile coaxial umbilical cable and a sterile electrical umbilical cable.
3. Connect the coaxial umbilical cable to the CryoConsole, and connect the electrical umbilical cable to the auto connection box.

Note: Use adequate signal clipping on distal ablation channel to allow continuous monitoring of other signals on the EP recording system.

7.2 Perform cryoablation

To perform cryoablation, follow these steps. (For CryoConsole operating instructions, refer to the *CryoConsole Operator's Manual*.)

Notes:

- If an unanticipated event occurs, the injection of refrigerant can be stopped at any time by pressing the Stop Current Action button on the console control panel, by pressing the Stop CryoAblation button on the screen, or by pushing down on the foot switch.
 - Because of the complexity of arrhythmia electrophysiology, fluoroscopy and ECG guidance may be used to assess catheter tip position in AVNRT ablations.
 - The catheter tip can be deflected to facilitate positioning by using the thumb knob to vary tip curvature. Pulling the thumb knob back causes the catheter tip to bend; pushing the knob forward causes the tip to straighten.
 - Prior to introducing the catheter into the patient, test the deflection mechanism to ensure that it is operational.
 - This procedure applies to both surgical and endocardial AVNRT approaches.
1. Follow aseptic techniques to introduce and position the catheter at the intended cryoablation site, using a compatible introducer or sheath or using appropriate surgical methods. Comply with the following practices:
 - Use fluoroscopic and electrogram guidance for endocardial catheter placement.
 - Ensure good tip contact.

Note: Cryoadhesion will ensure that the catheter tip does not move during energy delivery.

2. Set the treatment duration on the CryoConsole screen.

Note: The default preset duration is 240 seconds. Physicians may modify the preset cryoablation duration based on clinical judgment.

3. Perform cryoablation.

Note: Do not manipulate the catheter during therapy.

4. Wait for the cryoablation to finish; however, the injection may be terminated immediately, in cases such as the following:
 - if AV dysfunction occurs
 - if AV block occurs
 - if the desired cryoablation effect is not achieved
- Notes:**
 - To terminate the injection before the preset cryoablation duration, press the Stop Current Action button on the console control panel, press the Stop CryoAblation button on the screen, or push down on the foot switch.
 - Evaluate slow pathway effect early during the freeze.
5. For endocardial AVNRT ablation: If interruption of the slow pathway is observed, perform a second cryoablation at the successful site (confirmed by fluoroscopy, electrograms or 3D mapping), unless AV block or dysfunction occurred with the initial cryoablation.

Note: After the catheter reaches body temperature, ensure that there is no shaft deflection before removing the catheter from the point of cryoablation.
6. Ensure that the catheter is not adhered to the tissue, and then remove the catheter from the point of cryoablation.
7. If necessary, perform additional consolidation lesions or cryotherapy treatments; otherwise, remove the catheter from the patient.

8 Specifications

Catheter shaft size	2.5 mm (7 Fr)
Recommended introducer size	2.7 mm (8 Fr) minimum
Tip length	6 mm
Shaft length	108 cm
Number of electrodes on tip	4
Spacing between electrodes	2 mm, 5 mm, 2 mm
Number of thermocouples	1
Curves available	227F1 - 49 mm 227F3 - 55 mm 227F5 - 60 mm
Environmental parameters	
Recommended transit temperature	-35 °C to 58 °C (-31 °F to 136 °F); up to 85% relative humidity (non-condensing)
Recommended storage temperature	15 °C to 30 °C (59 °F to 86 °F)
Operation	15 °C to 30 °C (59 °F to 86 °F) at altitudes less than 2400 meters (8000 feet) above sea level
Refrigerant flow	
Flow ± 200 sccm	2550 sccm

9 Medtronic limited warranty

For complete warranty information, see the accompanying limited warranty document.

10 Service

Medtronic employs highly trained representatives and engineers located throughout the world to serve you and, upon request, to provide training to qualified hospital personnel in the use of Medtronic products. Medtronic also maintains a professional staff to provide technical consultation to product users. For more information, contact your local Medtronic representative, or call or write Medtronic at the appropriate telephone number or address listed on the back cover.



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Manuals for this product are available from the Medtronic website. To view, download, print, or order manuals for this product, go to www.medtronic.com/manuals or contact your Medtronic representative.

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