Medtronic

Clinical Evidence for patient with AVNRT

Freezor™ and Freezor™ *Xtra*
Cardiac Cryoablation Catheters

Atrioventricular nodal reentrant tachycardia (AVNRT) is one of the most common forms of supraventricular tachycardia (SVT), and is a life-threatening abnormal heart rhythm, with 89,000 cases each year and growing.[1] Up to 32% of AVNRT cases occur in pediatrics, or children under the age of 18.[2] SVT imposes a tremendous burden on patients' lives. Patients experiencing AVNRT in the first years of life are likely to exhibit particularly severe deficits in cognitive function, including memory.[3]

Accordingly, ablation has become a well-accepted strategy for long-term rhythm control.[4] In one study, after one month following an ablation procedure, patients reported dramatic reductions from baseline in frequency and duration of AVNRT episodes, number of symptoms, and in impact of SVT on routine activities. Patients had less restricted activity and improved quality of life following ablation.[5]

While radiofrequency (RF) is one energy source for arrhythmia, cryoablation is an alternative that may reduce the possible injury to adjacent tissue such as the AV node during ablation of AVNRT. RF has been associated with a higher rate of AV block versus cryoablation with complication rates reported for RF ablation ranging from 1.89–3% in AVNRT patients.[6-8] By comparison, the ICY-AVNRT study reported a complication rate of 1% (4/397 patients) and no permanent AV block for cryoablation AVNRT procedures.[9] This is also reinforced by the pediatric literature that demonstrated none of the AVNRT patients required a permanent pacemaker.[10-23]

The goal of this document is to summarize current evidence evaluating Medtronic focal cryoablation may help for the treatment of both pediatric† and adult patients with AVNRT. [10-12, 15-21, 23]

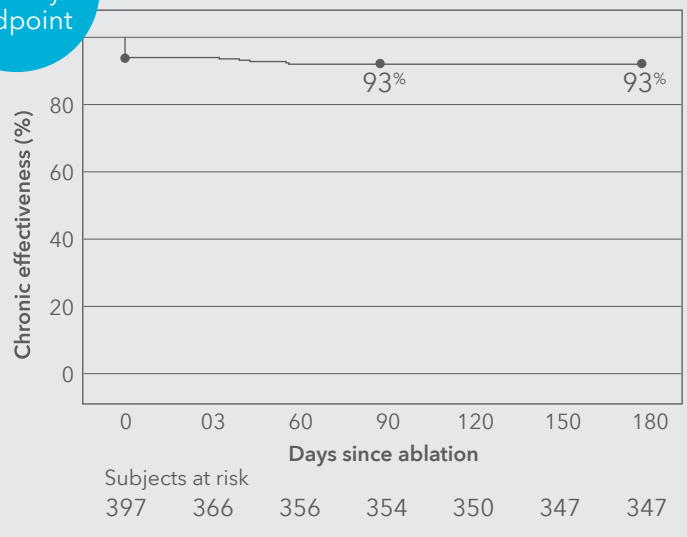
†Indicated for patients over two years of age.

ICY-AVNRT trial[9]

A prospective, unblinded, multicenter, single-arm, nonrandomized study evaluating the use of the Freezor *Xtra* cardiac cryoablation catheter for the treatment of AVNRT; 397 patients enrolled from 36 centers in the United States and Canada.

Study design	• Sites chosen for ablation were at the discretion of investigators • Cryomapping was not allowed • Cryoablation target temperature of –75° C	
Patient population	**Key inclusion criteria:** • Documented SVT thought to be AVNRT (documented by ECG, transtelephonic, Holter, or event monitors) • Age 18+	**Key exclusion criteria:** • History of a SVT or a reversible cause of SVT • A previous ablation for AVNRT • New York Heart Association (NYHA) class III or IV heart failure within the preceding 90 days • The presence of a permanent implantable cardiac rhythm device (including loop recorders) • History of AV conduction disturbances, including first-/second-/third-degree AV block or left bundle branch block
Primary endpoints	**Effectiveness:** Treatment success at six months Acute success is defined as: No more than a single echo beat after ablation with or without infusion of isoproterenol Chronic success is defined as: Composite of acute success and the lack of documented recurrent AVNRT during the six-month follow-up period	**Safety: Lack of a serious procedure-related or serious device-related adverse event during the study period** Primary safety events included: • 1 tamponade • 1 pulmonary embolism • 1 femoral vein hemorrhage • 1diagnostic EP catheter knotting None were related to catheter use AV block: First-degree AV block persisted beyond follow-up in one subject. No subject was symptomatic, and none required permanent pacing
Conclusions	• The data from the ICY-AVNRT study demonstrates the safety and effectiveness of the Freezor *Xtra* cardiac cryoablation catheter for the treatment of patients with AVNRT • All primary safety, primary effectiveness, and key secondary objectives met the prespecified performance criteria • ICY-AVNRT results support a reasonable assurance of safety • ICY-AVNRT results support a reasonable assurance of efficacy	

Primary efficacy endpoint



of AVNRT cases resulted in permanent pacemaker implantation

of AVNRT cases experienced a primary safety event, none of which resulted from the Freezor *Xtra* catheter

freedom from AVNRT at six months

Pediatric literature[10-23]

Three prospective and retrospective studies analyzing the clinical safety and efficacy of cryoablation using the Freezor or Freezor *Xtra* cardiac cryoablation catheters. An additional 11 studies were also part of a peer-reviewed literature review supporting expansion of the AVNRT indication to the pediatric population.

Primary safety endpoints

Drago[14]
Six cases of transient incomplete AV block

Cokkinakis[13]
Four cases of transient AV conduction occurred

Skaglione[22]
One transient lengthening of the atrial-Hissian interval after one minute

No permanent AV block requiring a pacemaker reported

Primary effectiveness endpoints

89.1%
Follow-up at 1, 6, 12, 18, and 24 months

84.3%
Mean follow-up of 45.8 ± 22 months

76.2%
Mean follow-up of 25 months

% of patients free from AVNRT at follow-up

Additional procedure outcomes

Cryoablation should be performed as early as possible, as patient's age is a predictive factor of lower recurrence rate

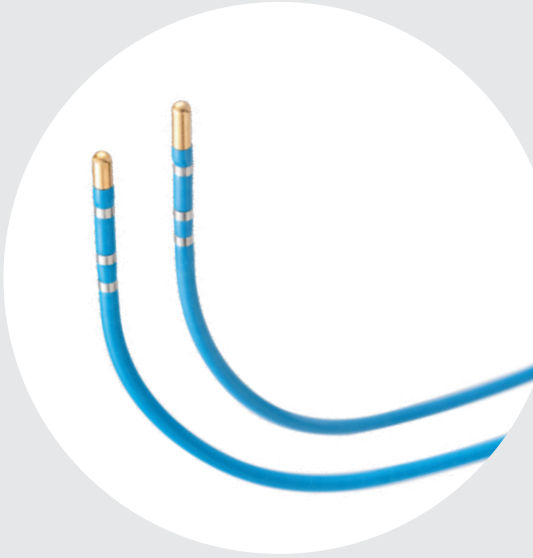
Cryoablation has an excellent success and safety profile, which can improve with increasing experience

Fluoroless cryoablation for AVNRT in children and adolescents is feasible and safe

An additional 11 pediatric studies[10-12, 15-21, 23] support cryoablation of AVNRT with Freezor and Freezor *Xtra* as safe and effective, with low risk of recurrence, an acceptable success rate, and no incidence of AV block requiring permanent pacing with cryoablation.

Catheter ablation is the AVNRT treatment of choice.

Supported by the results from ICY-AVNRT and multiple pediatric randomized, multicenter studies, the Freezor and Freezor *Xtra* catheters are proven safe and effective for the treatment of adult and pediatric AVNRT.



References

[1] Page RL, et al. *J Am Coll Cardiol*. 2016;67:e27-e115.
[2] Lee PC, et al. *Pediatr Cardiol*. 2003;24:6-9.
[3] Maryniak A, et al. *Pediatr Cardiol*. 2013;34:893-897.
[4] Saul JP, et al. *Heart Rhythm*. 2016;13:e251-e289.
[5] Wood KA, et al. *Heart Lung*. 2010;39:12-20.
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[7] Perez FJ, et al. *Circ Arrhythm Electrophysiol*. 2009;2:393-401.
[8] Hoffmann B, et al. *Heart Rhythm*. 2011;8:981-987
[9] Wells P, et al. *J Cardiovasc Electrophysiol*. 2018;29:167-176.
[10] Avari JN, et al. *Pacing Clin Electrophysiol*. 2008;31:454-460.
[11] Beach C, et al. *Cardiol Young*. 2016;26:1297-1302.
[12] Chanani NK, et al. *Pacing Clin Electrophysiol*. 2008;31:1152-1159.
[13] Cokkinakis C, et al. *Hellenic J Cardiol*. 2013;54:186-191.
[14] Drago F, et al. *J Cardiovasc Electrophysiol*. 2014;25:398-403.
[15] Drago F, et al. *Pacing Clin Electrophysiol*. 2010;33:475-481.
[16] Gist K, et al. *Pacing Clin Electrophysiol*. 2011;34:264-268.
[17] Papagiannis J, et al. *Hellenic J Cardiol*. 2010;51:122-126.
[18] Pieragnoli P, et al. *Heart Rhythm*. 2015;12:2125-2131.
[19] Qureshi MY, et al. *Pacing Clin Electrophysiol*. 2013;36:279-285.
[20] Reents T, et al. *Europace*. 2012;14:1629-1633.
[21] Russo MS, et al. *Cardiol Young*. 2016;26:931-940.
[22] Scaglione M, et al. *Pacing Clin Electrophysiol*. 2013;36:1460-1467.
[23] Young ML, et al. *J Arrhythm*. 2020;36:712-719.

Brief Statement
Freezor™ Cardiac Cryoablation Catheter

Indications:
The 7 Fr Freezor 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 cardiac arrhythmias.

Contraindications:
This device is contraindicated in patients with active systemic infection, where manipulation of the catheter would be unsafe (e.g., intracardiac mural thrombus) and in patients with cryoglobulinemia.

Warnings/Precautions:
The impact of cryomapping with respect to patient outcomes has not been fully characterized. The Freezor Catheter contains a pressurized refrigerant during operation. Release of this gas into the circulatory system due to equipment failure or misuse could result in gas embolism.Do not pull on the Freezor Catheter, umbilicals, or CryoAblation Console while the catheter tip is frozen to the endocardial tissue, as this could lead to cardiac or vascular damage. Do not connect the Freezor Catheter to any radiofrequency generator or use the Freezor Catheter to deliver RF ablation energy, because this could cause catheter malfunction and/or patient harm. Do not resterilize or re-use any Freezor Catheter or sterile accessory under any circumstances. Freezor Catheters and sterile accessories are designed for single use only. Do not attempt to operate the 7 Fr Freezor Cardiac CryoAblation Catheter prior to reading and understanding the Instructions for Use.

Potential Complications:
Potential complications that may be associated with cardiac catheterization and ablation listed alphabetically below include, but are not limited to:
Access site complications including pain, hematoma, ecchymosis, infection, thrombosis or AV fistula; cardiac arrest and/or death; chest pain; coronary artery spasm/dissection/thrombosis; endocarditis; heart block, partial or complete, potentially requiring implantation of a permanent pacemaker; hemorrhage; hemothorax; myocardial infarction; pericardial effusion; pericarditis or pericardial effusion; pleural effusion; pneumothorax; pseudoaneurysm; pulmonary edema; pulmonary embolism; stroke; thrombus, intravascular or intracardiac; thromboembolism with potential tissue infarction; transient ischemic attack;

See the device manual for detailed information regarding the indications, contraindications, warnings, precautions, and potential complications/adverse events. For further information, please callMedtronic at 1 (800) 328-2518 and/or consult Medtronic'swebsite at www.medtronic.com.

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

Freezor *Xtra*™ Cardiac Cryoablation Catheter

Indications:
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 cardiac arrhythmia. The Freezor Xtra catheter is also intended for cardiac surgery procedures including surgical treatment of cardiac arrhythmias.

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).

Warnings/Precautions:
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. Do not pull on the Freezor Xtra catheter, sheath, umbilical cables, or console while the catheter is frozen to the tissue, as this may lead to tissue injury. Do not connect the Freezor Xtra catheter to a radiofrequency (RF) generator or use it to deliver RF ablation energy. Doing this may cause device malfunction or patient harm. Do not resterilize this catheter for purpose of reuse. This catheter is intended only to be used once for a single patient. 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. 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. 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. Cryoablation procedures should be performed only in a fully equipped facility. This equipment should be used only by or under the supervision of physicians trained in surgical or endocardial cryoablation procedures. Do not attempt to operate the Freezor Xtra catheter prior to reading and understanding the Instructions for Use.

Potential Complications:
Potential complications/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, 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, Stoke/transient ischemic attack/embolism, Valvular damage, Vascular complication (e.g., stenosis).

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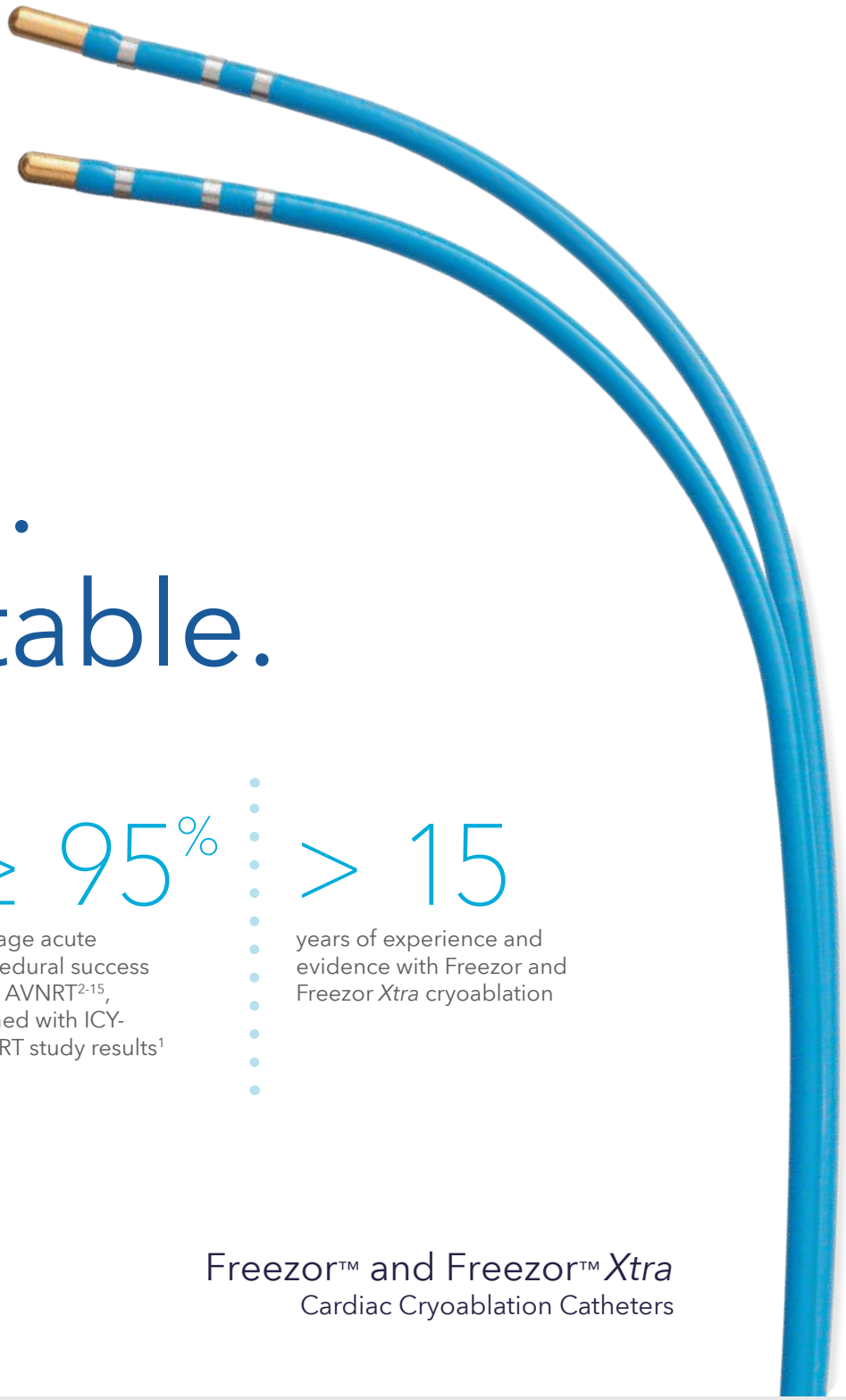

Proven. Predictable.

0%
of reported AVNRT cases have resulted in permanent AV block[1-16]

≥ 95%
average acute procedural success from AVNRT[2-15], aligned with ICY-AVNRT study results[1]

> 15
years of experience and evidence with Freezor and Freezor *Xtra* cryoablation

Freezor™ and Freezor™ *Xtra*
Cardiac Cryoablation Catheters

FDA - Approved

FDA-approved ablation catheter for treatment of AVNRT in both pediatric† and adult patients

†Indicated for patients over two years of age.

References

[1] Wells P, et al. *J Cardiovasc Electrophysiol*. 2018;29:167-176.
[2] Avari JN, et al. *Pacing Clin Electrophysiol*. 2008;31:454-460.
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[15] Young ML, et al. *J Arrhythm*. 2020;36:712-719.
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Contraindications:
This device is contraindicated in patients with active systemic infection, where manipulation of the catheter would be unsafe (e.g., intracardiac mural thrombus) and in patients with cryoglobulinemia.

Warnings/Precautions:
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Potential Complications:
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Access site complications including pain, hematoma, ecchymosis, infection, thrombosis or AV fistula; cardiac arrest and/or death; chest pain; coronary artery spasm/dissection/thrombosis; endocarditis; heart block, partial or complete, potentially requiring implantation of a permanent pacemaker; hemorrhage; hemothorax; myocardial infarction; pericardial effusion; pericarditis or pericardial effusion; pleural effusion; pneumothorax; pseudoaneurysm; pulmonary edema; pulmonary embolism; stroke; thrombus, intravascular or intracardiac; thromboembolism with potential tissue infarction; transient ischemic attack;

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Freezor *Xtra*™ Cardiac Cryoablation Catheter

Indications:
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 cardiac arrhythmia. The Freezor Xtra catheter is also intended for cardiac surgery procedures including surgical treatment of cardiac arrhythmias.

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).

Warnings/Precautions:
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. Do not pull on the Freezor Xtra catheter, sheath, umbilical cables, or console while the catheter is frozen to the tissue, as this may lead to tissue injury. Do not connect the Freezor Xtra catheter to a radiofrequency (RF) generator or use it to deliver RF ablation energy. Doing this may cause device malfunction or patient harm. Do not resterilize this catheter for purpose of reuse. This catheter is intended only to be used once for a single patient. 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. 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. 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. Cryoablation procedures should be performed only in a fully equipped facility. This equipment should be used only by or under the supervision of physicians trained in surgical or endocardial cryoablation procedures. Do not attempt to operate the Freezor Xtra catheter prior to reading and understanding the Instructions for Use.

Potential Complications:
Potential complications/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, 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, Stoke/transient ischemic attack/embolism, Valvular damage, Vascular complication (e.g., stenosis).

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Freezor™ Cardiac Cryoablation Catheter

Product specifications | 4 mm, 7 Fr

The Freezor™ Cardiac CryoAblation Catheter is a flexible and single-use device specifically designed to ablate cardiac tissue. It is used to create focal lesions to treat cardiac arrhythmias.

The Freezor catheter is a 7 Fr diameter catheter with a 4.3 mm tip. The catheter is available with multiple reaches. It has the ability to record from the tip and has three other recording electrodes.

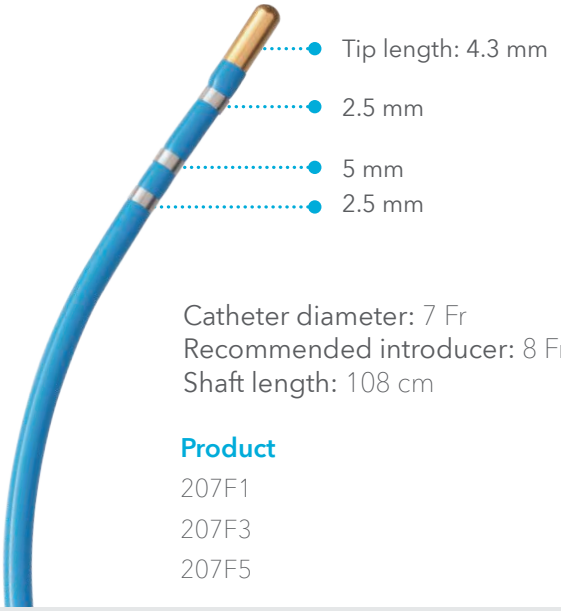
Product specifications

Ordering information

Order number	
207F1	Freezor cardiac cryoablation catheter – short/red
207F3	Freezor cardiac cryoablation catheter – medium/blue
207F5	Freezor cardiac cryoablation catheter – long/orange

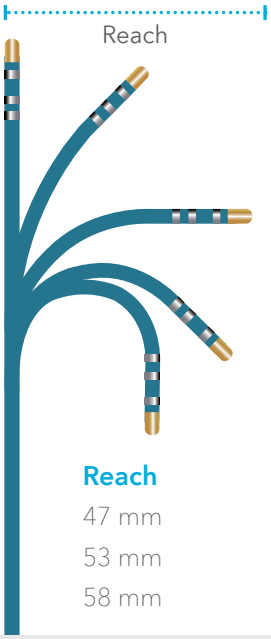
Catheter specifications

Freezor	
Size	
Tip length	4.3 mm
Electrode spacing	2.5-5-2.5
Catheter diameter	7 Fr
Shaft length	108 cm
Compatibility	
Recommended sheath introducer size	8 Fr



Catheter diameter: 7 Fr
Recommended introducer: 8 Fr
Shaft length: 108 cm

Product
207F1
207F3
207F5



Reach
47 mm
53 mm
58 mm

Brief Statement
7 Fr Freezor™ Cardiac CryoAblation Catheter

Indications:
The 7 Fr Freezor 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 cardiac arrhythmias.

Contraindications:
This device is contraindicated in patients with active systemic infection, where manipulation of the catheter would be unsafe (e.g., intracardiac mural thrombus) and in patients with cryoglobulinemia.

Warnings/Precautions:
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Potential Complications:
Potential complications that may be associated with cardiac catheterization and ablation listed alphabetically below include, but are not limited to: Access site complications including pain, hematoma, ecchymosis, infection, thrombosis or AV fistula; cardiac arrest and/or death; chest pain; coronary artery spasm/dissection/thrombosis; endocarditis; heart block, partial or complete, potentially requiring implantation of a permanent pacemaker; hemorrhage; hemothorax; myocardial infarction; pericardial effusion; pericarditis or pericardial effusion; pleural effusion; pneumothorax; pseudoaneurysm; pulmonary edema; pulmonary embolism; stroke; thrombus, intravascular or intracardiac; thromboembolism with potential tissue infarction; transient ischemic attack;

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Freezor™ *Xtra* Cardiac Cryoablation Catheter

Product specifications | 6 mm, 7 Fr

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 cardiac arrhythmia. The Freezor *Xtra* catheter is also intended for cardiac surgery procedures, including surgical treatment of cardiac arrhythmias.

The Freezor *Xtra* catheter is a 7 Fr diameter catheter with a 6 mm tip. The catheter is available with multiple reaches. It has the ability to record from the tip and has three other recording electrodes.

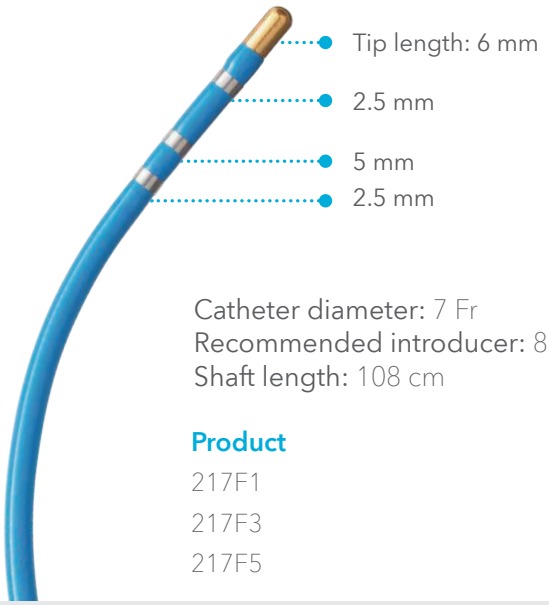
Product specifications

Ordering information

ORDER NUMBER	
217F1	Freezor *Xtra* cardiac cryoablation catheter – short/red
217F3	Freezor *Xtra* cardiac cryoablation catheter – medium/blue
217F5	Freezor *Xtra* cardiac cryoablation catheter – long/orange

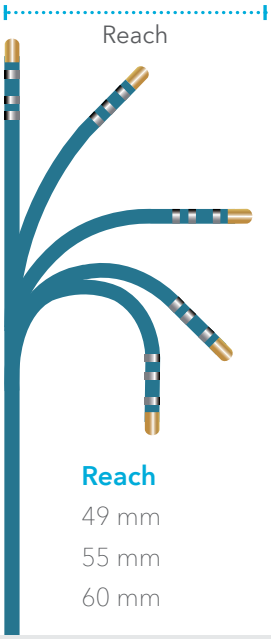
Catheter specifications

FREEZOR *XTRA*	
Size	
Tip length	6 mm
Electrode spacing	2.5-5.0-2.5
Catheter diameter	7 Fr
Shaft length	108 cm
Compatibility	
Recommended sheath introducer size	8 Fr



Catheter diameter: 7 Fr
Recommended introducer: 8 Fr
Shaft length: 108 cm

Product
217F1
217F3
217F5



Reach
49 mm
55 mm
60 mm

Brief Statement
Freezor *Xtra*™ Cardiac Cryoablation Catheter

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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 cardiac arrhythmia. The Freezor Xtra catheter is also intended for cardiac surgery procedures including surgical treatment of cardiac arrhythmias.

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).

Warnings/Precautions:
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. Do not pull on the Freezor Xtra catheter, sheath, umbilical cables, or console while the catheter is frozen to the tissue, as this may lead to tissue injury. Do not connect the Freezor Xtra catheter to a radiofrequency (RF) generator or use it to deliver RF ablation energy. Doing this may cause device malfunction or patient harm. Do not resterilize this catheter for purpose of reuse. This catheter is intended only to be used once for a single patient. 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. 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. 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. Cryoablation procedures should be performed only in a fully equipped facility. This equipment should be used only by or under the supervision of physicians trained in surgical or endocardial cryoablation procedures. Do not attempt to operate the Freezor Xtra catheter prior to reading and understanding the Instructions for Use.

Potential Complications:
Potential complications/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, 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, Stoke/transient ischemic attack/embolism, Valvular damage, Vascular complication (e.g., stenosis).

See the device manual for detailed information regarding the indications, contraindications, warnings, precautions, and potential complications/adverse events. For further information, please call Medtronic at 1-800-328-2518 and/or consult the Medtronic website at medtronic.com.

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

Medtronic

Medtronic Korea Ltd.
17F. Glass Tower, 534 Teheran-Ro.
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Tel: 82-2-3404-3600

MDTKOR-CAS-06

medtronic.com

Medtronic

Freezor™ *MAX* Cardiac Cryoablation Catheter

Product specifications | 8 mm, 9 Fr

The Freezor™ *MAX* Cardiac CryoAblation Catheter is a flexible and single-use device specifically designed to ablate cardiac tissue. It is used as an adjunctive device in the endocardial treatment of cardiac arrhythmia.

Freezor™ *MAX* is a 9 Fr diameter catheter with an 8.6 mm tip and is available with multiple reaches. It has the ability to record from the tip and three other recording electrodes.

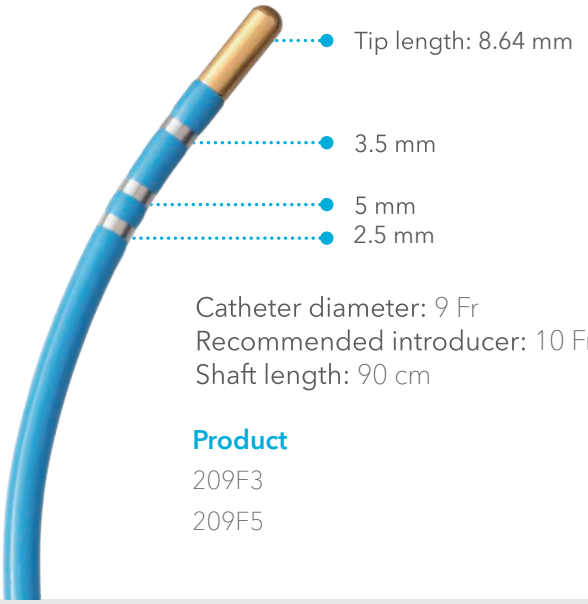
Product specifications

Ordering information

ORDER NUMBER	
209F3	Freezor *MAX* cardiac cryoablation catheter – medium/blue
209F5	Freezor *MAX* cardiac cryoablation catheter – long/orange

Catheter specifications

FREEZOR *MAX*	
Size	
Tip length	8.64 mm
Electrode spacing	3.5-5.0-2.5 mm
Catheter diameter	9 Fr
Shaft length	90 cm
Compatibility	
Recommended sheath introducer size	10 Fr

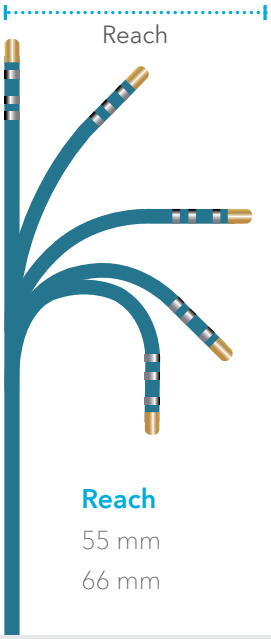


Catheter diameter: 9 Fr
Recommended introducer: 10 Fr
Shaft length: 90 cm

Product

209F3

209F5



Reach

55 mm

66 mm

Brief Statement
Freezor™ *MAX* Cardiac Cryoablation Catheter

Indications:
The Freezor™ *MAX* Cardiac CryoAblation Catheter is used as an adjunctive device in the endocardial treatment of cardiac arrhythmia.

Contraindications:
Use of Freezor *MAX* cryocatheter is contraindicated in patients with active systemic infections, in patients with cryoglobulinemia, and other conditions where the manipulation of the catheter would be unsafe (e.g., intracardiac mural thrombus).

Warnings/Precautions:
Do not resterilize this device for purpose of reuse. Do not connect the cryocatheter to a radiofrequency (RF) generator or use it to deliver RF energy because this may cause catheter malfunction or patient harm. Disconnect the catheter's electrical connection prior to defibrillation. The catheter contains pressurized refrigerant during operation; release of this gas into the circulatory system due to equipment failure or misuse could result in gas embolism. Do not pass the catheter through a prosthetic heart valve (mechanical or tissue) to avoid damage to the valve, valvular insufficiency, or premature failure of the prosthetic valve. Use adequate fluoroscopic visualization during a transaortic approach to avoid placing the ablation catheter within the coronary vasculature. 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. Always advance and withdraw components slowly to minimize the vacuum created and therefore minimize the risk of air embolism. This equipment should be used only by or under the supervision of physicians trained in left-atrial cryoablation procedures. Cryoablation procedures should be performed only in a fully equipped facility.

Potential Complications:
Potential complications/adverse events from cardiac catheterization and ablation include, but are not limited to the following: Anemia; Atrial flutter; Bleeding from puncture sites; Bradycardia; Bruising; Cardiac tamponade; Cardiopulmonary arrest; Cerebral vascular accident; Chest discomfort/pain/pressure; Death; Diarrhea; Myocardial infarction; Pericardial effusion; Pulmonary vein stenosis;

Refer to the device technical manual for detailed information regarding the procedure, indications, contraindications,warnings, precautions, and potential complications/adverse events. For further information, please call Medtronic at 1 (800) 328-2518 and/or consult Medtronic'swebsite at www.medtronic.com.

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