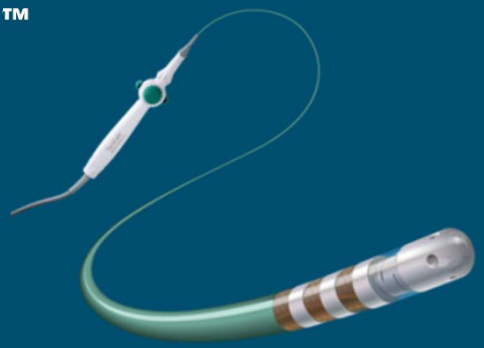
TACTICATH™ CONTACT FORCE ABLATION CATHETER, SENSOR ENABLED™

Clinical Study Summary



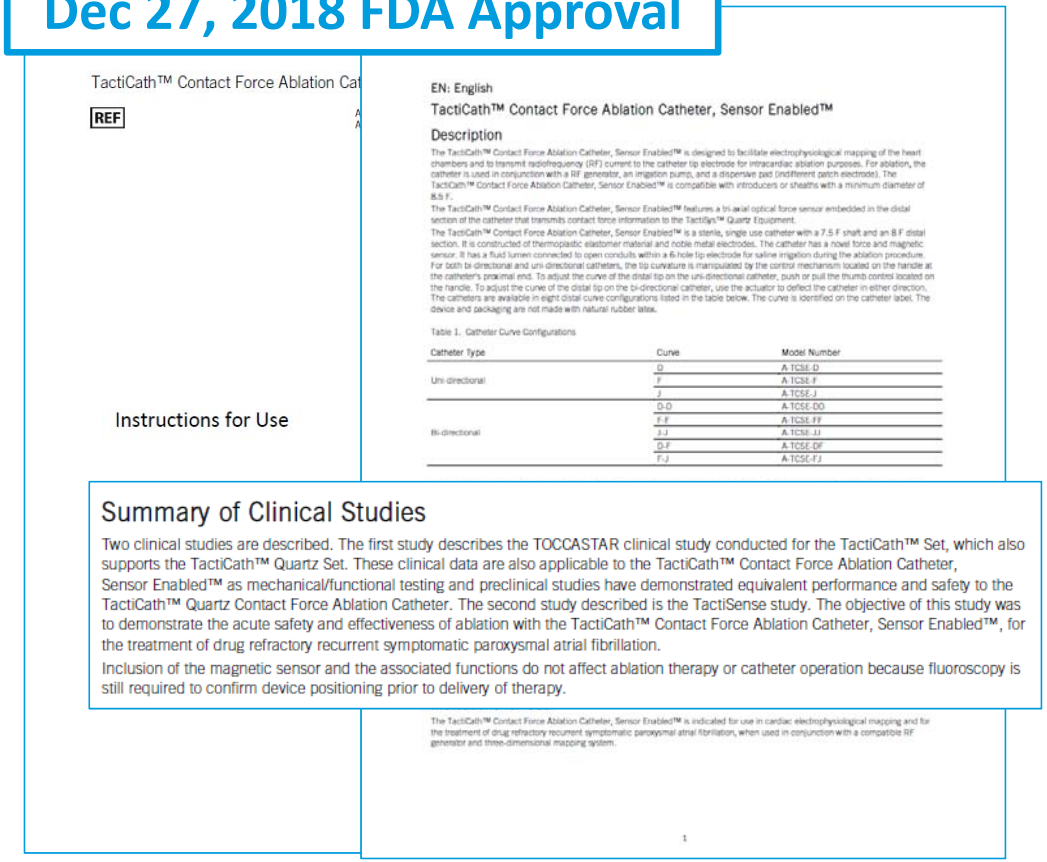
TACTICATH™ CATHETER, SENSOR ENABLED™ SAFETY AND EFFECTIVENESS

TactiSense IDE

Two clinical studies support TCSE. The TOCCASTAR clinical study conducted for the TactiCath™ Set, which also supports the TactiCath™ Quartz Set. These clinical data are also applicable to the TactiCath™ Contact Force Ablation Catheter, Sensor Enabled™ as mechanical/functional testing and preclinical studies have demonstrated equivalent performance and safety to the TactiCath™ Quartz Contact Force Ablation Catheter. The TactiSense study was conducted to demonstrate the acute safety and effectiveness of ablation with the TactiCath™ Contact Force Ablation Catheter, Sensor Enabled™, for the treatment of drug refractory recurrent symptomatic paroxysmal atrial fibrillation

TactiSense IDE study – included in TactiCath™ SE catheter IFU

Dec 27, 2018 FDA Approval



TactiCath™ Contact Force Ablation Cat

REF

Instructions for Use

EN: English

TactiCath™ Contact Force Ablation Catheter, Sensor Enabled™

Description

The TactiCath™ Contact Force Ablation Catheter, Sensor Enabled™ is designed to facilitate electrophysiological mapping of the heart chambers and to transmit radiofrequency (RF) current to the catheter tip electrode for intracardiac ablation purposes. For ablation, the catheter is used in conjunction with a RF generator, an irrigation pump, and a dispersive pad (indifferent patch electrode). The TactiCath™ Contact Force Ablation Catheter, Sensor Enabled™ is compatible with introducers or sheaths with a minimum diameter of 8.5 F.

The TactiCath™ Contact Force Ablation Catheter, Sensor Enabled™ features a tri-axial optical force sensor embedded in the distal section of the catheter that transmits contact force information to the TactiSys™ Quartz Equipment.

The TactiCath™ Contact Force Ablation Catheter, Sensor Enabled™ is a sterile, single use catheter with a 7.5 F shaft and an 8 F distal section. It is constructed of thermoplastic elastomer material and noble metal electrodes. The catheter has a novel force and magnetic sensor. It has a fluid lumen connected to open conduits within a 6-hole tip electrode for saline irrigation during the ablation procedure. For both bi-directional and uni-directional catheters, the tip curvature is manipulated by the control mechanism located on the handle at the catheter's proximal end. To adjust the curve of the distal tip on the uni-directional catheter, push or pull the thumb control located on the handle. To adjust the curve of the distal tip on the bi-directional catheter, use the actuator to deflect the catheter in either direction. The catheters are available in eight distal curve configurations listed in the table below. The curve is identified on the catheter label. The device and packaging are not made with natural rubber latex.

Table 1. Catheter Curve Configurations

Catheter Type	Curve	Model Number
Uni-directional	D	A-TCSE-D
	F	A-TCSE-F
	J	A-TCSE-J
Bi-directional	D-D	A-TCSE-DD
	F-F	A-TCSE-FF
	J-J	A-TCSE-JJ
	D-F	A-TCSE-DF
	F-J	A-TCSE-FJ

Summary of Clinical Studies

Two clinical studies are described. The first study describes the TOCCASTAR clinical study conducted for the TactiCath™ Set, which also supports the TactiCath™ Quartz Set. These clinical data are also applicable to the TactiCath™ Contact Force Ablation Catheter, Sensor Enabled™ as mechanical/functional testing and preclinical studies have demonstrated equivalent performance and safety to the TactiCath™ Quartz Contact Force Ablation Catheter. The second study described is the TactiSense study. The objective of this study was to demonstrate the acute safety and effectiveness of ablation with the TactiCath™ Contact Force Ablation Catheter, Sensor Enabled™, for the treatment of drug refractory recurrent symptomatic paroxysmal atrial fibrillation.

Inclusion of the magnetic sensor and the associated functions do not affect ablation therapy or catheter operation because fluoroscopy is still required to confirm device positioning prior to delivery of therapy.

The TactiCath™ Contact Force Ablation Catheter, Sensor Enabled™ is indicated for use in cardiac electrophysiological mapping and for the treatment of drug refractory recurrent symptomatic paroxysmal atrial fibrillation, when used in conjunction with a compatible RF generator and three-dimensional mapping system.

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TactiSense IDE

- **Prospective, multi-center, single-arm clinical trial to demonstrate acute safety and effectiveness of TCSE for treatment of PAF**
- **Study met primary endpoints**
  - **Safety**: rate of device or procedure-related primary SAEs within 7 days
  - **Effectiveness**: acute procedural success, defined as confirmation of entrance block in all pulmonary veins

Study Conclusion

The TactiSense IDE results through 30 days demonstrate that the TactiCath™ Contact Force Ablation Catheter, Sensor Enabled™, is safe and effective for the treatment of paroxysmal atrial fibrillation.

1. TactiSense IDE study. TactiCath SE IFU #ARTEN600049107 A, Dec 2018.

TactiSense IDE trial design

Multi-Center Acute Safety Trial of TactiCath™ Contact Force Ablation Catheter, Sensor Enabled™ (TactiCath SE) for the Treatment of Drug Refractory Recurrent Symptomatic Paroxysmal Atrial Fibrillation

Objective

- The objective of this study was to demonstrate the acute safety and effectiveness of ablation with the TactiCath™ Contact Force Ablation Catheter, Sensor Enabled™, for the treatment of drug refractory recurrent symptomatic PAF.

Study Design

- Prospective, multi-center, single-arm clinical trial to demonstrate the acute safety and effectiveness of the TactiCath™ Contact Force Ablation Catheter, Sensor Enabled™, for the treatment of PAF against a performance goal.
- Sample size: hundred fifty six (156) subjects were enrolled at 19 investigational sites in the US, Europe, and Australia.
- Study duration: 30 days (primary safety), 12 months total follow-up including 3-month blanking period (ongoing)

Sponsor

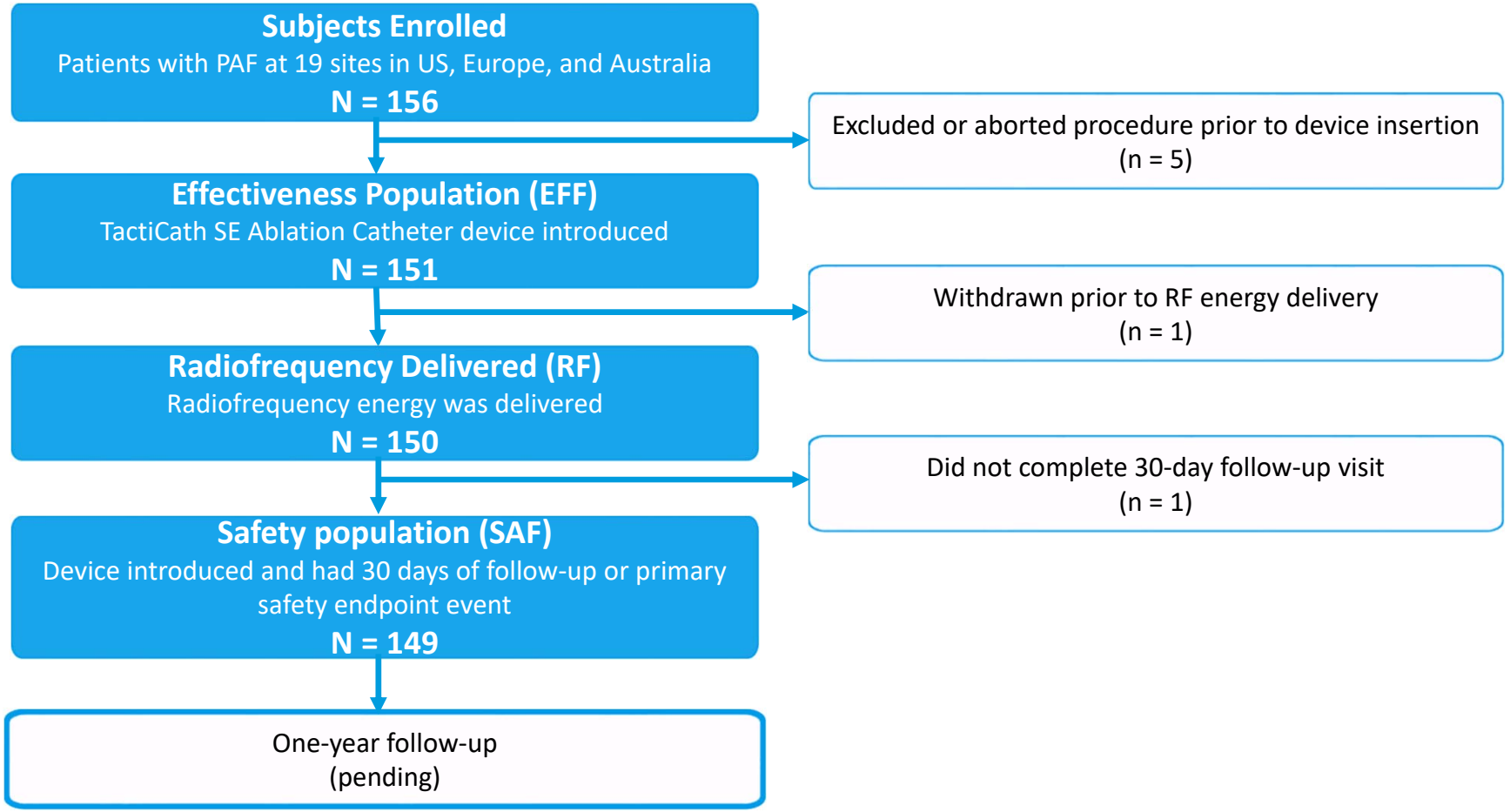
- Abbott, St. Paul, MN (formerly St. Jude Medical)

1. TactiSense IDE study. TactiCath SE IFU #ARTEN600049107 A, Dec 2018.

Endpoints

- There are two primary endpoints and ten descriptive endpoints. Results of the primary endpoints and first three descriptive endpoints were analyzed for this primary analysis. The remaining endpoints will be reported after 1-year follow up results are available.
- **Primary Safety**: the rate of primary device or procedure-related serious adverse events (SAEs) occurring within 7 days of the index procedure. Atrial-esophageal fistula, cardiac perforation/tamponade, and pulmonary vein stenosis that occur >7 days post procedure through 30 days also contributed to the primary endpoint. Primary event criteria were prespecified.
- **Primary Effectiveness**: acute procedural success, defined as confirmation of entrance block in all pulmonary veins.
- **Descriptive endpoints**:
  1. Ablation data collected during the procedure, including: Power, Temperature, Irrigation flow rate, Contact Force, Procedure time, Total ablation time, Total fluoroscopy time, Total RF application time, Use of AutoMark
  2. Proportion of index cases achieving ≥90% lesions with ≥10 g contact force
  3. SAEs and adverse events related to the procedure and/or ablation catheter through 30 days

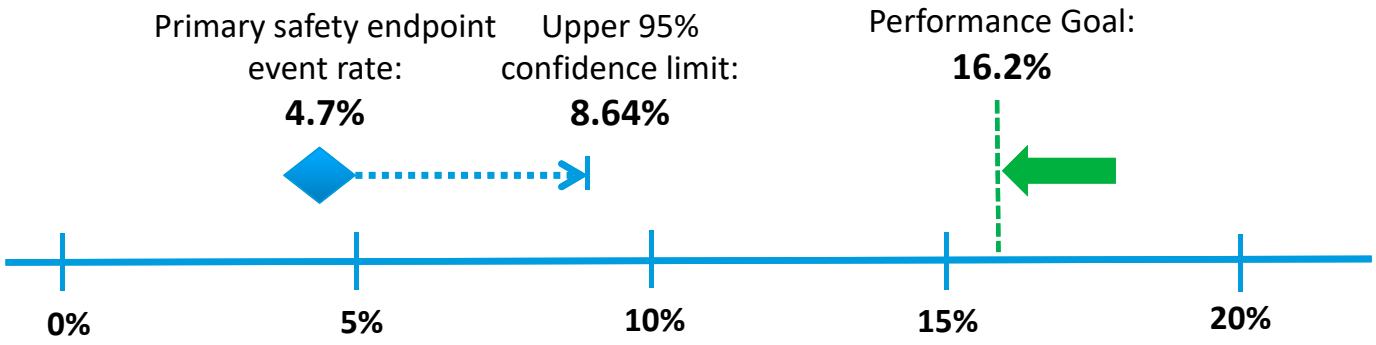
TactiSense IDE primary safety and effectiveness analysis populations



1. TactiSense IDE study. TactiCath SE IFU #ARTEN600049107 A, Dec 2018.

TactiSense met primary safety endpoint

The observed rate of primary safety endpoint events was 4.7% (one-sided 95% upper confidence limit: 8.64%) and was statistically significantly lower than the predetermined performance goal of 16.2% ($p<0.0001$) for the TactiCath™ Ablation Catheter, Sensor Enabled™



PRIMARY SAFETY ENDPOINT ANALYSIS (TactiCath™ Ablation Catheter, Sensor Enabled™)

PRIMARY SAFETY ENDPOINT (SAF population)	TactiCath SE (N = 149)	Upper One-Sided 95% CL	Performance Goal[1]	P-Value[2]
Subject experienced primary safety endpoint event (Device or Procedure-related primary SAE)	**7 (4.7%)**	**(8.64%)**	**16.2%**	**<0.0001**

16.l2%1 One-sided upper 95% confidence limit by Clopper Pearson Method.
[2] One-sided p-value by using Binomial Exact Test against the performance goal of 16.2%, to be compared with one-sided significance level of 0.05.

1. TactiSense IDE study. TactiCath SE IFU #ARTEN600049107 A, Dec 2018.

TactiSense primary safety endpoint events

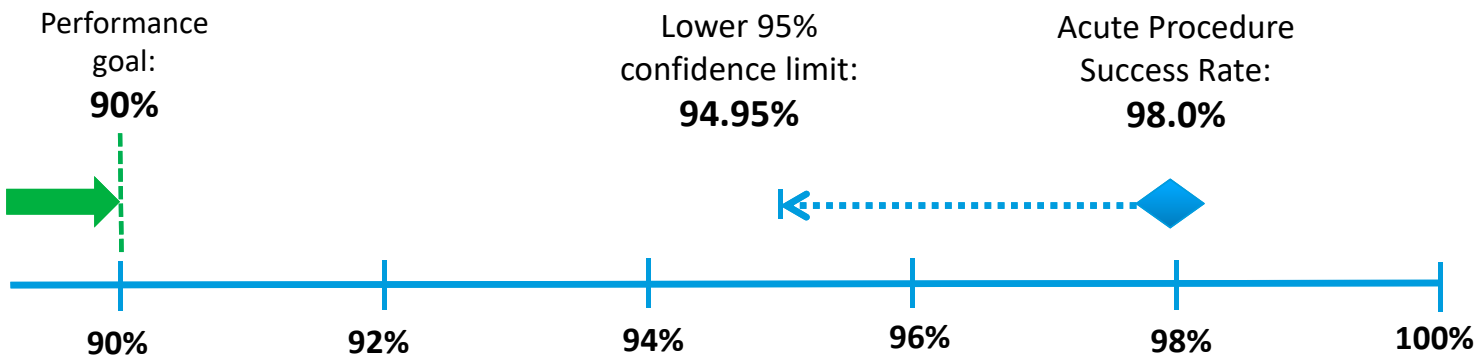
TactiSense IDE Primary Safety Endpoint Events (SAF population)	**n (%) Subjects,** N = 149
Atrial-esophageal fistula	1 (0.7%)
AV block	0 (0.0%)
Cardiac perforation / tamponade	3 (2.0%)
Death	0 (0.0%)
Diaphragmatic paralysis	0 (0.0%)
Gastroparesis	0 (0.0%)
Hospitalization	0 (0.0%)
Myocardial infarction	0 (0.0%)
Pericarditis	1 (0.7%)
Pneumothorax	0 (0.0%)
Pulmonary edema	0 (0.0%)
Pulmonary vein stenosis	0 (0.0%)
Stroke	0 (0.0%)
Thromboembolism	1 (0.7%)
Transient ischemic attack	0 (0.0%)
Vascular Access Complication	2 (1.3%)
Total Device or Procedure-related Primary SAEs	**7 (4.7%)**

Note: Some subjects may have experienced more than one event. Therefore, the total number of subjects may be fewer than the total number of events.

TactiSense IDE study. TactiCath SE IFU #ARTEN600049107 A, Dec 2018.

TactiSense met primary effectiveness endpoint

Acute procedural success was achieved in 98.0% (148/151) subjects who had the TactiCath™ Ablation Catheter, Sensor Enabled™ inserted into the vasculature. The lower bound of the one-sided 95% confidence interval was 94.95%, which is greater than the performance goal of 90%. Therefore, the null hypothesis was rejected and the primary effectiveness endpoint passed.



PRIMARY EFFECTIVENESS RESULTS (TactiCath™ Ablation Catheter, Sensor Enabled™)

PRIMARY EFFECTIVENESS ENDPOINT (EFF Population)	TACTICATH SE (N = 151)	LOWER ONE-SIDED 95% CL[1]	PERFORMANCE GOAL	P-VALUE[2]
Acute Procedure Success*	**98.0 (148/151)**	**94.95%**	**90%**	**0.0001**

[1] One-sided lower 95% confidence limit by Clopper Pearson Method.
[2] One-sided p-value by using Binomial Exact Test against the performance goal of 90% to be compared with a one-sided significance level of 0.05.

* The primary effectiveness endpoint was acute procedure success, defined as confirmation of entrance block at least 30 minutes after the last ablation in each pulmonary vein.

1. TactiSense IDE study. TactiCath SE IFU #ARTEN600049107 A, Dec 2018.

TactiSense IDE: Key Procedural Results

TactiSense IDE Descriptive Endpoints Procedural Characteristics	(EFF Population) Total N=150
Was the recommended power of 10-30W used? (% Yes)	**58.7%** (88/150)
Average RF power (W)	**Median** (Q1, Q3): **29.0** (26.0, 32.0) (n=149)
Average contact force (g) per subject	**Mean** ± SD: **12.1** ± 4.7 **Median** (Q1, Q3): **11.2** (8.5, 14.3) **Range** (**min, max**): (**5.0, 32.0**) (n=149)
% of patients achieving ≥ 90% lesions with ≥10 g contact force	**3.4%** (5/149)
Total procedure time (min)	**Median** (Q1, Q3): **159.5** (123.0, 206.0) (n=150)
Total RF time (entire case in min)	**Median** (Q1, Q3): **35.7** (28.9, 51.9) (n=149)
Fluoroscopy time (min)	**Median** (Q1, Q3): **9.0** (5.0, 16.0) (n=150)
AutoMark turned on for procedure? (Yes)	**99.3%** (149/150)
Was AutoMark used to guide therapy? (Yes)	**92.6%** (125/135)

CF range consistent with 2017 HRS Consensus Statement

Procedure time includes 30-min wait after last lesion

Median fluoroscopy time: **9 minutes**

1. TactiSense IDE study. TactiCath SE IFU #ARTEN600049107 A, Dec 2018.

TactiSense IDE study conclusion

TactiSense IDE

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Study Conclusion

The TactiSense IDE results through 30 days demonstrate that the TactiCath™ Contact Force Ablation Catheter, Sensor Enabled™, is safe and effective for the treatment of paroxysmal atrial fibrillation.

1. TactiSense IDE study. TactiCath SE IFU #ARTEN600049107 A, Dec 2018.

United States: Required Safety Information
Rx Only
Indications: The TactiCath™ Quartz Contact Force Ablation Catheter and TactiCath™ Ablation Catheter, Sensor Enabled™ are indicated for use in cardiac electrophysiological mapping and for the treatment of drug refractory recurrent symptomatic paroxysmal atrial fibrillation, when used in conjunction with a compatible RF generator and three-dimensional mapping system. **Contraindications:** Do not use for any of the following conditions: certain recent heart surgery; prosthetic valves; active systemic infection; use in coronary vasculature; myxoma or intracardiac thrombus, or an interatrial baffle or patch; retrograde trans-aortic approach in patients with aortic valve replacement. **Warnings:** It is important to carefully titrate RF power; too high RF power during ablation may lead to perforation caused by steam pop. Contact force in excess of 70 g may not improve the characteristics of lesion formation and may increase the risk for perforation during manipulation of the catheter. Patients undergoing septal accessory pathway ablation are at risk for complete AV block which requires the implantation of a permanent pacemaker. Implantable pacemakers and implantable cardioverter/defibrillator may be adversely affected by RF current. Always verify the tubing and catheter have been properly cleared of air prior to inserting the catheter into the vasculature since entrapped air can cause potential injury or fatality. The temperature data transmitted by the sensor in this catheter is representative of the irrigated electrode only and does not provide tissue temperature data. **Precautions:** The long-term risks of protracted fluoroscopy and creation of RF induced lesions have not been established; careful consideration must be given for the use of the device in prepubescent children. When using the catheter with conventional EP lab system or with a 3-D navigational system, careful catheter manipulation must be performed, in order to avoid cardiac damage, perforation, or tamponade. Always maintain a constant saline irrigation flow to prevent coagulation within the lumen of the catheter. Care should be taken when ablating near structures such as the sino-atrial and AV nodes. **Potential Adverse Events:** Potential adverse events include, but are not limited to, cardiovascular related complications, including groin hematoma, pericardial effusion and infection. More serious complications are rare, which can include damage to the heart or blood vessels; blood clots (which may lead to stroke); tamponade; severe pulmonary vein stenosis; heart attack; esophageal fistula, or death. Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

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