TactiCath™ Contact Force Ablation Catheter, Sensor Enabled™

REF A-TCSE-D, A-TCSE-F, A-TCSE-J, A-TCSE-DD, A-TCSE-FF, A-TCSE-JJ, A-TCSE-DF, A-TCSE-FJ

Instructions for Use

Abbott

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

⚠ WARNING: This product can expose you to chemicals including ethylene oxide, which is known to the State of California to cause cancer and birth defects or other reproductive harm. For more information, go to www.P65Warnings.ca.gov.

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

The catheter connects to the TactiSys Quartz Equipment (PN-004 400) and, directly or indirectly, to a compatible RF cardiac ablation generator, irrigation pump, and 3D mapping/contact force display system. Compatible systems components are listed below. For information regarding their use, refer to the appropriate instructions for use.

Table 2. Compatible Systems

System Device	Connect via (Model Number)	System Software
Ampere™ RF Ablation Generator	TactiSys™ Quartz RF cable for use with Ampere™ Generator (PN-004 515)	v1.04 or later
MediGuide™ Technology	10-pin connector from catheter integrated cable	v17.1 or later
Cool Point™ Irrigation Pump	Cool Point™ Tubing Set (85785)	v24 or later
EnSite Precision™ Cardiac Mapping System	Ethernet cable supplied with TactiSys™ Quartz equipment or EnSite™ Contact Force Module Kit	v2.2 or later
EnSite™ Contact Force Module	10-pin connector from catheter integrated cable	v2.0 or later

Indications for Use

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.

Contraindications

The catheter is contraindicated for:

- Patients who have had a ventriculotomy or atriotomy within the preceding four weeks as the recent surgery may increase the risk of perforation.
- Patients with prosthetic valves as the catheter may damage the prosthesis.
- Patients with an active systemic infection as this may increase the risk for cardiac infection.
- The use in coronary vasculature due to risk of damage to the coronary arteries.
- Patients with a myxoma or an intracardiac thrombus as the catheter could precipitate an embolus.
- The transseptal approach in a patient with an interatrial baffle or patch because the opening could persist and produce an iatrogenic atrial shunt.
- The retrograde trans-aortic approach in patients who have had aortic valve replacement.

Warnings

- Cases of delayed onset of atrioesophageal fistula (AEF) have been reported in association with radiofrequency catheter ablation procedures. While rare, AEF is associated with significant morbidity and mortality.
- The temperature sensor located within the electrode will not reflect either electrode tissue interface or tissue temperature due to the cooling effects of the saline irrigation of the electrode. The temperature displayed on the generator is the temperature of the cooled electrode, not tissue temperature. The temperature sensor is used to verify that the irrigation flow rate is adequate. Before initiating the application of RF current, a decrease in electrode temperature confirms the onset of saline irrigation of the ablation electrode. Recording temperature from the electrode during the application of RF current ensures that the irrigation flow rate is being maintained.
- 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. Permanent pacing may be required in patients who experience inadvertent complete AV block as a result of RF ablation.
- Implantable pacemakers and implantable cardioverter/defibrillator (ICDs) may be adversely affected by RF current. It is important to:
  - Have temporary external sources of pacing and defibrillation available during ablation.
  - Temporarily reprogram the pacing system to minimum output to minimize risk of inappropriate pacing.
  - Exercise extreme caution during ablation when in close proximity to atrial or ventricular permanent leads.
  - Program the ICD to the OFF mode during the ablation procedure.
  - Perform complete implantable device analysis on all patients after ablation.
- The combination of intracoronary placement of the ablation catheter and RF energy application has been associated with myocardial infarction.
- Significant x-ray exposure can result in acute radiation injury as well as increased risk for somatic and genetic effects, to both patients and laboratory staff. Therefore catheter ablation should only be performed after adequate attention has been given to the potential radiation exposure associated with the procedure, and steps taken to minimize this exposure. Careful consideration must therefore be given for the use of the device in pregnant women.
- Inspect saline irrigation for air bubbles prior to its use in the procedure. Air bubbles in the saline irrigation may cause emboli.
- When using the catheter in combination with a sheath and to prevent occlusion of the irrigation line:
  - Avoid applying simultaneous high torque and tensile stress (pulling) to the catheter while the catheter tip is engaged in the sheath in a curved position.
  - Release the steering (make the catheter straight) when pulling back the catheter into the sheath.
- Do not resterilize and reuse to avoid infection risks and incorrect catheter functionality.
- Do not immerse proximal handle or cable connector in fluids; electrical performance could be affected.
- The steerability feature of the catheter is designed to operate in a single plane of motion. Attempts to deflect the deflectable section in other planes (e.g. perpendicular to normal steering plane, etc.) may result in damage to the steering mechanism and impaired ability to position the catheter tip as desired by the operator. Do not use catheter with deflectable introducer sheaths that operate in multiple planes of motion. Do not use catheter with deflectable sheaths that may constrain catheter tip deflection through the use of manually operated hemostatic valves.

Precautions

- Cardiac ablation procedures must be performed by appropriately trained personnel in a fully-equipped operational electrophysiology laboratory.
- The long-term risks of protracted fluoroscopy and creation of RF induced lesions have not been established. Careful consideration must therefore be given for the use of the device in prepubescent children. Furthermore, the risk/benefit in asymptomatic patients has not been studied.
- To avoid thromboemboli, intravenous heparin should be used when entering the left heart during ablation. In general anticoagulation treatment should adhere to the ESC/AHA/ACC or any other consensus guidelines which includes intravenous heparin during left atrial ablation procedure and anticoagulation for a minimum period afterward.
- When using the catheter with conventional EP lab system (using fluoroscopy to determine catheter tip location) or with a 3D navigational system, careful catheter manipulation must be performed, especially when used in combination with a long sheath, in order to avoid cardiac damage, perforation, or tamponade. Do not use excessive force to advance or withdraw the catheter when resistance is encountered. The firmness of the tip dictates that care shall be taken to prevent perforation of the heart. If force sensing functionality is active, evaluate applied force to avoid applying excessive force.
- Always straighten the catheter tip before insertion or withdrawal.
- Always maintain a constant saline irrigation flow to prevent coagulation within the lumen of the catheter.
- A temperature or an impedance rise (the set limit is exceeded) may result in RF current interruption and may potentially be caused by coagulum or char formation at the catheter's tip. In this case, the catheter should be removed, and the tip cleaned of coagulum. When cleaning the tip electrode, be careful not to twist the tip electrode with respect to the catheter shaft; twisting may damage the tip electrode bond and loosen the tip electrode. Make sure the irrigation holes are not occluded prior to re-insertion.
- Apparent low power output, high impedance reading or failure of the RF equipment to function correctly at normal settings may indicate faulty application of the indifferent electrode(s) or failure of an electrical lead. Do not increase power before checking for obvious defects or misapplication.
- Read and follow the indifferent electrode manufacturer's instructions for use; indifferent electrodes that meet or exceed ANSI/AAMI requirements (HF18) should be used.
- Care should be taken when ablating near structures such as the sino-atrial and AV nodes.
- The sterile packaging and catheter integrity, including connectors, should be inspected prior to use.
- The catheter is intended for single use only.
- Do not expose catheter to organic solvents such as alcohol.
- The catheter used in conjunction with a RF generator is capable of delivering significant RF power. Patient or operator injury can result from improper handling of the catheter and indifferent electrode, particularly when operating the device. During energy delivery, the patient should not be allowed to come in contact with grounded metal surfaces. Position RF patient cables to avoid contact with the patient or other cables.
- The risk of igniting flammable gases or other materials is inherent in electrosurgery. Precautions must be taken to restrict flammable materials from the electrosurgical site. When using RF energy, non-flammable agents should be used for cleaning and disinfection wherever possible. Flammable agents used for cleaning or disinfecting, or as solvents of adhesives, should be allowed to evaporate before the application of high frequency surgery. There is a risk of pooling of flammable solutions under the patient or in body depressions such as the umbilicus, and in body cavities such as the vagina. Any fluid pooled in these areas should be mopped up before high frequency surgical equipment is used. Some materials, for example cotton and gauze, when saturated with oxygen may be ignited by sparks produced in normal use of the high frequency surgical equipment.
- Electromagnetic interference (EMI) produced by the catheter when used in conjunction with a RF generator during normal operation may adversely affect the performance of other equipment.
- Electrodes and probes for monitoring and stimulating devices can provide paths for high frequency current. The risk of burns can be reduced but not eliminated by placing the electrodes and probes as far away as possible from the ablation site and the indifferent electrode. Protective impedances may reduce the risk of burns, and permit continuous monitoring of the electrocardiogram during energy delivery. It is recommended to use monitoring systems incorporating high frequency current-limiting devices, and to not use needle monitoring electrodes.
- If the generator does not display temperature, verify that the appropriate cable is plugged into the generator. If temperature still is not displayed, there may be a malfunction in the temperature sensing system which must be corrected prior to applying RF power.
- Before use, check that irrigation holes are fully functional by infusing saline through the catheter.
- Regularly inspect and test cables and accessories.
- Store in a cool, dark place.

Caution

- Do not attempt to operate the device prior to completely reading and understanding the applicable instructions for use.

Adverse Events

The following adverse events have been documented for catheter ablation procedures:

- Air embolism
- Anesthesia reaction
- Aorto-right atrial fistula
- Arrhythmias, bradycardia, and tachycardia
- Arteriovenous fistula
- Cardiac perforation/tamponade
- Cardiac thromboembolism
- Cerebrovascular incident or Attack / Stroke
- Chest pain/discomfort
- Coronary artery dissection
- Coronary artery spasm
- Coronary artery thrombosis / occlusion
- Death
- Diaphragmatic paralysis
- Dislodgement of implantable cardioverter defibrillator or permanent pacing leads
- Endocarditis
- Gastroparesis
- Heart failure / pump failure
- Hemothorax
- Hospitalization (initial and prolonged)
- Increased creatinine phosphokinase (CPK) level
- Infections
- Laceration
- Leakage of air or blood into the lungs or other organs due to perforation
- Left atrial esophageal fistula
- Major bleeding, requiring surgery or transfusion
- Myocardial infarction
- Obstruction or perforation or damage to the vascular system
- Pericarditis
- Pericardial effusion
- Phrenic nerve damage including diaphragmatic paralysis
- Pleural effusion
- Pneumonia
- Pneumothorax
- Pseudoaneurysm
- Pulmonary edema
- Pulmonary embolism
- Pulmonary vein dissection
- Pulmonary vein thrombus
- Pulmonary hypertension
- Respiratory depression
- Skin burns
- Severe PV stenosis (>70%), or complete occlusion of a PV, even in the absence of symptoms
- Tamponade, potentially requiring surgery
- Temperature elevation or fever
- Transient ischemic attack (TIA)
- Thromboembolism
- Thrombosis
- Unintended complete or incomplete AV, sinus node, or other heart block or damage
- Valvular damage
- Vascular bleeding/local hematomas/ecchymosis
- Vasovagal reactions
- Ventricular tachyarrhythmia
- Volume overload

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.

TOCCASTAR

Study Objective

The primary objective of this study was to evaluate the safety and effectiveness of the TactiCath™ Set to treat drug refractory symptomatic Paroxysmal Atrial Fibrillation (PAF) when compared with the Biosense Webster Navistar ThermoCool Diagnostic Ablation Catheter (Control).

Study Design

The study was a prospective, randomized, multicenter, interventional clinical investigation conducted at 17 investigational sites (10 in the US and 7 outside of the US). The study was conducted on patients 18 or older.

Clinical Endpoints

The primary effectiveness endpoint was a noninferiority comparison of treatment success between the TactiCath™ Set and the control device and defined as combined Acute and Chronic success.

Acute success was defined as electrical isolation of all 4 PVs, or in the event of a common PV, the clinical equivalent of all PVs by the end of the index procedure.

Chronic success was defined as acute procedural success and freedom from recurrence of symptomatic PAF, Atrial Flutter, and Atrial Tachycardia lasting longer than 30 seconds through 9 months of follow-up after a 3 month blanking period. Reablation for AF occurring 80 or more days after the index procedure or the use of class I or class III AADs after the 3-month follow-up constitutes treatment failure.

The secondary effectiveness endpoints were related to the use of the contact force sensor and assess the procedural effectiveness superiority of the TactiCath™ Set over the control device by use of a hierarchical closed test procedure.

The primary safety endpoint was a noninferiority comparison of device-related early-onset primary serious adverse events (SAEs) between the TactiCath™ Set and the control device occurring within 7 days of the index procedure or hospital discharge, whichever was later, and diagnosed at any time during the follow up period.

Primary SAEs that met the severity criteria described below contributed to the primary safety endpoint only in subjects in whom a study device (TactiCath or control) was introduced. Hospitalizations solely for arrhythmia recurrence (without coexisting conditions such as thromboembolism, worsening heart failure, etc.) were not considered primary SAEs.

Table 3. Primary Serious Adverse Events and Severity Criteria

Primary Serious Adverse Event	Severity Criteria
Atrial perforation	Visible (either with radiographic and/or ultrasonagraphic imaging and/or direct visualization) movement of ablation catheter, needle or sheath through the atrial wall as evidenced by bleeding and the need for pericardial drainage or surgical intervention
AV block	New, persistent 2nd or 3rd degree AV block not attributable to a vasovagal reaction or medication effect and requiring permanent pacing
Death	Adverse event resulting in subject death
Diaphragmatic paralysis	Change in baseline diaphragmatic function as evidenced by elevation of a hemidiaphragm above its normal position or loss of normal respiratory excursion but not due to a pulmonary process such as atelectasis and persisting longer than the end of the procedure
Gastroparesis	Gastroparesis as a result of ablation requiring intervention or hospitalization
Hospitalization (initial or prolonged)	Adverse event leading to new hospital admission or extension of initial hospital stay beyond expected timeframe due to ablation procedure-related cause. Excludes hospitalization solely for arrhythmia recurrence.
Left atrial esophageal fistula	Creation of a direct communication (fistula) between the left atrium and esophagus necessitating surgical intervention or resulting in permanent impairment (eg, due to hemorrhage or septic emboli)
Myocardial infarction	Requires 2 of the following 3 criteria: – Elevation of biochemical markers of myocardial necrosis (preferably troponin levels) – Ischemic symptoms – Development of pathologic Q waves on the ECG or persistent ECG changes indicative of ischemia (ST segment elevation or depression)
Pericarditis	Pleuritic chest discomfort associated with either pericardial rub and/or ECG changes that requires or prolongs hospitalization
Pneumothorax	Identification of air in the pleural space which either prolongs hospital stay (for observation) or requires surgical intervention or chest tube placement
Pulmonary edema	Pulmonary alveolar fluid accumulation accompanied by typical symptoms (dyspnea), physical findings (rales, hypoxemia), radiologic findings, and response to diuretic therapy and requiring hospitalization
PV stenosis	Severe (≥70%), or complete occlusion of a PV, even in the absence of symptoms

Table 3. Primary Serious Adverse Events and Severity Criteria

Primary Serious Adverse Event	Severity Criteria
Stroke	Brain disorder involving loss of brain functions (that persists for >24 hours) that occurs when the blood supply to any part of the brain is interrupted as determined by the consulting neurologist
Tamponade	Pericardial effusion of sufficient size to cause hemodynamic compromise and requiring drainage based on hypotension, echocardiographic findings, or other clinical factors
Thromboembolism	Deep vein thrombosis or pulmonary embolism
Transient ischemic attack	Acute episode of temporary (<24 hrs.) and focal loss of cerebral function of vascular (occlusive) origin as determined by the consulting neurologist
Vascular access complications	Vascular access complication requiring surgical repair, blood transfusion (eg, groin hematoma, AV fistula) or significant intervention such as thrombin injection (eg, pseudoaneurysm)

The secondary safety endpoint was to evaluate the incidence of all SAEs during the 12-month follow-up period.

Subject Accountability

The following table provides a summary of the subject accountability and disposition for the study:

Table 4. Subject Accountability and Disposition

Subject Accountability	TactiCath		Control		Total	
Subjects enrolled in study	172		145		317	
Subjects in roll-in population		17		N/A		17
Full analysis population–all subjects randomized (FA)	155		145		300	
Subjects who had no study device introduced		3		2		5
Safety analysis population (SAF)	152		143		295	
Subjects who did not have PVI attempted		3		2		5
Modified intent-to-treat population (mITT)	149		141		290	
Subjects excluded from analysis due to major protocol deviation		3		7		10
Per protocol population (PP)	146		134		280	

Demographics

The tables below summarize the demographic information. Subjects were randomized 1:1 upon signing the informed consent.

Table 5. Subject Demographics (SAF Population)

Demographic		TactiCath N=152	Control N=143	Total N=295
Age, years		59.6 (9.32)	61.0 (10.84)	60.3 (10.09)
		61.0 [53.0, 66.0]	62.0 [53.0, 68.0]	61.0 [53.0, 67.0]
		31, 78	28, 82	28, 82
Sex, male		100 (65.8%)	91 (63.6%)	191 (64.7%)
Race	American Indian or Alaska Native	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Asian	1 (0.7%)	0 (0.0%)	1 (0.3%)
	Black	1 (0.7%)	0 (0.0%)	1 (0.3%)
	Native Hawaiian or Pacific Islander	0 (0.0%)	0 (0.0%)	0 (0.0%)
	White	148 (97.4%)	141 (98.6%)	289 (98.0%)

Table 5. Subject Demographics (SAF Population)

Demographic		TactiCath N=152	Control N=143	Total N=295
	Other	2 (1.3%)	2 (1.4%)	4 (1.4%)
Ethnicity	Hispanic or Latino	3 (2.0%)	5 (3.5%)	8 (2.7%)
	Not Hispanic or Latino	149 (98.0%)	138 (96.5%)	287 (97.3%)
Height (cm)[1]		174.6 (10.55) 175.0 [167.0, 182.0] 152, 205	174.5 (9.87) 175.0 [167.0, 180.0] 137, 203	174.5 (10.21) 175.0 [167.0, 182.0] 137, 205
Weight (kg)[1]		86.70 (17.290) 86.70 [75.00, 98.00] 37.8, 133.8	85.35 (17.246) 84.00 [72.00, 96.00] 54.0, 148.8	86.04 (17.252) 85.15 [74.00, 97.50] 37.8, 148.8

Continuous variables are presented as mean (SD), median [IQR], min, max; categorical variables are presented as n (%).

[1] Height and weight were not reported for 1 TactiCath subject.

Table 6. Medical History (SAF Population)

	TactiCath N=152		Control N=143		Total N=295	
Medical History	All History	Currently Active	All History	Currently Active	All History	Currently Active
Cardiovascular system	43 (28.3%)	31 (20.4%)	57 (39.9%)	44 (30.8%)	100 (33.9%)	75 (25.4%)
Head, eyes, ears, nose, throat	8 (5.3%)	4 (2.6%)	10 (7.0%)	5 (3.5%)	18 (6.1%)	9 (3.1%)
Respiratory system	31 (20.4%)	26 (17.1%)	16 (11.2%)	15 (10.5%)	47 (15.9%)	41 (13.9%)
Musculoskeletal system	29 (19.1%)	10 (6.6%)	27 (18.9%)	14 (9.8%)	56 (19.0%)	24 (8.1%)
Integumentary system	4 (2.6%)	2 (1.3%)	3 (2.1%)	1 (0.7%)	7 (2.4%)	3 (1.0%)
Gastrointestinal system	35 (23.0%)	16 (10.5%)	29 (20.3%)	17 (11.9%)	64 (21.7%)	33 (11.2%)
Genitourinary system	23 (15.1%)	7 (4.6%)	16 (11.2%)	4 (2.8%)	39 (13.2%)	11 (3.7%)
Nervous / neurological system	7 (4.6%)	5 (3.3%)	3 (2.1%)	2 (1.4%)	10 (3.4%)	7 (2.4%)
Endocrine system	13 (8.6%)	9 (5.9%)	21 (14.7%)	13 (9.1%)	34 (11.5%)	22 (7.5%)
Lymphatic system	1 (0.7%)	0 (0.0%)	3 (2.1%)	1 (0.7%)	4 (1.4%)	1 (0.3%)
Immunological system	3 (2.0%)	2 (1.3%)	3 (2.1%)	2 (1.4%)	6 (2.0%)	4 (1.4%)
Psychiatric	6 (3.9%)	6 (3.9%)	3 (2.1%)	3 (2.1%)	9 (3.1%)	9 (3.1%)
Allergic conditions	2 (1.3%)	2 (1.3%)	2 (1.4%)	2 (1.4%)	4 (1.4%)	4 (1.4%)

Procedural Data

The table below summarizes the index procedural data.

Table 7. Index Procedural Data (PP Population)

Index Procedure Data	TactiCath N=146	Control N=134
Total fluoroscopy time (minutes)	30.5 (17.6) 4.0, 131.8	27.3 (17.4) 3.8, 105.0
Number of RF applications	59.7 (32.6) 13.0, 204.0	64.7 (42.9) 10.0, 241.0
Total RF time (seconds)	3103 (1699) 709, 8728	3435 (1493) 1036, 10135

Table 7. Index Procedural Data (PP Population)

Index Procedure Data	TactiCath N=146	Control N=134
Duration of ablation (seconds)	56 (29) 24, 190	74 (62) 14, 464
Power (Watts)[1]	28.8 (4.4) 19.3, 41.1	28.5 (4.6) 19.0, 41.0

Results are presented as mean (SD), min, max. Includes data from all lesions delivered.
[1] Sample size for Power: TactiCath (n=148), Control (n=133).

Results

Primary Effectiveness Results

The primary effectiveness endpoint success criterion was met, to demonstrate noninferiority of the TactiCath™ device compared to the control.

Table 8. Summary of Treatment Success: Primary Effectiveness Analysis (PP Population)

Endpoint	TactiCath N=146	Control N=134
Acute procedural success	146 (100%)	134 (100%)
Acute procedural failure	0 (0.0%)	0 (0.0%)
Chronic success	99 (67.8%)	93 (69.4%)
Chronic failure	47 (32.2%)	41 (30.6%)

Figure 1 below presents the plot for time-to-treatment failure for protocol-defined effectiveness for the PP population.

Figure 1. Kaplan-Meier Plot for Time-to-Treatment Failure (PP Population)

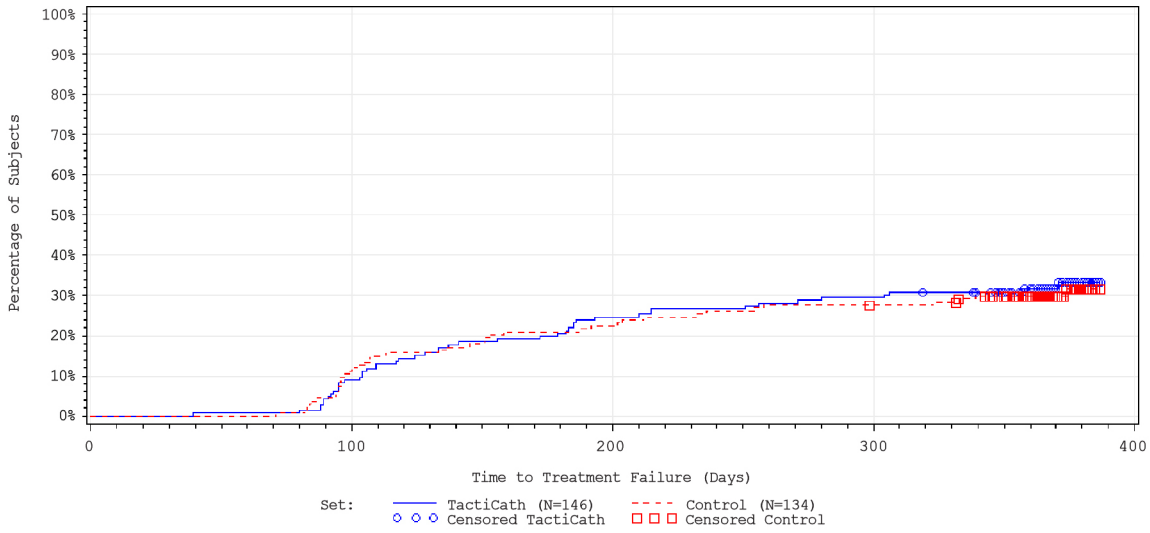
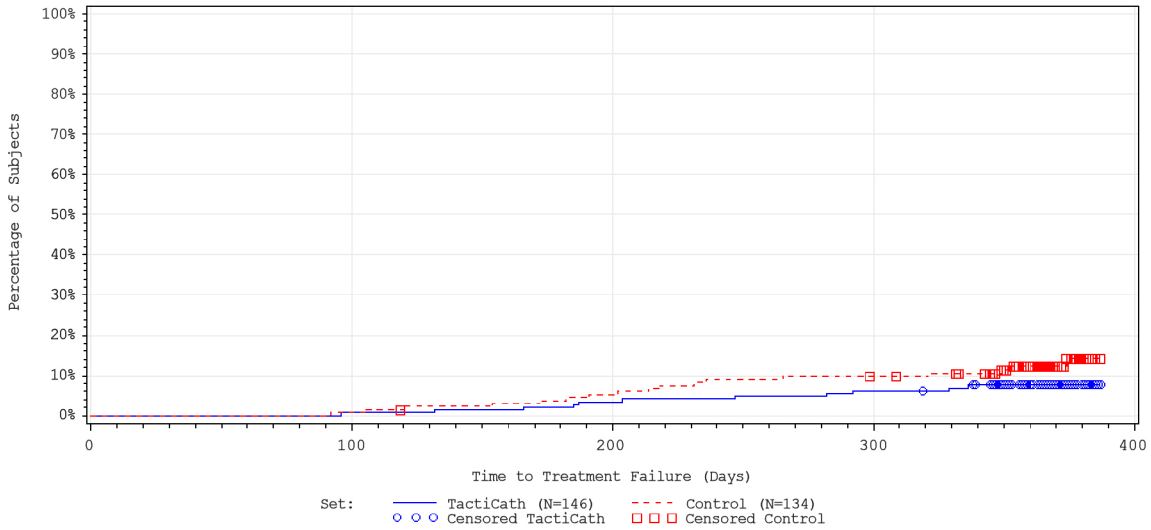


Figure 2 below presents the Kaplan-Meier plot for time-to-treatment failure due to the reablation procedure in the PP population. As shown, over time, more subjects in the control arm experienced reablation than in the TactiCath arm.

Figure 2. Kaplan-Meier Plot for Time-to-Treatment Failure Due to Re-Ablation Procedures (PP Population)



Secondary Effectiveness Results

The table below provides a summary of the procedural efficiency. The descriptive effectiveness endpoints in the study were related to the use of the contact force sensor and demonstrated a significant reduction in mean total RF application time with the TactiCath™ Set versus the control (51.7 vs 58.3 min, P=0.002).

Table 9. Summary of Procedural Efficiency (PP Population)

Secondary Effectiveness Endpoint	TactiCath N=146	Control N=134	P Value (1-sided)
Percentage of lesion sets with electrically reconnected PVs following a 30-minute waiting period assessed by entrance block (%) at index procedure	n=145	n=134	0.209
	11.09 (22.738)	14.61 (27.751)	
	0.00 [0.00, 0.00]	0.00 [0.00, 25.00]	
	0.0, 100.0	0.0, 100.0	
Time to achieve initial PV isolation at index procedure (minutes)	n=146	n=134	0.941
	90.4 (43.71)	86.4 (38.67)	
	87.0 [55.0, 117.0]	85.5 [58.0, 108.0]	
	16, 261	18, 224	
Total time of RF application at index procedure (minutes)	n=146	n=133	0.002
	51.72 (27.671)	58.31 (27.333)	
	46.40 [28.30, 65.30]	53.50 [40.80, 72.80]	
	13.0, 139.3	17.1, 196.0	

Continuous variables are presented as mean (SD), median [IQR], min, max.

Primary Safety Results

The primary safety endpoint of noninferiority when compared to the control device was met. The predefined analysis for the primary safety endpoint is based on the SAF cohort of 295 subjects.

Table 10. Primary Safety Endpoint (SAF Population)

			Difference in Primary SAE Rates (TactiCath Arm Minus Control Arm)	
Primary Safety Endpoint	**TactiCath N=152**	**Control N=143**	**Point Estimate**	**One-Sided 95% UCL[1]**
Subjects experienced primary SAEs	3 (2.0%)	2 (1.4%)	0.6%	3.0%

[1] Noninferiority of TactiCath™ catheter to the control device is demonstrated if the 95% UCL for the difference in rates (TactiCath arm minus control arm) is less than 9%.

Table 11. Summary of Primary SAEs by Term (SAF Population)

	TactiCath N=152		**Control N=143**		**Total N=295**	
Event	**Subjects (%)**	**Events**	**Subjects (%)**	**Events**	**Subjects (%)**	**Events**
Atrial perforation	0 (0.0%)	0	1 (0.7%)	1	1 (0.3%)	1
Cardiac perforation / cardiac tamponade	1 (0.7%)	1	0 (0.0%)	0	1 (0ght I .3%)	1
Pericarditis	2 (1.3%)	2	0 (0.0%)	0	2 (0.7%)	2
PV stenosis	0 (0.0%)	0	1 (0.7%)	2	1 (0.3%)	2
Total subjects with at least 1 primary SAE	**3 (2.0%)**	**3**	**2 (1.4%)**	**3**	**5 (1.7%)**	**6**

Secondary Safety Results

The secondary safety endpoint consists of an evaluation of all SAEs during the 12-month follow-up period. A total of 32 (10.8%) subjects experienced 39 safety-related SAEs in the study. Six (6) of these SAEs were primary safety events, the other 33 SAEs were non-primary events and are summarized in the tables below.

Table 12. Procedure-Related, Non-Primary SAEs (SAF Population)

	TactiCath N=152		**Control N=143**		**Total N=295**	
Serious Adverse Event	**Subjects n (%)**	**Events**	**Subjects n (%)**	**Events**	**Subjects n (%)**	**Events**
Total number (%) subjects with at least 1 non-primary SAE[1]	10 (6.6)	11	11 (7.7)	11	21 (7.1)	22
Atrial perforation[2]	0	0	1 (0.7)	1	1 (0.3)	1
Cardiac perforation / cardiac tamponade	1 (0.7)	1	0	0	1 (0.3)	1
Pulmonary edema	2 (1.3%)	2	2 (1.4)	2	4 (1.4)	4
Vascular access complications	3 (2.0)	3	3 (2.1)	3	6 (2.0)	6
Hospitalizations (initial or prolonged)	4 (2.6)	4	5 (3.5)	5	9 (3.1)	9
GI bleeding	1 (0.7)	1	0	0	1 (0.3)	1
Anemia	0	0	1 (0.7)	1	1 (0.3)	1
Hematuria	0	0	1 (0.7)	1	1 (0.3)	1
Rule out esophageal injury	0	0	1 (0.7)	1	1 (0.3)	1
Secondary to groin hematoma	1 (0.7)	1	0	0	1 (0.3)	1
Secondary to pneumonia	0	0	1 (0.7)	1	1 (0.3)	1

Table 12. Procedure-Related, Non-Primary SAEs (SAF Population)

	TactiCath N=152		Control N=143		Total N=295	
Serious Adverse Event	Subjects n (%)	Events	Subjects n (%)	Events	Subjects n (%)	Events
Secondary to small bowel obstruction	1 (0.7)	1	0	0	1 (0.3)	1
Secondary to urinary retention	0	0	1 (0.7)	1	1 (0.3)	1
Vascular access complication	1 (0.7)	1	0	0	1 (0.3)	1
Non-primary SAE (other)	1 (0.7)	1	0	0	1 (0.3)	1
Secondary to cardiac arrest	1 (0.7)	1	0	0	1 (0.3)	1

[1] Subjects reporting more than one SAE in each level are only counted once. Only SAEs adjudicated as non-primary SAE are included.

[2] Was not related to the use of a study device

Table 13. Not Procedure-Related, Non-Primary SAEs (SAF Population)

	TactiCath N=152		Control N=143		Total N=295	
Serious Adverse Event	Subjects n (%)	Events	Subjects n (%)	Events	Subjects n (%)	Events
Total number (%) subjects with at least 1 non-primary SAE[1]	6 (3.9)	7	5 (3.5)	5	11 (3.7)	12
Hospitalizations (initial or prolonged)	3 (2.0)	4	2 (1.4)	2	5 (1.7)	6
Pericardial effusion at redo (not with study device)	1 (0.7)	1	0	0	1 (0.3)	1
Coronary artery disease	1 (0.7)	1	1 (0.7)	1	2 (0.7)	2
Mitral valve incompetence	1 (0.7)	1	0	0	1 (0.3)	1
Pneumonia	0	0	1 (0.7)	1	1 (0.3)	1
Pulmonary hypertension	1 (0.7)	1	0	0	1 (0.3)	1
Non-primary SAE (other)	3 (2.0)	3	3 (2.1)	3	6 (2.0)	6
Pacemaker implant	0	0	1 (0.7)	1	1 (0.3)	1
Redo during blanking	3 (2.0)	3	2 (0.7)	2	5 (1.7)	5

[1] Subjects reporting more than one SAE in each level are only counted once. Only SAEs adjudicated as non-primary SAE are included

Contact Force Results

The TactiCath™ Set generates a summary of contact force parameters applied during the ablation procedure. A statistical summary of the distribution of contact force averaged over all subjects in the TactiCath arm is presented in the following table.

Table 14. Distribution of Contact Force in the TactiCath Arm (PP Population)

Contact Force Distribution	TactiCath N=146[1]
Number of ablations	n=145
	61.1 (32.97)
	55.0 [37.0, 76.0]
	17, 204
Average contact force (g)	n=144
	22.2 (7.47)
	22.0 [17.0, 27.0]
	7, 44
Standard deviation of contact force (per procedure) (g)	n=144
	12.3 (9.88)
	11.0 [8.0, 14.5]

Table 14. Distribution of Contact Force in the TactiCath Arm (PP Population)

Contact Force Distribution	TactiCath N=146[1]
	3, 113
Minimum contact force (g)	n=144
	4.2 (3.46)
	4.0 [2.0, 6.0]
	0, 16
5th percentile average contact force (g)	n=144
	7.8 (4.38)
	7.0 [5.0, 10.0]
	0, 30
95th percentile average contact force (g)	n=144
	42.6 (14.99)
	42.0 [33.0, 53.0]
	2, 80
Maximum average contact force (g)	n=144
	66.5 (95.35)
	53.0 [39.5, 69.5]
	17, 1111

Results are presented as mean (SD), median [IQR], min, max.

[1] For those subjects with evaluable data

Previous studies have suggested that optimizing contact force during lesion delivery yields better acute and chronic outcomes. Recent analysis of study subjects experiencing reablation procedures demonstrated a strong correlation between contact force parameters and site of reconnection. A significant determinant of durable PV isolation was the number of low contact force lesions.

A post hoc analysis of treatment success for all TactiCath subjects in the PP population who were treated with greater than or equal to 10 g of contact force in at least 90% of all lesions (n=83) is presented in the following table.

Table 15. Success Rates for TactiCath Subjects with a High and Low Percentage of Lesions above 10 g (PP Population)

Contact Force	Subjects (n)	Success (%)
≥90% of lesions with CF ≥10 g	83	75.9%
<90% of lesions with CF ≥10 g	62	58.1%

Using protocol-defined criteria for success, TactiCath subjects who had ≥90% of lesions with CF ≥10 g were significantly more successful (75.9% vs 58.1%) than those with <90% of lesions with contact force ≥10 g.

The table below summarizes failure modes for subjects with at least 90% of lesions with 10 g or more.

Table 16. Failure Mode for TactiCath Subjects Who Had ≥90% of Lesions with CF ≥10 g

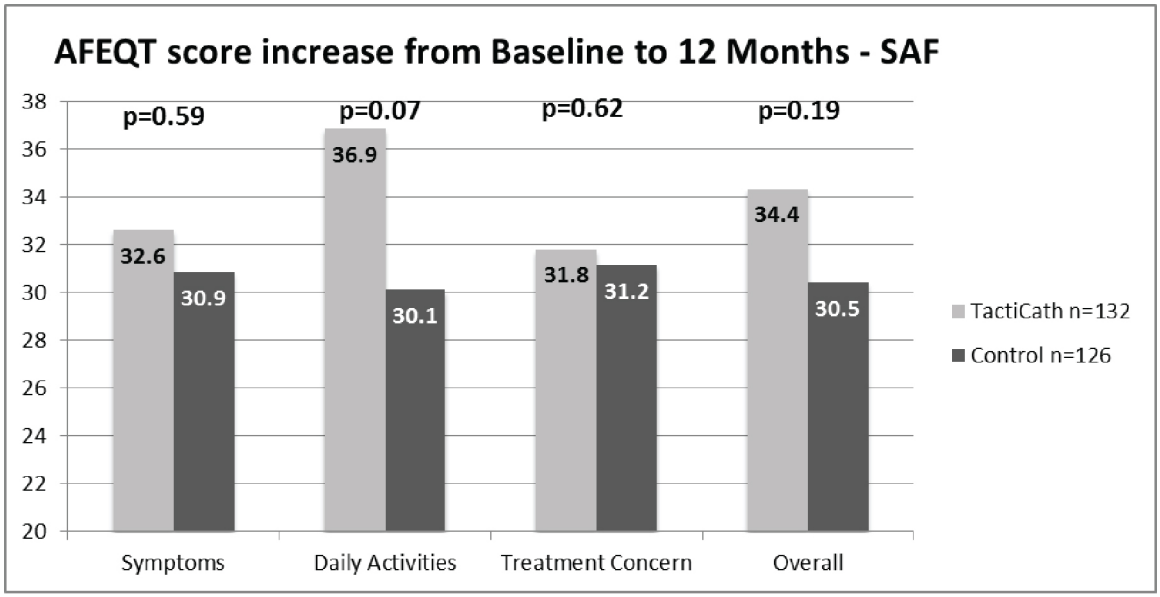
Reason for Failure	Subjects with Failure Mode (n)
Acute failure	0
Reablation only	1
AAD only	4
TTM / ECG only	8
Reablation + AAD	0
Reablation + TTM / ECG	1
Reablation + AAD + TTM / ECG	2
AAD + TTM / ECG	4
Total	**20**

Control subjects had a higher failure rate due to reablation procedures after the blanking period compared to TactiCath subjects (12.7% vs 7.5%, respectively). Only 4 of the 83 (4.8%) subjects who had ≥90% of lesions with CF ≥10 g required treatment with repeat ablation during the effectiveness assessment period compared to 17 of 134 (12.7%) subjects in the control arm (P=0.044).

Quality of Life Results

Quality of Life was measured at baseline and at 12 month follow-up, using the 'Atrial Fibrillation Effect on QualiTy-of-life' (AFEQT) questionnaire. From the 280 patients in the Per-Protocol (PP) Population, 254 patients answered to both questionnaires at baseline and 12 months. The results are represented in the graph below.

Figure 3. AFEQT Score Increase from Baseline to 12 Months - SAF



Gender Subgroup Analysis Results

A summary of treatment success by gender is provided in the following table.

Table 17. Treatment Success (Protocol Defined Effectiveness) by Gender (PP Population)

	Male		Female		Difference in Success Rates (TactiCath Arm Minus Control Arm)	
Endpoint	TactiCath N=97	Control N=86	TactiCath N=49	Control N=48	Male Point Estimate % [95% LCL]	Female Point Estimate % [95% LCL]
Acute procedural success	97 (100%)	86 (100%)	49 (100%)	48 (100%)	0 [NA]	0 [NA]
Acute procedural failure	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		
Chronic success	66 (68.0%)	56 (65.1%)	33 (67.3%)	37 (77.1%)	2.9 [-8.6]	-9.7 [-24.6]
Chronic failure	31 (32.0%)	30 (34.9%)	16 (32.7%)	11 (22.9%)		
Endpoint success / failures are reported as n (%), point estimate is reported as % [95% LCL].						

Study Conclusion

In conclusion, the results demonstrate that there is a reasonable assurance of safety and effectiveness to support the use of the TactiCath™ Contact Force Ablation Catheter for the treatment of drug refractory recurrent symptomatic paroxysmal atrial fibrillation, when used in conjunction with a compatible RF generator and three-dimensional electroanatomic mapping system.

TactiSense IDE

Study 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

The study is a 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. One hundred fifty six (156) subjects were enrolled at 19 investigational sites in the US, Europe, and Australia.

Clinical Endpoints

There are two primary endpoints and ten descriptive endpoints for this study. 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 primary safety endpoint is the rate of device or procedure-related serious adverse events occurring within 7 days of the index procedure. SAEs related solely to arrhythmia recurrence (without coexisting conditions such as thromboembolism, worsening heart failure, etc.) were not considered primary safety endpoint events. Atrial-esophageal fistula, cardiac perforation/tamponade, and pulmonary vein stenosis that occur >7 days post procedure through 30 days will also contribute to the primary endpoint. These events had to meet the criteria listed below to be included in the primary endpoint as adjudicated by the Clinical Events Committee.

Table 18. Primary Serious Adverse Events and Severity Criteria

Primary Serious Adverse Event	Criteria
Atrial esophageal fistula	Development of a connection between the atrium and the lumen of the esophagus
AV block	New, persistent 2nd or 3rd degree AV block not attributable to a vasovagal reaction or medication effect and requiring permanent pacing
Cardiac perforation / tamponade	Pericardial effusion that results in hemodynamic compromise, requires elective or urgent pericardiocentesis, or results in a 1-cm or more pericardial effusion as documented by echocardiography.
Death	Adverse event resulting in subject death
Diaphragmatic paralysis	Change in baseline diaphragmatic function as evidenced by elevation of a hemi-diaphragm above its normal position or loss of normal respiratory excursion but not due to a pulmonary process such as atelectasis and persisting longer than the end of the procedure
Gastroparesis	Vagal nerve injury that results in gastric dysmotility requiring intervention or hospitalization
Hospitalization (initial or prolonged)	Adverse event leading to new hospital admission or prolongation of initial hospital stay beyond expected timeframe due to ablation procedure-related cause. Excludes hospitalization solely for arrhythmia recurrence.
Myocardial infarction	Irreversible necrosis of heart muscle secondary to prolonged ischemia with at least one of the following three criteria: – Detection of ECG changes indicative of new detection of ECG changes indicative of new ischemia (new ST-T wave changes or new LBBB) that persist for more than 1 hour – Development of new pathological Q waves on an ECG – Imaging evidence of new loss of viable myocardium or new regional wall motion abnormality
Pericarditis	Inflammation of the pericardium resulting in chest discomfort/pain associated with either pericardial rub and/or ECG changes that requires or prolongs hospitalization
Pneumothorax	Abnormal collection of air in the pleural space between the lung and the chest wall that prolongs hospital stay (for observation) or requires surgical intervention or chest tube placement
Pulmonary edema	Excess fluid in the lungs that includes all of the following: – Symptoms (e.g. dyspnea) – Physical findings (e.g. rales, hypoxemia) – Radiologic findings – Respond to diuretic therapy – Require hospitalization
Pulmonary vein stenosis	Reduction in the diameter of a pulmonary vein (PV) or PV branch >70% confirmed via imaging (CT or MRI)
Stroke	Brain disorder involving loss of brain functions (that persists for > 24 hours) that occur when the blood supply to any part of the brain is interrupted as determined by the consulting neurologist

Table 18. Primary Serious Adverse Events and Severity Criteria

Primary Serious Adverse Event	Criteria
Thromboembolism	An arterial or venous thrombus that results in deep vein thrombosis, pulmonary embolism, or peripheral arterial embolism
Transient ischemic attack	Acute episode of temporary (< 24 hrs.) and focal loss of cerebral function of vascular (occlusive) origin as determined by the consulting neurologist
Vascular access complications	Adverse event related to vascular access requiring surgical repair, blood transfusion (e.g., groin hematoma, AV fistula) or significant intervention such as thrombin injection (e.g., pseudoaneurysm)

Primary Effectiveness Endpoint

The primary effectiveness endpoint was acute procedural success, where acute procedural success was defined as confirmation of entrance block in all pulmonary veins.

Descriptive Endpoint

There were ten types of descriptive endpoints. Descriptive endpoints are reported using summary statistics and no hypothesis testing was performed. The first three descriptive endpoints are reported for this interim analysis.

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
    - Usage of AutoMark
2. Proportion of index cases achieving ≥90% lesions with ≥10 g contact force.
3. Serious adverse events and adverse events related to the procedure and/or ablation catheter through 30 days post index ablation.
4. Serious adverse events and adverse events related to the procedure and/or ablation catheter through 1 year post index ablation.
5. One-year success defined as freedom from symptomatic AF/AFL/AT lasting at least 30 seconds without a new class I or III AAD or a higher dosage of pre-existing AAD as assessed from the end of the 3-month blanking period to 12 months following the ablation procedure.
6. One-year drug-free success defined as freedom from any AF/AFL/AT lasting at least 30 seconds or any class I or III AAD after removal from antiarrhythmic drug therapy as assessed from the end of the 3-month blanking period to 12 months following the ablation procedure.
7. Changes in EQ-5D-5L scores from baseline to follow up at 3, 6, and 12 months.
8. Changes in AFEQT scores from baseline to follow up at 3, 6, and 12 months.
9. Cardiovascular-related health care utilization through 12 months post index ablation.
10. Force time integral (FTI) and lesion index (LSI).

Subject Accountability

The following table provides a summary of the subject accountability and disposition for the study:

Table 19. Analysis Populations–Per Subject Analysis

Analysis Population (Abbreviation)	Description	Total N=156
Effectiveness (EFF)	Device introduced	151
Safety (SAF)	Device Introduced and 30 days of follow up or primary safety endpoint event[1]	149
Radiofrequency delivered (RF)	Subjects had the TactiCath™ Contact Force Ablation Catheter, Sensor Enabled™, inserted to their vasculature and radiofrequency energy was delivered	150

[1] This population includes all enrolled subjects who have also had the TactiCath™ Contact Force Ablation Catheter, Sensor Enabled™, inserted into their vasculature, and either had a primary safety endpoint event or completed a visit at or beyond their 30-day follow-up visit window.

Demographics

The tables below summarize the demographic information.

Table 20. Baseline Demographics (EFF Population)

	Total N=151
Age (year)	
Median (Q1, Q3) (n)	65.0 (56.0, 71.0) (151)
Age ≥ 65 years	50.3% (76/151)
Gender	
Male subjects	60.3% (91/151)
Ethnicity	
Hispanic or Latino	2.0% (3/151)
Not Hispanic or Latino	82.8% (125/151)
Declined / unknown	15.2% (23/151)
Race	
American Indian or Alaska Native	0.7% (1/151)
Asian	1.3% (2/151)
Black or African Heritage	0.7% (1/151)
Native Hawaiian or Pacific Islander	0.0% (0/151)
White	81.5% (123/151)
Other race	2.0% (3/151)
Declined / unknown	13.9% (21/151)
Height (cm)	
Mean ± SD (n)	173.8 ± 9.0 (151)
Weight (kg)	
Mean ± SD (n)	85.0 ± 18.1 (151)
BMI (kg/m2)	
Mean ± SD (n)	28.0 ± 5.0 (151)

Table 21. Medical History (EFF Population)

	Total N=151
Arrhythmia History	
Time since AF diagnosis (years)	
Median (Q1, Q3) (n)	1.8 (0.5, 4.4) (148)
Atrial flutter (typical)	22.5% (34/151)
Atrial flutter (atypical)	3.3% (5/151)
Atrial tachycardia	3.3% (5/151)
Ventricular tachycardia	4.6% (7/151)
1st degree heart block	3.3% (5/151)
2nd degree heart block	0.7% (1/151)
3rd degree heart block	0.0% (0/151)
AV nodal dysfunction	4.0% (6/151)
Other conduction abnormality[1]	11.9% (18/151)
Pacemaker or implantable cardiac monitor	12.6% (19/151)
Cardiovascular History	
Coronary artery disease	13.2% (20/151)
Heart failure	2.6% (4/151)
Hypertension	53.0% (80/151)
Diabetes	9.9% (15/151)
Stroke or TIA	9.3% (14/151)
Myocardial infarction	4.0% (6/151)
Thromboembolism	2.0% (3/151)
Obstructive sleep apnea	13.2% (20/151)
Chronic obstructive pulmonary disease	2.6% (4/151)
Structural heart disease	3.3% (5/151)
Known family history of cardiovascular disease	53.6% (81/151)
Other cardiovascular disease[2]	3.3% (5/151)
Other vascular disease	
Peripheral artery disease	0.0% (0/151)
Aortic plaque	0.0% (0/151)
Other[3]	4.0% (6/151)
Left ventricular ejection fraction (LVEF)	
Median (Q1, Q3) (n)	60.7 (55.0, 65.0) (151)
Left atrium diameter	
Median (Q1, Q3) (n)	3.8 (3.3, 4.3) (151)
Baseline Antiarrhythmic Drug Use	
Any AAD at baseline	96.0% (145/151)
AAD class I or III at baseline	80.1% (121/151)
Other AAD	66.2% (100/151)
Baseline Heart Failure Classification	
No heart failure	75.5% (114/151)
NYHA class I	21.9% (33/151)
NYHA class II	2.6% (4/151)
NYHA class III	0.0% (0/151)
NYHA class IV	0.0% (0/151)
Baseline 12-Lead Electrocardiogram Results	
In normal sinus rhythm	68.2% (103/151)
Not in normal sinus rhythm	31.8% (48/151)

Table 21. Medical History (EFF Population)

	Total N=151
Atrial fibrillation	13.9% (21/151)
Atrial flutter	0.7% (1/151)
Atrial tachycardia	0.0% (0/151)
Sinus bradycardia[4]	11.9% (18/151)
Other[5]	6.0% (9/151)

[1] Instances of "Other conduction abnormality" include: SVT (6), PVCs (2), Sick sinus syndrome (2), Sinus bradycardia (2), Bradycardia (1), LAHB (1), Right bundle branch block (1), Tachy-brady (1), Variable AV block and sinus node dysfunction (1), ventricular fibrillation (1), Wolff-Parkinson White Syndrome (1). These counts may add up to more than the total number of subjects with Other conduction abnormalities because some subjects may have experienced more than one type of abnormality.

[2] Cases of "Other cardiovascular disease' include: Carotid artery stenosis (1), Coronary sclerosis (1), Hyperlipidemia (1), Type A Aortic dissection & repair (1), Not specified (1).

[3] Cases of "Other vascular disease: Other" include: Iliac compression syndrome (1), Hypoplasy of vertebral artery (1), Varicosis (1), Stenosis of carotid arteries (1), Persistent dissection down left common iliac (1), Ruptured aortic aneurysm (1).

[4] Three patients with sinus bradycardia displayed additional symptoms: AV dissociation (1), PACs (1), and Sinus arrhythmia (1).

[5] Cases of "Not in normal sinus rhythm: Other" include: Atrial paced (2), Accelerated junctional rhythm (1), Atrial paced with regular ventricular rhythm (1), Electronic atrial PPM (1), NSR with PVC (1), Sinus rhythm with occasional premature ventricular complexes (1), Sinus rhythm with right bundle branch block (1), Undetermined rhythm (1).

Results

Primary Effectiveness Results

Table 22. Primary Effectiveness Endpoint Analysis (EFF Population)

	Total N=151	Lower One-Sided 95% CL[1]	GoalPerformance 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.

Primary Safety Results

Table 23. Primary Safety Endpoint Analysis (SAF Population)

Primary Safety Endpoint	TactiCath N=149	Upper One-Sided 95% CL	Performance Goal[1]	P-Value[2]
Subjects experienced primary safety endpoint event	4.7% (7/149)	(8.64%)	16.2%	<0.0001

[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 90%, to be compared with one-sided significance level of 0.05.

Table 24. Primary Safety Endpoint Events (SAF Population)

Description	Events	Subjects N=149
Atrial-esophageal fistula	1	0.7% (1/149)
AV block	0	0.0% (0/149)
Cardiac perforation / tamponade	3	2.0% (3/149)
Death	0	0.0% (0/149)
Diaphragmatic paralysis	0	0.0% (0/149)
Gastroparesis	0	0.0% (0/149)

Table 24. Primary Safety Endpoint Events (SAF Population)

Description	Events	Subjects N=149
Hospitalization	0	0.0% (0/149)
Myocardial infarction	0	0.0% (0/149)
Pericarditis	1	0.7% (1/149)
Pneumothorax	0	0.0% (0/149)
Pulmonary edema	0	0.0% (0/149)
Pulmonary vein stenosis	0	0.0% (0/149)
Stroke	0	0.0% (0/149)
Thromboembolism	1	0.7% (1/149)
Transient ischemic attack	0	0.0% (0/149)
Vascular access complication	2	1.3% (2/149)
Total	**8**	**4.7% (7/149)**

NOTE: N is the total number of subjects.

NOTE: Denominator in percentages is the number of subjects with available data.

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.

Procedural Results (Including Descriptive Endpoints #1 and #2)

Table 25. Procedural Results

Procedural Characteristics (EFF Population)	Total N=150
Average RF power (W)	
Median (Q1, Q3) (n)	29.0 (26.0, 32.0) (149)
Was the recommended power of 10-30W used? (% Yes)	58.7% (88/150)
Total procedure time (min)	
Median (Q1, Q3) (n)	159.5 (123.0, 206.0) (150)
TactiCath™ Contact Force Ablation Catheter, Sensor Enabled™, insertion to withdrawal (min)	
Median (Q1, Q3) (n)	131.5 (98.0, 173.0) (150)
Fluoroscopy time (min)	
Median (Q1, Q3) (n)	9.0 (5.0, 16.0) (150)
Total ablation time (first to last ablation in min)	
Median (Q1, Q3) (n)	84.0 (56.0, 127.0) (150)
Time to achieve initial PVI (first to last ablation in min)	
Median (Q1, Q3) (n)	78.0 (50.0, 120.0) (150)
Total RF time (entire case in min)	
Median (Q1, Q3) (n)	35.7 (28.9, 51.9) (149)
Was the recommended irrigation flow rate of 17-30 ml/min used? (% Yes)	93.3% (140/150)
Total irrigation fluid volume (mL)	
Median (Q1, Q3) (n)	1038.0 (844.0, 1450.0) (150)
Min ACT	
Median (Q1, Q3) (n)	274.0 (235.0, 304.0) (150)
Max ACT	
Median (Q1, Q3) (n)	358.5 (334.0, 386.0) (150)
Average temperature (°C)	
Median (Q1, Q3) (n)	33.4 (32.5, 34.6) (149)
Max temperature (°C)	
Median (Q1, Q3) (n)	41.0 (39.0, 43.0) (149)

Table 25. Procedural Results

Procedural Characteristics (EFF Population)	Total N=150
AutoMark turned on for procedure? (Yes)	99.3% (149/150)
Was AutoMark used to guide therapy? (Yes)	92.6% (125/135)
Lesion spacing parameter (mm)	
Median (Q1, Q3) (n)	3.0 (3.0, 5.0) (150)
Minimum lesion time parameter (sec)	
Median (Q1, Q3) (n)	3.0 (3.0, 4.0) (150)
Total number of lesions by AutoMark	
Mean ± SD (N)	171.1 ±84.7 (150)
Median (Q1, Q3)	152.0 (115.0, 213.0)
Range (min, max)	(0.0, 494.0)
Average contact force (g) per subject	
Mean ± SD (N)	12.1 ± 4.7 (149)
Median (Q1, Q3)	11.2 (8.5, 14.3)
Range (min, max)	(5.0, 32.0)
Standard deviation of contact force (g) per subject	
Mean ± SD (N)	7.2 ± 3.0 (149)
Median (Q1, Q3)	6.4 (5.4, 8.5)
Range (min, max)	(2.7, 21.9)
Minimum average contact force (g) per subject	
Mean ± SD (N)	1.4 ± 1.3 (149)
Median (Q1, Q3)	1.0 (1.0, 2.0)
Range (min, max)	(0.0, 7.0)
5th percentile average contact force (g) per subject	
Mean ± SD (N)	3.2 ± 2.0 (149)
Median (Q1, Q3)	3.0 (2.0, 4.0)
Range (min, max)	(1.0, 10.0)
95th percentile average contact force (g) per subject	
Mean ± SD (N)	26.0 ± 10.1 (149)
Median (Q1, Q3)	25.0 (19.0, 30.0)
Range (min, max)	(11.0, 76.0)
Maximum average contact force (g) per subject	
Mean ± SD (N)	39.7 ± 16.8 (149)
Median (Q1, Q3)	36.0 (29.0, 45.0)
Range (min, max)	(16.0, 113.0)
Descriptive Endpoint #2[1]	
% of patients achieving ≥90% lesions with ≥10 g contact force	3.4% (5/149)
[95% Confidence Interval][2]	[1.1%, 7.7%]

[1] The analysis population for descriptive endpoint #2 is the RF population.

[2] By Clopper-Pearson exact confidence interval.

Other Safety Results (Descriptive Endpoint #3)

Table 26. Descriptive Endpoint #3 Serious Adverse Events and Adverse Events Related to the Device and / or Procedure through 30 Days Post Ablation (EFF Population)

	Total		Serious Adverse Events		Non-Serious Adverse Events	
Event	N per Event Basis	N per Subject Basis (%)	N per Event Basis	N per Subject Basis (%)	N per Event Basis	N per Subject Basis (%)
Procedure Related						
Pericarditis	7	4.6% (7/151)	1	0.7% (1/151)	6	4.0% (6/151)
Infections	5	3.3% (5/151)	1	0.7% (1/151)	4	2.6% (4/151)
Chest pain / discomfort	4	2.6% (4/151)	0	0.0% (0/151)	4	2.6% (4/151)
Vascular bleeding / local hematomas / ecchymosis	3	2.0% (3/151)	0	0.0% (0/151)	3	2.0% (3/151)
Vascular access complication	2	1.3% (2/151)	0	0.0% (0/151)	2	1.3% (2/151)
Volume overload	2	1.3% (2/151)	0	0.0% (0/151)	2	1.3% (2/151)
Allergic reaction	1	0.7% (1/151)	0	0.0% (0/151)	1	0.7% (1/151)
Arrhythmias	1	0.7% (1/151)	1	0.7% (1/151)	0	0.0% (0/151)
Cerebrovascular accident / stroke	1	0.7% (1/151)	1	0.7% (1/151)	0	0.0% (0/151)
Epigastric fullness	1	0.7% (1/151)	0	0.0% (0/151)	1	0.7% (1/151)
Hypertension	1	0.7% (1/151)	1	0.7% (1/151)	0	0.0% (0/151)
Hypotension	1	0.7% (1/151)	0	0.0% (0/151)	1	0.7% (1/151)
Low grade temp	1	0.7% (1/151)	0	0.0% (0/151)	1	0.7% (1/151)
Pericardial effusion	1	0.7% (1/151)	0	0.0% (0/151)	1	0.7% (1/151)
Urinary retention	1	0.7% (1/151)	1	0.7% (1/151)	0	0.0% (0/151)
Subtotal	**32**	**18.5% (28/151)**	**6**	**3.3% (5/151)**	**26**	**15.2% (23/151)**
Device Related						
Pericarditis	5	3.3% (5/151)	1	0.7% (1/151)	4	2.6% (4/151)
Cerebrovascular accident / stroke	1	0.7% (1/151)	1	0.7% (1/151)	0	0.0% (0/151)
Chest pain / discomfort	1	0.7% (1/151)	0	0.0% (0/151)	1	0.7% (1/151)
Infections	1	0.7% (1/151)	1	0.7% (1/151)	0	0.0% (0/151)
Subtotal	**8**	**4.6% (7/151)**	**3**	**1.3% (2/151)**	**5**	**3.3% (5/151)**
Total[1]	**32**	**18.5% (28/151) [12.69%, 25.67%]**	**6**	**3.3% (5/151) [1.08%, 7.56%]**	**26**	**15.2% (23/151) [9.91%, 21.97%]**

[1]The 95% Confidence Interval is computed by Clopper-Pearson Exact Method.

NOTE: The denominator in percentages is the total number of subjects who have undergone a procedure.

NOTE: Subjects may experience more than one event. Therefore, the total number of subjects may be less than the sum of the number of subjects who experienced each event.

NOTE: There were 4 additional events for which device or procedure relatedness was "Unknown" that were not otherwise reported in this table.

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.

RF Ablation

For RF ablation, the catheter must be connected to the appropriate input connectors on the TactiSys™ Quartz Equipment, which is then connected to the RF generator. Refer to the TactiSys™ Quartz Equipment User Manual for more information. To complete the electrical circuit, an indifferent electrode must be connected to the reference electrode input on the generator. Circuit impedance prior to RF ablation should be approximately 100 Ohms. Verify that the generator displays a temperature near body temperature after the catheter is inserted into the patient and before applying RF power.

Generator Operation

Refer to the TactiSys™ Quartz Equipment User Manual as well as the applicable RF generator manual for proper connection of the catheter to the generator and for detailed instructions as to generator operation for RF ablation.

RF ablation application parameters will vary depending on the ablation site, the specific conditions present in each procedure and the RF generator control circuitry. The recommended RF application parameters are provided in the Parameters table under Applying RF Current. Always monitor temperature and impedance rise when using the TactiCath™ Contact Force Ablation Catheter, Sensor Enabled™.

Instructions for Use

Refer to both these Instructions for Use and the TactiSys™ Quartz Equipment User Manual when using the TactiCath™ Contact Force Ablation Catheter, Sensor Enabled™ in conjunction with TactiSys™ Quartz Equipment.

WARNING: Do not use the catheter if not working properly. Particular care must be taken to check functionality of irrigation and steering mechanism.

Preparing the Catheter for Use

1. Obtain vascular access in a large central vessel (e.g. in femoral vein) using aseptic techniques.
2. Remove the catheter from the package while transferring it to the sterile field. Inspect the electrodes and catheter carefully for integrity and overall condition.
3. Connect the catheter's 19-pin electrical connector to the TactiSys™ Quartz Equipment electrical socket.
4. Remove the optical connector protection cap and connect the catheter's optical connector to the optical socket. Do not force connectors or pin damage can occur.

   CAUTION: Carefully align the optical connector with the TactiSys™ Quartz Equipment optical socket while firmly pushing in order to ensure connection.
5. Use the 10-pin connector to connect to the navigation and positioning systems.
   - For the MediGuide™ System, connect to the MediGuide™ Cath Connect, Sensor Enabled™.
   - For the EnSite Precision™ System, connect to the EnSite Precision™ Link, Sensor Enabled™.
6. Power ON the generator and TactiSys™ Quartz Equipment and initialize the irrigation pump. Ensure the pump is connected to the RF generator. Refer to the RF generator Operator's Manual for a complete description of generator and pump set-up and communication.
7. Connect the TactiSys™ Quartz Equipment to the RF generator.
8. Connect the irrigation tubing to the Luer fitting of the catheter. A 3-way stopcock may also be used.

   CAUTION: Check that the connection to irrigation pump is properly secured.
9. Add heparin to the saline infusion medium according to the patient's anticoagulant condition.
10. Purge the irrigation tube at high flow rate to ensure that no air resides in the tubing system of the catheter. Confirm all irrigation ports are open.
11. Once the catheter is purged of all air bubbles, ensure a minimum flow of 2 ml/min throughout the entire procedure to prevent clotting and/or occlusion of the irrigation holes at the catheter's tip.
12. Deflect the catheter in one or both deflectable directions prior to insertion. Do not pull on the saline luer or connector.
    - For the uni-directional catheter, pushing the thumb knob forward causes the distal section of the catheter to deflect. When the thumb knob is pulled back, the distal portion of the catheter will straighten. If needed, use the tension control knob to adjust the steering tension. Out of the package, the knob will be in a locked position.

    NOTE: If necessary, the tension of the uni-directional catheter handle may be adjusted using the adjustable tension control knob. The operator can adjust the tension or unlock by rotating the tension control knob. Use caution when rotating the tension control knob as excessive over-rotation may lead to a loss of tension control.
    - For the bi-directional catheter, pulling one side of the deflection mechanism down from neutral will cause the catheter to deflect in that direction. Pushing the mechanism back to neutral will straighten the catheter. For asymmetric curve designs, the larger curve will have a small bump on the deflection mechanism for easy assessment of the curve type.

NOTE: The bi-directional handle has an adjustable tension control knob that allows the operator to use the actuator and deflectable section in an unlocked state or adjust the tension to where the actuator and deflectable section are locked in place. The amount of friction increases as the knob is rotated clockwise until it reaches the fully plus (+) position.

WARNING: Make sure that the tension is sufficient to hold the curve when the catheter is deflected. Insufficient tension may decrease the catheter stability.

Positioning the catheter

1. Ensure the indifferent electrode is appropriately placed on the patient's body and connected to the RF generator. Only one indifferent electrode should be used for ablation within the recommended ablation settings shown in the General Recommendations table under Recommended RF Application Parameters.
2. Make sure the catheter is in the neutral (straight) position before insertion. To verify compatibility between sheath and catheter, use caution when first advancing the catheter into the sheath.

   WARNING: Use a steerable or non-steerable introducer sheath with a minimum inner diameter of 8.5 F only.
3. To avoid occlusion of the irrigation conduits, the catheter must be continuously irrigated when within the vasculature. Irrigation should only be stopped after removal of the catheter from the body.
4. Insert the catheter via the vascular access. Access the left side of the heart only via a transseptal puncture.

   WARNING: To ensure correct use of the force sensor, the distal portion of the catheter should have the tip and two additional electrodes outside of the introducer sheath.

   WARNING: To ensure correct use of the intracardiac electrogram signals, the distal portion of the catheter should have the tip and all electrodes outside of the introducer sheath.

   WARNING: When using steerable sheaths, make sure the sheath tip is straight when the catheter tip is introduced. The TactiCath™ Contact Force Ablation Catheter, Sensor Enabled™ may be damaged during deflection that is perpendicular to the catheter steering plane, so the catheter steering plane should be aligned with the steering plane of the steerable sheath.
5. Advance the catheter to the area under investigation. The catheter should be passed from a peripheral vessel to the desired endocardiac position with the aid of fluoroscopy. Use both fluoroscopy and electrograms to aid in proper positioning.
6. Use the deflection mechanism to position the catheter tip in the proper location.

   WARNING: Excessive bending or kinking of the catheter may cause damage to the catheter. Manual pre-bending of the distal curve can impact catheter performance and irrigation flow, and may cause patient injury.

   CAUTION: Do not use contrast fluid in catheter.

Applying RF current

1. A stable catheter position should be verified prior to RF ablation (contact force of approximately 20 grams, with an absolute minimum of 10 grams).

Table 27. **Parameter**

	Recommended Contact Force Parameters
Target Contact Force	Average 20 g (10 – 30 g)
Absolute Minimum Contact Force	10 g
Minimum Force Time Integral (FTI™)	400 gs

WARNING: 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.

2. Ensure the irrigation pump is communicating with the RF generator.
3. Ensure the irrigation pump is set at the flow rate indicated in the table below for the appropriate power delivery settings. It is recommended to increase the irrigation to the high flow rate starting up to 3 seconds before the onset of RF energy delivery and maintaining this higher flow rate until 3 seconds after the termination of the energy application.

Table 28. Irrigation

Procedure step	**Recommended minimum irrigation flow**
Mapping and manipulation	2 ml/min
Ablation (power ≤30 W)	17 ml/min
Ablation (power >30 W)	30 ml/min
Power levels exceeding 30 W may be used when transmural lesions cannot be achieved at lower energy levels.	

WARNING: Application of RF energy at a power higher than 30 W is associated with a higher likelihood of audible steam pop occurrence. High power should only be used if the intended outcome cannot be achieved at lower power settings.

4. Ensure the circuit impedance is approximately 100 Ohms upon initiation of RF current.
5. Set the initial power level and the initial temperature limit according to the recommended conditions listed in the General Recommendations table under Recommended RF Application Parameters.
6. Start RF energy delivery and ensure that the irrigation pump properly ramps to the recommended flow rate in the General Recommendations table under Recommended RF Application Parameters and in the Irrigation Table.
7. If creating a drag lesion, move the catheter in a linear fashion remaining at one site for no more than 60 seconds.
8. Monitor the catheter tip temperature during ablation to detect insufficient irrigation. Monitor the impedance display on the RF generator, before, during, and after RF power delivery. If a sudden rise in impedance is noted during RF delivery that does not exceed the preset limit, manually discontinue the power delivery.

   NOTE: Temperature represents the tip electrode temperature only and does not reflect tissue temperature.
9. In case of a steam pop, an automatic generator shut off, a sudden rise in temperature or impedance or an occlusion notice on the pump, discontinue RF power delivery as needed. Remove the catheter for visual inspection and check for coagulum, charring, or other catheter defects.
   - Withdraw the catheter and clean the tip electrode of any coagulum. If present, gently wipe the tip section clean with a sterile gauze pad dampened with sterile saline.

   WARNING: Do not scrub or twist the tip electrode. Damage to the tip electrode bond may occur and loosen the tip electrode.
   - Prior to reinsertion, ensure that the irrigation line and holes are not occluded by flushing the catheter at a high flow rate.

   WARNING: Do not continue use of the catheter if holes are still occluded or if irrigation is not functioning properly.
10. After RF current is discontinued, ensure the irrigation rate returns to 2 ml/min on the irrigation pump.
11. From the initial power setting, power may be increased as needed to the maximum setting (30 W) to create an effective lesion. Intracardiac electrograms and impedance should be assessed prior to changing the power setting. Because there is a possibility of higher incidences of steam pops at power levels higher than 30 W, power should be increased only if lower energies do not achieve the intended results.
12. If initial temperature setting is reached but the preset power output is not, it is permissible to increase the temperature setting to the maximum setting (50° C). Intracardiac electrograms and impedance should be assessed prior to changing the temperature settings.
13. When the procedure is finished, bring the catheter to its neutral position (straight) before removing the catheter from the patient.
14. After use, dispose of product and packaging in accordance with hospital, administrative, and/or local government policy. The instructions for use is recyclable.

Recommended RF Application Parameters

Table 29. General recommendations

	Atrial ablation
Recommended power range	10 W to 30 W*
Contact Force	Target 20 g with a minimum of 10 g[1,2,3]
Temperature monitoring	37 to 50 °C**
Irrigation flow rate during RF application	17 to 30 ml/min

* Power levels exceeding 30 Watts may be used when transmural lesions cannot be achieved at lower energy levels. For power settings > 30 Watts, the recommended irrigation flow rate is 30 ml/min.

** The temperature displayed on the generator does not represent tissue temperature or electrode tissue interface temperature.

[1] TOCCATA: Reddy V, Shah D, Kautzner J, Schmidt B, Saoudi N, Herrera C, et al. The Relationship between Contact Force and Clinical Outcome during Radiofrequency Catheter Ablation of Atrial Fibrillation in the TOCCATA study. Heart Rhythm. 2012;9:1789-95

[2] EFFICAS I: Neuzil P, Reddy VY, Kautzner J, et al. Electrical reconnection after pulmonary vein isolation is contingent on contact force during initial treatment: results from the EFFICAS I study. Circ Arrhythm Electrophysiol. 2013; 6(2):327-33

[3] EFFICAS II: Kautzner J, Neuzil P, Lambert H, et.al. Optimization of catheter contact force improves outcome of pulmonary vein isolation for paroxysmal atrial fibrillation. Europace. 2015 Aug;17(8):1229-35

WARNING: Application of higher power is associated with a higher likelihood of audible steam pop occurrence. High power should only be used in special circumstances and only when good contact force cannot be achieved.

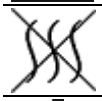
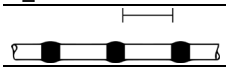
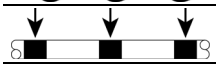
WARNING: Contact force in excess of 70 g may not improve the characteristics of lesion formation and may increase the risk for perforation during manipulation of the catheter.

NOTE: For isthmus dependent flutter ablation, power applications exceeding 30 Watts and up to 50 Watts maximum should only be used if conduction block cannot be achieved at lower power levels.

Warranty

Abbott Medical warrants that its products shall be free from defects in materials and workmanship under normal use. This warranty does not exceed the "Expiration" date stated on any product labeling. The authorized uses and approved methods of use of each of our products are set forth in the related "Instructions for Use" that accompany each product. Abbott Medical disclaims any responsibility and liability for the use of its products in a manner that has not been authorized or approved. Abbott Medical's liability under this warranty is limited to replacing its products. The foregoing warranty excludes and is in lieu of all other warranties whether expressed or implied including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose. Abbott Medical disclaims any liability for any incidental or consequential loss, damage, or expense directly or indirectly arising from the use of this product, other than as expressly provided by specific law. Abbott Medical neither assumes nor authorizes any other person to assume for it any other or additional liability for loss, damage, or expense in connection with this product. For more details please review complete Abbott Medical warranty policy available from Abbott Medical or on the back of an Abbott Medical invoice.

Symbols

Symbol	Description
	Sterilized using ethylene oxide
	Consult instructions for use
	Follow instructions for use on this website
	Do not use if package is damaged
	Do not reuse
	Lot number
	Use by
Ablation Catheter	Ablation catheter
Contact Force Ablation Catheter	Contact Force Ablation Catheter
	Reorder number
	Non-pyrogenic
	Manufacturer
	Usable Length
	Keep away from sunlight
	Spacing
	Electrodes
	Conformité Européenne (European Conformity). Affixed in accordance with European Council Directive 93/42/EEC (NB 2797) and 2011/65/EU. Hereby, Abbott Medical declares that this device is in compliance with the essential requirements and other relevant provisions of this directive.
	Date of Manufacture
	Quantity
	Authorized European representative

Symbol	Description
	Unique Device Identification
	Do not resterilize
	Outer Diameter
	Manufacturing Facility
	CAUTION: Federal law (U.S.) restricts this device to sale by or on the order of a physician.
	Keep dry
	Temperature limitations
	Humidity limitation

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