PN 004 165
PN 004 175

ENDOSENSE

TactiCath™ Quartz Contact Force Ablation Catheter

Instructions for use

For single use only

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

Use by

Serial number

Sterilized using ethylene oxide

Catalog Number

Do not resterilize

Do not use if package is open or damaged

Keep dry

Keep away from heat, store at room temperature

Manufactured by

Maximum input pressure at Luer fitting of the catheter

Package Contains 1 Item

Date of Manufacture

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

Contact Force Ablation Catheter

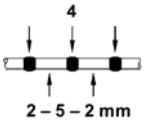
Contact Force Ablation Catheter

Contact force

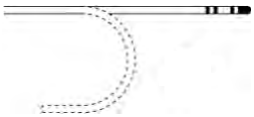
Irrigated tip

Catheter size

Catheter length



Electrode and spacing



Curve

TactiCath™ Quartz
Contact Force Ablation Catheter

CAUTION

- **Sterile. Sterilized with ethylene oxide gas.**
- **For single use only.**
- **Do not use if the package is open or damaged.**
- **Do not attempt to operate the device prior to completely reading and understanding the applicable instructions for use.**
- **Federal (USA) law restricts this device to sale by or on the order of a physician.**

1. CATHETER DESCRIPTION

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

The catheter has 7 F outer diameter and a deflectable distal section that includes four platinum-iridium electrodes (the tip and 3 rings). All of the electrodes may be used for recording and stimulation purposes. The tip electrode is used to deliver RF current from the RF generator to the desired ablation site. The catheter incorporates a thermocouple temperature sensor which is embedded in the 3.5 mm tip electrode. Deflection of distal section is controlled at the proximal end by a handpiece in which a piston slides; a thumbknob on the piston controls piston travel. When the thumbknob is pushed forward the tip is deflected (curved). When the thumbknob is pulled back the tip straightens. The deflectable section is available in lengths of 65 mm or 75 mm. The shaft also allows the plane of the curved tip to be rotated to facilitate accurate positioning of the catheter tip at the desired site.

At the proximal end of the catheter, a saline port with a standard Luer fitting terminates from the open lumen. This saline port is used to permit the delivery of isotonic saline solution to irrigate the tip electrode. During ablation, saline is passed through the 0.7 mm diameter lumen of the catheter and through the tip electrode, to irrigate and cool both the catheter tip and the ablation site.

The TactiCath™ Quartz Contact Force Ablation Catheter features a tri-axial optical force sensor embedded in the tip section of the catheter which transmits contact force information to the TactiSys™ Quartz Equipment.The catheter interfaces with standard recording equipment and a compatible RF generator via the TactiSys™ Quartz Equipment with the appropriate connectors. For use in conjunction with force sensing refer to the TactiSys™ Quartz Equipment User Manual.

The TactiCath™ Quartz catheters are available in two configurations. See table below:

Part number	Name	Description
PN-004 165	TactiCath™ Quartz 65	TactiCath™ Quartz Contact Force Ablation Catheter with 65 mm deflectable section
PN-004 175	TactiCath™ Quartz 75	TactiCath™ Quartz Contact Force Ablation Catheter with 75 mm deflectable section

2. INDICATIONS FOR USE

The TactiCath™ Quartz Contact Force Ablation Catheter 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.

3. CONTRAINDICATIONS

The TactiCath™ Quartz Contact Force Ablation 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.

4. WARNINGS

a) 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.

b) It is important to carefully titrate RF power. Too high RF power during ablation may lead to perforation caused by steam pop.

c) 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.

d) 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.

e) 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.

f) The combination of intracoronary placement of the ablation catheter and RF energy application has been associated with myocardial infarction.

g) 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.

h) Inspect saline irrigation for air bubbles prior to its use in the procedure. Air bubbles in the saline irrigation may cause emboli.

i) 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.

j) Do not resterilize and reuse to avoid infection risks and incorrect catheter functionality.

k) Do not immerse proximal handle or cable connector in fluids; electrical performance could be affected.

l) The steerability feature of the TactiCath™ Quartz 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 TactiCath™ Quartz Catheter with deflectable introducer sheaths that operate in multiple planes of motion. Do not use TactiCath™ Quartz Catheter with deflectable sheaths that may constrain catheter tip deflection through the use of manually operated hemostatic valves.

5. PRECAUTIONS

a) Cardiac ablation procedures must be performed by appropriately trained personnel in a fully-equipped operational electrophysiology laboratory.

b) 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.

c) 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.

d) When using the TactiCath™ Quartz 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.

e) Always pull the thumbknob back to straighten the catheter tip before insertion or withdrawal of the catheter.

f) Always maintain a constant saline irrigation flow to prevent coagulation within the lumen of the catheter.

g) Access the left side of the heart via a transseptal puncture. Do not access the left side of the heart in a retrograde way through the aorta, as it might require excessive force to pass the aortic valve, resulting in significant risk to damage the steering and/or irrigation of the TactiCath™ Quartz Catheter.

h) A temperature or an impedance rise (the set limit is exceeded) may result into 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.

i) 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.

j) Read and follow the indifferent electrode manufacturer's instructions for use; the use of indifferent electrodes, which meet or exceed ANSI/AAMI requirements (HF18), is recommended.

k) The TactiCath™ Quartz Catheter is intended to be connected to the TactiSys™ Quartz Equipment. The catheter should be used only with a legally marketed RF generator which has been shown to be safe and effective for cardiac ablation, and which is compatible with the specifications of the catheter and the TactiSys™ Quartz Equipment. Specifications for compatible RF generators are listed in section 13 of this IFU. (For TactiSys™ Quartz Equipment compatibility with RF generators please refer to TactiSys™ Quartz Equipment User Manual)

l) Care should be taken when ablating near structures such as the sino-atrial and AV nodes.

m) The sterile packaging and catheter integrity, including connectors, should be inspected prior to use.

n) The TactiCath™ Quartz Catheter is intended for single use only.

o) Do not expose catheter to organic solvents such as alcohol.

p) The TactiCath™ Quartz 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. It is recommended to position RF patient cables in such a way that contact with the patient or other cables is avoided.

q) 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.

r) Electromagnetic interference (EMI) produced by the TactiCath™ Quartz Catheter when used in conjunction with a RF generator during normal operation may adversely affect the performance of other equipment.

s) 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.

t) 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.

u) Before use, check that irrigation holes are fully functional by infusing saline through the catheter.

v) Regularly inspect and test cables and accessories.

6. 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
- Atrio-Ventricular 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

7. SUMMARY OF CLINICAL STUDY

The clinical study was conducted on the TactiCath™ Set, which also supports the TactiCath™ Quartz Set.

7.1 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).

7.2 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.

7.3 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 1. Primary serious adverse events and severity criteria

Primary SAE	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
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.

7.4 Subject Accountability

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

Table 2. Subject Accountability and Disposition

Subject Accountability	TactiCath	Control	Total
Subjects enrolled in study	172	145	317
Subjects in Roll-in population	17	NA	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

7.5 Demographics

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

Table 3. Subject Demographics (SAF Population)

Demographic		TactiCath N=152	Control N=143	Total N=295
Age, years		59.6 (9.32) 61.0 [53.0, 66.0] 31, 78	61.0 (10.84) 62.0 [53.0, 68.0] 28, 82	60.3 (10.09) 61.0 [53.0, 67.0] 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%)
	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)[a]		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)[a]		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 (%).
[a] Height and weight were not reported for 1 TactiCath subject.

Table 4. 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%)

7.6 Procedural Data

The table below summarizes the index procedural data.

Table 5. 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
Duration of ablation (seconds)	56 (29) 24, 190	74 (62) 14, 464
Power (Watts)[a]	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.
[a] sample size for Power: TactiCath (n=148), Control (n=133).

7.7 Results

7.7.1 Primary Effectiveness Results

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

Table 6. 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.

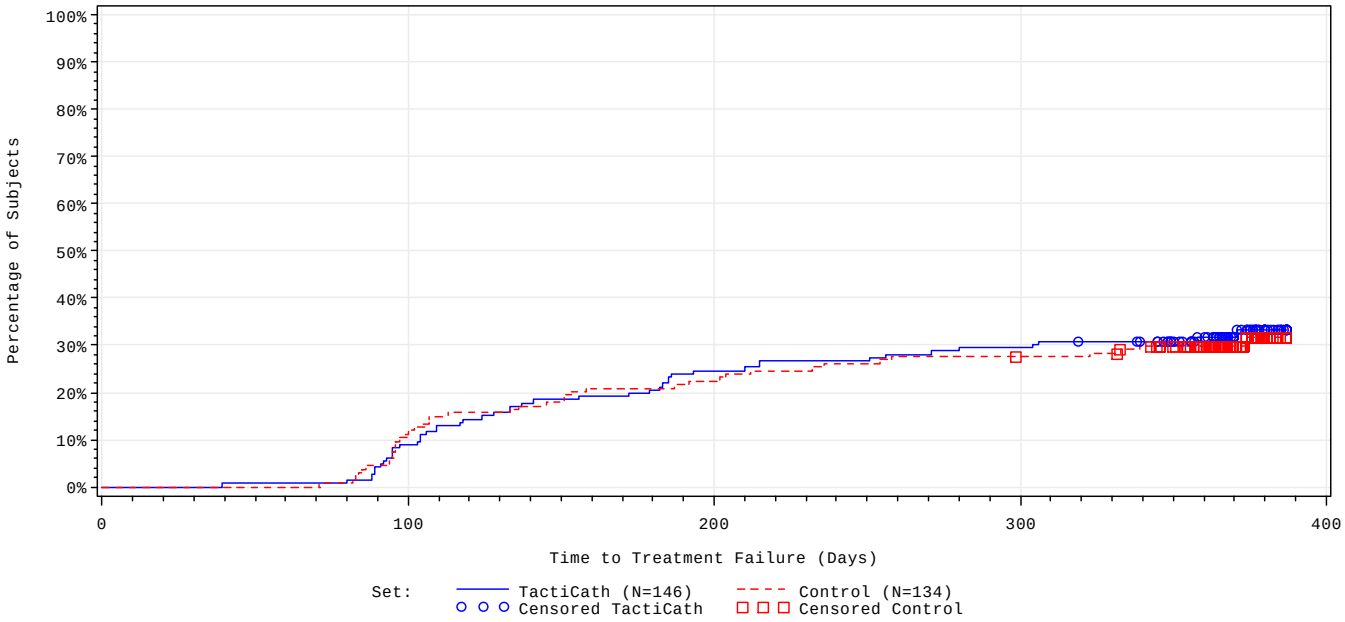


Figure 1. Kaplan-Meier Plot for Time-to-Treatment Failure (PP Population)

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.

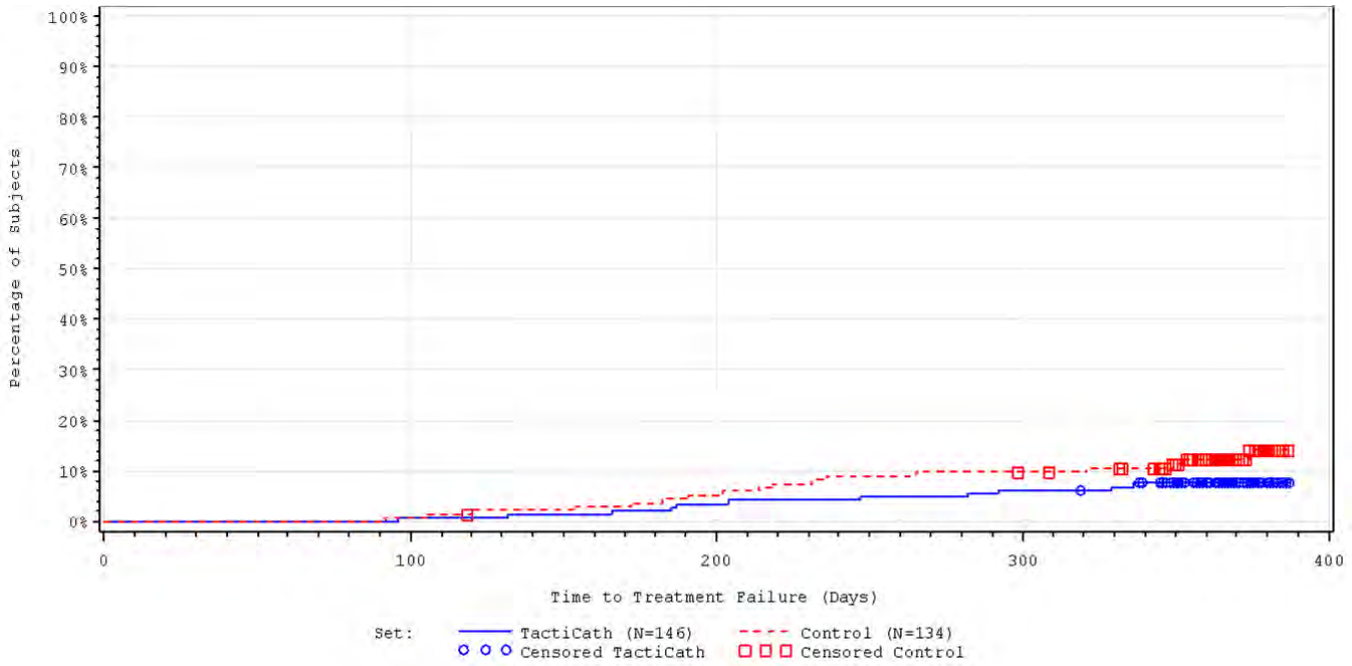


Figure 2. Kaplan-Meier Plot forTime-to-Treatment Failure Due to Re-Ablation Procedures (PP Population)

7.7.2 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 7. 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 11.09 (22.738) 0.00 [0.00, 0.00] 0.0, 100.0	n=134 14.61 (27.751) 0.00 [0.00, 25.00] 0.0, 100.0	0.209
Time to achieve initial PV isolation at index procedure (minutes)	n=146 90.4 (43.71) 87.0 [55.0, 117.0] 16, 261	n=134 86.4 (38.67) 85.5 [58.0, 108.0] 18, 224	0.941
Total time of RF application at index procedure (minutes)	n=146 51.72 (27.671) 46.40 [28.30, 65.30] 13.0, 139.3	n=133 58.31 (27.333) 53.50 [40.80, 72.80] 17.1, 196.0	0.002

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

7.7.3 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 8. Primary Safety Endpoint (SAF Population)

Primary safety endpoint	TactiCath N=152	Control N=143	Difference in primary SAE rates (TactiCath minus control)	
			Point estimate	One-sided 95% UCL[a]
Subjects experienced primary SAEs	3 (2.0%)	2 (1.4%)	0.6%	3.0%

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

Table 9. Summary of Primary SAEs by Term (SAF Population)

Event	TactiCath N=152		Control N=143		Total N=295	
	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 (0.3%)	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**

7.7.4 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 10. 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[a]	10 (6.6)	11	11 (7.7)	11	21 (7.1)	22
Atrial perforation[b]	0	0	1 (0.7)	1	1 (0.3)	1
Cardiac perforation/cardiac tamponade[b]	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
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

[a] Subjects reporting more than one SAE in each level are only counted once. Only SAEs adjudicated as non-primary SAE are included
[b] Was not related to the use of a study device

Table 11. 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[a]	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

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

7.7.5 TactiCath™ Set 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 12. Distribution of Contact Force in the TactiCath Arm (PP Population)

Contact Force Distribution	**TactiCath N=146[a]**
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

Contact Force Distribution	TactiCath N=146[a]
Standard deviation of contact force (per procedure) (g)	n=144 12.3 (9.88) 11.0 [8.0, 14.5] 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.
[a]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 10 g of contact force in at least 90% of all lesions (n=83) is presented in the following table.

Table 13. Success Rates for TactiCath™ Subjects with a High and Low Percentage of Lesions Above 10g (PP Population)

Contact force	Subjects (n)	Success (%)	*P* value
Optimal (≥90% of lesions with CF >10 g)	83	75.9%	0.018
Suboptimal (<90% of lesions with CF >10 g)	62	58.1%	

Using protocol-defined criteria for success, TactiCath subjects who were treated with “optimal” contact force (≥90% of lesions with CF >10 g) were significantly more successful (75.9% vs 58.1%, P=0.018) than those treated with suboptimal contact force.

Subjects treated with optimal contact force who failed after 12 months (n=20) tended to fail for TTM and/or AAD use, and less for reablation procedures as shown in **Table 14**.

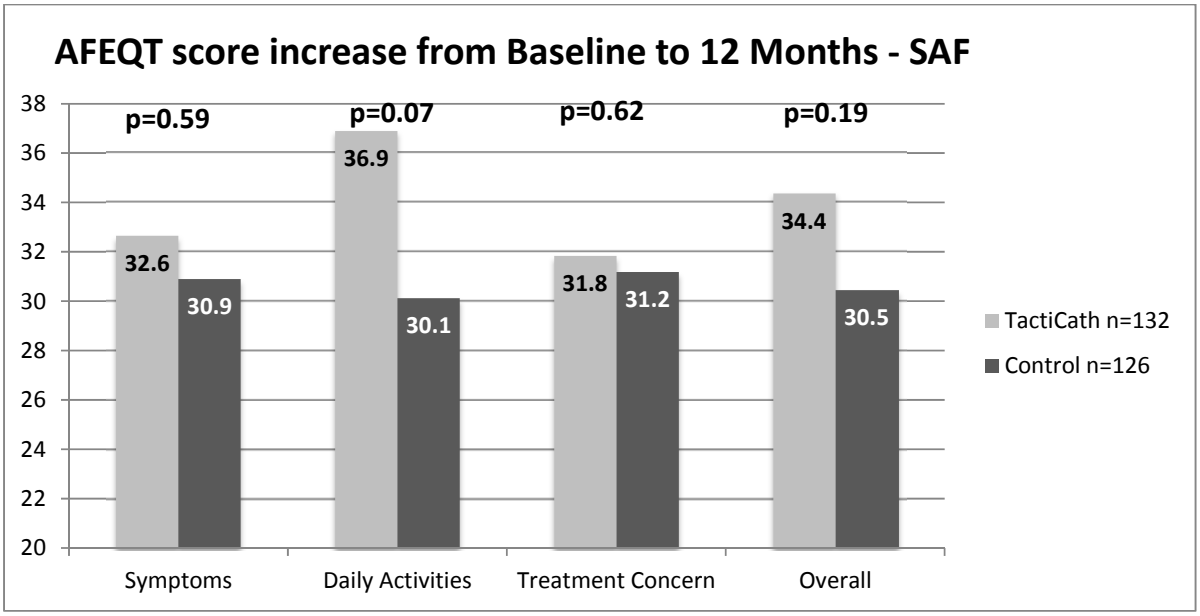
Table 14. Failure mode for TactiCath subjects treated with optimal contact force

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 treated with optimal contact force 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).

7.7.6 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.



7.7.7 Gender Subgroup Analysis Results

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

Table 15. Treatment Success (Protocol-Defined Effectiveness) by Gender (PP Population)

	Male		Female		Difference in success rates (TactiCath minus control)	
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].

7.8 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.

8. 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.

9. 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 below.

Always monitor temperature and impedance rise when using the TactiCath™ Quartz Catheter.

10. STERILIZATION/"USE BY" DATE

This catheter has been sterilized with ethylene oxide gas.

Do not use the catheter if the package is open or damaged.

Use the catheter prior to the “Use by” date shown on the package label.

11. SUGGESTED INSTRUCTIONS FOR USE

Refer to both these Instructions for Use and the TactiSys™ Quartz Equipment User Manual when using the TactiCath™ Quartz Catheter 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.

11.1 Preparing the catheter for use

1. Remove the catheter from the package and place it in a sterile work area.
2. Create a vascular access in a large central vessel (e.g. in femoral vein) using aseptic techniques.
3. Connect the catheter’s electrical connector to the TactiSys™ Quartz Equipment electrical socket. Remove the optical connector protection cap and connect the catheter’s optical connector to the optical socket. Caution: Carefully align the optical connector with the TactiSys™ Quartz Equipment optical socket while firmly pushing in order to ensure safe connection.
4. Connect the TactiSys™ Quartz Equipment to the RF generator.
5. Connect the irrigation tubing to the Luer fitting of the catheter. A 3-way stopcock may also be used. Precaution: Check that the connection to irrigation pump is properly secured.
6. Purge the irrigation tube at high flow rate to ensure that no air resides in the tubing system of the catheter. Check the purging success by immersing the catheter tip into a sterile liquid and observe bubbles while purging. Make sure that no bubbles are coming out the catheter while purging.
7. 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.
8. Deflect the catheter distal part. If necessary, i.e. the steering forces are too high, or too low, modify the steering friction using the hand-adjusting knob at the proximal end of the handle: follow the “+” direction to increase the steering friction; follow the “-” direction to decrease the steering friction.

Warning: Make sure that the steering friction is sufficient to hold the deflected position. In case of insufficient steering friction, the catheter tip may lose its position stability.

11.2 Positioning the catheter

1. Insert the catheter via the vascular access, using an introducer sheath. To verify compatibility between sheath and catheter, advance catheter through sheath prior to insertion.

Warnings:

- When using straight introducer sheaths, use ones with a minimum diameter of 8.5 F only.
- When using sheaths with deflectable tip (only sheaths with deflection in a single plane), make sure the sheath tip is straight when catheter tip is passing through. As the TactiCath™ Quartz Catheter can be damaged with bending the deflectable part perpendicular to its own steering direction, the catheter should be rotated in a way that its steering plane is aligned with the steering plane of the deflectable sheath.
- To ensure correct use of the Force Sensor and the intra-cardiac electrogram signals, catheter distal part should have at least the 4 electrodes outside of the long sheath.

2. Advance the catheter to the area under investigation. Use both fluoroscopy and electrograms to aid in proper positioning.
3. Use the thumb knob to facilitate the positioning of the catheter tip. Pushing the thumb knob forward causes the catheter distal part to deflect; when the thumb knob is pulled back, the distal part straightens. If needed, use the hand-adjusting knob to adjust the steering force.

Warning: Do not twist the catheter during the procedure, as it might adversely affect the irrigation flow.

Caution: Do not use contrast fluid in catheter.

11.3 Applying RF current

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

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. Recommendation for irrigation: Increase the irrigation to high flow rate starting up to 5 seconds before the onset of RF energy delivery and maintaining this higher flow rate until 5 seconds after the termination of the energy application.

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

3. Establish an irrigation flow at the high flow indicated in the table above. Watch the electrode tip temperature decrease.
4. When it has been determined that the tip electrode is in stable contact with the intended ablation site, switch on the delivery of RF current. Circuit impedance should be approximately 100 Ohms upon initiation of RF current.
5. Monitor the catheter tip temperature during ablation to detect insufficient irrigation.
6. After RF current is discontinued, turn irrigation flow back to minimum 2 ml/min on the irrigation pump.
7. RF current may be re-applied to the same or alternate sites using the same catheter. However, in the event of a generator cutoff (impedance or temperature) or in case the catheter tip temperature rises abnormally during ablation, proceed as follows:
   a) Withdraw the catheter and clean the tip electrode of any coagulum, if present, before reapplying RF current.
   b) 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.
   c) Prior to reinsertion, ensure that the irrigation line and holes are not occluded by purging them at high irrigation flow.

11.4 Dealing with irrigation hole or irrigation line occlusion

If irrigation hole or irrigation line occlusion occurs, proceed as follows:

1.Remove the catheter from the patient.

2. Fill a syringe with sterile saline and attach to the system (ideally using a 3-way stopcock).

   Note: A small syringe provides sufficient pressure to produce a visible stream of fluid.

3. Carefully inject the saline from the syringe into the catheter. A stream of fluid should be visible from all six (6) holes.
4. If necessary, repeat steps 2 and 3.
5. If the holes are cleared and the irrigation line not occluded, reintroduce the catheter into the patient.

Warning: Do not continue use of the catheter if holes are still occluded or if irrigation is not functioning properly.

12. RECOMMENDED RF APPLICATION PARAMETERS

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]
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.

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.

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

Additional recommendation:

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.

13. COMPATIBILITY WITH EXTERNAL DEVICES

13.1 Minimum RF Generator Requirements

RF Power Output	Adjustable 10-50 Watts
RF output Frequency	450 - 550KHz
Temperature Limit	Adjustable 30-50°C
Thermocouple	1 Type T
Operating Impedance Range	50-300 Ω

13.2 Compatible Irrigation Pumps

TactiCath™ Quartz is compatible with the following irrigation pumps:

- St. Jude Medical Cool Point Irrigation Pump
- Biosense Webster COOLFLOW Irrigation Pump

14. STORAGE

Store at room temperature.

15. DISPOSAL

Used products are contaminated and must be handled and disposed as contaminated hospital waste.

[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.

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