

# TACTICATH™ QUARTZ ABLATION CATHETER

## **Clinical Compendium:**

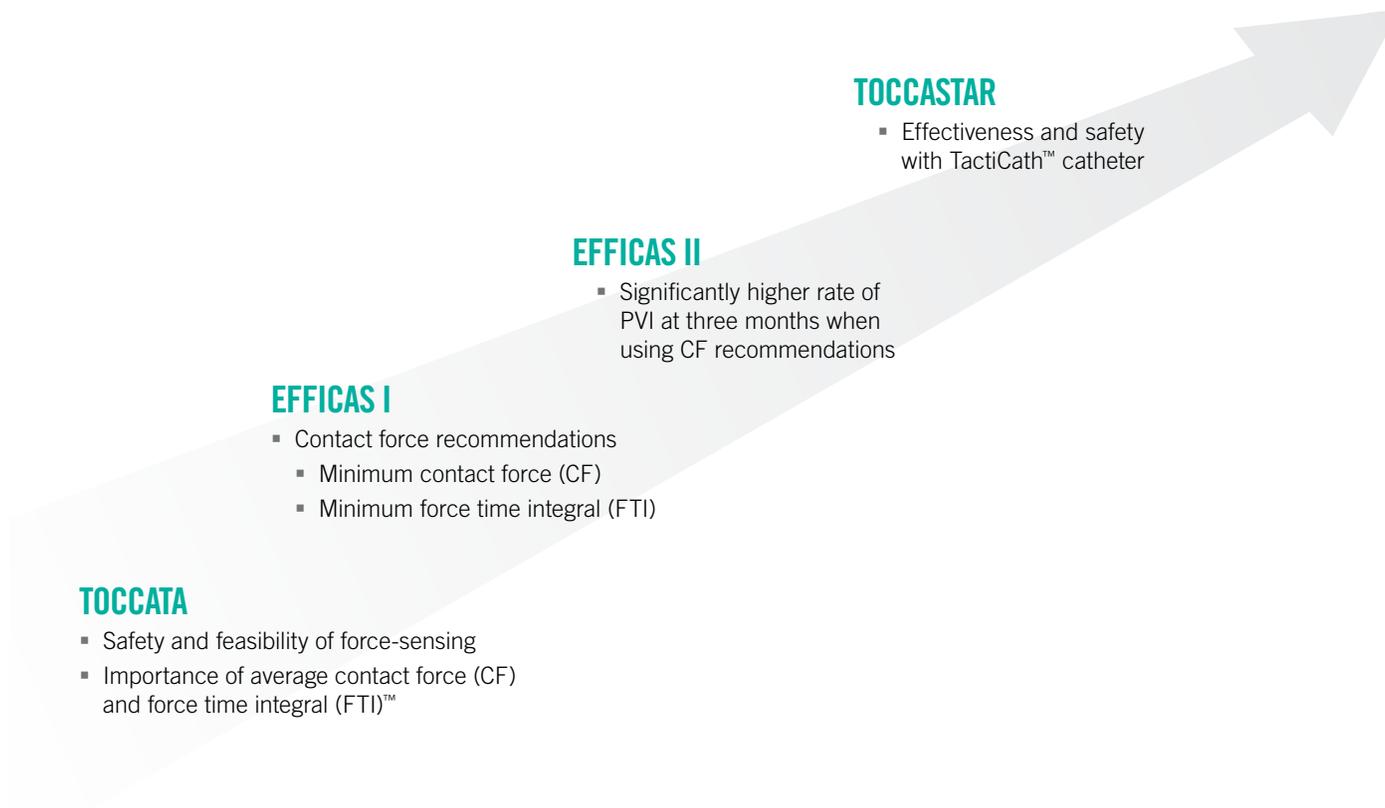
The TactiCath™ Quartz ablation catheter is an ablation catheter with contact force (CF) measuring capability and is the first to provide recommendations for CF sensing during pulmonary vein isolation (PVI) procedures. Measurement of CF between the catheter tip and the target tissue can help further guide physicians during mapping and ablation procedures. Data from several studies such as TOCCATA, EFFICAS I and EFFICAS II show that CF sensing is not only safe for use in PVI but also associated with lower rates of gap and atrial fibrillation (AF) recurrence.<sup>1-4</sup> The TOCCASTAR investigational device exemption (IDE) study provided evidence proving the safety and effectiveness of the TactiCath ablation catheter for the treatment of paroxysmal AF.<sup>5</sup> This compendium summarizes the clinical evidence supporting the use of the TactiCath Quartz™ system to guide PVI procedures.

# TABLE OF CONTENTS

Summary of Clinical Studies Using The Tacticath™ Contact Force Sensing Ablation Catheter	3
TOCCATA	4
EFFICAS I and EFFICAS II	5
TOCCASTAR	8
Summary of Publications on Lesion Index	11
Additional Studies Using the TactiCath™ Catheter with Contact Force	12
References	13

# SUMMARY OF CLINICAL STUDIES USING THE TACTICATH™ CONTACT FORCE SENSING ABLATION CATHETER

Clinical evidence strongly supports the need for CF measurement during ablation procedures. In ablations where CF data are not available, physicians can only estimate the amount of force that is being applied, and suboptimal CF values may result in ineffective outcomes.<sup>1</sup> The use of CF sensing can reduce procedural variability during ablation and is also associated with a lower risk of AF recurrence.<sup>2</sup> Endosense™, which was acquired by St. Jude Medical in 2013, sponsored the TOCCATA, EFFICAS I, EFFICAS II and TOCCASTAR studies that enrolled a total of 464 patients to provide peer-reviewed clinical evidence demonstrating that the TactiCath™ Quartz contact force sensing ablation catheter is safe for use in pulmonary vein isolation (PVI).<sup>1-5</sup> Applying the optimal CF recommendations developed from these studies has been associated with successful ablation outcomes, including high rates of durable PVI<sup>3,4</sup> and repeat ablation procedure rates of 7.2% in patients treated with optimal CF versus 16.1% with non-optimal CF, and 12.7% in control group patients treated with a non-CF catheter.<sup>5</sup> As the cost of care has been reported to increase approximately four times in the first year after ablation for patients with repeat ablations, increased effectiveness of single-ablation procedures for AF could substantially decrease health care costs for patients undergoing these procedures.<sup>6</sup>



## TOCCATA

- Safety and feasibility of force-sensing
- Importance of average contact force (CF) and force time integral (FTI)™

## EFFICAS I

- Contact force recommendations
  - Minimum contact force (CF)
  - Minimum force time integral (FTI)

## EFFICAS II

- Significantly higher rate of PVI at three months when using CF recommendations

## TOCCASTAR

- Effectiveness and safety with TactiCath™ catheter

# TOCCATA

## A Novel Radiofrequency Ablation Catheter Using Contact Force Sensing: Toccata Study

Kuck, et al. *Heart Rhythm*, 2012<sup>1</sup>

## The Relationship Between Contact Force and Clinical Outcome During Radiofrequency Catheter Ablation of Atrial Fibrillation in the TOCCATA Study

Reddy, et al. *Heart Rhythm*, 2012<sup>2</sup>

- The purpose of the TOCCATA clinical trial was to evaluate the safety and efficacy of CF sensing during ablation procedures (n = 72).<sup>1</sup>
  - Patients were divided into two groups: right-sided SVT (n = 43) and paroxysmal AF (n = 34).
  - Investigators were blinded to CF values during mapping but not during the actual ablation.
- PVI was successfully performed in all patients.
- There was high variability in CF applied by individual operators as well as between different operators (Figure 1).
- For right-sided SVT patients, significantly higher CFs were applied at the septum (p < 0.0001) and appendage (p = 0.0046) when compared to other right atrial sites.
  - The incidence of serious adverse events (SAEs) related to the device or procedure was 2%, well below the rate of 11.4% that was pre-specified for safety for these patients.
- For paroxysmal AF patients, the CFs were significantly higher at the septum (p < 0.0001) and significantly lower at the appendage (p < 0.0001) when compared to other left atrial sites.
  - For paroxysmal AF patients, the SAE rate was 12%, which was also below the pre-specified safety rate of 16.8%.<sup>1</sup>

- TOCCATA also investigated the relationship between CF and clinical outcomes from the AF subpopulation at 12 months post-PVI (n = 34).<sup>2</sup>
  - Acute isolation was achieved in 100% of PVs.
- Patients were classified into two groups: successful (no AF recurrence or AF recurrence with durable PVI confirmed) and unsuccessful (AF recurrences at any time during 12-month follow-up without durable PVI).
  - At 12 months, 80% of patients treated with an average CF ≥ 20 g were in the successful group, while 100% of patients with an average CF < 10 g were in the unsuccessful group (p = 0.01) (Figure 2).
- The recurrence of AF at 12 months was significantly higher in patients who had two or more lesion applications with CF < 5 g than patients who had 0 to 1 lesion applications with CF < 5 g (75% vs. 40%, respectively, p = 0.03).<sup>2</sup>

### Key takeaways

- TOCCATA was the first multicenter trial that used a direct CF catheter in human subjects.
- Real-time CF sensing is safe for use in RF ablation of SVT and AF.<sup>1</sup>
- The TOCCATA study results were the first to show that CF > 20 g is most likely to result in durable PVI at 12 months, while CF < 10 g is associated with unsuccessful PVI.<sup>2</sup>
- Using the TactiCath™ ablation catheter to measure CF helps ensure successful PVI regardless of anatomical location.<sup>2</sup>
- At least 10 g of force is needed to provide sufficiently stable catheter tip contact. Intermittent contact is correlated with low CF (p < 0.001).<sup>2</sup>
- TOCCATA validated the safety and feasibility of force-sensing, while confirming the importance of contact force (CF) technology.<sup>1,2</sup>

Figure 1: TOCCATA: Mean Contact Force Distribution by Operator<sup>1</sup>

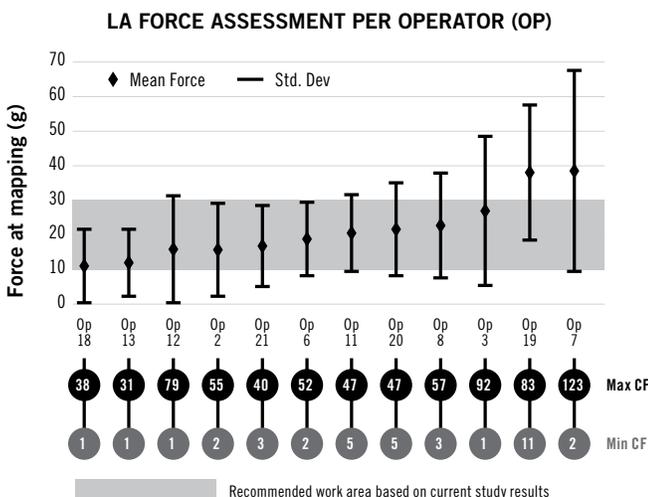
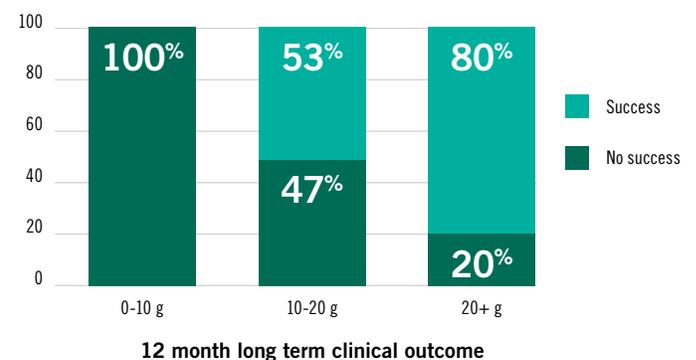


Figure 2: Recurrence Rates by Average Ablation Contact Force<sup>2</sup>



# EFFICAS I AND EFFICAS II

## Electrical Reconnection After Pulmonary Vein Isolation is Contingent on Contact Force During Initial Treatment: Results From the EFFICAS I Study

Neuzil, et al. *Circ Arrhythm Electrophysiol*, 2013<sup>3</sup>

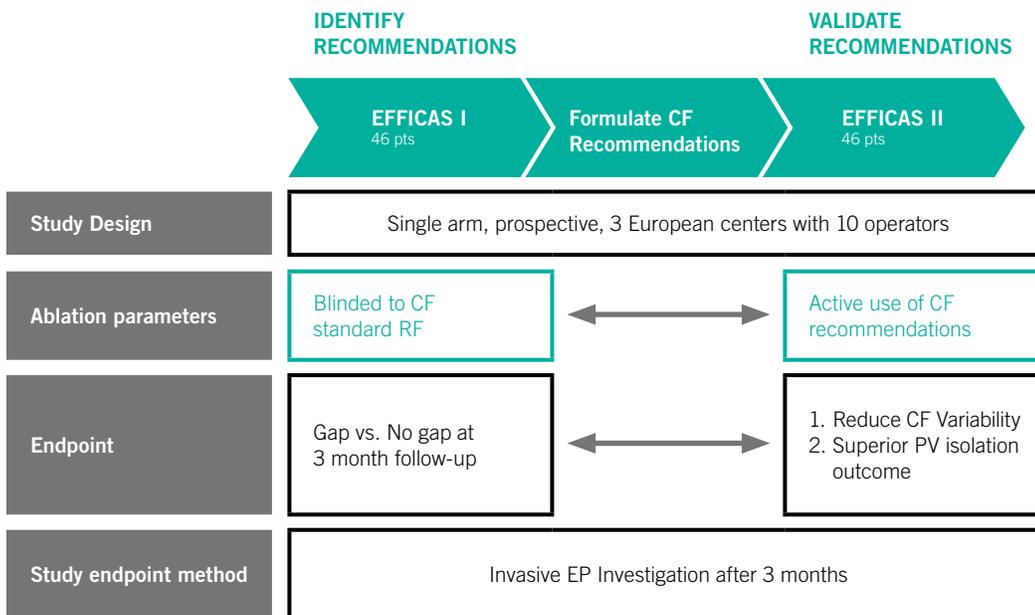
EFFICAS is a sequence of studies to (I) identify and (II) validate CF recommendations to ensure PV isolation (Figure 3).<sup>3,4</sup>

## EFFICAS II: Optimization of Catheter Contact Force Improves Outcome of Pulmonary Vein Isolation for Paroxysmal Atrial Fibrillation

Kautzner, et al. *Europace*, 2015<sup>4</sup>

Preliminary and subgroup analyses from the EFFICAS studies have also been presented at medical congresses.<sup>7-9</sup>

Figure 3: EFFICAS I and EFFICAS II Studies<sup>3,4</sup>



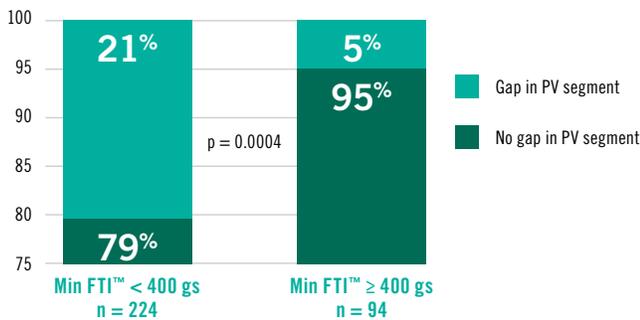
# EFFICAS I AND EFFICAS II (continued)

## EFFICAS I

- The EFFICAS I trial evaluated the association between CF and the existence of gaps during pulmonary vein (PV) isolation and at a three-month invasive follow-up.<sup>3</sup>
- Acute isolation success rate was 100% for all PVs (n = 46).
  - Without contact force information, a large proportion of the 3,152 ablations were made with low contact force and low force-time integral (FTI™).
- One or more PV segment isolation gaps (reconnections) were found in 65% of 40 patients evaluated at the three-month follow-up procedure.
  - When comparing segments with no gap vs. gap segments, a significant difference was noted in the *minimum* CF (8.1 g vs. 3.6 g, respectively,  $p < 0.0001$ ).
- The *minimum* FTI value was also correlated to PV gap reconnection at three months post-procedure (n = 40).<sup>3</sup>
- Minimum FTI was found to be the best statistical predictor of PV isolation at three months.

**Figure 4:** EFFICAS I: PVI Success Rates at Three Months by Minimum FTI<sup>3</sup>

Min CF and Min FTI™ are the best predictors for isolation – **CF Blinded**

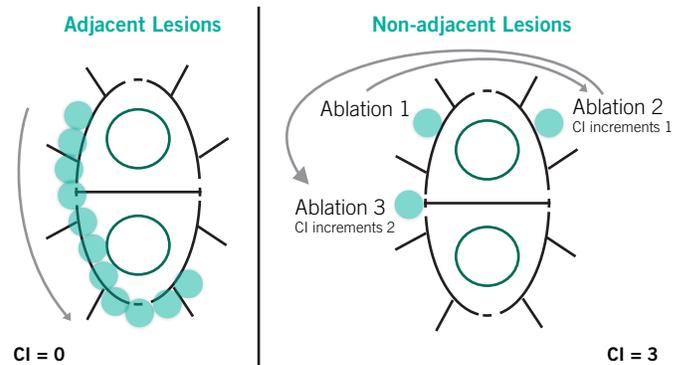


- Ablations with minimum FTI  $\geq 400$  gs, at 24.4 W average power, were associated with significantly higher PVI success ( $p = 0.0004$ ) (Figure 4).
  - Creating fewer lesions, efficiently, was associated with higher probability of PVI success.
  - The total number of ablations per segment was inversely correlated to isolation (median six for isolated segments vs. nine for segments with gaps,  $p < 0.0001$ ).
- Once an ablation with FTI  $< 400$  gs was made, the risk of gap increased. Thus, EFFICAS I data suggested that successful transmural lesions achieved in one shot do not require subsequent corrections.<sup>3</sup>

## EFFICAS II

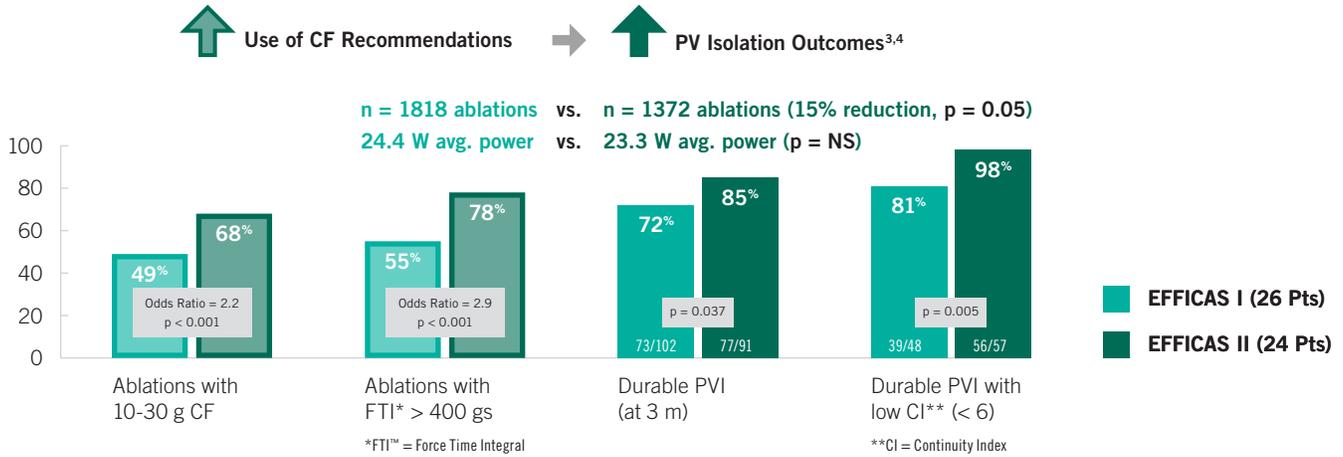
- The EFFICAS II study validated that contiguous lesions created following the CF recommendations identified in EFFICAS I (Min CF  $> 10$  g and Min FTI  $> 400$  gs) resulted in improved ablation outcomes.<sup>4</sup>
- Continuity of each PVI lesion line was quantified using a Continuity Index™ (CI) (previously referred to as “Jump Index”, JI)<sup>9</sup> that calculates how often the catheter is moved for ablation to noncontiguous locations (Figure 5).<sup>4</sup>
  - Each gap between non-adjacent lesion points increases the CI for the lesion line by one. A low CI (CI  $< 6$ ) is associated with good continuity and a high CI (CI  $\geq 6$ ) with poor continuity.
- In EFFICAS II, creating contiguous lesions with a low Continuity Index (CI  $< 6$ ) significantly increased the number of PVs isolated when compared to PVs isolated with a high Continuity Index (CI  $\geq 6$ ) (98% vs. 62%,  $p < 0.001$ ).

**Figure 5:** EFFICAS II: Continuity Index<sup>4</sup>



# EFFICAS I AND EFFICAS II (continued)

Figure 6: EFFICAS I vs. EFFICAS II Clinical Comparison<sup>3,4</sup>



- Five investigators treated patients in both EFFICAS studies, including 26 patients in EFFICAS I and 24 patients in EFFICAS II who completed the three-month remapping procedure that provided data for assessing the impact of the CF guidelines on PV isolation (Figure 6).<sup>4</sup>
  - Procedural efficiency improved from EFFICAS I to EFFICAS II, with the total number of ablations significantly reduced by 15% and no increase in average RF power.<sup>4</sup>
  - Use of CF recommendations (Figure 7) reduced PVI gaps, improving durable PV isolation at three months from 72% in EFFICAS I to 85% in EFFICAS II (p = 0.037).<sup>4</sup>
  - Using contiguous ablation lines (CI < 6) resulted in durable isolation without gaps at three months in 81% of PVs isolated in EFFICAS I, and in 98% of PVs isolated in EFFICAS II with the added use of CF recommendations (p = 0.005).<sup>4</sup>

### Key takeaways:

- Minimum CF and minimum FTI values are strong predictors of PVI gap likelihood.<sup>3</sup>
- Optimal Contact Force with the TactiCath™ catheter and contiguous lesion deployment reduces occurrence of PV gaps at three months, proven with a prospective clinical study.<sup>4</sup>
- Durable PV isolation appears to be further improved when ablation lesions are created point-by-point continuously around the pulmonary vein using a low CI (CI < 6).<sup>4</sup>

Figure 7: EFFICAS Contact Force Recommendations<sup>3,4</sup>

- TARGET **CF** 20 g with range (10 g, 30 g)<sup>3,4</sup>
- Min **CF** > 10 g for any ablation points<sup>3,4</sup>
- Min **FTI** > 400 gs for any ablation points<sup>4</sup>
- ONE SHOT: Transmurality should be achieved in one shot<sup>4</sup>

# TOCCASTAR

## A Randomized Controlled Trial of the Safety and Effectiveness of a Contact Force Sensing Irrigated Catheter for Ablation of Paroxysmal Atrial Fibrillation: Results of the Toccastar Study

Reddy, et al. *Circulation*, 2015<sup>5</sup>

Preliminary and subgroup analyses from the TOCCASTAR trial have also been presented at medical congresses.<sup>10-23</sup>

- The TOCCASTAR trial (**T**actiCath **C**ontact Force **A**blation Catheter **S**tudy for **A**trial Fibrillation) is the only prospective, randomized, controlled, multicenter study conducted to date to evaluate the safety and effectiveness of a contact force sensing ablation catheter for the treatment of symptomatic paroxysmal AF.<sup>5</sup>
- The TOCCASTAR trial was designed as a non-inferiority comparison of the St. Jude Medical™ TactiCath™ Quartz contact force sensing ablation catheter to the Biosense Webster Navistar™ ThermoCool™ ablation catheter.
- Subjects were enrolled at 17 clinical sites in Europe and the U.S.
- A total of 300 patients were randomized 1:1 to catheter ablation with either:
  - Contact Force (CF): TactiCath ablation catheter (with EnSite™ Velocity™ mapping system) or
  - Control: ThermoCool Navistar (with Biosense Webster CARTO™ mapping system).
- CF target guidelines were not specified in the study protocol – physicians applied CF during this study based on clinical experience that became available as this study progressed.
- **Primary Effectiveness** was strictly specified by the protocol as no documented, symptomatic recurrence of atrial arrhythmia > 30 seconds (off drug success).
  - The use of any class I or II anti-arrhythmia drugs (AADs) by patients after the three-month blanking period was considered a treatment failure.
  - Additionally, any transtelephonic monitoring (TTM) transmission or ECG indicating AF, AFL or AT lasting longer than 30 seconds was considered a treatment failure.
- **Clinically Relevant Success** was defined as no symptomatic recurrence of atrial arrhythmia > 30 seconds documented with TTM or ECG (patient could be on an AAD).
- The primary safety endpoint was defined as freedom from device-related serious adverse events.
- TOCCASTAR met its primary safety and effectiveness endpoints by showing TactiCath catheter non-inferiority to Control in both areas at 12 months post-ablation.

- Primary effectiveness rates were 67.8% for the TactiCath catheter CF group overall, vs. 69.4% for the non-CF Control.
- Device-related serious adverse events (SAEs) occurred in 1.97% and 1.40% of patients in the CF group and Controls, respectively (Table 1).

**Table 1:** TOCCASTAR Safety: Contact Force vs. non-CF Control

Serious Adverse Events (SAEs), n (%) of Patients	TactiCath n = 152	Control n = 143
<b>Device-related SAEs (primary)</b>	<b>3 (1.9%)</b>	<b>2 (1.40%)</b>
Cardiac tamponade/perforation	1 (0.66%)	1 (0.70%)
Pericarditis	2 (1.32%)	0 (0.0%)
Pulmonary vein stenosis	0 (0.0%)	1 (0.70%)

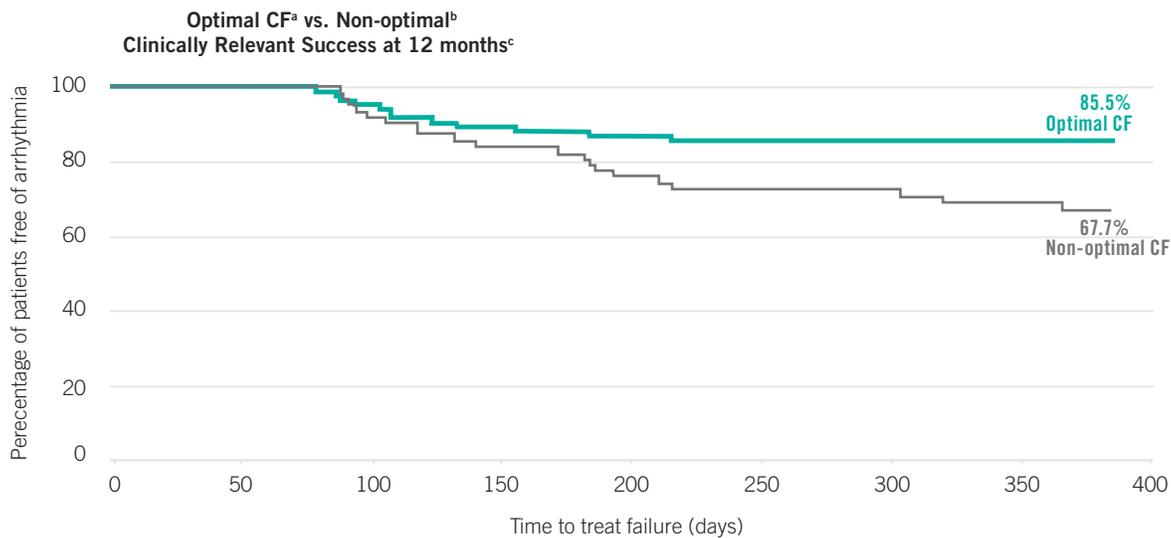
- TactiCath ablation catheter safety results were excellent with 0.7% tamponade.
- There were no deaths, strokes, transient ischemic attacks or atrioesophageal fistulas in either group.
- Pre-specified secondary endpoint analyses were performed to examine the ablation efficacy in two subgroups of patients within the TactiCath CF group (Table 2).
  - Optimal CF: patients with ≥ 90% of their lesions created at CF ≥ 10 g
  - Non-optimal CF: patients with < 90% of the lesions created at CF ≥ 10 g

**Table 2:** TOCCASTAR Effectiveness: Optimal vs. Non-optimal CF

12-month Outcomes, (%) of Patients	Optimal CF n = 83	Non-optimal CF n = 62
Primary effectiveness (off drug)	75.9%	58.1%
Clinically relevant success	85.5%	67.7%

# TOCCASTAR (continued)

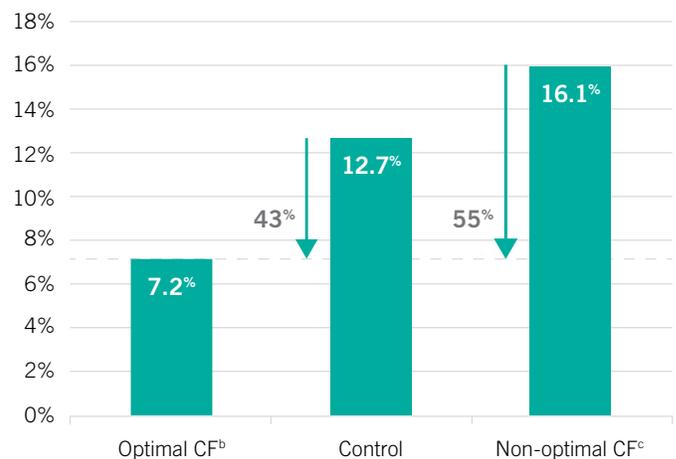
**Figure 8:** TOCCASTAR Optimal Contact Force Clinical Success



- a. Optimal CF cohort defined as those patients where  $\geq 90\%$  lesions  $\geq 10$  g
- b. Non-optimal CF cohort defined as those patients where  $< 90\%$  lesions  $\geq 10$  g
- c. Clinically relevant success: no documented, symptomatic recurrence of atrial arrhythmia  $> 30$  seconds (patient could use an AAD)

- Optimal CF (CF  $\geq 10$  g) with the TactiCath ablation catheter provided an arrhythmia-free clinically relevant success rate at 12 months of 85.5% compared to a non-optimal CF success rate of 67.7% (Table 2, Figure 8).
- Protocol-specified descriptive endpoint analyses were performed to assess the rate of repeat ablation in the “optimal CF”, “non-optimal CF” and vs. Control groups (Figure 9).
- Repeat ablation rates were 7.2% in patients with optimal CF vs. 16.1% with non-optimal CF, and 12.7% in the non-CF Control group at 12 months.
- With no target CF recommendations provided at study onset, the target CF selection varied widely between operators.

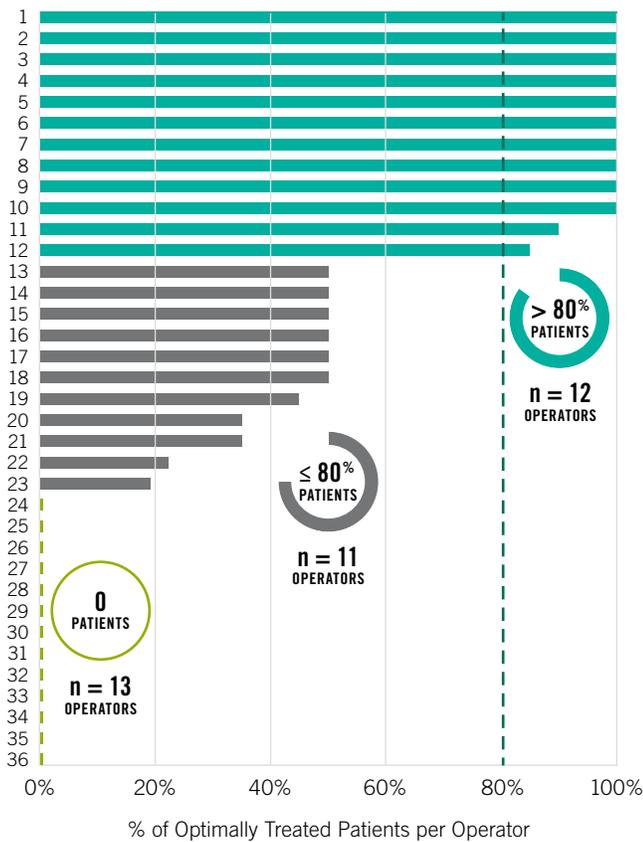
**Figure 9:** Contact Force and Control: Rate of Repeat Ablation<sup>a</sup>



- a. Repeat ablation after the protocol defined 3-month blanking period
- b. Optimal CF cohort defined as those patients where  $\geq 90\%$  lesions  $\geq 10$  g
- c. Non-optimal CF cohort defined as those patients where  $< 90\%$  lesions  $\geq 10$  g

# TOCCASTAR (continued)

**Figure 10:** Operators Delivering Optimal CF in TOCCASTAR Patients



- Optimal CF operators were defined as those operators who delivered an optimal CF ( $\geq 90\%$  of lesions created at CF  $\geq 10$  g) in  $> 80\%$  of their patients (Figure 10).
- Non-optimal CF operators were defined as those operators who delivered an optimal CF in  $\leq 80\%$  of their patients.
  - Ten operators delivered optimal CF in all (100%) of their patients.
  - Thirteen operators delivered optimal CF in none (0) of their patients.
- Operators delivering an optimal CF in  $> 80\%$  of their patients required RF power  $< 27$  W to achieve an off-drug success rate of 79.1%.
- Non-optimal CF operators used 28.0 W of power to achieve an off-drug success rate of 58.2%.
- The overall rate of SAEs was 6.0% in the optimal CF operators' patients vs. 6.3% for non-optimal CF operators.<sup>5</sup>
- An exploratory post hoc analysis was performed regarding the treatment success using a deflectable sheath (Agilis™) vs. a fixed sheath in all enrolled subjects.<sup>16,17</sup>
  - Patients in whom the Agilis sheath was used in conjunction with either ablation catheter had a treatment success rate of 74.0% vs. 62.7% for those treated with a fixed sheath.<sup>17</sup>

- When looking at the impact of the Agilis sheath on the TactiCath™ catheter only group, those cases that used the Agilis sheath had higher average contact force than when a fixed sheath was used (23.3 grams vs. 14.6 grams, respectively).<sup>16</sup>
- Quality of life improvement following successful PVI for paroxysmal AF with the TactiCath catheter was demonstrated using the AF Effect on Quality of life survey, and was sustained during long-term follow-up to 30 months.<sup>5,11</sup>

**Key takeaways:**

- The TOCCASTAR trial successfully met its primary safety and efficacy endpoints demonstrating the safety and effectiveness of the TactiCath™ Quartz contact force ablation catheter for the treatment of drug-refractory recurrent symptomatic paroxysmal atrial fibrillation.<sup>5</sup>
- TactiCath ablation catheter safety results were excellent with 0.7% tamponade.<sup>5</sup>
- Physicians who used optimal CF achieved 12-month clinical success in 85.5% of patients vs. 67.7% when non-optimal CF was used.<sup>5</sup>
  - This is consistent with findings from the TOCCATA and EFFICAS studies that fewer lesions at CF  $< 10$  g correlates with increased treatment success.<sup>2-4</sup>
- Optimal CF procedures were associated with similar or lower RF power than non-optimal CF procedures.<sup>5</sup>
- Furthermore, the rate of repeat ablation procedures at 12 months was 7.2% in patients with optimal CF vs. 16.1% with non-optimal CF and 12.7% in control group patients treated with a non-CF catheter.<sup>5</sup>

**Contact Force Sensing – The New Paradigm for RF Ablation**

Neuzil, et al. EHRA Europace, 2013<sup>10</sup>

- This abstract compared data from the TOCCATA study (n = 34) and the TOCCASTAR trial while it was ongoing (n = 165) to evaluate the use of the CF recommendations in AF ablation.
- While the TOCCASTAR trial was ongoing, investigators were provided with the following guidelines: targets of stable CF  $\geq 20$  g prior to RF, avoiding CF  $< 10$  g, and a minimum FTI of 400 gs.
- Results showed that the TOCCASTAR operators achieved higher CFs and FTIs as well as lower incidences of CF  $< 5$  g, CF  $< 10$  g, and FTI  $< 400$  gs compared to their TOCCATA counterparts (p  $< 0.0001$ ).

**Key takeaway:**

- The use of CF recommendations has greatly improved the parameters known to contribute to AF ablation success.<sup>10</sup>

## SUMMARY OF PUBLICATIONS ON LESION INDEX

Building upon the concept of CF and FTI™, the three-parameter lesion index (LSI™) algorithm was designed as another tool to predict key factors for PVI success. LSI is calculated using a non-linear function that combines CF, RF power and ablation duration to mimic the different stages of lesion formation. The following studies describe the utility of LSI in combination with the TactiCath™ Quartz ablation catheter.

### Lesion Size Index for Prediction of Reconnection Risk Following RF Ablation for PVI

Neuzil, et al. Heart Rhythm Society, 2012<sup>7</sup>

- In this abstract, LSI values calculated retrospectively from ablation procedure data were evaluated to determine if LSI was predictive of electrical reconnection (gap) formation observed clinically at three months post-PVI in 40 patients from the EFFICAS I study population.
- LSI was calculated for each of 2511 ablations, and 52 gaps were detected at the invasive three-month evaluation.
- A correlation analysis of LSI on the amount of gap formation showed that the LSI value was significantly lower in those with gaps than those without ( $5.2 \pm 1.0$  vs.  $5.7 \pm 1.3$ , respectively,  $p = 0.037$ ).
- The lowest LSI per segment was found to be the best predictor of gap formation ( $2.9 \pm 1.5$  vs.  $4.2 \pm 1.8$ ,  $p \leq 0.00001$ ).

#### Key takeaway:

- Along with CF and FTI targets from previous publications,<sup>3,9,10</sup> the authors suggest that LSI may help predict lesion size and may also correlate strongly with PV isolation at three months.<sup>7</sup>

### Segmental Variability in Lesion Size is Controlled Using Contact Force During Pulmonary Venous Isolation

Kautzner, et al. EHRA Europace, 2013<sup>19</sup>

- This study examined the use of CF and LSI to achieve uniform lesion quality in four anatomical segments from the TOCCASTAR trial ( $n = 165$ ).
- Results showed that the variability across all segments was 18.6% for CF and 4.9% for LSI, suggesting that the evaluation of time and power, in addition to CF, provides more uniform lesion delivery.

#### Key takeaway:

- This study suggests that the evaluation of time and power (LSI), in addition to CF, provides more uniform lesion delivery.<sup>19</sup>

### Application of Contact Force Guidelines Increases Durable Isolation After Pulmonary Vein Isolation for Paroxysmal Atrial Fibrillation

Mansour, et al. Heart Rhythm Society, 2013<sup>20</sup>

- This study examined the efficacy of the application of combined CF guidelines in a subgroup of TOCCASTAR patients who exhibited symptomatic AF recurrence and underwent a redo ablation after being treated with CF for paroxysmal AF ( $n = 14$  of 165 patients enrolled).
- The use of the following combined CF guidelines criteria derived from previous studies at the index procedure was retrospectively correlated with isolation success:
  - CF > 20 g, min FTI > 400 gs, and min LSI > 5.0
- Isolation rates were 80% when the combined CF guidelines criteria were applied vs. 46% when not all of the combined CF guidelines criteria were met ( $p = 0.004$ ).

#### Key takeaways:

- This study suggests that the use of combined CF guidelines derived from previous studies increases the success rate of durable PVI and leads to fewer PV reconnections.<sup>20</sup>
- Early study results suggest that the addition of LSI to the CF recommendations may lead to a higher rate of durable PVI.<sup>7,19,20</sup>

# ADDITIONAL STUDIES USING THE TACTICATH™ CATHETER WITH CONTACT FORCE

Several additional studies have been published that provide independent evidence supporting the clinical success of the contact force sensing TactiCath™ ablation catheter. Two separate meta-analyses published in 2015 reviewed clinical outcomes in the literature and concluded that the use of contact force sensing technology significantly decreases atrial fibrillation (AF) recurrence after ablation in comparison to conventional catheter ablation, without increased complications.<sup>24,25</sup>

- One meta-analysis showed a reduction in AF recurrences from 31% with conventional ablation to 15% with contact force (Odds Ratio 0.38 [95% CI 0.19-0.76], p = 0.007) based on four studies including only patients with paroxysmal AF.<sup>24</sup>
- The second included a total of six studies including patients with paroxysmal and/or persistent AF, and showed a 37% reduction in AF recurrence at a median follow-up of 12 months post-ablation for contact force technology (relative risk 0.63 [95% CI 0.44-0.91], p = 0.01).<sup>25</sup>
- The six individual studies summarized below included a total of 421 patients undergoing ablation with the TactiCath catheter, as well as additional patients treated with other contact force sensing catheters or with non-CF ablation (Table 3).<sup>26-31</sup>

**Table 3:** Summary of Published Clinical Outcomes with TactiCath™ Catheter for AF Ablation with Contact Force (CF)

Study, Year	Study Type, Type of AF	Number of Patients per Ablation Catheter Type			Follow-up Duration	Freedom from AF Recurrence (% of Patients)*			Complications
		TactiCath™	Other CF	Non-CF		TactiCath	Other CF	Non-CF	
Providencia, 2015 <sup>26</sup>	Single-center comparison, PAF (55.5%) or PeAF	110	253	358	12 mos.	PAF: 87.9 PeAF: 72.7	PAF: 89.3 PeAF: 73.4	PAF: 81.5 PeAF: 58.7	NR
Squara, 2015 <sup>27</sup>	Multi-center comparison, PAF	39	159	178 (CB2)	Median: 12 mos.	81.3		80.9	Total: 7.1% CF vs. 7.3% CB2 TPNP: 0 CF vs. 5.6% CB2 Embolism: 1% CF vs. 0 CB2 Tamponade: 1% CF vs. 0 CB2 Esophageal injury: 0.5% CF vs. 0 CB2
Akca, 2015 <sup>28</sup>	Single-center prospective registry safety data comparison (1517 total procedures: 557 AF, 715 SVT, 190 VT, 55 CHD)	189	59	813	> 30 days	NR	NR	NR	AF subgroup: Major: 2.1% CF vs. 7.8% non-CF Cardiac perforation: 0 CF vs. 3.3% non-CF Minor: 16.8% CF vs. 12.1% non-CF
Wutzler, 2014 <sup>29</sup>	Single-center prospective registry data comparison (PVI procedures, 73% PAF)	31	NA	112	12 mos.	83.9	NA	63.4	Major: Pericardial effusion: 0 CF vs. 0.9% non-CF Minor: Femoral hematoma: 3.2% CF vs. 2.7% non-CF
Casella, 2014 <sup>30</sup>	Single-center prospective randomized trial, PAF	20	NA	35	12 mos.	85	NA	80	No major complications
Wakili, 2014 <sup>31</sup>	Single-center prospective comparative study, PAF (58%) or PeAF	32	NA	35	12 mos.	PAF: 72.2 PeAF: 42.9 Overall: 59.4 (off AADs)	NA	PAF: 71.4 PeAF: 50.0 Overall: 62.9 (off AADs)	No severe complications Total: 6.3% CF vs. 5.7% non-CF Pericardial effusion (no pericardiocentesis): 3.1% CF vs. 3.1% non-CF Femoral AV fistula: 3.1% CF vs. 3.1% non-CF

\*Freedom from AF after ablation (following blanking period of 1-3 months in some studies)

PAF = paroxysmal AF; PeAF = persistent AF; NR = not reported; CB2 = second-generation cryoballoon; SVT = supraventricular tachycardia; VT = ventricular tachycardia; CHD = congenital heart disease; TPNP = transient phrenic nerve palsy; NA = not applicable; PVI = pulmonary vein isolation; AADs = anti-arrhythmic drugs

## References

1. Kuck, K. H., Reddy, V. Y., Schmidt, B., Natale, A., Neuzil, P., Saoudi, N., ... Shah, D.C. (2012). A novel radiofrequency ablation catheter using contact force sensing: Toccata study. *Heart Rhythm*, 9, 18-23.
2. Reddy, V., Shah, D., Kautzner, J., Schmidt, B., Saoudi, N., Herrera, C., ... Kuck, K. H. (2012). The relationship between contact force and clinical outcome during radiofrequency catheter ablation of atrial fibrillation in the TOCCATA study. *Heart Rhythm*, 9, 1789-1795.
3. Neuzil, P., Reddy, V., Kautzner, J., Petru, J., Wichterle, D., Shah, D., ... Kuck, K. H. (2013). Electrical reconnection after pulmonary vein isolation is contingent on contact force during initial treatment: results from the EFFICAS I study. *Circulation: Arrhythmia and Electrophysiology*, 6, 327-333.
4. Kautzner, J., Neuzil, P., Lambert, H., Peichl, P., Petru, J., Cihak, R., ... Kuck, K. H. (2015). EFFICAS II: optimization of catheter contact force improves outcome of pulmonary vein isolation for paroxysmal atrial fibrillation. *Europace*, 17(8), 1229-1235.
5. Reddy, V. Y., Dukkipati, S. R., Neuzil, P., Natale, A., Albenque, J. P., Kautzner, J., ... Mansour, M. (2015). A randomized controlled trial of the safety and effectiveness of a contact force sensing irrigated catheter for ablation of paroxysmal atrial fibrillation: results of the TOCCASTAR study. *Circulation*, 132, 907-15.
6. Mansour, M., Karst, E., Dalal, N., Heist, E. K., Packer, D., Calkins, H., ... Mahapatra, S. (2015). Economic impact of repeat ablation for atrial fibrillation [abstract]. Heart Rhythm Society, Boston, MA, May 13-16, 2015. *Heart Rhythm*, 12(5 Suppl 1), S114. Abstract P001-45.
7. Neuzil, P., Kuck, K. H., Nakagawa, H., et al. (2012). Lesion size index for prediction of reconnection risk following RF ablation for PVI [abstract]. Heart Rhythm Society, Boston, May 9-12, 2012. *Heart Rhythm*, 9(5 Suppl 1), S492. Abstract MP04-03.
8. Neuzil, P., Wissner, E., Kautzner, J., et al. (2012, June). EFFICAS II results: Contact force, FTI, lesion continuity roles at PVI [abstract]. Presented at Cardiotrim, Nice, France.
9. Kautzner, J., Neuzil, P., Peichl, P., et al. (2012). AB12-05 Contact force, force time integral and lesion continuity are critical to improve durable PV isolation: EFFICAS 2 results. [abstract]. Heart Rhythm Society, Boston, MA, May 9-12, 2012. *Heart Rhythm*, 9(5), S28.
10. Neuzil, P., Dukkipati, S., Cuoco, F., et al. (2013). Contact force sensing – the new paradigm for RF ablation [abstract]. European Heart Rhythm Association, EHRA EUROPACE 2013, Athens, Greece, June 23-26, 2013. *Europace*, 15(S2), ii104.
11. Albenque, J. P., Natale, A., Mansour, M., et al. (2015). Quality of life improvement following PVI for paroxysmal AF is sustained during long term follow-up [abstract]. European Heart Rhythm Association, EHRA EUROPACE 2015, Milan, Italy, June 21-24, 2015. *Europace*, 17(Suppl 3), iii65. Abstract P449.
12. Natale, A., Albenque J. P., Kautzner, J., et al. (2015). Acute isolation testing using adenosine and isoproterenol following pulmonary vein isolation predicts chronic treatment success [abstract]. Heart Rhythm Society, Boston, MA, May 13-16, 2015. *Heart Rhythm*, 12(5 Suppl 1), S261-S262.
13. Reddy VY, Neuzil P, Dukkipati SR, et al. (2015). Deflectable sheath reduces intermittent catheter contact force associated with ineffective lesions and arrhythmia recurrence [abstract]. Heart Rhythm Society, Boston, MA, May 13-16, 2015. *Heart Rhythm*, 12(5 Suppl 1), S444-S445.
14. Mansour M, Natale A, Heist EK, et al. (2015). Titration of RF power based on contact force is consistent with improved treatment outcome [abstract]. Heart Rhythm Society, Boston, MA, May 13-16, 2015. *Heart Rhythm*, 12(5 Suppl 1), S508.
15. Mansour M., Dukkipati S., Neuzil P., et al. (2014). Optimal contact force during pulmonary vein isolation improves chronic freedom from recurrence of AF [abstract]. Heart Rhythm Society, San Francisco, CA, May 7-10, 2014. *Heart Rhythm*, 11(5 Suppl 1), S353-S354.
16. Cuoco F., Michaud G.F., Shah D.C., et al. (2014). Steerable sheath promotes improved contact force parameters during pulmonary vein isolation [abstract]. Heart Rhythm Society, San Francisco, CA, May 7-10, 2014. *Heart Rhythm*, 11(5 Suppl 1), S518.
17. TOCCASTAR data as presented by Mansour, M. C., during "Force Sensing Ablation Catheters: Have our Hopes Been Realized" at the 2014 AF Summit at HRS. San Francisco, California, May 7-10, 2014.
18. Albenque J. P., Mansour M., Ruskin J., et al. (2013). Does acute reconnection following PVI predict chronic reconnection? [abstract] European Heart Rhythm Association, EHRA EUROPACE 2013, Athens, Greece, June 23-26, 2013. *Europace*, 15(Suppl 2), ii237.
19. Kautzner, J., Natale, A., Michaud, G., et al. (2013). Segmental variability in lesion size is controlled using contact force during pulmonary venous isolation [abstract]. European Heart Rhythm Association, EHRA EUROPACE 2013, Athens, Greece, June 23-26, 2013. *Europace*, 15(Suppl 2), ii56. Abstract P523.
20. Mansour, M., Shah, D., Kalbfleisch, S., et al. (2013). Application of contact force guidelines increases durable isolation after pulmonary vein isolation for paroxysmal atrial fibrillation [abstract]. Heart Rhythm Society, Denver, CO, May 8-11, 2013. *Heart Rhythm*, 10(5 Suppl 1), s131. Abstract P001-133.
21. Shah, D. C., D'Avila, A., Natale, A., et al. (2012). How do anatomical factors affect contact force during PV ablation [abstract]? Heart Rhythm Society, Boston, May 9-12, 2012. *Heart Rhythm*, 9(5 Suppl 1), S411.
22. Mansour, M., Shah, D., Heist, E. K., et al. (2012). JET ventilation stabilizes contact force during RF ablation for PVI [abstract]. Heart Rhythm Society, Boston, May 9-12, 2012. *Heart Rhythm*, 9(5 Suppl 1), S418.
23. Reddy, V.Y., Michaud, G.F., Shah, D., et al. (2012). Practical considerations for implementation of contact force targets during RF ablation for PVI [abstract]. Heart Rhythm Society, Boston, MA, May 9-12, 2012. *Heart Rhythm*, 9(5 Suppl 1), S470-S471.
24. Shurrab, M., Di Biase, L., Briceno, D. F., Kaoutskaia, A., Haj-Yahia, S., Newman, D., ... Crystal, E. (2015). Impact of contact force technology on atrial fibrillation ablation: a meta-analysis. *Journal of the American Heart Association*, 4(9), pii: e002476.
25. Afzal, M. R., Chatta, J., Samanta, A., Waheed, S., Mahmoudi, M., Vukas, R., ... Lakkireddy, D. (2015). Use of contact force sensing technology during radiofrequency ablation reduces recurrence of atrial fibrillation: A systematic review and meta-analysis. *Heart Rhythm*, 12(9), 1990-1996.
26. Providencia, R., Khoueiry, Z., Bouzeman, A., et al. (2015). Contact- force sensing using the SmartTouch and TactiCath catheter: head-to-head comparison and benefit on catheter ablation of paroxysmal and persistent atrial fibrillation [abstract]. Heart Rhythm Society, Boston, MA, May 13-16, 2015. *Heart Rhythm*, 12(5 Suppl 1), S66. Abstract AB29-03.
27. Squara F, Zhao A, Marijon E, Latcu DG, Providencia R, Di Giovanni G, ... Thomas, O. (2015). Comparison between radiofrequency with contact force-sensing and second-generation cryoballoon for paroxysmal atrial fibrillation catheter ablation: a multicentre European evaluation. *Europace*, 17(5), 718-724.
28. Akka, F., Janse, P., Theuns, D. A., & Szili-Torok, T. (2015). A prospective study on safety of catheter ablation procedures: contact force guided ablation could reduce the risk of cardiac perforation. *International Journal of Cardiology*, 179, 441-448.
29. Wutzler, A., Huemer, M., Parwani, A. S., Blaschke, F., Haverkamp, W., & Boldt, L. H. (2014). Contact force mapping during catheter ablation for atrial fibrillation: procedural data and one-year follow-up. *Archives of Medical Science*, 10(2), 266-272.
30. Casella, M., Dello Russo, A., Russo, E., Al-Mohani, G., Santangeli, P., Riva, S., ... Tondo, C. (2014). Biomarkers of myocardial injury with different energy sources for atrial fibrillation catheter ablation. *Cardiology Journal*, 21(5):516-523.
31. Wakili, R., Clauss, S., Schmidt, V., Ulbrich, M., Hahnefeld, A., Schüssler, F., ... Estner, H. L. (2014). Impact of real-time contact force and impedance measurement in pulmonary vein isolation procedures for treatment of atrial fibrillation. *Clinical Research in Cardiology*, 103(2), 97-106.

**Rx Only**

**Brief Summary:** Please review the Instructions for Use prior to using these devices for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

**Indications:** 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.

**Contraindications:** Do not use for any of the following conditions: certain recent heart surgery; prosthetic valves; active systemic infection; use in coronary vasculature; myxoma or intracardiac thrombus, or an interatrial baffle or patch; retrograde trans-aortic approach in patients with aortic valve replacement.

**Warnings:** It is important to carefully titrate RF power; too high RF power during ablation may lead to perforation caused by steam pop. Contact force in excess of 70 g may not improve the characteristics of lesion formation and may increase the risk for perforation during manipulation of the catheter. Patients undergoing septal accessory pathway ablation are at risk for complete AV block which requires the implantation of a permanent pacemaker. Implantable pacemakers and implantable cardioverter/defibrillator may be adversely affected by RF current. Always verify the tubing and catheter have been properly cleared of air prior to inserting the catheter into the vasculature since entrapped air can cause potential injury or fatality. The temperature data transmitted by the sensor in this catheter is representative of the irrigated electrode only and does not provide tissue temperature data.

**Precautions:** The long-term risks of protracted fluoroscopy and creation of RF induced lesions have not been established; careful consideration must be given for the use of the device in prepubescent children. When using the catheter with conventional EP lab system or with a 3D navigational system, careful catheter manipulation must be performed, in order to avoid cardiac damage, perforation, or tamponade. Always maintain a constant saline irrigation flow to prevent coagulation within the lumen of the catheter. Access the left side of the heart via a transseptal puncture. Care should be taken when ablating near structures such as the sino-atrial and AV nodes.

**Potential Adverse Events:** Potential adverse events include, but are not limited to, cardiovascular related complications, including groin hematoma, pericardial effusion and infection. More serious complications are rare, which can include damage to the heart or blood vessels; blood clots (which may lead to stroke); tamponade; severe pulmonary vein stenosis; heart attack; esophageal fistula, or death. Please refer to the Instructions for Use for a complete list.

Navistar, ThermoCool and CARTO are trademarks of Biosense Webster.

Unless otherwise noted, ™ indicates that the name is a trademark of, or licensed to, St. Jude Medical or one of its subsidiaries. ST. JUDE MEDICAL and the nine-squares symbol are trademarks and service marks of St. Jude Medical, Inc. and its related companies. © 2016 St. Jude Medical, Inc. All Rights Reserved.

**St. Jude Medical Inc.**  
Global Headquarters  
One St. Jude Medical Drive  
St. Paul, MN 55117  
USA  
T +1 651 756 2000 | F +1 651 756 3301

**St. Jude Medical S.C., Inc.**  
Americas Division  
6300 Bee Cave Road  
Bldg. Two, Suite 100  
Austin, TX 78746  
USA  
T +1 512 286 4000 | F +1 512 732 2418

**SJM Coordination Center BVBA**  
The Corporate Village  
Da Vincilaan 11-Box F1  
B-1935 Zaventem, Belgium  
T +32 2 774 68 11 | F +32 2 772 83 84

**St. Jude Medical Brasil Ltda.**  
Rua Itapeva, 538  
5º ao 8º andares  
01332-000 – São Paulo – SP  
Brazil  
T +55 11 5080 5400 | F +55 11 5080 5423

**St. Jude Medical (Hong Kong) Ltd.**  
Suite 1608, 16/F Exchange Tower  
33 Wang Chiu Road  
Kowloon Bay, Kowloon  
Hong Kong SAR  
T +852 2996 7688 | F +852 2956 0622

**St. Jude Medical Japan Co., Ltd.**  
Shiodome City Center 15F  
1-5-2 Higashi Shinbashi, Minato-ku  
Tokyo 105-7115  
Japan  
T +81 3 6255 6370 | F +81 3 6255 6371

**St. Jude Medical Australia Pty, Ltd.**  
17 Orion Road  
Lane Cove, NSW 2066  
Australia  
T +61 2 9936 1200 | F +61 2 9936 1222

