



**Abbott**

## 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. The fiberoptic force sensing technology in the TactiCath Quartz catheter has demonstrated a very high level of contact force measurement accuracy (within 1.2 g, mean error  $\leq$  0.5 g) and precision (within 3.8%) across orientation angles in test scenarios representative of clinical use conditions.<sup>1</sup> 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>2-5</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>6</sup> This compendium summarizes the clinical evidence supporting the use of the TactiCath Quartz™ system to guide PVI procedures.

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

Clinical evidence strongly supports the need for contact force (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>2</sup> The use of CF sensing can reduce procedural variability during ablation and is also associated with a lower risk of AF recurrence.<sup>3</sup> Endosense,<sup>TM</sup> which was acquired by Abbott 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<sup>TM</sup> Quartz\* contact force sensing ablation catheter is safe for use in pulmonary vein isolation (PVI).<sup>2-6</sup> Applying the optimal CF recommendations developed from these studies has been associated with successful ablation outcomes, including high rates of durable PVI<sup>4,5</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>6</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>7</sup>

## TOCCASTAR

- Effectiveness and safety with TactiCath<sup>TM</sup> catheter

## EFFICAS II

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

## EFFICAS I

- Contact force recommendations
  - Minimum CF
  - Minimum FTI<sup>TM</sup>

## TOCCATA

- Safety and feasibility of force-sensing
- Importance of average CF and force time integral (FTI<sup>TM</sup>)

\*The TactiCath<sup>TM</sup> Quartz catheter uses the same contact force sensing (optical) technology as the TactiCath catheter. Data from the TactiCath catheter are applicable to the TactiCath Quartz catheter as the design modifications made to the TactiCath catheter are fully verifiable in bench testing.

# TOCCATA

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

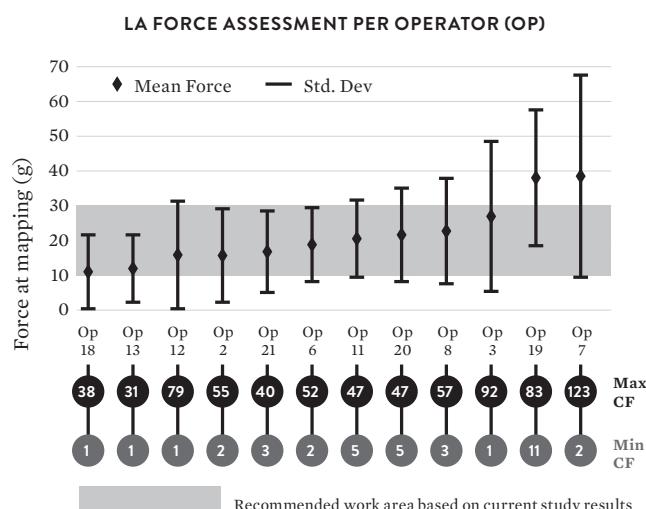
Kuck, et al. *Heart Rhythm*, 2012<sup>2</sup>

## 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>3</sup>

- The purpose of the TOCCATA clinical trial was to evaluate the safety and efficacy of CF sensing during ablation procedures (n = 72).
  - 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.

Figure 1: TOCCATA: Mean Contact Force Distribution by Operator<sup>2</sup>



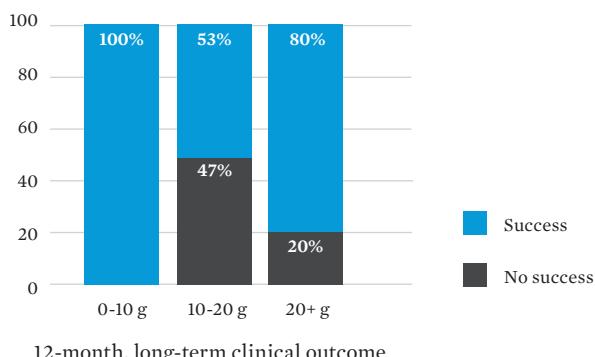
– For paroxysmal AF patients, the SAE rate was 12%, which was also below the pre-specified safety rate of 16.8%.<sup>2</sup>

- TOCCATA also investigated the relationship between CF and clinical outcomes from the AF subpopulation at 12 months post-PVI (n = 34).
  - 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  $\geq$  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>3</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>2</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>3</sup>
- Using the TactiCath™ ablation catheter to measure CF helps ensure successful PVI regardless of anatomical location.<sup>3</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>3</sup>
- TOCCATA validated the safety and feasibility of force-sensing, while confirming the importance of CF technology.<sup>3,4</sup>

Figure 2: Recurrence Rates by Average Ablation Contact Force<sup>3</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>4</sup>

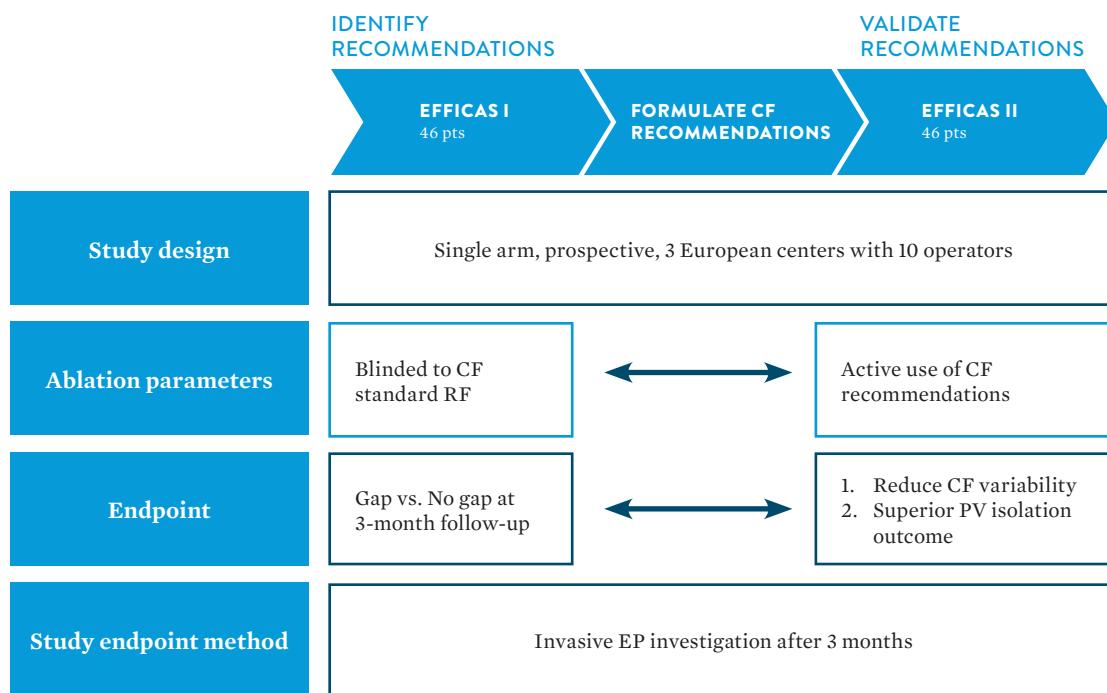
EFFICAS is a sequence of studies to (I) identify and (II) validate CF recommendations to ensure PV isolation (Figure 3).<sup>4,5</sup>

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

Kautzner, et al. *Europace*, 2015<sup>5</sup>

Preliminary and subgroup analyses from the EFFICAS studies have also been presented at medical congresses.<sup>8-10</sup>

Figure 3: EFFICAS I and EFFICAS II Studies<sup>4,5</sup>

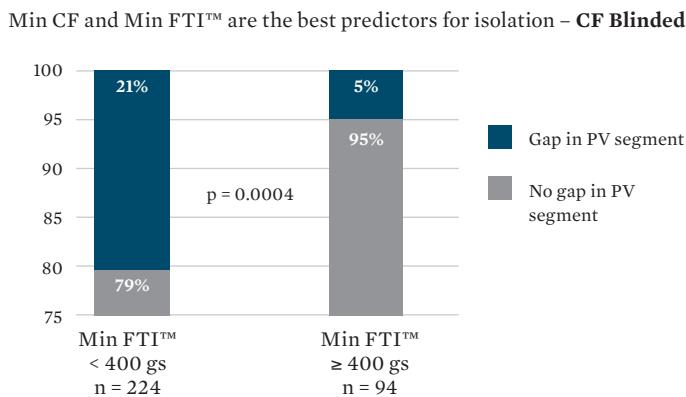


## EFFICAS I AND EFFICAS II (CONTINUED)

### 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>4</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>4</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>4</sup>

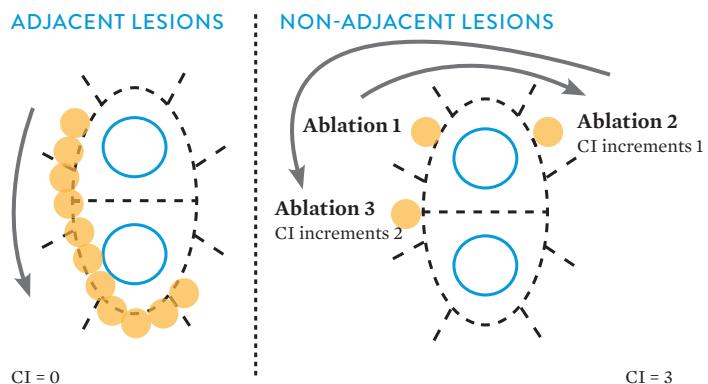


- Ablations with minimum FTI  $\geq 400$  gs, at 24.4 W average power, were associated with significantly higher PVI success (p = 0.0004) (Figure 4).
  - Creating fewer lesions, efficiently, was associated with higher probability of PVI success.
  - The total number of ablations per segment was inversely 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>4</sup>

### EFFICAS II

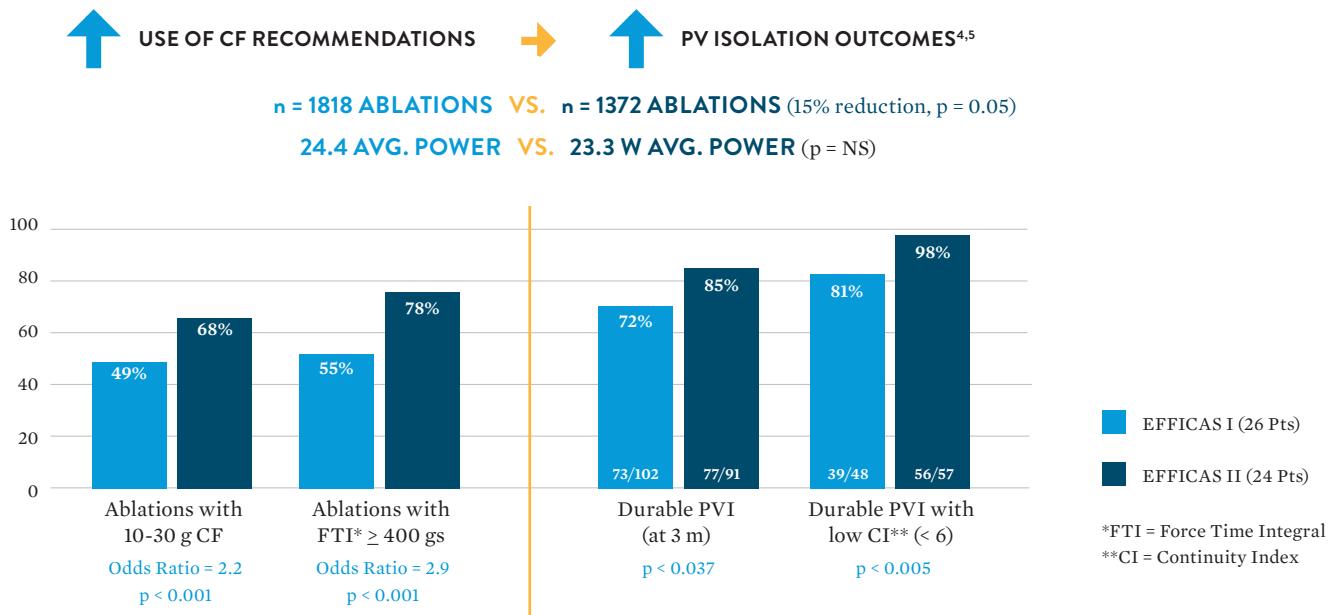
- The EFFICAS II study validated that contiguous lesions created following the CF recommendations identified in EFFICAS I (Min CF > 10 g and Min FTI  $\geq 400$  gs) resulted in improved ablation outcomes.<sup>5</sup>
- Continuity of each PVI lesion line was quantified using a Continuity Index™ (CI) (previously referred to as “Jump Index”, JI)<sup>10</sup> that calculates how often the catheter is moved for ablation to noncontiguous locations (Figure 5).<sup>5</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>5</sup>



## EFFICAS I AND EFFICAS II (CONTINUED)

**Figure 6:** EFFICAS I vs. EFFICAS II Clinical Comparison<sup>4,5</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>5</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>5</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>5</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>5</sup>

### Key takeaways:

- Minimum CF and minimum FTI values are strong predictors of PVI gap likelihood.<sup>4</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>5</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>5</sup>

**Figure 7:** EFFICAS Contact Force Recommendations<sup>4,5</sup>

- TARGET **CF** 20 g with range (10 g, 30 g)<sup>4,5</sup>
- Min **CF** 10 g for any ablation points<sup>4,5</sup>
- Min **FTI** 400 gs for any ablation points<sup>5</sup>
- ONE SHOT: Transmurality should be achieved in one shot<sup>5</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>6</sup>

Preliminary and subgroup analyses from the TOCCASTAR trial have also been presented at medical congresses.<sup>11-24</sup>

- The TOCCASTAR trial (**TactiCath Contact Force Ablation Catheter Study for Atrial 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>6</sup>
- The TOCCASTAR trial was designed as a non-inferiority comparison of the TactiCath™ contact force sensing ablation catheter from Abbott to the Biosense Webster Navistar<sup>‡</sup> ThermoCool<sup>‡</sup> 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/or:
  - Contact Force (CF): TactiCath ablation catheter (with EnSite™ Velocity™ mapping system).
  - Control: ThermoCool Navistar (with Biosense Webster CARTO<sup>‡</sup> 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.
- Acute procedural success (isolation of all targeted PVs) was achieved in all patients (100%) in both groups.
- Radiofrequency ablation times were 46.5 vs. 53.0 minutes ( $p = 0.018$ ), and fluoroscopy times were 27.0 vs. 23.0 minutes ( $p = 0.044$ ), for the TactiCath catheter and non-CF catheter Control groups, respectively.

- 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 [ $p = 0.798$ ; -1.6% absolute difference, -10.7% lower limit of 95% confidence interval, noninferiority  $p = 0.0073$ ].
  - Device-related serious adverse events (SAEs) occurred in 1.97% and 1.40% of patients in the CF group and Controls, respectively [0.57% absolute difference, 3.61% upper limit of 95% confidence interval, noninferiority  $p = 0.0004$ ] (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
Device-related SAEs (primary)	3 (1.9%)	2 (1.40%)
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%)

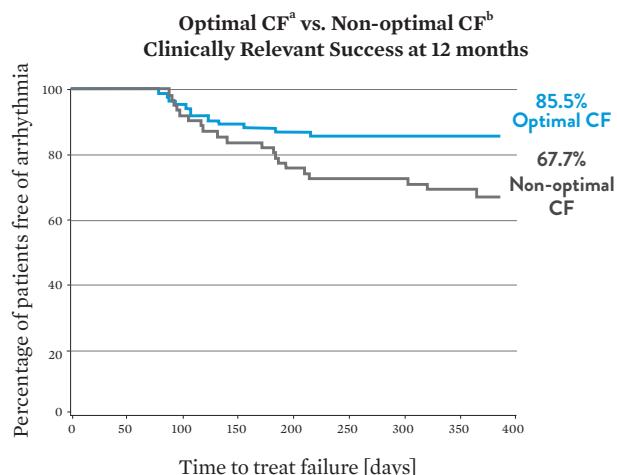
- TactiCath ablation catheter safety results were excellent with 0.7% tamponade.
- There were no deaths, strokes, transient ischemic attacks or atrioesophageal fistulas in either group.
- Clinically relevant success rates at 12 months were 78.1% for the TactiCath catheter group vs. 80.6% for the non-CF Control group ( $p = 0.659$ ).
- 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  $\geq 90\%$  of their lesions created at  $CF \geq 10$  g.
  - Non-optimal CF: patients with  $< 90\%$  of the lesions created at  $CF \geq 10$  g.
- 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).

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%	81.1%
Clinically relevant success	85.5%	67.7%

## TOCCASTAR (CONTINUED)

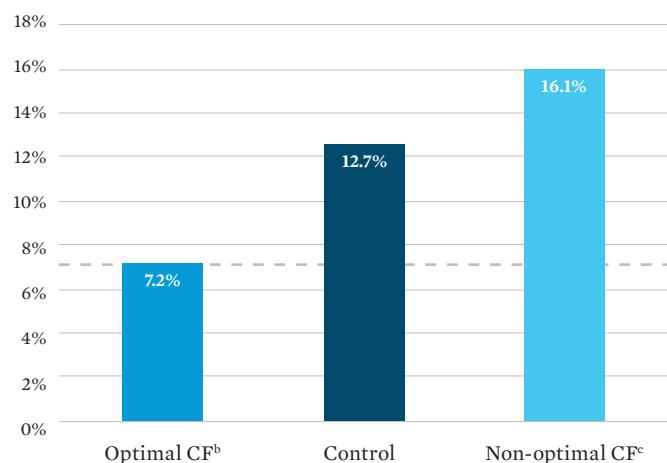
**Figure 8:** TOCCASTAR Optimal Contact Force Clinical Success<sup>6</sup>



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

- 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.
- An economic analysis of TOCCASTAR study and MarketScan<sup>#</sup> data compared post-ablation costs for patients treated with the TactiCath catheter and with the non-contact force sensing ThermoCool<sup>†</sup> catheter (Figure 10).
- This analysis retrospectively identified clinical events in the year after ablation for TOCCASTAR study patients, including 83 treated with TactiCath catheter using optimal CF and 62 with non-optimal CF (CF information was not available for one patient treated with the TactiCath catheter), and 134 treated with the non-CF control catheter.
- Clinical events included any complications after ablation, repeat ablations and use of antiarrhythmic drugs, and were matched to patients with AF catheter ablation and identical events from the MarketScan claims database to derive event costs.
- Total mean costs per patient in the year after ablation were \$19,271 for patients ablated with the TactiCath catheter using optimal CF vs. \$22,673 for patients treated with the non-CF ThermoCool catheter (\$3402 savings per patient, translating to a 15% reduction,  $p < 0.001$ ) and vs. \$24,093 with non-optimal CF (6% reduction,  $p < 0.001$ ).
- Post-ablation costs were lower, with mean savings reaching 15% for ablation with the TactiCath catheter using optimal contact force when compared with non-CF catheter ablation.

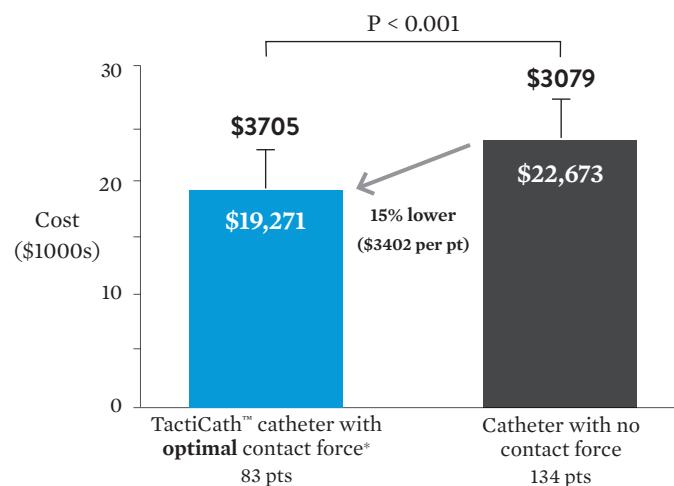
**Figure 9:** Contact Force and Control: Rate of Repeat Ablation<sup>6</sup>



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

**Figure 10:** Mean Cost in Year after Ablation Per Patient Treated with Optimal CF<sup>a</sup> vs. Non-CF Catheter

**Total Care Management Cost per Patient in Year after Ablation<sup>27</sup>**



\*Optimal contact force is defined as  $\geq 90\%$  of lesions with  $\geq 10\text{ g}$  force; contact force data were unavailable for 1 patient

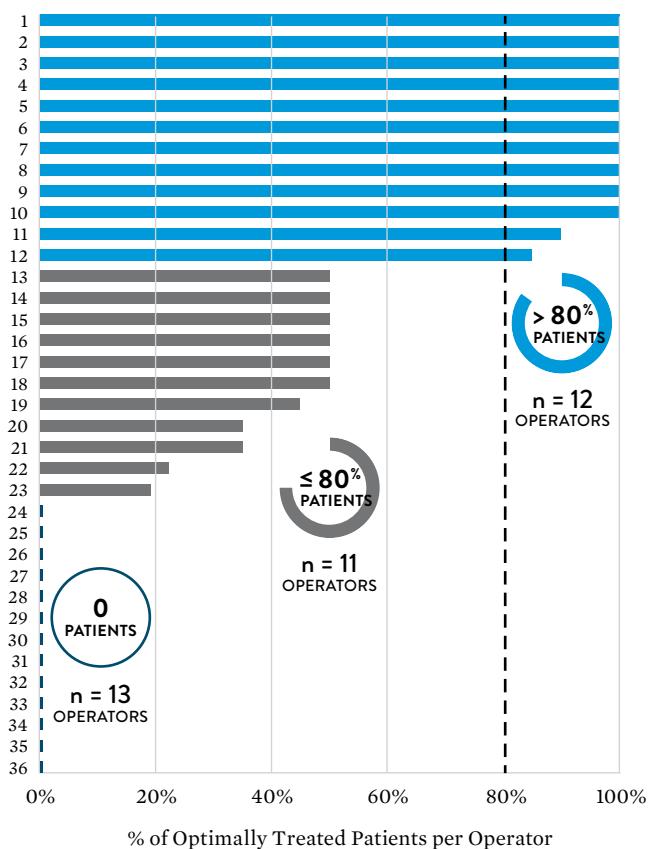
**Analysis limitations:** 1) Event rate in the TOCCASTAR clinical study may be lower than in nonclinical study practice; 2) Projecting from small number of events in study patients

**Claims data limitations:** 1) U.S. patients only, while study is international; 2) Cannot identify recurrent AF after ablation; 3) Unknown reasons for loss to follow up

## TOCCASTAR (CONTINUED)

- With no target CF recommendations provided at study onset, the target CF selection varied widely between operators.<sup>6</sup>
- 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 11).
- 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.

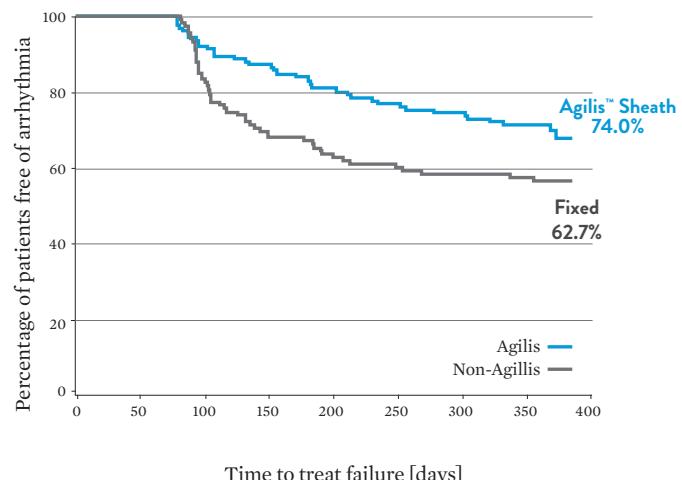
**Figure 11:** Operators Delivering Optimal CF in TOCCASTAR Patients



- 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>6</sup>

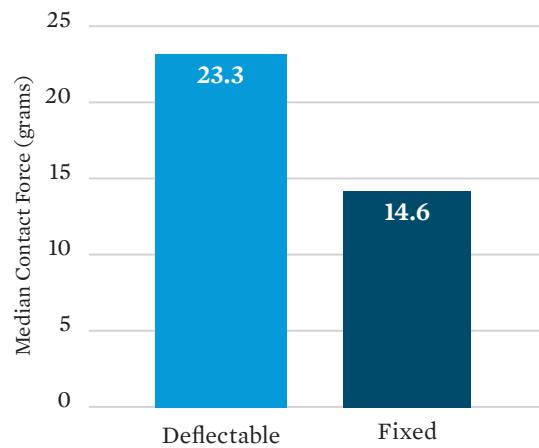
- An exploratory post hoc analysis was performed regarding the treatment success using a deflectable sheath (Agilis™ sheath) vs. a fixed sheath in all enrolled subjects.<sup>17,18</sup>
  - Patients in whom the Agilis sheath was used in conjunction with either ablation catheter had a treatment success rate of 74.0% vs. 62.7% for those treated with a fixed sheath (Figure 12).<sup>18</sup>

**Figure 12:** Protocol Defined Treatment Success by Sheath Usage



- When looking at the impact of the Agilis sheath within the TactiCath™ catheter per protocol group only, cases that used the Agilis sheath had higher median contact force than when a fixed sheath was used (23.3 grams vs. 14.6 grams, respectively (Figure 13).<sup>17</sup>

**Figure 13:** Average CF by Sheath Usage (contact force group only)<sup>17</sup>



## TOCCASTAR (CONTINUED)

- 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>6,12</sup>

### Key takeaways:

- The TOCCASTAR trial successfully met its primary safety and efficacy endpoints demonstrating the safety and effectiveness of the TactiCath™ contact force ablation catheter for the treatment of drug-refractory recurrent symptomatic paroxysmal atrial fibrillation.<sup>6</sup>
- TactiCath ablation catheter safety results were excellent with 0.7% tamponade.<sup>6</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>6</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>3-5</sup>
- Optimal CF procedures were associated with similar or lower RF power than non-optimal CF procedures.<sup>6</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>6</sup>
- An economic analysis of TOCCASTAR study clinical events and U.S. claims data shows a 15% reduction in post-ablation management costs in the year after ablation for patients treated with the TactiCath catheter using optimal CF, when compared with patients treated with a non-CF catheter.<sup>27</sup>

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

Neuzil, et al. EHRA Europace, 2013<sup>11</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:

- When compared with TOCCATA data, sharing results of concurrent studies with operators during TOCCASTAR resulted in increased utilization of CF parameters shown in the other studies to correlate with increased treatment success (CF  $\geq 10$  g, FTI  $\geq 400$  gs).<sup>11</sup>

## SUMMARY OF PUBLICATIONS ON LESION INDEX

Building upon the concept of CF and FTI™, the lesion index (LSI™) is a proprietary index combining contact force, radiofrequency (RF) application duration, and RF current.\* The following published abstracts describe early studies investigating the use of LSI in combination with the TactiCath™ contact force sensing ablation catheter.

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

Neuzil, et al. Heart Rhythm Society, 2012<sup>8</sup>

- This abstract clinically validated the use of the LSI to predict electrical reconnection (gap) formation at three months post-PVI in 40 patients from the EFFICAS I study population.
- LSI was calculated retrospectively 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>4,10,11</sup> the authors suggest that LSI may help predict lesion size and may also correlate strongly with PV isolation at three months.<sup>8</sup>

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

Kautzner, et al. EHRA Europace, 2013<sup>20</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>20</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>21</sup>

\*This parameter was displayed during ablation procedures in a 31-patient supplemental study to the TOCCASTAR clinical trial. However, the clinical utility of this parameter has not been evaluated.

- This study evaluated a subgroup of TOCCASTAR patients treated with CF who exhibited symptomatic AF recurrence and underwent a redo ablation ( $n = 14$ ).
- 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>21</sup>
- Early study results suggest that the addition of LSI to the CF recommendations may lead to a higher rate of durable PVI.<sup>8,20,21</sup>

### Optimal Contact Force During Pulmonary Vein Isolation Improves Chronic Freedom from Recurrence of AF

Mansour, et al. Heart Rhythm Society, 2014<sup>16</sup>

- This abstract reported on a retrospective analysis of 145 patients treated in the TOCCASTAR study with the TactiCath catheter, using optimal CF in 83 patients ( $\geq 90\%$  of lesions created with CF  $\geq 10$ g) and sub-optimal CF in 62 patients.
- Optimal CF was associated with a 12-month clinical success rate of 85.5% vs. 72.6% for sub-optimal CF.
- Across all pulmonary vein (PV) segments, median CF (26.0 g vs. 16.0 g), FTI (1227 gs vs. 897 gs) and LSI (6.9 vs. 5.9) values were greater for the optimal CF subgroup when compared with sub-optimal CF, respectively (all  $p < 0.01$ ).

#### Key takeaway:

- This analysis showed increased CF, FTI and LSI values used in the CF group appeared to correlate with optimal CF and clinical success at 12 months.

### Steerable Sheath Promotes Improved Contact Force Parameters During Pulmonary Vein Isolation

Cuoco, et al. Heart Rhythm Society, 2014<sup>17</sup>

- Contact force parameters were retrospectively compared for TOCCASTAR patients treated with the TactiCath catheter using either an Agilis™ steerable sheath ( $n = 79$ ) or a fixed sheath ( $n = 66$ ).
- Median CF (23.4 g vs. 14.6 g), FTI (915 gs vs. 551 gs) and LSI (6.7 vs. 5.7) values were higher for the steerable vs. fixed sheath subgroups, respectively (all  $p < 0.001$ ) across PV segments.

#### Key takeaway:

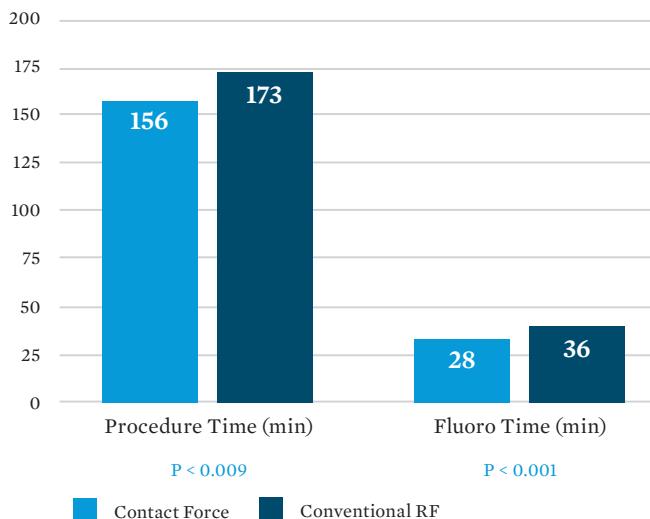
- Using a steerable sheath was associated with higher median CF ( $\geq 20$  g), FTI and LSI values. Average CF  $\geq 20$  g was previously correlated with durable lesions and improved long-term outcome.<sup>3</sup>

## ADDITIONAL STUDIES USING THE TACTICATH™ CATHETER WITH CONTACT FORCE

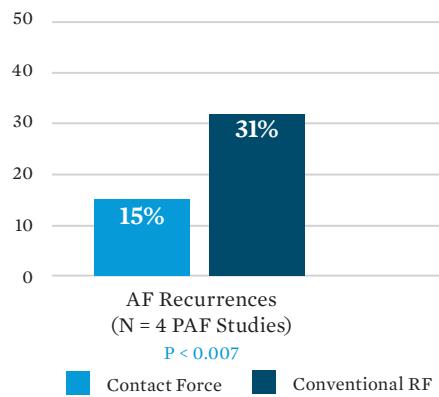
Several additional studies have been published that provide independent evidence supporting the clinical success of the contact force sensing TactiCath™ ablation catheter. Two separate meta-analyses published in 2015 reviewed clinical outcomes in the literature and concluded that the use of contact force sensing technology (CF, including but not limited to the TactiCath catheter) significantly decreases atrial fibrillation (AF) recurrence after ablation in comparison to conventional radiofrequency (RF) catheter ablation, without increased complications (Table 3).<sup>25,26</sup>

- One meta-analysis showed a 52% 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>25</sup> (Figures 14 and 15).
- Recurrence rates were also reduced significantly by 38% for CF ablation catheters (35.1% vs. 45.5% for non-CF catheters, Odds ratio 0.62 [95% CI 0.45–0.86], p = 0.004) when the ten paroxysmal and persistent AF studies that reported this endpoint were included.

**Figures 14 and 15:** Contact Force Impact on AF Ablation Procedures and Recurrences<sup>25</sup>



- In addition, this meta-analysis shows that contact force technology resulted in significant reductions in total AF ablation procedure time (17-minute reduction, p = 0.009), RF ablation time (4-minute reduction, p = 0.007), and fluoroscopy time (8-minute reduction, p = 0.01) when compared with non-CF catheters.
- The rate of major complications (1.3% for CF vs. 1.9% for non-CF catheter ablations, p = 0.45) and cardiac tamponade (1.2% for CF vs. 1.4% for non-CF catheter ablations, p = 0.70) were not significantly different between the two technology groups in this meta-analysis.
- 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>26</sup>
- Reductions in total procedure time (10.7-minute reduction, p = 0.17) or in fluoroscopic exposure time (4-minute reduction, p = 0.45) associated with the use of CF technology were not statistically significant in this analysis; however, the 7.3-minute reduction in RF ablation for the CF group time was significant (p = 0.03) when compared with standard non-CF ablation catheters.



**Table 3:** Meta-analyses Comparing AF Ablation Outcomes for Contact Force (CF) Versus Non-CF Catheters

Author, Year	# of Studies Included	Procedure Time [range]		RF Ablation Time [range]		Fluoroscopy Time [range]		AF Recurrence Rate [range]	
		# of studies = N   # of patients = n							
		CF	Non-CF	CF	Non-CF	CF	Non-CF	CF	Non-CF
Shurrab, 2015 <sup>25</sup>	N = 11	156 min [59–235 min] N = 7 n = 252	173 min [96–226 min] N = 7 n = 361	47 min [30–59 min] N = 9 n = 483	51 min [32–65 min] N = 9 n = 807	28 min [20–72 min] N = 8 n = 463	36 min [27–51 min] N = 10 n = 772	35.1% [10–64%] N = 10 n = 527	45.5% [16–62%] N = 10 n = 851
Afzal, 2015 <sup>26</sup>	N = 9	[59–235 min] N = 8 n = 496	[96–194 min] N = 8 n = 668	[25–59 min] N = 7 n = 309	[30–65 min] N = 7 n = 501	[9–72 min] N = 9 n = 526	[22–51 min] N = 9 n = 698	[5.3%–41%] N = 6 n = 210	[16%–42%] N = 6 n = 298

- The 13 individual studies summarized in Table 4 included more than 500 patients undergoing ablation with the TactiCath catheter, as well as additional patients treated with other contact force sensing catheters or with non-CF ablation.<sup>28-40</sup>

**Table 4:** Summary of Published Clinical Outcomes with TactiCath™ Catheter for AF Ablation with Contact Force (CF)

Author, Year	Study Type, Type of AF	Number of Patients per Ablation Catheter Type			Procedure/Ablation/Fluoroscopy Exposure Duration (min) [dose]			Follow-up Duration	Freedom from AF Recurrence (% of Patients)*			Complications	
		TactiCath™	Other CF	Non-CF	TactiCath™	Other CF	Non-CF		TactiCath™	Other CF	Non-CF		
Mantovan, 2016 [abstract] <sup>28</sup>	Single-center prospective, randomized controlled trial, PAF	47	NA	40 (Contact Therapy™ Cool Path™)	Median: 179/31/20 [NR]	NA	Median: 181/36/28 [NR]	9 mos. (interim)	89.3 (25/28)	NA	84.4 (27/32)	Peri-procedural through discharge: Total: 4.2% CF vs. 2.5% non-CF Hematoma: 2.1% CF vs. 0 non-CF PV stenosis: 2.1% CF vs. 0 non-CF Pericardial effusion: 0 CF vs. 2.5% non-CF	
Anter, 2016 [abstract] <sup>29</sup>	Three-center comparison PVI durability, PAF or PeAF	250		65	NR		NR	12 mos.	≥ 74 (185/250 with no redos for recurrence) (80% of 65 no PV reconnection at redo)		NR (50.8% of 65 no PV reconnection at redo)	Perforation: 1.5% (n = 1 each group)	
Leo, 2016 [abstract] <sup>30</sup>	Single-center retrospective comparison, PAF	50		50 (CB2)	NR/NR/15.4		NR/NR/23.8	9 mos.	80		76	Major complications: 4% CF vs. 4% CB2 TIA: 2% CF vs. 0 CB2 Vascular: 2% CF vs. 0 CB2 Transient PNP: 0 CF vs. 4% CB2	
Khoueiry, 2016 <sup>31</sup>	Single-center, nonrandomized, observational comparison, PAF	63	159	Plus 154 conventional irrigated non-CF (376 total in RF group)	311 (CB: 208 CBI plus 103 CB2)	114.2/NR/23.8 [NR]		132.8/NR/26.1 [NR]	14 mos.	85.9 (RF group including CF)		83.0	Procedural complications: 6.6% RF vs. 6.4% CB Pericarditis/tamponade: 1.6% RF vs. 0.3% CB Thromboembolic events: 0.3% RF vs. 0.3% CB Transient PNP: 0.3% RF vs. 2.3% CB Vascular/bleeding: 3.2% RF vs. 2.3% CB Other: 1.3% RF vs. 1.3% CB
Matsuda, 2015 <sup>32</sup>	Single-center prospective, operator-blinded, PAF (60%) or PeAF	25	NA	NA	142/30.2/NR [NR]	NA	NA	NA; procedure data only	NR (100% successful PVI)	NA	NA	NR (only assessed CF parameters used by anatomical location during AF and sinus rhythm)	
Cionte, 2015 <sup>33</sup>	Single-center comparison, PVI for PeAF	50		50 (CB2)	140.2/NR/19.8 [NR]		90.5/NR/14.5 [NR]	12 mos.	56 (off AADs)		60 (off AADs)	Tamponade: 1% CF vs. 0 CB2 Femoral pseudoaneurysm: 1% CF vs. 0 CB2 Transient PNP: 0 CF vs. 4% CB2	
le Polain deWaroux, 2015 <sup>34</sup>	Two-center prospective, non-randomized, operator-blinded, PVI for PAF	34	NA	NA	NR/66-77 (range)/NR [NR]	NA	NA	60 min.	NR (35% of 34 no dormant conduction)	NA	NA	NR (only assessed dormant conduction based on applied CF and FTI™ values per PV segment 1 hour after successful PVI)	
Providencia, 2015 [abstract] <sup>35</sup>	Single-center comparison, PAF (55.5%) or PeAF	110	253	358 (RF)	NR	NR	NR/NR/6-7 min longer than CF [NR]	12 mos.	PAF: 87.9 PeAF: 72.7	PAF: 89.3 PeAF: 73.4	PAF: 81.5 PeAF: 58.7	NR	
Squara, 2015 <sup>36</sup>	Multi-center comparison, PAF	39	159	178 (CB2)	122.5/NR/19.3 (4273 cGY cm <sup>2</sup> )		109.6/NR/17.6 (4853 cGY cm <sup>2</sup> )	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>37</sup>	Single-center prospective registry safety data comparison (1517 total procedures: 557 AF, 715 SVT, 190 VT, 55 CHD)	189	59	813 (RF)	AF subgroup: 191/25/57.5 [NR]		AF subgroup: 194/38/45.7 [NR]	> 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>38</sup>	Single-center prospective registry data comparison (PVI procedures, 73% PAF)	31	NA	112 (RF)	128.4/NR/39.7 [NR]	NA	157.7/NR/43.8 [NR]	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>39</sup>	Single-center prospective randomized trial, PAF	20 (or Contact Therapy™ Cool Path™)	NA	35 (RF)	NR/34.5/NR [NR]	NA	NR/51.0/NR [NR]	12 mos.	85	NA	80	No major complications	
Wakili, 2014 <sup>40</sup>	Single-center prospective comparative study, PAF (58%) or PeAF	32	NA	35 (RF)	78.1 (LA)/30.8/33.0 [NR]	NA	95.5 (LA)/31.7/51.4 [NR]	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) with or without the use of previous AADs except as noted.  
Mean values are provided for outcomes except as noted.

PAF = paroxysmal AF; PeAF = persistent AF; NR = not reported; SAE = serious adverse event; 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; LA = left atrial

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**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/defibrillators 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.

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