

TactiCath™
Contact Force Ablation Catheter
Sensor Enabled™





TactiCath™
Contact Force Ablation Catheter,
Sensor Enabled™

ACCURATE. EFFORTLESS. INTEGRATED.

TactiCath™ Contact Force Ablation Catheter, Sensor Enabled™ with EnSite Precision™ Cardiac Mapping System: The Innovative Solution for AF.

The TactiCath ablation catheter, Sensor Enabled elevates procedural effectiveness and efficiency for the treatment of AF through **accurate**,^{1,2} **effortless**^{3-6s} and **integrated**^{7,8} performance. With **unmatched clinical evidence**,* **advanced handle-shaft technology** and **full integration with the St. Jude Medical™ EnSite Precision cardiac mapping system**, you gain greater confidence in patient outcomes.

▶ **EXPERIENCE THE RESULTS**

▶ **FEEL THE DIFFERENCE**

▶ **DISCOVER THE SYNERGY**

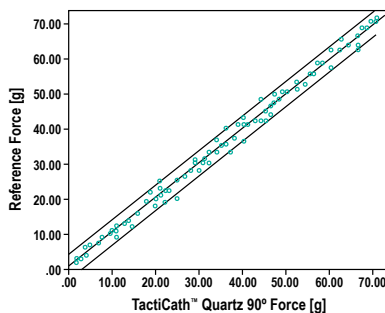
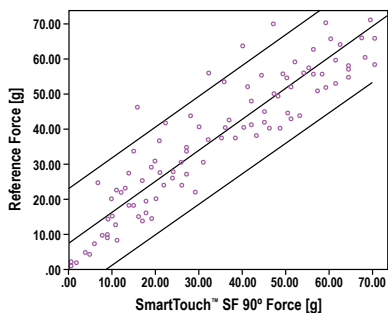
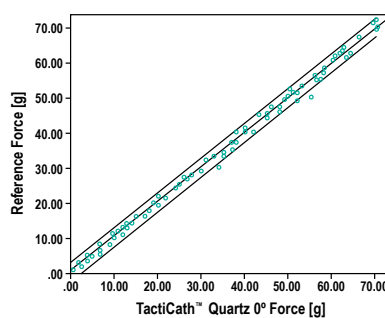
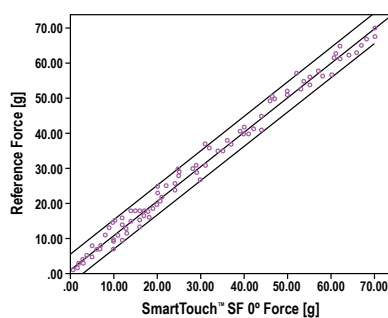
The TactiCath™ Contact Force Ablation Catheter, Sensor Enabled™ is an update to the TactiCath™ Contact Force Catheter family using the FlexAbility™ Catheter family platform handle and shaft and a tip and force sensor derived from TactiCath Quartz. TactiCath™ and TactiCath™ Quartz Contact Force Ablation Catheter clinical data are applicable to the TactiCath Ablation Catheter, Sensor Enabled as mechanical/function testing and preclinical studies have demonstrated equivalent performance and safety profile.⁹

EXPERIENCE THE RESULTS



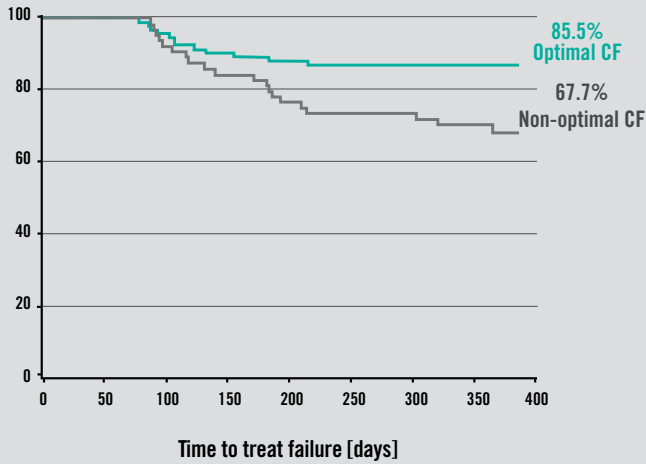
Cardiac ablation is highly intricate. With clinically validated recommendations,^{10,11} St. Jude Medical™ contact force technology delivers accuracy and results you can count on. Experience the safety and efficacy of the most-studied contact force ablation catheter platform to date.* TactiCath™ contact force ablation catheter technology demonstrated:

- **Significantly higher accuracy¹** in both axial (perpendicular) and parallel (lateral) orientations in an independent head-to-head comparison with the SmartTouch™ SF catheter; ThermoCool SmartTouch™ SF catheter showed significantly lower accuracy in parallel orientation.
 - ThermoCool SmartTouch SF catheter: 6.0 g mean absolute difference; 30 g maximum error
 - TactiCath™ catheter: ≤ 1.2 g mean absolute difference; 5 g maximum error

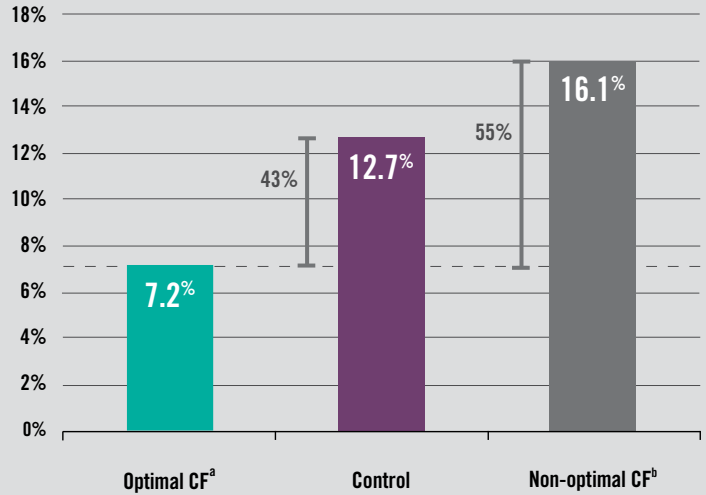


Rate of Repeat Ablation¹²

Optimal CF^a vs. Non-optimal CF^b
Clinically Relevant Success at 12 months

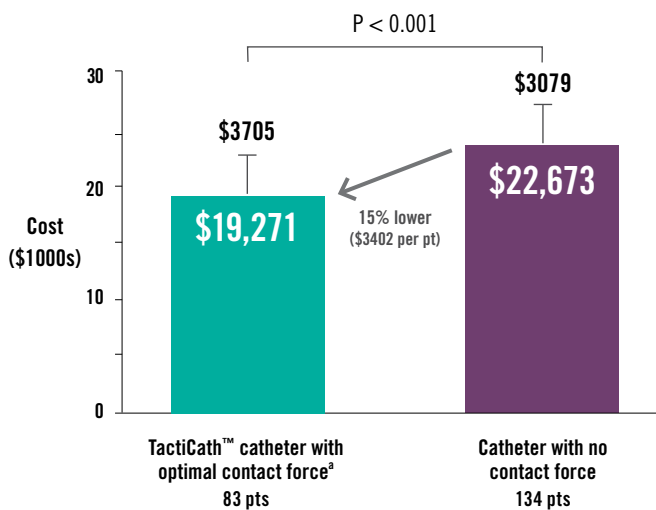


a. Optimal CF cohort defined as those patients where $\geq 90\%$ lesions ≥ 10 g
b. Non-optimal CF cohort defined as those patients where $< 90\%$ lesions ≥ 10 g



a. Optimal CF cohort defined as those patients where $\geq 90\%$ lesions ≥ 10 g
b. Non-optimal CF cohort defined as those patients where $< 90\%$ lesions ≥ 10 g

Total Care Management Cost per Patient in Year after Ablation¹³



a. Optimal contact force is defined as $\geq 90\%$ of lesions with ≥ 10 g force; contact force data were unavailable for 1 patient

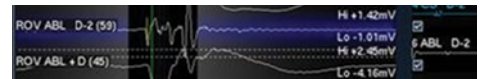
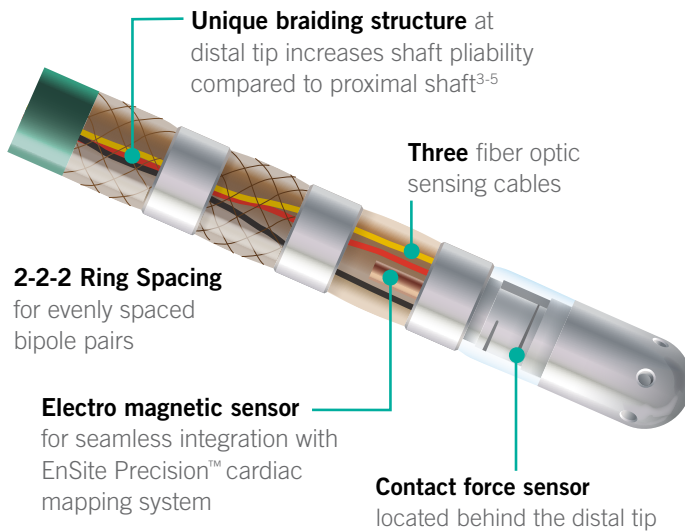
- **Clinical success** in 85.5% of patients** using optimal contact force¹²
- **Repeat ablation** after index procedure
 - 7.2% of TOCCASTAR patients with optimal CF vs. 16.1% with non-optimal CF and vs. 12.7% in non-CF control patients^{12***}
- **Reduced procedural costs**
 - Use of optimal contact force guided AF ablation[†] with the TactiCath™ Quartz catheter resulted in fewer post-ablation clinical events, translating to a 15% reduction in post-ablation management costs (\$3402 savings per patient) in the year after ablation vs. patients treated with a non-contact force ablation catheter¹³

FEEL THE DIFFERENCE



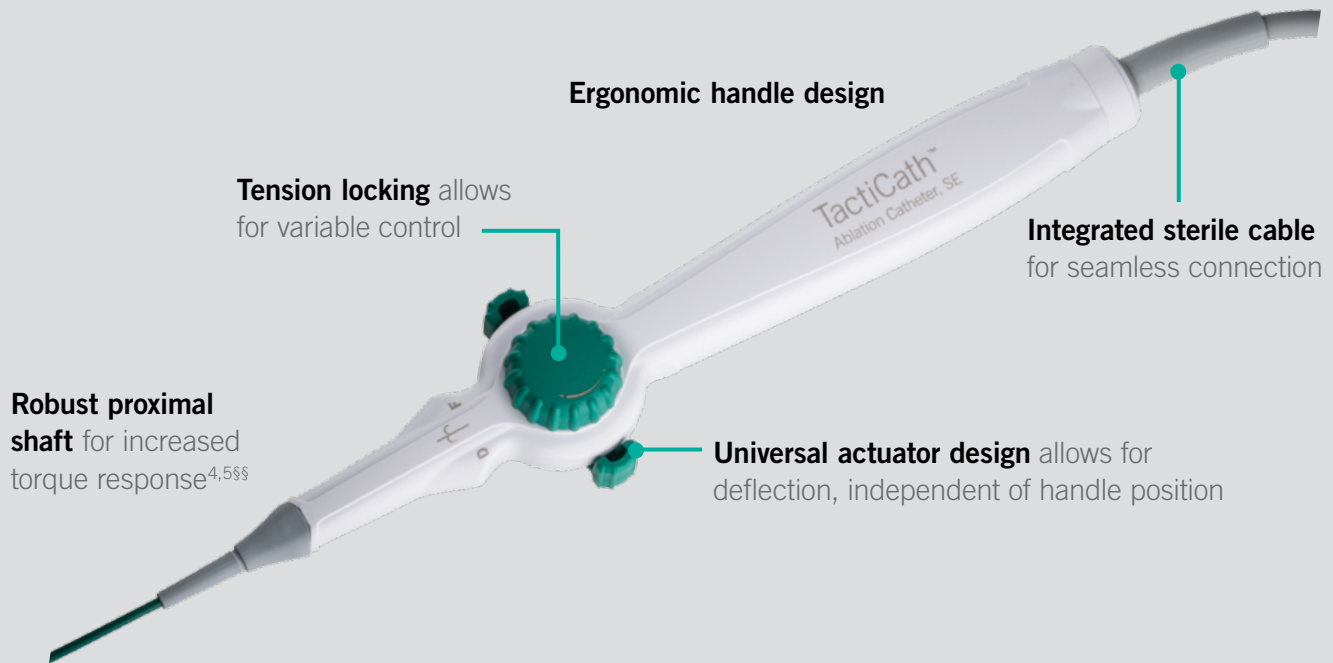
Ablation procedures are often long and complex. You need a catheter that gives you reliable, comfortable usability, with the goal to lead the way in clinical outcomes. Discover a contact force catheter uniquely designed for effortless performance.^{3-6§}

- **Reduce physical strain with** an advanced handle-shaft combination that offers maneuverability, along with comfort and ease-of-use.^{3-6§§}
- **Gain additional reach** by using a bi-directional handle with both symmetric and asymmetric curves, or select a uni-directional option.



Ablation Signal

BI-DIRECTIONAL HANDLE



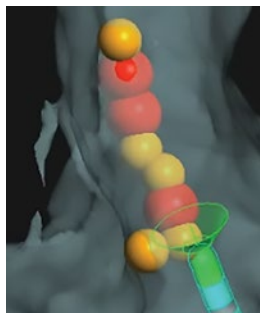
UNI-DIRECTIONAL HANDLE



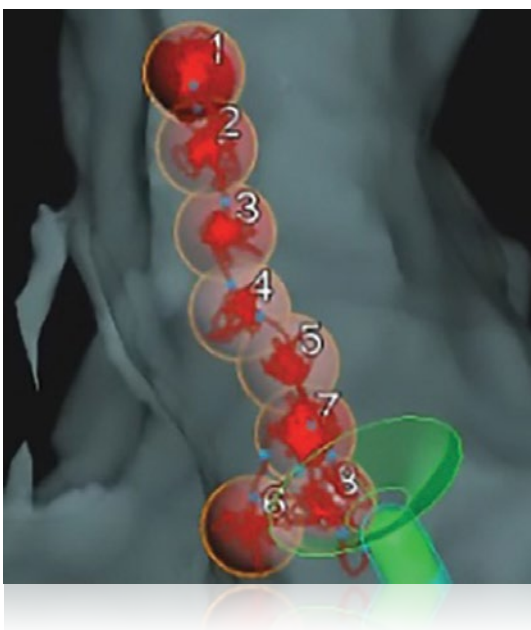
DISCOVER THE SYNERGY



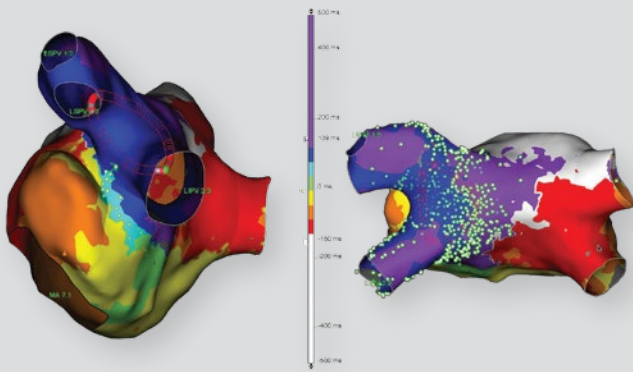
No two ablation procedures are alike. Seamless integration with the St. Jude Medical™ EnSite Precision™ cardiac mapping system enables automated,^{14,15} flexible^{14,15} and precise^{8,14,15} performance, designed to improve patient outcomes^{10,11††} and workflow efficiency. Get novel insight into mapping and lesion marking through AutoTrack advanced technology.



- **Increase procedural consistency** through automated guidance of lesion marking via the AutoMark feature.⁷



- **Verify ablation catheter stability** and AutoMark placement with the AutoTrack feature, which automatically records the precise location of the tip during RF energy application.⁷
 - Review and identify any potential gaps by viewing specific lesions from the display list.



- **Optimize your workflow** with customizable Contact Force display.
- **Map with precision** via EnSite™ AutoMap technology—designate the system to collect mapping points only if the contact force is within a specified range.^{7,8}
- **Have greater control and consistency** by uniquely integrating magnetic and impedance data.^{7,8}
- **Adapt to changing needs**—introduce the TactiCath™ contact force ablation catheter, Sensor Enabled™ at any point during the procedure.^{7,8}
- **Gain efficiency and integrity** in localized mapping through tight electrode spacing.

With unmatched clinical evidence,* advanced handle-shaft technology and full integration with the St. Jude Medical™ EnSite Precision™ cardiac mapping system, the TactiCath™ contact force ablation catheter, Sensor Enabled™ gives you the best in **accurate**,^{1,2} **effortless**^{3-6§} and **integrated**^{7,8} performance.

Experience the results, feel the difference and discover the synergy of the revolutionary next-generation catheter, based on proven TactiCath™ catheter technology.

▶ Learn more at [SJM.com](https://www.sjm.com)

The TactiCath™ Contact Force Ablation Catheter, Sensor Enabled™ is an update to the TactiCath™ Contact Force Catheter family using the FlexAbility™ Catheter family platform handle and shaft and a tip and force sensor derived from TactiCath Quartz. TactiCath™ and TactiCath™ Quartz Contact Force Ablation Catheter clinical data are applicable to the TactiCath Ablation Catheter, Sensor Enabled as mechanical/function testing and preclinical studies have demonstrated equivalent performance and safety profile.⁹

*Most studied contact force ablation catheter and unmatched clinical evidence claims based on number of completed prospective, protocol driven, industry sponsored, registered studies on Contact Force technology. Note that the TactiCath Quartz catheter is an evolution of the previous generation TactiCath catheter. TactiCath Quartz catheter uses the same contact force sensing technology (i.e. optical technology as TactiCath catheter. TOCCASTAR clinical 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.

**Clinically relevant success: no documented, symptomatic recurrence of atrial arrhythmia > 30 s (patient could be on an AAD).

***a. Repeat ablation after protocol-defined three-month blanking period.

b. Optimal CF defined as those patients where $\geq 90\%$ lesions ≥ 10 g.

c. Non-optimal CF defined as those patients where $< 90\%$ lesions ≥ 10 g.

†Optimal contact force is defined as $\geq 90\%$ of lesions with ≥ 10 g force; contact force data were unavailable for 1 patient

††Refers to the use of TactiCath™ Quartz ablation catheter when using contact force recommendations. The EnSite™ contact force module integrates the TactiCath Quartz ablation catheter.

§Effortless is based on comparison of the TactiCath™ Contact Force Ablation Catheter, Sensor Enabled™ to the TactiCath™ Quartz Ablation Catheter from physician feedback on catheter handling performance between the two catheters during preclinical and bench testing comparing the two catheters with respect to torque response and actuation force.

§§In comparison to TactiCath™ Quartz contact force ablation catheter.

References

1. Bourier, F., Gianni, C., Dare, M., Deisenhofer, I., Hessling, G., Reents, T., . . . Al-Ahmad, A. (2017). Fiberoptic contact-force sensing electrophysiological catheters: how precise is the technology? *Journal of Cardiovascular Electrophysiology*, 28(1), 109-114.
2. Yokoyama, K., Nakagawa, H., Shah, D. C., Lambert, H., Leo, G., Aeby, N., . . . Jackman, W. M. (2008). Novel contact force sensor incorporated in irrigated radiofrequency ablation catheter predicts lesion size and incidence of steam pop and thrombus. *Circulation: Arrhythmia and Electrophysiology*, 1, 354-362.
3. St. Jude Medical. Data on File. Report 90247461.
4. St. Jude Medical. Data on File. Report 90211752.
5. St. Jude Medical. Data on File. Report 90223883.
6. St. Jude Medical. Data on File. Report C278453.
7. St. Jude Medical. Data on File. Report 90214738.
8. St. Jude Medical. Data on File. Report 90253949.
9. St. Jude Medical. Data on File. Report 90195941.
10. 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.
11. 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. *Heart Rhythm*, 9(5), S28.
12. Reddy, V. Y., Dukkupati, 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, 907-915.
13. Mansour, M., Reddy, V. Y., Karst, E., Heist, E. K., Packer, D., Dalal, N., . . . Mahapatra, S. (2016, May). Contact force sensing on AF ablation catheter: A health-economic analysis. Abstract presented at Heart Rhythm Society, San Francisco, CA. *Heart Rhythm*, 13(Suppl 1), S227, Abstract P002-155.
14. Ptaszek, L., Moon, B., Sacher, F., Jais, P., Mahapatra, S., & Mansour, M. (2015). A novel tool for mapping multiple rhythms from a single mapping procedure. Poster abstract P849. *Europace*, 17(Suppl 3), iii115.
15. Ptaszek, L., Moon, B., Mahapatra, S., & Mansour, M. (2015, Nov). Rapid high density automated electroanatomical mapping using multiple catheter types. Poster presentation P097. APHRS Scientific Sessions, November 21, 2015, Melbourne.

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One St. Jude Medical Dr., St. Paul, MN 55117 USA, Tel: 1.651.756.2000

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St. Jude Medical is now Abbott.

Rx Only

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

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

Contraindications: 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 transeptal 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.

The TactiCath™ Contact Force Ablation Catheter, Sensor Enabled™ is indicated for use in cardiac electrophysiological mapping (stimulation and recording) and, when used in conjunction with a radiofrequency generator, for cardiac ablation of supraventricular arrhythmias in right and left atrium, including atrial fibrillation.

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