# TactiCath<sup>TM</sup>

CONTACT FORCE ABLATION CATHETER SENSOR ENABLED™







#### TactiCath™

Contact Force Ablation Catheter, Sensor Enabled™

## ACCURATE. EFFORTLESS. INTEGRATED.

TactiCath<sup>™</sup> Contact Force Ablation Catheter, Sensor Enabled<sup>™</sup> with EnSite Precision<sup>™</sup> 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**,<sup>1,2</sup> **effortless**<sup>3-6§</sup> and **integrated**<sup>7,8</sup> performance. With **unmatched clinical evidence**,\* **advanced handleshaft technology** and **full integration with the Abbott EnSite Precision cardiac mapping system**, you gain greater confidence in patient outcomes.

- **EXPERIENCE THE RESULTS**
- **FEEL THE DIFFERENCE**
- **DISCOVER THE SYNERGY**

The TactiCath<sup>™</sup> Contact Force Ablation Catheter, Sensor Enabled<sup>™</sup> is an update to the TactiCath<sup>™</sup> Contact Force Catheter family using the FlexAbility<sup>™</sup> Catheter family platform handle and shaft and a tip and force sensor derived from TactiCath Quartz. TactiCath<sup>™</sup> and TactiCath<sup>™</sup> 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.<sup>8</sup>

### EXPERIENCE THE RESULTS

Cardiac ablation is highly intricate. With clinically validated recommendations,<sup>10,11</sup> Abbott 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<sup>™</sup> contact force ablation catheter technology demonstrated:

- Significantly higher accuracy<sup>1</sup> in both axial (perpendicular) and parallel (lateral) orientations in an independent head-to-head comparison with the SmartTouch<sup>‡</sup> SF catheter; ThermoCool SmartTouch<sup>‡</sup> SF catheter showed significantly lower accuracy in parallel orientation.
- ThermoCool SmartTouch SF catheter: 6.0 g mean absolute difference; 30 g maximum error
- TactiCath<sup>™</sup> catheter: ≤ 1.2 g mean absolute difference; 5 g maximum error





#### **RATE OF REPEAT ABLATION<sup>12</sup>**



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  $\ge$  10 g

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



Total Care Management Cost per Patient in Year after Ablation<sup>13</sup>

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

- Clinical success\*\* in 85.5% of patients using optimal contact force<sup>12</sup>
- 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<sup>12\*\*\*</sup>
- Reduced procedural costs
  - Use of optimal contact force guided AF ablation<sup>†</sup> with the TactiCath<sup>™</sup> 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 catheter<sup>13</sup>

### 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.<sup>3-6§</sup>

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



located behind the distal tip

200 mm 2 200 mm		
CQ ( (M)	Current Map Type	
	- Desta de la com	
ECG II (55)	Peak-togative	
	TRANSPORT PARTY	
CG III (55)		
ECG IVA (SS)		0 00 40
ECG #VL (55)	25 ABL D-2	LAT-10.06 ms
		EARLY
ECG AVF (55)	24 ABL D-2	LAT -7.96 ms
	B	4
100 V1 (%)	20 ABL, D-2	LAT -2.86 ms
	R	100 C
ECG V2 (55)	18 ABL D-2	LAT -2.07 ms
		- Andrews
100 V3 (59)	15 ABL D-2	(LAT 1.03 ms
CCQ V4(55)	16 401 0-2	147.202 #4
	in the second	
CG V5 (55)	2	
	17 ADL 0-2	LAT 3.15 HB
ECG VE (55)	8	
	AND D-S	UAT 7.64 ms
EF ECG V4 (55)	8	
Hal Only		LAT 10.97 ms
NOV ABL D-2 (59)		4
Lo-1,010	6 ABL D-2	LAT 11.69 ms
ROV ABL + D (45)	8	1 A A A A A A A A A A A A A A A A A A A
LO - K ISHI		21 used / 26 total



**Ablation Signal** 

### **BI-DIRECTIONAL HANDLE**







### DISCOVER THE SYNERGY

No two ablation procedures are alike. Seamless integration with the Abbott EnSite Precision<sup>™</sup> cardiac mapping system enables automated,<sup>14,15</sup> flexible<sup>14,15</sup> and precise<sup>8,14,15</sup> performance, designed to improve patient outcomes<sup>10,11††</sup> 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.<sup>7</sup>



**Verify ablation catheter stability** and AutoMark placement with the AutoTrack feature, which automatically records the precise location of the tip during RF energy application.<sup>7</sup>

• 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<sup>™</sup> AutoMap technology designate the system to collect mapping points only if the contact force is within a specified range.<sup>7,8</sup>
- Have greater control and consistency by uniquely integrating magnetic and impedance data.<sup>7,8</sup>
- Adapt to changing needs introduce the TactiCath<sup>™</sup> contact force ablation catheter, Sensor Enabled<sup>™</sup> at any point during the procedure.<sup>7,8</sup>
- Gain efficiency and integrity in localized mapping through tight electrode spacing.

With unmatched clinical evidence,\* advanced handle-shaft technology and full integration with Abbott's EnSite Precision<sup>™</sup> cardiac mapping system, the TactiCath<sup>™</sup> contact force ablation catheter, Sensor Enabled<sup>™</sup> gives you the best in **accurate**,<sup>1,2</sup> **effortless**<sup>3-6§</sup> **and integrated**<sup>7,8</sup> performance.

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

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The TactiCath<sup>™</sup> Contact Force Ablation Catheter, Sensor Enabled<sup>™</sup> is an update to the TactiCath<sup>™</sup> Contact Force Catheter family using the FlexAbility<sup>™</sup> Catheter family platform handle and shaft and a tip and force sensor derived from TactiCath Quartz. TactiCath<sup>™</sup> and TactiCath<sup>™</sup> 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.<sup>9</sup>

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

+Optimal contact force is defined as ≥ 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<sup>™</sup> Contact Force Ablation Catheter, Sensor Enabled<sup>™</sup> to the TactiCath<sup>™</sup> 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. Abbott. Data on File. Report 90247461.
- 4. Abbott. Data on File. Report 90211752.
- 5. Abbott. Data on File. Report 90223883.
- 6. Abbott. Data on File. Report C278453.
- 7. Abbott. Data on File. Report 90214738.
- 8. Abbott. Data on File. Report 90253949.
- 9. Abbott. Data on File. Report 90195941.
- 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., 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*, 907-915.
- 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*(5 Suppl 1), S227, Abstract PO02-155.
- 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.
- 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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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.

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