

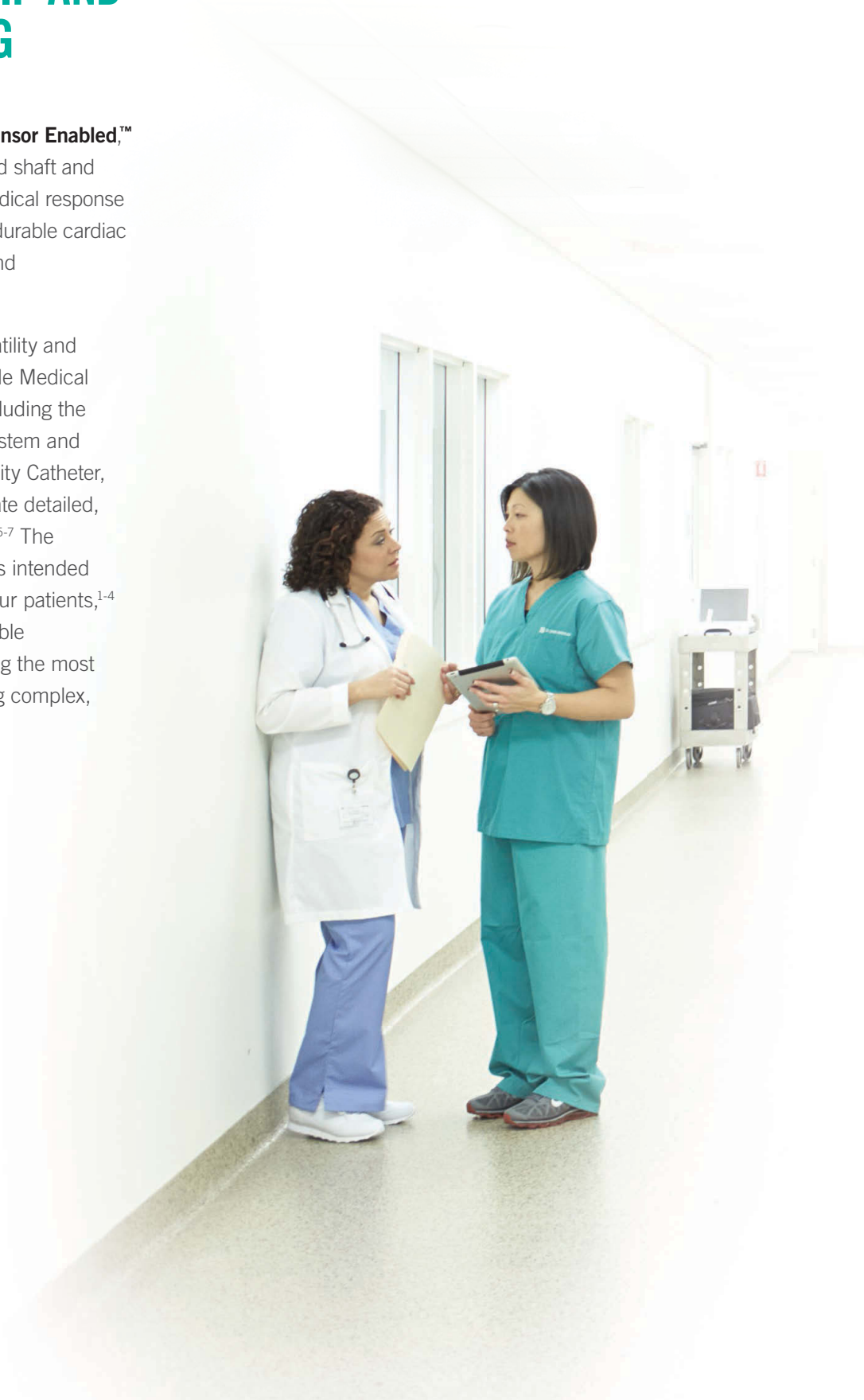
FlexAbility™ Ablation Catheter
Sensor Enabled™



EXPERIENCE THE DIFFERENCE OF AN ABLATION CATHETER WITH A FLEXIBLE TIP AND OPTIMAL HANDLING

The FlexAbility™ Ablation Catheter, Sensor Enabled™ with its unique flexible tip and advanced shaft and handle combination, is the St. Jude Medical response to the industry need for a predictable, durable cardiac ablation catheter with a strong safety and efficacy profile.¹⁻⁴

Designed to enhance procedural versatility and precision when integrating with St. Jude Medical mapping and navigation systems—including the EnSite Precision™ Cardiac Mapping System and MediGuide™ Technology—the FlexAbility Catheter, Sensor Enabled, was created to facilitate detailed, accurate mapping and lesion creation.⁵⁻⁷ The FlexAbility Catheter, Sensor Enabled, is intended to yield safe, effective outcomes for your patients,¹⁻⁴ while offering the consistent, comfortable performance you need when navigating the most challenging locations, especially during complex, lengthy procedures.





Unique flexible tip: Effective lesion formation with potentially fewer risks^{1,3}

Experience the flexible tip design of the FlexAbility™ Ablation Catheter, Sensor Enabled,™ that may reduce procedural risk with directed flow and tip temperature monitoring.^{1,3,4}

▪ Tip safety design

- In a comparative in vivo study, the FlexAbility Catheter, Sensor Enabled, demonstrated comparable lesion creation with significantly fewer steam pops.⁴
- A temperature-sensitive thermocouple, located 0.3 mm from the distal tip, serves as an important indicator for monitoring tip temperature.⁴
- No instances of charring or coagulum formation were observed during a 179-patient multicenter trial.²
- Directed irrigation optimizes cooling with flow directed to the tissue.⁸

▪ Tip conformance

- The flexible tip conforms to the myocardium and reduces operator-transmitted force into the tissue.^{**7}

▪ Electrode configuration

- One mm band distal electrodes and 1-4-1 mm spacing enhances ECG signals and reduces far-field sensing.⁹⁻¹¹



Next-generation shaft technology: Reliability, accuracy and consistent performance

Navigate with a catheter designed for accuracy and consistent performance.^{***9} The next-generation shaft technology of the FlexAbility™ Ablation Catheter, Sensor Enabled,[™] combines optimized planarity, torque response and durability.

▪ **Constructed for control**

- A new braid configuration on the proximal region optimizes torqueability.¹²
- The reconfigured shaft combines:
 - Greater curve angles (between 180 and 230 degrees).^{***}
 - Optimized torque response and deflection force.^{***9}
- The uni-directional handle option provides better return-to-straight functionality.^{***9,12}

▪ **Durable design**

- Wire management design maximizes planarity and significantly improves durability.^{***9}



Bi-directional handle



Uni-directional handle

Advanced handle-shaft combination: Maneuverability with comfort and ease of use

Reach challenging locations with less hand fatigue.^{***9} The handle and shaft of the FlexAbility™ Ablation Catheter, Sensor Enabled,[™] are designed for excellent maneuverability and reduced deflection force.^{***9}

▪ Designed for comfort

- A tension-locking mechanism allows for variable device control.
- The universal actuator design enables deflection independent of the handle position.
- A novel pull-wire approach is designed to reduce friction, resulting in lower deflection forces.^{***9}
- The bi-directional handle option offers symmetric and asymmetric curves for additional reach.

With its flexible tip and advanced handling characteristics, the FlexAbility™ Ablation Catheter, Sensor Enabled,[™] is designed for safe, consistent performance in multiple, often challenging cardiac anatomies, while enhancing control and comfort.

Experience the difference of the FlexAbility™ Ablation Catheter, Sensor Enabled![™]

Ordering Information

Contents: 8 F irrigated ablation catheter

Reorder Number	Description	Curve	French Size	Tip Electrode (mm)	Electrode Spacing (mm)	Length (cm)
A-FASE-DD	Sensor Enabled™ Bi-D Irrigated Ablation Catheter	D-D	8	4	1-4-1	115
A-FASE-DF	Sensor Enabled™ Bi-D Irrigated Ablation Catheter	D-F	8	4	1-4-1	115
A-FASE-FF	Sensor Enabled™ Bi-D Irrigated Ablation Catheter	F-F	8	4	1-4-1	115
A-FASE-FJ	Sensor Enabled™ Bi-D Irrigated Ablation Catheter	F-J	8	4	1-4-1	115
A-FASE-JJ	Sensor Enabled™ Bi-D Irrigated Ablation Catheter	J-J	8	4	1-4-1	115
A-FASE-D	Sensor Enabled™ Uni-D Irrigated Ablation Catheter	D	8	4	1-4-1	115
A-FASE-F	Sensor Enabled™ Uni-D Irrigated Ablation Catheter	F	8	4	1-4-1	115
A-FASE-J	Sensor Enabled™ Uni-D Irrigated Ablation Catheter	J	8	4	1-4-1	115

Required Catheter Connecting Cable: Model A-FASE-CBL4

*As compared to the ThermoCool™ SF catheter (Biosense Webster, Inc.).

**As compared to the St. Jude Medical Therapy™ Cool Path™ catheter.

***As compared to the St. Jude Medical Therapy™ Cool Flex™ ablation catheter.

1. St. Jude Medical. Data on File. Report 90058001.
2. St. Jude Medical. Data on File. Report 90122753. Based on Therapy™ Cool Flex™ ablation catheter tip.
3. Peichl, P., & Kautzner, J. (2013). Advances in irrigated tip catheter technology for treatment of cardiac arrhythmias. Recent Patents on Cardiovascular Drug Discovery, 8(1), 10-16.
4. Winterfield, J. R., Jensen, J., Gilbert, T., Marchlinski, F., Natale, A., Packer, D., . . . Wilber, D. J. (2015). Lesion size and safety comparison between the Novel flex tip on the FlexAbility ablation catheter and the solid tips on the ThermoCool and ThermoCool SF ablation catheters. Journal of Cardiovascular Electrophysiology, 2015 Sep.
5. St. Jude Medical. Data on File. Report 90213470.
6. St. Jude Medical. Data on File. Report 90212705.
7. St. Jude Medical. Data on File. Report 90214904.
8. St. Jude Medical. Data on File. Report 90042968.
9. St. Jude Medical. Data on File. Development report number 90168493.
10. St. Jude Medical. Data on File. Report 891607-R. Comparative In-vivo Study on Thigh Muscle Preparation.
11. Nakagawa, H., Wittkamp, F. H., Yamanashi, W. S., Pitha, J. V., Imai, S., Campbell, B., . . . Jackman, W. M. (1998). Inverse relationship between electrode size and lesion size during radiofrequency ablation with active electrode cooling. Circulation, 98, 458-465.
12. St. Jude Medical. Data on File. Report 90115246.

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 FlexAbility™ Ablation Catheter, Sensor Enabled™, is intended for use with the compatible irrigation pump and a compatible RF cardiac ablation generator. The catheter is intended for creating lesions during cardiac ablation procedures (mapping, stimulation, and ablation) for the treatment of arrhythmias. Sensor Enabled Ablation Catheters are used with compatible magnetic tracking systems to enable catheter positioning and navigation.

ThermoCool is a trademark of Biosense Webster, Inc.

Not for sale in the U.S.

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