

FlexAbility™
Ablation Catheter



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

As a leader in cardiac ablation products, St. Jude Medical has partnered with physicians worldwide to address the clinical need for a reliable, predictable and comfortable ablation catheter.

The result is the FlexAbility™ cardiac ablation catheter – the catheter with a unique flexible tip, and an advanced shaft and handle combination for optimal handling. Utilizing physician input from concept to completion, the FlexAbility catheter is intended to yield safe, effective outcomes for your patients,¹⁻³ and provide the consistent performance and fatigue-reducing enhancements^{*4} that you need during long procedures.

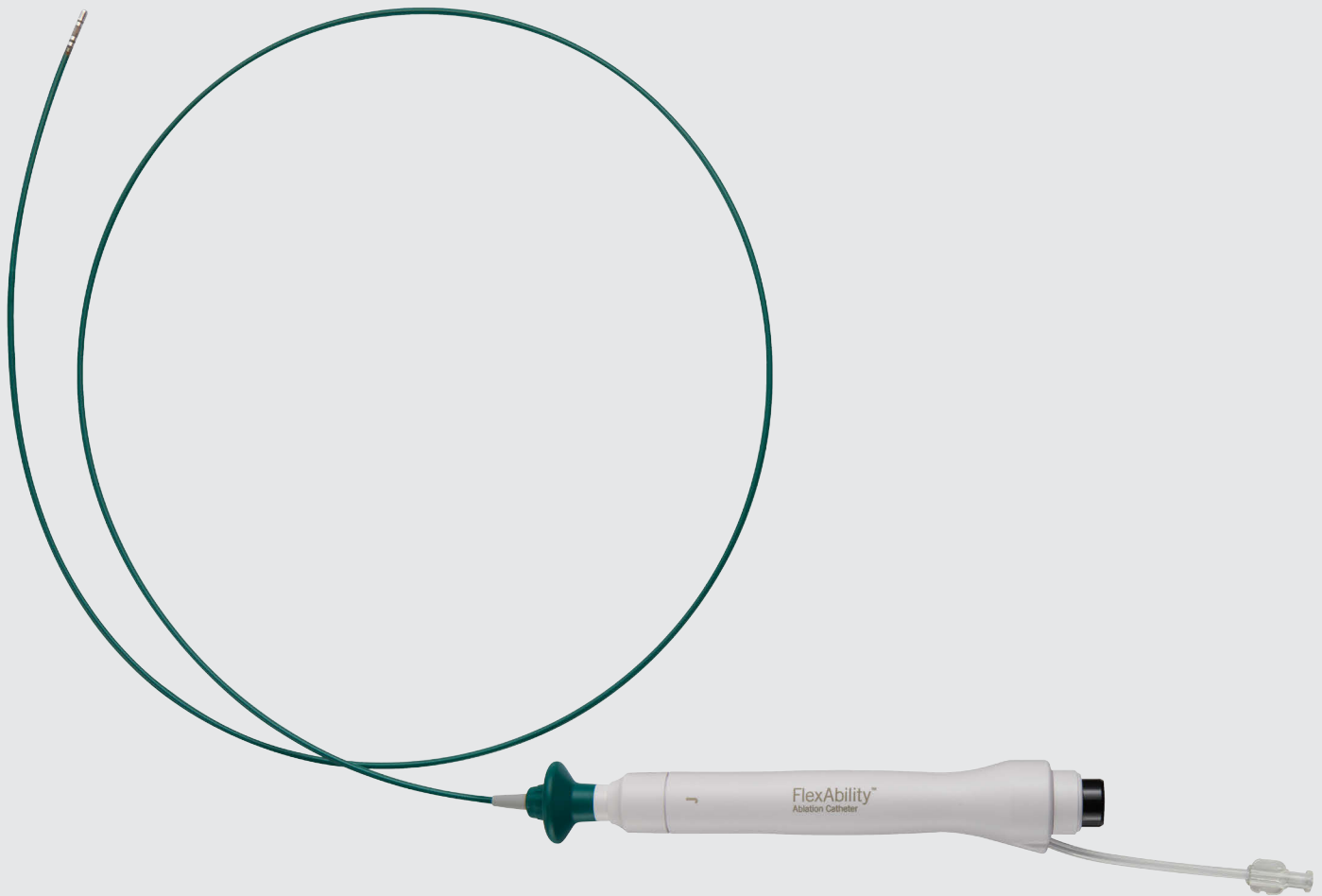




Unique flexible tip: Effective lesion formation with potentially fewer risks^{1,3}

Experience the flexible tip design of the FlexAbility™ ablation catheter that may potentially reduce procedural risk with directed flow and reduced tip temperature.^{1,3}

- **Cool running tip**
 - No instances of charring or coagulum formation were observed during a 179-patient multicenter trial.²
 - The tip measured 5 degrees cooler than a 12-hole rigid tip catheter.^{**5}
 - Directed irrigation optimizes cooling with 70% of the flow¹ directed to the tissue.
- **Tip conformance**
 - The flexible tip conforms to the myocardium and reduces operator-transmitted force into the tissue.^{***6}
- **Electrode configuration**
 - 1 mm band distal electrodes and 1-4-1 mm spacing enhances ECG signals and reduces far-field sensing.^{5,7,8}
- **Tissue contact**
 - The catheter tip has significantly more contact surface area compared to a rigid tip.^{*2}



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

Navigate anatomy with a catheter designed for accuracy and consistent performance.^{1,7} The next-generation shaft technology of the FlexAbility™ ablation catheter combines optimized planarity, torque response and durability.

- **Constructed for control**
 - A new braid configuration on the proximal region optimizes torqueability.⁴
 - The reconfigured shaft combines:
 - Greater curve angles (between 180 and 230 degrees).⁷
 - Optimized torque response and deflection force.⁷
 - The uni-directional handle option provides better return-to-straight functionality.^{4,7}
- **Durable design**
 - Wire management design maximizes planarity and significantly improves durability.⁷



Bi-directional handle



Uni-directional handle

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

Reach challenging locations with less hand fatigue.¹⁷ The handle and shaft of the FlexAbility™ ablation catheter are designed for excellent maneuverability and reduced deflection force.¹⁷

▪ 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.¹⁷
- The bi-directional handle option offers symmetric and asymmetric curves for additional reach.

With its flexible tip and advanced handling characteristics, the FlexAbility™ catheter is designed for safe, consistent performance in multiple, often challenging cardiac anatomy, while enhancing control and comfort.

Experience the difference of the FlexAbility catheter.

Ordering Information

Contents: 8 F irrigated ablation catheter

Reorder Number	Description	Curve	French Size	Tip Electrode (mm)	Electrode Spacing (mm)	Length (cm)
A701124	Bi-D Irrigated Ablation Catheter	D-D	8	4	1-4-1	115
A701125	Bi-D Irrigated Ablation Catheter	D-F	8	4	1-4-1	115
A701127	Bi-D Irrigated Ablation Catheter	F-F	8	4	1-4-1	115
A701128	Bi-D Irrigated Ablation Catheter	F-J	8	4	1-4-1	115
A701129	Bi-D Irrigated Ablation Catheter	J-J	8	4	1-4-1	115
A701157	Uni-D Irrigated Ablation Catheter	D	8	4	1-4-1	115
A701158	Uni-D Irrigated Ablation Catheter	F	8	4	1-4-1	115
A701159	Uni-D Irrigated Ablation Catheter	J	8	4	1-4-1	115

Required Catheter Connecting Cable: Model 1641

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

1. Report 90058001, on file.
2. Report 90122753, on file – 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. Report 90115246, on file.
5. Report 891607-R, on file – Comparative In-vivo Study on Thigh Muscle Preparation.
6. Report 90042968, on file.
7. Development report number 90168493, on file.
8. 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, 458-65.

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 is intended for use with the compatible irrigation pump and a compatible RF cardiac ablation generator. The catheter is intended for creating endocardial lesions during cardiac ablation procedures (mapping, stimulation, and ablation) for the treatment of typical atrial flutter. **Contraindications:** In patients with active systemic infection. In patients with intracardiac mural thrombus or those who have had a ventriculotomy or atriotomy within the preceding four weeks. **Warnings:** Catheter ablation procedures present the potential for significant x-ray exposure. The long-term risk of protracted fluoroscopy has not been established. Careful consideration must be given for the use of the device in prepubescent children and pregnant women. The long terms risks of RF ablation lesions have not been established. The temperature data transmitted by the sensor in this catheter is representative of the irrigated electrode only and does not provide tissue temperature data. 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. **Precautions:** If the irrigation pump alarm sounds, terminate RF delivery. If impedance rises suddenly that does not exceed the preset limit, power delivery should be manually discontinued. Always maintain constant irrigation to prevent coagulation within and around electrodes. Irrigated ablation systems have been shown to create larger lesions than standard radiofrequency ablation catheters. Care should be taken when ablation near electrically vulnerable, thin-walled or other arterial structures. If irrigation is interrupted, immediately inspect and flush the catheter outside of the patient. Reestablish irrigation flow prior to placing catheter in the body. Do not attempt ablation without using an irrigation pump.
Potential adverse events: Potential adverse events include, but are not limited to, cardiovascular and anesthesia-related complications, including inadvertent AV block. Please refer to the Instructions for Use of a complete list.

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