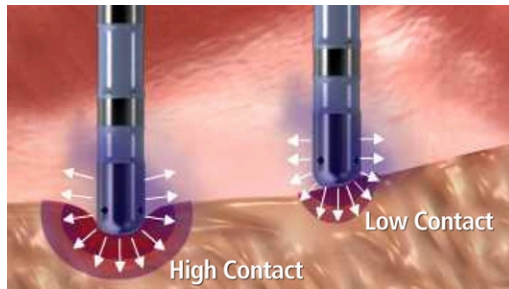


THERMOCOOL[®] SMARTTOUCH[®] Catheter Fact Sheet

approved in the United States to whether adequate contact force is the only therapeutic approach for atrial fibrillation (Afib) that

The THERMOCOOL[®] SMARTTOUCH[®] Catheter enhances a physician's ability to achieve stable application of contact force when applying radiofrequency energy (RF) to the heart wall to create lesions that block faulty electrical impulses that can trigger Afib. Providing doctors with contact force stability during catheter ablation has been shown to improve patient outcomes as poor and inconsistent tissue contact may result in incomplete lesion formation that could result in the need for additional treatment, and too much contact force may result in tissue injury, which may lead to complications.



Without the THERMOCOOL[®] SMARTTOUCH[®] Catheter technology, doctors have to estimate the amount of contact force being applied to the heart wall through other indirect measures such as electrogram parameters and impedance but they have been shown to be poor predictors of contact force.¹ This novel innovation enables doctors to accurately control both the amount of contact force, or pressure, being applied to the beating heart wall as well as the angle in which the force is being applied to the tissue.

Clinical Data

The safety and effectiveness of the THERMOCOOL[®] SMARTTOUCH[®] Catheter were evaluated as part a prospective, multicenter study called the SMART-AF Trial in patients with drug-resistant symptomatic paroxysmal atrial fibrillation. One-year results from the trial showed that patients experienced a 74% overall success rate after treatment with the THERMOCOOL[®] SMARTTOUCH[®] Catheter. The SMART-AF Trial demonstrated for the first time that it is the consistent and stable application of contact force on the heart wall that positively impacts the efficacy of the procedure in this patient population. Importantly, data from the trial showed higher success rates the longer physicians stayed within a targeted contact force range, with one-year results demonstrating an 88% success rate when physicians stayed within a targeted range greater than or equal to 85% of the time.

These findings are consistent with the growing body of clinical evidence in Europe, which demonstrate a link between contact force, lesion depth and improved outcomes.³⁻⁶ The THERMOCOOL[®] SMARTTOUCH[®] Catheter was FDA-approved in the U.S. in February 2014 and has been available in Europe since 2012.

THERMOCOOL[®] SMARTTOUCH[®] Catheter Features



- The THERMOCOOL[®] SMARTTOUCH[®] Catheter is seamlessly integrated with the CARTO[®] SMARTTOUCH[®] 3D Module, which enables physicians to tag, or label, lesions with customized parameters including the duration or level of RF energy applied as well as the amount of contact force applied to create each lesion to help ensure physicians are achieving catheter stability throughout the procedure. This complimentary technology helps determine whether the lesions they

have created during the procedure are adequate and to identify any gaps that may require additional ablation.

- A sensor in the tip of the catheter enables direct measurement of both the amount of contact force and the angle in which the force is being applied to the beating heart wall during catheter ablation.
- Data transmitted from the catheter is graphically displayed on a monitor in a 3D image and provides visual cues that guides appropriate treatment and alerts the doctor when not within a targeted contact force range.
- The catheter features continuous irrigation and cooling of the catheter tip, which helps prevent overheating and reduces the risk of charring and clot formation during radiofrequency energy application.

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THERMOCOOL® Navigation Catheters are approved for drug refractory recurrent symptomatic paroxysmal atrial fibrillation, when used with CARTO® Systems (excluding NAVISTAR® RMT THERMOCOOL® Catheter).

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