

# nContact to study new AF procedure in IDE trial

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**nContact Surgical** (Morrisville, North Carolina) said it has received the first investigational device exemption (IDE) from the FDA to evaluate the safety and efficacy of a combined surgical and catheter procedure, which the company has dubbed the convergent procedure, to treat patients with long-standing persistent atrial fibrillation (AF).

During the IDE study, nContact's Numeris-AF guided coagulation system with VisiTrax will be used in combination with **St. Jude Medical's** (St. Paul, Minnesota) Therapy Cool Path ablation catheter.

"I think that it's going to make a big difference," John Funkhouser, president/CEO of nContact, told *Medical Device Daily* as he spoke of the company's convergent procedure.

According to nContact, AF is the most common cardiac arrhythmia (abnormal heartbeat), affecting an estimated 3.3 million Americans and millions more worldwide. Long-standing persistent AF has historically been the most challenging cardiac arrhythmia to treat individually by either the electrophysiologist (EP) or cardiac surgeon. The condition is typically associated with other serious health issues such as structural heart disease and heart failure.

"We're looking at patients that really haven't had an effective treatment . . . this is a population that has had really very few treatment options," Funkhouser said. "It's the potential capability to treat all AF patients, regardless of type and stage, and I think the other thing it does is allows this to be done in a truly minimally invasive way."

During the convergent procedure, a cardiac surgeon and an EP work as a team to perform a closed chest epicardial ablation and endocardial catheter-based ablation procedure to treat a patient's AF. The procedure does not require chest incisions or ports and incorporates mapping and diagnostic endpoints, as measured by the EP, to determine procedure completion, Funkhouser said.

"After we're done, intraoperatively – while the patient is still on the table – we can confirm whether or not the [arrhythmia] has been isolated. We can look at electrograms to make sure they are silent before [the patient] even leaves the EP lab," Funkhouser said. He emphasized that this IDE study will evaluate a single-setting procedure performed in the EP lab, not the operating room, which is "very different from other people so far."

The study will enroll 25 patients at five sites, Funkhouser noted. He estimates it will take about six months to complete enrollment. nContact is hoping to prove that its technology is going to simplify the procedure and enhance the skills of both the surgeon and the EP.

"We want to expand physician adoption of ablation," Funkhouser said, adding that the company believes that is the "best way to get the best outcomes from a single procedure."

The IDE study is designed to evaluate the safety and efficacy of the convergent procedure. The primary effectiveness endpoint from the multicenter, prospective trial is freedom from AF and freedom of all class I and class III anti arrhythmic drugs, the company noted.

"Cardiologists, EPs, and cardiac surgeons understand the difficulties in treating long-standing persistent AF patients and the associated limited outcomes. It is our hope that a convergence of surgical and electrophysiology techniques in a single procedure may provide an effective, minimally invasive, closed chest treatment option for long-standing persistent AF patients," Funkhouser said.

nContact was founded in 2005 to develop devices for the endoscopic treatment of arrhythmias, including AF. According to the company, its Numeris coagulation system with VisiTrax is based on the unique integration of suction, perfusion, and radio frequency energy to ensure the creation of visible, non-conductive, bi-atrial epicardial lesions on a beating heart. The device is currently indicated for the coagulation of cardiac tissue in the U.S. It has CE mark approval in Europe for the specific indication for the coagulation of cardiac tissue for the treatment of AF and atrial flutter.

nContact noted that each component of the convergent procedure, epicardial and endocardial ablation, takes about an hour and a half. The patient will be followed immediately post-op in the cardiac ICU, moving to a step down unit in less than 24 hours, and should be discharged from the hospital within 48 hours to 72 hours post procedure, the company said.

The advantages of the procedure include the fact that there are no pericardial dissections, lung deflation or ports; complete visibility with access to the posterior of the heart; a comprehensive pattern plus diagnostic endpoints; the procedure is done in a single-setting, the EP lab; and shorter procedure times.

According to nContact, cofounders Jim Whyne, VP of research and clinicals, and Sid Fleischman, VP of development and operations, started nContact because they believed catheter and surgical ablation companies had not solved two technical issues: the ability to consistently create visible linear lesions, and the ability to position and ablate on the posterior of the atrium under direct visibility. The primary goal in founding nContact, they said, was to develop technology and access capability to perform truly minimally invasive ablation procedures on a beating heart without chest incisions or ports.

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