

# ENDOSENSE

## Makes Sense Out of Atrial Fibrillation

Atrial fibrillation affects six million people worldwide annually. Those afflicted with it run twice the risk of death, and suffer strokes up to seven times as frequently, as individuals who escape it. The condition is an abnormal heart rhythm that takes over the two upper chambers of the heart. It is caused by a surge of disorganized electrical impulses that overwhelm the sinoatrial node, a ball of cells that is an electronic command center, ordinarily sending out the impulses that produce a regular heartbeat. The failing heartbeat can cause pooling of blood in the chambers of the heart and blood vessels. This pooling induces clotting, which can result in a stroke.

*MEMS, sensor technology enable breakthrough.*

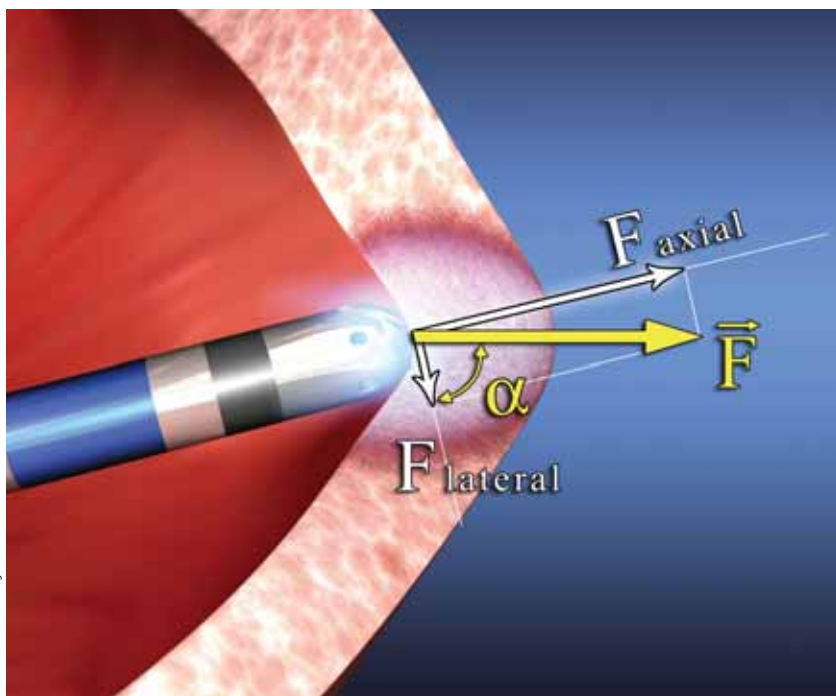


Illustration courtesy Endosense

The TactiCath sensor measures force against the wall of a beating heart.

While atrial fibrillation can be treated with drugs or surgery, both approaches have major downsides. Drugs can be expensive, with serious side effects when used long-term, and surgery of the heart is always dicey, even under the best of circumstances. So there is a lot of interest in less harsh approaches to improving the patient's outlook. Catheter-based cardiac ablation is a promising alternative.

The procedure consists of inserting a catheter through a vein in the groin area and threading it up into the heart. The catheter is equipped with a radiofrequency cauterizing device, and blasts out the cellular centers within the heart wall that are sending out the disruptive signals. The procedure is a standard one, and widely

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used, but there are risks involved. One recent study reported a rate of complications of 5%, including a number of vascular injuries. In rare cases, perhaps 1%, the catheter may perforate the heart wall and the closely allied esophagus with catastrophic, and often fatal, consequences. Such a rate of complications will certainly cause physicians to favor less-satisfactory but also less-dangerous alternatives.

Endosense (Geneva, Switzerland) has developed a new technology that promises to lower the risk of this procedure. In a conventional manual cardiac ablation procedure, the catheter must be pushed against the wall of the heart, and in the past it has been impossible to accurately measure its contact force against the beating heart wall. This placed the responsibility on the physician, who frequently had to guess the level of force required. Too great, and the catheter tip may perforate the heart wall; too slight, and the procedure may fail.

To deal with this challenge, Endosense scientists designed a catheter, dubbed TactiCath, with a fiber-optic sensor engineered into the tip, capable of real-time, accurate force and angle measurements. Modeled on widely accepted technology, it boasts a sensitivity of less than 1 gram.

According to Eric Le Royer, president and CEO of Endosense, "While there are a number of catheter devices on the market, the TactiCath is the first with a soft sensor incorporated in it."

While the TactiCath device has undergone preclinical testing in the US and Europe, and EU approval is expected in 2009, it currently is limited by the FDA to investigational use in the US.

To move the TactiCath system ahead, Endosense is conducting the TOCCATA (TouCh+ for CATHeter Ablation) clinical study, a 70-patient European multicenter safety investigation. The trial will garner information on whether force-sensing can successfully influence the outcome of the ablation procedure. Although the device has been tested extensively in animals, the trial is its first use as a sensing catheter in patients. As is standard in such clinical trials, the patients examined display different arrhythmia pathologies, including atrial fibrillation.

Le Royer anticipates that the Endosense catheter will be approved by the European regulatory agency, EMEA, in 2009. "We are looking forward to conducting a trial in the US, and hope to have FDA approval by 2012," he says.

New technologies in this area of medical science are fervently desired, as atrial fibrillation presents challenges not seen in other similar conditions. It has proven to be one of the most difficult cardiac arrhythmias to treat, since the electrical abnormalities associated with it are much more generalized, encompassing most of the left and right atrium. The most common approach to ablating atrial fibrillation has been to create a series of complex linear "scars" throughout the atria, a very difficult procedure to

## The device has over 110 components, and **80% of its manufacture takes place under 40× magnification.**

Le Royer continues, "The TactiCath catheter is the first force-sensing ablation catheter used in a clinical setting. It was designed to provide the physician with a critical parameter that has the potential to change the whole approach to catheter use in clinical practice."

The TactiCath catheter achieves its sensing capability through the technology of the Fiber Bragg Grating optic fiber, a type of reflector constructed in a short segment of optical fiber that reflects particular wavelengths of light and transmits all others. It possesses the properties of an inline optical filter that blocks certain wavelengths and acts as a wavelength-specific reflector. Optical fibers can be used as sensors to measure strain, temperature, pressure, and other quantities by modifying a fiber so that the quantity to be measured modulates the intensity, phase, polarization, wavelength, or transit time of light in the fiber. Sensors that vary the intensity of light are the simplest, since only a simple source and detector are required.

The fiber-optic component can be combined with a standard ablation catheter without modifying its therapeutic and dimensional characteristics. The sensing capability is integrated with a steerable 2.33-mm diam RF irrigated catheter. That integration relies upon a high degree of engineering. The device has over 110 components, from over 90 vendors, and 80% of its manufacture takes place under 40× magnification, according to Operations Manager Patrick Cotter. Endosense achieved ISO 13485:2003 certification in 2008.

perform with a catheter. A more recent approach is to ablate three or four specific areas within the left atrium, near the openings of the four pulmonary veins. This approach is technically easier, and could lend itself to the Endosense technology, however it is still a lengthy and difficult procedure, rife with landmines along the way.

Le Royer remains sanguine concerning possible competition for the Endosense technology. "Competition could be defined on two levels; narrowly as competitive force-sensing ablation catheters, or more broadly as all innovative technologies which can impact the outcome of catheter ablation."

He stresses that the Endosense device is the first force-sensor ablation catheter. Hansen Medical also has a force-sensing mechanism, positioned at the proximal end of their robotic sheath. The Hansen Sensei device obtained FDA approval in 2007, for use of the technology as a robotic placement device. However, its off-label application to cardiac ablation has a dismal safety record, with complication rates as high as 19%, including death. This is much higher than the reported rate for manual ablation of 4–5%.

Le Royer also acknowledges that there are very early development projects focused upon force-sensing ablation catheters among other major medical-device manufacturers. Alternative technologies include robotics, balloons, and linear-ablation catheters; Le Royer sees many of these as potentially complementary to force sensing. 