

Surgical-Device Firms Walk Fine Line

By [THOMAS M. BURTON](#)

Some 25,000 people last year underwent an operation in which tiny bits of heart tissue were burned into a maze pattern to reroute the heart's electrical system. This is done to fix the most common type of faulty heartbeat, atrial fibrillation.

The devices widely used for this operation haven't been approved by the U.S. government to treat that condition. Yet today these products, which have sales of about \$100 million a year, are used almost exclusively to treat atrial fibrillation, according to executives, doctors and others familiar with the industry.



Matt Eich/Luceo for The Wall Street Journal

Elaine George, an ex-medical-device saleswoman, has filed suit over marketing of surgical-ablation devices.

These devices were approved for "ablation," or the destruction of tissue, which historically has often meant sealing a wound to stop bleeding. But the devices aren't specifically approved by the Food and Drug Administration for atrial fibrillation treatment, a more complex procedure. To get approval for treating "A-fib," as it's known, would require companies to conduct expensive clinical testing.

The Justice Department is investigating whether companies that make these surgical-ablation devices have been violating the law by actively marketing them for non-FDA-approved uses, such as treating atrial fibrillation. While doctors may use drugs or devices for off-label treatments, companies are allowed to market them only for the uses for which they have been FDA-approved. The idea behind this restriction is to limit the number of U.S. patients exposed to experimental, relatively untested treatments.

In the case of surgical ablation, an examination of some documents from leading device makers suggests that the industry has been treading a fine line. Although the documents aren't always explicit, some companies seem to have encouraged hospitals and doctors to consider the possibility of using their devices specifically for A-fib.

So far, the government has won settlements from two makers of surgical-ablation devices after joining lawsuits filed by a whistleblower. "The misuse of medical devices has the potential of exposing patients to dangerous procedures," said Tim Johnson, U.S. Attorney for the Southern District of Texas, after settling with AtriCure Inc. in January.

AtriCure, of West Chester, Ohio, agreed to pay \$3.8 million to resolve allegations it marketed its surgical ablation devices for the unapproved purpose of treating these irregular heartbeats. The company didn't admit wrongdoing. Elaine George, a former medical-device saleswoman who brought the suit, will receive \$688,000 of the settlement. By law, if the government finds a whistleblower's information pivotal to a case, the whistleblower can receive 15% to 30%.

Closely held Estech, of San Ramon, Calif., agreed to pay \$1.5 million last year to settle such charges with the Justice Department, also without admitting wrongdoing. Ms. George, who brought that suit too, will receive \$226,000 of the settlement.

Ms. George, 44 years old, has lawsuits pending against three other companies—Boston Scientific Corp., Medtronic Inc. and St. Jude Medical Inc.—alleging they marketed surgical-ablation devices for the unapproved use of fixing these faulty heartbeats. The government hasn't joined those suits. The three companies deny their top executives approved any illegal marketing. All three confirm the Justice Department is investigating their marketing of surgical-ablation devices. The Department of Justice began investigating these issues as a result of Ms. George's litigation, according to her attorneys.

The surgical-ablation devices—each company makes several—were approved under a provision that allows products onto the U.S. market if they are similar enough to items already sold. That provision has been controversial partly because devices approved for a broad, general use may end up being used for something complicated, experimental or higher-risk.

Critics say it is a loophole that allows devices to be used for untested treatments. Companies have said the provision is an efficient way to get products onto the market that can benefit patients. The FDA says it is studying whether to revise the provision.

Surgical-ablation devices were allowed under this provision because they were similar to devices already approved to burn tissue to stop bleeding. Surgical-ablation devices can be legally marketed for some uses, but not to treat atrial fibrillation. There are no large studies comparing the safety of surgical ablation to that of other ways to treat A-fib.

"With surgical ablation, there just isn't that much data, which leads to uncertainty about what is the right approach," says Deepak L. Bhatt, director of interventional cardiology at Boston's Brigham and Women's Hospital.

Many doctors say surgical ablation is a good option for some patients. A. Marc Gillinov, surgical director of the Center for Atrial Fibrillation at the Cleveland Clinic, says if a patient has A-fib and is already getting heart surgery for another reason, "it's an easy call" to do surgical ablation. But he says having the surgery alone generally should be done after other therapies have been tried. Dr. Gillinov has successfully used the devices, but says there needs to be more evidence comparing surgical ablation to other treatments. "We have more technology than we do data," he says. Some companies are now conducting or planning clinical studies.

Since 2008, there have been at least five U.S. patient deaths reported to an FDA data base in procedures using AtriCure devices and one involving a Medtronic device. That database doesn't prove causality. Both companies declined to comment.

Atrial fibrillation is a potentially lucrative area. Medtronic, at an investor conference last year, called it a "fast growing, underpenetrated market." St. Jude, also at a 2009 investor conference, said atrial fibrillation "may be the best growth market in the medical device space for the next 5-7 years."

In atrial fibrillation, the heart's upper chambers quiver instead of beating. Blood pools and clots in the heart, posing a risk of stroke. Many patients suffer shortness of breath, chest pain or dizziness. A-fib afflicts at least 2.3 million Americans, most over 50.

It is estimated about 80% of patients are effectively treated with drugs.

The Heart Rhythm Society, the professional group of doctors who treat such problems, said in a consensus statement that "multicenter clinical trials are needed to better define the relative safety and efficacy of various surgical tools and techniques" used to treat A-fib. The group noted there have been "no head-to-head comparisons of the outcomes" of surgical ablation and another way of treating A-fib with catheters, called catheter ablation.

Though surgical-ablation devices aren't approved to treat A-fib, they are commonly used for that. Eric Prystowsky, a cardiologist treating heart-rhythm disorders who is affiliated with St. Vincent Hospital in Indianapolis, says surgical-ablation devices "are designed for A-fib. Theoretically, a surgeon could treat some other heart-rhythm problem with them, but well over 90% are used for A-fib." Nearly all of the \$100 million in annual sales of surgical-ablation devices are for treating atrial fibrillation, says Michael N. Weinstein, a medical-device analyst with J.P. Morgan.

In 2006, Ms. George, who had been in medical-device sales for 17 years, joined Boston Scientific as a St. Louis-based regional sales manager. At a training session, she says the

trainer told sales reps to use heart models to show doctors how to perform ablation surgery for A-fib.

Later that day, Ms. George says, the company's regulatory officials stressed sales people must be cautious about not promoting sales for off-label use. She was puzzled, she says, because she thought the messages were contradictory.

She says she assumed there would be an explanation of the conflict. She recalls asking, "Are there any legal uses of the product we can promote?" Another trainee, Paul Gaumond, who isn't a party to Ms. George's lawsuits, confirms hearing this question and says the trainer responded, "Don't worry about that. This is how you sell it."

Ms. George says she soon received a letter from her boss critical of her performance. She says she was fired two months later and sued. Her suit, filed in March 2007, alleges wrongful termination and retaliation by the company. Boston Scientific declined to comment on whether it fired Ms. George or to comment on any of her claims.

In documents filed under seal in the lawsuit, a Boston Scientific presentation prepared for a Peoria, Ill., hospital called surgical ablation "a new paradigm in patient care" and talked of "growing the market—developing a surgical ablation program." The document says 7,201 people in the Peoria area have A-fib, and that 720 are "good surgical candidates."

Boston Scientific, of Natick, Mass., notes it sold its surgical-ablation business in 2007. The company says it "established clear policies regarding the proper marketing" of products. It declined further comment.

Other companies also mentioned the surgical-ablation treatment, according to documents Ms. George says she was given when she worked at Boston Scientific or obtained later for litigation. Medtronic sponsored a June 2004 workshop in Chicago where doctors were taught, "Why Surgical Ablation for Your Patients: Patient Selection," according to documents filed in the lawsuit. The company paid for travel and hotel rooms of attendees, the documents show.

David E. Haines, chief of cardiovascular medicine at Beaumont Hospitals in Royal Oak, Mich., says he spoke to surgeons about the condition of atrial fibrillation, not about selling devices at that meeting and was paid an honorarium by Medtronic. Other talks at the conference were about surgical-ablation treatment, according to brochures for the event.

"Like all industry-sponsored medical meetings, the return on investment for the medical company is to increase physicians' familiarity with the device, [so] the physicians will choose that company's device," Dr. Haines says.

Minneapolis-based Medtronic says the documents "relate to past marketing practices of all companies" in surgical ablation and that its "rigorous processes" ensure proper marketing. The company didn't comment on the workshop and declined further comment.

Medtronic has said that its Cardioblade devices received FDA approval to "ablate cardiac tissue" and "ablate soft tissue" during "general surgery" or "cardiac surgery."

St. Jude training materials for sales personnel, reviewed by The Wall Street Journal, said its ablation device "represents the opportunity to own the category for surgical atrial fibrillation."

During product sales training for St. Jude, sales personnel listened to a presentation on "Surgical AF: The Opportunity," the documents showed. A presentation prepared for an Arizona hospital group said it could garner \$3.4 million in new revenue if it did 100 surgical-ablation cases in the next year, according to documents filed in Ms. George's lawsuit.

St. Jude, in St. Paul, Minn., says it does "not promote products for off-label use," and acts against employees who do. The company declined further comment, but referred to its recent filing with the Securities and Exchange Commission. In the filing, St. Jude said the Justice Department is investigating the company for possible violations relating to sales of its surgical ablation products. The company said it is cooperating with the investigation.

Ms. George says that after she asked about Boston Scientific's allegedly off-label sales at a training session, Meg Zavich, then her boss at Boston Scientific told her, "You have a bad attitude."

After being told her performance had to improve, Ms. George says she was fired by Ms. Zavich and a human resources official "for performance reasons" including delivering a report one day late.

Ms. George blames that delay on being instructed to attend a day-long heart surgery procedure the day before.

Before she left in the fall of 2006, Ms. George copied marketing materials on the advice of a local attorney.

Ms. Zavich, who no longer works for Boston Scientific, said in a brief telephone interview, "There are two sides to every story," adding, "I'm not going to speak about this."

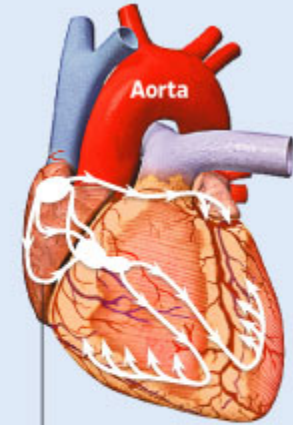
How Surgery Can Correct an Irregular Heart Rhythm

A healthy beat

Electrical signals tell the heart when to pump. They follow a path through the heart moving from top to bottom.



Front view
of the heart



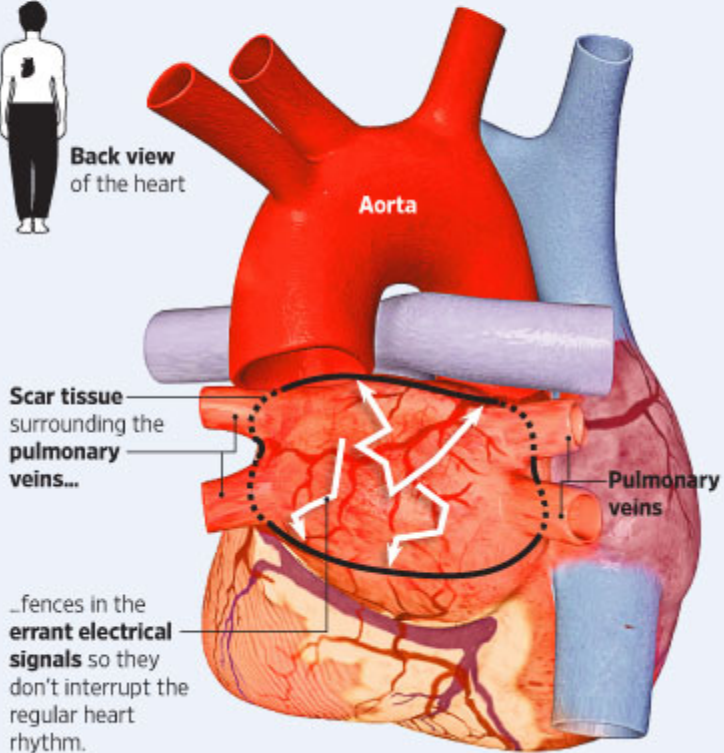
Normal path of
electrical signals

An irregular rhythm

Abnormal electrical signals can throw off the heart's normal rhythm. They almost always begin at the top, back area of the heart. Surgeons interrupt these signals by burning tissue around the pulmonary veins and elsewhere. This damaged tissue no longer conducts electrical signals, and normal rhythm resumes.



Back view
of the heart



Scar tissue
surrounding the
pulmonary
veins...

Pulmonary
veins

fences in the
errant electrical
signals so they
don't interrupt the
regular heart
rhythm.

Source: WSJ reporting; Northwestern Memorial Hospital

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