

AtriCure stock rises 20 percent on approval news

Mass Device

By [Mary Vanac](#) [1]

Shares of West Chester, Ohio-based AtriCure Inc. (NASDAQ:ATRC) rose more than 20 percent Tuesday, a day after the Food & Drug Administration approved the company's AtriClip system for sale in the United States.

AtriCure shares rose as high as \$7.20, ending the day up \$1.07 at \$6.30. More than 1 million AtriCure shares traded hands. That's 26 times as many shares than traded on any day in the last three months.

The keen investor interest makes sense. Chief Executive Officer David Drachman [called](#) [2] receiving the FDA's [510\(k\) clearance](#) [3] for his company's system "a major product and clinical milestone." The Cincinnati, Ohio-area company [received European clearance](#), [4] known as the CE Mark, to sell the device in October.

In May, during his company's first-quarter conference call with analysts, Drachman estimated the U.S. market for the AtriClip Gillinov-Cosgrove Left Atrial Appendage Exclusion System at "approximately 185,000 patients representing a [market opportunity for our AtriClip system of roughly \\$150 million per year](#) [5]."

That's a huge opportunity, especially considering AtriCure had [2009 revenue of only \\$54.5 million](#) [6], which was down 1 percent from \$55.3 million in 2008. The company that's barely past the development stage has yet to make an annual profit.

Yes, the system is partly named for Cleveland Clinic CEO Dr. Delos "Toby" Cosgrove, who co-invented it with colleague Dr. Marc Gillinov. The two thoracic and cardiovascular surgeons pioneered the practice of using a clip to block a thumb-sized pouch on top of the left side of the heart to cut down on blood clots that could lead to strokes for patients who have [atrial fibrillation](#) [7].

In fact, the Clinic chose the clip as [one of its Top 10 Medical Innovations for 2010](#) [8].

Another thing that makes AtriCure an attractive investment is the potential for the company's ablation technologies to treat atrial fibrillation, an increasingly common arrhythmia that can cause heart attacks or strokes.

So far, [neither drugs nor surgical procedures](#) [9] have offered sufferers much hope. The FDA has not approved cardiac ablation — scarring of the heart to disrupt bad electrical signals — as a treatment for atrial fibrillation. Yet, AtriCure has been [at the forefront of clinical trials](#) [10] that might convince the federal regulator to give its approval.

AtriCure stock rises 20 percent on approval news

Published on Medical Design Technology (<http://www.mdtmag.com>)

AtriCure also has at least two underdog stories that make you want to root for its success. One story involves the Cleveland Clinic and its chief executive.

In 2005, the *Wall Street Journal* investigated the complicated relationships among the Clinic, Cosgrove, the Clinic's venture capital fund and AtriCure, which licensed the AtriClip technology from the Clinic and got an investment from its venture fund, [according to the Health Care Renewal blog](#) [11].

Media reports led to the Clinic's promise in 2006 to revamp its conflict-of-interest policy to make it more transparent about professionals' commercial ties. Although Cosgrove has been eligible to receive royalties from sales of the AtriClip device, he has not received any, [according to the Cleveland Plain Dealer](#) [12]. Fairly or not, AtriCure got singled by the accusations of double-dealing.

Early this year, [AtriCure agreed to pay the federal government \\$3.76 million](#) [13] to settle a whistle-blower lawsuit and ensuing U.S. Department of Justice investigation that claimed the company marketed its ablation technologies as a treatment for atrial fibrillation.

The settlement included AtriCure's assertions that [the company and its employees did nothing wrong or illegal](#) [14]. Though AtriCure leaders believed they had good defenses against the lawsuit, litigation would have taken years and cost more than the settlement amount.

"Also, we are an emerging, growth-oriented company with a lean management structure," Drachman told analysts in November when his company announced a tentative settlement. "The discovery and litigation process would have distracted management from focusing on profitability and growth. We believe the contemplated resolution will allow us to execute our business strategy, maintain our credit facility and move toward profitability without materially impeding our current capital or ongoing revenue opportunities."

The whistle-blower case was filed in Texas by a former Boston Scientific employee. The [lawsuit also named device-making giants](#) [15] [Boston Scientific](#) [16], [St. Jude Medical](#) [17] and [Medtronic](#) [18], along with tiny companies [Endoscopic Technologies](#) [19] and AtriCure.

Let's be clear: the FDA has not approved cardiac ablation as a treatment for atrial fibrillation.

In recent investor presentations, however, AtriCure executives have been careful to repeat the FDA's stance on the regulatory limits of its technologies. Maybe that wasn't always the case. But it seems like AtriCure may have been caught up in the lawsuit largely because of its technologies and industry, not its marketing practices.

[SOURCE](#) [20]

AtriCure stock rises 20 percent on approval news

Published on Medical Design Technology (<http://www.mdtmag.com>)

Source URL (retrieved on 12/20/2014 - 3:46am):

<http://www.mdtmag.com/news/2010/06/atricure-stock-rises-20-percent-approval-news>

Links:

- [1] <http://www.medicitynews.com/author/mary/>
- [2] http://www.atricure.com/News_and_Events/AtriCure%2560s_AtriClip_System_Recieves_FDA_510%28k%29_Clearance/
- [3] <http://www.massdevice.com/node/6556>
- [4] <http://www.medicitynews.com/2009/10/atricure-gets-european-ok-for-atriclip-system/>
- [5] <http://www.medicitynews.com/2010/05/atricure-gets-fda-nod-to-try-hybrid-atrial-fibrillation-procedure/>
- [6] <http://www.massdevice.com/node/5797>
- [7] <http://www.mayoclinic.com/health/atrial-fibrillation/ds00291>
- [8] <http://www.medicitynews.com/2009/10/non-surgical-device-that-enables-people-deaf-in-one-ear-to-hear-tops-cleveland-clinics-top-10-list-of-innovations-for-2010/>
- [9] <http://www.the-infoshop.com/report/dc45845-fibrillation.html>
- [10] <http://www.massdevice.com/node/6351>
- [11] <http://hcrenewal.blogspot.com/2010/02/atricure-settles.html>
- [12] http://www.cleveland.com/medical/index.ssf/2010/02/ohio-based_atricure_pays_38_mi.html
- [13] <http://www.massdevice.com/node/5033>
- [14] <http://www.medicitynews.com/2009/11/atricure-tentatively-settles-department-of-justice-probe-looks-to-future-with-atriclip/>
- [15] <http://www.massdevice.com/node/4270>
- [16] <http://www.bostonscientific.com/home.bsci>
- [17] <http://www.sjm.com/>
- [18] <http://www.medtronic.com/>
- [19] <http://www.estech.com/>
- [20] <http://www.massdevice.com/news/atricure-stock-rises-20-percent-approval-news>