

AtriCure, Inc. (ATRC)

AtriCure Revenue Growth is Set to Short-Circuit

We are short shares of AtriCure, a \$1.9bn medical device company that manufactures and sells ablation equipment used in the surgical treatment of atrial fibrillation (AF). At about 7x forward revenues, AtriCure's valuation implies that the company's outlook is brighter than at any point in the last decade. But with the company's core surgical ablation market almost completely saturated, and the relentless improvements in catheter ablation technology accelerating, AtriCure is facing both rapidly decelerating revenue growth and the threat of technological obsolescence, simultaneously.

At the root of AtriCure's impending difficulties is the company's reliance on surgical cardiac ablation procedures, which underlie roughly 80% of the company's revenue. The overwhelming majority (over 90%) of these procedures are performed concomitantly with open-heart surgery that patients undergo irrespective of their AF – the chest is already open, so the surgeon takes some extra time to ablate the cardiac structures from which the AF originates. The problem for AtriCure is that, despite demographic tailwinds, the absolute number of open-heart surgeries has stagnated over the past decade as less invasive procedures, and earlier medical intervention, have successfully reduced the need for risky surgery. In stark contrast to AtriCure's claims, about a tenth of these procedures are performed on patients with preoperative AF, and the proportion of these procedures involving a concomitant ablation has steadily doubled to about 80% over the last decade, leaving little room for growth through further penetration. AtriCure's inability to turn a profit, even as it dominates an almost fully penetrated market, suggests that its core business is simply *structurally* unprofitable.

With the plateauing of surgical ablation growth in clear sight, AtriCure has been making a strong push for its “minimally invasive” Convergent procedure. While surgical ablation is usually restricted to patients already undergoing open-heart surgery, Convergent's minimally invasive nature aims to enable most of the benefits of surgical ablation on a *stand-alone* basis for *all* patients with persistent AF. Investor optimism about this market expansion has led to the explosion in AtriCure's valuation.

But Convergent will fail because it doesn't consider the role of electrophysiologists at the center of AF treatment. For AtriCure's gambit to succeed, EPs would have to refer their patients for a Convergent procedure, but they *already perform catheter ablations on an outpatient basis*, and without the risks of surgery. AtriCure claims that Convergent is far more effective for treating persistent AF than catheter ablation, but the EPs with whom we spoke found that claim laughable. The accelerating improvements in catheter ablation technology over the past decade have made it much easier for EPs to non-invasively create all the same cardiac lesions as Convergent. Asking EPs to split an ablation with a surgeon is tantamount to telling them they're not skilled enough to do it on their own. We expect that to work out very poorly for AtriCure.

Meanwhile, new technologies, particularly pulsed field ablation (PFA) and real-time electrical mapping, are set to dramatically advance catheter ablation. PFA creates lesions rapidly and precisely without any of the safety issues involved in thermal cardiac tissue ablation, while real-time cardiac mapping allows EPs to identify and eliminate sources of AF with much greater precision. The upshot is that catheter ablation is set to become safer, faster and more effective than ever, making any stand-alone surgical ablation – including Convergent – completely obsolete, while also encroaching on AtriCure's core surgical business. As Convergent fails and surgical ablation gives way to less invasive treatment modalities, we expect that profits will continue to remain elusive and that AtriCure's share price will suffer some ablation of its own.

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I. Investment Highlights

AtriCure will fail in its attempt to expand the surgical ablation market through the promotion of the Convergent procedure. AtriCure dominates the market for surgical ablation equipment used to treat atrial fibrillation (AF). Surgical ablation is generally performed by cardiac surgeons as an add-on to open-heart surgery at the end of the procedure. If a patient suffering AF undergoes bypass surgery, for example, the surgeon will take the opportunity of an open chest to ablate the cardiac tissue from which AF arrhythmias emanate. In almost every one of these procedures, the surgeon will also clip the patient's left atrial appendage (LAA), the source of over 90% of AF-related strokes, using AtriCure's AtriClip. Performing a concomitant ablation has become the standard of care for patients with preoperative AF and, as we discuss at length below, the proportion of these patients undergoing ablation during their surgeries has little room for further growth.

AtriCure has long understood that this growth deceleration would eventually arrive, and it has long attempted to preempt it with a simple strategy: turn surgical ablation into a stand-alone procedure. Restricting surgical ablation to those who are already undergoing open-heart surgery severely limits the addressable market. On an annual basis, there are over five times as many patients suffering from AF that could benefit from an ablation as there are AF patients who undergo open-heart surgery.¹

The problem with surgical ablation though is the surgery. From a risk/benefit standpoint, it's difficult for an EP to recommend cutting open a person's chest in order to fix (or attempt to fix) a chronic condition that's generally managed conservatively with medication, lifestyle adjustments, or [cardioversion](#). At a certain degree of severity, an EP will treat AF by performing an ablation exclusively from the inside of the heart (endocardium) with a catheter that is inserted into the patient through the femoral veins. But stand-alone surgical ablation has remained incredibly rare. AtriCure has long tried to change that by trying to advance a variety of "minimally invasive" surgical ablation procedures, which would theoretically alleviate some of the risks of open-heart surgery and minimize recovery time for the patient. Each of these successive attempts over the course of the last decade has been quietly abandoned by AtriCure with little explanation, though it's clear that the complication rates in trials of the procedures were unacceptably high – higher even than ablation complication rates in open-heart procedures – and thus wouldn't meet the bar for device-approval by the FDA.

Convergent, the minimally invasive procedure currently being touted by AtriCure, has avoided the safety issues that have plagued the company's previous attempts. But like those failed procedures, its minimally invasive nature poses significant limitations. In the first half of the Convergent procedure, a surgeon gains access to the exterior of the heart (epicardium) by way

¹ This estimate is based on the total number of catheter ablations performed in the US annually, which AtriCure estimates at approximately 150k.

of a small abdominal incision through which a tubular ablation device is inserted. The small incision means the device can only access a small section of cardiac tissue for ablation – the posterior left atrial wall – leaving the pulmonary veins, which are the most frequent trigger of AF, untouched. As a result, Convergent requires a second procedure – a standard endocardial catheter ablation, performed by an EP, to isolate the pulmonary veins, which are the most frequent trigger source of AF.

This “hybrid” approach to stand-alone ablation – combining a minimally invasive epicardial ablation with a standard endocardial catheter ablation – made some sense when the concept was first introduced about ten years ago. Pulmonary vein isolation (PVI) via catheter ablation was just being perfected, and it wasn't effective in most patients suffering from persistent AF, in which other areas of the heart besides the pulmonary veins also triggered arrhythmias. The addition of a minimally invasive procedure to ablate some of those other sources – as Convergent does with the posterior wall – would improve the efficacy of ablation for these patients.

The problem for AtriCure and Convergent, is that the ability to conduct complete posterior-wall isolation (PWI) as part of a standard catheter ablation has advanced dramatically in recent years. That's why the results of the recent CONVERGE IDE trial – hailed as some sort of conclusive victory for hybrid ablation procedures by AtriCure and its investors – are totally irrelevant, and even misleading. In the trial, two groups of patients with persistent AF were treated with ablation: the experimental arm underwent the Convergent procedures while the control arm underwent a catheter ablation that included only a PVI. Not shockingly, a larger percentage of the experimental group (68%) were free from AF 12 months post-procedure than the control group (50%). But the superiority of more extensive ablation – a combination of PVI and PWI compared to PVI-only – was never in doubt. That combination, though, can be accomplished more safely, and just as effectively, in a *single* catheter ablation procedure than in *two* ablation procedures, the first of which is a minimally invasive surgery.

Study after study has shown that a catheter procedure that isolates both the PVI and PWI can durably control AF as well as, or *better* than, the Convergent procedures did in the CONVERGE experimental group. None of this is lost on electrophysiologists. Every single EP we spoke with – and even some of the surgeons – was quick to point out the CONVERGE design flaws, and asserted their ability to perform a dual PVI/PWI ablation solely with a catheter in an outpatient procedure, sparing the patient a hole in the abdomen, a night in the hospital, and a longer recovery time. This doesn't bode well for the uptake of Convergent – surgeons can only perform the procedure if they get a referral from...the patient's electrophysiologist. Considering that EPs are supremely confident in their ability to isolate both cardiac structures, we expect Convergent to be a massive commercial failure, ending up exactly like AtriCure's previous attempts to popularize stand-alone surgical ablation.

AtriCure has been disingenuous about the addressable market for its surgical ablation products. The truth is that the market is small and already well-penetrated. AtriCure has long claimed (going back to investor presentations in 2010) that the total addressable market (TAM) for its core concomitant surgical ablation devices is about 85k patients annually. Given the approximately 300k open-heart surgery procedures performed in the US each year, AtriCure's claim is that just under a third of them are undergone by patients with pre-operative AF. Of these, AtriCure further claims that only about 20-25% – or 17k-21k patients – undergo an ablation. The implication for investors is clear: AtriCure's core business has many years of robust growth ahead as it continues to increase concomitant ablation penetration rates.

But AtriCure's contentions regarding the addressable patient population and penetration rates are so inflated, it's hard to believe the company is not intentionally misleading investors. The Society of Thoracic Surgeons (STS), the specialty society dedicated to cardiac surgery, maintains an adult cardiac surgery database (ACSD) that keeps detailed records on over 95% of all cardiac operations performed in the US annually. ACSD records are available for research, and the clinical literature that has resulted from a thorough analysis of these records paints a completely different picture of the addressable market than the TAM claims made by AtriCure:

- The most comprehensive [study](#) of the incidence of preoperative atrial fibrillation found that of the approximately 840k cardiac surgeries that took place between July 2011 and June 2014, about 90k patients would have been candidates for surgical ablation due to pre-operative AF. In other words, slightly more than 10% of patients undergoing open-heart surgery would be candidates for a surgical ablation – a *third* of the addressable patient population claimed by AtriCure.
- That same study found that over the 3 years studied, about 50% of patients with preoperative AF underwent ablations. In fact, the proportion of patients undergoing a concomitant ablation steadily increased over the three years studied, reaching over 60% by early 2014, a far cry from the 20-25% figure that AtriCure has been asserting for 10 years.
- By 2018, with the number of open-heart surgeries *below* the annual averages earlier in the decade, the penetration rate of concomitant ablation in open heart surgeries reached close to 75%.

In 2017, the STS finally issued a [Class I recommendation](#) for concomitant surgical ablation at the time of open-heart surgery, so while the 2019 data will not be compiled until early next year, it's safe to assume that 2019 saw another significant jump in the penetration rate of concomitant ablation, as the STS guidelines continued to gain traction. This is confirmed by the volume growth demonstrated by AtriCure last year in its open ablation segment. Our discussions with an array of cardiac surgeons from around the country further confirmed that it's rare for a patient with preoperative AF to undergo surgery without a concomitant ablation.

Debates surrounding TAM size might be irrelevant for a company attacking a new market, but for AtriCure, the data indicates that the surgical ablation market is much smaller than the company's claims, and almost fully penetrated at that. The devices sold through the company's Open Ablation and Appendage Management segments – which comprised 80% of US revenues in 2019, and 65% of total revenue – are sold into this market. The clear implication of the ACSD data is that, without the prospective success of Convergent – which we expect will fail – the growth engine for AtriCure's core business is all but tapped out.

An array of new technologies is changing the way catheter ablation procedures are performed, making them more effective, fast, and safe. AtriCure's devices stand to lose out.

In the medium-term, the biggest risk to AtriCure is that new technologies are making catheter ablation an even more robust ablation modality. The knock on catheter ablation has historically been that an endocardial catheter, even at the direction of the most skilled EP, cannot create the array of lesion sets that a surgeon does when performing a Cox-Maze IV ablation in an open-heart setting. As ablation practice has matured, though, it has become clear that a full Cox-Maze IV procedure is almost never necessary; a narrower focus on isolating the pulmonary veins, which *can* easily be achieved by catheter alone, is enough to restore normal rhythm in the vast majority of paroxysmal AF patients. For patients with persistent AF a variety of lesion sets, in addition to PVI, have been suggested over time, with the CONVERGE trial confirming the long-held view of several prominent EPs that complete ablation of the posterior wall is particularly helpful.

As mentioned previously, PW ablation can be performed by EPs via catheter. The procedure has had a reputation for being more laborious than PVI alone due to the physical size of the posterior wall, and for carrying a small risk of critical esophageal damage given the proximity of the esophagus to the posterior wall. But PW ablation via catheter has advanced significantly over the past 5 years through the introduction of new catheter technologies such as contact force (CF) and multi-electrode esophageal [temperature probes](#), as well as improvements in procedural methodology, such as the broad adoption of [high-power/short-duration](#) ablation. The advances have made PW ablation via catheter safer, as well as quicker and more effective.

Two recently introduced technologies are set to enhance the safety and efficacy of catheter ablation so dramatically, they will almost certainly destroy any remaining rationale for minimally invasive surgical ablation of the kind that AtriCure has incessantly tried – and failed – to promote. We expect that they will also begin to cannibalize concomitant surgical ablation procedures, threatening AtriCure's core open ablation business.

The first is pulsed field ablation (PFA). PFA uses a technique called electroporation, in which electric pulses are applied to the cardiac tissue, permanently damaging the tissue through the structural destabilization of cell membranes. PFA has two major benefits:

- The electroporation is tissue-specific – the pulsed electric fields can be calibrated so that they only impact the cardiac tissue, leaving the esophagus, proximal nerve cells, and any vasculature totally untouched. This makes PFA far safer than the thermal energy sources used in radiofrequency (RF) ablation or cryoablation approaches currently used in both catheter and surgical ablation.
- Rapidity – electroporation allows for the creation of tissue-destroying lesions to large areas of the myocardium, essentially instantaneously. Both RF and cryoablation take a long time, because the energy is applied to the tissue over a longer period so that the whole thickness of the cardiac wall is impacted.

PFA has already been studied in a large number of trials, and continues to quickly gain credibility. In the recent Heart Rhythm Society conference, several clinical [abstracts](#) with accompanying presentations highlighted both the safety and efficacy of the procedure. These were results obtained from the first generation of PFA systems, prior to any significant optimization that is in the process of being conducted. At least two startups, [Farapulse](#) and [Affera](#), as well as industry giants [Medtronic](#) and Abbott, are currently conducting a large number of trials with an array of different PFA approaches and devices. We expect the first generation of these devices to hit EP labs within the next 3-4 years, dealing the final blow to any rationale for broad adoption of hybrid/minimally-invasive surgical ablation approaches. Farapulse is also conducting a trial with its [Epi Faraone](#) device, which has already been used successfully in a small scale trial to create the classic Cox-Maze IV lesion set in the context of a concomitant procedure. In the open-heart setting, speed is of the essence and PFA will soon be threatening AtriCure's competitive position in what has historically been its core business.

The other technology we believe will challenge the logic for minimally invasive surgical ablation is Acutus Medical's AcQMap system. The difficulty with AF is that, even today, the actual source of the arrhythmias is uncertain. For persistent AF, non-pulmonary-vein triggers are known to play a significant role, and even the posterior wall is not always the answer. EPs can map the electrical activity of the heart in order to try and identify the AF triggers, but current mapping systems are contact-based and generate an electrical map of the heart that's a reconstruction of various data points obtained over the course of 20 minutes. Acutus' system is contactless and can generate a usable map of single points in time in less than 3 minutes. As a result, an EP can rapidly determine the physical location that is the source of the patient's AF, and target that area for ablation. In the prospective UNCOVER-AF trial, which reported [data](#) last year, EPs using the AcQMap technology achieved procedural efficacy – exclusively via catheter ablation – that was superior to that demonstrated by AtriCure in the CONVERGE trial. The implication, which Acutus continues to explore via trials, is that a more precise view of a patient's arrhythmias can lead to treatment that is safer and faster than, but as effective as, the shotgun approach to ablation advocated by the surgical field, including AtriCure.

Acutus's technology is already commercialized, and PFA is headed there shortly. While we expect the uptake on AtriCure's Convergent procedure and the associated devices will be

incredibly disappointing for investors, whatever modicum of success that AtriCure might achieve initially with its minimally invasive devices will be completely extinguished by the rapid improvements in efficacy, safety, and speed being achieved in the electrophysiology lab.

AtriCure is structurally unprofitable, even after having grown at a double digit rate for a decade. Since 2012, AtriCure's total revenue has more than tripled, with its domestic open-heart ablation business growing at a 13.5% CAGR, and its domestic AtriClip business having grown by a factor of 10. The growth has been a reflection of the swift adoption of concomitant surgical ablation on the part of cardiac surgeons, and the even swifter adoption of the AtriClip as the almost-automatic choice for surgeons to clip the left atrial appendage in patients undergoing a concomitant ablation. Strangely though, almost every metric on the company's income statement has shown *nothing* in the way of operating leverage:

- Gross margins are not meaningfully different: 73.8% in 2019 vs 71.2% in 2012
- The rate of R&D spend has remained constant at 17.9% vs 17.3% over that time
- The rate of SG&A spend as a percentage of revenue has in fact *increased* from 64.3% in 2012 to 70.3% in 2019.

It's difficult to understand how a company that has achieved close to maximum penetration of its core products has so poorly managed to translate that into profit, or even positive EBITDA, or even exhibit some degree of leverage. The number of AtriCure domestic sales reps has grown 15% annually since 2012, compared to a 20% CAGR for domestic revenues, so even from the narrow vantage point of sales expenses the company hasn't generated almost any operating leverage once adjusting for moderate increases in compensation and ASPs. Research and development expenses have also remained elevated as a percentage of revenue, given the degree of competition and technological advance that have characterized cardiac ablation.

AtriCure is a relatively small player operating a structurally unprofitable business that's positioned to be overwhelmed by the near-term changes in ablation practice. Even if it *could* grow in the future like it did in the past, it's unlikely that shareholders would benefit – its overall 18.5% annual revenue growth rate since 2012 looks pedestrian in the context of the 15.7% growth in the share count over that time. But AtriCure *can't* continue to grow at that pace – we expect that its core business will imminently hit the proverbial wall, and that its hope for growth is sure to fail. At 7.5x 2019 revenues, investors are paying way too high a price for a company with growth prospects this poor.

II. Company Overview

AtriCure: Capitalization and Financial Results							
Capitalization				Financial Results			
Share price (\$)	\$40.02				2017	2018	2019 TTM
Fully diluted shares (mm):				Revenue	\$ 175	\$ 202	\$ 231 \$ 212
Shares outstanding	44.9			EBITDA	(20)	(19)	(24) (38)
Dilutive impact of options/RSUs	2.2			EBITDA Margin	-11%	-10%	-10% -18%
Total	47.2						
				Domestic Surgical Revenue	\$ 102	\$ 125	\$ 148 \$ 142
Fully diluted market cap (mm)	\$1,888						
Debt	67						
Less: cash	232						
Enterprise value	\$1,723						
EV/revenue (trailing)	8.1x						
EV/2019 revenue	7.5x						

Source: company filings, Kerrisdale analysis

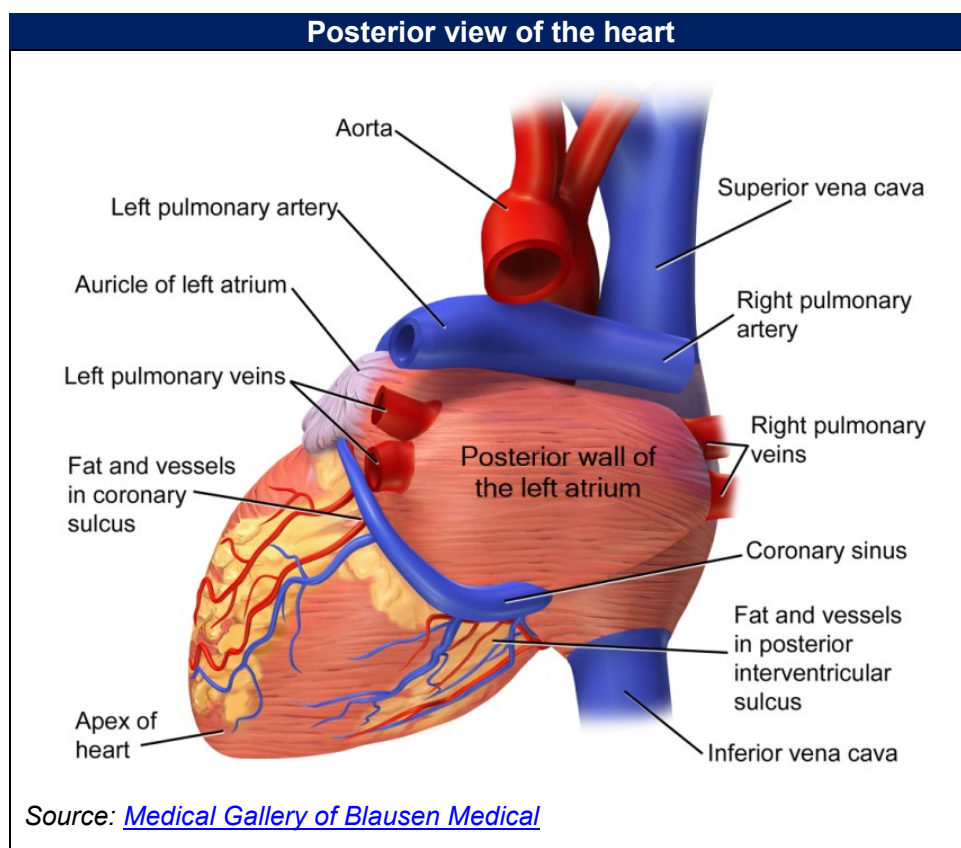
Atrial fibrillation (AF) is a relatively common arrhythmia (irregular heart rhythm) that causes rapid heart rate and is associated with increased risk of heart failure, dementia, and stroke. Symptomatic AF usually begins as *paroxysmal* – in other words, the patient will experience occasional episodes of arrhythmia that, when symptomatic, can manifest as palpitations, fainting, lightheadedness, shortness of breath, or chest pain. If not treated (and sometimes even if treated), AF can progress to become *persistent*, which means that the episodes of arrhythmia last for longer than seven days, and from there it can progress to *longstanding persistent* AF, which means the patient has had uninterrupted AF for over a year. Left untreated, AF significantly increases a patient's risk for heart failure, stroke, and dementia.

The classifications – paroxysmal vs. persistent vs. longstanding-persistent – are not mutually exclusive: patients can suffer episodes of more than one kind. They're also important because they've been shown to be loosely correlated with the AF trigger. Normally, the sinoatrial node – a group of cells in the wall of the heart's right atrium – spontaneously generates electrical impulses that travel through the heart causing it to contract. This is done continuously, which sets the heart's natural rhythm. In an arrhythmia, the electrical conduction is dysregulated, which causes the heart to beat irregularly. The underlying causes and proximate triggers for that dysregulation have been difficult to precisely identify. In atrial fibrillation, the dysregulation is most frequently triggered by electrical impulses emanating from the left atrium near the pulmonary veins and, over time, the area from which the arrhythmia is triggered expands beyond that.

AF is generally treated with recommendations for lifestyle changes (diet, exercise, etc.) and medication, the latter of which is targeted at either reining in the rapid heart rate or the irregular rhythm. In 1987, surgeon James Cox innovated a procedure called "cut and sew" in his open-heart surgery patients suffering from AF. He literally cut through various portions of the heart

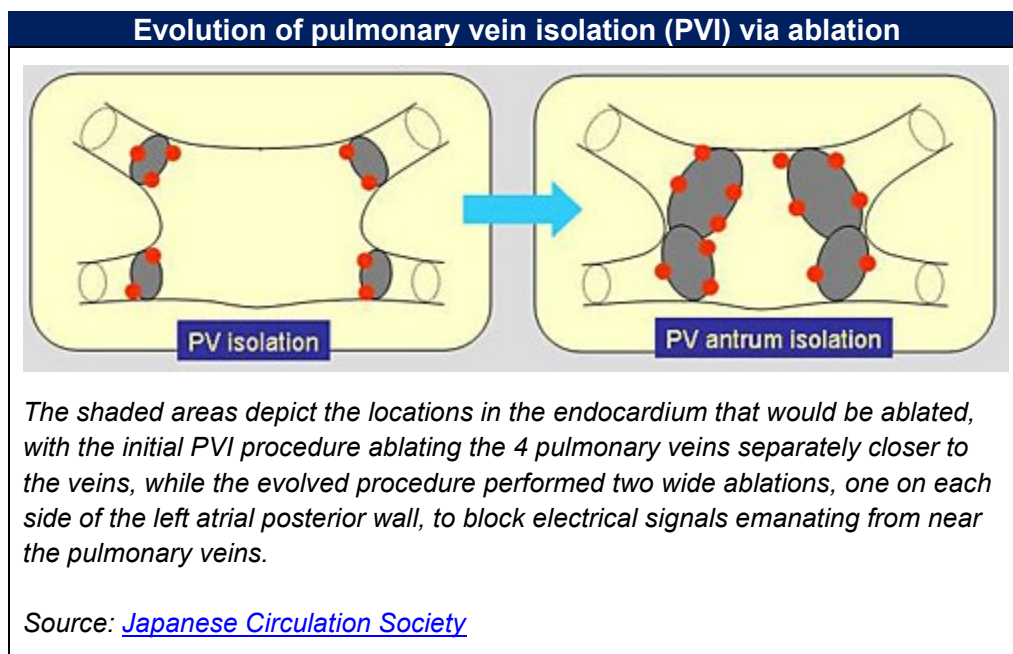
and sewed them back together, aiming to create scar tissue that would block the abnormal electrical impulses causing AF, while guiding the regular impulses to their normal atrial destinations. That procedure has evolved over the last 35 years, culminating in what is now called the Cox-Maze IV (CM-IV) procedure, which similarly aims to ablate various portions of cardiac tissue – either with heat-generating radiofrequency energy or with the ice-crystal formation of cryoablation – in order to block errant AF electrical impulses.²

AtriCure’s core business has historically been the design and sale of the RF and cryo devices used by surgeons performing CM-IV (as well as other more limited ablations) concomitantly with open-heart surgery. The popularity of this procedure has exploded in the last 5-10 years, and AtriCure’s Open-Heart Ablation segment has grown revenue at a 13.5% annual rate from 2012 through 2019. Over that time, AtriCure has also used the increasing prevalence of concomitant ablation to successfully promote the AtriClip, a relatively simple, but extraordinarily effective, device used by surgeons to “clip” a patient’s left atrial appendage (LAA) during open-heart surgery. The LAA is known to be the origin for over 90% of the clots that result in AF-related strokes, and sealing it shut stops the flow of blood into (and out of) it, markedly reducing the risk of stroke. AtriCure’s open-heart ablation devices and its AtriClip together amounted to about 80% of total 2019 revenues, highlighting the company’s current dependence on procedures performed concomitantly with open-heart surgery.



² For an exhaustive description of the Cox-Maze IV procedure, see Robertson J et al, [Illustrated techniques for performing the Cox-Maze IV procedure through a right mini-thoracotomy](#)

Of course, only a small proportion of patients suffering from AF undergo open-heart surgery, and full-blown surgical ablation is too risky and invasive to perform on a stand-alone basis. While most patients are adequately treated with medication (for rate-control or rhythm-control) or an electrical cardioversion,³ those who are refractory or intolerant of those treatments are candidates for catheter ablation. Catheter ablation for the treatment of AF is relatively new: it was only in 1998 that Michel Haissaguerre and his colleagues mapped the origin of the electrical triggers for AF, locating them next to the pulmonary veins (see the diagram below).⁴ Haissaguerre was only moderately successful in his original attempts at an ablation procedure performed via catheter, which aimed to isolate the pulmonary veins thereby disrupting the path of the errant arrhythmia-inducing impulses. That procedure has since progressed into the standard “wide area circumferential ablation” (WACA), also known as “pulmonary vein antral isolation” (PVAI or PVI), that is depicted in the diagram below.



The problem with PVI, though, was that it only targeted AF triggers adjacent to the pulmonary veins. In a small number of patients with paroxysmal AF, and in a larger number of patients with more persistent forms of AF, PVI was not effective at preventing the recurrence of AF, implying that there were other trigger sites for AF. But identifying those trigger sites has been difficult. The posterior wall of the left atrium, which is physically connected to the PVs, has long been hypothesized as a non-PV trigger, with a long list of studies dating back to at least 2007 strongly

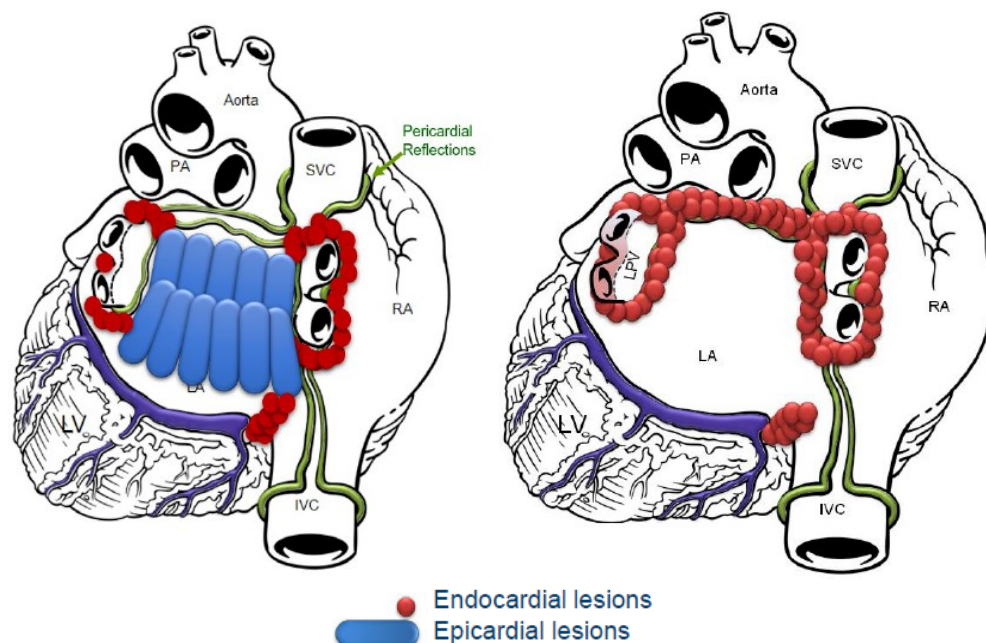
³ For a broad discussion of electrical cardioversion in atrial fibrillation, see Sucu M *et al*, [Electrical Cardioversion](#). For an analysis of the success rate of cardioversion in patients with AF, see e.g., Hellman, T *et al*, [Prediction of ineffective elective cardioversion of atrial fibrillation: a retrospective multi-center patient cohort study](#). Hellman’s findings are broadly similar to other survey literature on cardioversion success rates for treating AF.

⁴ Haïssaguerre, M *et al* [Spontaneous Initiation of Atrial Fibrillation by Ectopic Beats Originating in the Pulmonary Veins](#)

suggesting the superiority of combined PVI and PW ablation, compared to PVI alone, in patients with persistent AF. Other trigger sites that have been hypothesized include the superior vena cava, the coronary sinus, and the left atrial appendage, among others.⁵

Evidence for the posterior wall's role in triggering AF has recently been strengthened by the CONVERGE clinical trial run by AtriCure. CONVERGE compared two groups of AF patients with a range of severities from paroxysmal to longstanding persistent. The first group underwent the Convergent procedure, which is in fact a set of two procedures – 1) a minimally invasive surgical procedure, in which AtriCure's EPI-Sense device was inserted into the chest cavity through a subxiphoid incision (right below the sternum/breastbone) and used to perform an epicardial ablation of the posterior wall, and 2) a traditional endocardial catheter-based PVI.⁶ The control group just underwent a slightly modified catheter-based PVI (see below for a comparison of the lesion sets). After a year, a higher proportion of patients in the Convergent arm (68%) compared to the control arm (50%) were totally free from any atrial arrhythmia.

Comparison of the CONVERGE Convergent and control group ablations



On the left is a depiction of the Convergent Procedure lesion sets: blue capsules represent the area ablated by the EPI-Sense device during the minimally invasive surgical procedure (the left atrial posterior wall) and red dots represent the catheter-based PVI ablation. On the right is a depiction of the modified PVI performed on the control group.

Source: AtriCure investor presentation, Kerrisdale analysis

⁵ For a review of the various hypotheses advanced over the years, see Briceno, D et al [Beyond Pulmonary Vein Isolation in Nonparoxysmal Atrial Fibrillation](#)

⁶ A good visualization of the epicardial procedure was produced by AtriCure and can be found [here](#)

There are two ways to interpret the CONVERGE results. AtriCure's interpretation is that the "hybrid" Convergent procedure(s), which combines a surgical epicardial ablation using an AtriCure device and a catheter endocardial ablation, is superior to performing a catheter ablation alone. That's not what we heard from the electrophysiologists with whom we spoke, who explained that the novelty of the CONVERGE trial was that an RCT finally proved the efficacy of ablating the posterior wall in patients with persistent AF. Of course, that PW ablation could be accomplished with a catheter too. The relative efficacy of the two Convergent procedures – one of which requires an abdominal incision, general anesthesia, and an overnight hospital stay, with the attendant risks of surgery – was just an artifact of the CONVERGE trial design: the control arm patients underwent a PVI alone, rather than a combined PVI and PW ablation via catheter. Had they undergone a catheter procedure that applied all the same lesion sets as the Convergent arm, their results would have been similar because a PW ablation is simply not unique to the Convergent procedures. As a result, nothing about the CONVERGE results should be interpreted as endorsing minimally invasive surgery.

III. The ill-conceived Convergent procedure will fail to gain any traction against catheter ablation in persistent AF

It was always understood by AtriCure's management team that limiting surgical ablation primarily to patients who were undergoing open-heart surgery would severely restrict the company's addressable market. The saturation of the concomitant ablation market (which, as we discuss in the next section, has already occurred) would leave AtriCure with no catalyst for growth in its primary business. That's why the company has tried multiple times to extend the domain of surgical ablation from concomitant procedures to the stand-alone setting. If only surgical ablation could just be performed on its own, the addressable patient population could expand by over 5x, with an even larger addressable revenue opportunity given the higher ASPs of minimally invasive surgical devices.

Since 2005, with the initiation of the [RESTORE-SR II](#) trial, AtriCure has tried to develop a minimally invasive surgical ablation procedure that would require only minor incisions in the patient's chest through which an ablation device could be inserted. At the beginning of this process, the minimally invasive procedure was aimed at performing primarily a PVI with some optional ablative lesions.⁷ Over time though, AtriCure abandoned the idea of a pure stand-alone ablation in favor of a "hybrid" approach. A hybrid ablation is actually two separate procedures: initially, a minimally invasive epicardial ablation would be performed by a surgeon on *non-pulmonary-vein* AF triggers (posterior wall, LAA, etc.). That would be followed up with a catheter ablation by an electrophysiologist, who would isolate the pulmonary veins.

⁷ That is the clear implication of the description and outcome measures of the [RESTORE-SR IIB](#) trial, which was a follow up to the RESTORE-SR II trial that seems to have never been adequately enrolled. The role of triggers beyond the pulmonary veins was not well-understood 15 years ago.

The shift to hybrid ablation was an implicit admission on behalf of AtriCure of two critical points we believe are once again relevant in assessing the Convergent procedures. First, by 2010, the efficacy of catheter ablation had improved quite a bit since the discovery of PV triggers in 1998. There was no longer any doubt that a patient with paroxysmal AF could be treated exclusively via endocardial catheter ablation, with no need for a surgical epicardial ablation. Second, a surgical ablation – concomitant or stand-alone – almost always required a referral from the patient's EP. An EP wouldn't hesitate to recommend a surgical ablation for a patient already undergoing open-heart surgery, but would almost never recommend a stand-alone surgical ablation that could be performed entirely by catheter. Hence, AtriCure focused on the ablation of *non-PV triggers* during the surgical portion of the hybrid procedures it was developing: an EP might recommend a hybrid ablation if they believed a patient's AF was sufficiently advanced that a catheter-PVI alone would not suffice.

Several attempts by AtriCure at innovating a hybrid procedure have so far failed. In 2010, the company launched the [DEEP AF](#) trial, its first attempt at a hybrid procedure. The two procedures would be arranged in rapid succession, with the catheter ablation taking place immediately after the surgical ablation. AtriCure cut the trial off early, [blaming](#) "scheduling and logistical challenges." More likely though is that awful safety data virtually guaranteed that the device would not be approved for the procedure: 7 of the 24 enrolled patients experienced primary adverse events related to the procedure, including one death, highlighting the risks inherent in surgically treating AF on a stand-alone basis. Efficacy was probably also subpar considering that AtriCure never followed up with the data that was surely available for the 24 trial enrollees.

In its second [attempt](#), AtriCure enrolled patients for the same hybrid procedure as in the DEEP AF trial, but staged the two ablations 1-10 days apart from each other. The safety data this time around was even worse, with 6 of the 25 enrolled patients suffering from a "serious device or procedure-related adverse event," and 12 patients suffering from serious adverse events in the 24 months following the procedures.⁸ The DEEP procedure assessed in both of these failed trials is the subject of still another [trial](#) that is expected to read out in early 2024, but it's not something we expect will ever gain much adoption. Surgeons with whom we spoke described the procedure as very technically challenging, which explains the high rate of adverse events, and said they hadn't heard about anyone performing it recently, portraying it as a relic of a different era.

In the wake of the failures of the DEEP trials, and the high rates of associated adverse events, AtriCure adjusted its hybrid strategy and in 2015 acquired nContact Surgical, which had developed the Convergent procedure and the device with which it would be performed (the Epi-Sense Coagulation Device). Convergent is much simpler than DEEP in that it requires a single subxiphoid incision through which the ablation device is inserted into the patient's chest cavity, rather than the 3 surgical punctures next to the ribs that the DEEP procedure requires. It's also more modest in its aims: while DEEP included multiple epicardial lesion sets in the surgical

⁸ The full results of the trial can be found in the ["Results"](#) tab of the clinical trial record.

portion of the procedure, Convergent is focused only on ablation of the posterior wall.⁹ The overall reduction in complexity would theoretically reduce the rate of adverse events, while potentially increasing the adoption rate among surgeons.

At the time of the acquisition, nContact had already initiated a randomized controlled trial – [CONVERGE](#) – which sought to compare the efficacy of the Convergent hybrid procedure to that of PVI by catheter ablation. The 153 patients with persistent or longstanding-persistent AF participating in the trial were randomized 2:1 into two arms:

- The Hybrid Convergent Arm, in which 102 patients underwent an epicardial surgical ablation of the left atrial posterior wall using the EPi-Sense device at the hands of a surgeon, followed by an endocardial ablation via catheter by an EP.
- The Endocardial Catheter Ablation arm, in which 51 patients underwent only a catheter ablation using commercially approved RF catheters.

The primary effectiveness endpoint was freedom from AF, atrial tachycardia (AT), and atrial flutter (AFL) as measured by a 24-hour Holter monitor 12 months after the procedure (AT and AFL are other atrial arrhythmias that can present in AF patients undergoing ablation). The procedures would be considered effective even if patients went back to their anti-arrhythmic drugs (AADs), as long as they were only taking the same drug that had previously failed, and at the same dose.

That trial was completed in August of last year, with the results presented by AtriCure at the recent Heart Rhythm Society conference in May:

- In the Convergent arm, **67.7% of patients were free from AF/AFL/AT at 12 months, while in the Endocardial Catheter Ablation arm, that proportion was only 50%.**
- Through 30 days post-procedure, the Hybrid Convergent arm had “only” 8 patients – 7.8% of the group – experience a severe primary adverse event.
- AtriCure did not disclose how many patients continued on the AAD to which they were previously refractory.

Having *seemingly* demonstrated an “acceptable safety profile and superior effectiveness when compared to endocardial catheter ablation alone for the treatment of persistent AF” in an RCT, AtriCure’s contention is that CONVERGE is definitive proof of the utility of a stand-alone surgical ablation procedure. But a detailed examination of the trial design and the results suggests that Convergent will end up at the same impasse as AtriCure’s prior minimally invasive endeavors – an overly complicated procedure offering few incremental benefits for the incremental cost.

The major flaw in the trial design is that the catheter ablation control group just isn’t comparable to the Convergent group. The control group underwent a PVI (along with a “roof line” ablation,

⁹ A detailed discussion of the DEEP procedure is undertaken by Jared Beller and colleagues in Beller, J, et al, [Minimally Invasive Atrial Fibrillation Surgery: Hybrid Approach](#)

which creates a lesion along the roof of the posterior wall connecting the pulmonary veins on each side – see the diagram on page 12), whereas the Convergent arm underwent a full ablation of the posterior wall. By the standards of 2013, which is when the trial was designed by nContact, the comparison made some sense, as ablating the posterior wall via catheter was a technique that was still early in its development. But by today's standards, a proper assessment of Convergent would compare the Convergent procedures with a catheter-based procedure that ablates the pulmonary veins *and* the entire posterior wall.

In fact, there have been multiple studies of the efficacy of a combined PVI and PW ablation performed via catheter:

- In a prospective (but admittedly non-randomized) study published in January of 2016, Bai and colleagues split 52 consecutive patients with persistent AF into a group of 20 that underwent a PVI alone, and a group of 32 that had an additional ablation of the posterior wall. Both groups underwent two RF-catheter ablation procedures, which makes them comparable to the patients undergoing Convergent, itself composed of two procedures. **Of the group that underwent PVI and PW ablation, 65% were free of AF/AT/AFL at 12 months compared to only 20% of the group that underwent PVI alone.** None of the members in the experimental group were on anti-arrhythmic drugs (AADs) at 12 months, and the adverse event rate was less than 2%. Importantly, the study was conducted at the *end of 2010*, in the very early days of PW ablation via catheter.¹⁰
- A prospective randomized study conducted in South Korea between 2011 and 2012 compared two groups of 60 persistent AF patients undergoing catheter ablation. The first group underwent a PVI plus a roof line ablation (similar to the control arm in CONVERGE), and the second group had an additional “box lesion” ablation aimed at isolating the PW. The box lesion set is actually taken from the CM-IV procedure, but it is somewhat controversial as it doesn't ablate the entire posterior wall, only the borders of the wall (hence the “box” label). The study only measured freedom from AF rather than freedom from AF/AT/AFL, **but 83% (50/60) of the box lesion group were free from AF at 12 months compared to only 63% (38/60) of the PVI-only group.**¹¹ Freedom from AF was considered achieved only in the absence of AADs, and none of the patients suffered an adverse event.
- The most recent, largest, and significant study of PW ablation via catheter in patients with persistent AF was conducted between October 2014 and February 2017. In 390 consecutive patients in multiple centers, the first 222 received a PVI and PW ablation, while the next 168 received only a PVI. **At 12 months, 70% of the group undergoing a single-procedure PVI and PW ablation were free from all atrial arrhythmias compared to 42% in the**

¹⁰ Bai, R, et al, [Proven isolation of the pulmonary vein antrum with or without left atrial posterior wall isolation in patients with persistent atrial fibrillation](#)

¹¹ Kim, JS, et al, [Does isolation of the left atrial posterior wall improve clinical outcomes after radiofrequency catheter ablation for persistent atrial fibrillation? A prospective randomized clinical trial](#)

group undergoing PVI alone.¹² Seventeen percent of these patients remained on AADs and the rate of adverse events was 3%.

All of the above studies conducted somewhat “primitive” catheter ablation procedures compared to the technology that’s available to EPs today, and yet their efficacy rates are broadly similar to those demonstrated by the Convergent arm in CONVERGE, while their safety results are better. The recently published results of the PRECEPT trial suggest that even slightly more modern catheter ablation technology and methods would lead to even better results. The trial measured the safety and efficacy of catheter ablation in a group of 344 patients with persistent AF (though excluding longstanding persistent patients) and was conducted between July 2016 and February 2018 using the most advanced catheter ablation tools available. These included electro-anatomical mapping (by J&J subsidiary Biosense Webster), which helps the EP to determine whether errant electrical impulses are being blocked, and a contact force RF-powered catheter (also by Biosense), an innovation that allows the EP to precisely measure the force with which the catheter is pressing against the endocardial tissue.

The PRECEPT trial gave EPs a large degree of discretion in deciding what to ablate. The only requirement was that a PVI be performed, with non-PV triggers ablated only at the EP’s discretion, depending on the feedback from the electrical mapping. Considering that 55% of procedures were PVI-only, the results of the trial were even more impressive:

- The study’s primary effectiveness endpoint was defined as freedom from documented AF/AT/AFL episodes of 30 seconds or longer at *15 months*, with no repeat ablations, and no new or higher dosage of AADs. At 15 months, primary effectiveness was 62%, **and at 12 months, the primary effectiveness was ~68%.**
- Clinical success, a secondary effectiveness endpoint, was defined as freedom from AF/AT/AFL at 15 months while allowing for a second ablation or a new/higher-dosage AAD regimen. On that measure, the 15-month success rate was ~80%, **and the 12-month success rate was ~85%.**
- To make it simpler to compare the results of PRECEPT with the standard effectiveness endpoints in other AF-ablation trials, including CONVERGE, the trial participants had a 12-month follow-up with ECG/Holter monitoring, **and the single-ablation success rate at 12 months was 73.2%.**
- On the safety front, the primary adverse event rate was 3.8%, well below the 8% seen in CONVERGE.

The PRECEPT results strongly indicate that, *even without the systematic ablation of the posterior wall*, standard catheter ablation procedures have become quite effective at treating even the more intractable cases of AF. Of course, catheter ablation technology has continued to advance in the 2-3 years since the PRECEPT procedures were performed. The PRECEPT

¹² Aryana, A, et al, [Posterior wall isolation using the cryoballoon in conjunction with pulmonary vein ablation is superior to pulmonary vein isolation alone in patients with persistent atrial fibrillation: A multicenter experience](#)

results show that AtriCure today faces the same industry landscape it has continuously faced since 2005, when it attempted to develop a minimally invasive PVI: each time it pioneers a minimally invasive surgical ablation procedure, the rapid improvement in lower-risk catheter ablation technology makes it almost completely obsolete. As we discuss at further length below, this time is likely to be different only to the extent that new catheter technologies are making even more dramatic technological leaps than they have historically, to the detriment of AtriCure.

Exacerbating that trend is the other factor that has historically held back AtriCure's minimally invasive strategy – the electrophysiologist as the gatekeeper to surgical ablation. Almost any minimally invasive procedure, including Convergent, will require a referral from an EP.

AtriCure's unstated assumption regarding Convergent is that, because the EP will be performing one of the two procedures – and getting paid for it like with a normal catheter ablation – EPs will be eager to refer their persistent AF patients for a Convergent procedure. That assumes that the Medicare reimbursement regime currently operating – which considers the two parts of the Convergent procedure as two totally different ablation procedures as long as they are performed 30 days apart – will endure once the FDA approves the EPI-Sense device and the Convergent procedure. That's certainly possible, but we're less confident that commercial insurers will be so generous in overlooking the subterfuge of purposely separating procedures by 30 days.

More importantly, based on our extensive discussions with EPs, the field is overwhelmingly dubious of the entire idea of the Convergent procedure, mostly because they're not ignorant of all the research we've discussed to this point. EPs are almost unanimously confident of their ability to do a posterior wall ablation via catheter. There's no question that the CONVERGE trial suggests that a PW ablation is indicated in addition to a PVI for some of their patients, but it's the culmination of many years of strong suspicion that this was the case. As several EPs quickly pointed out to us, the CONVERGE results are less about the Convergent procedure than they are about the benefits of posterior wall ablation. EPs are likely to alter their ablation practice going forward not by referring patients for a Convergent procedure, but by more frequently ablating the posterior wall when performing a catheter ablation procedure on a patient with persistent or longstanding persistent AF.

EPs are also acutely aware of the Convergent procedure's safety characteristics. In a recent fairly positive assessment of Convergent in the *Arrhythmia and Electrophysiology Review*, the authors highlight that even before the CONVERGE trial, the Convergent procedure had been the subject of 16 different clinical studies, mostly observational.¹³ Aside from the simple inference that the ranges of efficacy reported in these studies is, unsurprisingly, no different than PW ablation via catheter, it's striking just how high the rate of complications/adverse events has been in Convergent procedures *outside the CONVERGE trial*. The 8% rate in

¹³ Wats, K, et al, [The Convergent AF Ablation Procedure: Evolution of a Multidisciplinary Approach to AF Management](#) We extensively reviewed the references used in this study and believe that the characterization of many references was sloppy. For example, both [Jan, M et al](#) and [Gulkarov et al](#) are labeled as transabdominal studies when both clearly state that the Convergent procedure was performed through a subxiphoid incision. Conveniently, these mistakes paint the current iteration of Convergent in a better light given the low efficacy and high level of complications of the studies omitted.

CONVERGE was *lower* than the historical experience that had been reported by other Convergent studies, which have ranged from 8-17%. While the increased rate of adverse events in the Convergent arm was not statistically significantly larger than that in the control, the history of documented Convergent studies indicates that the procedure is *2-4 times* more likely to result in an adverse safety event than a combined PVI and PW ablation via catheter.

Of course, that kind of risk shouldn't be all that surprising – the minimally invasive piece of Convergent is still, in the end, minimally invasive *surgery*. The patient's abdomen is cut open, and the pericardium is punctured for access to the exterior of the heart. That's certainly an improvement upon open heart surgery, but it's much riskier than sticking a catheter into the heart through the femoral veins. That increased risk is not lost upon the EPs who would need to refer patients for Convergent.

EPs will also consider that scheduling procedures 30 days apart needlessly extends the time frame of the more critical PVI procedure (which is the second of the Convergent procedures), and adds a level of logistical complication. Combined with the poor safety record of Convergent and the overwhelming evidence that an endocardial PW ablation is just as effective as a surgical epicardial procedure, we expect that the EP community will react to the final approval of Convergent with a collective shrug. Convergent will likely end up like AtriCure's other attempts at expanding the surgical ablation market: foiled by the relentless progress made in the EP lab.

IV. The addressable market for AtriCure's core surgical ablation business is small and saturated, with meager growth prospects

*The core business that AtriCure was founded and started on...is the surgical ablation. And that is concomitant with other cardiac surgeries...In the United States alone, there are 300,000 patients that have cardiac surgery. Of those, **one-third have Afib. Today, only 25% of those are getting treated.** Now, that is a vast improvement though over 10 years ago when 10%. And the reason for that is that we got our device approved through the FDA and PMA. The guidelines changed and **we have moved that needle, where we're now treating 20,000 to 25,000 patients per year...** Now, it also shows you that there is a big market opportunity on top of that... **you get the sense that it's under-penetrated and we've got many years of growth even with the guidelines there. And we are going to bring out new technology to improve the adoption of that from 25%. So hopefully get into 50% and 75% over the coming decade.***

Michael Carrel, AtriCure CEO
May 12th, 2020

The concomitant open heart market, meaning patients who undergo elective open heart surgical procedures such as a bypass or a valve operation and have a pre-existing history of atrial fibrillation...This is a \$250 million annual U.S. market opportunity...The important

thing to notice: patients are already in the operating room so AF treatment makes sense. So potential market on an annual basis is 85,000 U.S. patients per year; only 30% of the patients today are currently being treated. So there is significant opportunity for further penetration and growth.

David Drachman, AtriCure's Then-CEO
JMP Securities Research Conference – **May 11th, 2010**

As the two preceding quotes attest, AtriCure's assertions over time regarding the market opportunity of concomitant surgical ablation are irreconcilable. Somehow, over the full decade from May 2010 to May 2020:

- The number of patients with AF undergoing open-heart surgery has remained constant: 85k patients in 2010 compared to “about a third” of 300k patients in 2020, which AtriCure narrows down to 85,000 in its most recent investor presentation.¹⁴
- The percentage of those patients being treated with an ablation has come *down*, from 30% in 2010 to 25% in 2020.

Over that time, AtriCure's open-heart ablation revenue has tripled, with little competition of which to speak. Some of AtriCure's revenue growth has come from the modest amount of industry consolidation that occurred in the early half of the last decade, and some has come from the die-hard adherents of the “cut and sew” procedure either retiring or finally adopting RF ablation. But it's impossible to take seriously the notion that AtriCure's revenue has *tripled* as the number of AF patients undergoing ablation during open-heart surgery has somehow remained stagnant – or declined slightly from 30% to 25% of the addressable market. At best, the company seems to have no idea as to the size of the addressable market, or the penetration rate, and has just been repeating the same story to investors for the last decade. More likely, given surprisingly copious amounts of publicly available information on the topic, the company is being willfully disingenuous.

The best data on the topic come from the Society of Thoracic Surgeons (STS), which has maintained a prospective database of patients undergoing cardiothoracic surgery since 1987. Since at least 2010, the database has included *all* the operations from more than 90% of the centers performing cardiac surgery in the US, which includes over 95% of procedures in the country. While the data are not publicly available, investigators have access for [clinical research purposes](#), and the number of patients undergoing open-heart surgery with preoperative AF has been a topic of ongoing interest. Multiple publications over the past ten years clearly demonstrate that AtriCure's claims about the size of its addressable patient population are completely at odds with the reality.

In 2012, the first multi-year survey of surgical ablation of AF based on the STS database was published in the Journal of Thoracic and Cardiovascular Surgery. The study covered all patients between January 1, 2005 and December 31, 2010 who had undergone surgical ablation either

¹⁴ On page 19, in the “Supplemental Information” section of the [presentation](#), as filed with the SEC.

as a stand-alone procedure, or concomitantly with other cardiac procedures. Over that period, the authors found that “of patients undergoing elective or urgent non-redo cardiac surgery in North America, **11% presented with a history of AF.**” That’s a far cry from the estimate of one third used by AtriCure to obtain an addressable patient population of 85k. Further, “**the frequency of concomitant surgical ablations performed between 2005 and 2010 was 40.6%.**” In the last year of the study’s survey – 2010 – about 29k patients undergoing open-heart surgery had preoperative AF, and 39% underwent a concomitant surgical ablation. Even 10-15 years ago, the penetration of surgical ablation in patients with preoperative AF was quite a bit higher than the 20-25% that AtriCure claims is currently the case.¹⁵

That 2012 publication was updated in 2017 by Vinay Badhwar and his colleagues with a study that surveyed concomitant surgical ablation in the period stretching from July 2011 to June 2014.¹⁶ Similar to the earlier data, **Badhwar found that over the period surveyed, about 10.7% of patients undergoing open-heart surgery had preoperative AF and would have been candidates for concomitant ablation.** Of those, **48.3% underwent a concomitant ablation, but the proportion was increasing over the three years such that by 2014, the penetration rate of concomitant ablation was closer to 60%,** compared to 40% at the beginning of the survey period. Those figures are consistent with AtriCure’s >50% cumulative revenue growth in open-heart ablation from 2010 to 2014, but they are *entirely inconsistent* with AtriCure’s TAM and penetration claims.

Based on the most recent STS database update, published this past March, the proportion of patients with preoperative AF undergoing a surgical ablation had increased to about 75% by 2018.¹⁷ AtriCure’s volume growth in 2019 suggests that the penetration rate increased again in 2019, by at least a mid-single-digit rate, indicating that the current penetration rate is in the low-80% range. That’s not particularly surprising considering that in early 2017, the STS changed its clinical guidelines to make concomitant ablation a Class I recommendation. Any surgeons holding out until that point (and there weren’t many) no longer had much of an excuse *not* to perform a concomitant ablation. The almost wholesale adoption of concomitant surgical ablation leaves little opportunity for volume growth out of AtriCure’s core open-heart ablation and AtriClip segments.¹⁸

The looming collapse in the prospective growth rate of the company’s core business has not gone unnoticed by AtriCure’s management. That is, after all, what the strong push behind the Convergent procedure is all about. But, somewhat amusingly, the company has also gone out of its way to have its TAM story represented in the academic setting, where it could attain the patina of “science.” In a study published in July of 2019, in which seven of the eight authors

¹⁵ Ad, N, et al [Surgical ablation of atrial fibrillation trends and outcomes in North America](#)

¹⁶ Badhwar, V, et al, [Surgical Ablation of Atrial Fibrillation in the United States: Trends and Propensity Matched Outcomes](#)

¹⁷ See the number of AF correction operations in 2018 in Bowdish, M, et al, [The Society of Thoracic Surgeons Adult Cardiac Surgery Database: 2020 Update on Outcomes and Research](#)

¹⁸ The ceiling for the penetration rate is in the low-90% range as some proportion of higher-risk patients cannot undergo concomitant ablation due to their inability to undergo a lengthier surgery.

reported a financial relationship with AtriCure (including two employees of the company), and which was explicitly described as sponsored by AtriCure, a group of investigators found that the prevalence of AF in patients undergoing cardiac surgery was “substantially higher” than previously published rates of preoperative AF (i.e., the rates exhibited in the STS database), and that concomitant ablation was performed in fewer than a quarter of relevant patients. Coincidentally, the numbers match the story AtriCure has been telling for the last ten years.¹⁹

But an even cursory review of the study reveals its shoddiness:

- Though the investigators had access to the STS database, which covers over 95% of surgical procedures, they instead chose to use the much sparser Medicare data series for only one year, 2014, which is strange considering that there is more recent Medicare data to evaluate. The Medicare database included only a quarter of the total open-heart procedures captured by the STS database.
- The major bias of Medicare data is that it *only includes Medicare patients*, a population that is massively different from the average patient who undergoes open-heart surgery. The median patient with AF in the AtriCure study was a few years over 75, while the median patient with AF in the STS database was 71 years old. The gap of over 5 years explains at least some of the difference in preoperative AF rates.
- Medicare data doesn’t actually report whether a patient undergoing open-heart surgery has AF. So the AtriCure investigators matched patient data with hospital admissions in the prior 3 years, and if a patient had *1 hospital admission* with a *diagnosis code* corresponding to AF in that time, the patient would be considered to have preoperative AF. The authors admit that a “hospital admission with a diagnosis of AF” is actually “**not specific for the presence of AF**” and “**could be used for admission to rule out AF.**” One thing the study authors *don’t* admit is that the AF diagnosis code could also have been related to an actual ablation – catheter or surgical – which, of course, would mean the patient was not a *subsequent* candidate for a concomitant ablation. Such glaring flaws in the basic classification of the data apparently did not give much pause to the study authors.
- 20% of the procedures in the Medicare sample were classified as emergency surgery, while that category represents about 3.5% of the overall patients undergoing open heart surgery in the STS database. Unsurprisingly, patients undergoing emergency surgery are extremely unlikely to undergo any concomitant procedure besides the one for which they were rushed to the hospital. The penetration rate of ablation in a sample with an inordinate number of emergency surgeries will necessarily be much lower than an unbiased sample of patients.
- 10% of the Medicare sample used by the AtriCure study was comprised of patients with endocarditis or undergoing a repeat or follow-up procedure. The former category is contra-indicated for an ablation, and the inclusion of the latter category is double counting in the denominator, as if an ablation would be performed, it could only be performed in *one* of the procedures.

¹⁹ McCarthy, PM, et al, [*Prevalence of atrial fibrillation before cardiac surgery and factors associated with concomitant ablation*](#)

The biased and deeply flawed study of 2014 Medicare data says nothing useful about the company's TAM or the penetration rate of concomitant ablation, particularly when the STS database, which includes more detailed and abundant data, tells a richer and more consistent story about the need for, and prevalence of, concomitant ablation. But the AtriCure's attempt at substantiating its investor relations effort by giving it the aura of scientific legitimacy undermines its credibility. AtriCure seems overly concerned with the *perception* of its prospects, even as they deteriorate. The reality is that the engines of AtriCure's revenue growth for the past decade – open heart ablation and the associated AtriClip – have likely run out of steam.

Despite a decade of growth and market penetration, and little direct competition, AtriCure remains unprofitable

The obvious inference to be made from the STS data is that about a tenth of the approximately 285k patients undergoing open-heart surgeries annually suffer from preoperative AF, and that just about 80-85% of those – about 25k patients – undergo a concomitant ablation. AtriCure's segment revenue and average sales price disclosures indicate that the company thoroughly dominates the domestic concomitant ablation market having participated in 23k-25k open-heart ablations in 2019, a market share above 90%.²⁰

Based on our extensive discussions with cardiac surgeons, as well as the rapid revenue growth the product has generated, almost every single one of those procedures is accompanied by an exclusion of the patient's left atrial appendage carried out with the AtriClip. Like AtriCure's open-heart ablation devices, the AtriClip has no notable competition – when it comes to excluding the LAA surgically, the AtriClip is basically the only product that surgeons use.

Oddly, such near-total dominance of open-heart ablation has not led to *any* profits. On the contrary, AtriCure hasn't generated any free cash flow, or even positive EBITDA, since it went public in 2005. As the financials below indicate, AtriCure hasn't realized even a modicum of operating leverage as its total revenue has more than tripled over the 7 years to 2019 and the penetration rate of its open-heart devices has approached the point of saturation.

²⁰ AtriCure's most recent investor presentation implies an average sales price per concomitant ablation of approximately \$3,000 - \$3,500.

AtriCure: Domestic Financial Results 2012-2019								
	2012	2013	2014	2015	2016	2017	2018	2019
Total domestic revenue	52.6	62.3	80.2	102.2	122.4	138.4	162.1	185.8
Domestic Open-heart ablation	32.9	37.8	44.7	53.5	58.1	64.5	72.3	80.2
Domestic AtriClip	7.0	10.8	16.7	24.4	30.3	37.3	52.9	68.2
Total international revenue	17.6	19.6	27.3	27.5	32.7	36.3	39.5	45.0
Total revenue	70.2	81.9	107.5	129.8	155.1	174.7	201.6	230.8
Gross profit	50.0	59.6	75.8	92.9	111.1	126.2	147.1	170.3
R&D Expense	(12.1)	(13.4)	(18.6)	(25.7)	(35.8)	(34.1)	(34.7)	(41.2)
SG&A Expense	(45.1)	(57.0)	(73.5)	(93.9)	(106.4)	(117.0)	(129.5)	(162.2)
Total Operating Income	(7.2)	(10.9)	(16.4)	(26.7)	(31.1)	(25.0)	(17.1)	(33.1)
Total Domestic Revenue Growth		18.4%	28.7%	27.4%	19.7%	13.1%	17.2%	14.6%
Domestic Open-heart		15.1%	18.0%	19.9%	8.4%	11.1%	12.0%	11.0%
Domestic Atriclip		54.5%	54.1%	46.2%	24.4%	23.0%	41.9%	28.9%
Gross Margin	71.2%	72.7%	70.5%	71.6%	71.6%	72.2%	73.0%	73.8%
R&D Rate	17.3%	16.4%	17.3%	19.8%	23.1%	19.5%	17.2%	17.9%
SG&A Rate	64.2%	69.6%	68.4%	72.3%	68.6%	67.0%	64.2%	70.3%

Source: company filings, Kerrisdale analysis

The inescapable conclusion we draw from AtriCure's financials is that developing and selling surgical ablation devices is a structurally unprofitable business. From the standpoint of research and development, the lack of operating leverage is understandable: AtriCure's surgical ablation devices may not compete with other surgical ablation devices, but they indirectly compete with continuously advancing catheter ablation technology, which is itself characterized by intense competition among the major medical device companies. As they improve their catheter ablation devices by incorporating the latest discoveries and findings of cardiac rhythm research, AtriCure must do the same. That's in addition to the array of expensive clinical trials that AtriCure must sponsor to try and prove (unsuccessfully) the utility of minimally invasive surgical procedures such as Convergent.

Surprisingly though, AtriCure has also been unable to generate any leverage on its other operating expense lines. The company's salesforce disclosures reveal that, as domestic revenues grew 19.8% annually over the period included in the above chart, the number of sales reps grew at an only slightly lower rate of 15%. After accounting for pricing increases (that flow through to commissioned sales reps) and moderate increases in annual compensation, the sales organization has been totally incapable of leveraging its human capital. Selling surgical ablation tools is evidently too personnel-intensive to lend itself to efficiency gains and associated increases in profitability, *even in product lines that face no material competition*. As for operating expenses besides sales, it's unclear if they generate some leverage that's swamped by the inefficiency of the sales organization or if they too simply don't scale.

Either way, AtriCure has been unable to demonstrate *any* operating leverage, let alone a trivial accounting profit, even as its core products have saturated their addressable market with little direct competition. That is the hallmark of a structurally unprofitable business, and it partly explains why the major device companies, including Medtronic, Abbott, and J&J, have been totally uninterested in trying to capture any part of this market. Of course, the other reason these players have ceded the market entirely to AtriCure is because it's just not that much of a market. As much as AtriCure may protest, at approximately \$150 million in domestic revenue, the days of double-digit growth are over.

V. New technologies are revolutionizing cardiac ablation to the detriment of AtriCure

In its [presentation](#) on the CONVERGE trial results, AtriCure references the results of the STAR AF II trial as evidence that catheter ablation can't effectively treat patients suffering from persistent AF.²¹ The problem with that evidence, aside from AtriCure's deceptive interpretation of the data, is that the STAR AF II trial was conducted between the end of 2010 and July of 2012, with results published in mid-2015.²² Catheter ablation technology has advanced dramatically over the past ten years, a period that spans practically half of the existence of catheter ablation, which began as a treatment modality only after Haissaguerre's findings in 1998.

Technological advancement of catheter ablation has consistently meant improving efficacy and speed, while maintaining high standards of safety.

- Efficacy is defined in two ways: acutely and chronically. Acute, or immediate, success is defined by the successful electrical isolation of the targeted area, as determined by the cardiac electrical map. Longer term efficacy is defined as the durability of that isolation and, more importantly, the ability of the ablation to prevent the occurrence of atrial arrhythmias.
- Speed has always been defined by the length of time it takes to perform the catheter ablation procedure. The faster the procedure can be performed, the lower the probability of adverse events, and the more likely an EP is to perform an ablation.
- Safety, as defined by low rates of adverse events, has primarily focused on preventing phrenic nerve injury, which could cause phrenic nerve palsy, and esophageal injury, which

²¹ Verma, A, et al, [Approaches to Catheter Ablation for Persistent Atrial Fibrillation](#)

²² AtriCure's presentation of the STAR AF II results cuts off the published table documenting the trial's major efficacy outcomes, conveniently omitting the fact that – even 10 years ago! – two catheter ablation procedures consisting of *PVI alone* resulted in freedom from AF/AT/AFL *18 months after the initial procedure* in 61% of patients suffering from *persistent AF*, with 49% of patients free from AF/AT/AFL after *only one procedure*. That's not too far off from the Convergent arm's 68% *at 12 months* demonstrated in the CONVERGE trial, and it's potentially *better* considering the 6 extra months until patient evaluation.

could result in death. Esophageal injury is particularly relevant to PW ablation via catheter because the esophagus runs adjacent to the left atrial posterior wall, and ablating the posterior wall endocardially could result in a fatal thermal injury to the esophagus without the proper precautions being taken by the EP.

Since the STAR AF II trial took place, several major technological and methodological innovations have advanced the efficacy, speed, and safety of catheter ablation procedures.²³ Contact Force (CF) catheters, which were introduced commercially in 2014, allowed EPs to physically sense the catheter's contact with the cardiac tissue, as well as quantitatively monitor the parameters of that contact. Before that, EPs would use catheter tip temperature, weak tactile feedback, catheter motion and stability, and other indirect measures, to assess whether they were making durable lesions. While CF was initially less impactful than might be expected, as more studies were conducted, and various quantitative measures derived from the data that were newly accessible, clinicians learned to use CF to make more durable lesions, reducing the recurrence of arrhythmias. At the same time, the technology helped reduce the fluoroscopy time of a procedure (resulting in less radiation applied to the patient) and reduce the overall procedure time. CF has been instrumental in increasing both the efficacy and speed of catheter ablation.²⁴

From a methodological standpoint, High-Power, Short-Duration (HPSD) ablation has been another significant advance. As catheter ablation matured, academic clinicians theorized different power application strategies that could potentially increase the efficacy of catheter ablation. HPSD applied a higher dose of RF power to the cardiac tissue than had been previously used with RF catheters, but applied that power for shorter durations. The technique has been shown to result in fewer arrhythmia recurrences, while speeding up procedure time and reducing complication rates.²⁵

Beyond CF catheters and the HPSD techniques, many smaller advances have improved the catheter ablation procedure. These include esophageal [temperature probes](#), which help prevent injury to the esophagus while performing a PW ablation, and cryo-balloon catheters, which ablate tissue by freezing it, but also do so more rapidly and reliably in cases where large swaths of tissue require ablation. But all the innovation of the past decade seems marginal compared to Pulsed Field Ablation (PFA) and real time electrical mapping of the heart.

²³ For a survey of these advances, see Rottner, L, et al, [Innovative tools for atrial fibrillation ablation](#)

²⁴ For a review of the initial disappointing efficacy results of CF, see Ariyaratna, N, et al, [Role of Contact Force Sensing in Catheter Ablation of Cardiac Arrhythmias](#). For a review of how Ablation Index (AI), a measure that can only be derived using a CF catheter, has been used to improve efficacy and speed of catheter ablation procedures, see Pranata, R, et al, [Ablation-index guided versus conventional contact-force guided ablation in pulmonary vein isolation – Systematic review and meta-analysis](#)

²⁵ A prospective trial of HPSD that resulted in higher efficacy rates is described in Yavin, HD, et al, [Impact of High-Power Short-Duration Radiofrequency Ablation on Long-Term Lesion Durability for Atrial Fibrillation Ablation](#). Lower complication rates are discussed in Winkle, RA, et al, [Low complication rates using high power \(45–50 W\) for short duration for atrial fibrillation ablations](#)

Pulsed Field Ablation (PFA) is a revolution in the safety and speed of catheter ablation, and will render a lot of surgical ablation obsolete

As discussed previously, the two procedures that comprise Convergent – an endocardial catheter-based PVI, and an epicardial PW ablation – can be performed just as effectively, and more safely, in a single catheter ablation procedure. Still, there are potential downsides to a PW ablation using a catheter. The procedure can be a bit tedious using an RF catheter, because ablating the posterior wall with the catheter tip requires the repeated application of power through that tip across a large area. Imagine covering a swath of paper with a dot-marker, but with the marker being held a few feet away with a flexible tube. Additionally, the posterior wall of the left atrium abuts the esophagus. While the tough myocardial tissue can withstand the thermal impact of RF or cryo-ablation, too much power applied for too long can cause ulceration of the esophagus, or, in extremely rare cases, the perforation of the esophageal tissue, which is almost always fatal. Despite these drawbacks, PW ablation via catheter remains substantially safer than even minimally invasive surgical procedures, primarily because surgical complications occur, on average, with greater frequency and severity.

But pulsed field ablation (PFA), an ablation modality that gained renewed interest from investigators about seven years ago, will soon completely transform catheter ablation by specifically addressing the speed and safety issues presented by traditional thermal power sources like RF and cryo. PFA uses a technique called electroporation, which has long been used in [microbiology research](#). Cell membranes are made up of two layers of phospholipids. By shooting electrical pulses at a predetermined voltage for a few microseconds through cells, electroporation rearranges the phospholipid layers that make up the membrane, opening pores into the cells. If the pores are large enough, their presence is permanent, and the cells die through lysis. Though the cells die, the extracellular matrix remains intact and the tissue structure is *perfectly preserved*, making electroporation a possible ablation modality. Two qualities of electroporation make it a potentially *ideal* ablation modality:

- Tissue selectivity – at a given voltage, electroporation is tissue-selective. Through an accident of nature, myocytes – the cells that make up the myocardial tissue that is ablated – have a much lower electric field threshold than nerves, vasculature, or the esophagus. In practice, that means that the voltage that needs to be applied to the cardiac tissue in order to kill the cells and shut down errant electrical signals is much lower than the voltage needed to kill nerve, vascular, or esophageal cells, which are completely spared even if the ablation is overpowered. As a result, it's practically impossible for a PFA procedure to result in phrenic nerve injury, blood vessel occlusion, or esophageal perforation. The resulting pristine safety profile of PFA essentially completely solves the major safety problems associated with ablation.
- Speed – what's being delivered to the tissue in PFA is an instantaneously large voltage field. The procedure times of the first few in-human trials of PFA were relatively long as the details of the procedure were still in the process of being optimized. But the most recent

documented trial, in which EPs performed both a PVI and PW ablation, provides an interesting point of reference. In the 25 patients included in the study, the average ablation time for the PVIs was 22 minutes, and the PW ablation took an average of 10 minutes. Those numbers compare extremely favorably to the average ablation time of 108 minutes recorded in the PRECEPT trial discussed previously, in which PW ablation was not even performed on all the patients.

While PFA has demonstrated an unmatched safety and speed profile, the method's efficacy has been detailed in several trials over the last two years, and the number of ongoing trials continues to grow. A recent [presentation](#) at HRS reviewed the data from three clinical trials that included 117 patients suffering from paroxysmal AF on whom a PVI was performed using a basket-shaped PFA catheter designed by Farapulse. 42 patients underwent the procedure *after* the electric pulse waveforms were optimized on the initial cohorts of patients. Of these 42 patients, 83% showed all 4 of their pulmonary veins electrically isolated when they went for a catheter-based electrical mapping of their heart 3 months after the procedure. Of those 42 patients, 15 had made it to the one-year mark for the presentation's data cut-off, and 14 of those remained free of AF at that point. The Kaplan-Meier estimate of freedom from *all atrial arrhythmias* at the one-year mark for that cohort was 84%, comparable to the efficacy rate for RF- or cryo-based catheter ablation in similar patient populations.²⁶

PFA is not yet ready for commercialization. While the safety and speed of the various devices are virtually guaranteed, the EPs involved with the various device makers and clinical trials told us that efficacy is going to continue to improve over the near term. There are multiple variables in the context of PFA that will affect the durability of the lesions formed during the procedure, including the parameters of the pulse's waveform (width, frequency, pulse grouping, and intervals between pulses), magnitude of the electric field used, and the applied voltage. The only one of these that will be adjustable by the EP controlling the procedure is the applied voltage. The rest will be intrinsic to the device used, and device makers are racing to optimize these variables in the pursuit of maximally durable lesions. If Farapulse's first cut at an optimized system is any indication, the durability of ablations using PFA is going to be more than adequate. Over time, we expect that further results from improved Farapulse devices, but also from Medtronic, Abbott, and Affera, will improve upon what can now be achieved with the most optimized system from Farapulse.

Like many of the most [prominent electrophysiologists](#) in the world, we expect the impact of PFA on ablation treatment to be revolutionary. The reduced procedural time will mean that many of the logistical hurdles that currently prevent EPs from performing too many ablations will be removed, expanding the overall market for cardiac ablation. Dramatic reductions in catheter ablation procedural times and safety risks will also negatively impact AtriCure's core open-heart business. It's been well-documented that in-hospital outcomes of patients with preoperative AF undergoing open-heart surgery are much worse than for those not suffering AF. In patients with

²⁶ Reddy, VY, et al, [One Year Clinical Outcomes Following Pulsed Field Ablation for Paroxysmal AF](#)

preoperative AF undergoing coronary artery bypass grafting (CABG), for example, in-hospital mortality was 50% greater and risk of renal failure or stroke during the surgery was 35% and 20% higher, respectively, than patients not suffering from AF.²⁷ With a rapid ablation modality available, several EPs told us they'd be able to easily perform an ablation on their patients *before* they went in for surgery, reducing the risk of surgical complications. Those patients will no longer undergo concomitant ablation.

More importantly, the immaculate safety profile and rapid application will result in even more widespread performance of PW ablation via catheter. As if to highlight that, a small feasibility study was recently conducted on 25 patients on whom combined PVI and PW ablation were performed using a Farapulse catheter. When mapped right after the ablation, the entire posterior wall was successfully isolated in all 25 patients.²⁸ In a [follow-up](#) of that study at HRS, remapping of the 16 patients with evaluable data at the 3-month mark showed successful isolation of the posterior wall in 100% of the patients. Longer term durability data on these patients will be presented eventually, but already this trial is showing even better electrical isolation results than the three aforementioned trials focused on paroxysmal AF. We expect that the ability to perform PW ablation rapidly and safely via catheter will put the final nail in the coffin of minimally invasive surgical procedures such as Convergent.

Real-time mapping devices, such as those from Acutus, will change the ablation treatment paradigm to the detriment of AtriCure

Part of the problem with the efficacy of catheter ablation is that AF is still a bit of a mystery. In patients with paroxysmal AF, the physical source of the errant electrical signals causing the arrhythmia is known to be proximate to the pulmonary veins *most of the time*. But left untreated, the source of the arrhythmias expands beyond the PVs. The CONVERGE trial showed that, for a significant portion of patients suffering from persistent or longstanding persistent AF, the left atrial posterior wall is a common source of errant electrical signals. But the results of CONVERGE, in which about a third of patients experienced a recurrence of an atrial arrhythmia within a year, suggest that the PW is also not always the definitive source of the arrhythmias.

Until recently, mapping out the electrical activity in the heart in real time has been impossible. The mapping catheters sold by the major cardiac device companies are contact-based catheters, which require the EP to touch the endocardial surface with the catheter point-by-point over the course of 15-20 minutes to produce a cardiac electrical map that indicates the presence or absence of electrical activity. This allows the EP to determine whether they isolated

²⁷ Malaisrie, SC, et al, [Burden of preoperative atrial fibrillation in patients undergoing coronary artery bypass grafting](#) It's also worth pointing out that the investigators found that only 6.9% of patients undergoing CABG surgery suffered from AF, another data point that stands in stark contrast to AtriCure's claim that 25-30% of open-heart surgery patients suffer from AF.

²⁸ Reddy, V, et al, [Pulsed Field Ablation in Patients With Persistent Atrial Fibrillation](#)

the PVs, or the PW, or any other cardiac structure targeted, *after* performing the ablation itself. But it's impossible for the EP to see the continuous electrical activity as it's occurring in the heart.

Acutus, a medical device company that recently went public, has changed that by designing a mapping catheter with a spherical shape that uses ultrasound to create a comprehensive cardiac map of not only the actual cardiac anatomy, but also the electrical propagation pathways. The catheter never actually touches the endocardial surface, and it creates this "activation map" by sampling the voltage in the cardiac cavity at 150k times per second and then processing that data through its algorithm to derive the distribution of electrical charges across the chamber's surface. It does this in under three minutes.²⁹

The ability to actually visualize the heart's electrical rhythm with each heartbeat allows an EP to more accurately observe the probable source of the arrhythmia, and then perform the ablation at that site. This is not just theoretical – Acutus has shown that its technology can improve outcomes for patients with persistent AF. In the single-arm [UNCOVER AF](#) trial, 127 patients with persistent AF underwent a catheter ablation, with 121 of these (6 patients either withdrew consent or were lost to follow-up) evaluated 7 days, and 1, 3, 6, 9, and 12 months post-procedure. In addition to a PVI, the EPs conducting the procedure in the trial were trained to identify different patterns of abnormal electrical activation, identifiable on Acutus's AcQMap system, that correspond to AF arrhythmias.³⁰ If identified, the trial protocol required the EPs to ablate the associated cardiac tissue.

The results of the trial indicate that real-time mapping of arrhythmias would help EPs significantly improve the efficacy of ablation procedures compared to PVI alone.³¹ 12 months from the procedure, 69% of patients were free from AF/AT/AFL after only the initial procedure. Including the patients that underwent a second ablation, 86% of the trial participants were free from AF/AT/AFL at the 12-month mark.³² The single-procedure efficacy of a catheter ablation aided only by real-time mapping matches the double-procedure efficacy of Convergent, and the double-procedure efficacy using AcQMap is a vast improvement. Real-time mapping, which unlike PFA is already commercialized but is only beginning to gain adherents, enables precision ablation that makes minimally invasive surgical ablation completely unnecessary.

The technology for so precisely analyzing the heart's electrical signaling system in the context of arrhythmias like AF is still incredibly new and, over time, we expect that it will be able to detect

²⁹ Acutus demonstrates this technology through multiple videos on its [website](#)

³⁰ The activation patterns are detailed in Grace, A, et al, [High-resolution noncontact charge-density mapping of endocardial activation](#), and in particular in [Figure 6](#). Most, though not all, of the abnormal activation locations identified by the investigators were on the left atrial posterior wall.

³¹ It's much less clear whether real-time mapping would help improve upon a protocol that called for a PVI and PW ablation for all persistent AF patients, though it would help reduce procedure times, and improve safety by reducing the physical area requiring ablation.

³² Willems, S, et al, [Targeting Nonpulmonary Vein Sources in Persistent Atrial Fibrillation Identified by Noncontact Charge Density Mapping](#)

AF (and other arrhythmias) emanating from other locations around the heart that have yet to be identified. As that happens, the superiority of catheter ablation over the blunt instrument of a surgical procedure will be further enhanced. In addition, Acutus is in the process of developing a [PFA ablation system](#) of its own to use in conjunction with its AcQMap system, with the goal of even more drastic reductions in procedure times.

The future of catheter ablation is bright, and by delivering the fatal blow to minimally invasive ablation and even eating into the concomitant surgical ablation market, it threatens AtriCure's very existence.

VI. Conclusion

The performance of AtriCure's stock price over the past six months, particularly around the results of the CONVERGE trial presented in May, indicates that investors see the Convergent procedures as a powerful growth lever over the medium term. In our view, nothing could be further from reality. The CONVERGE results are clearly good *enough* for AtriCure's EPi-Sense device to receive FDA approval for the first Convergent procedure. But just because a device is approved, that doesn't mean it will be used. Unfortunately for AtriCure, after a decade's worth of technological improvement in catheter ablation equipment, Convergent is just overkill. There's simply no need for a surgical procedure, and the risks that it entails, to treat patients with persistent or longstanding persistent AF.

Even the well-designed catheter ablation trials conducted 8-10 years ago, such as STAR AF II, suggest that the safest way to treat these patients is with a single catheter ablation procedure, followed by another one in the half of patients in which atrial arrhythmias recur. The efficacy of this treatment paradigm – even ten years ago – rivaled the efficacy demonstrated by Convergent much more recently, and the safety profile was better. Using updated approaches – contact force catheters, high-power low-duration ablation, esophageal temperature monitoring, and most significantly, ablation of the posterior wall – has vastly improved catheter ablation. The most recent clinical research strongly supports the assumption of the overwhelming majority of electrophysiologists: catheter ablation is demonstrably safer, and almost certainly more effective, than the minimally invasive surgery involved in Convergent. The implication for AtriCure is that its best hope for growth is already dead, and it hasn't even been approved yet.

If that weren't enough, new catheter technologies such as pulsed field ablation and real time electrical mapping are on the verge of completely revolutionizing the nature of catheter ablation. The speed, safety, and efficacy of catheter ablation will soon reach levels that will make the procedure a reasonable option *even for patients who are set to undergo open heart surgery*. We expect this will be the nail in the coffin of minimally invasive stand-alone ablation, as well as a completely new source of competition for concomitant surgical ablation, a market that AtriCure has heretofore had all to itself.

That market, which underlies AtriCure's core open-heart and AtriClip segments, and over two thirds of its revenues, has been portrayed by the company as vast and underpenetrated. Investors have accepted the proposition that AtriCure's core surgical business has many years of growth before it. But an even cursory look into the data reveals a reality at odds with the company's portrayal of the market. The addressable surgical ablation market comprises only about 10% of overall open-heart surgeries, in contrast to AtriCure's claims that one third of those patients suffer preoperative AF. Meanwhile, the market is approximately 80% penetrated, rather than the 20-25% figure that AtriCure asserts, and AtriCure's share of that market is over 90%. The unfortunate implication for investors is that while AtriCure's core business has grown at a double-digit rate for over a decade, that growth will come to a screeching halt in the very near term.

AtriCure currently trades at 7.5x the revenue generated in 2019, and about 7x consensus estimates of the revenue to be generated in the next twelve months. We expect that AtriCure will recover from the pandemic-driven decline in cardiac surgeries to eventually regain its peak revenues, but that will be thin gruel for investors. The company operates a business that has shown itself to be structurally unprofitable and incapable of generating operating leverage even in the best of times. But those times are over. A likely side effect of the rapid technological advancement of catheter ablation will be the complete collapse of AtriCure's business.

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