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**SECURITIES AND EXCHANGE COMMISSION**  
WASHINGTON, D.C. 20549

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**FORM 8-K**

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**CURRENT REPORT**

**PURSUANT TO SECTION 13 OR 15(d) of the  
SECURITIES EXCHANGE ACT OF 1934**

**Date of Report (Date of earliest event reported): January 9, 2017**

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**ATRICURE, INC.**

(Exact name of registrant as specified in charter)

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**Delaware**  
(State or other jurisdiction  
of incorporation)

**000-51470**  
(Commission  
File Number)

**34-1940305**  
(IRS Employer  
Identification No.)

**7555 Innovation Way**  
**Mason, OH**  
(Address of principal executive offices)

**45040**  
(Zip Code)

**Registrant's telephone number, including area code: (513) 755-4100**

**Not Applicable**

(Former name or former address, if changed since last report)

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Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
  - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
  - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
  - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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**Item 2.02. Results of Operations and Financial Condition.**

On January 9, 2017, AtriCure, Inc. (“AtriCure” or the “Company”) issued a press release announcing its preliminary financial results for the fourth quarter and full year ended December 31, 2016. A copy of the press release is furnished as Exhibit 99.1 to this Form 8-K and is incorporated herein by reference.

**Item 7.01. Regulation FD Disclosure.**

During the week of January 9, 2017, the Company is holding meetings with investors discussing, among other topics, an overview of the Company’s business and growth strategy. A copy of the investor presentation, which is available at [www.atricure.com](http://www.atricure.com), is furnished as Exhibit 99.2 to this Form 8-K and is incorporated herein by reference.

The Company’s presentation discloses certain financial results both in accordance with generally accepted accounting principles (“GAAP”) and on a non-GAAP basis with adjustments for certain items. The Company’s management believes that presentation of these non-GAAP financial measures and their related reconciliations are useful to investors because the non-GAAP financial measures provide investors with a basis for comparing the results to financial results from prior periods.

Information in the presentation contains forward-looking statements regarding future events and performance of the Company. All such forward-looking statements are based largely on the Company’s experience and perception of current conditions, trends, expected future developments and other factors, and on management’s expectations, and are subject to risks and uncertainties that could cause actual results to differ materially, including, but not limited to, those factors described in the presentation and in the Company’s filings with the Securities and Exchange Commission. The Company disclaims any intention or obligation to update or revise any financial or other projections or other forward-looking statements, whether because of new information, future events or otherwise.

The information in each of Item 2.02 and Item 7.01 of this Form 8-K and in the press release attached as Exhibit 99.1 and the presentation attached as Exhibit 99.2 is being furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that Section. The information in each of Item 2.02 and Item 7.01 of this Form 8-K and each of Exhibit 99.1 and Exhibit 99.2 shall not be incorporated by reference in any filing (whether made before or after the date hereof) or any other document under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in any such filing or document.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

<u>No.</u>	<u>Description</u>
99.1	Press Release dated January 9, 2017
99.2	Investor Presentation

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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ATRICURE, INC.

Dated: January 9, 2017

By: /s/ M. Andrew Wade

M. Andrew Wade

Senior Vice President and Chief Financial Officer

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**For immediate release**

January 9, 2017

## **AtriCure Announces Preliminary Results for Fourth Quarter and Full Year 2016**

MASON, Ohio, January 9, 2017 – AtriCure, Inc. (Nasdaq: ATRC), a leading innovator in treatments for atrial fibrillation (Afib) and left atrial appendage (LAA) management, today announced preliminary financial results for the fourth quarter and full year 2016 and provided 2017 financial guidance.

Preliminary and unaudited revenue for fourth quarter 2016 is expected to be approximately \$41.2 million, reflecting growth of approximately 15% over the fourth quarter of 2015. Based on this preliminary estimate, revenue from U.S. customers is expected to be \$32.7 million, reflecting growth of 13%. Expectations of U.S. revenue by product category are as follows: open chest ablation of \$14.6 million, growth of 1%; minimally invasive (MIS) ablation of \$8.9 million, growth of 25%; AtriClip system of \$8.4 million, growth of 26%; and valve instrumentation revenue of approximately \$0.7 million.

Revenue from international customers is expected to be approximately \$8.5 million, an increase of 22% as reported and 23% on a constant currency basis.

Preliminary revenue for full year 2016 is expected to be \$155.1 million, reflecting growth of approximately 20% over full year 2015. The Adjusted EBITDA loss (a non-GAAP measure consistently calculated as in previous releases) for the full year 2016 is currently estimated to be less than the previously communicated range of \$12 to \$14 million. AtriCure will provide a reconciliation of this non-GAAP measure to the related GAAP measure in the release of final 2016 results.

“Our fourth quarter sales results were marked by mixed performance – weak U.S. Open sales were partially offset by robust U.S. Clip and Epi-Sense sales results as well as solid international sales. We are disappointed with the softness in our U.S. Open sales performance which was not attributable to any one factor. We will continue to investigate the dynamics of our U.S. Open sales performance, both internal and external, to forecast with greater accuracy. However, we do not believe there have been any fundamental changes in the market opportunity,” said Mike Carrel, President and Chief Executive Officer of AtriCure. “At the same time, we are excited about the uptick in our Clip and MIS sales results.”

Mr. Carrel continued, “Our revenue guidance for 2017 reflects continued strength in our U.S. MIS and Clip franchises and our U.S. Open business growth remaining in the single digits. Additionally, we have a clear line of sight to significant bottom line improvement in 2017 and remain confident in our expectation for EBITDA profitability for full year 2018.”

### **The Society for Thoracic Surgeons Updates Guidelines**

The Society for Thoracic Surgeons recently updated its guidelines for the surgical treatment of Afib. Most notable is the elevation of surgical ablation for Afib to a Class 1 recommendation at the time of mitral valve surgery, aortic valve surgery, and coronary artery bypass grafting.

Mr. Carrel noted, “This reflects increasing adoption of surgical ablation techniques for the treatment of Afib and is a result of the large body of scientific evidence showing that concomitant surgical ablation is safe and effective. We believe this is a significant advancement for the concomitant treatment of Afib, and we are committed to driving further adoption of Afib treatment globally and serving this under-penetrated market.”

### **2017 Financial Guidance**

Management projects 2017 revenue growth of approximately 13% to 15% over full year 2016 at current exchange rates.

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Adjusted EBITDA, a non-GAAP measure, is projected to be a loss in the range of \$4 to \$6 million for 2017. Net loss per share is expected to be in the range of \$0.88 to \$0.96. The Company continues to expect positive adjusted EBITDA for full year 2018.

#### **About AtriCure**

AtriCure, Inc. is a medical device company that provides innovative solutions designed to decrease the global Afib epidemic. AtriCure's Isolator® Synergy™ Ablation System is the first and only surgical device approved for the treatment of persistent and longstanding persistent forms of Afib in patients undergoing certain open concomitant procedures. AtriCure's AtriClip® Left Atrial Appendage Management (LAAM) exclusion device is the most widely sold device worldwide that is indicated for the occlusion of the left atrial appendage. AtriCure believes electrophysiologists and cardiothoracic surgeons are adopting its technologies for the treatment of Afib and reduction of Afib related complications. Afib affects more than 33 million people worldwide. For more information, visit [AtriCure.com](http://AtriCure.com) or follow us on Twitter @AtriCure.

#### **Forward-Looking Statements**

This press release contains "forward-looking statements"—that is, statements related to future events that by their nature address matters that are uncertain. For details on the uncertainties that may cause our actual results to be materially different than those expressed in our forward-looking statements, visit <http://www.atricure.com/fls> as well as our Annual Reports on Form 10-K and Quarterly Reports on Form 10-Q which contain risk factors. We do not undertake to update our forward-looking statements. This document also includes forward-looking projected financial information that is based on current estimates and forecasts. Actual results could differ materially.

#### **CONTACTS:**

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# AtriCure® Investor Presentation

January 2017



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## Forward Looking Statements/Non-GAAP Measures

This presentation contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include statements that address activities, events or developments that AtriCure expects, believes or anticipates will or may occur in the future, such as earnings estimates (including projections and guidance), other predictions of financial performance, launches by AtriCure of new products and market acceptance of AtriCure's products. Forward-looking statements are based on AtriCure's experience and perception of current conditions, trends, expected future developments and other factors it believes are appropriate under the circumstances and are subject to numerous risks and uncertainties, many of which are beyond AtriCure's control. These risks and uncertainties include the rate and degree of market acceptance of AtriCure's products, AtriCure's ability to develop and market new and enhanced products, the timing of and ability to obtain and maintain regulatory clearances and approvals for its products, the timing of and ability to obtain reimbursement of procedures utilizing AtriCure's products, AtriCure's ability to consummate acquisitions or, if consummated, to successfully integrate acquired businesses into AtriCure's operations, AtriCure's ability to recognize the benefits of acquisitions, including potential synergies and cost savings, failure of an acquisition or acquired company to achieve its plans and objectives generally, risk that proposed or consummated acquisitions may disrupt operations or pose difficulties in employee retention or otherwise affect financial or operating results, competition from existing and new products and procedures or AtriCure's ability to effectively react to other risks and uncertainties described from time to time in AtriCure's SEC filings, such as fluctuation of quarterly financial results, reliance on third party manufacturers and suppliers, litigation or other proceedings, government regulation, and stock price volatility. AtriCure does not guarantee any forward-looking statements, and actual results may differ materially from those projected. AtriCure undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. A further list and description of risks, uncertainties and other matters can be found in AtriCure's Annual Report on Form 10-K for the previous year and in AtriCure's reports on Forms 10-Q and 8-K. This presentation includes the use of non-GAAP measures. Reference AtriCure's Form 8-K filings which include the furnishing of our earnings releases for a reconciliation to the related GAAP measures.

Atrial fibrillation (Afib) is an irregular and often rapid heart rate that can increase the risk of stroke, heart failure and other heart-related complications.



## It is Bad, It Is Growing, and It Is Untreated <sup>1-9</sup>

### Afib Risks & Symptoms

- 5-6x higher risk of STROKE (2<sup>nd</sup> leading cause; due to LAA)
- May lead to Congestive Heart Failure
- 60-90% are symptomatic
- Chest pain, pressure, or discomfort (angina)
- Shortness of breath (dyspnea)
- Hypotension (low BP)
- Palpitations
- Confusion, dizziness, fainting
- Fatigue, loss of ability to exercise

### A Growing Epidemic

- **33M** people affected WW, **15M** suffering from Afib in Developed Countries
- **6M+** suffering from Afib in US alone; **10M+** by 2025
- Aging baby boomers aggressively seeking therapy, improved Afib diagnostics, and novel treatments
- **1.2M** new AF diagnoses in the U.S. every year
- Direct medical costs are ~73% higher in AFib patients

# Addressing the Growing Afib Epidemic

## Undisputed Leader

- The only FDA-approved devices for surgical Afib ablation: 250,000+ cases in 900 US centers
- Leading KOL support and enthusiasm

## Large Underpenetrated Markets

- 15M AFib patients in developed countries
- Estimated 25% penetrated in cardiac surgery patients
- Multi-billion market opportunity – over \$3.5BM annual potential



## Strong Growth and Pipeline

- 4 years of 15%+ organic growth
- Solid commercial team
- Robust R&D Pipeline and IP (over 100 issued patents)

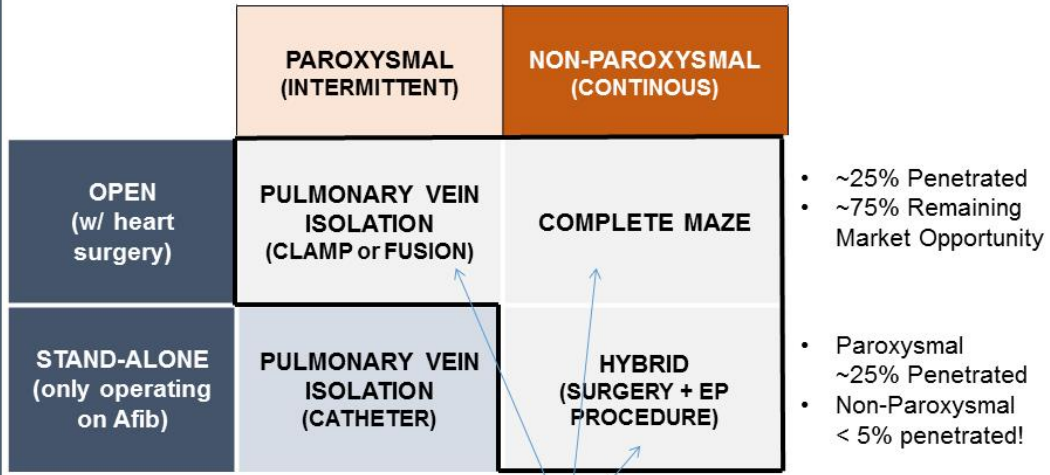
## Commitment to Science

- Several FDA International Clinical trials underway
- Well-established Afib Training programs delivered to 2,000+ surgeons

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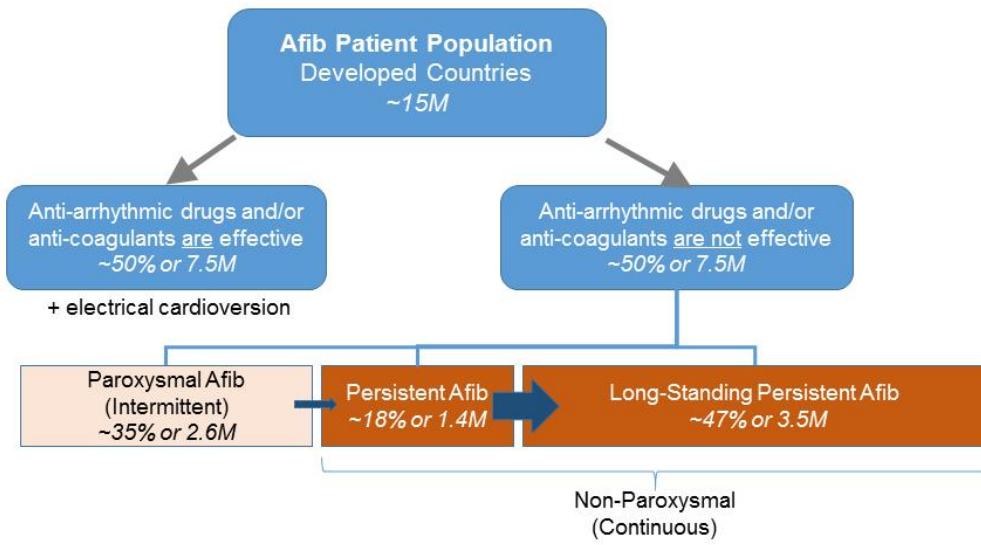
AtriCure®

## Two Distinct Procedure Types



**AtriCure is the Leader in this Space**

# Afib Clinical Hierarchy<sup>10</sup>



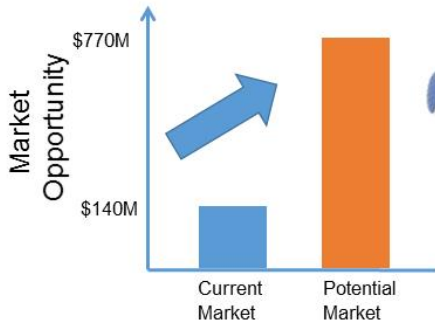
# Global Market Opportunity – Afib OPEN

## OPEN Ablation

Estimated open heart surgeries per year	900,000
Estimated % that have Afib	~30%
Estimated Afib patients undergoing surgery	270,000
<b>Estimated Market Opportunity – Annual</b>	<b>\$770,000,000</b>

- Labeling advantage in U.S.
- Best products
- High gross margins
- Education is key
- Competition is large device

AtriCure has the only ON-LABEL product



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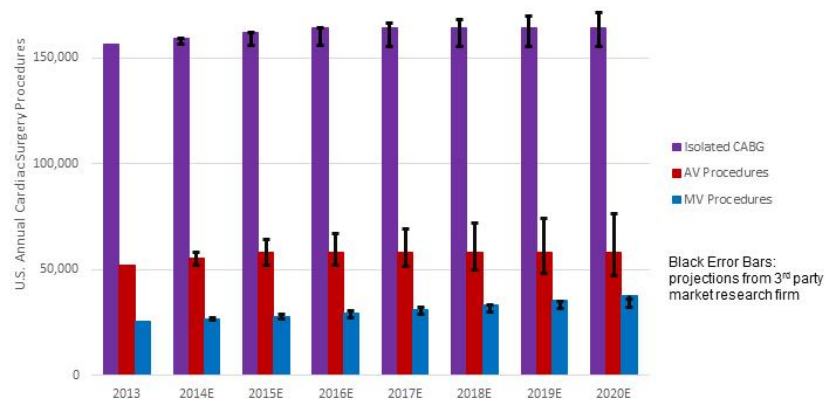
Source: AtriCure estimates. US, EU, JP, CH included in analysis.



AtriCure®

## Stable Underlying US Heart Surgery Market<sup>11-12</sup>

- CABG procedures expected to grow
- AVR procedures will remain steady to slightly down
- MVR procedures projected to grow



## The Society of Thoracic Surgeons 2017 Clinical Practice Guidelines for the Surgical Treatment of Atrial Fibrillation



### CLASS OF RECOMMENDATION – I



- Surgical ablation for AF can be performed without additional risk of operative mortality or major morbidity, and is **RECOMMENDED** at the time of **concomitant mitral operations** to restore sinus rhythm. (Class I, Level A)
- Surgical ablation for AF can be performed without additional operative risk of mortality or major morbidity, and is **RECOMMENDED** at the time of **concomitant isolated aortic valve replacement, isolated coronary artery bypass graft surgery, and aortic valve replacement plus coronary artery bypass graft operations** to restore sinus rhythm. (Class I, Level B nonrandomized)

## The Society of Thoracic Surgeons 2017 Clinical Practice Guidelines for the Surgical Treatment of Atrial Fibrillation



- **2 Years** in STS's "working committee", **125 publications** to support recommendation.
- Applies to **ALL-COMERS** Afib patients, previously only "symptomatic patients refractory or intolerant to at least one AAD"
- **LAAM** in conjunction with ablation or alone during cardiac surgery "is reasonable" (Class 2). LAAM has never previously been mentioned.
- Multi-disciplinary Heart Team (EP+CS) pre-op, operatively, and post-op "can be useful and beneficial" (Class 1). Acknowledging the positive impact of **hybrid ablations**.

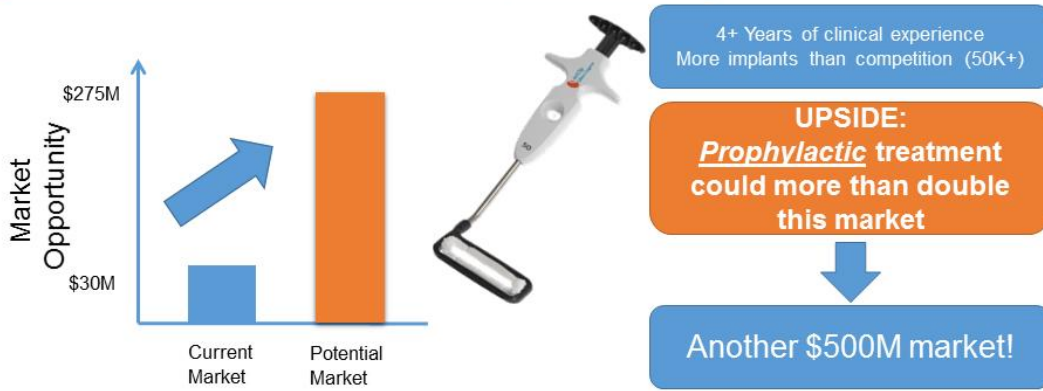


# Global Market Opportunity – OPEN LAA (AtriClip)

## OPEN LAA (AtriClip)

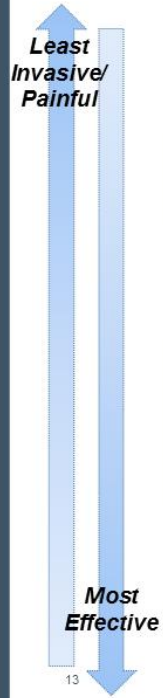
Estimated Open heart surgeries per year	900,000
Estimated % that have Afib	~30%
Estimated Afib patients undergoing surgery	270,000
<b>Estimated Market Opportunity – Annual</b>	<b>\$275,000,000</b>

- Best in class LAA management
- Superior safety - No adverse events
- Mechanical & Electrical Solution
- Competition includes staple, suture, ligature (endo loop)

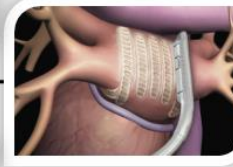


Source: AtriCure estimates. US, EU, JP, CH included in analysis.

# Non-Drug Options of Care For Non-Paroxysmal Afib



Therapy	Acute Clinical Success
Catheter Ablation (Endocardial)	30% single treatment
Hybrid - CONVERGENT (Trans-Diaphragmatic)	70-80% on AADs 60-65% off AADs
Hybrid - DEEP (Bi-Lateral Totally-Thoracoscopic)	80-90% on AADs 70-80% off AADs
MAZE Ablation (Right-Lateral Thoracotomy)	90+% on AADs
Cut-and-Sew MAZE	95+% on AADs



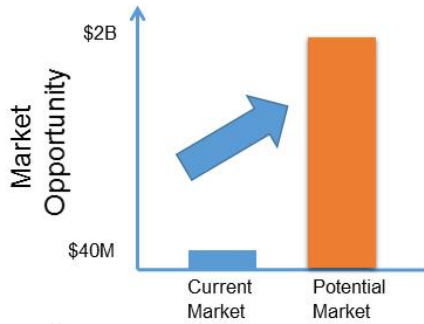
AtriCure

# MIS Ablation – Another \$2B+ Market

MIS Ablation	
Estimated Afib patients	15,000,000
Estimated Persistent and Longstanding Persistent subset	~ 65%
Subtotal	9,750,000
Estimated % drug refractory and symptomatic	~ 50%
Subtotal - Patients	4,875,000
<b>Estimated Market Opportunity – Total</b>	<b>\$42,000,000,000</b>
Estimated % treated annually	5%
<b>Estimated Market Opportunity – Annual</b>	<b>\$2,100,000,000</b>

- High reimbursement
- High gross margins
- Growing internationally
- Development needed
- Competition is start-ups

**BIG MARKET**  
 Developing Market  
 Trials Key For Broad  
 Adoption



**AtriCure**

# Global Market Opportunity – LAA MIS (AtriClip PRO)

## MIS Clip With MIS Ablation

Estimated Afib patients	15,000,000
Estimated Persistent and Longstanding Persistent subset	65%
Subtotal	9,750,000
Estimated % drug refractory and symptomatic	50%
Subtotal - Patients	4,875,000
<b>Estimated Market Opportunity – Total</b>	<b>\$17,000,000,000</b>
Estimated % treated annually	5%
<b>Estimated Market Opportunity – Annual</b>	<b>\$850,000,000</b>

## MIS Clip With MIS Heart Surgery

**UPSIDE!**



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Source: AtriCure estimates. US, EU included in analysis.

### One Product, Two Markets

#### *Concomitant with MIS Ablation*

- Today's market ...will draft MIS growth
- 90% attach rate

#### *Concomitant with other MIS Surgery*

- Today's market is relatively small
- Opportunity for other MIS heart surgeries, such as valve repair

**AtriCure**

# Potential Market ... With FDA Trial

## Sole Therapy LAAM Market

Estimate of treatment-resistant Afib patients	1,000,000
Estimated global revenue per device (all modes)	\$3,500
<b>Estimated Market Opportunity – Total</b>	<b>\$3,500,000,000</b>
Estimated % treated annually	10%
<b>Estimated Market Opportunity – Annual</b>	<b>\$350,000,000</b>

Source: AtriCure estimates US, EU, JP, CH included in analysis

### *Potential sole therapy market*

- NEW market for us...
- Today done percutaneous
- Competition includes implants and EP closure (without FDA approval)
- Stroke trial key to success



## Market Summary

### **Strong Revenue Growth**

*2016 Revenue – \$155.1M (20% constant currency growth)*

*2013-2016 – Consistent 15+% organic growth*

### **Open Ablation**

*\$770M+ market – 5+ years of strong growth*

### **Stand Alone Ablation**

*\$2B+ Market and trial key*

### **Clip**

*\$1B+ Market and growth accelerating*

### **Cryo A**

*NEW \$100M+ Pain-Management Market and growth accelerating*

### **International**

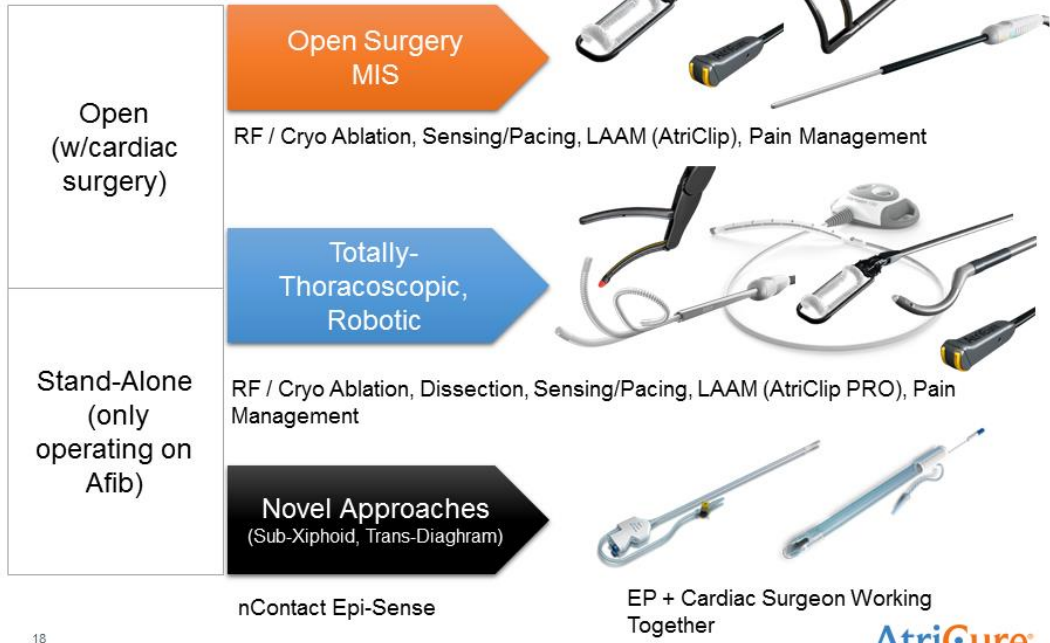
*New products*

*Market penetration*

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**AtriCure**

# Afib Solutions for Multiple Approaches



## Franchise / Business Overview

Focus Areas	2016 Full-Year Revenue	2015 Full-Year Revenue	Global Market Potential
OPEN Ablation (Concomitant)	\$58.0M US +8%	\$53.5M US +20%	\$770M Annually
OPEN Clip	\$20.4M US +17%	\$17.5M US +40%	\$275M+ Annually
MIS Ablation	\$31.2M US +44%	\$21.6M U.S. +34%	\$2B+ Annually
MIS Clip	\$9.9M US +43%	\$6.9M US +63%	\$850M+ Annually
International	\$32.7M +19% (19% CC)	\$27.5M +1% (13%CC)	Included above
Overall	\$155.1M +20% (+20%CC)	\$129.8M +21% (+24%CC)	<b>\$3.5B+ Annually</b>

2017 Guidance → 13% to 15%



## Franchise / Business Overview

Focus Areas	Products	Keys to Success	Trials/Data
OPEN Ablation (Concomitant)		<ul style="list-style-type: none"> <li>FDA PMA label for Afib (2011)</li> <li>Advanced Training – CABG/AVR/Fellowships</li> <li>Conversions and add-on sales - cryoFORM adoption</li> <li>Guideline changes w/ Societies</li> <li>Synergy II</li> </ul>	<ul style="list-style-type: none"> <li>Ablate = PMA</li> <li>PMA Post Approval Study (365 Patients)</li> <li>STS/Medicare retrospective studies</li> <li>Guidelines key – supporting many grants</li> </ul>
OPEN Clip		<ul style="list-style-type: none"> <li>Exclude trial (510k data)</li> <li>Continued education and awareness</li> <li>Tie to ablation growth</li> <li>New Clip in 2018</li> <li>ATLAS and other data</li> </ul>	<ul style="list-style-type: none"> <li>EXCLUDE Complete</li> <li>ATLAS - Enrolling</li> </ul>
MIS Ablation		<ul style="list-style-type: none"> <li>Trials – DEEP and CONVERGE</li> <li>Collaborative care</li> <li>Convergent growth</li> </ul>	<ul style="list-style-type: none"> <li>CONVERGE IDE</li> <li>DEEP IDE</li> </ul>
MIS Clip		<ul style="list-style-type: none"> <li>Awareness</li> <li>Trial</li> <li>Product expansion (Pro2, ProV)</li> </ul>	<ul style="list-style-type: none"> <li>Stroke Safety Feasibility Complete</li> <li>No trial planned</li> </ul>
International		<ul style="list-style-type: none"> <li>Product expansion in Asia</li> <li>Reimbursement in EU</li> <li>Sales team coverage</li> </ul>	<ul style="list-style-type: none"> <li>CEASE AF (DEEP for EU)</li> <li>HISTORIC AF (Complete)</li> <li>Several Clip registries</li> </ul>

**New Products, New Labels, More Education = Success**

# How do we develop these markets?

## Three Pillars + Execution

### Education & Awareness- Treat, Treat, Treat

*Guidelines, MAZE IV Courses, AATS Fellowships, Case Observations, Cardiology campaign*

### Clinical Trials and Data (Science)

*DEEP, CONVERGE, ATLAS, CEASE AF, FROST, PAS, TRAC AF, REGISTRIES*

### New Products and Approaches

*ProV, Pro2, ACHV, CryoA, nGen, Sub-X Ablation (EP), Sub-X Clip, Epi-Sense 2*



### New Markets and Regulatory Approvals

*Japan Clip and Cryo, China Clip and Cryo, UK Direct, France*

### Building and Fostering Great Talent

*Recruiting powerhouse/branding, on-boarding, on-going training*

# ATRC Company Overview

500+ AtriCure employees globally and growing:

Clinical: 15+ FTE's, in-sourcing trial work

R&D: 50+ FTE's across multiple US offices

Sales/Mkt: 150+ FTE's incl. sales support, and training/education

Intl: 30+ FTE's covering EU, Japan, China, and LA



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AtriCure®

# Robust Infrastructure

## Sales/Marketing

- Highly experienced sales and marketing team (US and International)
- 100+ employees supporting ~60 US sales territories, EU subsidiary and 30 countries
- Well established International network of independent distributors

## Education & Training

- Significant resources focus on physician education
- FDA-approved; STS and EACTS endorsed training program
- Education Steering Committee comprised of highly regarded KOL's
- Established strong network of revered physician trainers at prestigious institutions

AtriCure has established a strong infrastructure through investments in sales & marketing and education, which will drive superior growth going forward

# U.S. Commercial Sales Structure

	2012	Today	2016	2017
<b>COO</b>	0	1	1	1
<b>VPs</b>	1	2	2	2
<b>Area Directors</b>	7	11	11	12
<b>Regional Sales Manager (RSM)</b>	36	53	53	56
<b>Clinical/Ablation Specialist (ABS)</b>	13	39	48	53
<b>MIS or Other Specialist</b>	0	9	11	14
<b>Total</b>	57	115	126	138

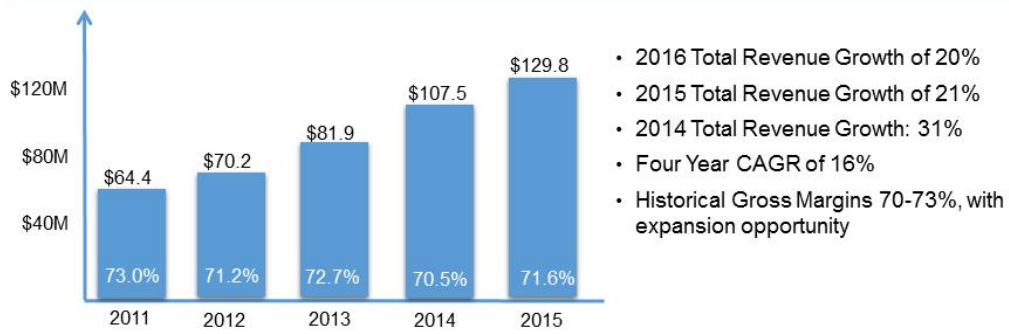
**Each Area Includes:**

- 5-6 Regional Sales Managers
- 4-6 Clinical Specialists
- 1-2 Minimally Invasive Manager(s)
- (New Area is created beyond this)

- Shifting headcount growth from RSMs to ABSs (Case Coverage)
- Allows RSM to spend time building relationships and selling broader adoption
- Onboarding and training of current team #1 priority

# Financial Snapshot

## Revenue and Gross Margin



## Balance Sheet and Share Statistics

- Approximately \$48 million in cash and investments at 9/30/2016
- Approximately 33.3 million shares outstanding; basic weighted average shares of 31.8 million for the quarter

## In 2017 We ...

- Are on the cusp of profitability
  - Expect \$4M to \$6M EBITDA loss for the year and
  - Committed to positive full year EBITDA profit for 2018
- Will serve over 65,000 patients and grow revenue 13% to 15%
  - Open will grow 5-10%
  - MIS and Clip will continue to see strong growth of over 20%
- Are ready to take advantage of all the new hires the past 24 months
- Have significant experience with our new products (Pro2, CryoForm)
  - ASP and volumes will go up ... helping improve margins
- Expect trial enrollment to kick-in and the end is in sight for a new label and more data

# AtriCure... Positioned for Success

## **Strong Foundation**

Products, Approvals, Brand, Education Platform, Trials and Science,  
International

+

## **Strong Revenue Base and Momentum**

Over 15% Organic Revenue Growth in 2013 - 2016

+

## **Key Investments and Execution**

Stroke and DEEP Trial, Cease AF, ATLAS, Education, Product innovation,  
Commercial Expansion

## **Will Lead To**

500,000 patients served by 2020  
Better patient care



**Thank You!**

# References

1. *Clinical Epidemiology* 2014.
2. *American Col of Card* 2013.
3. *Am J Card* 2013, 112: 1142-1147.
4. *Am J Card. Vol 87. June 1, 2001.*
5. *NIH Incidence Prevalence Chartbook 2006.*
6. *Circulation.* 2006;114:119-125.
7. Kim M, et al. *Circ Cardiovasc Qual Outcomes.* 2011; 4:313-320
8. 2012 HRS/EHRA/ECAS Expert Consensus Statement on Catheter and Surgical Ablation of Atrial Fibrillation
9. [www.StopAfib.org](http://www.StopAfib.org)
10. Meitz A, et al. *Europace.* 2008;10:674-680.
11. 2010-2013: STS Adult Cardiac Surgery Database
12. 2014-2020: MRG, iData, Medtech Insights, The Advisory Board Group

## Appendix – Afib information

# Atrial Fibrillation Overview

## Condition Overview

- Abnormal electrical impulses cause the upper chambers of the heart to quiver at rapid rates of 400 to 600 BPM
- Frequently associated with cardiovascular disease, in particular hypertension, congestive heart failure, coronary artery disease, etc.

## Types

- Paroxysmal: rapid heart rate begins and stops suddenly lasting 24 hours – 1 week
- Persistent: abnormal heart rate continuing for more than a week
- Permanent: normal heart rhythm can't be restored; often the result of paroxysmal and persistent Afib becoming more frequent

## Effects

- Causes blood in the atria to become static, increasing the risk of blood clot formation, stroke, and other serious complications
- Symptoms include heart palpitations, dizziness, fatigue and shortness of breath, and these symptoms can be debilitating / life threatening

## Continuum of Care

- Initial treatments include electrical cardioversion (shock to return heart to normal rhythm) and anticoagulant medicines such as warfarin
- If persistent, anticoagulants are augmented by rate-control medicines such as beta blockers
- When drugs fail, MIS catheter ablation and open-procedure surgical ablation are used to disrupt the electric impulses that cause Afib

# Afib Population: Large, Growing & Undertreated

Afib affects over 5 million in the U.S.<sup>(1)</sup>

- U.S. prevalence projected to grow to 12-15 million by 2050
- International prevalence is comparable to the U.S.
- Most common sustained cardiac arrhythmia<sup>(2)</sup>
- Lifetime risk of Afib: ~1 in 4 for adults ≥40 years of age<sup>(3)</sup>

Afib increases 5-fold the risk of stroke<sup>(4,5)</sup>

- Afib is leading cause of stroke – over 15% in U.S. linked to Afib<sup>(5)</sup>
- Afib results in early mortality and cause of stroke in elderly<sup>(4)</sup>
- Afib-related strokes are more severe<sup>(5)</sup>

Issues with non-surgical treatment of Afib

- Warfarin drug therapy has complications
- Anti-arrhythmic drugs often not well-tolerated and ineffective
- <3% of Afib patients are treated with catheter or surgical ablation

Significant costs to healthcare system

- Direct medical costs are ~73% higher in Afib patients<sup>(6)</sup>
- Net incremental cost of \$8,705 per patient per annum<sup>(6)</sup>
- U.S. annual incremental cost of Afib is ~\$26.0 billion<sup>(6)</sup>

(1) Miyasaka Y, et al. *Circulation*. 2006;114(2):119-125  
(2) Lloyd-Jones D, et al. [published online ahead of print December 17, 2009]. *Circulation*. doi:10.1161/CIRCULATIONAHA.109.192667.  
(3) Lloyd-Jones DM, et al. *Circulation*. 2004;110(3):1042-1046.

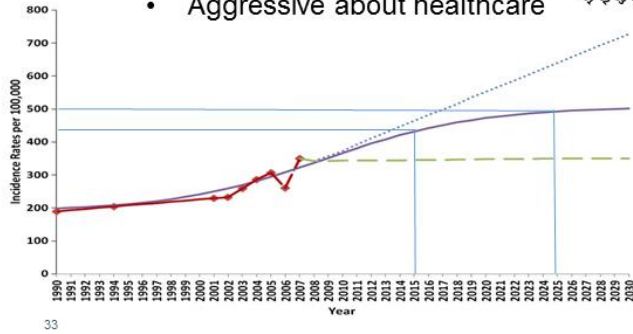
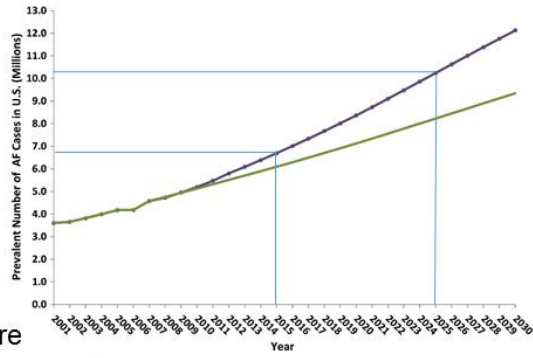
(4) Fuster V, et al. *J Am Coll Cardiol*. 2001;38(4):1231-1265  
(5) Benjamin EJ, et al. *Circulation*. 1998;98(10):946-952.  
(6) Kim M, et al. *Circ Cardiovasc Qual Outcomes*. 2011; 4:313-320

# U.S. Afib Prevalence and Incidence Projections

**33M** suffering from AF globally  
**15M** suffering from AF in Developed Countries

**6M+** suffering from AF in U.S. today → 10M+ in 2025

- Aging “Baby-boomers”
- Aggressive about healthcare

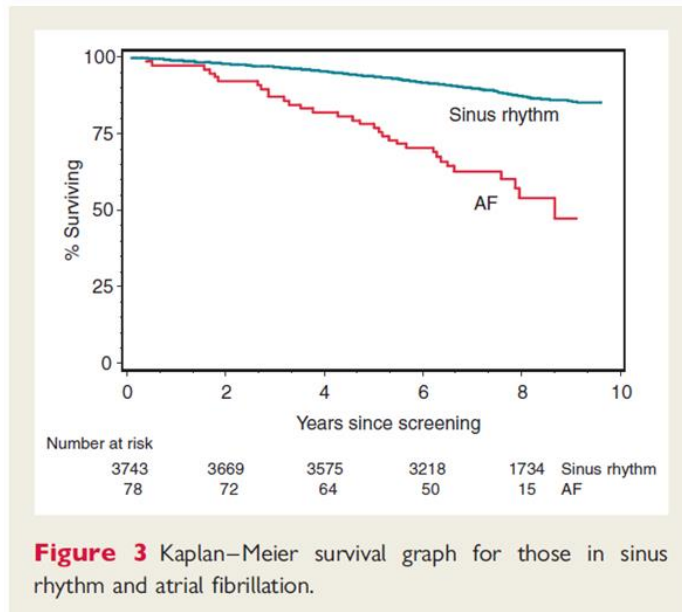


**1.2M+** new U.S. patients diagnosed with AF annually

*Am Journal of Cardiology* 2013, 112: 1142-1147  
*Clinical Epidemiology* 2014  
*American Col of Card* 2013  
*NIH Incidence Prevalence Chartbook* 2006.  
*Circulation*. 2006;114:119-125.)



# Afib Increases Mortality



**Figure 3** Kaplan–Meier survival graph for those in sinus rhythm and atrial fibrillation.

# Efficacy of Afib Ablation – Pivotal Trial

## The ABLATE Trial: Safety and Efficacy of Cox Maze-IV Using a Bipolar Radiofrequency Ablation System

Jonathan M. Philpott, MD, Christian W. Zemlin, PhD, James L. Cox, MD, Mack Stirling, MD, Michael Mack, MD, Robert L. Hooker, MD, Allen Morris, MD, David A. Heimansohn, MD, James Longoria, MD, Divyakant B. Gandhi, MD, and Patrick M. McCarthy, MD

Prospective, multi-center, randomized trial of 55 patient with Persistent & LS Persistent Afib undergoing Cardiac Surgery

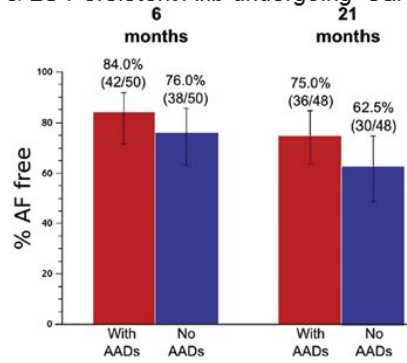


Fig 3. Efficacy endpoint results. Error bars indicate 95% confidence interval as computed by the Wilson score method. (AAD = antiarrhythmia drug; AF = atrial fibrillation.)



# Efficacy of Afib Ablation – Mitral Valve

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

## Surgical Ablation of Atrial Fibrillation during Mitral-Valve Surgery

A. Marc Gillinov, M.D., Annetine C. Gelijns, Ph.D., Michael K. Parides, Ph.D.,

Prospective, multi-center, randomized trial of 260 patients with Persistent & LS Persistent Afib undergoing Mitral Valve Surgery w/ or w/o AF ablation

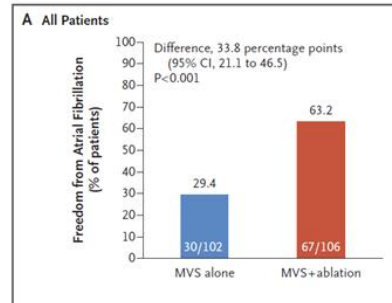
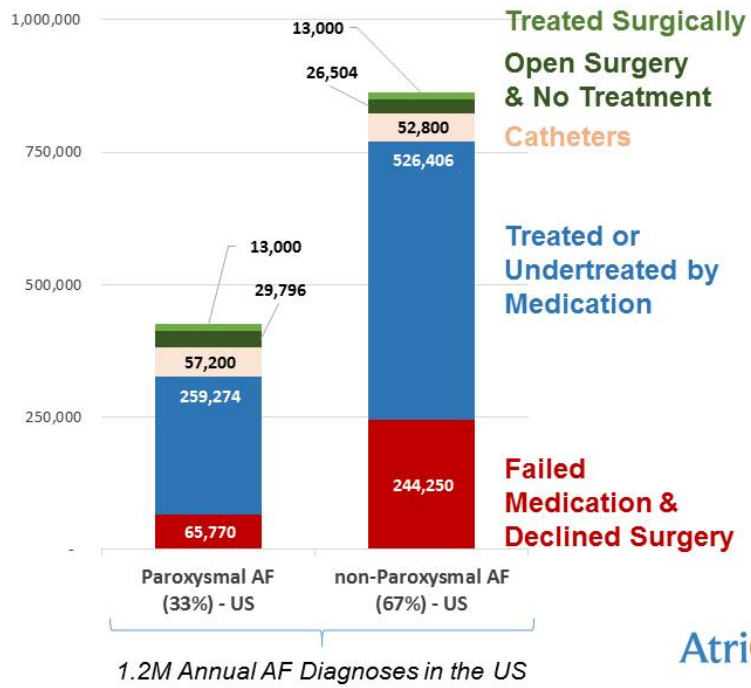


Figure 1. Freedom from Atrial Fibrillation.

Freedom from atrial fibrillation was defined as the absence of the condition at both 6 months and 12 months, as assessed by means of 3-day Holter monitoring. MVS denotes mitral-valve surgery, and PVI pulmonary-vein isolation.

# Treatment of Afib Patients in 2015



# Society Guidelines for Treatment of AF

Society	Recommendation
<b>STS (2016)</b> <sup>1</sup>	<i>Surgical ablation for AF can be performed without additional operative risk of mortality or major morbidity, and is recommended at the time of concomitant isolated aortic valve replacement, isolated coronary artery bypass graft surgery, and aortic valve replacement plus coronary artery bypass graft operations to restore sinus rhythm.</i>  <i>Surgical ablation for AF can be performed without additional operative risk of mortality or major morbidity, and is recommended at the time of concomitant mitral operations to restore sinus rhythm.</i>
<b>AHA/ACC/HRS (2014)</b> <sup>2</sup>	<i>An AF surgical ablation procedure is reasonable for selected patients with AF undergoing cardiac surgery for other indications.</i>  <i>A stand-alone AF surgical ablation procedure may be reasonable for selected patients with highly symptomatic AF not well managed with other approaches.</i>
<b>HRS/ACC/AHA/STS/EHRA/ECAS (2012)</b> <sup>3</sup>	<i>"It is advisable that all patients with documented AF referred for other cardiac surgeries undergo a left or biatrial procedure for AF at an experienced center, unless it...will add significant RISK..."</i>
<b>ISMICS (2009)</b> <sup>4</sup>	<i>"Concomitant surgical ablation is recommended .... to increase the incidence of sinus rhythm both at short- and long-term follow-up .... to improve ejection fraction and exercise tolerance .... to reduce the risk of stroke and thromboembolic events .... and to improve long-term survival."</i>
<b>UK NICE (2014)</b> <sup>5</sup>	<i>Surgical ablation of AF should be considered in patients with persistent AF, or with symptomatic AF undergoing cardiothoracic surgery.</i>
<b>ESC (2010)</b> <sup>6</sup>	<i>Surgical ablation of AF should be considered in patients with symptomatic or asymptomatic AF undergoing cardiac surgery.</i>  <i>Minimally invasive surgical ablation of AF without concomitant cardiac surgery is feasible and may be performed in patients with symptomatic AF after failure of catheter ablation</i>

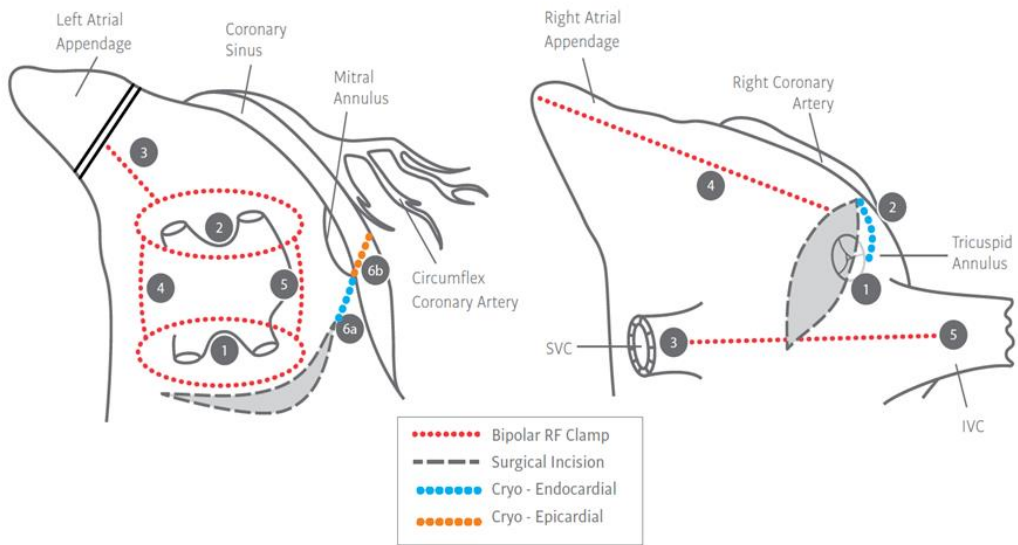
1. Badhwar et al.; Society of Thoracic Surgeons 2017 Clinical Practice Guidelines for the Surgical Treatment of Atrial Fibrillation, Ann Thorac Surg 2017;103:329-41
2. Craig et al.; 2014 AHA/ACC/HRS Guideline for the Management of Patients with Atrial Fibrillation, JACC. Vol 64, no 21. 2014
3. Calkins et al.; HRS/EHRA/ECAS Catheter and Surgical Ablation. Heart Rhythm, vol. 9, no 4, April 2012.
4. Ad et al.; Surgical ablation for atrial fibrillation in cardiac surgery. Innovations, vol 5, no 2, March/April 2010.
5. National Institute for Health and Care Excellence. Atrial fibrillation: management, clinical guideline. June 18, 2014.
6. Camm et al.; Guidelines for the management of atrial fibrillation. European Heart Journal, 2010.

# Society Guidelines for LAAM

Society	Recommendation
STS (2016) <sup>1</sup>	<i>It is reasonable to perform left atrial appendage excision or exclusion in conjunction with surgical ablation for AF for longitudinal thromboembolic morbidity prevention.</i>
AHA/ACC/HRS (2014) <sup>2</sup>	<i>Surgical excision of the left atrial appendage may be considered in patients undergoing cardiac surgery.</i>
UK NICE (2014) <sup>3</sup>	<i>Consider LAA occlusion if anticoagulation is contraindicated or not tolerated and discuss the benefits and risks of LAAO with patient.</i>
EJCTS (2013) <sup>4</sup>	<i>We conclude that there has been no proven benefit of surgical LAA exclusion in terms of stroke reduction or mortality benefit... If exclusion is contemplated, devices designed for appendage exclusion should be used rather than a cut-and-sew or stapling technique.</i>
EHRA/EAPCI <sup>5,6</sup>	<i>OAC (with VKA or NOACs) is the standard therapy; however, for patients who are contraindicated or refuse (N) OACs... the main indication for LAA occlusion is a relative or absolute contraindication to (N)OACs in patients with AF and a CHADS2 score of <math>\geq 1</math> or CHA2-DS2-VASc score <math>\geq 2</math></i>

1. Badhwar et al.; Society of Thoracic Surgeons 2017 Clinical Practice Guidelines for the Surgical Treatment of Atrial Fibrillation, Ann Thorac Surg 2017;103:329-41
2. January et al.; AHA/ACC/HRS Atrial Fibrillation Guideline, JACC Vol 64, no. 21, December 2, 2014.
3. National Institute for Health and Care Excellence. Atrial fibrillation: management, clinical guideline. June 18, 2014.
4. Dunning et al.; Guideline for the surgical treatment of atrial fibrillation. European Journal of Cardio-Thoracic Surgery. Vol 44. 2013.
5. Meier et al.; EHRA/EAPCI expert consensus statement on catheter-based left atrial appendage occlusion. EuroIntervention. 2014
6. Thambo et al.; The future of left atrial appendage occlusions: When extraordinary claims require evidence... Archives of Cardiovascular Disease 2015 vol 108.

# Maze IV Procedure



# DEEP Pivotal Study

## Objective

**Establish the safety and effectiveness of a dual epicardial and endocardial ablation procedure** for patients presenting with Persistent Atrial Fibrillation or Longstanding Persistent Atrial Fibrillation utilizing the AtriCure Bipolar System and AtriClip® PRO LAA Exclusion System in an endoscopic or open ablation procedure, followed by an endocardial mapping and ablation procedure utilizing commercially available RF based, irrigated, power controlled, ablation catheters for endocardial lesions.

## Study Design

**Study Design:** Prospective, multicenter, single arm, pivotal study

**Number of Subjects and Sites:** Up to 220 subjects / up to 25 sites (23 US and 2 OUS)

**Study Duration:** 5 year follow-up of all subjects

**Study Status:** Enrolling

## Key Criteria

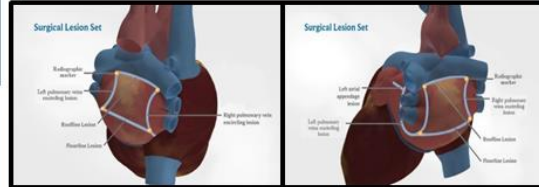
**Key Inclusion Criteria:** Patient is >18 years of age and < 75 years of age at time of consent. Patient has symptomatic (e.g. palpitations, shortness of breath, fatigue) Persistent Atrial Fibrillation or Longstanding Persistent Atrial Fibrillation refractory to a minimum of one Class I or Class III AADs.

**Key Exclusion Criteria:** Patient has a documented history of AF >10 years. Patient has had an EP catheter ablation procedure to treat atrial fibrillation within 6 months prior to signing consent.

## Primary Endpoints

**Effectiveness:** The primary effectiveness endpoint is freedom from any documented AF, atrial flutter, or atrial tachycardia lasting >30 seconds duration through the 12 month follow-up visit in the absence of Class I or III AADs (with the exception of previously failed AADs at doses not exceeding those previously failed).

**Safety:** The primary safety endpoint is 19% freedom from MAE's adjudicated by the CEC related to the AtriCure Bipolar System, the AtriClip Pro LAA Exclusion System, within 30 days of the epicardial surgical ablation procedure, or within 7 days of the index endocardial procedure, or within 7 days after a repeat endocardial procedure within the blanking period.



AtriCure®



# CONVERGE Pivotal Study

## Objective

Evaluate the safety and efficacy of the nContact Epi-Sense Guided Coagulation System to treat Symptomatic Persistent AF patients, refractory or intolerant to at least one Class I and/or III AADs.

## Study Design

**Study Design:** Multi-center, prospective, open label randomized 2:1 (Convergent procedure vs endocardial catheter ablation) pivotal study

**Number of Subjects and Sites:** Up to 153 subjects / up to 17 sites (15 US and 2 OUS)

**Study Duration:** 5 year follow-up of all subjects

**Study Status:** Enrolling

## Key Criteria

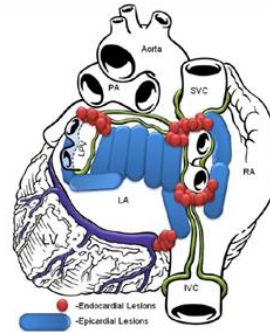
**Key Inclusion Criteria:** Patient is >18 years; < 80 years. Patient has a left atrium  $\leq$  6.0cm. Patient is refractory or intolerant to one AAD (class I and/or III). Patient has documentation of persistent AF.

**Key Exclusion Criteria:** Patients requiring concomitant surgery such as valvular repair or replacement, coronary artery bypass graft (CABG) surgery and atrial septal defect closure. Patients who have had a previous left atrial catheter ablation for AF (does not include ablation for AFL or other supraventricular arrhythmias).

## Primary Endpoints

**Effectiveness:** The primary efficacy endpoint is success or failure to be AF/AT/AFL free absent class I and III AADs except for a previously failed or intolerant class I or III AAD with no increase in dosage following the 3 month blanking period through the 12 months post procedure follow-up visit.

**Safety:** The primary safety endpoint for the study is 12% freedom from MAE's as adjudicated by the CEC for the procedural to 30 day post procedure time period.



AtriCure®