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## AtriCure (ATRC): Addressing the Sell-Side Response

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*“Well, you know what I say: Never trust a man with two first names...”*  
*– Joel Hodgson, Mystery Science Theater 3000*

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AtriCure chose not to provide a response to our initial report, apart from a short email statement to Bloomberg that it “contained unfounded, misleading claims.” We take this lack of detailed response to indicate that the Company prefers to avoid drawing further attention to the issues we outlined in our original report.

As of Friday, 7 of the 8 analysts covering the Company have also chosen to remain silent, while one has decided to stick his neck out in a poorly constructed, single page defense of the Company. We are aware that this morning, an additional firm has put out a defense, yet we have yet to review it. We stand by our initial research and remain short AtriCure.

### Safety of “Minimally Invasive” Surgeries and Adverse Events

The analyst’s emphasis on differentiation between device malfunction and procedural error cleverly avoids tackling the key issue we highlighted in our initial report: “minimally invasive” surgeries pushed by AtriCure’s “Starting Five” are prone to errors and complications not only due to the devices used, but due to the nature of the “minimally invasive” surgery.

We believe that choosing to focus on the MDR database as a “more accurate reflection of device-related issues” is akin to focusing on the number of times a hammer “malfunctioned” while being used as a cleaning tool in a China shop. Separately, we believe it’s illogical to disregard data reported by the numerous physicians utilizing these devices in the MAUDE database and solely focus on company reported data.

Investors who wish to dig into the granular detail provided by [the MAUDE database](#) can easily do so. We expect they will find plenty of detail, including causation and differentiation between physician error and device malfunction. To classify it as “unreliable source of information with no details around causation of material adverse events required or provided” is puzzling. To that end, we’ve provided several event descriptions in the table below, as well as the associated comments, if available, of the renowned cardiologist we consulted who provided his opinions on these events. Note that in some cases, we’ve shortened descriptions for brevity due to the sheer lengthiness of the details included:

Date	Device	Report Number, Event Description, and Cardiologist Comment
2/21/19	Epi-Sense	3011706110-2019-00010  IT WAS REPORTED THAT A (B)(6) MALE PATIENT WITH AN EJECTION FRACTION OF 30% UNDERWENT A CONVERGENT PROCEDURE IN 2018. THERE WAS NO REPORTED PROCEDURAL COMPLICATION OR DEVICE MALFUNCTION AT THE TIME OF THE PROCEDURE. THE PATIENT WAS REVIEWED ONE-MONTH POST PROCEDURE AND WAS ASSESSED AS DOING WELL. THREE MONTHS POST-PROCEDURE PATIENT COMPLAINED

		<p>OF CHEST PAINS AND NOT FEELING WELL. <b><u>AN ECG DONE AT THAT TIME, REVEALED THAT HE WAS IN NORMAL SINUS RHYTHM BUT WAS ASSESSED AS HAVING DRESSLER'S SYNDROME AND WAS ADMITTED TO THE HOSPITAL ON THAT VISIT.</u></b> AN MRI WAS PERFORMED WHICH REVEALED A MODERATE PERICARDIAL EFFUSION AND THERE WAS NO EVIDENCE OF CARDIAC TAMPONADE. A PERICARDIAL TAP WAS PERFORMED, AND 425CC OF BLOOD-STAINED FLUID WAS DRAINED. THE PATIENT WAS ADMITTED TO THE HOSPITAL FOR 3 DAYS AND WAS DISCHARGED HOME IN A STABLE CONDITION. FOUR DAYS POST DISCHARGE, THE SURGEON WAS TOLD BY THE PATIENT'S WIFE THAT HER HUSBAND COLLAPSED AND DIED THAT SAME DAY (B)(6) 2019. <b><u>THE CORONER STATED THAT THE PATIENT HAD A SUDDEN CARDIAC DEATH. CAUSE OF THE SUDDEN CARDIAC DEATH WAS NOT COMMUNICATED AND AN AUTOPSY WAS NOT PERFORMED. THIS EVENT IS A PROCEDURE RELATED COMPLICATION.</u></b> THERE WAS NO REPORTED DEVICE MALFUNCTION. Manufacturer Narrative: (B)(4): THE DEVICE WAS NOT RETURNED FOR EVALUATION AND A DEVICE HISTORY REVIEW WAS UNABLE TO BE COMPLETED AS THE RELEVANT LOT NUMBER FOR THE EPI-SENSE DEVICE WAS NOT REPORTED OR ABLE TO BE SUBSEQUENTLY ASCERTAINED. THE COMPLAINT COULD NOT BE CONFIRMED. THERE WERE NO PROCEDURAL REPORTED DEVICE MALFUNCTIONS OR COMPLICATIONS.</p> <p><b><u>Cardiologist comment:</u></b> <i>direct consequence of surgical procedure</i></p>
8/14/18	Epi-Sense	<p>3011706110-2018-00196</p> <p>ON (B)(6) 2018 A (B)(6) YEAR OLD MALE UNDERWENT A SAME DAY, OFF PUMP EPICARDIAL AND ENDOCARDIAL CONVERGENT PROCEDURE. ON (B)(6) 2018 IT WAS REPORTED THAT THE PATIENT HAD PRESENTED TO THE ER WITH MULTIPLE STROKES AND CEREBRAL AIR EMBOLISM AS DIAGNOSED, BASED ON AN MRI DONE AT ANOTHER HOSPITAL. TWO CT SCANS DONE AT (B)(6) SUBSEQUENT TO THE MRI AT THE INITIAL ADMITTING HOSPITAL DID NOT CONFIRM THE DIAGNOSIS HOWEVER, A THIRD CT SCAN CONFIRMED THE ORIGINAL DIAGNOSIS DENSE STROKE AND SIGNS AND SYMPTOMS SUGGESTIVE OF AN ATRIO-ESOPHAGEAL FISTULA, NOW INTUBATED AND BEING VENTILATED. THE PATIENT IS CURRENTLY ADMITTED TO (B)(6) WITH AN ESOPHAGEAL STENT PLACED. NEUROLOGICALLY THE PATIENT HAS BEEN ASSESSED AS HAVING A DENSE STROKE AND CONSIDERED NOT A GOOD CANDIDATE FOR SURGERY. THERE ARE NO PLANS FOR IMMEDIATE OPERATION HE IS NOW BEING TREATED CONSERVATIVELY. Manufacturer Narrative: (B)(4) INFORMATION WAS RECEIVED THAT PATIENT WAS MOVED TO HOSPICE, EXPIRED ON (B)(6) 2018.</p> <p><b><u>Cardiologist Comment:</u></b> <i>Wow, terrible outcome from a procedural complication</i></p>
1/4/18	Bipolar System (incl. add'l devices)	<p>3011706110-2018-00112</p> <p>ON (B)(6) 2017, A (B)(6) MALE PATIENT RECEIVED A TOTALLY THORACOSCOPIC VATS/MAZE PROCEDURE USING AN ABLATION SYSTEM WITH AN ISOLATOR SYNERGY CLAMP (EMR2) ... AFTER THE SIXTH (6) LESION WAS CREATED, THE CLAMP WAS RELEASED AND THERE WAS VISIBLE BLEEDING. THE TISSUE WAS PERFORATED; THE</p>

		<p>HOLE WAS ON THE ANTERIOR SIDE OF THE RIGHT PULMONARY VEIN. THE SURGICAL TEAM QUICKLY CONVERTED THE PROCEDURE TO A STERNOTOMY, CONTROLLED THE BLEEDING, AND PROCEEDED WITH THE SURGERY AS AN ON-PUMP ASSIST WITHOUT ARRESTING THE HEART. THE SURGEON COMPLETED THE LESION SET AND THE PROCEDURE WAS PROLONGED FOR TWO HOURS. AS OF (B)(6) 2017, THE PATIENT WAS IN STABLE CONDITION. THERE WAS NO REPORTED DEVICE MALFUNCTION WITH THIS PROCEDURE ... ON (B)(6) 2017, THE PATIENT HAD A STROKE. THE PATIENT THEN DEVELOPED PNEUMONIA, HAD OTHER UNSPECIFIED COMPLICATIONS AND DIED (B)(6) 2017.</p> <p><b>Cardiologist Comment:</b> <i>surgical complication requiring conversion from minimally invasive to sternotomy (full chest incision)</i></p>
1/4/18	Epi-Sense	<p>3011706110-2018-00111</p> <p>ON (B)(6) 2017, A (B)(6) FEMALE UNDERWENT A STAGED CONVERGENT PROCEDURE WITH THE SUB-XIPHOID APPROACH WITH THE EP PORTION TO BE DONE LATER ... DAY 2 POST OP, THE PATIENT BECAME HYPOTENSIVE, HYPOXIC, AND IMAGING SHOWED A RIGHT PLEURAL EFFUSION AND WAS INTUBATED. FOR THE NEXT COUPLE OF DAYS, PATIENT REMAINED UNSTABLE REQUIRING INOTROPIC SUPPORT, BLOOD RESULTS REVEALED ELEVATED WBCS AND SHOWED SIGNS OF SEPSIS. DAY 7 POST OP, A CT SCAN WITH PO CONTRAST SHOWED ESOPHAGEAL PERFORATION. THE PATIENT UNDERWENT EXPLORATORY THORACOTOMY. THE ESOPHAGOSCOPY FINDINGS WERE A FULL THICKNESS NECROSIS OF THE ESOPHAGUS. THE MICROSCOPY FINDINGS WERE A SEGMENT OF ESOPHAGUS WITH TRANSMURAL NECROSIS, ACUTE AND CHRONIC INFLAMMATION, AND EPITHELIAL REACTIVE CHANGES. <b><u>DAY 9 POST OP, THE PATIENT BECAME BRADYCARDIC AND DIED. THERE WERE NO PRODUCT MALFUNCTIONS, THIS WAS A PROCEDURAL COMPLICATION.</u></b></p>
12/12/17	Epi-Sense	<p>3011706110-2017-00104</p> <p>ON (B)(6) 2017, A (B)(6) MALE PATIENT RECEIVED AN OFF-PUMP CONVERGENT EPICARDIAL/ENDOCARDIAL ABLATION PROCEDURE USING AN EPISENSE GUIDED COAGULATION SYSTEM (CDK-1413) AND THE PATIENT WAS DISCHARGED ON (B)(6) 2017. ON (B)(6) 2017, THE PATIENT PRESENTED TO THE ER WITH SHORTNESS OF BREATH, PERIPHERAL EDEMA AND CHEST PAIN. THE PATIENT'S CHEST X-RAY WAS CLEAR WITH NO PLEURAL EFFUSION. <b><u>HOWEVER, A CT SCAN PERFORMED REVEALED SMALL LEFT AND TRACE RIGHT PLEURAL EFFUSION, WITH SMALL PERICARDIAL EFFUSION.</u></b> THE PATIENT WAS PLACED UNDER OBSERVATION, TREATED WITH AN IV DIURETIC AND DISCHARGED WITH MAJOR IMPROVEMENT IN CONDITION. ON (B)(6) 2017, AN ECHO PERFORMED ON THE PATIENT SHOWED NO PERICARDIAL OR PLEURAL EFFUSION. <b><u>ON (B)(6) 2017, THE PATIENT RETURNED TO HIS PRIMARY CARE PHYSICIAN WHO REPORTED AN EF 55%, AND THE PATIENT WAS DIRECTED TO CONSULT WITH THE CARDIAC SURGEON ON ADMINISTRATION OF MEDICINE.</u></b> THE DIURETIC WAS INCREASED TO 80MG FOR THE DAY, AND THEN RETURNED TO 40MG/DAY. ON (B)(6) 2017, THE PATIENT RETURNED TO THE ER PRESENTING WITH</p>

		AFIB AND CHF EXACERBATION. HIS WHITE CELL BLOOD COUNT WAS 19.7 AND CHEST X-RAY INDICATED HIS LUNGS WERE CLEAR AND UNREMARKABLE. THE PATIENT WAS KEPT IN THE HOSPITAL OVERNIGHT FOR OBSERVATION. <b><u>ON (B)(6) 2017, WHILE BEING PREPARED FOR CARIOVERSION, THE PATIENT STOPPED BREATHING, LOST PULSE, AND WAS UNRESPONSIVE. AFTER UNSUCCESSFUL ATTEMPTS AT REVIVING, THE PATIENT PASSED AWAY ON (B)(6) 2017.</u></b>
9/14/17	Epi-Sense	3011706110-2017-00080  A (B)(6) MALE PATIENT RECEIVED A STAGED CONVERGENT SUBXIPHOID PROCEDURE PERFORMED ON (B)(6) 2017. THE PATIENT HAD A NORMAL LV SYSTOLIC FUNCTION WITH NORMAL EF. HIS EF WAS 55-60% IN (B)(6) 2017 AND 65-70% ON THE ECHOS THAT HE HAD DONE WHEN HE WAS IN THE HOSPITAL AFTER THE CONVERGENCE PROCEDURE. HIS MITRAL VALVE WAS NORMAL IN THE (B)(6) 2017 ECHO. ANTI-COAGULATION THERAPY WAS ADMINISTERED DURING THE INITIAL PROCEDURE AND THE ACT WAS MEASURED. THE EP PORTION OF THE PROCEDURE WAS NOT PERFORMED. THE PATIENT HAD RENAL FAILURE POST-PROCEDURE. CREATININE LEVELS WERE MEASURED AT BASELINE OF 2.1 AND ELEVATED TO 7.2. THE PATIENT CODED SIX (6) DAYS POST-OPERATION AND WAS REVIVED. <b><u>A LARGE PERICARDIAL EFFUSION WAS DIAGNOSED ON AN ECHO AND PATIENT WAS SCHEDULED TO HAVE A WINDOW, BUT EXPIRED PRIOR TO SURGERY.</u></b> A CHEST X-RAY WAS DONE AND DID NOT SHOW ANY SIGNIFICANT PLEURAL EFFUSION. THE PATIENT DIED SIX (6) DAYS POST-OPERATION WHILE STILL IN THE HOSPITAL ON (B)(6) 2017. NO DEVICE MALFUNCTION WAS REPORTED DURING THE PROCEDURE.
10/7/16	Epi-Sense	3003502395-2016-00129  PATIENT HAD SURGERY ON (B)(6) 2016, OF A CONVERGENT PROCEDURE. THE SURGICAL APPROACH WAS TRANSDIAPHRAGMATIC AND THE EP USED A CRYO BALLOON FOR PVI. THE PATIENT WAS APPARENTLY FINE FOR A WEEK AND BEGAN FEELING BAD FOR FOUR DAYS BEFORE HE CALLED THE OFFICE ON (B)(6) 2016 AND DIED LATER THAT DAY. THE ECHO THAT WAS DONE BEFORE THEY PULLED THE DRAIN SHOWED NO PERICARDIAL EFFUSION. <b><u>THE OFFICIAL CORONER CAUSE OF DEATH IS PULMONARY EMBOLISM.</u></b>

## Off-Label Promotion

The analyst characterized AtriCure's physician training as "a prudent strategy, which is completely certified in practice." We believe this mis-characterizes our initial report, which highlighted multiple examples of AtriCure-sponsored presentations given by Dr. Makati through the years where off-label usage is apparently being promoted. See again below:

# Achieving Optimal Outcomes for Persistent Atrial Fibrillation Patients through Hybrid Ablation

This activity is supported through an educational grant from:

**AtriCure**

Joint Providership:

**MediaSphere Medical and Ciné-Med**

## Improving Persistent AF Ablation Outcomes through a Multidisciplinary Approach

This activity is supported through an educational grant from:

**AtriCure**

Joint Providership:

**MediaSphere Medical and Cine-Med**

"This program is not part of the Heart Rhythm 2017 Official Scientific Sessions as planned by the Heart Rhythm Society Scientific Sessions Program Committee. The event is neither sponsored nor endorsed by the Heart Rhythm Society"

We take no issue with the Company training doctors on how to use its devices, so long as this training pertains to FDA-approved indications for that device.

### Physician Payments

On the topic of physician payments, the analyst states that "a key misinterpretation of this dataset is that the reason for payment is missing," yet himself fails to offer a reason for payments. To that end, we question whether the analyst spent much time in the Open Payments database, because the deeper one looks at these payments, the less favorable that AtriCure appears.

In 2018, AtriCure's "consulting" payments (of which 1,077 were made) totaled \$2.7 million, while education payments (of which 59 were made) totaled \$4,977 (no, we're not missing any commas). Data also indicate that \$2.1 million of the \$3.6 million of payments made in 2018 were associated with the Epi-Sense system. Of the Company's \$2.7 million in consulting payments, \$1.8 million were associated with the Epi-Sense system:

AtriCure 2018 General Payments	Amount	AtriCure 2018 Consulting Payments	Amount
Epi-Sense	\$2,116,419	Epi-Sense	\$1,774,290
Left Blank	\$631,988	Left Blank	\$439,099
All Other	\$845,326	All Other	\$500,859
Total General Payments	\$3,593,733	Total Consulting Payments	\$2,714,248
Epi-Sense % of Total	59%	Epi-Sense % of Total	65%

Against these figures, the Company's minimally invasive segment revenues in the US were just \$35 million in 2018, or 22% of total US revenues. Moreover, the Company also sells the Isolator Synergy Access Clamp, Fusion System, and Subtle System, among other products in this segment. Thus, we estimate that Epi-Sense sales were no more than one-third of this segment's revenues, or just 7% of total US revenues.

AtriCure 2018 US Revenues	\$ Mil	Minimally Invasive Offerings	\$ Mil (est)
Open Ablation	72.3	Isolator Synergy Access Clamp	14.0
Minimally Invasive Solutions	35.1	COBRA Fusion, Suble, All Others	9.3
Appendage Management	52.9	Epi-Sense Guided Coagulation	11.7
Valve Tools	2.0	Total Minimally Invasive	35.1
Total US Revenues	162.1	Epi-Sense as % of US Revenues	7%

We find it troubling that AtriCure pays such a robust level of consulting payments related to a device that both (1) remains unapproved by the FDA for the treatment of Afib, and (2) is responsible for a relatively minor portion of the Company's revenues. Note that investors are unable to explain these figures as being related to CONVERGE, as they exclude research payments, which totaled \$1.3 million in 2018. Perhaps the analyst can take another shot at offering his own interpretation of this more detailed payment data.

Broadly, we raised three additional issues in our initial report that remain unaddressed:

1. One of the Company's own physician spokespersons stated that a portion of AtriCure's customer base is double billing for minimally-invasive hybrid procedures, which we've confirmed in the original report.
2. Surgeons who are highly-paid by AtriCure are marketing surgical ablation procedures directly to patients, hence subverting EP-based lines of treatment. We are yet to receive clarification on true ownership of [www.wolfminimize.com](http://www.wolfminimize.com), as well as the source of the anonymous donation to the "American Foundation for Women's Health" otherwise d/b/a [www.StopAfib.org](http://www.StopAfib.org).
3. The Company remains under DOJ investigation and has received a Civil Investigative Demand.
4. Over the past several years, AtriCure has guided to profitability several times, yet continues to burn cash and thus rely on the capital markets.

We remain short AtriCure.