

AtriCure, Inc.  
Form S-3/A  
July 17, 2007  
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As filed with the Securities and Exchange Commission on July 17, 2007

Registration No. 333-144126

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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**AMENDMENT NO. 1**  
**TO**  
**FORM S-3**  
**REGISTRATION STATEMENT**

*UNDER*

*THE SECURITIES ACT OF 1933*

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**AtriCure, Inc.**

(Exact name of Registrant as specified in its charter)

**Delaware**  
(State or Other Jurisdiction of  
Incorporation or Organization)

**3841**  
(Primary Standard Industrial  
Classification Code Number)

**34-1940305**  
(I.R.S. Employer  
Identification Number)

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6033 Schumacher Park Drive

West Chester, OH 45069

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(513) 755-4100

(Address, including zip code, and telephone number, including area code, of Registrant's principal executive offices)

---

David J. Drachman

President and Chief Executive Officer

AtriCure, Inc.

6033 Schumacher Park Drive

West Chester, OH 45069

(513) 755-4100

(Name, address, including zip code, and telephone number, including area code, of agent for service)

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*Copies to:*

Theodore L. Polin

Epstein Becker & Green, P.C.

250 Park Avenue

New York, New York 10177

(212) 351-4500

David J. Drachman

President and Chief Executive Officer

AtriCure, Inc.

6033 Schumacher Park Drive

West Chester, OH 45069

(513) 755-4100

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**Approximate date of commencement of proposed sale to the public:** As soon as practicable after this Registration Statement becomes effective.

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If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box. "

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box. x

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. "

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. "

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box. "

## Edgar Filing: AtriCure, Inc. - Form S-3/A

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box. "

If delivery of the prospectus is expected to be made pursuant to Rule 434, check the following box. "

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**The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to Section 8(a), may determine.**

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**The information in this preliminary prospectus is not complete and may be changed without notice. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities, and it is not soliciting an offer to buy these securities, in any jurisdiction where the offer or sale is not permitted.**

**Subject to Completion, dated July 17, 2007**

**PRELIMINARY PROSPECTUS**

**1,789,649 Shares**

**AtriCure, Inc.**

**Common Stock**

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This prospectus relates to the offer for resale, from time to time, by the Selling Stockholders named in this prospectus of up to 1,789,649 shares of our common stock. See **Selling Stockholders** beginning on page 26 for a list of the Selling Stockholders.

You should read this prospectus and any prospectus supplement, as well as the documents incorporated or deemed to be incorporated by reference in this prospectus, carefully before you invest.

The prices at which the Selling Stockholders may sell the shares in this offering will be determined by the prevailing market price for the shares or in negotiated transactions. We will not receive any of the proceeds from the sale of the shares.

Our common stock is traded on The Nasdaq Global Market under the symbol **ATRC**. On July 16, 2007, the last reported sale price of our common stock as reported on Nasdaq was \$9.37 per share.

**Investing in our common stock involves a high degree of risk. Before buying any securities, you should read the discussion of material risks of investing in our securities in Risk Factors beginning on page 3 of this prospectus.**

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.**

**This prospectus may not be used to consummate sales of securities unless accompanied by the applicable prospectus supplement.**

The date of this prospectus is \_\_\_\_\_, 2007

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AtriCure is a registered trademark of AtriCure, Inc. All other service marks, trademarks and trade names referred to in this prospectus are the property of their respective owners.

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**PROSPECTUS SUMMARY**

*This summary highlights selected information appearing elsewhere or incorporated by reference in this prospectus and may not contain all the information that is important to you. This prospectus includes information about the securities we are offering as well as information regarding our business and detailed financial data. You should carefully read this prospectus and the registration statement of which this prospectus is a part in their entirety before investing in our common stock, including the section entitled Risk Factors, and the information incorporated by reference in this prospectus. As used in this prospectus, the words our company, we, us, our or AtriCure refer to AtriCure, Inc., unless the context requires otherwise.*

**BUSINESS SUMMARY**

We develop, manufacture and sell innovative surgical devices designed to create precise lesions, or scars, in cardiac and soft tissues. Our primary product line is our AtriCure Isolator<sup>®</sup> bipolar ablation system. Our Isolator<sup>®</sup> system consists of a compact power generator that uses our proprietary software and delivers bipolar radio-frequency energy, multiple configurations of our Isolator<sup>®</sup> bipolar ablation clamps and our multifunctional bipolar Pen. We sell two configurations of our Isolator<sup>®</sup> clamps, one designed for ablation during open-body, or open, procedures and one designed for ablation during minimally invasive procedures, which are performed on patients who are not undergoing a separate open procedure.

Medical journals have described the adoption by leading cardiothoracic surgeons of our Isolator<sup>®</sup> clamps as a treatment alternative during open-heart surgical procedures to create lesions in cardiac tissue to block the abnormal electrical impulses that cause atrial fibrillation, or AF, a rapid, irregular quivering of the upper chambers of the heart. Additionally, leading cardiothoracic surgeons have described our Isolator<sup>®</sup> clamps as a promising treatment alternative for patients who may be candidates for minimally invasive sole-therapy procedures.

During the third quarter of 2006, we released Isolator<sup>®</sup> clamps designed for ablation during open procedures, which feature an ergonomic design that improves the surgeon's access to key anatomical structures and simplifies the ablation procedure. During the first quarter of 2007, we introduced the new Isolator Synergy ablation clamps designed for ablation during open procedures, which are the next generation of our Isolator<sup>®</sup> clamps for open procedures. Our Isolator<sup>®</sup> clamps have been cleared by the Food and Drug Administration, or FDA, for the ablation of cardiac and soft tissues, but have not been approved by the FDA for the treatment of AF.

We also sell a pen-shaped ablation device known as the multifunctional bipolar Pen, which has been cleared by the FDA for the surgical ablation of cardiac tissue and for temporary pacing, sensing, stimulating and recording during the evaluation of cardiac arrhythmias, but has not been approved by the FDA for the treatment of AF. Because of its broad range of capabilities, surgeons are using this device during both open-heart and minimally invasive sole-therapy procedures in combination with our Isolator<sup>®</sup> clamps. We released the Pen for sale in the third quarter of 2005.

Additionally, we are developing the Cosgrove-Gillinov Left Atrial Appendage Occlusion Clip, which is designed to exclude the left atrial appendage, the small appendage that is attached to the left atrium, during open-heart surgical procedures and which may also be used to provide an option for high risk patients as a stand-alone left atrial appendage exclusion procedure following catheter ablation or pacemaker implantation. During the first quarter of 2007, we filed with the FDA a 510(k) notification for the Clip for an indication that includes left atrial appendage exclusion.

In September 2006, we expanded our CE Mark indications and received approval to market our Isolator<sup>®</sup> clamps for the treatment of cardiac arrhythmias, including atrial fibrillation. Our Isolator<sup>®</sup> clamps are the only bipolar radiofrequency clamps that are approved for this indication in the European Union.

From our inception in November 2000 through the first half of 2002, our operations consisted primarily of development-stage activities, including the development of our Isolator<sup>®</sup> clamps, raising capital, obtaining product clearances, conducting product testing and evaluations, and recruiting personnel. After limited sales of our Isolator<sup>®</sup> clamps in 2002, we commenced the general commercial release of our clamps designed for open procedures in January 2003.

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We currently sell our Isolator<sup>®</sup> system to customers in the United States primarily through our direct sales force. Our European subsidiary, based in the Netherlands, markets and sells our products throughout Europe, primarily through distributors. Additionally, we sell our products to other international distributors, primarily in Asia, Europe, Central America, South America, Canada and the Middle East. Our business is primarily transacted in U.S. dollars, with the exception of transactions with our European subsidiary, which are primarily transacted in Euros. Our sales outside of the United States were approximately 11% and 10% of our total revenues for the three months ended March 31, 2007 and March 31, 2006, respectively. We expect international sales to be relatively constant as a percentage of total sales for the foreseeable future.

None of our products have been approved by the FDA for the treatment of AF. However, substantially all of our revenues are currently generated through the off-label use of our Isolator<sup>®</sup> system for the treatment of AF. While the FDA does not prevent doctors from using products off-label, we cannot legally market a product for an off-label use. Because our Isolator<sup>®</sup> system is currently our only significant product line, the sustainability of our current operations, as well as our future viability, is dependent upon the continuation of sales of our Isolator<sup>®</sup> system. We believe that minimally invasive sole-therapy treatment for AF represents the largest growth opportunity for us. We are in the process of conducting clinical trials and if these trials are successful, we intend to seek FDA approval as early as 2009 for the use of our Isolator<sup>®</sup> system to treat AF, which we view as our market opportunity.

An investment in our shares involves a high degree of risk. You should consider carefully the risks described in the **Risk Factors** section of this prospectus before purchasing any shares.

## **CORPORATE INFORMATION**

We were incorporated in the State of Delaware as AtriCure, Inc. on October 31, 2000 in connection with a spin-off transaction from Enable Medical Corporation, in which shares of our common stock were given to the Enable shareholders. The spin-off was intended to allow us to focus on the development of products designed to treat AF and to raise capital for that purpose, while Enable continued its broader research and manufacturing activities. On August 5, 2005, we completed an initial public offering of our common stock. On August 10, 2005 we acquired Enable Medical Corporation, the manufacturer of our Isolator<sup>®</sup> clamps, which are an essential part of our Isolator<sup>®</sup> system. Additionally, in December 2005, we formed AtriCure Europe, B.V., our wholly-owned subsidiary incorporated in the Netherlands.

Our principal executive offices are located at 6033 Schumacher Park Drive, West Chester, Ohio 45069, and our telephone number is 513.755.4100. We maintain an Internet website at <http://www.atricure.com>. We have not incorporated by reference into this prospectus the information in, or that can be accessed through, our website, and you should not consider it to be a part of this prospectus.

## **RECENT DEVELOPMENTS**

On May 24, 2007, we entered into a Securities Purchase Agreement pursuant to which we agreed to issue to certain institutional investors 1,789,649 shares of common stock for gross proceeds of \$16.5 million. Pursuant to the terms of the Securities Purchase Agreement, 1,683,060 shares were sold at \$9.15 per share and 106,589 shares were sold to an entity affiliated with one of our directors at \$10.32 per share, the closing bid price on

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May 23, 2007. Net proceeds to us from the sale of the shares will be approximately \$15.2 million, after deducting a 6% placement agent's fee and transaction expenses. We closed the transaction on May 30, 2007.

In connection with the financing, we entered into a Registration Rights Agreement, under which we agreed to file a Registration Statement with the Securities and Exchange Commission, or SEC, for the resale of the shares of common stock sold in the private placement on or prior to the 30<sup>th</sup> calendar day following the closing date. Pursuant to the Registration Rights Agreement, we have agreed to use our reasonable best efforts to cause the Registration Statement to be declared effective by the SEC as soon as practicable but in no event later than the earlier of (i) the 90<sup>th</sup> calendar day following the closing date; provided, that, if the SEC reviews and has written comments to the Registration Statement, then the 120<sup>th</sup> calendar day following the closing date, and (ii) the fifth trading day following the date on which we are notified by the SEC that the Registration Statement will not be reviewed or is no longer subject to further review and comments. We have also agreed to use our reasonable best efforts to keep the Registration Statement continuously effective under the Securities Act of 1933, as amended, until the earlier of (i) such time as all of the shares covered by the Registration Statement have been publicly sold, or (ii) the date that all of the shares covered by the Registration Statement may be sold by non-affiliates without volume restrictions pursuant to Rule 144(k) promulgated by the SEC pursuant to the Securities Act. Failure to file the Registration Statement in a timely manner will result in payment by us to the purchasers of liquidated damages equal to 1% of their purchase price per month, prorated for any period of less than one month and subject to a cap of 10% of the purchase price paid by each purchaser. Such penalties are also payable in the event that the Registration Statement has not been declared effective within certain time periods or if sales cannot be made pursuant to the Registration Statement following its effectiveness, each as described in the Registration Rights Agreement.

On July 5, 2007, our Isolator<sup>®</sup> bipolar ablation clamp system received clearance from the FDA for the ablation of cardiac tissue during surgical procedures.

**SUMMARY OF OFFERING**

Common stock offered by Selling Stockholders	1,789,649
Common stock issued and outstanding as of June 15, 2007	14,121,134
Use of proceeds	We will not receive any proceeds from the sale of the shares of common stock covered by this prospectus.
Nasdaq symbol	ATRC

**RISK FACTORS**

**Risks Relating To Our Business**

**We expect to derive substantially all of our future revenue from sales of our AtriCure Isolator<sup>®</sup> bipolar ablation system. If our Isolator<sup>®</sup> system fails to gain or loses market acceptance for the treatment of AF, we may not generate sufficient revenue to continue our operations.**

Currently, our primary product line is our AtriCure Isolator<sup>®</sup> bipolar ablation system, which we commercially introduced beginning in 2002 in the United States and in 2003 outside of the United States. We expect that sales of our Isolator<sup>®</sup> system will account for substantially all of our revenue for the foreseeable future and that our future revenue will depend on the increasing acceptance by the medical community of our Isolator<sup>®</sup> system as a standard treatment alternative for the surgical treatment of AF during open-heart surgical procedures and as a sole-therapy minimally invasive procedure.

Acceptance of our Isolator<sup>®</sup> system for the treatment of AF is dependent upon, among other factors, the level of screening for AF and the awareness and education of the medical community about the surgical treatment of AF, in general, and the existence, effectiveness and, in particular, the safety of our Isolator<sup>®</sup> system. Our Isolator<sup>®</sup> system and the procedures involved with the treatment of AF using our system is relatively new. We cannot assure you that doctors will continue to use our Isolator<sup>®</sup> system or that demand for the surgical treatment of AF will not decline or will not increase as quickly as we expect.



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We may not be able to maintain or increase market acceptance of our Isolator<sup>®</sup> system for a number of additional reasons, including:

our inability to promote any of our products for the treatment of AF until we obtain additional FDA approvals;

our inability to train doctors in the use of any of our products for the treatment of AF until we obtain additional FDA approvals;

our inability to sustain acceptance of our Isolator<sup>®</sup> system within the medical community;

liability risks for doctors and hospitals associated with the off-label use of our Isolator<sup>®</sup> system and the use of new technologies or procedures;

findings or perceptions relating to the safety or effectiveness of our Isolator<sup>®</sup> system or the safety or effectiveness of the surgical treatment of AF;

medical device reports to the FDA and foreign regulatory authorities, which are required in the event our products malfunction or cause or contribute to a death, serious injury or other adverse event;

publicity concerning our Isolator<sup>®</sup> system, competing products or the surgical treatment of AF;

the cost of our Isolator<sup>®</sup> system;

the availability of alternative treatments or procedures that may be, or may be perceived as, more effective, safer, faster, easier to use or less costly than our Isolator<sup>®</sup> system; and

policies of healthcare payors with respect to coverage and reimbursement.

Since we do not believe that doctors are using our Isolator<sup>®</sup> system for any purpose other than the surgical treatment of AF, if doctors do not use our Isolator<sup>®</sup> system to treat AF, we would lose substantially all of our revenue.

**Use of our Isolator<sup>®</sup> system as a sole-therapy minimally invasive treatment for AF, which is not currently a well-established market, represents our major growth opportunity. If this market does not further develop or our Isolator<sup>®</sup> system is not widely adopted for use in this market, it may adversely impact our ability to grow our revenue.**

We believe that sole-therapy minimally invasive treatment for AF, which is not currently a well-established market, will ultimately represent the largest segment of the market for the surgical treatment of AF. If this market fails to further develop, or if our Isolator<sup>®</sup> system is not widely adopted for use in this market, it may adversely impact our ability to grow our revenue. In order to further establish the sole-therapy minimally invasive AF treatment market, doctors treating patients with AF who would not otherwise require an open-heart surgical procedure must change their current practice of referring patients to cardiologists and electrophysiologists and instead refer these patients to cardiothoracic surgeons for surgical AF treatment. Doctors may decide not to change their referral patterns for a variety of reasons including, for example, negative publicity relating to our ongoing clinical studies, including publicity focusing on the doctors and institutions carrying out such clinical studies, that limited clinical data is available relating to the safety and effectiveness of our Isolator<sup>®</sup> clamps, that clinical testing of our Isolator<sup>®</sup> system is in the feasibility stage, that doctors who refer their patients to cardiothoracic surgeons may risk losing their patients and that doctors may prefer to treat patients using drugs or catheter-based ablation. If doctors do not refer their patients to cardiothoracic surgeons for surgical AF treatment, we will

not be able to further establish a market for the use of our Isolator<sup>®</sup> system for the sole-therapy minimally invasive treatment of AF, and our future growth and revenue will suffer.

**The failure to educate or train a sufficient number of doctors in the use of our Isolator<sup>®</sup> system could reduce the market acceptance of our system and reduce our revenue.**

It is critical to the success of our sales efforts to ensure that there are a sufficient number of doctors familiar with, trained on and proficient in the use of our Isolator<sup>®</sup> system. While we educate and train doctors as to the

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skills involved in the proper use of our Isolator<sup>®</sup> system, it is not our policy to educate or train them to use our Isolator<sup>®</sup> system for the surgical treatment of AF. Currently, doctors learn to use our Isolator<sup>®</sup> system for the treatment of AF through independent training programs provided by hospitals and universities and through independent peer-to-peer training among doctors. We provide research and educational grants to institutions, some of which are used to fund programs to teach the procedures involved in the surgical treatment of AF, including the use of our Isolator<sup>®</sup> system for such treatment. However, while we make doctors generally aware of these programs, these institutions determine the faculty and the content of the programs. We also rely on doctors to independently inform their colleagues about these programs. We cannot assure you that a sufficient number of doctors will become aware of training programs or that doctors will dedicate the time, funds and energy necessary for adequate training in the use of our Isolator<sup>®</sup> system.

**Unless we obtain additional FDA approvals, we will not be able to promote our Isolator<sup>®</sup> system to treat AF and our ability to maintain and grow our business could be harmed.**

Generally, a medical device company must first obtain either FDA clearance through the submission to the FDA of a 510(k) notification or FDA approval through the submission of a pre-market approval application, or PMA, before a company may market a medical device in the United States. Certain modifications to a previously marketed device, including a proposed new use or new indication for the device, also require the submission to the FDA of either a 510(k) or PMA before such device with the modifications may be marketed. The process of obtaining these clearances and approvals can be lengthy and expensive. The PMA process is more costly, lengthy and uncertain than the 510(k) process and requires that the device be found to be safe and effective and must be supported by extensive data, including data from preclinical studies and human clinical trials. Though less likely, a 510(k) application may require human clinical trials as well. Because we cannot assure you that any new products, or any product enhancements, that we develop will be subject to the shorter 510(k) clearance process, significant delays in the introduction of any new products or product enhancement may occur.

We have not received FDA approval to promote any of our products, including our Isolator<sup>®</sup> system, for the treatment of AF. In July 2007, our Isolator<sup>®</sup> bipolar ablation clamp system received clearance from the FDA for the ablation of cardiac tissue during surgical procedures. However, we will need to obtain separate approvals from the FDA for use of our Isolator<sup>®</sup> system in the treatment of AF as part of an open-heart procedure and as a sole-therapy minimally invasive procedure through the submission of separate PMAs to the FDA.

Unless and until we obtain FDA approval for the use of our products for the treatment of AF, we and others acting on our behalf may not promote our products for such use, make any claim that our products are safe and effective for such use, or proactively discuss or provide information on the use of our products in connection with such use.

We cannot assure you that future clearances or approvals of our Isolator<sup>®</sup> system will be granted or that current or future clearances or approvals of our system will not be withdrawn. Failure to obtain a clearance or approval or loss of an existing clearance or approval, could hurt our ability to maintain and grow our business.

**Unless we are able to complete the clinical trials required to support future submissions to the FDA, and unless the data generated by such trials supports the use of our Isolator<sup>®</sup> system for the treatment of AF as safe and effective, we may not be able to secure additional FDA clearances or approvals and our ability to maintain and grow our business could be harmed.**

In order to obtain FDA approvals to promote our Isolator<sup>®</sup> system for the treatment of AF, we will need to demonstrate in clinical trials that our system is safe and effective for such use. In order to conduct clinical trials, it is necessary to receive an investigational device exemption, or IDE, from the FDA. While we have obtained the required IDE from the FDA for the conduct of clinical trials for the use of our Isolator<sup>®</sup> clamps as a treatment for AF during open-heart surgical procedures, the FDA or institutional review boards, or IRBs, that also oversee the trials for the purpose of protecting the study subjects can halt clinical trials at any time for safety reasons or because we or any of our clinical investigators do not follow the FDA's requirements for conducting clinical

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trials. In addition, the FDA may modify its requirements with respect to various aspects of our clinical study, in which case our ongoing clinical trial may not be achievable. Moreover, future clinical trials of our Isolator<sup>®</sup> system to treat AF as a sole-therapy minimally invasive procedure will likely proceed in phases beginning with a further feasibility trial. The FDA has granted us an IDE to conduct a feasibility study relating to the use of our Isolator<sup>®</sup> clamps for the sole-therapy minimally invasive treatment of AF, but there is no guarantee that the FDA will grant us approval to conduct broader clinical trials. If we are unable to receive approval to conduct broader clinical trials or the trials are halted by the FDA or others, we would not be able to promote our Isolator<sup>®</sup> system for use in the treatment of AF in the United States.

Since 2004, we have been conducting the RESTORE-SR trial, a clinical trial to support the submission of our PMA seeking FDA approval to use our Isolator<sup>®</sup> clamps for the treatment of AF during elective open-heart procedures and enrollment in the trial was slower than expected. On June 5, 2007, enrollment in this clinical trial closed prior to full enrollment. We have worked with the FDA to redesign the RESTORE-SR trial, now referred to as ABLATE, and have filed a new IDE and plan to start enrollment into the redesigned trial in the summer of 2007. As with the current RESTORE-SR trial, we cannot assure you that this new clinical trial will be approved by the FDA or will be completed in a timely manner or successfully or that the results obtained will be acceptable to the FDA.

As of May 31, 2006, we completed enrollment in our RESTORE-SR II study, a clinical study to evaluate the feasibility of using our Isolator<sup>®</sup> clamps as a sole-therapy minimally invasive treatment for AF. This study enrolled 25 patients at 5 leading US centers. We are currently working with our investigators to write a final clinical report to the FDA and hope to use this clinical data in support of adding a new arm to this study, RESTORE-SR IIB. In RESTORE-SR IIB, we intend to study patients experiencing persistent and permanent AF using an expanded lesion set and new technologies. We cannot assure you that this study will be approved by the FDA or completed in a timely manner or successfully or that the results obtained will be acceptable to the FDA. In 2006, the FDA conducted an inspection of one of the lead investigators of our Restore-SR II clinical study and identified a number of adverse observations concerning his compliance with good clinical practice requirements. The FDA has found no deficiencies at the conclusion of a subsequent related inspection of AtriCure. However, we cannot assure you that the FDA's inspections will not effect subsequent FDA review of the data from that study or that other issues with the FDA will arise in the future as a result of this inspection.

Clinical trials and regulatory approval of our Isolator<sup>®</sup> system for the treatment of AF can take a number of years to accomplish and require the expenditure of substantial financial, managerial and other resources, and we may never obtain regulatory approval for the use of our Isolator<sup>®</sup> system to treat AF in either an open-heart procedure or a sole-therapy minimally invasive procedure. The FDA may not grant approval to use our Isolator<sup>®</sup> system for the treatment of AF in all types of patients that experience AF, if any, or could limit the type of AF that could be treated using our system. If we do not secure required FDA approval to promote our Isolator<sup>®</sup> system for either or both types of procedures, our business, results of operations and prospects would be negatively affected as a result.

Further, we cannot make comparative claims regarding the use of our Isolator<sup>®</sup> system against any alternative treatments without conducting comparative clinical studies, which would be expensive and time consuming. We do not have any current plans to conduct such comparative clinical studies to evaluate our Isolator<sup>®</sup> system against any alternative method of treatment.

If the available data on the use of our Isolator<sup>®</sup> system from clinical trials and marketing experience does not establish the safety or effectiveness of our system, our clinical trials may be halted, our system may be withdrawn from the market and we may be prohibited from further distribution and sale of our system.

If the results obtained from our clinical trials, any other clinical studies, or clinical or commercial experience indicate that our Isolator<sup>®</sup> system is not safe or effective, or not as safe or effective as other treatment options, the FDA may not approve our system for the treatment of AF, adoption of the use of our system for the treatment of AF may suffer and our business would be harmed.

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**We have experienced and may continue to experience unfavorable publicity relating to our business and our industry. This publicity has had and may continue to have a negative impact on our ability to attract and retain customers, our sales, clinical studies involving our products, our reputation and our stock price.**

We believe that we have experienced a negative impact on our business from newspaper articles published in December 2005 and February 2006 relating to, among other things, concerns of conflicts of interest between the Cleveland Clinic and us, our compliance with FDA regulations for medical device reporting, and concerns that certain of our consultants who are involved with clinical studies of and the publication of articles concerning our products failed to adequately disclose their financial relationships with us. Because these articles relate to the validity of important clinical data on the use of our Isolator<sup>®</sup> system and involve a prominent surgeon and two of the pioneering institutions which have been proponents and investigators of our system, some current and potential customers have been and may continue to be reluctant to purchase our system. We also believe that this publicity has had and may continue to have a negative impact on clinical studies involving our Isolator<sup>®</sup> system. We cannot assure you that this publicity or similar unfavorable publicity will not adversely impact future clinical studies involving our products or adversely impact our current or future submissions to the FDA. We believe that this publicity has had and may continue to have a negative impact on our business, results of operations, financial condition and stock price. We also believe that future unfavorable publicity could cause other adverse effects, including a further decline in the price of our stock.

**We may be subject to fines, penalties, injunctions and other sanctions if we are deemed to be promoting the use of our products for non-FDA-approved, or off-label, uses.**

Our business and future growth depend on the continued use of our Isolator<sup>®</sup> system in the treatment of AF, which is considered an off-label use of our system. Under the Federal Food, Drug, and Cosmetic Act and other laws, we are prohibited from promoting our products, including our Isolator<sup>®</sup> system, for off-label uses. This means that we may not make claims about the safety or effectiveness of our Isolator<sup>®</sup> system for the treatment of AF and may not proactively discuss or provide information on the use of our system for the treatment of AF, except in certain limited scientific and other settings.

Due to these legal constraints, our sales and marketing efforts focus only on the general technical attributes and benefits of our Isolator<sup>®</sup> system and the use of our system for the ablation of cardiac tissue, but not on the use of our system for AF treatment. At the same time, we provide certain support for the use of our Isolator<sup>®</sup> system in the treatment of AF that we believe is non-promotional and therefore permitted. In particular, since our Isolator<sup>®</sup> system is only being used by doctors for the treatment of AF, we train our sales force on the use of our system by cardiothoracic surgeons to treat AF, and off-label sales are included in our sales force compensation structure. Sales personnel call on cardiothoracic surgeons, electrophysiologists, and other doctors to discuss the general attributes of our Isolator<sup>®</sup> system and respond in a non-promotional manner to unsolicited requests for information from doctors on the use of our system in the treatment of AF by providing copies of and citations to peer-reviewed journal articles and/or other training and instructional tools. In addition, medically trained clinical application specialists attend surgical procedures to discuss the general attributes of our Isolator<sup>®</sup> system and respond to unsolicited requests for information on the use of our system for the treatment of AF. We have entered into consulting agreements with prominent cardiothoracic surgeons and electrophysiologists who assist us with, among other things, product development and clinical development. In addition, we provide financial support in the form of research and educational grants to several leading institutions in the cardiac field, which they may use to conduct physician training programs, including programs relating to the surgical treatment of AF using our Isolator<sup>®</sup> system. We also provide some guidance to physicians and medical institutions regarding what physicians are available and qualified for training other physicians on the use of our Isolator<sup>®</sup> system in the treatment of AF. We also continue to make improvements in our Isolator<sup>®</sup> system which could be viewed as supporting the treatment of AF.

There is a material risk that the FDA or other federal or state law enforcement authorities could determine that the nature and scope of these activities constitute the promotion of our Isolator<sup>®</sup> system for a non-FDA-approved use in violation of the law. We also face the risk that the FDA or other regulatory authorities

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might pursue enforcement based on past activities that we have discontinued or changed, including sales activities, arrangements with institutions and doctors, educational and training programs and other activities.

Government investigations concerning the promotion of off-label uses and related issues are typically expensive, disruptive and burdensome and generate negative publicity. If our promotional activities are found to be in violation of the law or if we agree to a settlement in connection with an enforcement action, we would likely face significant fines and penalties and would likely be required to change substantially our sales, promotion, grant and educational activities. For example, in November 2004, we received a letter from the FDA relating to certain cardiac-related information on our website in connection with our Isolator<sup>®</sup> clamps, which information we subsequently removed. There is also a possibility that we could be enjoined from making sales of our Isolator<sup>®</sup> system for any non-FDA-approved use, which effectively would bar all sales of our system until we receive FDA clearances or approval, if ever. In addition, as a result of enforcement actions against us or our senior officers, we could be excluded from participation in government healthcare programs such as Medicare and Medicaid.

**The use of products we sell may result in injuries or other adverse events that lead to product liability suits, which could be costly to our business or our customers' business.**

The use of products we sell may result in a variety of serious complications, including damage to the heart, internal bleeding, death, or other adverse events, potentially leading to product liability claims. Serious complications, including death, have been encountered in connection with the surgical treatment of AF, including in connection with a limited number of sole-therapy minimally invasive procedures in which our Isolator<sup>®</sup> system was used. Although our manufacturing processes and those of our suppliers are required to comply with the FDA's quality system regulations, or QSR, covering the procedures and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of our products, if products we sell are defectively designed, manufactured or labeled, contain inadequate warnings, contain defective components or are misused, we may become subject to costly litigation by our customers or their patients.

We carry product liability insurance that is limited in scope and amount and may not be adequate to fully protect us against product liability claims. We could be required to pay damages that exceed our insurance coverage. Any product liability claim, with or without merit, could result in an increase in our product liability insurance rates or our inability to secure coverage on reasonable terms, if at all. Even in the absence of a claim, our insurance rates may rise in the future. Any product liability claim, even a meritless or unsuccessful one, would be time consuming and expensive to defend and could result in the diversion of our management's attention from our business and result in adverse publicity, withdrawal of clinical trial volunteers, injury to our reputation and loss of revenue. Any of these events could negatively affect our earnings and financial condition.

**Our current inability to educate or train doctors in the use of our Isolator<sup>®</sup> system for the treatment of AF, due to legal prohibitions on off-label promotion of medical devices, could result in injuries to patients or other adverse events that lead to litigation against us, which could be costly to our business.**

Our sales team educates doctors in the technology and general application of our Isolator<sup>®</sup> system, but it is our policy not to educate or train doctors to use our system for the surgical treatment of AF. Hospitals and universities offer independent educational programs for the treatment of AF utilizing our Isolator<sup>®</sup> system, and there is independent doctor-to-doctor training to use our system for the treatment of AF. We do not require that doctors who use our Isolator<sup>®</sup> system have any specific training in the use of our system. We cannot assure you that doctors utilizing our Isolator<sup>®</sup> system are using it correctly. Because we rely on training by hospitals and universities and doctor-to-doctor training, we do not control the quality of the training received by the doctors who use our Isolator<sup>®</sup> system. Not requiring training on the use of our Isolator<sup>®</sup> system may expose us to greater risk of product liability for injuries occurring during procedures utilizing our system. If demand for our Isolator<sup>®</sup> system grows, the increased number of procedures performed using our system may potentially lead to more injuries and an increased risk of product liability. In addition, the off-label use of our Isolator<sup>®</sup> system by the doctors may expose us to greater risks relating to product liability claims.

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### **Serious complications arising out of surgical procedures for the treatment of AF, including surgical AF treatments involving our Isolator® system, could harm our business in a variety of important ways.**

Serious complications, including death, have been encountered in connection with the surgical treatment of AF, including in connection with a limited number of sole-therapy minimally invasive procedures in which our Isolator® system was used. The rate of serious complications associated with surgical AF treatments in general, or surgical AF treatments involving the use of our Isolator® system in particular, may be greater than the rate of serious complications associated with alternative therapies for the treatment of AF or AF itself.

Adverse outcomes, or the perception that surgical AF treatments, including treatments involving the use of our Isolator® system, are not safe, could harm our business, including in the following ways:

our Isolator® system may fail to gain or may lose market acceptance;

the market for the sole-therapy minimally invasive treatment of AF may fail to further develop;

the medical community may fail to further adopt our Isolator® system for the sole-therapy minimally invasive treatment of AF;

the FDA or foreign regulatory authorities may refuse, delay or revoke clearances, approvals or clinical trials of our Isolator® system for the ablation of cardiac tissue or the treatment of AF; and

the FDA or other domestic or foreign regulatory or enforcement authorities may be more likely than otherwise to pursue an action against us for promoting our products for off-label uses.

The significance of each of these identified risks is discussed elsewhere under the caption Risks Relating To Our Business.

### **Competition from existing and new products and procedures may decrease our market share and cause our revenue to decline.**

The medical device industry, including the market for the treatment of AF, is highly competitive, subject to rapid technological change and significantly affected by new product introductions and promotional activities of other participants. We cannot assure you that our Isolator® system will compete effectively against drugs, catheter-based ablation, implantable devices such as pacemakers or defibrillators, other ablation systems or other surgical AF treatments, which may be more well-established among doctors and hospitals. Many companies are promoting devices for the treatment of AF, and we anticipate that new or existing competitors may develop competing products, procedures or clinical solutions. There are few barriers to prevent new entrants or existing competitors from developing products to compete directly with ours. Some companies also compete with us to attract qualified scientific and technical personnel as well as funding. Our primary competitors include Medtronic, Inc., St. Jude Medical Inc., Boston Scientific Corporation, Medical CV and CryoCath Technologies Inc. These companies may enjoy competitive advantages, including:

broader product offerings;

established and more comprehensive distribution networks;

less expensive products and procedures that take less time to perform;

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greater resources, including financial resources and more extensive experience in product development, manufacturing, regulatory clearance and approval, promotion, distribution and selling and patent litigation; and

established relationships with hospitals, healthcare providers and payors.

Some competitors have FDA clearance for the use of their products to ablate cardiac tissue or FDA approval for the use of their products to ablate cardiac tissue during open-heart surgery. Some of our competitors are currently conducting clinical trials for the use of their products in the treatment of AF, which if successful, may



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impact the future sales of our Isolator<sup>®</sup> system. Furthermore, demand for our Isolator<sup>®</sup> system could be diminished by equivalent or superior products and technologies being offered by competitors, including products utilizing bipolar technology which could prove to be more effective, faster, safer or less costly than our Isolator<sup>®</sup> system. The introduction of new products, procedures or clinical solutions by competitors may result in price reductions, reduced margins or loss of market share and may render our products obsolete, which could adversely affect our net revenue and future profitability.

**Our intellectual property rights may not provide meaningful commercial protection for our products, which could enable third parties to use our technology or methods, or very similar technology or methods, and could reduce our ability to compete.**

Our success depends significantly on our ability to protect our proprietary rights to the technologies used in our products. We rely on patent protection, as well as a combination of copyright, trade secret and trademark laws and nondisclosure, confidentiality and other contractual restrictions to protect our proprietary technology. However, these legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. Our patent applications may not issue as patents at all or in a form that will be advantageous to us. Our issued patents and those that may issue in the future may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing related products. We cannot assure you that third parties will not be able to design around our patents or, if they do infringe upon our technology, that we will be successful in or have sufficient resources to pursue a claim of infringement against those third parties. We believe that third parties may have developed or are developing products that could infringe upon our patent rights. Any pursuit of an infringement claim by us may involve substantial expense or diversion of management attention. In addition, although we have entered into confidentiality agreements and intellectual property assignment agreements with our employees, consultants, investigators and advisors, such agreements may not be enforceable or may not provide meaningful protection for our trade secrets or other proprietary information in the event of unauthorized use or disclosure or other breaches of the agreements.

Furthermore, the laws of foreign countries may not protect our intellectual property rights to the same extent as the laws of the United States. Foreign countries generally do not allow patents to cover methods for performing surgical procedures. If our intellectual property does not provide significant protection against foreign or domestic competition, our competitors could compete more directly with us, which could result in a decrease in our market share. All of these factors may harm our competitive position.

**The medical device industry is characterized by patent litigation and any litigation or claim against us may cause us to incur substantial costs, could place a significant strain on our financial resources, divert the attention of management from our business and harm our reputation. The medical device industry is characterized by extensive litigation and administrative proceedings over patent and other intellectual property rights.**

Whether a product infringes a patent involves complex legal and factual issues, the determination of which is often uncertain. Any patent dispute, even a meritless or unsuccessful one, would be time consuming and expensive to defend and could result in the diversion of our management's attention from our business and result in adverse publicity, the disruption of development and marketing efforts, injury to our reputation and loss of revenue. Any of these events could negatively affect our earnings and financial condition.

Our competitors or others may assert that our Isolator<sup>®</sup> system or the methods employed in the use of our system infringes on United States or foreign patents held by them. This risk is exacerbated by the fact that there are numerous issued and pending patents relating to surgical ablation, the surgical treatment of AF and other surgical devices. Because patent applications can take many years to issue, there may be applications now pending of which we are unaware that may later result in issued patents that our Isolator<sup>®</sup> system may infringe. There could also be existing patents of which we are unaware that one or more components of our Isolator<sup>®</sup>

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system may inadvertently infringe. As the number of competitors in the market for the treatment of AF grows, the possibility of inadvertent patent infringement by us or a patent infringement claim against us increases.

If a third-party's patents were upheld as valid and enforceable and we were found to be infringing, we could be prevented from selling our Isolator® system unless we were able to obtain a license to use technology or ideas covered by such patent or are able to redesign our system to avoid infringement. A license may not be available at all or on terms acceptable to us, and we may not be able to redesign our products to avoid any infringement. Modification of our products or development of new products could require us to conduct additional clinical trials and to revise our filings with the FDA and other regulatory bodies, which would be time-consuming and expensive. If we are not successful in obtaining a license or redesigning our products, we may be unable to sell our products and our business could suffer.

### **We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed alleged trade secrets of their former employers.**

Many of our employees were previously employed at other medical device companies. We may be subject to claims that these employees, or we, have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of these former employers. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. A loss of key research or sales personnel or their work product could hamper or prevent our ability to improve our products or sell our existing products, which would harm our business.

### **The increase in cost of medical malpractice premiums to doctors and hospitals or the lack of malpractice insurance coverage due to the use of our Isolator® system by doctors for an off-label indication may cause certain doctors or hospitals to decide not to use our system and may damage our ability to grow and maintain the market for our system.**

Insurance carriers have been raising premiums charged for medical malpractice insurance due, at least in part, to increased risks associated with off-label procedures, including higher damage awards for successful plaintiffs. Insurance carriers may continue to raise premiums or they may deny malpractice coverage for procedures performed using products such as ours on an off-label basis. If this trend continues or worsens, our revenue may fall as doctors or hospitals decide against purchasing our Isolator® system due to the cost or unavailability of insurance coverage.

### **We have a limited history of operations and a history of net losses available to common stockholders and we may never become profitable.**

We have a limited operating history and have incurred net losses each year since our inception, including net losses available to common stockholders of \$13.7 million in 2006, \$12.7 million in 2005, \$9.5 million in 2004 and \$7.1 million in 2003. As of March 31, 2007, we had an accumulated deficit of \$60.4 million.

Our net losses available to common stockholders have resulted principally from costs and expenses relating to sales and promotional efforts, research and development activities, seeking regulatory clearances and approvals, public company expenses, and general operating expenses. We expect to continue to make substantial expenditures and to incur additional operating losses in the future as we expand our manufacturing, marketing and product development activities, and further develop and commercialize our products, including completing clinical trials and seeking regulatory clearances and approvals for our Isolator® system. If sales of our Isolator® system do not continue to grow as we anticipate, we will not be able to achieve profitability. Our expansion efforts may prove more expensive than we currently anticipate, and we may not succeed in increasing our revenue sufficiently to offset these higher expenses. Our losses have had, and are expected to continue to have, an adverse impact on our working capital, total assets and stockholders' deficit and we may never become profitable.

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**Our federal tax net operating loss carryforwards will be limited or lost, resulting in greater income tax expense because we experienced an ownership change of more than 50 percentage points upon the initial public offering of our common stock.**

In connection with our initial public offering in August 2005, we experienced an ownership change as defined by the Internal Revenue Code of 1986 that will limit the availability of our net operating loss carryforwards to offset any future taxable income, which may increase our future income tax expense. Our inability to use these net operating loss carryforwards to reduce taxable income is based on an ownership change of more than 50 percentage points under rules contained in the United States Internal Revenue Code. We had federal income tax net operating loss carryforwards of \$21 million at December 31, 2006 that, if not utilized to reduce our taxable income, will begin to expire in 2021.

**Our capital needs after the next 12 months are uncertain and we may need to raise additional funds in the future and such funds may not be available on acceptable terms, if at all.**

We believe that our current cash, cash equivalents and short-term investments, will be sufficient to meet our projected capital requirements for at least the next 12 months. Our capital requirements will depend on many factors, including:

the revenue generated by sales of our products;

the costs associated with expanding and growing our business;

the rate of progress and cost of our research and development activities;

the costs of obtaining and maintaining FDA and other regulatory clearances and approvals of, and intellectual property protection for, our products and products in development;

the effects of competing technological and market developments; and

the number and timing of acquisitions and other strategic transactions.

As a result of these factors, we may need to raise additional funds, and we cannot be certain that such funds will be available to us on acceptable terms, if at all. Furthermore, if we issue equity securities to raise additional funds, our existing stockholders may experience dilution, and if we issue equity or debt securities, such securities may have rights, preferences and privileges senior to those of our existing stockholders. In addition, if we raise additional funds through collaboration, licensing or other similar arrangements, it may be necessary to relinquish potentially valuable rights to our future products or proprietary technologies, or grant licenses on terms that are not favorable to us. If we cannot raise funds on acceptable terms, we may not be able to expand our operations, develop new products, take advantage of future opportunities or respond to competitive pressures or unanticipated customer requirements.

**If we are unable to manage the anticipated growth of our business, our future revenue and operating results may be adversely affected and our growth could be limited.**

The growth that we may experience in the future may require us to rapidly expand our personnel and manufacturing operations. As of June 15, 2007, we had approximately 200 employees. Rapid expansion in personnel could result in unanticipated costs and disruptions to our operations. Organizational growth could strain our existing managerial, operational, financial and other resources. We may need to expand our current, or implement new, financial and operating systems, which could be costly and time-consuming. For us to maintain and expand our business successfully, we must manufacture commercial quantities of our Isolator<sup>®</sup> system's components, as well as components for other existing and future products, in compliance with regulatory requirements, including the FDA's Quality System Regulation, or QSR, at an acceptable cost and on a timely basis. Our anticipated growth may strain our ability to manufacture an increasingly large variety and supply of our products. Manufacturing facilities often experience difficulties in scaling up production, including problems with production yields and quality control and assurance. If we cannot scale and manage our business or our



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manufacturing operations appropriately, maintain control over expenses or otherwise adapt to future growth, our growth may be impaired and our future revenue and operating results will suffer.

**We depend upon single and limited source third-party suppliers, making us vulnerable to supply problems and price fluctuations, which could harm our business.**

We currently rely on single and limited source third-party vendors for the manufacture of many of the components used in our Isolator<sup>®</sup> system. For example, we rely on one vendor to manufacture our ASU, and we have not been able to identify any alternate supplier to manufacture our ASU if it becomes unable to do so. In addition, in some cases there are relatively few, or no, alternative sources of supply for certain other components that are critical to our Isolator<sup>®</sup> system. We also distribute a cryotherapy, or extreme cold, ablation device that doctors have used to make specialized lesions in the heart for the treatment of AF in addition to the lesions made by our Isolator<sup>®</sup> system, and our inability to offer this device to potential users of our system could negatively affect sales of our system.

Our reliance on these outside manufacturers and suppliers also subjects us to risks that could harm our business, including:

we may not be able to obtain adequate supply in a timely manner or on commercially reasonable terms;

we may have difficulty locating and qualifying alternative suppliers;

switching components may require product redesign and new submissions to the FDA which could significantly delay production or, if the FDA refuses to approve the changes, completely eliminate our ability to manufacture or sell our Isolator<sup>®</sup> system;

our suppliers manufacture products for a range of customers, and fluctuations in demand for the products those suppliers manufacture for others may affect their ability to deliver components to us in a timely manner; and

our suppliers may encounter financial hardships unrelated to our demand for components, which could inhibit their ability to fulfill our orders and meet our requirements.

Identifying and qualifying additional or replacement suppliers for any of the components used in our Isolator<sup>®</sup> system, if required, may not be accomplished quickly or at all and could involve significant additional costs. Any interruption or delay in the supply of components or materials, or our inability to obtain components or materials from alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand of our customers and cause them to cancel orders or switch to competitive products, and could therefore have a material adverse effect on our business, financial condition and results of operations.

**If the value of our goodwill becomes impaired, it could materially reduce the value of our assets and reduce our net income for the year in which the write-off occurs.**

At the time we acquired Enable, we recorded an asset called goodwill for the amount we paid for Enable, including liabilities assumed, in excess of the fair value of the assets we acquired. As of March 31, 2007, we have recorded \$3.8 million of goodwill in connection with the acquisition of Enable. The Financial Accounting Standards Board's (FASB) Statement of Financial Accounting Standards (SFAS) No. 142, Goodwill and Other Intangible Assets, requires that goodwill be tested at least annually (absent any impairment indicators). The testing includes comparing the fair value of each reporting unit with its carrying value. Fair value is determined using discounted cash flows, market multiples and market capitalization. Impairment adjustments, if any, are required to be recognized as operating expenses. We may have future impairment adjustments to our recorded goodwill. We performed an impairment test of the assets acquired from Enable as of September 30, 2006. Any finding that the value of our goodwill has been impaired would require us to write-off the impaired portion, which could materially reduce the value of our assets and reduce our net income for the year in which the write-off occurs.

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### **An inability to forecast future revenue or estimated life cycles of products may result in inventory-related charges that would negatively affect our gross margins and results of operations.**

To mitigate the risk of supply interruptions, we may determine to maintain excess inventory of the products or components supplied to us by third parties. Managing our inventory levels is important to our cash position and results of operations. As we expand, managing our inventory levels becomes more difficult. An excessive amount of inventory reduces our cash available for operations and may result in excess or obsolete materials. Inadequate inventory levels may make it difficult for us to meet customer product demand, resulting in decreased revenue. An inability to forecast future revenue or estimated life cycles of products may result in inventory-related charges that would negatively affect our gross margins and results of operations.

### **If we or our third party vendors fail to comply with extensive FDA regulations relating to the manufacturing of our products or any component part, we may be subject to fines, injunctions and penalties, and our ability to commercially distribute and sell our products may be hurt.**

Our manufacturing facility and the manufacturing facility of any of our third-party component manufacturers, critical suppliers or third-party sterilization facility are required to comply with the FDA's quality systems regulations, or QSR, which sets forth minimum standards for the procedures, execution and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of our Isolator<sup>®</sup> system and other products that we sell. The FDA may enforce its QSR, among other ways, through periodic unannounced inspections. If our manufacturing facility or the manufacturing facility of any of our third-party component manufacturers, critical suppliers or third-party sterilization facility, fails a QSR inspection, our and their operations could be disrupted, and manufacturing interrupted. Failure to take adequate and timely corrective action in response to an adverse QSR inspection could force a shutdown of our manufacturing operations or a recall of our products. Adverse QSR inspections could delay FDA approval of our Isolator<sup>®</sup> system and could have an adverse effect on our production, sales and profitability. We and any of our third party vendors may also encounter other problems during manufacturing including failure to follow specific protocols and procedures, equipment malfunction and environmental factors, any of which could delay or impede our ability to meet demand. The manufacture of our product also subjects us to risks that could harm our business, including problems relating to the sterilization of our products or facilities and errors in manufacturing components that could negatively affect the efficacy or safety of our products or cause delays in shipment of our products. Any interruption or delay in the manufacturer of the product or any of its components could impair our ability to meet the demand of our customers and cause them to cancel orders or switch to competitive products, and could therefore have a material adverse effect on our business, financial condition and results of operations.

### **If we fail to comply with the extensive FDA regulations relating to our business, we may be subject to fines, injunctions and penalties and our ability to commercially distribute and promote our products may be hurt.**

Our products are classified by the FDA as medical devices and as such are subject to extensive regulation in the United States by the FDA and numerous other federal, state and foreign governmental authorities. FDA regulations, guidance, notices and other issuances specific to medical devices are broad and regulate, among other things:

product design, development, manufacturing and labeling;

product testing, including electrical testing, transportation testing and sterility testing;

pre-clinical laboratory and animal testing;

clinical trials in humans;

product safety, effectiveness and quality;

product manufacturing, storage and distribution;

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premarket clearance or approval;

record keeping and document retention procedures;

product advertising, sales and promotion;

post-market surveillance and medical device reporting, including reporting of deaths, serious injuries or other adverse events or device malfunctions;

product corrective actions, removals and recalls; and

import and export.

Compliance with FDA, state and other regulations can be complex, expensive and time-consuming. The FDA and state authorities have broad enforcement powers. Furthermore, changes in the applicable governmental regulations could prevent further commercialization of our products and technologies and could materially harm our business.

Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA or state agencies, which may include any of the following sanctions:

warning letters, fines, injunctions, consent decrees and civil penalties;

repair, replacement, refunds, recall or seizure of our products;

operating restrictions, partial suspension or total shutdown of production;

refusing or delaying our pending requests for 510(k) clearance or premarket approval of new products, new intended uses or modifications to existing products;

withdrawing 510(k) clearance or premarket approvals that have already been granted; and

criminal prosecution.

If any of these events were to occur, we could lose customers, and our production, product sales, business, results of operations and financial condition would be harmed.

We are also subject to medical device reporting regulations that require us to file reports with the FDA if our products reasonably are the cause of or contribute to an adverse event, death, serious injury or in the event of product malfunction. During 2006 and through June 15, 2007, we have submitted a total of fifteen medical device reports to the FDA involving our products. There have also been other incidents, including patient deaths, that have occurred during open-heart and sole-therapy minimally invasive procedures using our products that we have not, and believe were not required to be, reported to the FDA because we determined that these incidents were not related to the use of our products. If the FDA disagrees with us, however, and determines that we should have submitted reports for these adverse events, we could be subject to significant regulatory fines or other penalties. In addition, the number of medical device reports we make, or the magnitude of the problems



reported, could cause the FDA or us to terminate or modify our clinical trials or recall or cease the sale of our products, and could hurt commercial acceptance of our product in the market.

**Modifications to our Isolator<sup>®</sup> system may require new clearances or approvals or require us to cease promoting or recall the modified products until such clearance or approvals are obtained.**

Any modification to a 510(k)-cleared device that would constitute a change in its intended use, design or manufacture, could require a new 510(k) clearance or, possibly, submission and FDA approval of a PMA. The FDA requires every medical device company to make the determination as to whether a new 510(k) is to be filed in the first instance, but the FDA may review any medical device company's decision. We have previously made modifications to our Isolator<sup>®</sup> system but do not believe such modifications require us to submit an additional 510(k) clearance. The FDA may not agree with our decisions regarding whether new clearances or approvals are required. If the FDA disagrees with us and requires us to submit a new 510(k) or PMA for then-existing

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modifications, we may be required to cease promoting or to recall the modified product until we obtain clearance or approval. In addition, we could be subject to significant regulatory fines or other penalties. Furthermore, our products could be subject to recall if the FDA determines, for any reason, that our products are not safe or effective or that appropriate regulatory submissions were not made. Delays in receipt or failure to receive clearances or approvals, the loss of previously received clearances or approvals, or the failure to comply with existing or future regulatory requirements, could reduce our sales, profitability and future growth prospects.

**We will spend considerable time and money complying with federal, state and foreign regulations in addition to FDA regulations, and, if we are unable to fully comply with such regulations, we could face substantial penalties.**

We are subject to extensive regulation by the federal government and the states and foreign countries in which we conduct our business. The laws that affect our ability to operate our business in addition to the Federal Food, Drug, and Cosmetic Act and FDA regulations include, but are not limited to, the following:

state food and drug laws, including laws regulating the manufacture, promotion and distribution of medical devices;

state consumer protection, fraud and business practice laws;

the federal Anti-Kickback Statute, which prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce either the referral of an individual, or furnishing or arranging for a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid Programs;

the federal False Claims Act, which prohibits submitting a false claim or causing of the submission of a false claim to the government;

Medicare laws and regulations that prescribe the requirements for coverage and payment, including the amount of such payment, and laws prohibiting false claims for reimbursement under Medicare and Medicaid;

the federal doctor self-referral prohibition, commonly known as the Stark Law, which, in the absence of a statutory or regulatory exception, prohibits the referral of Medicare patients by a doctor to an entity for the provision of certain designated healthcare services including inpatient and outpatient hospital services, if the doctor or a member of the doctor's immediate family has a direct or indirect financial relationship, including an ownership interest in, or a compensation arrangement with, the entity and also prohibits that entity from submitting a bill to a federal payor for services rendered pursuant to a prohibited referral;

state laws that prohibit the practice of medicine by non-doctors and by doctors not licensed in a particular state, and fee-splitting arrangements between doctors and non-doctors, as well as state law equivalents to the Anti-Kickback Statute and the Stark Law, which may not be limited to government-reimbursed items;

Federal and State healthcare fraud and abuse laws or laws protecting the privacy of patient medical information, including the Health Insurance Portability and Accountability Act, or HIPAA;

the Federal Trade Commission Act and similar laws regulating advertising and consumer protection; and

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similar and other regulations outside the United States.

Certain federal and state laws regarding Medicare, Medicaid and physician self-referrals are broad and we may be required to change one or more of our practices to be in compliance with these laws. Healthcare fraud and abuse regulations are complex and even minor, inadvertent irregularities in submissions can potentially give rise to claims that a statute has been violated. Any violations of these laws could result in a material adverse effect on our business, financial condition and results of operations. For example, if we were found to be in

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violation of the federal False Claims Act, we would likely face significant fines and penalties and would likely be required to change substantially our sales, promotion, grant and educational activities. There is also a possibility that we could face an injunction that would prohibit in whole or in part our current business activities, and, as a result of enforcement actions against us or our senior officers, we could be excluded from participation in government healthcare programs such as Medicare and Medicaid. If there is a change in law, regulation or administrative or judicial interpretations, we may have to change our business practices or our existing business practices could be challenged as unlawful, which could have a material adverse effect on our business, financial condition and results of operations.

If our past or present operations are found to be in violation of any of the laws described above or the other governmental regulations to which we, our distributors or our customers are subject, we may be subject to the applicable penalty associated with the violation, including civil and criminal penalties, damages, fines, exclusion from the Medicare and Medicaid and other government programs and the curtailment or restructuring of our operations. If we are required to obtain permits or licensure under these laws that we do not already possess, we may become subject to substantial additional regulation or incur significant expense. Any penalties, damages, fines, curtailment or restructuring of our operations would adversely affect our ability to operate our business and our financial results. The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully or clearly interpreted by the regulatory authorities or the courts, and their provisions are subject to a variety of interpretations and additional legal or regulatory change. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management's attention from the operation of our business and damage our reputation.

**If doctors or hospitals were to receive inadequate levels of reimbursement for surgical AF treatments using our Isolator® system from governmental or other third-party payors, it could affect the adoption or use of our system and may cause our revenue to decline.**

Widespread adoption or use of our Isolator® system by the medical community is unlikely to occur if doctors and hospitals do not receive sufficient reimbursement from payors for surgical treatment of AF using our system. Currently, hospitals do not receive any additional reimbursement from the fee-for-service Medicare program, which is administered by the Centers for Medicare and Medicaid Services, or CMS, for the cost of AF treatment, or for the cost of our Isolator® system, as part of an open-heart procedure. However, doctors performing AF treatment during an open-heart surgical procedure are eligible to receive separate reimbursement for performing these AF treatments. Sole-therapy minimally invasive AF treatment does qualify for reimbursement from the fee-for-service Medicare program allowing both doctors and hospitals to receive reimbursement for this type of AF treatment. In addition, the Medicare program has already adopted specific hospital inpatient treatment codes describing AF treatment by ablation in sole-therapy minimally invasive procedures such as that provided through the use of our Isolator® system.

On January 1, 2007, several new CPT codes for sole-therapy surgical ablation procedures were published by the American Medical Association (AMA) in the CPT coding book for 2007. The "one-size fits all" maze CPT code was deleted effective December 31, 2006. In its place, surgeons now have the choice of five different CPT codes for sole-therapy ablation procedures. The new limited CPT choices are expected to reimburse physicians less than the "one-size fits all" CPT code of 2006 for sole-therapy procedures. For open-heart concomitant ablation procedures, the AMA recommends use of the miscellaneous CPT code. We expect that the reimbursement for open-heart concomitant procedures will be less when compared to the preceding year and this could negatively impact the demand for our products.

Many private payors look to CMS as a guideline in setting their reimbursement policies and amounts. If CMS or other agencies decrease or limit reimbursement payments for doctors and hospitals, this may affect coverage and reimbursement determinations by many private payors. Additionally, some private payors do not follow the Medicare guidelines and those payors may reimburse only a portion of the cost of AF treatment or not at all. Furthermore, for some governmental payors, such as the Medicaid program, reimbursement differs from

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state to state, and some state Medicaid programs may not reimburse for our procedure in an adequate amount, if at all.

We are unable to predict all changes to the coverage or reimbursement methodologies that will be employed by private or governmental third-party payors. We cannot be certain that under prospective payment systems and applicable fee schedules, such as those used by CMS and by many private healthcare payors, the cost of the procedures utilizing our Isolator<sup>®</sup> system will be adequately reimbursed or that it will receive reimbursement consistent with historical levels or at all. Any denial of private or governmental third-party payor coverage or inadequate reimbursement for procedures performed using our Isolator<sup>®</sup> system could harm our business and reduce our revenue.

### **Adverse changes in payors' policies toward coverage and reimbursement for surgical AF treatment would harm our ability to promote and sell our Isolator<sup>®</sup> system.**

Third-party payors are increasingly exerting pressure on medical device companies to reduce their prices. Even to the extent that the treatment of AF using our Isolator<sup>®</sup> system is reimbursed by private payors and governmental payors, adverse changes in payors' policies toward coverage and reimbursement for surgical AF treatment would also harm our ability to promote and sell our system. Payors continue to review their policies and can, without notice, deny coverage for treatments that include the use of our products. Because each third-party payor individually approves coverage and reimbursement, obtaining these approvals may be time-consuming and costly. In addition, third-party payors may require us to provide scientific and clinical support for the use of our Isolator<sup>®</sup> system. Alternatively, government or private payors may deem the treatment of AF utilizing our Isolator<sup>®</sup> system experimental or not medically necessary and, as such, not provide coverage. Adverse changes in coverage and reimbursement for surgical AF treatment could harm our business and reduce our revenue.

### **We have limited long-term clinical data regarding the safety and efficacy of our Isolator<sup>®</sup> system. Any long-term data that is generated may not be positive or consistent with our limited short-term data, which would affect the rate at which our Isolator<sup>®</sup> system is adopted by the medical community.**

Our success depends upon the increasing acceptance of our Isolator<sup>®</sup> system by the medical community as safe and effective in the treatment of AF. Serious complications, including death, have been encountered in connection with the surgical treatment of AF, including in connection with a limited number of sole-therapy minimally invasive procedures in which our Isolator<sup>®</sup> system was used. Important factors upon which the efficacy of our Isolator<sup>®</sup> system will be measured include long-term data on the number of patients that continue to experience AF following treatment with our system and the number of patients that have serious complications resulting from AF treatment using our system. Our clinical trials may produce limited data regarding the efficacy of our Isolator<sup>®</sup> system for the treatment of AF, or may identify unexpected safety issues. We cannot provide any assurance that the data collected during our clinical trials will be compelling to the medical community or to the FDA, because it may not be scientifically meaningful and may not demonstrate that our Isolator<sup>®</sup> system is an attractive procedure when compared against data from alternative procedures and products. In addition, the long-term effects of ablation system procedures are not known.

The results of short-term clinical experience of our Isolator<sup>®</sup> system do not necessarily predict long-term clinical benefit. If the long-term clinical trial results are not as positive as the short-term results or the long-term results do not otherwise meet doctors' expectations, the FDA may not approve our Isolator<sup>®</sup> system for the treatment of AF, our system may not become widely adopted, and doctors may recommend alternative treatments for their patients. Another significant factor is acute safety data on complications that occur during the treatment of AF during open-heart surgical procedures and as a sole-therapy minimally invasive treatment.

If the results obtained from our RESTORE-SR trial or any other clinical studies or clinical or commercial experience indicate that our Isolator<sup>®</sup> system is not safe or effective, or not as safe or effective as other treatment

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options or than current short-term data would suggest, the FDA may not approve our Isolator<sup>®</sup> system for the treatment of AF, adoption of the use of our system for the treatment of AF may suffer and our business would be harmed.

Even if we believe the data collected from clinical studies or clinical experience indicates positive results, each doctor's actual experience with our Isolator<sup>®</sup> system may vary. Clinical studies conducted with our Isolator<sup>®</sup> clamps have involved procedures performed by doctors who are technically proficient. Consequently, both short- and long-term results reported in these studies may be significantly more favorable than typical results of practicing doctors, which could negatively impact rates of adoption of our Isolator<sup>®</sup> system.

**We sell our Isolator<sup>®</sup> system outside of the United States and we are subject to various risks relating to international operations, which could harm our international revenue and profitability.**

During the twelve months ended December 31, 2006 and the three months ended March 31, 2007, approximately 11% of our revenues were attributable to sales in markets outside of the United States. We currently primarily depend on third-party distributors to sell our Isolator<sup>®</sup> system outside of the United States, and if these distributors underperform, we may be unable to increase or maintain our level of international revenue. Over the long term, we intend to grow our business outside of the United States, and to do so we will need to attract additional distributors or hire direct sales personnel to expand the territories in which we sell our Isolator<sup>®</sup> system. Distributors may not commit the necessary resources to promote and sell our Isolator<sup>®</sup> system to the level of our expectations. If current or future distributors do not perform adequately, or we are unable to locate distributors in particular geographic areas, we may not realize expected long-term international revenue growth.

Doing business outside of the United States exposes us to risks distinct from those we face in our domestic operations. For example, our operations outside of the United States are subject to different regulatory laws and requirements in each jurisdiction where we operate or have sales. Our or our distributors' failure to comply with current or future foreign regulatory requirements, or the assertion by foreign authorities that we or they have failed to comply, could result in adverse consequences, including enforcement actions, fines and penalties, recalls, cessation of sales, civil and criminal prosecution, and the consequences could be disproportionate to the relative contribution of our international operations to our results of operations. Moreover, if political or economic conditions deteriorate in these countries, our ability to conduct our international operations could be limited and the costs could be increased, which could negatively affect our operating results. Engaging in business outside of the United States inherently involves a number of other difficulties and risks, including:

export restrictions and controls relating to technology;

pricing pressure that we may experience internationally;

difficulties in enforcing agreements and collecting receivables through certain foreign legal systems;

political and economic instability;

potentially adverse tax consequences, tariffs and other trade barriers;

the need to hire additional personnel to promote our Isolator<sup>®</sup> system outside of the United States;

international terrorism and anti-American sentiment;

fluctuations in exchange rates for future sales denominated in foreign currency; and

difficulty in obtaining and enforcing intellectual property rights.

Our exposure to each of these risks may increase our costs and require significant management attention. We cannot assure you that one or more of these factors will not harm our business.

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**If coverage and adequate levels of reimbursement from governmental and third-party payors outside of the United States are not attained and maintained, sales of our Isolator<sup>®</sup> system outside of the United States may decrease and we may fail to achieve or maintain significant sales outside of the United States.**

Our revenue generated from sales outside of the United States is also dependent upon the availability of coverage and reimbursement within prevailing foreign healthcare payment systems. In general, foreign healthcare payors do not provide reimbursement for sole-therapy minimally invasive procedures utilizing ablation devices such as our Isolator<sup>®</sup> system. In addition, healthcare cost containment efforts similar to those we face in the United States are prevalent in many of the other countries in which we sell our Isolator<sup>®</sup> system, and these efforts are expected to continue. To the extent that use of an ablation device such as our Isolator<sup>®</sup> system has historically received reimbursement under a foreign healthcare payment system, if any, such reimbursement has typically been significantly less than the reimbursement provided in the United States. If coverage and adequate levels of reimbursement from governmental and third-party payors outside of the United States are not attained and maintained, sales of our Isolator<sup>®</sup> system outside of the United States may decrease and we may fail to achieve or maintain significant sales outside of the United States.

**If we choose to acquire new and complementary businesses, products or technologies, we may be unable to complete these acquisitions or to successfully integrate them in a cost-effective and non-disruptive manner.**

Our success depends on our ability to continually enhance and broaden our product offerings in response to changing customer demands, competitive pressures and technologies. Accordingly, we may in the future pursue the acquisition of, or joint ventures relating to, complementary businesses, products or technologies instead of developing them ourselves. We do not know if we will be able to successfully complete any acquisitions or joint ventures, or future acquisitions or joint ventures, or whether we will be able to successfully integrate any acquired business, product or technology or retain any key employees. Integrating any business, product or technology we acquire could be expensive and time consuming, disrupt our ongoing business and distract our management. If we are unable to integrate any acquired businesses, products or technologies effectively, our business will suffer. In addition, any amortization or charges resulting from the costs of acquisitions could increase our expenses.

**The outcome of litigation in which we have been named as a defendant, including class action shareholder lawsuits, is unpredictable and an adverse decision in any such matter could have a material adverse affect on our financial position and results of operations.**

We, along with certain of our current and former officers, were named defendants in purported securities class action lawsuits filed in the United States District Court for the Southern District of New York. The plaintiffs allege violations of the federal securities laws and seek damages on behalf of purchasers of our common stock during the period from our initial public offering in August 2005 through February 16, 2006. These proceedings have resulted, and are expected to continue to result, in a diversion of management's attention and resources and in significant professional fees. These professional fees have increased, and in the near term may continue to increase our cash needs.

We have certain obligations to indemnify our officers and directors and to advance expenses to such officers and directors. Although we have purchased liability insurance for our directors and officers, if our insurance carriers should deny coverage, or if the indemnification costs exceed the insurance coverage, we may be forced to bear some or all of these indemnification costs directly, which could be substantial and may have an adverse effect on our business, financial condition, results of operations and cash flows. If the cost of our liability insurance increases significantly, or if this insurance becomes unavailable, we may not be able to maintain or increase our levels of insurance coverage for our directors and officers, which could make it difficult to attract or retain qualified directors and officers.

We are not able to estimate the amount of any damages that may arise from these legal proceedings and the internal efforts associated with defending ourselves and current or former officers. If we are unsuccessful in



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defending ourselves, these lawsuits could adversely affect our business, financial condition, results of operations and cash flows as a result of the damages that we would be required to pay. It is possible that our insurance policies either may not cover potential claims of this type or may not be adequate to indemnify us for all liability that may be imposed. While we believe that the allegations and claims made in these lawsuits are wholly without merit and intend to defend these actions vigorously, we cannot be certain that we will be successful in any or all of these actions.

These claims, as well as any others, may divert financial and management resources that could otherwise be used to benefit our operations. Although we believe that we have meritorious defenses to the claims, no assurances can be given that the results of these matters will be favorable to us. An adverse resolution of any lawsuits could have a material adverse affect on our financial position and results of operations. Concerns with respect to the circumstances surrounding our pending litigations may have created uncertainty regarding our ability to focus on our business operations and remain competitive with other companies in our industry. Because of this uncertainty, we may have difficulty retaining personnel or replacing personnel who leave us.

**We depend on our officers and other skilled and experienced personnel to operate our business effectively. If we are not able to retain our current employees or recruit additional qualified personnel, our business will suffer and our future revenue and profitability will be impaired.**

We are highly dependent on the skills and experience of our President and Chief Executive Officer, David J. Drachman, and other employees. We do not have any insurance in the event of the death or disability of our key personnel other than Mr. Drachman. Our officers and key employees, with the exception of our CEO and CFO, do not have employment agreements and they may terminate their employment and work elsewhere without notice and without cause or good reason. Currently we have non-compete agreements with our officers and other employees. Due to the specialized knowledge that each of our officers possesses with respect to our Isolator<sup>®</sup> system and our operations and the limited pool of people with relevant experience in the medical device field, the loss of service of one or more of these individuals could significantly affect our ability to operate and manage our business. The announcement of the loss of one or more of our key personnel could negatively affect our stock price.

We depend on our scientific and technical personnel for successful product development and innovation, which are critical to the success of our business. In addition, to succeed in the implementation of our business strategy, our management team must rapidly execute our sales strategy, obtain expanded FDA clearances and approvals, achieve market acceptance for our Isolator<sup>®</sup> system and further develop products, while managing anticipated growth by implementing effective planning, manufacturing and operating processes. Managing this growth will require us to attract and retain additional management and technical personnel. Our offices are located in West Chester, Ohio where it is difficult to attract and retain employees with experience in the medical device industry. We rely on direct sales employees and manufacturer's representatives to sell our Isolator<sup>®</sup> system in the United States and failure to adequately train them in the use and benefits of our products will prevent us from achieving our market share and revenue growth goals. We have key relationships with doctors that involve procedure and tool development, market development and clinical development. If any of these doctors end their relationship with us, our business would be negatively impacted. We cannot assure you that we will be able to attract and retain the personnel and doctor relationships necessary to grow and expand our business and operations. If we fail to identify, attract, retain and motivate these highly skilled personnel and doctors, we may be unable to continue our development and sales activities.

**Compliance with environmental laws and regulations may be expensive. Failure to comply with environmental laws and regulations could subject us to significant liability.**

Our manufacturing operations and research and development activities involve the use of biological materials and hazardous substances and are subject to a variety of federal, state and local environmental laws and regulations relating to the storage, use, discharge, disposal, remediation of, and human exposure to, hazardous substances. Our research and development and manufacturing operations may produce biological waste

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materials, such as animal tissues, and certain chemical waste. These operations are permitted by regulatory authorities, and the resultant waste materials are disposed of in material compliance with environmental laws and regulations. Compliance with these laws and regulations may be expensive and non-compliance could result in substantial liabilities. In addition, we cannot completely eliminate the risk of accidental contamination or injury to third parties from the use, storage, handling or disposal of these materials. In the event of contamination or injury, we could be held liable for any resulting damages, and any liability could exceed any applicable insurance coverage we may have. In addition, our manufacturing operations may result in the release, discharge, emission or disposal of hazardous substances that could cause us to incur substantial liabilities, including costs for investigation and remediation.

## **Risks Relating To Our Common Stock**

**The price and trading volume of our common stock may experience extreme fluctuations and you could lose some or all of your investment.**

Because we operate within the medical device segment of the healthcare industry, our stock price is likely to be volatile. The market price of our common stock may fluctuate substantially due to a variety of factors, including:

doctor and patient acceptance of the surgical treatment of AF using our Isolator<sup>®</sup> system;

adverse regulatory developments with respect to our products, such as recalls, new regulatory requirements, changes in regulatory requirements or guidance and timing of regulatory clearances and approvals for new products;

coverage and reimbursement determinations for our products and the related procedures;

the timing of orders received;

delays or interruptions in manufacturing or shipping of our products;

pricing of our products;

media reports and publications and announcements about products or new innovations that could compete with our products or about the medical device product segment in general;

market conditions or trends related to the medical device and healthcare industries or the market in general;

additions to or departures of our key personnel;

disputes, litigation or other developments relating to proprietary rights, including patents, and our ability to obtain patent protection for our technologies;

changes in financial estimates, investors' perceptions or recommendations by securities analysts;

variations in our quarterly financial and operating results;

changes in accounting principles; and

failure to achieve and maintain an effective internal control environment.

These factors, some of which are not within our control, may cause the price of our stock to fluctuate substantially. For example, we believe that negative publicity in the fourth quarter of 2005 and the first quarter of 2006 caused our stock price to decline.

If our quarterly or annual operating results fail to meet or exceed the expectations of securities analysts or investors, our stock price could drop suddenly and significantly. We believe the quarterly and annual comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

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The market prices of the securities of medical device companies, particularly companies like ours without consistent product revenue and earnings, have been highly volatile and are likely to remain highly volatile in the future. This volatility has often been unrelated to the operating performance of particular companies. These market prices generally are not sustainable and are highly volatile. In the past, companies that experience volatility in the market price of their securities have often faced securities class action litigation. Whether or not meritorious, litigation brought against us could result in substantial costs, divert our management's attention and resources and harm our ability to grow our business.

### **The future sale of our common stock could dilute your investment and negatively affect our stock price.**

We had approximately 14.1 million shares of common stock outstanding as of June 15, 2007, including 1,789,649 shares of our common stock, the resale of which are being registered pursuant to the registration statement of which this prospectus forms a part. The sale of securities pursuant to this prospectus may significantly affect the market price of our common stock. If our common stockholders sell substantial amounts of our common stock in the public market, or the market perceives that such sales may occur, the market price of our common stock could fall. The holders of up to approximately 3.8 million shares of our common stock have rights, subject to some conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. Furthermore, if we were to include in a company-initiated registration statement shares held by those holders pursuant to the exercise of their registration rights, the sale of those shares could impair our ability to raise needed capital by depressing the price at which we could sell our common stock. In addition, we may need to raise capital in the future to fund our operations. If we raise funds by issuing equity securities, our stock price may decline and our existing shareholders may experience significant dilution. Furthermore, we may enter into financing transactions at prices that represent a substantial discount to market price. A negative reaction by investors and securities analysts to any sale of our equity securities could result in a decline in the trading price of our common stock.

### **If our principal stockholders, executive officers and directors choose to act together, they may be able to control our management and operations, which may prevent us from taking actions that may be favorable to you.**

As of June 15, 2007, our executive officers, directors and principal stockholders, and entities affiliated with them, beneficially owned in the aggregate approximately 35% of our common stock. This significant concentration of share ownership may adversely affect the trading price of our common stock because investors often perceive disadvantages in owning stock in companies with controlling stockholders. These stockholders, acting together, will have the ability to exert substantial influence over all matters requiring approval by our stockholders, including the election and removal of directors and any proposed merger, consolidation or sale of all or substantially all of our assets. In addition, they could dictate the management of our business and affairs. This concentration of ownership could have the effect of delaying, deferring or preventing a change in control of us or impeding a merger or consolidation, takeover or other business combination that could be favorable to you.

### **Anti-takeover provisions in our amended and restated certificate of incorporation and amended and restated bylaws and under Delaware law could inhibit a change in control or a change in management that you consider favorable.**

Provisions in our certificate of incorporation and bylaws could delay or prevent a change of control or change in management that would provide you with a premium to the market price of your common stock. These provisions include those:

authorizing the issuance without further approval of blank check preferred stock that could be issued by our board of directors to increase the number of outstanding shares and thwart a takeover attempt;

prohibiting cumulative voting in the election of directors, which would otherwise allow less than a majority of stockholders to elect director candidates;

limiting the ability to remove directors;

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limiting the ability of stockholders to call special meetings of stockholders;

prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of stockholders;  
and

establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon by stockholders at stockholder meetings.

In addition, Section 203 of the Delaware General Corporation Law limits business combination transactions with 15% stockholders that have not been approved by our board of directors. These provisions and others could make it difficult for a third party to acquire us, or for members of our board of directors to be replaced, even if doing so would be beneficial to our stockholders. Because our board of directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt to replace the current management team. If a change of control or change in management is delayed or prevented, you may lose an opportunity to realize a premium on your shares of common stock or the market price of our common stock could decline.

**We do not expect to pay dividends in the foreseeable future. As a result, you must rely on stock appreciation for any return on your investment.**

We do not anticipate paying cash dividends on our common stock in the foreseeable future. Any payment of cash dividends will also depend on our financial condition, results of operations, capital requirements and other factors and will be at the discretion of our board of directors. Accordingly, you will have to rely on capital appreciation, if any, to earn a return on your investment in our common stock. Furthermore, pursuant to our credit facility, we are currently subject to restrictions on our ability to pay dividends and we may in the future become subject to other contractual restrictions on, or prohibitions against, the payment of dividends.

**The requirements of being a public company may strain our resources and distract management.**

As a public company, we are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act. These requirements may place a strain on our systems and resources. The Exchange Act requires that we file annual, quarterly and current reports with respect to our business and financial condition. The Sarbanes-Oxley Act requires that we maintain effective disclosure controls and procedures and internal controls over financial reporting. In order to maintain and improve the effectiveness of our disclosure controls and procedures and internal control over financial reporting, significant resources and management oversight will be required. This may divert management's attention from other business concerns, which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

**SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS**

This prospectus, including the documents that we incorporate by reference, contains forward-looking statements regarding our future performance. All forward-looking information is inherently uncertain and actual results may differ materially from assumptions, estimates or expectations reflected or contained in the forward-looking statements as a result of various factors, including those set forth under Risk Factors and elsewhere in this prospectus. Forward-looking statements convey our current expectations or forecasts of future events. All statements contained in this prospectus other than statements of historical fact are forward-looking statements. Forward-looking statements include statements regarding our future financial position, business strategy, budgets, projected costs, plans and objectives of management for future operations. The words may, continue, estimate, intend, plan, will, believe, project, expect, anticipate and similar expressions are used in forward-looking statements, but the absence of these words does not necessarily mean that a statement is not forward-looking. With respect to the forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

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These forward-looking statements speak only as of the date of this prospectus. Unless required by law, we undertake no obligation to publicly update or revise any forward-looking statements to reflect new information or future events or otherwise.

**USE OF PROCEEDS**

We are registering these shares pursuant to registration rights granted to the Selling Stockholders. We are not selling any securities under this prospectus and will not receive any proceeds from sales of the shares of common stock sold from time to time under this prospectus by the Selling Stockholders.

We have agreed to pay all costs, expenses and fees relating to registering the shares of our common stock referenced in this prospectus. The Selling Stockholders will pay any brokerage commissions and/or similar charges incurred for the sale of such shares of our common stock.

**Table of Contents****SELLING STOCKHOLDERS**

This prospectus relates to the possible resale or other disposition by the Selling Stockholders of 1,789,649 shares of common stock that we sold in a private placement. The shares listed below were acquired by the Selling Stockholders pursuant to a Securities Purchase Agreement, dated May 30, 2007, between each Selling Stockholder and us. As part of the transaction, we entered into a Registration Rights Agreement, which contains a covenant by us to register the resale of the shares being purchased thereunder pursuant to a registration statement on Form S-3. The shares of our common stock held by the Selling Stockholders are being registered for resale by the Selling Stockholders from time to time. See Plan of Distribution. The sale by us and purchase by the Selling Stockholders of the shares listed below was completed on May 30, 2007.

The following table lists the Selling Stockholders and presents certain information regarding their beneficial ownership of our common stock as well as the number of shares of our common stock they may sell from time to time pursuant to this prospectus. This table is prepared based on information supplied to us by the Selling Stockholders, and reflects holdings as of June 15, 2007. As of June 15, 2007, 14,121,134 shares of our common stock were issued and outstanding. As used in this prospectus, the term Selling Stockholders includes the entities listed below and any donees, pledges, transferees or other successors in interest selling shares received after the date of this prospectus from any of the Selling Stockholders as a gift, pledge or other transfer.

Name and Address of Selling Stockholders	Shares Owned Prior to Offering	Shares Offered Pursuant to this Offering	Shares Owned After Offering <sup>(1)</sup>	Percentage of Shares Owned After Offering <sup>(1)</sup>
Camden Partners Strategic Fund II-A, L.P. <sup>(2)</sup>  500 East Pratt Street, Suite 1200  Baltimore, MD 21202	969,225	100,620	868,605	6.2%
Camden Partners Strategic Fund II-B, L.P. <sup>(3)</sup>  500 East Pratt Street, Suite 1200  Baltimore, MD 21202	57,496	5,969	51,527	*
Broadview Partners, L.P. <sup>(4)</sup>  152 West 57 <sup>th</sup> Street, 48 <sup>th</sup> Floor  New York, NY 10019	10,001	10,001		
The Jay Goldman Master L.P. <sup>(5)</sup>  152 West 57 <sup>th</sup> Street, 48 <sup>th</sup> Floor  New York, NY 10019	218,288	218,288		
Woodmont Investments, Ltd. <sup>(6)</sup>  152 West 57 <sup>th</sup> Street, 48 <sup>th</sup> Floor  New York, NY 10019	206,547	206,547		
CD Investment Partners, Ltd. <sup>(7)</sup>  c/o CD Capital Management LLC  111 S. Wacker Drive, Suite 3950  Chicago, IL 60606	81,967	81,967		

Radcliffe SPC, Ltd. for and on behalf of the Class A  
Segregated Portfolio<sup>(8)</sup>

c/o RG Capital Management, L.P.	125,000	125,000
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3 Bala Plaza East, Suite 501

Bala Cynwyd, PA 19004

Capital Ventures International<sup>(9)</sup>

81,967	81,967
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c/o Heights Capital Management

101 California Street, Suite 3250

San Francisco, CA 94111



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Name and Address of Selling Stockholders	Shares Owned Prior to Offering	Shares Offered Pursuant to this Offering	Shares Owned After Offering <sup>(1)</sup>	Percentage of Shares Owned After Offering <sup>(1)</sup>
Black River Long/Short Fund Ltd. <sup>(10)</sup>  c/o Black River Asset Management  12700 Whitewater Drive  Minnetonka, MN 55343	427,700	260,000	167,700	1.2%
Black River Long/Short Opportunity Fund LLC <sup>(11)</sup>  c/o Black River Asset Management  12700 Whitewater Drive  Minnetonka, MN 55343	75,800	40,000	35,800	*
SF Capital Partners Ltd. <sup>(12)</sup>  c/o Stark Offshore Management LLC  3600 South Lake Drive  St. Francis, WI 53235	300,000	300,000		
Millenium Partners, L.P. <sup>(13)</sup>  c/o Millenium Management, L.L.C.  666 Fifth Avenue, 8 <sup>th</sup> Floor  New York, NY 10103	109,290	109,290		
Pacific Asset Partners <sup>(14)</sup>  Two Embarcadero Center, Suite 1340  San Francisco, CA 94111	100,000	25,000	75,000	*
Highbridge International LLC <sup>(15)</sup>  c/o Highbridge Capital Management  9 West 57 <sup>th</sup> Street, 27 <sup>th</sup> Floor  New York, NY 10019	200,000	200,000		
Cranshire Capital, L.P. <sup>(16)</sup>  3100 Dundee Road, Suite 703  Northbrook, IL 60062	25,000	25,000		

\* Indicates ownership of less than 1%.

<sup>(1)</sup> Assumes the sale of all of the shares offered by this prospectus.

<sup>(2)</sup>

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*Camden Partners Strategic II, LLC is the general partner of Camden Partners Strategic Fund II-A, L.P. Richard M. Johnston, who is also Chairman of the Board of the Company, David L. Warnock, Richard M. Berkeley and Donald W. Hughes each may be deemed to share voting and investment power with respect to the securities held by this entity and disclaims beneficial ownership of the securities held by this entity, except as to his pecuniary interest therein.*

- (3) *Camden Partners Strategic II, LLC is the general partner of Camden Partners Strategic Fund II-B, L.P. Richard M. Johnston, who is also Chairman of the Board of the Company, David L. Warnock, Richard M. Berkeley and Donald W. Hughes each may be deemed to share voting and investment power with respect to the securities held by this entity and disclaims beneficial ownership of the securities held by this entity, except as to his pecuniary interest therein.*
- (4) *Jay G. Goldman may be deemed to share voting and investment power with respect to the securities held by this entity and therefore may be deemed to beneficially own such securities. He disclaims beneficial ownership of the securities held by this entity, except as to his pecuniary interest therein.*
- (5) *Jay G. Goldman may be deemed to share voting and investment power with respect to the securities held by this entity and therefore may be deemed to beneficially own such securities. He disclaims beneficial ownership of the securities held by this entity, except as to his pecuniary interest therein.*
- (6) *Jay G. Goldman may be deemed to share voting and investment power with respect to the securities held by this entity and therefore may be deemed to beneficially own such securities. He disclaims beneficial ownership of the securities held by this entity, except as to his pecuniary interest therein.*
- (7) *CD Capital Management LLC ( CD Capital ), as investment manager for CD Investment Partners, Ltd. ( CDIP ), ZP-II LP ( ZP II ), as the manager and sole member of CD Capital, C3 Management Inc. ( C3 ), as the general partner of ZP II, and John D. Ziegelman, as the Chairman of the Board, President*

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- and Treasurer and the beneficial owner of 100% of the outstanding shares of common stock of C3, each may be deemed to have beneficial ownership of the shares owned by CDIP which are being registered hereunder.
- (8) Pursuant to an investment management agreement, RG Capital Management, L.P. ( *RG Capital* ) serves as the investment manager of Radcliffe SPC, Ltd. 's Class A Segregated Portfolio. RGC Management Company, LLC ( *Management* ) is the general partner of RG Capital. Steve Katznelson and Gerald Stahlecker serve as the managing members of Management. Each of RG Capital, Management and Messrs. Katznelson and Stahlecker disclaims beneficial ownership of the securities owned by Radcliffe SPC, Ltd. for and on behalf of the Class A Segregated Portfolio.
- (9) Heights Capital Management, Inc., the authorized agent of Capital Ventures International ( *CVI* ), has discretionary authority to vote and dispose of the shares held by CVI and may be deemed to be the beneficial owner of these shares. Martin Kobinger, in his capacity as Investment Manager of Heights Capital Management, Inc., may also be deemed to have investment discretion and voting power over the shares held by CVI. Mr. Kobinger disclaims any such beneficial ownership of the shares.
- (10) Gregg Groechel, Senior Portfolio Manager for Black River Long/Short Fund Ltd. may be deemed to share voting and investment power with respect to the securities held by this entity and therefore may be deemed to beneficially own such securities. He disclaims beneficial ownership of the securities held by this entity, except as to his pecuniary interest therein.
- (11) Gregg Groechel, Senior Portfolio Manager for Black River Long/Short Opportunity Fund LLC may be deemed to share voting and investment power with respect to the securities held by this entity and therefore may be deemed to beneficially own such securities. He disclaims beneficial ownership of the securities held by this entity, except as to his pecuniary interest therein.
- (12) Michael A. Roth and Brian J. Stark each may be deemed to share voting and investment power with respect to the securities held by this entity and therefore each may be deemed to beneficially own such securities. Each disclaims beneficial ownership of the securities held by this entity, except as to his pecuniary interest therein.
- (13) Millennium Management, L.L.C., a Delaware limited liability company, is the general partner of Millennium Partners, L.P., a Cayman Islands exempted limited partnership, and consequently may be deemed to have voting control and investment discretion over securities owned by Millennium Partners, L.P. Israel A. Englander is the managing member of Millennium Management, L.L.C. As a result, Mr. Englander may be deemed to be the beneficial owner of any shares deemed to be beneficially owned by Millennium Management, L.L.C. The foregoing should not be construed in and of itself as an admission by either of Millenium Management, L.L.C. or Mr. Englander as to beneficial ownership of the shares of the Company 's common stock owned by Millennium Partners, L.P.
- (14) Robert M. Stafford, Managing General Partner of Pacific Asset Partners, may be deemed to share voting and investment power with respect to the securities held by this entity and therefore may be deemed to beneficially own such securities. He disclaims beneficial ownership of the securities held by this entity, except as to his pecuniary interest therein.
- (15) Highbridge Capital Management, LLC is the trading manager of Highbridge International LLC and has voting control and investment discretion over the securities held by Highbridge International LLC and therefore may be deemed to beneficially own such securities. Glenn Dubin and Henry Swieca control Highbridge Capital Management, LLC and have voting control and investment discretion over the securities held by Highbridge International LLC and therefore may be deemed to beneficially own such securities. Each of Highbridge Capital Management LLC, Glenn Dubin and Henry Swieca disclaims beneficial ownership of the securities held by Highbridge International LLC.
- (16) Mitchell P. Kopin, President of Downsvie Capital, Inc., the General Partner of Cranshire Capital, L.P. has sole voting power and dispositive control over the securities held by this entity and therefore may be deemed to beneficially own such securities. Each of Mr. Kopin and Downsvie Capital, Inc. disclaims beneficial ownership of the securities.

The Selling Stockholders have not within the past three years had any position, office or other material relationship with our company, except that Richard M. Johnston, who is affiliated with Camden Partners Strategic Fund II-A, L.P. and Camden Partners Strategic Fund II-B, L.P., two of the Selling Stockholders, is Chairman of our Board of Directors.

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**PLAN OF DISTRIBUTION**

We are registering the shares of common stock issued to the Selling Stockholders to permit the resale of these shares of common stock by the holders of the shares of common stock from time to time after the date of this prospectus. We will not receive any of the proceeds from the sale by the Selling Stockholders of the shares of common stock. We will bear all fees and expenses incident to our obligation to register the shares of common stock.

The Selling Stockholders may sell all or a portion of the shares of common stock beneficially owned by them and offered hereby from time to time directly or through one or more underwriters, broker-dealers or agents. If the shares of common stock are sold through underwriters or broker-dealers, the Selling Stockholders will be responsible for underwriting discounts or commissions or agent's commissions. The shares of common stock may be sold on any national securities exchange or quotation service on which the securities may be listed or quoted at the time of sale, in the over-the-counter market or in transactions otherwise than on these exchanges or systems or in the over-the-counter market and in one or more transactions at fixed prices, at prevailing market prices at the time of the sale, at varying prices determined at the time of sale, or at negotiated prices. These sales may be effected in transactions, which may involve crosses or block transactions. The Selling Stockholders may use any one or more of the following methods when selling shares:

ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;

block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;

purchases by a broker-dealer as principal and resale by the broker-dealer for its account;

an exchange distribution in accordance with the rules of the applicable exchange;

privately negotiated transactions;

settlement of short sales entered into after the effective date of the registration statement of which this prospectus is a part;

broker-dealers may agree with the Selling Stockholders to sell a specified number of such shares at a stipulated price per share;

through the writing or settlement of options or other hedging transactions, whether such options are listed on an options exchange or otherwise;

a combination of any such methods of sale; and

any other method permitted pursuant to applicable law.

The Selling Stockholders also may resell all or a portion of the shares in open market transactions in reliance upon Rule 144 under the Securities Act, as permitted by that rule, or Section 4(1) under the Securities Act, if available, rather than under this prospectus, provided that they meet the criteria and conform to the requirements of those provisions.

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Broker-dealers engaged by the Selling Stockholders may arrange for other broker-dealers to participate in sales. If the Selling Stockholders effect such transactions by selling shares of common stock to or through underwriters, broker-dealers or agents, such underwriters, broker-dealers or agents may receive commissions in the form of discounts, concessions or commissions from the Selling Stockholders or commissions from purchasers of the shares of common stock for whom they may act as agent or to whom they may sell as principal. Such commissions will be in amounts to be negotiated, but, except as set forth in a supplement to this prospectus, in the case of an agency transaction will not be in excess of a customary brokerage commission in compliance with NASD Rule 2440; and in the case of a principal transaction a markup or markdown in compliance with NASD IM-2440.

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In connection with sales of the shares of common stock or otherwise, the Selling Stockholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the shares of common stock in the course of hedging in positions they assume. The Selling Stockholders may also sell shares of common stock short and if such short sale shall take place after the date that this registration statement is declared effective by the SEC, the Selling Stockholders may deliver shares of common stock covered by this prospectus to close out short positions and to return borrowed shares in connection with such short sales. The Selling Stockholders may also loan or pledge shares of common stock to broker-dealers that in turn may sell such shares, to the extent permitted by applicable law. The Selling Stockholders may also enter into option or other transactions with broker-dealers or other financial institutions or the creation of one or more derivative securities which require the delivery to such broker-dealer or other financial institution of shares offered by this prospectus, which shares such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction). Notwithstanding the foregoing, the Selling Stockholders have been advised that they may not use shares registered on this registration statement to cover short sales of our common stock made prior to the date the registration statement, of which this prospectus forms a part, has been declared effective by the SEC.

The Selling Stockholders may, from time to time, pledge or grant a security interest in some or all of the shares of common stock owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell the shares of common stock from time to time pursuant to this prospectus or any amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act of 1933, as amended, amending, if necessary, the list of Selling Stockholders to include the pledgee, transferee or other successors in interest as Selling Stockholders under this prospectus. The Selling Stockholders also may transfer and donate the shares of common stock in other circumstances in which case the transferees, donees, pledgees or other successors in interest will be the selling beneficial owners for purposes of this prospectus.

The Selling Stockholders and any broker-dealer or agents participating in the distribution of the shares of common stock may be deemed to be underwriters within the meaning of Section 2(11) of the Securities Act in connection with such sales. In such event, any commissions paid, or any discounts or concessions allowed to, any such broker-dealer or agent and any profit on the resale of the shares purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. Selling Stockholders who are underwriters within the meaning of Section 2(11) of the Securities Act will be subject to the prospectus delivery requirements of the Securities Act and may be subject to certain statutory liabilities of, including but not limited to, Sections 11, 12 and 17 of the Securities Act and Rule 10b-5 under the Securities Exchange Act of 1934, as amended, or the Exchange Act.

Each Selling Stockholder has informed us that it is not a registered broker-dealer and does not have any written or oral agreement or understanding, directly or indirectly, with any person to distribute the common stock. Upon us being notified in writing by a Selling Stockholder that any material arrangement has been entered into with a broker-dealer for the sale of common stock through a block trade, special offering, exchange distribution or secondary distribution or a purchase by a broker or dealer, a supplement to this prospectus will be filed, if required, pursuant to Rule 424(b) under the Securities Act, disclosing (i) the name of each such Selling Stockholder and of the participating broker-dealer(s), (ii) the number of shares involved, (iii) the price at which such the shares of common stock were sold, (iv) the commissions paid or discounts or concessions allowed to such broker-dealer(s), where applicable, (v) that such broker-dealer(s) did not conduct any investigation to verify the information set out or incorporated by reference in this prospectus, and (vi) other facts material to the transaction. In no event shall any broker-dealer receive fees, commissions and markups, which, in the aggregate, would exceed eight percent (8%).

Under the securities laws of some states, the shares of common stock may be sold in such states only through registered or licensed brokers or dealers. In addition, in some states the shares of common stock may not be sold unless such shares have been registered or qualified for sale in such state or an exemption from registration or qualification is available and is complied with.

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There can be no assurance that any Selling Stockholder will sell any or all of the shares of common stock registered pursuant to the shelf registration statement, of which this prospectus forms a part.

The Selling Stockholder and any other person participating in such distribution will be subject to applicable provisions of the Securities Exchange Act of 1934, as amended, and the rules and regulations thereunder, including, without limitation, Regulation M of the Exchange Act, which may limit the timing of purchases and sales of any of the shares of common stock by the Selling Stockholder and any other participating person. Regulation M may also restrict the ability of any person engaged in the distribution of the shares of common stock to engage in market-making activities with respect to the shares of common stock. All of the foregoing may affect the marketability of the shares of common stock and the ability of any person or entity to engage in market-making activities with respect to the shares of common stock.

We will pay all expenses of the registration of the shares of common stock pursuant to the registration rights agreement, including, without limitation, Securities and Exchange Commission filing fees and expenses of compliance with state securities or blue sky laws; *provided, however*, that a Selling Stockholder will pay all underwriting discounts and selling commissions, if any and any related legal expenses incurred by it. We will indemnify the Selling Stockholders against certain liabilities, including some liabilities under the Securities Act, in accordance with the registration rights agreements, or the Selling Stockholders will be entitled to contribution. We may be indemnified by the Selling Stockholders against civil liabilities, including liabilities under the Securities Act, that may arise from any written information furnished to us by the Selling Stockholders specifically for use in this prospectus, in accordance with the related registration rights agreements, or we may be entitled to contribution.

### **INCORPORATION OF CERTAIN INFORMATION BY REFERENCE**

The following documents are specifically incorporated by reference into this prospectus:

- (1) Our annual report on Form 10-K for the year ended December 31, 2006;
- (2) Our proxy statement on Form DEF14A for our annual meeting of stockholders held on June 20, 2007;
- (3) Our quarterly report on Form 10-Q for the quarter ended March 31, 2007;
- (4) Our current reports on Form 8-K filed with the SEC on January 5, 2007, January 9, 2007, February 14, 2007, February 15, 2007, April 20, 2007, May 10, 2007, May 25, 2007, and July 9, 2007;
- (5) All other reports filed pursuant to Section 13(a) or 15(d) of the Exchange Act since the end of the fiscal year covered by the document referred to in (1) above;
- (6) The description of our common stock contained in our registration statement on Form 8-A filed with the SEC on August 1, 2005, including any amendments or reports filed for the purpose of updating that description; and
- (7) All documents that we file with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act prior to the termination of the offering.

We will provide each person, including any beneficial owner, to whom a prospectus is delivered, a copy of any or all of the information that has been incorporated by reference in this prospectus but not delivered with the prospectus. We will provide this information upon written or oral request at no charge to the requester. The request for this information must be made to the following:

Investor Relations

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AtriCure, Inc.

6033 Schumacher Park Drive

West Chester, Ohio 45069

513.755.4100

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**WHERE YOU CAN FIND MORE INFORMATION**

We file annual, quarterly and current reports, proxy statements and other information with the SEC. You may read and copy these documents at the SEC's Public Reference Room, which is located at 100 F Street, NE, Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for more information about the operation of the SEC's Public Reference Room. In addition, the SEC maintains an Internet website, which is located at <http://www.sec.gov>, which contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC. Copies of our SEC filings are also available through our website ([www.atricure.com](http://www.atricure.com)) as soon as reasonably practicable after we electronically file the material with, or furnish it to, the SEC.

We have filed with the SEC a registration statement on Form S-3 under the Securities Act of 1933 to register the common stock offered by this prospectus. This prospectus, which constitutes a part of the registration statement, does not contain all of the information in the registration statement and the exhibits of the registration statement. For further information with respect to us and our common stock, we refer you to the registration statement and to the exhibits to the registration statement. A copy of the registration statement may be inspected, without charge, at the offices of the SEC at 100 F Street, NE, Washington, DC 20549, and copies of all or any part of the registration statement may be obtained from the SEC's public reference room at 100 F Street, NE, Washington, DC 20549, upon the payment of any fees required by the SEC. The registration statement is also available on the SEC's website at <http://www.sec.gov>.

**LEGAL MATTERS**

The validity of the common stock offered hereby will be passed upon for us by Epstein Becker & Green, P.C., New York, New York. As of the date of this prospectus, a member of Epstein Becker & Green, P.C. and his spouse hold an aggregate of 105,857 shares of our common stock and an option to purchase an aggregate of 3,947 shares of our common stock. Another member of Epstein Becker & Green, P.C. is our corporate secretary.

**EXPERTS**

The financial statements and the related financial statement schedule as of December 31, 2006 and 2005, and for each of the three years in the period ended December 31, 2006 incorporated by reference in this prospectus have been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their reports incorporated by reference herein (which report expresses an unqualified opinion on the financial statements and financial statement schedule and includes an explanatory paragraph relating to the adoption of Statement of Financial Accounting Standards No. 123(R), *Share Based Payment*), and have been so incorporated in reliance upon the reports of such firm given upon their authority as experts in accounting and auditing.

**Table of Contents****PART II****INFORMATION NOT REQUIRED IN PROSPECTUS****Item 14. Other Expenses of Issuance and Distribution**

The following table sets forth various costs and expenses payable by the registrant in connection with the sale of the securities being registered. All such costs and expenses shall be borne by the undersigned registrant. Except for the SEC registration fee, all the amounts shown are estimates.

SEC registration fee	\$ 499
Legal fees and expenses	50,000
Accounting fees and expenses	25,000
Printing and related expenses	5,000
Miscellaneous	5,000
Total	\$ 85,499

**Item 15. Indemnification of Officers and Directors**

Section 145 of the Delaware General Corporation Law authorizes a court to award, or a corporation's board of directors to grant, indemnity to directors and officers in terms sufficiently broad to permit such indemnification under certain circumstances for liabilities (including reimbursement for expenses incurred) arising under the Securities Act of 1933, as amended (the Securities Act).

As permitted by the Delaware General Corporation Law, the Registrant's amended and restated certificate of incorporation includes a provision that eliminates the personal liability of its directors for monetary damages for breach of fiduciary duty as a director.

As permitted by the Delaware General Corporation Law, the bylaws of the Registrant provide that (1) the Registrant is required to indemnify its directors and officers to the fullest extent permitted by the Delaware General Corporation Law, subject to certain exceptions, (2) the Registrant is required to advance expenses, as incurred, to its directors and executive officers in connection with a legal proceeding to the fullest extent permitted by the Delaware General Corporation Law, subject to certain exceptions and (3) the rights conferred in the restated bylaws are not exclusive.

The Registrant has entered into indemnification agreements with each of its directors and executive officers to give such directors and officers additional contractual assurances regarding the scope of the indemnification set forth in the Registrant's restated certificate of incorporation and to provide additional procedural protections. The Registrant also intends to enter into indemnification agreements with any new directors and executive officers in the future.

The indemnification provisions in the Registrant's restated certificate of incorporation, restated bylaws and the indemnification agreements entered into between the Registrant and each of its directors and executive officers may be sufficiently broad to permit indemnification of the Registrant's directors and executive officers for liabilities arising under the Securities Act.

The Registrant has obtained liability insurance for its officers and directors.

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**Item 16. Exhibits**

<b>Exhibit No.</b>	<b>Description</b>
3.1 <sup>(1)</sup>	Amended and Restated Certificate of Incorporation.
3.2 <sup>(1)</sup>	Second Amended and Restated Bylaws.
4.1 <sup>(2)</sup>	Specimen common stock certificate.
5.1*	Opinion of Epstein, Becker & Green, P.C.
10.1 <sup>(3)</sup>	Securities Purchase Agreement, dated May 24, 2007, by and between AtriCure, Inc. and those purchasers executing the Securities Purchase Agreement.
10.2 <sup>(3)</sup>	Registration Rights Agreement, dated May 24, 2007, by and between AtriCure, Inc. and those purchasers executing the Registration Rights Agreement.
23.1	Consent of Deloitte & Touche LLP
24.1*	Power of Attorney

\* Previously filed.

(1) Incorporated by reference to our Registration Statement on Form S-1 (Registration No. 333-124197), filed on April 20, 2005, which was declared effective on August 4, 2005.

(2) Incorporated by reference to Amendment No. 2 to our Registration Statement on Form S-1 (Registration No. 333-124197), filed on July 7, 2005, which was declared effective on August 4, 2005.

(3) Incorporated by reference to Exhibits 10.1 and 10.2, respectively, to our Current Report on Form 8-K, filed on May 25, 2007.

**Item 17. Undertakings**

The undersigned registrant hereby undertakes:

(1) That, for the purpose of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered herein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(2) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(3) That, for purposes of determining any liability under the Securities Act, each filing of the registrant's annual report pursuant to Section 13(a) or Section 15(d) of the Exchange Act (and, where applicable, each filing of an employee benefit plan's annual report pursuant to section 15(d) of the Exchange Act) that is incorporated by reference in the Registration Statement shall be deemed to be a new registration statement relating to the securities offered herein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(4) The undersigned registrant hereby undertakes to deliver or cause to be delivered with the prospectus, to each person to whom the prospectus is sent or given, the latest annual report to security holders that is incorporated by reference in the prospectus and furnished pursuant to and meeting the requirements of Rule 14a-3 or Rule 14c-3 under the Securities Exchange Act of 1934; and, where interim financial information required to be presented by Article 3 of Regulation S-X is not set forth in the prospectus, to deliver, or cause to be delivered to each person to whom the prospectus is sent or given, the latest quarterly report that is specifically incorporated by reference in the prospectus to provide such interim financial information.

(5) Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission

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such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of our counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by us is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

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**SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this amendment to the registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of West Chester, State of Ohio, on the 16<sup>th</sup> day of July, 2007.

**ATRICURE, INC.**

By: /s/ DAVID J. DRACHMAN  
 Name: **David J. Drachman**  
 Title: **President and Chief Executive Officer**

Pursuant to the requirements of the Securities Act of 1933, as amended, this amendment to the registration statement has been signed by the following persons in the capacities indicated on July 16, 2007.

Signature	Title(s)
*	
<b>Richard M. Johnston</b>	<b>Richard M. Johnston</b>
	<i>Chairman of the Board</i>
/s/ DAVID J. DRACHMAN	
<b>David J. Drachman</b>	<b>David J. Drachman</b>
	<i>President, Chief Executive Officer and Director</i>
	<i>(principal executive officer)</i>
/s/ JULIE A. PITON	
<b>Julie A. Piton</b>	<b>Julie A. Piton</b>
	<i>Vice President and Chief Financial Officer</i>
	<i>(principal financial and accounting officer)</i>
*	
<b>Donald C. Harrison</b>	<b>Donald C. Harrison</b>
	<i>Director</i>
*	
<b>Michael D. Hooven</b>	<b>Michael D. Hooven</b>
	<i>Director</i>
*	
<b>Elizabeth D. Krell</b>	<b>Elizabeth D. Krell</b>
	<i>Director</i>

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<b>Signature</b>	<b>Title(s)</b>
*	<b>Mark R. Lanning</b>
<b>Mark R. Lanning</b>	<i>Director</i>
*	<b>Karen P. Robards</b>
<b>Karen P. Robards</b>	<i>Director</i>
*	<b>Lee R. Wrubel</b>
<b>Lee R. Wrubel</b>	<i>Director</i>

\*By: /s/ DAVID J. DRACHMAN  
**Attorney-in-Fact**

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**EXHIBIT INDEX**

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