AtriCure®

P000730 revE

AtriCure® Synergy Ablation System

(OLL2, OSL2)

Instructions for Use

DESCRIPTION

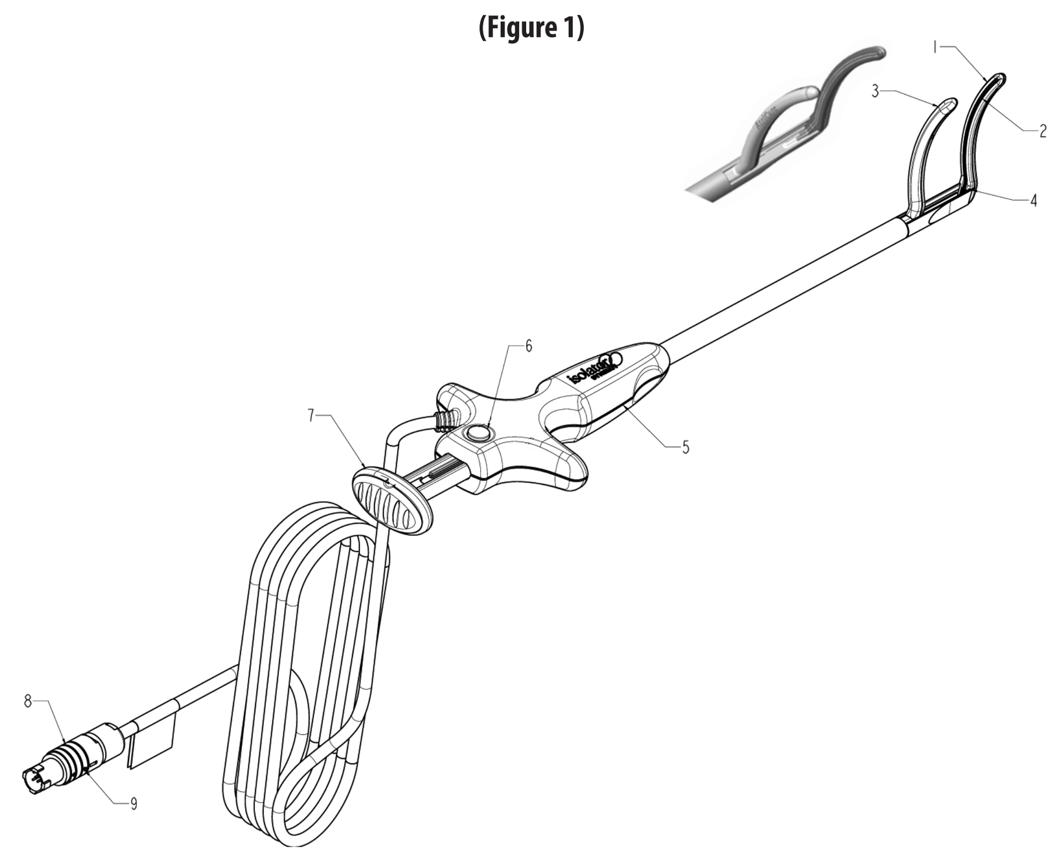
The AtriCure Synergy Ablation System is comprised of the Ablation and Sensing Unit (ASU2), an AtriCure Switch Box (ASB3), an AtriCure Synergy Ablation Clamp, and a footswitch. The AtriCure Synergy Ablation Clamp is a single patient use electrosurgical instrument designed for use only with the ASU2. The Synergy Ablation Clamp is intended to ablate cardiac tissue for the treatment of patients with persistent or longstanding persistent atrial fibrillation who are undergoing open concomitant coronary artery bypass grafting and/or valve replacement or repair. When activated, the ASU2 delivers radiofrequency (RF) energy to the linear electrodes on the insulated jaws of the Synergy Ablation Clamp. The Operator controls the application of this RF energy by pressing the Footswitch.

The Synergy™ Ablation (See Figure 1) Clamps feature two pairs of opposing dual electrodes, an in-line handle with syringe-type actuation and button release mechanisms. The Synergy Ablation Clamp requires the use of the AtriCure Switch Box (ASB3) and Ablation Sensing Unit (ASU2).

NOTE: **Please refer to the AtriCure ASU2 and ASB3 Instructions for Use for information specific to the ASU2 and ASB3.**

AtriCure Synergy Ablation Clamp
ILLUSTRATION AND NOMENCLATURE

(Figure 1)



(AtriCure SYNERGY ABLATION CLAMP)

1. Distal Jaw
2. Electrodes
3. Proximal Jaw
4. Jaw Heel
5. Handle
6. Release Mechanism
7. Closure Lever
8. Connector
9. Connector Alignment Arrow

INDICATION FOR USE

The AtriCure Synergy Ablation System is intended to ablate cardiac tissue for the treatment of persistent atrial fibrillation (sustained beyond seven days, or lasting less than seven days but necessitating pharmacologic or electrical cardioversion) or longstanding persistent atrial fibrillation (continuous atrial fibrillation of greater than one year duration) in patients who are undergoing open concomitant coronary artery bypass grafting and/or valve replacement or repair.

CONTRAINDICATIONS

The AtriCure Synergy Ablation System should not be used for contraceptive coagulation of the fallopian tubes. The device is not designed for safe and effective use for that purpose.

WARNINGS

- Do not touch the electrodes of the Synergy Ablation Clamp while activating the ASU2. Touching the Synergy Ablation Clamp electrodes during ASU2 activation could result in an electrical shock or burn to the operator.
- Do not touch the electrodes of the Synergy Ablation Clamp to metal staples or clips, or to sutures while activating the ASU2. This may damage the Synergy Ablation Clamp or tissue, or result in an incomplete ablation.
- Do not use abrasive cleaners or electrosurgical tip cleaners to clean debris from the Jaws. Use of abrasive cleaners or electrosurgical tip cleaners can damage the electrodes and result in device failure. Use saline-soaked gauze to clean debris off the electrodes.
- Do not immerse any part of the Synergy Ablation Clamp in liquids as this may damage the device.
- Always wear appropriate surgical gloves when using the AtriCure Synergy Ablation System to avoid shock/burn hazards.
- Inspect the product packaging prior to opening to ensure that the sterility barrier is not breached. If the sterility barrier is breached, do not use the Synergy Ablation Clamp to avoid the risk of patient infection.
- Electrosurgery should be used with caution in the presence of internal or external pacemakers. Interference produced with the use of electrosurgical devices can cause devices such as a pacemaker to enter an asynchronous mode or can block the pacemaker entirely. Consult the pacemaker manufacturer or hospital Cardiology department for further information when use of electrosurgical appliances is planned in patients with cardiac pacemakers.
- The AtriCure Synergy Ablation System has not been studied in the reoperative setting, so safe and effective use can not be assured.
- The full Maze IV procedure cannot be completed with the AtriCure Synergy Ablation System alone. See Table 2 for a description of the devices used in the ABLATE Clinical study.

Potential Complications

The AtriCure Synergy Ablation System is indicated for use as a concomitant procedure with open coronary artery bypass grafting and/or valve replacement or repair. Below is a list of potential adverse effects (e.g., complications) that are associated with this combined procedure:

- Death,
- Excessive bleeding that may require re-intervention,
- Cardiac tamponade,
- Pulmonary vein stenosis,
- Restrictive or constrictive pericarditis,
- Infection that may result in sepsis or endocarditis,
- Myocardial infarction (MI),
- Stroke or transient ischemic attack (TIA),
- Thromboembolism,
- Diaphragmatic (phrenic nerve) paralysis,
- Esophageal-left atrial fistula or esophageal rupture,
- Atrial perforation or rupture,
- Ventricular perforation or rupture,
- Atelectasis,
- Pneumonia,
- Congestive heart failure,
- Cardiac valve injury,
- Persistent pneumothorax,
- Excessive pain and discomfort,
- Deep sternal wound infection (mediastinitis),
- Perioperative atrial or ventricular rhythm/conduction disturbance,
- Pericardial effusion,
- Injury to the great vessels,
- Injury to unintended surrounding tissues, including tears and punctures,
- Extension of cardiopulmonary bypass time or aortic cross clamp time.

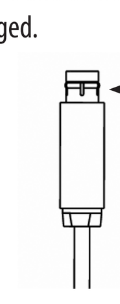
PRECAUTIONS

- Read all instructions carefully for the AtriCure Synergy Ablation System, prior to using the device. Failure to properly follow instructions may lead to electrical or thermal injury and may result in improper functioning of the device.
- The use of the AtriCure Synergy Ablation System is limited to physicians with specific training on the procedure and product.
- Use the Synergy Ablation Clamp only as indicated. Variations in specific procedures may occur due to individual physician techniques and patient anatomy.
- Do not drop or throw the Synergy Ablation Clamp as this may damage the device. If the Synergy Ablation Clamp is dropped, do not use. Replace with a new Synergy Ablation Clamp.
- Do not use the Synergy Ablation Clamp in the presence of flammable materials.
- Do not re-sterilize or reuse the Synergy Ablation Clamp.
- Keep the jaws of the Synergy Ablation Clamp clean of debris during surgery to avoid loss of power.
- Do not use of the Synergy Ablation Clamp with another manufacturer's generator to avoid damage to the device, which may result in patient injury. The Synergy Ablation Clamp is only compatible with the AtriCure ASU2 and ASB3.
- Do not ablate tissue greater than 10 mm thick with the Synergy Ablation Clamp. Tissues greater than 10 mm thick may not be fully ablated.
- Do not use the Synergy Ablation Clamp for coagulation or ablation of veins or arteries.
- Inspect the area between the jaws of the Synergy Ablation Clamp for foreign matter before activating the ASU2 or ASB3. Foreign matter captured between the jaws will adversely affect the ablation.
- Do not insert excessive tissue into the jaw heel as it may result in poor ablation at the jaw heel.
- Do not ablate in a pool of blood or other fluids as this may extend the ablation time. Users should suction excess fluids away from the jaws prior to ablation.
- Do not attempt to use a Synergy Ablation Clamp that has reached its time limit expiration. The Synergy Ablation Clamp has an 8-hour useful life that is tracked by the ASU2. The Synergy Ablation Clamp will no longer function after 8 hours of use and the ASU2 will display a message indicating that the Synergy Ablation Clamp must be replaced.
- Do not use the Synergy Ablation Clamp if signs of damaged wire insulation are noted upon inspection of the area around the jaw heel as it may adversely affect ablation performance.
- When the ASU2 (RF generator) and Synergy Ablation Clamp are used on a patient simultaneously with physiological monitoring equipment, ensure that the monitoring electrodes are placed as far as possible from the surgical electrodes. Be sure to position the Synergy Ablation Clamp cables so that they do not come in contact with the patient or the other leads.
- Needle monitoring electrodes are not recommended for use when operating the ASU2 (RF generator) and Synergy Ablation Clamp.
- Monitoring systems that incorporate high frequency current-limiting devices are recommended for use with the ASU2 (RF generator) and Synergy Ablation Clamp.
- When the ASU2 (RF generator) is activated in conjunction with the Synergy Ablation Clamp, the conducted and radiated electrical fields may interfere with other electrical medical equipment. Refer to the ASU2 IFU for more information regarding potential electromagnetic or other interference, and advice regarding avoidance of such interference.

INSTRUCTIONS FOR USE

SET UP

1. Examine the packaging of the device to ensure the sterility of the product has not been breached. Remove the sterilized instrument from its package per standard sterile technique.
2. With the Connector Alignment Arrow symbol in the 12 o'clock position, push the connector into the appropriate Synergy Ablation Clamp receptacle on the front of the ASB3. Each Synergy Ablation Clamp has a unique receptacle on the ASB3. To ensure device performance, verify proper connections to the ASB3 by consulting the ASB3 package insert. Verify that the connections between the Synergy Ablation Clamp and the ASB3 are secure. If the connections are loose, do not use the Synergy Ablation Clamp. Inspect the cable and do not use the Synergy Ablation Clamp if the cable is frayed or the insulation is damaged.



Insert with Connector Alignment Arrow at the 12 o'clock position

ABLATION

3. Place the targeted tissue between the distal and proximal jaws of the Synergy Ablation Clamp.
4. Depress the Closure Lever to close the Jaws. Ensure that no target tissue extends beyond the Indicator Line on either the distal or proximal jaws or into the jaw heel.
5. Activate the ASU2 by depressing the footswitch. When the ASU2 is activated, the ASU2 will emit an audible tone indicating that current is flowing between the jaws of the Synergy Ablation Clamp. When the continuous tone switches to intermittent, release the footswitch.
6. The AtriCure Synergy Ablation System measures tissue impedance and temperature throughout the ablation cycle and uses this information to control the application of energy to the tissue. The amount of energy delivered to the tissue is driven solely by tissue impedance. The System determines the minimum energy delivery required to create a transmural (full thickness) lesion based on tissue impedance and delivers only that amount of energy to the tissue. Energy delivery changes throughout the ablation cycle as tissue impedance changes. The lesion is visible as a white coloration of the tissue. The device is designed such that the lesions will not spread beyond the jaw width.

   Note: All of the clamps have been designed to maintain less than 50ºC temperature outside of the clamped region.

   Note: The time necessary to create a transmural lesion depends on tissue thickness, composition, and the length of tissue captured between the electrodes. The following table describes the average expected time (seconds) and energy delivery (joules) for respective tissue thicknesses. Values are expressed per unit volume of tissue captured between the electrodes. These data were obtained during ablations on ex vivo (excised bovine) tissues and will generally be lower on in vivo (live human) tissues.

Table 1: Average Time vs. Energy Delivery

Tissue Thickness	Time to Transmurality per unit volume (sec/mm^3)		Energy Delivered per Unit Volume (J/mm^3)	
	AVG	STDDEV	AVG	STDDEV
2 mm	0.049	0.007	0.76	0.11
5 mm	0.033	0.006	0.57	0.10
10 mm	0.032	0.009	0.55	0.16

7. To open the jaws, press the Release Mechanism and slowly release the Closure Lever. Do not allow the jaws to spring back. Be aware of any surrounding tissues that could be damaged as the jaws open.
8. Inspect the surgical area to ensure adequate ablation.
9. Between ablations, wipe the jaws clean with a saline-soaked gauze pad. Important: For optimal performance, keep the Synergy Ablation Clamp electrodes clear of coagulum. To ensure the electrodes are clear of coagulum:
   Use a saline soaked gauze pad to clean the electrodes after each ablation. If coagulum is present, it is much easier to remove within the first several seconds after ablation. In a brief period of time, the coagulum could dry out making removal more difficult.

   Check both electrodes before each ablation to ensure that the gold of the electrode is visible and coagulum is removed.

   If the Synergy Ablation Clamp is idle between ablations, clamp the jaws onto a saline soaked gauze pad to prevent any coagulum on the electrodes from drying.
10. Repeat the ablation process as necessary.

REMOVAL AND DISPOSAL

11. Discard the Synergy Ablation Clamp after use. Follow local governing ordinances and recycling plans regarding disposal or recycling of device components.

SUMMARY OF CLINICAL STUDIES CONDUCTED FOR ATRIAL FIBRILLATION TREATMENT INDICATION

The ABLATE (AtriCure Synergy Bipolar RF Energy Lesions for Permanent Atrial Fibrillation Treatment during Concomitant On-Pump Endo/Epicardial Cardiac Surgery) clinical study has been performed in demonstration of the AtriCure Synergy Ablation System's safety and effectiveness for the treatment of persistent or longstanding persistent atrial fibrillation (AF) in patients undergoing concomitant coronary artery bypass grafting and/or valve replacement or repair.

A continued registry study (ABLATE AF) was established following ABLATE. The ABLATE AF study had identical inclusion and exclusion criteria as ABLATE, except that ABLATE enrolled patients with "permanent AF" (per 2006 ACC/AHA/ESC Guidelines) and ABLATE AF enrolls patients with "persistent or longstanding persistent AF" (per the 2007 HRS Consensus Statement). Results of both studies are presented.

Study Design

ABLATE was a multi-center, prospective, non-randomized study based on a Bayesian adaptive design that provides high probability of demonstrating safety and effectiveness of the AtriCure Synergy Ablation System for the treatment of permanent atrial fibrillation. The safety and effectiveness of the device was compared to performance goals derived from historical information. The Bayesian adaptive clinical design incorporated interim analyses of the data to determine the point of completion of trial enrollment. Enrollment was targeted to be between 50 and 100 subjects at 20 sites. The study was designed to have an initial assessment of results at the point that 50 subjects were enrolled with a minimum of 20 subjects completing their six-month follow-up visit. Nine investigational sites enrolled 55 subjects.

In the Bayesian setting probabilistic statements are made about parameters given observed data (as compared to the frequentist setting where probabilistic statements are made about the data given an assumed parameter value, e.g. a p-value). Two such Bayesian constructs are the posterior probability and credible interval. A posterior probability conveys the probability that the true but unknown effectiveness rate or MAE rate lies above (effectiveness) or below (safety) the stated threshold. For example "There is a 97.9% chance that the true but unknown effectiveness rate is greater than or equal to 60% in this patient population." Similarly a Bayesian credible interval gives a range for the likely values: a 95% credible interval conveys there is a 95% chance that the true but unknown parameter lies between the interval's lower and upper bounds. For example "given the results of the trial, there is a 95% probability that the chance of success ranges from 60.4% to 82.5%". A narrower interval conveys greater precision in the estimate.

Inclusion and Exclusion criteria

Key Inclusion Criteria included:

- ≥ 18 years of age
- History of permanent AF in which cardioversion (electrical and/or pharmacologic) has failed or has not been attempted (as defined by the 2006 ACC/AHA/ESC Guidelines).
- Scheduled to undergo elective cardiac surgical procedure(s) to be performed on cardiopulmonary bypass
- Left Ventricular Ejection Fraction ≥ 30%

Key Exclusion Criteria included:

- Class IV NYHA heart failure symptoms
- Preoperative need for intra-aortic balloon pump or intravenous inotropes
- Left atrial size ≥ 8cm
- Cerebrovascular accident within the prior 6 months
- Myocardial Infarction within the prior 6 weeks
- Need for emergent cardiac surgery
- Renal failure requiring dialysis or hepatic failure
- Repeat (re-do) cardiac surgical procedure

Maze IV Procedure

Figure 1 and Table 2 below summarize the lesions specified by the ABLATE protocol for completion of the Maze IV lesion set, as well as which lesions were to be performed using the AtriCure Synergy Ablation System or other devices.

Figure 1: Maze IV Procedure Lesion Set

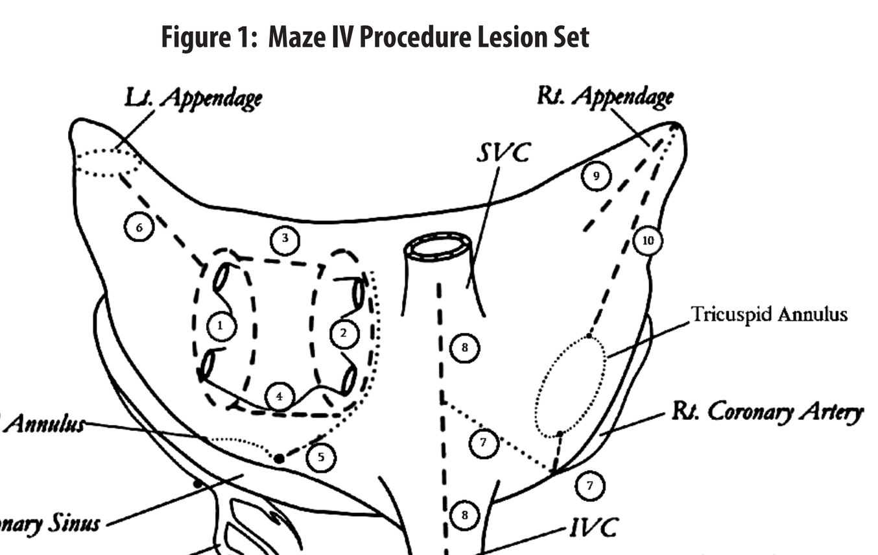


Table 2: Lesions for Maze IV per ABLATE Protocol

Lesion Name	Device to be Used
Pulmonary Vein Lesions	AtriCure Synergy Ablation Clamp
Box Lesion	ROOF and FLOOR lines: AtriCure Synergy Ablation Clamp
Mitral Valve Annulus Lesion	The AtriCure Synergy Ablation clamp is used to start the lesion and the AtriCure Cryoablation System or the AtriCure Bipolar Pen is used to complete the lesion at the annulus of the tricuspid and mitral valve.
LA Appendage Lesion	AtriCure Synergy Ablation Clamp
Tricuspid Valve Lesion	To be performed with the modality of ablation desired by the surgeon.
SVC to IVC Lesion	AtriCure Synergy Ablation Clamp
Right Atrial Free Wall Appendage Lesion	AtriCure Synergy Ablation Clamp
Right Atrial Appendage to Tricuspid Annulus Lesion	The AtriCure Synergy Ablation clamp is used to start the lesion and the AtriCure Cryoablation System or the AtriCure Bipolar Pen is used to complete the lesion at the annulus.

Study Endpoints

The Primary Effectiveness endpoint is the rate of subjects free of AF without the need for Class I and III antiarrhythmic drugs six months after treatment with the system. Freedom from AF is defined as no events of AF longer than 5 minutes and combined events of AF do not exceed 1 hour per 24-hour period assessed by a 24-hour Holter that was reviewed by an independent core laboratory. The effectiveness performance goal was extrapolated from literature to be 60% AF Free and off any AADs at six months.

The Primary Safety endpoint is a composite rate of acute major adverse events within 30 days post procedure or hospital discharge, whichever is later. This composite safety endpoint includes death, stroke (resulting in significant permanent disability), TIA, myocardial infarction, and excessive bleeding (requiring >2 units of blood replacement and surgical intervention). It also included deaths after 30 days if the death was procedure related. The safety performance goal was extrapolated from literature to be 18.95%.

Subject Accountability

Table 3 demonstrates the accountability of subjects enrolled in the ABLATE and ABLATE AF studies.

Table 3: Subject Accountability

Parameter	ABLATE N=55	ABLATE Non-Paroxysmal N=51	ABLATE + ABLATE AF N=69	ABLATE + ABLATE AF Non-Paroxysmal N=64
Patients Enrolled [n] [1]	55	51	69	64
Procedure and Follow-up visit data available [% (n/N)]	N=55	N=51	N=69	N=64
Procedure	100.0% (55/55)	100.0% (51/51)	100.0% (69/69)	100.0% (64/64)
Discharge	96.4% (53/55)	96.1% (49/51)	97.1% (67/69)	96.9% (62/64)
30 Day [2]	96.4% (53/55)	96.1% (49/51)	97.1% (67/69)	96.9% (62/64)
3 Month [3]	87.3% (48/55)	86.3% (44/51)	88.4% (61/69)	87.5% (56/64)
6 Month[4]	90.9% (50/55)	90.2% (46/51)	89.9% (62/69)	89.1% (57/64)
12 Months or later [5]	87.3% (48/55)	88.2% (45/51)		
Follow-up Time in Study (Days) [6]				
Mean +/- SD (N)	555.6 +/- 208.1 (55)	555.8 +/- 208.0 (51)	491.9 +/- 227.9 (69)	492.5 +/- 227.5 (64)
Median	554.0	554.0	547.0	547.0
Min, Max	4.0, 743.0	4.0, 743.0	4.0, 743.0	4.0, 743.0

[1] All subjects treated with Ablation procedure.
[2] Two ABLATE subjects expired prior to 30 days. One subject discharged at 35 days. Assessment performed on that day included in both discharge and 30 days summaries.
[3] One ABLATE subject withdrew prior to 3 month assessment, three ABLATE subjects missed the 3 month visit, and one ABLATE subject expired prior to the 3 month assessment.
[4] One ABLATE subject expired prior to 6 months. Subjects in ABLATE AF are shown with completed assessment at 6 months or later. Two ABLATE AF subjects were not evaluated at 6 months or later at the time of this analysis
[5]] Subjects are shown with completed assessment at 12 months or later. Two ABLATE subjects expired between the 6 month and long-term follow-up assessments.
[6] Study entry to last scheduled follow-up assessment or study exit.

Table 4 demonstrates the population of subjects represented in this dataset. The data are presented for all treated subjects and for the indicated (longstanding persistent and persistent) subjects. In the ABLATE population, there were 4 subjects with paroxysmal AF and 51 subjects with persistent or long-standing persistent AF (hereafter referred to as non-paroxysmal AF). When also including the ABLATE AF registry subjects, there were 5 subjects with paroxysmal AF and 64 subjects with non-paroxysmal AF.

Table 4: AF Classification

	ABLATE	ABLATE AF	ABLATE + ABLATE AF
AF Classification			
Paroxysmal	4	1	5
Persistent	22	2	24
Longstanding Persistent	29	11	40
Indicated Population	**51**	**13**	**64**

Subject Demographics

Table 5 demonstrates subject demographics for all groups.

Table 5: Subject Demographics

Parameter	ABLATE N=55	ABLATE Non-Paroxysmal N=51	ABLATE + ABLATE AF N=69	ABLATE + ABLATE AF Non-Paroxysmal N=64
Age [years]				
Mean +/- SD (N)	70.5 +/- 9.3 (55)	70.8 +/- 9.6 (51)	70.4 +/- 9.0 (69)	70.8 +/- 9.2 (64)
Median	72.0	73.0	72.0	72.5
Min, Max	45.0, 88.0	45.0, 88.0	45.0, 88.0	45.0, 88.0
Gender [% (n/N)]				
Male	58.2% (32/55)	60.8% (31/51)	62.3% (43/69)	64.1% (41/64)
Female	41.8% (23/55)	39.2% (20/51)	37.7% (26/69)	35.9% (23/64)
Time since AF onset (months)				
Mean +/- SD (N)	61.2 +/- 49.5 (55)	61.7 +/- 51.1 (51)	67.3 +/- 55.6 (69)	68.4 +/- 57.3 (64)
Median	48.6	48.6	54.8	55.8
Percentile: 25th, 75th	20.1, 96.1	19.5, 98.4	20.5, 98.4	19.8, 99.9
Min, Max	1.78, 188.39	1.78, 188.39	1.78, 247.17	1.78, 247.17
Left Atrial Size (cm)				
Mean +/- SD (N)	5.9 +/- 1.0 (50)	6.0 +/- 1.0 (46)	5.8 +/- 1.1 (64)	5.9 +/- 1.1 (59)
Median	6.0	6.0	5.7	5.8
Min, Max	3.9, 7.7	3.9, 7.7	3.0, 7.7	3.0, 7.7
>= 5 cm	86.0% (43/50)	87.0% (40/46)	81.3% (52/64)	81.4% (48/59)
Surgical Procedure Type(s)				
CABG only	18.2% (10/55)	19.6% (10/51)	21.7% (15/69)	23.4% (15/64)
Valve Surgery	40.0% (22/55)	37.3% (19/51)	34.8% (24/69)	32.8% (21/64)
Mitral Valve Repair/ Replacement	18.2% (10/55)	17.6% (9/51)	15.9% (11/69)	15.6% (10/64)
Aortic Valve Repair/ Replacement	21.8% (12/55)	19.6% (10/51)	18.8% (13/69)	17.2% (11/64)
Double Valve Surgery	16.4% (9/55)	17.6% (9/51)	14.5% (10/69)	15.6% (10/64)
Aortic & Mitral	7.3% (4/55)	7.8% (4/51)	5.8% (4/69)	6.3% (4/64)
Mitral & Tricuspid	9.1% (5/55)	9.8% (5/51)	8.7% (6/69)	9.4% (6/64)
CABG and Valve Surgery	16.4% (9/55)	15.7% (8/51)	21.7% (15/69)	20.3% (13/64)
CABG + Mitral Valve Repair/ Replacement	10.9% (6/55)	9.8% (5/51)	11.6% (8/69)	10.9% (7/64)
CABG + Aortic Valve Repair/ Replacement	5.5% (3/55)	5.9% (3/51)	10.1% (7/69)	9.4% (6/64)
CABG + Double Valve Surgery	9.1% (5/55)	9.8% (5/51)	7.2% (5/69)	7.8% (5/64)
Aortic & Mitral	5.5% (3/55)	5.9% (3/51)	4.3% (3/69)	4.7% (3/64)
Mitral & Tricuspid	3.6% (2/55)	3.9% (2/51)	2.9% (2/69)	3.1% (2/64)
Any Mitral Valve Surgery	54.5% (30/55)	54.9% (28/51)	49.3% (34/69)	50.0% (32/64)

Primary Safety Results

The Primary Safety Endpoint for ABLATE has been evaluated in both the treated population and the non-paroxysmal AF study population that were enrolled and treated with the AtriCure Synergy Ablation System. A clinic visit was performed at 30 days to fully assess the patient for potential adverse events. An evaluation of all subjects was available to assess this primary safety endpoint. There were five safety failures in the cohort including two deaths, two excessive bleeds and one stroke, as outlined in Table 6. When tested against the objective performance goal, the upper bound of the Bayesian Credible Interval fell below 0.1895 for the full ABLATE population, but above 0.1895 for the non-paroxysmal subpopulation.

Table 6: Primary Safety Endpoint

Primary Safety Endpoint	ABLATE N=55	ABLATE Non-paroxysmal N=51	ABLATE + ABLATE AF N=69	ABLATE + ABLATE AF Non-paroxysmal N=64
Primary Safety Endpoint	**% (n/N) [BCI] [1] PP [2]**	**% (n/N) [BCI] [1] PP [2]**	**% (n/N)**	**% (n/N)**
Primary Endpoint (Acute MAE within 30 days post procedure)	9.1% (5/55) [0.00, 0.179] PP = 0.967	9.8% (5/51) [0.00, 0.192] PP = 0.946	7.2% (5/69)	7.8% (5/64)
Death	3.6% (2/55)	3.9% (2/51)	2.9% (2/69)	3.1% (2/64)
<=30 days	3.6% (2/55)	3.9% (2/51)	2.9% (2/69)	3.1% (2/64)
>30 days, procedure related	0.0% (0/55)	0.0% (0/51)	0.0% (0/69)	0.0% (0/64)
Stroke/TIA	1.8% (1/55)	2.0% (1/51)	1.4% (1/69)	1.6% (1/64)
Stroke (with significant permanent disability)	1.8% (1/55)	2.0% (1/51)	1.4% (1/69)	1.6% (1/64)
TIA	0.0% (0/55)	0.0% (0/51)	0.0% (0/69)	0.0% (0/64)
MI	0.0% (0/55)	0.0% (0/51)	0.0% (0/69)	0.0% (0/64)
Excessive Bleeding (>2 units blood and surgical intervention)	3.6% (2/55)	3.9% (2/51)	2.9% (2/69)	3.1% (2/64)

[1] "BCI" is the 95% one-sided Bayesian Credible Interval. Beta (1,1) prior in accordance with the statistical plan.
[2] "PP" is the posterior probability the safety rate is less than 0.1895, $Pr(qT < 0.1895 \mid \text{Trial Results})$.

Primary Effectiveness Results

The primary effectiveness endpoint was defined as the rate of subjects that achieved successful obliteration of atrial fibrillation while off of any antiarrhythmic medication (Class I or III) evaluated at six months post procedure via 24 hour Holter monitor assessment (or permanent pacemaker interrogation in the case of those subjects who had a pacemaker implanted). The effectiveness results are presented in Table 7. When tested against the objective performance goal, the lower bound of the Bayesian Credible Interval exceeded 0.60 for the full ABLATE population, but was below 0.60 in the non-paroxysmal subpopulation. The results for pulmonary vein isolation are presented in Table 8.

Table 7: Primary Effectiveness Endpoint

	ABLATE	ABLATE Non-paroxysmal	ABLATE + ABLATE AF	ABLATE + ABLATE AF Non-paroxysmal
Summary of Effectiveness Endpoints	**% (n/N) [BCI] [1] PP [2]**	**% (n/N) [BCI] [1] PP [2]**	**% (n/N)**	**% (n/N)**
Effectiveness Evaluable at 6 month Follow-up	N=50	N=46	N=62	N=57
Free of AF and off AAD	74.0% (37/50) [0.604, 1.00] PP = 0.978	73.9% (34/46) [0.597, 1.00] PP = 0.972	75.8% (47/62)	75.4% (43/57)
Free of AF	84.0% (42/50)	82.6% (38/46)	85.5% (53/62)	84.2% (48/57)

[1] "BCI" is the 97.5% one-sided Bayesian Credible Interval. Beta (1,1) prior in accordance with the statistical plan.
[2] "PP" is the posterior probability that the effectiveness rate exceeds 0.60, $Pr(pT > 0.60 \mid \text{Trial Results})$.

Table 8: Pulmonary Vein Isolation Summary

	ABLATE N=55	ABLATE Non-paroxysmal N=51	ABLATE + ABLATE AF N=69	ABLATE + ABLATE AF Non-paroxysmal N=64
Parameter	**% (n/N)**	**% (n/N)**	**% (n/N)**	**% (n/N)**
Both Right & Left Pulmonary Vein Isolation Evaluated [1]	41.8% (23/55)	43.1% (22/51)	47.8% (33/69)	48.4% (31/64)
Both Right & Left Pulmonary Vein Isolation Confirmed [2]	100.0% (23/23)	100.0% (22/22)	100.0% (33/33)	100.0% (31/31)

[1] Includes subjects evaluable on both sides.
[2] Successful pulmonary vein isolation on both left and right side.

Secondary Safety and Effectiveness Results

Table 9 demonstrates primary and secondary effectiveness endpoints, including long-term effectiveness. ABLATE AF subjects had not reached the 12-month follow-up at the time of review.

Table 9: Primary and Secondary Effectiveness Endpoints

	ABLATE	ABLATE Non-paroxysmal	ABLATE + ABLATE AF	ABLATE + ABLATE AF Non-paroxysmal
Summary of Effectiveness Endpoints	**% (n/N) [BCI] [1] PP [2]**	**% (n/N) [BCI] [1] PP [2]**	**% (n/N)**	**% (n/N)**
Effectiveness Evaluable at 6 month Follow-up	N=50	N=46	N=62	N=57
Free of AF and off AAD	74.0% (37/50) [0.604, 1.00] PP = 0.978	73.9% (34/46) [0.597, 1.00] PP = 0.972	75.8% (47/62)	75.4% (43/57)
Free of AF	84.0% (42/50)	82.6% (38/46)	85.5% (53/62)	84.2% (48/57)
AF Burden [3]				
= 0 min	82.0% (41/50)	82.6% (38/46)	83.9% (52/62)	84.2% (48/57)
<= 5 min	2.0% (1/50)	0.0% (0/46)	1.6% (1/62)	0.0% (0/57)
> 5 min - 1 hr	2.0% (1/50)	2.2% (1/46)	1.6% (1/62)	1.8% (1/57)
> 1 hr	14.0% (7/50)	15.2% (7/46)	12.9% (8/62)	14.0% (8/57)
Effectiveness Evaluable at 12 month Follow-up or greater	N=48	N=45		
Time to Evaluation (days)				
Mean +/- SD (N)	640.9 +/- 147.3	641.7 +/- 151.7		
Min, Max	365.0, 952.0	365.0, 952.0		
Method of Evaluation				
Holter	81.3% (39/48)	82.2% (37/45)		
Pacemaker Interrogation (PMI)	2.1% (1/48)	2.2% (1/45)		
ECG	6.3% (3/48)	4.4% (2/45)		
Other/Telephone Assessment	10.4% (5/48)	11.1% (5/45)		
Free of AF and off AAD (12 month follow-up or greater)	62.5% (30/48)	62.2% (28/45)		
Free of AF (12 month follow-up or greater)	75.0% (36/48)	73.3% (33/45)		
AF Burden (initial 24 hrs or >24 - 48 hrs) [3] [4]				
= 0 min	77.5% (31/40)	76.3% (29/38)		
<= 5 min	0.0% (0/40)	0.0% (0/38)		
> 5 min - 1 hr	0.0% (0/40)	0.0% (0/38)		
> 1 hr	22.5% (9/40)	23.7% (9/38)		

[1] "BCI" is the 97.5% one-sided Bayesian Credible Interval. Beta (1,1) prior in accordance with the statistical plan.
[2] "PP" is the posterior probability that the effectiveness rate exceeds 0.60, $Pr(pT > 0.60 \mid \text{Trial Results})$.
[3] Patients with Pacemaker Interrogation (PMI) included as 0 min if no Atrial Fibrillation (AFib) on PMI, otherwise included based on equivalent proportion of AFib burden per total pacemaker interrogation period.
[4] Evaluable only in patients with a Holter or Pacemaker Interrogation (PMI)

Table 10 demonstrates the pacemaker implantation rate through 30 days.

Table 10: Pacemaker Implantation Through 30 days

	ABLATE N=55	ABLATE Non-paroxysmal N=51	ABLATE + ABLATE AF N=69	ABLATE + ABLATE AF Non-paroxysmal N=64
	% (n/N)	**% (n/N)**	**% (n/N)**	**% (n/N)**
Pacemaker Pre-procedure	12.7% (7/55)	9.8% (5/51)	14.5% (10/69)	12.5% (8/64)
Post Procedure				
Permanent Pacemaker Implantation, as Adjudicated [1] [2]	25.0% (12/48)	26.1% (12/46)	20.3% (12/59)	21.4% (12/56)
AV node dysfunction	8.3% (4/48)	8.7% (4/46)	6.8% (4/59)	7.1% (4/56)
Sinus node dysfunction	16.7% (8/48)	17.4% (8/46)	13.6% (8/59)	14.3% (8/56)

[1] One subject has both an AV Nodal Block and a Bradycardia event leading to permanent pacemaker implant.
[2] One subject had a single chamber pacemaker present at baseline which was upgraded to dual chamber at follow-up.

The rate of serious device- and ablation procedure-related adverse events through 6 months is demonstrated in Table 11. Table 12 lists the observed serious device- or ablation procedure-related adverse events. There were four subjects with AV node dysfunction who received pacemakers. Using the most conservative approach, these were attributed to the MAZE procedure. However, the need for a pacemaker could be attributed to the primary procedure. Three events occurred during surgical access. They included one case of a pulmonary vein tear when dissecting the vein to place the clamp, one torn IVC during cannulation and one left atrial tear which occurred when lifting the heart for surgical access. The final case of akinesis caused by ischemia was associated with possible coronary injury from an ancillary ablation pen. The event was successfully treated with two bypass grafts.

Table 11: Serious Device- and Ablation Procedure-Related Adverse Events Through 6 Months

	ABLATE N=55		ABLATE Non-paroxysmal N=51		ABLATE + ABLATE AF N=69		ABLATE + ABLATE AF Non-paroxysmal N=64	
Parameter [1] [2]	**# of Evts**	**% (n/N) of Pts with Event**	**# of Evts**	**% (n/N) of Pts with Event**	**# of Evts**	**% (n/N) of Pts with Event**	**# of Evts**	**% (n/N) of Pts with Event**
Investigational Device	0	0.0% (0/55)	0	0.0% (0/51)	0	0.0% (0/69)	0	0.0% (0/64)
AF Procedure	7	12.7% (7/55)	7	13.7% (7/51)	7	10.1% (7/69)	7	10.9% (7/64)
Ancillary Device	1	1.8% (1/55)	1	2.0% (1/51)	1	1.4% (1/69)	1	1.6% (1/64)

[1] As Adjudicated or site reported if not yet adjudicated.
[2] Relationship presented hierarchally as listed in table.

Table 12:
Listing of Observed Serious Device- or Ablation Procedure-Related Serious Adverse Events

Event Name	Relationship	Description
A-V Node Dysfunction	AF Ablation Procedure	AV-Node dysfunction requiring permanent pacemaker implantation. Conservatively attributed to the MAZE procedure, however the need for a pacemaker could be attributed to the primary procedure.
A-V Node Dysfunction	AF Ablation Procedure	AV-Node dysfunction requiring permanent pacemaker implantation. Conservatively attributed to the MAZE procedure, however the need for a pacemaker could be attributed to the primary procedure.
A-V Node Dysfunction	AF Ablation Procedure	AV-Node dysfunction requiring permanent pacemaker implantation. Conservatively attributed to the MAZE procedure, however the need for a pacemaker could be attributed to the primary procedure.
A-V Node Dysfunction	AF Ablation Procedure	AV-Node dysfunction requiring permanent pacemaker implantation. Conservatively attributed to the MAZE procedure, however the need for a pacemaker could be attributed to the primary procedure.
Cardiac Akinesis	Ancillary Device Related	Cardiac akinesis caused by ischemia was associated with possible coronary injury from an ancillary ablation pen. The event was successfully treated with two bypass grafts.
Pulmonary Vein Tear (LPV)	AF Ablation Procedure	Pulmonary vein tear during surgical access when dissecting the vein to place the clamp. The event was successfully treated with a suture to repair the tear.
Torn IVC Cannulation Site	AF Ablation Procedure	During surgical access, the IVC was torn during cannulation. The event was successfully treated with a patch to repair the tear.
Left Atrial Tear	AF Ablation Procedure	A left atrial tear which occurred when lifting the heart for surgical access, prior to use of the AtriCure Synergy Ablation System. The event was successfully treated with epicardial and endocardial sutures.

Table 13 demonstrates a summary of adverse events through 6 months for the ABLATE populations.

Table 13: Summary of Adverse Events by Attribution through 6 Months

	ABLATE N=55		ABLATE Non-paroxysmal N=51	
Parameter [1] [2]	**# of Evts**	**% (n/N) of Pts with Event**	**# of Evts**	**% (n/N) of Pts with Event**
Any Adverse Event	198	90.9% (50/55)	188	94.1% (48/51)
Investigational Device	0	0.0% (0/55)	0	0.0% (0/51)
AF Procedure	8	14.5% (8/55)	8	15.7% (8/51)
Ancillary Device	1	1.8% (1/55)	1	2.0% (1/51)
General Surgical Procedure	144	87.3% (48/55)	138	90.2% (46/51)
Other Relationship	45	41.8% (23/55)	41	43.1% (22/51)
Serious Adverse Event	106	74.5% (41/55)	99	76.5% (39/51)
Investigational Device	0	0.0% (0/55)	0	0.0% (0/51)
AF Procedure	7	12.7% (7/55)	7	13.7% (7/51)
Ancillary Device	1	1.8% (1/55)	1	2.0% (1/51)
General Surgical Procedure	70	61.8% (34/55)	66	62.7% (32/51)
Other Relationship	28	32.7% (18/55)	25	33.3% (17/51)

[1] As Adjudicated or site reported if not yet adjudicated.
[2] Relationship presented hierarchally as listed in table.

Table 14 through Table 18 demonstrate the rates of device use for the Maze IV procedure per subject and per lesion.

Table 14: Ablation Procedure Summary

	ABLATE N=55	ABLATE Non-paroxysmal N=51	ABLATE + ABLATE AF N=69	ABLATE + ABLATE AF Non-paroxysmal N=64
Parameter	**% (n/N)**	**% (n/N)**	**% (n/N)**	**% (n/N)**
Ablation Procedure Summary				
Complete MAZE Procedure [1]	90.9% (50/55)	92.2% (47/51)	92.8% (64/69)	93.8% (60/64)
Lesion Set Deviations				
Incomplete Lesion Set				
Pulmonary Vein Isolation Only	1.8% (1/55)	0.0% (0/51)	1.4% (1/69)	0.0% (0/64)
Incomplete Right Atrial Ablation Lesion Set	7.3% (4/55)	7.8% (4/51)	5.8% (4/69)	6.3% (4/64)
Right Anterior freewall appendage lesion not done	7.3% (4/55)	7.8% (4/51)	5.8% (4/69)	6.3% (4/64)
Lesion from right atrial appendage to tricuspid annulus not done	1.8% (1/55)	2.0% (1/51)	1.4% (1/69)	1.6% (1/64)
Incomplete Left Atrial Ablation Lesion Set	0.0% (0/55)	0.0% (0/51)	0.0% (0/69)	0.0% (0/64)
Required Lesion Completed with Method other than Synergy Ablation Clamp				
Floor Lesion [2]	12.7% (7/55)	13.7% (7/51)	13.0% (9/69)	14.1% (9/64)
LA Appendage [2]	3.6% (2/55)	3.9% (2/51)	2.9% (2/69)	3.1% (2/64)
Roof [2]	1.8% (1/55)	2.0% (1/51)	1.4% (1/69)	1.6% (1/64)
Mitral Annulus [2]	1.8% (1/55)	2.0% (1/51)	1.4% (1/69)	1.6% (1/64)

[1] Complete MAZE IV procedure includes subjects in which required lesions were performed using methods not specified in the protocol.
[2] Alternative methods for ABLATE include Cut & Sew (6 Floor lesions), Cryoablation (2 LA appendage lesions and 1 mitral annulus lesion), and RF pen (One Floor lesion and one roof lesion). Alternative methods for ABLATE AF include Cut & Sew (2 floor lesions).

Table 15: Biatrial Lesion Details - Left Atrial Lesions

	ABLATE N=55	ABLATE Non-paroxysmal N=51	ABLATE + ABLATE AF N=69	ABLATE + ABLATE AF Non-paroxysmal N=64
Parameter	**% (n/N)**	**% (n/N)**	**% (n/N)**	**% (n/N)**
Left Sided Lesions [1]				
I. Mitral Valve Connecting Lesion [2]	100.0% (54/54)	100.0% (51/51)	100.0% (68/68)	100.0% (64/64)
AtriCure Clamp	33.3% (18/54)	29.4% (15/51)	35.3% (24/68)	32.8% (21/64)
Cryo	1.9% (1/54)	2.0% (1/51)	22.1% (15/68)	23.4% (15/64)
AtriCure Clamp and AtriCure Pen	27.8% (15/54)	29.4% (15/51)	32.4% (22/68)	32.8% (21/64)
AtriCure Clamp and Cryo	29.6% (16/54)	31.4% (16/51)	8.8% (6/68)	9.4% (6/64)
AtriCure Clamp and Surgical (cut and sew)	7.4% (4/54)	7.8% (4/51)	1.5% (1/68)	1.6% (1/64)

Table 15: Biatrial Lesion Details - Left Atrial Lesions (continued)

	ABLATE N=55	ABLATE Non-paroxysmal N=51	ABLATE + ABLATE AF N=69	ABLATE + ABLATE AF Non-paroxysmal N=64
Parameter	**% (n/N)**	**% (n/N)**	**% (n/N)**	**% (n/N)**
II. Floor Line Lesion	100.0% (54/54)	100.0% (51/51)	100.0% (68/68)	100.0% (64/64)
AtriCure Clamp	87.0% (47/54)	86.3% (44/51)	86.8% (59/68)	85.9% (55/64)
AtriCure Pen	1.9% (1/54)	2.0% (1/51)	1.5% (1/68)	1.6% (1/64)
Surgical (cut and sew)	11.1% (6/54)	11.8% (6/51)	11.8% (8/68)	12.5% (8/64)
III. Roof Line Lesion	100.0% (54/54)	100.0% (51/51)	100.0% (68/68)	100.0% (64/64)
AtriCure Clamp	98.1% (53/54)	98.0% (50/51)	98.5% (67/68)	98.4% (63/64)
AtriCure Pen	1.9% (1/54)	2.0% (1/51)	1.5% (1/68)	1.6% (1/64)
IV. LAA Appendage to Pulmonary Vein	100.0% (54/54)	100.0% (51/51)	100.0% (68/68)	100.0% (64/64)
AtriCure Clamp	96.3% (52/54)	96.1% (49/51)	97.1% (66/68)	96.9% (62/64)
Cryo	3.7% (2/54)	3.9% (2/51)	2.9% (2/68)	3.1% (2/64)
[1] One subject did not undergo the Maze IV procedure. [2] Mitral valve connecting lesion includes the full complement of the mitral valve annular lesion (lesion taken from the atriotomy to the mitral valve annulus and lesion completed on the posterior mitral valve annulus).				

Table 16: Biatrial Lesion Details - Right Atrial Lesions

	ABLATE N=55	ABLATE Non-paroxysmal N=51	ABLATE + ABLATE AF N=69	ABLATE + ABLATE AF Non-paroxysmal N=64
Parameter	**% (n/N)**	**% (n/N)**	**% (n/N)**	**% (n/N)**
Right Sided Lesions [1]				
I. Tricuspid Valve Annulus lesion	100.0% (54/54)	100.0% (51/51)	100.0% (68/68)	100.0% (64/64)
AtriCure Clamp	46.3% (25/54)	43.1% (22/51)	50.0% (34/68)	46.9% (30/64)
AtriCure Pen	14.8% (8/54)	15.7% (8/51)	13.2% (9/68)	14.1% (9/64)
Surgical (cut and sew)	1.9% (1/54)	2.0% (1/51)	1.5% (1/68)	1.6% (1/64)
Cryo	14.8% (8/54)	15.7% (8/51)	17.6% (12/68)	18.8% (12/64)
AtriCure Clamp and AtriCure Pen	9.3% (5/54)	9.8% (5/51)	7.4% (5/68)	7.8% (5/64)
AtriCure Clamp and Cryo	11.1% (6/54)	11.8% (6/51)	8.8% (6/68)	9.4% (6/64)
AtriCure Clamp and Surgical (cut and sew)	1.9% (1/54)	2.0% (1/51)	1.5% (1/68)	1.6% (1/64)
II. Ablation of SVC / IVC	100.0% (54/54)	100.0% (51/51)	100.0% (68/68)	100.0% (64/64)
AtriCure Clamp	100.0% (54/54)	100.0% (51/51)	100.0% (68/68)	100.0% (64/64)
III. Freewall Appendage Lesion	92.6% (50/54)	92.2% (47/51)	94.1% (64/68)	93.8% (60/64)
AtriCure Clamp	100.0% (50/50)	100.0% (47/47)	100.0% (64/64)	100.0% (60/60)
IV. Right Atrial Appendage Lesion	98.1% (53/54)	98.0% (50/51)	98.5% (67/68)	98.4% (63/64)
AtriCure Clamp	54.7% (29/53)	52.0% (26/50)	52.2% (35/67)	50.8% (32/63)
AtriCure Pen	9.4% (5/53)	10.0% (5/50)	9.0% (6/67)	9.5% (6/63)
Cryo	18.9% (10/53)	20.0% (10/50)	22.4% (15/67)	22.2% (14/63)
AtriCure Clamp and AtriCure Pen	7.5% (4/53)	8.0% (4/50)	7.5% (5/67)	7.9% (5/63)
AtriCure Clamp and Cryo	5.7% (3/53)	6.0% (3/50)	6.0% (4/67)	6.3% (4/63)
AtriCure Clamp and Surgical (cut and sew)	1.9% (1/53)	2.0% (1/50)	1.5% (1/67)	1.6% (1/63)
Surgical (cut and sew) and Cryo	1.9% (1/53)	2.0% (1/50)	1.5% (1/67)	1.6% (1/63)
[1] One subject did not undergo the Maze IV procedure.				

Table 17: Biatrial Lesion Details - Optional Procedures

	ABLATE N=55	ABLATE Non-paroxysmal N=51	ABLATE + ABLATE AF N=69	ABLATE + ABLATE AF Non-paroxysmal N=64
Parameter	**% (n/N)**	**% (n/N)**	**% (n/N)**	**% (n/N)**
Right atrial appendage removal [1]	1.9% (1/54)	2.0% (1/51)	1.5% (1/68)	1.6% (1/64)
Surgical (cut and sew)	100.0% (1/1)	100.0% (1/1)	100.0% (1/1)	100.0% (1/1)
Septal lesion [1]	20.4% (11/54)	21.6% (11/51)	17.6% (12/68)	18.8% (12/64)
AtriCure Clamp	63.6% (7/11)	63.6% (7/11)	66.7% (8/12)	66.7% (8/12)
Cryo	36.4% (4/11)	36.4% (4/11)	33.3% (4/12)	33.3% (4/12)
[1] One subject did not undergo the Maze IV procedure.				

Table 18: Left Atrial Appendage Exclusion

	ABLATE N=55	ABLATE Non-paroxysmal N=51	ABLATE + ABLATE AF N=69	ABLATE + ABLATE AF Non-paroxysmal N=64
Parameter	**% (n/N)**	**% (n/N)**	**% (n/N)**	**% (n/N)**
Left Atrial Appendage [1]				
Excised	88.9% (48/54)	88.2% (45/51)	91.2% (62/68)	90.6% (58/64)
Excluded Only	11.1% (6/54)	11.8% (6/51)	8.8% (6/68)	9.4% (6/64)
[1] One subject did not undergo the Maze IV procedure.				

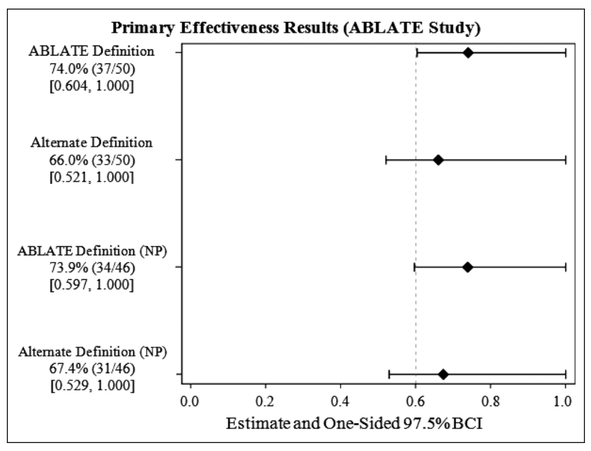
Additional Data Analysis

Table 19 and Figure 2 present results considering the following factors that affect interpretation of the effectiveness results. First, current definitions for freedom from atrial fibrillation would categorize subjects having any episode of AF, atrial flutter or atrial tachycardia > 30 seconds and/or subjects that were cardioverted after a 3 month blanking period as treatment failures. In addition, one subject had not completed the AAD washout at their 6-month effectiveness evaluation, but was considered to be an effectiveness success based on freedom from AF at later timepoints.

Table 19: Summary of Effectiveness Endpoints for New Definition

	ABLATE N=55	ABLATE Non-paroxysmal N=51	ABLATE + ABLATE AF N=69	ABLATE + ABLATE AF Non-paroxysmal N=64
Primary Effectiveness through 6 Months	**% (n/N) [BCI] [1]**	**% (n/N) [BCI] [1]**	**% (n/N)**	**% (n/N)**
Effectiveness Evaluable at 6 month Follow-up	N=50	N=46	N=62	N=57
ABLATE Definition (AF Free and Off AADs)	74.0% (37/50) [0.604, 1.00]	73.9% (34/46) [0.597, 1.00]	75.8% (47/62)	75.4% (43/57)
Alternate Definition [2]	66.0% (33/50) [0.521, 1.00]	67.4% (31/46) [0.529, 1.00]	64.5% (40/62)	64.9% (37/57)
Primary Effectiveness Failures by Alternate Definition [3]				
Failure by Rhythm Atrial Fibrillation Atrial Flutter Atrial Tachycardia	11 (9) (2) (0)	10 (8) (2) (0)	13 (10) (2) (1)	12 (9) (2) (1)
Failure by AAD Inadequate drug washout	6 (3)	5 (3)	9 (5)	8 (5)
Failure by CV between 3 and 6 Months	4	4	4	4
[1] 97.5% one-sided Bayesian Credible Interval. Beta (1,1) prior in accordance with the statistical plan. [2] Alternate definition defined as AF free and off AADs with no Atrial fibrillation, Atrial flutter, or Atrial tachycardia > 30 seconds, AADs washed out and no cardioversion after 3 months. [3] Overall rate cannot be computed by simple summation of counts for individual failure modes as several subjects failed by more than one mode: Late CV and AAD (1); Rhythm (AFL) and AAD (1); Late CV and Rhythm (AF) (2).				

Figure 2: Forest Plot, Primary Effectiveness Success



Additional sources of data corroborate the results observed in ABLATE and ABLATE AF. These sources include the RESTORE clinical trial, the predecessor pivotal trial to ABLATE, and institutional database repositories of consecutively collected procedural and follow up clinical data. RESTORE was a multi-center, prospective, match-controlled clinical trial to evaluate the safety and effectiveness of the AtriCure Ablation System. The Washington University Institutional Database was a prospective single center registry of baseline, procedure, and follow-up data from a repository of information on all AF treated subjects at the institution. The Baylor Plano Institutional Database was a prospective single center registry of baseline, procedure, and follow-up data from a repository of information on all AF treated subjects at the institution. Table 20 and Table 21 demonstrate the data for the non-paroxysmal subjects from these sources.

Table 20: Primary Safety Endpoint, Additional Sources of Data

	ABLATE Non-Paroxysmal (N=51)	ABLATE+ ABLATE AF Non-Paroxysmal (N=64)	RESTORE (N=36)	Wash U. (N=56)	Baylor (N=8)
Primary Safety Endpoint (Acute MAE within 30 days post procedure) Frequentist Observed % (n/N)	9.8% (5/51)	7.8% (5/64)	8.3% (3/36)	14.3% (8/56)	25.0% (2/8)
Death (<= 30 days or > 30 days procedure related)	3.9% (2/51)	3.1% (2/64)	5.6% (2/36)	3.6% (2/56)	12.5% (1/8)
Stroke/TIA	2.0% (1/51)	1.6% (1/64)	0.0% (0/36)	1.8% (1/56)	0.0% (0/8)
MI	0.0% (0/51)	0.0% (0/64)	0.0% (0/36)	0.0% (0/56)	0.0% (0/8)
Excessive Bleeding (>2 units blood and surgical intervention)	3.9% (2/51)	3.1% (2/64)	8.3% (3/36)	8.9% (5/56)	25.0% (2/8)

Table 21: Effectiveness Endpoints

	ABLATE Non-Paroxysmal	ABLATE+ ABLATE AF Non-Paroxysmal	RESTORE	Wash U.	Baylor
6 Month Follow-Up Assessment	N = 46	N = 57	N = 33[1]	N = 47	N = 2
Primary Effectiveness Endpoint 6 mo AF Free and off AADs Frequentist Observed % (n/N)	73.9% (34/46)	75.4% (43/57)	64.3% (18/28)	74.5% (35/47)	0% (0/2)
6 mo AF Free Frequentist Observed % (n/N)	82.6% (38/46)	84.2% (48/57)	81.8% (27/33)	91.5% (43/47)	50.0% (1/2)
12 Month or Greater Follow-Up Assessment	N = 45		N = 24	N = 46	N = 3
12 mo (or greater) AF Free and off AADs Frequentist Observed % (n/N)	62.2% (28/45)		45.8% (11/24)	84.8% (39/46)	0% (0/3)
12 mo (or greater) AF Free Frequentist Observed % (n/N)	73.3% (33/45)		66.7% (16/24)	91.3% (42/46)	0% (0/3)
[1]Subjects off AAD's at 6 months and AF Free but not through the wash-out period are not evaluable.					

Conclusions:

The results demonstrate that there is a reasonable assurance of safety and effectiveness to support the use of the AtriCure Synergy Ablation System for the treatment of persistent or longstanding persistent atrial fibrillation in patients who are undergoing open concomitant coronary artery bypass grafting and/or valve replacement or repair.

HOW SUPPLIED

The Synergy Ablation System is supplied as a STERILE clamp and is for single patient use only. Sterility is guaranteed unless the package is opened or damaged. Do not resterilize.

The other components (ASU2 and ASB3) are not sterile and may be reused.

RETURN OF USED PRODUCT

If for any reason these products must be returned to AtriCure, a return goods authorization (RGA) number is required from AtriCure prior to shipping.

If the products have been in contact with blood or body fluids, they must be thoroughly cleaned and disinfected before packing. They should be shipped in either the original carton or an equivalent carton, to prevent damage during shipment; and they should be properly labeled with an RGA number and an indication of the biologically hazardous nature of the contents of shipment.

Instructions for cleaning and materials, including appropriate shipping containers, proper labeling, and an RGA number may be obtained from AtriCure, Inc.

CAUTION: It is the responsibility of the health care institution to adequately prepare and identify the products for shipment.

DISCLAIMER STATEMENTS

Users must assume responsibility for approving the condition of these products before they are used. AtriCure, Inc. cannot be held liable for any consequential damage, personal injury or damage to property nor for the misuse of these products.

AtriCure, Inc. will not be liable for any damage caused by the reuse of these products.

This Instruction for Use describes the procedures for proper use of the products. Any deviation from these procedures, which may compromise the function of the products, is the responsibility of the user.

PYROGEN	Non-Pyrogenic		Expiration Date
STERILE EO	Sterilized by Ethylene Oxide		Follow instructions for use
	Single Use Only		Manufactured By
Rx ONLY	Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician	LATEX	Latex Free
LOT	Lot Number		

Manufactured by:
AtriCure Incorporated
7555 Innovation Way
Mason, Ohio 45040 USA
Customer Service:
1-866-349-2342 (toll free)
513-755-4100