

AtriCure® Synergy Ablation System Instructions for Use

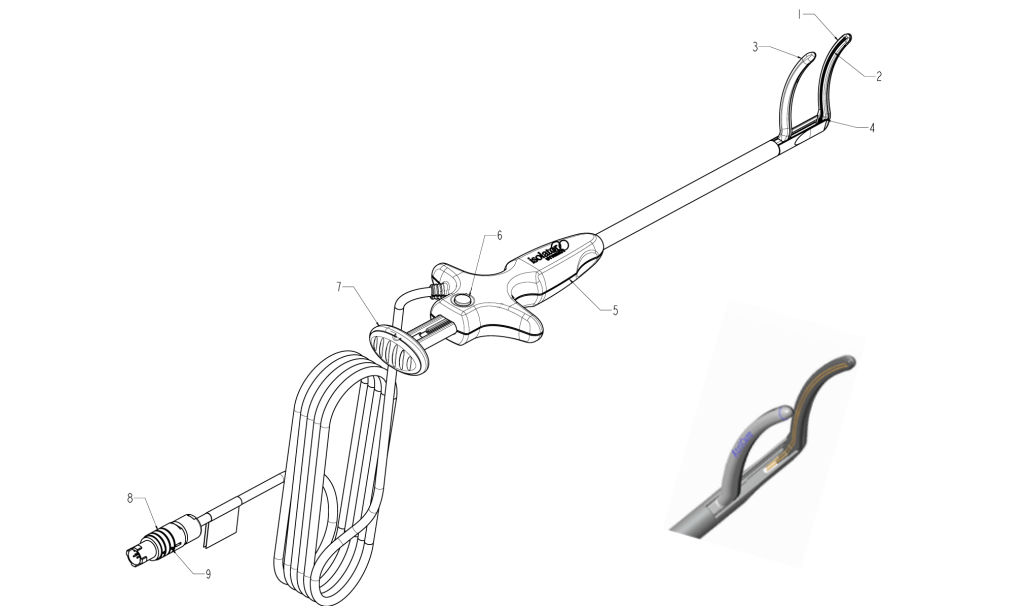
DESCRIPTION
The AtriCure Synergy Ablation System is comprised of the Ablation and Sensing Unit (ASU) and an AtriCure Switch Box (ASB), or the Multifunctional Generator (MAG), an AtriCure Synergy Ablation Clamp, and a footswitch. The AtriCure Synergy Ablation System is a single-patient open electro-anatomical instrument designed for use only with the ASU or MAG. 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 (CABG) and/or valve replacement or repair. When activated, the ASU or MAG generates a radio frequency (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™ ASU (See Figure 1) Clamps feature two pairs of opposing dual electrodes, an in-line handle with syringe-type actuation and button release mechanism. The Synergy Ablation Clamp requires the use of the AtriCure Switch Box (ASB) and Ablation Sensing Unit (ASU) or MAG.

NOTE:
• The AtriCure Synergy Ablation System has not been studied in the retrospective setting, so safe use and effectiveness cannot be assured.
• The full Moxi IV procedure cannot be completed with the AtriCure Synergy Ablation System. See Table 1 for a description of the devices used in the ABLATE Clinical study.

NOTE: Please refer to the AtriCure ASU/ASB3 or MAG Instructions for Use for information specific to the ASU/ASB3 or MAG.

AtriCure Synergy Ablation Clamp ILLUSTRATION AND NOMENCLATURE (Figure 1)



	1. Distal Jaw	6. Release Mechanism
2. Electrode	7. Closure Lever	
3. Preload Jaw	8. Connector	
4. Jaw Hook	9. Connector Alignment Arrow	
5. Handle		

INDICATION FOR USE
The AtriCure Synergy Ablation System is indicated for ablation catheter use for the treatment of persistent and longstanding (isolated beyond seven days of history less than one year) but not persistent or longstanding persistent atrial fibrillation or longstanding persistent atrial fibrillation (continuous atrial fibrillation 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 contraindications of the following table. The device is not designed for safe and effective use for that purpose.

WARNINGS

- Any tissue within the RF energy field may experience heating and/or tissue damage. Ensure that non-target tissue is adequately separated from the RF field. Ensure non-target tissue is protected and cooled by saline irrigation and/or wetting the electrode. Refer to Precaution 1, Contraindications.
- 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 as the risk of infection exists.
- Electrosurgery should be used with caution in the presence of internal and external pacemakers and/or internal cardiac defibrillators (ICD). Interference produced by the use of electro-surgical devices can cause device such as a pacemaker and ICD to enter an asynchronous mode, block pacemaker output, or deliver inappropriate shock therapy. Consult the pacemaker manufacturer or hospital cardiologist/physician for further information when use of electro-surgical appliances is planned in patients with cardiac pacemakers and/or ICD.
- Do not install or remove the Synergy Ablation Clamp as this could damage the device or result in infection.

Read all instructions cautions for the AtriCure Synergy Ablation System, prior to using the device. Review a properly follow instructions you read to electrical or thermal injury and may result in improper functioning of the device.

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 (i.e., complications) that are associated with this combined procedure:

- Excessive bleeding that may require re-intervention.
- Cardiac tamponade.
- Pulmonary artery stenosis.
- Resection of 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.
- Animal perforation or rupture.
- Pericardial perforation or rupture.
- Aortic dissection.
- Pneumonia.
- Coronary heart failure.
- Cardiac valve injury.
- Persistent pericarditis.
- Excessive pain and discomfort.
- Deep sternal wound infection (mediastinitis).
- Pericardial effusion.
- Damage to adjacent nerve and/or blood vessels.
- Injury to unintended surrounding tissues, including tears and punctures.
- Extension of cardioplegic bypass time or aortic cross clamp time.

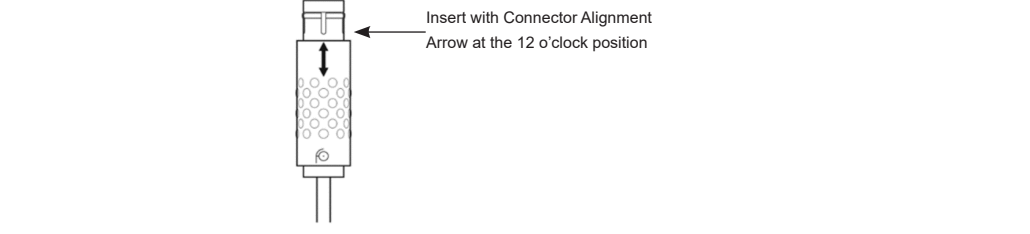
PRECAUTIONS

- Do not drop 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 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 ASU or MAG and ASB.
 - Do not allow tissue greater than 10 mm thick with the Synergy Ablation Clamp. Tissue greater than 10 mm thick may not be fully ablated.
 - The use of the AtriCure Synergy Ablation System is limited to physicians with specific training on the procedure and the product.
 - Inspect the area between the jaws of the Synergy Ablation Clamp for foreign matter before activating the ASU or MAG or ASB. Foreign matter captured between the jaws will adversely affect the ablation.
 - Do not insert excessive tissue into the jaw head as it may result in poor ablation of the jaw head.
 - Do not ablate in the area of blood or other fluids as this may extend the ablation time. Burns should occur once fluids away from the jaws prior to ablation. Irrigation of any of the Synergy Ablation Clamp is highly risky and should be avoided.
 - Do not attempt to use Synergy Ablation Clamp that has reached its time limit expiration. The Synergy Ablation Clamp has an in-built life that is tracked by the ASU or MAG. The Synergy Ablation Clamp may no longer function after 4 hours of use and the ASU or MAG will display a message indicating that the Synergy Ablation Clamp is no longer functional.
- WHEN THE ASU OR MAG (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.
- Heavily irrigate that area with normal saline if bleeding occurs or if the ASU or MAG is activated. The ASU or MAG will display a message indicating that the Synergy Ablation Clamp is no longer functional.
 - When the ASU or MAG (generator) is activated in conjunction with the Synergy Ablation Clamp, the conducted and radiated electrical field may interfere with other medical equipment. Refer to the ASU or MAG IUI for more information regarding potential electromagnetic or other interference, and advice regarding avoidance of such interference.
 - Do not use the Synergy Ablation Clamp if there is any sign of damage as it may adversely affect ablation performance.
 - Do not connect the Synergy Ablation Clamp to the ASB if the connector pins are bent.
 - Do not drop the device or damage the electrical wiring or the device. The use of abrasive cleaners or electro-surgical tip cleaners can damage the electrodes and result in device failure. Use saline-soaked gauze to clean debris off the electrodes.
 - Do not touch the electrodes of the Synergy Ablation Clamp while the ASU or MAG is active. Touching the Synergy Ablation Clamp electrodes during ASU or MAG activation could result in harm to the operator.
 - Do not touch the electrodes of the Synergy Ablation Clamp to metallic objects or clips, or to surfaces while activating the ASU or MAG.
 - Do not use the device in the presence of flammable anesthetics, other flammable gases, non-flammable fluids such as skin prep agents and lotions, flammable objects, or with volatile agents. Observe appropriate fire precautions at all times.

INSTRUCTIONS FOR USE

SETUP

- 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.
- 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 mark on the ASB3. To ensure proper alignment, verify proper connection to the ASB3 by ensuring the ASB3 package fully seals. The connection between the Synergy Ablation Clamp and the ASB3 is secure. The connection arrow is located on the ASB3 package. Verify the cable and do not use the Synergy Ablation Clamp if the cable is damaged or the insulation is damaged.



- Place the targeted tissue between the distal and proximal jaws of the Synergy Ablation Clamp.
- Engage 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 head and that no target tissue extends beyond the jaw head.
- Activate the ASU or MAG by depressing the footswitch. When the ASU or MAG is activated, the ASU or MAG will emit an audible tone indicating contact between the jaws of the Synergy Ablation Clamp. When the continuous tone ceases to indicate, release the footswitch.
- The AtriCure Synergy Ablation System uses time impedance monitoring to ensure impedance throughout the ablation cycle and the time to completion of treatment. Endpoints are targeted to be between 50 and 100 seconds of time. The study was designed to have an initial assessment of results at the point at 30 seconds were enrolled with a minimum of 20 subjects completed their six-month follow-up. Nine investigators also enrolled 55 subjects.

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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 (i.e., complications) that are associated with this combined procedure:

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Table 3: Subject Accountability		ABLA TE		ABLA TE		ABLA TE + ABLATE AF		ABLA TE + ABLATE AF	
Parameter		N=55	N=51	N=51	N=49	N=49	N=44	N=44	N=44
Patients Enrolled (n)		55	51	51	49	49	44	44	44
Procedure and follow-up not data available (% (n/N))		N=51	N=51	N=51	N=49	N=49	N=44	N=44	N=44
Discharge		100.0% (55/55)	100.0% (51/51)	100.0% (50/50)	100.0% (49/49)	100.0% (49/49)	100.0% (44/44)	100.0% (44/44)	100.0% (44/44)
30-day		96.4% (53/55)	96.1% (49/51)	97.7% (49/50)	96.9% (48/49)	96.9% (48/49)	96.9% (44/44)	96.9% (44/44)	96.9% (44/44)
3 Months		87.3% (48/55)	86.3% (44/51)	87.7% (44/50)	88.4% (43/49)	88.4% (43/49)	87.3% (43/44)	87.3% (43/44)	87.3% (43/44)
6 Months		80.9% (45/55)	80.2% (41/51)	80.9% (41/50)	80.9% (40/49)	80.9% (40/49)	80.9% (37/44)	80.9% (37/44)	80.9% (37/44)
12 Months or later		87.3% (48/55)	86.3% (44/51)	87.7% (44/50)	88.4% (43/49)	88.4% (43/49)	87.3% (43/44)	87.3% (43/44)	87.3% (43/44)
Follow-up in Study (Days) (n)		55	51	51	49	49	44	44	44
Mean +/- SD (N)		55.6 +/- 208.1 (55)	55.8 +/- 208.0 (51)	49.1 +/- 227.0 (49)	49.2 +/- 227.0 (44)	49.2 +/- 227.0 (44)	49.2 +/- 227.0 (44)	49.2 +/- 227.0 (44)	49.2 +/- 227.0 (44)
Median		55.0	55.0	49.0	49.0	49.0	49.0	49.0	49.0
Min, Max		4.0, 743.0	4.0, 743.0	4.0, 743.0	4.0, 743.0	4.0, 743.0	4.0, 743.0	4.0, 743.0	4.0, 743.0

1 All subjects treated with Ablation procedure.
2 One ABLATE subject expired prior to 30 days. One subject discharged at 15 days. Assessment performed on that day included in both discharge and 30 days summaries.
3 One ABLATE subject withdrew prior to 3 month assessment. One ABLATE subject missed the 12 month visit, and one ABLATE subject expired prior to the 12 month assessment.
4 One ABLATE subject expired prior to 6 months. Subjects in ABLATE AF are shown with completed assessment of 6 months or later. Two ABLATE AF subjects were not evaluated at 6 months or later due to the end of the analysis.
5 Subjects are shown with completed assessment at 12 months or later. Two ABLATE AF subjects expired between the 6 month and long-term follow-up assessments.
6 Study entry last scheduled follow-up assessment or study exit.

Table 3 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 subjects with paroxysmal AF and 5 subjects with persistent or long-term 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 persistent or long-term standing persistent AF.

Table 3: AF Classification		ABLA TE		ABLA TE AF		ABLA TE + ABLATE AF	
AF Classification		N=55	N=51	N=51	N=49	N=49	N=44
Paroxysmal		4	1	5	5	5	5
Persistent		22	2	24	24	24	24
Longstanding Persistent		29	11	40	40	40	40
Indicated Population		51	13	64	64	64	64

Table 4 demonstrates subject demographics for all groups.

Age (years)		ABLA TE		ABLA TE Non-Paroxysmal		ABLA TE + ABLATE AF	
Mean $\pm$ SD (N)	70.5 $\pm$ 9.3 (55)	70.8 $\pm$ 9.6 (51)	70.4 $\pm$ 9.0 (49)	70.8 $\pm$ 9.2 (44)	70.8 $\pm$ 9.2 (44)	70.8 $\pm$ 9.2 (44)	70.8 $\pm$ 9.2 (44)
Median	72.0	73.0	72.0	72.0	72.0	72.0	72.0
Min, Max	45.0, 88.0	45.0, 88.0	45.0, 88.0	45.0, 88.0	45.0, 88.0	45.0, 88.0	45.0, 88.0
Gender (% In (%))		ABLA TE		ABLA TE Non-Paroxysmal		ABLA TE + ABLATE AF	
Male	58.2% (32/55)	60.8% (31/51)	62.2% (32/49)	64.1% (31/44)	64.1% (31/44)	64.1% (31/44)	64.1% (31/44)
Female	41.8% (23/55)	39.2% (20/51)	37.7% (26/49)	35.9% (13/44)	35.9% (13/44)	35.9% (13/44)	35.9% (13/44)
Time since AF onset (months)		ABLA TE		ABLA TE Non-Paroxysmal		ABLA TE + ABLATE AF	
Mean $\pm$ SD (N)	61.2 $\pm$ 49.5 (55)	61.7 $\pm$ 51.1 (51)	62.7 $\pm$ 55.6 (49)	68.4 $\pm$ 57.3 (44)	68.4 $\pm$ 57.3 (44)	68.4 $\pm$ 57.3 (44)	68.4 $\pm$ 57.3 (44)
Median	46.6	46.6	54.8	55.8	55.8	55.8	55.8
Percentile 25th, 75th	20.1, 76.1	19.5, 84.4	20.5, 80.4	19.8, 99.9	19.8, 99.9	19.8, 99.9	19.8, 99.9
Min, Max	1.7, 188.39	1.7, 188.39	1.7, 247.17	1.7, 247.17	1.7, 247.17	1.7, 247.17	1.7, 247.17
Left Atrial Size (cm)		ABLA TE		ABLA TE Non-Paroxysmal		ABLA TE + ABLATE AF	
Mean $\pm$ SD (N)	5.9 $\pm$ 1.0 (55)	6.0 $\pm$ 1.0 (46)	5.8 $\pm$ 1.1 (46)	5.9 $\pm$ 1.1 (39)	5.9 $\pm$ 1.1 (39)	5.9 $\pm$ 1.1 (39)	5.9 $\pm$ 1.1 (39)
Median	6.0	6.0	5.7	5.8	5.8	5.8	5.8
Min, Max	3.9, 7.7	3.9, 7.7	3.0, 7.7	3.0, 7.7	3.0, 7.7	3.0, 7.7	3.0, 7.7
>= 5 cm	86.0% (49/55)	87.0% (40/46)	81.3% (32/46)	81.4% (48/59)	81.4% (48/59)	81.4% (48/59)	81.4% (48/59)
Surgical Procedure Type(s)		ABLA TE		ABLA TE Non-Paroxysmal		ABLA TE + ABLATE AF	
CABG only	18.2% (10/55)	19.6% (10/51)	21.7% (15/49)	23.4% (15/44)	23.4% (15/44)	23.4% (15/44)	23.4% (15/44)
Valve Surgery	40.0% (22/55)	37.3% (19/51)	34.8% (24/49)	32.8% (21/44)	32.8% (21/44)	32.8% (21/44)	32.8% (21/44)
Mitral Valve Repair/Replacement	18.2% (10/55)	17.6% (9/51)	15.9% (11/49)	15.9% (11/44)	15.9% (11/44)	15.9% (11/44)	15.9% (11/44)
Aortic Valve Repair/Replacement	21.8% (12/55)	19.6% (10/51)	18.8% (13/49)	17.2% (11/44)	17.2% (11/44)	17.2% (11/44)	17.2% (11/44)
Double Valve Surgery	16.4% (9/55)	17.6% (9/51)	14.5% (10/49)	15.6% (10/44)	15.6% (10/44)	15.6% (10/44)	15.6% (10/44)
Aortic & Mitral	7.3% (4/55)	7.8% (4/51)	5.8% (4/49)	6.3% (4/44)	6.3% (4/44)	6.3% (4/44)	6.3% (4/44)
Mitral & Tricuspid	9.1% (5/55)	9.8% (5/51)	8.7% (6/49)	9.4% (6/44)	9.4% (6/44)	9.4% (6/44)	9.4% (6/44)
CABG and Valve Surgery	16.4% (9/55)	15.7% (8/51)	21.7% (15/49)	20.3% (13/44)	20.3% (13/44)	20.3% (13/44)	20.3% (13/44)
CABG + Mitral Valve Repair/Replacement	10.9% (6/55)	9.8% (5/51)	11.6% (8/49)	10.9% (7/44)	10.9% (7/44)	10.9% (7/44)	10.9% (7/44)
CABG + Aortic Valve Repair/Replacement	5.5% (3/55)	5.5% (3/51)	10.1% (7/49)	9.4% (6/44)	9.4% (6/44)	9.4% (6/44)	9.4% (6/44)
CABG + Double Valve Surgery	9.1% (5/55)	9.8% (5/51)	7.2% (5/49)	7.8% (5/44)	7.8% (5/44)	7.8% (5/44)	7.8% (5/44)
Aortic & Mitral	5.5% (3/55)	5.5% (3/51)	4.3% (3/49)	4.7% (3/44)	4.7% (3/44)	4.7% (3/44)	4.7% (3/44)
Mitral & Tricuspid	3.6% (2/55)	3.9% (2/51)	2.9% (2/49)	3.1% (2/44)	3.1% (2/44)	3.1% (2/44)	3.1% (2/44)
Any Mitral Valve Surgery	54.5% (30/55)	54.9% (28/51)	49.3% (34/49)	50.0% (32/44)	50.0% (32/44)	50.0% (32/44)	50.0% (32/44)

Deaths

A total of 62 subjects died during follow-up. None of the deaths were attributed to the study device or ablation procedure.

Subgroup Analysis

Several subgroup analyses were performed per the study protocol to evaluate the probability of the primary endpoints. The primary effectiveness and safety outcomes were similar by gender, cardiac surgical procedure type, and user experience (enlisting users vs new users). Subjects with persistent AF had a greater effectiveness success at 36 months compared to subjects with longstanding persistent AF (Table 31). Additionally, the rate of device related and procedure related SAEs did not vary across cardiac surgery type. Race showed statistically significantly different results, likely due to small numbers of non-Caucasian subjects. Black subjects had a higher rate of serious device or procedure related AEs within 30 days (11.8% of subjects) as compared to subjects of other races (0-6.6%, p=0.039). Given that only 17 black subjects were treated in the study and there were 2 primary safety events, cautious interpretation of this finding is warranted. However, higher mortality rates post cardiac surgery in blacks and minorities have been observed (Khera et al. Racial disparities in outcomes after cardiac surgery: the role of hospital quality. *Curr Cardiol Rep* 2015, May; 17(5):29). likely associated with differences in biology, comorbid health conditions, socioeconomic background, and quality of hospital care. When adjusting for these factors, race was frequently not identified to be independently predictive. (IEF- [Iw] et al. *Circulation* 2012 April 4; 126:1000) "A risk score for predicting long-term mortality following coronary artery bypass graft surgery" doi.org/10.1161/CIRCULATIONAHA.111.055993L [Blumfeld et al. *JACC* 2002 Nov 19; 40, Issue 10] "The impact of ethnicity on outcomes following coronary artery bypass graft surgery in the Veterans Health Administration" DOI: 10.1016/S0735-1007(02)00445-3; [Lacour et al. "Race and surgical mortality in the United States". *Ann Surg*. 2006;243(2):281-286].

Table 31 summarizes the primary safety and effectiveness outcomes by AF type

Table 31				
Primary Safety and Effectiveness Outcomes by AF Type				
Outcome	Persistent AF ⁽¹⁾		Longstanding Persistent ⁽²⁾	
	# of Events	% (n/N) of Subjects with Event	# of Events	% (n/N) of Subjects with Event
Primary Safety: ⁽³⁾				
Serious Device or Procedure Related Adverse Event (excluding pacemaker implantation) within 30 days	3	1.5% (3/207)	1	0.6% (1/157)
Investigational Device	0	0.0% (0/207)	0	0.0% (0/157)
AF Procedure	3	1.5% (3/207)	1	0.6% (1/157)
Primary Effectiveness:				
Primary Success: Free from AF while off AADs at 36 months		63.0% (102/160)		51.2% (44/86)
Follow-up AAD		9.6% (14/146)		14.0% (12/86)
Follow-up by Filter/Pacemaker Interrogation ⁽⁴⁾				
		10.3% (12/116)		33.7% (29/86)
Follow-up by both AAD and Filter/Pacemaker Interrogation				
		4.8% (7/146)		1.2% (1/86)
⁽¹⁾ Persistent AF is defined as AF which is sustained beyond seven days or lasting less than seven days but necessitating pharmacologic or electrical cardioversion. ⁽²⁾ Longstanding persistent AF is defined as continuous AF of greater than one-year duration. ⁽³⁾ As adjudicated. ⁽⁴⁾ Pacemaker calculated using Fisher's Exact test. ⁽⁵⁾ Rhythm surveillance was obtained at 12, 24- and 36- months using a 48-hour Holter monitor (or equivalent).				

Adverse Events

An adverse event was any untoward medical occurrence (signs, symptoms, abnormal laboratory findings) in a patient regardless of relationship to the device or procedure. Each adverse event was evaluated to be either anticipated or unanticipated as described below. The sites reported all adverse events that occurred in the study.

Table 32 summarizes all the adverse events that occurred on the study:

Table 32: Summary of Adverse Events – Cumulative ¹						
	In Hospital N=365		Cumulative to 30 days N=365		All Events across All Visits N=365	
Parameter	# of Events	% (n/N) of Subjects with Event	# of Events	% (n/N) of Subjects with Event	# of Events	% (n/N) of Subjects with Event
Any Adverse Event	159	43.6% (159/365)	159	43.6% (159/365)	159	43.6% (159/365)
AE (any device)	24	6.6% (24/365)	24	6.6% (24/365)	24	6.6% (24/365)
AE (procedure)	24	6.6% (24/365)	24	6.6% (24/365)	24	6.6% (24/365)
Other (not device or procedure)	111	30.4% (111/365)	111	30.4% (111/365)	111	30.4% (111/365)
Concomitant Surgical Procedure	248	67.9% (248/365)	248	67.9% (248/365)	248	67.9% (248/365)
Other (not device or procedure)	111	30.4% (111/365)	111	30.4% (111/365)	111	30.4% (111/365)
AE (any device)	24	6.6% (24/365)	24	6.6% (24/365)	24	6.6% (24/365)
AE (procedure)	24	6.6% (24/365)	24	6.6% (24/365)	24	6.6% (24/365)
Other (not device or procedure)	111	30.4% (111/365)	111	30.4% (111/365)	111	30.4% (111/365)
Concomitant Surgical Procedure	248	67.9% (248/365)	248	67.9% (248/365)	248	67.9% (248/365)
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AE (any device)	24	6.6% (24/365)	24	6.6% (24/365)	24	6.6% (24/365)
AE (procedure)	24	6.6% (24/365)	24	6.6% (24/365)	24	6.6% (24/365)
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AE (any device)	24	6.6% (24/365)	24	6.6% (24/365)	24	6.6% (24/365)
AE (procedure)	24	6.6% (24/365)	24	6.6% (24/365)	24	6.6% (24/365)
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AE (procedure)	24	6.6% (24/365)	24	6.6% (24/365)	24	6.6% (24/365)
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Concomitant Surgical Procedure	248	67.9% (248/365)	248	67.9% (248/365)	248	67.9% (248/365)
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