

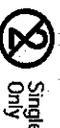
Atricure®

Atricure® Synergy Ablation System Instructions for Use

DRAFT



Read
Instructions
Before Use



Single Use
Only



Latex
Free

Rx ONLY



OLL2
OSL2

Atricure® Synergy Ablation System Instructions for Use

DESCRIPTION

The ATRICURE Synergy Ablation System is comprised of the Ablation and Sensing Unit (ASU), 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 ASU. 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 ASU 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 (ASU and ASB3).

NOTE: Please refer to the ATRICURE ASU and ASB3 Instructions for Use for information specific to the ASU and ASB3.

INDICATION FOR USE

The AtriCure Synergy Ablation System is intended to ablate cardiac tissue 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.

CONTRAINDICATIONS

The ATRICURE Synergy Ablation System is not indicated for contraceptive coagulation of the fallopian tubes.

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 related to the procedure which may require reintervention,
- Cardiac tamponade (if either open or catheter drainage is required),
- Pulmonary vein stenosis,
- Restrictive (constrictive) pericarditis,
- Infection which may include Sepsis or Endocarditis,
- Myocardial Infarction (MI) per ACC guidelines,
- Stroke or Transient Ischemic Attack (TIA),
- Thromboembolism,
- Diaphragmatic paralysis,
- Esophageal-LA fistula or esophageal rupture,
- Atrial perforation or rupture,
- Ventricular perforation or rupture,
- Atelectasis,
- Pneumonia,
- Congestive Heart Failure,
- Cardiac Valve Injury,
- Persistent Pneumothorax (requiring intervention),
- Excessive Pain and Discomfort,
- Deep Sternal Wound/Infection,
- Ventricular Arrhythmia (V Tachycardia or V Fibrillation),
- Drug Reaction,
- Perioperative heart rhythm/conduction disturbance (atrial and/or ventricular),
- Pericardial effusion or tamponade,
- Injury to the great vessels,
- Injury to unintended surrounding tissue structures, including tears and punctures,
- Extension of cardiopulmonary bypass.

WARNINGS

- Do not touch the electrodes of the Synergy Ablation Clamp while activating the ASU. Touching the Synergy Ablation Clamp electrodes during ASU 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 ASU. This may damage the Synergy Ablation Clamp or tissue, or result in an incomplete ablation.

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- 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 ASU 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 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 an 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 ASU. The Synergy Ablation Clamp will no longer function after 8 hours of use and the ASU 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 ASU (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 ASU (RF generator) and Synergy Ablation Clamp.
- Monitoring systems that incorporate high frequency current-limiting devices are recommended for use with the ASU (RF generator) and Synergy Ablation Clamp.
- When the ASU (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 ASU IFU for more information regarding potential electromagnetic or other interference, and advice regarding avoidance of such interference.

INSTRUCTIONS FOR USE

SETUP

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.

HOW SUPPLIED

The Synergy Ablation Clamp is supplied as STERILE instruments and is for single patient use only.

Sterility is guaranteed unless the package is opened or damaged. Do not resterilize.

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 biohazardous 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.

If the products have been in contact with blood or body fluids, they must be thoroughly cleaned and disinfected before packing. The products 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 biohazardous nature of the contents of shipment.

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.

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Table 1: Average Time vs. Energy Delivery

Tissue Thickness	Time to Transmurality per unit volume (sec/cm ³)	Energy Delivered per Unit Volume (J/mm ³) *
	AVG	AVG
2 mm	0.049	0.76
5 mm	0.053	0.57
10 mm	0.032	0.35
	STDDDEV	STDDDEV
	0.007	0.11
	0.006	0.10
	0.009	0.16

*Energy Delivery per unit volume of tissue ablated is below the threshold of 0.94 J/mm³ for 2 mm tissue thickness reported for other similar commercially available ablation devices.

- 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.
- Inspect the surgical area to ensure adequate ablation.
- 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 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 saline soaked gauze to prevent any coagulum on the electrodes from drying.
- Repeat the ablation process as necessary.

REMOVAL AND DISPOSAL

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

CLINICAL TRIAL RESULTS

The ABLATE clinical study has been performed in demonstration of the Atricure Synergy Ablation System safety and efficacy. The objective of the ABLATE study, to support the marketing application, was to show that the Atricure Synergy Ablation System for the treatment of persistent or longstanding persistent (i.e. non-paroxysmal) atrial fibrillation (AF) is non-inferior to current practices regarding efficacy and safety. The Primary Efficacy is based on demonstrating that subjects are free of AF without the need for Class I and III antiarrhythmic drugs. Primary Safety is established by demonstrating that use of the system is not associated with a higher composite rate of acute major adverse events (MAE). A continued registry study (ABLATE AF) was established following ABLATE. Results of both studies are presented.

Safety Results

Primary Safety is a composite rate of acute major adverse events within 30 days post procedure or hospital discharge. 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) events within 30

days post-procedure or hospital discharge (whichever is longer) and deaths after 30 days if the death is procedure related.

The Primary Safety Endpoint for ABLATE and ABLATE AF has been evaluated in the 64 non-paroxysmal AF subjects that were enrolled and treated with the Atricure Synergy Ablation System. Subjects were considered to be safety failures if any Major Adverse Events (MAE) were observed within the initial 30 days following operation. MAE consist of: Death within 30 days or beyond 30 days if considered device related, Excessive Bleeding (defined as > 2 units of RBCs with reoperation), Stroke, TIA or MI). 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 2. The safety results demonstrate that the Primary safety endpoint event rate through 30 days is acceptable.

Table 2: Primary Safety Endpoint

Primary Safety Endpoint	ABLATE % (n/N)	ABLATE AF % (n/N)	ABLATE + ABLATE AF % (n/N)
Major Adverse Event through 30 days	9.8% (5/51)	0.0% (0/13)	7.8% (5/64)
95% 1-sided Bayesian Credible Interval [1]:			(0.0, 0.155)
POSTERIOR PROBABILITY			0.990
[1] Beta (0.005, 0.005) prior in accordance with the statistical plan.			

Efficacy Results

The primary efficacy endpoint was defined as the rate of subjects that achieved successful ablation 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 that have a pacemaker implanted). The efficacy results are presented in Table 3. The results demonstrate the successful outcome of the ABLATE trials for a non-paroxysmal AF patient population with the statistical endpoint being achieved.

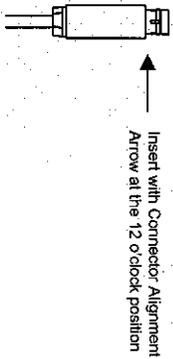
Table 3: Primary Efficacy Endpoint

Primary Efficacy Endpoint	ABLATE % (n/N)	AF ABLATE % (n/N)	ABLATE + ABLATE AF % (n/N)
AF Free and Off AADs at 6 months	73.9% (34/46)	81.8% (9/11)	75.4% (43/57)
95% 1-sided Bayesian Credible Interval ^[1] :			(0.628, 1.00)
POSTERIOR PROBABILITY >			0.992
[1] Beta (0.005, 0.005) prior in accordance with the statistical plan.			

Conclusions:

- a) The overall rate of Primary Endpoint Events proposed for labeling is 7.8%.
- b) The resulting rate for labeling for any device/procedure related SAE is 12.5%.
- c) The overall rate of Primary Efficacy Endpoint Success (AF Free and off AADs) proposed for labeling is 75.4%.
- d) Pulmonary Vein isolation was identified in 100% of those subjects amenable to the procedure for confirming block.

- 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 ASU or 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 ASU or 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.



ABLATION

NOTE: A minimum tissue incision of 12 mm is recommended for insertion of the Synergy Ablation Clamp.

- 3. Place the targeted tissue between the Distal and Proximal Jaws.
 - 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 ASU by depressing the footswitch. When the ASU is activated, the ASU 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 ATTRICURE 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 50°C 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.

PYROGENIC

Non-Pyrogenic

STERILE EO

Sterilized by Ethylene Oxide



Single Use Only



Expiration Date

LOT

Lot Number

Rx ONLY



Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician
Attention: See Instructions for Use



Manufactured by:
AtriCure® Incorporated
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West Chester, Ohio 45069-3866
Customer Service:
1-866-349-2342 (toll free)
513-755-4100

- 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 the 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.

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.

- Use of the Synergy Ablation Clamp should be limited to properly trained and qualified medical personnel.

- Use Synergy Ablation Clamp only as indicated. Variations in specific procedures may occur due to individual physician techniques and patient anatomy.

- Do not drop or loss 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.

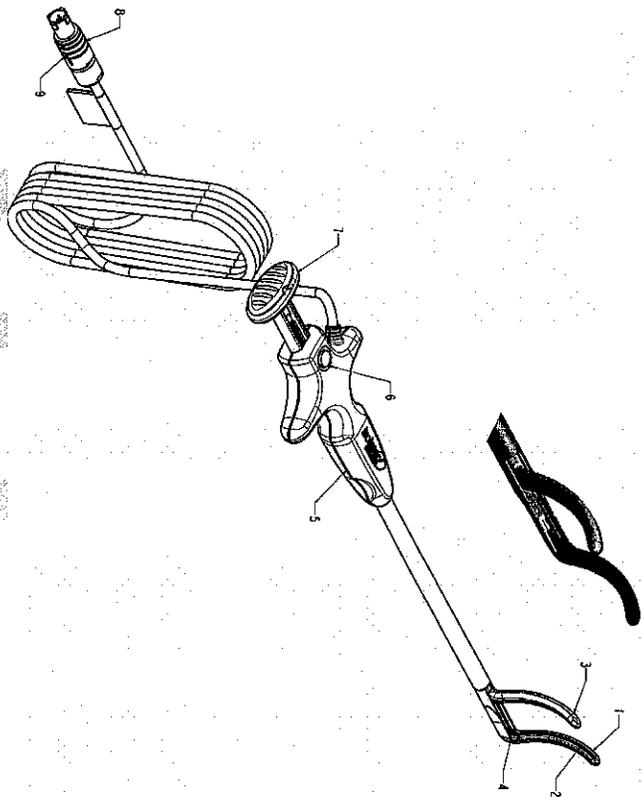
- Keep the Jaws of the Synergy Ablation Clamp clean of debris during surgery to avoid loss of power.

- 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 ASU 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.

**ATRICURE Synergy Ablation Clamp
ILLUSTRATION AND NOMENCLATURE**

(Figure 1)



- (ATRICURE SYNERGY ABLATION CLAMP)
- | | | | |
|----|--------------|----|---------------------------|
| 1. | Distal Jaw | 6. | Release Mechanism |
| 2. | Electrodes | 7. | Closure Lever |
| 3. | Proximal Jaw | 8. | Connector |
| 4. | Jaw Heel | 9. | Connector Alignment Arrow |
| 5. | Handle | | |