AtriCure

AtriCure® Isolator® Synergy Access® Ablation System

Instructions for Use

 # EMT1, GPT200

FIGURE 1: ATRICURE ISOLATOR SYNERGY ACCESS ILLUSTRATION

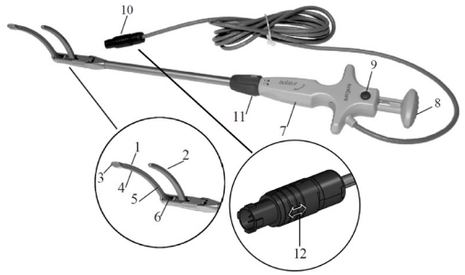


FIGURE 2: GLIDEPATH TAPE INSTRUMENT GUIDE ILLUSTRATION

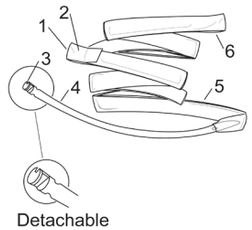


FIGURE 3: POSITIONING OF GLIDEPATH TAPE GUIDE

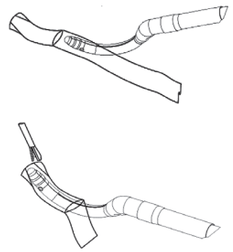
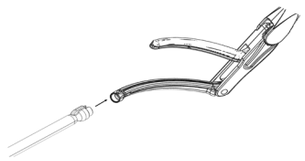


FIGURE 4: INSTRUMENT EXCHANGE (DETACHABLE GUIDE)



SYSTEM AND PRODUCT DESCRIPTION

The AtriCure Isolator Synergy Access Ablation System is comprised of an AtriCure RF generator (ASU3 and ASB3 or MAG™, referred to hereafter as GENERATOR), the Isolator Synergy Access clamp (referred to hereafter as CLAMP), and Footswitch. The CLAMP is a single patient use electrosurgical instrument designed for use with an AtriCure RF GENERATOR. The CLAMP is used for cardiac tissue ablation. When activated, the GENERATOR delivers radiofrequency (RF) energy to the linear electrodes on the insulated jaws of the device. The Operator controls the application of this RF energy by pressing the Footswitch. The CLAMP features two pairs of opposing dual electrodes, an articulating end-effector, and an in-line handle with syringe-type actuation and button release mechanisms. There is a Glidepath™ Tape Instrument GUIDE (referred to hereafter as GUIDE) that is designed to attached to the distal jaw of the device with a twist on detachable connection. The GUIDE is a single patient, detachable, optional component designed to facilitate the guidance of surgical instruments around target tissue during general surgical procedures.

INDICATION FOR USE

The ATRICURE Bipolar (Transpolar) System is intended to ablate cardiac tissue during surgery.

CONTRAINDICATIONS

The Bipolar (Transpolar) System is not indicated for contraceptive coagulation of the fallopian tubes.

ENVIRONMENT SPECIFICATIONS

Operational	Storage	Transit
Temperature: 10°C/50°F to 40°C/104°F	Temperature: -29°C/-20°F to 60°C/140°F	Temperature: -29°C/-20°F to 60°C/140°F
Relative Humidity: 15% to 90%, non-condensing	Relative Humidity: 15% to 85%	Relative Humidity: 30% to 85%
Atmospheric Pressure: 80.0 kPa/11.6 psi to 106 kPa/15.4 psi	N/A	N/A

PACKAGING CONTENTS

1. One (1) AtriCure Isolator Synergy Access CLAMP
2. One (1) Glidepath Tape with detachable connection (GPT200)

The CLAMP and GUIDE are supplied STERILE and is NON-PYROGENIC in unopened, undamaged package. For single use only. Do not re-sterilize. Do not re-use.

NOMENCLATURE

This instruction refers to features of the CLAMP as follows (see Figure 1).

CLAMP FEATURES

[1] Distal Jaw
[2] Proximal Jaw
[3] Distal Jaw Plug
[4] Attachment Tip
[5] Electrodes
[6] Jaw Heel
[7] Handle
[8] Closure Lever
[9] Release Mechanism
[10] Connector
[11] Articulation Knob
[12] Connector Alignment Arrow

GUIDE FEATURES

[1] Lateral Tab
[2] Distal Pocket
[3] Instrument Attachment Tip
[4] Red Elastic Leader
[5] Clear Ribbon
[6] Accessory Ribbon

POTENTIAL COMPLICATIONS

DEVICE

Possible complications related to the creation of the linear lesions in cardiac tissue using a clamp-type device maybe be included but not limited to:

- Tissue Cutting
- Perioperative heart rhythm disturbance (atrial and/or ventricular)
- Postoperative embolic complications
- Pericardial effusion or tamponade
- Injury to the great vessels
- Valve leaflet damage
- Conduction disturbances (SA/AV node)
- Acute ischemic myocardial event
- Injury to unintended surrounding tissue structures, including tears and punctures
- Bleeding requiring intervention to repair
- Extension of cardiopulmonary bypass

PROCEDURE

Serious adverse events that may be associated with surgical ablation procedures on the heart (stand alone or concomitant to other cardiac surgery), include:

- Death
- Excessive bleeding related to the procedure (defined as bleeding which requires >3 units of blood products and/or surgical intervention)
- Cardiac tamponade (if either open or catheter drainage is required)
- Pulmonary vein stenosis
- Restrictive (constrictive) pericarditis
- Endocarditis
- Myocardial infarction (MI) per ACC guidelines
- Stroke (resulting in permanent neurological deficit)
- 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)
- New Sinus Node Dysfunction
- Drug Reaction

⚠WARNING⚠

Read all instructions carefully for the AtriCure Isolator Ablation System, prior to using the CLAMP. Failure to properly follow instructions may lead to injury and/or improper device function

Electrosurgery should be used with caution in the presence of internal or external pacemakers and/or internal cardiac defibrillators (ICD). Interference produced with the use of electrosurgical devices can cause devices such as a pacemaker and/or ICD to enter an asynchronous mode, block pacemaker conduction, or deliver inappropriate shock therapy. Consult the pacemaker manufacturer or hospital Cardiology department for further information when use of electrosurgical appliances is planned in patients with cardiac pacemakers and/or ICD.

The use of the CLAMP and/or GUIDE should be limited to properly trained and qualified medical personnel. The use of the CLAMP and/or GUIDE from non-trained or unqualified medical personnel could potentially result in death or serious injury.

Use of the CLAMP and GUIDE on patients who have undergone previous cardiac surgeries could increase risk of damage to surrounding structures due to presence of adhesions in the tissue planes.

Use of the CLAMP and GUIDE while off cardiopulmonary bypass could cause increased risk of tissue perforation and/or circulatory interruption.

⚠WARNING⚠

This device contains small amounts of Nickel (CAS# 7440-02-0) and Cobalt (CAS# 7440-48-4). Do not use the device if the patient has sensitivity to Nickel or Cobalt as this may result in an adverse patient reaction.

This product may expose you to Di(Iso-Nonyl) Phthalate (DINP) and Di-Isodecyl Phthalate (DIDP), a chemical which is known to the State of California to cause cancer and birth defects or other reproductive harm. For more information: www.P65Warnings.ca.gov.

⚠CAUTIONS:

- Do not drop the CLAMP as this may damage the device. If the CLAMP is dropped, do not use. Replace with a new CLAMP.
- Do not attempt to use a CLAMP that has reached its time limit expiration. The CLAMP has an 8-hour useful life that is tracked by the GENERATOR. The CLAMP will no longer function after 8 hours of use and the GENERATOR will display a message indicating that the CLAMP must be replaced.
- Monitoring systems that incorporate high frequency RF filtering devices are recommended for use with the GENERATOR and CLAMP.
- When the GENERATOR is activated in conjunction with the CLAMP, the conducted and radiated electrical fields may interfere with other electrical medical equipment. Refer to the GENERATOR IFU for more information regarding potential electromagnetic or other interference, and advice regarding avoidance of such interference.
- Do not touch the Electrodes of the CLAMP to metal staples or clips, or to sutures while activating the GENERATOR.
- Do not use the CLAMP in the presence of flammable anesthetics; other flammable gases; near flammable fluids such as skin prepping agents and tinctures; flammable objects; or with oxidizing agents. Observe appropriate fire precautions at all times.

INSTRUCTIONS FOR USE SET UP

⚠WARNING⚠

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 CLAMP to avoid the risk of patient infection.

Do not use the CLAMP if there is any sign of damage as it may adversely affect ablation performance.

1. Examine the packaging of the devices to ensure the sterility of the product has not been breached. Remove the sterilized instruments from their package per standard sterile technique.

⚠CAUTION: Do not use the CLAMP with another manufacturer's generator to avoid damage to the device. The CLAMP is only compatible with an AtriCure RF GENERATOR.

⚠CAUTION: Do not connect the CLAMP to the GENERATOR if the Connector pins are bent.

2. Inspect the Cable and Connector pins and do not use the CLAMP if the Cable is frayed or if the insulation is damaged or if the Connector pins are bent. With the Connector Alignment Arrow symbol in the 12 o'clock position, push the Connector into the appropriate CLAMP receptacle on the front of the GENERATOR. Avoid twisting the Connector during insertion into the receptacle, which could cause bent pins in the Connector. Each CLAMP has a unique receptacle on the GENERATOR. To ensure device performance, verify proper connections to the GENERATOR by consulting the GENERATOR package insert. Verify that the connections between the CLAMP and the GENERATOR are secure.
3. If the CLAMP is to be used with a supplied GLIDEPATH Instrument Guide (Detachable Guide - Figure 2), go to Step 4. If the CLAMP is not to be used with the GUIDE, go to step 18.

POSITIONING OF GLIDEPATH TAPE GUIDE (SEE FIGURE 3)

⚠WARNING⚠

If using auxiliary tools to retrieve the GUIDE, use caution to avoid tissue perforation.

4. The GUIDE may be used with commercially available general dissection or surgical clamping tools (auxiliary tools) to create and maintain a dissection plane that facilitates placement of the CLAMP around structures per standard surgical technique.
5. Examine the GUIDE package to ensure the sterility of the product has not been breached. Remove the GUIDE from its packaging per standard sterile technique.
6. Secure the proximal end of the GUIDE to the sterile drape near the surgical site.
7. Insert the distal end of the auxiliary tool completely into the Distal Pocket of the Clear Ribbon portion of the GUIDE.
8. Maintain attachment of the distal portion of the GUIDE to the auxiliary tool during positioning of the GUIDE. Lubrication may be applied to the GUIDE at the user's discretion.
9. Once the desired placement of the GUIDE is achieved, use a grasping device to grasp one of the Lateral Tabs (Figure 3) on the GUIDE and remove the GUIDE from the auxiliary tool. Externally secure the distal end of the GUIDE near the surgical site. If an articulating dissection tool is used, un-articulating the device may facilitate removal of the GUIDE.
10. If desired, the GUIDE can be used for soft tissue retraction or to introduce additional Instruments through the previously created positioning plane.

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INSTRUMENT EXCHANGE (DETACHABLE GUIDE) (SEE FIGURE 4)

⚠WARNING⚠

Failure to pull the TEE probe back away from the CLAMP site prior to routing may cause damage to surrounding structures.

⚠**CAUTION:** A minimum tissue incision of 12 mm is recommended for insertion of the CLAMP.

⚠**CAUTION:** CLAMP leaks CO2 if used under insufflation.

11. Prior to attaching the GUIDE to the CLAMP, unclamp the proximal end of the Leader from the sterile drape.
12. Remove the Distal Jaw Plug by rotating the Distal Jaw Plug counter-clockwise.
13. While holding the GUIDE as shown in Figure 4, align the rib with the top surface of Distal Jaw and insert the Instrument Attachment Pin into the CLAMP Attachment Tip (Figure 1) and turn clockwise 180° until secured. Once GUIDE is secured, do not attempt to remove by forcibly pulling on GUIDE.
14. Use the GUIDE to facilitate the placement of the CLAMP in the previously created positioning plane.
15. Carefully remove the GUIDE from the Distal Jaw after CLAMP placement by turning the GUIDE counterclockwise180°. The Accessory Ribbon allows the surgeon to create a dissection plane in one direction (inferior or superior) and maneuver the tape and Leader through the dissection plane so that an instrument (CLAMP) can be used from the opposite direction.
16. If it is required to reverse the direction of device placement, the Accessory Ribbon is attached to the Distal Pocket of the primary transfer tape.
17. After creation of the dissection plane, pull the distal end of the primary tape while providing counter traction on the proximal end of the Accessory Ribbon so that the Leader is pulled through the dissection plane.
18. The CLAMP has a passive articulation joint. At any time during the procedure, the user may lock the end effector at a desired angle (± 30 degree range) by rotating the Articulation Knob clockwise. The user may unlock the articulation joint by rotating the knob counter-clockwise

ABLATION

⚠**CAUTION:** 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.

⚠WARNING⚠

Use caution when routing, positioning, and removing the CLAMP to avoid damage to surrounding structures.

19. Position the CLAMP while keeping the Jaw Heel away from cannulas, catheters, sutures and non-target tissue structures. Place the targeted tissue between the Distal and Proximal Jaws.

⚠**CAUTION:** Inspect the area between the Jaws of the CLAMP for foreign matter before activating the GENERATOR. Foreign matter captured between the Jaws will adversely affect the ablation.

⚠**CAUTION:** Do not insert excessive tissue into the Jaw Heel as it may result in poor ablation at the Jaw Heel.

20. Depress the Closure Lever until it latches 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 and that the target tissue is firmly clamped between the Jaws by visualization.

⚠**CAUTION:** 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. Immersion of any part of the CLAMP in fluids may also damage the device.

⚠**CAUTION:** When the GENERATOR and the 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 CLAMP cables so that they do not come in contact with the patient or the other leads.

⚠**CAUTION:** Do not touch the Electrodes of the CLAMP while activating the GENERATOR. Touching the CLAMP Electrodes during GENERATOR activation could result in burn to the operator.

⚠WARNING⚠

Any tissue within the RF energy field may experience heating and/or tissue damage. Ensure non-target tissue is adequately separated or protected from the RF field. Refer to the Potential Complications List.

Do not ablate with the Closure Lever unlatched. Ablating with the Closure Lever unlatched could result in tissue perforation.

21. Activate the GENERATOR by depressing the Footswitch. When the GENERATOR is activated, the GENERATOR will emit an audible tone indicating that current is flowing between the Jaws of the CLAMP. When the continuous tone switches to intermittent, release the Footswitch.
22. The CLAMP and GENERATOR measure tissue impedance throughout the ablation cycle and uses this information alone to control the application of energy to the tissue. The System determines the minimum energy delivery and time required to create a transmural (full thickness) lesion based on tissue impedance and delivers only that amount of energy to the tissue. The measured impedance, and therefore the time and energy required for a transmural lesion, depends on the tissue thickness, composition, and length of tissue captured between the Electrodes. 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. See GENERATOR Instructions for Use for complete list of Error Codes. Recoverable E errors will remain on the display until RF is activated again.
23. 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. If the Jaws do not open after pressing the Release Button pull the Closure Lever.
24. Inspect the surgical area to ensure adequate ablation.

⚠WARNING⚠

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.

25. Between ablations, wipe the Jaws clean with a saline-soaked gauze pad to eliminate coagulum and inspect both Electrodes to ensure the gold Electrode is visible and coagulum is removed. This will ensure optimal performance during ablation. It is easier to remove coagulum withing first several seconds after ablation. If the CLAMP is idle between ablations, clamp the Jaws onto saline soaked gauze to prevent any coagulum on the Electrodes from drying.

⚠**CAUTION:** If greater than 18 individual ablations are required, it is recommended to use a second CLAMP.

26. Repeat the ablation process as necessary.

REMOVAL AND DISPOSAL

⚠WARNING⚠

Do not re-sterilize or reuse the Synergy Ablation Clamp as this could damage the device or result in infection

27. To remove the Detachable Guide from the CLAMP, grasp the Instrument Attachment Tip and rotate counterclockwise until the GUIDE is detached.
28. Ensure the GUIDE is removed from the surgical field prior to the completion of the surgical procedure. After use this device should be treated as medical waste and disposed of following hospital protocol
29. Discard the CLAMP after use. After use this device should be treated as medical waste and disposed of following hospital protocol.

SERIOUS INCIDENT

Any serious incident that has occurred in relation to this device should be reported to AtriCure.

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 assume responsibility for approving the acceptable condition of this product before it is used, and for ensuring that the product is only used in the manner described in these instructions for use, including, but not limited to, ensuring that the product is not re-used.

Under no circumstances will AtriCure, Inc. be responsible for any incidental, special or consequential loss, damage, or expense, which is the result of the deliberate misuse or re-use of this product, including any loss, damage, or expense which is related to personal injury or damage to property.

EXPLANATION OF SYMBOLS ON PACKAGE LABELING

REFER TO THE OUTER PACKAGE LABEL TO SEE WHICH SYMBOLS APPLY TO THIS PRODUCT.

	Manufacturer	US	Country And Date of Manufacture
	Caution		Contains Hazardous Materials
	Non-pyrogenic	LATEX	Not made with natural rubber latex
	Refer to instruction manual		Waste Electrical and Electronic Equipment
	Do not re-use	2 STERILIZE	Do not re-sterilize
	Do not use if package is damaged	STERILE EO	Sterilized by Ethylene-Oxide
#	Model Number	REF	Catalogue Number
LOT	Lot Number	UDI	Unique Device Identifier
Rx ONLY	Caution: Federal Law (US) restricts this device to sale by or on the order of a physician		Use-by date
PHT DEHP BBP DBP	Does not contain Phthalate		Defibrillation Proof Type CF Applied Part
	Single Sterile Barrier System with protective packaging inside		Single Sterile Barrier System with protective packaging outside
140°F (60°C) -20°F (-29°C)	Temperature Storage and Transit Limit	85% 30%	Humidity Storage and Transit Limit
	Keep dry		

AtriCure Inc.
7555 Innovation Way
Mason, Ohio 45040 USA
+1 866 349 2342
+1 513 755 4100