Summary of Safety and Clinical Performance (SSCP)

AtriCure Isolator Synergy Clamps

01 April 2024

CEM-278 Rev D

OVERVIEW

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the device.

The SSCP is not intended to replace the Instructions for Use as the main document to ensure the safe use of the device, nor is it intended to provide diagnostic or therapeutic suggestions to intended users or patients.

INFORMATION INTENDED FOR USERS/ HEALTHCARE PROFESSIONALS:

1. Device Identification and General Information

Product Name:	AtriCure® Isolator® Synergy™ Ablation System with Glidepath Tape (referred to by product codes OLL2/OSL2 with GPT300) AtriCure® Isolator® Synergy Access® Ablation System with Glidepath Tape (referred to by product code EMT with GPT200) AtriCure® Isolator® Synergy™ Ablation System with Glidepath Tape (referred to by product codes EMR2/EML2 with GPT100) AtriCure® Isolator® Synergy™ EnCompass® Ablation System with Glidepath Magnetic Guide (referred to by product code OLH/OSH with GPM100)
Product Group/Family Basic UDI-DI	OLL2/OSL2: 08401439000000000000014ZL EMT1: 0840143900000000000014ZL EMR2/EML2: 08401439000000000000014ZL OLH/OSH: 08401439000000000000014ZL
Manufacturer Legal Name and Address: Single Registration Number (SRN)	AtriCure, Inc. 7555 Innovation Way Mason, OH 45040 USA SRN: US-MF-000002974
EU Auth Representative: Single Registration Number (SRN)	AtriCure Europe B.V. De entree 260 1101 EE Amsterdam The Netherlands SRN: NL-AR-000000165
Medical Device Scope Expression and Code:	EMDN: codes: OLL2/OSL2, EMT, EMR2/EML2, OLH/OSH: C020399 - Cardiac Surgery Ablation Devices, Other CND codes: OLL2/OSL2, EMT, EMR2/EML2, OLH/OSH: C020301 - Cardiac Tissue Ablation Electrocatheters, Radiofrequency

Product Classification and Rule (per MDR):	OLL2/OSL2 with GPT300: Class III, Rule 6 EMT with GPT100: Class III, Rule 6 EMR2/EML2 with GPT200: Class III, Rule 6 OLH/OSH with GPM100: Class III, Rule 6
Year when the first certificate (CE) was issued covering the device:	OLL2: 2007 OSL2: 2009 EMR2/EML2: 2009 EMT1: 2015 OLH/OSH: 2024
Notified Body Name, Address & Number:	BSI Say Building John M. Keynesplein 9 1066 EP Amsterdam The Netherlands +31 20 346 0780 CE 2797

2. Intended Use of the Device

2.1. Intended Purpose

The AtriCure Isolator Synergy CLAMP is a sterile, single use electrosurgery device intended to ablate cardiac tissue when connected to a compatible AtriCure radiofrequency generator.

2.2. Indication(s) and target populations

Indication:
The AtriCure Isolator Synergy Ablation System is indicated for ablation of cardiac tissue for the treatment of cardiac arrhythmias, including atrial fibrillation.

Target population:
Adult patients with cardiac arrhythmias including atrial fibrillation.

2.3. Contraindications and/ or limitations

AtriCure Isolator Synergy Ablation System is not indicated for contraceptive coagulation of the fallopian tubes.

3. Device Description

3.1. Description of the device

OLL2/OSL2 with GPT300 (Figure 1): The AtriCure Isolator Synergy Ablation System is comprised of an AtriCure RF generator (ASU3 and ASB3 or MAG™, referred to hereafter as GENERATOR), the Isolator Synergy 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. 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 in-line handle with syringe-type actuation and button release mechanisms. The OLL2 and OSL2 CLAMPs vary only in jaw length. There is a Glidepath™ Tape Instrument Guide (referred to hereafter as GUIDE) that is designed to attach to the distal jaw of the CLAMP with a press fit 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.

Figure 1. OLL2 Isolator Synergy Clamp, Long Jaw Left Curve (left) and OSL2 Isolator Synergy Clamp, Standard Jaw Left Curve

EMT1 with GPT200 (Figure 2): 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. 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 design 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.

Figure 2. EMT1 Isolator Synergy Access Clamp

EMR2/EML2 with GPT100 (Figure 3): The AtriCure Isolator Synergy Ablation System is comprised of an AtriCure RF GENERATOR (ASU3 and ASB3 or MAG™, referred to hereafter as GENERATOR), the Isolator Synergy 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. 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 in-line handle with syringe-type actuation and button release mechanisms. The EMR2 and EML2 CLAMPs vary only in jaw curvature. There is a Glidepath™ Tape Instrument Guide (referred to hereafter as GUIDE), that is designed to attached to the distal jaw of

the CLAMP with a snap pin fit non-detachable connection. The GUIDE is a single patient, non-detachable once attached, optional component designed to facilitate the guidance of surgical instruments around target tissue during general surgical procedures.

Figure 3. EML2 Isolator Synergy Clamp, Left Curve (left); EMR2 Isolator Synergy Clamp, Right Curve (right)

OLH/OSH with GPM100 (Figure 4): The AtriCure® Isolator® Synergy™ EnCompass® Ablation System is comprised of an AtriCure RF generator (ASU3 and ASB3 or MAG™, referred to hereafter as GENERATOR), the Isolator Synergy EnCompass 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. 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 in-line handle with syringe-type actuation and button release mechanisms. The OLH and OSH CLAMPs vary only in jaw length. There is a Glidepath™ Magnetic Instrument Guide (referred to hereafter as GUIDE) that is designed to attach each of the jaws of the CLAMP with a magnetic fit 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.

Figure 4. OLH Isolator Synergy EnCompass Clamp (left); OSH Isolator Synergy EnCompass Clamp (right)

3.2. A reference to previous generation(s) or variants if such exist, and a description of the differences

- Note: all the Isolator Synergy Clamps are sterile, single-use devices, feature parallel jaw closure, a plunger with single position latch and release button, and 2 pairs of bipolar linear electrodes. The design variants listed in this section are to accommodate user preferences.
- In 2007, the OLL2 clamp was CE marked with TUV. This variant was designed for open surgical access; features distal curved jaws (left); working length is approximately 218mm; Jaw aperture 26.9mm; works with GPT300
- In 2009, EMR2, EML2, OLL2, and OSL2 clamps were CE-marked with BSI
    - EMR2 and EML2 variants were designed for open or minimally invasive surgical access; EML2 and EMR2 feature distal curved jaws (left or right

curves, respectively); clamp working length is approximately 218 cm; jaw aperture 25mm; works with GPT100;
    - OSL2 was designed for open surgical access; features distal curved jaws (left) with a clamp working length of approximately 206mm; Jaw aperture 26.9mm; works with GPT300
- In 2012, an acrylonitrile butadiene styrene (ABS) material was added as an alternate insulator base material
- In 2014, alternate overmold assembly process was added; alternate ABS insulator materials and epoxy resins were added
- In 2015, EMT was CE-marked with BSI; this variant was designed for open surgical or minimally invasive surgical access; features distal curved jaws; clamp working length is approximately 248 mm; jaw aperture 35mm; clevis pivots jaw ±30 degrees (up/down) to aid placement; works with GPT200
- In 2016, Tyvek change to latest flash-spinning technology
- In 2022, OLH and OSH are new design variants to be reviewed for CE-marking; these design variants were designed for open surgical access; Distal curved jaws approximately 117mm long (OLH) or 94 mm long (OSH); clamp working length of approximately 243.8mm; works with GPM100; Jaw aperture 24.9mm

3.3. Description of any accessories which are intended to be used in combination with the device

None

3.4. Description of any other devices and products which are intended to be used in combination with the device

Devices that may be used with the Isolator Synergy Clamps include:

AtriCure RF GENERATORS:
- ASU3 and ASB3
- MAG™

AtriCure Isolator Pens and Dissectors:
- AtriCure Isolator® Coolrail® Linear Pen (MCR1)
- AtriCure Isolator® Transpolar Pen (MAX3, MAX5)
- AtriCure Isolator® Linear Pen (MLP1)
- AtriCure Dissector (aka Wolf™ Lumitip™ Dissector) (MID1, GPD1)

4. Risks and warnings

4.1. Residual risks and undesirable effects

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:

	Estimated peri-operative residual risk rate
Tissue Cutting	<0.1%, <1 in 1,000 patients[a]
Perioperative heart rhythm disturbance (atrial and/or ventricular)	<0.1%, <1 in 1,000 patients[a]
Postoperative embolic complications	<0.1%, <1 in 1,000 patients[a]
Pericardial effusion or tamponade	<0.1%, <1 in 1,000 patients[a]

Injury to the great vessels	<0.1%, <1 in 1,000 patients[a]
Valve leaflet damage	<0.1%, <1 in 1,000 patients[a]
Conduction disturbances (SA/AV node)	<0.1%, <1 in 1,000 patients[a]
Acute ischemic myocardial event	<0.1%, <1 in 1,000 patients[a]
Injury to unintended surrounding tissue structures, including tears and punctures	<0.1%, <1 in 1,000 patients[a]
Bleeding requiring intervention to repair	<0.1%, <1 in 1,000 patients[a]
Extension of cardiopulmonary bypass	Surgical ablation adds cardiopulmonary bypass time to concomitant procedures, however the American Association for Thoracic Surgery consensus guidelines report that this does not translate into increase patient risk.[1]
[a]Estimated occurrence rates were <0.5% and ≥0.1% (between 1 in 200 and 1 in 1,000 patients) before risk control measures based on AtriCure risk management files; estimated risks may be underestimated due to use of commercial rates.	

PROCEDURE
Additional serious adverse events that may be associated with surgical ablation procedures on the heart (stand alone or concomitant to other cardiac surgery) are listed in the subject device IFUs.

Among these, based on a 2017 Society of Thoracic Surgeons database analysis of concomitant surgical ablation, the estimated perioperative rates of sternal infection, phrenic nerve injury, and transient ischemic attack are estimated to be <1% (<1 in 100 people); 30-day mortality, excessive bleeding, and permanent stroke to be <5% (<5 in 100 people); and the rate of new sinus node dysfunction (based on permanent pacemaker implantation) is expected to be <10%.[2] By propensity matching, the STS database analysis reported that the incidences of excessive bleeding, transient ischemic attack, and phrenic nerve injury were not significantly different between cardiac surgery with or without surgical ablation. Mortality within 30 days and permanent stroke were significantly decreased with concomitant surgical ablation compared to no ablation. Pacemaker implantation was significantly increased with concomitant surgical ablation compared to no ablation. In unmatched analysis, sternal infection was not significantly different with or without concomitant surgical ablation.

4.2. Warnings and precautions

OLL2/OSL2 Warnings:

- 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.
- 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.
- 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.
- If using auxiliary tools to retrieve the GUIDE, use caution to avoid tissue perforation.
- Failure to pull the TEE probe back away from the CLAMP site prior to routing may cause damage to surrounding structures.
- Use caution when routing, positioning, and removing the CLAMP to avoid damage to surrounding structures.
- 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.
- 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 re-sterilize or reuse the Synergy Ablation Clamp as this could damage the device or result in infection

OSL2/OLL2 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.
- The CLAMP is intended for single use. To prevent re-use, CLAMP use 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.
- 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.
- Do not connect the CLAMP to the GENERATOR if the connector pins are bent.
- 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
- 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.

- 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. Immersion of any part of the CLAMP in fluids may also damage the device.
- 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.
- 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.
- The useful life of the device is 18 individual ablations. If additional ablations are required, it is recommended to use a second CLAMP.
- It is the responsibility of the health care institution to adequately prepare and identify the products for shipment.

EMT Warnings:

- 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.
- 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.
- 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.
- If using auxiliary tools to retrieve the GUIDE, use caution to avoid tissue perforation.
- Failure to pull the TEE probe back away from the CLAMP site prior to routing may cause damage to surrounding structures.
- Use caution when routing, positioning, and removing the CLAMP to avoid damage to surrounding structures.
- 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
- 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 re-sterilize or reuse the Synergy Ablation Clamp as this could damage the device or result in infection

EMT 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.
- The CLAMP is intended for single use. To prevent re-use, CLAMP use 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.
- 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.
- Do not connect the CLAMP to the GENERATOR if the connector pins are bent.
- A minimum tissue incision of 12 mm is recommended for insertion of the CLAMP.
- Clamp leaks CO2 if used under insufflation.
- 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.
- 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.
- 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. Immersion of any part of the CLAMP in fluids may also damage the device.
- 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.
- 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.
- The useful life of the device is 18 individual ablations. If additional ablations are required, it is recommended to use a second CLAMP.
- It is the responsibility of the health care institution to adequately prepare and identify the products for shipment.

EMR2/EML2 Warnings:

- 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.
- 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.
- 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.
- If using auxiliary tools to retrieve the GUIDE, use caution to avoid tissue perforation.
- Failure to pull the TEE probe back away from the CLAMP site prior to routing may cause damage to surrounding structures. Use caution when routing, positioning, and removing the CLAMP to avoid damage to surrounding structures.
- 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. 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 re-sterilize or reuse the Synergy Ablation Clamp as this could damage the device or result in infection

EMR2/EML2 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.
- The CLAMP is intended for single use. To prevent re-use, CLAMP use 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.
- 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.
- Do not connect the CLAMP to the GENERATOR if the connector pins are bent.
- Clamp leaks CO2 if used under insufflation.
- A minimum tissue incision of 12 mm is recommended for insertion of the CLAMP.
- 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.
- 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.
- 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. Immersion of any part of the CLAMP in fluids may also damage the device.
- 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.
- 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.
- The useful life of the device is 18 individual ablations. If additional ablations are required, it is recommended to use a second CLAMP.
- It is the responsibility of the health care institution to adequately prepare and identify the products for shipment.

OLH/OSH Warnings:

- Read all instructions carefully for the AtriCure Isolator Synergy EnCompass 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.
- Due to the length of the jaws, the CLAMP should only be used with open surgical access where the CLAMP and adjacent structures can be easily visualized, to prevent collateral injury. Refer to Potential Complications list.
- Use of the CLAMP and GUIDE on patients who have undergone previous cardiac surgeries may increase risk of damage during dissection and routing due to presence of adhesions in the tissue plans.
- Use of the CLAMP and GUIDE while off cardiopulmonary bypass could increased

risk of tissue perforation and/or circulatory interruption.

- 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.
- Inspect the product packaging prior to opening to ensure the sterility barrier is not breached. If the sterility barrier is breached, do not use the CLAMP or GUIDE 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.
- Dissection of epicardial fat where the CLAMP may interact with the Epicardium during placement may increase the potential for tissue damage.
- If using auxiliary tools to retrieve the GUIDE, use caution to avoid tissue perforation.
- Failure to pull the TEE probe back away from the CLAMP site prior to routing may cause damage to surrounding structures.
- When placing the CLAMP, caution should be taken to pull the CLAMP into position with the GUIDE when possible. Pushing the CLAMP into position may cause damage to surrounding structures.
- Unnecessary removal of the GUIDE while the CLAMP is in position may cause damage to the surrounding structures. There is no need to remove the GUIDE at this step as the GUIDE does not interfere with clamping or ablation.
- 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.
- 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 re-sterilize or reuse the CLAMP and GUIDE as this could damage the device or result in infection.

OLH/OSH 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.
- The CLAMP is intended for single use. To prevent re-use, CLAMP use 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 regard- ing potential electromagnetic or other interference, and advice regarding avoidance of such interference.
- 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.
- The CLAMP is only compatible with the AtriCure RF GENERATOR. Do not use the CLAMP with any other system, to prevent injury and/or equipment damage.
- Do not connect the CLAMP to the GENERATOR if the Connector pins are bent.
- 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.

- Do not insert excessive tissue into the Jaw Cover as it may result in poor ablation at the Jaw Cover.
- Do not ablate tissue greater than 15 mm thick with the CLAMP. Tissues greater than 15 mm thick may not be fully ablated.
- 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.
- 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.
- When the GENERATOR and 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.
- Do not touch the Electrodes of the CLAMP to metal staples or clips, or to sutures while activating the GENERATOR.
- The useful life of the device is 12 individual ablations. If additional ablations are required, it is recommended to use a second CLAMP.
- It is the responsibility of the health care institution to adequately prepare and identify the products for shipment.

4.3. Other relevant aspects of safety, including a summary of any field safety corrective action (FSCA including FSN) if applicable

There have been no recalls, FSCAs, or FSNs for the subject devices of this SSCP.

5. Summary of clinical evaluation and post-market clinical follow-up (PMCF)

This section is intended to summarise, in a comprehensive manner, the clinical evaluation results and the clinical data forming the clinical evidence for the confirmation of conformity with relevant general safety and performance requirements, the evaluation of undesirable side-effects and the acceptability of the benefit-risk ratio. It shall be an objective and balanced summary of the clinical evaluation results of all the available clinical data related to the device in question, whether favourable, unfavourable, and/or inconclusive.

5.1. Summary of clinical data related to equivalent device, if applicable

The conformities of the Encompass (OLH/OSH) clamp and Glidepath Magnetic Guide (GPM100) and the Isolator Synergy Access (EMT) clamp and Glidepath Tape (GPT200) were assessed and endorsed by the Notified Body on the basis of equivalency to the Isolator Synergy (EMR/EML) clamps and Glidepath Tape (GPT100). The conformity of the Glidepath Tape GPT300 was assessed and endorsed by the Notified Body on the basis of equivalency to GPT100. Clinical data including the CEASE-AF clinical trial and published literature, on the Isolator Synergy (EMR/EML) clamps are described in this SSCP, in sections 5.2 and 5.3

5.2. Summary of clinical data from conducted investigations of the device before the CE-Marking, if applicable

Identity of the investigation/study	ABLATE; IDE: G070080; clinicaltrials.gov: NCT00560885; Philpott et al. Ann Thorac Surg 2015;100:1541-8.
Identity of the device	Isolator Synergy Clamps (OLL2/OSL2) Ablation and Sensing Unit and Source Switch (ASU2/ASB)
Intended use of the device in the investigation	To ablate cardiac tissue for the treatment of patients with non-paroxysmal Atrial Fibrillation who are undergoing open concomitant cardiac surgery
Objectives of the study	The primary objective of the ABLATE study was to demonstrate the safety and efficacy of the AtriCure Radiofrequency Clamps in the treatment of subjects with permanent atrial fibrillation that were undergoing a cardiac surgery procedure primarily for significant structural and/or coronary heart disease indications.
Study design and duration of follow-up	Prospective, non-randomized multi-center clinical trial with Bayesian adaptive design. Follow-up was through discharge, 30-days, 3-months, 6 months, 12 months, 18 months, 2 years, and annually for 5 years
Primary and secondary endpoint(s)	The primary efficacy endpoint was defined as the rate of subjects that achieved successful obliteration of atrial fibrillation while off any antiarrhythmic medication (Class I or III) evaluated at six months post-procedure via Holter monitor assessment (or permanent pacemaker (PPM) interrogation in the case of those subjects that have a pacemaker implanted). The primary safety endpoint for the study was defined as the rate of Major Adverse Events (MAEs) occurring within the initial 30 days post procedure or discharge (whichever was later). The MAEs consist of: death, excessive bleeding (defined as >2 units of red blood cells requiring reoperation), stroke, trans-ischemic attack (TIA) or myocardial infarction (MI).
Inclusion/exclusion criteria for subject selection	Inclusion criteria: • Subject is greater than or equal to 18 years of age. • Subject has history of permanent atrial fibrillation as defined by the ACC/AHA/ESC Guidelines. • Subject is scheduled to undergo elective on-pump cardiac surgical procedure(s) for one or more of

	the following: Mitral valve repair or replacement; Aortic valve repair or replacement; Tricuspid valve repair or replacement; Coronary Artery Bypass procedures; Atrial Septal Defect Repair; Patent Foramen Ovale closure • Subject's Left Ventricular Ejection Fraction ≥ 30% • Subject is able and willing to provide written informed consent and comply with study requirements • Subject has life expectancy of at least 1 year • Exclusion criteria: Stand alone AF without indication(s) for concomitant CABG, valve surgery, ASD repair, or PFO closure • Previous cardiac ablation including catheter ablation, AV-nodal ablation, or surgical Maze procedure • Wolff-Parkinson-White syndrome • Prior cardiac surgery (Redo) • Class IV NYHA heart failure symptoms • Prior history of cerebrovascular accidents within 6 months or at any time if there is residual neurological deficit • Documented MI within 6 weeks prior to study enrollment • Need for emergent cardiac surgery (i.e. cardiogenic shock) • Known carotid artery stenosis greater than 80% • LA size greater than or equal to 8cm • Current diagnosis of active systemic infection • Severe peripheral arterial occlusive disease defined as claudication with minimal exertion • Pregnancy or desire to get pregnant within 12-months of the study enrollment • Preoperative need for an intra-aortic balloon pump or intravenous inotropes • Renal failure requiring dialysis or hepatic failure • Requires anti-arrhythmic drug

	therapy for the treatment of a ventricular arrhythmia • Therapy resulting in compromised tissue integrity including: thoracic radiation, chemotherapy, long term treatment with oral or injected steroids, or known connective tissue disorders
Number of enrolled patients	55 patients
Study population	N=55 Mean age: 70.5 ± 9.3 years Sex: 58% male; 42% female Left atrium size 5.93 ± 0.97 cm AF duration: 61.2 ± 49.5 months Paroxysmal AF: 7.3% Persistent AF: 27.3% Longstanding Persistent AF: 65.5% LVEF: 50.0 ± 10.3 $CHADS_2$ 0: 18.2%; 1: 27.3%; 2: 54.5%
Summary of study methods	A total of 57 subjects were screened and consented for enrollment in the multi-center, prospective, non-randomized study based on a Bayesian adaptive design to provide high probability of demonstrating non-inferiority of the AtriCure radiofrequency clamps for the treatment of permanent atrial fibrillation. Investigators were required to perform a near-complete CMP-IV lesion set concomitant with an open chest structural heart procedure.
Summary of results	At six months follow-up: • Seventy-four percent (74%) of patients were free of atrial fibrillation and off antiarrhythmic drugs. • Eighty-four percent (84%) of patients were free of atrial fibrillation. Long-term follow-up (median of 48.5 months post-procedure): • Sixty-two and a half percent (62.5%) of patients were free of atrial fibrillation and off antiarrhythmic drugs. • Seventy-five percent (75%) of patients were free of atrial fibrillation. Safety: • There were no device-related adverse events in the series.

	• There were 5 primary safety events within 30 days: 2 deaths; 2 excessive bleeds and 1 stroke
Study Limitations	Ablation at coronary sinus was not mandatory; number of radiofrequency/cryoablation applications was not recorded; relatively small number of patients and deviation from prescribed lesion set resulted in large 95% confidence intervals for several study endpoints
Any device deficiency or device replacements related to safety or performance during the study	There were no device malfunctions reported.

Identity of the investigation/study	ABLATE Post-Approval Study (ABLATE-PAS); clinicaltrials.gov NCT01694563; McCarthy et al. J Thorac Cardiovasc Surg. 2022 Aug;164(2):519-527.e4.
Identity of the device	Isolator Synergy Clamps (OLL2/OSL2) Ablation and Sensing Unit and Source Switch (ASU2/ASB) Isolator Transpolar Pen (MAX3, MAX5)
Intended use of the device in the investigation	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 12 months duration) in patients who are undergoing open concomitant coronary artery bypass grafting and/or valve replacement or repair.
Objectives of the study	The primary objective of this post-approval study was to evaluate clinical outcomes in a cohort of patients treated during commercial use of the AtriCure Synergy Ablation System by physicians performing the Maze IV procedure.
Study design and duration of follow-up	This prospective, open label, multi-center, observational, single arm registry was designed to monitor the AtriCure Synergy Ablation System continued safety and efficacy during the peri-procedural and long-term phase during commercial use in patients being treated for non- paroxysmal forms of atrial fibrillation (AF) who were undergoing a concomitant open, on-pump cardiac surgical procedure.

Primary and secondary endpoint(s)	Primary effectiveness: The number of participants free from AF, atrial flutter or atrial tachycardia while off Class I and Class III antiarrhythmic drugs for at least 4 weeks (Time Frame: 36 months post-operatively) Primary safety: The proportion of patients with any serious device or ablation procedure-related adverse events (excluding pacemaker implantation) within 30 days post-procedure or hospital discharge (whichever was later) as adjudicated by a Clinical Events Committee.
Inclusion/exclusion criteria for subject selection	Inclusion: • Age > or equal to 18 years of age • History of non-paroxysmal form of Atrial Fibrillation (AF) as defined by the Heart Rhythm Society/European Heart Rhythm Association/European Cardiac Arrhythmia Society Consensus Statement: ○ Persistent AF shall be defined as continuous AF that is sustained beyond seven days. Episodes of AF in which a decision is made to electrically or pharmacologically cardiovert the patient after greater than or equal to 48 hours of AF but prior to 7 days, should also be classified as persistent AF episodes. ○ Longstanding persistent AF shall be defined as continuous AF of greater than 12 months duration. The performance of a successful cardioversion (sinus rhythm >30 seconds) within 12 months of an ablation procedure with documented early recurrence of AF with 30 days should not alter the classification of AF as longstanding persistent. • Subject is scheduled to undergo elective open cardiac surgical

	procedure(s) to be performed on cardiopulmonary bypass for one or more of the following: Coronary Artery Bypass Grafting, Mitral valve repair or replacement, Aortic valve repair or replacement, Tricuspid valve repair or replacement. In conjunction with these procedure patent foramen ovale (PFO) or atrial septal defect (ASD) repair are allowed. • The patient (or their legally authorized representative) agrees to participate in this study by singing the Institutional Review Board (IRB) approved informed consent form. • Willing and able to return for scheduled follow up visits. Exclusion Criteria: • Stand along AF without indication(s) for concomitant cardiac surgery. • Need for emergent cardiac surgery (i.e., cardiogenic shock). • Preoperative need for an intra-aortic balloon pump or intravenous inotropes. • Pregnancy or desire to get pregnant for the duration of the study concomitant surgical procedure through the thirty six (36) month follow up period). • Enrolled in another clinical trial that could confound the results of this study.
Number of enrolled patients	N=365
Study population	N=365 Age (years): 69.8 ± 9.3 Male: 217 (59.5%) Duration of atrial fibrillation (months): 60.0 ± 84.2 Type of atrial fibrillation Paroxysmal: 1 (0.3%) Persistent: 207 (56.7%) Longstanding Persistent: 157 (43%) CHADs Score Risk Category Low Risk: (score=0) 0 Medium Risk: (score=1) 22 (6.1) High Risk: (score>=2) 340 (93.9) Not Assessed: 3 (0.8)

Summary of study methods	Descriptive analyses were provided for patient demographics, clinical device/procedural success, medical histories, and comorbidities. The primary safety hypothesis test was conducted using a 1-sided exact binomial test for proportions at the 0.05 overall level of significance. Serious device and ablation procedure-related AE rates and confidence intervals were summarized at discharge, 30 days, and 1 year with a hypothesis test per-formed on the cumulative 30-day serious device and ablation procedure-related AE rate. The efficacy outcome rate of freedom from AF, off antiarrhythmic drugs along with confidence intervals were summarized at 1, 2, and 3 years (ie,12-, 24-, 36-month follow-ups), with a hypothesis test performed on the3-year success outcome. The primary efficacy hypothesis test was conduct-ed using a 1-sided exact binomial test for proportions at the .05 overall level of significance. Secondary outcomes were summarized for the analysis population and certain subpopulations. Two-sided 95%confidence intervals were calculated for all presented rates. Overall survival since enrollment was estimated using the Kaplan–Meier estimator. Probabilities of stroke, cardioversion, or catheter ablation over time were estimated using the cumulative incidence functions calculated using semi-competing risks methodology.
Summary of results	Primary success rates were as follows: • 12-months: 66.2% (184/278) [95% CI: 60.6%, 71.8%] • 24-months: 64.9% (159/245) [95% CI: 58.9%, 70.9%] • 36-months: 62.9% (146/232) [p-value<0.0001; 95% CI: 56.7%, 69.2%] The primary safety event rate was 1.1% (4/365) [p-value<0.0001; 95% CI: 0.3%, 2.8%]. The events reported included cardiac arrest, ventricular tachycardia, blood loss requiring transfusion, and pulmonary vein tear. • There were no device malfunctions or complications from the device. • There were no deaths attributable to the AtriCure Synergy Ablation System or the ablation procedure.
Study Limitations	Episodes of paroxysmal AF may have been missed; the decision to use anti-

	arrhythmic medications and oral anticoagulation was not mandated by the protocol. Surgeon preference directed the fashion in which the clamp was applied and number of applications.
Any device deficiency or device replacements related to safety or performance during the study	There were no device malfunctions.

Identity of the investigation/study	Feasibility Trial of a Staged Epicardial & Endocardial Approach for Treatment of Patients With Persistent or Long Standing Persistent Atrial Fibrillation With Radiofrequency Ablation (Staged DEEP); clinicaltrials.gov NCT01661205
Identity of the device	Isolator Synergy Clamps (EMR2, EML2, EMT) and Glidepath Tapes Ablation and Sensing Unit and Source Switch (ASU2/ASB) AtriCure Isolator Pens MAX1, MAX5, MCR1, MLP1 Dissector MID1 AtriCure AtriClip: LAA0, PRO1, CGG100 (Selection Guide)
Intended use of the device in the investigation	Cardiac ablation for persistent or longstanding persistent AF
Objectives of the study	To assess the safety and technical feasibility of treating subjects with persistent or longstanding persistent atrial fibrillation using a minimally invasive thoracoscopic ablation procedure utilizing the AtriCure Bipolar System.
Study design and duration of follow-up	Feasibility, open label, single arm
Primary and secondary endpoint(s)	The primary safety endpoint was a composite of the following adjudicated endpoint events that met the definition of a serious adverse event, and are attributed to any of the following: • AtriCure Bipolar System investigational devices; or • Epicardial surgical procedure; or • Endocardial procedure. These events must occur in the first 30 days post-index endocardial EP procedure or hospital discharge, whichever is longer (unless otherwise noted). Serious adverse events included: death (all-cause mortality); myocardial Infarction, stroke or TIA; excess bleeding, intra-procedure: conversion to sternotomy or cardiopulmonary bypass to control bleeding, post-operative excessive

	bleeding (≥ 2 units blood transfused in a 24 hour period, or reoperation to control bleed, in the first 7 days post-index surgical procedure); pulmonary vein stenosis (from the time of index surgical procedure through 12 month follow-up); atrio-esophageal fistula (from the time of index surgical procedure through 12 month follow-up); phrenic nerve paralysis; pericardial effusion requiring drainage or causing tamponade, vascular access complications including development of a hematoma, an arteriovenous fistula, or pseudoaneurysm that required surgical intervention or transfusion, prolonged hospital stay, or required hospital admission; injury to the specialized conduction system requiring permanent pacemaker implantation; and/or mediastinitis. The primary efficacy endpoint was absence of AF at 12- month follow-up assessment, based on continuous 14-day ECG monitoring (e.g., Holter, ILR, Zio Patch
Inclusion/exclusion criteria for subject selection	Inclusion Criteria: • Age > 18 year • Patients with symptomatic persistent or longstanding persistent AF refractory to a minimum of one Class I or III antiarrhythmic drug (AAD) • Patients with failed catheter ablation attempts are eligible if the patients are symptomatic with persistent or longstanding persistent AF. (catheter ablation procedure must be more than 3 months prior to index procedure) • Life expectancy of at least two years • Patient will and able to provide informed consent • Patient is willing and able to attend the scheduled follow-up visits Exclusion Criteria: • Prior Cardiothoracic Surgery • Patient has NYHA (New York Heart Association) Class IV heart failure • Evidence of underlying structural heart disease requiring surgical treatment

	• Surgical procedure within the 30 days prior to the index procedure • Ejection fraction < 30% • Measured left atrial diameter > 6.0 cm • Renal Failure • Stroke within previous 6 months • Known carotid artery stenosis greater than 80% • Evidence of significant active infection or endocarditis • Pregnant woman or women desiring to become pregnant in the next 24 months • Presence of thrombus in the left atrium determined by echocardiograph • History of blood dyscrasia • Contraindication to anticoagulation, based on Investigator's opinion • Mural thrombus or tumor • Moderate to Severe COPD
Number of enrolled patients	31 (26 treated)
Study population	Mean age : 61.7±9.5 years Male: 21 (80.8%) BMI: 30.8±3.9
Summary of study methods	The first subject was enrolled and treated in the Staged DEEP AF clinical study on September 11, 2012. In total, thirty-one (31) subjects were enrolled. Thirty (30) subjects signed thirty-one (31) consents from six (6) sites. All subjects treated in the Staged DEEP clinical study completed a 30-day follow-up visit and were followed through 24 months post index endocardial EP procedure, as outlined in the clinical protocol.
Summary of results	Primary adverse events occurred in 12% (3/25) of subjects. All three were adjudicated to be related to the epicardial procedure. • Death: one (1) subject at 35 days post-procedure • Phrenic nerve paralysis: two (2) subjects Primary efficacy: Primary efficacy was 78.3% (18/23 subjects).
Study Limitations	Feasibility study, small sample size

Any device deficiency or device replacements related to safety or performance during the study	Four device observations/malfunctions associated with the Coolrail linear pen (MCR1) were reported. • Two (2) Coolrail linear pens (MCR1) and two (2) AtriClips were observed to be contaminated or damaged during or prior to the procedure. • Mechanical breakage during the epicardial surgical procedure was reported for 2 additional Coolrail linear pens (MCR1). • In all instances an additional device was used. • No adverse event resulted from any of the observations

Identity of the investigation/study	Feasibility Trial of a Hybrid Approach for Treatment of Patients With Persistent or Longstanding Persistent Atrial Fibrillation With Radiofrequency Ablation (NCT01246466)
Identity of the device	AtriCure Synergy Ablation System: ASU2, ASB3, Isolator Synergy Clamps (EML2, EMR2, EMT1) and Glidepath Tape AtriCure Isolator Pens: MCR1, MAX3/MAX5, MLP1 Dissector MID1 AtriClip PRO1
Intended use of the device in the investigation	Cardiac ablation for persistent and longstanding persistent AF
Objectives of the study	The objective of the study was to assess the safety and technical feasibility of treating subjects with persistent atrial fibrillation or longstanding persistent atrial fibrillation procedure in a minimally invasive thoracoscopic ablation procedure utilizing the AtriCure Bipolar System, with mapping and optimization of lesions provided by currently approved catheter technology.
Study design and duration of follow-up	Prospective, multi-center, single arm, feasibility
Primary and secondary endpoint(s)	The primary endpoint for safety was a composite of adjudicated endpoints (e.g., adverse events) occurring within the first 30 days post-procedure or discharge (whichever is longer, unless otherwise noted). These events included death, major bleeding, stroke, transient ischemic attack, myocardial infarction, cardiac tamponade, pulmonary embolism, peripheral embolism, atrioesophageal

	fistula, diaphragmatic paralysis, pulmonary vein stenosis, serious skin burns, 2nd/3rd degree atrial-ventricular block requiring permanent pacemaker implantation, skin burns occurring within 48 hours after the procedure, emergency conversion to thoracotomy or sternotomy, and serious adverse events related to the catheter and/or the surgical procedure. The primary outcome for determining efficacy was absence of atrial fibrillation (AF) at twelve-month follow-up based on the 14-day auto trigger event monitor i.e., no episodes of AF, atrial flutter, or atrial tachycardia lasting > 30 continuous seconds, while off all Class I and III antiarrhythmic therapy for at least 4 weeks (except amiodarone which must be 12 weeks), prior to assessment.
Inclusion/exclusion criteria for subject selection	Inclusion Criteria: • Age > 18 years • Patients with symptomatic (e.g. palpitations, shortness of breath, fatigue) persistent or longstanding persistent AF Persistent • Patient is willing and able to provide written informed consent. • Patient has a life expectancy of at least 2 years. • Patient is willing and able to attend the scheduled follow-up visits. Exclusion Criteria: • Prior Cardiothoracic Surgery. • Patient has NYHA Class IV heart failure. • Evidence of underlying structural heart disease requiring surgical treatment. • Ejection fraction < 30% • Measured left atrial diameter > 6.0 cm • Renal Failure • Stroke within previous 6 months. • Known carotid artery stenosis greater than 80%. • Evidence of significant active infection or endocarditis. • Pregnant woman or women desiring to become pregnant in the next 24

	months. • Presence of thrombus in the left atrium determined by echocardiography. • History of blood dyscrasia. • Contraindication to anticoagulation, based on Investigator's opinion. • Mural thrombus or tumor. • Moderate to Severe COPD
Number of enrolled patients	N=24
Study population	Age: 60.1±8.4 years Male: 22 (91.7%) BMI: 30.4±4.2
Summary of study methods	Subjects were followed through twenty-four (24) months with the primary efficacy endpoint evaluated at twelve (12) months.
Summary of results	Primary safety events (adverse event within 30 days post-procedure) occurred in 29.2% (7/24) of the subjects. 12.5% (3/24) were related to the catheter and its procedure. • Conversion to median sternotomy (1/24) • Stroke 20.8% (5/24) were related to the surgical procedure. • Bleeding during the epicardial procedure (1/24): conversion to mini-thoracotomy. • Stroke resulting in death on day 27 • Two subjects had infection at the port site; both were treated with antibiotics. • Vocal cord paralysis occurred in one subject Note: One patient experienced a myocardial infarction that was adjudicated to be due to both the endocardial catheter procedure and the epicardial ablation procedure. The primary efficacy endpoint was achieved in 68.4% (13/19) [95% CI 43.4, 87.4].
Study Limitations	Feasibility study, single arm, small sample size
Any device deficiency or device replacements related to safety or performance during the study	Device observations/malfunctions were observed in six (6) subjects: • Isolator Synergy Clamp (EML2) (n=1) - The Glidepath Tape

	(connection separated from the tip of the clamp jaw. A second EML2 device was used to complete the procedure without incident. • Isolator Transpolar Pen (n=1) - A 60 cycle (e.g., 60 Hertz) interference was noted and thought to be caused by a faulty pen. Use of the device with the associated observation was discontinued and replaced with an additional study device Isolator Transpolar Pen, which was used to complete the procedure without incident. • Coolrail Linear Pen (n=4): • Overheating (n=2) - Use of this device was discontinued and replaced with a commercially available Coolrail Linear Pen, which was used to successfully complete the procedure. • In one patient, a competitive device was used as a backup research device was not available. • In one patient, another Coolrail device from the investigational device inventory was used to complete the procedure without incident. • Mechanical breakage (n=2) – In both cases, the devices were replaced with another Coolrail Linear Pen from the investigational device inventory. • Note: None of these device observations/malfunctions was associated with an adverse event. Despite the temporary interruption of the procedure in these cases mentioned above, ablation of the specified lesion set was completed.

Identity of the investigation/study	Combined Endoscopic Epicardial and Percutaneous Endocardial Ablation Versus Repeated Catheter Ablation in Persistent and Longstanding Persistent Atrial Fibrillation (CEASE-AF) (NCT02695277)
Identity of the device	AtriCure Bipolar System (MAX5, ASU, ASB, GPT200, MID1, EMR2, EML2)

	AtriClip PRO LAA Exclusion System (PRO1/PRO2) and CGG100 (Selection Guide)
Intended use of the device in the investigation	Cardiac ablation
Objectives of the study	The objective of this study is to compare the efficacy and safety of two interventional approaches in preventing the recurrence of AF in symptomatic, drug-refractory patients with persistent or longstanding persistent atrial fibrillation.
Study design and duration of follow-up	The prospective 2:1 randomized study is designed to compare the effects of combined epicardial endoscopic surgical and endocardial catheter techniques versus standard endocardial catheter ablation strategies with regard to safety, efficacy, and quality of life. Effects on health economics of the two treatment strategies will also be evaluated. Duration of follow-up is 36 months.
Primary and secondary endpoint(s)	Primary effectiveness: • Number of subjects free from documented Atrial Fibrillation (AF), Atrial Flutter (AFL) or Atrial Tachycardia (AT) episodes >30 seconds in duration through 12-months follow-up, in the absence of Class I or III Antiarrhythmic Drugs (AADs). Secondary effectiveness: • Number of subjects free from documented AF, AFL or AT episodes > 30 seconds in duration through 24- and 36-months follow-up, in the absence of Class I or III AADs. [Time Frame: Through 24- and 36-months post the Endocardial procedure (Hybrid Procedure) or last allowed Catheter Ablation (Catheter Procedure)] Safety: Composite major complications and adverse events will be analyzed during follow-up, comparing cumulative complication rates occurring during the repeated procedures in the two study arms. Adverse events may include the following: death, stroke, transient ischemic attack, myocardial infarction in the context of AF Ablation, pericarditis, bleeding, wound infection, atrio-esophageal fistula, esophageal injury, permanent phrenic nerve paralysis, permanent pacemaker, pulmonary vein

	(PV) stenosis of >70%, cardiac tamponade/cardiac perforation, empyema, superficial wound infections or vascular access complications, pneumonia, and pneumothorax requiring intervention.
Inclusion/exclusion criteria for subject selection	Inclusion criteria: • Patient has a history of symptomatic Persistent AF and a left atrium (LA) > 4cm or Long Standing Persistent AF as defined by the HRS/EHRA/ECAS expert consensus statement • Patient is refractory to or intolerant of at least one antiarrhythmic drug (class I or III) • Patient is mentally able and willing to give informed consent Exclusion criteria: • Patient has longstanding persistent AF > 10 years • Patient presenting with paroxysmal AF • Patient with persistent AF and a LA-diameter ≤ 4cm • AF is secondary to electrolyte imbalance, thyroid disease, or other reversible or non-cardiovascular cause • Patient underwent previous ablation procedure or heart surgery • Patient needs other cardiac surgery procedures besides AF treatment (valve, coronary, others) • Contraindication for either catheter ablation or epicardial surgery (including, but not limited to: previous thoracic radiation, previous perimyocarditis, Previous cardiac tamponade, Pleural adhesions, Prior thoracotomy) • Body mass index > 35 • LA Diameter > 6 cm • Left ventricular ejection fraction < 30 % • Severe mitral regurgitation (>II) • Patient unable to undergo TransEsophageal Echocardiogram (TEE) • Presence of LA thrombus by TEE, CT scan, MRI or angiography • History of cerebrovascular disease, including stroke or transient ischemic attack (TIA) within 6 months prior to

	enrollment • Active infection or sepsis • Other clinical conditions precluding inclusion (e.g., organ disease, disturbances of hemostasis) • Contraindication to anticoagulant therapy, or inability to comply with anticoagulant therapy • Pregnancy, planned pregnancy or breastfeeding • Life expectancy is less than 12 months • Patient is involved in another study involving an investigational drug or device
Number of enrolled patients	N=170
Study population	N=154
Summary of study methods	From November 2015 to May 2020, 170 patients from 9 centers in Czechia (Czech Republic), Germany, the Netherlands, Poland, and the United Kingdom were enrolled and randomized 2:1 to Hybrid Ablation (N=114) or repeat Catheter Ablation (N=56). Of enrolled patients, 152 were treated with the index procedure (intention to treat, ITT, population). The modified ITT population consistent of 146 patients had at least one follow-up visit after T0 (6-months post index procedure).
Summary of results	Primary effectiveness (N=146 patients, n=95 Hybrid Ablation; n=51 Catheter Ablation) • Freedom from AF/AFL/AT in the absence of Class I/III AADs except those not exceeding previously failed doses through 12-months visit post-T0 was 71.6% (68/95) in the Hybrid Ablation arm versus 39.2% (20/51) in the repeat Catheter Ablation arm (absolute benefit increase 32.4%, p<0.001) • Persistent AF/enlarged left atrium subgroup: Freedom from AF/AFL/AT in the absence of Class I/III AADs except those not exceeding previously failed doses through 12-months visit post-T0 was 72.7% (56/77) in the Hybrid Ablation arm versus 41.9% (18/43) in the repeat Catheter Ablation arm (absolute

	benefit increase 30.9%, p<0.001). • Longstanding persistent AF subgroup: Freedom from AF/AFL/AT in the absence of Class I/III AADs except those not exceeding previously failed doses through 12-months visit post-T0 was 66.7% (12/18) in the Hybrid Ablation arm versus 25.0% (2/8) in the repeat Catheter Ablation arm (absolute benefit increase 41.7%, p=0.090). • Safety (N=154): Composite major complication rates through 30-days post-index and second stage/repeat endocardial catheter ablation were 7.8% (8/102) in the Hybrid Ablation arm and 5.8% (3/52) in the Catheter Ablation arm (n=0.751); Composite major complication rates through 1-year post index procedure were 8.8% (9/102) and 5.8% (3/52) (p=0.752). No device-related complications occurred per Clinical Events Committee adjudication
Study Limitations	• Minimal lesion sets were required in each arm, but additional epicardial or endocardial lesions could be made per institutional practice or physician discretion
Any device deficiency or device replacements related to safety or performance during the study	There was one (1) generator malfunction, which did not result in any adverse event or adverse outcome. The patient was treated by an alternative method and exited from the study protocol following the procedure.

5.3. Summary of clinical data from other sources, if applicable

Based on a comprehensive, systematic literature search performed as part of the Clinical Evaluation for the subject devices, more than 20 published literature studies specifically describe the safety and/or performance of the Isolator Synergy Ablation System clamps in concomitant or standalone surgical cardiac ablation procedures for atrial fibrillation[3-25] or IST[26-28]. Based on published clinical data, the pooled incidence of major adverse events related to the device or procedure was <9% in >2100 patients with AF[3-25] and <6% in patients with IST in 305 patients[26-28]. In patients treated with surgical ablation for AF, restoration of sinus rhythm/freedom from atrial arrhythmias was >75% in >2500 patients[3-16]. In patients treated for IST, freedom from IST was >80% in 255 patients[26-28].

5.4. An overall summary of the clinical performance and safety

The clinical benefit of the AtriCure Isolator Synergy Ablation clamps with Glidepath Tapes are return to normal sinus rhythm (i.e., freedom from atrial arrhythmia), reduce arrhythmia symptoms, and improve quality of life. Based on the totality of clinical data from published literature including registry data and clinical trials as well as equivalency to legacy devices (where applicable), the AtriCure Isolator Synergy Ablation clamps with Glidepath

Tapes/Magnetic Guide met the safety and performance objectives defined in the Clinical Evaluation. The overall rate of MAEs within 30 days after concomitant surgical ablation met the safety objective of <15%, and after thoracoscopic surgical ablation procedures including hybrid procedures met the safety objective of <19%. The overall rate of MAEs that occurred during surgical ablation in patients with IST was lower than the safety objective of 15%. The overall freedom from AF/AFL/AT or normal sinus rhythm rates or freedom from IST were >55% (performance objective) after surgical ablation with the Isolator Synergy Clamps either in concomitant or standalone surgical ablation procedures, including hybrid procedures.

5.5. Ongoing or planned post-market clinical follow-up

The ongoing clinical trials CEASE-AF, DEEP Pivotal, and HEAL-IST will provide post-market clinical follow-up data, as well as investigator sponsored research studies and the TRAC-AF registry. The information generated from these studies and registry and AtriCure's post-market surveillance program will be used to monitor and identify residual risks from use of the devices or performance-related impacts to the benefit-risk ratio.

6. Possible diagnostic or therapeutic alternatives

Atrial fibrillation

Rhythm control can be pursued pharmacologically among some patients with AF. The 2020 ESC Guidelines recommend amiodarone for long-term rhythm control in all AF patients, but urge trying other AADs first due to the extracardiac toxicity[29]. These guidelines also recommend rhythm control be pursued by AF catheter ablation for pulmonary vein isolation after one failed or intolerant class I or class III anti-arrhythmic drug in patients with paroxysmal AF or persistent AF with or without major risk factors for AF recurrence ("Catheter or surgical ablation should be considered in patients with symptomatic persistent or long-standing persistent AF refractory to AAD therapy to improve symptoms")[29]. Although antiarrhythmic drugs are useful, the Journal of American College of Cardiology described AF ablation as the primary therapeutic strategy in their 2020 Council Perspective paper[30]. A variety of ablative procedures have been investigated as potentially curative approaches, or as modifiers of the arrhythmia such that drug therapy becomes more effective. Further, ablation may be a suitable treatment option in patients for whom AAD treatment has not been successful or is not well tolerated.

Ablative approaches focus on interruption of the electrical pathways that contribute to atrial fibrillation, through modifying the triggers of atrial fibrillation and/or the myocardial substrate that maintains the aberrant rhythm. The most common types of energy for ablation include radiofrequency, high-intensity ultrasound, laser, cryoenergy, and microwave. These energy sources ablate the cardiac tissue by scarring and creating lesion sets which disrupt the electrical signals. Among the various energy sources, RF and cryothermal energy are the most applied to ablate cardiac tissue[30]. Various RF ablation devices are on the market, and several also have cardiac electrophysiology diagnostic capabilities; these devices enable the physician to monitor (e.g., sensing, pacing, and recording) the success of the lesions in real-time[31]. Surgical ablation can be performed as either part of an open-heart surgery with a concomitant cardiac procedure or as a standalone thoracoscopic procedure. Both types of procedures have been assessed for safety and performance outcomes in clinical trials, some of which are reviewed in this SSCP. The frequency of surgical ablation performance and durable rhythm success, as a primary or stand-alone procedure, has steadily increased. Current guidelines from multiple physician societies have evaluated the use of surgical ablation to treat AF[1, 2, 29, 31].

Inappropriate Sinus Tachycardia

Currently, there is no FDA approved therapy for the treatment of IST. According to the 2015 Heart Rhythm Society (HRS) Expert Consensus Statement, evidence-based treatment options for IST are limited and there is no standard of care therapy for this debilitating disease[32].
Drug treatments such as beta blockers or calcium channel blockers are generally chosen as the first line of treatment but have not proven effective. Ivabradine, an inhibitor of the hyperpolarizing sodium current, is a more recent drug that has exhibited better results. Data has suggested that a combination of ivabradine and metoprolol might be safe and effective or Ivabradine may also provide benefits when added to a beta-blocker therapy.
RF catheter ablation involving sinus node (SN) ablation has been a potential alternative in patients with IST refractory to medical therapy. Often, the symptoms worsen or necessitate a permanent pacemaker. Other complications include phrenic nerve damage or transient superior vena cava syndrome. It is generally felt that the risks involved outweigh the benefit of this treatment.
Because of the complex psychosocial relationship to IST, treatment often involves a multi-disciplinary approach. Managing the heart rate does not always relieve the distress the patient has been experiencing. Other treatment options have included, erythropoietin, fludrocortisone, volume expansion, compression garments, phenobarbital, clonidine, psychiatric evaluation, and exercise training.

7. Suggested profile and training for users

Licensed medical doctors who perform cardiac and/or thoracic surgical procedures. AtriCure offers additional comprehensive education and training on the use of the Isolator Synergy Ablation Clamps and Glidepath Tapes/Magnetic for cardiac ablation as per the device instructions for use. This may include didactic review with an experienced operator and optional simulator/cadaver lab.

8. Reference to any harmonized standards and CS applied

Standard	Compliance – Full, Partial, or No	Justification if Partial or No
BS EN ISO 13485: 2016 + A11 2021 Medical devices — Quality management systems – Requirements for regulatory purposes	Full	N/A
BS EN ISO 14971:2019+A11:2021 Medical devices - Application of Risk Management to Medical Devices	Full	N/A
BS EN ISO 14155: 2020 Clinical investigation of medical devices for human subjects - Good clinical practice	Full	N/A
BS EN ISO 10993-1:2020 Biological evaluation of medical devices – Part 1: Evaluation and testing	Full	N/A
BS EN ISO 10993-4: 2017 Biological evaluation of medical devices – Part 4: interactions with Blood	Full	N/A
BS EN ISO 10993-5: 2009 Biological evaluation of medical devices – Part 5: Cytotoxicity	Full	N/A
BS EN ISO 10993-7: 2008 Biological evaluation of medical devices –Part 7 EO Residuals	Full	N/A
BS EN ISO 10993-10: 2013 Biological evaluation of medical devices – Part 10: Skin irritation/sensitization	Full	N/A

BS EN ISO 10993-11: 2018 Biological evaluation of medical devices – Part 11: Test for systemic toxicity	Full	N/A
BS EN ISO 10993-12: 2021 Biological evaluation of medical devices – Part 12: Sample Prep	Full	N/A
BS EN ISO 10993-18: 2020 Biological evaluation of medical devices – Chemical characterization	Full	N/A
BS EN ISO 10993-23 2021 Biological evaluation of medical devices — Part 23: Tests for irritation	Full	N/A
BS EN 60601-1: 2006+A2:2021 Medical electrical equipment Part 1: General requirements for basic safety and essential performance	Full	N/A
BS EN 60601-1-2: 2015+A1:2021 Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic disturbances — Requirements and tests	Full	N/A
BS EN 60601-1-6: 2010+A2:2021 Medical electrical equipment: Part 1-6: General requirements for basic safety and essential performance — Collateral standard: Usability	Full	N/A
BS EN 60601-2-2: 2018 Medical electrical equipment Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories	Full	N/A
BS EN ISO 11135:2014:+A1 2019 Sterilization of health-care products -Ethylene Oxide	Full	N/A
BS EN ISO 11737-1 2018/A1:2021 Sterilization of health care products. Microbiological methods	Full	N/A
BS EN ISO 11737-2: 2020 Sterilization of health care products. Microbiological methods	Full	N/A
BS EN ISO 11607-1: 2020+A11:2022: Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier Systems, and packaging Systems	Full	N/A
BS EN ISO 11607-2:2020+A11: 2022: Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes	Full	N/A
ISTA 3A: 2018 Performance testing of Shipping Containers and Systems	Full	N/A
ASTM F1980: 2021 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices	Full	N/A
ASTM F88/F88M-21: 2021 Standard Test Method for Seal Strength of Flexible Barrier Materials	Full	N/A
ASTM F2096-11: 2019 Detecting Gross Leaks in Packaging – Bubble Test	Full	N/A
ASTM F1929-15: 2015 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration	Full	N/A
BS EN ISO 15223-1: 2021 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements	Full	N/A

BS EN ISO 20417:2021 Medical Devices – Information to be supplied by the manufacturer	Full	N/A
BS EN IEC 62366-1: 2015 + A1 2020 Medical devices - Application of usability engineering to medical devices	Full	N/A
EN IEC 63000: 2018 Technical documentation for the assessment for electrical and electronic products for the restriction of hazardous substances	Full	N/A
RoHS3 (2015/863): 2015 RoHS 3 (EU Directive 2015/863) adds Category 11 (catch-all) products and adds four new restricted substances - all phthalates.	Full	N/A
EN ISO 14644-1: 2015 Cleanrooms and Associated Controlled Environments – Classification	Full	N/A
EN ISO 14644-2: 2015 Cleanrooms and Associated Controlled Environments – Monitoring	Full	N/A
N/A – not applicable		

9. Revision history

SSCP Revision Number	Date Issued	Change Description	Validated by Notified Body (Yes or No)	Validation Language
A	See CEM-278 Rev A for release date	Initial release	No	English
B	See CEM-278 Rev B for release date	Section 1: Removal of Glidepath Basic UDI-DI codes. Updated legal name and single registration number for manufacturer. Section 3.4: Added description of AtriCure RF generators and other devices (e.g., AtriCure Isolator Pens) that may be used with Clamps.	No	English
C	See CEM-278 Rev C for release date	Updated two cautions across all clamps to align with IFUs.	Yes	English
D	See CEM-278 Rev D for release date	Validated by BSI with CEM-278.C and revised to CEM-278.D to update CE Mark status for OLH/OSH, and attach translations files. Cover page date reflects Rev C approval date.	Yes	English

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