

# Isolator<sup>®</sup> Synergy<sup>™</sup> EnCompass<sup>®</sup> Clamp

## Clinical Compendium



AtriCure

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# Introduction

This compendium presents key clinical studies supporting the use of the Isolator Synergy EnCompass Clamp in cardiac ablation. Each entry includes a citation, summary (if available) and article link. The document will be updated as new research emerges.

**U.S. Indications:** The AtriCure Isolator Synergy EnCompass Clamp and Guide system is intended to ablate cardiac tissue during surgery. The safety and effectiveness of this device for the treatment of atrial fibrillation has not been established.

Please review the Instructions for Use for a complete listing of contraindications, warnings, precautions and potential adverse events prior to using these devices..

**Rx Only.**

## Efficacy of a Novel Bipolar Radiofrequency Clamp: An Acute Porcine Model

Yates, T.A., McGilvray, M., Razo, N. et al. (2022). Efficacy of a Novel Bipolar Radiofrequency Clamp: An Acute Porcine Model. *Innovations: Technology and Techniques in Cardiothoracic and Vascular Surgery*, 17(5):409-415. doi:10.1177/15569845221126524

**Background:** Expert consensus guidelines recommend surgical ablation (SA) for patients with symptomatic atrial fibrillation (AF), but less than half of patients with AF undergoing cardiac procedures receive concomitant SA. Complete isolation of the left atrial posterior wall (LAPW) has been shown to be the most critical part of the Cox maze procedure. The purpose of this study was to investigate the performance of a novel radiofrequency (RF) bipolar device, EnCompass Clamp (AtriCure, Inc., Mason, Ohio, USA), designed to isolate the LAPW in a single application.

**Methods:** Five adult pigs underwent SA in a beating heart model. After a single ablation, the heart was arrested, explanted, and stained with triphenyl-tetrazolium-chloride for histological assessment. Each lesion was sectioned, and the ablation depth, muscle, and fat thickness were determined. The lesion width, energy delivery, and ablation times were compared with those from a reference RF clamp (Isolator<sup>®</sup> Synergy<sup>™</sup> Clamp, AtriCure, Inc., Mason, Ohio, USA).

**Results:** Transmurality was documented in 100% of lesions (5 of 5) and cross sections (160 of 160). Electrical isolation was documented in every instance. There was no evidence of clot, charring, or pulmonary vein stenosis. Compared with the reference clamp, the lesions created by the EnCompass Clamp were 1.5 times wider on average. The average energy delivered was 5 times higher over a duration that was 4.5 times longer due to the increased volume of tissue ablated.

**Conclusions:** The EnCompass Clamp reproducibly created transmural isolation of the LAPW with a single application. This may allow for simplification of the SA strategy and increased adoption of AF treatment during concomitant surgery.

## First-in-Man Use of Intraoperative Electrophysiological Mapping to Evaluate the Efficacy of the EnCompass Clamp During a Cox-IV Maze Procedure

Khalpey, Z., Aslam, U., Kumar, U. et al. (2024). First-in-Man Use of Intraoperative Electrophysiological Mapping to Evaluate the Efficacy of the EnCompass Clamp During a Cox-IV Maze Procedure. *Cureus*, 16(8):e66131. doi:10.7759/cureus.66131

**Overview:** This case report describes the first-in-man use of intraoperative electrophysiological (EP) mapping to evaluate the efficacy of the EnCompass Clamp (AtriCure, Inc., Mason, Ohio, USA) during a Cox-IV Maze procedure. A 53-year-old male with paroxysmal atrial fibrillation and severe mitral valve regurgitation underwent mitral valve repair with concomitant surgical ablation for atrial fibrillation. Intraoperative 3D EP mapping was performed using the Abbott EnSite Precision system (Abbott Inc., Chicago, IL) before ablation, after initial radiofrequency ablation with the EnCompass Clamp, and after the full Cox-IV Maze procedure was completed. The pre-ablation map showed approximately 80-85% high voltage areas in the posterior left atrial wall. Initial ablation with the EnCompass Clamp reduced high voltage areas to 30-35%. The final map following the Cox-IV Maze procedure demonstrated near-complete electrical silence, with only 5-10% of the atrial surface retaining high voltage activity. This represents an estimated 88% reduction in high-voltage areas from baseline. The patient had an uncomplicated postoperative course apart from one episode of postoperative atrial fibrillation requiring direct current (DC) cardioversion. This case demonstrates the utility of intraoperative EP mapping in guiding and confirming the efficacy of surgical ablation procedures.

## Practical approaches to concomitant surgical ablation of atrial fibrillation: Matching the ablation to the patient

McCarthy, P.M. & Cox, J.L. (2025). Practical approaches to concomitant surgical ablation of atrial fibrillation: Matching the ablation to the patient. *J Thorac Cardiovasc Surg*, 169(3):907-915. doi:10.1016/j.jtcvs.2024.03.023

**Overview:** Atrial fibrillation (AF) substantially increases the risks of heart failure, stroke, and death, reduces patient quality of life and productivity, and increases healthcare resource utilization and costs. Many of the comorbidities present in cardiac surgery patients overlap with the risk factors for AF. AF can precede and contribute to the development of structural heart disease or can progress as atrial pathology worsens, creating substrate for AF across both atria. Published evidence makes clear that not treating pre-existing AF has negative consequences for patients undergoing cardiac surgery. Therefore, concomitant treatment of AF during cardiac surgery is paramount. The objective of this review is to provide expert perspective on current treatment options for patients with AF and concomitant structural heart disease, including a discussion of relevant literature. Ideally, bi-atrial Cox-Maze surgical ablation will be performed, which is supported by long-term data on its benefits including sinus rhythm restoration, reduced anti-arrhythmic drug (AAD) dependency, and mortality. When Cox-Maze is not appropriate either due to patient or operator factors, there is a role for limited lesion sets that prioritize the left atrial pathology and give primacy to isolation of the left atrial posterior wall and pulmonary veins (PVs). Always, effective closure of the left atrial appendage must be included. Consensus guidelines recommend surgical ablation to treat AF in patients with structural heart disease, which should be part of the comprehensive management of patients with heart disease requiring intervention accompanied by AF.

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## Mid-Term follow-up (24 month) of concomitant non-atriotomy surgical ablation (GP-Maze) during coronary surgical revascularization

Rushing, G.D. & Ruda Vega, P.F. (2025). Mid-Term follow-up (24 month) of concomitant non-atriotomy surgical ablation (GP-Maze) during coronary surgical revascularization. Abstract presented at STS Coronary Conference, June 13, 2025. [https://www.sts.org/sites/default/files/events/2025-STs-Coronary-Conference\\_Accepted-Abstracts.pdf](https://www.sts.org/sites/default/files/events/2025-STs-Coronary-Conference_Accepted-Abstracts.pdf)

**Background:** Atrial fibrillation (AF) treatment during cardiac surgery is a Class I STS recommendation, yet AF undertreatment persists, particularly in non-MV surgeries. This study evaluates safety and efficacy of the concomitant bi-atrial GP-Maze procedure, which accomplishes the Cox-Maze IV lesion set without bi-caval cannulation or atriotomy, in patients undergoing CABG.

**Methods:** Patients who underwent GP-Maze during surgical coronary revascularization were included. The left atrial posterior wall and pulmonary veins were encircled with a bipolar radiofrequency energy clamp. A cryoprobe was inserted through the tip of the left atrial appendage (LAA) and lines were made to interrupt the mitral valve annular and LAA circuits. The LAA was excluded using retrograde coronary sinus catheter purse-string access, the tricuspid annular circuit was interrupted with cryoablation. Other right atrial and coronary sinus lesions were created with epicardial cryoablation. Electrocardiogram and 7-day Holter monitoring occurred prospectively at 3, 6, 12 and 24 months.

**Results:** Thirty-five patients with a median age of 68 years (58, 77) were included. Seventy-five percent (n=26) of patients were male, 47% (n=16) had paroxysmal AF, 53% (n= 19) had non-paroxysmal AF, and 21% (n= 7) had failed prior catheter ablations. All concomitant procedures were CABG. Median cardiopulmonary bypass time was 148 min (70, 210) and cross-clamp time was 89 min (75, 148). There were no intraoperative complications or deaths. The rate of postoperative stroke was 2% (n=1) and there were no pacemaker implantations. Two readmissions (4%) occurred due to GI bleed and heart failure exacerbation.

Of 23 patients with 12-month follow-up, freedom from AF/AT was 96% (n=22), with 96% (n=22) of patients not requiring anti-arrhythmic drugs and 74% (n=17) not requiring anticoagulation. Of 17 patients with 24-month follow-up, freedom from AF/AT was 96% (n=16), with 96% (n=16) of patients not requiring anti-arrhythmic drugs and 80% (n=13) not requiring anticoagulation.

**Conclusion:** The GP Maze is effective at maintaining sinus rhythm without anti-arrhythmics in most patients followed through 2 years. The GP Maze can be safely performed without formal atriotomy or altered cannulation strategy and aims to reduce time and complexity of surgical ablation during CABG, where treating AF is still underperformed.

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## Non-Atriotomy Surgical Ablation Is Associated with a Reduction of Postoperative Atrial Fibrillation.

Kiankhooy, A., Sertic, F., Daw, M. et al. (2024). Non-Atriotomy Surgical Ablation Is Associated with a Reduction of Postoperative Atrial Fibrillation. *Ann Thorac Surg Short Rep*, 2(1):25-29. doi:10.1016/j.atssr.2023.09.007

**Background:** Postoperative atrial fibrillation (POAF) is common after cardiac operations, and effective intraoperative techniques aimed at reducing POAF focus on limiting left atrial triggers through posterior pericardiotomy or pulmonary vein isolation. Prophylactic left atrial appendage occlusion (LAAO) is increasingly used in hopes of preventing POAF-associated strokes. We sought to compare the incidence of POAF in patients undergoing prophylactic LAAO with or without a prophylactic non-atriotomy surgical ablation (NASA).

**Methods:** A retrospective observational cohort comparison study of patients undergoing first-time isolated coronary artery bypass grafting (CABG) with LAAO only (n = 90) or NASA+LAAO (n = 42) was conducted from July 2020 through November 2022. In-hospital POAF was defined by standard Society of Thoracic Surgeons (STS) definitions using 24-hour continuous telemetry and daily electrograms. Standard STS outcomes were also examined. Data are represented as mean ± SD. P values <.05 are considered significant.

**Results:** STS-collected patient demographics, operative characteristics, and major complications did not differ significantly between cohorts. The rate of POAF (LAAO only, 41.1%; NASA+LAAO, 4.7%; P < .0001; odds ratio, 0.07; 95% CI, 0.016-0.27) and amiodarone on discharge (LAAO only, 42.5%; NASA+LAAO, 7.3%; P < .0001; odds ratio, 0.11; 95% CI, 0.03-0.33) differed significantly between cohorts. Total hospital costs were similar.

**Conclusions:** In patients with isolated coronary artery bypass grafting undergoing LAAO, NASA was associated with a reduction of in-hospital POAF and need for antiarrhythmic medications on discharge. Future randomized prospective controlled studies are needed to prove safety and effectiveness.

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## Non-Atriotomy Surgical Ablation is Safe and Effective: A Multicenter Study.

Kiankhooy, A., Rushing, G., Pelletier, M. et al. (2025). Non-Atriotomy Surgical Ablation is Safe and Effective: A Multicenter Study. Abstract presented at STS Coronary Conference, June 14, 2025. [https://www.sts.org/sites/default/files/events/2025-STs-Coronary-Conference\\_Accepted-Abstracts.pdf](https://www.sts.org/sites/default/files/events/2025-STs-Coronary-Conference_Accepted-Abstracts.pdf)

**Background:** Less than 30% of patients with preoperative atrial fibrillation (AF) undergoing CABG receive concomitant surgical ablation. Left Atrial ablation classically requires atriotomy which increases ischemic time and surgical risk. We sought to evaluate a multi-institutional experience with non-atriotomy surgical ablation (NASA) of the left atrium using a radiofrequency clamp.

**Methods:** Consecutive cases with preoperative AF undergoing isolated CABG with concomitant NASA were evaluated. Cases where NASA was combined with additional ablations were excluded. The primary outcome

was freedom from atrial fibrillation (FFAF) beyond a 2-month blanking period as assessed by EKG or continuous ambulatory monitoring (CAM). Additional outcomes included FFAF beyond 12-months with CAM and NASA related intra-operative complications. Data are reported as mean (range).

**Results:** A total of 83 patients had concomitant NASA and isolated CABG with follow-up beyond the 2-month blanking period. The average age was 71 years (49-84), CHA<sub>2</sub>DS<sub>2</sub>Vasc 4.0 (0-7), ejection fraction 52% (13-73), left atrial diameter 4.2 cm (3.0-6.4), and most patients had paroxysmal AF (86%, 71/83). The primary outcome of FFAF occurred in 95% (79/83) of patients with an average follow-up of 12.5 months (2-36). Forty-one patients (41/83, 49%) had continuous monitoring and 98% (40/41) demonstrated FFAF. Thirty-three patients had greater than 12-months follow-up (mean 19, range 12-36) with CAM and FFAF were 97% (32/33). Institutional utilization of anti-arrhythmic drugs (AAD) and oral anticoagulation (OAC) on hospital discharge varied widely, with 61% (51/83) of patients discharged on Class I or III AADs and 48% (40/83) discharged on OAC. No intraoperative complications attributed to NASA were observed.

**Conclusion:** In patients with mostly paroxysmal preoperative AF undergoing CABG surgery, concomitant NASA with bipolar radiofrequency clamp to isolate the left atrium was associated with significant restoration of normal sinus rhythm and safety.

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### Avoiding Atriotomy; the University Hospitals GP Maze: Operative Technique and Early Results.

Rushing, G. & P. Ruda Vega. (2024). Avoiding Atriotomy; the University Hospitals GP Maze: Operative Technique and Early Results. Abstract presented at the Society of Thoracic Surgeons meeting, January 28, 2024, STS 2024 Annual Meeting. <https://sts2024.eventscribe.net/fsPopup.asp?PosterID=639037&mode=posterInfo>

**Background:** The Cox-Maze procedure, for surgical treatment of atrial fibrillation, traditionally has required formal left/right atriotomies (even minimally invasive approaches). This study describes a method using ablation technologies to create the full Cox-Maze lesion set, through the left atrial appendage, and purse-string access, used for retrograde cardioplegia cannula.

**Methods:** Sixteen consecutive patients, without need for atriotomy, received full Cox-IV maze lesions, using sternotomy and cardiopulmonary bypass. Surgical procedures included isolated CABG, combined CABG/AVR, and combined AVR/Ascending Aortic Aneurysm repair. The lesion sets were performed using a combination of radiofrequency and cryo-ablation energy sources. A box pulmonary vein isolation was performed using a bipolar radiofrequency energy clamp. Through the tip of the left atrial appendage, the mitral valve annular circuit interruption, and left atrial appendage circuit interruption lines were completed, using a cryoprobe. The Tricuspid annular circuit interruption line was completed using a cryoprobe via the retrograde coronary sinus catheter purse-string access. All other right atrial and coronary sinus lesions were completed epicardial, using a cryoprobe. Patients were followed prospectively with electrocardiogram and 7-day Holter monitoring at 3, 6, and 12 months.

**Results:** All operations were performed via full median sternotomy. The mean cardiopulmonary oxygenator time was (142 ± 12 min); the mean aortic cross-clamp time was (95 ± 5). There were no operative mortality or intraoperative complications. One patient developed a post-operative stroke. No patients required a permanent pacemaker. At last follow-up (mean 12.5 ± 10 months); all patients (n=16) were free from atrial dysrhythmias. At 3 months (n=14), 87% of patients were off antiarrhythmic drugs. At 6 and 12 months (n=15), 94% of patients were free from AF and off antiarrhythmic medications. Three patients (19%) remained on anticoagulation for non-arrhythmia indications.



**Conclusions:** A full set of Cox-IV lesions can be performed without need for bi-caval cannulation or atriotomy, with excellent short term results. Traditionally, these patients receive just a pulmonary vein isolation, or limited lesion sets. This procedure offers a complete ablation to patients without cumbersome access or cannulation techniques.

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### Initial Experience of Non-atriotomy surgical ablation (NASA) during CABG with Preexisting Atrial Fibrillation: A Multicenter Study

Kiankhooy, A., Rushing, G, Pelletier, M. et al. (2025). Initial Experience of Non-atriotomy surgical ablation (NASA) during CABG with Preexisting Atrial Fibrillation: A Multicenter Study. *Annals of Thoracic Surg Short Reports*. In press. doi:10.1016/j.atssr.2025.10.010

**Background:** Guideline concordance with surgical ablation in isolated coronary artery bypass grafting (CABG) patients is poor. Additional atriotomy and safety concerns are barriers to ablation. We sought to evaluate the initial safety and associated rhythm outcomes of a novel non-atriotomy surgical ablation (NASA) left atrial box lesion in isolated CABG patients.

**Methods:** A multicenter retrospective review included all concomitant NASA in isolated CABG patients with pre-existing atrial fibrillation. The primary outcome was NASA related intraoperative complications. Associated rhythm outcomes were per the Heart Rhythm Society definition of freedom from atrial fibrillation, atrial flutter, and atrial tachycardia (FFAF) less than 30 seconds at 12-months off Class I or III antiarrhythmic medications (AAD) by greater than 24 hour continuous monitoring. Data are reported as median (inter-quartile range, IQR). Results: Ninety-seven patients were analyzed. The median age was 73 years (IQR 68-76), CHA<sub>2</sub>DS<sub>2</sub>Vasc 4.0 (IQR 3-5), left ventricular ejection fraction 55% (IQR 45-60), left atrial diameter 4.0 cm (IQR 3.6-4.7), and most patients had paroxysmal AF (86%, 83/97). The primary safety outcome of intraoperative complications attributed to NASA was not observed (0%, 0/97). Thirty-five patients (35/97, 36%) had at least 12-months (median 12, IQR 12-24) with continuous ambulatory monitoring and FFAF was 94% (33/35), while 91% (32/35) showed FFAF off AAD.

**Conclusions:** In patients with mostly paroxysmal atrial fibrillation undergoing isolated CABG surgery, concomitant NASA was safe and was associated with favorable restoration of normal sinus rhythm at one year.

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### The Effectiveness of Isolating the Left Atrial Posterior Wall in Patients with Atrial Fibrillation

Obiarinze, R., Sinn, L.A., Brescia, A.A. et al. (2025). The Effectiveness of Isolating the Left Atrial Posterior Wall in Patients with Atrial Fibrillation. Abstract presented at the Eastern Cardiothoracic Surgical Society meeting on October 16, 2025. <https://ectss.org/meeting/program/2025/C09.cgi>

**Background:** Fewer than half of patients with atrial fibrillation (AF) undergoing cardiac surgery receive concomitant surgical ablation. The purpose of this study was to evaluate the effectiveness of left atrial posterior wall (LAPW) isolation with a box lesion for concomitant surgical ablation of AF.

**Methods:** Sixty-eight consecutive patients underwent concomitant surgical ablation using a radiofrequency clamp designed for LAPW isolation between September 2022 and January 2025. Freedom from AF on and off antiarrhythmic drugs (AADs) were evaluated from discharge to >1 year ( $\pm 3$  months). Freedom from AF was ascertained using an electrocardiogram (EKG), Holter, or pacemaker interrogation from discharge to >1 year ( $\pm 3$  months).

**Results:** Eight patients had paroxysmal AF, 47 had persistent AF, and 13 had longstanding persistent AF. There was no operative mortality. Rhythm follow-up was available in 68/68 (100%) of the patients at discharge and

in 36/41 (87%) of the patients at >1 year. Most (32/36) late follow-up was by prolonged monitoring. Freedom from AF at discharge and at >1 year, was 66/68 (97%) and 33/36 (92%), respectively. Freedom from AF off AADs at >1 year was 25/36 (69%).

**Conclusions:** LAPW isolation may be effective concomitant surgical ablation in select patients who are poor candidates for the Cox-Maze IV procedure.

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### No Abstract Available

Torregrossa, G., Baudo, M., Yakobitis, A.M. et al. (2024). Isolator Synergy EnCompass clamp: surgical notes. *Ann Cardiothorac Surg*, 13(2):184–186. doi:10.21037/acs-2024-afm-22

Gerdish, M.W. (2022). The most beneficial options for patients with arrhythmia and concomitant structural heart disease: a review. *AME Surgical Journal*, 3. doi:10.21037/asj-22-18

## Tampa 2 Maze: Novel Left Heart Lesion Set Using New Isolation Clamp & Cryoablation Lines, Validated With High-resolution Mapping

Makati, K.J., Sherman, A.J. & Cox, J.L. (2024). Tampa 2 Maze: Novel Left Heart Lesion Set Using New Isolation Clamp & Cryoablation Lines, Validated with High-resolution Mapping. Abstract presented at the International Society for Minimally Invasive Cardiothoracic Surgery meeting, May 31, 2024. <https://meetings.ismics.org/program/2024/C31.cgi>

**Background:** A newly designed ablation clamp was used with cryoablation via left atrial appendage (LAA) entry & exclusion to create a first in human left-sided Maze. Endocardial ultrasensitive mapping (EUM) was used to validate endpoints similar to traditional Cox-Maze IV but using an efficient approach to improve adoption.

**Methods:** In a retrospective study, patients presenting for open heart surgery with either valvular and/or coronary artery disease with known non-paroxysmal AF underwent concomitant AF ablation. A magnetized catheter was used to assist in placement of a bipolar RF clamp around pulmonary veins (PVs) & left atrial posterior wall (LAPW) to achieve en-bloc electrical isolation. A linear cryoprobe was then used to create endocardial connecting lesions from opened LAA back to en-bloc isolation and down to anterior mitral valve annulus. The ligament of Marshall (LOM) was interrupted, and LAA was ligated using a clip. Following ablation, EUM was performed to ensure transmural electrical isolation.

**Results:** A series of 12 patients had the novel left-sided Maze with endocardial mapping. The cohort included 58.3% male patients (mean 68.3 years), left atrial mean diameter 4.4 cm. 33% of patients had CABG, 41.7% had mitral valve repair/replacement, & 16.6% had AVR. Average CHA<sub>2</sub>DS<sub>2</sub>-VASc was 3.6. Mean ablation time was 15 minutes. Transmurality & electrical isolation were documented of LAPW & PVs using the lowest detectable EUM voltage sensitivity (0.01mV) in 100% of patients. Integrity of the anterior peri-mitral cryoprobe line was assessed using high-density electroanatomic wavefront mapping showing bidirectional block of the annulus. Standard epicardial/endocardial posterior mitral isthmus ablation was not required to achieve isolation. The final lesion set consisted of electrical isolation of PVs, LAPW, LAA, LOM, left superior PV to LAA and LAA to mitral annulus. No complications were observed.

**Conclusions:** This novel left-sided Maze lesion set represents several multidisciplinary achievements including application of a new RF ablation clamp & implementation of iterative lesion design using EUM to not only improve efficacy but also to create a comparable lesion set lowering the steep learning curve needed to effectively perform Cox-Maze IV ablation; the latter explaining poor procedural adoption.

Not all products/models may be available in your specific country. Contact your local AtriCure representative to check availability.

#### **Isolator Synergy Clamps**

**Argentina, Colombia Indications:** The ATRICURE Bipolar (Transpolar) System is intended to ablate soft tissue during General surgical procedures.

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

**Bahrain, Belarus, Chile, EU Region, Korea, Kuwait, New Zealand, Qatar, Russia, Saudi Arabia, Serbia, South Africa, Taiwan, UAE, UK Indications:** The ATRICURE Bipolar (Transpolar) System is intended to ablate cardiac tissue during surgery.

**Brazil Indications:** The AtriCure Isolator Synergy Ablation System is indicated for ablation and coagulation of soft tissue in general, ENT, thoracic, urological, gynecological surgical procedures and ablation of cardiac tissue during surgery including pulmonary vein isolation and atrial connecting lesions for the Maze procedure for the treatment of cardiac arrhythmias, including atrial fibrillation.

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

**China Indications:** AtriCure bipolar radiofrequency ablation forceps are used to ablate cardiac tissue during surgery.

**Hong Kong Indications:** The ATRICURE Bipolar (Transpolar) System is indicated for ablation of cardiac tissue during surgery including pulmonary vein isolation and atrial connecting lesions for the Maze procedure for the treatment of cardiac arrhythmias, including atrial fibrillation.

**Japan Indications:** This device is intended for use in ablation of cardiac tissue during surgery by use of high-frequency current.

**Singapore Indications:** The ATRICURE Bipolar (Transpolar) System is indicated for ablation of cardiac tissue during surgery including pulmonary vein isolation and atrial connecting lesions for the treatment of atrial fibrillation.

#### **Isolator Synergy EnCompass Clamps**

**Australia, Bahrain, EU Region, New Zealand, Russia, UK Indications:** The AtriCure Isolator Synergy Ablation System is indicated for ablation of cardiac tissue for the treatment of cardiac arrhythmias, including atrial fibrillation.

**Canada, Hong Kong, Indications:** The AtriCure Isolator Synergy EnCompass Clamp and Guide System is intended to ablate cardiac tissue during surgery.

**U.S. Indication:** The AtriCure Isolator Synergy EnCompass Clamp and Guide system is intended to ablate cardiac tissue during surgery.

The safety and effectiveness of this device for the treatment of atrial fibrillation has not been established.

Please review the Instructions for Use for a complete listing of contraindications, warnings, precautions, and potential adverse events prior to using these devices.