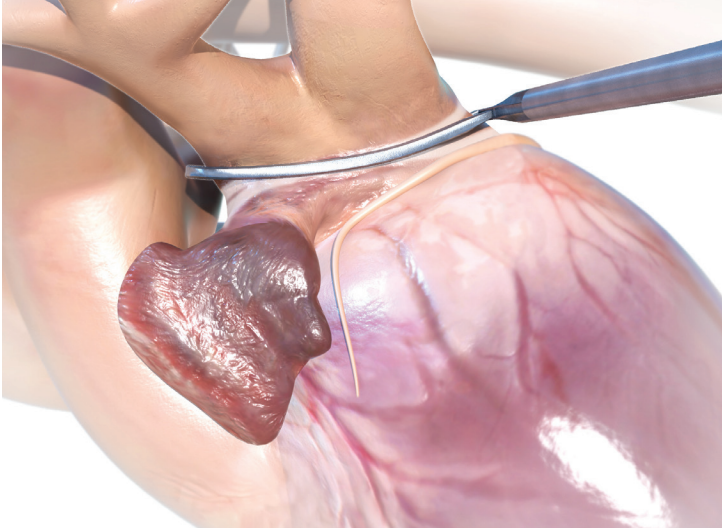
AtriCure

Maze IV Techniques

RF + Cryo Lesion Set

01 Ablation of the Right Pulmonary Veins (RPVs)

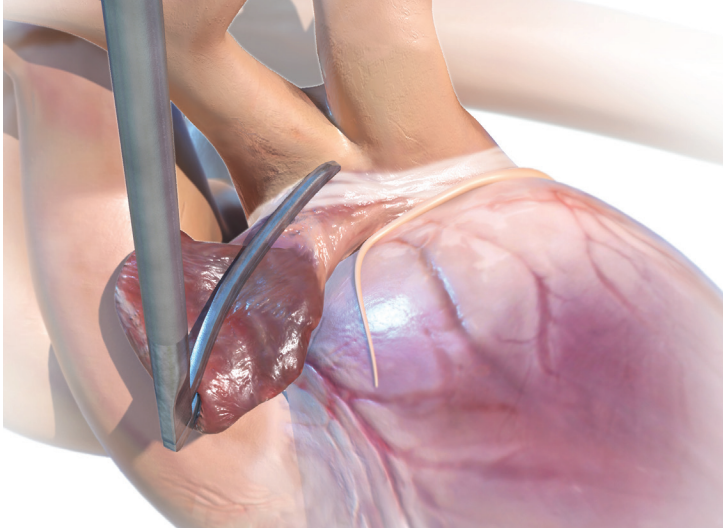
- Develop the plane of dissection between the right and left atrium.
- Dissect out the RPVs from any surrounding tissue using blunt dissection.
- The Isolator® Synergy™ Bipolar RF Clamp should be placed around the RPVs and positioned well up on the atrial muscle to avoid ablating the orifices of the RPVs themselves.



02 Ablation of the Left Pulmonary Veins (LPVs)

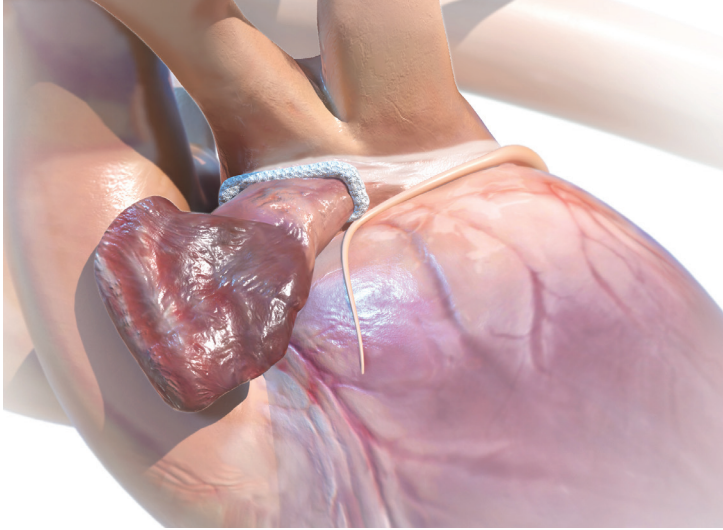
- Dissect out the LPVs from any surrounding tissue using blunt dissection.
- The Isolator Synergy Bipolar RF Clamp should be placed around the LPVs and positioned well up on the atrial muscle to avoid ablating the orifices of the LPVs themselves.

Note: It is easier to get around the LPVs by obliterating the Ligament of Marshall.



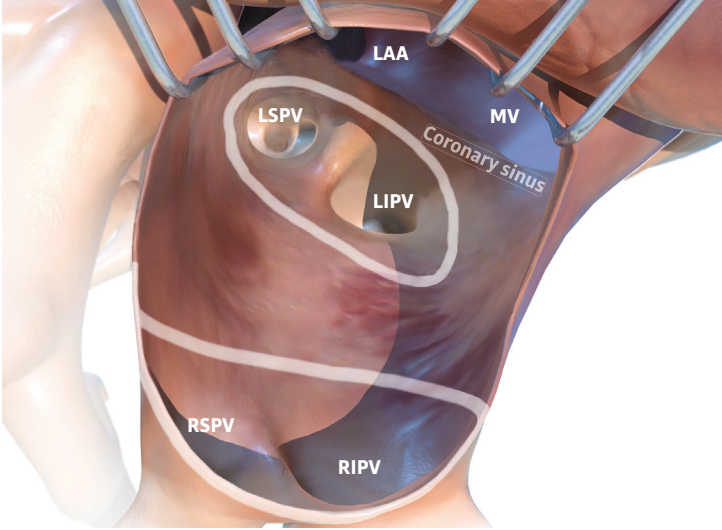
03 Left Atrial Appendage to Left Superior Vein Lesion

- Via a purse string suture, one jaw of the Isolator Synergy Bipolar RF Clamp is placed inside the left atrial appendage with the other jaw of the clamp on the outside.
- The clamp is positioned from the left atrial appendage tip to the left superior pulmonary vein, and a lesion is created.



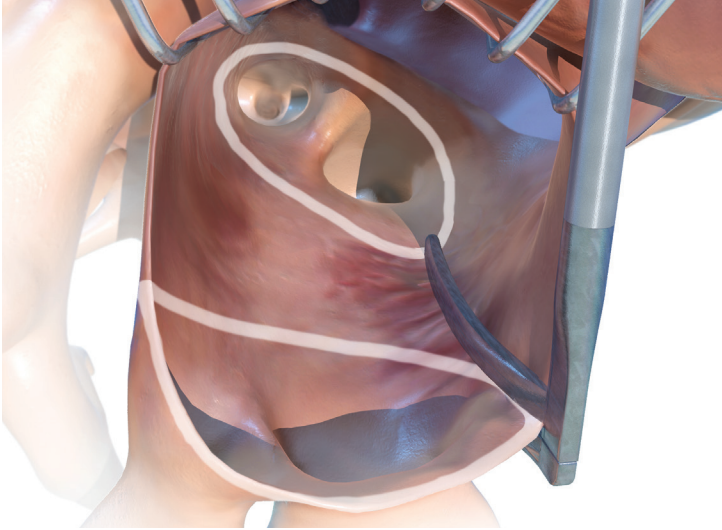
04 Left Atrial Appendage Management

· An AtriClip® device is placed on the left atrial appendage at its base.



05 Left Atriotomy

- A standard left atriotomy is performed in the inter-atrial groove (Waterston's groove) to expose the interior of the left atrium.
- The left atriotomy exposes the interior orifices of the left atrium including all four pulmonary vein orifices, the orifice to the left atrial appendage (LAA), and the mitral valve.
- The position of the coronary sinus is also shown, though it cannot actually be seen through the wall of the posterior-inferior left atrium.

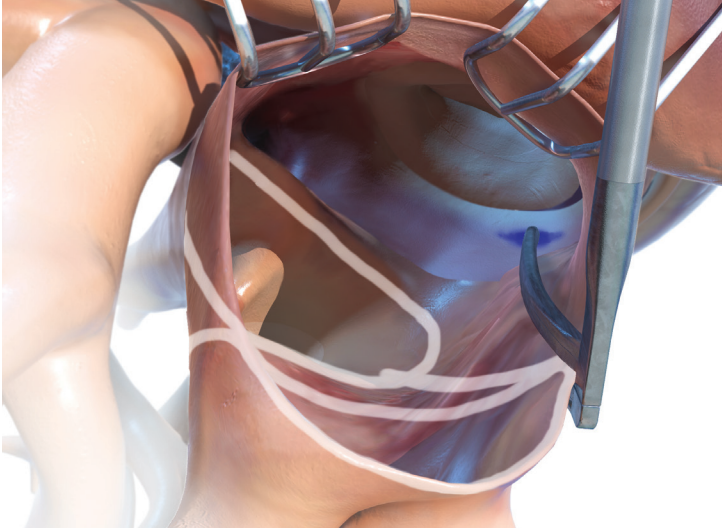


06 Construction of the Floor Lesion

- Create an inferior connecting lesion (floor lesion) by placing the Isolator Synergy Bipolar RF Clamp from the inferior edge of the atriotomy across the LPV lesion.
- Ensure the floor lesion forms a complete connection between the RPV lesion and LPV lesion.

07 Construction of the Roof Lesion

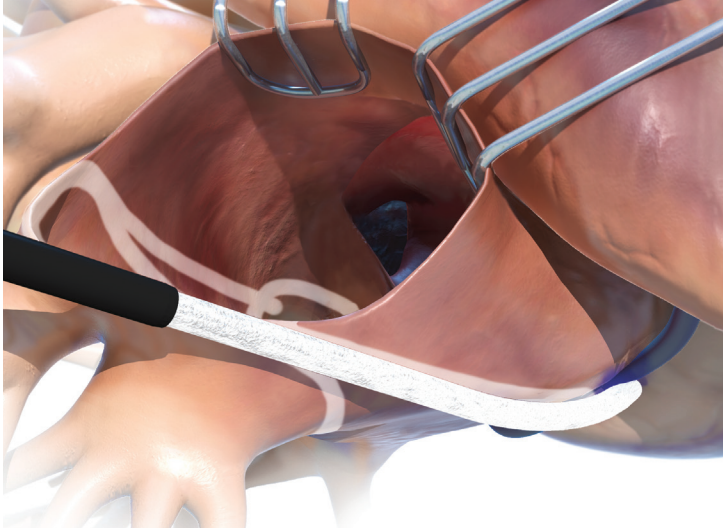
- Create a superior connecting lesion (roof lesion) by placing the Isolator Synergy Bipolar RF Clamp through the transverse sinus from the superior edge of the atriotomy across the LPV lesion.
- Ensure the roof lesion forms a complete connection between the RPV lesion and LPV lesion.



08 Mitral Valve Isthmus Lesion

· Create the mitral valve isthmus lesion by placing the Isolator Synergy Bipolar RF Clamp from the lower edge of the left atriotomy, directly across the endocardial methylene blue mark.

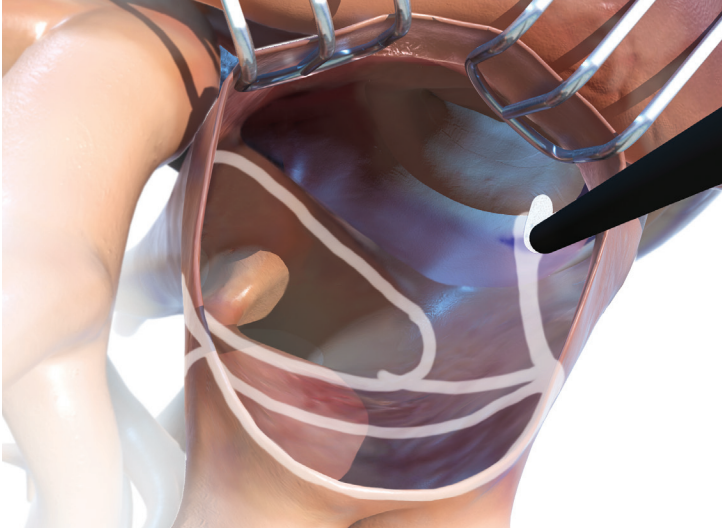
Note: Being able to see the methylene blue mark on the endocardium assures that the endocardial mitral valve isthmus line will be in precise alignment with the epicardial coronary sinus lesion.



09 Coronary Sinus Ablation

- Elevate the lower end of the atriotomy to visualize the coronary sinus on the epicardial surface of the AV groove fat pad posteriorly.
- Use a cryoprobe to create a transmural lesion across the coronary sinus.
- As the cryolesion envelops the collapsed coronary sinus, the surgeon will see an “ice ball” form on the endocardium of the left atrium.

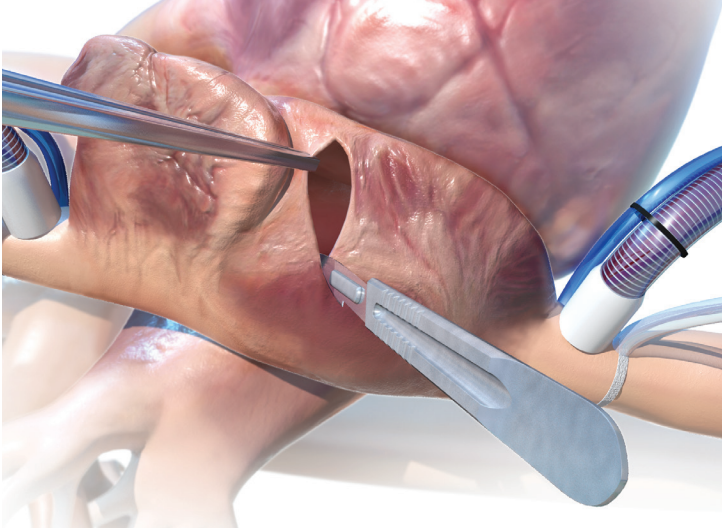
Note: The “ice ball” confirms the coronary sinus lesion is transmural.



10 Mitral Valve Anchor Lesion

· Use a cryoprobe to completely anchor the mitral line to the mitral valve annulus.

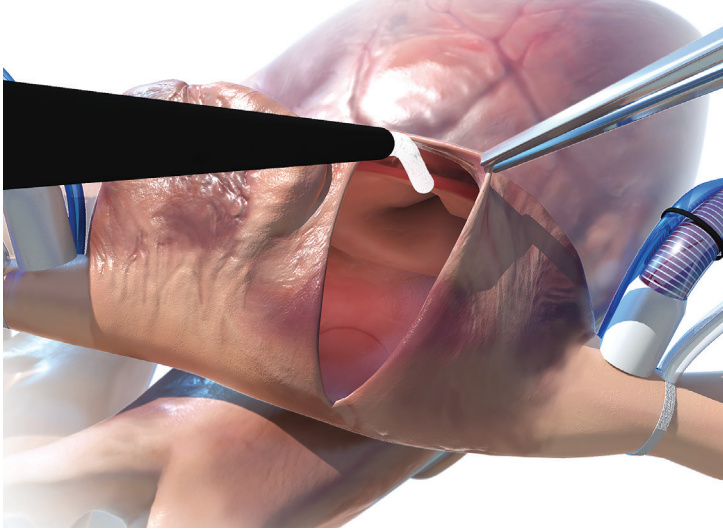
Note: Being able to see the methylene blue mark on the endocardium assures that the endocardial mitral valve isthmus line will be in precise alignment with the epicardial coronary sinus lesion.



11 Vertical Atriotomy

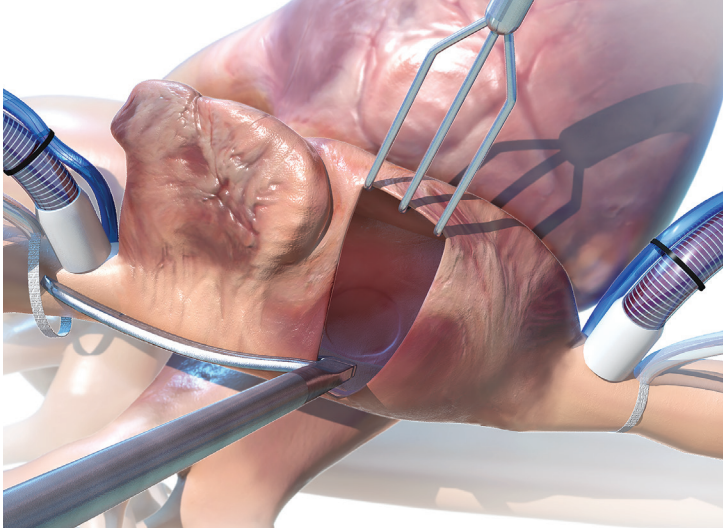
· Make a short vertical incision in the right atrial free-wall.

Note: Ensure a safe distance from the sinoatrial nodal complex.



12 Tricuspid Valve Anchor Lesion

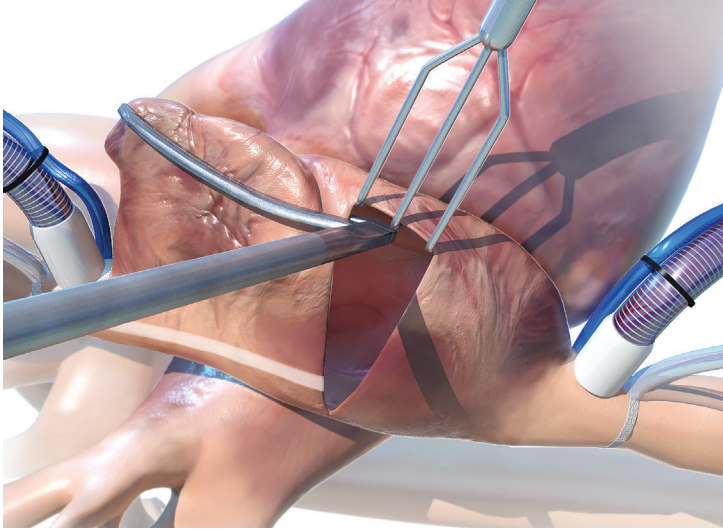
· Place an endocardial cryolesion from the distal end of the vertical atriotomy to the tricuspid valve annulus.



13 Superior Vena Cava Lesion

· Create a lesion from the proximal end of the right atriotomy into and beyond the orifice of the SVC.

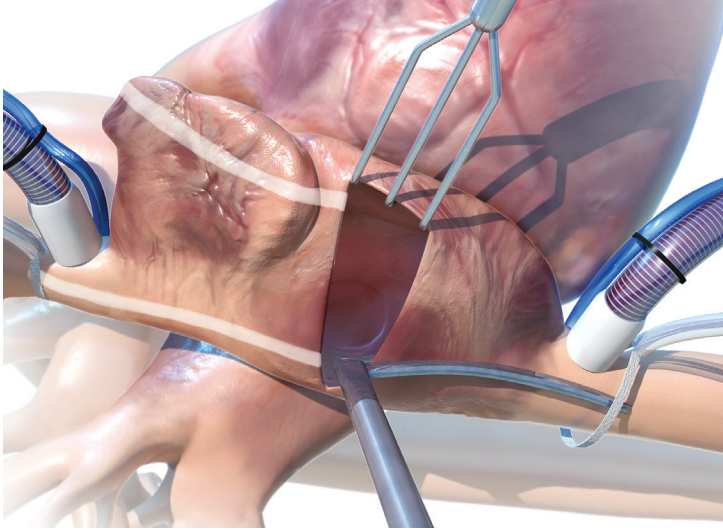
Note: Ensure a safe distance from the sinoatrial nodal complex.



14 Right Atrial Appendage Lesion

· Create a lesion extending from the vertical atriotomy to the tip of the right atrial appendage.

Note: Ensure a safe distance from the sinoatrial nodal complex.



15 Inferior Vena Cava Lesion

· Create a lesion from the proximal end of the right atriotomy into and beyond the orifice of the IVC.

Disclaimers - General

This material is intended to provide general information, including opinions and recommendations, contained herein for educational purposes only. Such information is not intended to be a substitute for professional medical advice, diagnosis or treatment. The material is not intended to direct clinical care in any specific circumstance. The judgement regarding a particular clinical procedure or treatment plan must be made by a qualified physician in light of the clinical data presented by the patient and the diagnostic and treatment options available.

Indications

US Only: AtriCure Synergy™ OLL2/OSL2 clamps are approved to ablate cardiac tissue for the treatment of persistent AF or LSP AF in patients who are undergoing open concomitant CABG and/or valve replacement or repair. AtriCure Synergy Access© and Synergy EMR2/EML2 clamps are cleared for cardiac tissue ablation. The AtriCure Isolator© multifunctional pen and Isolator linear pen are cleared to both diagnose cardiac arrhythmias and ablate cardiac tissue. ACC2 and cryoICE© BOX devices, manufactured by AtriCure, are cleared for the treatment of cardiac arrhythmias when used with cryoICE. The AtriClip© LAA Exclusion System is indicated for the occlusion of the left atrial appendage, under direct visualization, in conjunction with other open cardiac surgical procedures.

Europe only: AtriCure clamps are approved for the treatment of AF. The Isolator pens and Isolator Synergy Access are cleared to ablate cardiac tissue. In addition, the Isolator linear pen is cleared to temporarily pace, sense, record, and stimulate during evaluation of cardiac arrhythmias. The cryoICE BOX devices are cleared for the treatment of cardiac arrhythmias. The AtriClip LAA Exclusion System is used for occlusion of the heart's left atrial appendage.

Non-European International: Registration and indications of these devices vary by geography.

See www.atricure.com for more information.

Risk and Safety Concerns

Isolator Transpolar pen / Isolator linear pen

Possible complications related to the creation of spot or linear lesions in cardiac and soft tissues are: Tissue perforation; Postoperative embolic complications; Extension of extracorporeal bypass; Perioperative heart rhythm disturbance (atrial/or ventricular); Pericardial effusion or tamponade; Injury to the great vessels; Valve leaflet damage; Conduction disturbances (SA/AV node); Acute ischemic myocardial event.

AtriClip LAA Exclusion System

Possible complications related to surgical LAA exclusion, apart from those that may occur as a result of surgical/mechanical manipulation of the target tissues, include, but are not limited to: tissue trauma, dehiscence, tissue tearing, displacement, lack of desired homeostasis.

AtriCure Synergy Ablation System (OLL2, OSL2) (Transpolar) System

Possible complications related to the creation of the linear lesions in cardiac tissue using a clamp-type device may include, but are not limited to: Tissue cutting; Perioperative heart rhythm disturbance (atrial and/or ventricular); Postoperative embolic complications; Pericardial effusion or tamponade; Injury to the great vessels; Valve leaflet damage; Conduction disturbances (SA/AV node); Acute ischemic myocardial event; Injury to unintended surrounding tissue structures, including tears and punctures; Bleeding requiring intervention to repair; Extension of cardiopulmonary bypass.

AtriCure Cryo Module System (ACM)

The ACM System requires use of the cryo-ablation probe. Use of this probe with another manufacturer's system may damage the device and result in patient injury. Do not use the probe to freeze tissue on the beating heart. Use of the probe to freeze tissue on the beating heart may result in severe injury to the patient. Cryo-ablation involving coronary vessels has been associated with subsequent clinically significant arterial stenosis. It is unknown whether cryo-ablation with the probe will have such an effect, but as in all such procedures, care should be taken to minimize unnecessary contact with coronary vessels during cryo-ablation. Do not pull on the probe or console while the malleable tip is frozen to tissue as this could lead to inadvertent tissue damage. Do not use excessive force when using the probe in order to avoid tissue damage. Cardiac surgical procedures may mechanically induce arrhythmias.

AtriCure

AtriCure, Inc.
7555 Innovation Way
Mason, OH 45044
Customer Service: 1-866-349-2342
customerservice@atricure.com
www.atricure.com

Atricure Europe B.V.
De Entrée 260
1101 EE Amsterdam Z.O.
Netherlands
Tel: +31 (0) 20-7005560
Fax: +31 (0) 20-7005561
customerserviceeurope@atricure.com

MKT-1731E-G