Left Atrial Appendage (LAA) Exclusion That Results in Electrical Isolation

AtriClip[®] LAA Exclusion Systems



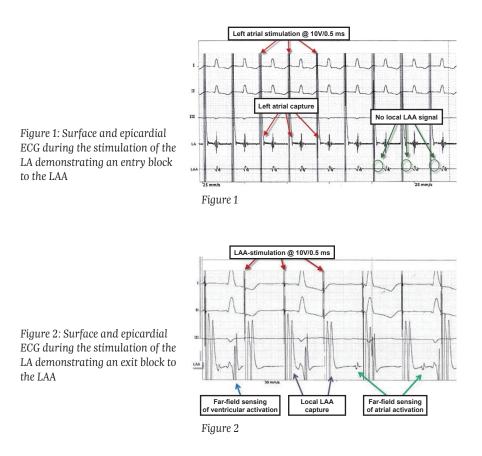


LAA Exclusion That Results in Electrical Isolation

Within minutes of the epicardial application of the AtriClip device, the LAA becomes electrically isolated from the rest of the left atrium and ischemic injury results in the cessation of electrical activity in the LAA.¹² Postoperatively, the excluded and necrosed LAA is resorbed and is no longer a factor in the propagation of electrical activity.³⁻¹⁰

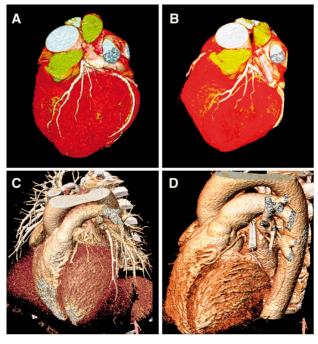
AtriClip Device LAA Electrical Isolation Results

Starck et al conducted entrance and exit block testing on patients treated with the AtriClip device that demonstrated electrical isolation of the LAA.²



Ischemia by application of the AtriClip device causes necrosis and ultimate resorption of the LAA.³⁻⁵ Studies using computed tomography (CT) imaging have demonstrated the AtriClip Device is stable and effectively excludes the LAA long-term.⁶⁻¹⁰

Figure 3: Computed tomography (CT) before and at 3-year follow-up after clip implantation. Exemplary CT before clip placement (A and C) and after clip implantation depicting the clip in stable position and fully excluding the left atrial appendage at a 3-year follow-up (B and D).⁸



Mechanisms of LAA exclusion and subsequent electrical isolation:

The *epicardial* application of the AtriClip device excludes vascularization to the LAA. Ischemic injury to the LAA ceases all electrical activity within minutes.²

The AtriClip devices continue to exclude throughout tissue changes that occur as the tissue becomes necrosed. This **continuous closing force** maintains LAA exclusion.

Parallel closing bars along the long axis of the LAA ostia appose the tissue without folds that can leave residual flow.

Figure 4: AtriClip V-Clip device applied to the base of a LAA results in electrical isolation.



Warning: The safety and effectiveness of this device in atrial rhythm control management, either alone or in combination with ablative treatment, has not been established.

Note: The safety and effectiveness of this device for stroke prevention, either alone or in combination with cardiac surgery, has not been established.

References

- ¹ Benussi, S. et al. (2011). Thoracoscopic Appendage Exclusion With an AtriClip Device As a Solo Treatment for Focal Atrial Tachycardia. Circulation, 123:1575–8.
- ² Starck, C.T. et al. (2012). Epicardial left atrial appendage clip occlusion also provides the electrical isolation of the left atrial appendage. Interactive Cardiovascular and Thoracic Surgery, 15(3):416–9.
- ³ Kamohara, K. et al. (2005). A novel device for left atrial appendage exclusion. J Thorac Cardiovasc Surg, 130(6):1639–44.
- ⁴ Kamohara, K. et al. (2006). Evaluation of a novel device for left atrial appendage exclusion: the second-generation atrial exclusion device. J Thorac Cardiovasc Surg, 132(2):340–6.
- ⁵ Fumoto H. et al. (2008). A novel device for left atrial appendage exclusion: the third-generation atrial exclusion device. J Thorac Cardiovasc Surg,136(4):1019–27.
- ⁶Ailawadi, G. et al. (2011). Exclusion of the left atrial appendage with a novel device: early results of a multicenter trial. J Thorac Cardiovasc Surg, 142(5):1002–9.
- ⁷ Caliskan, E. et al. (2018). Epicardial left atrial appendage AtriClip occlusion reduces the incidence of stroke in patients with atrial fibrillation undergoing cardiac surgery. Europace, 20(7):e105–14.
- ⁸ Emmert, M.Y. et al. (2014). Safe, effective and durable epicardial left atrial appendage clip occlusion in patients with atrial fibrillation undergoing cardiac surgery: first long-term results from a prospective device trial.Eur J Cardiothorac Surg, 45(1):126–31.
- ⁹ Gerdisch, M. et al. AtriClip PRO•V Left Atrial Appendage Occlusion Study. AtriCure post-market field evaluation of the AtriClip PRO•V device. PM-US-0071A-1020-G.
- ¹⁰ Ellis, C.R. et al. (2017). Angiographic Efficacy of the AtriClip Left Atrial Appendage Exclusion Device Placed by Minimally Invasive Thoracoscopic Approach. JACC Clinical Electrophysiology, 3(12):1356–65.

U.S. Indication: The AtriClip LAA Exclusion System is indicated for the exclusion of the heart's left atrial appendage, performed under direct visualization and in conjunction with other cardiac surgical procedures.

Direct visualization in this context, requires that the surgeon is able to see the heart directly, with or without assistance from a camera, endoscope, etc., or other appropriate viewing technologies.

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

Rx Only.

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