AtriClip[®] LAA Exclusion Systems

97% Successful Left Atrial Appendage (LAA) Closure Rate*

No Device Migrations^{*}

No Device Related Complications*

With More Than 5 Years Follow-Up

The body of clinical evidence for the AtriCure AtriClip LAA exclusion systems identifies an average LAA closure success rate of 97% (93-100%) including more than 5 years of follow-up (peri-procedure to 8 years) and including 991 cardiac surgery patients. In these peer-reviewed and pre-market clinical science reports, success was defined as no residual blood flow from the LAA into the left atrium and less than 1 cm residual LAA neck (0 to less than 10 mm). AtriClip device implants were stable with no reports of device migrations and no reports of device related complications.

Reference	Results	Reference	Results
Ailawadi (2011) ¹	98.4% successful LAA closure3 month follow-up	Ad (2015) ⁷	 100% successful LAA closure 1 year follow-up
Caliskan (2017)²	 100% successful close rate More than 5 years follow-up	Gerdisch (2017) ⁸	98.7% successful LAA closure30 day follow-up
van Laar (2018) ³	95% successful LAA closure rate6 month follow-up	Mokracek (2015) ⁹	93% successful LAA closure11 month follow-up
Ellis (2017) ⁴	93.9% successful LAA closure rate183 patient years follow-up	Page (2017) ¹⁰	 100% successful LAA closure More than 1 year follow-up
Kurfirst (2017) ⁵	98% successful LAA closure rate18 month follow-up	Beaver (2016) ¹¹	 100% successful closure 1 year follow-up
Emmert (2013) ⁶	 100% successful LAA closer 3.5 year follow-up		

AtriClip Devices exclude the LAA resulting in electrical isolation.

*Weighted average based on the number of patients.

* Based on the results of the 11 referenced articles. These articles reported on follow-up times ranging from 6 months to 5 years. These may not be predictive of future results.

AtriCure

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References:

¹Ailawadi, 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.

²Caliskan, E. et al. (2017). Epicardial left atrial appendage AtriClip occlusion reduces the incidence of stroke in patients with atrial fibrillation undergoing cardiac surgery. Europace, 20. 10.1093/europace/eux211.

³van Laar, C. et al. (2018). Thoracoscopic Left Atrial Appendage Clipping: A Multicenter Cohort Analysis. JACC Clin Electrophysiol, 4(7):893-901.

⁴Ellis, C.R. et al. (2017). Angiographic Efficacy of the AtriClip Left Atrial Appendage Exclusion Device Placed by Minimally Invasive Thoracoscopic Approach. JACC Clin Electrophysiol, 3(12):1356-1365.

⁵Kurfirst, V. et al. (2017). Epicardial clip occlusion of the left atrial appendage during cardiac surgery provides optimal surgical results and long-term stability. Interact Cardiovasc Thorac Surg, 25(1):37-40.

⁶Emmert, 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 Cardiothoracic Surg, 45(1):126-31.

⁷Ad, N. et al. (2015). New Approach to Exclude the Left Atrial Appendage During Minimally Invasive Cryothermic Surgical Ablation. Innovations, 10(5):323-7.

⁸Gerdisch, M. et al. AtriClip PRO•V™ Left Atrial Appendage Occlusion Study, AtriCure Inc., Post Market Field Evaluation of the PRO•V Device, PM-US-0071A-1020-G.

⁹Mokracek, A. et al. (2015). Thoracoscopic Occlusion of the Left Atrial Appendage. Innovations, 10(3):179-82.

¹⁰Page, S. et al. (2019). Left Atrial Appendage Exclusion Using the AtriClip Device: A Case Series. Heart Lung Circ., 28(3):430-35.

¹¹Beaver, T.M. et al. (2016). Thoracoscopic Ablation With Appendage Ligation Versus Medical Therapy for Stroke Prevention: A Proof-of-Concept Randomized Trial. Innovations, 11(2):99-105.

Results from case studies are not predictive of results in other cases. Results in other cases may vary.

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.

U.S. Indications: 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 contraindications, warnings, precautions and potential adverse events prior to using these devices.

Rx Only.

AtriCure