Angio-Seal™ Evolution™

Vascular Closure Device

ST. JUDE MEDICAL™

MORE CONTROL. LESS RISK.

Controlled Deployment for Confident Closure in More Patients.

The Angio-Seal™ Evolution™ device features a standardized deployment system that is designed to assist in overcoming many procedural variables and deliver a virtually instantaneous seal of the arteriotomy. It may also support increased confidence in the number of cases where use of a mechanical seal is possible.

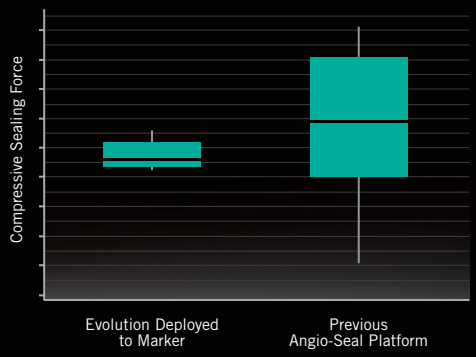
The Most Advanced Angio-Seal Device Ever

Angio-Seal Evolution, the eighth generation of the proven Angio-Seal vascular closure device platform, features improvements designed for added reliability and ease of use.

Standardized Deployment: Automated deployment provides more control throughout the deployment process, which may reduce procedural variables and accommodate more cases.

Instant Compaction: Controlled deployment instantly initiates consistent collagen compaction, providing control of the arteriotomy and enabling an optimal seal.

Compressive Sealing Force Comparison*



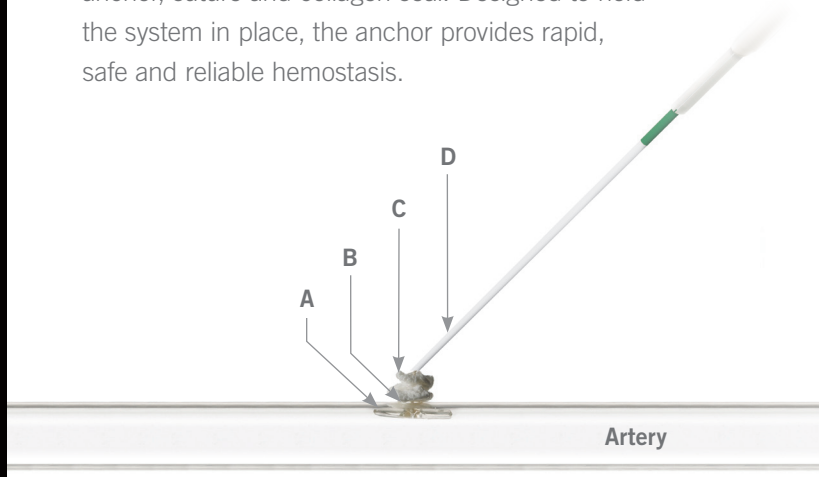
* Compressive sealing force is the predetermined force between the collagen and the anchor at the arteriotomy after completion of the Angio-Seal deployment.

All measured forces are less than 1 lb.

Internal bench test shows consistency in the compressive sealing force with the Angio-Seal Evolution device in comparison to the variability in previous Angio-Seal platforms.

The Active Closure System

Angio-Seal Evolution features the fully bioabsorbable Active Closure System with an innovative intra-arterial anchor, suture and collagen seal. Designed to hold the system in place, the anchor provides rapid, safe and reliable hemostasis.



8 mm vessel, actual size

A. Bioabsorbable Anchor: Low profile shape is designed to fit closely against the arterial wall, leaving blood flow undisturbed while maintaining vessel diameter.

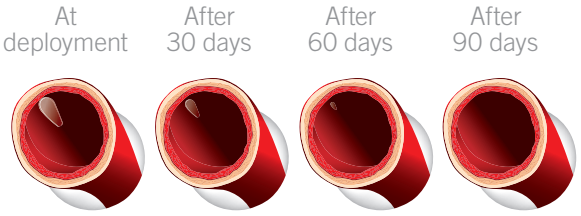
B. Bioabsorbable Collagen: Designed to conform to the arteriotomy for confident closure.

C. Bioabsorbable Suture: Tethers the anchor and collagen together, providing a secure seal.

D. Compaction Tube: Automatically moves forward to create instant collagen compaction upon deployment.

Intra-arterial Conformance: The bioabsorbable anchor fits closely against the inner vessel wall while the suture allows the collagen to compact and create broad coverage over the arteriotomy.

Fully Bioabsorbable: The suture, collagen and anchor components completely bioabsorb in 60–90 days.



BIOABSORPTION RATE OF ANCHOR

Compared to Manual Compression

Rapid, Effective Hemostasis: Immediate compaction and broad coverage of the collagen seal over the arteriotomy provides virtually instantaneous hemostasis.[1]

Improved Patient Satisfaction: Patients report significantly less discomfort during and after closures with the Angio-Seal device.[2]

Clinical Efficiency and Productivity: Early patient ambulation and discharge can dramatically enhance the overall cost-effectiveness and productivity of the cath lab.[3]

Low Complication Rates: Studies have shown that the Angio-Seal device may reduce the risk of access-site complications in both diagnostic and interventional patients.[4,5]

Compared to Other Mechanical Closure Devices

Early Ambulation: Anchored placement of the collagen seal provides reliable hemostasis and promotes earlier patient ambulation.[6]

Easy Deployment: Single-handed, standardized deployment reduces risk of procedural variables.

Safe Restick: Immediate arterial restick can be performed safely without increased vascular complications.[7]

Proven Efficacy: More than 325 studies have proven that the Angio-Seal device is safe and effective in a broad range of patients and procedures.[8,9]

The Angio-Seal Evolution device features design improvements that may increase confidence in the number of cases where use of a mechanical seal is possible. The innovative standardized deployment system is designed to assist in overcoming procedural variables and deliver a virtually instantaneous seal of the arteriotomy, making Evolution the most advanced Angio-Seal device ever.

As the market leader for more than a decade, the Angio-Seal device has been extensively studied, providing physicians with confidence in its clinical performance.

Instant Hemostasis

[1] Angio-Seal Evolution Instructions for Use.

Improved Patient Satisfaction

[2] Duffin DC, Muhlestein JB, Allisson SB, et al. Femoral arterial puncture management after percutaneous coronary procedures: A comparison of clinical outcomes and patient satisfaction between manual compression and two different vascular closure devices. *J Invasive Cardiol*. 2001;13(5):354-62.

Improved Clinical Efficacy and Productivity

[3] Resnic FS, Arora N, Matheny M, et al. A cost-minimization analysis of the Angio-Seal vascular closure device following percutaneous coronary intervention. *Am J Cardiol*. 2007;99(6):766-70.

Low Complication Rates

[4] Kussmaul WG, Buchbinder M, Whitlow PL, et al. Rapid arterial hemostasis and decreased access site complications after cardiac catheterization and angioplasty: Results of a randomized trial of a novel hemostatic device. *J Am Coll Cardiol*. 1995;25(7):

[5] Arora N, Matheny ME, Sepke C, et al. A propensity analysis of the risk of vascular complications after cardiac catheterization procedures with the use of vascular closure devices. *Am Heart J*. 2007;153(4):606-11.

Earlier Ambulation

[6] Angio-Seal Evolution Instructions for Use (Results of a clinical study demonstrate that patients who have undergone diagnostic angiography and have received a 6 F Angio-Seal device can safely and effectively ambulate in less than 20 minutes).

Safer Restick

[7] Applegate RJ, Rankin KM, Little WC, et al. Restick following initial Angio-Seal use. *Catheter Cardiovasc Interv*. 2003;58(2):181-4.

Proven Efficacy

[8] Martin JL, Pratsos A, Magargee E, et al. A randomized trial comparing compression, Perclose Proglide™ and Angio-Seal VIP™ for arterial closure following percutaneous coronary intervention: The CAP trial. *Catheter Cardiovasc Interv*. 2008;71(1):1-5.

[9] Nikolsky E, Mehran R, Halkin A, et al. Vascular complications associated with arteriotomy closure devices in patients undergoing percutaneous coronary procedures: A meta-analysis. *J Am Coll Cardiol*. 2004;44(6):1200-9.

St. Jude Medical is focused on reducing risk by continuously finding ways to put more control into the hands of those who save and enhance lives.

Ordering Information

Reorder Number	French Size
C610134	6 F
C610135	8 F

ATRIAL FIBRILLATION CARDIAC RHYTHM MANAGEMENT CARDIOVASCULAR NEUROMODULATION

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Rx Only

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

Indications: St. Jude Medical Angio-Seal Vascular Closure Device product family, including the STS Plus, VIP and Evolution platforms, is indicated for use in closing and reducing time to hemostasis at the femoral arterial puncture site in patients who have undergone diagnostic angiography procedures or interventional procedures using an 8 French or smaller procedural sheath for the 8 F Angio-Seal device and a 6 French or smaller procedural sheath for the 6 F Angio-Seal device. The Angio-Seal STS Plus, VIP and Evolution platform devices are also indicated for use to allow patients who have undergone diagnostic angiography to safely ambulate as soon as possible after sheath removal and device placement, as well as to allow patients who have undergone an interventional procedure to safely ambulate after sheath removal and device placement. Possible adverse events for vascular closure devices include, but are not limited to: bleeding or hematoma, AV fistula or pseudoaneurysm, infection, allergic reaction, foreign body reaction, inflammation or edema.

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