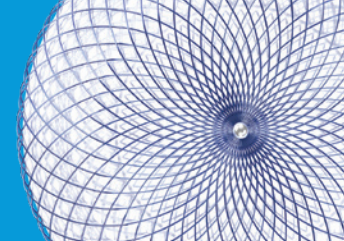
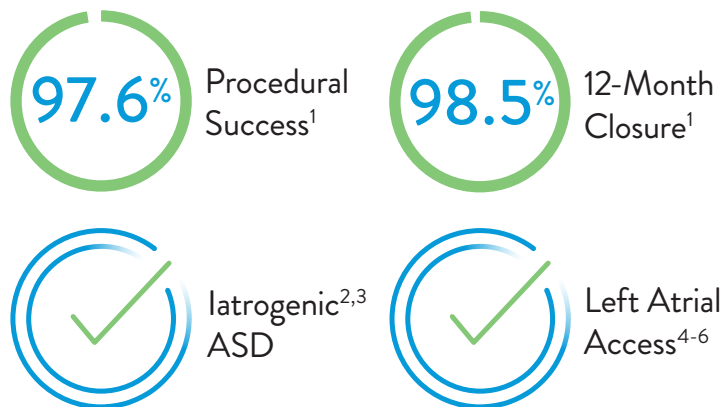


Amplatzer™ Septal Occluder



Ease of Use and High Procedural Success



Strong Safety Profile (Minimal Adverse Events)

0.0%^{1,9}

Wire Frame Fractures

0.2%⁹

Device Embolization

0.5%¹

Clinically Significant New Arrhythmias

0.012%⁷

Erosion

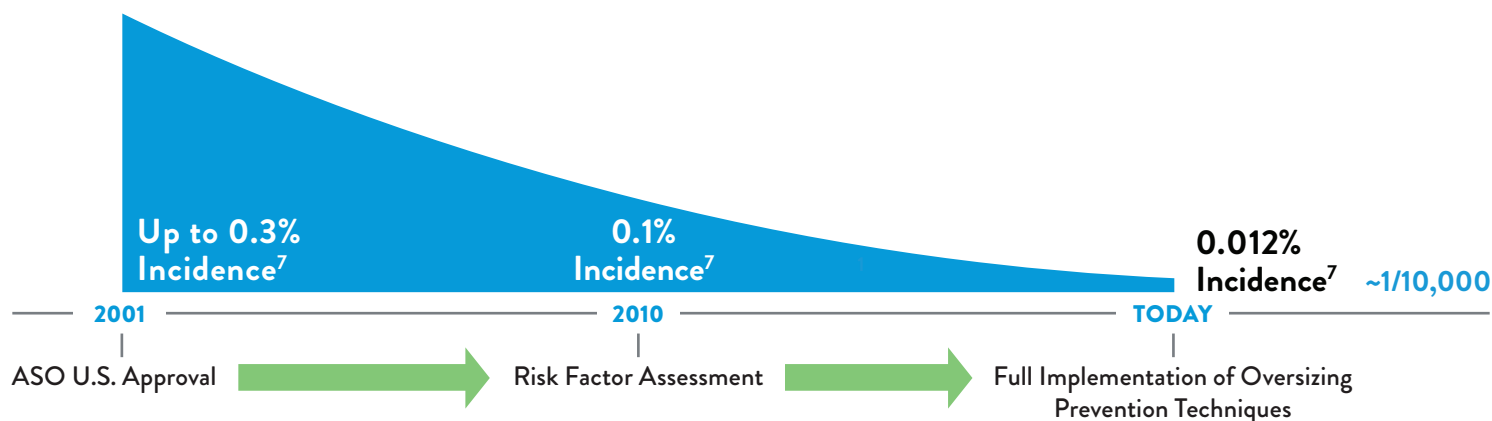
0.1%⁹

Thrombus

6-12F
Trevisio™

Delivery System

Minimal Erosion Risk with Amplatzer™ Septal Occluder (ASO)



Abbott Structural Heart's Leading Product and Industry Expertise



Dedicated Clinical Support Team



World Class Educational Offerings



Largest Structural Heart Portfolio



500,000+ ASO Devices Sold⁸

Contact Your Local Abbott Sales Representative for More Information

See Important Safety Information referenced within.



IMPORTANT SAFETY INFORMATION

Rx Only

AMPLATZER™ SEPTAL OCCLUDER AND DELIVERY SYSTEM

Indication for Use

The Amplatzer™ Septal Occluder is a percutaneous, transcatheter, atrial septal defect closure device intended for the occlusion of atrial septal defects (ASD) in secundum position or patients who have undergone a fenestrated Fontan procedure and who now require closure of the fenestration. Patients indicated for ASD closure have echocardiographic evidence of ostium secundum atrial septal defect and clinical evidence of right ventricular volume overload (such as, 1.5:1 degree of left-to-right shunt or RV enlargement).

Contraindications

The Amplatzer™ Septal Occluder is contraindicated for the following: Any patient known to have extensive congenital cardiac anomaly which can only be adequately repaired by way of cardiac surgery; Any patient known to have sepsis within 1 month prior to implantation, or any systemic infection that cannot be successfully treated prior to device placement; Any patient known to have a bleeding disorder, untreated ulcer, or any other contraindications to aspirin therapy, unless another antiplatelet agent can be administered for 6 months; Any patient known to have a demonstrated intracardiac thrombi on echocardiography (especially left atrial or left atrial appendage thrombi); Any patient whose size (such as, too small for transesophageal echocardiography probe, catheter size) or condition (active infection, etc.) would cause the patient to be a poor candidate for cardiac catheterization; Any patient where the margins of the defect are less than 5 mm to the coronary sinus, inferior vena cava rim, AV valves, or right upper lobe pulmonary vein.

Potential Adverse Events

Potential adverse events may occur during or after a procedure placing this device may include, but are not limited to: Air embolus; Allergic dye reaction; Anesthesia reactions; Apnea; Arrhythmia; Cardiac tamponade; Death; Embolization; Fever Hypertension/hypotension; Infection including endocarditis; Need for surgery; Pericardial effusion; Perforation of vessel or myocardium; Pseudoaneurysm including blood loss requiring transfusion; Stroke; Tissue erosion; Thrombus formation on discs; Valvular regurgitation.

1. Du, Hijazi, Kleinman, Silverman, Larntz. Comparison between transcatheter and surgical closure of secundum atrial septal defect in children and adults. *Journal of the American College of Cardiology*. 2002;39(11):1836-1844.
2. Shetty M, Lampert M, Levisay J, et al. Iatrogenic Atrial Septal Defect Closure Following Mitral Transcatheter Edge-to-Edge Repair When Do You Close? *JACC: CASE REPORTS*, VOL. 3, NO. 3, 2021 MARCH 2021:357 -60.
3. Beri, N. (2019). Iatrogenic atrial septal defect closure after transseptal mitral valve interventions: Indications and outcomes [Abstract]. *Catheterization & Cardiovascular Interventions*, 94(6), 829-836.
4. Santangelo P, Di Biase L, Burkhardt JD, et al. Transseptal access and atrial fibrillation ablation guided by intracardiac echocardiography in patients with atrial septal closure devices. *Heart rhythm*. 2011;8(11):1669-1675.
5. Villablanca PA, Lee J, Wang DD, et al. Transseptal Puncture Through an Amplatzer Atrial Septal Occluder for Edge-to-Edge Repair With MitraClip NTr System. *Cardiovascular revascularization medicine : including molecular interventions*. 2020;21(11S):63-64.
6. Gloekler S, Shakir S, Meier B. Transseptal Puncture Through Amplatzer Atrial Septal Occluder for Left Atrial Appendage Closure. *JACC Cardiovascular Interventions*. 2017;10(21):2222-2223.
7. SCAI presentation by Dr. Brian Boe, Amplatzer™ Septal Occluder Safety and Performance, Understanding the Data, May 2, 2024.
8. Data on File at Abbott.
9. Daniel R. Turner, MD; Carl Y. Owada, MD; Charlie J. Sang, Jr, MD; Muhammad Khan, MD; D. Scott Lim, MD. **Closure of Secundum Atrial Septal Defects With the AMPLATZER Septal Occluder A Prospective, Multicenter, Post-Approval Study**

CAUTION: Product(s) intended for use by or under the direction of a physician. Prior to use, reference the Instructions for Use inside the product carton (when available) or at www.eifu.abbott for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

Photo on file at Abbott.

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