Leading the Standard of Care[1,2]

The AMPLATZER Septal Occluder (ASO) is the most studied pediatric intra-cardiac, percutaneous device in the marketplace today.

AMPLATZER SEPTAL OCCLUDER

What does it take to lead the standard of care in atrial septal defect closure?

- Over 1,480 ASO recipients followed in the included studies[a]
- Over 1,500 patient years experience in the included studies[b]
- 15 years of clinical data[c]
- High procedural success rates: 96%-98.4%[d]
- Low major adverse events: 1.6% and lower[e]

THE AMPLATZER PRODUCT FAMILY

What does it take to be a leader in minimally invasive structural heart and vascular treatments?

- 26 AMPLATZER products[f]
- >100 countries[f]
- 1650 publications[g]

a. Sum of patients studied in Pivotal Trial, ASO Post Market Approval Interim Results and MAGIC study.

b. Pivotal Trial and ASO Post Market Approval Results.

c. Masura J, Gavora P, Formanek A, et al. Transcatheter Closure of Secundum Atrial Septal Defects Using the New Self-Centers Amplatzer Septal Occluder: Initial Human Experience. *Cathet Cardiovasc Diagn.* 1997;42(4):388-93.

d. As reported by Pivotal Trial, ASO Post Market Approval Interim Results and MAGIC study.

e. Pivotal trial, other included study results show lower rates.

f. Since 1998, 26 AMPLATZER devices, delivery systems and accessories have received CE mark and/or FDA approval and are marketed in over 100 countries around the world.

g. More than 1,650 peer-reviewed articles have been published supporting the benefits of AMPLATZER devices.

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.

References

1. AMPLATZER Septal Occluder Instructions for Use.
2. Kashour TS, Latroche B, Elhoury ME, et al. Successful Percutaneous Closure of a Secundum Atrial Septal Defect through Femoral Approach in a Patient with Interrupted Inferior Vena Cava. *Congenital Heart Disease.* 2010;5(6):620-3.

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MORE CONTROL. LESS RISK.

MM00854EN

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.

Product referenced is approved for CE Mark. Device depicted may not be available in all countries. Check with your St. Jude Medical representative for product availability in your country.

MM00854 (04.2) EN Global 02/12 IPN 1876-12

AMPLATZER™ Septal Occluder

Structural Heart Therapy

Over 15 years of Demonstrated Clinical Experience

We'll show you our data. Ask to see theirs.

ST. JUDE MEDICAL
MORE CONTROL. LESS RISK.

Pivotal Trial

1998-2001
Safety and Efficacy Data

442	Patients included in the device closure arm of the study
97.6%	Procedural success rate[a]
97.2%	Closure rate at 6 months[b]
6.1%	Minor adverse events at 12 months[c]
1.6%	Major adverse events at 12 months[d]
911.5	Total patient years of device experience[e]

a. Successful closure of the defect as measured immediately following the procedure (less than or equal to a 2 mm residual shunt).
b. Defined as a shunt less than or equal to 2 mm without the need for surgical repair.
c. Device embolization with percutaneous retrieval, cardiac arrhythmia with treatment, phrenic nerve injury, hematoma, other vascular access site adverse events, retroperitoneal hematoma, other procedural adverse events, pericardial effusion requiring medical management, evidence of device associated thrombus formation without embolization (with or without treatment), marker band embolization without known sequlae.
d. Events that are life threatening, prolong hospitalization or have long-term consequences or need for ongoing therapy.
e. As reported in the ASO Pivotal Trial.

Post Market Approval

Interim Results[a]

Study initiated March 2008
Evaluating Long-term Safety and Efficacy

50	Participating US centers
564	Patients reported upon the interim study results analysis (July 2011)
1,000	Patients to be enrolled in the study
98.4%	Technical success rate[b]
96.8%	Closure rate at one month[c]
1.8%	Non serious adverse events that were device or procedure related
0.4%	Serious adverse events that were device or delivery system related
>93%	Patient follow-up rate
>625	Patient years of device experience

a. AMPLATZER Septal Occluder Interim Post Market Approval Study Results as presented on July 23, 2011 by Dr. Thomas Forbes at PICS-AICS.
b. Successful deployment of the device percutaneously.
c. Defined as a shunt less than or equal to 2 mm as assessed by Echo without the need for surgical repair.

MAGIC[A]

2004-2007
Determine the Initial Safety and Results of Unrestricted Multi-institution Routine Community Use of the AMPLATZER Septal Occluder (ASO) for Atrial Septal Defect (ASD) Closure

13	Participating US pediatric centers
478	Patients included in the study
96%	Procedural success rate[b]
99.6%	Closure rate at 24 hours[c]
4.8%	Minor adverse events at 24 hours[d]
1.1%	Major adverse events at 24 hours[e]

a. Everett AD, Jennings J, Sibinga E, et al. Community use of the Amplatzer atrial septal defect occluder: results of the multicenter MAGIC atrial septal defect study. *Pediatr Cardiol.* 2009;30(3):240-7.
b. Successful AMPLATZER Septal Occluder implantation.
c. Defined as no to a small residual shunt.
d. Includes procedure related arrhythmias, device embolization with percutaneous retrieval, heparin overdosage that required reversal, asymptomatic thrombus in the pulmonary artery that resolved with heparin therapy over 24 hours.
e. Includes device embolization with surgical removal.