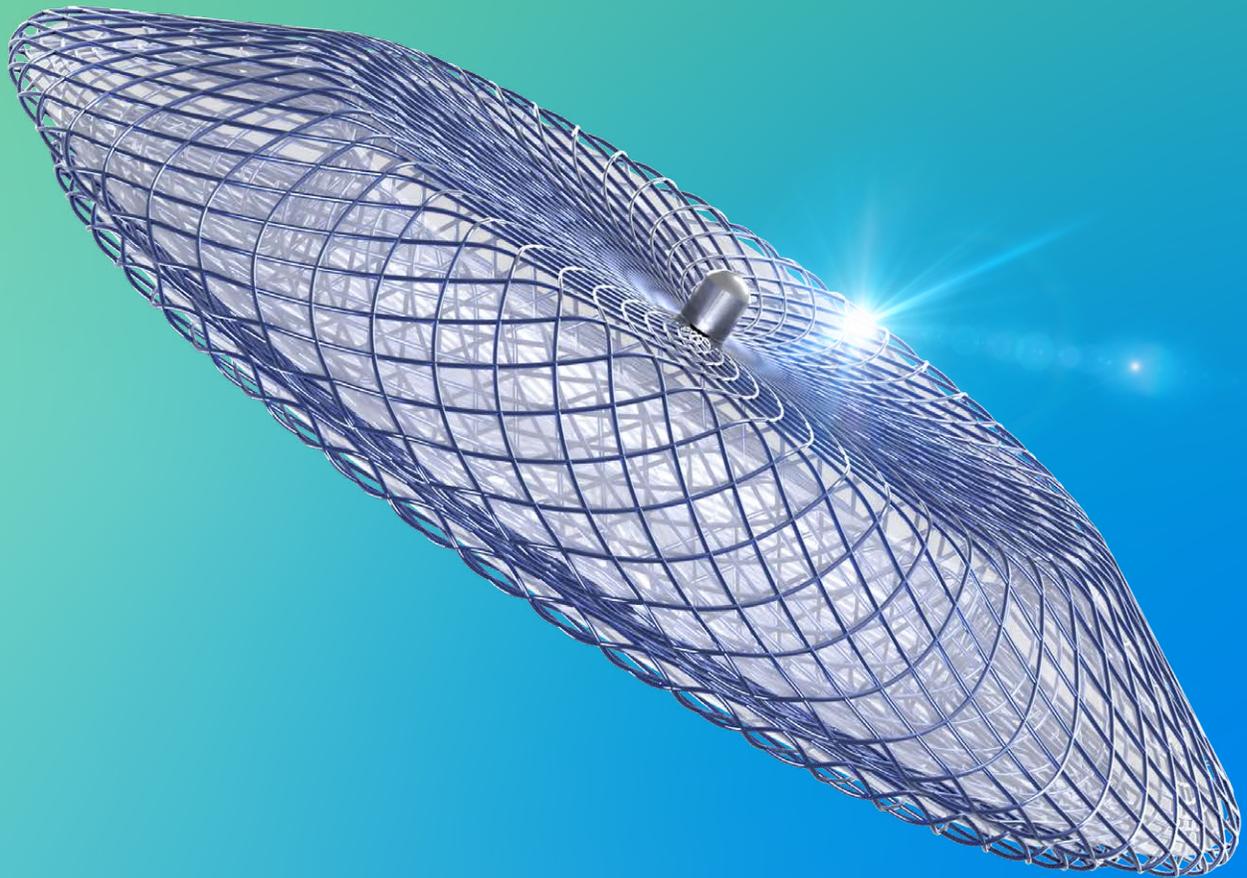


Amplatzer™ Septal Occluder

OPTIMAL OCCLUSION, **PROVEN RESULTS**



STRUCTURAL HEART | STRUCTURAL INTERVENTIONS



WHAT HAS MADE
THE AMPLATZER™
SEPTAL OCCLUDER
(ASO) **THE WORLD'S
LEADING AND MOST
TRUSTED** DEVICE
FOR ATRIAL SEPTAL
DEFECT (ASD)
CLOSURE FOR
OVER 25 YEARS?

1 PROVEN SAFE AND EFFECTIVE CLOSURE

Since ASO's first formal approval in 1998, over 500,000 patients¹ across the globe have benefitted from this innovative technology.

ASO has long been considered the standard of care, with a clinically validated 98.5% closure rate² and extremely low major and minor complications.

2 CLINICAL EVIDENCE AND EXPERTISE YOU CAN TRUST

No other ASD closure device comes close to having the amount of clinical data gleaned over the past quarter-century as ASO. In addition to multiple clinical trials, there have also been over 750 peer-reviewed articles about its safety and effectiveness. By contrast, some competitive devices have no clinical trial data of their own, and in some cases have leveraged ASO's data for their regulatory approvals.

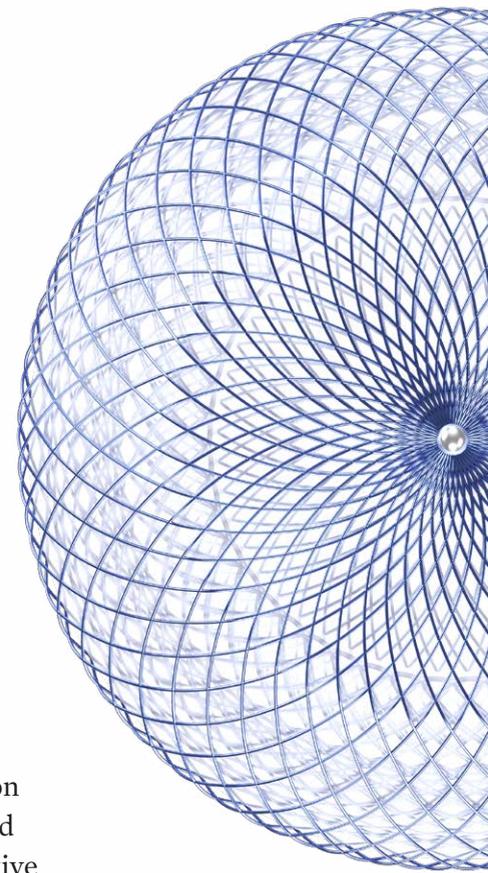
With nearly 1,400 combined years of ASD closure experience, our product support reps are trusted partner of interventional cardiologists who provide unmatched case support and education.

3 SMART PRODUCT DESIGN AND EASE-OF-USE

The braiding pattern of the ASO has an optimal design for defect closure as well as allowing access for future left side heart interventions.

The ASO device is compatible with the Amplatzer™ Trevisio™ Intravascular Delivery System, providing a simple procedure and confident septal alignment prior to device release.

ASO offers the widest range of sizes on the market – from 4 mm up to 40 mm³ – so you can find the right device for every patient.



1 PROVEN SAFE AND EFFECTIVE CLOSURE

Backed by PIVOTAL study among others, plus 750+ peer reviewed journals

Since its introduction over 25 years ago, ASO has consistently provided safe and effective closure, with minimal adverse events^{2,4}

NOTE: Comparing to competitive products is often challenging due to their lack of independent clinical studies.

EASE-OF-USE AND HIGH PROCEDURAL SUCCESS AS SHOWN IN THE US PIVOTAL TRIAL 1998-2001²



PROCEDURAL SUCCESS RATE



24-HOUR CLOSURE RATE



TECHNICAL SUCCESS



12-MONTH CLOSURE RATE

With no significant residual shunt (less than or equal to 2 MM) at 1-year follow-up

ASO LEADS IN SAFETY WITH A SUPERB CLINICALLY-VALIDATED SAFETY PROFILE AND MINIMAL ADVERSE EVENTS

EROSION RATE⁴

0.043%-0.3%

No erosions reported for sizes smaller than 13 MM. Erosion can be mitigated by sizing technique.

DEVICE EMBOLIZATION² with percutaneous removal

0.2%

NOTE: A competitive ASD product shows a 20x higher embolization rate.⁵

WIRE FRAME FRACTURES²

0.0%

NOTE: A competitive ASD product study at 36 months shows wire frame fracture rate of 57% with rates ranging from 38% to 89.5% depending on the device size.⁶

NEW ARRHYTHMIAS² requiring major treatment

0.5%

NOTE: A competitive ASD product showed a real-world rate of new arrhythmias requiring hospitalization or intervention of 4.8%.⁷

2 CLINICAL EVIDENCE AND EXPERTISE YOU CAN TRUST

No ASD device in the world has been more studied than ASO

Unmatched clinical evidence

The Amplatzer™ Septal Occluder is the most studied transcatheter atrial septal defect (ASD) closure device available today, with over 25 years of demonstrated clinical experience.

THESE 3 CLINICAL STUDIES ENCOMPASS OVER 1,900 ASO PATIENTS

- U.S. PIVOTAL Trial: 442 patients
- Amplatzer Septal Occluder Post-Approval Study: 1000 patients
- Magic Atrial Septal Defect Study: 478 patients



AMPLATZER™ SEPTAL OCCLUDER DEVICES SOLD¹



PATIENTS STUDIED^{3, 4, 8}



PEER-REVIEWED ARTICLES

UNMATCHED PRODUCT AND INDUSTRY EXPERTISE



WORLD-CLASS EDUCATION AND SUPPORT

Providing expert instruction to ensure your team has convenient access to the latest training



LARGEST PORTFOLIO

Offering the broadest product portfolio focused on helping people live fuller, healthier lives



EMPATHIC PATIENT SUPPORT

Providing world-class patient materials and resources to ensure positive experiences



CLINICAL TRIALS

Ongoing world-class research to balance risk/benefit ratio, improve safety and advance standard-of-care

3 SMART PRODUCT DESIGN AND EASE-OF-USE

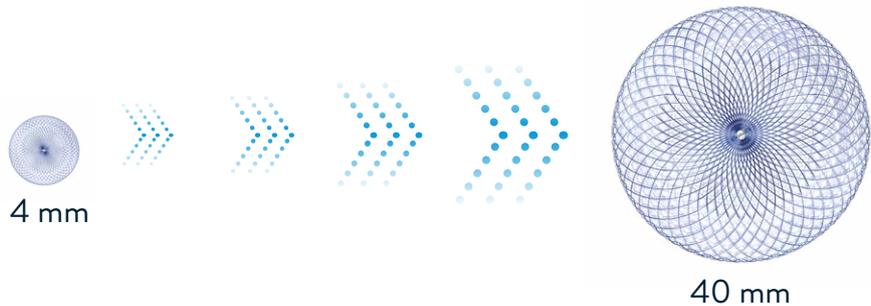
with key product features that support excellent outcomes

TREATMENT RANGE 3 MM TO 40 MM

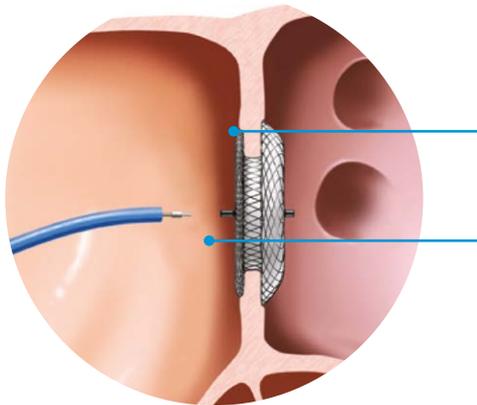
No other ASD closure device on the market today can match ASO's wide range of device sizes.

AVAILABLE IN 27 DIFFERENT SIZES³

Ranging from 4 mm to 40 mm, designed to treat most patient anatomies and constructed to accommodate various septal morphologies.



UNIQUE PRODUCT FEATURES



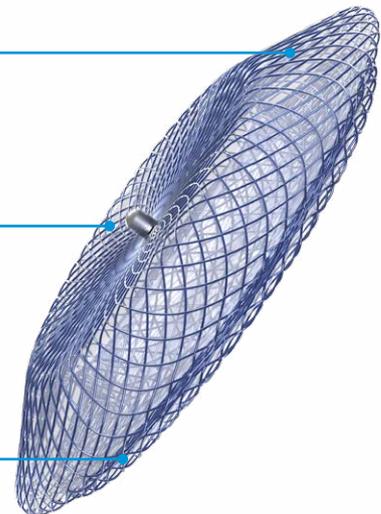
DOUBLE DISCS are designed to securely appose both sides of the septal wall.

The **WIDE CONNECTING WAIST** is designed to center the device and fill the ASD.

SHAPE-MEMORY NITINOL MESH
Designed to securely appose both sides of the septal wall.

INTAGLIO™
A proprietary wire treatment for Amplatzer™ Nitinol wire. The only treatment proven to reduce nickel leaching by more than 95%¹.

POLYESTER MATERIAL
Promotes occlusion and tissue in-growth.



Enables left atrium access for future procedures including ablation procedures, mitral valve procedures, and left atrial appendage closure.⁹⁻¹¹

AMPLATZER™ TREVISIO™ INTRAVASCULAR DELIVERY SYSTEM

From delivery to deployment, physicians appreciate the Amplatzer Trevisio Delivery System's ideal combination of torque strength, sheath diameter, reliable performance and ease-of-use.

The Trevisio Delivery System is an ultra-flexible delivery system enabling interventional cardiologists to perform transcatheter ASD closures work with complete confidence.

Compatible with all Amplatzer Septal Occluders

- A unique one-piece cable design improves control, flexibility, and predictability
- Ideal for a wide range of heart morphologies

ULTRA-FLEXIBLE TIP

Improves assessment of device position before cable release and reduces bias on the device.

FLEXIBLE TRANSION SECTION

Provides structure, pushability, and maintains sheath position during deployment of the device.

STIFF PROXIMAL SECTION

Provides reliable and steady pushability and control



WATCH THE TREVISIO
DELIVERY SYSTEM IN ACTION

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

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Always check the regulatory status of the device in your region.

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