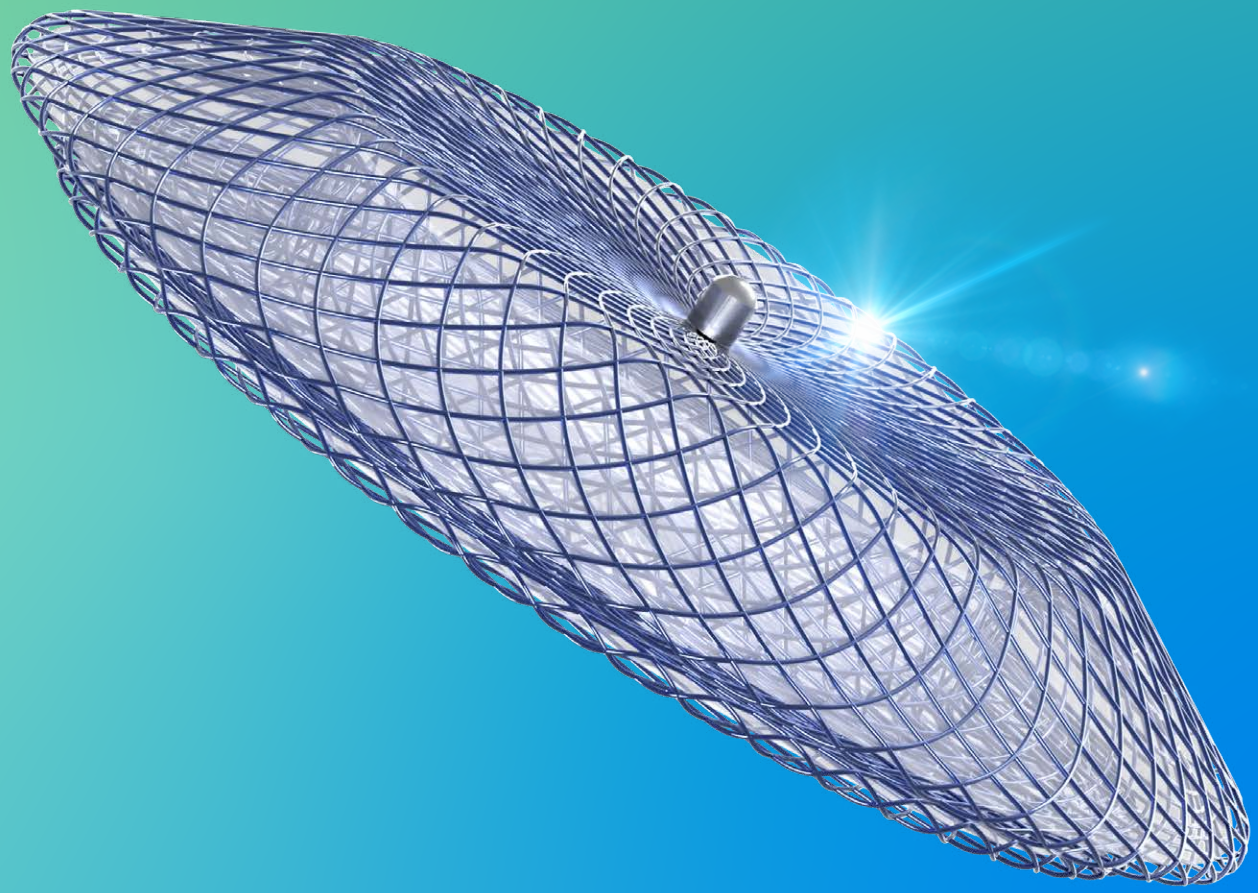
Amplatzer™ Septal Occluder

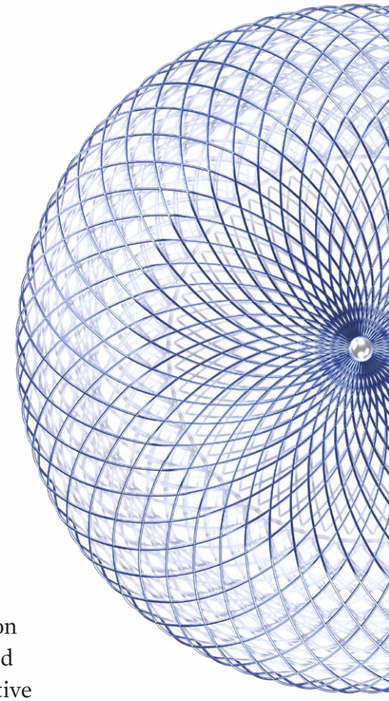
# OPTIMAL OCCLUSION, **PROVEN RESULTS**



STRUCTURAL HEART | STRUCTURAL INTERVENTIONS

Abbott

# 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 patients[1] 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 rate[2] 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 38 mm[3] – so you can find the right device for every patient.

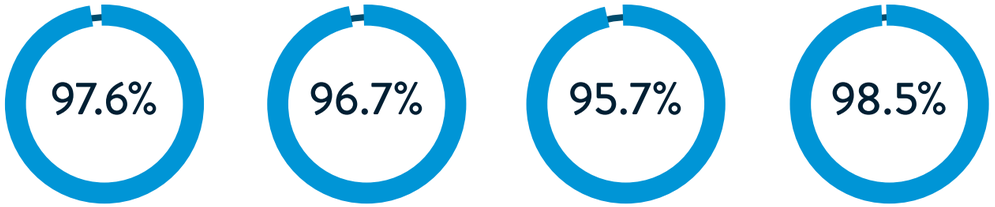
# 1 PROVEN SAFE AND EFFECTIVE CLOSURE

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 1998-2001[2]




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 RATE[3]

0.043%-0.3%

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

### WIRE FRAME FRACTURES[2]

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]

### DEVICE EMBOLIZATION[2]

with percutaneous removal

0.2%

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

### NEW ARRHYTHMIAS[2]

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]



See Important Safety Information referenced within

# 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


## 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

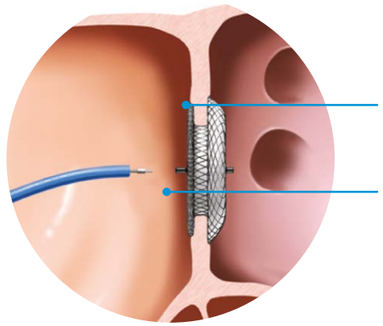
## TREATMENT RANGE 3 MM TO 38 MM

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

### AVAILABLE IN 26 DIFFERENT SIZES[3]

Ranging from 4 mm to 38 mm, designed to treat most patient anatomies and constructed to accommodate various septal morphologies.


## UNIQUE PRODUCT FEATURES



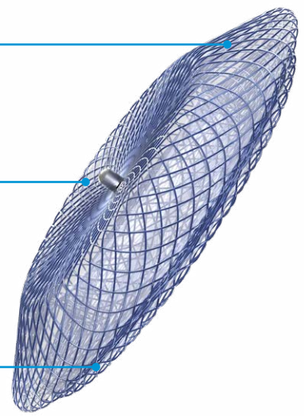
**DOUBLE DISCS** are designed to securely appose both sides of the septal wall.

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]



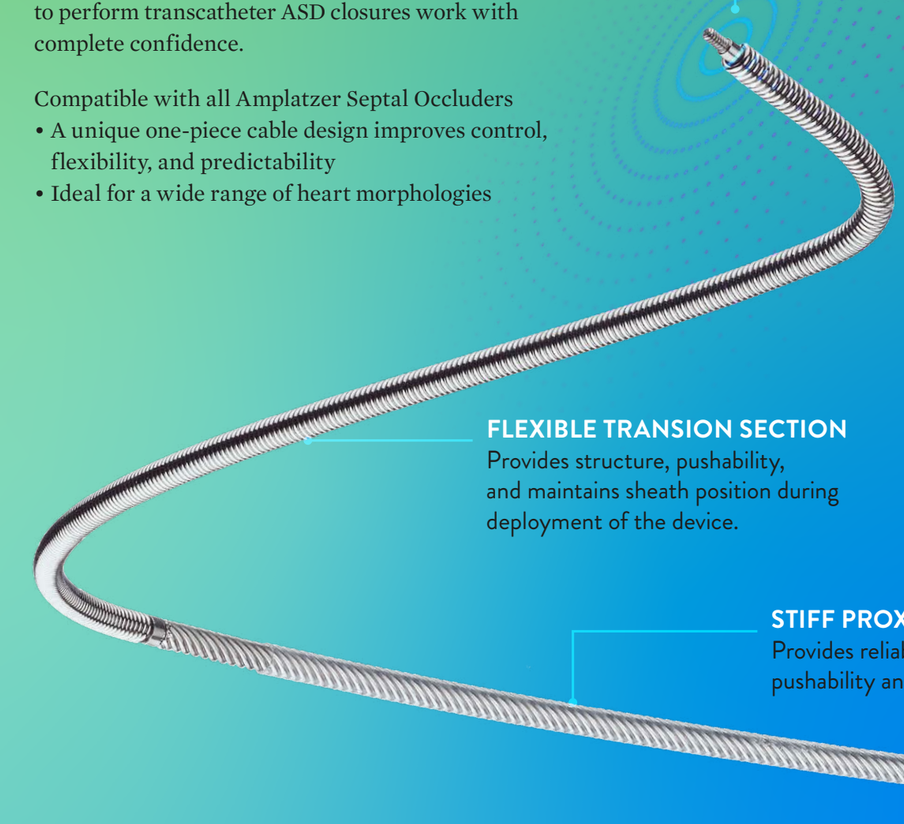
# AMPLATZER™ TREVISIO™ INTRAVASCULAR DELIVERY SYSTEM

**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**

# REFERENCES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# IMPORTANT SAFETY INFORMATION
## AMPLATZER™ SEPTAL OCCLUDER

Rx ONLY

### 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.

# IMPORTANT SAFETY INFORMATION
## AMPLATZER™ TREVISIO™ INTRAVASCULAR DELIVERY SYSTEM

Rx ONLY

### INDICATIONS AND USAGE
The Amplatzer™ Trevisio™ Intravascular Delivery System is intended to provide a pathway through which devices are introduced within the chambers and coronary vasculature of the heart or in the peripheral vasculature.

### CONTRAINDICATIONS
None known.

### WARNINGS
- This device was sterilized with ethylene oxide and is for single use only. Do not reuse or resterilize this device. Attempts to resterilize this device can cause a malfunction, insufficient sterilization, or harm to the patient.
- Do not use this device if the sterile package is open or damaged.
- Use on or before the last day of the expiration month that is printed on the product packaging label.
- The sheath is designed to be used with the loader. Do not attach a syringe directly to the sheath because the sizing is incompatible and may result in ingress of air or excessive bleeding.
- Use the hemostasis valve to impede the backflow of blood during the implant procedure.
- Do not use a power injection syringe to inject contrast solution through the sheath.
- Remove the dilator and sheath from the patient slowly to prevent an ingress of air.

### PRECAUTIONS
- Store in a dry place.
- This device should be used only by physicians who are trained in standard transcatheter techniques. The physician should determine which patients are candidates for procedures that use this device.
- The physician should exercise clinical judgment in situations that involve the use of anticoagulants or antiplatelet drugs before, during, and/or after the use of this delivery system.
- Use caution when advancing the dilator and sheath to avoid damaging tissue and vessels or interfering with previously implanted medical devices.
- Use standard transcatheter techniques when using Amplatzer™ products.

### POTENTIAL ADVERSE EVENTS
Potential adverse events that may occur during or after a procedure using this delivery system may include, but are not limited to: Air embolism, Arrhythmia, Arteriovenous fistulae, Bleeding, Brachial plexus injury, Cardiac tamponade, Death, Dissection, Endocarditis, Hematoma, Infection, Myocardial, infarction, Perforation, Peripheral embolism, Peripheral pulse loss, Stroke, Thrombosis, Tissue trauma/damage, Valve damage, Vascular occlusion, Vessel trauma/damage

**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.

See Important Safety Information referenced within.

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**Abbott**
3200 Lakeside Dr., Santa Clara, CA. 95054 USA, Tel: 1.800.227.9902


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