

AMPLATZER™ TREVISIO™
INTRAVASCULAR DELIVERY SYSTEM

**MORE FLEXIBILITY,
MORE CONTROL**

The Road to Excellence

DISCOVER THE UNIQUE
AMPLATZER™ TREVISIO™

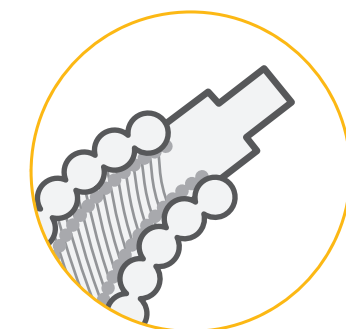


RELIABLE PRECISION WHEN IT MATTERS MOST

The Amplatzer™ Trevisio™ Intravascular Delivery System is an ultra-flexible delivery system enabling interventional cardiologists to perform their work with complete confidence. It leverages the one-piece cable design utilized by the Amplatzer™ TorqVue™ Delivery System, also known as the Classic Amplatzer™ Delivery System*. Trevisio is designed for no compromises on torque strength, sheath diameter and pushability.

ULTRA-FLEXIBLE TIP

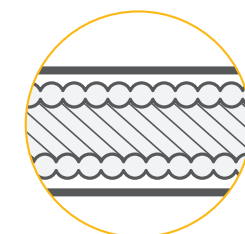
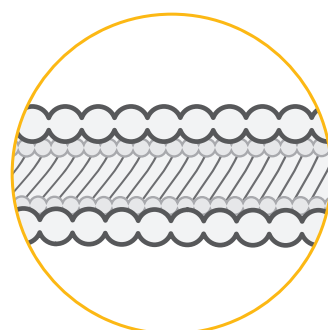
- Improves assessment of device position before cable release
- Reduces bias on the device



NEW ULTRA SHORT SCREW

FLEXIBLE TRANSITION SECTION

Maintains sheath position during deployment of the device.



STIFF PROXIMAL SECTION

Maintains pushability of the delivery system.

CLASSIC AMPLATZER™ DELIVERY SYSTEM*

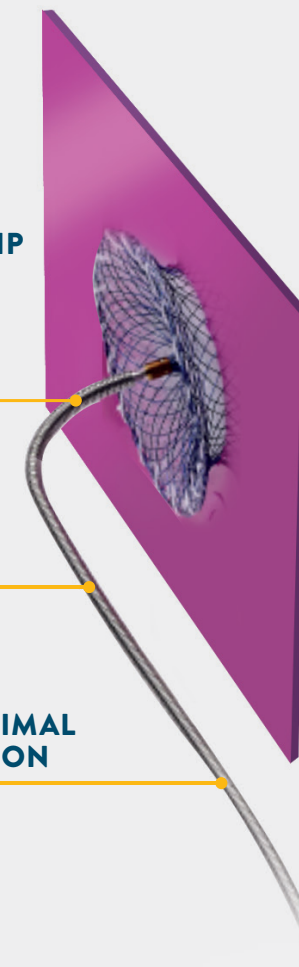


AMPLATZER™ TREVISIO™ INTRAVASCULAR DELIVERY SYSTEM

ULTRA- FLEXIBLE TIP

FLEXIBLE TRANSITION SECTION

STIFF PROXIMAL SECTION



Flexible tip reduces the bias on the device and improves the assessment of device position prior to cable release.

IMPORTANT SAFETY INFORMATION

AMPLATZER™ TREVISIO™ INTRAVASCULAR DELIVERY SYSTEM

INDICATIONS AND USAGE
ONLY 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

Compatibility Chart for Amplatzer™ Trevisio™ Intravascular Delivery System and Amplatzer™ Devices

	Amplatzer™ Trevisio™ Intravascular Delivery System Sizes					
	6 Fr	7 Fr	8 Fr	9 Fr	10 Fr	12 Fr
Amplatzer™ Septal (ASD) Occluder	4–10 mm	11–17 mm	18 mm 19 mm	20–24 mm	26–30 mm	32–38 mm
Amplatzer™ Multi-fenestrated ASD (Cribiform) Occluder	---	---	18 mm 25 mm	30 mm 35 mm	---	---
Amplatzer™ Muscular VSD Occluder	4–10 mm	12 mm	14 mm 16 mm	18 mm	---	---
Amplatzer™ P.I. Muscular VSD Occluder	---	---	---	16 mm 18 mm	20 mm 22 mm 24 mm	---
Amplatzer™ PFO Occluder	---	---	18 mm 25 mm	30 mm 35 mm	---	---

Delivery System Dimensions

Delivery system (sheath) size	Inner diameter of sheath	Outer diameter of sheath	Model Number/Delivery System Size (mm)
6 Fr	2.11 mm (0.08 in)	2.79 mm (0.11 in)	9-ATV06F45/60
7 Fr	2.44 mm (0.10 in)	3.18 mm (0.13 in)	9-ATV07F45/60
7 Fr	2.44 mm (0.10 in)	3.18 mm (0.13 in)	9-ATV07F45/80
8 Fr	2.69 mm (0.11 in)	3.45 mm (0.14 in)	9-ATV08F45/60
8 Fr	2.69 mm (0.11 in)	3.45 mm (0.14 in)	9-ATV08F45/80
9 Fr	3.00 mm (0.12 in)	3.81 mm (0.15 in)	9-ATV09F45/80
10 Fr	3.30 mm (0.13 in)	4.14 mm (0.16 in)	9-ATV10F45/80
12 Fr	3.99 mm (0.16 in)	4.80 mm (0.19 in)	9-ATV12F45/80

CAUTION: This product is 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 eifu.abbottvascular.com or at medical.abbott/manuals for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

Illustrations are artist's representations only and should not be considered as engineering drawings or photographs.

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3200 Lakeside Dr., Santa Clara, CA. 95054 USA, Tel: 1.800.227.9902
www.cardiovascular.abbott

† Indicates a third party trademark, which is property of its respective owner.

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