AMPLATZER™ TREVISIO™
INTRAVASCULAR DELIVERY SYSTEM

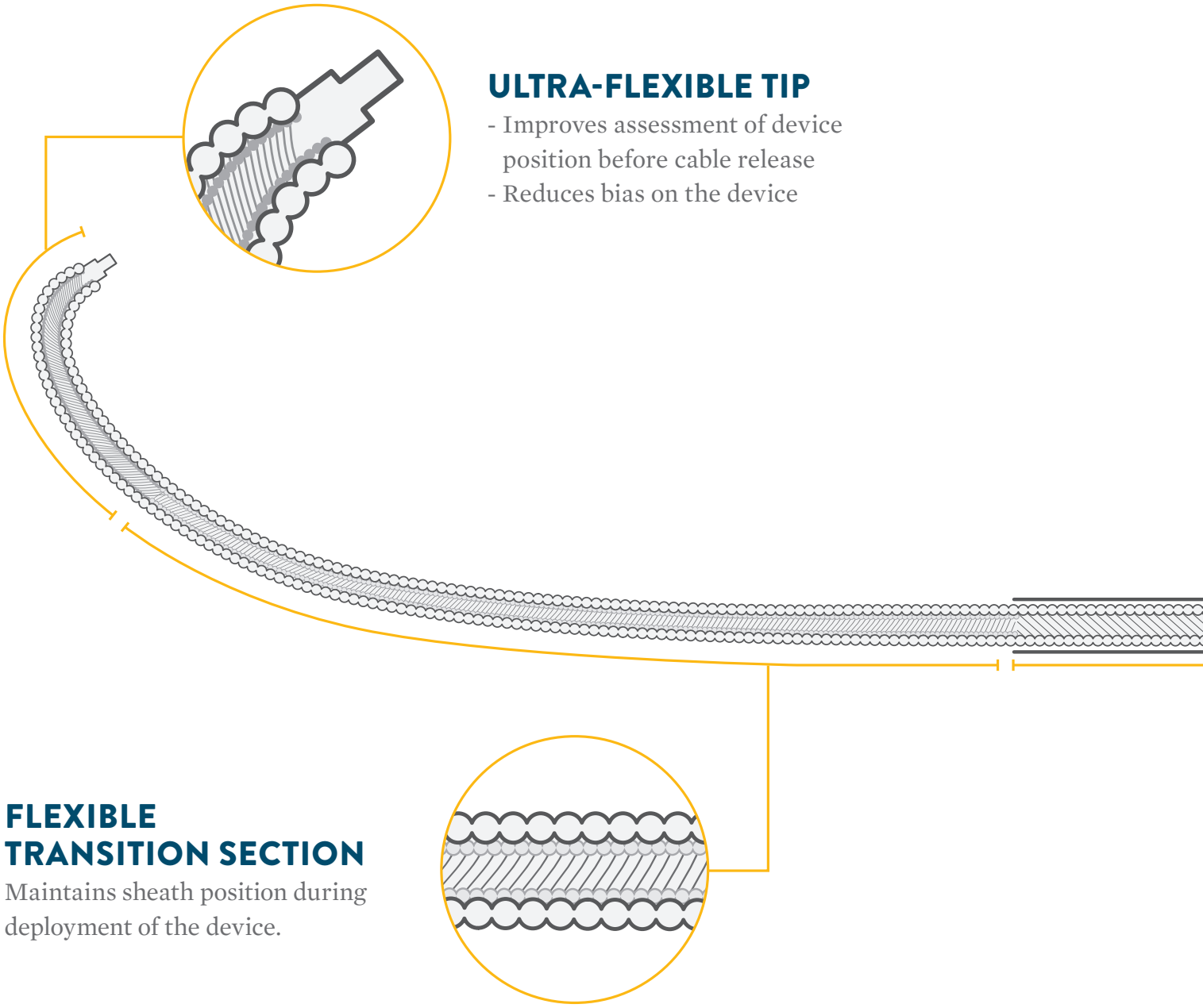
MORE FLEXIBILITY, MORE CONTROL

DISCOVER THE UNIQUE
AMPLATZER™ TREVISIO™

Abbott

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 know 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

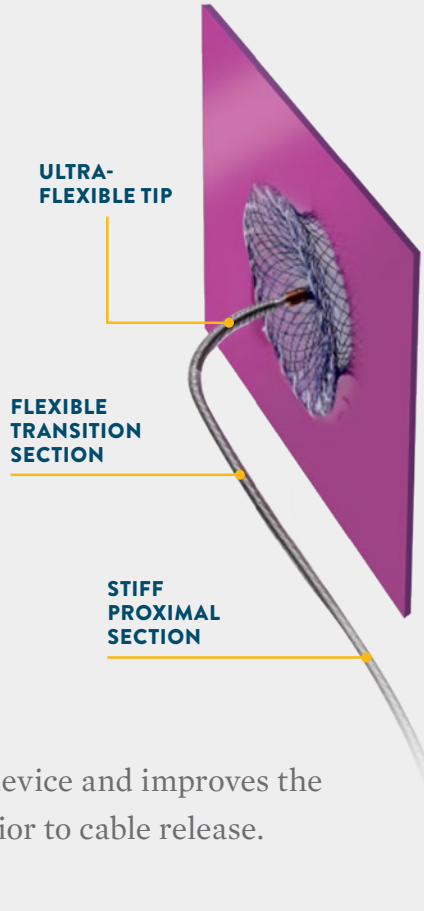
FLEXIBLE TRANSITION SECTION

Maintains sheath position during deployment of the device.

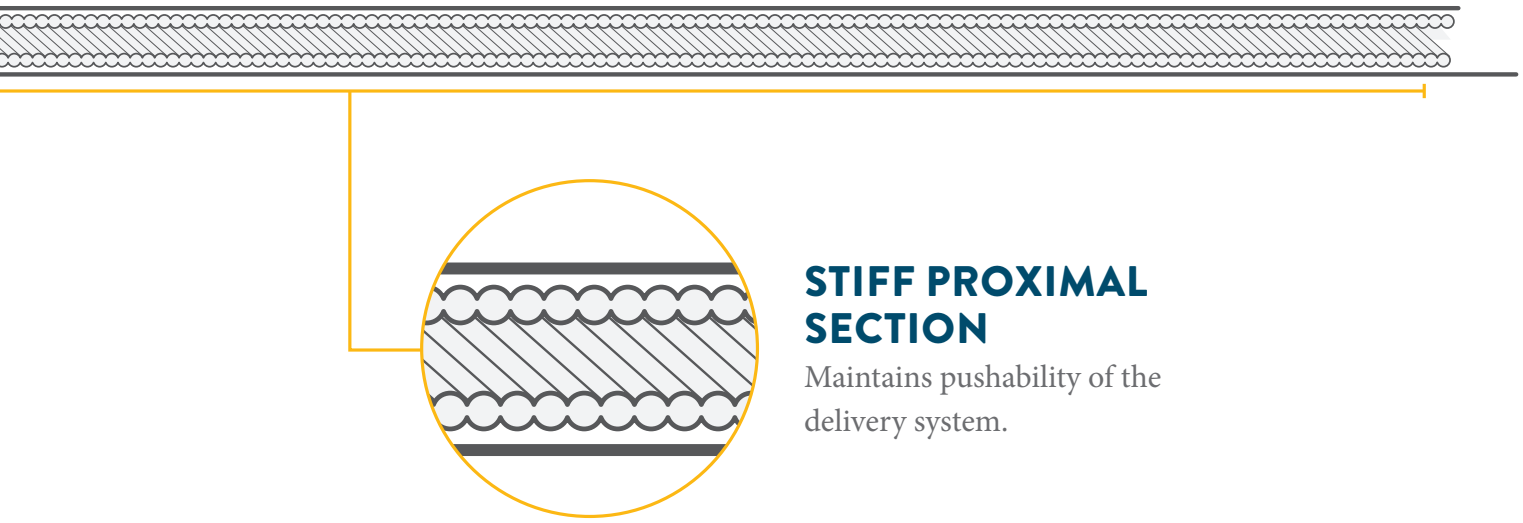
See Important Safety Information referenced within.

CLASSIC AMPLATZER™ DELIVERY SYSTEM*

AMPLATZER™ TREVISIO™ INTRAVASCULAR DELIVERY SYSTEM



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



STIFF PROXIMAL SECTION

Maintains pushability of the delivery system.

IMPORTANT SAFETY INFORMATION

AMPLATZER™ TREVISIO™, INTRAVASCULAR DELIVERY SYSTEM

INDICATIONS AND USAGE

Rx 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

AMPLATZER™ TORQVUE™ 45° AND 180° DELIVERY SYSTEMS, IMPORTANT SAFETY INFORMATION

INDICATIONS AND USAGE

Rx ONLY The AMPLATZER™ TorqVue™ 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

- 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.
- Use on or before the last day of the expiration month that is printed on the product packaging label.
- 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.

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

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

DELIVERY SYSTEM DIMENSIONS

DELIVERY SYSTEM (SHEAT SIZE)	INNER DIAMETER OF SHEAT	OUTER DIAMETER OF SHEAT	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

*Amplatzer™ TorqVue™ Delivery System

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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