

AMPLATZER™ TREVISIO™ INTRAVASCULAR DELIVERY SYSTEM

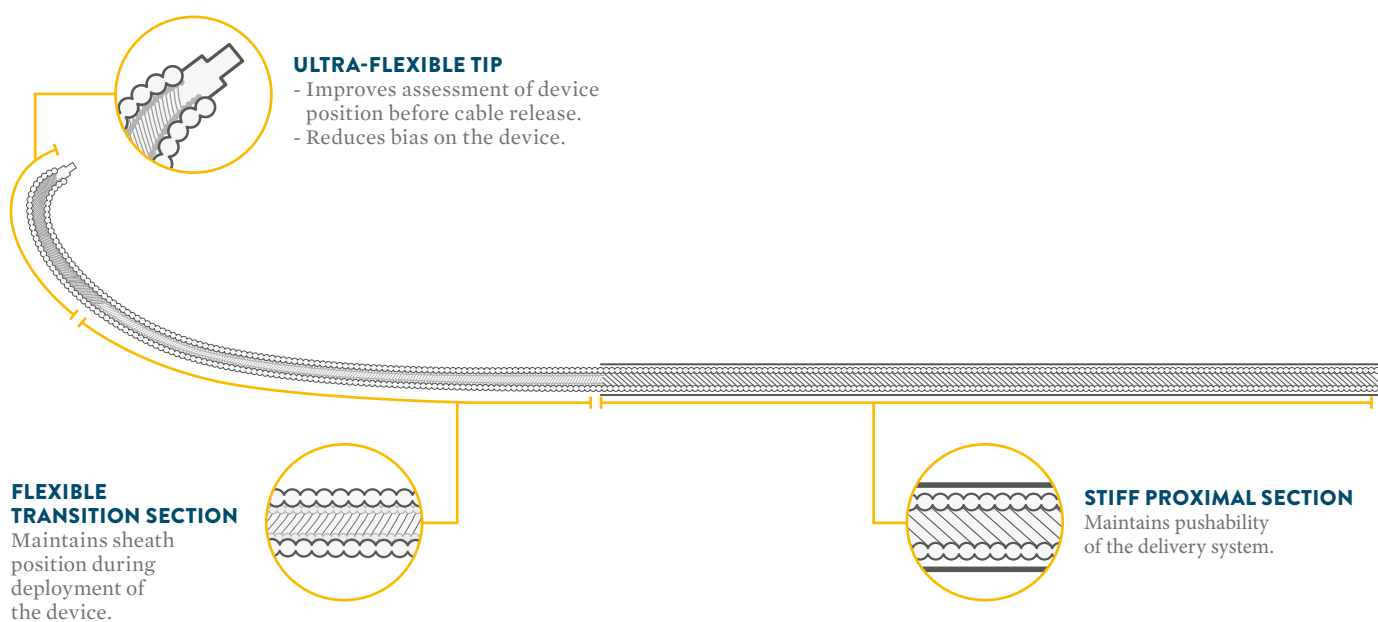
DEVICE DESCRIPTION

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.

The Amplatzer™ Trevisio™ Intravascular Delivery System comes with a 45° sheath curve in 60 or 80 cm lengths from 6Fr to 13Fr.

INDICATIONS AND USAGE

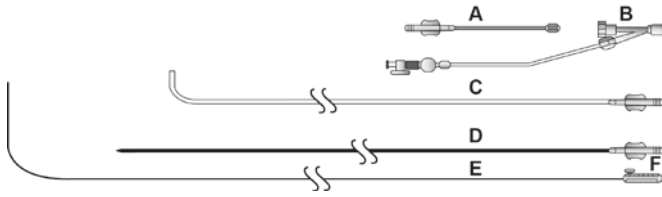
The Amplatzer™ Trevisio™ Intravascular Delivery System is intended to facilitate the attachment, loading, delivery and deployment of the Amplatzer™ Occluder devices. The Amplatzer™ Trevisio™ Intravascular Delivery System is indicated for use by interventional cardiologists to place an Amplatzer™ Occluder device.



DEVICE SPECIFICATIONS

Model Number/ Delivery System Size mm	Delivery System (Sheath Size) Fr	Inner Diameter of Sheath mm (inch)	Outer Diameter of Sheath mm (inch)	Length cm
9-ATV06F45/60	6	2.11 (0.08)	2.79 (0.11)	60
9-ATV07F45/60	7	2.44 (0.10)	3.18 (0.13)	60
9-ATV07F45/80	7	2.44 (0.10)	3.18 (0.13)	80
9-ATV08F45/60	8	2.69 (0.11)	3.45 (0.14)	60
9-ATV08F45/80	8	2.69 (0.11)	3.45 (0.14)	80
9-ATV09F45/80	9	3.00 (0.12)	3.81 (0.15)	80
9-ATV10F45/80	10	3.30 (0.13)	4.14 (0.16)	80
9-ATV12F45/80	12	3.99 (0.16)	4.80 (0.19)	80
9-ATV13F45/80	13	4.32 (0.17)	5.13 (0.20)	80

PACKAGING INFORMATION



- A. Loader – Introduces an Amplatzer™ device into the sheath
- B. Hemostasis valve with extension tube and stopcock – Allows flushing of the delivery system and controls blood backflow
- C. Sheath – Provides a pathway through which an Amplatzer™ device is delivered
- D. Dilator – Eases penetration of tissue and minimizes vessel trauma
- E. Delivery cable – Attaches to the device to control its movement through the sheath
- F. Plastic vise – Attaches to the delivery cable and serves as a handle for disconnecting (unscrewing) the delivery cable from a device

Note that the device and the delivery system are being sold separately.

ASSOCIATED AMPLATZER™ PRODUCTS

Amplatzer™ Trevisio™ Intravascular Delivery System Sizes							
	6 Fr	7 Fr	8 Fr	9 Fr	10 Fr	12 Fr	13 Fr
Amplatzer™ Septal (ASD) Occluder	9-ASD-004	9-ASD-011	9-ASD-018	9-ASD-020	9-ASD-026	9-ASD-032	9-ASD-032
	9-ASD-005	9-ASD-012	9-ASD-019	9-ASD-022	9-ASD-028	9-ASD-034	9-ASD-034
	9-ASD-006	9-ASD-013	–	9-ASD-024	9-ASD-030	9-ASD-036	9-ASD-036
	9-ASD-007	9-ASD-014	–	–	–	9-ASD-038	9-ASD-038
	9-ASD-008	9-ASD-015	–	–	–	9-ASD-040	9-ASD-040
	9-ASD-009	9-ASD-016	–	–	–	–	–
	9-ASD-010	9-ASD-017	–	–	–	–	–
Amplatzer™ Multi-fenestrated ASD (Cribriform) Occluder	–	–	9-ASD-MF-018	–	–	–	–
	–	–	9-ASD-MF-025	9-ASD-MF-035	9-ASD-MF-040	–	–
	–	–	9-ASD-MF-030	–	–	–	–
Amplatzer™ PFO Occluder	–	–	9-PFO-018	–	–	–	–
	–	–	9-PFO-025	9-PFO-035	–	–	–
	–	–	9-PFO-030	–	–	–	–
Amplatzer™ Muscular VSD Occluder	9-VSD-MUSC-004	–	–	–	–	–	–
	9-VSD-MUSC-006	9-VSD-MUSC-012	9-VSD-MUSC-014	9-VSD-MUSC-018	–	–	–
	9-VSD-MUSC-008	–	9-VSD-MUSC-016	–	–	–	–
	9-VSD-MUSC-010	–	–	–	–	–	–
Amplatzer™ Muscular PI VSD Occluder	–	–	–	9-VSDMUSCPI-016	9-VSDMUSCPI-020	–	–
	–	–	–	9-VSDMUSCPI-018	9-VSDMUSCPI-022	–	–
	–	–	–	–	9-VSDMUSCPI-024	–	–

LATEX-FREE INFORMATION

These Amplatzer™ products do not contain latex.

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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. Photo(s) on file at Abbott. Information contained herein for DISTRIBUTION in Europe, Middle East and Africa ONLY. Please check the regulatory status of the device before distribution in areas where CE marking is not the regulation in force.

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