

AMPLATZER™ TREVISIO™

INTRAVASCULAR DELIVERY SYSTEM

MORE FLEXIBILITY,
MORE CONTROL



DISCOVER THE UNIQUE
AMPLATZER™ TREVISIO™

Information contained herein for **DISTRIBUTION outside of the U.S. ONLY**. Check the regulatory status of the device in areas where CE marking is not the regulation in force.



RELIABLE PRECISION WHEN IT MATTERS MOST

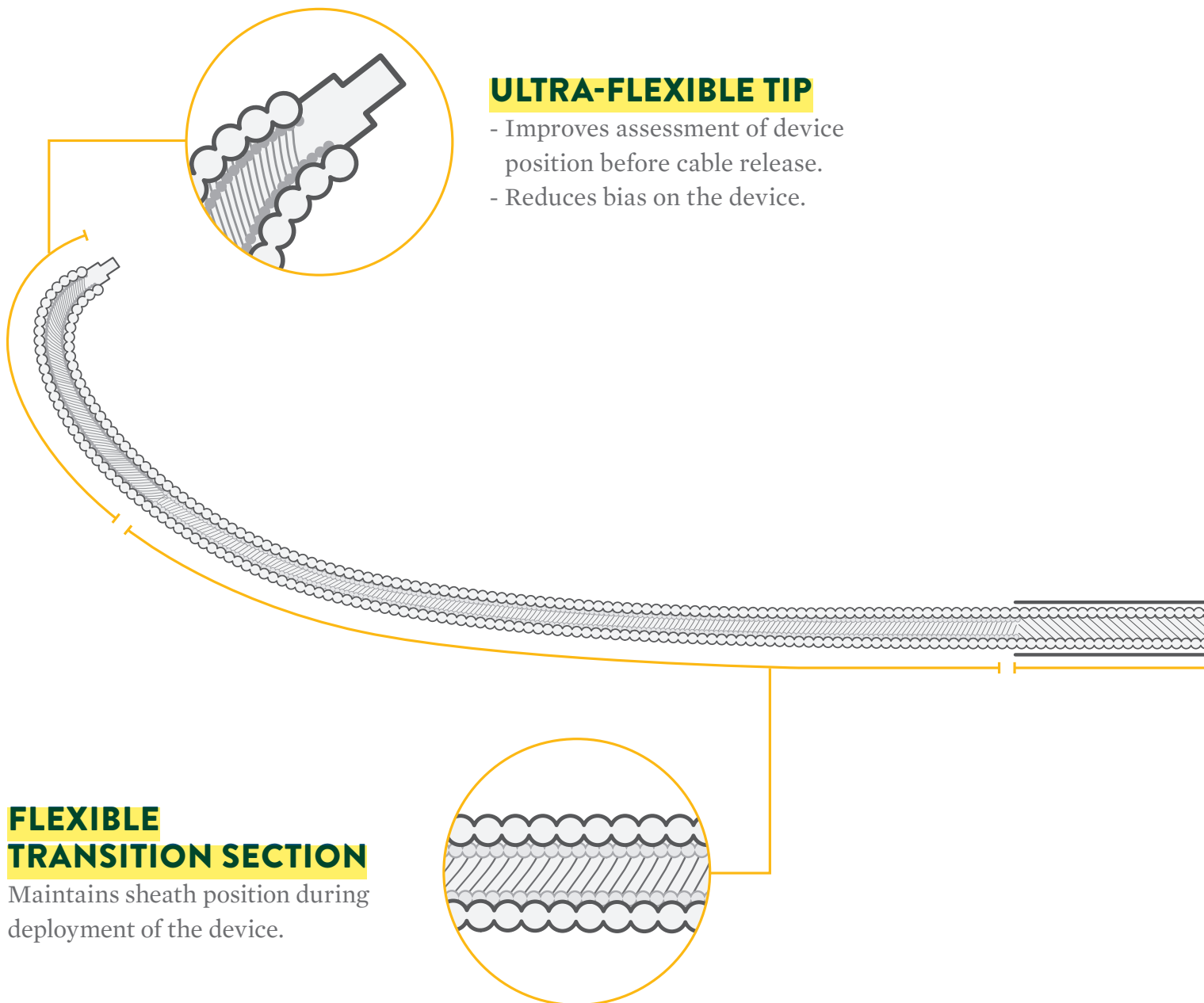
The Amplatzer™ Trevisio™ Intravascular Delivery System is an ultra-flexible delivery system enabling interventional cardiologists to perform their work with complete confidence. It leverages the one-piece cable design utilized by the Amplatzer™ TorqVue™ Delivery System, also known as the Classic Amplatzer™ 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.

FLEXIBLE TRANSITION SECTION

Maintains sheath position during deployment of the device.



CLASSIC AMPLATZER™ DELIVERY SYSTEM*

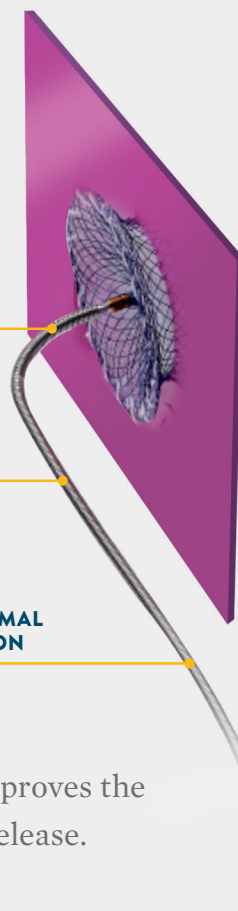


AMPLATZER™ TREVISIO™ INTRAVASCULAR DELIVERY SYSTEM

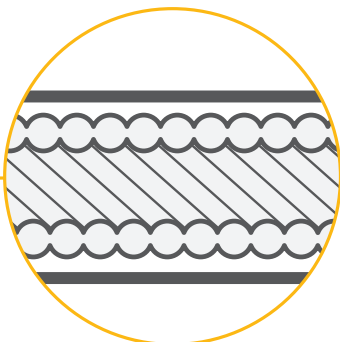
ULTRA-
FLEXIBLE TIP

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.



STIFF PROXIMAL SECTION

Maintains pushability of the
delivery system.

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
13 Fr	4.32 mm (0.17 in)	5.13 mm (0.20 in)	9-ATV13F45/80

*Amplatzer™ TorqVue™ Delivery System



DOWNLOAD NOW

Download the free Amplatzer™ Portfolio App from your favorite app store.



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.

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Abbott

Park Lake, Culliganlaan 2b, 1831 Diegem, Belgium
www.cardiovascular.abbott

™ Indicates a trademark of the Abbott group of companies.

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

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AMPLATZER™ TREVISIO™ INTRAVASCULAR DELIVERY SYSTEM

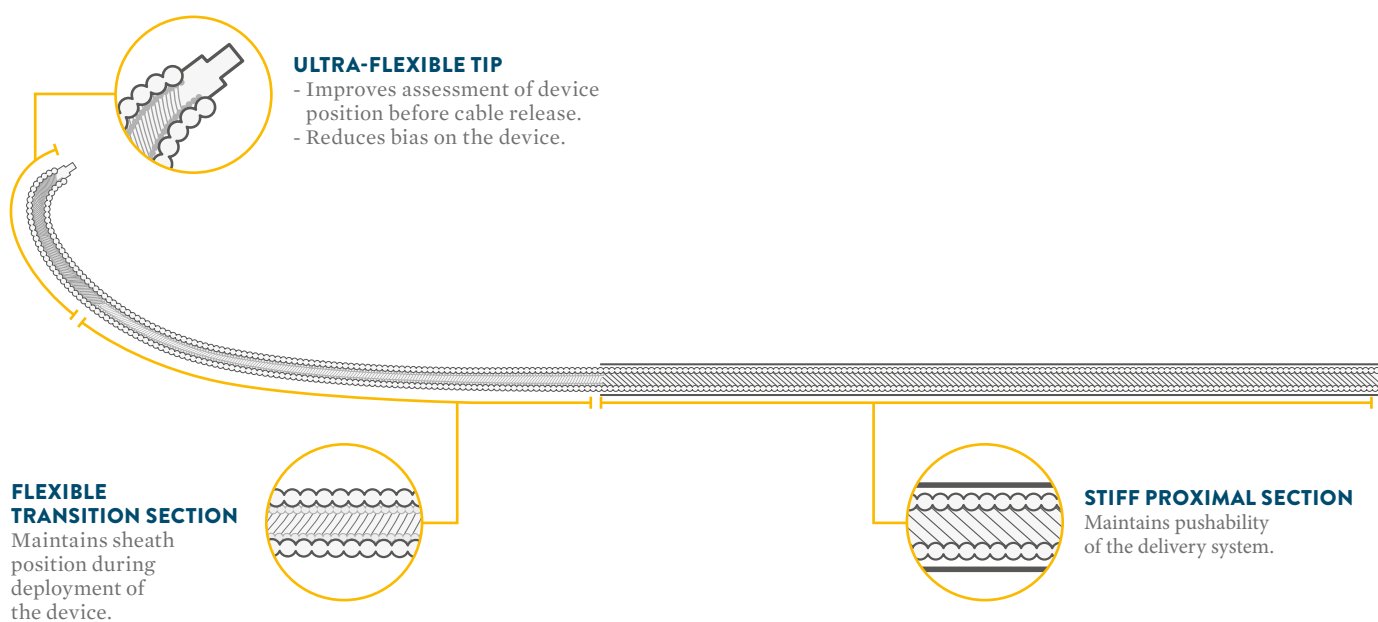
DEVICE DESCRIPTION

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.

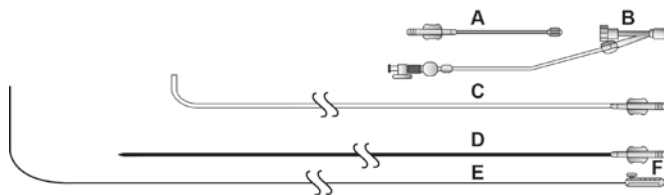


DEVICE SPECIFICATIONS

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

teacă de livrare!



- 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.

Abbott Vascular International BVBA

Park Lane, Culliganlaan 2B, B-1831 Diegem, Belgium, Tel: +32 2 714 14 11

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For more information, visit our web site at www.abbott.com

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Abbott Medical Declaration of Conformity

Abbott Medical (Abbott) hereby declares that the following Abbott facilities and products conform to the applicable provisions of Annex II of the Medical Device Directive (MDD) 93/42/EEC. All supporting documentation is retained under the premises of Abbott. We declare no application has been lodged with any other notified body for the same products. This declaration is issued under the sole responsibility of the manufacturer. This declaration supersedes any declaration issued previously for the same product(s).

Manufacturer Address:

Abbott Medical
5050 Nathan Lane North
Plymouth, Minnesota 55442, USA

European Representative:

Abbott Medical
The Corporate Village
Da Vincilaan 11 Box F1
1935 Zaventem, Belgium

Product Type:

Cardiac Occluder Delivery Kit

Product Name(s):

Amplatzer TorqVue Delivery System
Amplatzer TorqVue Exchange System
Amplatzer TorqVue 2 Delivery Sheath
Amplatzer TorqVue LP Delivery System
Amplatzer TorqVue LP Catheter
Amplatzer TorqVue Delivery System with Pusher Catheter
Amplatzer TorqVue 45°x45° Delivery Sheath
Amplatzer Amulet Delivery Sheath
Amplatzer Trevisio Intravascular Delivery System

Signature:

Michelle Grossman
Director, Regulatory Affairs


April 21, 2020
Issue Date

Abbott Medical Declaration of Conformity

Model Number(s):

Product	Model Numbers	Original CE Mark Date
Amplatzer TorqVue Delivery System	9-ITV06F45/60 9-ITV13F45/80 9-ITV07F45/60 9-ITV05F180/60 9-ITV07F45/80 9-ITV06F180/60 9-ITV08F45/60 9-ITV06F180/80 9-ITV08F45/80 9-ITV07F180/80 9-ITV09F45/80 9-ITV08F180/80 9-ITV10F45/80 9-ITV09F180/80 9-ITV12F45/80	10 October 2005
Amplatzer TorqVue Exchange System	9-EITV09F45/80 9-EITV12F45/80 9-EITV06F180/80 9-EITV08F180/80 9-EITV10F180/80	10 October 2005
Amplatzer TorqVue 2 Delivery Sheath	9-TV2-05F120 9-TV2-06F120 9-TV2-07F120	19 February 2010
Amplatzer TorqVue LP Delivery System	9-TVLP4F90/060 9-TVLP4F90/080 9-TVLP5F90/060 9-TVLP5F90/080	07 February 2008
Amplatzer TorqVue LP Catheter	9-TVLPC4F90/080	28 April 2011
Amplatzer TorqVue Delivery System with Pusher Catheter	9-ITVP07F-180/80 9-ITVP08F-180/80 9-ITVP09F-180/80	21 June 2011
Amplatzer TorqVue 45°x45° Delivery Sheath	9-TV45X45-09F-100 9-TV45X45-10F-100 9-TV45X45-12F-100 9-TV45X45-13F-100 9-TV45X45-14F-100	03 December 2008 (9-13 Fr) 24 February 2012 (14 Fr)
Amplatzer Amulet Delivery Sheath	DS-TV45X45-12F-080 DS-TV45X45-14F-080	08 February 2017
Amplatzer Trevisio Intravascular Delivery System	9-ATV06F45/60 9-ATV09F45/80 9-ATV07F45/60 9-ATV10F45/80 9-ATV07F45/80 9-ATV12F45/80 9-ATV08F45/60 9-ATV13F45/80 9-ATV08F45/80	20 April 2020

Signature:




 Michelle Grossman
 Director, Regulatory Affairs

April 21 2020

 Issue Date

Abbott Medical Declaration of Conformity

Classification:	Class III (Rule 7) Annex II, Section 4 GHTF Class D
GMDN Code(s):	45419
EC Design Certificate No and Expiration Date:	Certificate No: CE 694956 Expiration Date: 23 February 2023
Annex II, Clause 3 Certificate No and Expiration Date:	Certificate No: CE 694788 Expiration Date: 23 February 2023
Applicable Quality System Standards:	ISO 13485
Notified Body:	BSI Group The Netherlands B.V. Say Building John M. Keynesplein 9 1066 EP Amsterdam The Netherlands
Notified Body Number:	2727

Signature:
Michelle Grossman
Director, Regulatory Affairs
Issue Date

EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices, Annex II Section 4

No.**CE 694956****Issued To:****Abbott Medical
5050 Nathan Lane North
Plymouth
Minnesota
55442
USA****In respect of:****Amplatzer Delivery Systems**

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: 2018-09-03**Date: 2020-04-20****Expiry Date: 2023-02-23**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

EC Design-Examination Certificate

Supplementary Information to CE 694956

Issued To:

Abbott Medical
5050 Nathan Lane North
Plymouth
Minnesota
55442
USA

Amplatzer™ TorqVue™ Delivery System			
Intended purpose per IFU:			
The Amplatzer™ TorqVue™ Delivery System is intended to facilitate the attachment, loading, delivery and deployment of the Amplatzer™ Occluder devices.			
Classification: Class III			
Catalogue Number	Model, Type		
	Sheath Size (Fr)	Tip Angle	Usable Length (cm)
9-ITV06F45/60	6	45°	60
9-ITV07F45/60	7	45°	60
9-ITV07F45/80	7	45°	80
9-ITV08F45/60	8	45°	60
9-ITV08F45/80	8	45°	80
9-ITV09F45/80	9	45°	80
9-ITV10F45/80	10	45°	80
9-ITV12F45/80	12	45°	80
9-ITV13F45/80	13	45°	80
9-ITV05F180/60	5	180°	60
9-ITV06F180/60	6	180°	60
9-ITV06F180/80	6	180°	80
9-ITV07F180/80	7	180°	80
9-ITV08F180/80	8	180°	80
9-ITV09F180/80	9	180°	80

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Amplatzer™ TorqVue™ Exchange System			
Intended purpose per IFU: The Amplatzer™ TorqVue™ Exchange System is intended for removal of an Amplatzer™ Delivery Sheath and subsequent exchange for an Amplatzer™ Delivery Sheath of equal or larger diameter.			
Classification: Class III			
Catalogue Number	Model, Type		
	Sheath Size (Fr)	Tip Angle	Usable Length (cm)
9-EITV09F45/80	9	45°	80
9-EITV12F45/80	12	45°	80
9-EITV06F180/80	6	180°	80
9-EITV08F180/80	8	180°	80
9-EITV10F180/80	10	180°	80

Amplatzer™ TorqVue™ 2 Delivery Sheath			
Intended purpose per IFU: The Amplatzer™ TorqVue™ 2 Delivery Sheath 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.			
Classification: Class III			
Catalogue Number	Model, Type		
	Sheath Size (Fr)	Tip Angle	Usable Length (cm)
9-TV2-05F120	5	none	120
9-TV2-06F120	6	none	120
9-TV2-07F120	7	none	120

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Amplatzer™ TorqVue™ Delivery System with Pusher Catheter			
Intended purpose per IFU: The Amplatzer™ TorqVue™ Delivery System with Pusher Catheter is intended to facilitate the attachment, loading, delivery and deployment of the Amplatzer™ Membranous VSD Occluder device.			
Classification: Class III			
Catalogue Number	Model, Type		
	Sheath Size (Fr)	Tip Angle	Usable Length (cm)
9-ITVP07F180/80	7	180°	80
9-ITVP08F180/80	8	180°	80
9-ITVP09F180/80	9	180°	80

Amplatzer™ TorqVue™ LP Delivery System				
Intended purpose per IFU: The Amplatzer™ TorqVue™ LP Delivery System is intended to facilitate the attachment, loading, delivery, and deployment of the Amplatzer™ devices.				
Classification: Class III				
Catalogue Number	Model, Type			
	Device Size (Fr)	Curve Dimension	Length (cm)	Delivery Wire Length (cm)
9-TVLP4F90/060	4	90°	60	160
9-TVLP4F90/080	4	90°	80	195
9-TVLP5F90/060	5	90°	60	160
9-TVLP5F90/080	5	90°	80	195

First Issued: **2018-09-03**

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Amplatzer™ Trevisio™ Intravascular Delivery System

Intended purpose per IFU:

The Amplatzer™ Trevisio™ Intravascular Delivery System is intended to facilitate the attachment, loading, delivery and deployment of the Amplatzer™ Occluder devices.

Classification: Class III

Catalogue Number	Model, Type		
	Sheath Size (Fr)	Tip Angle	Usable Length (cm)
9-ATV06F45/60	6	45°	60
9-ATV07F45/60	7	45°	60
9-ATV07F45/80	7	45°	80
9-ATV08F45/60	8	45°	60
9-ATV08F45/80	8	45°	80
9-ATV09F45/80	9	45°	80
9-ATV10F45/80	10	45°	80
9-ATV12F45/80	12	45°	80
9-ATV13F45/80	13	45°	80

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Amplatzer™ TorqVue™ LP Catheter				
Intended purpose per IFU: The TorqVue™ LP Catheter is intended to facilitate the loading, delivery, and deployment of Amplatzer™ devices.				
Classification: Class III				
Catalogue Number	Model, Type			
	Device Size (Fr)	Usable Length (cm)	Tip Outer Diameter mm (in)	Tip Inner Diameter mm (in)
9-TVLPC4F90/080	4	80	1.40 (.055)	1.17 (0.046)

Amplatzer™ TorqVue™ 45x45 Delivery Sheath		
Intended purpose per IFU: The Amplatzer™ TorqVue™ Delivery Sheath is intended to provide a pathway through which devices are introduced within the chambers of the heart.		
Classification: Class III		
Catalogue Number	Model, Type	
	Sheath Size (Fr)	Length (cm)
9-TV45X45-09F-100	9	100
9-TV45X45-10F-100	10	100
9-TV45X45-12F-100	12	100
9-TV45X45-13F-100	13	100
9-TV45X45-14F-100	14	100

First Issued: **2018-09-03**

Date: **2020-04-20**

Expiry Date: **2023-02-23**

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Amplatzer™ Amulet™ Delivery Sheath

Intended purpose per IFU:

The Amplatzer™ Amulet™ Delivery Sheath is intended to provide a pathway through which devices are introduced within the chambers of the heart.

Classification: Class III

Catalogue Number	Model, Type	
	Sheath Size (Fr)	Length (cm)
DS-TV45X45-12F-080	12	80
DS-TV45X45-14F-080	14	80

First Issued: **2018-09-03**

Date: **2020-04-20**

Expiry Date: **2023-02-23**

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Certificate History

Date	Reference Number	Action
03 September 2018	8957249	First Issue. Mirror certificate to CE 594294.
20 February 2019	8243107	Traceable to NB 0086.
20 March 2019	9738457	Addition of Sterigenics US LLC, Salt Lake City, Utah for ETO Sterilization.
16 December 2019	3053900	Addition of Midwest Sterilization Corporation, Jackson, Missouri USA for ETO Sterilization in chambers 1, 2, 3, 6, and 13.
Current	9784335	Extension to scope to include the Amplatzer™ Trevisio™ Intravascular Delivery System. Revision to scope statement to remove "TorqVue" brand name. Reformat product tables. Correction of delivery wire length for Amplatzer™ TorqVue™ LP Delivery System. Correction of tip outer diameter for Amplatzer™ TorqVue™ LP Catheter.

First Issued: **2018-09-03**

Date: **2020-04-20**

Expiry Date: **2023-02-23**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

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