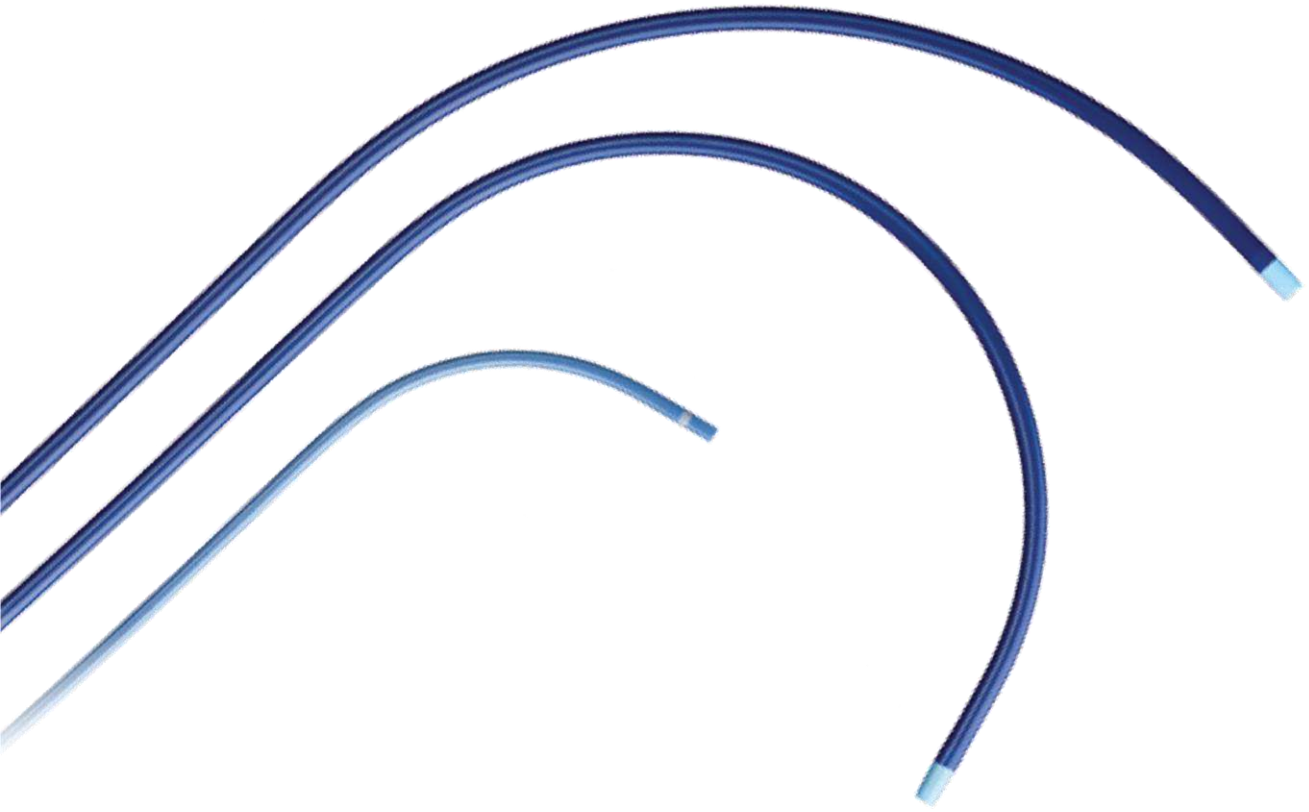
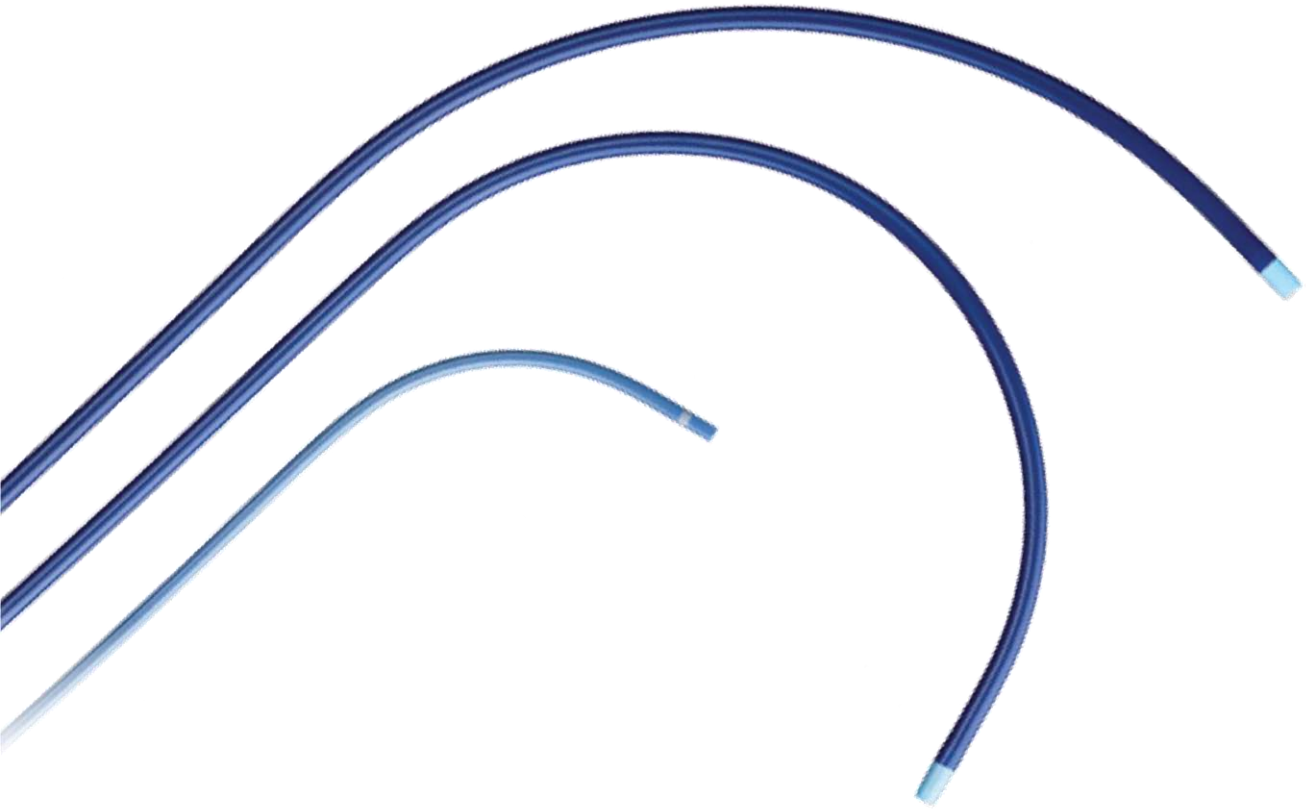
Abbott

AMPLATZER™ TORQVUE™ ȘI AMPLATZER™ TREVISIO™

SISTEME DE LIVRARE INTRAVASCULARĂ



Informațiile conținute aici pentru DISTRIBUȚIE NUMAI în afara S.U.A.
Verificați întotdeauna starea de reglementare a dispozitivului din regiunea dvs.



SISTEME DE LIVRARE CONFECȚIONTE DIN POLIMERI ARMAȚI OFERIND O **LIVRAE VERSATILĂ, CONTROLATĂ A DISPOZITIVELOR**

CONTROL

Sistemele de Livrare intravasculară Amplatzer™ TorqVue™ şi Amplatzer™ Trevisio™ sunt concepute pentru a oferi o cale controlată către locul de ocluzie.

Teacă de livrare din polimer armat

- Proiectat pentru a oferi rezistenţă suplimentară la îndoire printr-o împletitură internă din oţel inoxidabil[1]

Materialul din care este confecționată teaca trece de la o secțiune proximală mai rigidă la o secțiune distală mai moale

- Construită pentru a uşura împingerea şi manevrabilitatea în anatomia sinuoasă

Vârf moale, radioopac

- Proiectat pentru a minimiza riscul de deteriorare a vasului şi pentru a îmbunătăţi vizualizarea poziţiei

CONFIDENCE

Performanţa tecii este critică. Sistemele de livrare intravasculară Amplatzer TorqVue şi Amplatzer Trevisio sunt proiectate pentru a uşura poziţionarea şi deschiderea ocluderilor Amplatzer™

Radiopaque Distal Tip

- Facilitează poziţionarea şi plasarea precisă a dispozitivului

Teacă din PTFE cu frecare redusă

- Permite o livrare lină, controlată

Încărcător transparent

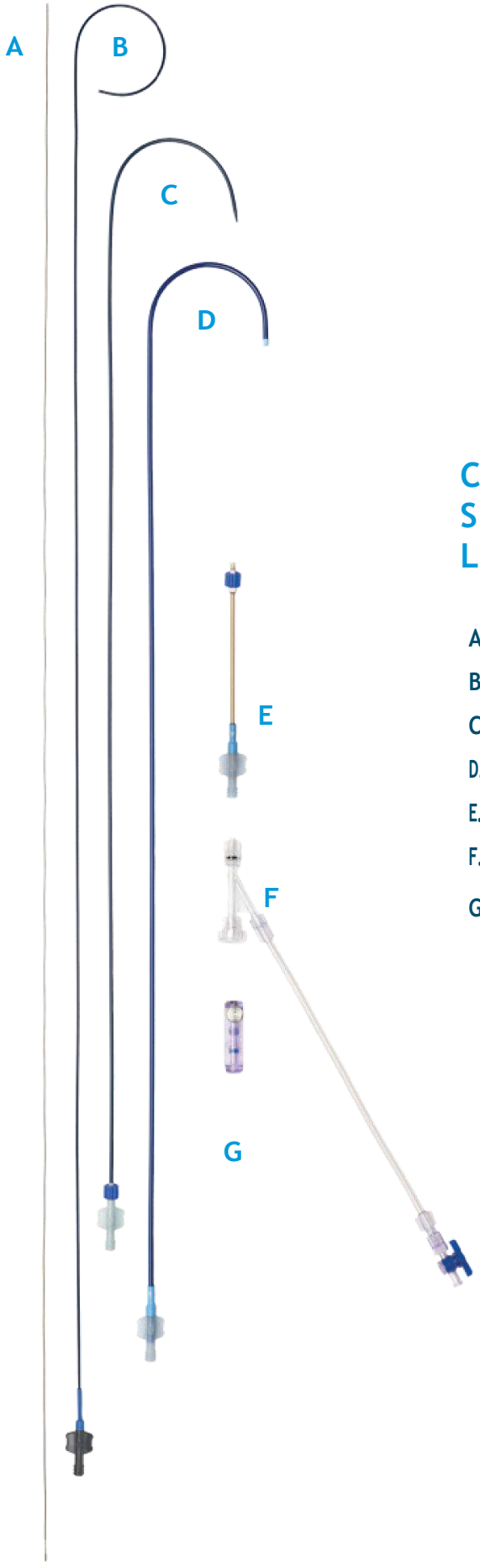
- Ajută la confirmarea încărcării dispozitivului, spălarea şi eliminarea aerului

Cabluri și fire de livrare în diferite calibre și flexibilitate

- Sunt concepute special pentru a ajuta la livrarea fiecărui Amplatzer Occluder

1. Teste efectuate de şi date în dosar la Abbott.

Informaţiile conţinute aici pentru DISTRIBUŢIE NUMAI în afara S.U.A. Verificaţi întotdeauna starea de reglementare a dispozitivului din regiunea dvs.



COMPONENTE SISTEM DE LIVRARE*

A. Cablu de livrare

B. Cateter de împingere

C. Dilatator

D. Teacă de livrare

E. Incărcător

F. Valvă hemostatică

G. Mâner din plastic

*Componentele variază în funcţie de sistemul de livrare. Pentru o listă a componentelor care alcătuiesc fiecare sistem de administrare intravascular Amplatzer™ TorqVue™ Amplatzer™ Trevisio™, vă rugăm să consultaţi informaţiile de comandă din paginile următoare.

INFORMAȚII DE COMANDĂ

AMPLATZER™ TORQVUE™ 45˚ AND 180˚ DELIVERY SYSTEMS

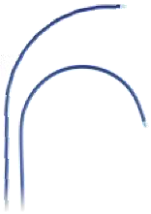
MODEL/REORDER NUMBER	SHEATH SIZE (F)	TIP ANGLE	USEABLE LENGTH (CM)	RECOMMENDED FOR USE WITH
9-ITV06F45/60	6	45°	60	Amplatzer™ Septal Occluder and Muscular VSD Occluder
9-ITV07F45/60	7	45°	60	Amplatzer™ Septal Occluder and Muscular VSD Occluder
9-ITV07F45/80	7	45°	80	Amplatzer™ Septal Occluder and Muscular VSD Occluder
9-ITV08F45/60	8	45°	60	Amplatzer™ Septal Occluder, Cribriform Occluder, PFO Occluder and Muscular VSD Occluder
9-ITV08F45/80	8	45°	80	Amplatzer™ Septal Occluder, Cribriform Occluder, PFO Occluder and Muscular VSD Occluder
9-ITV09F45/80	9	45°	80	Amplatzer™ Septal Occluder, Cribriform Occluder, PFO Occluder, Muscular VSD Occluder and P.I. Muscular VSD Occluder
9-ITV10F45/80	10	45°	80	Amplatzer™ Septal Occluder and P.I. Muscular VSD Occluder
9-ITV12F45/80	12	45°	80	Amplatzer™ Septal Occluder
9-ITV13F45/80a	13	45°	80	Amplatzer™ Septal Occluder
9-ITV05F180/60	5	180°	60	Amplatzer™ Duct Occluder and Muscular VSD Occluder
9-ITV06F180/60	6	180°	60	Amplatzer™ Duct Occluder and Muscular VSD Occluder
9-ITV06F180/80	6	180°	80	Amplatzer™ Duct Occluder and Muscular VSD Occluder
9-ITV07F180/80	7	180°	80	Amplatzer™ Duct Occluder and Muscular VSD Occluder
9-ITV08F180/80	8	180°	80	Amplatzer™ Muscular VSD Occluder
9-ITV09F180/80	9	180°	80	Amplatzer™ Muscular VSD Occluder and P.I. Muscular VSD Occluder

Sistemele de livrare Amplatzer™ TorqVue™ 45˚ și 180˚ includ un cablu de livrare, tecă de livrare, dilatator, valvă hemostatică, încărcător și mâner din plastic.

AMPLATZER™ TREVISIO™ 45˚ DELIVERY SYSTEM

MODEL/REORDER NUMBER	SHEATH SIZE (F)	TIP ANGLE	USEABLE LENGTH (CM)	RECOMMENDED FOR USE WITH
9-ATV06F45/60	6	45°	60	Amplatzer™ Septal Occluder, PFO Occluder, Muscular VSD Occluder
9-ATV07F45/60	7	45°	60	Amplatzer™ Septal Occluder, PFO Occluder, Muscular VSD Occluder
9-ATV07F45/80	7	45°	80	Amplatzer™ Septal Occluder, PFO Occluder, Muscular VSD Occluder
9-ATV08F45/60	8	45°	60	Amplatzer™ Septal Occluder, PFO Occluder, Muscular VSD Occluder
9-ATV08F45/80	8	45°	80	Amplatzer™ Septal Occluder, PFO Occluder, Muscular VSD Occluder
9-ATV09F45/80	9	45°	80	Amplatzer™ Septal Occluder, PFO Occluder, Muscular VSD Occluder
9-ATV10F45/80	10	45°	80	Amplatzer™ Septal Occluder, PFO Occluder, Muscular VSD Occluder
9-ATV12F45/80	12	45°	80	Amplatzer™ Septal Occluder
9-ATV13F45/80	13	45°	80	Amplatzer™ Septal Occluder

INFORMAȚII DE COMANDĂ



AMPLATZER™ TORQVUE™ EXCHANGE SYSTEMS

MODEL/REORDER NUMBER	SHEATH SIZE (F)	TIP ANGLE	USEABLE LENGTH (CM)	RECOMMENDED FOR USE WITH
9-EITV09F45/80	9	45°	80	Amplatzer™ Septal Occluder, Cribriform Occluder, PFO Occluder and Muscular VSD Occluder
9-EITV12F45/80	12	45°	80	Amplatzer™ Septal Occluder, Cribriform Occluder, PFO Occluder and Muscular VSD Occluder
9-EITV06F180/80	6	180°	80	Amplatzer™ Duct Occluder and Muscular VSD Occluder
9-EITV08F180/80	8	180°	80	Amplatzer™ Duct Occluder and Muscular VSD Occluder

Notă: Sistemele de schimb Amplatzer™ TorqVue™ includ o teacă de livrare, dilatator, sârmă de schimb, valvă hemostatică, încărcător și mâner din plastic.

AMPLATZER™ TORQVUE™ LP DELIVERY SYSTEM[A]

MODEL/REORDER NUMBER	SHEATH SIZE (F)	TIP ANGLE	USEABLE LENGTH (CM)	DELIVERY CABLE LENGTH (CM)	RECOMMENDED FOR USE WITH
9-TVLP4F90/060	4	90°	60	160	Amplatzer™ Duct Occluder II
9-TVLP4F90/080	4	90°	80	195	Amplatzer™ Duct Occluder II
9-TVLP5F90/060	5	90°	60	160	Amplatzer™ Duct Occluder II
9-TVLP5F90/080	5	90°	80	195	Amplatzer™ Duct Occluder II

Notă: Sistemul de livrare Amplatzer™ TorqVue™ LP include un cablu de livrare, tecă de livrare, valvă hemostatică, încărcător și mâner din plastic.

AMPLATZER™ TORQVUE™ LP CATHETER[A]

MODEL/REORDER NUMBER	SHEATH SIZE (F)	TIP ANGLE	USEABLE LENGTH (CM)	DELIVERY CABLE LENGTH (CM)	RECOMMENDED FOR USE WITH
9-TVLPC4F90/080	4	90°	80	190	Amplatzer Piccolo™ Occluder

Notă: Cateterul Amplatzer™ TorqVue™ Exchange LP include un cateter de livrare, o valvă hemostatică, un încărcător și o valvă hemostatică cu auto-etanșare.

ORDERING INFORMATION

AMPLATZER™ TORQVUE™ DELIVERY SYSTEM WITH PUSHER CATHETER

MODEL/REORDER NUMBER	SHEATH SIZE (F)	TIP ANGLE	USEABLE LENGTH (CM)	RECOMMENDED FOR USE WITH
9-ITVP07F180/80	7	180°	80	Amplatzer™ Membranous VSD Occluder
9-ITVP08F180/80	8	180°	80	Amplatzer™ Membranous VSD Occluder
9-ITVP09F180/80	9	180°	80	Amplatzer™ Membranous VSD Occluder

Notă: Sistemul de eliberare Amplatzer™ TorqVue™ cu cateter împingător include un cablu de livrare, teacă de livrare, dilatator, valvă hemostatică, încărcător, mâner din plastic și cateter de împingere.

AMPLATZER™ TORQVUE™ 2 DELIVERY SHEATH

MODEL/REORDER NUMBER	SHEATH SIZE (F)	TIP ANGLE	USEABLE LENGTH (CM)	RECOMMENDED USE
9-TV2-05F120	5	Straight	120	Intended to provide a pathway through which devices are introduced within the chambers and coronary vasculature of the heart or in the peripheral vasculature.
9-TV2-06F120	6	Straight	120	
9-TV2-07F120	7	Straight	120	

Notă: Teaca de livrare Amplatzer™ TorqVue™ 2 include o teacă de livrare și un dilatator.

AMPLATZER™ AMULET™ DELIVERY SHEATH

MODEL/REORDER NUMBER	SHEATH SIZE (F)	TIP ANGLE	USEABLE LENGTH (CM)	RECOMMENDED FOR USE WITH
DS-TV45X45-12F-080	12	45° x 45°	80	Amplatzer™ Left Atrial Appendage Occluder
DS-TV45X45-14F-080	14	45° x 45°	80	Amplatzer™ Left Atrial Appendage Occluder

Notă: Teaca de livrare Amplatzer™ Amulet™ include o teacă de livrare și un dilatator. Tecile de livrare 12 și 14 F includ un adaptor de închidere pentru a facilita atașarea componentelor suplimentare ale dispozitivului.

ATENŢIE: Acest produs este destinat utilizării de către sau sub îndrumarea unui medic. Înainte de utilizare, consultaţi Instrucţiunile de utilizare, în interiorul cutiei produsului (dacă este disponibil) sau la eifu.abbottvascular.com sau la edical.abbott/manuals pentru informaţii mai detaliate despre indicaţii, contraindicaţii, avertismente, precauţii şi evenimente adverse.

Informaţiile conţinute aici pentru DISTRIBUŢIE NUMAI în afara S.U.A. Verificaţi întotdeauna starea de reglementare a dispozitivului din regiunea dvs.

Ilustraţiile sunt doar reprezentări ale artiştilor şi nu trebuie considerate desene sau fotografii de inginerie.

Abbott
3200 Lakeside Dr., Santa Clara, CA 95054, USA Tel: 1 800 227 9902
www.cardiovascular.abbott

MAT-2002247 v2.0 | Item approved for Global OUS use only.

Abbott

OBTURATOARE DE DUCT AMPLATZER™

INDICAȚII

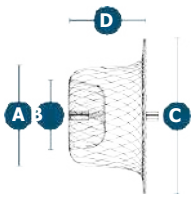
Obturatorul de duct Amplatzer™ și Obturatorul de duct Amplatzer™ II sunt dispozitive de ocluzie percutanată, transcateter, destinate închiderii nechirurgicale a unui canal arterial permeabil (PDA) la pacienții cu o greutate de 6 kg sau mai mult.

Ocluderul Amplatzer Piccolo™ este un dispozitiv de ocluzie percutanat, transcateter, destinat închiderii nechirurgicale a unui canal arterial permeabil (PDA) la pacienții cu o greutate de 700 de grame și mai mult la momentul procedurii.

INFORMAȚII DE SIGURANȚĂ IRM

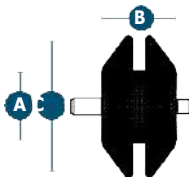
Prin teste non-clinice, s-a dovedit că dispozitivele AMPLATZER™ sunt condiționate RM. Consultați Instrucțiunile de utilizare respective pentru a obține informații de scanare IRM mai detaliate.

Calitatea imaginii RM poate fi compromisă dacă zona de interes se află exact în aceeași zonă sau relativ aproape de poziția dispozitivului. Prin urmare, poate fi necesară optimizarea parametrilor de imagistică RM pentru a compensa prezența acestui implant.



SPECIFICAȚII DISPOZITIV ȘI COMPATIBILITATEA SISTEMULUI DE LIVRARE

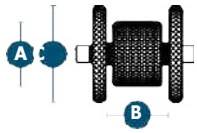
Obturatorul de duct Amplatzer™					Sistemul de livrare Amplatzer™ TorqVue™ 180˚			
Număr model/ de comandă	Diametru dispozitiv la aorta descendentă (mm) A	Diametru dispozitiv la artera pulmonară (mm) B	Diametru cămașă de retenție (mm) C	Lungime dispozitiv (mm) D	Număr model/ de comandă	Dimensiune minimă recomandată teacă	Diametru interior teacă (mm [inch])	Diametru exterior teacă (mm [inch])
9-PDA-003	5	4	9	5	9-ITV05F180/60	5 F	1.83 [0.072]	2.51 [0.099]
9-PDA-004	6	4	10	7	9-ITV06F180/80	6 F	2.11 [0.083]	2.79 [0.110]
9-PDA-005	8	6	12	7				
9-PDA-006	10	8	16	8				
9-PDA-007	12	10	18	8	9-ITV07F180/80	7 F	2.44 [0.096]	3.18 [0.125]
9-PDA-008	14	12	20	8				
9-PDA-009	16	14	22	8				



SPECIFICAȚII DISPOZITIV ȘI COMPATIBILITATEA SISTEMULUI DE LIVRARE

Obturatorul de duct Amplatzer™ II — Sistemul de livrare Amplatzer™ TorqVue™ LP

Număr model/ de comandă	Diametru zonă mediană (mm) A	Lungime dispozitiv (mm) B	Diametru disc (mm) C	Număr model/ de comandă	Dimensiune minimă recomandată cateter	Diametru interior cateter (mm [inch])	Diametru exterior cateter (mm [inch])
9-PDA2-03-04	3	4	9	9-TVLP4F90/060 sau 9-TVLP4F90/080	4 F	1.17 [0.046]	1.40 [0.055]
9-PDA2-03-06	3	6	9				
9-PDA2-04-04	4	4	10				
9-PDA2-04-06	4	6	10				
9-PDA2-05-04	5	4	11	9-TVLP5F90/060 sau 9-TVLP5F90/080	5 F	1.50 [0.059]	1.73 [0.068]
9-PDA2-05-06	5	6	11				
9-PDA2-06-04	6	4	12				
9-PDA2-06-06	6	6	12				



SPECIFICAȚII DISPOZITIV ȘI COMPATIBILITATEA SISTEMULUI DE LIVRARE

Ocluderul Amplatzer™ Piccolo™ — Cateterul Amplatzer™ TorqVue™ LP

Număr model/ de comandă	Diametru zonă mediană (mm) A	Lungime între discurile de retenție (mm) B	Diametru disc (mm) C	Număr model/ de comandă	Dimensiune minimă recomandată cateter	Diametru interior cateter (mm [inch])	Diametru exterior cateter (mm [inch])
9-PDAP-03-02-L	4.00(0.157)	3.00(0.118)	2.00(0.079)	9-TVLPC4F90/080	4 F	1.17 [0.046]	1.4 [0.055]
9-PDAP-03-04-L	4.00(0.157)	3.00(0.118)	4.00(0.157)				
9-PDAP-03-06-L	4.00(0.157)	3.00(0.118)	6.00(0.236)				
9-PDAP-04-02-L	5.25(0.207)	4.00(0.157)	2.00(0.079)				
9-PDAP-04-04-L	5.25(0.207)	4.00(0.157)	4.00(0.157)				
9-PDAP-04-06-L	5.25(0.207)	4.00(0.157)	6.00(0.236)				
9-PDAP-05-02-L	6.50(0.256)	5.00(0.197)	2.00(0.079)				
9-PDAP-05-04-L	6.50(0.256)	5.00(0.197)	4.00(0.157)				
9-PDAP-05-06-L	6.50(0.256)	5.00(0.197)	6.00(0.236)				

SPECIFICAȚII PRODUSE AUXILIARE

Firul de ghidare Amplatzer™

Număr model/de comandă	Diametru (inch)	Corp	Descriere vârf	Lungime utilă (cm)
9-GW-001	0.035	Super rigid	7.5 mm, vârf J modificat	260

INFORMAȚII PRODUSE FĂRĂ LATEX

Aceste produse Amplatzer™ nu conțin latex.

ATENȚIE: Acest produs este destinat utilizării de către sau sub îndrumarea unui medic. Înainte de utilizare, consultați Instrucțiunile de utilizare din interiorul cutiei produsului (dacă sunt disponibile) sau la eifu.abbottvascular.com sau la medical.abbott/manuals pentru informații mai detaliate despre indicații, contraindicații, avertismente, precauții și evenimente adverse.

Informațiile conținute aici sunt destinate **NUMAI DISTRIBUȚIEI în afara S.U.A.** Verificați întotdeauna starea de reglementare a dispozitivului din regiunea dvs.

Ilustrațiile sunt doar reprezentări artistice și nu trebuie considerate ca fiind fotografii sau desene tehnice.

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

37971 MAT-2002324 v2.0 | Articol aprobat numai pentru Global OUS.

Abbott

AMPLATZER™ DUCT OCCLUDERS

INDICATIONS

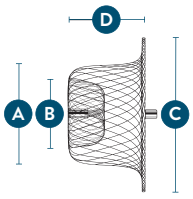
The Amplatzer™ Duct Occluder and Amplatzer™ Duct Occluder II are percutaneous, transcatheter occlusion devices intended for the nonsurgical closure of a patent ductus arteriosus (PDA) in patients with a weight of 6 kg or larger.

The Amplatzer Piccolo™ Occluder is a percutaneous, transcatheter occlusion device intended for the nonsurgical closure of a patent ductus arteriosus (PDA) in patients with a weight 700 grams and up at time of the procedure.

MRI SAFETY INFORMATION

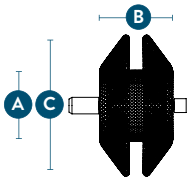
Through nonclinical testing, Amplatzer™ devices have been shown to be MR Conditional. Refer to the appropriate Instructions for Use to obtain more detailed MRI scanning information.

MR image quality may be compromised if the area of interest is in the same area as or relatively close to the position of the device. Therefore, it may be necessary to optimize MR imaging parameters for the presence of this implant.



DEVICE SPECIFICATIONS AND DELIVERY SYSTEM COMPATIBILITY

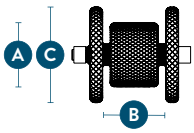
Amplatzer™ Duct Occluder					Amplatzer™ TorqVue™ 180° Delivery System			
Model/ Reorder Number	Device Diameter at Descending Aorta (mm) A	Device Diameter at Pulmonary Artery (mm) B	Retention Skirt Diameter (mm) C	Device Length (mm) D	Model/Reorder Number	Minimum Recommended Sheath Size	Sheath Inner Diameter (mm [inch])	Sheath Outer Diameter (mm [inch])
9-PDA-003	5	4	9	5	9-ITV05F180/60	5 F	1.83 [0.072]	2.51 [0.099]
9-PDA-004	6	4	10	7				
9-PDA-005	8	6	12	7	9-ITV06F180/80	6 F	2.11 [0.083]	2.79 [0.110]
9-PDA-006	10	8	16	8				
9-PDA-007	12	10	18	8				
9-PDA-008	14	12	20	8	9-ITV07F180/80	7 F	2.44 [0.096]	3.18 [0.125]
9-PDA-009	16	14	22	8				



DEVICE SPECIFICATIONS AND DELIVERY SYSTEM COMPATIBILITY

Amplatzer™ Duct Occluder II — Amplatzer™ TorqVue™ LP Delivery System

Model/Reorder Number	Waist Diameter (mm) A	Device Length (mm) B	Disc Diameter (mm) C	Model/Reorder Number	Minimum Recommended Catheter Size	Catheter Inner Diameter (mm [inch])	Catheter Outer Diameter (mm [inch])
9-PDA2-03-04	3	4	9	9-TVLP4F90/060 or 9-TVLP4F90/080	4 F	1.17 [0.046]	1.40 [0.055]
9-PDA2-03-06	3	6	9				
9-PDA2-04-04	4	4	10				
9-PDA2-04-06	4	6	10				
9-PDA2-05-04	5	4	11	9-TVLP5F90/060 or 9-TVLP5F90/080	5 F	1.50 [0.059]	1.73 [0.068]
9-PDA2-05-06	5	6	11				
9-PDA2-06-04	6	4	12				
9-PDA2-06-06	6	6	12				



DEVICE SPECIFICATIONS AND DELIVERY SYSTEM COMPATIBILITY

Amplatzer™ Piccolo™ Occluder — Amplatzer™ TorqVue™ LP Catheter

Model/Reorder Number	Waist Diameter (mm) A	Length Between Retention Discs (mm) B	Disc Diameter (mm) C	Model/Reorder Number	Minimum Recommended Catheter Size	Catheter Inner Diameter (mm [inch])	Catheter Outer Diameter (mm [inch])
9-PDAP-03-02-L	4.00(0.157)	3.00(0.118)	2.00(0.079)	9-TVLPC4F90/080	4 F	1.17 [0.046]	1.4 [0.055]
9-PDAP-03-04-L	4.00(0.157)	3.00(0.118)	4.00(0.157)				
9-PDAP-03-06-L	4.00(0.157)	3.00(0.118)	6.00(0.236)				
9-PDAP-04-02-L	5.25(0.207)	4.00(0.157)	2.00(0.079)				
9-PDAP-04-04-L	5.25(0.207)	4.00(0.157)	4.00(0.157)				
9-PDAP-04-06-L	5.25(0.207)	4.00(0.157)	6.00(0.236)				
9-PDAP-05-02-L	6.50(0.256)	5.00(0.197)	2.00(0.079)				
9-PDAP-05-04-L	6.50(0.256)	5.00(0.197)	4.00(0.157)				
9-PDAP-05-06-L	6.50(0.256)	5.00(0.197)	6.00(0.236)				

ANCILLARY PRODUCT SPECIFICATIONS

Amplatzer™ Guidewire

Model/Reorder Number	Diameter (inch)	Body	Tip Description	Useable Length (cm)
9-GW-001	0.035	Super Stiff	7.5 mm, Modified J-tip	260

LATEX-FREE INFORMATION

These Amplatzer™ products do not contain latex.

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.

Information contained herein for **DISTRIBUTION outside of the U.S. ONLY**. Always check the regulatory status of the device in your region.

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

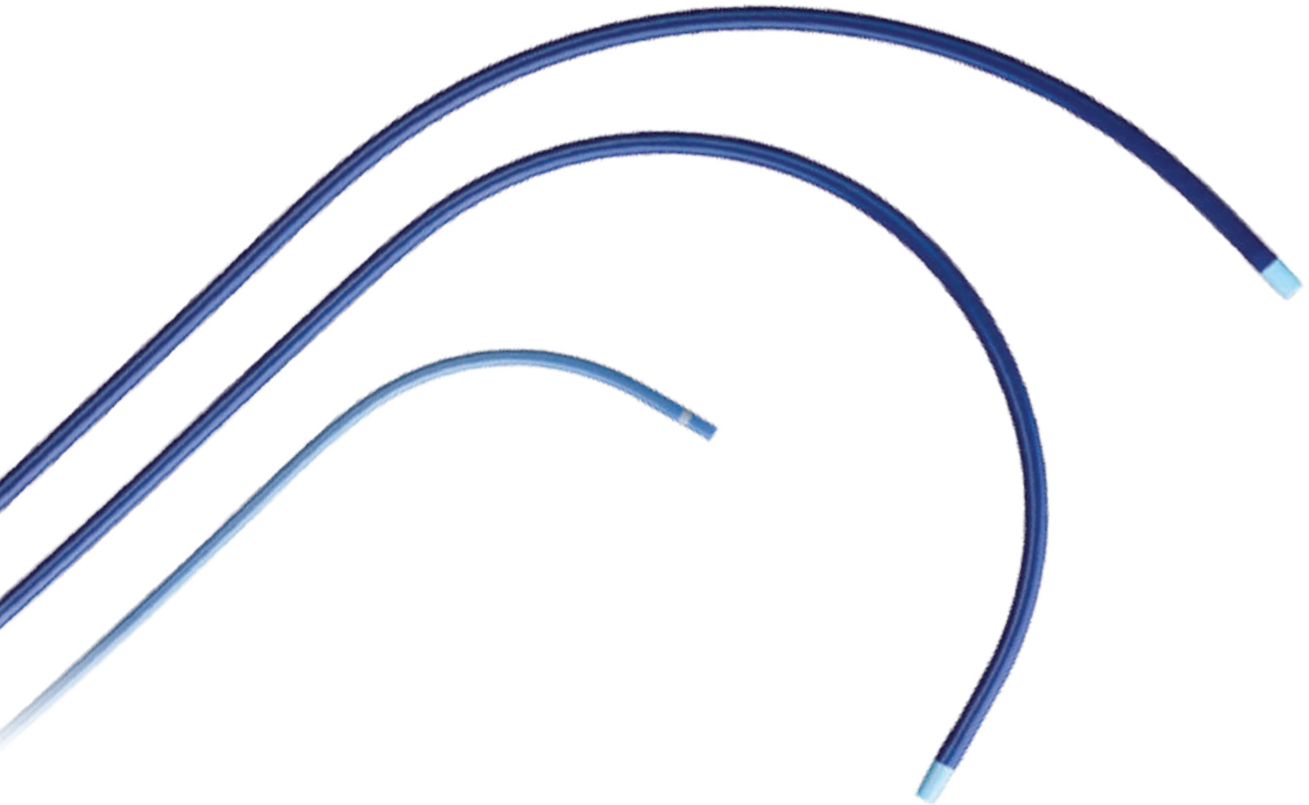
Abbott
3200 Lakeside Dr, Santa Clara, CA 95054, USA Tel: 1.800.227.9902
www.cardiovascular.abbott

37971 MAT-2002324 v2.0 | Item approved for Global OUS only.

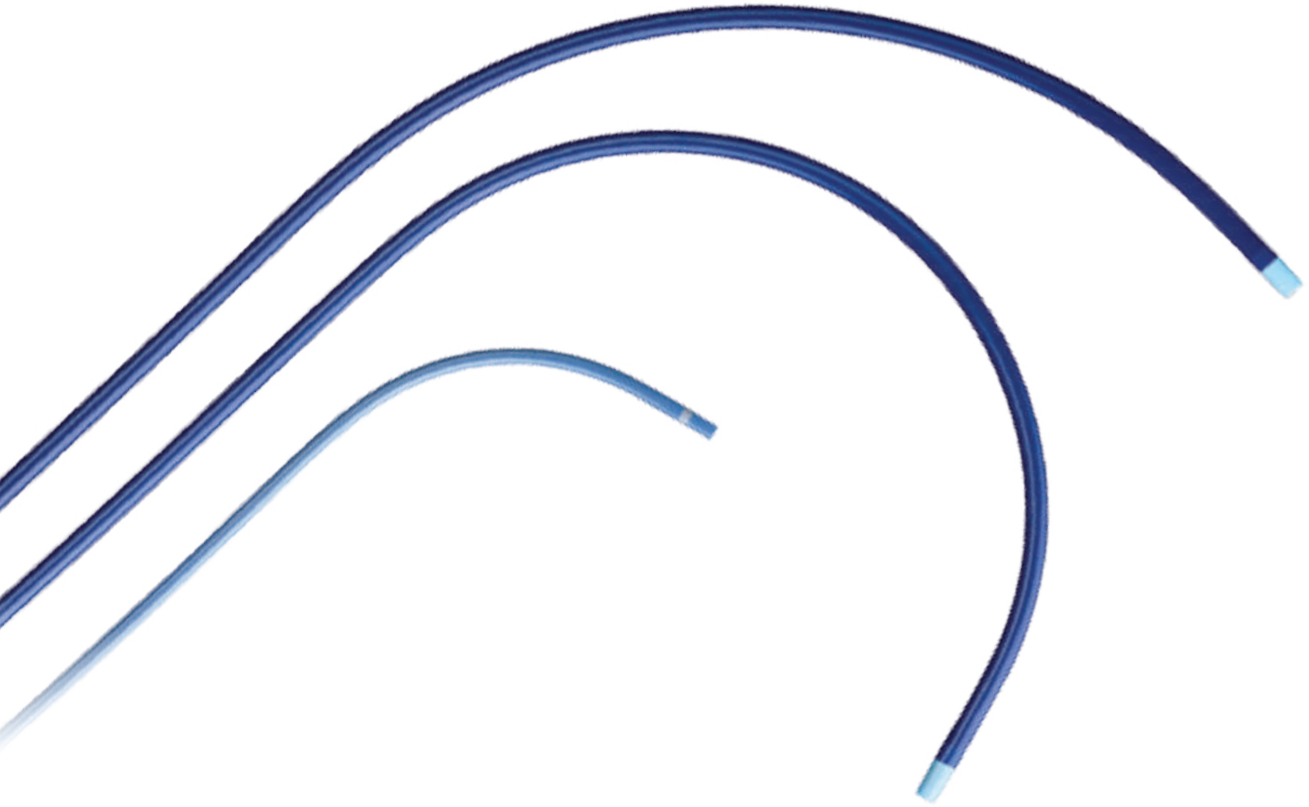
Abbott

Abbott

AMPLATZER™ TORQVUE™ AND AMPLATZER™ TREVISIO™ INTRAVASCULAR DELIVERY SYSTEMS



Information contained herein for **DISTRIBUTION outside of the U.S. ONLY**.
Always check the regulatory status of the device in your region.



REINFORCED
POLYMER DELIVERY
SYSTEMS PROVIDING
VERSATILE, CONTROLLED
DEVICE DELIVERY

CONTROL

Amplatzer™ TorqVue™ and Amplatzer™ Trevisio™ Intravascular Delivery Systems are designed to provide a controlled pathway to the occlusion site.

Reinforced Polymer Delivery Sheath

- Engineered to provide added kink resistance through an internal stainless steel braid[1]

Shaft Material Transitions From a Stiffer Proximal Section to a Softer Distal Section

- Built to ease pushability and maneuverability in tortuous anatomy

Soft, Radiopaque Tip

- Designed to minimize the risk of vessel damage and improve visualization of position

CONFIDENCE

Sheath performance is critical. Amplatzer TorqVue and Amplatzer Trevisio Intravascular Delivery Systems are designed to ease positioning and deployment of Amplatzer™ Occluders.

Radiopaque Distal Tip

- Facilitates precise positioning and accurate device placement

Low-friction PTFE Sheath Lining

- Allows for smooth, controlled delivery

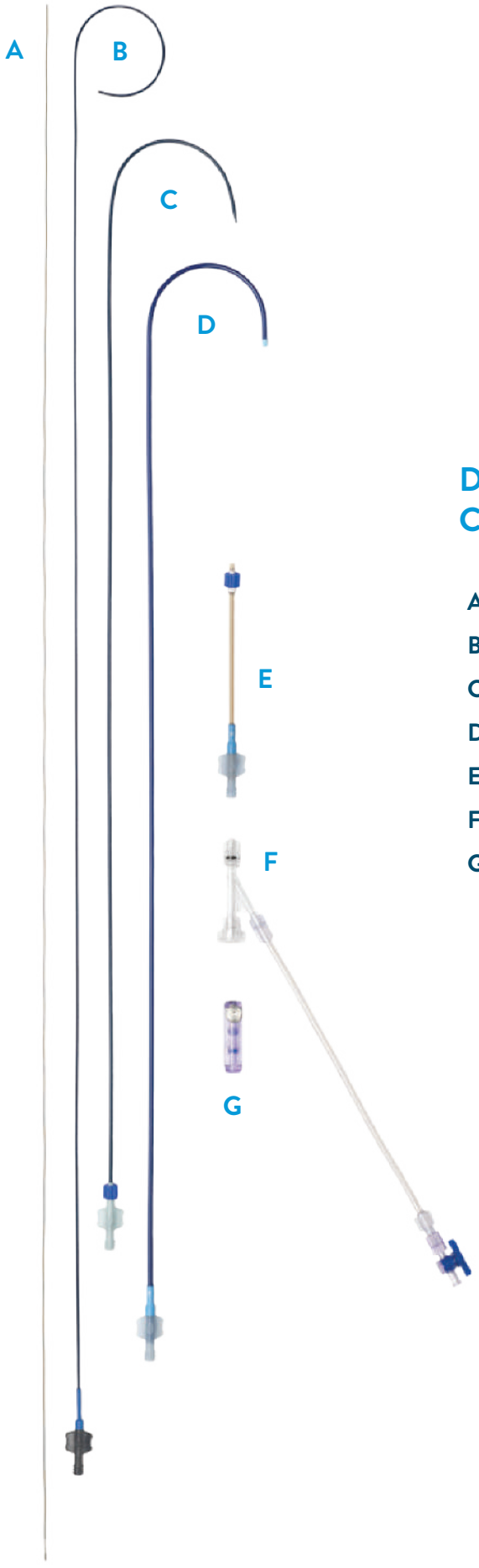
Semi-clear Loader

- Assists in the confirmation of device collapse, flushing and air removal

Delivery Cables and Wires in Varying Gages and Flexibility

- Are specifically designed to aid in the delivery of each Amplatzer Occluder

1. Test(s) performed by and data on file at Abbott.



DELIVERY SYSTEM COMPONENTS*

A. Delivery Cable
B. Pusher Catheter
C. Dilator
D. Delivery Sheath
E. Loader
F. Hemostasis Valve
G. Plastic Vise

*Components vary by delivery system. For a list of components that make up each Amplatzer™ TorqVue™ Amplatzer™ Trevisio™ Intravascular Delivery System, please see the ordering information on the following pages.

ORDERING INFORMATION

AMPLATZER™ TORQVUE™ 45° AND 180° DELIVERY SYSTEMS

MODEL/REORDER NUMBER	SHEATH SIZE (F)	TIP ANGLE	USEABLE LENGTH (CM)	RECOMMENDED FOR USE WITH
9-ITV06F45/60	6	45°	60	Amplatzer™ Septal Occluder and Muscular VSD Occluder
9-ITV07F45/60	7	45°	60	Amplatzer™ Septal Occluder and Muscular VSD Occluder
9-ITV07F45/80	7	45°	80	Amplatzer™ Septal Occluder and Muscular VSD Occluder
9-ITV08F45/60	8	45°	60	Amplatzer™ Septal Occluder, Cribriform Occluder, PFO Occluder and Muscular VSD Occluder
9-ITV08F45/80	8	45°	80	Amplatzer™ Septal Occluder, Cribriform Occluder, PFO Occluder and Muscular VSD Occluder
9-ITV09F45/80	9	45°	80	Amplatzer™ Septal Occluder, Cribriform Occluder, PFO Occluder, Muscular VSD Occluder and P.I. Muscular VSD Occluder
9-ITV10F45/80	10	45°	80	Amplatzer™ Septal Occluder and P.I. Muscular VSD Occluder
9-ITV12F45/80	12	45°	80	Amplatzer™ Septal Occluder
9-ITV13F45/80a	13	45°	80	Amplatzer™ Septal Occluder
9-ITV05F180/60	5	180°	60	Amplatzer™ Duct Occluder and Muscular VSD Occluder
9-ITV06F180/60	6	180°	60	Amplatzer™ Duct Occluder and Muscular VSD Occluder
9-ITV06F180/80	6	180°	80	Amplatzer™ Duct Occluder and Muscular VSD Occluder
9-ITV07F180/80	7	180°	80	Amplatzer™ Duct Occluder and Muscular VSD Occluder
9-ITV08F180/80	8	180°	80	Amplatzer™ Muscular VSD Occluder
9-ITV09F180/80	9	180°	80	Amplatzer™ Muscular VSD Occluder and P.I. Muscular VSD Occluder

Note: Amplatzer™ TorqVue™ 45° and 180° Delivery Systems include a delivery cable, delivery sheath, dilator, hemostasis valve, loader and plastic vise.

AMPLATZER™ TREVISIO™ 45° DELIVERY SYSTEM

MODEL/REORDER NUMBER	SHEATH SIZE (F)	TIP ANGLE	USEABLE LENGTH (CM)	RECOMMENDED FOR USE WITH
9-ATV06F45/60	6	45°	60	Amplatzer™ Septal Occluder, PFO Occluder, Muscular VSD Occluder
9-ATV07F45/60	7	45°	60	Amplatzer™ Septal Occluder, PFO Occluder, Muscular VSD Occluder
9-ATV07F45/80	7	45°	80	Amplatzer™ Septal Occluder, PFO Occluder, Muscular VSD Occluder
9-ATV08F45/60	8	45°	60	Amplatzer™ Septal Occluder, PFO Occluder, Muscular VSD Occluder
9-ATV08F45/80	8	45°	80	Amplatzer™ Septal Occluder, PFO Occluder, Muscular VSD Occluder
9-ATV09F45/80	9	45°	80	Amplatzer™ Septal Occluder, PFO Occluder, Muscular VSD Occluder
9-ATV10F45/80	10	45°	80	Amplatzer™ Septal Occluder, PFO Occluder, Muscular VSD Occluder
9-ATV12F45/80	12	45°	80	Amplatzer™ Septal Occluder
9-ATV13F45/80	13	45°	80	Amplatzer™ Septal Occluder

ORDERING INFORMATION

AMPLATZER™ TORQVUE™ EXCHANGE SYSTEMS

MODEL/REORDER NUMBER	SHEATH SIZE (F)	TIP ANGLE	USEABLE LENGTH (CM)	RECOMMENDED FOR USE WITH
9-EITV09F45/80	9	45°	80	Amplatzer™ Septal Occluder, Cribriform Occluder, PFO Occluder and Muscular VSD Occluder
9-EITV12F45/80	12	45°	80	Amplatzer™ Septal Occluder, Cribriform Occluder, PFO Occluder and Muscular VSD Occluder
9-EITV06F180/80	6	180°	80	Amplatzer™ Duct Occluder and Muscular VSD Occluder
9-EITV08F180/80	8	180°	80	Amplatzer™ Duct Occluder and Muscular VSD Occluder

Note: Amplatzer™ TorqVue™ Exchange Systems include a delivery sheath, dilator, exchange wire, hemostasis valve, loader and plastic vise.

AMPLATZER™ TORQVUE™ LP DELIVERY SYSTEM[A]

MODEL/REORDER NUMBER	SHEATH SIZE (F)	TIP ANGLE	USEABLE LENGTH (CM)	DELIVERY CABLE LENGTH (CM)	RECOMMENDED FOR USE WITH
9-TVLP4F90/060	4	90°	60	160	Amplatzer™ Duct Occluder II
9-TVLP4F90/080	4	90°	80	195	Amplatzer™ Duct Occluder II
9-TVLP5F90/060	5	90°	60	160	Amplatzer™ Duct Occluder II
9-TVLP5F90/080	5	90°	80	195	Amplatzer™ Duct Occluder II

Note: Amplatzer™ TorqVue™ LP Delivery System includes a delivery cable, delivery catheter, hemostasis valve, loader and plastic vise.

AMPLATZER™ TORQVUE™ LP CATHETER[A]

MODEL/REORDER NUMBER	SHEATH SIZE (F)	TIP ANGLE	USEABLE LENGTH (CM)	DELIVERY CABLE LENGTH (CM)	RECOMMENDED FOR USE WITH
9-TVLPC4F90/080	4	90°	80	190	Amplatzer Piccolo™ Occluder

Note: Amplatzer™ TorqVue™ Exchange LP Catheter includes a delivery catheter, hemostasis valve, loader and self-sealing hemostasis valve.

ORDERING INFORMATION

AMPLATZER™ TORQVUE™ DELIVERY SYSTEM WITH PUSHER CATHETER

MODEL/REORDER NUMBER	SHEATH SIZE (F)	TIP ANGLE	USEABLE LENGTH (CM)	RECOMMENDED FOR USE WITH
9-ITVP07F180/80	7	180°	80	Amplatzer™ Membranous VSD Occluder
9-ITVP08F180/80	8	180°	80	Amplatzer™ Membranous VSD Occluder
9-ITVP09F180/80	9	180°	80	Amplatzer™ Membranous VSD Occluder

Note: Amplatzer™ TorqVue™ Delivery System with Pusher Catheter includes a delivery cable, delivery sheath, dilator, hemostasis valve, loader, plastic vise and pusher catheter.

AMPLATZER™ TORQVUE™ 2 DELIVERY SHEATH

MODEL/REORDER NUMBER	SHEATH SIZE (F)	TIP ANGLE	USEABLE LENGTH (CM)	RECOMMENDED USE
9-TV2-05F120	5	Straight	120	Intended to provide a pathway through which devices are introduced within the chambers and coronary vasculature of the heart or in the peripheral vasculature.
9-TV2-06F120	6	Straight	120	
9-TV2-07F120	7	Straight	120	

Note: The Amplatzer™ TorqVue™ 2 Delivery Sheath includes a delivery sheath and dilator.

AMPLATZER™ AMULET™ DELIVERY SHEATH

MODEL/REORDER NUMBER	SHEATH SIZE (F)	TIP ANGLE	USEABLE LENGTH (CM)	RECOMMENDED FOR USE WITH
DS-TV45X45-12F-080	12	45° x 45°	80	Amplatzer™ Left Atrial Appendage Occluder
DS-TV45X45-14F-080	14	45° x 45°	80	Amplatzer™ Left Atrial Appendage Occluder

Note: The Amplatzer™ Amulet™ Delivery Sheath includes a delivery sheath and dilator. The 12 and 14 F delivery sheaths include a flush adapter to facilitate attachment of additional device components.

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.

Information contained herein for **DISTRIBUTION outside of the U.S. ONLY**. Always check the regulatory status of the device in your region.

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

Abbott
3200 Lakeside Dr., Santa Clara, CA 95054, USA Tel: 1 800 227 9902
www.cardiovascular.abbott

MAT-2002247 v2.0 | Item approved for Global OUS use only.

Abbott

AMPLATZER™ GUIDEWIRES

CONCEPUT INTUITIV PENTRU O GAMĂ LARGĂ DE ANATOMII VASCULARE

Amplatzer Guidewires oferă suport pentru cateter și au capacitate de urmărire pentru o gamă largă de anatomii vasculare. Ele sunt proiectate și testate pentru a funcționa împreună cu dispozitivele de închudere Amplatzer.

Informațiile conținute aici pentru DISTRIBUȚIE NUMAI în afara S.U.A. Verificați întotdeauna starea de reglementare a dispozitivului din regiunea dvs.

Abbott

GUIDEWIRES AMPLATZER OFERĂ LUBRIFIERE ŞI POZIŢIONARE EXCELENTĂ **CAPACITĂŢI CU MINIME INTERFERENŢE CU SISTEMUL VASCULAR.**

DESIGN INTUITIV

Oţel inoxidabil

- Permite o capacitate de poziţionare îmbunătăţită *

Acoperire cu PTFE

- Oferă lubrifiere pentru o navigare lină prin anatomie sinuoasă *

Design cu vârf J

- Reduce riscul de deteriorare a peretelui intern pentru poziţionarea atraumatică*

Lungime de schimb până la 300 cm

- Asigură o lungime adecvată pentru schimbul unei game largi de dispozitive peste fir *

Proprietăţi Patru curbe

- Proiectat pentru a atinge anatomia vizată *

Tipul corpului

- Super Stiff
  - Oferă suport pentru urmărirea sistemului de livrare Amplatzer TorqVue™ la locul de tratament*

* Teste efectuate de şi date în dosar la Abbott

INFORMATII PENTRU COMANDA

CARACTERISTICI AMPLATZER GUIDEWIRE

Model / Număr comană	Diametru (inch)	Corp	Descriere Vârf	Lungime utilizabilă (cm)
9-GW-001	0.035	Super Stiff	7.5 mm, Modified J-tip	260
9-GW-002	0.035	Super Stiff	1.5 mm, Modified J-tip	260
9-GW-003	0.035	Super Stiff	6 mm, J-tip	300

GHIDURILE AMPLATZER SUNT PROIECTE PENTRU A FI UTILIZATE CU URȘĂMĂTOARELE AMPLATZER OCCLUDERE

Model	Use with the following Amplatzer™ Occluders
9-GW-001	Amplatzer™ Duct Occluder Amplatzer™ Duct Occluder II Amplatzer Piccolo™ Occluder
9-GW-002	Amplatzer™ Septal Occluder Amplatzer™ Cribriform Occluder Multi-Fenestrated Septal Occluder Amplatzer™ Talisman™ PFO Occluder Amplatzer™ Amulet™ Left Atrial Appendage Occluder
9-GW-003	Amplatzer™ Muscular VSD Occluder Amplatzer™ P.I. Muscular VSD Occluder

Abbott se concentrează pe reducerea riscului prin găsirea continuă **a modalităților de a pune mai mult control în mâinile celor care salvează și îmbunătățesc vieți.**

ATENȚIE: Acest produs este destinat utilizării de către sau sub îndrumarea unui medic. Înainte de utilizare, consultați Instrucțiunile de utilizare, în cutia produsului (dacă este disponibil) sau la eifu. abbottvascular.com sau la medical.abbott/manuals pentru informații mai detaliate despre indicații, contraindicații, avertismente, precauții și evenimente adverse

Informațiile conținute aici pentru DISTRIBUȚIE NUMAI în afara S.U.A. Verificați întotdeauna starea de reglementare a dispozitivului din regiunea dvs.

Ilustrațiile sunt doar reprezentări ale artiștilor și nu trebuie considerate desene sau fotografii de inginerie. Fotografii din dosar la Abbott.

Abbott
3200 Lakeside Dr, Santa Clara, CA 95054, USA

www.structuralheart.abbott

Abbott

AMPLATZER™ GUIDEWIRES

INTUITIVELY DESIGNED FOR A WIDE RANGE OF VASCULAR ANATOMY

Amplatzer Guidewires offer catheter support and tracking capabilities for a wide range of vascular anatomy. They are designed and tested to perform in conjunction with Amplatzer occluders.

Abbott

AMPLATZER GUIDEWIRES OFFER EXCELLENT LUBRICITY AND POSITIONING **CAPABILITIES WITH MINIMAL INTERFERENCE TO VASCULATURE.**

INTUITIVELY DESIGNED

Stainless Steel

- Allows for enhanced positing capability*

PTFE-coating

- Provides lubricity for smooth navigation through tortuous anatomy*

J-tip Design

- Reduces the risk of internal wall damage for atraumatic positioning*

Exchange Length up to 300 cm

- Assures adequate length for exchange of a wide variety of devices over the wire*

Four Curve Properties

- Designed to reach targeted anatomy*

Body Type

- Super Stiff
  - Provides support to track the Amplatzer TorqVue™ Delivery System to the treatment site*

* Test(s) performed by and data on file at Abbott.

Information contained herein for **DISTRIBUTION outside of the U.S. ONLY**. Always check the regulatory status of the device in your region.

ORDERING INFORMATION

AMPLATZER GUIDEWIRE SPECIFICATIONS

Model / Reorder Number	Diameter (inch)	Body	Tip Description	Usable Length (cm)
9-GW-001	0.035	Super Stiff	7.5 mm, Modified J-tip	260
9-GW-002	0.035	Super Stiff	1.5 mm, Modified J-tip	260
9-GW-003	0.035	Super Stiff	6 mm, J-tip	300

AMPLATZER GUIDEWIRES ARE DESIGNED TO BE USED WITH THE FOLLOWING AMPLATZER OCCLUDERS.

Model	Use with the following Amplatzer™ Occluders
9-GW-001	Amplatzer™ Duct Occluder Amplatzer™ Duct Occluder II Amplatzer Piccolo™ Occluder
9-GW-002	Amplatzer™ Septal Occluder Amplatzer™ Cribriform Occluder Multi-Fenestrated Septal Occluder Amplatzer™ Talisman™ PFO Occluder Amplatzer™ Amulet™ Left Atrial Appendage Occluder
9-GW-003	Amplatzer™ Muscular VSD Occluder Amplatzer™ P.I. Muscular VSD Occluder

Abbott is focused on reducing risk by continuously finding **ways to put more control into the hands of those who save and enhance lives.**

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.

Information contained herein for **DISTRIBUTION outside of the U.S. ONLY**. Always check the regulatory status of the device in your region.

Illustrations are artist's representations only and should not be considered as engineering drawings or photographs. Photo(s) on file at Abbott.

Abbott
3200 Lakeside Dr, Santa Clara, CA 95054, USA

www.structuralheart.abbott

Abbott

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-ITV07F45/60 9-ITV07F45/80 9-ITV08F45/60 9-ITV08F45/80 9-ITV09F45/80 9-ITV10F45/80 9-ITV12F45/80 9-ITV13F45/80 9-ITV05F180/60 9-ITV06F180/60 9-ITV06F180/80 9-ITV07F180/80 9-ITV08F180/80 9-ITV09F180/80	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-ATV07F45/60 9-ATV07F45/80 9-ATV08F45/60 9-ATV08F45/80 9-ATV09F45/80 9-ATV10F45/80 9-ATV12F45/80 9-ATV13F45/80	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

April 21, 2020
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**

...making excellence a habit.™

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

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

...making excellence a habit.™

EC Design-Examination Certificate

Supplementary Information to CE 694956

Issued To:

Abbott Medical
5050 Nathan Lane North
Plymouth
Minnesota
55442
USA

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

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

...making excellence a habit.™

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 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** Date: **2020-04-20** Expiry Date: **2023-02-23**

...making excellence a habit.™

EC Design-Examination Certificate

Supplementary Information to CE 694956

Issued To:

Abbott Medical
5050 Nathan Lane North
Plymouth
Minnesota
55442
USA

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

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

...making excellence a habit.™

EC Design-Examination Certificate

Supplementary Information to CE 694956

Issued To:

Abbott Medical
5050 Nathan Lane North
Plymouth
Minnesota
55442
USA

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**

...making excellence a habit.™

EC Design-Examination Certificate

Supplementary Information to CE 694956

Issued To:

Abbott Medical
5050 Nathan Lane North
Plymouth
Minnesota
55442
USA

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**

...making excellence a habit.™

EC Design-Examination Certificate

Supplementary Information to CE 694956

Issued To:

Abbott Medical
5050 Nathan Lane North
Plymouth
Minnesota
55442
USA

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**

...making excellence a habit.™

Declarație de conformitate ABT

Abbott Medical (ABT) declară prin prezenta că următoarele unități și produse ABT respectă prevederile aplicabile din anexa II la Directiva privind dispozitivele medicale (MDD) 93/42/CEE. Toate documentele justificative sunt păstrate în incinta ABT. Declarăm că nu a fost depusă nicio cerere la niciun alt organism notificat pentru aceleași produse. Această declarație este eliberată sub răspunderea exclusivă a producătorului. Această declarație înlocuiește orice declarație emisă anterior pentru același produs (aceleași produse).

Adresă producător:	Abbott Medical 5050 Nathan Lane North Plymouth, Minnesota 55442, SUA
Reprezentant european:	Abbott Medical The Corporate Village Da Vincilaan 11 Box F1 1935 Zaventem, Belgia
Tip produs:	Set de livrare ocluzor cardiac
Nume produs:	Sistem de livrare TorqVue Amplatzer Sistem de schimb TorqVue Amplatzer Teacă de livrare TorqVue 2 Amplatzer Sistem de livrare TorqVue LP Amplatzer Cateter TorqVue LP Amplatzer Sistem de livrare TorqVue Amplatzer cu cateter împingător Teacă de livrare TorqVue 45°x45° Amplatzer Teacă de livrare Amulet Amplatzer

Semnătură:

_____ _____

Gabrielle Zaeska
Manager, Reglementare

Data emiterii

Declarație de conformitate ABT

Nr. model:

Produs	Numere model	Dată marcaj CE original
Sistem de livrare TorqVue Amplatzer	9-ITV06F45/60 9-ITV07F45/60 9-ITV07F45/80 9-ITV08F45/60 9-ITV08F45/80 9-ITV09F45/80 9-ITV10F45/80 9-ITV12F45/80 9-ITV13F45/80 9-ITV05F180/60 9-ITV06F180/60 9-ITV06F180/80 9-ITV07F180/80 9-ITV08F180/80 9-ITV09F180/80	10 octombrie 2005
Sistem de schimb TorqVue Amplatzer	9-EITV09F45/80 9-EITV12F45/80 9-EITV06F180/80 9-EITV08F180/80 9-EITV10F180/80	10 octombrie 2005
Teacă de livrare TorqVue 2 Amplatzer	9-TV2-05F120 9-TV2-06F120 9-TV2-07F120	19 februarie 2010
Sistem de livrare TorqVue LP Amplatzer	9-TVLP4F90/060 9-TVLP4F90/080 9-TVLP5F90/060 9-TVLP5F90/080	07 februarie 2008
Cateter TorqVue LP Amplatzer	9-TVLPC4F90/080	28 aprilie 2011
Sistem de livrare TorqVue Amplatzer cu cateter împingător	9-ITVP07F-180/80 9-ITVP08F-180/80 9-ITVP09F-180/80	21 iunie 2011
Teacă de livrare TorqVue 45°x45° Amplatzer	9-TV45X45-09F-100 9-TV45X45-10F-100 9-TV45X45-12F-100 9-TV45X45-13F-100 9-TV45X45-14F-100	03 decembrie 2008 (9-13 Fr) 24 februarie 2012 (14 Fr)
Teacă de livrare Amulet Amplatzer	DS-TV45X45-12F-080 DS-TV45X45-14F-080	08 februarie 2017

Semnătură:

Gabrielle Zaeska
Manager, Reglementare

Data emiterii

Declarație de conformitate ABT

Clasificare:	Clasa III (norma 7) anexa II, secțiunea 4 GHTF Clasa D
Cod (uri) GMDN:	45419
Certificat de proiectare CE nr. și data expirării:	Certificat nr.: CE 694956 Data expirării: 23 februarie 2023
Certificat anexa II, clauza 3 nr. și data expirării:	Certificat nr.: CE 694788 Data expirării: 23 februarie 2023
Standarde aplicabile sistem de calitate:	ISO 13485
Organism notificat:	BSI Group The Netherlands B.V. Say Building John M. Keynesplein 9 1066 EP Amsterdam Olanda
Număr organism notificat:	2797 (identificabil la NB 0086, referință nr. 8243107)

Gabrielle Zaeska
Manager, Reglementare

Data emiterii

Proiectare CE - Certificat de examinare

Directiva 93/42/CEE privind dispozitivele medicale, anexa II secțiunea 4

Nr. **CE 694956**

Eliberat pentru: **Abbott Medical**
5050 Nathan Lane North
Plymouth
Minnesota
55442
SUA

Cu privire la:

Sisteme de livrare TorqVue Amplatzer

BSI a efectuat o examinare a proiectării dispozitivelor de mai sus, în conformitate cu Directiva 93/42/CEE a Consiliului, anexa II secțiunea 4. Proiectarea este conformă cu cerințele acestei directive. Pentru comercializarea acestor produse este necesar un certificat suplimentar cu anexa II, cu excepția secțiunii 4.

Pentru și în numele BSI, un Organism Notificat pentru Directiva de mai sus (număr Organism Notificat 2797):

Albert Roossien, Conducere Reglementare

Prima emitere: **2018-09-03** Data: **2019-02-20** Data expirării: **2023-02-23**

...making excellence a habit.™

Proiectare CE - Certificat de examinare

Informații suplimentare la CE 694956

Eliberat pentru:

Abbott Medical
5050 Nathan Lane North
Plymouth
Minnesota
55442
SUA

Numere de model și specificații cheie Sistem de livrare TorqVue

Număr model	Dimensiune teacă (franceză)	Unghi vârf	Lungime utilă (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

Prima emitere: **2018-09-03** Data: **2019-02-20** Data expirării: **2023-02-23**

...making excellence a habit.™

Proiectare CE - Certificat de examinare

Informații suplimentare la CE 694956

Eliberat pentru:

Abbott Medical
5050 Nathan Lane North
Plymouth
Minnesota
55442
SUA

Numere de model și specificații cheie Sistem de schimb TorqVue

Număr model	Dimensiune teacă (franceză)	Unghi vârf	Lungime utilă (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

Numere de model și specificații cheie Teacă de livrare TorqVue 2

Număr model	Dimensiune teacă (franceză)	Unghi vârf	Lungime utilă (cm)
9-TV2-05F120	5	none	120
9-TV2-06F120	6	none	120
9-TV2-07F120	7	none	120

Prima emitere: **2018-09-03** Data: **2019-02-20** Data expirării: **2023-02-23**

...making excellence a habit.™

Proiectare CE - Certificat de examinare

Informații suplimentare la CE 694956

Eliberat pentru:

Abbott Medical
5050 Nathan Lane North
Plymouth
Minnesota
55442
SUA

Numere de model și specificații cheie Sistem de livrare LP TorqVue

Dimensiune dispozitiv (franceză)	Număr model	Dimensiune curbă	Dimensiune lungime (cm)	Lungime fir de livrare (cm)
4 franceză, 60 cm	9-TVLP4F90/060	90 grade	60cm	165
4 franceză, 80 cm	9-TVLP4F90/080	90 grade	80cm	190
5 franceză, 60 cm	9-TVLP5F90/060	90 grade	60cm	165
5 franceză, 80 cm	9-TVLP5F90/080	90 grade	80cm	190

Numere de model și specificații cheie Cateter LP TorqVue

Număr model	Dimensiune dispozitiv	Lungime utilă	Diametru exterior vârf mm (in)	Diametru interior vârf mm (in)
9-TVLPC4F90/080	4 Fr	80 cm	1.63 (0.064)	1.17 (0.046)

Numere de model și dimensiuni cheie Sistem de livrare TorqVue cu cateter împingător

Număr model	Dimensiune teacă (franceză)	Unghi vârf	Lungime utilă (cm)
9-ITVP07F-180/80	7	180	80
9-ITVP08F-180/80	8	180	80
9-ITVP09F-180/80	9	180	80

Prima emitere: **2018-09-03** Data: **2019-02-20** Data expirării: **2023-02-23**

...making excellence a habit.™

Proiectare CE - Certificat de examinare

Informații suplimentare la CE 694956

Eliberat pentru:

Abbott Medical
5050 Nathan Lane North
Plymouth
Minnesota
55442
SUA

Numere de model și specificații cheie Teacă de livrare TorqVue 45x45

Număr model	Dimensiune teacă (fr)	Lungime (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

Numere de model și specificații cheie Teacă de livrare Amulet AMPLATZER

Număr model	Dimensiune teacă (fr)	Lungime (cm)
DS-TV45X45-12F-080	12	80
DS-TV45X45-14F-080	14	80

Prima emitere: **2018-09-03** Data: **2019-02-20** Data expirării: **2023-02-23**

...making excellence a habit.™

Proiectare CE - Certificat de examinare

Informații suplimentare la CE 694956

Eliberat pentru:

Abbott Medical
5050 Nathan Lane North
Plymouth
Minnesota
55442
SUA

Istoric certificat

Data	Număr de referință	Acțiune
03 septembrie 2018	8957249	Prima emitere. Certificat în oglindă la CE 594294.
Curentă	8243107	Identificabil la NB 0086.

Prima emitere: **2018-09-03** Data: **2019-02-20** Data expirării: **2023-02-23**

...making excellence a habit.™

Subsemnatul **DUMITRACHE CRISTINA** interpret şi traducător autorizat pentru limba străină engleza în temeiul autorizaţiei nr. 4044 din data de 11.12.2000 , eliberată de Ministerul Justiţiei din România, certific exactitatea traducerii efectuate din limba engleza în limba romana, că textul prezentat a fost tradus in totalitate, fără omisiuni, şi că, prin traducere, înscrisului nu i-a fost denaturat conţinutul şi sensul.

INTERPRET ŞI TRADUCĂTOR AUTORIZAT,

ST. JUDE MEDICAL

SJM Declaration of Conformity

St. Jude Medical (SJM) hereby declares that the following SJM facilities and products conform to the applicable provisions of Annex II of the Medical Device Directive (MDD) 93/42/ECC. All supporting documentation is retained under the premises of SJM. 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:	AGA Medical Corporation 5050 Nathan Lane North Plymouth, Minnesota 55442, USA
European Representative:	St. Jude Medical Coordination Center BVBA The Corporate Village Da Vincilaan 11 Box F1 1935 Zaventem, Belgium
Product Type:	Catheter Guide Wire
Product Name(s):	AMPLATZER Guidewires
Model Number(s):	9-GW-001, 9-GW-002, 9-GW-003, 9-GW-004
Classification:	Class III (Rule 7) Annex II, Section 4 GHTF Class D
GMDN Code(s):	35094
Original CE Mark Date:	22 March 2001 (1-3), 22 Sept 2003 (4, Noodlewire)
EC Certificate No and expiration date:	Certificate No: CE 594293 Expiration Date: 23 Feb 2023
Annex II, Clause 3:	Certificate No: CE 590631 Expiration Date: 23 Feb 2023
Applicable Quality System Standards:	ISO 13485
Notified Body:	BSI Kitemark Court Davy Avenue Knowlhill Milton Keynes MK5 8PP UK
Notified Body Number:	0086

Signature:

Lisa Becker
Senior Director, Regulatory Affairs

21Feb18
Issue Date

EC Design-Examination Certificate

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

No. **CE 594293**

Issued To: **AGA Medical Corporation**
5050 Nathan Lane North
Plymouth
Minnesota
55442
USA

In respect of:

AMPLATZER Guidewires

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 0086):

Stewart Brain, Head of Compliance & Risk - Medical Devices

First Issued: **2013-02-24** Date: **2018-01-10** Expiry Date: **2023-02-23**

...making excellence a habit.™

EC Design-Examination Certificate

Supplementary Information to CE 594293

Issued To:

AGA Medical Corporation
5050 Nathan Lane North
Plymouth
Minnesota
55442
USA

Part Number	Description
9-GW-001	JFC-SS Modified J, Fixed, PTFE Coated, Super Stiff
9-GW-002	J1.5FC-SS, Modified J, Fixed, PTFE Coated, Super Stiff
9-GW-003	J9FC-FS-LLLT Fixed Core, Long (20 cm) PTFE Coated, Finger-Straightenable
9-GW-004	Noodlewire Guidewire

First Issued: **2013-02-24** Date: **2018-01-10** Expiry Date: **2023-02-23**

...making excellence a habit.™

EC Design-Examination Certificate

Supplementary Information to CE 594293

Issued To:

AGA Medical Corporation
5050 Nathan Lane North
Plymouth
Minnesota
55442
USA

Certificate History

Date	Reference Number	Action
24 February 2013	10139225	First Issue – Transfer from another Notified Body
27 May 2015	10155539	Process changes for the addition of a shelf carton, Instructions for Use and final labels prior to sterilization.
25 August 2015	10156926	DuPont Tyvek Medical Transition Project update.
Current	8864595	Certificate renewal.

First Issued: **2013-02-24** Date: **2018-01-10** Expiry Date: **2023-02-23**

...making excellence a habit.™

EC Certificate - Full Quality Assurance System

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

No. **CE 590631**

Issued To: **AGA Medical Corporation**
5050 Nathan Lane North
Plymouth
Minnesota
55442
USA

In respect of:

The design, development, and manufacturing of occluders, plugs , delivery and exchange systems, catheters, sheaths, introducers, guidewires, sizing balloons, and related accessories for cardiovascular occlusion and vascular closure.

Those aspects of Annex II related to securing and maintaining sterility in the respect of sizing plates.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Stewart Brain, Head of Compliance & Risk - Medical Devices

First Issued: **2012-11-01** Date: **2018-02-13** Expiry Date: **2023-02-23**

...making excellence a habit.™

EC Certificate - Full Quality Assurance System

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

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 590631**
Date:	**2018-02-13**
Issued To:	**AGA Medical Corporation** **5050 Nathan Lane North** **Plymouth** **Minnesota** **55442** **USA**

Subcontractor:	**Service(s) supplied**
Creganna Medical also doing business as Creganna Tactx Medical 5905 Trenton Lane North Plymouth MN 55442 USA	**Manufacture**
Creganna Medical also doing business as LSA 5015 Cheshire Parkway Plymouth Minnesota 55446 USA	**Manufacture**
Isomedix Operations, Inc 380 90th Avenue NW Minneapolis Minnesota 55433 USA	**ETO Sterilization**

...making excellence a habit.™

EC Certificate - Full Quality Assurance System

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

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 590631**
Date:	**2018-02-13**
Issued To:	**AGA Medical Corporation** **5050 Nathan Lane North** **Plymouth** **Minnesota** **55442** **USA**

Subcontractor:	**Service(s) supplied**
Lake Region Medical Ltd. Butlersland New Ross Co. Wexford Ireland	**Manufacture**
St. Jude Medical Coordination Center BVBA The Corporate Village Da Vincilaan 11 Box F1 1935 Zaventem Belgium	**EU Representative** **Labelling** **Packaging**
St. Jude Medical Costa Rica Ltda. Edificio #44B Calle 0, Ave. 2 Zona Franca Coyol El Coyol, ALAJUELA Costa Rica	**Manufacture**

...making excellence a habit.™

EC Certificate - Full Quality Assurance System

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

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 590631**
Date:	**2018-02-13**
Issued To:	**AGA Medical Corporation** **5050 Nathan Lane North** **Plymouth** **Minnesota** **55442** **USA**

Subcontractor:	**Service(s) supplied**
Sterigenics US, LLC 7775 South Quincy Willowbrook Illinois 60527 USA	**ETO Sterilization**
Synergy Health AST SRL B13.1 Street 4, Avenue 1 El Coyol Free Zone 20102 El Coyol Alajuela Costa Rica	**ETO Sterilization**

...making excellence a habit.™

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 590631**
Date: **2018-02-13**
Issued To: **AGA Medical Corporation**
5050 Nathan Lane North
Plymouth
Minnesota
55442
USA

Date	Reference Number	Action
1 November 2012	7880237	First Issue – Transfer from another Notified Body.
24 February 2013	7929572	Phase 2 of the transfer from another Notified Body. Extension to the scope to include all occluders, plugs, delivery and exchange systems, catheters, sheaths, introducers, guidewires, sizing balloons, and related accessories. Extension to the scope to include the sterility aspects in respect of sizing plates. Addition of Lake Region Medical and Creggana-Tactx as significant subcontractors.
24 February 2013	7945311	Certificate renewal.
06 February 2015	8254477	Addition of St. Jude Medical Costa Rica Ltda. as a significant subcontractor for manufacturing. Addition of Synergy Health AST, SRL as a significant subcontractor for sterilization.
16 March 2015	8297445	Addition of Packaging & Labelling to activities of St. Jude Medical Coordination Center BVBA.
23 October 2015	8424620	Creganna address update (from Xenium Lane N to Trenton Lane North) following transfer of facility.
07 December 2015	8433259	Add Sterigenics as a significant subcontractor for sterilization.
Current	8887945	Certificate renewal and changes of subcontractor operating titles.

Proiectare CE - Certificat de examinare

Directiva 93/42/CEE privind dispozitivele medicale, anexa II secțiunea 4

Nr. **CE 694955**

Eliberat pentru: **Abbott Medical**
5050 Nathan Lane North
Plymouth
Minnesota
55442
SUA

Cu privire la:

Fire de ghidaj AMPLATZER

BSI a efectuat o examinare a proiectării dispozitivelor de mai sus, în conformitate cu Directiva 93/42/CEE a Consiliului, anexa II secțiunea 4. Proiectarea este conformă cu cerințele acestei directive. Pentru comercializarea acestor produse este necesar un certificat suplimentar cu anexa II, cu excepția secțiunii 4.

Pentru și în numele BSI, un Organism Notificat pentru Directiva de mai sus (număr Organism Notificat 2797):

Albert Roossien, Conducere Reglementare

Prima emitere: **2018-09-03** Data: **2019-02-20** Data expirării: **2023-02-23**

...making excellence a habit.™

Proiectare CE - Certificat de examinare

Informații suplimentare la CE 694955

Eliberat pentru:

Abbott Medical
5050 Nathan Lane North
Plymouth
Minnesota
55442
SUA

Număr articol	Descriere
9-GW-001	JFC-SS, J modificat, fix, acoperit PTFE, foarte rigid
9-GW-002	J1.5FC-SS, J modificat, fix, acoperit PTFE, foarte rigid
9-GW-003	J9FC-FS-LLLT, miez fix, lung (20 cm) acoperit PTFE, poate fi îndreptat cu degetele
9-GW-004	Fir de ghidaj „Noodlewire”

Prima emitere: **2018-09-03** Data: **2019-02-20** Data expirării: **2023-02-23**

...making excellence a habit.™

Proiectare CE - Certificat de examinare

Informații suplimentare la CE 694955

Eliberat pentru:

Abbott Medical
5050 Nathan Lane North
Plymouth
Minnesota
55442
SUA

Istoric certificat

Data	Număr de referință	Acțiune
03 septembrie 2018	8957249	Prima emitere. Certificat în oglindă la CE 594293.
Curentă	8243107	Identificabil la NB 0086.

Prima emitere: **2018-09-03** Data: **2019-02-20** Data expirării: **2023-02-23**

...making excellence a habit.™

EC Design-Examination Certificate

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

No. **CE 694955**

Issued To: **Abbott Medical**
5050 Nathan Lane North
Plymouth
Minnesota
55442
USA

In respect of:

AMPLATZER Guidewires

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):

Albert Roossien, Regulatory Lead

First Issued: **2018-09-03** Date: **2019-02-20** Expiry Date: **2023-02-23**

...making excellence a habit.™

EC Design-Examination Certificate

Supplementary Information to CE 694955

Issued To:

Abbott Medical
5050 Nathan Lane North
Plymouth
Minnesota
55442
USA

Part Number	Description
9-GW-001	JFC-SS Modified J, Fixed, PTFE Coated, Super Stiff
9-GW-002	J1.5FC-SS, Modified J, Fixed, PTFE Coated, Super Stiff
9-GW-003	J9FC-FS-LLLT Fixed Core, Long (20 cm) PTFE Coated, Finger-Straightenable
9-GW-004	Noodlewire Guidewire

First Issued: **2018-09-03** Date: **2019-02-20** Expiry Date: **2023-02-23**

...making excellence a habit.™

EC Design-Examination Certificate

Supplementary Information to CE 694955

Issued To:

Abbott Medical
5050 Nathan Lane North
Plymouth
Minnesota
55442
USA

Certificate History

Date	Reference Number	Action
03 September 2018	8957249	First Issue. Mirror certificate to CE 594293.
Current	8243107	Traceable to NB 0086.

First Issued: **2018-09-03** Date: **2019-02-20** Expiry Date: **2023-02-23**

...making excellence a habit.™

22 March 2023

To Whom it May concern

We, Abbott Medical, located at 5050 Nathan Lane North, Plymouth, MN USA 55442, hereby confirm that the devices listed in Table 1 meet the following conditions as laid out in Regulation (EU) 2023/607 dated 20 March 2023:

(a) those devices continue to comply with Directive 90/385/EEC or Directive 93/42/EEC, as applicable;

(b) there are no significant changes in the design and intended purpose;

(c) the devices do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health;

(d) no later than 26 May 2024, the manufacturer has put in place a quality management system in accordance with Article 10(9);

(e) no later than 26 May 2024, the manufacturer or the authorised representative has lodged a formal application with a notified body in accordance with Section 4.3, first subparagraph, of Annex VII for conformity assessment in respect of a device referred to in paragraph 3a or 3b of this Article or in respect of a device intended to substitute that device, and, no later than 26 September 2024, the notified body and the manufacturer have signed a written agreement in accordance with Section 4.3, second subparagraph, of Annex VII.

Sincerely,

MGROSSMA

Digitally signed by MGROSSMA
Date: 2023.03.22 18:35:08 -07'00'

Michelle Grossman
Sr. Director Regulatory Affairs

Table 1.

Device Name	MDD Certificate Number[i]	First issued	Expiry Date[ii]
Amplatzer™ Guidewires	CE 694955	03-Sep-18	23-Feb-23
Amplatzer™ TorqVue™ LP Delivery System	CE 694956	03-Sep-18	23-Feb-23
Amplatzer™ TorqVue™ LP Catheter	CE 694956	03-Sep-18	23-Feb-23
Amplatzer™ Muscular VSD Occluder	CE 694951	03-Sep-18	23-Feb-23
Amplatzer™ P.I. Muscular VSD Occluder	CE 694951	03-Sep-18	23-Feb-23
Amplatzer™ Multifenestrated Septal Occluder-"Cribriform"	CE 694948	03-Sep-18	23-Feb-23
Amplatzer™ Duct Occluder	CE 694957	03-Sep-18	23-Feb-23
Amplatzer™ Duct Occluder II	CE 694957	03-Sep-18	23-Feb-23
Amplatzer Piccolo™ Occluder	CE 694957	03-Sep-18	23-Feb-23
Amplatzer™ Septal Occluder	CE 694948	03-Sep-18	23-Feb-23
Amplatzer Valvular Plug III	CE 707326	20-Jan-20	26-May-24
Amplatzer™ Amulet™ Delivery Sheath	CE 694956	03-Sep-18	23-Feb-23
Amplatzer™ TorqVue™ 2 Delivery System	CE 694956	03-Sep-18	23-Feb-23
Amplatzer™ TorqVue™ Delivery System Amplatzer™ TorqVue™ Exchange System	CE 694956	03-Sep-18	23-Feb-23
Amplatzer™ Trevisio™ Intravascular Delivery System	CE 694956	03-Sep-18	23-Feb-23
Amplatzer™ Sizing Balloon II	CE 694959	03-Sep-18	23-Feb-23

[i] Number of certificate issued under Directive 90/385/EEC (MDD)

[ii] The expiry date on the certificate issued under Directive 90//385/EEC (MDD)

22 Martie 2023

Pentru cei interesaţi,

Noi, Abbott Medical, cu sediul la 5050 Nathan Lane North, Plymouth, MN USA 55442, confirmăm prin prezenta că dispozitivele enumerate în Tabelul 1 îndeplinesc următoarele condiții, astfel cum sunt prevăzute în Regulamentul (UE) 2023/607 din 20 martie 2023:

(a) dispozitivele respective continuă să respecte Directiva 90/385/CEE sau Directiva 93/42/CEE, după caz;

(b) nu există modificări semnificative în proiectarea și scopul propus;

(c) dispozitivele nu prezintă un risc inacceptabil pentru sănătatea sau siguranța pacienților, utilizatorilor sau a altor persoane sau pentru alte aspecte ale protecției sănătății publice;

(d) până la 26 mai 2024, producătorul a instituit un sistem de management al calității în conformitate cu articolul 10 alineatul (9);

(e) până la 26 mai 2024, producătorul sau reprezentantul autorizat a depus o cerere oficială la un organism notificat în conformitate cu secțiunea 4.3 primul paragraf din anexa VII pentru evaluarea conformității cu privire la un dispozitiv menționat la alineatul (3a). sau 3b din prezentul articol sau în ceea ce privește un dispozitiv destinat să înlocuiască acel dispozitiv și, până la 26 septembrie 2024, organismul notificat și producătorul au semnat un acord scris în conformitate cu secțiunea 4.3 al doilea paragraf din anexa VII.

Cu sinceritate,

MGROSSMA

Digitally signed by MGROSSMA
Date: 2023.03.22 18:35:08 -07'00'

Michelle Grossman
Director Senior, Departament Reglementare

Table 1.

Nume Articol	Numar certificate MDD	Prima Editie	Data Expirare
Amplatzer™ Guidewires	CE 694955	03-Sep-18	23-Feb-23
Amplatzer™ TorqVue™ LP Delivery System	CE 694956	03-Sep-18	23-Feb-23
Amplatzer™ TorqVue™ LP Catheter	CE 694956	03-Sep-18	23-Feb-23
Amplatzer™ Muscular VSD Occluder	CE 694951	03-Sep-18	23-Feb-23
Amplatzer™ P.I. Muscular VSD Occluder	CE 694951	03-Sep-18	23-Feb-23
Amplatzer™ Multifenestrated Septal Occluder-"Cribriform"	CE 694948	03-Sep-18	23-Feb-23
Amplatzer™ Duct Occluder	CE 694957	03-Sep-18	23-Feb-23
Amplatzer™ Duct Occluder II	CE 694957	03-Sep-18	23-Feb-23
Amplatzer Piccolo™ Occluder	CE 694957	03-Sep-18	23-Feb-23
Amplatzer™ Septal Occluder	CE 694948	03-Sep-18	23-Feb-23
Amplatzer Valvular Plug Ill	CE 707326	20-Jan-20	26-May-24
Amplatzer™ Amulet™ Delivery Sheath	CE 694956	03-Sep-18	23-Feb-23
Amplatzer™ TorqVue™ 2 Delivery System	CE 694956	03-Sep-18	23-Feb-23
Amplatzer™ TorqVue™ Delivery System Amplatzer™ TorqVue™ Exchange System	CE 694956	03-Sep-18	23-Feb-23
Amplatzer™ Trevisio™ Intravascular Delivery System	CE 694956	03-Sep-18	23-Feb-23
Amplatzer™ Sizing Balloon II	CE 694959	03-Sep-18	23-Feb-23

[i] Numărul certificatului eliberat în conformitate cu Directiva 90/385/CEE (MDD)

[ii] Data de expirare de pe certificatul eliberat în conformitate cu Directiva 90//385/CEE (MDD)

Subsemnatul **DUMITRACHE CRISTINA** interpret şi traducător autorizat pentru limba străină engleza în temeiul autorizaţiei nr. 4044 din data de 11.12.2000 , eliberată de Ministerul Justiţiei din România, certific exactitatea traducerii efectuate din limba engleza în limba romana, că textul prezentat a fost tradus in totalitate, fără omisiuni, şi că, prin traducere, înscrisului nu i-a fost denaturat conţinutul şi sensul.

INTERPRET ŞI TRADUCĂTOR AUTORIZAT,