# AMPLATZER®
# Structural Heart Occlusion Systems & Vascular Plug Family

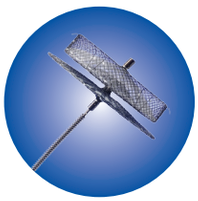
## AMPLATZER Product Catalog

AGA MEDICAL CORPORATION
HOME OF AMPLATZER® PRODUCTS

Note: Refer to The Instructions For Use for complete listing of Indications and Usage, Contraindications, Warnings and Precautions. Contact AGA Medical Corporation for further information. Delivery Sheath sizing based on TorqVue® Sheath dimensions only. Minimum size requirements with other catheter/sheath systems have not been verified.

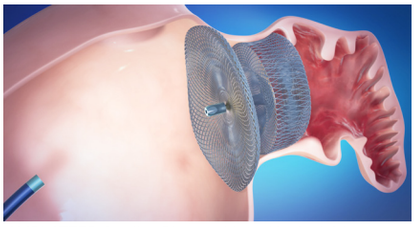
AGA MEDICAL CORPORATION
HOME OF AMPLATZER® PRODUCTS

## AMPLATZER PRODUCTS



## AMPLATZER®
# Cardiac Plug

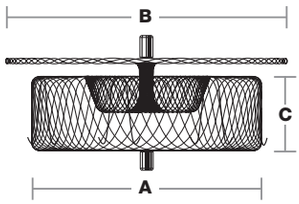
*The intuitive, transcatheter solution for complete closure of the left atrial appendage (LAA).*



*AMPLATZER Cardiac Plug positioned in the LAA*

The AMPLATZER Cardiac Plug (ACP) is a percutaneous transcatheter device intended to prevent thrombus embolization from the LAA in patients who have nonvalvular atrial fibrillation. The ACP has the ability to be recaptured and repositioned. The unique lobe design was created to conform to the LAA. The waist acts as an articulating, compliant connection between the disc and lobe, thus allowing the disc to self-orient to the LAA wall. The disc provides complete coverage of the LAA orifice and provides apposition against the chamber wall with gentle tension. Two radiopaque markers and two radiopaque threads enhance the device visibility.

**ORDERING INFORMATION**



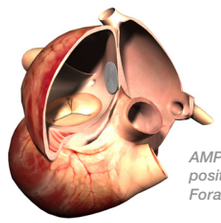

| ACP Order Numbers | [A] Lobe Diameter (mm) | [B] Disc Diameter (mm) | [C] Lobe Length (mm) | RECOMMENDED SHEATH SIZE: Minimum Sheath Size (Fr) | Minimum Sheath ID mm (in) | Recommended Sheath Length* (cm) |
|---|---|---|---|---|---|---|
| 9-ACP-007-016 | 16 | 20 | 6.5 | 9 | ≥ 3.0 (0.118) | ≤ 100 |
| 9-ACP-007-018 | 18 | 22 | 6.5 | 10 | ≥ 3.3 (0.130) | ≤ 100 |
| 9-ACP-007-020 | 20 | 24 | 6.5 | 10 | ≥ 3.3 (0.130) | ≤ 100 |
| 9-ACP-007-022 | 22 | 26 | 6.5 | 10 | ≥ 3.3 (0.130) | ≤ 100 |
| 9-ACP-007-024 | 24 | 30 | 6.5 | 13 | ≥ 4.3 (0.170) | ≤ 100 |
| 9-ACP-007-026 | 26 | 32 | 6.5 | 13 | ≥ 4.3 (0.170) | ≤ 100 |
| 9-ACP-007-028 | 28 | 34 | 6.5 | 13 | ≥ 4.3 (0.170) | ≤ 100 |
| 9-ACP-007-030 | 30 | 36 | 6.5 | 13 | ≥ 4.3 (0.170) | ≤ 100 |

*The AMPLATZER Cardiac Plug is packaged with a delivery cable 145 cm in length.

| RECOMMENDED ACCESSORIES | PAGE |
|---|---|
| AMPLATZER TorqVue 45° x 45° Delivery Sheath (60 or 80 cm length) | 12 |
| AMPLATZER .035" Guidewire | 15 |

## AMPLATZER®
# PFO Occluder

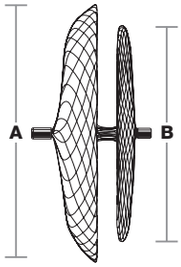
*Simple and confident transcatheter closure for Patent Foramen Ovale.*



*AMPLATZER PFO Occluder positioned in the Patent Foramen Ovale*

The AMPLATZER PFO Occluder (PFO) is a self-expandable, double-disc device made from a Nitinol wire mesh. The two discs are linked together by a short connecting waist allowing free motion of each disc. In order to increase its closing ability, the discs contain thin polyester fabric. The polyester fabric is securely sewn to each disc by a polyester thread. Transcatheter Patent Foramen Ovale closure with the PFO reports over 98.5% occlusion rates at six and 12 month follow-up with a simple-to-perform procedure and low adverse event risk.[1]

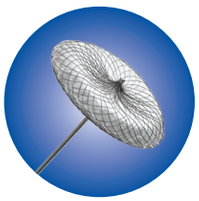
**ORDERING INFORMATION**




| PFO Order Numbers | [A] RA Disc Diameter (mm) | [B] LA Disc Diameter (mm) | RECOMMENDED SHEATH SIZE: Minimum Recommended Sheath Size AMPLATZER TorqVue Delivery System (Fr; ° Curve) |
|---|---|---|---|
| 9-PFO-018 | 18 | 18 | 8; 45° |
| 9-PFO-025 | 25 | 18 | 8; 45° |
| 9-PFO-030 | 30 | 30 | 8; 45° |
| 9-PFO-035 | 35 | 25 | 9; 45° |

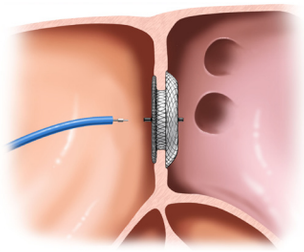
[1] Data on file at AGA Medical Corporation.

| RECOMMENDED ACCESSORIES | PAGE |
|---|---|
| AMPLATZER TorqVue Delivery System 45° (60 or 80 cm length) | 11 |
| AMPLATZER TorqVue Exchange System 45° (60 or 80 cm length) | 12 |
| AMPLATZER .035" Guidewire | 15 |



# AMPLATZER® Septal Occluder

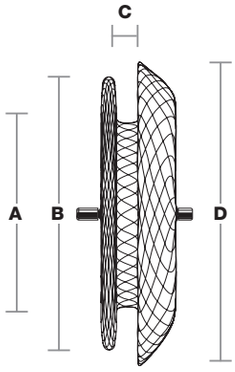
*The Proven Standard for Transcatheter Atrial Septal Defect (ASD) Closure[1].*



*AMPLATZER Septal Occluder positioned in the ASD*

The AMPLATZER Septal Occluder (ASO) is a self-expandable, double-disc device made from a Nitinol wire mesh. The two discs are linked together by a short connecting waist corresponding to the size of the ASD. In order to increase its closing ability, the discs and the waist are filled with polyester patches. The polyester patches are securely sewn to each disc by a polyester thread. The device is securely screwed onto a delivery cable and loaded into an introducer sheath. The ASO has a closure rate of approximately 96% with no residual significant shunt (> 2 mm) based on Doppler echo follow-up at one and five years post-implantation and low complication rates post-procedure and long-term, based on follow-up to five years.[1]

**ORDERING INFORMATION**

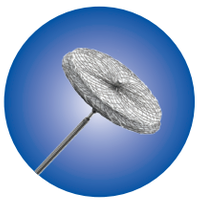



| ASO Order Numbers | [A] Device Size or Waist Diameter (mm)* | [B] RA Disc Diameter (mm) | [C] Waist Width (mm) | [D] LA Disc Diameter (mm) | RECOMMENDED SHEATH SIZE: Minimum Recommended Sheath Size AMPLATZER TorqVue Delivery System (Fr; ° Curve) |
|---|---|---|---|---|---|
| 9-ASD-004 | 4 | 12 | 3 | 16 | 6; 45° |
| 9-ASD-005 | 5 | 13 | 3 | 17 | 6; 45° |
| 9-ASD-006 | 6 | 14 | 3 | 18 | 6; 45° |
| 9-ASD-007 | 7 | 15 | 3 | 19 | 6; 45° |
| 9-ASD-008 | 8 | 16 | 3 | 20 | 6; 45° |
| 9-ASD-009 | 9 | 17 | 3 | 21 | 6; 45° |
| 9-ASD-010 | 10 | 18 | 3 | 22 | 6; 45° |
| 9-ASD-011 | 11 | 21 | 4 | 25 | 7; 45° |
| 9-ASD-012 | 12 | 22 | 4 | 26 | 7; 45° |
| 9-ASD-013 | 13 | 23 | 4 | 27 | 7; 45° |
| 9-ASD-014 | 14 | 24 | 4 | 28 | 7; 45° |
| 9-ASD-015 | 15 | 25 | 4 | 29 | 7; 45° |
| 9-ASD-016 | 16 | 26 | 4 | 30 | 7; 45° |
| 9-ASD-017 | 17 | 27 | 4 | 31 | 7; 45° |
| 9-ASD-018 | 18 | 28 | 4 | 32 | 8; 45° |
| 9-ASD-019 | 19 | 29 | 4 | 33 | 8; 45° |
| 9-ASD-020 | 20 | 30 | 4 | 34 | 9; 45° |
| 9-ASD-022 | 22 | 32 | 4 | 36 | 9; 45° |
| 9-ASD-024 | 24 | 34 | 4 | 38 | 9; 45° |
| 9-ASD-026 | 26 | 36 | 4 | 40 | 10; 45° |
| 9-ASD-028 | 28 | 38 | 4 | 42 | 10; 45° |
| 9-ASD-030 | 30 | 40 | 4 | 44 | 10; 45° |
| 9-ASD-032 | 32 | 42 | 4 | 46 | 12; 45° |
| 9-ASD-034 | 34 | 44 | 4 | 50 | 12; 45° |
| 9-ASD-036 | 36 | 46 | 4 | 52 | 12; 45° |
| 9-ASD-038 | 38 | 48 | 4 | 54 | 12; 45° |
| 9-ASD-040 | 40 | 50 | 4 | 56 | 12; 45° |

*The size of the ASD is the waist diameter. Device selection is based on the balloon measured diameter of the defect (i.e., a 10 mm defect will require a 10 mm device.)

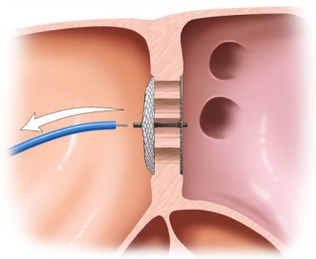
[1] Closure data based on standard Septal Occluder only. Data on file. AGA Medical Corporation Post-market Evaluation Annual Report.

| RECOMMENDED ACCESSORIES | PAGE |
|---|---|
| AMPLATZER TorqVue Delivery System 45° (60 or 80 cm length) | 11 |
| AMPLATZER TorqVue Exchange System 45° (60 or 80 cm length) | 12 |
| AMPLATZER .035” Guidewire | 15 |
| AMPLATZER Sizing Balloon II | 15 |



## AMPLATZER®
# Cribriform Occluder

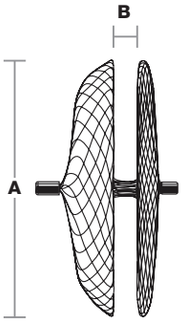
*Transcatheter closure for the majority of Atrial Septal Defects (ASD).*



*AMPLATZER Cribriform Occluder in the ASD*

The AMPLATZER Cribriform Occluder (ACO) is a self-expandable, double-disc device made from a Nitinol wire mesh. The two discs are linked together by a short connecting waist. In order to increase its closing ability, the discs are filled with polyester fabric. The polyester fabric is securely sewn to each disc by a polyester thread. Matched disc diameter for broad contact surface to cover fenestrations. Stocking both AMPLATZER Septal and Cribriform Occluders provides you the ability to choose the appropriate devices for a wide size range of defects.

**ORDERING INFORMATION**

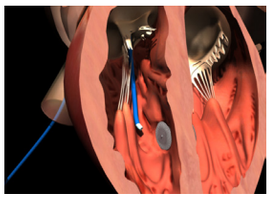



| ACO Order Numbers | [A] Device Size or RA & LA Disc Diameter (mm) | [B] Waist Length (mm) | RECOMMENDED SHEATH SIZE<br>Minimum Recommended Sheath Size AMPLATZER TorqVue Delivery System (Fr; ° Curve) |
|---|---|---|---|
| 9-ASD-MF-018 | 18 | 3 | 8; 45° |
| 9-ASD-MF-025 | 25 | 3 | 8; 45° |
| 9-ASD-MF-030 | 30 | 3 | 8; 45° |
| 9-ASD-MF-035 | 35 | 3 | 9; 45° |
| 9-ASD-MF-040 | 40 | 3 | 10; 45° |

| RECOMMENDED ACCESSORIES | PAGE |
|---|---|
| AMPLATZER TorqVue Delivery System 45° (60 or 80 cm length) | 11 |
| AMPLATZER TorqVue Exchange System 45° (60 or 80 cm length) | 12 |
| AMPLATZER .035” Guidewire | 15 |

## AMPLATZER®
# Muscular VSD Occluder

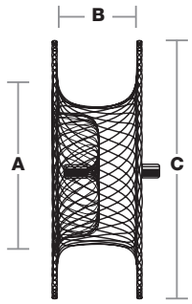
*The innovative answer to closure of Muscular Ventricular Septal Defects (VSD).*



*AMPLATZER Muscular VSD Occluder in the VSD*

The AMPLATZER Muscular VSD Occluder (MuscVSD) is a self-expandable, double-disc device made from a Nitinol wire mesh. The two discs are linked together by a connecting waist corresponding to the size of the VSD. In order to increase its closing ability, the discs and waist are filled with polyester patches. The polyester patches are securely sewn in the device with a polyester thread. The device is specifically designed with 7 mm waist length to accommodate the muscular septal wall. The MuscVSD can be implanted either by venous or arterial catheter technique.

**ORDERING INFORMATION**



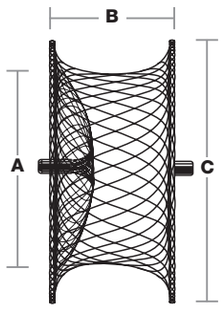

| | | | | RECOMMENDED SHEATH SIZE |
|---|---|---|---|---|
| MuscVSD Order Numbers | [A] Device Size or Waist (mm) | [B] Device Length (mm) | [C] Diameter of Discs (mm) | AMPLATZER TorqVue Delivery System (Fr; ° Curve) |
| 9-VSDMUSC-004 | 4 | 7 | 9 | 5 or 6; 45° or 180° |
| 9-VSDMUSC-006 | 6 | 7 | 14 | 6; 45° or 180° |
| 9-VSDMUSC-008 | 8 | 7 | 16 | 6; 45° or 180° |
| 9-VSDMUSC-010 | 10 | 7 | 18 | 6; 45° or 180° |
| 9-VSDMUSC-012 | 12 | 7 | 20 | 7; 45° or 180° |
| 9-VSDMUSC-014 | 14 | 7 | 22 | 8; 45° or 180° |
| 9-VSDMUSC-016 | 16 | 7 | 24 | 8; 45° or 180° |
| 9-VSDMUSC-018 | 18 | 7 | 26 | 9; 45° or 180° |

| RECOMMENDED ACCESSORIES | PAGE |
|---|---|
| AMPLATZER TorqVue Delivery System 45° or 180° (60 or 80 cm length) | 11 |
| AMPLATZER TorqVue Exchange System 45° or 180° (60 or 80 cm length) | 12 |
| AMPLATZER Noodlewire | 14 |
| AMPLATZER Guidewire | 15 |

## AMPLATZER®
# P.I. Muscular VSD Occluder

The AMPLATZER P.I. Muscular VSD Occluder (PIMuscVSD) is an extension of the AMPLATZER Muscular VSD Occluder family of devices. The PIMuscVSD is a self-expandable, double disc device made from a Nitinol wire mesh. The two discs are linked together by a connecting waist corresponding to the size of the VSD. In order to increase the occlusion ability, the discs and waist are filled with polyester patches which are securely sewn to the Nitinol wire mesh with a polyester thread. Patients with an acute VSD rupture following myocardial infarction typically have a “thicker” ventricular septum therefore the length of the device waist is longer than the Muscular VSD device.

**ORDERING INFORMATION**

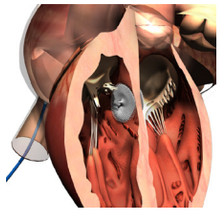



| | | | | RECOMMENDED SHEATH SIZE |
|---|---|---|---|---|
| PIMuscVSD Order Numbers | [A] Device Size or Waist (mm) | [B] Device Length (mm) | [C] Diameter of Discs (mm) | AMPLATZER TorqVue Delivery System (Fr; ° Curve) |
| 9-VSD-MUSC-PI-016 | 16 | 10 | 26 | 9; 45° or 180° |
| 9-VSD-MUSC-PI-018 | 18 | 10 | 28 | 9; 45° or 180° |
| 9-VSD-MUSC-PI-020 | 20 | 10 | 30 | 10; 45° |
| 9-VSD-MUSC-PI-022 | 22 | 10 | 32 | 10; 45° |
| 9-VSD-MUSC-PI-024 | 24 | 10 | 34 | 10; 45° |

| RECOMMENDED ACCESSORIES | PAGE |
|---|---|
| AMPLATZER TorqVue Delivery System 45° or 180° (60 or 80 cm length) | 11 |
| AMPLATZER TorqVue Exchange System 45° or 180° (60 or 80 cm length) | 12 |
| AMPLATZER Noodlewire | 14 |
| AMPLATZER Guidewire | 15 |

## AMPLATZER®
# Membranous VSD Occluder

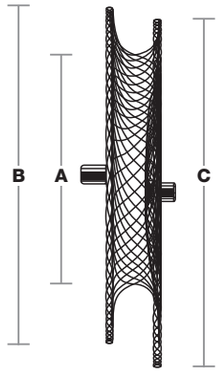
*The innovative answer to closure of Membranous Ventricular Septal Defects (VSD).*



*AMPLATZER Membranous VSD Occluder in the VSD*

The AMPLATZER Membranous VSD Occluder (MembVSD) is a self-expandable, double disc device made from Nitinol wire mesh. The two discs are connected by a short cylindrical waist which corresponds to the defect size. In order to increase its closing ability, the device is filled with polyester fabric. The fabric is sewn into the device with polyester thread. Due to the close proximity of perimembranous ventricular septal defects to the aortic valve, the device has been designed with eccentric discs to avoid interference with the aortic valve.

**ORDERING INFORMATION**

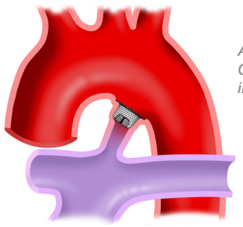



| MembVSD Order Numbers | [A] Device Size or Waist (mm) | [B] RV Disc Diameter (mm) | [C] LV Disc Diameter (mm) | RECOMMENDED SHEATH SIZE: AMPLATZER TorqVue Delivery System with Pusher Catheter (Fr; ° Curve) |
|---|---|---|---|---|
| 9-VSD-MEMB-004 | 4 | 8 | 10 | 7; 180° |
| 9-VSD-MEMB-005 | 5 | 9 | 11 | 7; 180° |
| 9-VSD-MEMB-006 | 6 | 10 | 12 | 7; 180° |
| 9-VSD-MEMB-007 | 7 | 11 | 13 | 7; 180° |
| 9-VSD-MEMB-008 | 8 | 12 | 14 | 7; 180° |
| 9-VSD-MEMB-009 | 9 | 13 | 15 | 7; 180° |
| 9-VSD-MEMB-010 | 10 | 14 | 16 | 7; 180° |
| 9-VSD-MEMB-011 | 11 | 15 | 17 | 7; 180° |
| 9-VSD-MEMB-012 | 12 | 16 | 18 | 7; 180° |
| 9-VSD-MEMB-013 | 13 | 17 | 19 | 8; 180° |
| 9-VSD-MEMB-014 | 14 | 18 | 20 | 8; 180° |
| 9-VSD-MEMB-015 | 15 | 19 | 21 | 9; 180° |
| 9-VSD-MEMB-016 | 16 | 20 | 22 | 9; 180° |
| 9-VSD-MEMB-017 | 17 | 21 | 23 | 9; 180° |
| 9-VSD-MEMB-018 | 18 | 22 | 24 | 9; 180° |

| RECOMMENDED ACCESSORIES | PAGE |
|---|---|
| AMPLATZER TorqVue Delivery System with Pusher Catheter | 13 |
| AMPLATZER Noodlewire | 14 |

## AMPLATZER®
# Duct Occluder

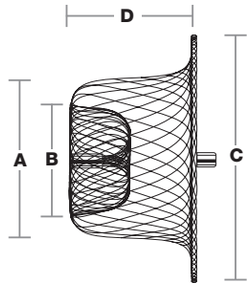
*Patent Ductus Arteriosus (PDA) occlusion transcatheter closure with confidence, precision and efficacy.*



*AMPLATZER Duct Occluder placed in the PDA*

The AMPLATZER Duct Occluder (ADO) is a self-expandable device made from a Nitinol wire mesh in a cone shaped design. The cone shape allows the device to conform evenly to the ductus shape for optimal occlusion. A retention skirt on the aortic side provides secure positioning in the ampulla of the ductus. Polyester fabric is sewn into the occluder to induce thrombosis that closes the communication. Occlusion rates with the ADO are over 98.5% at six and 12-month follow-up with a simple-to-perform procedure and low adverse event risk.[1, 2]

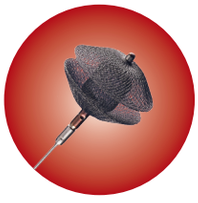
**ORDERING INFORMATION**




| ADO Order Numbers | [A] Device Diameter at Descending Aorta (mm) | [B] Device Diameter at Pulmonary Artery (mm) | [C] Retention Skirt (mm) | [D] Device Length (mm) | RECOMMENDED SHEATH SIZE: AMPLATZER TorqVue Delivery System (Fr; ° Curve) |
|---|---|---|---|---|---|
| 9-PDA-003 | 5 | 4 | 9 | 5 | 5; 180° |
| 9-PDA-004 | 6 | 4 | 10 | 7 | 6; 180° |
| 9-PDA-005 | 8 | 6 | 12 | 7 | 6; 180° |
| 9-PDA-006 | 10 | 8 | 16 | 8 | 6; 180° |
| 9-PDA-007 | 12 | 10 | 18 | 8 | 7; 180° |
| 9-PDA-008 | 14 | 12 | 20 | 8 | 7; 180° |
| 9-PDA-009 | 16 | 14 | 22 | 8 | 7; 180° |

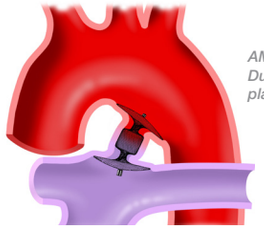
1. Data on file. AGA Medical Corporation PMA Filing and Post-market Evaluation Annual Report.
2. Hong TE; Hellenbrand WB, Hijazi ZM; Transcatheter closure of Patent Ductus Arteriosus in Adults Using the Amplatzer Duct Occluder: Initial Results and Follow-up. Indian Heart Journal 2002; 54: 384-389.

| RECOMMENDED ACCESSORIES | PAGE |
|---|---|
| AMPLATZER TorqVue Delivery System 180° (60 or 80 cm length) | 11 |
| AMPLATZER TorqVue Exchange System 180° (60 or 80 cm length) | 12 |
| AMPLATZER .035" Guidewire | 15 |



## AMPLATZER®
# Duct Occluder II

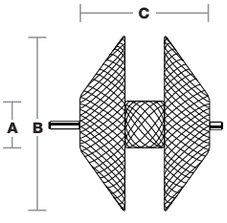
*A revolution in the effective treatment of Patent Ductus Arteriosus (PDA).*



*AMPLATZER Duct Occluder II placed in the PDA*

The AMPLATZER DUCT Occluder II (ADO II) is a self-expandable device made from flexible Nitinol wire mesh for ease of device positioning and deployment within various duct configurations. The occluder has three articulated mesh lobes that provide six planes of occlusion with full cross sectional and complete coverage. The fabric-free technology also allows for low-profile devices and delivery systems creating superior deliverability and a choice between aortic or pulmonary artery approaches. The flexible mesh and dual articulations provide high conformability to treat all classifications of PDA from 5.5 mm to less than 2.5 mm in diameter.

**ORDERING INFORMATION**




| ADO II Order Numbers | [A] Device Waist (mm) | [B] Disc Diameter (mm) | [C] Device Length (mm) | RECOMMENDED SHEATH SIZE: AMPLATZER TorqVue LP Delivery System (Fr) |
|---|---|---|---|---|
| 9-PDA2-03-04 | 3 | 9 | 4 | 4 |
| 9-PDA2-03-06 | 3 | 9 | 6 | 4 |
| 9-PDA2-04-04 | 4 | 10 | 4 | 4 |
| 9-PDA2-04-06 | 4 | 10 | 6 | 4 |
| 9-PDA2-05-04 | 5 | 11 | 4 | 5 |
| 9-PDA2-05-06 | 5 | 11 | 6 | 5 |
| 9-PDA2-06-04 | 6 | 12 | 4 | 5 |
| 9-PDA2-06-06 | 6 | 12 | 6 | 5 |

**The ADO II offers a choice in device lengths and diameters to treat a wide range of duct size and morphology:**

| Measured Ductus Diameter (mm) | < 5 | 5 – 8 | 8.1 – 10 | 10.1 – 11 | 11.1 – 12 |
|---|---|---|---|---|---|
| < 2.5 | 9-PDA2-03-04 | 9-PDA2-03-06 | 9-PDA2-04-06 | 9-PDA2-05-06 | 9-PDA2-06-06 |
| 2.5 – 3.5 | 9-PDA2-04-04 | 9-PDA2-04-06 | 9-PDA2-05-06 | 9-PDA2-06-06 | 9-PDA2-06-06 |
| 3.6 – 4.5 | 9-PDA2-05-04 | 9-PDA2-05-06 | 9-PDA2-05-06 | 9-PDA2-06-06 | 9-PDA2-06-06 |
| 4.6 – 5.5 | 9-PDA2-06-04 | 9-PDA2-06-06 | 9-PDA2-06-06 | 9-PDA2-06-06 | 9-PDA2-06-06 |

| RECOMMENDED ACCESSORIES | PAGE |
|---|---|
| AMPLATZER TorqVue LP Delivery System (60 or 80 cm length) | 12 |
| AMPLATZER .035" Guidewire | 15 |

# AMPLATZER®
# Vascular Plug Family

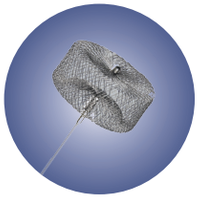
*Advancing the standard of care in peripheral embolization.*

With the AMPLATZER Vascular Plug , AMPLATZER Vascular Plug II, AMPLATZER Vascular Plug III and AMPLATZER Vascular Plug 4 you are now given the tools necessary to select the right vascular plug based on vessel type, blood flow, and the available landing zone.

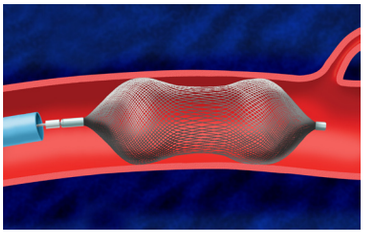
***Benefits include:***

- ***Precise delivery and secure positioning***
- ***Fast procedure times with low radiation exposure for physician and patient[1]***
- ***A cost-effective solution for peripheral embolization[2]***

[1] Mangini M, Use of Amplatzer Vascular Plug (AVP) in emergency embolization: preliminary experience and review of literature, Emergency Radiology, May 2008; 153-160. Ferro C, Vascular Percutaneous transcatheter embolization with a new device: Amplatzer Vascular Plug, Radiol Med, March 2007; 239-251.
[2] Ha C, Amplatzer Vascular Plug to occlude the internal iliac arteries in patients undergoing aortoiliac aneurysm repair, J Vasc Surg 2005; 42: 1058-62. Klein G, Extracranial Aneurysm and Arteriovenous Fistula: Embolization with the Guglielmi Detachable Coil, Radiology 1996; 201:489-494.



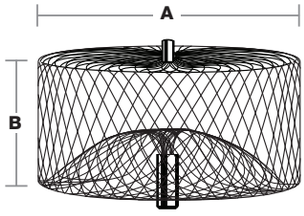
## AMPLATZER®
## Vascular Plug



*AMPLATZER Vascular Plug deployed in peripheral vasculature*

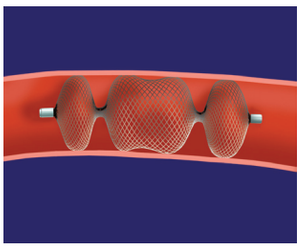
The AMPLATZER Vascular Plug (AVP) is a self-expandable, cylindrical device made from a Nitinol wire mesh. The AVP is a catheter delivered occlusion system for treating many common peripheral vascular disorders. Unlike coil products, which may be difficult to control, the AVP can be deployed, repositioned for optimal occlusion, and released with precision. The device is secured on both ends with platinum marker bands. A stainless steel micro screw is welded to one of the platinum marker bands, which allows attachment to the 135 cm long pusher wire.

*The AVP is indicated for arterial and venous embolizations in the peripheral vasculature and may be used to treat:*
*Aortopulmonary Collaterals • Arteriovenous Malformation • Surgical Aortopulmonary Shunts*
*Anomalous Venovenous Connections • Arteriovenous Fistulas • Peripheral Vessels*

| ORDERING INFORMATION | | | | DELIVERY SYSTEM MINIMUM REQUIREMENTS | | | | |
|---|---|---|---|---|---|---|---|---|
|   | AVP Order Numbers | [A] Device Diameter (mm) | [B] Pre-Implanted Device Length (mm) | Sheath Minimum Size (Fr) | OR* | Guide Catheter Minimum Size (Fr) | Minimum ID Required (in) | Maximum Length (cm) |
| | 9-PLUG-004 | 4 | 7 | 4 | | 5 | 0.056 | 100 |
| | 9-PLUG-006 | 6 | 7 | 4 | | 5 | 0.056 | 100 |
| | 9-PLUG-008 | 8 | 7 | 4 | | 5 | 0.056 | 100 |
| | 9-PLUG-010 | 10 | 7 | 5 | | 6 | 0.066 | 100 |
| | 9-PLUG-012 | 12 | 8 | 5 | | 6 | 0.066 | 100 |
| | 9-PLUG-014 | 14 | 8 | 6 | | 8 | 0.087 | 100 |
| | 9-PLUG-016 | 16 | 8 | 6 | | 8 | 0.087 | 100 |

*The AVP is delivered utilizing either a Sheath or Guide Catheter meeting the minimum internal diameter requirements.

## AMPLATZER®
# Vascular Plug II

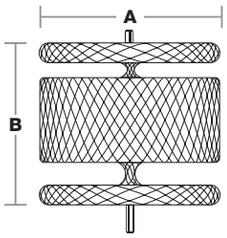


*AMPLATZER Vascular Plug II deployed in peripheral vasculature*

The AMPLATZER Vascular Plug II (AVP II) utilizes the shape memory of Nitinol, providing the practitioner the ability to deploy, recapture and redeploy ensuring precise placement. Once expanded, the 360° of vessel wall apposition creates a secure fit in the target vessel. The AVP II's unique multi-segmented, multi-layered design significantly reduces the time to occlusion for transcatheter embolization procedures while maintaining complete control during positioning and delivery of the occluder.

*Common but not exclusive applications of AVP II include:*
*Gastro-Intestinal Bleeding • Gastroduodenal Artery (GDA) prior to Radio-Embolization*
*Gonadal Vein • Pulmonary Arterio-Venous Malformations (PAVM) • Renal Artery • Splenic Artery*

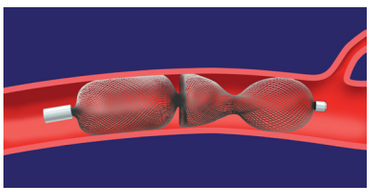
**ORDERING INFORMATION**




| | | | DELIVERY SYSTEM MINIMUM REQUIREMENTS | | | | |
|---|---|---|---|---|---|---|---|
| AVP II Order Numbers | [A] Device Diameter (mm) | [B] Pre-Implanted Device Length (mm) | Sheath Minimum Size (Fr) | OR* | Guide Catheter Minimum Size (Fr) | Minimum ID Required (in) | Maximum Length (cm) |
| 9-AVP2-003 | 3 | 6 | 4 | | 5 | 0.056 | 100 |
| 9-AVP2-004 | 4 | 6 | 4 | | 5 | 0.056 | 100 |
| 9-AVP2-006 | 6 | 6 | 4 | | 5 | 0.056 | 100 |
| 9-AVP2-008 | 8 | 7 | 4 | | 5 | 0.056 | 100 |
| 9-AVP2-010 | 10 | 7 | 5 | | 6 | 0.070 | 100 |
| 9-AVP2-012 | 12 | 9 | 5 | | 6 | 0.070 | 100 |
| 9-AVP2-014 | 14 | 10 | 6 | | 8 | 0.086 | 100 |
| 9-AVP2-016 | 16 | 12 | 6 | | 8 | 0.086 | 100 |
| 9-AVP2-018 | 18 | 14 | 7 | | 9 | 0.098 | 100 |
| 9-AVP2-020 | 20 | 16 | 7 | | 9 | 0.098 | 100 |
| 9-AVP2-022 | 22 | 18 | 7 | | 9 | 0.098 | 100 |

*** The AVP II is delivered utilizing either a Sheath or Guide Catheter meeting the minimum internal diameter requirements.**

## AMPLATZER®
# Vascular Plug III

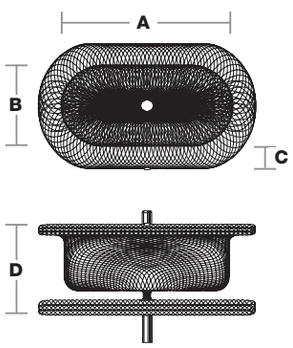


*AMPLATZER Vascular Plug III deployed in peripheral vasculature*

The AMPLATZER Vascular Plug III (AVP III) utilizes unique lobe shapes and additional layer(s) of dense Nitinol mesh to provide controlled, precise deployment and the fastest full cross-sectional vessel occlusion all with a single device. The unique shape and oblong cross section of the AVP III provides greater conformability to a wide range of vessel shapes. Stability is enhanced in high flow vessels by the extended rims; 2 mm larger than the distal lobe body. In addition, the small radiopaque marker centered on the long edge of the distal rim provides improved visualization of orientation.

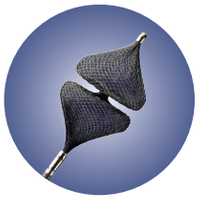
*Common but not exclusive applications of AVP III include:*
*High Flow Trauma • High Flow AVM / AVF*

**ORDERING INFORMATION**

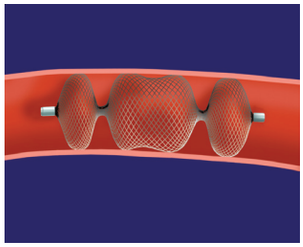



| | | | DELIVERY SYSTEM MINIMUM REQUIREMENTS | | | | | |
|---|---|---|---|---|---|---|---|---|
| AVP III Order Numbers | [A] Device Long Axis (mm) | [B] Device Short Axis (mm) | Sheath Minimum Size (Fr) | OR* | Guide Catheter Minimum Size (Fr) | Minimum ID Required (mm; in) | Maximum Length (cm) | Comparable Circular Diameter (mm) |
| 9-AVP3-042 | 4 | 2 | 4 | | 6 | 1.65; 0.065 | 120 | 2.8 |
| 9-AVP3-063 | 6 | 3 | 4 | | 6 | 1.65; 0.065 | 120 | 4.2 |
| 9-AVP3-084 | 8 | 4 | 5 | | 7 | 1.83; 0.072 | 120 | 5.7 |
| 9-AVP3-103 | 10 | 3 | 5 | | 7 | 1.83; 0.072 | 120 | 5.5 |
| 9-AVP3-105 | 10 | 5 | 5 | | 7 | 1.83; 0.072 | 120 | 7.1 |
| 9-AVP3-123 | 12 | 3 | 7 | | 9 | 2.49; 0.098 | 120 | 6.0 |
| 9-AVP3-125 | 12 | 5 | 7 | | 9 | 2.49; 0.098 | 120 | 7.7 |
| 9-AVP3-143 | 14 | 3 | 7 | | 9 | 2.49; 0.098 | 120 | 6.5 |
| 9-AVP3-145 | 14 | 5 | 7 | | 9 | 2.49; 0.098 | 120 | 8.4 |

*** The AVP III is delivered utilizing either a Sheath or Guide Catheter meeting the minimum internal diameter requirements.**
**The device is packaged with a Nitinol delivery wire with 155cm length and 0.025 inches diameter at the proximal end.**
**Device size based on long [A] and short [B] axes of Distal Lobe Body**
**• Extended Rims [C] are 2mm larger than the Distal Lobe Body**
**• Unconstrained Length [D] is 6.5 mm**



# AMPLATZER®
# Vascular Plug 4

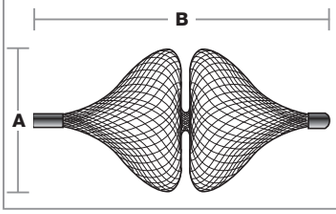


*AMPLATZER Vascular Plug 4 deployed in tortuous, distal peripheral vasculature*

The AMPLATZER Vascular Plug 4 (AVP 4) is indicated for arterial and venous embolizations in the peripheral vasculature and is ideal for reaching through tortuous vessels to distal anatomy. The device can be delivered through a 0.038" guidewire compatible diagnostic catheter eliminating the need for catheter exchange.

*Common but not exclusive applications of AVP 4 include:*
*Gastro-Intestinal Bleeding • Gastroduodenal Artery (GDA) prior to Radio-Embolization • Gonadal Vein Pulmonary Arterio-Venous • Malformations (PAVM) • Renal Artery • Splenic Artery*

**ORDERING INFORMATION**




| AVP 4 Order Numbers | [A] Device Diameter (mm) | [B] Pre-Implated Device Length (mm) |
|---|---|---|
| 9-AVP038-004 | 4 | 10.0 |
| 9-AVP038-005 | 5 | 10.5 |
| 9-AVP038-006 | 6 | 11.0 |
| 9-AVP038-007 | 7 | 12.5 |
| 9-AVP038-008 | 8 | 13.5 |

**DELIVERY SYSTEM MINIMUM REQUIREMENTS**

| Diagnostic Catheter* (Fr) | Required Guidewire Compatibility of Catheter** (in) | Maximum Length*** (cm) |
|---|---|---|
| 5 Fr AMPLATZER® TorqVue DX Diagnostic Catheter | 0.038 | 125 |
| 5 Fr Boston Scientific Imager™ II | 0.038 | 100 |
| 4 Fr Cordis TEMPO® | 0.038 | 100 |
| 4 Fr Cordis TEMPO® AQUA™ | 0.038 | 100 |
| 5 Fr Merit Medical IMPRESS® | 0.038 | 125 |

*** Use of other diagnostic catheters may result in an inability to deliver or deploy the device. Refer to the manufacturers' Instructions For Use of these diagnostic catheters as the manufacturer may make changes without notice that may impact the suitability for use with our AMPLATZER Vascular Plug 4.**

**** The AMPLATZER Vascular Plug 4 is delivered utilizing a 0.038" guidewire compatible diagnostic catheter.**

***** The AMPLATZER Vascular Plug 4 is packaged with a 155 cm long PTFE coated delivery wire.**

# AMPLATZER®
# TorqVue 45° and 180° Delivery System

The AMPLATZER TorqVue 45° and 180° Delivery System (ITV) consists of a delivery sheath, dilator, loader, plastic vise and delivery cable. The ITV is engineered specifically to provide easy loading, advancement, positioning and release of the AMPLATZER Occluder devices. Product features include a reinforced polymer delivery sheath with stainless steel braid for added kink-resistance, PTFE internal lumen for reduced friction during occluder advancement and transitions to a softer distal segment for improved maneuverability in tortuous anatomy.

**ORDERING INFORMATION**

| ITV Order Numbers | Sheath Size (Fr) | Tip Angle (°) | Usable Length (cm) | Device Best Used With |
|---|---|---|---|---|
| 9-ITV06F45/60 | 6 | 45 | 60 | ASO & MuscVSD |
| 9-ITV07F45/60 | 7 | 45 | 60 | ASO & MuscVSD |
| 9-ITV07F45/80 | 7 | 45 | 80 | ASO & MuscVSD |
| 9-ITV08F45/60 | 8 | 45 | 60 | ASO, ACO, MuscVSD & PFO |
| 9-ITV08F45/80 | 8 | 45 | 80 | ASO, ACO, MuscVSD & PFO |
| 9-ITV09F45/80 | 9 | 45 | 80 | ASO, ACO, MuscVSD, PIMuscVSD & PFO |
| 9-ITV10F45/80 | 10 | 45 | 80 | ASO & PIMuscVSD |
| 9-ITV12F45/80 | 12 | 45 | 80 | ASO |
| 9-ITV13F45/80 | 13 | 45 | 80 | ASO |
| 9-ITV05F180/60 | 5 | 180 | 60 | ADO & MuscVSD |
| 9-ITV06F180/60 | 6 | 180 | 60 | ADO & MuscVSD |
| 9-ITV06F180/80 | 6 | 180 | 80 | ADO & MuscVSD |
| 9-ITV07F180/80 | 7 | 180 | 80 | ADO & MuscVSD |
| 9-ITV08F180/80 | 8 | 180 | 80 | MuscVSD |
| 9-ITV09F180/80 | 9 | 180 | 80 | MuscVSD & PIMuscVSD |

*The ITV has been tested for compatibility with each AMPLATZER Occluder device to determine the minimum French size required for device advancement.*

**ITV DELIVERY SHEATH***

| | 5 Fr 60 cm | 6 Fr 60 or 80 cm | 7 Fr 60 or 80 cm | 8 Fr 60 or 80 cm | 9 Fr 80 cm | 10 Fr 80 cm | 12 Fr 80 cm | 13 Fr 80 cm |
|---|---|---|---|---|---|---|---|---|
| AMPLATZER Septal Occluder (ASO) | | 4-10mm | 11-17mm | 18-19mm | 20-24mm | 26-30mm | 32-40mm | |
| AMPLATZER Cribriform Occluder (ACO) | | | | 18-30mm | 35mm | 40mm | | |
| AMPLATZER PFO Occluder (PFO) | | | | 18-30mm | 35mm | | | |
| AMPLATZER Duct Occluder (ADO) | 5/4mm | 6/4mm<br>8/6mm<br>10/8mm | 12/10mm<br>14/12mm<br>16/14mm | | | | | |
| AMPLATZER Muscular VSD Occluder (MuscVSD) | 4mm | 6-10mm | 12mm | 14-16mm | 18mm | | | |
| AMPLATER P.I. Muscular VSD Occluder (PIMuscVSD) | | | | | 16-18mm | 20-24mm | | |

* Delivery Catheter based on TorqVue Sheath dimensions only. Minimum size requirements with other catheter/sheath systems have not been verified.
Note: Measurements in [mm] 1 FR [French]=0.33mm (inner ø)

## AMPLATZER®
# TorqVue 45° and 180° Exchange System

The AMPLATZER TorqVue 45° and 180° Exchange System (EITV) is a delivery system especially adapted for use in conjunction with the AMPLATZER Occluder devices. The system components are identical to the ITV, with the exception of the dilator, which incorporates an enlarged inner lumen for passage over a delivery cable. The EITV is intended for removal of the ITV and subsequent exchange for an ITV of equal or larger diameter.

**ORDERING INFORMATION**

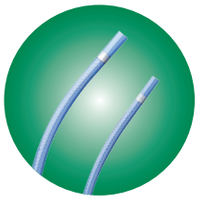
| EITV Order Numbers | Sheath Size (Fr) | Tip Angle (°) | Usable Length (cm) | Device Best Used With |
|---|---|---|---|---|
| 9-EITV09F45/80 | 9 | 45 | 80 | ASO, ACO, MuscVSD & PFO |
| 9-EITV12F45/80 | 12 | 45 | 80 | ASO, ACO, MuscVSD & PFO |
| 9-EITV06F180/80 | 6 | 180 | 80 | ADO & MuscVSD |
| 9-EITV08F180/80 | 8 | 180 | 80 | ADO & MuscVSD |

## AMPLATZER®
# TorqVue 45° x 45° Delivery Sheath

The AMPLATZER TorqVue 45° x 45° Delivery Sheath (TV45x45) is a delivery system intended to provide a pathway through which devices are introduced within the chambers and coronary vasculature of the heart or in the peripheral vasculature. The distal segment, with two 45° angles, is designed to ease access to the left atrial appendage (LAA) using a transseptal approach for LAA closure with the ACP. The system includes a delivery sheath, dilator and flush adapter. *Note the 9 Fr delivery system does not include a flush adapter.*

**ORDERING INFORMATION**

| TV45x45 Order Numbers | Sheath Size (Fr) | Tip Angle (°) | Usable Length (cm) |
|---|---|---|---|
| 9-TV45x45-09F-100 | 9 | 45x45 | 100 |
| 9-TV45x45-10F-100 | 10 | 45x45 | 100 |
| 9-TV45x45-13F-100 | 13 | 45x45 | 100 |



## AMPLATZER®
# TorqVue LP Delivery System

The AMPLATZER TorqVue LP (Low Profile) Delivery System (TVLP) is a braided catheter delivery system available in 4 and 5 French sizes. The flexible distal catheter segment allows for ease of use in tortuous anatomy. It also features a braided delivery cable with flexible Nitinol tip. The delivery system is especially designed for use in conjunction with the AMPLATZER Duct Occluder II (ADO II).

**ORDERING INFORMATION**

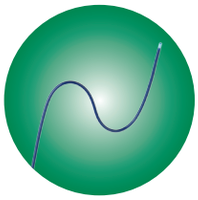
| TVLP Order Numbers | Catheter Size (Fr) | Catheter Length (cm) | Delivery Wire Length (cm) |
|---|---|---|---|
| 9-TVLP4F-060 | 4 | 60 | 165 |
| 9-TVLP4F-080 | 4 | 80 | 190 |
| 9-TVLP5F-060 | 5 | 60 | 165 |
| 9-TVLP5F-080 | 5 | 80 | 190 |

## AMPLATZER®
# TorqVue Delivery System with Pusher Catheter

The AMPLATZER TorqVue Delivery System with Pusher Catheter (ITVP) provides rotational control of the AMPLATZER Membranous VSD Occluder (MembVSD) for confident placement in the defect. It offers enhanced torque control, kink resistance and sheath radiopacity to facilitate device attachment, loading, delivery and deployment. The pusher catheter allows for orientation of the device within the defect. The ITVP also contains a translucent loader to allow confirmation of collapse, flush and air removal.

**ORDERING INFORMATION**

| ITVP Order Numbers | 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 |



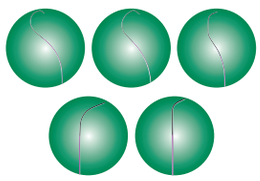
## AMPLATZER®
# TorqVue 2 Delivery Sheath

The AMPLATZER TorqVue 2 Delivery Sheath (TV2) consists of a delivery sheath and dilator. The TV2 is engineered specifically to provide a delivery solution with increased kink resistance, improved maneuverability and minimal risk of vessel damage and agitation.[1] The radiopaque tip of the TV2 facilities in precise positioning and accurate device placement. With a low-friction PTFE sheath the lining also allows for a smooth, controlled device delivery.

**ORDERING INFORMATION**

| TV2 Order Numbers | Sheath Size (Fr) | Inner Diameter (in) | Curve | Sheath Usable Length (cm) |
|---|---|---|---|---|
| 9-TV2-05F120 | 5 | 0.072 | Straight | 120 |
| 9-TV2-06F120 | 6 | 0.083 | Straight | 120 |
| 9-TV2-07F120 | 7 | 0.096 | Straight | 120 |

[1] Data on file at AGA Medical (3020740-001) (302678).

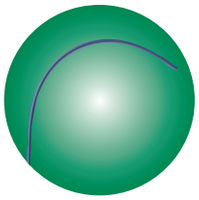


## AMPLATZER®
# TorqVue DX Diagnostic Catheter

The AMPLATZER TorqVue DX Diagnostic Catheter (TVDX) is the reliable choice for peripheral diagnostic catheterization. The soft tip segment is designed to reduce vessel trauma and is visible under fluoroscopy. The smooth catheter surface is also designed to improve tracking in tortuous vasculature. The catheter is designed with a flexible braid pattern allowing for improved steerability.

**ORDERING INFORMATION**

| TVDX Order Numbers | Catheter Size (Fr) | Usable Length (CM) | Guidewire Size (in) | Tip Shape |
|---|---|---|---|---|
| 9-TVDX-5F-035-125HH1 | 5 | 125 | 0.035 | Head Hunter 1 |
| 9-TVDX-5F-038-100MPA1 | 5 | 100 | 0.038 | Multipurpose 1 |
| 9-TVDX-5F-038-100VER | 5 | 100 | 0.038 | Vertebral |
| 9-TVDX-5F-038-65VER | 5 | 65 | 0.038 | Vertebral |
| 9-TVDX-5F-038-65CB1 | 5 | 65 | 0.038 | Cobra 1 |
| 9-TVDX-5F-038-65CB2 | 5 | 65 | 0.038 | Cobra 2 |

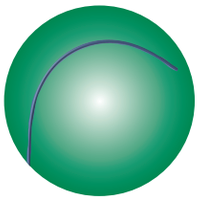


## AMPLATZER®
# 45° and 180° Delivery System

The AMPLATZER 45° and 180° Delivery System (DEL) consists of a delivery sheath, dilator, loader, plastic vice and delivery cable. The delivery system was designed to facilitate attachment, loading, delivery and deployment of the AMPLATZER Occluder devices.

**ORDERING INFORMATION**

| DEL Order Numbers | Sheath Size (Fr) | Tip Angle (°) | Usable Length (cm) | Device Best Used With |
|---|---|---|---|---|
| 9-DEL-6F-45/60 | 6 | 45 | 60 | ASO, MuscVSD |
| 9-DEL-7F-45/60 | 7 | 45 | 60 | ASO, MuscVSD |
| 9-DEL-7F-45/80 | 7 | 45 | 80 | ASO, MuscVSD |
| 9-DEL-8F-45/60 | 8 | 45 | 60 | ASO, MuscVSD |
| 9-DEL-8F-45/80 | 8 | 45 | 80 | ASO, MuscVSD |
| 9-DEL-9F-45/80 | 9 | 45 | 80 | ASO, MuscVSD |
| 9-DEL-10F-45/80 | 10 | 45 | 80 | ASO |
| 9-DEL-12F-45/80 | 12 | 45 | 80 | ASO |
| 9-DEL-5F-180/60 | 5 | 180 | 60 | ADO |
| 9-DEL-6F-180/80 | 6 | 180 | 60 | ADO, MuscVSD |
| 9-DEL-7F-180/80 | 7 | 180 | 80 | ADO, MuscVSD |
| 9-DEL-8F-180/80 | 8 | 180 | 80 | ADO, MuscVSD |
| 9-DEL-9F-180/80 | 9 | 180 | 80 | ADO, MuscVSD |

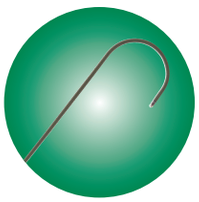


## AMPLATZER®
# 45° and 180° Exchange System

The AMPLATZER 45° and 180° Exchange System (EXCH) consists of a delivery sheath, dilator, loader, plastic vice and delivery cable. The delivery system was designed to facilitate attachment, loading, delivery and deployment of the AMPLATZER Occluder devices.

**ORDERING INFORMATION**

| EXCH Order Numbers | Sheath Size (Fr) | Tip Angle (°) | Usable Length (cm) | Device Best Used With |
|---|---|---|---|---|
| 9-EXCH-9F-45/80 | 9 | 45 | 60 | ASO, MuscVSD |
| 9-EXCH-12F-45/80 | 12 | 45 | 60 | ASO |
| 9-EXCH-6F-180/80 | 6 | 180 | 80 | ADO, MuscVSD |
| 9-EXCH-8F-180/80 | 8 | 180 | 80 | ADO, MuscVSD |

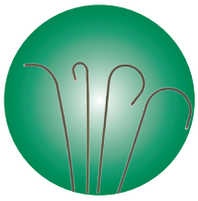


## AMPLATZER®
# Noodlewire

The AMPLATZER Noodlewire (Noodlewire) is developed for use with the MuscVSD, PIMuscVSD and MembVSD Occluders. The Noodlewire facilitates crossing of the VSD for device delivery. It has PTFE coating for excellent glide and positioning capabilities for arterial – venous (A-V) loop formation and an atraumatic J-Tip design to reduce the risk of internal wall damage.

**ORDERING INFORMATION**

| Noodlewire Order Number | Wire Size (in) | Type | Tip Description (mm) | Usable Length (cm) |
|---|---|---|---|---|
| 9-GW-004 | .035 | Soft Tip, Fixed Core | 6, J-Tip | 300 |



## AMPLATZER®
# Guidewires

AMPLATZER Guidewires (GW) are manufactured from stainless steel and are coated with PTFE, offering excellent glide or positioning capabilities. Guidewire length, diameter, core configuration and tip configuration are all indicated on the product label.

**ORDERING INFORMATION**

| GW Order Number | Wire Size (in) | Type | Tip Description (mm) | Usable Length (cm) |
|---|---|---|---|---|
| 9-GW-001 | .035 | Super Stiff | 7.5, Modified J-Tip | 260 |
| 9-GW-002 | .035 | Super Stiff | 1.5, Modified J-Tip | 260 |
| 9-GW-003 | .035 | Super Stiff | 6, J-Tip | 300 |

| RECOMMENDED FOR USE WITH THE FOLLOWING AMPLATZER OCCLUDERS | |
|---|---|
| 9-GW-001 | ADO, ADOII |
| 9-GW-002 | ASO, ACO, ACP, PFO |
| 9-GW-003 | MuscVSD, PIMuscVSD |

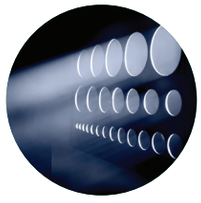
## AMPLATZER®
# Sizing Balloon II

The AMPLATZER Sizing Balloon II (SB) is a triple lumen balloon catheter with three radiopaque marker bands located inside the balloon to allow for radiographic measurement. The center of the balloon contains a pair of marker bands 0.4 mm apart (inside to inside) and one marker band 15 mm proximal of that pair (15 mm from the proximal edge of the pair of marker bands).

**ORDERING INFORMATION**

| SB Order Numbers | Max Defect Size (mm)* | Balloon Length (mm) | Shaft Size (Fr) | Usable Length (cm) | Guidewire (in) | Max Balloon Inflation Volume (cc) |
|---|---|---|---|---|---|---|
| 9-SB-018 | 20 | 35 | 6 | 70 | 0.035 | 12 |
| 9-SB-024 | 27 | 45 | 7 | 70 | 0.035 | 25 |
| 9-SB-034 | 40 | 55 | 8 | 70 | 0.035 | 90 |

NOTE: Do not insert the balloon catheter through an introducer sheath.
*Maximum defect size refers to diameter of native defect as measured by echocardiography.



## AMPLATZER®
# Sizing Plate

**ORDERING INFORMATION**

| Order Number | Description |
|---|---|
| 9-ASD-SZP | Measuring plate with circular openings of 4-38 mm |

**AMPLATZER®**

# Sheath ID and Sheath OD Measurements

**ORDERING INFORMATION**

| Product Number | Product Family | Sheath Outer Diameter (in) | Sheath Inner Diameter (in) |
|---|---|---|---|
| 9-DEL-5F-180/60 | PTFE | 0.094 | 0.076 |
| 9-DEL-6F-180/80 | PTFE | 0.107 | 0.087 |
| 9-DEL-6F-45/60 | PTFE | 0.107 | 0.087 |
| 9-DEL-7F-180/80 | PTFE | 0.12 | 0.1 |
| 9-DEL-7F-45/60 | PTFE | 0.12 | 0.1 |
| 9-DEL-7F-45/80 | PTFE | 0.12 | 0.1 |
| 9-DEL-8F-180/80 | PTFE | 0.133 | 0.111 |
| 9-DEL-8F-45/60 | PTFE | 0.133 | 0.111 |
| 9-DEL-8F-45/80 | PTFE | 0.133 | 0.111 |
| 9-DEL-9F-180/80 | PTFE | 0.145 | 0.123 |
| 9-DEL-9F-45/80 | PTFE | 0.145 | 0.123 |
| 9-DEL-10F-45/80 | PTFE | 0.158 | 0.136 |
| 9-DEL-12F-45/80 | PTFE | 0.186 | 0.162 |
| 9-ITV05F180/60 | ITV | 0.099 | 0.077 |
| 9-ITV06F180/60 | ITV | 0.11 | 0.088 |
| 9-ITV06F180/80 | ITV | 0.11 | 0.088 |
| 9-ITV06F45/60 | ITV | 0.11 | 0.088 |
| 9-ITV07F180/80 | ITV | 0.125 | 0.101 |
| 9-ITV07F45/60 | ITV | 0.125 | 0.101 |
| 9-ITV07F45/80 | ITV | 0.125 | 0.101 |
| 9-ITV08F180/80 | ITV | 0.136 | 0.112 |
| 9-ITV08F45/60 | ITV | 0.136 | 0.112 |
| 9-ITV08F45/80 | ITV | 0.136 | 0.112 |
| 9-ITV09F180/80 | ITV | 0.15 | 0.124 |
| 9-ITV09F45/80 | ITV | 0.15 | 0.124 |
| 9-ITV10F45/80 | ITV | 0.163 | 0.137 |
| 9-ITV12F45/80 | ITV | 0.189 | 0.163 |
| 9-ITV13F45/80 | ITV | 0.202 | 0.176 |
| 9-ITVP07F180/80 | ITVP | 0.125 | 0.101 |
| 9-ITVP08F180/80 | ITVP | 0.136 | 0.112 |
| 9-ITVP09F180/80 | ITVP | 0.15 | 0.124 |
| 9-EITV06F180/80 | EITV | 0.11 | 0.088 |
| 9-EITV08F180/80 | EITV | 0.136 | 0.112 |
| 9-EITV09F45/80 | EITV | 0.15 | 0.124 |
| 9-EITV12F45/80 | EITV | 0.189 | 0.163 |
| 9-TVLP4F90/060 | TVLP | 0.055 | 0.046 |
| 9-TVLP4F90/080 | TVLP | 0.055 | 0.046 |
| 9-TVLP5F90/060 | TVLP | 0.068 | 0.059 |
| 9-TVLP5F90/080 | TVLP | 0.068 | 0.059 |
| 9-EXCH-6F-180/80 | EXCH | 0.107 | 0.087 |
| 9-EXCH-8F-180/80 | EXCH | 0.133 | 0.111 |
| 9-EXCH-9F-45/80 | EXCH | 0.145 | 0.123 |
| 9-EXCH-12F-45/80 | EXCH | 0.186 | 0.162 |
| 9-TV45X45-09F-100 | ITV | 0.15 | 0.124 |
| 9-TV45X45-10F-100 | ITV | 0.163 | 0.137 |
| 9-TV45X45-13F-100 | ITV | 0.202 | 0.176 |
| 9-TV2-05F120 | TV2 | 0.099 | 0.072 |
| 9-TV2-06F120 | TV2 | 0.110 | 0.083 |
| 9-TV2-07F120 | TV2 | 0.125 | 0.096 |
| 9-TVDX-5F-035-125HH1 | TVDX | 0.066 | ..... |
| 9-TVDX-5F-038-100MPA1 | TVDX | 0.066 | ..... |
| 9-TVDX-5F-038-100VER | TVDX | 0.066 | ..... |
| 9-TVDX-5F-038-65VER | TVDX | 0.066 | ..... |
| 9-TVDX-5F-038-65CB1 | TVDX | 0.066 | ..... |
| 9-TVDX-5F-038-65CB2 | TVDX | 0.066 | ..... |

## AMPLATZER®

# Terms And Conditions Of Sale

**1.CONTRACT TERMS.**
These terms and conditions govern the sale of all devices and accessories ("Product") manufactured for or on behalf of AGA Medical Corporation. No terms and conditions other than the terms and conditions contained herein shall be binding upon Seller unless accepted in writing and signed by an officer of Seller. All terms and conditions contained in any prior oral or written communication, including, without limitation, Buyer's purchase order, which are different from or in addition to the terms and conditions herein are hereby rejected and shall not be binding on Seller, whether or not they would materially alter this document, and Seller hereby objects thereto. All prior proposals, negotiations and representations, if any, are merged herein. Buyer will be deemed to have assented to all terms and conditions contained herein if any part of the Products and/or services described herein are shipped or an invoice is presented in connection with the said Products and/or services. Buyer shall pay all shipping costs and Product shall be shipped F.O.B. manufacturing facility.

**2. PRICES.**
A. The Prices for Product shall be that contained in the Seller's Shipping Confirmation.
B. Prices are firm and are not subject to any reduction from the price stated on the Seller's Shipping Confirmation.

**3. TAXES.**
Any sales, use or manufacturer's tax which may be imposed upon the sale or use of Products, or any Federal excise tax, license or similar fee required under this transaction, shall be shown separately on the Invoice and paid by the Buyer.

**4. TERMS OF PAYMENT.**
A. A service charge of 1½% per month, not to exceed the maximum rate allowed by law, shall be made on any portion of Buyer's outstanding balance which is not paid within net thirty (30) days period.
B. Disputes. All communications regarding billing disputes and payments of any disputed or delinquent amount must be sent to: Attn: Accounting Department, 5050 Nathan Lane N, Plymouth, MN 55442.
C. In the event Buyer fails to make payment in full to Seller when due, Buyer's entire account(s) with Seller shall become immediately due and payable without notice or demand.

**5. RETURNED GOODS AUTHORIZATION POLICY.**
A. Product Returns. No Products may be returned to Seller except as provided for herein.
B. Expired Product. A Product that has exceeded the validated shelf life as listed on the packaging may not be returned or exchanged for any reason. All sales are final for Expired Products.
C. Physician Mis-sizing. A Cardiac Device Product may be returned in exchange for an item of the same family in the event all of the following conditions are fulfilled to the satisfaction of the Seller:
1. The user is certified by the Seller to implant the Product and attempts to implant the Product following all of the Instructions For Use regarding proper Product selection and sizing; and
2. The Product selected for implant is determined to be the incorrect size to properly occlude the defect.
D. Product Complaint. A Product may be returned in exchange for an item of the same family in the event all of the following conditions are fulfilled to the satisfaction of the Seller:
1. The Product, for a period equal to the validated shelf life of the Product, does not perform in accordance to the Product specifications established by the manufacturer or is otherwise defective in materials or workmanship, as confirmed by the manufacturer; and
2. The user of the Product communicates the nature of the complaint to the Seller promptly after discovery of the problem and the user cooperates fully in the manufacturer's investigation of the complaint; and
3. The Product is returned to the manufacturer promptly after discovery of the problem.
E. Order Error. A Product may be returned in exchange for an item of the same family in the event all of the following conditions are fulfilled to the satisfaction of the Seller:
1. The Product is returned within 30 days of the original shipment from AGA Medical, and
2. A 10% restocking fee will be applied.
F. Returned Goods Authorization.
1. Returned Product will not be accepted without a Returned Goods Authorization ("RGA") number. Buyer may then return Product with a valid RGA number for Seller's determination whether to authorize a Product exchange under the Physician Mis-sizing or Product Complaint sections described above.
2. The cost to return a Product for any reason will be at the expense of Buyer.
3. To obtain an RGA number:
a. Contact Technical Services via phone (888)546-4407, via fax (763)647-5928 or via mail/courier to 5050 Nathan Lane N Plymouth, MN 55442.
b. Complete the RGA Request Form providing as much information as possible for the item(s) to be returned.
c. Return the completed RGA Request Form to Amplatzer Medical Sales Corporation.
d. Completed RGA Request Forms will be reviewed within two business days of receipt. If approved, an RGA Acknowledgment Form will be sent to you.
e. Return instructions are located on the RGA Acknowledgment Form.
4. Any questions regarding the Returned Goods Authorization Policy should be directed to Technical Services.

**6. REMEDIES OF SELLER.**
Upon default by Buyer, Buyer agrees to reimburse Seller all attorney fees and court costs incurred by Seller in connection therewith. Buyer agrees that any of the following shall constitute an event of default which shall enable Seller, at its option, to exercise any right or remedy which it may have by law: (a) the failure of Buyer to perform any term or condition contained herein; (b) any failure of Buyer to give required notice; (c) the insolvency of Buyer or its failure to pay debts as they mature, an assignment by Buyer for benefit of its creditors, the appointment of receiver for Buyer or for the materials covered by this order or the filing of any petition to adjudicate Buyer bankrupt; (d) the death, incompetence, dissolution or termination of existence of Buyer; (e) a failure by Buyer to provide adequate assurance of performance within ten (10) days after a justified demand by Seller or (f) if Seller, in good faith, believes that Buyer's prospect of performance under this Agreement is impaired. All rights and remedies of Seller herein are in addition to, and shall not exclude, any rights or remedies that Seller may have by law. In the event it becomes necessary to incur any expense for collection of any overdue account, reasonable collection charges, including reasonable attorneys' fees, will be added to the balance due and Buyer shall pay all such charges.

**7. DISCLAIMER OF WARRANTY.**
Seller warrants to Buyer that, for a period equal to the validated shelf life of the Product, the Product shall meet the Product specifications established by the manufacturer when used in accordance with the manufacturer's instructions for use and shall be free from defects in materials and workmanship, as confirmed by the manufacturer. Seller's obligation under this warranty is limited to replacing or repairing, at its option, at its factory, any of the Products, excepting expendable parts thereof, that within the warranty period are returned to Seller and that have been confirmed to be defective by the manufacturer. EXCEPT AS IS EXPRESSLY PROVIDED IN THIS WARRANTY, SELLER DISCLAIMS ANY REPRESENTATION OR WARRANTY OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY AS TO MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

**8. LIABILITY.**
A. Seller shall not be liable for any loss of use, revenue or anticipated profits, or for any incidental, unforeseen, punitive or consequential damages arising out of or in connection with these Terms and Conditions or the sale or use of any Products.
B. Except as may be implied by law, in the event of any breach of these Conditions by the Seller the remedies of the Buyer shall be limited to damages which shall in no circumstances exceed the price of the Products stated on the Shipping Confirmation and the Seller shall under no circumstances be liable for any indirect, incidental or consequential damage.

**9. FORCE MAJEURE.**
Seller shall not be liable for damage or loss occurring as a result of any delay or failure of performance due to any causes beyond Seller's control, including, without limitation, any act of God, act of Customer or any of its representatives or agents, embargo or other governmental act, regulation or order, fire, flood, freezing, storm, accident, explosion, strike, slow down, labor disturbance, war (whether declared or not), riot, delay in transportation, inability to obtain necessary labor, materials, fuel or manufacturing facility problems or any other circumstance whether similar to dissimilar to the foregoing. In the event of such delay or failure, the date of delivery shall be extended for a period equal to the time lost by reason of such delay or failure. In no event shall the obligation of Buyer to pay for delivered Products be suspended. In addition, if due to any such use Seller is unable to produce sufficient Products to meet all demands from customers and internal users, Seller shall have the right to allocate production among its customers in any manner which Seller may determine to be equitable.

**10. MODIFICATION.**
These Terms and Conditions may not be changed, modified or amended except in writing signed by duly authorized representatives of the parties.

**11. SUCCESSION.**
These Terms and Conditions shall inure to and be binding upon the parties and their respective successors, assigns and legal representatives.

**12. CHOICE OF LAW.**
Any action arising out of or relating to these Terms and Conditions or the sale or use of any Products shall be brought only in Hennepin County District Court or the United States District Court of Minnesota. Buyer hereby consents to and waives any objection to venue and personal jurisdiction in any such action. These Terms and Conditions shall be governed by the internal laws of the State of Minnesota.

**MM00111(05) GLOBAL 11/08**


AGA MEDICAL CORPORATION
**HOME OF AMPLATZER® PRODUCTS**

**763.531.3076** Direct
**763.531.9227** Main
**763.647.5821** Fax
**763.719.1318** Mobile
**bhaydon@amplatzer.com**

**Bill Haydon**
*Director of Marketing*

5050 Nathan Lane North • Plymouth, Minnesota 55442 USA

## For ordering information, please contact your AGA Medical Corporation representative.

### AGA Medical Corporation International Offices:

**Amplatzer Medical Limited**
Suite 1, 3500 Parkside
Birmingham Business Park,
Birmingham, B37 7YG
United Kingdom

0121-788-4620 **Customer Service**
0121-788-4610 **Phone**
0121-788-2142 **Fax**

**Amplatzer Medical España S.L.**
Parque Empresarial Alvento
Calle Via de los Poblados 1
Edificio D, Bajo C
28033 Madrid
Spain

034-91-3823010 **Customer Service**
034-91-3823030 **Phone**
034-91-3818628 **Fax**

**AGA Medical Italia srl**
Viale E. Forlanini, 23
20134 Milano
Italy

39 02-32-16-02-01 **Phone**
39 02-73-95-42-67 **Fax**

**AGA Medical Asia Pacific Office**
Suite 811, Tsimshatsui Center
East Wing, 66 Mody Road
Tsimshatsui, Kowloon,
Hong Kong

852-2268-6566 **Phone**
852-2268-6741 **Fax**

**Amplatzer Deutschland GmbH**
Speicherstrasse 57
60327, Frankfurt
Germany

069-907483-325 **Customer Service**
069-907483-300 **Phone**
069-24249621 **Fax**

**Amplatzer Medical France SAS**
47-53 rue Raspail
92300 Levallois-Perret
France

01-40-87-25-30 **Phone**
01-40-87-25-31 **Fax**

**AGA Medical Polska Sp. z o. o.**
Emilii Plater 53
00-113 Warsaw
Poland

48 22 528-94-45 **Phone**
48 22 528-93-09 **Fax**

**AGA Medical South America**
Avenida Libertador 2442
Olivos, Buenos Aires 1636
Argentina

54-11-47118278 **Phone**
54-11-47118201 **Fax**

Caution: USA Federal law restricts the sale, distribution, or use of these devices to, by or on the order of a physician.

Note: Refer to The Instructions For Use for complete listing of indications and Usage, Contraindications, Warnings and Precautions. Contact AGA Medical Corporation for further information.



MM00047 (06) Intl 03/10

AGA MEDICAL CORPORATION

**AGA Medical Corporation**
5050 Nathan Lane North
Plymouth, Minnesota 55442

888.546.4407 **Toll Free**
763.513.9227 **Phone**
763.513.9226 **Fax**
www.amplatzer.com
info@amplatzer.com