AMPLATZER®
TorqVue Delivery System

AMPLATZER®
SEPTAL OCCLUDER

AMPLATZER®
CRIBRIFORM OCCLUDER

AMPLATZER®
PFO OCCLUDER

AMPLATZER®
DUCT OCCLUDER

AMPLATZER®
MUSCULAR VSD OCCLUDER

For Controlled Delivery of AMPLATZER® Occluders
The AMPLATZER TorqVue Delivery System's braided design and increased radiopacity provides confidence during delivery, positioning and deployment of the AMPLATZER Occluders.

- Reinforced polymer delivery catheter with stainless steel braid for added kink-resistance
- PTFE internal lumen coating for reduced friction during occluder advancement
- Transition to a softer distal segment for improved maneuverability in tortuous anatomy
- Semi-clear loader for confirmation of collapse, flushing and air removal
- Radiopaque distal marker band with soft atraumatic tip for precise location and visibility
- Glow-in-the-dark hubs for low-light visibility
DELIVERY SYSTEM COMPONENTS

A Loader
B Hemostasis Valve
C Delivery Sheath
D Dilator
E Delivery Cable
F Plastic Vise
### AMPLATZER TorqVue Delivery System - Sizing Information

The AMPLATZER TorqVue Delivery System has been tested with each AMPLATZER Occluder to determine the recommended French size required for device delivery.

<table>
<thead>
<tr>
<th>Occluder Type</th>
<th>5Fr</th>
<th>6Fr</th>
<th>7Fr</th>
<th>8Fr</th>
<th>9Fr</th>
<th>10Fr</th>
<th>12Fr</th>
<th>13Fr***</th>
</tr>
</thead>
<tbody>
<tr>
<td>Septal Occluder (ASO)</td>
<td>4 mm</td>
<td>10 mm</td>
<td>11 mm</td>
<td>17 mm</td>
<td>18 mm</td>
<td>19 mm</td>
<td>20 mm</td>
<td>24 mm</td>
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<tr>
<td>Cribriform Occluder (Crib)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>35 mm</td>
<td>40 mm***</td>
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<tr>
<td>PFO Occluder (PFO)**</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>18 mm</td>
<td>30 mm</td>
<td>35 mm***</td>
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<tr>
<td>Duct Occluder (ADO)</td>
<td></td>
<td></td>
<td>5/4 mm</td>
<td>6/4 mm</td>
<td>12/10 mm</td>
<td>8/6 mm</td>
<td>14/12 mm***</td>
<td>10/6 mm</td>
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<tr>
<td>Muscular VSD Occluder (Musc VSD)</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>14 mm</td>
<td>16 mm</td>
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<tr>
<td>PI Muscular VSD Occluder (PI Musc VSD)***</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
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<td></td>
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<td></td>
<td></td>
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<td></td>
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<td></td>
<td></td>
<td>16 mm</td>
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### AMPLATZER TorqVue Delivery System

<table>
<thead>
<tr>
<th>Order No.</th>
<th>Sheath Size</th>
<th>Tip Angle</th>
<th>Usable Length</th>
<th>Best Used With</th>
</tr>
</thead>
<tbody>
<tr>
<td>9-ITV06F45/60</td>
<td>6 French</td>
<td>45°</td>
<td>60 cm</td>
<td>ASO / MUSCVSD</td>
</tr>
<tr>
<td>9-ITV07F45/60</td>
<td>7 French</td>
<td>45°</td>
<td>60 cm</td>
<td>ASO / MUSCVSD</td>
</tr>
<tr>
<td>9-ITV07F45/60</td>
<td>7 French</td>
<td>45°</td>
<td>80 cm</td>
<td>ASO / MUSCVSD</td>
</tr>
<tr>
<td>9-ITV07F45/80</td>
<td>8 French</td>
<td>45°</td>
<td>80 cm</td>
<td>ASO / MUSCVSD</td>
</tr>
<tr>
<td>9-ITV08F45/80</td>
<td>8 French</td>
<td>45°</td>
<td>60 cm</td>
<td>ASO / CRIB / PFO* / MUSCVSD</td>
</tr>
<tr>
<td>9-ITV09F45/80</td>
<td>9 French</td>
<td>45°</td>
<td>80 cm</td>
<td>ASO / CRIB / PFO* / MUSCVSD</td>
</tr>
<tr>
<td>9-ITV10F45/80</td>
<td>10 French</td>
<td>45°</td>
<td>80 cm</td>
<td>ASO / CRIB / PFO* / MUSCVSD</td>
</tr>
<tr>
<td>9-ITV12F45/60</td>
<td>12 French</td>
<td>45°</td>
<td>60 cm</td>
<td>ASO / CRIB / PFO* / MUSCVSD</td>
</tr>
<tr>
<td>9-ITV12F45/80</td>
<td>12 French</td>
<td>45°</td>
<td>80 cm</td>
<td>ASO / CRIB / PFO* / MUSCVSD</td>
</tr>
<tr>
<td>9-ITV05F180/60</td>
<td>5 French</td>
<td>180°</td>
<td>60 cm</td>
<td>ASO / CRIB / PFO* / MUSCVSD</td>
</tr>
<tr>
<td>9-ITV06F180/60</td>
<td>6 French</td>
<td>180°</td>
<td>60 cm</td>
<td>ASO / CRIB / PFO* / MUSCVSD</td>
</tr>
<tr>
<td>9-ITV06F180/60</td>
<td>6 French</td>
<td>180°</td>
<td>80 cm</td>
<td>ASO / CRIB / PFO* / MUSCVSD</td>
</tr>
<tr>
<td>9-ITV07F180/60</td>
<td>7 French</td>
<td>180°</td>
<td>80 cm</td>
<td>ASO / CRIB / PFO* / MUSCVSD</td>
</tr>
<tr>
<td>9-ITV08F180/80</td>
<td>8 French</td>
<td>180°</td>
<td>80 cm</td>
<td>ASO / CRIB / PFO* / MUSCVSD</td>
</tr>
<tr>
<td>9-ITV09F180/80</td>
<td>9 French</td>
<td>180°</td>
<td>80 cm</td>
<td>ASO / CRIB / PFO* / MUSCVSD</td>
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</tbody>
</table>

### TorqVue Exchange System - Ordering Information 45° and 180° Angle

<table>
<thead>
<tr>
<th>Order No.</th>
<th>Sheath Size</th>
<th>Tip Angle</th>
<th>Usable Length</th>
<th>Best Used With</th>
</tr>
</thead>
<tbody>
<tr>
<td>9-EITV09F45/60</td>
<td>9 French</td>
<td>45°</td>
<td>80 cm</td>
<td>ASO / CRIB / PFO* / MUSCVSD</td>
</tr>
<tr>
<td>9-EITV12F45/60</td>
<td>12 French</td>
<td>45°</td>
<td>80 cm</td>
<td>ASO / CRIB / PFO* / MUSCVSD</td>
</tr>
<tr>
<td>9-EITV05F180/60</td>
<td>6 French</td>
<td>180°</td>
<td>80 cm</td>
<td>ASO / CRIB / PFO* / MUSCVSD</td>
</tr>
<tr>
<td>9-EITV06F180/60</td>
<td>8 French</td>
<td>180°</td>
<td>80 cm</td>
<td>ASO / CRIB / PFO* / MUSCVSD</td>
</tr>
</tbody>
</table>

* Device is for investigational use only in the US.  ** TorqVue sheath dimensions only; size requirements with other catheters/sheath systems have not been verified.  *** Device not available in the US.  Note: Measurements in millimeters; 1 French (FR) = 0.33 mm (internal diameter).
Guidewires Offering Catheter Support and Tracking Capabilities Across a Wide Range of Vascular Anatomy
AMPLATZER® Guidewires are intended for percutaneous vessel entry typically using the Seldinger technique to facilitate subsequent introduction of an intravascular device. Manufactured from stainless steel and are pre-coated with PTFE, AMPLATZER Guidewires offer excellent lubricity and positioning capabilities. Guidewire length, diameter, core configuration, and tip configuration are all indicated on the product label. The Noodlewire is a soft tip, flexible guidewire recommended for establishing an AV (Arterial-Venous) loop for crossing the defect from the left ventricle.

All AMPLATZER Guidewires offer:
• Atraumatic "J" tip design to reduce the risk of internal wall damage
• Exchange length up to 300 centimeters
• Softer tip design allows atraumatic positioning
• Ultra short flexible tips

AMPLATZER GUIDEWIRE – ORDERING INFORMATION

<table>
<thead>
<tr>
<th>Order No.</th>
<th>Diameter</th>
<th>Body</th>
<th>Tip Description</th>
<th>Usable Length</th>
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</thead>
<tbody>
<tr>
<td>9-GW-001</td>
<td>.035&quot;</td>
<td>Super Stiff</td>
<td>7.5 mm Modified J-Tip</td>
<td>260 cm</td>
</tr>
<tr>
<td>9-GW-002</td>
<td>.035&quot;</td>
<td>Super Stiff</td>
<td>1.5 mm Modified J-Tip</td>
<td>260 cm</td>
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<tr>
<td>9-GW-003</td>
<td>.035&quot;</td>
<td>Super Stiff</td>
<td>6 mm J-Tip</td>
<td>300 cm</td>
</tr>
<tr>
<td>9-GW-004</td>
<td>.035&quot;</td>
<td>Soft Tip, Fixed Core</td>
<td>6 mm J-Tip</td>
<td>300 cm</td>
</tr>
</tbody>
</table>

THE AMPLATZER GUIDEWIRES ARE DESIGNED TO WORK WITH THE FOLLOWING AMPLATZER OCCLUDERS

9-GW-001 Guidewire  
AMPLATZER® PDA Occluder
9-GW-002 Guidewire  
AMPLATZER® ASD Occluder, AMPLATZER® PFO Occluder*  
9-GW-003 Guidewire  
AMPLATZER® Muscular VSD Occluder
9-GW-004 Noodlewire  
AMPLATZER® Membranous VSD Occluder*, AMPLATZER Muscular VSD Occluder

*Device not available in the US.
AMPLATZER®

ALAMBRES GUIA

Alambres guía que ofrecen soporte y seguimiento de los catéteres
Con capacidades de atravesar una amplia gama de anatomías vasculares
AMPLATZER®

ALAMBRES GUIA

Los alambres guía de AMPLATZER® están destinados a la entrada a vasos de forma percutánea, usada comúnmente en la técnica Seldinger para facilitar la subsecuente introducción de un dispositivo intravascular. Es fabricado con acero inoxidable y pre-cubierto con PTFE, las guías Amplatzer ofrecen excelente lubricación y capacidades de posicionamiento. El largo, diámetro, configuración del núcleo y de la punta, de los alambres guía están indicados en la etiqueta del producto. El alambre fideo es de punta flexible y alambre flexible, recomendado para establecer una curva AV (Arterial-Venoso) para cruzar el defecto en el ventrículo izquierdo.

Todos los alambres guía de Amplatzer ofrecen:

- Punta atraumática con diseño de “J” que reduce el riesgo de daño en la pared interna
- Cambio de longitud hasta 300 centímetros
- Diseño de punta suave que permite posicionamiento atraumático
- Puntas ultracortas y flexibles

Alambres guías Amplatzer – Información para pedidos

(Ver tabla)

Los Alambres guía están diseñados para ser utilizados con los siguientes oclusores Amplatzer

(Ver tabla)
AMPLATZER®
Duct Occluders

Advancing the Standard of Care in Patent Ductus Arteriosus Closure
The AMPLATZER Duct Occluders are percutaneous, transcatheter occlusion devices intended for the nonsurgical closure of a patent ductus arteriosus (PDA).

**AMPLATZER® Duct Occluder**

*Unique Features*
- Transcatheter PDA closure with the ADO reports over 98.5% occlusion rates at 6 and 12-month follow-up with a simple-to-perform procedure and low adverse event risk.
- The Nitinol and polyester construction of the Duct Occluder allows its use on varied PDA shapes and sizes, with the same ease-of-use and confidence of occlusion seen with AGA Medical Corporation's range of occlusion systems.
- Polyester material sewn into each device increases the occlusive properties and provides a substrate for tissue ingrowth.
- 5-7Fr ITV compatible

**AMPLATZER® Duct Occluder II**

*Unique Features*
- Fabric-free technology allows for low-profile devices and delivery systems designed for superior deliverability and expanded procedural options.
- Flexible mesh and dual articulations provide high conformability, to treat all classifications of PDAs
- Multi-layered mesh lobes create six planes of occlusion with full cross-sectional coverage and complete closure.
- 4-5Fr TVLP compatible

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1 Data on file; AGA Medical Corporation PMA Filing and Post-market Evaluation Annual Report.
3 Krichenko et al: Am J Cardiol 1999; 83:777
4 Not indicated for the treatment of "window" PDAs
5 Data on file at AGA Medical

* AMPLATZER Duct Occluder can be used in any length defect as long as the device does not extend >3mm into the pulmonary artery or doesn't occupy over half of the pulmonary artery lumen.
AMPLATZER® Delivery Systems

AMPLATZER® TorqVue® 180° Delivery System
Used with: AMPLATZER Duct Occluder
- Reinforced polymer delivery sheath with stainless steel braid for added kink-resistance
- PTFE internal lumen for reduced friction during occluder advancement
- Transition to a softer distal segment for improved maneuverability in tortuous anatomy

AMPLATZER® TorqVue® Low Profile Delivery System* Used with: AMPLATZER Duct Occluder II
- Low profile catheter delivery system available in 4 and 5 French sizes
- Flexible distal catheter segment allows for easy aortic or pulmonary artery approaches for PDA closure with the ADO II
- Braided delivery wire with flexible Nitinol tip for ease of device positioning and deployment within various duct configurations

AMPLATZER® TorqVue® Low Profile Catheter* Used with: AMPLATZER Duct Occluder II AS
- Low profile catheter available in a 4 French size
- Flexible distal catheter segment allows for easy aortic or pulmonary artery approaches for PDA closure with the ADO II AS

AMPLATZER® Duct Occluder II Additional Sizes*
Unique Features
- 4Fr TVLP compatible
- Flexible delivery wire for optimal deployment and visualization prior to release
- Low profile retention discs and end screw designed to accommodate smaller vasculature

AMPLATZER Duct Occluder II Additional Sizes
Ductus Diameter: ≤4mm
Ductus Length: ≤8mm
# AMPLATZER Duct Occluders

## AMPLATZER DUCT OCCLUDER - ORDERING INFORMATION

<table>
<thead>
<tr>
<th>ADO Order No.</th>
<th>Device Diameter at Descending Aorta</th>
<th>Device Diameter at Pulmonary Artery</th>
<th>Retention Skirt</th>
<th>Length</th>
<th>Recommended Sheath Size (with AMPLATZER TorqVue® Delivery System)</th>
</tr>
</thead>
<tbody>
<tr>
<td>9-PDA-003</td>
<td>5 mm</td>
<td>4 mm</td>
<td>9 mm</td>
<td>5 mm</td>
<td>5 French, 180° Curve</td>
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<tr>
<td>9-PDA-004</td>
<td>6 mm</td>
<td>4 mm</td>
<td>9 mm</td>
<td>5 mm</td>
<td>6 French, 180° Curve</td>
</tr>
<tr>
<td>9-PDA-005</td>
<td>8 mm</td>
<td>6 mm</td>
<td>10 mm</td>
<td>7 mm</td>
<td>6 French, 180° Curve</td>
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<tr>
<td>9-PDA-006</td>
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<td>9-PDA-007</td>
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<td>9-PDA-008*</td>
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<td>18 mm</td>
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<td>9-PDA-009*</td>
<td>16 mm</td>
<td>14 mm</td>
<td>20 mm</td>
<td>8 mm</td>
<td>7 French, 180° Curve</td>
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</table>

**Only AMPLATZER TorqVue 180° Delivery and Exchange System sizes compatible with ADO listed. Contact AGA Medical Corporation for complete listing of AMPLATZER 180° and 45° Delivery and Exchange Systems.

## AMPLATZER TORQUE 180° DELIVER SYSTEM** ORDERING INFORMATION

<table>
<thead>
<tr>
<th>ITV Order Number</th>
<th>Sheath Size</th>
<th>Tip Angle</th>
<th>Usable Length</th>
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</thead>
<tbody>
<tr>
<td>9-ITV05F180/60</td>
<td>6Fr</td>
<td>180°</td>
<td>60cm</td>
</tr>
<tr>
<td>9-ITV06F180/60</td>
<td>6Fr</td>
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</tr>
<tr>
<td>9-ITV07F180/60</td>
<td>7Fr</td>
<td>180°</td>
<td>80cm</td>
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## AMPLATZER DUCT OCCLUDER II - ORDERING INFORMATION

<table>
<thead>
<tr>
<th>ADO II Order No.</th>
<th>Device Diameter</th>
<th>Disc Diameter</th>
<th>Device Length</th>
<th>Minimum Size</th>
<th>Delivery Catheter</th>
<th>Catheter Length</th>
<th>Tip Angle</th>
<th>Delivery Wire Length</th>
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</thead>
<tbody>
<tr>
<td>9-PDA2-03-04</td>
<td>3mm</td>
<td>9mm</td>
<td>4mm</td>
<td>4Fr</td>
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<td>160cm</td>
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<tr>
<td>9-PDA2-03-06</td>
<td>3mm</td>
<td>9mm</td>
<td>6mm</td>
<td>4Fr</td>
<td>90°</td>
<td>160cm</td>
<td>90°</td>
<td>195cm</td>
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<tr>
<td>9-PDA2-04-04</td>
<td>4mm</td>
<td>10mm</td>
<td>4mm</td>
<td>4Fr</td>
<td>90°</td>
<td>160cm</td>
<td>90°</td>
<td>195cm</td>
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<tr>
<td>9-PDA2-04-06</td>
<td>4mm</td>
<td>10mm</td>
<td>6mm</td>
<td>4Fr</td>
<td>90°</td>
<td>160cm</td>
<td>90°</td>
<td>195cm</td>
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<tr>
<td>9-PDA2-05-04</td>
<td>5mm</td>
<td>11mm</td>
<td>4mm</td>
<td>5Fr</td>
<td>90°</td>
<td>190cm</td>
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<td>190cm</td>
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<tr>
<td>9-PDA2-05-06</td>
<td>5mm</td>
<td>11mm</td>
<td>6mm</td>
<td>5Fr</td>
<td>90°</td>
<td>190cm</td>
<td>90°</td>
<td>195cm</td>
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<tr>
<td>9-PDA2-06-04</td>
<td>6mm</td>
<td>12mm</td>
<td>4mm</td>
<td>5Fr</td>
<td>90°</td>
<td>190cm</td>
<td>90°</td>
<td>190cm</td>
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<tr>
<td>9-PDA2-06-06</td>
<td>6mm</td>
<td>12mm</td>
<td>6mm</td>
<td>5Fr</td>
<td>90°</td>
<td>190cm</td>
<td>90°</td>
<td>190cm</td>
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</tbody>
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**Note: Refer to Instructions for Use for complete listing of Indications and Usage, Contraindications, Warnings and Precautions. Contact AGA Medical Corporation for further information.

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*This device may not be available in the US.

MM00732 (01.1) Int 1/11
AMPLATZER®
Vascular Plug II

The Singular Solution for Rapid Embolization Technology
The new AMPLATZER® Vascular Plug II's, an addition to the AMPLATZER® Plug family, unique multi-segmented, multi-layered design significantly reduces the time to occlusion¹ for transcatheter embolization procedures while maintaining complete control during positioning and delivery of the occluder.

- Self expanding design provides full cross-sectional vessel coverage and reduced migration potential¹
- Multi-layered mesh lobes create 6 occlusive planes, inducing rapid¹ vessel occlusion
- Broad array of sizes (3 mm - 22 mm) to treat a wide range of vessels
- Can be deployed, recaptured and redeployed for precise placement

¹Data on file at AGA Medical
The AMPLATZER Vascular Plug II has many potential applications as it is indicated for Arterial and Venous occlusions in the peripheral vasculature.

**Common But Not Exclusive Applications:**

- Subclavian occlusion prior to thoracic grafting
- Pulmonary Arteriovenous Fistula occlusion
- GDA occlusion prior to chemo embolization
- Gonadal vein occlusion
- Renal artery occlusion prior to organ ablation
- Internal iliac occlusion pre-EVAR

**The AMPLATZER Vascular Plug II May Be Used To Treat:**

- Arteriovenous Fistulas
- Arteriovenous Malformations
- Aortopulmonary Collaterals
- Surgical Aortopulmonary Shunts
- Anomalous Venovenous Connections
- Additional Peripheral Vessels
# AMPLATZER® Vascular Plug II

**Vascular Plug II**  
The Singular Solution for Rapid Embolization Technology

### Delivery System Minimum Requirements

<table>
<thead>
<tr>
<th>AMPLATZER Vascular Plug II Order Number</th>
<th>AMPLATZER Vascular Plug II Diameter (mm)</th>
<th>Pre-Implanted Device Length (mm)</th>
<th>Sheath Minimum Size</th>
<th>Minimum ID Required (inches)</th>
<th>Guide Catheter Minimum Size</th>
<th>Maximum Length (cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>9-AVP2-003</td>
<td>3</td>
<td>6</td>
<td>4 Fr</td>
<td>0.056′′</td>
<td>5 Fr</td>
<td>100</td>
</tr>
<tr>
<td>9-AVP2-004</td>
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<td>6</td>
<td>4 Fr</td>
<td>0.056′′</td>
<td>5 Fr</td>
<td>100</td>
</tr>
<tr>
<td>9-AVP2-006</td>
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<td>6</td>
<td>4 Fr</td>
<td>0.056′′</td>
<td>5 Fr</td>
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</tr>
<tr>
<td>9-AVP2-008</td>
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<td>4 Fr</td>
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<td>5 Fr</td>
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<td>5 Fr</td>
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<tr>
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<td>9</td>
<td>5 Fr</td>
<td>0.070′′</td>
<td>6 Fr</td>
<td>100</td>
</tr>
<tr>
<td>9-AVP2-014</td>
<td>14</td>
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<td>0.086′′</td>
<td>8 Fr</td>
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</tr>
<tr>
<td>9-AVP2-016</td>
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</tr>
<tr>
<td>9-AVP2-018</td>
<td>18</td>
<td>14</td>
<td>7 Fr</td>
<td>0.098′′</td>
<td>9 Fr</td>
<td>100</td>
</tr>
<tr>
<td>9-AVP2-020</td>
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<tr>
<td>9-AVP2-022</td>
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<td>7 Fr</td>
<td>0.098′′</td>
<td>9 Fr</td>
<td>100</td>
</tr>
</tbody>
</table>

To order, please call AGA Medical at 1-888-546-4407 and ask for customer service.

*Data on file at AGA Medical

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**AGA Medical Corporation**  
5050 Nathan Lane North  
Plymouth, MN 55442 U.S.A.

(888) 546-4407 Toll Free  
(763) 513-9227 Phone  
(763) 513-9226 Fax  
www.amplatz.com Internet

**CE 0473**

Only

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.

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Contact AGA Medical Corporation for availability.

MM00265 (01) Global 08/07
AMPLATZER® Vascular Plug 4

AMPLATZER® Vascular Plug Family
Advancing the Standard of Care in Peripheral Embolization
AMPLATZER Vascular Plugs are designed to provide optimal embolization through single device occlusion, full cross sectional vessel coverage and controlled, precise deployment. Vascular Plugs have the ability to be recaptured and repositioned, if necessary.

AMPLATZER Vascular Plug Family Benefits Include:
- Flexibility to select the right vascular plug based on vessel type, blood flow, and the available landing zone
- Precise delivery and secure positioning
- Fast procedure times with low radiation exposure for physician and patient
- A cost-effective solution for peripheral embolization

The AMPLATZER Vascular Plug 4 is delivered through a 0.038 diagnostic catheter further extending the reach of the AMPLATZER Vascular Plug Family.

Common but not Exclusive Applications of AMPLATZER Vascular Plug 4 Include:
- Gastro-Intestinal Bleeding
- Gastroduodenal Artery (GDA) prior to Radio-Embolization
- Gonadal Vein
- Pulmonary Arterio-Venous Malformations (PAVM)
- Renal Artery
- Splenic Artery

AMPLATZER Vascular Plug 4 tracks through tortuous vasculature to deploy in distal locations.

---


3 Study data on file at ASA Medical.
The AMPLATZER Vascular Plug 4 is indicated for arterial and venous embolizations in the peripheral vasculature and is ideal for navigating through tortuous vessels to distal anatomy.

**Design Benefits and Features:**
- Simple delivery through a 0.038 diagnostic catheter eliminating the need for catheter exchange
- Easy tracking through tortuous anatomy due to the flexible mesh of the device and the floppy distal section of the delivery wire
- Extended reach to distal vasculature due to the device’s low profile
- Rapid™ embolization provided by the device’s multi-layered, double-lobed design

**VASCULAR PLUG 4**
- A Fine Mesh Lobes
- B Radiopaque Markers
- C Microscrew attachment

**AMPLATZER VASCULAR PLUG 4 DELIVERY WIRE**
# Vascular Plug 4

## Vascular Plug 4 Ordering Information

<table>
<thead>
<tr>
<th>Order Number</th>
<th>Device Diameter (mm)</th>
<th>Unconstrained Length (mm)</th>
<th>Constrained Length of Vascular Plug 4 (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>9-AVP038-004</td>
<td>4</td>
<td>10.0</td>
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<td>9-AVP038-005</td>
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<td>15.0</td>
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<td>9-AVP038-006</td>
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<td>11.0</td>
<td>16.7</td>
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<td>9-AVP038-007</td>
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<td>12.5</td>
<td>19.3</td>
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<td>9-AVP038-008</td>
<td>8</td>
<td>13.5</td>
<td>23.1</td>
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### Constrained Length of Vascular Plug 4

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<th>Diameter of Rigid Tube (mm)</th>
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<th>4.2</th>
<th>4.6</th>
<th>5.0</th>
<th>5.4</th>
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<td>12.0</td>
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<td>15.0</td>
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<tr>
<td>16.7</td>
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</table>

## AMPLATZER TорqVue® DX Diagnostic Catheter Ordering Information

<table>
<thead>
<tr>
<th>Order Number</th>
<th>Catheter Size (Fr)</th>
<th>Catheter Length (cm)</th>
<th>Guidewire Compatibility (in)</th>
<th>Tip Shape</th>
</tr>
</thead>
<tbody>
<tr>
<td>9-TVDX-5F-035-125H1</td>
<td>5</td>
<td>125</td>
<td>0.035</td>
<td>Headhunter 1</td>
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<tr>
<td>9-TVDX-5F-038-100MPA1</td>
<td>5</td>
<td>100</td>
<td>0.038</td>
<td>Multipurpose A1</td>
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<tr>
<td>9-TVDX-5F-038-100VER</td>
<td>5</td>
<td>100</td>
<td>0.038</td>
<td>Vertebral</td>
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<tr>
<td>9-TVDX-5F-038-65VER</td>
<td>5</td>
<td>65</td>
<td>0.038</td>
<td>Vertebral</td>
</tr>
<tr>
<td>9-TVDX-5F-038-65CB1</td>
<td>5</td>
<td>65</td>
<td>0.038</td>
<td>Cobra 1</td>
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<tr>
<td>9-TVDX-5F-038-65CB2</td>
<td>5</td>
<td>65</td>
<td>0.038</td>
<td>Cobra 2</td>
</tr>
</tbody>
</table>

### Catheter Tip Shapes

- **A** Headhunter 1
- **B** Cobra 1
- **C** Cobra 2
- **D** Multipurpose A1
- **E** Vertebral

### AMPLATZER TорqVue®

- 5 Fr AMPLATZER® TorqVue® DX (125 cm or less)
- 5 Fr Cordis TEMPO® AQUA® (100 cm or less)
- 5 Fr Cordis TEMPO® (100 cm or less)
- 4 Fr Boston Scientific Image™ II (100 cm or less)
- 5 Fr Merit Medical IMPRESS® (125 cm or less)

### Notes

- The AMPLATZER Vascular Plug 4 is packaged with a 155 cm long PTFE coated delivery wire.
- The AMPLATZER Vascular Plug 4 is delivered utilizing a 0.035" guidewire compatible diagnostic catheter.
- The AMPLATZER Vascular Plug 4 has been tested for compatibility with the following diagnostic catheters and corresponding lengths:
  - 5 Fr AMPLATZER® TorqVue® DX (125 cm or less)
  - 5 Fr Cordis TEMPO® AQUA® (100 cm or less)
  - 4 Fr Cordis TEMPO® (100 cm or less)
- NOTE: Use of other diagnostic catheters may result in the inability to deliver, deploy or recapture the device.

### Additional Information

- Corresponding average deployed lengths listed in this table are results from testing performed in a rigid, non-compliant tube on benchtop. Deployed lengths are intended as a guide and may vary.
- The 0.035 TorqVue® DX diagnostic catheter in the Headhunter 1 configuration has been tested and found compatible with the AMPLATZER Vascular Plug 4.

- Device not available in the US.

To order, please call AGA Medical at phone numbers listed below and ask for customer service.

---

**AGA Medical Corporation**

5050 Nathan Lane North  
Plymouth, MN 55442 U.S.A.

(888) 546-4407 Toll Free  
(763) 513-9227 Phone  
(763) 513-9226 Fax  
info@amplatzer.com Email  
www.amplatzer.com Internet

---

**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.

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MM00392 (02) Global 04/10
AMPLATZER®
PFO Occluder

Simple and Confident Transcatheter Closer for Patent Foramen Ovale

AGA MEDICAL CORPORATION
HOME OF AMPLATZER PRODUCTS
Transcatheter PFO closure with the AMPLATZER PFO Occluder reports over 98.5% occlusion rates at six and 12 month follow-up with a simple-to-perform procedure and low adverse event risk. The Nitinol and polyester construction of the PFO Occluder allows rapid closure success and enhanced tissue ingrowth, with the simple delivery and procedural flexibility seen with all of AGA Medical Corporation occlusion systems.

- 18, 25, 30 and 35mm right atrial disc sizes (A) for a wide range of defect sizes
- Nitinol mesh conforms to septal wall
- Narrow woven waist flexes for optimal fit
- Polyester material provides occlusion and substrate for tissue ingrowth
- AMPLATZER TorqVue® Delivery System allows confident placement, repositioning and recapture

**AMPLATZER PFO OCCLUDER**

A Proximal Disc
B Waist
C Distal Disc
D Delivery Cable Connector
Closure

The AMPLATZER PFO Occluder is designed for secure apposition on each side of the defect for complete closure and tissue ingrowth.

- Device/cable connection system allows confident placement, repositioning and recapture prior to release.
- Over 98.5% occlusion rate with complete closure based on Doppler echo follow-up at 6 months and 1 year post implantation¹.
- Low complication rates post procedure and long-term¹.

Radiopaque end hubs and Nitinol wire provide good visualization under fluoroscopy.
AMPLATZER

PFO Occluder

AMPLATZER PFO Occluders are available in four sizes to properly fit the occluder to PFO size.

**PFO OCCLUDER – ORDERING INFORMATION**

<table>
<thead>
<tr>
<th>Order Number</th>
<th>RA Disc Diameter</th>
<th>LA Disc Diameter</th>
</tr>
</thead>
<tbody>
<tr>
<td>9-PFO-018</td>
<td>18mm</td>
<td>18mm</td>
</tr>
<tr>
<td>9-PFO-025</td>
<td>25mm</td>
<td>18mm</td>
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<tr>
<td>9-PFO-030</td>
<td>30mm</td>
<td>30mm</td>
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<tr>
<td>9-PFO-035</td>
<td>35mm</td>
<td>25mm</td>
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</table>

**RECOMMENDED SHEATH SIZE**

<table>
<thead>
<tr>
<th></th>
<th>New AMPLATZER TorqVue® Delivery System</th>
</tr>
</thead>
<tbody>
<tr>
<td>9-PFO-018</td>
<td>8 French, 45° Curve</td>
</tr>
<tr>
<td>9-PFO-025</td>
<td>8 French, 45° Curve</td>
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<tr>
<td>9-PFO-030</td>
<td>8 French, 45° Curve</td>
</tr>
<tr>
<td>9-PFO-035</td>
<td>9 French, 45° Curve</td>
</tr>
</tbody>
</table>

Contact your AGA Medical Corporation representative for ordering information on AMPLATZER TorqVue Delivery Systems.

1 Data on file at AGA Medical

AGA Medical Corporation
5060 Nathan Lane North
Plymouth, MN 55442 U.S.A.
(888) 646-4407 Toll Free
(763) 513-5227 Phone
(763) 513-5226 Fax
info@amplatzer.com Email
www.amplatzer.com Internet

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

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MM00151 (C2) Int10/10
AMPLATZER®
Sizing Balloon II

For Rapid and Precise Measurement of Cardiovascular Defects
AMPLATZER® SIZING BALLOON II

The AMPLATZER® Sizing Balloon II provides a simple, precise method for sizing cardiovascular defects, and is an important step when selecting the appropriate Occluder size. Publications support balloon sizing of Atrial Septal Defects as an effective method to properly size the occluder for each defect. Proper sizing may potentially reduce complications due to oversized devices.¹

Featuring radiopaque marker system for better visualization and positioning, the Sizing Balloon II is designed for accurate measurement and confident device size selection.

- Soft distal tip and flexible shaft for improved balloon positioning
- Radiopaque marker bands inside the balloon to enhance imaging and defect measurement
- Three balloon sizes to measure defects up to 40 mm
- Compliant balloon material for low pressure inflation

![Image of Sizing Balloon II with markers and shaft]

**SIZING BALLOON II – ORDERING INFORMATION**

<table>
<thead>
<tr>
<th>Order No.</th>
<th>Max Defect Size* (mm)</th>
<th>Balloon Length (cm/mm)</th>
<th>Shaft Size (Fr)</th>
<th>Usable Length (cm/mm)</th>
<th>Guidewire (inch)</th>
<th>Max Balloon Inflation Volume (cc)</th>
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</thead>
<tbody>
<tr>
<td>9-SB-018</td>
<td>20</td>
<td>3.5 / 35</td>
<td>6 Fr</td>
<td>70 / 700</td>
<td>0.035</td>
<td>12</td>
</tr>
<tr>
<td>9-SB-024</td>
<td>27</td>
<td>4.5 / 45</td>
<td>7 Fr</td>
<td>70 / 700</td>
<td>0.035</td>
<td>25</td>
</tr>
<tr>
<td>9-SB-034</td>
<td>40</td>
<td>5.5 / 55</td>
<td>8 Fr</td>
<td>70 / 700</td>
<td>0.035</td>
<td>90</td>
</tr>
</tbody>
</table>

**NOTE:** Do not insert the balloon catheter through an introducer sheath.

*Maximum defect size refers to diameter of native defect as measured by echocardiography.