# AMPLATZER™ VASCULAR PLUGS

Embolization Therapy

## PRECISE PLACEMENT AND RAPID EMBOLIZATION WITH A SINGLE DEVICE[1,2,3]

Amplatzer™
Vascular Plug (AVP)

Amplatzer™
Vascular Plug II (AVP II)

Amplatzer™
Vascular Plug 4 (AVP 4)


1. Pech M, Kraetsch A, Wieners G, et al. Embolization of the Gastroduodenal Artery Before Selective Internal Radiotherapy: A prospectively Randomized Trial Comparing Platinum-Fibered Microcoils with the AMPLATZER Vascular Plug II. CVIR 2009(32)3:455-61.
2. Kucukay F, Özdemir M, Şenol E, Okten S, Ereren M, Karan A. Large pulmonary arteriovenous malformations: long-term results of embolization with AMPLATZER vascular plugs. J Vasc Interv Radiol. 2014 Sep;25(9):1327-32. doi: 10.1016/j.jvir.2014.01.031. Epub 2014 Mar 18.
3. Tests performed by and data on file at Abbott.


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Abbott

# AMPLATZER™ FAMILY OF VASCULAR PLUGS

Peripheral Vascular Embolization

## ADVANCING THE STANDARD OF CARE IN PERIPHERAL EMBOLIZATION WITH ABBOTT

- A single device solution that allows for faster procedure times, less radiation exposure and lower procedural costs[1,2]
- Rapid embolization even in high-flow vessels[1,3,4]
- Designed for precise placement, controlled delivery and fully recapturable
- A family of plugs for different vessel conditions

1. Pech M, Kraetsch A, Wieners G, et al. Embolization of the Gastroduodenal Artery Before Selective Internal Radiotherapy: A prospectively Randomized Trial Comparing Platinum-Fibered Microcoils with the AMPLATZER Vascular Plug II. CVIR 2009(32)3:455-61.

2. Jackson J, Hart J, Aldin Z, et al. Embolization of pulmonary arteriovenous malformations using the AMPLATZER vascular plug: successful treatment of 69 consecutive patients. Eur Radiol 2010;20(11)2663-70.

3. Kucukay F, Özdemir M, Şenol E, Okten S, Ereren M, Karan A. Large pulmonary arteriovenous malformations: long-term results of embolization with AMPLATZER vascular plugs. J Vasc Interv Radiol. 2014 Sep;25(9):1327-32. doi: 10.1016/j.jvir.2014.01.031. Epub 2014 Mar 18.

4. Tests performed by and data on file at Abbott.

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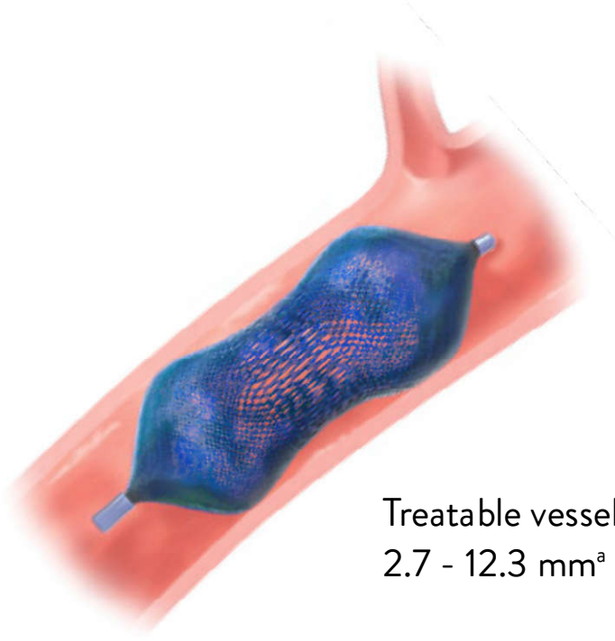
# AMPLATZER™ VASCULAR PLUG

## Short Landing Zone Embolization

**Compact design:** Single-lobe nitinol mesh design ideal for short landing zones[1]

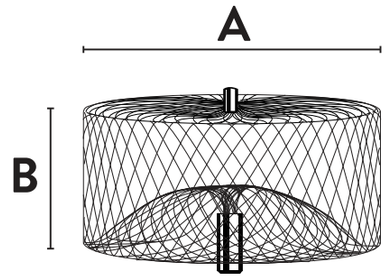
**Guide catheter or sheath deliverable:** Compatible with 4-6F sheaths or 5-8F guide catheters depending on device size



Treatable vessel size range:
2.7 - 12.3 mm[a]

## SIZING AND DEVICE SELECTION

| Vessel size | Device dimensions | | | Delivery catheter requirements[2] | | | | |
|---|---|---|---|---|---|---|---|---|
| Treatable vessel diameter range† | Model / reorder number | Vascular plug diameter [A] | Unconstrained length [B] | Minimum internal diameter | Minimum sheath Size | or | Minimum guide catheter size | Maximum delivery catheter length[3] |
| 2.5 mm - 3.0 mm | 9-PLUG-004 | 4 mm | 7 mm | ≥ 1.42 mm / ≥ 0.056 in | ≥ 4 F | | ≥ 5 F | ≤ 100 cm |
| 4.0 mm - 4.5 mm | 9-PLUG-006 | 6 mm | 7 mm | ≥ 1.42 mm / ≥ 0.056 in | ≥ 4 F | | ≥ 5 F | ≤ 100 cm |
| 5.5 mm - 6.0 mm | 9-PLUG-008 | 8 mm | 7 mm | ≥ 1.42 mm / ≥ 0.056 in | ≥ 4 F | | ≥ 5 F | ≤ 100 cm |
| 6.5 mm - 7.5 mm | 9-PLUG-010 | 10 mm | 7 mm | ≥ 1.68 mm / ≥ 0.066 in | ≥ 5 F | | ≥ 6 F | ≤ 100 cm |
| 8.0 mm - 9.0 mm | 9-PLUG-012 | 12 mm | 8 mm | ≥ 1.68 mm / ≥ 0.066 in | ≥ 5 F | | ≥ 6 F | ≤ 100 cm |
| 9.5 mm - 11.0 mm | 9-PLUG-014 | 14 mm | 8 mm | ≥ 2.21 mm / ≥ 0.087 in | ≥ 6 F | | ≥ 8 F | ≤ 100 cm |
| 10.5 mm - 12.5 mm | 9-PLUG-016 | 16 mm | 8 mm | ≥ 2.21 mm / ≥ 0.087 in | ≥ 6 F | | ≥ 8 F | ≤ 100 cm |




† Treatable vessel diameter range based on the devices Instructions for Use to select a plug that is oversized by approximately 30-50% at the occlusion site.

a. Treatable vessel size range based on the device's Instructions for Use to select a device with a diameter approximately 30-50% larger than the vessel diameter at the occlusion site.

1. Lopera, Jorge E. "The Amplatzer vascular plug: review of evolution and current applications." Seminars in interventional radiology. Vol. 32. No. 04. *Thieme Medical Publishers*, 2015.

2. The AMPLATZER Vascular Plug is delivered utilizing either a sheath or guide catheter meeting the minimum internal diameter requirements above.

3. Each AMPLATZER Vascular Plug comes pre-loaded on a 135cm nitinol delivery wire.

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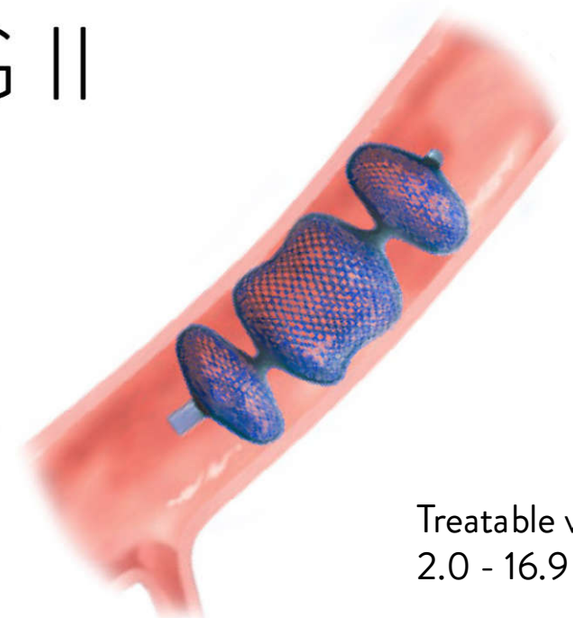
# AMPLATZER™ VASCULAR PLUG II

## Variable Landing Zone Embolization[1]

**Rapid embolization**[2]: Multi-layered, multiple-lobed nitinol mesh design provides for rapid embolization within the vessel

**Secure positioning:** Multiple points of contact with the vessel wall for secure positioning in medium- and high-flow vessels

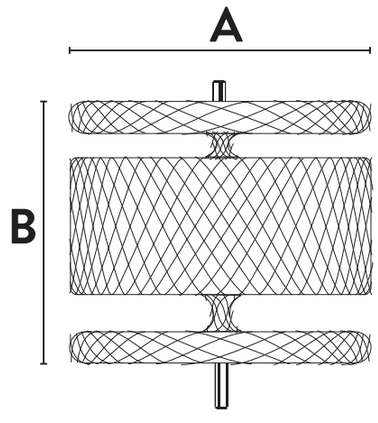
**Guide catheter or sheath deliverable**[3]**:** Compatible with 4-7F sheaths or 5-9F guide catheters depending on device size



Treatable vessel size range:
2.0 - 16.9 mm[a]

## SIZING AND DEVICE SELECTION

| Vessel size | Device dimensions | | | Delivery catheter requirements | | | | |
|---|---|---|---|---|---|---|---|---|
| Treatable vessel diameter range† | Model / reorder number | Vascular plug diameter [A] | Unconstrained length [B] | Minimum and maximum internal diameter | Minimum sheath size | or[3] | Minimum guide catheter Size | Maximum delivery catheter length[4] |
| 2.0 mm - 2.5 mm | 9-AVP2-003 | 3 mm | 6 mm | 1.42 - 1.70 mm / 0.056 - 0.067 in | ≥ 4 F | | ≥ 5 F | ≤ 100 cm |
| 2.5 mm - 3.0 mm | 9-AVP2-004 | 4 mm | 6 mm | 1.42 - 2.50 mm / 0.056 - 0.098 in | ≥ 4 F | | ≥ 5 F | ≤ 100 cm |
| 4.0 mm - 4.5 mm | 9-AVP2-006 | 6 mm | 6 mm | 1.42 - 2.50 mm / 0.056 - 0.098 in | ≥ 4 F | | ≥ 5 F | ≤ 100 cm |
| 5.5 mm - 6.0 mm | 9-AVP2-008 | 8 mm | 7 mm | 1.42 - 2.69 mm / 0.056 - 0.106 in | ≥ 4 F | | ≥ 5 F | ≤ 100 cm |
| 6.5 mm - 7.5 mm | 9-AVP2-010 | 10 mm | 7 mm | 1.78 - 2.69 mm / 0.070 - 0.106 in | ≥ 5 F | | ≥ 6 F | ≤ 100 cm |
| 8.0 mm - 9.0 mm | 9-AVP2-012 | 12 mm | 9 mm | 1.78 - 2.69 mm / 0.070 - 0.106 in | ≥ 5 F | | ≥ 6 F | ≤ 100 cm |
| 9.5 mm - 11.0 mm | 9-AVP2-014 | 14 mm | 10 mm | 2.18 - 2.69 mm / 0.086 - 0.106 in | ≥ 6 F | | ≥ 8 F | ≤ 100 cm |
| 10.5 mm - 12.5 mm | 9-AVP2-016 | 16 mm | 12 mm | 2.18 - 2.69 mm / 0.086 - 0.106 in | ≥ 6 F | | ≥ 8 F | ≤ 100 cm |
| 12.0 mm - 14.0 mm | 9-AVP2-018 | 18 mm | 14 mm | 2.49 - 2.69 mm / 0.098 - 0.106 in | ≥ 7 F | | ≥ 9 F | ≤ 100 cm |
| 13.5 mm - 15.5 mm | 9-AVP2-020 | 20 mm | 16 mm | 2.49 - 2.69 mm / 0.098 - 0.106 in | ≥ 7 F | | ≥ 9 F | ≤ 100 cm |
| 14.5 mm - 17.0 mm | 9-AVP2-022 | 22 mm | 18 mm | 2.49 - 2.69 mm / 0.098 - 0.106 in | ≥ 7 F | | ≥ 9 F | ≤ 100 cm |




a. Treatable vessel size range based on the device's Instructions for Use to select a device with a diameter approximately 30-50% larger than the vessel diameter at the occlusion site. † Treatable vessel diameter range based on the devices Instructions for Use to select a plug that is oversized by approximately 30-50% at the occlusion site. 1. AVP II is available in 8 unconstrained lengths ranging from 6 -18 mm. 2. Pech M., Kraetsch A., Wieners G., et al. Embolization of the Gastroduodenal Artery Before Selective Internal Radiotherapy: A Prospectively Randomized Trial Comparing Platinum-Fibered Microcoils with the AMPLATZER Vascular Plug II. Cardiovasc Intervent Radiol. 2009;32(3)455-61. 3. The AMPLATZER Vascular Plug II is delivered utilizing either a sheath or guide catheter meeting the minimum internal diameter requirements above. 4. Each AMPLATZER Vascular Plug II comes pre-loaded on a 135cm nitinol delivery wire.

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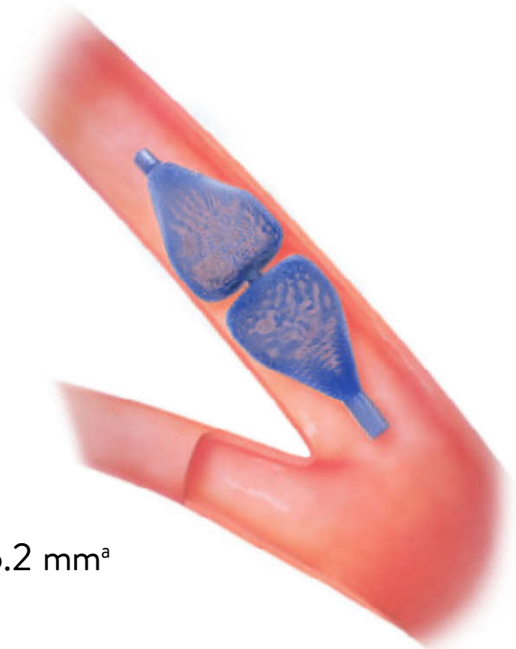
# AMPLATZER™ VASCULAR PLUG 4

## Low-Profile Embolization

**Diagnostic catheter deliverable:** Simple delivery through a 0.038" guide wire-compatible diagnostic catheter

**Improved navigation:** Low-profile design and more flexible delivery wire allow the device to navigate through tortuous anatomies with ease[2]

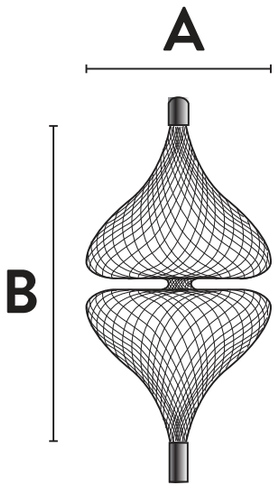
**Rapid embolization[1]:** Multi-layered, double-lobed nitinol mesh design provides for rapid embolization within the vessel



Treatable vessel
size range: 2.6 - 6.2 mm[a]

## SIZING AND DEVICE SELECTION

| Vessel size | Device dimensions | | Diagnostic catheter requirements | |
|---|---|---|---|---|
| Treatable vessel diameter range† | Model / reorder number | Vascular plug diameter [A] | Unconstrained length [B] | Requirements for diagnostic catheters[3,4] | Maximum delivery catheter length[5] |
| 2.5 - 3.0 mm | 9-AVP038-004 | 4 mm | 10.0 mm | 0.038" Guide Wire-Compatible Diagnostic Catheter | ≤ 125 cm |
| 3.5 - 4.0 mm | 9-AVP038-005 | 5 mm | 10.5 mm | 0.038" Guide Wire-Compatible Diagnostic Catheter | ≤ 125 cm |
| 4.0 - 4.5 mm | 9-AVP038-006 | 6 mm | 11.0 mm | 0.038" Guide Wire-Compatible Diagnostic Catheter | ≤ 125 cm |
| 4.5 - 5.5 mm | 9-AVP038-007 | 7 mm | 12.5 mm | 0.038" Guide Wire-Compatible Diagnostic Catheter | ≤ 125 cm |
| 5.5 - 6.0 mm | 9-AVP038-008 | 8 mm | 13.5 mm | 0.038" Guide Wire-Compatible Diagnostic Catheter | ≤ 125 cm |




† Treatable vessel diameter range based on the devices Instructions for Use to select a plug that is oversized by approximately 30-50% at the occlusion site.

a. Treatable vessel size range based on the device's Instructions for Use to select a device with a diameter approximately 30-50% larger than the vessel diameter at the occlusion site.

1. Tests performed by and data on file at Abbott.
2. Lopera, Jorge E. "The Amplatzer vascular plug: review of evolution and current applications." Seminars in interventional radiology. Vol. 32. No. 04. *Thieme Medical Publishers*, 2015.
3. The AMPLATZER Vascular Plug 4 is delivered utilizing an 0.038" Guidewire-Compatible Diagnostic Catheter with adequate wall strength.
4. The AMPLATZER Vascular Plug 4 has been tested for compatibility with the following diagnostic catheters and corresponding lengths:
   5F Dx Catheters: Boston Scientific IMAGER II (≤ 100 cm in length) and Merit Medical Impress (≤ 125 cm in length)
   4F Dx Catheters: Cordis TEMPO or TEMPO AQUA (≤ 100 cm in length)
5. Each AMPLATZER Vascular Plug 4 comes pre-loaded and packaged on an 0.038" x 155cm-long PTFE-coated delivery wire.

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The AMPLATZER™ Vascular Plug, AMPLATZER™ Vascular Plug II, and AMPLATZER™ Vascular Plug 4 are each indicated for arterial and venous embolizations in the peripheral vasculature.

CAUTION: This product is intended for use by or under the direction of a physician. Prior to use, reference the Instructions for Use, inside the product carton (when available) or at *www.vascular.eifu.abbott* or at *medical.abbott/manuals* for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

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

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