

AMPLATZER®

Vascular Plug II Instructions for Use

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician (or properly licensed practitioner.)

Device Description

The AMPLATZER® Vascular Plug II is a self-expandable nitinol mesh occlusion device (see Figure 1).

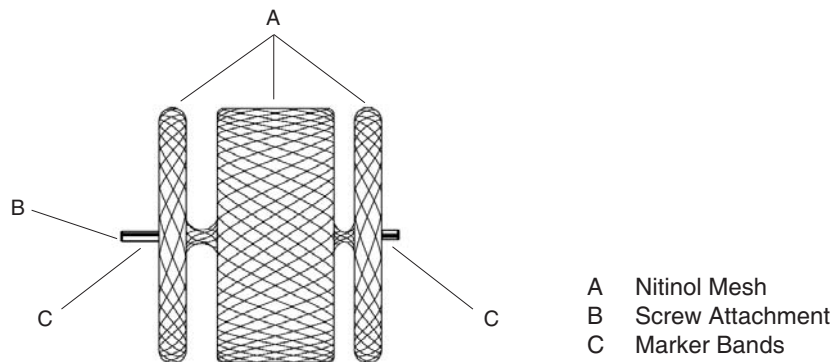


Figure 1. AMPLATZER Vascular Plug II

The device has a screw attachment for a delivery wire and radiopaque marker bands at both ends. The AMPLATZER Vascular Plug II is attached to a 135 cm delivery wire with a stainless steel screw. The AMPLATZER Vascular Plug II is packaged within a loader, pre-connected to the delivery wire in a hoop dispenser. A plastic vise is included with each device (Figure 2).

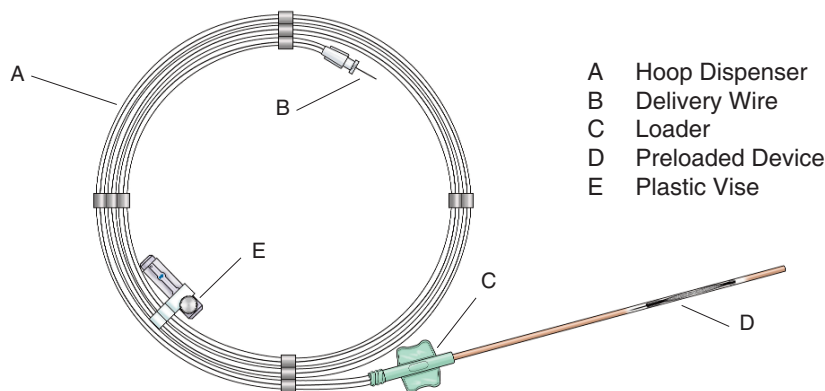


Figure 2. AMPLATZER Vascular Plug II Preloaded Device

STERILE EO



Single Use Only

Rx ONLY

Not in any way connected with medical gas or equipment sold under the "AGA" brand by AGA AB or its successors.
Manufactured in the U.S.A. AMPLATZER is a registered trademark of AGA Medical Corporation.

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Do not use open or damaged packages. Store in a dry place.



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Plugs are available† in the sizes referenced in Table 1.

Table 1. AMPLATZER Vascular Plug II

Order Number†	Vascular Plug II Diameter Fully Expanded (mm)	Vascular Plug II Length Fully expanded (mm)	Minimum Delivery Catheter or Sheath ID* (inch)	Maximum Delivery Catheter or Sheath ID* (inch)	Maximum Delivery Catheter or Sheath Length (cm)
9-AVP2-003	3	6	0.056	0.067	100
9-AVP2-004	4	6	0.056	0.098	100
9-AVP2-006	6	6	0.056	0.098	100
9-AVP2-008	8	7	0.056	0.106	100
9-AVP2-010	10	7	0.070	0.106	100
9-AVP2-012	12	9	0.070	0.106	100
9-AVP2-014	14	10	0.086	0.106	100
9-AVP2-016	16	12	0.086	0.106	100
9-AVP2-018	18	14	0.098	0.106	100
9-AVP2-020	20	16	0.098	0.106	100
9-AVP2-022	22	18	0.098	0.106	100

†Some sizes not available in all areas.

*Refer to delivery catheter or sheath manufacturer's product labeling for inner diameter (ID).

Intended Use

The AMPLATZER Vascular Plug II is indicated for arterial and venous embolizations in the peripheral vasculature.

Contraindications

None known.

Warnings

The safety and effectiveness of this device for cardiac uses (for example, patent ductus arteriosus or paravalvular leak closures) and neurological uses have not been established.

Potential Adverse Events

Potential complications include, but are not limited to: vessel perforation or migration of the device.

Precautions

- For single use only. Do not reuse or re-sterilize.
- Use before the expiration date noted on the product packaging.
- Patients with nickel allergy may experience an allergic reaction to this device.
- Store in a dry place.
- Do not use if the packaging sterile barrier is opened or damaged.
- MR Conditional

Through non-clinical testing, AMPLATZER devices have been shown to be MR Conditional. A patient with an implanted AMPLATZER device can be scanned safely immediately after placement of the device under the following conditions:

- Static magnetic field of 3 T or less
- Spatial gradient magnetic field of 720 G/cm or less
- Maximum MR system-reported, whole-body-averaged specific absorption rate (SAR) of 3 W/kg for 15 minutes of scanning

During testing, the device produced a clinically non-significant temperature rise at a maximum MR system-reported, whole-body-averaged specific absorption rate (SAR) of 3 W/kg for 15 minutes of MR scanning in a 3-tesla MR system using a transmit/receive body coil.

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

Directions for Use

1. Access the vessel and perform an angiogram using standard technique to measure the diameter of the vessel at the desired occlusion site.
2. Select an AMPLATZER Vascular Plug II with a diameter approximately 30-50% larger than the vessel diameter at the occlusion site. Ensure that the occlusion site has sufficient length to accommodate the deployed device length so that the device will not obstruct other vessels or anatomical structures.
3. Flush the hoop dispenser and loader with sterile saline until fluid exits the distal tip to purge air from the loader.
4. Remove the device (in the loader) and the delivery wire from the hoop dispenser.
5. Select a delivery catheter (see Table 1 for delivery catheter size).
NOTE: If the inner diameter of the original access catheter is sufficient for the device size selected, that catheter may be used for delivery.
NOTE: The delivery catheter length should be no more than 100 cm.
6. Advance the delivery catheter over the guide wire until the distal tip of the catheter is at the distal edge of the occlusion site.
7. Remove the guidewire.
8. Insert the loader into the delivery catheter through the Y-connector or hemostasis valve.
NOTE: A single Y-Connector kit is recommended for use with the AMPLATZER Vascular Plug II. B. Braun Medical Inc., Order No. 610400.
9. Allow blood backflow or aspirate the system to ensure air is purged from the catheter and loader.
Caution: Do not overtighten Y-connector screw to avoid damaging loader.
10. Push on the delivery wire to advance the device into the delivery catheter. Remove the loader from the wire if desired.
11. Advance the delivery wire and device to the distal end of delivery catheter. Do not twist or rotate the delivery wire during advancement to ensure device does not prematurely detach.
12. Hold the delivery wire in place and slowly withdraw the delivery catheter to deploy the device at the occlusion site.
13. Verify position of the device.
14. If device position is unsatisfactory:
 - a. Stabilize the wire and re-advance the delivery catheter until the device is completely within the catheter.
 - b. Reposition and deploy, or remove the device from the patient.
15. If the device position is satisfactory:
 - a. Attach the plastic vise to the wire, and release the device by rotating the delivery wire counterclockwise until it separates from the device.
 - b. Remove the delivery catheter and wire from the patient.