AMPLATZER™

Vascular Plug II

Instructions for Use

Device Description

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

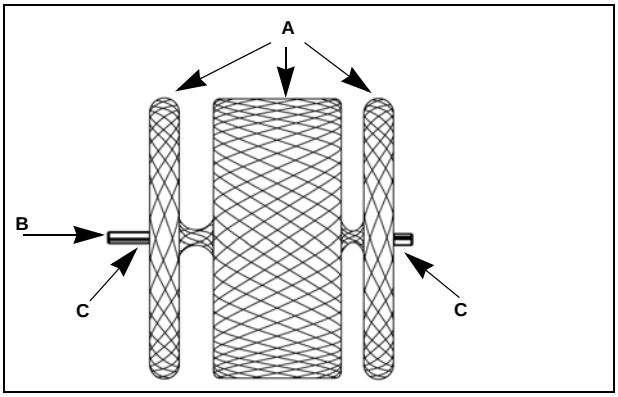
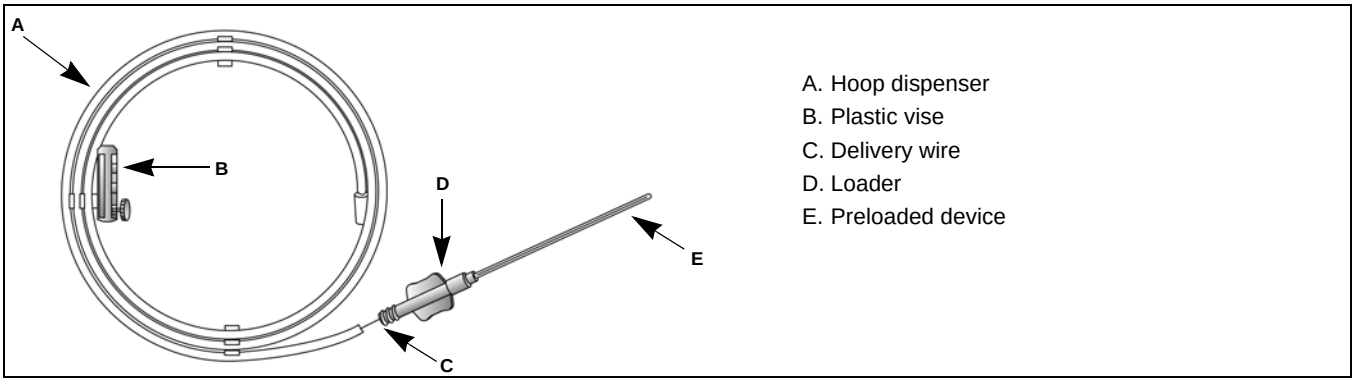


Figure 1. AMPLATZER™ Vascular Plug II

A. Nitinol mesh
B. Screw attachment
C. Marker bands

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).



A. Hoop dispenser
B. Plastic vise
C. Delivery wire
D. Loader
E. Preloaded device

Figure 2. AMPLATZER™ Vascular Plug II preloaded device.

STERILE EO

℞Only

Does not contain natural rubber latex components

MR

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Plugs are available in the sizes referenced in Table 1.

Table 1. Recommended delivery catheter or delivery sheath size

Order Number[a]	Vascular Plug II Diameter Fully Expanded (mm)	Vascular Plug II Length Fully Expanded (mm)	Minimum Delivery Catheter or Delivery Sheath ID[b] (inch)	Maximum Delivery Catheter or Delivery Sheath ID[b.] (inch)	Maximum Delivery Catheter or Delivery 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

a. Some sizes not available in all areas.
b. Refer to delivery catheter or delivery 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: death, migration of the device, stroke, or vessel perforation.

Precautions

- This device was sterilized with ethylene oxide and is for single use only. Do not reuse or resterilize this device. Attempts to resterilize this device can cause a malfunction, insufficient sterilization, or harm to the patient.
- Use on or before the last day of the expiration month that is printed on the product packaging label.
- Patients with nickel allergy can experience an allergic reaction to this device.
- Do not use this device if the sterile package is open or damaged.
- This device should be used only by physicians who are trained in standard endovascular techniques. The physician should determine which patients are candidates for procedures that use this device.
- The physician should exercise clinical judgment in situations that involve the use of anticoagulants or antiplatelet drugs before, during, and/or after the use of this device.
- Store in a dry place.
- MR Conditional[1]

  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 tesla 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

1. MR Conditional as defined in ASTM F 2503-05.

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 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 guidewire 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.
9. A single Y-Connector kit is recommended for use with the AMPLATZER™ Vascular Plug II. B. Braun Medical Inc., Order No. 610400.
10. 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.
11. Push on the delivery wire to advance the device into the delivery catheter. Remove the loader from the wire if desired.
12. 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.
13. Hold the delivery wire in place and slowly withdraw the delivery catheter to deploy the device at the occlusion site.
14. Verify position of the device.
15. If device position is unsatisfactory:
    - Stabilize the wire and re-advance the delivery catheter until the device is completely within the catheter.
    - Reposition and deploy, or remove the device from the patient.
16. If the device position is satisfactory:
    - Attach the plastic vise to the wire, and release the device, by rotating the delivery wire counterclockwise until it separates from the device.
    - Remove the delivery catheter and wire from the patient.

Post-procedure Instructions

- Temporary patient ID card – Go to www.amplatzer.com/tempIDcard to print the temporary patient identification card. Complete this card and give it to the patient.

Disposal

- The carton and Instructions for Use are recyclable. Dispose of all packaging materials as appropriate.
- Devices can be returned to AGA Medical for disposal. Contact an AGA Medical representative or returns@amplatzer.com for instructions.
- Use solid biohazard waste procedures to discard devices.

Warranty

AGA Medical Corporation warrants to buyer that, for a period equal to the validated shelf life of the product, this 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. AGA Medical Corporation's obligation under this warranty is limited to replacing or repairing at its option, at its factory, this product if returned within the warranty period to AGA Medical Corporation and after confirmed to be defective by the manufacturer.

EXCEPT AS EXPRESSLY PROVIDED IN THIS WARRANTY, AGA MEDICAL CORPORATION DISCLAIMS ANY REPRESENTATION OR WARRANTY OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY AS TO MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

See the Terms and Conditions of Sale for further information.

State of California (USA) Only:

WARNING: This product and its packaging have been sterilized with ethylene oxide. The packaging may expose you to ethylene oxide, a chemical known to the State of California to cause cancer or birth defects or other reproductive harm.

Symbol Definitions

The following symbols may appear on the device packaging:

Symbol	Definition
	Manufacturer
	Contains Phthalate
	EU authorized representative
	Reference number
	Product serial number
	Product lot number
	Use by date (Use on or before the last day of the expiration month noted on the product packaging.)
	Do not reuse
	Sterilized using ethylene oxide
	Consult instructions for use
	Keep dry
	Do not use if package is damaged
	Does not contain natural rubber latex components
	MR Conditional
	Inner diameter

	Outer diameter
	Length
	Usable length
	Hydrophilic coating
	Recommended delivery sheath/catheter dimensions
	Indication of conformity with the essential health and safety requirements set out in European Directives
	Federal law (USA) restricts this device to sale by or on the order of a physician (or properly licensed practitioner).
	Quantity
	Date of manufacture