Amplatzer™ Vascular Plug 4

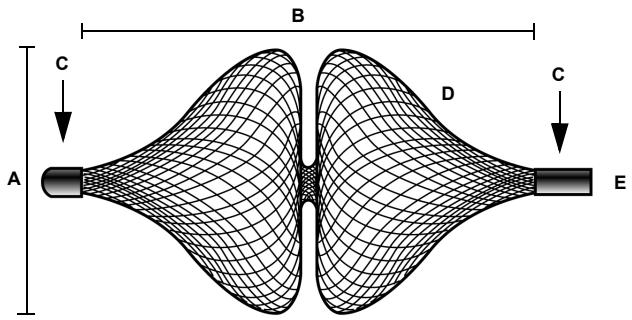
Instructions for Use

Device Description

The Amplatzer™ Vascular Plug 4 is a self-expanding nitinol mesh occlusion device. The device has a radiopaque marker band at each end and a micro screw attachment at one end for attaching to the delivery wire.

The device is shipped attached to a 155-cm delivery wire in a hoop dispenser. The device is preloaded in a loader. A plastic vise is also included and may be attached to the delivery wire to facilitate device detachment.

Device dimensions are provided in Table 1.



A. Device diameter
B. Device length
C. Radiopaque marker bands
D. Nitinol braid
E. Micro screw attachment

Figure 1. Amplatzer™ Vascular Plug 4 Device

Table 1. Device Dimensions

Order number	A Device diameter (mm)	B Device length (unconstrained) (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

ARTEN600196859 B
2022-11

STERILE EO

℞ ONLY

Not made with natural rubber latex

MR

Abbott

Manufacturing facility:
Abbott Medical
5050 Nathan Lane North
Plymouth, MN
55442 USA
+1 855 478 5833
+1 651 756 5833

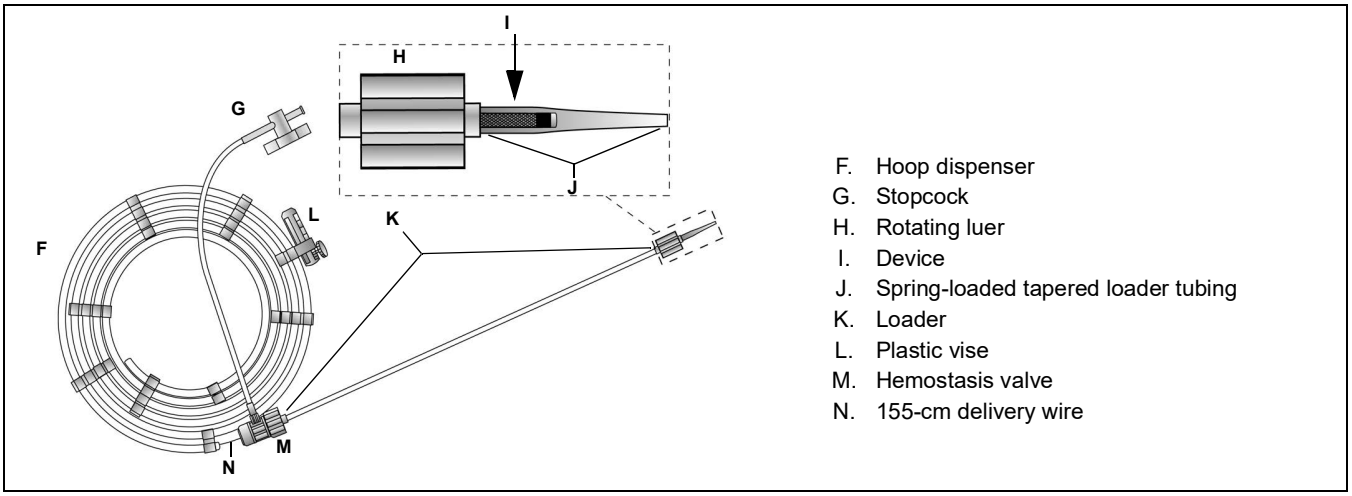
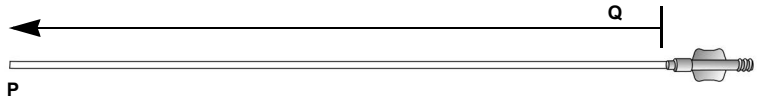


Figure 2. Amplatzer™ Vascular Plug 4 Complete Assembly

Table 2. 0.038-Guidewire-compatible Diagnostic Catheters



Product	P Catheter outer diameter (French)[a]	Q Catheter length (cm)
Boston Scientific Imager‡ II	5	≤ 100
Cordis TEMPO‡	4	≤ 100
Cordis TEMPO‡ AQUA‡	4	≤ 100
Merit Medical IMPRESS‡	5	≤ 125

a. Catheter availability may vary by geography.

Indications and Usage

The Amplatzer™ Vascular Plug 4 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 (eg, cardiac septal occlusion, patent ductus arteriosus, paravalvular leak closures) and neurologic uses have not been established.
- Do not use this device if the sterile package is open or damaged.
- Use on or before the last day of the expiration month that is printed on the product packaging label.
- The 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.
- Do not use a power injection syringe to inject contrast solution through this device.
- Physicians must be prepared to deal with urgent situations, such as device embolization, which require removal of the device. This includes the availability of an on-site surgeon.

Precautions

- The Amplatzer™ Vascular Plug 4 device consists of a nickel-titanium alloy, which is generally considered safe. However, in vitro testing has demonstrated that nickel is released from this device for a minimum of 60 days. Patients who are allergic to nickel may have an allergic reaction to this device, especially those with a history of metal allergies. Certain allergic reactions can be serious; patients should be instructed to notify their physicians immediately if they suspect they are

experiencing an allergic reaction such as difficulty breathing or inflammation of the face or throat. Some patients may also develop an allergy to nickel if this device is implanted.

- The physician should exercise clinical judgment in situations that involve the use of anticoagulants or antiplatelet drugs before, during, and/or after use of the device.
- Store in a dry place.
- 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.
- Use in specific populations
  - Pregnancy - care should be taken to minimize the radiation exposure to the fetus and the mother.
  - Nursing mothers - there has been no quantitative assessment of the presence of leachables in breast milk.

MRI Safety Information

MR	A patient with the Amplatzer™ Vascular Plug 4 may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.
Device Name	Amplatzer™ Vascular Plug 4
Static Magnetic Field Strength (B_0)	1.5 T or 3.0 T
Maximum Field Spatial Gradient	19T/m (1900 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Body Coil
Operating Mode	Normal Operating Mode
Maximum Whole Body SAR	2.0W/kg (Normal Operating Mode)
Maximum Head SAR	N/A
Scan Duration	2.0W/kg whole-body-averaged SAR for 15 minutes of continuous scanning
MR Image Artifact	The presence of this implant may produce an image artifact.

Potential Adverse Events

Potential adverse events that may occur during or after a procedure placing this device include, but are not limited to:

- Air embolus
- Allergic reaction/toxic effects
- Bleeding
- Death
- Device migration
- Fever
- Foreign material embolic event
- Hemolysis
- Infection
- Occlusion of unintended vessel
- Peripheral embolism
- Recanalization
- Residual flow
- Stroke/TIA
- Surgical intervention
- Vascular access site complication
- Vessel trauma/perforation

Materials Required for Use with the Amplatzer™ Vascular Plug 4

- Delivery of the Amplatzer™ Vascular Plug 4 device requires the use of a 0.038-guidewire–compatible diagnostic catheter (refer to Table 2) with adequate wall strength. The device has been tested for compatibility with the following diagnostic catheters:
  - Boston Scientific IMAGER‡ II (5 Fr)
  - Cordis TEMPO‡ AQUA‡ (4 Fr)
  - Cordis TEMPO‡ (4 Fr)
  - Merit Medical IMPRESS‡ (5 Fr)

  NOTE: Physicians should exercise their clinical judgment in selection and use of catheters. Refer to the instructions for use for each product listed. Manufacturers may make changes to their catheters without notice which may impact their suitability for use with Amplatzer™ Vascular Plugs. Abbott Medical provides no warranty for use of third party catheters with its products.

  The use of other diagnostic catheters may result in an inability to deliver, deploy, or recapture the device.

  NOTE: The delivery catheter length must be less than or equal to 125 cm.

  NOTE: Catheter availability may vary by geography.
- A 10-cc syringe with sterile saline

Procedure

1. Access the vessel and perform an angiogram using standard technique to measure the vessel diameter at the desired occlusion site. Select a device that is appropriately 30%–50% larger in diameter than the corresponding vessel diameter.
2. Make sure that the occlusion site is long enough to accommodate the implanted device without obstructing unintended vessels. Table 1 lists the dimensions of the uncompressed device.
3. Select a 0.038-guidewire–compatible diagnostic catheter and prepare the catheter according to the manufacturer's instructions for use.

   NOTE: The delivery catheter length must be less than or equal to 125 cm.
4. Insert the guidewire and advance the 0.038-guidewire–compatible diagnostic catheter over the guidewire until the distal tip is at the leading edge of the occlusion site.
5. Remove the guidewire.
6. Prepare the device for use:
   - Inspect the sterile pouch and verify that it is unopened and undamaged. Do not use the device if the sterile pouch is open or damaged.
   - Gently open the sterile pouch and inspect the components for damage. Do not use the device if damage is evident.
   - Connect a 10-cc syringe of sterile saline to the stopcock and open to positively flush the loader and device. Flush until sterile saline exits the distal tip of the loader through the device.

   CAUTION: Do not advance or retract the device from the loader without attaching the loader to a catheter hub. Leave the device in the loader.

   - If the device is accidentally deployed, grasp the spring-loaded tapered loader tubing and the rotating luer in one hand and retract the delivery wire with the other hand. Continue to retract the delivery wire until both the single white marker and the double white markers on the delivery wire are visible (see Figure 3). Make sure the device is fully retracted into the loader. Reflush the device if necessary.

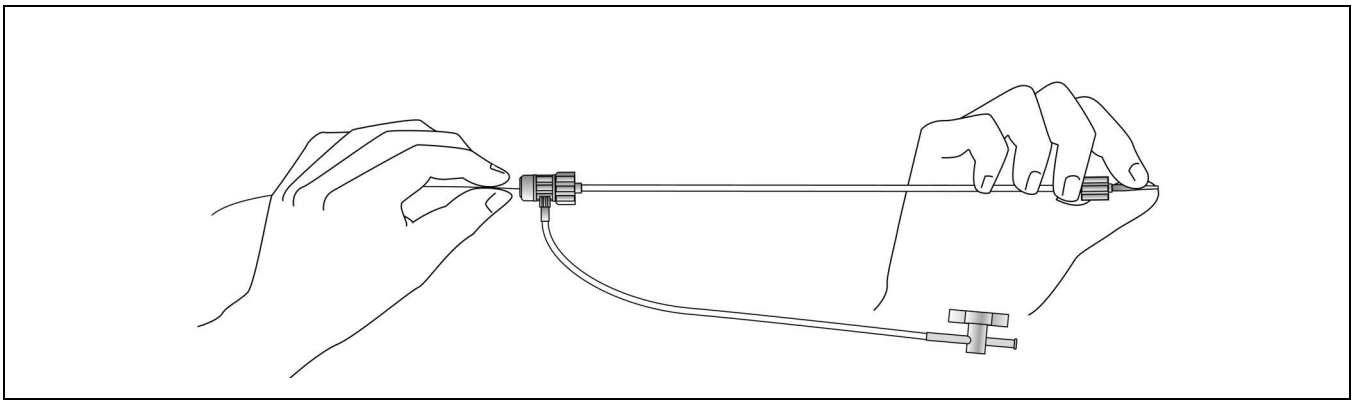


Figure 3. Retracting the Device into the Loader

7. Remove the loader and the delivery wire from the hoop dispenser.
8. Insert the tapered tip of the loader into the hub of the 0.038-guidewire–compatible diagnostic catheter.

   CAUTION: Do not connect the luer through a stopcock, hemostasis valve, Y-connector, or other valve. This will result in damage to the loader.

   NOTE: The spring-loaded tapered loader tubing cannot be detached from the loader.
9. Grasp the rotating luer and press the luer to the hub of the catheter and rotate clockwise to ensure full engagement of the loader to the catheter hub.
10. Open the stopcock to allow blood backflow to ensure that air is purged from the catheter and the loader. Close the valve.

    CAUTION: Aspiration can introduce air into the loader at the hemostasis valve or stopcock.
11. Advance the delivery wire to move the device into the 0.038-guidewire–compatible diagnostic catheter until the double white marker is at the hemostasis valve.

    CAUTION: Do not advance the device if you experience excessive force.

    NOTE: You may choose to remove the loader at this time. Removing the loader allows for delivery through longer catheters. This may be necessary if the catheter that is used is longer than 100 cm.
12. Advance the delivery wire and device to the distal end of the 0.038-guidewire–compatible diagnostic catheter.

    CAUTION: Do not advance the device if you experience excessive force.

WARNING: Do not twist or rotate the delivery wire or the device may detach prematurely. If rotation is required, rotate the delivery wire and 0.038-guidewire–compatible diagnostic catheter together.

13. Hold the delivery wire in place and slowly retract the 0.038-guidewire–compatible diagnostic catheter to deploy the device at the occlusion site.
14. Verify the position of the device using the radiopaque marker bands.

    NOTE: The injection of contrast may or may not be possible while the delivery wire is in the catheter.
15. If the device position is unsatisfactory:
    - Stabilize the delivery wire and readvance the 0.038-guidewire–compatible diagnostic catheter until the device is at least partially recaptured within the catheter.
    - Reposition and redeploy the device, or remove the device from the patient.
16. If the device position is satisfactory:
    - Attach the plastic vise to the delivery wire, and detach the device by rotating the delivery wire counterclockwise until it separates from the device.

    WARNING: Do not advance the delivery wire after detaching it from the device.
    - Retract the delivery wire into the 0.038-guidewire–compatible diagnostic catheter.
    - Remove the delivery wire from the patient and complete the procedure following standard technique.

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.
- MedicAlert‡ service – Recommend the patient become a MedicAlert member by calling +1.888.633.4298 or enrolling online at www.medicalert.org. The patient will be asked to provide his condition, implanted device name, and restrictions concerning the use of an MRI.

Disposal

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

Warranty

Abbott Medical 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. Abbott Medical'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 Abbott Medical and after confirmed to be defective by the manufacturer.

EXCEPT AS EXPRESSLY PROVIDED IN THIS WARRANTY, ABBOTT MEDICAL 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.

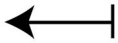
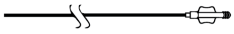
State of California (USA) Only:

⚠ WARNING: This product can expose you to chemicals including ethylene oxide, which is known to the State of California to cause cancer and birth defects or other reproductive harm. For more information, go to www.P65Warnings.ca.gov.

Symbol Definitions

The following symbols may appear on the device packaging:

Symbol	Definition
	Caution, consult accompanying documents
	Manufacturer

Symbol	Definition
	Reference number
	Product serial number
	Batch Code
	Use-by date
	Do not re-use
	Unique device identification
	Sterilized using ethylene oxide
	Consult instructions for use
	Follow instructions for use on this website
	Keep dry; keep away from rain
	Do not use if package is damaged
	Not made with natural rubber latex
	MR Conditional
	Inner diameter
	Outer diameter
	Length
	Usable length
	Recommended delivery catheter dimensions
	Federal law restricts this device to sale by or on the order of a physician.
	Quantity

Symbol	Definition
	Date of manufacture
Vascular Plug	Vascular Plug