Amplatzer™ Vascular Plug

STERILE EO

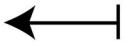
CE 2797

MR

Abbott

Symbols and Definitions

The symbols below and harmonized symbols may be found on the product or product label. For harmonized symbols, refer to the Universal Symbols Glossary at https://medical.abbott.com/manuals.

Symbols	Definitions
	Length
	Usable length
	Recommended delivery sheath dimensions
Vascular Plug	Vascular Plug
	Follow instructions for use on this website
UDI	Unique device identifier
CE 2797	Affixed in accordance with European Union Medical Device Regulation 2017/745 (NB 2797). Hereby, Abbott Medical declares that this device is in compliance with the relevant provisions of this regulation.
	Do not resterilize
	Does not contain natural rubber latex components
	Contains hazardous substances (Cobalt CAS No. 7440-48-4)
	Single sterile barrier system with protective packaging inside
	Importer

Symbols	Definitions
MD	Medical device
medical.abbott/manuals	Patient information website
UKRP	United Kingdom Responsible Person
UK CA 0086	United Kingdom Conformity Assessed
UA.TR.101	Ukrainian mark of conformity to the technical regulations, where 101 is the assessment body
31	Date
	Patient identification
	Health care center physician
	Physician telephone

Amplatzer™ Vascular Plug

EN: Instructions for Use

CAUTION: Read all instructions carefully. Failure to follow these instructions, warnings, and precautions may lead to patient injury or device damage.

Device Description

The Amplatzer™ Vascular Plug is a self-expanding nitinol mesh occlusion device. It has a screw attachment for a delivery wire and radiopaque marker bands at both ends and is attached to a 135-cm delivery wire with a stainless steel screw. The Amplatzer™ Vascular Plug is packaged within a loader, pre-connected to the delivery wire in a hoop dispenser.

Refer to the figures and tables in Appendix A: Supplemental Information for more information about the device. Device dimensions and recommended delivery catheter or sheath dimensions are provided in Table 1. The following device components are identified in Figure 1 and Figure 2.

Figure 1

E	Nitinol mesh
F	Radiopaque marker bands
G	Screw attachments

Figure 2

H	Hoop dispenser
I	Preloaded device
J	Loader
K	Delivery wire

Intended Purpose

The Amplatzer™ Vascular Plug is intended for therapeutic embolization to reduce or obstruct blood flow.

Indication for Use

The Amplatzer™ Vascular Plug is indicated for arterial and venous embolizations in the peripheral vasculature.

Device Lifetime

The Amplatzer™ Vascular Plug is a permanent implantable device used to embolize blood vessels in the peripheral vasculature. Its active lifetime is 28 days. During this time, blood coagulates, fibrin is activated, and smooth muscle cells proliferate, strengthening the occlusion at the site of the plug. Once the natural occlusion of the vessel is complete, the implant no longer serves a therapeutic purpose. The Amplatzer™ Vascular Plug is not intended to be removed after implementation.

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.
- Do not use the device if the packaging sterile barrier is open or damaged.
- The device is sterilized using ethylene oxide and is for single use only. Do not reuse or resterilize. Attempts to resterilize the device may result in device malfunction, inadequate sterilization, or patient harm.
- DO NOT use the Amplatzer™ Vascular Plug after the Use-by date stated on the package label.
- 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

- 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.
- Patients who are allergic to nickel can have an allergic reaction to this device.
- The physician should exercise clinical judgment in situations that involve the use of antithrombotic (anticoagulant or antiplatelet) drugs before, during, and/or after use of the device.

MR Conditional

Non-clinical testing has demonstrated that the Amplatzer™ Vascular Plug is MR Conditional. A patient with the Amplatzer™ Vascular Plug can be safely scanned in an MR system under the following conditions:

- Static magnetic field of 1.5 Tesla (1.5T) or 3.0 Tesla (3.0T)
- Maximum spatial gradient field of 19 T/m (1900 G/cm)
- Maximum MR system reported, whole-body averaged specific absorption rate (SAR) of 2.0 W/kg (normal operating mode)

Under the scan conditions defined above, the device is expected to produce a maximum temperature rise of less than or equal to 3°C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 12 mm from the Amplatzer™ Vascular Plug when imaged with a spin echo pulse sequence in a 3.0T MR system.

Precautions for Special Populations

- Pregnancy: The safety and effectiveness of this plug has not been established during pregnancy. Fluoroscopic x-ray guidance is used during placement of the device. The risk of increased X-ray exposure for patients who are pregnant must be weighed against the potential benefits of this technique.
- Nursing mother: The safety and effectiveness of this plug has not been established in lactating mothers. There has been no quantitative assessment for the presence of leachables in breast milk.
- Pediatric Population: The safety and effectiveness of this plug has not been established in a pediatric population.

Potential Adverse Events

Potential complications include, but are not limited to the following:

- air embolus
- allergic reactions/toxic effects
- bleeding
- death
- embolization of the device
- fever
- foreign material embolic events
- hematoma at the site entry
- hemolysis
- infection
- migration of the device
- occlusion of unintended vessel
- peripheral embolism
- pulmonary embolism/infarct
- recanalization
- residual flow
- stroke/TIA
- surgical intervention
- unintended thrombosis
- vessel trauma/perforation

Intended Clinical Benefit

The intended clinical benefit of the Amplatzer™ Vascular Plug is the percutaneous embolization of arterial and venous peripheral vasculature.

The following safety outcomes are expected to be achieved:

1. avoid or limit migrations[1,2,3,4,5,6,7]
2. avoid or limit unintended embolizations[3,4,8,9]
3. embolization of high flow vessels[10,11,12]

The following performance outcome is expected to be achieved:

- improved performance outcomes when used as intended
- Amplatzer™ vascular plugs act as embolic agents that promote rapid clot formation, creating a physical barrier to blood flow and alternative therapies (for example, coils)

Storage and Handling

- There are no special storage requirements beyond what is typical for medical devices.
- This instructions for use is recyclable.

Summary of Safety and Clinical Performance

A summary of the safety and clinical performance for this device is available at https://ec.europa.eu/tools/eudamed : This is the SSCP location after the launch of the European Database on Medical Devices/ Eudamed. Search for the device using the device model numbers located on the device package.

Patient Identification Card

A patient identification card is included with product documentation. The implanting physician is responsible for filling in the card and providing it to the patient. The card label includes the patient's name, implant date, physician/healthcare facility information, and contact number. Obtain a peel-away label from the sterile package of each implanted device related to the Amplatzer™ Vascular Plug and apply to the back of the card. If this label is not available, write in the device information by hand. Contact Abbott Technical Support if you have any questions or need to request a replacement card.

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1. Bui, J., et al., Amplatzer™ Vascular Plug for arteriovenous hemodialysis access occlusion: initial experience. The Journal of Vascular Access, 2009. 10(1): p. 5-10
2. Warein, E., et al., Amplatzer™ Plug to Occlude the Internal Iliac Artery During Endovascular Aortic Aneurysm Repair: A Large Multicenter Study. Eur J Vasc Endovasc Surg, 2016. 51(5):
3. Dierks, A., et al., Proximal occlusion of unaffected internal iliac artery versus distal occlusion of aneurysmatic internal iliac artery prior to EVAR: a comparative evaluation of efficacy and clinical outcome. The British journal of radiology, 2017. 90(1072): p. 20160527
4. Bozkurt, A., et al., Use of the Amplatzer™ type 2 plug for flow redirection in failing autogenous hemodialysis fistulae. Cardiovascular and interventional radiology, 2015. 38(4): p. 887-893.
5. Bourquelot, P., et al., Amplatzer™ vascular plug for occlusion or flow reduction of hemodialysis arteriovenous access. Journal of Vascular Surgery, 2014. 59(1): p. 260-263.
6. Hongku, K., et al., Applicability and midterm results of branch cuff closure with vascular plug in branched endovascular repair for thoracoabdominal aortic aneurysms. J Vasc Surg, 2017. 66(2): p. 367-374.
7. Matsumoto, K., et al., Compressed Amplatzer™ Vascular Plug II Embolization of the Left Subclavian Artery for Thoracic Endovascular Aortic Repair is Efficient and Safety Method Comparable to Conventional Coil Embolization. Yonago Acta Med, 2019. 62(1): p. 24-29.
8. Ryer, E.J., et al., Comparison of outcomes with coils versus vascular plug embolization of the internal iliac artery for endovascular aortoiliac aneurysm repair. Journal of vascular surgery, 2012. 56(5): p. 1239-1245.
9. Libicher, M., et al., Occlusion of the internal iliac artery prior EVAR: comparison of coils and plugs. Vascular and endovascular surgery, 2012. 46(1): p. 34-39.
10. Pech M, Kraetsch A, Winers G, et al. Embolization of the Gastroduodenal Artery Before Selective Internal Radiotherapy: A Prospectively Randomized Trial Comparing Pla tinum Fibered Microcoils with the Amplatzer™ Vascular Plug II. CVIR 2009(32)3:455 61.
11. 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.
12. Test performed by and data on file at Abbott Vascular. (AGA report on occlusion times)

Product Materials

The following materials are intended to come into contact with tissue:

Material description	Component name	CAS number	Substances in material	Percentage concentration (% w/w) AVP	Total mass (mg)
Nitinol (Ni 56%/Ti 44%) NiTi	Nitinol Wire	7440-02-0	Nickel	55-57	9-74
		7440-44-0	Carbon	0-1	0-1
		7440-48-4	Cobalt	0-1	0-1
		7440-50-8	Copper	0-1	0-1
		7440-47-3	Chromium	0-1	0-1
		1333-74-0	Hydrogen	0-1	0-1
		7439-89-6	Iron	0-1	0-1
		7440-03-1	Niobium	0-1	0-1
		7727-37-9	Nitrogen	0-1	0-1
		7780-44-7	Oxygen	0-1	0-1
		7440-32-6	Titanium	43-45	7-59
Platinum/ 20% Iridium Alloy	Marker Band	7440-06-4	Platinum	80	2-4
		7439-88-5	Iridium	20	0-1
316L/316 LVM Stainless Steel[a]	End Screw	7439-89-6	Iron	45-90	4-14
		7440-02-0	Nickel	0-40	0-6
		7440-47-3	Chromium	11-30	1-5
		7439-96-5	Manganese	0-15	0-2
		7439-98-7	Molybdenum	0-5	0-1
		7440-50-8	Copper	0-5	0-1
		7440-21-3	Silicon	0-3	0-1
		7429-90-5	Aluminum	0-1	0-1
		7440-48-4	Cobalt	0-1	0-1
		7440-32-6	Titanium	0-1	0-1
		1314-62-1	Vanadium	0-1	0-1
		7440-33-7	Tungsten	0-1	0-1
		7440-25-7	Tantalum	0-1	0-1
		7439-92-1	Lead	0-1	0-1
CAUTION: One or more components of this device contains the following substance defined as CMR 1B in a concentration above 0.1% weight by weight: Cobalt; Chemical Abstracts Services (CAS) No. 7440-48-4; EC No. 231-158-0. **Current scientific evidence supports that medical devices manufactured from cobalt alloys and stainless steel alloys containing cobalt do not cause an increased risk of cancer or adverse reproductive effects.[b, c, d, e, f]**					

a. The End Screw contains the following substance defined as CMR 1B; Cobalt - <1% w/w (CAS No. 7440-48-4).
b. Michael Kovochich, et al. 'Carcinogenic Hazard Assessment of Cobalt-Containing Alloys in Medical Devices: Review of in vivo Studies'; *Regulatory Toxicology and Pharmacology* 122 (2021)

c. Shumin Zhang et al. 'Carcinogenic Assessment of Cobalt-Containing Alloys in Medical Devices or Cobalt in Occupational Settings: A Systematic Review and Meta-Analysis of Overall cancer Risk from Published Epidemiologic Studies'; *Regulatory Toxicology and Pharmacology* 125 (2021)
d. Chantal E. Holy et al. 'Site-specific Cancer Risk from Exposure via Orthopedic Implants or in Occupational Settings: A Systematic Review and Meta-Analysis'; *Regulatory Toxicology and Pharmacology* 129 (2021)
e. Andrew D. Monnot et al. 'A Hazard Evaluation of the Reproductive/Developmental Toxicity of Cobalt in Medical Devices'; *Regulatory Toxicology and Pharmacology* 123 (2021)
f. Gary Eichenbaum, et al. 'An Integrated Benefit-Risk Assessment of Cobalt-Containing Alloys used in Medical Devices: Implications for regulatory requirements in the EU; *Regulatory Toxicology and Pharmacology* 125 (2021)

Directions for Use

Materials recommended for use with the Amplatzer™ Vascular Plug

- Y-connector kit (B. Braun Medical, order number 610400)
- Syringe
- Delivery catheter

Procedure

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 a device 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 in Appendix A: Supplemental Information 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. 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.

    WARNING: 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:
    - 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.
15. 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.

Reporting Device Incidents

If, in the course of use of this device, you have reason to believe that a serious incident occurred, please report it to the manufacturer. For customers in the European Union, report the serious incident to your national authority as well as to the manufacturer.

Disposal

Amplatzer™ Vascular Plug accessories should be appropriately classified as biohazards and disposed of in compliance with applicable facility procedures and local and country laws and regulations. Return the vascular plug accessories to Abbott Medical at the end of their operating life.

The carton and instructions for use are recyclable. Dispose of all packaging as appropriate.

Devices can be returned to Abbott Medical for disposal. Contact your Abbott Medical representative or returns@amplatzer.com for instructions.

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.

Australian Warranty

This section is only provided in English.

This warranty is given by Abbott Medical. To make inquiries regarding this warranty, use the contact information for either the manufacturer or Australian Sponsor.

Our goods come with guarantees that cannot be excluded under the Australian Consumer Law. You are entitled to a replacement or refund for a major failure and compensation for any other reasonably foreseeable loss or damage. You are also entitled to have the goods repaired or replaced if the goods fail to be of acceptable quality and the failure does not amount to a major failure.

The benefits to you given by this warranty are in addition to your other rights and remedies under the Australian Consumer Law.

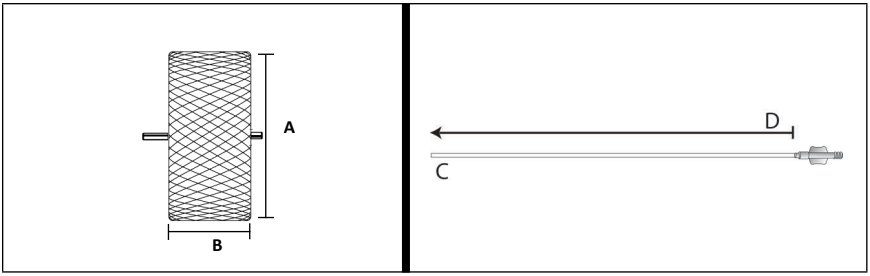
Abbott Medical warrants to the buyer that the goods, for a period equal to the validated shelf life of the goods (the "Warranty Period"), shall meet the product specifications established by the manufacturer when used in accordance with the manufacturer's instructions for use and shall be free from defects in materials and workmanship. Unless otherwise obligated by law or mandatory consumer guarantees, under this warranty Abbott Medical will, at its option, replace or repair the goods at its factory, if the buyer, at the buyer's expense, returns the goods within the Warranty Period to Abbott Medical at the address provided with the product and after Abbott Medical confirms that the goods are defective.

To the maximum extent permitted by law, if a mandatory term is implied by law or a mandatory consumer guarantee applies to the goods, and the goods are not of a kind ordinarily acquired for personal, domestic or household use or consumption, Abbott Medical’s liability for the breach of the term or guarantee is limited to, at Abbott Medical’s option, either replacement or repair of the goods or payment of the costs of replacing or repairing the goods.

EXCEPT FOR MANDATORY TERMS IMPLIED BY LAW, MANDATORY CONSUMER GUARANTEES, OR AS EXPRESSLY PROVIDED IN THIS WARRANTY, ABBOTT MEDICAL DISCLAIMS ANY REPRESENTATION OR WARRANTY OF ANY KIND, EXPRESS OR IMPLIED. See the Terms and Conditions of Sale for further information.

Appendix A: Supplemental Information

Table 1. Amplatzer™ Vascular Plug and delivery catheter dimensions (sold separately)



REF	A	B	Fr	C	D
	mm	mm		mm (inch)[a]	cm
9-PLUG-004	4	7	5	≥1.42 (0.056)	≤100
9-PLUG-006	6	7	5	≥1.42 (0.056)	≤100
9-PLUG-008	8	7	5	≥1.42 (0.056)	≤100
9-PLUG-010	10	7	6	≥1.70 (0.067)	≤100
9-PLUG-012	12	8	6	≥1.70 (0.067)	≤100
9-PLUG-014	14	8	8	≥2.24 (0.088)	≤100
9-PLUG-016	16	8	8	≥2.24 (0.088)	≤100

a. For use with standard delivery catheters meeting internal diameter requirements.

Figure 1. Amplatzer™ Vascular Plug

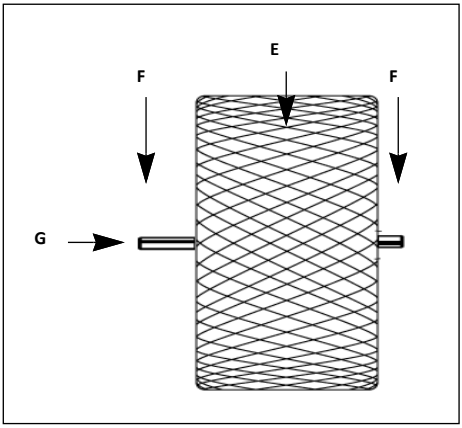
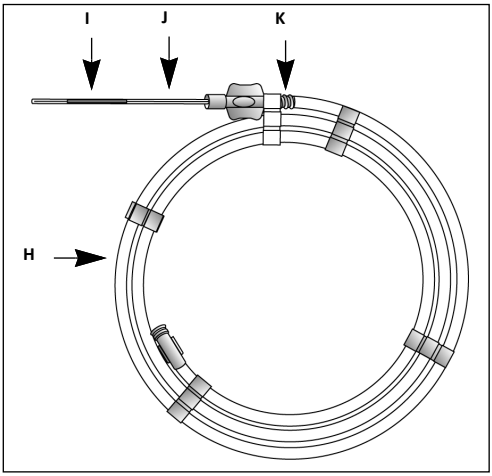


Figure 2. Amplatzer™ Vascular Plug components



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