

AMPLATZER PICCOLO™ DELIVERY SYSTEM

Important Safety Information Master

NOTE: Choose only the section applicable to the material where it will be placed. Do not include any text in red in material.

HCP Abbreviated ISI

Rx Only

Important Safety Information

AMPLATZER PICCOLO™ DELIVERY SYSTEM

Indication Of Use

The Amplatzer Piccolo™ Delivery System is indicated to facilitate the delivery of an Amplatzer Piccolo™ Occluder through the heart of a patient with a patent ductus arteriosus.

Contraindications

No known contraindications.

Potential Adverse Events

Potential adverse events that may occur during or after a procedure using this device may include, but are not limited to: Air embolus, Allergic reaction/toxic effects due to anesthesia, contrast medium, etc., Arrhythmia, Arteriovenous fistulae, Bleeding, Brachial plexus injury, Cardiac injury, Cardiac perforation, Cardiac tamponade, Death, Embolic event, Fever, Foreign material embolic event, Hematoma, Hemodynamic compromise, Hemolysis, Infection, Myocardial infarction, Pericardial effusion, Peripheral pulse loss, Pseudoaneurysm, Stroke, Thrombus formation, Tissue trauma/damage (cardiac), Transient ischemic attack, Valve damage, Valvular insufficiency, Vascular access site injury, Vascular occlusion, Vessel dissection.

HCP Full ISI

Rx Only

Important Safety Information

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Indication of Use

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Contraindications

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Warnings

- The Amplatzer Piccolo™ Delivery System should be used only by physicians who are trained in standard transcatheter techniques. The physician should determine which patients are candidates for procedures that use this device.
- DO NOT use the Amplatzer Piccolo™ Delivery System after the Use-by date stated on the package label.
- Do not use the Amplatzer Piccolo™ Delivery System if the sterile package is open or damaged. Inspect all components before use. Do not use if the package or items appear to be damaged or defective.
- The Amplatzer Piccolo™ Delivery System was sterilized with ethylene oxide and is for single use only. Do not reuse or resterilize this device. Attempts to reuse or 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 the delivery catheter.
- Use the hemostasis valve to impede blood backflow and prevent air ingress during the implant procedure.
- Remove the delivery catheter from the patient slowly to prevent an ingress of air.

Precautions

- The physician should exercise clinical judgment in situations that involve the use of antithrombotic (anticoagulants or antiplatelet) drugs before, during, or after the use of the Amplatzer Piccolo™ Delivery System.
- Use standard transcatheter techniques when using Amplatzer™ products.
- Prolonged procedure time may increase the risk of exposure to anesthesia, contrast media, or radiation.
- Use caution and rely on imaging guidance when advancing the catheter to avoid damaging tissue and vessels or interfering with previously implanted medical devices.
- If strong resistance is met during manipulation, pause the procedure and determine the cause of resistance before proceeding. If the cause of the resistance cannot be determined, withdraw all components.

Potential Adverse Events

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

- | | |
|--|--------------------------|
| • Air embolism | • Brachial plexus injury |
| • Allergic reaction/toxic effects due to anesthesia, contrast medium, etc. | • Cardiac injury |
| • Arrhythmia | • Cardiac perforation |
| • Arteriovenous fistulae | • Cardiac tamponade |
| • Bleeding | • Death |

- Embolic event
- Fever
- Foreign material embolic event
- Hematoma
- Hemodynamic compromise
- Hemolysis
- Infection
- Myocardial infarction
- Pericardial effusion
- Peripheral pulse loss
- Pseudoaneurysm
- Stroke
- Thrombus formation
- Tissue trauma/damage (cardiac)
- Transient ischemic attack
- Valve damage
- Valvular insufficiency
- Vascular access site injury
- Vascular occlusion
- Vessel dissection

This end matter is not for insertion into materials that have their own end matter.

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

Abbott

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