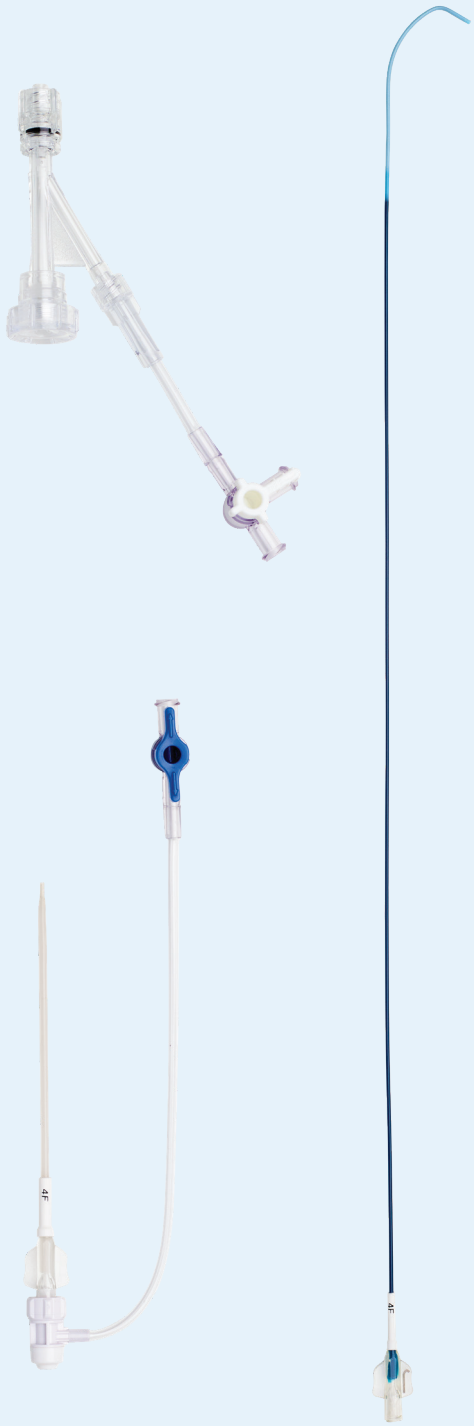
PICCOLO DELIVERY SYSTEM
PURPOSE BUILT FOR PREEMIES

Advancing Care for the Tiniest Hearts the Amplatzer Piccolo™ delivery system is purposefully designed for premature patients receiving the Amplatzer Piccolo™ Occluder to close their patent ductus arteriosus[1,2,3]



Shaped for Consistent Deployment

Distal curvature aligns with ductus for optimal deployment. 45 cm length for preemie patients.

Softness Provides Confidence

Soft catheter and low profile facilitate navigating tiny heart structures, like the tricuspid.

No Catheter Exchange

Designed for access *plus* device delivery. No need for a delivery sheath exchange.

Model/Reorder Number	French	Outer Diameter mm (in)	Inner Diameter mm (in)	Usable Length (cm)
9-PDS-04f-045	4	1.40 (0.055)	1.09 (0.043)	45

1. Windchill 91102617 – Piccolo Delivery System Design Verification Report
2. Windchill 91060911 – Design description document (DDD)
3. Windchill 91064365 – HFE summary report
4. 91061375 - CER

EXPERT SUPPORT AT **EVERY TURN**

CLINICAL CASE SUPPORT

- Experienced field personnel
- Over two decades of excellence

CLINICAL TRAINING PROGRAMS

- Training centers and online courses
- Fellows programs

For more information about the Amplatzer Piccolo™ Occluder and delivery systems, contact your Abbott sales representative or scan the QR code.

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.

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
- 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

Rx Only
Important Safety Information

AMPLATZER PICCOLO™ OCCLUDER

INDICATIONS AND USAGE

The Amplatzer Piccolo™ Occluder is a percutaneous, transcatheter occlusion device intended for the nonsurgical closure of a patent ductus arteriosus (PDA).

CONTRAINDICATIONS

- Weight < 700 grams at time of the procedure;
- Age < 3 days at time of procedure;
- Coarctation of the aorta;
- Left pulmonary artery stenosis;
- Cardiac output that is dependent on right to left shunt through the PDA due to pulmonary hypertension;
- Intracardiac thrombus that may interfere with the implant procedure;
- Active infection requiring treatment at the time of implant;
- Patients with a PDA length smaller than 3 mm;
- Patients with a PDA diameter that is greater than 4 mm at the narrowest portion.

POTENTIAL ADVERSE EVENTS

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

- Air embolus
- Allergic reaction
- Anemia
- Anesthesia reactions
- Apnea
- Arrhythmia
- Bleeding
- Cardiac perforation
- Cardiac tamponade
- Chest pain
- Device embolization
- Device erosion
- Death
- Endocarditis
- Fever
- Headache/migraine
- Hemolysis
- Hematoma
- Hypertension
- Hypotension
- Infection
- Myocardial infarction
- Palpitations
- Partial obstruction of aorta
- Partial obstruction of pulmonary artery
- Pericardial effusion
- Pericarditis
- Peripheral embolism
- Pleural effusion
- Pulmonary embolism
- Re-intervention for device removal
- Respiratory distress
- Stroke
- Thrombus
- Transient ischemic attack
- Valvular regurgitation
- Vascular access site injury
- Vascular occlusion
- Vessel perforation

References

1. Data on file at Abbott.
2. Michael T. Kuntz, Steven J. Staffa, Dionne Graham, et al. Trend and Outcomes for Surgical Versus Transcatheter Patent Ductus Arteriosus Closure in Neonates and Infants at US Children's Hospitals. Journal of the American Heart Association: Cardiovascular and Cerebrovascular Disease. 2022;11(1). doi:10.1161/JAHA.121.022776
3. Sathanandam SK, Gutfinger D, O'Brien L, et al. Amplatzer Piccolo Occluder clinical trial for percutaneousclosure of the patent ductus arteriosus in patients ≥ 700 grams. Catheter Cardiovasc Interv. 2020;1-11
4. Zahn, E. The Amplatzer Piccolo™ (ADOIIAS) U.S. Clinical Trial 3-Year Follow-up Report. Presented at: CSI Frankfurt; June 22-25, 2022.

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

Illustrations are artist's representations only and should not be considered as engineering drawings or photographs.
Photo(s) on file at Abbott.

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