
AMPLATZER PICCOLO™ OCCLUDER
CLOSING TODAY'S PDAs.
OPENING TOMORROW'S
BIG POSSIBILITIES.
PROVEN PDA CLOSURE FOR
PATIENTS 700 GRAMS AND UP.
INDICATION: The Amplatzer Piccolo™ Occluder is a percutaneous, transcatheter occlusion device intended for the nonsurgical closure of a patent ductus arteriosus (PDA).
See Important Safety Information referenced within.
Abbott

PATENT DUCTUS ARTERIOSUS (PDA)

A SIGNIFICANT CHALLENGE

Constriction of the ductus arteriosus is a critical step in postnatal circulatory transition. If the ductus remains open, Patent Ductus Arteriosus (PDA) occurs, resulting in left-to-right shunting that can create significant challenges, especially in premature infants. Challenges include:

- Pulmonary over-circulation in lungs that are already under duress[1]
- Systemic hypoperfusion[1]

A COMMON OCCURRENCE

- A PDA is present in approximately 1 in 2,000 newborns[1]
- The incidence of PDA in preterm babies is considerably higher (20-60%)[2]
- For low birth weight infants (< 1,200g), PDA incidence is > 80%[2]

THE INCIDENCE OF PRETERM PDA[2]

>50% PDAS REMAIN OPEN AT 3 WEEKS FOR INFANTS <1,000g[10]

See Important Safety Information referenced within.

SURGICAL LIGATION LIMITATIONS

While surgical ligation has been performed extensively with high closure rates, studies indicate significant procedural complications. Data shows 32% of premature infants required inotropes following PDA ligation.[3] Other risks associated with PDA ligation include:

- Bleeding, infection[4]
- Neurodevelopmental delay[4]
- Recurrent laryngeal nerve injury (vocal cord paralysis)[5,6]
- Injury to lymphatic vessels (chylothorax)[6,7]
- Post ligation syndrome (hemodynamic compromise post procedure)[8]

"Use of surgical ligation, however, was significantly associated with the development of chronic lung disease and was independent of immature gestation, other patent ducts arteriosus related variables, or other perinatal and neonatal risk factors known to be associated with chronic lung disease."

—CHANE N, ET AL. *PEDIATRICS.* 2007; 199;1185.[9]

AMPLATZER PICCOLO™ OCCLUDER

A NEW LEVEL OF VERSATILITY AND PROVEN SAFETY FOR THE YOUNGEST INFANTS AND UP.

As the only PDA closure solution indicated for premature infants ≥700g + ≥3 days old and proven to deliver safe and effective closure, Amplatzer Piccolo™ Occluder offers new opportunities to care for a wider range of patients than ever before.

BUILT ON THE EXTENSIVE AMPLATZER™ LEGACY OF SAFETY AND EFFICACY

- Pioneered transcatheter occlusion
- Over 1.25 million devices implanted worldwide[11]
- More than 20 years of clinical experience

 See Important Safety Information referenced within.

CLINICALLY PROVEN OUTCOMES.

A recent study using the Amplatzer Piccolo™ Occluder for PDA closure demonstrated safety and effectiveness with a low rate of major complications and a high rate of PDA closure.

	PIVOTAL TRIAL	CONTINUED ACCESS PROTOCOL
TOTAL # OF PATIENTS	**50** Patients ≤ 2 kg = 18 Patients > 2 kg = 32	**150** Patients ≤ 2 kg = 82 Patients > 2 kg = 68
FLUOROSCOPY TIME (MIN) MEAN ± SD	**10.5 ± 7.3**	**10.2 ± 10.8**
ANTEROGRADE IMPLANT VENOUS APPROACH	**78.3% (36/46)** (100% ≤ 2 kg, 64.3% > 2 kg)	**90.3% (131/145)** (100% ≤ 2 kg, 78.1% > 2 kg)
NICU AT BASELINE TREATED PRIOR TO NICU DISCHARGE	**50% (25/50)** (100% ≤ 2 kg, 21.9% > 2 kg)	**71.3% (107/150)** (100% ≤ 2 kg, 36.8% > 2 kg)
IMPLANT SUCCESS (%)	**92%** (100% ≤ 2 kg, 87.5% > 2 kg)	**96.7%** (98.8% ≤ 2 kg, 94.1% > 2 kg)
EFFECTIVE CLOSURE RATE*	**100%** At 6 months	**Data to be released Fall 2019**
MAJOR COMPLICATIONS**	**0** Through 180 days	**Data to be released Fall 2019**

*Assessed by echocardiography and defined as the presence of either a grade 0 (none) or grade 1 (trivial) shunt.
**Major complications were defined as "device or procedure-related adverse events resulting in death, life-threatening adverse event, persistent or significant disability and/or surgical intervention".

ONLY YOU CAN REDUCE RISKS WITH A TRANSCATHETER PDA CLOSURE REFERRAL.

NEONATOLOGIST CONSIDERS

- Is the PDA hemodynamically significant based on echocardiographic and clinical assessment?
- Is medical therapy contraindicated or has it already failed?

MULTI-DISCIPLINARY TEAM DETERMINES

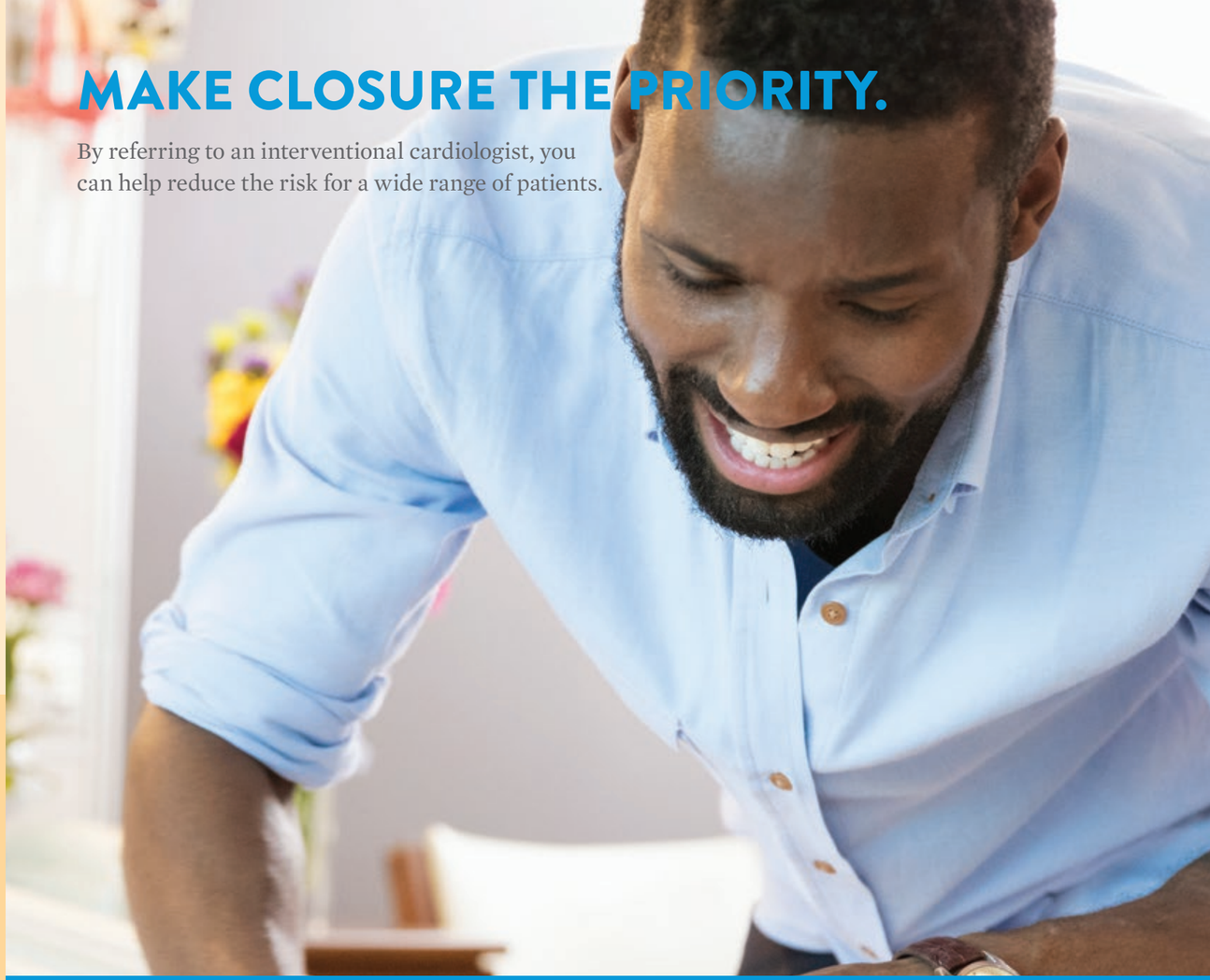
- Is transcatheter PDA closure clinically appropriate?

PDA CLOSURE

See Important Safety Information referenced within.

MAKE CLOSURE THE PRIORITY.

By referring to an interventional cardiologist, you can help reduce the risk for a wide range of patients.



For more information about the Amplatzer Piccolo™ Occluder, contact your Abbott sales representative or visit INFANTPDA.COM

IMPORTANT SAFETY INFORMATION

℞ ONLY 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

WARNINGS

- This device was sterilized with ethylene oxide and is for single use only. Do not reuse or re-sterilize this device. Attempts to resterilize this device can cause a malfunction, insufficient sterilization, or harm to the patient.
- Do not use the 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.
- Patients who are allergic to nickel can have an allergic reaction to this device.
- Prepare for situations that require the removal of this device. Preparation includes access to a transcatheter snare kit and an on-site surgeon.
- Accurate measurements of the ductus are crucial for correct occluder size selection.
- Do not release the occluder from the delivery wire if either a retention disc protrudes into the pulmonary artery or aorta; or if the position of the occluder is not stable.
- Remove embolized devices. Do not remove an embolized occluder through intracardiac structures unless the occluder is fully recaptured inside a catheter.

PRECAUTIONS

- This device should be used only by physicians who are trained in standard transcatheter techniques. 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 and antiplatelet drugs before, during, and/or after the use of this device.
- Patients should have an activated clotting time (ACT) of greater than 200 sec prior to device placement, unless the patient has a significant risk for bleeding and is unable to be anti-coagulated.
- The device may be delivered via an anterograde (venous) or a retrograde (arterial) approach. However, in small infants (≤2 kg), the device should be delivered using the anterograde (venous) approach since small infants are at an increased risk for arterial injury.
- The AMPLATZER Piccolo™ Occluder contains 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 following implant. 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 seek immediate medical attention if there is suspicion of an allergic reaction. Symptoms may include difficulty in breathing or swelling of the face or throat. While data are currently limited, it is possible that some patients may develop an allergy to nickel if this device is implanted.
- Use in specific populations
  - *Pregnancy* — Minimize radiation exposure to the fetus and the mother.
  - *Nursing mothers* — There has been no quantitative assessment for the presence of leachables in breast milk.
- Store in a dry place.
- Do not use contrast power injection with delivery catheter.

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 dye reaction
- Allergic drug reaction
- Anesthesia reactions
- Apnea
- Arrhythmia
- Bacterial endocarditis
- Bleeding
- Cardiac perforation
- Cardiac tamponade
- Chest pain
- Device embolization
- Device erosion
- Death
- 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. Schneider DJ, Moore JW. Patent ductus arteriosus. *Circ*. 2006;114(17), 1873-18. **2.** Dice DE. and Bhatia J. Patent Ductus Arteriosus: An Overview. *J Pediatr Pharmacol Ther* .2007;12(3), 138-146. **3.** Moin F, Kennedy KA, Maya FR. Risk factors predicting vasopressor use after patent ductus arteriosus ligation. *Am J Perinatol*. 2003;20:313-20. **4.** J.C. Madan, D. Kendrick, J.I. Hagadorn, I.D. Frantz 3rd, Patent ductus arteriosus therapy: impact on neonatal and 18-month outcome. *Pediatrics*. 123 (2) (2009) 674–681. **5.** Rodríguez Ogando A, Planelles Asensio I, de la Blanca ARS, et al. Surgical ligation versus percutaneous closure of patent ductus arteriosus in very low-weight preterm infants: Which are the real benefits of the percutaneous approach? *Pediatr Cardiol*. 2017. **6.** Noori S (2012) Pros and cons of patent ductus arteriosus ligation: hemodynamic changes and other morbidities after patent ductus arteriosus ligation. *Sem Perinatol*. 36(2):139–145. **7.** Pamukcu O, Tuncay A, Narin N, et al. Patent ductus arteriosus closure in preterms less than 2kg: Surgery versus transcatheter. *Int J Cardiol*. 2018; 250:110-115. **8.** A.F. El-Khuffash, A. Jain, P.J. McNamara, Ligation of the patent ductus arteriosus in preterm infants: understanding the physiology. *J. Pediatr*. 162 (6) (2013) 1100–1106. **9.** Chane N, et al. *Pediatrics*. 2007;199;1185. **10.** Semberova J, et al. Spontaneous Closure of Patent Ductus Arteriosus in Infants </= 1500g. *Pediatrics*. 2017;149 (2). **11.** Data on file at Abbott.

CAUTION: This product is 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 eifu.abbottvascular.com or at medical.abbott/manuals 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.

Abbott
3200 Lakeside Dr., Santa Clara, CA. 95054 USA, Tel: 1.800.227.9902
www.cardiovascular.abbott

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