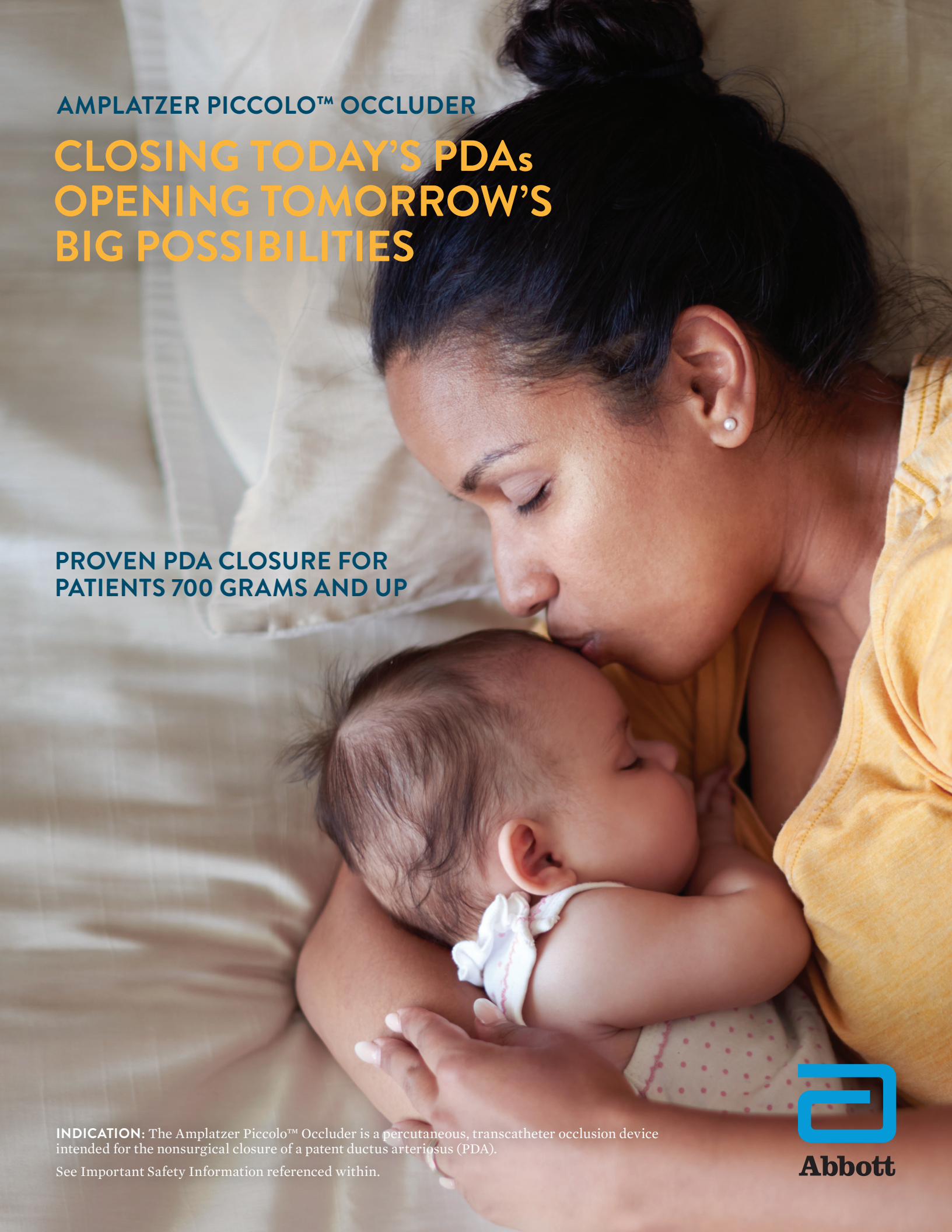


AMPLATZER PICCOLO™ OCCLUDER

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.

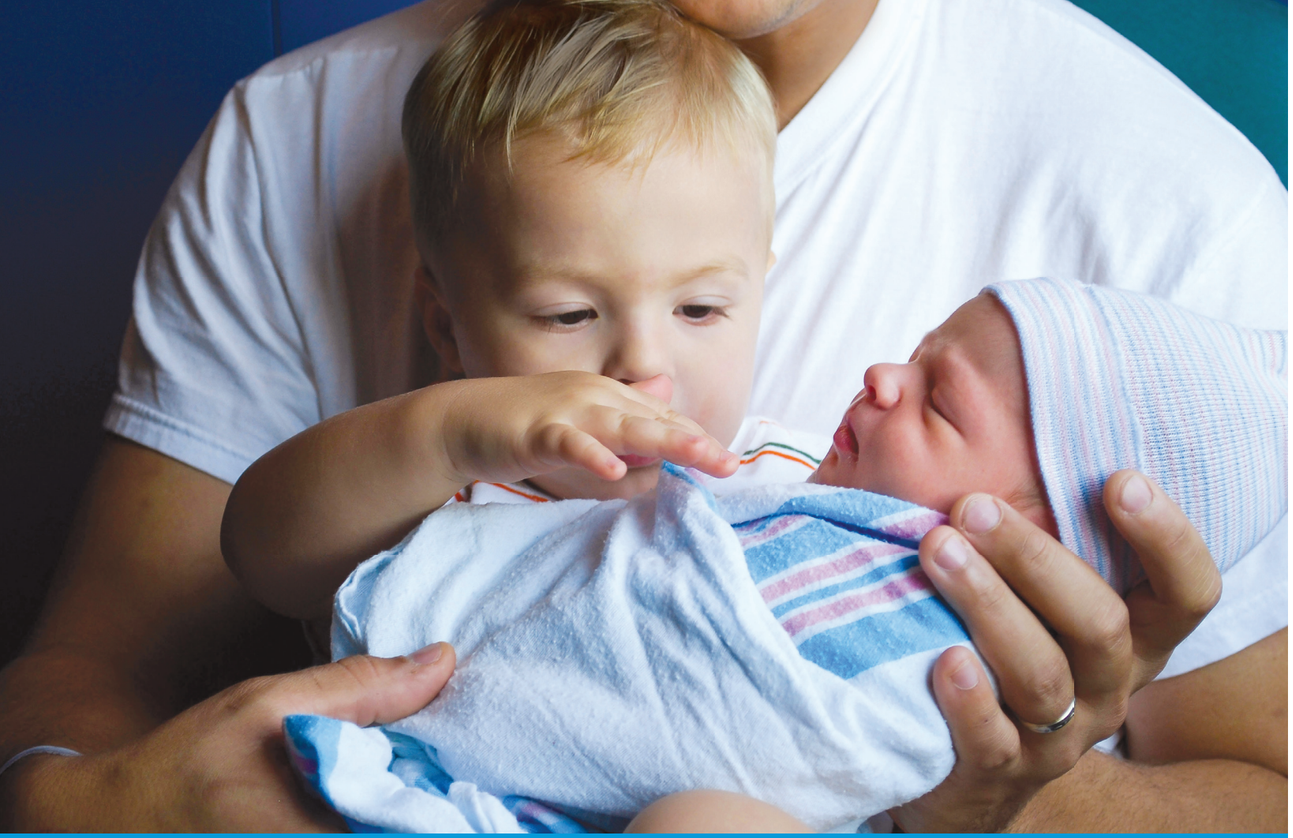
SURGICAL LIGATION LIMITATIONS

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 cardiac 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."

—CHORNE 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

The safety and efficacy of the Amplatzer Piccolo™ Occluder in patients weighing ≥ 700 grams was studied in a 50 patient pivotal trial and 150 additional patients under a continued access protocol. When combined, the studies enrolled a total of 200 patients. At the time of the procedure, 100 patients weighed ≤ 2 kg and the other 100 patients weighed >2 kg.

AMPLATZER PICCOLO™ 3-YEAR FOLLOW-UP DATA

95.5% Average

IMPLANT SUCCESS[13]
99.0% for patients ≤ 2kg
92.0% for patients > 2kg

100%

EFFECTIVE CLOSURE[14]
At 3-year follow-up
Only IDE patients included
a 3 year echo.

>95%

3-YEAR SURVIVAL[14]
No deaths were directly attributed to the procedure or device itself.

TOTAL NUMBER OF PATIENTS: 200	≤ 2 kg (N=100)	> 2 kg (N=100)	Total (N=200)
DEMOGRAPHICS			
Age, Months			
Mean ± SD	1.25 ± 0.60	26.58 ± 44.32	3.92 ± 33.74
Range	(0.30 - 3.15)	(0.49 - 216.80)	(0.30 - 216.80)
Weight (kg)			
Mean ± SD	1.25 ± 0.35	11.25 ± 13.52	6.25 ± 10.77
Range	(0.70 - 2.00)	(2.02-68.50)	(0.70 - 68.50)
PDA CHARACTERISTICS (by angiography)			
Minimal PDA Diameter (mm)			
Mean ± SD	2.8 ± 0.7	2.4 ± 0.7	2.6 ± 0.7
Range	(1.4 - 4.0)	(1.0 - 4.0)	(1.0 - 4.0)
PDA Length (mm)			
Mean ± SD	10.6 ± 2.2	10.1 ± 3.4	10.4 ± 2.9
Range	(5.3 - 19.2)	(4.1 - 20.0)	(4.1 - 20.0)
PROCEDURE CHARACTERISTICS			
Implant Success (%)	99.0% (99/100)	92% (92/100)	95.5% (191/200)
Fluoroscopy Time (min)			
Mean ± SD	10.5 ± 12.4	10.1 ± 7.0	10.3 ± 10.0
Range	(3 - 103)	(3 - 43)	(3 - 103)
Anterograde Implant	100.0% (99/99)	73.9% (68/92)	87.4% (167/191)
Femoral Arterial Access	2.0% (2/100)	48.0% (48/100)	25.0% (50/200)
In NICU at time of baseline assessment	100.0% (100/100)	32.0% (32/100)	66.0% (132/200)
OUTCOMES			
Major complications rate through 180 days (%)**	4.2% (4/96)	0% (0/98)	2.1% (4/194)
Effective closure at 6 months (%)	100% (89/89)	98.8% (83/84)	99.4% (172/173)

*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 PICCOLODEVICE.COM or SCAN THE QR CODE.

AMPLATZER PICCOLO™ OCCLUDER
IMPORTANT SAFETY INFORMATION

℞ ONLY

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 that 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

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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.

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