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.
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
- Systemic hypoperfusion

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

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. Other risks associated with PDA ligation include:
- Bleeding, infection
- Neurodevelopmental delay
- Recurrent laryngeal nerve injury (vocal cord paralysis)
- Injury to lymphatic vessels (chylothorax)
- Post ligation syndrome (hemodynamic compromise post procedure)

“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.
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
- More than 20 years of clinical experience

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.

<table>
<thead>
<tr>
<th>PIVOTAL TRIAL</th>
<th>CONTINUED ACCESS PROTOCOL</th>
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<tbody>
<tr>
<td>TOTAL # OF PATIENTS</td>
<td>50 Patients ≤ 2 kg = 18</td>
</tr>
<tr>
<td></td>
<td>Patients &gt; 2 kg = 32</td>
</tr>
<tr>
<td></td>
<td>150 Patients ≤ 2 kg = 82</td>
</tr>
<tr>
<td></td>
<td>Patients &gt; 2 kg = 68</td>
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<tr>
<td>FLUOROSCOPY TIME (MIN)</td>
<td>10.5 ± 7.3</td>
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<tr>
<td></td>
<td>10.2 ± 10.8</td>
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<tr>
<td>ANTEROGRADE IMPLANT</td>
<td>78.3% (36/46)</td>
</tr>
<tr>
<td>VENOUS APPROACH</td>
<td>(100% ≤ 2 kg, 64.3% &gt; 2 kg)</td>
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<tr>
<td></td>
<td>90.3% (131/145)</td>
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<tr>
<td></td>
<td>(100% ≤ 2 kg, 78.1% &gt; 2 kg)</td>
</tr>
<tr>
<td>NICU AT BASELINE</td>
<td>50% (25/50)</td>
</tr>
<tr>
<td>TREATED PRIOR TO</td>
<td>(100% ≤ 2 kg, 21.9% &gt; 2 kg)</td>
</tr>
<tr>
<td>NICU DISCHARGE</td>
<td>71.3% (107/150)</td>
</tr>
<tr>
<td></td>
<td>(100% ≤ 2 kg, 36.8% &gt; 2 kg)</td>
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<tr>
<td>IMPLANT SUCCESS (%)</td>
<td>92% (100% ≤ 2 kg, 87.5% &gt; 2 kg)</td>
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<tr>
<td></td>
<td>96.7% (98.8% ≤ 2 kg, 94.1% &gt; 2 kg)</td>
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<tr>
<td>EFFECTIVE CLOSURE RATE</td>
<td>100%</td>
</tr>
<tr>
<td></td>
<td>Fall 2019</td>
</tr>
<tr>
<td>MAJOR COMPLICATIONS</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Fall 2019</td>
</tr>
</tbody>
</table>

* Assessed by echocardiography and defined as the presence of either a grade 1 (mild) or grade 2 (trivial) shunt.
** Major complications were defined as life-threatening adverse events resulting in death. Life-threatening adverse events, permanent or significant disability and/or surgical intervention.
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

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

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

See Important Safety Information referenced within.
**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 re-sterilize this device. Attempts to re-sterilize 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 package labeling.
- 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.
- Patients who are allergic to nickel if this device is implanted. It is possible that some patients may develop 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.

**REFERENCES**


**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.

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