AMPLATZER PICCOLO™ OCCLUDER

UNIQUE DEVICE FOR CLOSING PDAS DEMONSTRATES HIGH LEVELS OF SAFETY AND EFFECTIVENESS.

The Amplatzer Piccolo™ Occluder offers new opportunities to care for more patients than ever before. A recent clinical trial using the Amplatzer Piccolo™ demonstrated safe and effective PDA closure for patients weighing 700 grams and up.

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METHODOLOGY.

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 study 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.

- **HIGH** implant success rate
- **EXCELLENT** closure rate
- **LOW** rate of complications

PIVOTAL TRIAL

- Single arm, prospective, multicenter, non-randomized trial
- 50 patients: 18 ≤ 2kg, 32 > 2kg
- Primary endpoints:
  - Effective closure of the ductus arteriosus at 6 months
  - Rate of major complications through 180 days

CONTINUED ACCESS PROTOCOL

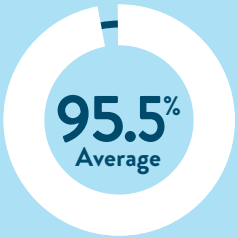
- 150 patients: 82 ≤ 2kg, 68 > 2kg
- Primary endpoints:
  - Effective closure of the ductus arteriosus at 6 months
  - Rate of major complications through 180 days

FOR MORE INFORMATION, VISIT INFANTPDA.COM.

CLINICALLY PROVEN OUTCOMES.

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

STUDY HIGHLIGHTS



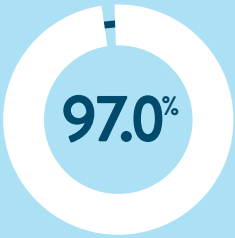
IMPLANT SUCCESS

99.0% for patients ≤ 2kg
92.0% for patients >2kg

EFFECTIVE CLOSURE*

At 6 months

100.0% for patients ≤ 2kg
98.8% for patients > 2kg



6 MONTH SURVIVAL

Overall survival for the IDE and CAP patients at 6 months

96.0% for patients ≤ 2kg
98.0% for patients > 2kg

MAJOR COMPLICATIONS**

Through 180 days

4.2% for patients ≤ 2kg
0% for patients > 2kg

TOTAL NUMBER OF PATIENTS: 200	≤ 2 kg (N=100)	> 2 kg (N=100)	> 2 kg (N=100)
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 echocardiography)			
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 (%)**	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. Two subjects experienced procedural blood loss requiring transfusion ≥ 20 cc/kg. One subject with a history of congenital thrombocytopenia experienced hemolysis and required transfusions totaling ≥ 20 cc/kg until the event resolved without sequalae. One subject experienced device-related obstruction of the aorta 6 days post procedure which was treated by stent implantation. The subject died 14 days post procedure secondary to respiratory failure and pulmonary hypertension.

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

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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Abbott Vascular International BVBA
Park Lake, Culliganlaan 2b, 1831 Diegem, Belgium
www.cardiovascular.abbott

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