AMPLATZER PICCOLO™ OCCLUDER

As the only PDA closure solution indicated for patients ≥700g & ≥3 days old—and safe and effective—Amplatzer Piccolo™ offers new opportunities to care for more patients than ever before, including infants. All with the built-in assurance provided by the renowned Amplatzer™ portfolio of trusted occlusion devices.

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

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AMPLATZER PICCOLO™ OCCLUDER

NEW 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.

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

METHODOLOGY

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

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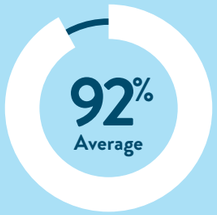
PIVOTAL TRIAL

CLINICALLY PROVEN OUTCOMES.

A recent pivotal 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.

STUDY HIGHLIGHTS



IMPLANT SUCCESS

100% for patients ≤ 2kg

87.5% for patients >2kg

EFFECTIVE CLOSURE*

At 6 months

MAJOR COMPLICATIONS**

Through 180 days

TOTAL NUMBER OF PATIENTS: 50	≤ 2 kg (N=18)	> 2 kg (N=32)
DEMOGRAPHICS		
Age, Months		
Mean ± SD	1.23 ± 0.55	24.88 ± 38.17
Range	(0.49 - 2.30)	(0.66 - 168.54)
Weight (kg)		
Mean ± SD	1.34 ± 0.38	10.29 ± 10.42
Range	(0.76 - 1.90)	(2.03 - 47.80)
PDA CHARACTERISTICS (by echocardiography)		
Minimal PDA Diameter (mm)		
Mean ± SD	2.72 ± 0.65	2.64 ± 0.58
Range	(1.4 - 4.0)	(1.5 - 4.0)
PDA Length (mm)		
Mean ± SD	8.81 ± 2.55	7.98 ± 2.78
Range	(4.6 - 14.0)	(3.1 - 16.0)
PROCEDURE CHARACTERISTICS		
Implant Success (%)	100.0% (18/18)	87.5% (28/32)
Fluoroscopy Time (min)		
Mean ± SD	9.8 ± 4.9	10.9 ± 8.5
Range	(4 - 22)	(5 - 43)
Anterograde Implant	100.0% (18/18)	64.3% (18/28)
Femoral Arterial Access	0.0% (0/18)	46.9% (15/32)
In NICU at time of baseline assessment	100.0% (18/18)	21.9% (7/32)
OUTCOMES		
Major complications rate (%)**	0% (0/18)	0% (0/32)
Effective closure at 6 months (Echo Core Lab Assessed) (%)***	100% (17/17)	100% (27/27)
Effective closure at 6 months (Site Assessed) (%)	100% (18/18)	100% (28/28)

*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.
***The core lab was unable to determine shunt grade in two subjects due to incomplete imaging views.

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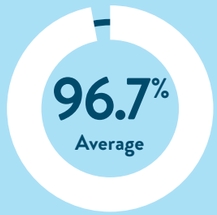
CONTINUED ACCESS PROTOCOL

CLINICAL RESULTS.

The safety and efficacy of the Amplatzer Piccolo™ Occluder is further supported by additional experience with the device under a continued access protocol involving 150 additional patients.

STUDY HIGHLIGHTS



IMPLANT SUCCESS

98.8% for patients ≤ 2kg

94.1% for patients > 2kg

Complete data results to be released Fall 2019.

TOTAL NUMBER OF PATIENTS: 150	≤ 2 kg (N=82)	> 2 kg (N=68)
DEMOGRAPHICS		
Age, Months		
Mean ± SD	1.26 ± 0.61	27.38 ± 47.18
Range	(0.30, 3.15)	(0.49, 216.80)
Weight (kg)		
Mean ± SD	1.22 ± 0.34	11.68 ± 14.80
Range	(0.70, 2.00)	(2.05, 68.50)
PDA CHARACTERISTICS (by echocardiography)		
Minimal PDA Diameter (mm)		
Mean ± SD	2.64 ± 0.63 (74)	2.59 ± 0.70 (51)
Range	(1.5, 4.0)	(1.0, 4.0)
PDA Length (mm)		
Mean ± SD	9.41 ± 2.76 (73)	9.62 ± 3.30 (51)
Range	(3.1, 18.0)	(4.0, 16.0)
PROCEDURE CHARACTERISTICS		
Implant Success (%)	98.8% (81/82)	94.1% (64/68)
Fluoroscopy Time (min)		
Mean ± SD	10.6 ± 13.5	9.8 ± 6.2
Range	(3, 103)	(3, 35)
Anterograde Implant	100.0% (81/81)	78.1% (50/64)
Femoral Arterial Access	2.4% (2/82)	47.1% (32/68)
In NICU at time of baseline assessment	100.0% (82/82)	36.8% (25/68)

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