AMPLATZER PICCOLO™ OCCLUDER

CLOSES EARLY PDAs.
FILLS LOVING HEARTS.

PROVEN PDA CLOSURE
FOR PATIENTS 700G AND UP.

Information contained herein for **DISTRIBUTION** in Australia and New Zealand only.

Abbott

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

BUILT ON THE EXTENSIVE AMPLATZER™ LEGACY OF SAFETY AND EFFICACY

- Pioneered transcatheter occlusion
- Over 1.25 million devices implanted worldwide[1]
- More than 20 years of clinical experience

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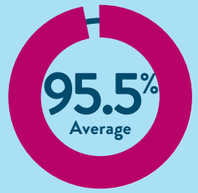
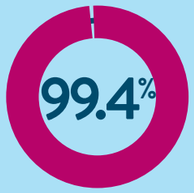
CLINICALLY PROVEN OUTCOMES.

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 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.

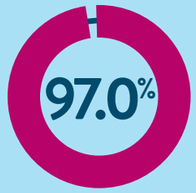
STUDY HIGHLIGHTS



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

ADVANCING A PROVEN PLATFORM FOR PREDICTABLE RESULTS.

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 new opportunities to care for a wider range of patients than ever before.

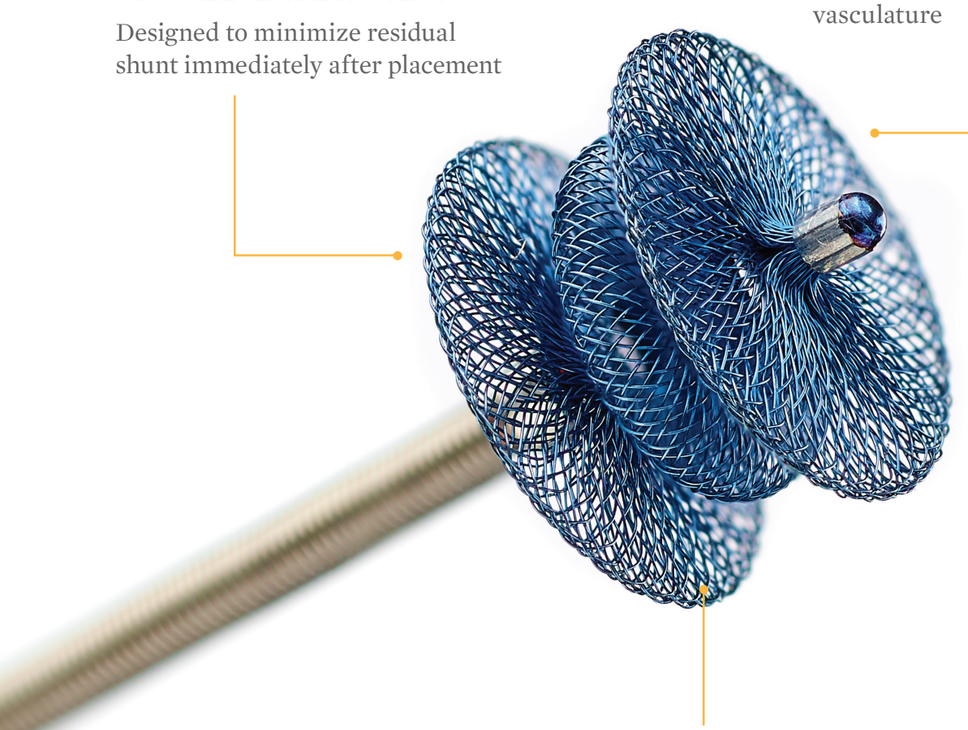
RELIABILITY BY DESIGN.

TIGHTLY WOVEN SINGLE-LAYER MESH

Designed to minimize residual shunt immediately after placement

ENGINEERED FOR STRUCTURE AND STRENGTH

Occludes ducts while minimizing protrusion into surrounding vasculature



INTAGLIO WIRE TREATMENT

Designed to reduce nickel leaching

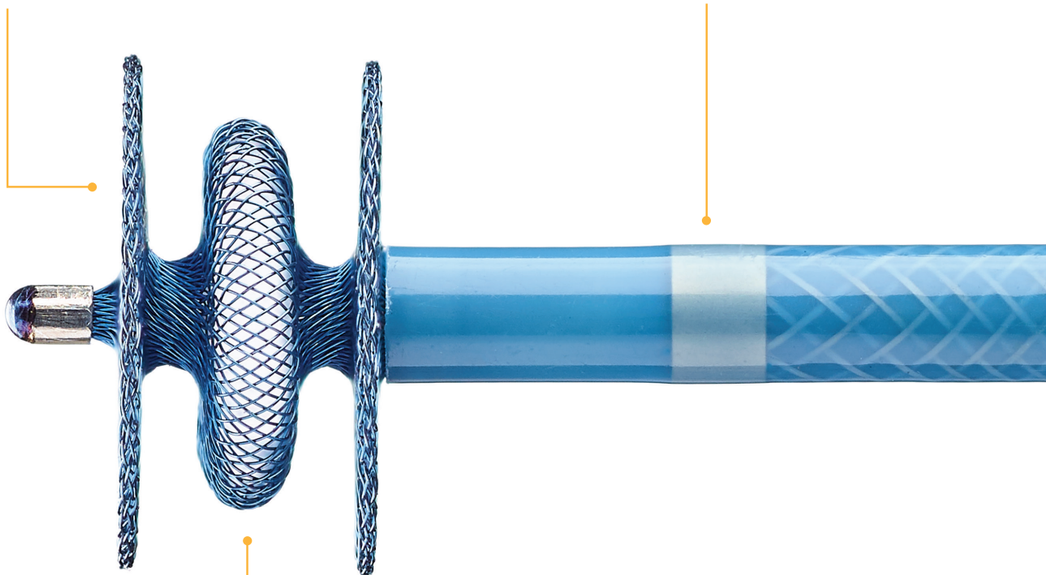
SMOOTH DELIVERY IN EVEN THE MOST CHALLENGING MORPHOLOGIES.

PREDICTABLE PLACEMENT

Disc size and shape designed for predictable positioning in the duct

DELIVERABLE IN 4 FRENCH SYSTEM

4 F catheter facilitates delivery in small vasculatures

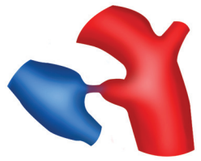
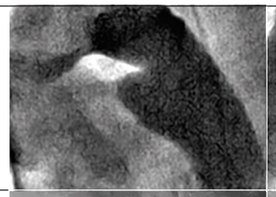
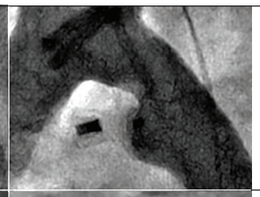
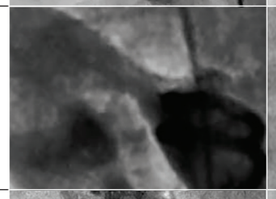
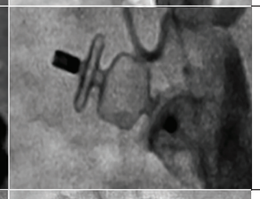
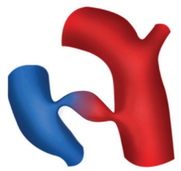
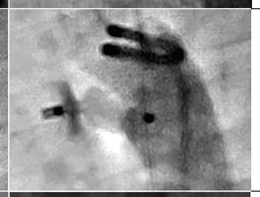
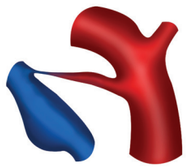
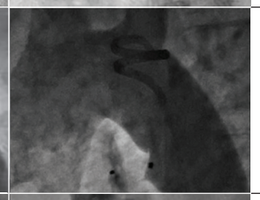
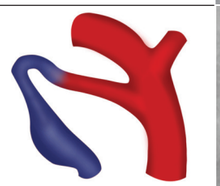
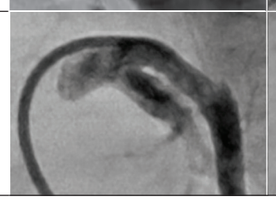
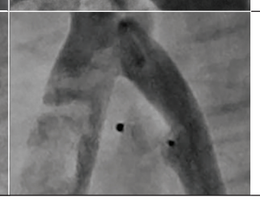


PROCEDURAL FLEXIBILITY

Symmetrical design offers procedural flexibility to choose an anterograde (venous) or retrograde (arterial) approach. For infants ≤ 2kg, a venous approach is recommended.

THE RIGHT CHOICE FOR A WIDE RANGE OF ANATOMIES.

The versatile design and predictable performance of the Amplatzer Piccolo™ Occluder make it ideal for a variety of morphologies. From “conical” ductus to “fetal type” ductus, the Piccolo device has you covered.

PDA TYPE DESCRIPTION[2]		PDA[2]	DEVICE CLOSURE[2]	≤ 2KG[3]	> 2KG[3]
TYPE A: **“Conical” ductus,** with well defined aortic ampulla and constricted pulmonary artery end.				6%	43%
TYPE B: **“Window” ductus,** with short length, slightly constricted aortic end and wide pulmonary artery end.				1%	2%
TYPE C: **“Tubular” ductus,** without any constrictions at the aortic end or the pulmonary artery end.				16%	12%
TYPE D: **“Saccular” ductus,** with constricted aortic end and pulmonary artery end with a wide center.				0%	5%
TYPE E: **“Elongated” ductus,** which is narrow with a constricted pulmonary artery end.				5%	13%
TYPE F: **“Fetal Type” ductus,** found exclusively in children born prematurely and is long, wide and tortuous.				70%	21%

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EXPERT SUPPORT AT EVERY TURN.

CLINICAL CASE SUPPORT

- Experienced field personnel
- Over two decades of excellence

CLINICAL TRAINING PROGRAMS

- Training centers and online courses
- Fellows programs

AMPLATZER PICCOLO™ OCCLUDER

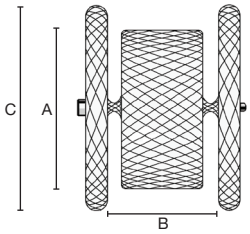
Device Specifications

SIZING AND DEVICE SELECTION

Model/Reorder Number	Waist Diameter (mm) [A]	Length between discs (mm) [B]	Disc Diameter (mm) [C]	Recommended Sheath Size
9-PDAP-03-02-L	3 mm	2 mm	4.00	4 F; 90° Curve
9-PDAP-03-04-L	3 mm	4 mm	4.00	4 F; 90° Curve
9-PDAP-03-06-L	3 mm	6 mm	4.00	4 F; 90° Curve
9-PDAP-04-02-L	4 mm	2 mm	5.25	4 F; 90° Curve
9-PDAP-04-04-L	4 mm	4 mm	5.25	4 F; 90° Curve
9-PDAP-04-06-L	4 mm	6 mm	5.25	4 F; 90° Curve
9-PDAP-05-02-L	5 mm	2 mm	6.50	4 F; 90° Curve
9-PDAP-05-04-L	5 mm	4 mm	6.50	4 F; 90° Curve
9-PDAP-05-06-L	5 mm	6 mm	6.50	4 F; 90° Curve

T1 Dimensions

[A] Waist diameter
[B] Length between retention discs
[C] Retention disc diameter



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

References

1. Data on file at Abbott. **2.** Philip, R., Rush Waller, B., Agrawal, V., Wright, D., Arevalo, A., Zurakowski, D. and Sathanandam, S. (2016), Morphologic characterization of the patent ductus arteriosus in the premature infant and the choice of transcatheter occlusion device. *Cathet. Cardiovasc. Intervent.*, 87: 310–317. **3.** Sathanandam SK, Gutfinger D, O'Brien L, et al. Amplatzer Piccolo Occluder clinical trial for percutaneous closure of the patent ductus arteriosus in patients ≥700 grams. *Catheter Cardiovasc Interv*. 2020;1–11.

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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