

AMPLATZER PICCOLO™ OCCLUDER

CLOSES EARLY PDA_s FILLS LOVING HEARTS

PROVEN PDA CLOSURE
FOR PATIENTS 700G AND UP.

Information contained herein for **DISTRIBUTION outside of the U.S. ONLY**. Check the regulatory status of the device in areas where CE marking is not the regulation in force.





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

**BUILT ON THE EXTENSIVE AMPLATZER™ LEGACY
OF SAFETY AND EFFICACY**

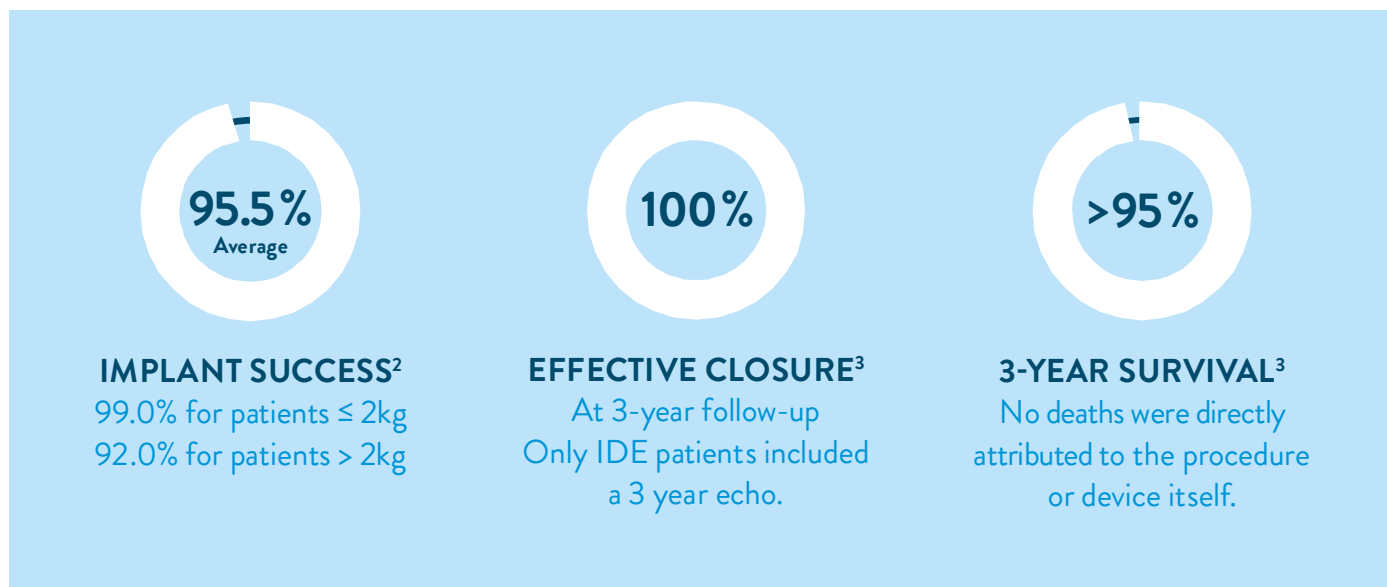
- Pioneered transcatheter occlusion
- Over 1.25 million devices implanted worldwide¹
- More than 20 years of clinical experience

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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 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



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 ± 10.77w
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)

ADVANCING A PROVEN PLATFORM FOR PREDICTABLE RESULTS

As the only PDA closure solution indicated for premature infants ($\geq 700\text{g} + \geq 3$ 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.

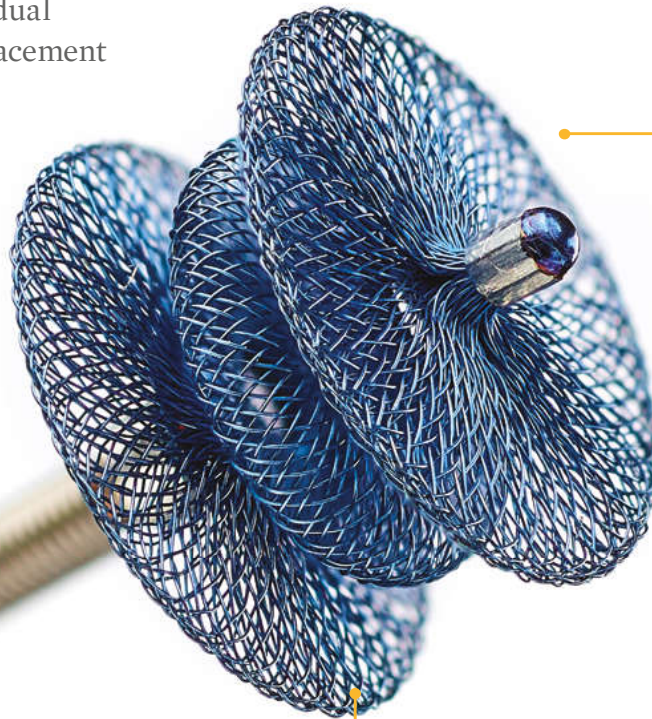
RELIABILITY BY DESIGN

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

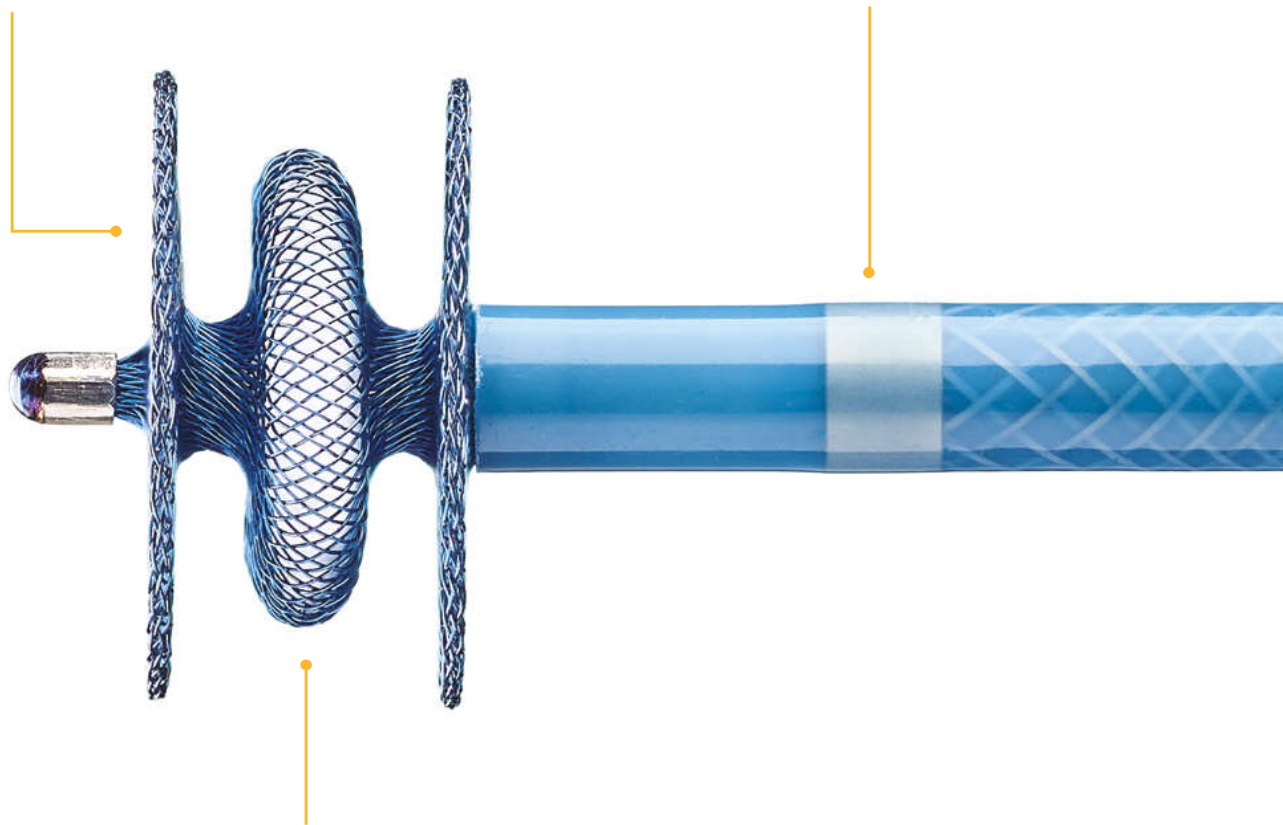
SMOOTH DELIVERY IN EVEN THE MOST CHALLENGING MORPHOLOGIES.

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

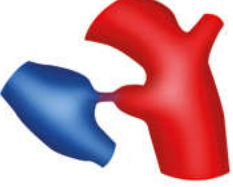
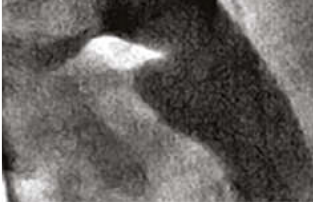

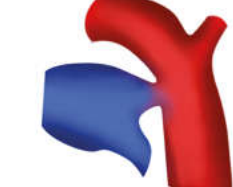


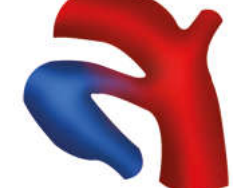


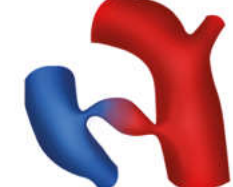


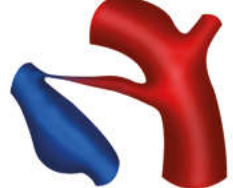



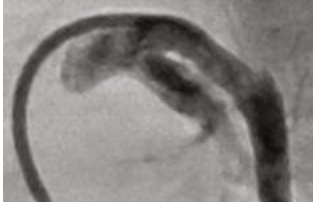



PROCEDURAL FLEXIBILITY

Symmetrical design offers procedural flexibility to choose an antegrade (venous) or retrograde (arterial) approach. For infants $\geq 2\text{kg}$, a venous approach is recommended.

THE RIGHT CHOICE FOR A WIDE RANGE O

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 ⁴
<p>TYPE A: “Conical” ductus, with well defined aortic ampulla and constricted pulmonary artery end.</p>			
<p>TYPE B: “Window” ductus, with short length, slightly constricted aortic end and wide pulmonary artery end.</p>			
<p>TYPE C: “Tubular” ductus, without any constrictions at the aortic end or the pulmonary artery end.</p>			
<p>TYPE D: “Saccular” ductus, with constricted aortic end and pulmonary artery end with a wide center.</p>			
<p>TYPE E: “Elongated” ductus, which is narrow with a constricted pulmonary artery end.</p>			
<p>TYPE F: “Fetal Type” ductus, found exclusively in children born prematurely and is long, wide and tortuous.</p>			

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F ANATOMIES

$\leq 2\text{KG}^2$	$> 2\text{KG}^2$
6%	43%
1%	2%
16%	12%
0%	5%
5%	13%
70%	21%

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



For more information about the Amplatzer Piccolo™ Occluder, contact your Abbott sales representative or **SCAN THE QR CODE.**

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Device Specifications

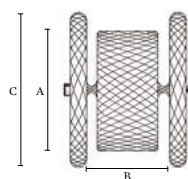
SIZING AND DEVICE SELECTION				
Model/Reorder Number	Waist Diameter (mm) [A]	Length between discs (mm) [B]	Disc Diameter (mm) [C]	Recommended Sheath Size
9-PDAP-03-02-L	3 mm	2 mm	4.00	4 F; 90° Curve
9-PDAP-03-04-L	3 mm	4 mm	4.00	4 F; 90° Curve
9-PDAP-03-06-L	3 mm	6 mm	4.00	4 F; 90° Curve
9-PDAP-04-02-L	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 download the Amplatzer Portfolio App.



REFERENCES

1. Data on file at Abbott. 2. Sathanandam SK, Gutfinger D, O'Brien L, et al. Amplatzer Piccolo Occluder clinical trial for percutaneous closure of the patent ductus arteriosus in patients \leq 700 grams. *Catheter Cardiovasc Interv.* 2020;1-11 3. Zahn, E. The Amplatzer Piccolo™ (ADOIIAS) U.S. Clinical Trial 3-Year Follow-up Report. Presented at: CSI Frankfurt; June 22-25, 2022. 4. 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.

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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