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

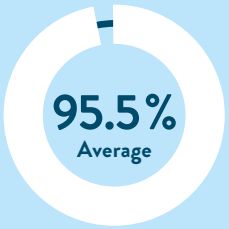
- 150 patients: 82 ≤ 2kg, 68 > 2kg
- Primary endpoints:
  - Effective closure of the ductus arteriosus at 6 months
  - Rate of major complications through 180 days

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

# 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.

## AMPLATZER PICCOLO™ 3-YEAR FOLLOW-UP DATA




### IMPLANT SUCCESS[1]

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


### EFFECTIVE CLOSURE[2]

At 3-year follow-up
Only IDE patients included a 3 year echo.


### 3-YEAR SURVIVAL[2]

No deaths were directly attributed to the procedure or device itself.

| 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) |

**For more information about the Amplatzer Piccolo™ Occluder and the complete line of Amplatzer heart occluders, contact your Abbott sales representative or download the Amplatzer Portfolio App.**

Download on the App Store

ANDROID APP ON Google play


**REFERENCES**

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