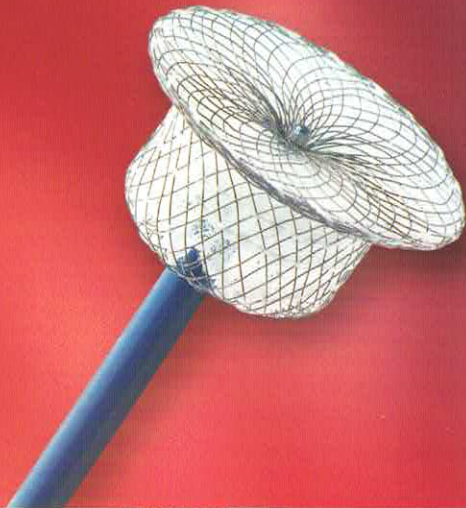


Duct Occluder



**Secure Anchoring
Mechanism for Ease
of Deployment**

**Ability to Recapture and
Reposition the Device**

**Fits all types of PDA
Shapes**



*Designed for the Non-Surgical
Closure of Patent Ductus
Arteriosus (PDA).*

*Helping Hearts Heal
Themselves*

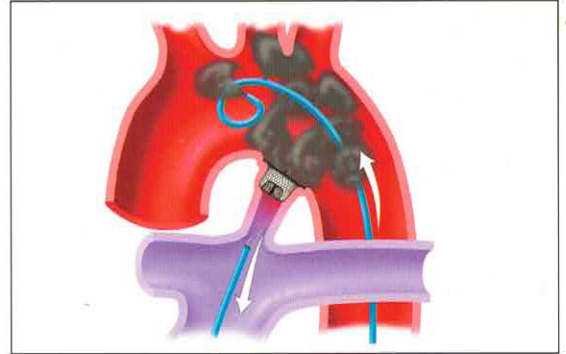
AMPLATZER® Duct Occluder

Intended Use

The AMPLATZER Duct Occluder is a percutaneous, transcatheter occlusion device intended for the non-surgical closure of patent ductus arteriosus (PDA). The device has been developed as an alternative to heart surgery, endoscopic closure and other currently available transcatheter occlusion devices.

Description

The AMPLATZER Duct Occluder is a self-expandable device made from a Nitinol wire mesh. A retention skirt on the aortic side provides secure positioning in the ampulla of the ductus. As the occluder is implanted, it expands outward and the wires push against the wall of the ductus. Polyester fabric is sewn into the occluder with polyester thread. The fabric induces thrombosis that closes the communication.



Secured placement and detachment of the AMPLATZER Duct Occluder

| AMPLATZER Duct Occluder Ordering Information | | A = Device Diameter at Descending Aorta B = Device Diameter at Pulmonary Artery C = Retention Skirt D = Length | | | |
|---|--|---|------------------------|---------------|--------------------------------|
| | A | B | C | D | |
| Order Number | Device Diameter at Descending Aorta | Device Diameter at Pulmonary Artery | Retention Skirt | Length | Recommended Sheath Size |
| 9-PDA-003 | 5 mm | 4 mm | 9 mm | 5 mm | 5-6 F |
| 9-PDA-004 | 6 mm | 4 mm | 10 mm | 7 mm | 5-6 F |
| 9-PDA-005 | 8 mm | 6 mm | 12 mm | 7 mm | 6 F |
| 9-PDA-006 | 10 mm | 8 mm | 16 mm | 8 mm | 6-7 F |
| 9-PDA-007 | 12 mm | 10 mm | 18 mm | 8 mm | 6-7 F |
| 9-PDA-008* | 14 mm | 12 mm | 20 mm | 8 mm | 7 F |
| 9-PDA-009* | 16 mm | 14 mm | 22 mm | 8 mm | 7 F |



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* CAUTION: The 14-12 mm and 16-14 mm AMPLATZER Duct Occluders are not available in the U.S.A. AMPLATZER® is a registered trademark of AGA Medical Corporation. ©AGA MEDICAL CORPORATION, 2003. Not in any way connected with medical gas or equipment sold under the "AGA" brand by AGA AB or its successors.

Manufactured under one or more of the following patents: U.S. Patent 5,725,552; 5,846,261; 5,944,738; 6,123,715 & Other U.S. and Foreign patents pending.

AMPLATZER®
Duct Occluder II



A Revolution in the
Effective Treatment of
Patent Ductus Arteriosus



AGA Medical
CORPORATION

AMPLATZER® Duct Occluder II

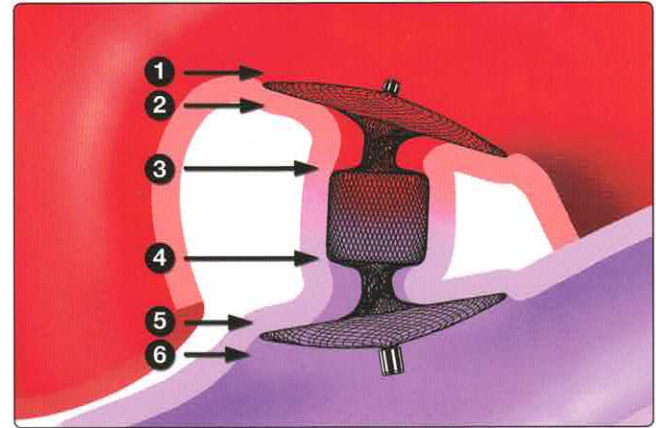
A Revolution in the Effective Treatment of

The AMPLATZER® Duct Occluder II allows controlled and precise transcatheter delivery for closure of all classifications of Patent Ductus Arteriosus (PDA) from 5.5 mm to less than 2.5 mm in diameter.

- Fabric-free technology allows for low-profile devices and delivery systems creating superior deliverability and expanded procedural options
- Flexible mesh and dual articulations provide high conformability to treat all classifications^{1,2} of Patent Ductus Arteriosus
- Multi-layered mesh lobes create six planes of occlusion with full cross sectional coverage for complete closure³

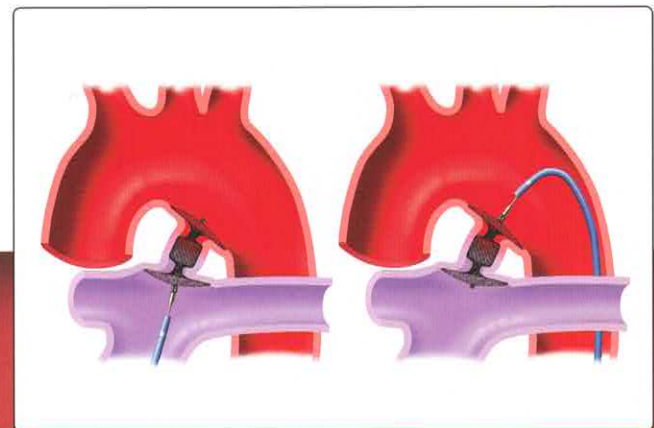


**AMPLATZER®
DUCT OCCLUDER II**



The AMPLATZER Duct Occluder II has three articulated mesh lobes which create six planes of occlusion with full cross sectional coverage

- The selection of waist sizes, from 3 to 6 mm, and lengths, 4 or 6 mm, can treat most PDAs from 5.5 mm to less than 2.5 mm in diameter
- Can be deployed, recaptured and redeployed for precise and secure placement



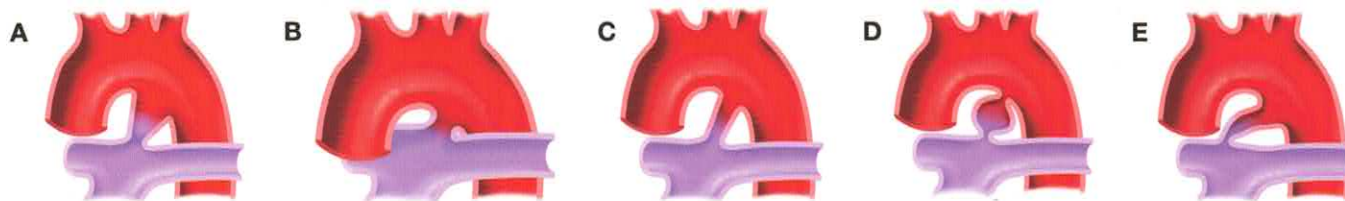
The symmetrical design of the device and the low profile delivery allow choice between aortic artery and pulmonary artery approaches

¹ Krichenko et al: Am J Cardiol 1989; 63:877

² Not indicated for the treatment of "window" PDAs

³ Data on file at AGA Medical

Patent Ductus Arteriosus



The AMPLATZER Duct Occluder II allows controlled and precise transcatheter delivery for closure of all PDA classifications^{1,2}

TYPE A Cone shaped ductus with well defined aortic ampulla and constriction at the PA end

TYPE B Short length ductus without constriction

TYPE C Tubular ductus without constriction

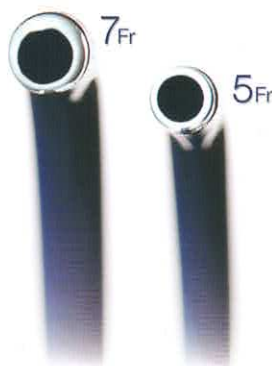
TYPE D Complex ductus with multiple constrictions

TYPE E Elongated ductus with the constriction remote from the anterior edge of the trachea

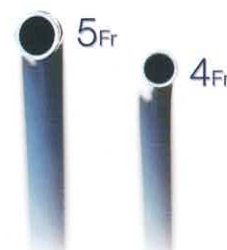
The AMPLATZER® TorqVue® Low Profile:

- New low profile braided catheter delivery system available in 4 and 5 French sizes
- Flexible distal catheter segment allows for easy aortic or pulmonary artery approaches for PDA closure with ADO-II
- Braided delivery wire with flexible Nitinol tip for ease of device positioning and deployment within various duct configurations

TorqVue® Delivery System

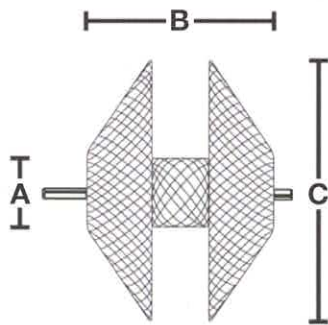


New TorqVue® LP Delivery System



Magnified view for comparison

AMPLATZER® Duct Occluder II



DUCT OCCLUDER II - ORDERING INFORMATION

| Order No. | A - Waist Diameter (mm) | B - Length (mm) | C - Disc Diameter (mm) | Delivery Catheter Minimum Size |
|--------------|-------------------------|-----------------|------------------------|--------------------------------|
| 9-PDA2-03-04 | 3 mm | 4 mm | 9 mm | 4 Fr |
| 9-PDA2-03-06 | 3 mm | 6 mm | 9 mm | 4 Fr |
| 9-PDA2-04-04 | 4 mm | 4 mm | 10 mm | 4 Fr |
| 9-PDA2-04-06 | 4 mm | 6 mm | 10 mm | 4 Fr |
| 9-PDA2-05-04 | 5 mm | 4 mm | 11 mm | 5 Fr |
| 9-PDA2-05-06 | 5 mm | 6 mm | 11 mm | 5 Fr |
| 9-PDA2-06-04 | 6 mm | 4 mm | 12 mm | 5 Fr |
| 9-PDA2-06-06 | 6 mm | 6 mm | 12 mm | 5 Fr |

AMPLATZER TORQVUE LP - ORDERING INFORMATION

| Order No. | Catheter Size | Catheter Length (cm) | Tip Angle | Delivery Cable Length (cm) |
|----------------|---------------|----------------------|-----------|----------------------------|
| 9-TVLP4F90/060 | 4 Fr | 60 | 90° | 160 |
| 9-TVLP4F90/080 | 4 Fr | 80 | 90° | 195 |
| 9-TVLP5F90/060 | 5 Fr | 60 | 90° | 160 |
| 9-TVLP5F90/080 | 5 Fr | 80 | 90° | 195 |

The AMPLATZER Duct Occluder II offers a choice in device lengths and diameters to treat a wide range of duct size and morphology:

| MEASURED DUCTUS DIAMETER | MEASURED DUCTUS LENGTH | | | | |
|--------------------------|------------------------|--------------|----------------|-----------------|-----------------|
| | < 5 mm | 5 mm - 8 mm | 8.1 mm - 10 mm | 10.1 mm - 11 mm | 11.1 mm - 12 mm |
| < 2.5 mm | 9-PDA2-03-04 | 9-PDA2-03-06 | 9-PDA2-04-06 | 9-PDA2-05-06 | 9-PDA2-06-06 |
| 2.5 mm - 3.5 mm | 9-PDA2-04-04 | 9-PDA2-04-06 | 9-PDA2-05-06 | 9-PDA2-06-06 | 9-PDA2-06-06 |
| 3.6 mm - 4.5 mm | 9-PDA2-05-04 | 9-PDA2-05-06 | 9-PDA2-05-06 | 9-PDA2-06-06 | 9-PDA2-06-06 |
| 4.6 mm - 5.5 mm | 9-PDA2-06-04 | 9-PDA2-06-06 | 9-PDA2-06-06 | 9-PDA2-06-06 | 9-PDA2-06-06 |

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CE 0473

Note: Refer to The Instructions for Use for complete listing of indications and Usage, Contraindications, Warnings and Precautions. Contact AGA Medical Corporation for further information.

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