AMPLATZER™ VALVULAR PLUG III (FORMERLY AVP III)

CLOSES LEAKS
OPENS OPPORTUNITIES

ONE-CLASS IMPROVEMENT IN THE NYHA CLASSIFICATION IN UP TO 90% OF PATIENTS[1,2,3,4]

Abbott

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DELIVERING **AN EFFECTIVE SOLUTION** FOR A WIDE RANGE OF PVL MORPHOLOGIES[1,5,6]

INTRODUCING THE AMPLATZER VALVULAR PLUG III

Paravalvular leaks can be found in a variety of shapes and sizes. To tackle the leaks and fill the gaps of different morphologies, the Amplatzer Valvular Plug III is designed in a rectangular oval shape that fits a wide range of paravalvular leaks (PVL). As such, the Amplatzer Valvular Plug III can provide effective closure in over 90% of patients at 30 day follow up.[6,7,8]

A SOLUTION TO A KEY ISSUE

Around the world, paravalvular leaks are a common and challenging problem: paravalvular leaks occur in 7% to 17% of mitral valve replacements (MVRs) and 5% to 10% of aortic valve replacements (AVRs).[9] By providing an effective solution to this key issue, the Amplatzer Valvular Plug III is improving life quality and longevity to an increasing number of patients.[1,2,3,4]

BUILT ON THE EXTENSIVE AMPLATZER™ LEGACY OF SAFETY AND EFFICACY

- Pioneered transcatheter cardiovascular and peripheral vascular occlusion
- Over 1.25 million Amplatzer devices implanted worldwide[11]
- More than 20 years of clinical experience and global leadership

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CLINICALLY PROVEN OUTCOMES

Clinical studies continue to show that the Amplatzer Valvular Plug III, formerly known as AVP III, is a highly effective solution in closing PVLs near mechanical surgical valves.[1]

≥90% OF PVLS EFFECTIVELY CLOSED AT 30 DAY FOLLOW-UP [6,7,8]

UP TO 90% PATIENTS REPORT ONE-CLASS NYHA CLASSIFICATION IMPROVEMENT[1,2,3,4]

A SOLUTION THAT HAS RECEIVED CLOSE ATTENTION - AND STRONGLY POSITIVE REVIEWS.[11]

NR: Data not reported in the article. NS: Not significant. n/a: Not applicable. Range instead of total was provided for follow-up > 30d as the follow up durations differ greatly between studies.

*In Smolka 2016, small PVLs causing significant hemolysis but no heart failure symptoms was an exclusion criteria; therefore patients with hemolytic anemia only were not included. Total percentages may underrepresent the actual population with hemolytic anemia only and overrepresent the population with heart failure only.

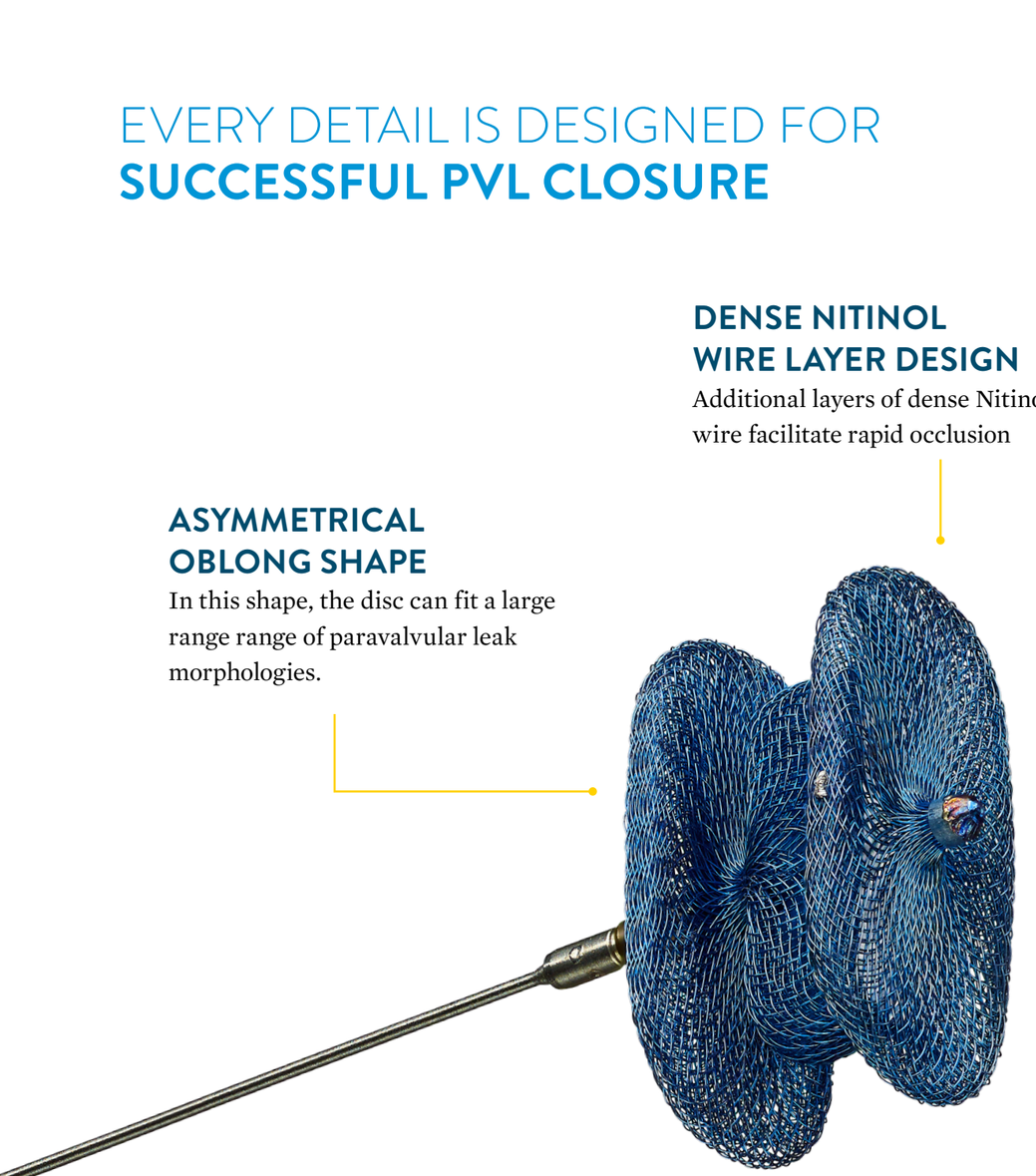
OVERALL – Mitral and Aortic		Cruz-Gonzalez 2014	Smolka 2016		Davidavicius 2014	Swaans 2012	Werner 2018
Number of patients (number of PVLs)		33 (34)	49 (49)		7 (9)	7 (7)	10 (17)
Mitral / Aortic PVLs		27 / 7	29 / 20		9 / 0	6 / 1	12 / 5
Mechanical		32	30		4	4	6
Indication for PVL (% patients (N))	Heart failure	21.2% (7)	89.8% (44)		57.1% (4)	14.2% (1)	50% (5)
	Hemolytic anemia	3% (1)	0%*		0%	42.9% (3)	0%
	Both	75.7% (25)	10.2% (5)		42.9% (3)	42.9% (3)	50% (5)
Access (TA: transapical, TS: transseptal, TF: transfemoral)		Mitral: TF, TS Aortic: TF	Mitral: TS, TA Aortic: TF		Mitral:TA Aortic: n/a	Mitral:TA Aortic: TA	Mitral: TS, TA Aortic: TF
Follow-up		90 d	6 mo, 1 y		40 – 364 d	3 mo	1 y
COMPOSITE ENDPOINT							
Technical success (overall)		90.9%	93.9%		100%	100%	86%
Mitral		92.3%	89.7%		100%	100%	NR
Aortic		100%	100%		n/a	100%	NR
SAFETY ENDPOINTS							
Survival	Intra-procedural	100%	100%		100%	100%	100%
	30 d	100%	98%		100%	100%	80%
	Follow-up	100%	95.9%		85.7%	85.7%	70%
Stroke (30 d)		0	2%		NR	0	0
Conversion to surgery		6%	NR		0	14.2%	0
Bleeding / vascular complications		12%	2%		28.6%	14.2%	20%
EFFECTIVENESS ENDPOINTS							
% patients with absent to moderate PVL regurgitation		100%	93.8%		100%	100%	NR
% patients with reduction in NYHA class		90.3%	90.5%		85.7%	71.4%	NR
Hemolysis		Improved	Improved		Improved	NS	NR

NOTE: Results from clinical studies are not directly comparable.
Information provided for educational purposes only.

EVERY DETAIL IS DESIGNED FOR **SUCCESSFUL PVL CLOSURE**

DENSE NITINOL WIRE LAYER DESIGN
Additional layers of dense Nitinol wire facilitate rapid occlusion

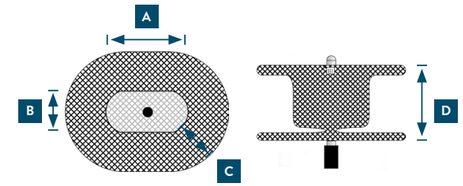
ASYMMETRICAL OBLONG SHAPE
In this shape, the disc can fit a large range range of paravalvular leak morphologies.



SMALL RETENTION FEATURES
Designed to minimize valve leaflet interference

DESIGN SPECIFICATIONS

The Amplatzer™ Valvular Plug III comes in nine different sizes in order to facilitate optimal PVL closure for a range of gaps.[10]



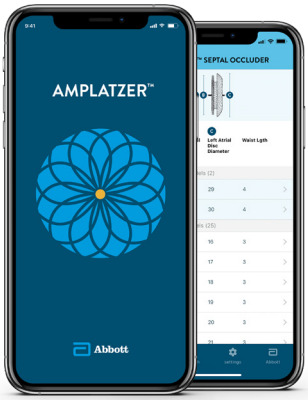
Model Number	Type Amplatzer Valvular Plug III	A Waist Long Axis (mm)	B Waist Short Axis (mm)	C Overhang (mm)	D Plug Length (+1.0 mm / - 0.5 mm)
9-APVL3-042	4x2 mm	4	2	2	6.5
9-APVL3-063	6x3 mm	6	3	2	6.5
9-APVL3-084	8x4 mm	8	4	2	6.5
9-APVL3-103	10x3 mm	10	3	2	6.5
9-APVL3-105	10x5 mm	10	5	2	6.5
9-APVL3-123	12x3 mm	12	3	2	6.5
9-APVL3-125	12x5 mm	12	5	2	6.5
9-APVL3-143	14x3 mm	14	3	2	6.5
9-APVL3-145	14x5 mm	14	5	2	6.5

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™ Valvular Plug III, contact your Abbott sales representative



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11. Data on File at Abbott

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