

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}

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Abbott

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 up to 93% of patients at 12 month follow-up.³

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 quality of life for 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 surgical valves.^{1,3,5}



UP TO 93% OF PVL
REDUCED TO MODERATE
OR LESS^{3,7}



UP TO 90% OF PATIENTS
REPORT ONE-CLASS
NYHA CLASSIFICATION
IMPROVEMENT¹



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

OVERALL – Mitral and Aortic		Cruz-Gonzalez 2014	Smolka 2016	
Number of patients (number of PVLs)		33 (34)	49 (49)	
Mitral / Aortic PVLs		27 / 7	29 / 20	
Mechanical / Tissue		32 / 1	30 / 19	
Indication for PVL (% patients (N))	Heart failure	21.2% (7)	89.8% (44)	
	Hemolytic anemia	3% (1)	0%*	
	Both	75.7% (25)	10.2% (5)	
Access (TA: transapical, TS: transseptal, TF: transfemoral)		Mitral: TF, TS Aortic: TF	Mitral: TS, TA Aortic: TF	
Follow-up		90 d	6 mo, 1 y	
COMPOSITE ENDPOINT				
Technical success (overall)		90.9%	93.9%	
Mitral		92.3%	89.7%	
Aortic		100%	100%	
SAFETY ENDPOINTS				
Survival	Intra-procedural	100%	100%	
	30 d	100%	98%	
	Follow-up	100%	95.9%	
Stroke (30 d)		0	2%	
Conversion to surgery		6%	NR	
Bleeding / vascular complications		12%	2%	
EFFECTIVENESS ENDPOINTS				
% patients with absent to moderate PVL regurgitation		100%	93.8%	
% patients with reduction in NYHA class		90.3%	90.5%	
Hemolysis		Improved	Improved	

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

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.

	Davidavicius 2014	Swaans 2012	Werner 2018
	7 (9)	7 (7)	10 (17)
	9 / 0	6 / 1	12 / 5
	4 / 3	4 / 3	4 / 6
	57.1% (4)	14.2% (1)	50% (5)
	0%	42.9% (3)	0%
	42.9% (3)	42.9% (3)	50% (5)
	Mitral:TA Aortic: n/a	Mitral:TA Aortic: TA	Mitral: TS, TA Aortic: TF
	40 – 364 d	3 mo	1 y
	100%	100%	86%
	100%	100%	NR
	n/a	100%	NR
	100%	100%	100%
	100%	100%	80%
	85.7%	85.7%	70%
	NR	0	0
	0	14.2%	0
	28.6%	14.2%	20%
	100%	100%	NR
	85.7%	71.4%	NR
	Improved	NS	NR

EVERY DETAIL IS DESIGNED FOR SUCCESSFUL PVL CLOSURE

DENSE NITINOL WIRE LAYER DESIGN

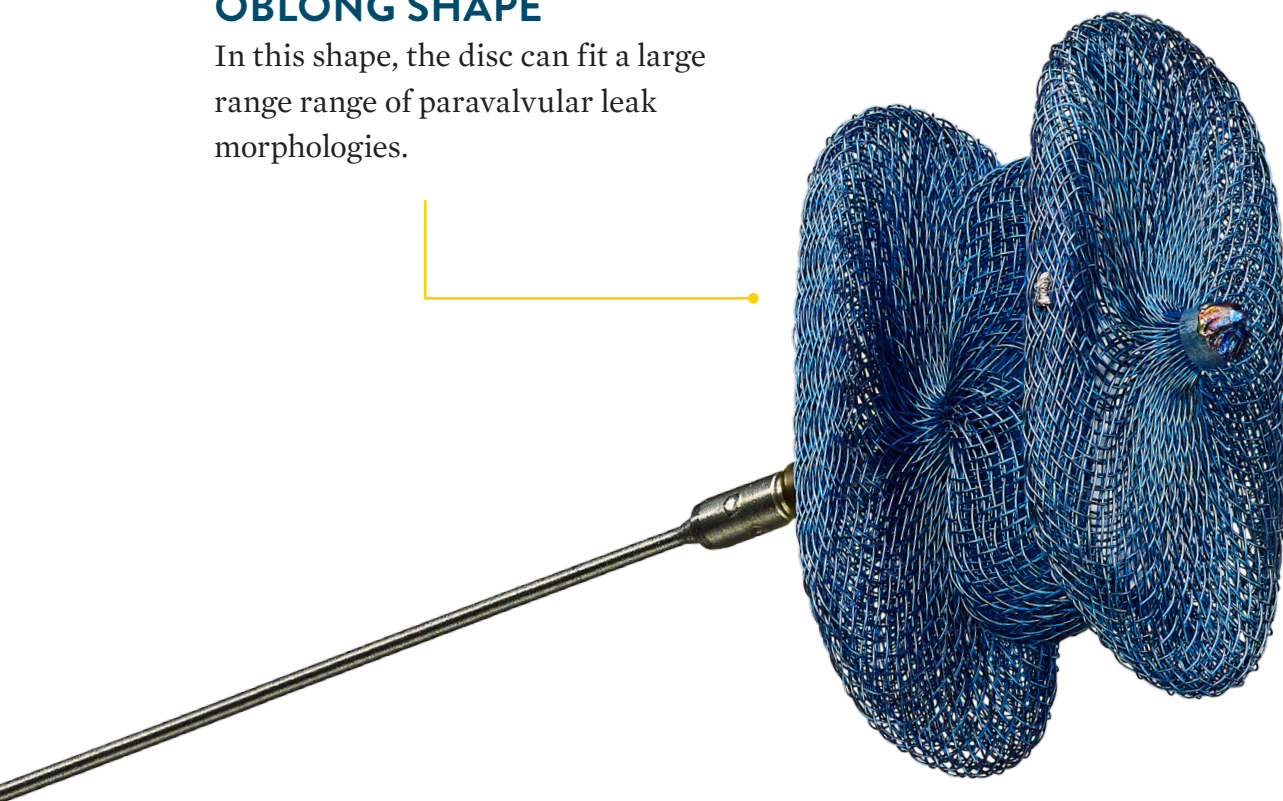
Additional layers of dense Nitinol wire facilitate rapid occlusion.

ASYMMETRICAL OBLONG SHAPE

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

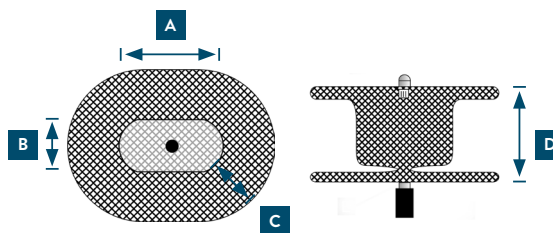
SMALL RETENTION FEATURES

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.

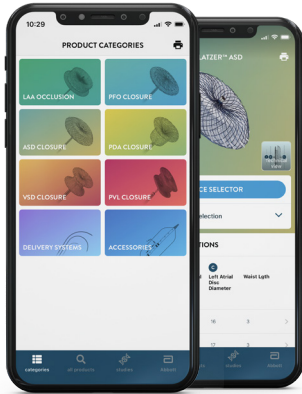
CLINICAL CASE SUPPORT

- 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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REFERENCES:

- Calvert et al. Percutaneous device closure of paravalvular leak. *Circulation*. 2016;134(13):934-944.
- Yildirim A, Goktekin O, Gorgulu S, et al. A new specific device in transcatheter prosthetic paravalvular leak closure: a prospective two-center trial. *Catheter Cardiovasc Interv*. 2016;88(4):618-624.
- Smolka G, Pysz P, Jasinski M, et al. Multiplug paravalvular leak closure using Amplatzer Vascular Plugs III: A prospective registry. *Catheter Cardiovasc Interv*. 2016;87(3):478-487.
- Angulo-Llanos R, Sarnago-Cebada F, Rivera AR, et al. Two-Year Follow Up After Surgical Versus Percutaneous Paravalvular Leak Closure: A Non-Randomized Analysis. *Catheterization and cardiovascular interventions* : official journal of the Society for Cardiac Angiography & Interventions. 2016;88(4):626-634.
- Garcia et al. Outcomes and predictors of success and complications for paravalvular leak closure: an analysis of the Spanish real-world paravalvular Leaks closure (HOLE) registry. *EuroIntervention*. 2017;12(16):1962-1968.
- Davidavicius G, Rucinskas K, Drasutiene A, et al. Hybrid approach for transcatheter paravalvular leak closure of mitral prosthesis in high-risk patients through transapical access. *J Thorac Cardiovasc Surg*. 014;148(5):1965-1969.
- Cruz-Gonzalez I, Rama-Merchan J, Arribas-Jimenez A, et al. Prevalence and severity of paravalvular regurgitation in the Artificial Valve Endocarditis Reduction Trial (AVERT) echocardiography study. *Rev Esp. Cardiol*. 2014;67:593-6.
- Werner N, Zeymer U, Fraiture B, et al. Interventional treatment of paravalvular regurgitation by plug implantation following prosthetic valve replacement: a single-center experience. *Clin Res Cardiol*. 2018.
- Cruz-Gonzalez I, Rama-Merchan JC, Rodriguez-Collado J, et al. Transcatheter closure of paravalvular leaks: state of the art. *Neth Heart J*. 2017;25(2):116-124.
- Nietlispach F, Eckstein F, Seeberger M, Osswald S, Kaufmann BA, Reuthebuch O. Closure of apical access site after transapical, transcatheter paravalvular leak closure. *Can J Cardiol*. 2012;28:516.e5-7.
- Data on File at Abbott.

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