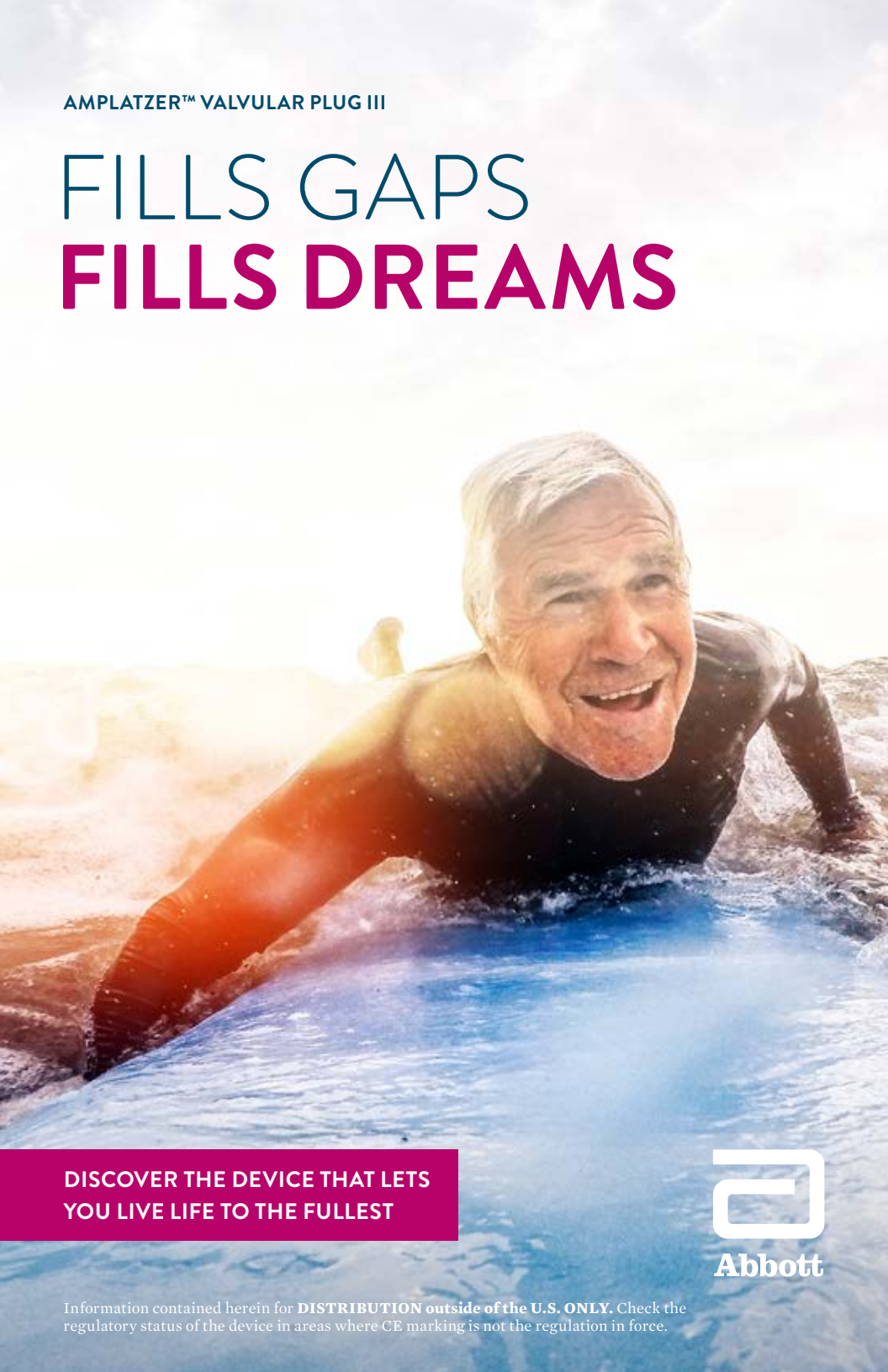
AMPLATZER™ VALVULAR PLUG III

FILLS GAPS
FILLS DREAMS



DISCOVER THE DEVICE THAT LETS YOU LIVE LIFE TO THE FULLEST

Abbott

WHAT IS A PVL?

When you had your valve replacement surgery, a new valve was inserted into your heart. This valve is usually put in place with no gaps between the edges of the valve and the surrounding natural heart tissue. Sometimes gaps can be left or develop around the replaced valve – these are known as paravalvular defects. When blood leaks through these gaps, this is known as a paravalvular leak (PVL) or paravalvular regurgitation (PVR).

WHAT ARE SOME OF THE SYMPTOMS OF A PVL?

If a PVL is small, patients can feel little to nothing. If the PVL is moderate or severe, it can lead to the symptoms associated with heart failure, including shortness of breath, unexplained weight gain, and swelling of legs and feet. In addition, the destruction of red blood cells passing through the gaps between the artificial valve and the surrounding tissue may cause severe anemia.

PVL FACTS

Paravalvular leaks occur in 5 to 17% of patients who undergo surgical valve implantation in the aortic or mitral locations.[1]

Risk factors for PVL development include: annular calcification, tissue friability, prior endocarditis, or other inflammatory processes and recent initiation of corticosteroid therapy.[12]

A majority (74%) of PVL occurs within the first year of valve implantation.[12]

Transcatheter (percutaneous) PVL closure first emerged as an alternative to surgery in the early 1990s.

AMPLATZER PARAVALVULAR PLUG III FOR SURGICALLY IMPLANTED VALVES

- Most commonly used device to plug instances of PVL worldwide[2]
- Over 90% of PVL effectively closed at 30 day follow up[3,4,5]
- Comes with Abbott service and education

AMPLATZER™ VALVULAR PLUG III **CLINICALLY PROVEN IN INDEPENDENT STUDIES TO BE SAFE AND EFFECTIVE**

The Amplatzer Valvular Plug III, formerly known as AVP III, has been specially designed to offer patients an effective solution to PVL, opening up a new horizon of better health and life quality. This oblong, self-expanding device is made from braided Nitinol wires with shape memory characteristics, making it well suited to PVL closure.[2,6,7,8]

To close PVLs with different morphologies, the Amplatzer Valvular Plug III comes in a range of nine sizes and has a flexible Nitinol waist, ensuring an excellent device-to-patient fit. The Amplatzer Valvular Plug III can provide an excellent solution to closure – and significantly improve your quality of life, wherever you are.[7,9,10,11]

AMPLATZER VALVULAR PLUG III **TRIED AND TESTED**

The Amplatzer Valvular Plug III leverages over 2 decades of nitinol wire design experience. It has been used extensively for more than a decade on patients all over the world.[2]

Consistently over time, clinical studies have shown that the Amplatzer Valvular Plug III is an effective solution in closing PVLs near mechanical surgical valves. In fact, up to 90% of patients who receive the device indicate improvements of one class in the New York Heart Association (NYHA) classification.[7,9,10,11]

What does this mean? Patients report easier breathing, the ability to engage in more intense physical exertion, and higher levels of physical durability.

AMPLATZER™ VALVULAR PLUG III **PROCEDURE**

The Amplatzer Valvular Plug III procedure is minimally invasive. It involves making a small incision, and inserting a small tube, called a catheter, to navigate the blood vessels in order to reach the procedure site within the heart.

The doctor guides the device through the catheter to seal the PVL. Once the device is placed in the PVL, the doctor will carefully study its position using cardiac imaging systems. Once satisfied with the position, the device is released to remain permanently in the PVL. The catheter is removed, and the procedure is completed. The procedure itself takes place in a heart catheterization laboratory, where many minimally invasive, nonsurgical procedures are performed. Patients may be offered an anesthetic, so that no significant discomfort is felt.

WHAT HAPPENS **AFTER THE PROCEDURE?**

Your doctor will provide guidelines for activities and may prescribe medications that should be taken at home at their discretion.

Many doctors require follow-up appointments over the next year to ensure your recovery is going well. What to expect during and after the procedure will vary, so it is important to discuss any questions and concerns you may have with your doctor.

REFERENCES:
1. Hwang, Ho Young, Jae-Woong Choi, Hyung-Kwan Kim, Kyung-Hwan Kim, Ki-Bong Kim, and Hyuk Ahn. "Paravalvular leak after mitral valve replacement: 20-year follow-up." The Annals of thoracic surgery 100, no. 4 (2015): 1347-1352.

2. Data on File at Abbott

3. 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.

4. Smolka G, Pysz P, Jasiński M, et al. Multiplug paravalvular leak closure using Amplatzer Vascular Plugs III: A prospective registry. Catheter Cardiovasc Interv. 2016;87(3):478-487.

5. 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.

6. 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.

7. Calvert et al. Percutaneous device closure of paravalvular leak. Circulation. 2016;134(13):934-944.

8. Sanchez-Recalde et al. Immediate and Mid-term Clinical Course After Percutaneous Closure of Paravalvular Leakage. Rev Esp Cardiol. 2014;67(8):615–62

9. 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.

10. Smolka G, Pysz P, Kozłowski M, et al. Transcatheter closure of paravalvular leaks using a paravalvular leak device - a prospective Polish registry. Postepy Kardiol Interwencyjnej. 2016;12(2):128-134.

11. 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.

12. Ruiz CE, Hahn RT, Berrebi A, et al. Clinical trial principles and endpoint definitions for paravalvular leaks in surgical prosthesis: an expert statement. J Am Coll Cardiol. 2017;69(16):2067-2087.

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