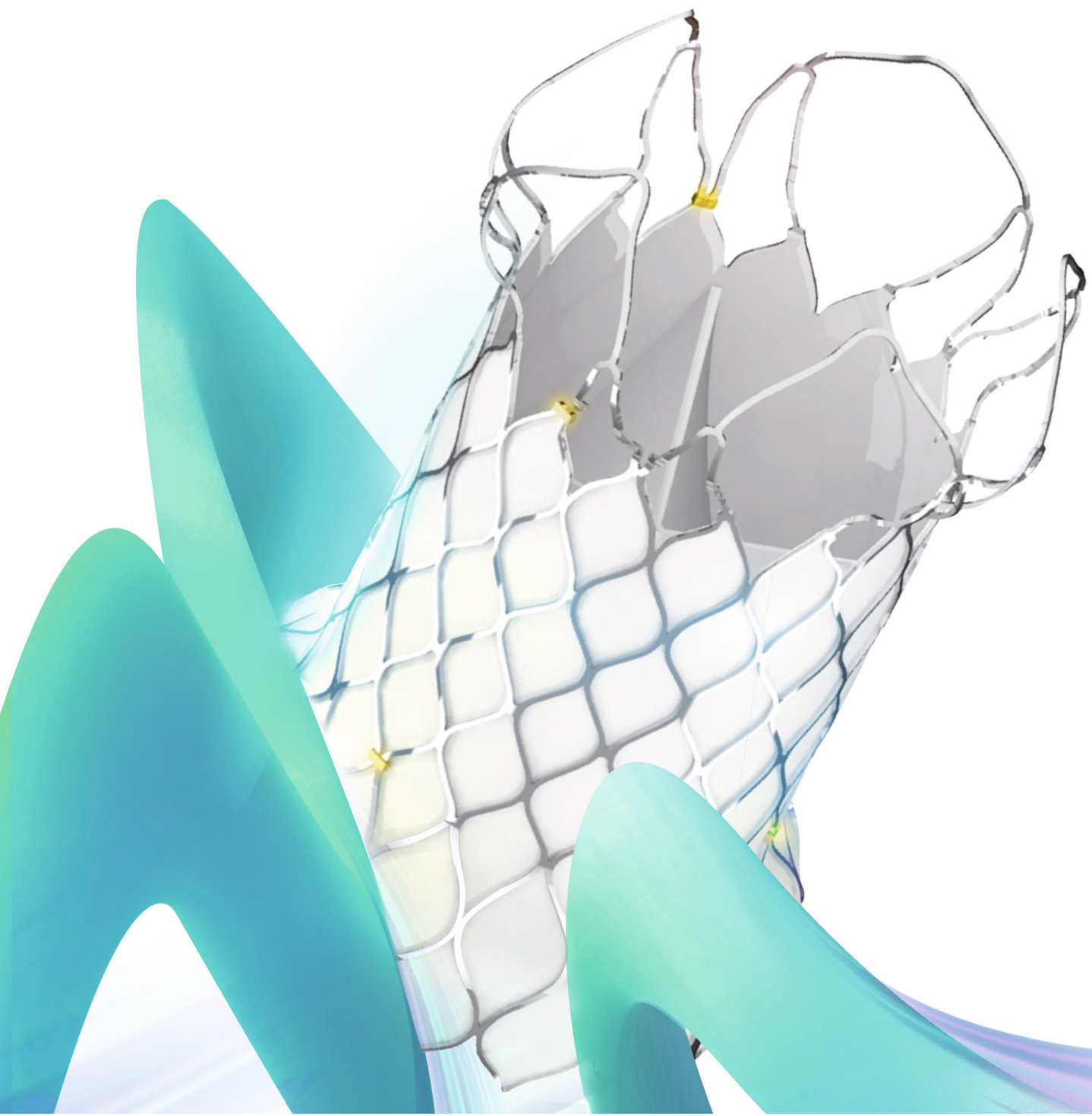
VENUSMEDTECH™

VenusP-Valve™ System

Percutaneous Pulmonary Valve System



BROADER VALVE SIZE RANGE

Wider patient population coverage

STRONG ANCHORING CAPABILITIES

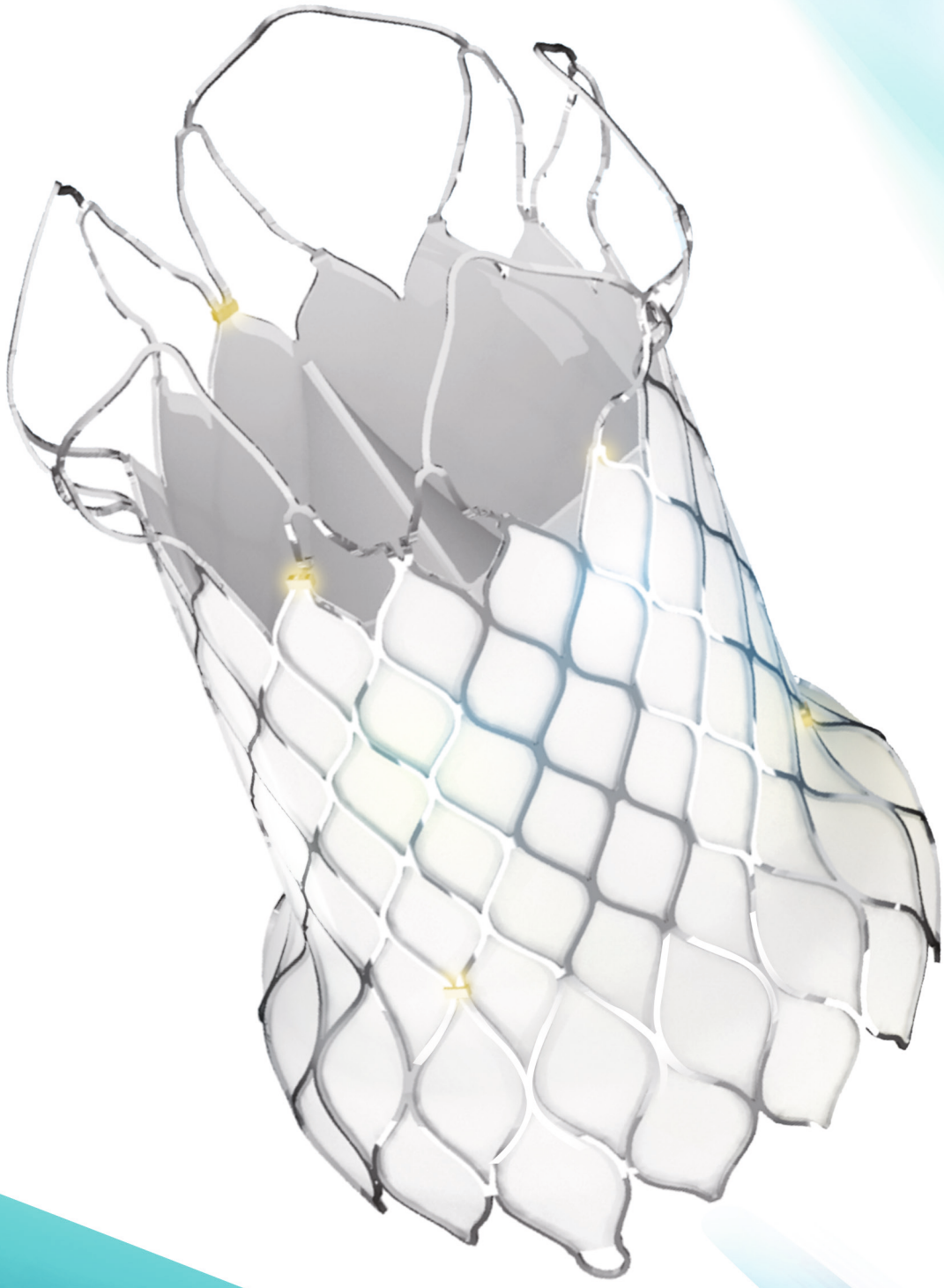
Easy valve deployment

SIX RADIOPAQUE MARKER

Precise valve positioning

SELF-EXPANDING VALVE

No pre-stenting or balloon expansion



VenusP–Valve ™ System – Clinical Benefits

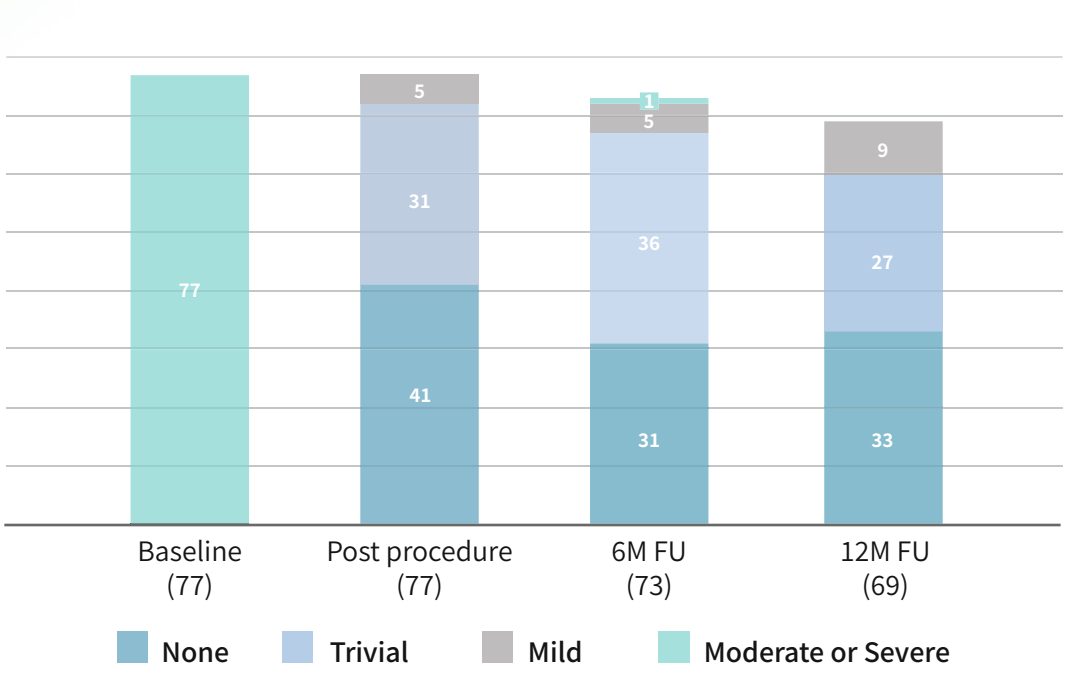
Most patients receiving a VenusP-Valve can expect symptom relief:

Relief of leaking (regurgitation): Improvement in pulmonary regurgitation compared to pre-procedure as demonstrated by transthoracic echocardiography.

Increased cardiac function: Significant improvement in New York Heart Association (NYHA) Functional Classification compared with pre-procedure.

Restored right ventricular function: Improvement in right ventricular remodeling and right ventricular function at 6 months after implantation.

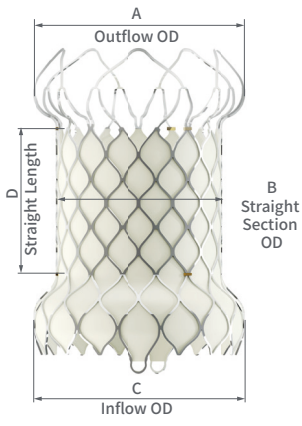
Pulmonary regurgitation



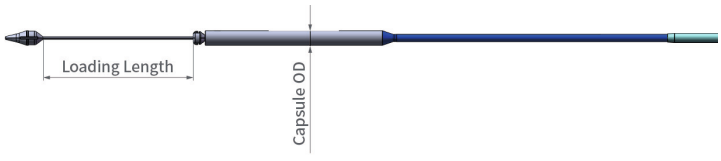
NYHA Class	Baseline (N=79)	6M FU (N=76)	12M FU (N=69)
I	16 (20.3%)	45 (59.2%)	61 (88.4%)
II	39 (49.4%)	26 (34.2%)	8 (11.6%)
III	5 (6.3%)	1 (1.3%)	0 (0%)
IV	0 (0%)	1 (1.3%)	0 (0%)
Not Evaluated	19 (24.1%)	3 (3.9%)	0 (0%)

*Clinical data from VenusP-Valve System CE Study 1 year follow-up

Dimension of VenusP – Valve™ when fully expanded



Model	Specification	Diameter [mm]			D [mm]
		A	B	C	
L28P	P28-25	38.0	28.0	38.0	25.0
	P28-30				30.0
L30P	P30-25	40.0	30.0	40.0	25.0
	P30-30				30.0
L32P	P32-25	42.0	32.0	42.0	25.0
	P32-30				30.0
L34P	P34-25	44.0	34.0	44.0	25.0
	P34-30				30.0
L36P	P36-25	46.0	36.0	46.0	25.0
	P36-30				30.0



Dimension of Delivery Catheter System

Model	Specification	Delivery Catheter System [mm]	
		Capsule OD	Loading Length
22Fr	DS22-P77	7.33	77
	DS22-P70		70
24Fr	DS24-P87	8.00	87
	DS24-P81		81
	DS24-P75		75

Device components matching table. VenusP – Valve ™ with matching Delivery Catheter System

Percutaneous Pulmonary Valve		Delivery Catheter System	
Model	Specification	Model	Specification
L28P	P28-25	22FR	DS22-P70
	P28-30		DS22-P77
L30P	P30-25		DS22-P70
	P30-30		DS22-P77
L32P	P32-25	24FR	DS24-P75
	P32-30		DS24-P81
L34P	P34-25		DS24-P81
	P34-30		DS24-P87
L36P	P36-25		DS24-P81
	P36-30		DS24-P87

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INDICATION

The VenusP-Valve System is designed to replace the pulmonary heart valve with an artificial valve using a minimally invasive transcatheter approach. VenusP-Valve System is used for the treatment of moderate or severe (~3+) pulmonary regurgitation with or without stenosis in patients with native right ventricular outflow tracts therefore reducing pulmonary regurgitation. The VenusP-Valve System is indicated for use in the following clinical conditions: 12 years old up to 70 years old. Weight ~30kg. With evidence of moderate or severe {~3+) pulmonary regurgitation by Transthoracic Echocardiography (TTE). With >30% pulmonary regurgitation fraction as defined by cardiac Magnetic Resonance Imaging (MRI). Subject is symptomatic from his/her pulmonary regurgitation or meets MRI criteria for intervention Right Ventricular Ejection Fraction (RVEF) <45%, Pulmonary Regurgitant Fraction (PRRF) >30% and increased Right Ventricular End Diastolic Volume Index (RVEDVI) >150mL/m^2.

CONTRAINDICATIONS

Known hypersensitivity or contraindication to aspirin, heparin, ticlopidine, clopidogrel, nitinol or sensitivity to contrast media which cannot be adequately pre-medicated. Septicemia, including active, endocarditis. Recent myocardial infarction (<30 days). Echocardiographic evidence of intracardiac mass, thrombus, or vegetation. Any Contraindication of extracorporeal assist Evotutive or recent cerebral vascular accident (CVA). Obstruction of the central veins Bleeding diathesis, coagulopathy, patient refusal of blood transfusion. Creatinine Clearance Calculator (CCR) <20ml/min Pregnancy Patients with known allergies to porcine materials. Patients who are breastfeeding.

POTENTIAL RISKS

Associated with transfemoral access and general anesthesia
Death. Cardiovascular or vascular injury, such as perforation or damage (dissection) of vessels, myocardium, or valvar structures, that may require intervention. Arrhythmia Pericardial effusion/cardiac tamponade. Perforation or damage of vessels. Embolization: air or thrombus. Hematoma Hemorrhage requiring transfusion. Hypertension/hypotension. Infection including endocarditis and septicemia. Systemic peripheral ischemia/nerve injury. Allergic dye reaction. Anesthesia reactions. Radiation injury. Fever ...

POTENTIAL RISKS

Associated with the VenusP-Valve System
Myocardial infarction. Arteriovenous fistula. Bleeding. Coronary artery compression. Device embolization requiring intervention. Device explant. Device migration or malposition requiring intervention. Device thrombosis requiring intervention. Emergency cardiac surgery. Endocarditis. Hemolysis. Hemolytic anemia. Important Information About Stent Fracture. In some patients, the wire frame (Stent) of the VenusP-Valve System may fracture because of the forces it is exposed to in the body. In some cases, the fractured stent may not require any additional treatment. However, the patients should realize a fractured stent has the potential to become serious and could result in the need for another procedure. The doctor will decide the best treatment option. In the VenusP-Valve System CE Clinical Interim Report data, eleven (11) stent fractures (14.5%) have been identified, which did not affect the valve functionality and no need for additional treatment.

Product not intended to enter the market in Germany, Ireland or France.

CE 0344