




Product Name	VersaFlex™ <i>Semi-Stented Porcine Bioprosthesis</i>	
Model Name	NRV	
Model Number (Valve Size)	<i>Model</i>	<i>Size</i>
	▶ NRV-00021	21 mm
	▶ NRV-00023	23 mm
	▶ NRV-00025	25 mm
	▶ NRV-00027	27 mm
	▶ NRV-00029	29 mm
Materials	<ul style="list-style-type: none"> ▶ Porcine pericardium ▶ Porcine valve ▶ Medical grade plastic stent 	
Storage	Between 5°C to 25°C	
Packaging	<ul style="list-style-type: none"> ▶ Sterile glass jar with plastic cap ▶ Cardbox box with cardboard jar holder ▶ Patient stickers ▶ Instructions for use (IFU) ▶ Freeze indicator 	
Regulatory		
Expiry Date	Four years from date of manufacture	
Features	<ul style="list-style-type: none"> ▶ Using common implantation technique, the Versaflex can be oversized by one size (e.g., 27 mm instead of a 25 mm annulus), providing maximum EOA and flow ▶ If implanted in the sub-annular position, valves can be oversized by TWO sizes (e.g., 27 instead of a 23 mm valve) ▶ “Volume-less” annulus, maximizing flow 	

Indications

Replacement for damaged or diseased aortic heart valves

Statistics**Table 1** – EOA, Max BSA, and EOAI

Valve Size (mm)	EOA (cm ²)	Max BSA (m ²)	EOAI (cm ² /m ²)
21	1.61	1.8	0.89
23	1.80	2.0	0.90
25	2.13	2.2	0.97
27	2.30	2.4	0.96

Note: EOAI value must be greater than 0.85 cm²/m² to prevent patient-prosthesis mismatch.**Table 2** – Clinical Results

Statistic	Results
Freedom from structural deterioration	100.0%
Freedom from thromboembolism	100.0%
Freedom from endocarditis	98.5%
Freedom from reoperation	96.8%
Gradient, mean	12.4 ± 4.4 mm Hg
Gradient, peak	18.2 ± 8.7 mm Hg

Source: BioIntegral Surgical, Inc., clinical publications.

Table 3 – Dimensions in millimeters

Product code	Valve size	Internal orifice diameter	Sewing ring diameter	Valve height
NRV-00021	21	20.4	21.6	15.3
NRV-00023	23	21.5	23.8	15.6
NRV-00025	25	22.5	25.6	15.8
NRV-00027	27	23.3	27.8	15.9
NRV-00029	29	24.0	29.6	16.0

Source: BioIntegral Surgical, Inc.

Adverse Events Summary

Years in market	11
Total implants	Over 20,000
Complaints	22

Adverse events¹

Structural deterioration	0
Thromboembolism	0
Valve thrombosis	0
All hemorrhage	0
Paravalvular leak	3
Endocarditis	1
Reoperation	2
Total adverse events	3

Device-related events	1
Device-related event rate (%)	< 0.1%

¹ Excludes cases involving reinfection/treatment of endocarditis.