

SJM Regent[®]

Heart Valve

REDEFINING HEMODYNAMIC PERFORMANCE.™



THE NEWEST MEMBER OF THE ST. JUDE MEDICAL
MECHANICAL HEART VALVES FAMILY

REACHING NEW LEVELS.

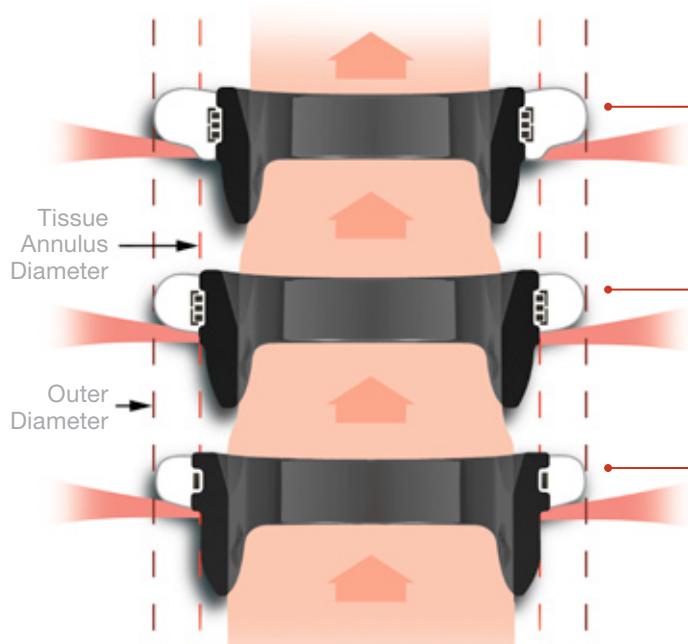
The SJM Regent® heart valve represents a significant step forward in prosthetic valve design. It provides outstanding hemodynamics while maintaining the traditional quality and proven features that have established St. Jude Medical® mechanical valves as the gold standard.



Regent™ Valve

Evolutionary improvement

Development of the St. Jude Medical® mechanical heart valve has led to a progressively greater geometric orifice area within a given tissue annulus dimension.



SJM® Masters Series mechanical heart valve

- Intraannular cuff.
- Intraannular carbon rim.

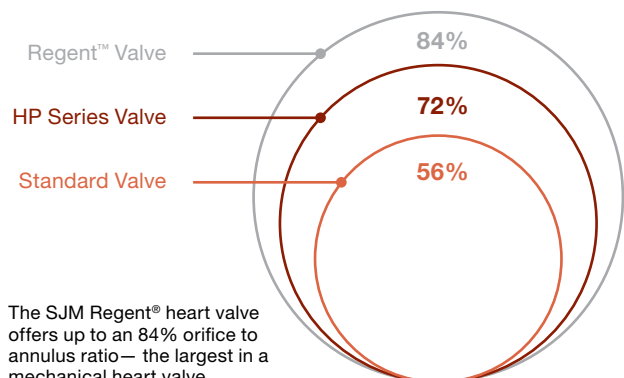
SJM® Masters Series Hemodynamic Plus valve

- Supraannular cuff.
- Carbon rim remains intraannular.

SJM Regent® heart valve

- Supraannular cuff.
- Carbon rim shifts to supraannular position.
- New rotation mechanism is completely housed within the carbon rim.

Orifice to annulus ration — 19mm valve²



The SJM Regent® heart valve offers up to an 84% orifice to annulus ratio— the largest in a mechanical heart valve.

"The energy loss results show an approximate one-size increment improvement of the SJM Regent™ heart valve over the St. Jude Medical® HP Series valve, which is equivalent to a two-size increment improvement over the standard valve."

(Walker et al, 1999)¹

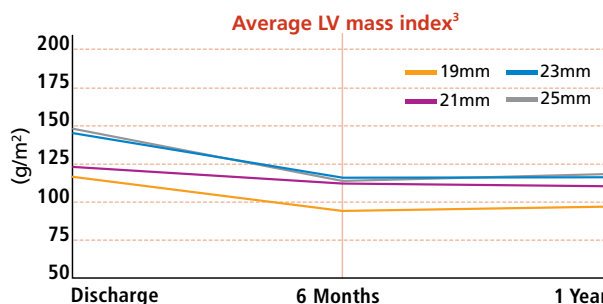
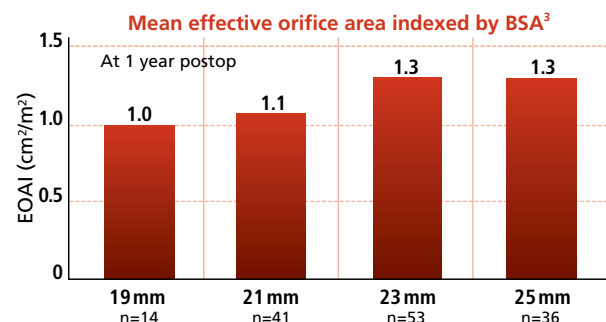
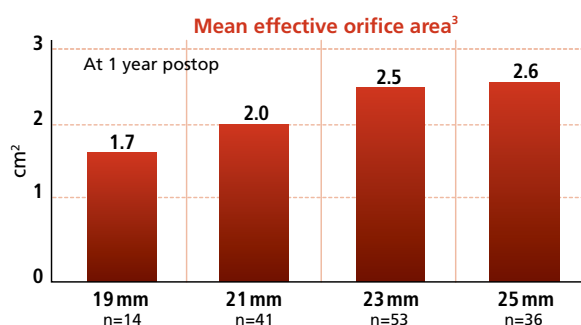
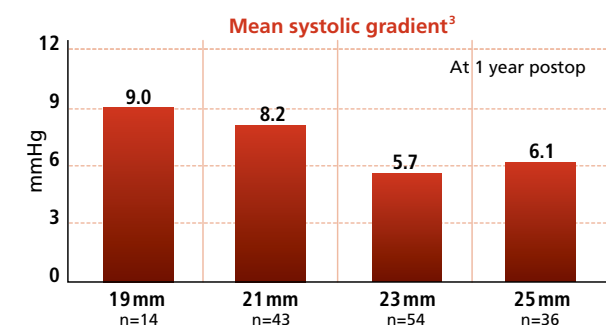
SJM REGENT® HEART VALVE

Redefining Hemodynamic Performance.™

Unprecedented hemodynamics

The SJM Regent® heart valve delivers exceptional hemodynamics and performance while maintaining the design features that have set the standard for low complication rates, structural integrity, and durability in a mechanical valve. The SJM Regent® heart valve provides:

- Single digit in vivo pressure gradients—even in valve sizes as small as 19mm.³
- Significantly larger EOAs.³
- Excellent patient-prosthesis match⁴—even in small sizes.
- Significant reduction of LV Mass.³ Numerous studies have shown a direct correlation between LV hypertrophy and morbidity and mortality.⁵⁻¹⁶ Even moderate LV hypertrophy can result in: congestive heart failure,¹⁷ arrhythmias,⁵ myocardial infarction,¹⁷ and sudden death.^{5,17}



"Significant and rapid left ventricular mass regression with all valve sizes confirms excellent hemodynamics associated with the valve. . . ."

(Bach et al, 2001)¹⁸

Traditional reliability

The SJM Regent® heart valve retains the same design features that have made St. Jude Medical® mechanical heart valves the standard for reliability and proven performance for more than 25 years.

- All blood-contact surfaces remain unchanged.
- In seven broad categories of structural integrity and durability tests, the SJM Regent® heart valve met all the demanding standards set by previous St. Jude Medical® mechanical heart valves.²
- The SJM Regent® heart valve is made of the same pyrolytic carbon used in more than one million St. Jude Medical® mechanical heart valve implants.

FAMILIAR TECHNIQUE

The technique for implanting the SJM Regent® heart valve remains the same as for other St. Jude Medical® mechanical heart valves. For added convenience, it's available in two cuff configurations to suit your implant preferences.

FlexCuff™ sewing ring

- Provides enhanced conformability and maximum suture target area while offering lateral flange to accommodate the tissue annulus.



Standard cuff sewing ring

- Rounded cuff designed for excellent conformability and suturability.

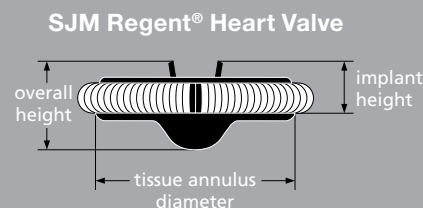


Product Specifications*

Valve Size (mm)	Tissue Annulus Diameter (mm)	Overall Height Open (mm)	Implant Height (mm)	Geometric Orifice Area (cm ²)
17	17.0	10.6	5.3	1.87
19	19.0	11.5	5.9	2.39
21	21.0	12.5	6.7	2.90
23	23.0	13.7	7.3	3.45
25	25.0	13.9	7.6	4.02
27	27.0	14.9	8.5	4.69
29	29.0	16.1	9.1	5.44

*From manufacturer's data

Sizes 17 mm and 29 mm are not currently approved in the United States



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St. Jude Medical prosthetic heart valves are indicated for use as replacement valves in patients with a diseased, damaged, or malfunctioning native or prosthetic valve. Possible side effects for all valvular implants include, but are not limited to, regurgitation, thromboembolic phenomena, resistance to flow, infection, hemolysis, dysrhythmias, and prosthetic dehiscence or failure. Anticoagulation is recommended for patients with mechanical valve implants. See the physician's manual for a full description of indications, contraindications, side effects, precautions, warnings and instructions for use.

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