St. Jude Medical® vs. Medtronic Advantage®

A Design and Performance Comparison

ST. JUDE MEDICAL

PART I: IMPLANTABILITY & HEMODYNAMICS

Implantability

St. Jude Medical® Valve

A **large variety** of cuff configurations to accommodate surgeons' preferences regardless superb hemodynamics

- Shape: traditional or Flex Cuff
- Thickness: Standard or Expanded Cuff
- Material: Double Velour Polyester or PTFE

Medtronic Advantage® Valve

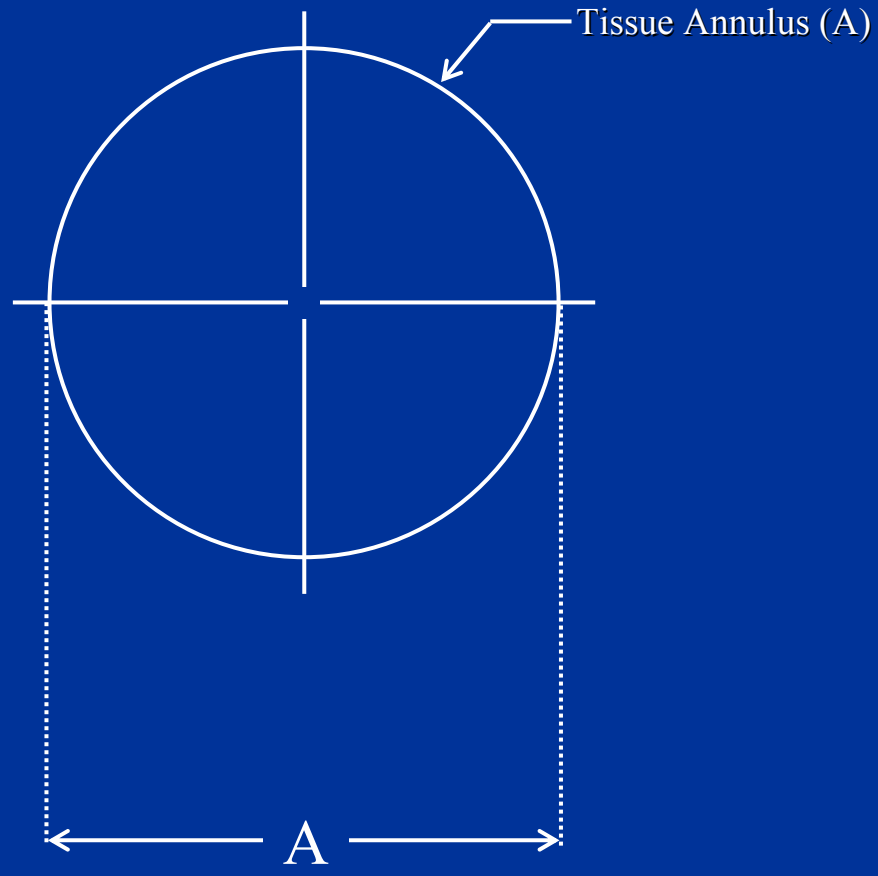
Only 1 cuff option available:

- Shape: traditional
- Thickness: Standard
- Material: Double Velour Polyester

Hemodynamics

Design Objective

- **100% utilization of the native annulus area**
- **Minimal myocardial workload**
- **Minimal turbulence generation**



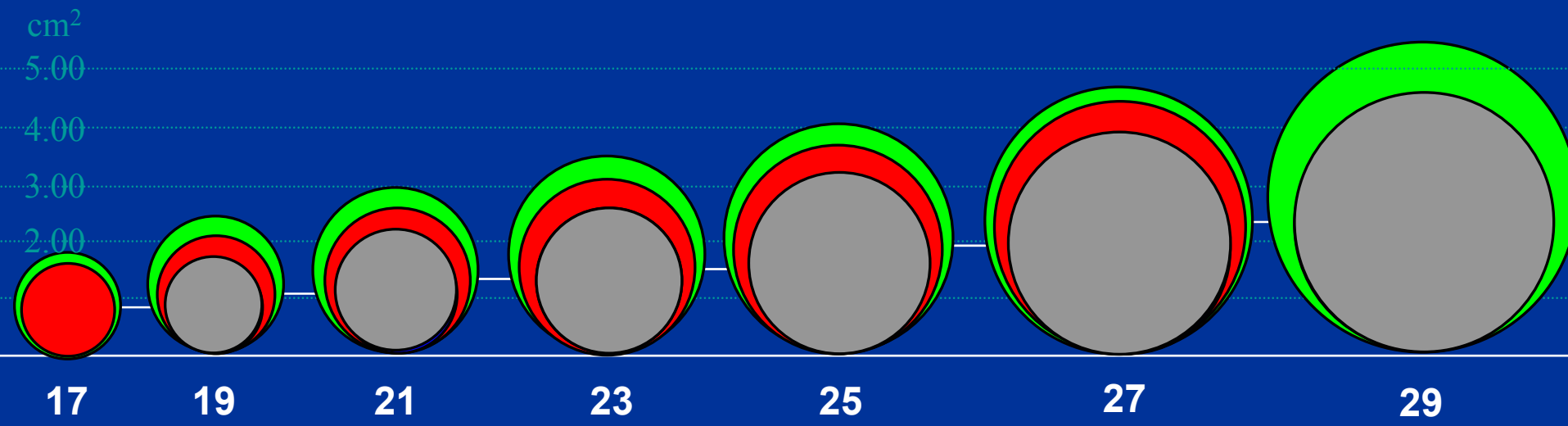
Importance of hemodynamics

Avoidance patient prosthesis mismatch

- Higher transprosthetic gradients
- LVOT obstruction
- Decreased post-operative cardiac index
- Decreased NYHA functional class improvement
- Decreased Quality of Life
- Higher incidence of late adverse complications (Pibarot, Patracek)
- Decreased late survival (Pibarot, Rao, Rahimtoola)
- Sudden death (Kratz, Hachida, Rahimtoola, Bach, Renzulli)

Comparison

Geometric Orifice Areas (GOA)



SJM® Standard Valve | SJM® HP Valve | SJM Regent™ Valve

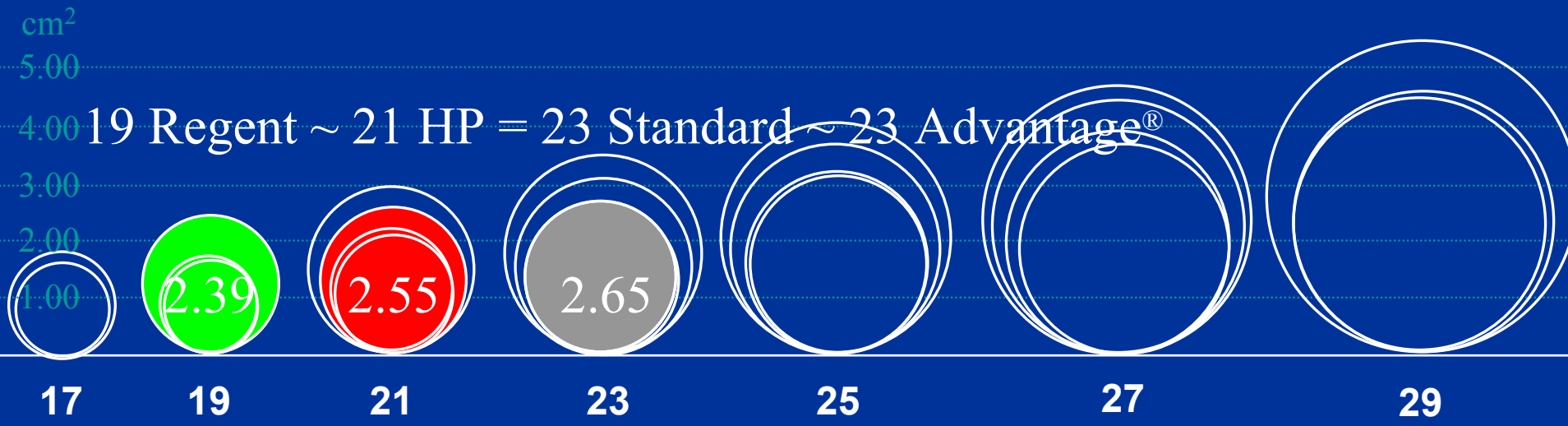
Medtronic Advantage®

SJM Regent : Improvements up to **47%** over the Standard and 17% over the HP

SJM Regent : Improvements up to **41%** over the Medtronic Advantage® Valve

Comparison

Geometric Orifice Areas (GOA)



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Forward Flow Hemodynamics

St. Jude Medical® Valve

Medtronic Advantage® Valve

Test conditions: compliant to ISO 6540 guideline

Forward Flow Hemodynamics

St. Jude Medical® Valve

Medtronic Advantage® Valve

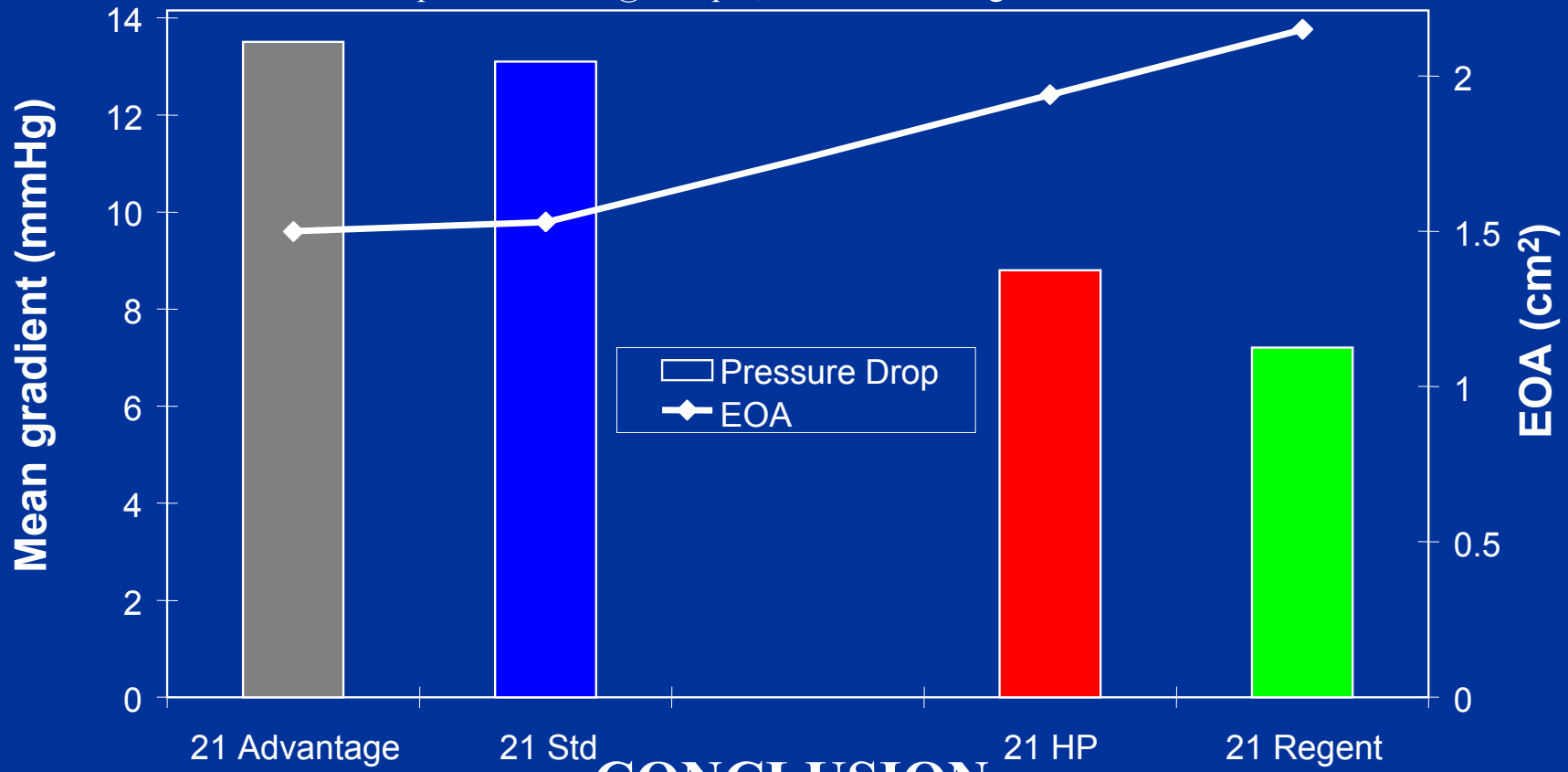
CONCLUSIONS Medtronic Advantage®:

Central vs. lateral pressure battle on leaflets leads to:

- **Incomplete leaflet opening and flutter resulting in**
  -> SMALLER effective central opening area
  -> SMALLER effective lateral opening area

In-vitro mean gradient and EOA 21mm valves

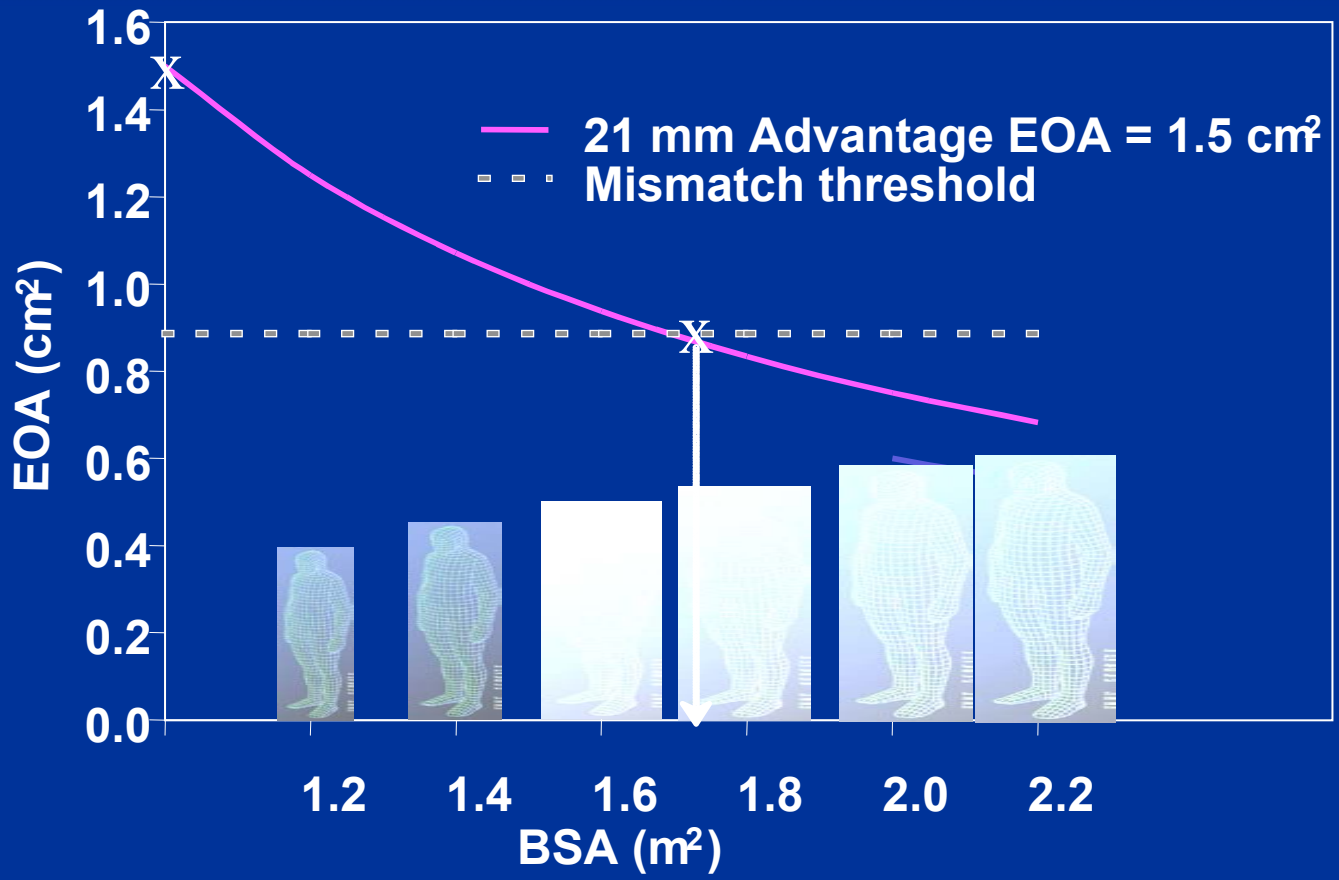
Test conditions: pulsatile flow @ 70 bpm;5l/min according to SJM Test Lab Standard



CONCLUSION:

21mm Medtronic Advantage® Valve = 21mm SJM® Standard Valve

Hemodynamics & Patient-Prosthesis Mismatch



<u>CONCLUSION</u>: 21mm Medtronic Advantage® Valve causes Patient-Prosthesis Mismatch as of BSA > 1.7 m^2

PART II: THROMBORESISTANCE & DURABILITY

Thromboresistance : Manufacturing process differences

St. Jude Medical® Valve

Machining & polishing:
results in a **smooth & clean** carbon surface

Medtronic Advantage® Valve

Surface Engineering & polishing:
results in **visual bumps** on the carbon surface

CONCLUSION: Medtronic Advantage® carbon surface shows visual bumps, which are potential sites for thrombus formation

Thromboresistance : Hinge mechanism

St. Jude Medical® Valve

Proven hinge mechanism

28 NOV 2000
Data confirmed *in vivo*
31M-101 S/N 11637

- 19 years implanted
- WEAR : LESS THAN 1 MICRON

Medtronic Advantage® Valve

Copy of St. Jude Medical's hinge mechanism; no proven wear rates

<u>CONCLUSION</u>: Medtronic Advantage® Sure-Flow™ butterfly pivot recesses is a copy St. Jude Medical's hinge recess but without St. Jude Medical Quality Control Label.

Durability : Clinical Evidence

St. Jude Medical® Valve

- Proven design: subject of over 1000 clinical papers & > 25 years of clinical history
- Over 1.2 million implants

Medtronic Advantage® Valve

- Unproven design: No follow-up data exisiting
- Less than 1000 implants

CONCLUSION: Medtronic Advantage ® is a NEW valve with design question marks and no clinical proof

CONCLUSION

What are the advantages of the Advantage® valve?

DESIGN CLAIM		FACT
• **Wider central flow area**	→	"wider" becomes "smaller" due to incomplete leaflet opening
• **SureFlow ™ butterfly pivot system**	→	unproven copy of St. Jude Medical's mated sphere pivot system
• **No obstructive pivot guards**	→	leads to dysfunctional fluttering of valve leaflets
• **Lower velocities**	→	only lower than caged-ball designs

CONCLUSION

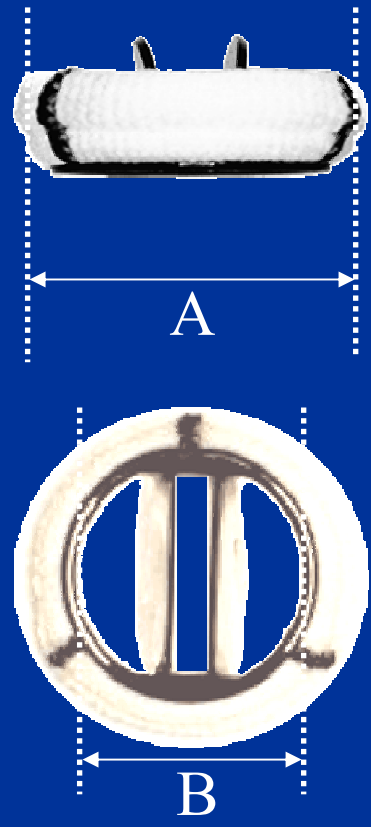
There are no advantages to the Advantage® Valve ;
but there are risks….

- Patient-prosthesis mismatch
- Potential for higher TE or thrombus due to unproven "Surface Engineering"
- Turbulence due to leaflet flutter
- Lack of clinical evidence
- Company with history of bileaflet design issues

…so do you want to put your patients at risk ???

Product specifications*

Labeled Size	Valve type	Tissue Annulus Diameter (A) (mm)	Inner Diameter (B) (mm)	Geometric Orifice Area (cm^2)
17	SJM HP	17.0	14.7	1.63
	SJM Regent™	17.0	15.9	1.87
19	SJM Standard	19.0	14.7	1.63
	SJM HP	19.0	16.7	2.06
	SJM Regent™	19.0	17.8	2.39
	MDT Advantage®	19.0	15.1	1.70
21	SJM Standard	21.0	16.7	2.06
	SJM HP	21.0	18.5	2.55
	SJM Regent™	21.0	19.6	2.90
	MDT Advantage®	21.0	16.9	2.13
23	SJM Standard	23.0	18.5	2.55
	SJM HP	23.0	20.4	3.09
	SJM Regent™	23.0	21.4	3.45
	MDT Advantage®	23.0	18.8	2.65
25	SJM Standard	25.0	20.4	3.09
	SJM HP	25.0	22.3	3.67
	SJM Regent™	25.0	23.0	4.02
	MDT Advantage®	25.0	20.6	3.19
27	SJM Standard	27.0	22.3	3.67
	SJM HP	27.0	24.1	4.41
	SJM Regent™	27.0	24.9	4.69
	MDT Advantage®	27.0	22.7	3.90
29	SJM Standard	29.0	24.1	4.41
	SJM HP	29.0	26.0	5.18
	SJM Regent™	29.0	26.8	5.44
	MDT Advantage®	29.0	24.5	4.55
31	SJM Standard	31.0	26.0	5.18
	MDT Advantage®	31.0	24.5	4.55



***From manufacturers' data.**

Key:

SJM HP = SJM ® Masters Series HP Cuffed Valve

SJM Std. = SJM ® Masters Series Standard Cuffed valve

VISIT OUR WEBSITE AT http://www.sjm.com

CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN OR PROPERLY LICENSED PRACTITIONER.

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 dehiscense or failure. Anticoagulation is recommended for patients with mechanical valve implants. Please see the physician's manual for a full description of indications, contraindications, side effects, precautions, warnings and instructions for use.

Corporate Headquarters St. Jude Medical, Inc. One Lillehei Plaza, St. Paul, Minnesota 55117 USA **24-Hour Technical/Professional Consultation** (800) 328-9634 (USA) (651) 483-2000 Fax: (651) 482-8318 **Customer Service** (800) 544-1664 (USA) (651) 490-4410 Fax: (651) 481-7702 **European Headquarters** SJM International, Inc., The Corporate Village, Figueras Building, Avenue Da Vincilaan, 11, 1930 Zaventem, Belgium **Customer Service** Tel: 32-2-774-68-11 Fax: 32-2-772-83-84 **Asian Headquarters** St. Jude Medical Hong Kong Limited, Room 2705-2708, China Merchants Tower, Shun Tak Centre, 168-200 Connaught Road, Central, Hong Kong Tel: (852) 2996-7688 Fax: (852) 2956-0622

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