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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. CE 578287
Issued To: St. Jude Medical
177 County Road B East
St Paul
Minnesota
55117
USA

In respect of:

Design and manufacture of Mechanical and Tissue Heart Valves, Transcatheter Heart Valves, Valved Grafts, Annuloplasty Rings and Related Accessories.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack

Gary E Slack, Senior Vice President Medical Devices

First Issued: 2012-01-30

Date: 2019-12-11

Expiry Date: 2024-05-26

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Page 1 of 4

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.
Information and Contact: BSI, 389 Chiswick, Uxbridge, Middlesex, UK. Telephone: +44 (0)1875 930100
BSI Group The Netherlands B.V. registered in The Netherlands under 33264294.
A member of BSI Group of Companies.

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Supplementary Information to CE 578287

Issued To: St. Jude Medical
177 County Road B East
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Number	Device Name	Intended Purpose per IFU
Class III		
—	<ul style="list-style-type: none">Masters Series Mechanical Heart Valve – Mechanical Heart ValvesMasters Series Mechanical Heart Valve with Expanded Polyester Sewing Cluff – Mechanical Heart ValvesMasters Series Mechanical Heart Valve with PTFE Sewing Cluff – Mechanical Heart ValvesMasters Series Mechanical Heart Valve with Expanded PTFE Sewing Cluff – Mechanical Heart ValvesMasters Series Mechanical Heart Valve with Hemodynamic Plus (HP) Sewing Cluff – Mechanical Heart ValvesMasters Series Mechanical Heart Valve with Expanded Hemodynamic Plus (HP) Sewing Cluff – Mechanical Heart ValvesRegent Heart Valve – Mechanical Heart ValvesRegent Heart Valve with FlexCluff – Mechanical Heart Valves	See CE 578290

First Issued: 2012-01-30

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Number	Device Name	Intended Purpose per IFU
Class III		
---	Masters HP Valved Graft with Gelweave Valsalva Technology (VAVG) - Valved Grafts	See CE 578291
---	Masters Valved Graft with Hemashield Graft Technology (CAVG) - Valved Grafts	See CE 578292
---	Tailor Annuloplasty Ring and Tailor Annuloplasty Band - Annuloplasty Rings	See CE 578289
---	Rigid Saddle Ring Annuloplasty Ring - Annuloplasty Rings	
---	Sequin Annuloplasty Ring - Annuloplasty Rings	See CE 578288
---	Portico Transcatheter Aortic Heart Valve System - Transcatheter Heart Valves	See CE 585003
---	Trifecta and Trifecta GT - Tissue Heart Valves	See CE 617862
---	Biocor, Epic and Epic Supra - Tissue Heart Valves	See CE 617865

First Issued: 2012-01-30

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Number	Device Name	Intended Purpose per IFU
Class IIa		
MD0106, MDS/006	Mechanical Heart Valve Leaflet Tester - Related Accessories	---
MD0106	<ul style="list-style-type: none">Masters Series Mechanical Heart Valve ReplacementHolder/Rotators - Related AccessoriesMasters Series Hemodynamic Plus (HP) Mechanical Heart Valve Replacement Holder/Rotators - Related AccessoriesRegent Mechanical Heart Valve Replacement Holder/Rotators - Related AccessoriesRigid Saddle Ring Annuloplasty Sizer Set - Related AccessoriesTailor Annuloplasty Ring Sizer Set - Related AccessoriesTailor Ring Robotic Sizer Set - Related AccessoriesSequin Annuloplasty Ring Sizer Set - Related AccessoriesMechanical Heart Valve Sizer - Related AccessoriesRegent Mechanical Heart Valve Sizer Set - Related AccessoriesTrifecta Valve Sizer Set - Related AccessoriesBioprosthetic Heart Valve Sizer Set - Related Accessories	

First Issued: 2012-01-30

Date: 2019-12-11

Expiry Date: 2024-05-26

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Page 4 of 4

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 578287**
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 Issued To: **St. Jude Medical**
177 County Road B East
St Paul
Minnesota
55117
USA

Subcontractor:

Abbot Medical
 5050 Nathan Lane North
 Plymouth
 Minnesota
 55442
 USA

Service(s) supplied

Manufacture

Animal Tissues / Derivatives

Abbyland PortPak Inc.
 539 North Meridian Street
 Curtis
 Wisconsin
 54422
 USA

Animal Tissues / Derivatives

Agrodaniel Industria e Comércio Ltda
 Rodovia 403, KM 14,5
 Distrito Industrial
 Vila Langaro
 Rio Grande do Sul
 Brazil

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Subcontractor:

Agropecuária Bolson Ltda.
 (Bolson)
 Rua Vereador Waldomiro Franco de
 Souza, S/N - Zona Suburbana
 Toledo
 Paraná
 Brazil

Service(s) supplied

Animal Tissues / Derivatives

Animal Tissues / Derivatives

Bien Brothers Inc.
 3539 Kelly Ct.
 Vineland
 New Jersey
 08360
 USA

Animal Tissues / Derivatives

BRF - Brasil Foods S.A.
 Rua Senador Atilio Fontana, 86,
 Corumbá/SC
 Brazil

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Subcontractor:	Service(s) supplied
Frigeestreia S.A. Estrada Vicinal Romão Lopes Martins, S/N - KM 0+700M, Jardim Marabá, Itupã/SP Brasil	Animal Tissues / Derivatives
Frigorifico Mocar Ltda Estrada para Fazenda Mezurana S/N, Dios Vizinhos/PR Brasil	Animal Tissues / Derivatives
Frimesa Cooperativa Central Rua Bahia, 159, Medianeira/PR Brasil	Animal Tissues / Derivatives
Hereaus Medical Components, LLC 5030 Centerville Road St. Paul Minnesota 55127 USA	Manufacture

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Subcontractor:	Service(s) supplied
InterVascular SAS Z.I. Athéla 1 13705 La Clotat Cedex France	Manufacture
Irmãos do Valle (DDV) Rodovia BR 116, KM 116 Caixa Postal 04 - Bairro: Campo Alto - Santa Cecilia Santa Catarina Brasil	Animal Tissues / Derivatives
Isoretek Operations, Inc. 380 90th Avenue NW Minneapolis Minnesota 55433 USA	ETO Sterilization

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Subcontractor:	Service(s) supplied
JBS Aves Ltda Rua João Antello, 1167, Ana Rech Caxias do Sul/RS Brasil	Animal Tissues / Derivatives
JBS S.A. Parque Industrial S/N Distrito Industrial, LINS/SP Brasil	Animal Tissues / Derivatives
JBS S.A. Rodovia, GO 164, Km 167 S/N, Zona Rural, Mozarlândia/GO Brasil	Animal Tissues / Derivatives
JBS S.A. Rua Principal S/N, Vila Misca, Iturubá/MG Brasil	Animal Tissues / Derivatives

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 USA

Subcontractor:	Service(s) supplied
JBS S.A. Facility 1 Av. Duque de Caxias 7255 Vila Nova Campo Grande/MS Brasil	Animal Tissues / Derivatives
Mec Frios Rod. Antônio de Paiva Cantelmo, PR 366- KM 02, Zona Rural, Francisco Beltrão/PR Brasil	Animal Tissues / Derivatives
Marcho Farms Inc. 519 Allentown Road Frankonia Pennsylvania 18924 USA	Animal Tissues / Derivatives

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St. Jude Medical
177 County Road B East
St Paul
Minnesota
55117
USA

Subcontractor:

Service(s) supplied

Midwest Sterilization Corporation

1204 Lenco Avenue

Jackson

Missouri

63755

USA

ETO Sterilization

Oakey Abattoir

Lot 1, Oakey Connection Road,

Oakey QLD 4401

Australia

Animal Tissues / Derivatives

P&N Packaging Inc.

11627 Route 187

Wyalusing

Pennsylvania

18853

USA

Animal Tissues / Derivatives

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Subcontractor:

Service(s) supplied

Phillips-Medsize, LLC

705 Wisconsin Drive

New Richmond

Wisconsin

54017

USA

Manufacture

POCO Graphite, Inc. an Enrigis Company

300 Old Greenwood Road

Decatur

Texas

76234

USA

Crucial Supplier

Quality Central de Esterilização

Estrada Celso Chatur, 123

Aracoba de Serra

Sao Paulo

18190-000

ETO Sterilization

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USA

Subcontractor:

Service(s) supplied

Rio Branco Alimentos S.A. (Pir Par) BR 365 Km 455, Petrolio/MG Brasil	Animal Tissues / Derivatives
Seara Alimentos Ltda Rua Tranquilo Dermo, 209 -Santo Antonio, Frederico Westphalen/RS Brasil	Animal Tissues / Derivatives
Sioux-Preme Packing Company 4241 U.S. 75 Ave Sioux Center Iowa 1250 USA	Animal Tissues / Derivatives

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USA

Subcontractor:

Service(s) supplied

St. Jude Medical 14901 Deveau Place Minnetonka Minnesota 55345-2126 USA	Manufacture
St. Jude Medical 177 County Road B East St. Paul Minnesota 55117 USA	Final Inspection Labelling Manufacture Moist Heat Sterilization Packaging
St. Jude Medical Brasil Ltda. Rua Professor Jose Verra de Mendonca 1301 Bairro Engenho Nogueira Pampulha, Belo Horizonte Minas Gerais 31.310-026 Brasil	Manufacture

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USA

Subcontractor:	Service(s) supplied
St. Jude Medical Coordination Center BVBA The Corporate Village Da Vincklaan 11 Box F1 1935 Zaventem Belgium	EU Representative Labelling Packaging
St. Jude Medical Costa Rica Ltda. Edificio #44 Calle 0, Ave. 2 Zona Franca Coyol El Coyol, Alajuela Costa Rica	Manufacture
St. Jude Medical PR LLC Caguas West Industrial Park Lot 20 Caguas 00725 Puerto Rico	Final Inspection Manufacture Moist Heat Sterilization

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St Paul
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55117
USA

Subcontractor:	Service(s) supplied
St. Jude Medical Puerto Rico LLC Lot A Interior - #2 Rd Km. 6.75 Santana Industrial Park Arecibo Puerto Rico 00612 USA	ETO Sterilization
Stergenics Costa Rica S.R.L. Zona Franca Propark Calle Principal, Edificio 10, El Coyol Alajuela 20101 Costa Rica	ETO Sterilization
Stergenics US, LLC 7775 South Quincey Willowbrook Illinois 60527 USA	ETO Sterilization

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 177 County Road B East
 St. Paul
 Minnesota
 55117
 USA

Subcontractor:	Service(s) supplied
Stenigenics US, LLC 5725 West Harold Gatty Drive Salt Lake City Utah 84116 USA	ETO Sterilization
Steiris Isomedix Puerto Rico LLC State Road 690 KM 1.7 Barrio Sabana Hoyos Vega Alta 00692 Puerto Rico USA	Gamma Irradiation
Tegs Australia Southern, Tamworth Phoenix street Tamworth, NSW 2340 Australia	Animal Tissues / Derivatives

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 177 County Road B East
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 USA

Subcontractor:	Service(s) supplied
Vasotek Limited Newmans Avenue Inchinnan PA4 9PR United Kingdom	Animal Tissues / Derivatives Manufacture

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EC Certificate - Full Quality Assurance System

Certificate History

Certificate No:

CE 578287

Date:

2019-12-11

Issued To:

St. Jude Medical
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Date	Reference Number	Action
30 January 2012	7727627	First issue of mirror certificate to CE 544668.
8 June 2012	7816634	Addition of significant subcontractor for sterilization to St Jude Medical Puerto Rico LLC for VAVG devices.
16 November 2012	7910273	Transcatheter valves added to the scope. Addition of St. Jude Medical (Minnesota), St. Jude Medical (Maple Grove), Marchio Farms and Abbyland PortPak to the list of subcontractors.
13 December 2012	7930677	Update to subcontractor address St. Jude Medical PR LLC.
16 January 2013	7943381	St Jude Medical (Costa Rica) added to the list of subcontractors.
18 April 2013	7984806	St Jude Medical (Maple Grove) removed from the list of subcontractors.
10 November 2013	8071312	Addition of significant subcontractor InterVascular SAS (Maquet) La Crotat France facility as a fabric supplier for SJM Mechanical Heart Valves, Valved Grafts and Annuloplasty Rings.
19 November 2014	8245105	Certificate renewal.
01 December 2014	8194269	Tissue valves and pericardial patches added to the scope (transferred from another Notified Body). St Jude Medical Brasil, Phillips Plastics and bovine porcine abattoirs added to the list of subcontractors.

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Page 1 of 3

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Certificate History

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Date	Reference Number	Action
16 March 2015	8297445	Addition of Packaging & Labelling to activities of St. Jude Medical Coordination Center BVBA.
08 July 2015	8288225	Addition of the US abattoir Greater Omaha Packaging Company as a Bovine Tissue Source for "Trifecta™" Heart Valve. Removal of subcontractors STERIS Spartanburg and Maquet Cardiovascular.
03 August 2015	8351515	Addition of Brazilian abattoirs Frigorifico K-Ceet Alimentos, Primaz Frigorifico Ltda. and SPR Sinos Brazil Ltda as porcine cusps suppliers for the manufacture of the Biocor, Epic and Epic Supra Heart Valves.
07 December 2015	8433259	Addition of Sterigenics US, LLC, Willowbrook, IL as a significant subcontractor for ETO sterilization.
01 August 2016	8520657	JBS S.A. Facility 1 added as a bovine pericardium supplier.
23 January 2017	8632751	Removal of subcontractor W&G Marketing.
30 March 2017	8576083	Addition of Agropecuária Bolson Ltda., Imaãos do Valle and W&G Marketing Company as animal tissue suppliers.
4 September 2017	8693815	Addition of subcontractor Quality Central de Esterilização, Brasil as an alternate sterilizer for Biocor Pericardial Patch.
26 October 2017	8694458	Addition of Poco Graphite as crucial supplier and Sterigenics Costa Rica as EO sterilizer. Removal of Steris Minneapolis.
02 May 2018	8917138	Addition of Biering Brothers Inc. and P&N Packaging Inc. as bovine pericardium suppliers for the Portico valve.

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Page 2 of 3

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Date	Reference Number	Action
07 March 2019	7780704	Traceable to NB 0086.
07 May 2019	9752176	Addition of Sterigenics US, LLC, Salt Lake City, Utah USA as a significant subcontractor for ETO Sterilization.
03 December 2019	9688437	Addition of Isomedix Operations Inc. (Steris), Minneapolis USA as a significant subcontractor for ETO sterilization, following inadvertent deletion.
Current	9775758	Certificate Renewal. Removal of Percutaneous patches from the scope. Addition of product table. Removal of discontinued animal tissue suppliers: Greater Omaha Packaging Company, Frigorifico Argus Ltda, Frigorifico K-Celet Alimentos, Primaz Frigorifico Ltda and W&G Marketing Company. Addition of Abbott Medical Plymouth Site as a subcontractor for Manufacture. Addition of Midwest Sterilization Corporation as a subcontractor for ETO sterilization. Change subcontractor name 'SBR Suinos Brazil Ltda' to 'Agrodanieli Industria e Comercio Ltda'. Additional minor alignments of subcontractor name and addresses with ISO certificates.

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BSI Group The Netherlands B.V. registered in The Netherlands under 332624294.
A member of BSI Group of Companies

SJM Declaration of Conformity
Mechanical Heart Valves and Valved Grafts

St. Jude Medical (SJM) hereby declares that the following SJM facilities and products conform to the applicable provisions of Annex II of the Medical Device Directive (MDD) 93/42/EEC as amended by 2007/47/EC. Valved Graft products containing bovine material conform to Regulation 722/2012. All supporting documentation is retained under the premises of SJM. We declare no application has been lodged with any other notified body for the same products. This declaration is issued under the sole responsibility of the manufacturer. This declaration supersedes any declaration issued previously for the same product(s).

Manufacturer Address:

St. Jude Medical
177 County Road B East
St. Paul, Minnesota 55117 USA

European Representative:

St. Jude Medical Coordination Center BVBA
The Corporate Village
Da Vinciiaan 11 Box F1
1935 Zaventem, Belgium

Product Type:

Mechanical Heart Valves
Valved Grafts
Annuloplasty Rings

Product Name(s):

SJM Masters Series (Rotatable)
SJM Regent Valve (Rotatable)
SJM™ Masters Series Aortic Valved Graft with
Hemashield™ graft technology
SJM Masters HP™ Valved Graft with Gelweave
Valsalva™ Technology
Rigid Saddle Ring
St. Jude Medical Seguin Annuloplasty Ring
Tailor Annuloplasty Ring
Tailor Annuloplasty Band

Model Number(s):

See attached.

Classification:

Mechanical Heart Valves: Class III per MDD, Annex IX,
rule 8

Valved Grafts: Class III per MDD, Annex IX, rule 17

Annuloplasty Rings: Class III per MDD, Annex IV, rule 8

GMDN Code(s):

Mechanical Heart Valves:
• Aortic - 60240
• Mitral - 60241

Valved Grafts:

• Aortic - 60423
Annuloplasty Rings:
• Mitral - 45377
• Mitral/Tricuspid - 45573



SJM Declaration of Conformity
Mechanical Heart Valves and Valved Grafts

Original CE Mark Date:

See attached.

FDA Certificate No and expiration date:

Certificate No: CE 578287
Expiration Date: 26 May 2024

Annex II DE Certificate No and expiration date:

See attached.

Applicable Quality System Standards:

ISO 13485: 2003 + AC:2007

Notified Body:

BSI Group The Netherlands B.V.
Say Building
John M. Keynesplein 9
1066 EP Amsterdam
The Netherlands

Notified Body Number:

2797

Manufacturing Facilities:

St. Jude Medical
177 County Road B East
St. Paul, Minnesota 55117 USA

St. Jude Medical Puerto Rico LLC Lot 20-B Street
Caguas West Industrial Park Caguas, Puerto Rico 00725
USA

Signature:

Jeff Sturm
Associate Director, Regulatory Affairs

Issue Date

Masters Series Mechanical Heart Valve (Page 1 of 3)

Mitral Valves

Product Highlights

- * Pyrolytic carbon leaflets and orifice ring offer exceptional durability and increased thromboresistance^{1a}
- * 85 degree leaflet opening angle offers improved laminar flow and reduces turbulence^{2,4}
- * Controlled torque rotation mechanism allows for easy rotation and intraoperative adjustment
- * St. Jude Medical heart valves are MR conditional⁵

Ordering Information

Contents: Mitral Valve (1 unit per box)

Model/Reorder Number	Tissue Annulus Diameter (mm)	Valve Orifice Inner Diameter (mm)	Geometric Orifice Area (cm ²)	Cuff Style
19MJ-501	19	14.8	1.63	Standard
21MJ-501	21	16.7	2.06	Standard
23MJ-501	23	18.6	2.55	Standard
25MJ-501	25	20.4	3.09	Standard
27MJ-501	27	22.5	3.67	Standard
29MJ-501	29	24.2	4.41	Standard
31MJ-501	31	26.1	5.18	Standard
33MJ-501	33	26.1	5.18	Standard
35MJ-501	35	26.1	5.18	Standard
37MJ-501	37	26.1	5.18	Standard



Product referenced is approved for CE Mark

ST. JUDE MEDICAL
A BILTRON COMPANY, ILLINOIS

Page M1E

Cardiac Surgery International Catalogue
GMS017651 (June 2010)
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Masters Series Mechanical Heart Valve (Page 2 of 3)

Mitral Valves

Product Highlights

- * Pyrolytic carbon leaflets and orifice ring offer exceptional durability and increased thromboresistance^{1a}
- * 85 degree leaflet opening angle offers improved laminar flow and reduces turbulence^{2,4}
- * Controlled torque rotation mechanism allows for easy rotation and intraoperative adjustment
- * The expanded mitral cuff has approximately 25% more cuff than the standard mitral cuff
- * St. Jude Medical heart valves are MR conditional⁵

Ordering Information

Contents: Mitral Valve (1 unit per box)

Model/Reorder Number	Tissue Annulus Diameter (mm)	Valve Orifice Inner Diameter (mm)	Geometric Orifice Area (cm ²)	Cuff Style
19MECJ-502	19	14.8	1.63	Expanded
21MECJ-502	21	16.7	2.06	Expanded
23MECJ-502	23	18.6	2.55	Expanded
25MECJ-502	25	20.4	3.09	Expanded
27MECJ-502	27	22.5	3.67	Expanded
29MECJ-502	29	24.2	4.41	Expanded
31MECJ-502	31	26.1	5.18	Expanded
33MECJ-502	33	26.1	5.18	Expanded



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Masters HP™ Mechanical Heart Valve (Page 1 of 2)

Aortic Valves

Product Highlights

- Sewing cuff redesigned to facilitate supra-annular placement, allowing for an increase in orifice size for a given tissue annulus diameter
- Increased effective orifice area (EOA), lower pressure gradients, and improved performance^{4,12}
- 85 degree leaflet opening angle offers improved laminar flow and reduces turbulence⁴
- Controlled torque rotation mechanism allows for easy rotation and intraoperative adjustment
- St. Jude Medical heart valves are MR conditional⁵

Ordering Information

Contents: Aortic Valve (1 unit per box)

Model/Reorder Number	Tissue Annulus Diameter (mm)	Valve Orifice Inner Diameter (mm)	Geometric Orifice Area (cm ²)	Effective Orifice Area ⁶ (cm ²)	Cuff Style
17AHPJ-505	17	14.8	1.63	1.16	Standard
19AHPJ-505	19	16.7	2.06	1.51	Standard
21AHPJ-505	21	18.6	2.55	2.03	Standard
23AHPJ-505	23	20.4	3.09	2.59	Standard
25AHPJ-505	25	22.5	3.67	3.08	Standard
27AHPJ-505	27	24.2	4.41	3.73	Standard



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ST. JUDE MEDICAL
St. Jude Medical, Inc.
2615 Lakeside Drive
St. Louis, MO 63103

Masters HP™ Mechanical Heart Valve (Page 2 of 2)

Aortic Valves

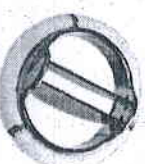
Product Highlights

- Sewing cuff redesigned to facilitate supra-annular placement, allowing for an increase in orifice size for a given tissue annulus diameter
- Increased effective orifice area (EOA), lower pressure gradients, and improved performance^{4,12}
- 85 degree leaflet opening angle offers improved laminar flow and reduces turbulence⁴
- Controlled torque rotation mechanism allows for easy rotation and intraoperative adjustment
- The expanded HP cuff has approximately 15% more cuff than the standard HP cuff
- St. Jude Medical heart valves are MR conditional⁵

Ordering Information

Contents: Aortic Valve (1 unit per box)

Model/Reorder Number	Tissue Annulus Diameter (mm)	Valve Orifice Inner Diameter (mm)	Geometric Orifice Area (cm ²)	Effective Orifice Area (cm ²)	Cuff Style
17AHPJ-505	17	14.8	1.63	1.16	Expanded
19AHPJ-505	19	16.7	2.06	1.51	Expanded
21AHPJ-505	21	18.6	2.55	2.03	Expanded
23AHPJ-505	23	20.4	3.09	2.59	Expanded
25AHPJ-505	25	22.5	3.67	3.08	Expanded
27AHPJ-505	27	24.2	4.41	3.73	Expanded



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Epic[™] Supra Stented Tissue Valve with Linx[™] AC Technology Aortic Supra-Annular Stented Valves

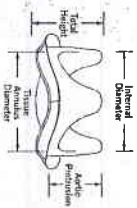
Product Highlights

- Provides a larger stent-to-annulus ratio than Epic aortic valve
- Includes Linx AC Technology which is designed to improve long-term performance and valve durability*
- Three separate porcine leaflets are matched to optimize leaflet coaptation and reduce stress
- The outflow edge is covered with a pericardial shield, providing a tissue-to-tissue interface to reduce the risk of abrasion
- FlexFit[™] stent reduces leaflet stress, adapts easily to annulus to enhance knot positioning, and returns stent posts to original shape after deflection
- Low profile design provides optimal coronary/costia clearance
- Short 2 x 10 second rise time

Ordering Information

Contents: Aortic Supra-Annular Stented Tissue Valve (1 unit per box)

Model/Reorder Number	Valve Size (mm)	Tissue Annulus Diameter (mm)	Internal Diameter (mm)	Aortic Protrusion (mm)	Total Height (mm)
ESP100-19	19	19	19	11	14
ESP100-21	21	21	21	11	15
ESP100-23	23	23	23	13	16
ESP100-25	25	25	25	13	17
ESP100-27	27	27	27	14	19
ESP100-29	29	29	29	15	20



*There is no clinical data currently available that evaluates the long-term impact of anticalcification on tissue treatment purposes.
Product references is approved for CE Mark



Epic™ Stented Tissue Valve with Linx™ AC Technology Mitral Stented Valves

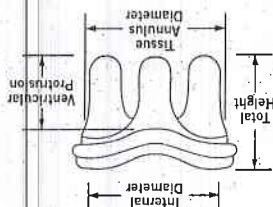
Product Highlights

- Identical in design to the Biocor™ stented tissue valve which delivers proven 20 year durability results^{3,4}
- Includes Linx AC Technology which is designed to improve long-term performance and valve durability²
- Three separate porcine leaflets are matched to optimize leaflet coaptation and reduce stress
- The outflow edge is covered with a pericardial shield, providing a tissue-to-tissue interface to reduce the risk of abrasion
- FlexFit™ mitral valve holder provides stent deflection (ratcheting), which reduces the potential for suture looping and maximizes visibility and access to the valve cuff
- Low combined valve and holder height facilitates minimally invasive surgical procedures
- Low profile design reduces the risk of LV outflow tract obstruction
- FlexFit stent reduces leaflet stress, adapts easily to annulus to enhance knot positioning, and returns stent posts to original shape after deflection
- Short 2 x 10 second rinse time

Ordering Information

Contents: Mitral Stented Tissue Valve (1 unit per box)

Model/Reorder Number	Valve Size (mm)	Tissue Annulus Diameter (mm)	Internal Diameter (mm)	Venticle Protusion (mm)	Total Height (mm)
E100-25M	25	25	23	9	25
E100-27M	27	27	25	9	27
E100-29M	29	29	27	10	29
E100-31M	31	31	29	10	31
E100-33M	33	33	31	11	33



*There is no clinical data currently available that evaluates the long-term impact of anticalcification tissue treatment in humans.

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SJM™ Rigid Saddle Ring Rigid/Semi-Rigid Rings

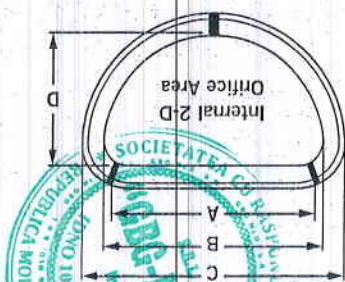
Product Highlights

- Designed to restore the shape of a healthy mitral annulus¹
- Titanium core maintains the anatomical shape and provides annular remodeling
- Saddle shape contributes to efficient distribution of leaflet stress and chordal tension which may increase repair durability²
- EZ Suture Cuff is supported by a unique triangular core for a larger suture target

Ordering Information

Contents: Rigid Saddle Ring (1 unit per box)

Model/Reorder Number	Ring Size	Commissure Dimension (mm) (A)	Inside Dimension (mm) (B)	Outside Dimension (mm) (C)	A-P Dimension (mm) (D)	Internal 2-D Office Area (mm ²)
RSAR-24	24	24	22	30	13.6	227
RSAR-26	26	26	24	32	15.1	276
RSAR-28	28	28	26	34	16.2	331
RSAR-30	30	30	28	26	17.9	387
RSAR-32	32	32	30	38	19.2	450
RSAR-34	34	34	32	40	20.6	511



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