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Nr. <u>12/01-504</u> 18 23, 2016

# CERTIFICAT PRIVIND EXISTENTA CONTURILOR CURENTE

Prin prezentul, <u>BC "Mobiasbancă – Groupe Societe Generale" S.A.</u>, codul băncii (BIC): <u>MOBBMD22</u>, confirmă că compania <u>OXIVIT-MED SRL</u>, cod fiscal (IDNO) <u>1007600044280</u>, deține următoarele conturi curente la BC "Mobiasbancă-Groupe Societe Generale" S.A., Filiala. 1 Stejaur :

- 1. MDL 2224710SV23488147100; IBAN- MD09MO2224ASV23488147100
- 2. EUR 2224710SV22227957100; IBAN- MD17MO2224ASV22227957100
- 3. USD 2224710SV22214937100; IBAN- MD86MO2224ASV22214937100

Certificatul este emis în baza cererii întreprinderii: Oxivit-Med SRL.

EPUBLICA

ciete Gener

Dumitru Popa

Director filială "Stejaur"

Executor : Mariana Guzun Tel: 022 812 614



# CENTIFICAT DE ÎNDECISTRADE

Societatea Comercială "OXIVIT-MED" S.R.L.

ESTE ÎNREGISTRATĂ LA CAMERA ÎNREGISTRĂRII DE STAT

Numărul de identificare de stat - codul fiscal 1007600044280

Data înregistrării

30.07.2007

Data eliberării

30.07,2007

Bordeianu Tatiana, registrator de stat

Funcția, numele, prenumele persoanei care a eliberat certificatul



MD 0067985





# I.P. "AGENTIA SERVICII PUBLICE"

Departamentul înregistrare și licențiere a unităților de drept

# **EXTRAS** din Registrul de stat al persoanelor juridice

nr. 8871 din 05.05.2021

Denumirea completă: Societatea Comercială «OXIVIT-MED» S.R.L.

Denumirea prescurtată: S.C. «OXIVIT-MED» S.R.L.

Forma juridică de organizare: Societate cu Răspundere Limitată. Numărul de identificare de stat și codul fiscal: 1007600044280.

Data înregistrării de stat: 30.07.2007.

Sediul: MD-2032, bd. Decebal, 82, ap.(of.) 90, mun. Chişinău, Republica Moldova.

Modul de constituire: nou creată. Obiectul principal de activitate:

- 1 Importul, fabricarea, comercializarea, asistența tehnică și (sau) reparația dispozitivelor medicale și (sau) a opticii;
- 2 Comerțul cu ridicata al parfumurilor și produselor cosmetice;
- 3 Comerțul cu amănuntul al produselor cosmetice și de parfumerie, articolelor de toaletă;
- 4 Intermedieri pentru vînzarea unui asortiment larg de mărfuri;
- 5 Alte tipuri de comert cu amănuntul în magazine nespecializate;
- 6 Alte tipuri de comert cu ridicata;
- 7 Închirierea altor mașini și echipamente.

Capitalul social: 5400 lei.

Administrator: KOJEVNIKOV DMITRII, IDNP 0972305012362,

1. KOJEVNIKOV DMITRII, IDNP 0972305012362

cota 5400.00 lei, ce constituie 100 %.

Prezentul extras este eliberat în temeiul art. 34 al Legii nr. 220-XVI din 19 octombrie 2007 privind înregistrarea de stat a persoanelor juridice și a întreprinzătorilor individuali și confirmă datele din Registrul de stat la data de: 05.05.2021.

Specialist coordonator tel 022-207-840

Course Lazari Aliona

telefon: + 373 22 808002; fax: + 373 22 808003 web: www.oxivit-med.com; e-mail:info@oxivit-med.com

# Lista fondatorilor companiei SRL "Oxivit-Med"

Nr.	Numele, Prenumele	Codul Personal
1	Kojevnikov Dmitrii	0972305012362







# **EC** Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 039709 1263 Rev. 00

Manufacturer: Medtronic, Inc.

710 Medtronic Parkway Minneapolis MN 55432

**USA** 

Product Category(ies): •Autotransfusion Systems and

**Associated Disposables** 

Centrifugal Blood Pumps

•Bio-Console Drive Units

•Flow Monitoring Systems

Bio-Cal Blood Temperature Controller

Temperature Monitoring Systems and

**Associated Disposables** 

Blood Monitoring Systems

Cardioplegia Delivery Systems

•Disposable Blood Handling Devices

used for Open Heart Surgery

Arterial Filters

 Oxygenators including Heat Exchangers, with and without Cardiotomy Reservoirs

Cardiotomy Venous Reservoirs

Venous Reservoir Bags

 Perfusion Equipment and Disposable Perfusion Devices

 Disposable Medical Devices for Drainage Systems

•Disposable Medical Devices for use in Cardiopulmonary Surgery: Cardioplegia, Cannulae, Venting, Suction

Pressure Display System & related accessories of class IIa

Tissue Positioning/Stabilizing Devices

Surgical Site Clearing Devices

Intravascular Shunts

Surgical Retractors

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final

Page 1 of 3

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123





# **EC Certificate**

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 039709 1263 Rev. 00

inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

**Report No.:** 72150396

 Valid from:
 2020-02-12

 Valid until:
 2024-05-26

**Date**, 2020-02-12

Christoph Dicks

Head of Certification/Notified Body





# **EC** Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 039709 1263 Rev. 00

Facility(ies): Medtronic Mexico S.de R.L.de CV

Av. Paseo Cucapah, 10510 El Lago, C.P. 22210 Tijuana, Baja

California, MEXICO

Medtronic Perfusion Systems

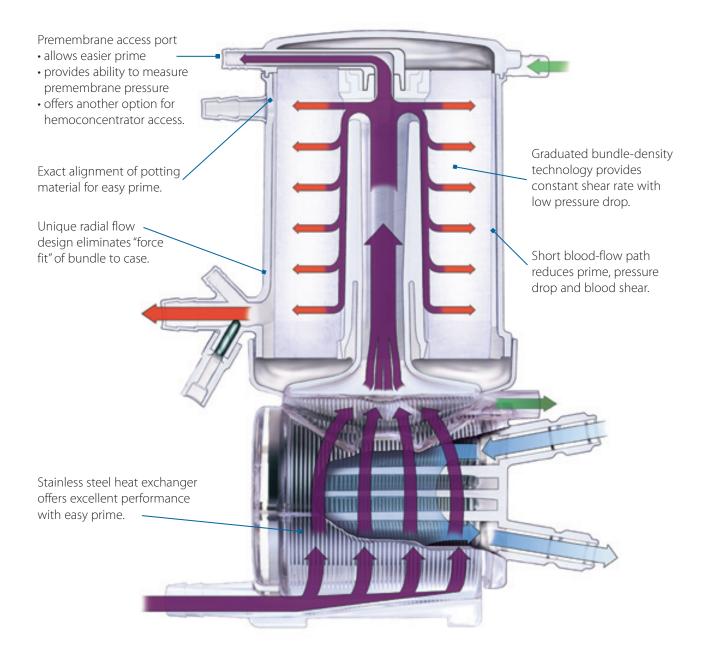
7611 Northland Drive, Minneapolis, MN 55428, USA

Medtronic, Inc.

710 Medtronic Parkway, Minneapolis MN 55432, USA

.

# Totally clear design gives you unobstructed visibility of blood, gas and water phases.



# BOTTOM ENTRY/BOTTOM EXIT BLOOD-FLOW DESIGN FOR ENHANCED AIR HANDLING AND PRIMEABILITY.

The TRILLIUM® AFFINITY NT® oxygenator extends the AFFINITY® tradition of consistent, efficient gas transfer due to patented radial flow design. The graduated packing density bundle design of the AFFINITY NT® oxygenator maximizes gas transfer while minimizing blood shear and priming volume.

Radial flow design ensures consistent performance. Proven PRF fiber increases plasma resistance up to 2.5 times longer. The efficient stainless steel heat exchanger delivers high performance with minimal pressure drop.

#### TRILLIUM\* AFFINITY NT\* OXYGENATION SYSTEM SPECIFICATIONS

ORDERING INFORMATION	Model #	No. Units
Trillium* AFFINITY NT* Hollow Fiber Oxygenator	511T	4 units/case
Trillium® AFFINITY NT® Hollow Fiber Oxygenator with Integrated AFFINITY® CVR	541T	2 units/case
Trillium* AFFINITY NT* Hollow Fiber Oxygenator with Integrated Trillium* AFFINITY* CVR	541TT	2 units/case
AFFINITY® CVR Cardiotomy/Venous Reservoir with Filter	540	4 units/case
Trillium* AFFINITY* CVR Cardiotomy/Venous Reservoir with Filter	540T	4 units/case
AFFINITY* Venous Reservoir Bag	321	8 units/case
MVR Venous Reservoir Bag• 800 ml	MVR800	6 units/case
MVR Venous Reservoir Bag•1600 ml	MVR1600	6 units/case

#### MVR VENOUS RESERVOIR BAG

Reservoir Capacity: 800 ml 1600 ml Faceplate Volume Settings:  Setting 1: 450 ml 700 ml Setting 2: 650 ml 1200 ml Screen: 105 micron 105 micron Venous Inlet: ½" ½" Venous Outlet: ¾" ¾" Recirculation: ¼" ¼"		MVR-800	MVR-1600
Volume Settings:         Setting 1:       450 ml       700 ml         Setting 2:       650 ml       1200 ml         Screen:       105 micron       105 micron         Venous Inlet:       ½"       ½"         Venous Outlet:       %"       %"	Reservoir Capacity:	800 ml	1600 ml
Setting 2:       650 ml       1200 ml         Screen:       105 micron       105 micron         Venous Inlet:       ½"       ½"         Venous Outlet:       ¾8"       ¾8"	•		
Screen:         105 micron 105 micron           Venous Inlet:         ½"         ½"           Venous Outlet:         ¾"         ¾"	Setting 1:	450 ml	700 ml
Venous Inlet: ½" ½" Venous Outlet: ¾" ¾"	Setting 2:	650 ml	1200 ml
Venous Outlet: %" %"	Screen:	105 micron	105 micron
	Venous Inlet:	1/2"	1/2"
Recirculation: 1/4" 1/4"	Venous Outlet:	3/8"	3/8"
	Recirculation:	1/4"	1/4"

#### AFFINITY CVR NT

Reservoir Volume Capacity: 4000 ml Recommended Blood Flow Rate:

Minimum Operating Level: 200 Cardiotomy Filtration: 30-micron

Venous Inlet Screen: 200 micron Final Reservoir Screen: 150 micron



	OXYGENATOR		
e	Membrane Type: Microporous Polypropylene Hollow Fibers		
	Membrane Surface Area: 2.5 m <sup>2</sup>		
Static Priming Volume: 270 ml			
<b>P</b>	Recommended Blood-Flow Rate: 1-7 L/min		
_	Maximum Water Side Pressure: 30 psi		
e	Arterial Outlet Port: 3%"		
	Venous Inlet Port: ¾"		
2	Arterial Sample Port: Female Luer Port		
_	Access Port: Female Luer Port		
e	Recirculation Port: 1/4"		
	Gas Inlet Port: 1/4"		
e	Gas Outlet Port: ¾" Nonbarbed		

TRILLIUM AFFINITY NT

#### AFFINITY VENOUS RESERVOIR BAG Reservoir Capacity: 1250 ml

Faceplate Volume Settings:

Setting 1: 900 ml Setting 2: 550 ml

Screen: 105 micron

Venous Inlet: 1/2"

Water Ports:

Venous Outlet: 3/8" Recirculation: 1/4" Cardiotomy Inlet: 3/8"



Cardiotomy Inlet: 3/8"

www.medtronic.eu

Route du Molliau 31

Tel: +41 (0) 21 802 70 00 Fax: +41 (0) 21 802 79 00

Case postale CH-1131 Tolochenaz

Medtronic International Trading Sàrl

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- 16. Cazzaniga A, et al. Trillium™ biopassive surface: a new biocompatible treatment for extracorporeal
- Int J Artif Organs 2000;23:319-24.
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### RESPONDING TO THE CHALLENGES OF A CHANGING ENVIRONMENT

With new medications, older patients and repeat surgeries, your cardiac surgery environment is constantly changing. To help you respond, we've created an oxygenation system that's more compatible with the challenges you face. The AFFINITY NT® oxygenator is a low-prime, highefficiency oxygenator that offers consistent performance and convenience. The AFFINITY® CVR is available with optional Trillium® Biosurface for your tip-to-tip coverage needs.

#### TRILLIUM® BIOSURFACE®

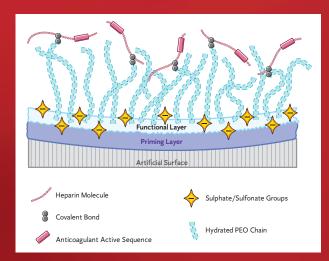
#### •TRIPLE ENDOTHELIAL-LIKE ACTION FOR BIOCOMPATIBILITY

Trillium<sup>®</sup> Biosurface provides endothelial-like benefits for routine use during cardiopulmonary bypass procedures.

HEPARIN	NEGATIVE CHARGE	HYDROPHILICITY	
Nonleaching heparin molecules are covalently bonded into the surface to provide anticoagulant and additional beneficial effects	Sulphate and sulfonate groups are incorporated into the Trillium* functional layer to mimic the negative charge of vascular endothelium.	Polyethylene oxide (PEO) polymer is extremely hydrophilic along its entire chain, creating an "insulating" water layer structure between the blood and artificial surface to resist cell adhesior and protein deposition.	
as <b>heparan sulfate</b> does in	Research demonstrates that negatively	and protein deposition.	
the natural endothelium.	charged sulphonated polymers:	PEO-water interface has very low free energy and,	
	• Repel the negatively charged platelets <sup>1,2,3</sup>	therefore, a low driving force for protein adsorption or platelet adhesion. <sup>9,10</sup>	
	<ul> <li>Inhibit thrombin by binding to antithrombin in a heparin-like manner<sup>4,5,6</sup></li> </ul>	PEO chains are in continuous motion, due to their flexible molecular structure. The dynamic hydrated	
	<ul> <li>May impair additional processes required for thrombus formation<sup>7,8</sup></li> </ul>	surface created by PEO chains is believed to repel proteins and platelets. <sup>11,12</sup>	
	Heparin in Trillium® Biosurface is naturally negatively charged.	<b>Hydrophilic priming layer</b> is strongly bonded to th artificial surface.	

# PEER-REVIEWED PUBLISHED CLINICAL AND SCIENTIFIC FINDINGS

- Decreased likelihood to require blood products<sup>13</sup>
- Platelet count preservation 14,15,16,17,18
- Affords the same protective effects on circulating platelet count drops as adding albumin
- Less complement activation after protamine administration 16
- Less platelet activation<sup>17</sup>
- Less granulocyte activation<sup>17</sup>
- Fewer circuit clots and no renal emboli<sup>18</sup>







Scanning electron micrographs of oxygenator fiber surfaces after one hour of in vitro circulation in a closed system using heparinized, diluted human blood. (100x magnification).

UNCOATED

# Clearly the oxygenation System of Choice and Performance



# flexibility in set-up

sampling lines for your convenience

## Optimum Operating Levels -

Maximum capacity of 4000 ml to meet all your patient needs

Designed for excellent low-level visualization with color-coded volume measurements

Offers low minimum operating level of 200 ml with low 50-cc vortex level

#### AFFINITY® CVR —

Now available with optional Trillium® Biosurface

# TRILLIUM® AFFINITY NT® Hollow Fiber Oxygenator

Premembrane access port now available for easy prime and new user options

Proven PRF fiber for greater plasma breakthrough resistance

Continuing to offer total visibility premembrane and postmembrane for your priming confidence

Stainless steel heat exchanger delivers high performance with minimal pressure drop

Trillium® Biosurface



# Vacuum Assisted Venous Drainage Compatible

A negative/positive pressure-relief valve is built into the lid (-150mmHg/0±5mmHg), which features a special obturator valve cap to insure valve patency



# Optimal Visibility Achieved

With clear lid and the elimination of traditional "outer sock" design

Allows excellent visibility of venous inlet column on the outside of the cardiotomy

# Simple Drop-in Holder

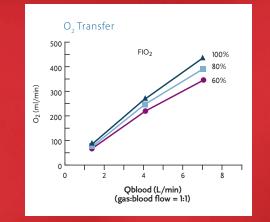
Articulated design is compatible with left- and right-hand setup

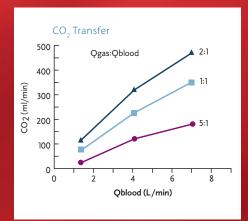
# Excellent Defoaming Capabilities

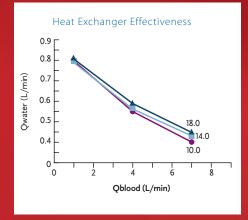
Two-stage defoaming design offers consistent air handling even on tough valve cases

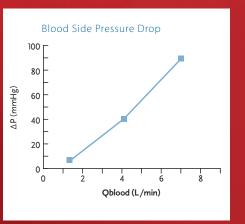
# **PERFORMANCE DATA**

Data on file—ISO Standard Conditions









# DESIGNED BY PERFUSIONISTS. ENGINEERED BY MEDTRONIC.



# THE PRODUCT OF TRUE COLLABORATION

The Affinity Fusion oxygenation system

- Built on input from more than500 perfusionists worldwide
- Represents a unique fusion of clinical insight and engineering expertise
- Features 79 new design enhancements

Designed by perfusionists. Engineered by Medtronic.

# DESIGN, SIMPLY ADVANCED.

# Proactive Air Management

An entire oxygenation system designed to handle air upfront.

- Unique curved venous inlet reduces blood turbulence and GME generation
- A pre-membrane bubble trap is designed to purge air before it enters the fiber membrane
- An oxygenator with integrated arterial filter removes particulates and air



# Uniform Flow Distribution

Designed to reduce blood trauma, lower rates of hemolysis and minimize exposure to foreign surfaces.

- Curved venous inlet for smooth, fluid pathways and low resistance to flow
- Venous inlet tube's flared design reduces blood velocity and resistance to flow
- Cardiotomy cone shape design allows for gentle blood flow
- Oxygenator's radial flow design results in short blood flow paths that avoid areas of stasis

# Perfusion-practical Ergonomics

Improved flexibility, ease of use and set-up, and enhanced customization capabilities.

- Orbit holder system with 360 degrees of flexibility
- Ambidextrous design
- Convenient port locations and spacing
- Independent adjustment of the reservoir and oxygenator

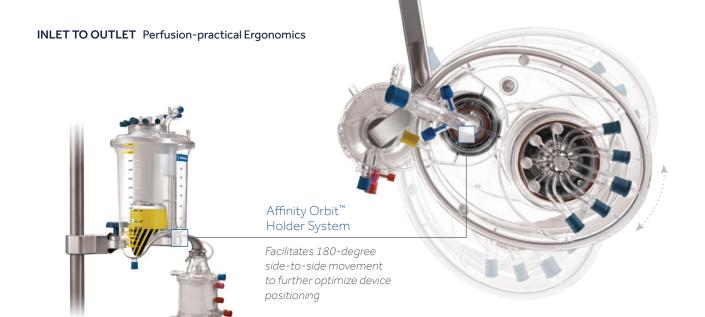
# Progressive Fiber Filtration

Gas exchange and particulate filtration occur simultaneously, enabled by Medtronic's proprietary Graduated Fiber Bundle Density Technology.

- A fully integrated oxygenator and arterial filter
- A compact, low-prime design
- Radial flow for short, uniform blood paths, minimizing blood's contact with foreign surfaces
- Low pressure drop

# Finely tuned, carefully considered parameters, from inlet to outlet.

Designed to achieve the optimal blend of performance providing expanded heat exchange and oxygenation capability, while maintaining low prime and low pressure drop.





Easy access, low-profile venous temperature port

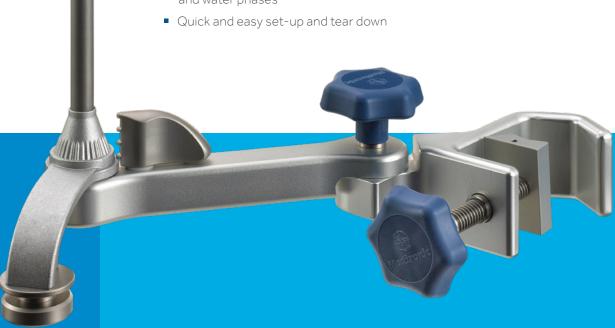


Volume-displacing luer caps to prevent areas of stasis

# MORE ROOM TO SHORTEN LINES.

The Fusion system delivers Perfusion-practical Ergonomics, providing improved flexibility, ease of use and set-up, and enhanced customization capabilities.

- The unique Affinity Orbit holder system allows 360-degree positioning and placement flexibility
- Ambidextrous design
- Independent adjustment of the oxygenator and reservoir
- Convenient port locations and spacing
- Non-vented caps for ease of set-up for VAVD procedures (except inlet, outlet and vent/vacuum port)
- Totally clear design for unobstructed visibility of blood, gas and water phases



THOUGHTFUL DESIGN, FROM INLET TO OUTLET

# The Affinity Fusion oxygenation system takes a fundamentally different design approach.

- Proactive air handling
- Uniquely designed for hemocompatibility
- Improved flexibility and ease of use
- Oxygenator with integrated arterial filter
- Expanded heat exchanger and gas transfer capabilities

### Both oxygenator and reservoir devices have:

- Blood-contacting materials made from BPA\*and DEHP-free polymers
- 1 to 7 L/min flow rate
- Low system priming volume
- Biocompatible surface coatings

## Cardiotomy/Venous Reservoir available in:

Balance Biosurface<sup>1</sup>

# Oxygenator available in two biocompatible surface options:

- Balance Biosurface
- Cortiva BioActive Surface

#### Balance<sup>™</sup> Biosurface

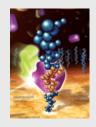
A hydrophilic biosurface option without heparin

- Reduces platelet activation
- Lowers platelet adhesion
- Preserves platelet function<sup>2</sup>

#### Cortiva™ BioActive Surface

- Durable, Non-leaching End Point Attached Heparin
- Provides thromboresistance and enhanced blood compatibility







The Affinity Fusion oxygenation system is indicated for use in an extracorporeal circulation circuit during cardiopulmonary bypass procedures up to 6 hours in duration.

**Warning:** A strict anticoagulation protocol should be followed and anticoagulation should be routinely monitored during all procedures. The benefits of extracorporeal support must be weighed against the risk of systematic anticoagulation and must be assessed by the prescribing physician.

For a complete listing of indications, contraindications, precautions and warnings, please refer to the Instructions for Use which accompany each product.

THE AFFINITY FUSION  $^{\text{\tiny TM}}$ 

CARDIOTOMY/VENOUS RESERVOIR

- Curved venous inlet, flared walls of the venous inlet down tube and gradual slope of the reservoir contribute to Uniform Flow Distribution
- Separate venous and cardiotomy filter chambers
- Low minimum operating level
- Low dynamic and static hold-up
- Low resistance to flow
- Proactive removal of GME and gross air
- Vacuum Assisted Venous Drainage (VAVD) ready with built-in pressure relief valve and non-vented cardiotomy port covers
- Removable sampling manifold
- Indicated for use for chest drainage collection

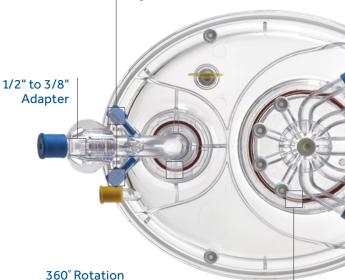




#### **Angled Venous Luer Ports**

Chamber

- Facilitate gentle merging of peripheral blood flow
- For reduced blood turbulence that could create gaseous micro emboli from gross air



For flexibility in circuit set-up

# DESIGNED FOR **CAREFUL BLOOD HANDLING** AND AIR MANAGEMENT.



**Caution:** Federal law (USA) restricts these devices to sale by or on the order of a physician. For a complete listing of indications, contraindications, precautions and warnings, please refer to the Instructions for Use.

# THE AFFINITY FUSION OXYGENATOR

- 260 mL prime volume
- Enhanced gas transfer and heat exchange performance
- Indicated for use as both an oxygenator and arterial filter
- 25µm filtration
- Efficiently handles air and particulates



#### **Recirculation Port**

With volume- displacing cap

#### Cardioplegia Port

With volume- displacing cap

#### **Temperature Port**

#### **Dual Outlet Port**

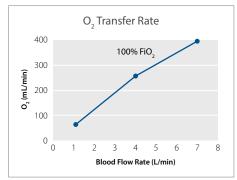
- Oxygenated blood exits the device through a unique dual outlet, minimizing areas of stasis, shear or hemolysis
- Provides good temperature and sampling accuracy

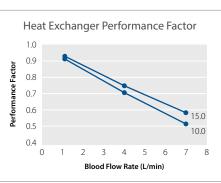


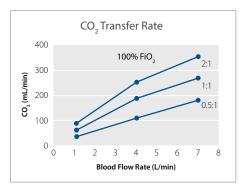
With volume-displacing cap

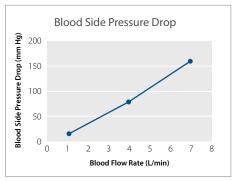
# Oxygenator Performance Data<sup>3</sup>

Testing performance per ISO 7199, 2009 standard conditions. Based on in vitro data; may not be indicative of clinical results.



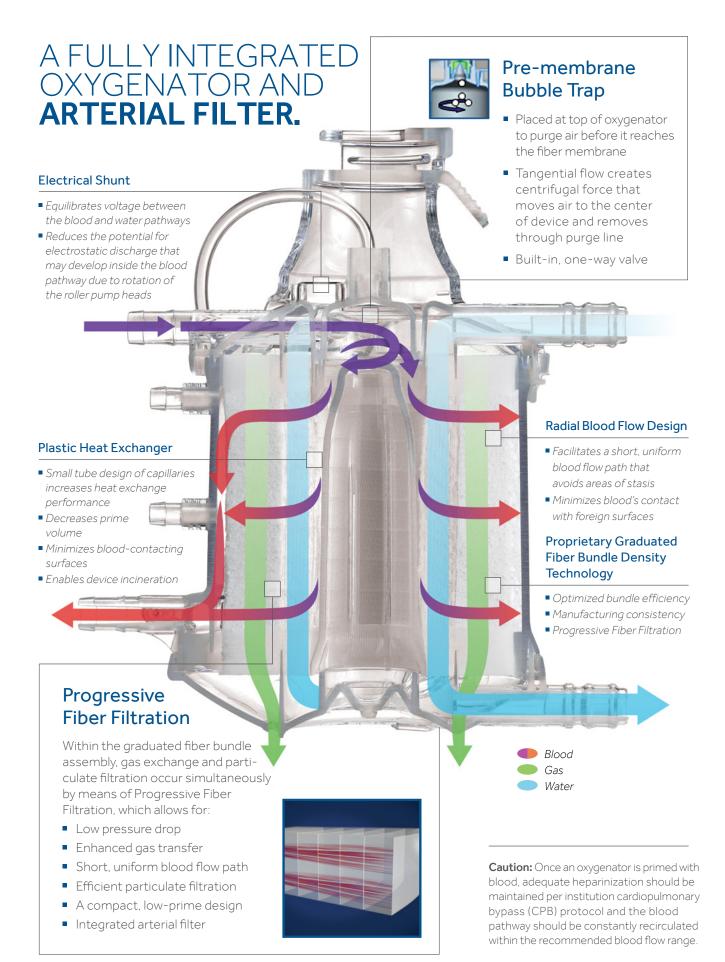








pressure build-up in the oxygenator chamber



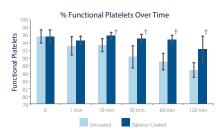
# Affinity Fusion Oxygenation System

	Affinity Fusion Oxygenation Syster	ns
Model#	Product Description	Units/case
BB841	Oxygenator with Integrated Arterial Filter and Cardiotomy/ Venous Reservoir with Balance Biosurface	1
CB841	Oxygenator with Integrated Arterial Filter with Cortiva BioActive Surface and Cardiotomy/Venous Reservoir with Balance Biosurface	1
BB811	Oxygenator with Integrated Arterial Filter and Balance Biosurface	1
CB811	Oxygenator with Integrated Arterial Filter and Cortiva BioActive Surface	1

Affinity Fusion Accessories and Holders			
Model#	Product Description	Units/case	
AUH2093	Affinity Orbit Holder System	1	
ATP210	Temperature Probe	1	
AMH2014	Affinity Manifold Holder	1	
RCL841	Recirculation Line	12	
AUH4014	Affinity Orbit Arterial Filter Arm	1	

#### References

- ${\bf 1.} \ {\bf Technology} \ licensed \ under \ agreement \ from \ Biointeractions, \ Limited, \\ \ United \ Kingdom.$
- 2. % Functional Platelets Over Time.



Comparison between Balance-coated and uncoated in vitro bench test circuits of percentage of platelets that are activated with adenosine diphosophate (ADP @02 µM) in circulating heparinized human blood over time. Error bars represent standard deviation. († indicates p<0.05)

3. Data on file at Medtronic.

#### Specifications

#### Oxygenator

Membrane Type Microporous polypropylene

hollow fiber

Membrane Surface Area 2.5 m<sup>2</sup>

Heat Exchange Material Polyethylene Terephthalate (PET)

Static Priming Volume 260 mL
Recommended Blood Flow Rate 1-7 L /min
Maximum Water Side Pressure 30 psi
Maximum Blood Pressure 750 mmHg
Arterial Outlet Port 3/8"
Venous Inlet Port 3/8"

Arterial Sample Port Female Luer Port

Recirculation Port 1/4" Cardioplegia Port 1/4"

Gas Inlet Port 1/4" Nonbarbed
Gas Outlet Port 3/8" Nonbarbed
Water Ports 1/2" Quick Disconnects

Filtration 25 µm

#### Cardiotomy/Venous Reservoir

 $\begin{array}{lll} \mbox{Reservoir Volume Capacity} & 4500 \ \mbox{ml} \\ \mbox{Recommended Blood Flow Rate} & 1-7 \ \mbox{L/min} \\ \mbox{Maximum Cardiotomy Flow Rate} & 6 \ \mbox{L/min} \\ \mbox{Minimum Operating Level} & 200 \ \mbox{at 7 L/min} \\ \mbox{Cardiotomy Filtration} & 30 \ \mbox{\mu m} \end{array}$ 

Venous Screen 105 µm
Venous Inlet, Rotatable 1/2" with 3/8" adapter

Venous Reservoir Outlet 3/8"

Vent/VAVD Port 1/4" Nonbarbed

Cardiotomy Port (4) 1/4"
Cardiotomy Port (1) 3/8"

Prime Port 1/4" Nonbarbed

Recirculation Port 1/4"
Filtered Luer Lock Ports 4
Non-filtered Luer Lock Ports 2
Venous Luer Lock Ports 2

Positive Pressure Relief Valve Crack < 5 mmHg

Vacuum Pressure Relief Valve Crack >100 mmHg average

For information on Affinity Fusion visit: www.fusionoxygenator.com

For information on other Medtronic technologies for extracorporeal circulation, blood processing and diagnostics, visit: www.perfusion.medtronic.com

# Medtronic

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# SURGICAL HEART THERAPIES PRODUCT CATALOG

- Heart Valves
- > Surgical Ablation
- Revascularization



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# Freestyle<sup>™</sup> Aortic Root Bioprosthesis

A stentless valve that is naturally designed to maximize flow, particularly for young patients.

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# Superior Hemodynamics<sup>1,2,3</sup>

Intelligently Designed

- Functions like a native valve with low gradients and laminar flow<sup>1</sup>
- Absence of stent and sewing ring leaves more room for blood to flow through the valve; improves postoperative coronary flow more than a stented bioprosthesis<sup>2,3</sup>

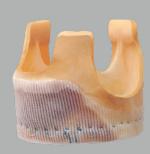
# Maximum Flow

- Designed to function like a native valve with physiologic hemodynamics
- Excellent mean pressure gradients and EOAs out to 10 years<sup>4</sup>
- Strong clinical outcomes and excellent durability at 15 years<sup>4</sup>



#### References

- Westaby S., et al. Valve replacement with a stentless bioprosthesis: Versatility of the porcine aortic root. J Thorac Cardiovasc Surg 1998;116:477-84.
- 2.Bakhtiary F, et al. Stentless bioprostheses improve postoperative coronary flow more than stented prostheses after valve replacement for aortic stenosis. J Thorac Cardiovasc Sura 2006:131:883-8.
- 3. Silberman S, et al. Exercise hemodynamics of aortic prostheses: Comparison between stentless bioprostheses and mechanical valves.
- 4. Freestyle Aortic Root Bioprosthesis 15-year clinical







# Freestyle<sup>™</sup> Aortic Root Bioprosthesis

A stentless valve that is naturally designed to maximize flow, particularly for young patients.

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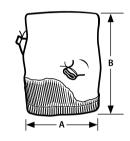
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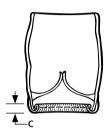
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# Freestyle Full Root Bioprosthesis

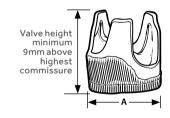
<b>3</b>				
Order Number	Size (mm)	A Outside Diameter	B Profile Height	C Inner Cloth Height
		(± 0.2mm)	(± 2mm)	(±0.5mm)
FR99519	19	19.0	30	3.0
FR99521	21	21.0	32	3.0
FR99523	23	23.0	32	3.0
FR99525	25	25.0	34	3.0
FR99527	27	27.0	34	3.0
FR99529	29	29.0	39±0.3	3.0

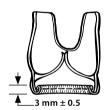




# Prestyled Freestyle Complete Subcoronary Bioprosthesis

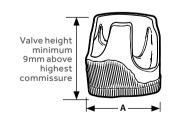
Order Number	Size (mm)	A Outside Diameter
		(+0.5mm - 0.0mm)
995CS19	19	19.0
995CS21	21	21.0
995CS23	23	23.0
995CS25	25	25.0
995CS27	27	27.0
995CS29	29	29.0

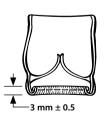




# Prestyled Freestyle Modified Subcoronary Bioprosthesis

Order Number	Size (mm)	A Outside Diameter
		(+0.5mm - 0.0mm)
995MS19	19	19.0
995MS21	21	21.0
995MS23	23	23.0
995MS25	25	25.0
995MS27	27	27.0
995MS29	29	29.0





# Freestyle Valve Accessories

Order Number	Description
T7625FR	Freestyle Accessory Tray
7639	Handle (234mm length) pliant, without locknut to be used with Freestyle bioprosthesis
7639XL	Handle (368mm length) pliant, without locknut to be used with Freestyle bioprosthesis
7990SET	Freestyle Obturator Set (no handles)

# Hancock<sup>™</sup> II Bioprosthetic Valve

The valve that has stood the test of time to make outcomes as predictable as procedures.

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# The Standard For Reliability and Consistency

- Proven durability in all patients, especially those ≥60 years of age<sup>1,2</sup>
- Highly studied surgical valve delivering strong results and consistent outcomes from multiple centers<sup>1,3</sup>
- More than 97% freedom from SVD after 20 years for patients ≥65 years of age¹
- Radiopaque for future valve-in-valve procedures
- Optimal performance and value



#### Reference

- David T, et al, Hancock II Bioprosthesis for aortic valve replacement: The gold standard of bioprosthetic valves durability. Apr. Physics 2010;90: 775-81.
- 2. Borger M, et al. Twenty year results of the Hancock II bioprosthesis. *Journal of Heart Valve Disease*. January
- 3. Valfre C, et al. The fate of Hancock II porcine valve recipients 25 years after implant. European Journal of





# **Hancock**™ **II** Bioprosthetic Valve

The valve that has stood the test of time to make outcomes as predictable as procedures.

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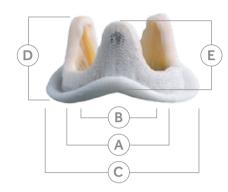
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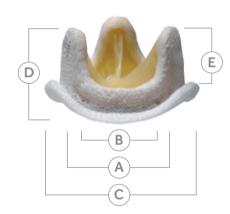
#### Hancock II Aortic Heart Valve

Order Number	A Valve Size (Stent O.D.†)	B Orifice Diameter (Stent I.D.)	C Suture Ring Diameter	D Valve Height	E Aortic Protrusion
	(±0.5mm)	(±0.5mm)	(±1mm)	(±0.5mm)	(±0.5mm)
T505C221	21	18.5	27.0	15.0	12.0
T505C223	23	20.5	30.0	16.0	13.5
T505C225	25	22.5	33.0	17.5	15.0
T505C227	27	24.0	36.0	18.5	15.5
T505C229	29	26.0	39.0	20.0	16.0



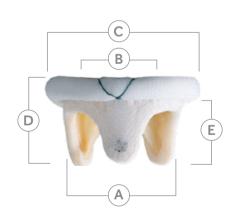
# Hancock II Ultra<sup>™</sup> Aortic Heart Valve

Order Number	A Valve Size (Stent O.D.†)	B Orifice Diameter (Stent I.D.)	C Suture Ring Diameter	D Valve Height	E Aortic Protrusion
	(±0.5mm)	(±0.5mm)	(±1mm)	(±0.5mm)	(±0.5mm)
T505U221	21	18.5	26.0	15.0	12.0
T505U223	23	20.5	28.0	16.0	13.5
T505U225	25	22.5	30.0	17.5	15.0
T505U227	27	24.0	32.0	18.5	15.5
T505U229	29	26.0	34.0	20.0	16.0



# Hancock II Mitral Heart Valve

Order Number	Valve Size (Stent O.D.†) A	Orifice Diameter (Stent I.D.) B	Suture Ring Diameter C	Valve Height D	Ventricular Protrusion E
	(±0.5mm)	(±0.5mm)	(±1mm)	(±0.5mm)	(±0.5mm)
T510C25	25	22.5	33.0	18.0	13.5
T510C27	27	24.0	35.0	19.0	14.0
T510C29	29	26.0	38.0	20.5	15.5
T510C31	31	28.0	41.0	22.0	17.0
T510C33	33	30.0	43.0	23.0	17.5



# Hancock II Tissue Valve Accessories

Order Number	Description
T7610HKA	Tray, Accessory, Hancock II, Aortic
T7610HKM	Tray, Accessory, Hancock II, Mitral
T7505UX	Tray, Accessory, Hancock II Ultra, Supra-X Aortic Sizer Set
7505UX	Hancock II Ultra, Supra-X Aortic Sizer Set
7639	Handle (234mm length) pliant, without locknut handle to be used with Hancock II, Hancock II ULTRA prostheses
7639XL	Handle (368mm length) pliant, without locknut handle to be used with Hancock II, Hancock II ULTRA prostheses
7505SET	Hancock II Aortic Obturator Set (no handles, no tray)
7510SET	Hancock II Mitral Obturator Set (no handles, no tray)

# **Mosaic**<sup>™</sup> Bioprosthesis

A versatile platform designed to easily facilitate aortic or mitral valve replacement in open or minimally invasive procedures. **TABLE OF CONTENTS** 

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# **Undeniably Durable**

- Designed to facilitate aortic and mitral valve replacement in open or minimally invasive procedures
- 80% freedom from explant due to SVD at 16 years in the mitral position¹
- 81% freedom from explant due to SVD at 17 years in the aortic position<sup>2</sup>









#### References

- Compendium. ©2016 Medtronic.
- 2. Medtronic Mosaic Aortic Bioprosthesis 17-year Clinica

# **Mosaic**<sup>™</sup> Bioprosthesis

A versatile platform designed to easily facilitate aortic or mitral valve replacement in open or minimally invasive procedures.

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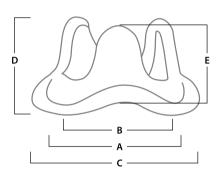
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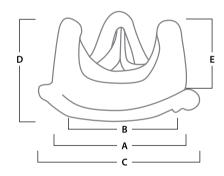
# Mosaic Aortic Valve, Model 305

Order Number	A Valve Size (Stent O.D.†)	B Orifice Diameter (Stent I.D.)	C Suture Ring Diameter	D Valve Height	E Aortic Protrusion
	(±0.5mm)	(±0.5mm)	(±1mm)	(±0.5mm)	(±0.5mm)
305C219	19	17.5	25.0	13.5	11.0
305C221	21	18.5	27.0	15.0	12.0
305C223	23	20.5	30.0	16.0	13.5
305C225	25	22.0	33.0	17.5	15.0
305C227	27	24.0	36.0	18.5	15.5
305C229	29	26.0	39.0	20.0	16.0



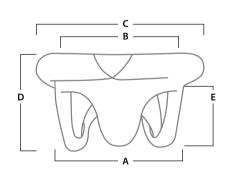
# Mosaic Ultra Aortic Valve, Model 305

Order Number	A Valve Size (Stent O.D.†)	B Orifice Diameter (Stent I.D.)	C Suture Ring Diameter	D Valve Height	E Ventricular Protrusion
	(±0.5mm)	(±0.5mm)	(±1mm)	(±0.5mm)	(±0.5mm)
305U219	19	17.5	24.0	13.5	11.0
305U221	21	18.5	26.0	15.0	12.0
305U223	23	20.5	28.0	16.0	13.5
305U225	25	22.5	30.0	17.5	15.0
305U227	27	24.0	32.0	18.5	15.5
305U229	29	26.0	34.0	20.0	16.0



# Mosaic Mitral Valve, Model 310

Order Number	A Valve Size (Stent O.D.†)	B Orifice Diameter (Stent I.D.)	C Suture Ring Diameter	D Valve Height	E Ventricular Protrusion
	(±0.5mm)	(±0.5mm)	(±1mm)	(±0.5mm)	(±0.5mm)
310C25	25	22.5	33.0	18.0	13.5
310C27	27	24.0	35.0	19.0	14.0
310C29	29	26.0	38.0	20.5	15.5
310C31	31	28.0	41.0	22.0	17.0
310C33	33	30.0	43.0	23.0	17.5



# Mosaic Bioprosthesis Accessories

Order Number	Description
T7308C	Mosaic Aortic Sizers
T7615MSM	Tray, Accessory, Mosaic, Mitral
T7308U	Tray, Accessory, Mosaic Ultra Aortic
7308U	Mosaic Ultra Aortic Sizers
7639	Handle (234mm length) pliant, without locknut to be used with Mosaic or Mosaic Ultra prostheses
7639XL	Handle (368mm length) pliant, without locknut to be used with Mosaic or Mosaic Ultra prostheses
7308C	Mosaic Aortic Sizer Set (no handles, no tray)
7310	Mosaic Mitral Obturator Set (no handles, no tray)

# Medtronic **Open Pivot**™ Mechanical Heart Valves

Optimal performance with excellent quality of life benefits.

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# Fundamentally Different Design

- Unique axis of suspension results in leaflet movement responsive to physiological demands
- Gentle, passive washing ensures complete washing of the pivot in both open and closed positions

# Quiet

- Most patients cannot hear the sound of their valve after implantation1
- Low levels of hemolysis and thromboembolic events<sup>2,3</sup>
- Orifice design and unique leaflet movement result in excellent EOAs, even in small sizes<sup>4,5</sup>



- . Sezai A, et al. Fifteen years of experience with ATS mechanical heart valve prostheses. *J Thorac Cardio Surg*. 2010;139(6):1494-500.

  ATS Medical Inc. Pre-market Approval Application Summary of Safety and Effectiveness: 2000. Washir DC; U.S. Food and Drug Administration. 2000:P99004 Feng Z, et al. In vitro hydrodynamic characteristics at three bileaflet valves in the mitral position. *Artif Orga* 2000;24(5):346-54.



# Open Pivot Standard



## Open Pivot AP



# Open Pivot AP360

# Medtronic Open Pivot<sup>™</sup> Mechanical Heart Valves

Optimal performance with excellent quality of life benefits.

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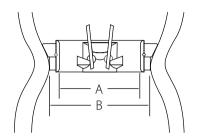
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# Open Pivot Standard Heart Valve Aortic

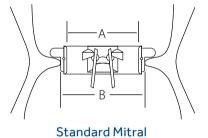
Order Number	Valve Size (mm)	A Orifice Inner Diameter (mm)	B Tissue Annulus (mm)	Geometric Orifice Area (cm²)
500FA19	19	14.8	19.5	1.55
500FA21	21	16.8	21.5	2.02
500FA23	23	18.8	23.5	2.56
500FA25	25	20.8	25.5	3.17
500FA27	27	22.8	27.5	3.84
500FA29	29	24.8	29.5	4.59
500FA31	31	26.8	31.5	5.35



Standard Aortic

# Open Pivot Standard Heart Valve Mitral

Order Number	Valve Size (mm)	A Orifice Inner Diameter (mm)	B Tissue Annulus (mm)	Geometric Orifice Area (cm²)
500DM19	19	14.8	19.5	1.55
500DM21	21	16.8	21.5	2.02
500DM23	23	18.8	23.5	2.56
500DM25	25	20.8	25.5	3.17
500DM27	27	22.8	27.5	3.84
500DM29	29	24.8	29.5	4.59
500DM31	31	26.8	31.5	5.35
500DM33	33	26.8	33.5	5.35



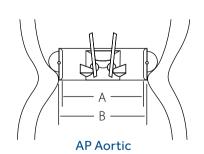
## **Open Pivot Accessories**

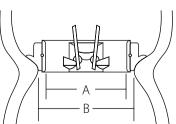
•	
Order Number	Description
576	OPHV Sizer Set, (Std, AP series, Handle, Tray)
556	OPHV Aortic and Mitral Handle Rotator Set
558	OPHV Leaflet Actuators (Non-sterile bag of 5)
569	OPHV Bendable Handle
577	OPHV Standard Sizer Set (just sizers)
578	OPHV AP Series Sizer Set (just sizers)
579	OPHV Sizer Sterilization Tray (tray only)
580	OPHV Screw-on Mitral Rotator End Set

# Open Pivot AP and AP360° Heart Valves Aortic

Order Number	Valve Size (mm)	A Orifice Inner Diameter (mm)	B Tissue Annulus(mm)	Geometric Orifice Area (cm²)
501DA16/505DA16	16	14.8	16.2	1.55
501DA18/505DA18	18	16.8	18.2	2.02
501DA20/505DA20	20	18.8	20.2	2.56
501DA22/505DA22	22	20.8	22.2	3.17
501DA24/505DA24	24	22.8	24.2	3.84
501DA26/505DA26	26	24.8	26.2	4.59
501DA28/505DA28	28	26.8	28.2	5.35

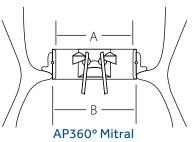
Open Pivot AP360° Heart Valves Mitral





AP360° Aortic







# Contegra<sup>™</sup> Pulmonary Valve Conduit

An integrated valved conduit for reconstruction or replacement of the natural right ventrical outflow tract (RVOT) or replacement of a failed hemograft or composite pulmonary conduit.

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# Natural

- Derived from a bovine jugular vein
- Flexible for unique tailoring as only natural tissue can offer
- Blood passes easily across a continuous tissue interface and natural sinus

# Versatile

- Proximal length allows for infundibular shaping without patching
- Resilient wall retains suture and supports hemostatic suture line
- No additional materials necessary for proximal anastomosis

# Convenient

- Available in supported and unsupported models
- Preserved in buffered glutaraldehyde
- Readily available—no thawing or preclotting required

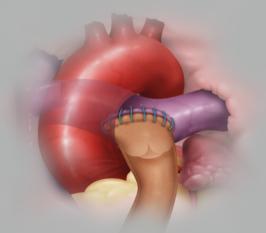




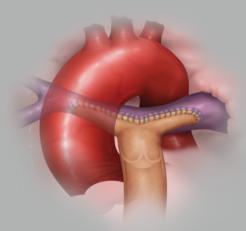
No discontinuity between the lumen and valve



Thin, compliant leaflets open fully and close readily with minimal pressure



Thin, extensible tissue is especially suited for anastomosis



Easily customized to individual needs

# Contegra<sup>™</sup> Pulmonary Valve Conduit

An integrated valved conduit for reconstruction or replacement of the natural right ventrical outflow tract (RVOT) or replacement of a failed hemograft or composite pulmonary conduit. **TABLE OF CONTENTS** 

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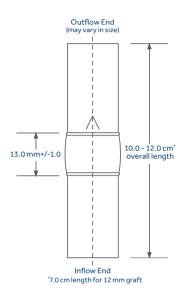
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# Contegra Pulmonary Valve Conduit - Supported

Order Number	Internal Diameter (Inflow End) (mm)
200SH12	12
200SH14	14
200SH16	16
200SH18	18

Model 01-0055 Torque Wrench (optional reusable jar opener)



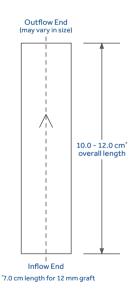


# Contegra Pulmonary Valve Conduit - Unsupported

Order Number	Internal Diameter (Inflow End) (mm)
200H12	12
200H14	14
200H16	16
200H18	18

 ${\color{red}Model\,01\text{--}0055\,Torque\,Wrench\,(optional\,reusable\,jar\,opener)}$ 





# Hancock<sup>™</sup> Bioprosthetic Valved Conduit

With options for right and left heart applications.

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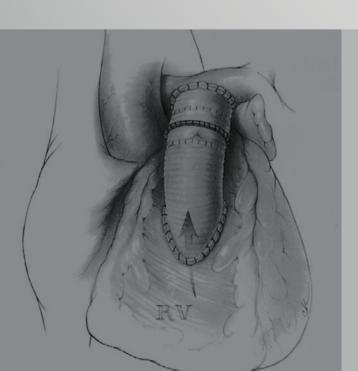
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# A Proven Alternative

Hancock valved conduits offer proven performance for reconstruction of congenital or acquired cardiac and great vessel malformations or pathologies for right heart applications.

- Porcine aortic valve sutured into a Dacron woven fabric conduit
- Stentless—optimizes the ratio of the conduit outer diameter to the inner diameter
- An external reinforcing ring at the valve annulus supports leaflet coaptation and allows radiographic visualization





# Hancock™ Bioprosthetic Valved Conduit

With options for right and left heart applications.

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# Model 150 | Hancock Modified Oriface Bioprosthetic Standard-Porosity Valved Conduits

Order Number	Valve Size (mm)
HC15012	12
HC15014	14
HC15016	16
HC15018	18
HC15020	20
HC15022	22
HC15025	25

For right heart applications

# Model 105 | Hancock Bioprosthetic Low-Porosity Valved Conduits

Order Number	Valve Size (mm)
HC05012	12
HC05014	14
HC05016	16
HC05018	18
HC05020	20
HC05022	22
HC05025	26

For right and left heart applications



# CG Future<sup>™</sup> Semi-Rigid Annuloplasty Ring and Band

More physiologically-based mitral solutions.

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# Intentional Design

Unique composite design considers both cardiac cycles

- Cardiac Systole
   The ring remodels the mitral valve orifice to normal 3:4 ratio between the anteroposterior and transverse diameters
- Cardiac Diastole
   The ring's dynamic characteristics allow physiologic motion and movement to maintain the normal 4:4 ratio between anteroposterior and transverse diameters





# Implant Ease

- Low profile design allows for ease of implant
- Unique eyelet design allows for easy anchoring to the trigones





# CG Future<sup>™</sup> Semi-Rigid Annuloplasty Ring and Band

More physiologically-based mitral solutions.

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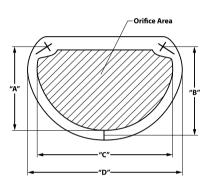
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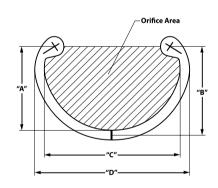
# CG Future Annuloplasty Ring, Model 638R

Order Number	Ring Size (mm)	A (mm)	B (mm)	C (mm)	D (mm)	Orifice Area (mm²)
638RL24	24	15.27	16.53	24.0	28.9	269.3
638RL26	26	16.38	17.64	26.0	30.9	314.9
638RL28	28	17.48	18.73	28.0	32.9	364.3
638RL30	30	18.59	19.85	30.0	34.9	417.3
638RL32	32	19.71	20.97	32.0	36.9	474.7
638RL34	34	20.83	22.09	34.0	38.9	536.0
638RL36	36	21.92	23.18	36.0	40.9	600.9
638RL38	38	23.04	24.29	38.0	42.9	669.4



# CG Future Annuloplasty Band, Model 638B

Order Number	Band Size (mm)	A (mm)	B (mm)	C (mm)	D (mm)	Orifice Area (mm²)
638BL26	26	16.38	17.64	26.0	30.9	332.0
638BL28	28	17.48	18.73	28.0	32.9	382.8
638BL30	30	18.59	19.85	30.0	34.9	437.4
638BL32	32	19.71	20.97	32.0	36.9	496.3
638BL34	34	20.83	22.09	34.0	38.9	559.2
638BL36	36	21.92	23.18	36.0	40.9	625.1
638BL38	38	23.04	24.29	38.0	42.9	695.7



# CG Future Annuloplasty Band Accessories

Order Number	Description
T7630	CG Future Accessory Tray
7615	Annuloplasty Handle (216mm length)
7615XL	Annuloplasty Handle (373mm length)
7638S	CG Future Sizer Set (8 reusable sizers, 24 - 38mm)

## Contour 3D<sup>™</sup> Tricuspid Annuloplasty Ring

Accommodates anterior motion; provides posterior support.

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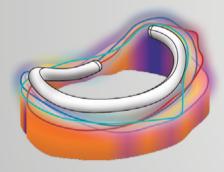
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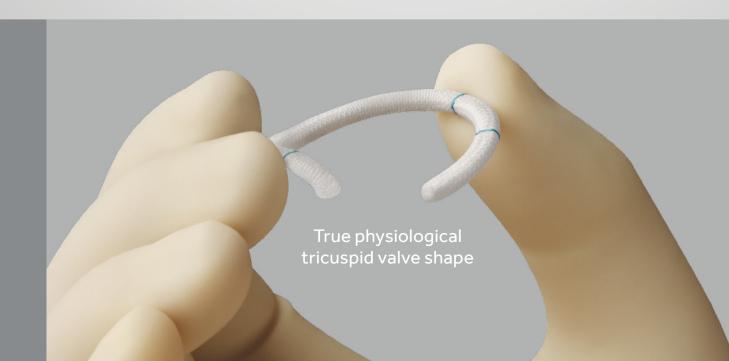
## Restores Anatomic 3D Shape

 Design of the Contour 3D ring is based on CT data from functional human tricuspid valves—offering surgeons a 3D remodeling ring anatomically shaped to the normal tricuspid annulus



- Low profile and smooth penetration
- Low profile height of 3.3mm helps to avoid interference with the heart's conduction system. In addition, unique fabric allows for smooth needle penetration





## Contour 3D™ Tricuspid Annuloplasty Ring

Accommodates anterior motion; provides posterior support.

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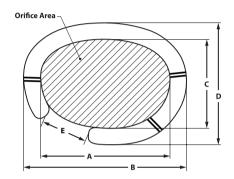
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## Contour 3D Annuloplasty Ring, Model 690R

Order Number	Ring Size (mm)	A (mm)	B (mm)	C (mm)	D (mm)	E (mm)	F (mm)	Orifice Area (mm²)
690R26	26	24	32	16	24	10	7	326.1
690R28	28	26	34	18	25	11	7	387.2
690R30	30	28	36	19	27	12	8	449.2
690R32	32	30	38	21	28	13	8	512.4
690R34	34	32	40	22	30	14	9	588.6
690R36	36	34	42	23	31	15	9	665.1



## Contour 3D Annuloplasty Ring Accessories

Order Number	Description
T7690	Contour 3D Accessory Tray
7686	Annuloplasty Handle (216mm length)
7686XL	Annuloplasty Handle (373mm length)
7690S	Contour 3D Sizer Set (6 reusable sizers, 26 - 36mm)
7690SD	Contour 3D Sizer Set (6 disposable silicone sizers, 26 - 36mm)



## Duran AnCore<sup>™</sup> Flexible Annuloplasty Ring and Band

A clinically inspired design by Carlos Duran, MD, PhD, with technology proven by more than 36 years of clinical experience.

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## Duran AnCore Ring

- Flexibility allows preservation of the natural physiologic motion of the annulus resulting in optimal hemodynamics<sup>1</sup>
- Adapts to changes in the mitral orifice area during entire cardiac cycle<sup>2</sup>

## Duran AnCore Band

- Optimum choice when only posterior annulus support is required<sup>3,4</sup>
- Band length extends beyond the trigones to provide secure suturing

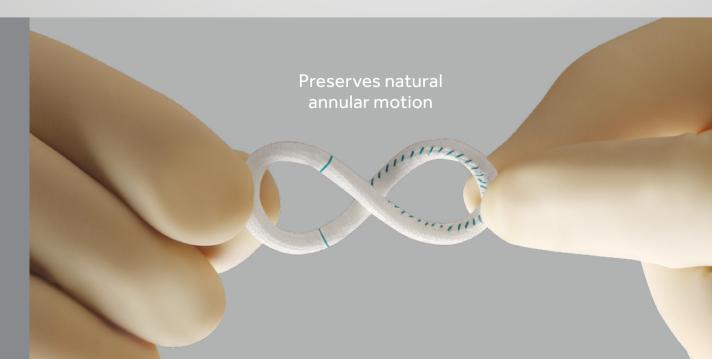
## Ease of Implant

 Patented chordal guide facilitates replacement of mitral valve chordae tendineae



#### References

- Kunzelman KS, Reimink MS, Cochran RP. Flexible Versus Rigid Ring Annuloplasty for Mitral Valve Annular Dilatation: A Finite Element and Model. *J Heart Valve* 100-7-100-7-116
- Yamaura Y, Yoshikawa J, Yoshida K, et al. Threedimensional Analysis of Configuration and Dynamics in patients with an Annuloplasty Ring by Multiplane Transesophageal Echocardiography: Comparison Between Flexible and Rigid Annuloplasty Rings. J Heart Valve Dis. 1995;4:618-22
- Duran CMG. Duran Flexible Annuloplasty Repair of the Mitral and Tricuspid Valves: Indications, Patient Selection, and Surgical Techniques using the Duran Flexible Annuloplasty Ring, Medtronic, Inc. 1992.
- 4. Odell Ja, Schaff HV, Orszulak TA. Early Results of Simplified Method of Mitral Valve Annuloplasty.



## **Duran AnCore**<sup>™</sup> Flexible Annuloplasty Ring and Band

A clinically inspired design by Carlos Duran, MD, PhD, with technology proven by more than 36 years of clinical experience.

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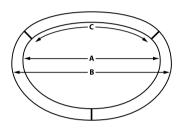
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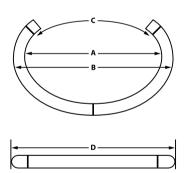
## Duran AnCore Annuloplasty Ring, Model 620R

Order Number	Ring Size (mm)	A (mm)	B (mm)	C (mm)
620RG23	23	25.8	31.8	23
620RG25	25	27.8	33.8	25
620RG27	27	29.8	35.8	27
620RG29	29	31.7	37.7	29
620RG31	31	33.8	39.8	31
620RG33	33	35.8	41.8	33
620RG35	35	37.7	43.7	35



### Duran AnCore Annuloplasty Band, Model 620B

Order Number	Band Size (mm)	A (mm)	B (mm)	C (mm)	D (mm)
620BG23	23	25.8	31.8	23	59
620BG25	25	27.8	33.8	25	63
620BG27	27	29.8	35.8	27	67
620BG29	29	31.7	37.7	29	73
620BG31	31	33.8	39.8	31	77
620BG33	33	35.8	41.8	33	81
620BG35	35	37.7	43.7	35	85



## Duran AnCore Annuloplasty Ring and Band Accessories

Order Number	Description
T7660	Duran AnCore Accessory Tray
7620H/7686	Annuloplasty Handle (216mm length)
7620HXL/7686XL	Annuloplasty Handle (373mm length)
7620S	Duran AnCore Sizer Set

## **Profile 3D**™ Rigid Annuloplasty Ring

Engineered to maintain anterior and posterior dimensions of the mitral annulus.

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## Restoring Annular Geometry

 Unique asymmetrical 3D design engineered to maintain anterior and posterior dimensions of mitral annulus to restore annular geometry

## Saddle Shape

- The saddle shape, based on the annular geometry of normal human mitral annuli, may reduce stress and increase mitral valve durability<sup>1,2</sup>
- Design provides a consistent 25% anterior curvature and 15% posterior curvature reducing peak leaflet stress<sup>3</sup>

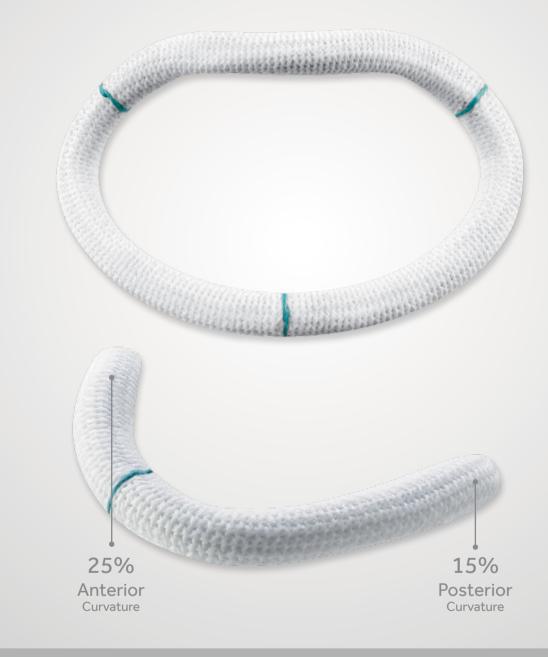






#### References

- 1. Published U.S. Patent Application Nos. 2005-0021135
- Fedak P, McCarthy P, Bonow R. Evolving concepts and technologies in mitral valve repair. Circulation. 2008:117:963-74.
- 3. Salgo I, Gorman J, Gorman R, et al. Effect of annula shap on leaflet curvature in reducing mitral leaflet





## **Profile 3D**<sup>™</sup> Rigid Annuloplasty Ring

Engineered to maintain anterior and posterior dimensions of the mitral annulus.

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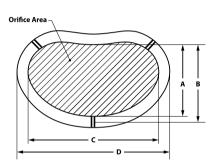
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## Profile 3D Annuloplasty Ring, Model 680R

Order Number	Ring Size (mm)	A (mm)	B (mm)	C (mm)	D (mm)	Orifice Area (mm²)
680R24	24	13.4	15.0	24.2	30.5	278
680R26	26	14.5	16.1	26.2	32.5	325
680R28	28	15.6	17.2	28.2	34.5	376
680R30	30	16.7	18.3	30.2	36.5	430
680R32	32	17.8	19.4	32.2	38.5	489
680R34	34	18.9	20.5	34.2	40.5	550
680R36	36	19.8	21.4	36.2	42.5	612
680R38	38	20.9	22.5	38.2	44.5	683
680R40	40	22.0	23.6	40.2	46.5	756



### Profile 3D Annuloplasty Ring Accessories

Order Number	Description
T7680	Profile 3D Accessory Tray
7686	Annuloplasty Handle (216mm length)
7686XL	Annuloplasty Handle (373mm length)
7680S	Profile 3D Sizer Set (6 reusable sizers, 26-36mm)

## Simplici-T<sup>™</sup> Flexible Annuloplasty Band

Designed to repair annular dilation while preserving 3D motion during the cardiac cycle.

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## Eliminate the Need for Traditional Sizing

- Provides a custom fit for mitral and tricuspid patients through graduated markings that can be used to measure the implanted band length
- Unique, low-profile flexible band is supplied in a length of 100mm

## Adapts to Pathology

 Adapts to the unique needs of every patient based on pathology.
 Band length is determined by the annular size and degree of plication.





## Simplici-T<sup>™</sup> Flexible Annuloplasty Band

Designed to repair annular dilation while preserving 3D motion during the cardiac cycle.

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## Simplici-T Annuloplasty Band, Model 670

Order Number	Band Size (mm)	Description
607100	100	Simplici-T Annuloplasty Band



## **Simulus**<sup>™</sup> Flexible Annuloplasty Ring and Band

Flexible ring and band enabling easy manipulation in varied approaches and exposures.

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## Unique Braided Polyester

- Discourages bunching or crimping while enabling low resistance, smooth needle penetration
- Accommodates sternotomy, thoracotomy and minimally invasive procedures

## Ease of Implant

- Trigone and midline posterior markers assist in precise suture placement and band positioning
- Flexible throughout cardiac cycle with a low profile design





## Simulus<sup>™</sup> Flexible Annuloplasty Ring and Band

Flexible ring and band enabling easy manipulation in varied approaches and exposures.

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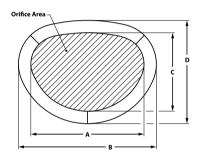
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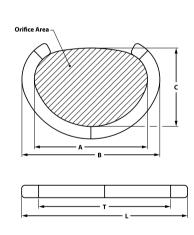
## Simulus Flexible Annuloplasty Ring, Model 700FF

			<b>3</b> ,			
Order Number	Ring Size (mm)	A (mm)	B (mm)	C (mm)	D (mm)	Orifice Area (mm²)
700FF23	23	24	30	17.1	23.1	325
700FF25	25	27	33	19.5	25.5	418
700FF27	27	29	35	20.9	26.9	481
700FF29	29	31	37	22.3	28.3	550
700FF31	31	33	39	23.8	29.8	622
700FF33	33	35	41	25.2	31.2	700
700FF35	35	37	43	26.6	32.6	781
700FF37	37	39	45	28.0	34.0	867
700FF39	39	41	47	29.4	35.4	958



### Simulus Flexible Annuloplasty Band, Model 700FC

Order Number	Band Size (mm)	A (mm)	B (mm)	C (mm)	L Straight Length (mm)	T Straight Length Between Trigone Markers (mm)	Orifice Area (mm²)
700FC23	23	24	30	17.1	59	53	325
700FC25	25	27	33	19.5	63	57	418
700FC27	27	29	35	20.9	67	61	481
700FC29	29	31	37	22.3	73	65	550
700FC31	31	33	39	23.8	77	69	622
700FC33	33	35	41	25.2	81	73	700
700FC35	35	37	43	26.6	85	77	781
700FC37	37	39	45	28.0	89	81	867
700FC39	39	41	47	29.4	93	85	958



### Simulus Flexible Annuloplasty Ring and Band Accessories

Order Number	Description
750	Simulus Flexible Ring/Band Accessory Kit
755	Simulus Flexible Ring/Band Robotic Accessory Kit
752	Annuloplasty Handles (254mm length) (2)

## Simulus<sup>™</sup> Semi-Rigid Annuloplasty Ring and Band

Distinctive hybrid design enable shaping by dynamic annular motion.

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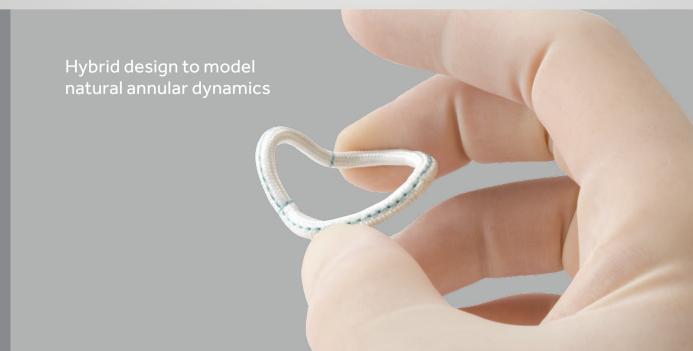
## Saddle and Flat Shape

- Defined suture area, and braided fabric for smooth needle penetration and one cut release
- Takes the shape of the annulus rising as a saddle in systole and flattening to a planar shape in diastole
- Respects annular motion while preserving posterior support

## Sew-Easy Implant

- Braided polyester materials enables smooth needle penetration anywhere along ring or band preventing crimping or bunching
- Trigone markers assist in suture placement and positioning
- Flexible tips allow secure attachment at the trigones





## Simulus<sup>™</sup> Semi-Rigid Annuloplasty Ring and Band

Distinctive hybrid design enable shaping by dynamic annular motion.

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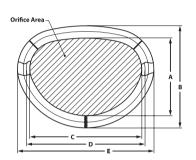
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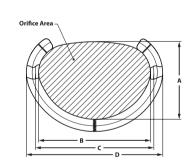
## Simulus Semi-Rigid Annuloplasty Ring, Model 800SR

	<u> </u>		J J				
Order Number	Ring Size (mm)	A (mm)	B (mm)	C (mm)	D (mm)	E (mm)	Orifice Area (mm2)
800SR24	24	15.6	23.4	22.6	24	30.3	281
800SR26	26	17.0	24.4	24.5	26	31.9	329
800SR28	28	18.3	25.6	26.3	28	33.7	381
800SR30	30	19.6	27.3	28.2	30	36.0	436
800SR32	32	20.9	28.3	30.1	32	37.6	497
800SR34	34	22.2	29.6	32.0	34	39.4	561
800SR36	36	23.5	30.9	33.9	36	41.3	630
800SR38	38	24.8	32.2	35.8	38	43.2	702
800SR40	40	26.1	33.5	37.6	40	45.1	779



## Simulus Semi-Rigid Annuloplasty Band, Model 800SC

Order Number	Band Size (mm)	A (mm)	B (mm)	C (mm)	D (mm)	Orifice Area (mm²)
800SC24	24	15.6	22.6	24	30.3	281
800SC26	26	17.0	24.5	26	31.9	329
800SC28	28	18.3	26.3	28	33.7	381
800SC30	30	19.6	28.2	30	36.0	436
800SC32	32	20.9	30.1	32	37.6	497
800SC34	34	22.2	32.0	34	39.4	561
800SC36	36	23.5	33.9	36	41.3	630
800SC38	38	24.8	35.8	38	43.2	702
800SC40	40	26.1	37.6	40	45.1	779



## Simulus Semi-Rigid Annuloplasty Ring and Band Accessories

Order Number	Description
850	Simulus Semi-Rigid Ring/Band Accessory Kit
752	Annuloplasty Handles (254mm length) (2)

## Tri-Ad<sup>™</sup> Adams Tricuspid Annuloplasty Ring

Designed to repair annular dilation while preserving 3D motion during the cardiac cycle.

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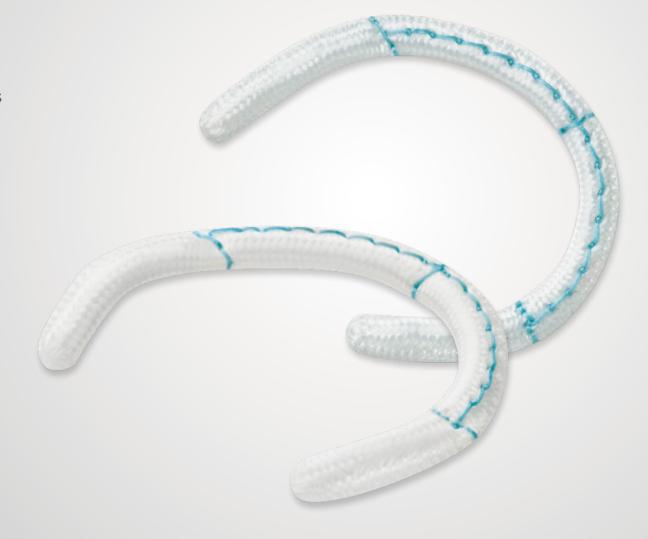
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## Smooth Implantation

- Braided sewing ring construction provides smooth needle penetration that prevents bunching; one-cut release
- Large open area minimizes potential suture injury to conduction tissue

## Adapts to Tricuspid Anatomy<sup>1</sup>

- Repairs annular dilation while preserving 3D motion during cardiac cycle
- Enables adaption to non-planar geometry of the tricuspid valve in systole and diastole
- Semi rigid segment addresses annular dilation along right ventrical free wall





References

Trind, r. et al. Nationale an initial experience with the Tri-Ad Adams tricuspid annuloplasty ring. *Journal of Thoracic and Cardiovascular Surgery* 143;4S:S71-3.

## **Tri-Ad**<sup>™</sup> Adams Tricuspid Annuloplasty Ring

Designed to repair annular dilation while preserving 3D motion during the cardiac cycle.

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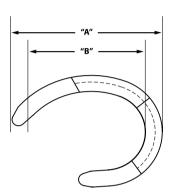
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## Tri-Ad Adams Tricupsid Annuloplasty Ring, Model 900SFC

Order Number	Ring Size (mm)	A (mm)	B (mm)	C (mm)	D (mm)	E (mm)	Orifice Area (mm²)
900SFC26	26	17.4	25.8	25.6	33.2	15.5	365
900SFC28	28	19.4	27.6	28.1	24.9	17.1	435
900SFC30	30	20.9	29.1	30.6	37.2	18.5	502
900SFC32	32	22.3	30.7	31.5	38.2	20.0	557
900SFC34	34	24.0	32.3	34.7	41.1	20.9	654
900SFC36	36	25.5	33.8	36.3	42.9	21.9	730



## Tri-Ad Adams Tricupsid Annuloplasty Ring Accessories

Order Number	Description
950	Tri-Ad Adams Ring Accessory Kit
951	Tri-Ad Adams Ring Sizer Set (polysulfone & silicone)
752	Annuloplasty Handles (254mm length) (2)

## **Streamline**™ Temporary Pacing Leads

The Streamline family is the gold standard in temporary pacing leads.

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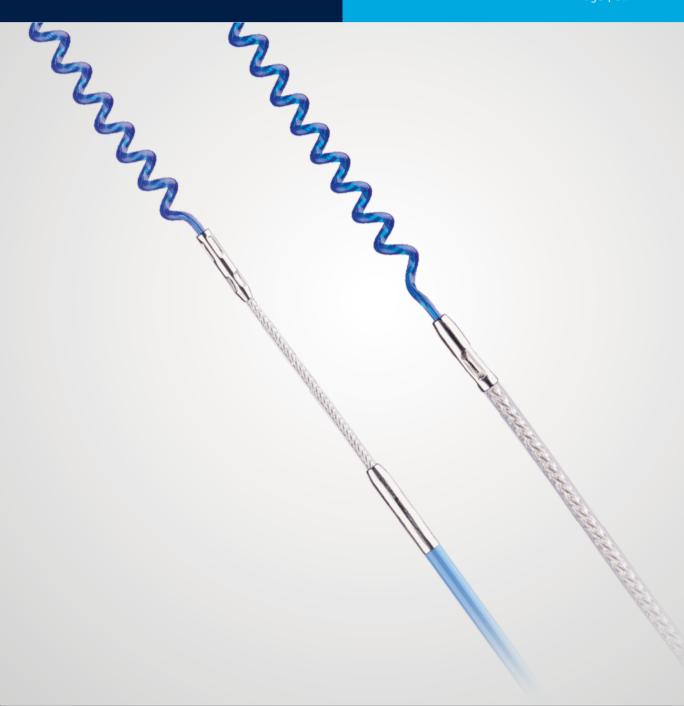
**SURGICAL ABLATION** 

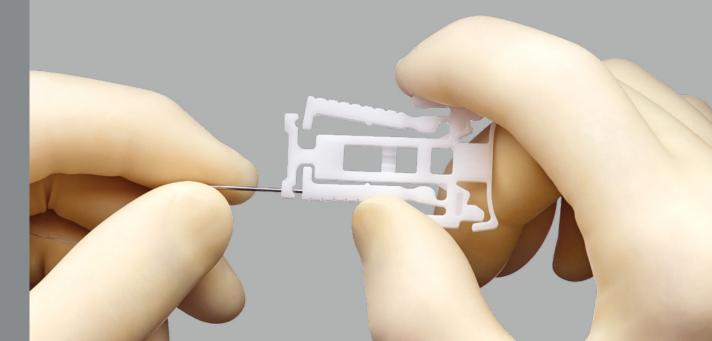
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## Generations of Innovation

The Streamline family is designed for temporary pacing and sensing during and after cardiac surgery. The Streamline family includes models that offer consistent unipolar atrial and ventricular pacing, pediatric unipolar pacing and bipolar pacing. All Medtronic temporary pacing leads are compatible with Medtronic external pulse generators. Integrating more than 50 years of scientific and technological pacing expertise into our temporary pacing leads, Streamline is the lead you can trust.





## Streamline™ Temporary Pacing Leads

The Streamline family is the gold standard in temporary pacing leads.

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### Premium 6500 Unipolar Temporary Myocardial Pacing Lead

- Relaxed fixation coil minimizes trauma during pacing lead insertion
- Diameter of the curved myocardial needle has been reduced from 0.66mm to 0.61mm to minimize tissue perforation
- Discrete electrode for consistent sensing and pacing
- Easy-to-use breakaway chest needle has been reduced in diameter from 1.00mm to 0.86mm to minimize perforation
- Silastic fixation disc for atrial placement
- Connector pin sleeves insulate connector pins while not in use

### Bipolar Coaxial 6495 Bipolar Temporary Myocardial Pacing Lead

- Features coaxial lead body for excellent electrical performance
- Curved myocardial needle is slimmer reduced from 0.66mm to 0.61mm to minimize tissue perforation
- Two discrete electrodes are optimally spaced for consistent pacing and sensing
- Proximal electrode is swaged for smoother transition through tissue
- Relaxed fixation coil minimizes tissue trauma while securely positioning electrode
- Connector pin sleeves insulate connector pins while not in use

## Pediatric 6491 Unipolar Pediatric Temporary Pacing Lead

- Smaller fixation coil well suited for thinner pediatric tissue
- Curved chest needle for greater leverage through small chest cavity
- Discrete electrode for consistent sensing and pacing
- Connector pin sleeves insulate connector pins while not in use

## Atrial 6492 Unipolar Temporary Atrial Pacing Lead

- Smaller fixation coil well suited for thinner atrial tissue
- Discrete electrode for consistent sensing and pacing
- Straight breakaway chest needle diameter reduced from 1.00mm to 0.86mm minimizes trauma during lead insertion
- Connector pin sleeves insulate connector pins while not in use

## Convenience 6494 Unipolar Temporary Myocardial Pacing Wire

The Convenience wire is a temporary pacing wire designed for either atrial or ventricular sensing and pacing.

- Conductive wire length extended from 50mm to 70mm
- Curved myocardial needle diameter reduced from 0.55mm to 0.43mm to minimize trauma during heart wire insertion
- Chest needle diameter reduced from 1.00 mm to 0.86 mm to minimize perforation
- Color-coded leads come conveniently packaged, two per sleeve
- Connector pin sleeves insulate connector pins while not in use

#### **Important Safety Information**

The possibility of dislodgement, lead fractures, threshold elevation and sensing inconsistency exists. Other potential complications include, but are not limited to, myocardial irritability, septicaernia and myocardial infections, myocardial bleeding and damage, especially during removal of the pacing lead(s).

## Streamline Temporary Pacing Leads

Streamline Family	Description	Quantity
PREMIUM 6500	Model 6500 Unipolar Temporary Myocardial Pacing Lead	12
BIPOLAR COAXIAL 6495	Model 6495 Bipolar Temporary Myocardial Pacing Lead	6
PEDIATRIC 6491	Model 6491 Unipolar Pediatric Temporary Pacing Lead	12
ATRIAL 6492	Model 6492 Unipolar Temporary Atrial Pacing Lead	12
CONVENIENCE 6494	Model 6494 Unipolar Temporary Myocardial Pacing Wire	24

## Cardioblate™ iRF Surgical Ablation System

Unique malleability delivers irrigated RF to confidently create transmural lesions.

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## Designed For Easy Access

Cardioblate iRF surgical ablation systems are designed with maneuverability, placement and visualization in mind. Uniquely malleable devices put surgeons in control of every procedure with superior energy sources that give greater confidence of lesion transmurality.





Malleable Jaws | Conforms to pulmonary veins and atrial anatomies.



Rotatable Jaws | Rotate the head up to 300° to facilitate placement.

## Cardioblate™ iRF Surgical Ablation System

Unique malleability delivers irrigated RF to confidently create transmural lesions.

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## Cardioblate iRF Surgical Ablation Systems

	can great to take the control
Order Number	Description
68000	Cardioblate Surgical Ablation System (includes generator, power cord and foot switch)
60813	Cardioblate Surgical Ablation Pen
60814	Cardioblate XL Surgical Ablation Pen
49205	Cardioblate MAPS Device
60831	Cardioblate PB2 Surgical Ablation Device
60841	Cardioblate LP Surgical Ablation Device
49260	Cardioblate Gemini™-s Surgical Ablation Device



### Cardioblate iRF Clamps, Pens & MAPS Device

Order Number	Description
60832	BP2 & Pen (1 each packed and shipped together)
CK9014R	BP2 & XL Pen
60842	LP & XL Pen
CK9016R	LP & XL Pen (1 each packed and shipped together)
SGEMPACK	Cardioblate Gemini-s Surgical Ablation Device & Cardioblate MAPS Device (1 each packed and shipped separately)



## Cardioblate iRF Accessories

Order Number	Description
60883	iRF Generator Footswitch
4807	iRF Generator Power Cord
10004D	DLP "Y" Connectors
68005	EGM Cable
5103	Y-adaptor for 2090/2290 Programmer
5437	EKG Slave Cable for 2090/2290 Programmer





# CyroFlex<sup>™</sup> Surgical Ablation System

Unique malleability delivers argon-powered cryoablation for reproducible, transmural lesions with a single probe.

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## Designed For Easy Access

CryoFlex surgical ablation systems are designed with maneuverability, placement and visualization in mind. Uniquely malleable devices put surgeons in control of every procedure with superior energy sources that give greater confidence of lesion transmurality.





## **CyroFlex**<sup>™</sup> Surgical Ablation System

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## CryoFlex Surgical Ablation Systems

Order Number	Description
65CS1	CryoFlex Control Panel
60SF7	CryoFlex Probe, 7cm
60SF2	CryoFlex Probe, 10cm
60SF3	CryoFlex 10-S Probe, 10cm
60CM1	CryoFlex Clamp and Probe, 10cm

#### CryoFlex Control Console



## CryoFlex and Cardioblate iRF Bundles

Order Number	Description
BP2CF	BP2 & CryoFlex 10cm Probe
BP2CF3	BP2 & CryoFlex 10-S Probe
LPCF	LP & CryoFlex 10cm Probe
LPCF3	LP & CryoFlex 10-S Probe

## **CryoFlex Accessories**

Order Number	Description
67RAXNA	CryoFlex Regulator (with pressure sensor cables)
671PCNA	Power Cord; CryoFlex Control Panel
67H08	Gase Hose; CryoFlex System
65TC1	CryoFlex Tank Carrier



## **OPCAB**

## Conventional Beating Heart Surgery

Reliable stability for completing a beating heart anastomosis based on each surgeons preference.

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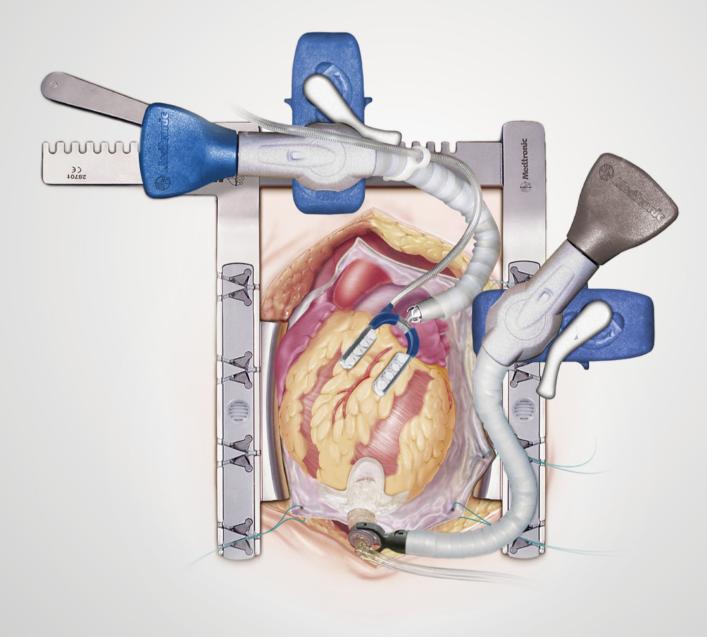
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## Facilitating Solutions

Urchin™ and Starfish™ Heart
Positioners work in concert
with the Octopus™ Tissue
Stabilizers to facilitate
clinical solutions for OPCAB
procedures. Cardiac Surgeons
can choose from two
positioner options, both
of which provide enhanced
visualization of the
anastomotic sites.





## OPCAB

## Conventional Beating Heart Surgery

Reliable stability for completing a beating heart anastomosis based on each surgeons preference.

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#### **Stabilizers**

Order Number	Description
TS2500	Octopus Evolution AS Tissue Stabilizer
TS2000	Octopus Evolution Tissue Stabilizer
29403	Octopus 4.3 Tissue Stabilizer
29400	Octopus 4 Tissue Stabilizer



### **Positioner**

HP3500	Urchin Evo Heart Positioner
Order Number	Description



#### Positioner

Order Number	Description
HP3000	Starfish Evo Heart Positioner



## Beating Heart Stabilizer & Positioner Bundles

Order Number	Description	
EASE	Octopus Evolution AS Tissue Stabilizer and Starfish Evo Heart Positioner	
EAUE	Octopus Evolution AS Tissue Stabilizer and Urchin Evo Heart Positioner	
ESE	Octopus Evolution Tissue Stabilizer and Starfish Evo Heart Positioner	
EUE	Octopus Evolution Tissue Stabilizer and Urchin Evo Heart Positioner	
43ES	Octopus 4.3 Tissue Stabilizer and Starfish Evo Heart Positioner	
43EU	Octopus 4.3 Tissue Stabilizer and Urchin Heart Positioner	
4EU	Octopus 4 Tissue Stabilizer and Urchin Evo Heart Positioner	

#### **MICS Bundles**

Order Number	Description
NUB3	1 Starfish NS, 1 Octopus Nuvo
MICS 3	5 Octopus Nuvo, 5 Starfish NS, and 1 Thoratrak Retractor System
4ES	1 Octopus 4, 1 Starfish Evo

NOTE: Table clamps are not provided in the MICS Bundles

### **MICS Accessories**

Order Number	Description
28042	Table Clamp



Order Number	Description
28045	Octopus Retractor Adaptor



### Octobase Sternal Retractor System

Order Number	Description
28701	Retractor with reusable stainless steel blade inserts
28702	Stainless steel blanks - standard (reusable)
28703	Swivel blades - standard depth (reusable)
28704	Swivel blades - deep (reusable)
28705	Fixed blades - standard depth (reusable)
28706	Fixed blades - deep (reusable)
28707	Suture holder inserts (disposable)
28709	Retractor handle - replacement component
28710	Fixed skirted blades - deep (reusable)



## Minimally Invasive Cardiac Surgery MICS CABG

The stability and familiarity of OPCAB — now available for minimally invasive procedures.

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## Direct Visualization, MICS Made Possible

Medtronic offers a complete portfolio of MICS enabling technologies and training opportunities for today's cardiac surgeons. Consider your options for CABG, Valve and Hybrid Coronary Revascularization (HCR) procedures using minimally invasive techniques and technologies.





## Minimally Invasive Cardiac Surgery MICS CABG

The stability and familiarity of OPCAB — now available for minimally invasive procedures.

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## Stabilizer

TSMICS1	Octopus Nuvo Tissue Stabilizer
Order Number	Description

#### Stabilizer

Stabilizer		
Order Number	Description	
TS102	Octopus NS Tissue Stabilizer	
		3

#### Positioner

Order Number	Description	1:10
HP102	Starfish NS Heart Positioner	

#### **MISC Bundles**

Order Number	Description	
NUB3	1 Starfish NS, 1 Octopus Nuvo	
MICS 3	5 Octopus Nuvo, 5 Starfish NS, and 1 Thoratrak Retractor System	
4ES	1 Octopus 4, 1 Starfish Evo	

NOTE: Table clamps are not provided in the MICS Bundles

#### **MICS Accessories**

Order Number	Description
28042	Table Clamp
	•



Order Number	Description
28045	Octopus Retractor Adaptor



## Thoratrak MICS Retractor System

Order Number	Description
28601	Blade - LIMA standard
28602	Blade - LIMA deep
28603	Blade - long thoracotomy standard
28604	Blade - long thoracotomy deep
28604B	Blade - long extended mount standard
28605	Blade - short thoracotomy standard
28606	Blade - short thoracotomy deep
28606B	Blade - short extended mount standard
28610	Thoratrak Retractor System (retractor + multiple blade sets)
28611	Retractor rack



## OPCAB Accessories Enabling Technologies

Contributing to the ease and success of your procedures.

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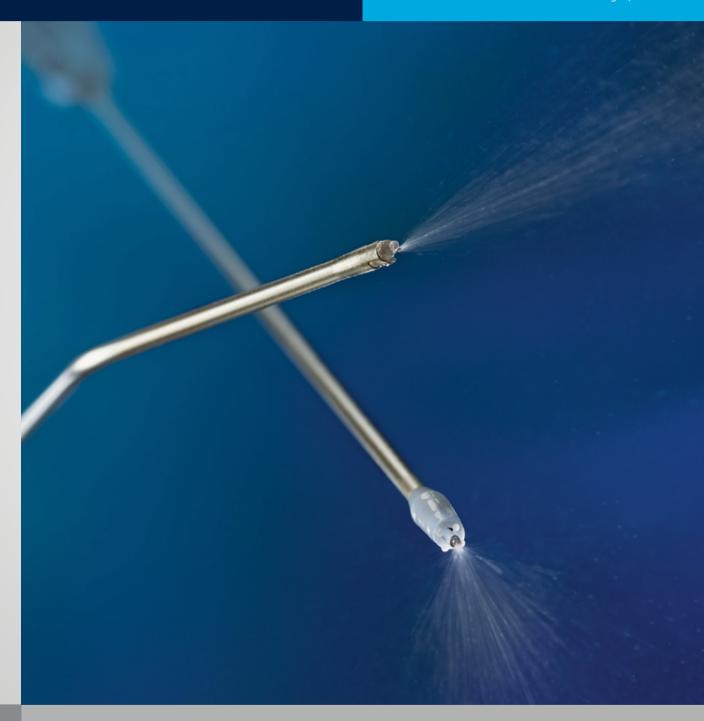
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## More Options for Beating Heart Surgery

Medtronic's numerous accessories can make OPCAB procedures easier and more successful. The Blower/Mister options facilitate a bloodless field. Shunts too provide a clear anastomotic site during the procedure while providing blood flow to the distal myocardium. And, QuickFlow DPS contains a complete set of components designed to establish rapid aorta-to-coronary perfusion during the beating heart procedure.



## OPCAB Accessories Enabling Technologies

Contributing to the ease and success of your procedures.

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### Clearview<sup>™</sup> Blower/Mister

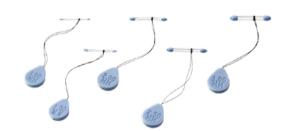
Order Number	Description	
22120	Clearview Blower/Mister (handpiece only) (qty 10)	
22150	Clearview Blower/Mister (with attached tubing set) (qty 5)	

### AccuMist<sup>™</sup> Blower/Mister

Order Number	Description	
29150	Accumist Blower/Mister (qty 10)	

#### ClearView Shunt

Order Number	Description
31100	1.00mm shunt, 14mm between bulbs (qty 5)
31125	1.25mm shunt, 14mm between bulbs (qty 5)
31150	1.50mm shunt, 14mm between bulbs (qty 5)
31175	1.75mm shunt, 14mm between bulbs (qty 5)
31200	2.00mm shunt, 14mm between bulbs (qty 5)
31225	2.25mm shunt, 14mm between bulbs (qty 5)
31250	2.50mm shunt, 14mm between bulbs (qty 5)
31275	2.75mm shunt, 14mm between bulbs (qty 5)
31300	3.00mm shunt, 14mm between bulbs (qty 5)



## Quickflow DPS Distal Perfusion System

Order Number	Description	
33100	Quickflow DPS Distal Perfusion System includes: 1-tubing set; 2-2.00mm elongated arteriotomy cannula; 1-3.00mm elongated arteriotomy cannula; 1-4.00mm elongated arteriotomy cannula; 1-14 gauge aortic root cannula	



## Off-Pump Accessories

Order Number	Description	
28030	Vacuum Regulator	
VP700	Portable Vacuum Pump with Regulator	



For a listing of indications, contraindications, precautions, warnings, and potential adverse events, please refer to the Instructions for Use. INTERNATIONAL

 ${\sf CAUTION:} \ For \ distribution \ only \ in \ markets \ where \ the \ products \ have \ been \ approved.$ 

## **Medtronic**

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Toll-free: (800) 328-2518

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