Medtronic

INSTRUCTIONS FOR USE

Contegra® Pulmonary Valved Conduit

Caution:

Single Use Only

Humanitarian Use Device.

Authorized by Federal law (USA) for use in patients under 18 years of age for the correction or reconstruction of the right ventricular outflow tract (RVOT) in the following congenital heart malformations:

- **pulmonary stenosis**
- **tetralogy of Fallot**
- **truncus arteriosus**
- **transposition with ventricular septal defect (VSD)**
- **pulmonary atresia**

In addition, the Contegra pulmonary valved conduit is indicated for the replacement of previously implanted, but dysfunctional, pulmonary homografts or valved conduits. The effectiveness of this device for these uses has not been demonstrated.

1 Device Description

The Contegra® pulmonary valved conduit consists of a heterologous (bovine) jugular vein with a trileaflet venous valve and a natural sinus slightly larger in diameter than its lumen. A final sterilization step is performed using a proprietary sterilant that contains 1% glutaraldehyde and 20% isopropyl alcohol, in which the conduit is preserved and packaged until used. Adequate rinsing with isotonic saline solution must be performed before implantation to reduce the glutaraldehyde concentration. The sterilization process is certified after the quarantine interval. The Contegra pulmonary valved conduit, Model 200S, is supported with 2 polyester-covered, polypropylene rings located at the valve annulus and at the level of the commissures. The Contegra pulmonary valved conduit, Model 200, is unsupported.

Both ring-supported and unsupported models are available in the following sizes: 12 mm, 14 mm, 16 mm, 18 mm, 20 mm, and 22 mm. Sizes are based on the inside diameter of the conduit's inflow side. The outflow side of the conduit may be larger.

Both the ring-supported and unsupported models have a minimum overall length of 10 cm, except for the 12 mm size, which is about 7 cm long. The conduit extensions on either side of the rings are approximately 4 cm in length (3 cm for the 12 mm size). In the case of the unsupported model, approximately 4 cm of jugular vein tissue is present on either side of the valve (3 cm for the 12 mm size). These dimensions allow for adequate trimming of the conduit to fit the patient.

2 Indications for Use

The Contegra pulmonary valved conduit is indicated for correction or reconstruction of the right ventricular outflow tract (RVOT) in patients aged less than 18 years with any of the following congenital heart malformations:

- Pulmonary stenosis
- Tetralogy of Fallot
- Truncus arteriosus
- Transposition with ventricular septal defect (VSD)
- Pulmonary atresia

In addition, the conduit is indicated for the replacement of previously implanted, but dysfunctional, pulmonary homografts or valved conduits.

3 Contraindications

None known

4 Warnings and Precautions

4.1 Warnings

This device was designed for single patient use only. Do not reuse, reprocess, or resterilize this product. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or create a risk of contamination of the device, which could result in patient injury, illness, or death.

Do not resterilize the conduit by any method.

Exposure of the conduit and its container to irradiation, steam, ethylene oxide, or other chemical sterilants will render the conduit unfit for use.

Do not use the conduit if:

- The conduit has been dropped, damaged, or mishandled in any way
- The Use By date has elapsed
- All tamper strips on the glass jar-and-lid container are damaged
- The shipping temperature indicator window has turned black
- The serial number tag does not match the container label
- The storage solution does not completely cover the conduit

Do not expose the conduit to solutions other than the storage and rinsing solutions.

Do not allow the conduit to dry. Maintain conduit moisture with irrigation or immersion during surgery.

Do not attempt to repair a damaged conduit.

Do not use cutting needles, as they may cause structural damage to the conduit.

Do not pass a catheter through the conduit, as this may damage the conduit.

4.2 Precautions

The size of the conduit is based on the inside diameter of the inflow side (end). The outflow side (end) may be larger.

Valve competency is improved at lower pressure loads; therefore, physicians may want to consider alternate procedures or therapies for patients exhibiting or at risk for high pulmonary pressures.

The supported Contegra conduit, Model 200S, contains polypropylene support rings. Coronary artery compression could potentially result if the conduit is placed over, or in close proximity, to a coronary artery.

Glutaraldehyde may cause irritation of the eyes, nose, skin, and throat if continued exposure occurs. Avoid prolonged exposure or breathing of the chemical vapor. Use only with adequate ventilation. If skin contact occurs, immediately flush the affected area with copious amounts of water for 10 to 15 minutes. If eye contact has occurred, flush the eye with water for 15 minutes and seek immediate medical attention.

5 Adverse Events

5.1 Observed Adverse Events

Contegra Pulmonary Valved Conduit Clinical Study

A prospective, nonrandomized, multi-center evaluation was conducted of patients implanted with the Contegra pulmonary valved conduit. Three-hundred seventy-four (374) patients consented and were implanted at 18 centers. Cumulative follow-up for these 374 patients was 1188.6 patient-years with a median follow-up of 3.0 years (range 0 years to 7.1 years). Adverse events, including death, were captured throughout the postoperative period and are summerized in Table 1 and Table 2.

Table 1. Mortality Rates Following Implant with the Contegra Pulmonary Valved Conduit

European Companion Study and US Study (N=374)	Early Events[1] n (% of patients)	Late Events[2] n (% patient-year)[3]	Freedom From[4] Death at 1 Year (SE)	Freedom From[4] Death at 2 Years (SE)	Freedom From[4] Death at 5 Years (SE)
All Death	32 (8.6%)	16 (1.4%)	88.3% (1.7%)	87.4% (1.9%)	86.4% (3.3%)
Not Device-Related	30 (8.0%)	8 (0.7%)	89.9% (1.6%)	89.9% (1.8%)	89.5% (3.0%)
Device-Related or Unexplained	2 (0.5%)	8 (0.7%)	98.2% (0.8%)	97.2% (1.0%)	96.6% (1.9%)
Device-Related	0 (0.0%)	7 (0.6%)	98.8% (0.6%)	97.7% (0.9%)	97.7% (1.5%)
Unexplained	2 (0.5%)	1 (0.1%)	99.4% (0.4%)	99.4% (0.5%)	98.8% (1.1%)

1. ≤30 days postoperative if the patient was discharged from the hospital, or at any time after implant if the patient was not discharged from the hospital.
2. Greater than 30 days postoperative if the patient was discharged from the hospital.
3. Calculations were based on 1135.9 late patient-years.
4. Kaplan-Meier method was used to estimate survival, and Peto's formula was used for the calculation of the standard errors of these estimates.

Table 2. Morbidity Rates Following Implant with the Contegra Pulmonary Valved Conduit

European Companion Study and US Study (N=374)	Early Events[1] n (% of patients)	Late Events[2] n (% / patient-year[3])	Freedom From[4] Event at 1 Year (SE)	Freedom From[4] Event at 2 Years (SE)	Freedom From[4] Event at 5 Years (SE)
Endocarditis	1 (0.3%)	13 (1.1%)	98.5% (0.7%)	97.8% (0.9%)	93.7% (2.5%)
Hemolysis	9 (2.4%)	12 (1.0%)	95.4% (1.2%)	95.4% (1.3%)	94.1% (2.5%)
All Hemorrhage[5]	83 (15.5%)	31 (2.7%)	82.2% (2.2%)	81.8% (2.4%)	80.4% (4.2%)
Minor Hemorrhage	17 (4.0%)	24 (2.1%)	94.6% (1.3%)	94.3% (1.4%)	92.0% (2.9%)
Major Henorrhage	66 (11.8%)	7 (0.6%)	86.6% (2.0%)	86.6% (2.1%)	86.6% (3.6%)
Nonstructural Dysfuntion	3 (0.8%)	49 (4.2%)	95.0% (1.3%)	92.5% (1.6%)	83.5% (3.9%)
Structural Deterioration	0 (0.0%)	7 (0.6%)	99.7% (0.3%)	99.3% (0.5%)	98.0% (1.4%)
Thrombus[6]	9 (2.1%)	14 (1.2%)	94.4% (1.3%)	93.4% (1.5%)	93.4% (2.5%)
Reoperation[7]	3 (0.5%)	65 (5.6%)	93.3% (1.4%)	88.7% (1.9%)	76.0% (4.1%)
Explant	1 (0.3%)	51 (4.4%)	96.3% (1.1%)	91.7% (1.6%)	80.7% (3.7%)
Repair	2 (0.5%)	14 (1.2%)	96.6% (1.0%)	95.9% (1.2%)	94.3% (2.5%)
Catheter Intervention[8]	2 (0.3%)	116 (10.0%)	86.5% (2.0%)	80.6% (2.4%)	70.2% (4.5%)

Table 2. Morbidity Rates Following Implant with the Contegra Pulmonary Valved Conduit

European Companion Study and US Study (N=374)	Early Events[1] n (% of patients)	Late Events[2] n (% / patient-year[3])	Freedom From[4] Event at 1 Year (SE)	Freedom From[4] Event at 2 Years (SE)	Freedom From[4] Event at 5 Years (SE)
Device-Related	2 (0.3%)	60 (5.2%)	95.0% (1.3%)	91.1% (1.7%)	83.7% (3.8%)
Not Device-Related	0 (0.0%)	56 (4.8%)	91.5% (1.6%)	89.4% (1.9%)	85.0% (3.5%)

1. ≤30 days postoperative.
2. Greater than 30 days postoperative.
3. Calculations were based on 1159.7 late patient-years.
4. Kaplan-Meier method was used to estimate survival, and Peto's formula was used for the calculation of the standard errors of these estimates.
5. Seven patients had 2 early major hemorrhages, 1 patient had 3 early minor hemorrhages, 1 patient had 1 early major and 1 early minor hemorrhage, 3 patients had 3 early major hemorrhages, 1 patient had 4 early major hemorrhages, and 1 patient had 7 early major hemorrhages.
6. One patient had 2 early thromboses.
7. One patient had an early repair and an early explant.
8. One patient had 2 early catheter interventions.

5.2 Potential Adverse Events

Prosthetic heart valves have been associated with serious complications, sometimes leading to reoperation and/or death. In addition, complications caused by immunogenic response to the conduit or to physical, chemical, or biological changes, may occur at undetermined intervals and may require reoperation and replacement of the conduit. As this conduit is indicated for patients under 18 years of age, reoperation and replacement of the Contegra pulmonary valved conduit may be indicated because of the patient's physical growth.

General complications reported with valved conduits and biological tissue valves implanted in the heart include:

- Endocarditis
- Hemolysis
- Hemorrhage (including anticoagulant-related hemorrhage)
- Immunologic rejection
- Prosthesis calcification (intrinsic and extrinsic)
- Prosthesis (conduit) dilatation
- Prosthesis (conduit) dissection
- Prosthesis nonstructural dysfunction (for example, neointimal thickening or neointimal peeling/dehiscence)
- Prosthesis regurgitation
- Prosthesis structural deterioration (perforation, tear, thickening, dissection, or myxomatous degeneration)
- Prosthesis stenosis
- Prosthesis thrombosis
- Pulmonary hypertension
- Thromboembolism
- Residual or increasing transvalvular pressure gradient
- Obstruction of implant
- Pulmonary embolism
- Coronary artery compression

It is possible that these complications could lead to:

- Reoperation
- Explantation
- Permanent disability
- Death

These complications may present clinically with abnormal heart murmur, shortness of breath, exercise intolerance, dyspnea, orthopnea, anemia, fever, arrhythmia, hemorrhage, low cardiac output, pulmonary edema, myocardial infarction, hemolytic anemia, and congestive heart failure.

6 Instructions for Use

The function of a pulmonary valved conduit is sensitive to surgical implantation techniques. Physicians performing the implantation must be familiar with the techniques for implanting a pulmonary homograft or valved conduit.

The Contegra pulmonary valved conduit is packaged **sterile** in a hermetically sealed jar. Before opening, carefully examine the jar and lid for damage, leakage, or broken seals. The jar should contain enough sterilant to cover the conduit.

Caution: Rinse the conduit continuously for a minimum of 15 minutes to reduce the glutaraldehyde concentration from the conduit. Aseptic technique must be used in the following steps:

1. Prepare 4 sterile bowls, 3 of which contain isotonic saline solution (500 mL) for rinsing.
2. Remove the conduit by grasping the serial number tag with atraumatic forceps and lifting it from the jar. The serial number tag is sutured to the outflow end of the conduit. Verify that the serial number tag matches the jar label. If any difference is noted, the conduit should not be used. This tag should not be detached from the conduit until implantation is imminent.

   Note: The outside of the jar is not sterile.
3. Drain the residual storage solution from the conduit into the empty **Discard Bowl (Bowl 1)** by holding the conduit (with fingers) with the serial tag (outflow) downward and inflow end upward.

   Note: The slightly larger central portion of the conduit, the sinus, contains the valve. Do not handle the sinus area.
4. Gently squeeze (with fingers) the conduit below the sinus to eliminate most of the sterilant solution.
5. Transfer the conduit to the **First Rinse Bowl (Bowl 2)**. Immerse and gently squeeze (with fingers) above and below the sinus area. Fill the conduit with rinse solution and empty by tilting the serial number tag (outflow) downward, and inflow end upward with fingers. Alternately swirl, gently squeeze, empty, and fill the conduit for **5 minutes**. Remove all solution from the conduit before transferring.
6. Transfer the conduit to the **Second Rinse Bowl (Bowl 3)** and repeat step 4 for a minimum of **5 minutes**.
7. Transfer the conduit to the **Third Rinse Bowl (Bowl 4)**. Continue rinsing for a minimum of **5 minutes** using the same technique described for Bowls 2 and 3. Leave the conduit in the Third Rinse Bowl until needed for implantation to prevent the tissue from drying.
8. Empty the rinse solution from the conduit before handing the device into the surgical field. The surgeon or assistant will remove the serial number tag and attaching suture.

7 Surgical Procedure

Cardiac surgical procedures can be complex and subject to variability. The Contegra® pulmonary valved conduit may be used for several indications. Valve competency is improved at lower pressure loads; therefore, physicians may want to consider alternate procedures or therapies for patients exhibiting, or at risk for, high pulmonary pressures. These factors suggest that the choice of surgical technique must be left to the discretion of the individual surgeon, observing the **Warnings** and **Instructions for Use** described herein.

Surgical Precautions: The conduit should be handled carefully and gently. Examine the conduit, and note the direction of the arrow. The arrow denotes the direction of flow.

Note: The arrow does **not** indicate location of the valve. If the conduit is dropped, damaged by cutting, or in any way mishandled, it **must not** be used for human implantation.

During implantation, the conduit must be kept moist with isotonic saline solution until circulation is restored.

8 Clinical Study

Contegra Pulmonary Valved Conduit Clinical Study

A prospective, nonrandomized, multi-center evaluation was conducted of patients implanted with the Contegra pulmonary valved conduit. Three-hundred seventy-four (374) patients consented and were implanted at 18 centers. Cumulative follow-up for these 374 patients was 1188.6 patient years with a median follow-up of 3.0 years (range 0 years to 7.1 years). Preoperative data, safety, effectiveness, and comparative literature data are presented in the tables below.

Table 3. Preoperative Data (N=374)

Variable	Category	n	%
Age at Implant	Less than 3 months	73	19.5
	3 to 12 months	64	17.1
	13 to 24 months	62	16.6
	25 months to 5 years	77	20.6
	6 to 10 years	48	12.8
	Greater than 10 years	50	13.4
Gender	Male	219	58.6
	Female	155	41.4
Cardiovascular Presentaion[1]	Pulmonary Stenosis	173	46.3
	Tetralogy of Fallot	139	37.2
	Pulmonary Insufficiency	125	33.4
	Pulmonary Atresia	121	32.4
	Truncus Arteriosus	101	27.0
	Failed Repair	82	21.9
	Failed Homograft	79	21.1
	Congestive Heart Failure	66	17.6
	Pulmonary Hypertension	58	15.5
	Failed Composite Conduit	43	11.5
	Double Outlet	45	12.0

Table 3. Preoperative Data (N=374)

Transposition of Great Arteries	33	8.8
Systemic Hypertension	8	2.1
Bacterial Endocarditis	5	1.3
Ross Procedure	2	0.5
Rheumatic Etiology	0	0.0

1. Patients may have more than 1 cardiovascular presentation.

Table 4. Risk Factors Associated with Time to Death (All Causes) (n=374)

Risk Factor	Relative Risk	95% Confidence Interval	P-Value
Age at Implant			
Less than 3 months	2.87	1.60- 5.12	0.0004
Concomitant Procedure			
Any	6.34	1.91 - 20.99	0.003

Cox Proportional Hazards Survival regression analysis was used to assess the association of risk factors and time to event.

Table 5. Risk Factors Associated with Time to Reoperation (n=374)

Risk Factor	Relative Risk	95% Confidence Interval	P-Value
Cardiovascular Presentation			
Tetralogy of Fallot	2.06	1.26 - 3.37	0.004
Valve Size			
12 mm or 14 mm	2.82	1.70 - 4.68	<0.0001

Cox Proportional Hazards Survival regression analysis was used to assess the association of risk factors and time to event.

Table 6. Risk Factors Associated with Time to Explant (n=374)

Risk Factor	Relative Risk	95% Confidence Interval	P-Value
Age at Implant			
Less Than 1 Year	3.18	1.84 - 5.51	<0.0001
Cardiovascular Presentation			
Tetrology of Fallot	3.12	1.78 - 5.49	<0.0001

Cox Proportional Hazards Survival regression analysis was used to assess the association of risk factors and time to event.

Table 7. Comparative Literature (Homograft vs. Contegra Pulmonary Valved Conduit)

Author/yr	# pts	Mean age (SD or range) d=day m=month y=year	Death (%)		Freedom From reop @ 1 yr (%)	Catheter Intervention- % of pts having a cath interv. %	Regurgitation	
			Early	Freedom From @ 1 yr			# valves eval.	≥ mod regurg (%)
Medtronic, Contegra 2006	374	2.0y[1] (1d-19y)	9	88	93	11[2]	246[3]	20
Albert, 1993	115	3.5y (6d-17y)	16	80[4]	98[4]			
Baskett, 1996	44	6.2y[1] (3d-20y)	7	93[4]	95[4]		38[5]	29
Baskett, 2003[6]	83	3.0y[1] (1d-19y)	6		95[4]		90[5]	53
Bielefield, 2001	223	2.8y (5d-17y)	14	84[4]	97[4]			
Boethig, 2005	52	1.5y[1] (6d-6y)	15	85[4]	90[4]			
Chan, 1994	41	3.1y[1] (3m-28y)				10	43[7]	35
Christenson, 2004	59	6.4y (1m-14y)	0	100	96[4]			
Daenen, 1997	187	25y (7d-20+y)	1	96			88[8]	19
Dittrich, 2000	23	1.9y (5d-9y)	13		93	4	20[5]	15
Hopkins, 1996	98		10	90[4]				
Lamberti, 1991	60	2.9y (15d-22y)	3	96				
LeBlanc, 1998	76	3.1y (6d-19y)	5	93	96			
Levine, 2001	17	16d (1d-92d)	24		100			
Perron, 1999	84	26d (1d-3m)	11	81	91	20		
Salim, 1995	43	4.7y (0.2-21y)	19		98			
Schorn, 1997	63	1.3y (±0.9y)	27		92	13		
Sinzobahamvya, 2001	76	46d[1] (2d-1.1y)	9	87		13		
Sinzobahamvya, 2007	13	198d (10d-371d)	8	77	100			
Stark, 1998	405	6.8y (--)			97[4]	3		
Tam, 1995	56	3.6y[1] (1d-24y)	16	84[4]	100		39[9]	36
Tweddell, 2000	205	6.9y (3d-48y)	11	89[4]	95			
Yankah, 1995	53	-- (1m-24m)	28	71	94	28		

1. median
2. device-related catheter interventions
3. at 1 year
4. estimated from graph in article
5. time of evaluation not indicated
6. same population as Baskett, 1996
7. at last follow-up, median=28.5 months
8. at last follow-up, mean=34 months
9. at last follow-up, median=8.6 years

shaded cells: no data available

Since literature data could not be found, note that the morbidity rates of the Contegra pulmonary valved conduit could not be compared with those of the control for the following complications: hemolysis and thrombosis.

The effectiveness parameters that were collected included peak gradient, mean gradient, and regurgitation data. The data were sufficient to provide reasonable assurances of the probable benefit of the Contegra pulmonary valved conduit.

The clinical experience to date was limited in the following areas:

- Patients above the age of 4 years at implant accounted for 34% of the total patient population.
- Model 200S was used in 14.7% of the total implants.
- Orthotopic placement was 25.1% of the total implants.

9 Individualization of Treatment

9.1 Specific Patient Populations

The safety and probable benefit of the Contegra pulmonary valved conduit has not been established for the following specific populations because it has not been studied in these populations:

- Patients who are pregnant
- Nursing mothers
- Patients with abnormal calcium metabolism (eg, chronic renal failure, hyperparathyroidism)
- Patients with aneurysmal aortic degenerative conditions (eg, cystic medial necrosis, Marfan's Syndrome)

In addition, the clinical data provided to support the safety and probable benefit of the Contegra pulmonary valved conduit were limited in some areas, as identified in the Clinical Study section.

10 Patient Counseling Information

Patients may require anticoagulation and/or antiplatelet therapy for an indefinite period based on each patient's condition.

Patients with bioprostheses are at risk for bacteremia (for example, undergoing dental procedures) and should be advised about prophylactic antibiotic therapy.

Patients should be encouraged to carry the Implanted Device Identification Card, provided by Medtronic, with them at all times.

11 How Supplied

11.1 Packaging

The Contegra pulmonary valved conduit is provided **sterile** and **nonpyrogenic** in a sealed container made of glass and a screw cap with a gasket.

Sterility is compromised if the glass jar-and-lid container is opened and/or damaged. The outside of the container is nonsterile and should not be placed in the sterile field.

11.2 Storage

The Contegra pulmonary valved conduit must be stored between 15°C and 25°C (59°F and 77°F). Refrigeration is not required, and freezing may damage the device. Room temperature storage up to 25°C (77°F) is satisfactory provided the device is not exposed to sunlight or other ultraviolet light sources or placed where significant temperature fluctuations may occur.

Appropriate inventory control should be maintained so that devices with earlier Use By dates are preferentially implanted and expiration is avoided.

11.3 Return of Explanted Devices

Medtronic is interested in obtaining recovered Contegra pulmonary valved conduits. When determined to be appropriate, explants will be studied by a consulting pathologist. A written report summarizing the findings will be returned to the physician. Product return kits, including an explant information form, are available by contacting Medtronic distribution centers or a Medtronic sales representative. It is important that the explant form be completely filled out. If a kit is not available, place the explanted bioprosthesis in a container of glutaraldehyde or 10% buffered formalin immediately after excision. For further instructions on the return of an explanted device, contact a Medtronic sales representative.

12 Patient Information

Note: Patient registration does not apply in countries where patient privacy laws conflict with providing patient information, including countries from the EU.

A patient registration form is included in each package. After implantation, please complete all requested information. The serial number is located on both the package and the identification tag attached to the conduit. Return the original form to the Medtronic address indicated on the form, and provide the temporary identification card to the patient prior to discharge.

An Implanted Device Identification Card is provided to the patient. The card contains the name and telephone number of the patient's physician as well as information that medical personnel would require in an emergency.

Medtronic has made available a patient information booklet that the physician may provide to the patient. Copies of this booklet are available on request from a Medtronic sales representative.

13 Postoperative Information

13.1 Magnetic Resonance Imaging (MRI) Compatibility

The Contegra pulmonary valved conduit, Model 200 and 200S, is Magnetic Resonance (MR) safe. The Contegra pulmonary valved conduit contains no metal and, therefore, poses no known hazards in all MR environments.

The device will not cause any harm to the patient when exposed to MR scanning immediately after implantation. MRI at 3.0 T and 1.5 T may be performed immediately following the implantation of the device.

13.2 Image Artifact

MR image quality may be compromised if the area of interest is in the same area, or relatively close to the position of the device. It may be necessary to optimize MR imaging parameters for the presence of this implant.

14 Disclaimer of Warranty

THE FOLLOWING DISCLAIMER OF WARRANTY APPLIES TO UNITED STATES CUSTOMERS ONLY:

ALTHOUGH THE CONTEGRA PULMONARY VALVED CONDUIT, MODELS 200 AND 200S, HEREAFTER REFERRED TO AS "PRODUCT", HAVE BEEN MANUFACTURED UNDER CAREFULLY CONTROLLED CONDITIONS, MEDTRONIC HAS NO CONTROL OVER THE CONDITIONS UNDER WHICH THIS PRODUCT IS USED. MEDTRONIC, THEREFORE, DISCLAIMS ALL WARRANTIES, BOTH EXPRESS AND IMPLIED, WITH RESPECT TO THE PRODUCT, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. MEDTRONIC SHALL NOT BE LIABLE TO ANY PERSON OR ENTITY FOR ANY MEDICAL EXPENSES OR ANY DIRECT, INCIDENTAL, OR CONSEQUENTIAL DAMAGES CAUSED BY ANY USE, DEFECT, FAILURE, OR MALFUNCTION OF THE PRODUCT, WHETHER A CLAIM FOR SUCH DAMAGES IS BASED UPON WARRANTY, CONTRACT, TORT, OR OTHERWISE. NO PERSON HAS ANY AUTHORITY TO BIND MEDTRONIC TO ANY REPRESENTATION OR WARRANTY WITH RESPECT TO THE PRODUCT.

The exclusions and limitations set out above are not intended to, and should not be construed so as to, contravene mandatory provisions of applicable law. If any part or term of this DISCLAIMER OF WARRANTY is held by any court of competent jurisdiction to be illegal, unenforceable, or in conflict with applicable law, the validity of the remaining portion of the DISCLAIMER OF WARRANTY shall not be affected, and all rights and obligations shall be construed and enforced as if this DISCLAIMER OF WARRANTY did not contain the particular part or term held to be invalid.

Explanation of symbols on package labeling

Refer to the device labeling to see which symbols apply to this product.

	Use By
STERILE LC	Sterile LC: Device has been sterilized using Liquid Chemical Sterilants according to EN/ISO 14160.
	Temperature Limit
	Size
SN	Serial Number
Model	Model
	For US Audiences Only
	Do Not Reuse
	Consult Instructions for Use
REF	Catalog Number
MR	MR Safe
	Do Not Use if Package is Damaged
2 STERILIZE	Do Not Resterilize
	Nonpyrogenic
	Quantity
	Manufactured In
	Do Not Use if Indicator Turns Black
	Manufacturer

Manufacturer:
Medtronic, Inc.
710 Medtronic Parkway
Minneapolis, MN 55432
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www.heartvalves.com
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Fax 763-526-7888
Toll-Free:
1-877-526-7890
(24-hour consultation service)

Manufactured In:
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Santa Ana, CA 92705 USA

M057066T001 Rev. 1A

M057066T001