

LABELING



Medtronic

**INSTRUCTIONS FOR USE
CONTEGRA® PULMONARY VALVED CONDUIT**

CAUTION:

Single Use Only

Humanitarian Use Device. Authorized by Federal law 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 (conduit) consists of a heterologous (bovine) jugular vein with a tri-leaflet 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, and 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 during a quarantine interval. The Contegra® Pulmonary Valved Conduit, Model 200S, is supported with two 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.

2. INDICATIONS

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 & PRECAUTIONS

4.1 Warnings

FOR SINGLE USE ONLY.

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 under the following conditions:

- the conduit has been dropped, damaged, or mishandled in any way
- the “Use By” date has elapsed
- the seal is broken
- the serial number tag does not match the container label
- the conduit has been exposed to freezing or to prolonged heat (Check freeze indicator. If exposed to a freeze-thaw condition, the indicator vial will break causing the dye to escape and stain the paper backing.)
- 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

CAUTION: Exposure to glutaraldehyde may cause irritation of the skin, eyes, nose, and throat. Avoid prolonged or repeated exposure or breathing of the chemical vapor. Use only with adequate ventilation. If skin contact occurs, immediately flush the affected area with water (minimum of 15 minutes). In the event of eye contact, flush with water for a minimum of 15 minutes and seek medical attention immediately.

5. ADVERSE EVENTS

5.1 Observed Adverse Events

Contegra® Pulmonary Valved Conduit Clinical Study

The following clinical data are interim data from an ongoing clinical investigation of the Contegra® Pulmonary Valved Conduit.

A prospective, non-randomized, multi-center evaluation is being conducted of patients implanted with the Contegra® Pulmonary Valved Conduit. The following data were obtained from 237 patients implanted at sixteen centers. Cumulative follow-up for these 237 patients was 307.7 patient-years with a median follow-up of 1.0 year (range 0 years to 3.5 years). Adverse events, including death, were captured throughout the postoperative period and are summarized in the tables below.

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

European Companion Study and US Study (N=237)	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)
All Death	22 (9.3%)	6 (2.1%)	88.1% (2.7%)	87.3% (3.9%)
Non Device-Related ⁵	18 (7.6%)	0 (0.0%)	92.1% (2.3%)	92.1% (3.3%)
Device-Related or Unexplained	4 (1.7%)	6 (2.1%)	95.6% (1.8%)	94.8% (2.7%)
Device-Related	2 (0.8%)	5 (1.8%)	97.0% (1.5%)	96.2% (2.4%)
Unexplained	2 (0.8%)	1 (0.4%)	98.6% (1.1%)	98.6% (1.5%)

Notes:

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 284.0 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. Twelve early deaths were cardiac and six early deaths were noncardiac.

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

European Companion Study and US Study (N=237)	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)
Endocarditis	1 (0.4%)	2 (0.7%)	98.6% (1.0%)	98.6% (1.5%)
Thrombus ⁵	5 (2.1%)	6 (2.1%)	95.4% (1.8%)	93.7% (3.0%)
Reoperation ^{6,7}	3 (0.8%)	22 (7.6%)	92.4% (2.3%)	86.1% (4.1%)
Explant	1 (0.4%)	11 (3.8%)	97.6% (1.4%)	92.0% (3.3%)
Minor Hemorrhage ⁸	12 (4.2%)	2 (0.7%)	94.4% (2.0%)	94.4% (2.9%)
Major Hemorrhage ⁹	31 (10.5%)	4 (1.4%)	88.0% (2.9%)	88.0% (4.1%)
Catheter Intervention ^{7,10}	2 (0.4%)	39 (13.5%)	86.8% (3.0%)	80.2% (4.7%)

Notes:

1. ≤30 days postoperative
2. Greater than 30 days postoperative
3. Calculations were based on 289.7 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. There were four (4) additional cases of focal thrombus deposition on the valve surface, on the conduit, or at the pulmonary artery anastomosis of the conduit which were considered by the core lab pathologist to be of insufficient amount to be primary valve thrombosis or to interfere with valve function.
6. Reoperation includes explant and surgical repair involving the Contegra device.
7. One patient had two early events.
8. Two patients had two early events.
9. Three patients had two early events and one patient had four early events.
10. Catheter intervention includes balloon dilation or stent placement in the branch PA, PA bifurcation, and/or distal anastomosis.

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 aged less than 18 years, 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 the following:

- Endocarditis
 - Hemolysis
 - Hemorrhage (including anticoagulant-related hemorrhage)
 - Immunologic rejection
 - Prosthesis calcification (intrinsic and extrinsic)
 - Prosthesis (conduit) dilatation
 - Prosthesis nonstructural dysfunction (e.g., neointimal thickening and peeling)
 - Prosthesis regurgitation
 - Prosthesis structural deterioration (perforation, thickening, myxomatous degeneration)
 - Prosthesis stenosis
 - Prosthesis thrombosis
 - Pulmonary hypertension
 - Thromboembolism
- 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. CLINICAL STUDY

Contegra® Pulmonary Valved Conduit Clinical Study

The following clinical data are interim data from an ongoing clinical investigation of the Contegra® Pulmonary Valved Conduit.

A prospective, non-randomized, multi-center evaluation is being conducted of patients implanted with the Contegra® Pulmonary Valved Conduit. The following data were obtained from 237 patients implanted at sixteen centers. Cumulative follow-up for these 237 patients was 307.7 patient-years with a median follow-up of 1.0 year (range 0 years to 3.5 years). Preoperative data, safety, effectiveness, and comparative literature data are presented in the tables below.

Table 3: Preoperative Data (N=237)

Variable	Category	n	%
Age at Implant	Less than 3 months	46	19.4
	3 to 12 months	37	15.6
	13 to 24 months	44	18.6
	25 months to 5 years	48	20.3
	6 to 10 years	33	13.9
	Greater than 10 years	29	12.2
Gender	Male	138	58.2
	Female	99	41.8
Primary Indication for Surgery	Replacement of Previous Conduit	77	32.5
	Tetralogy of Fallot	62	26.2
	Truncus Arteriosus	38	16.0
	Aortic Valve Disease	21	8.9
	Double Outlet	15	6.3
	Pulmonary Atresia	13	5.5
	Transposition of Great Arteries	8	3.4
	Pulmonary Stenosis	3	1.3

Table 4. Risk Factors Associated with Time to Death (All Causes) (n=237)

Risk Factor	Relative Risk	95% Confidence Interval	P-Value
Age at Implant			
Less Than 3 Months	4.81	1.99 - 11.61	0.0005
Concomitant Procedure			
Mitral/Tricuspid Valve Repair	20.42	5.96 - 70.44	< 0.0001
Aortic Valve/Root Replacement	8.62	2.60 - 28.38	0.0004
Ventricular Septum Repair	4.56	1.50 - 13.97	0.0082

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=237)

Risk Factor	Relative Risk	95% Confidence Interval	P-Value
Age at Implant			
Less Than 24 Months	4.11	1.39 - 12.04	0.0105

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=237)

Risk Factor	Relative Risk	95% Confidence Interval	P-Value
Primary Indication for Surgery			
Tetralogy of Fallot	16.05	1.92 – 132.53	0.0102
Truncus Arteriosus	12.44	1.38 – 111.63	0.0246

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 @1yr ⁴ (%)	Catheter intervention- % of pts having a cath interv. (%)	Regurgitation	
			Early	Freedom From @1yr			# pts eval.	≥ mod regurg (%)
Medtronic, Contegra 2003	237	2.0 y ¹ (1d-19y)	9	88	92	12.2	95 ²	21 ²
Albert, 1993	139	3.0 y (6d-17y)	17	83 ³	98 ³			
Baskett, 1996	44	6.2y (3d-20y)	7	93 ³	95 ³		38	29
Bielefeld, 2001	223	2.8y (5d-17y)	14	84 ³	97 ³			
Chan, 1994	41	3.1y ¹ (3m-28y)				9.8	43	35
Dittrich, 2001	23	1.9y (5d-9y)	13	--	93	4.3	20	15
LeBlanc, 1998	76	3.1y (6d-19y)	5	93	96			
Perron, 1999	84	26d (1d-3m)	11	81	91	20.2		
Schorn, 1997	63	1.3y (±0.9y)	27	--	92	12.7		
Stark, 1998	405	6.8y (--)			97 ³	3.2		
Tam, 1995	56	3.6y ¹ (1d-24y)	16	84 ³	100		39	36
Tweddell, 2000	205	6.9y (3d-48y)	11	89 ³	95			

¹median

²at one year

³estimated from graph in article

⁴For Homograft references: Freedom from reoperation is explant; for Medtronic, Freedom from reoperation includes explant and surgical repair.

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 accounted for only approximately 30% of the total patient population.
- The primary indication for surgery was dominated by, “replacement of previously implanted but dysfunctional pulmonary homografts or valved conduits”, “tetralogy of Fallot”, and “Truncus Arteriosus”; the other indications accounted for only approximately 26% of the intended indications.
- The use of the Model 200S was limited to only approximately 14.3% of the total implants.
- Orthotopic placement was limited to only approximately 24.1% of the total implants.

7. INDIVIDUALIZATION OF TREATMENT

7.1 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 (e.g., chronic renal failure, hyperparathyroidism)

Patients with aneurismal aortic degenerative conditions (e.g., 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.

8. PATIENT COUNSELING

In some conditions, patients may require anticoagulation and/or antiplatelet therapy for an indefinite period.

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

9. HOW SUPPLIED

9.1 Available Models and Sizes

The Contegra® Pulmonary Valved Conduit is sized in even increments between 12 and 22 mm (inside diameter), measured at the inflow end. The overall length of the Contegra® Pulmonary Valved Conduit is about 10 cm, except for the 12 mm diameter conduits which are approximately 7 cm in length. The valve and valve sinus (about 2 cm in length) are located at approximately the middle of the device, and approximately 3-4 cm of conduit are included on either end of the valve.

The device is available in two models: one without external ring support (Model 200), and the other with ring support modification (Model 200S). The latter consists of an attachment of two polyester-knit-cloth covered polypropylene rings sutured to the adventitial layer of the device (with polytetrafluoroethylene suture). One ring is attached at the level of the commissures, and the other is attached at the level of the annulus. This is approximately the levels of beginning and end of the valve sinus.

9.2 Packaging

The Contegra® Pulmonary Valved Conduit is provided **STERILE** and **NONPYROGENIC** in a sealed container made of borosilicate glass and a polypropylene screw cap with an ethylene propylene gasket.

9.3 Storage

The Contegra® Pulmonary Valved Conduit has been qualified for a maximum storage life of 2 years from the date of manufacture. The storage life of the device is recorded on the outer package label. Appropriate inventory control should be maintained so that prostheses with earlier 'Use By' dates are preferentially implanted and expiration is avoided. The storage environment should be clean, cool, and dry. Store conduits at 15°C to 25°C (59° to 77°F).

9.4 Accessories

None

10. DIRECTIONS FOR USE

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: The conduit should be rinsed 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 four sterile bowls, three 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.] Gently squeeze (with fingers) the conduit below the sinus to eliminate most of the sterilant solution.
4. 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 conduit before transferring.
5. Transfer the conduit to the **Second Rinse Bowl (Bowl 3)** and repeat step 4 for a minimum of **5 minutes**.
6. 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.
7. 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 green attaching suture.

10.1 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 Directions 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.

11. POSTOPERATIVE INFORMATION

11.1 Magnetic Resonance Imaging (MRI) Compatibility

The device contains no metals and, accordingly, would pose no substantial or increased risk to a patient undergoing an MRI procedure.

11.2 Return Of Explanted Bioprostheses

Medtronic is interested in obtaining recovered Contegra® Pulmonary Valved Conduits. Specific pathological studies of the explanted conduit will be conducted under the direction of a consulting pathologist. A written summary of the findings will be returned to the physician. To obtain a product

return kit, contact a Medtronic distribution center or your Medtronic sales representative. If a kit is not available, place the explanted conduit in a container of glutaraldehyde or 10% buffered formalin immediately after excision. For further instructions on the return of an explanted device, contact your Medtronic sales representative.

12. PATIENT INFORMATION

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

12.1 Registration Information

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.

12.2 Patient Record Card

Medtronic will provide an Implanted Device Identification Card 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. Patients should be encouraged to carry this identification card with them at all times.

12.3 Patient Information Booklet

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 your Medtronic sales representative.

13. DISCLAIMER OF WARRANTIES

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

ALTHOUGH THE MEDTRONIC 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.

14. REFERENCES

Contegra® Pulmonary Valved Conduit articles

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