Contegra™
Pulmonary Valved Conduit

VERSATILE.
CONVENIENT.
THE NATURAL CHOICE.

This device has been approved as a humanitarian use device in the U.S.

Medtronic
Further, Together

CONTEGRA™ PULMONARY VALVED CONDUIT

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

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

No discontinuity between the lumen and valve

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

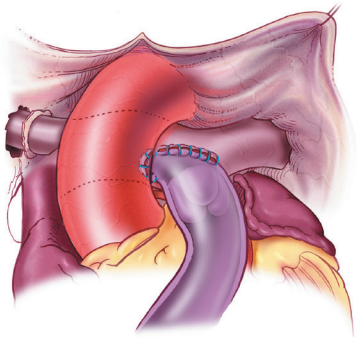
"...its function early is comparable if not superior to the PH [pulmonary homograft] because it has developed less obstruction and regurgitation than has been reported with PHs at the same time interval..."[1]

Versatile

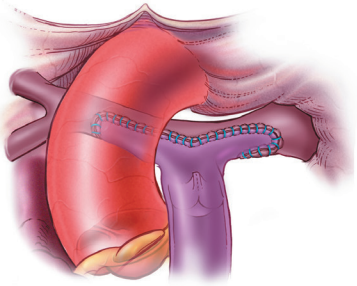
- Thin, extensible tissue is especially suited for anastomosis (figure 1)
- Easily customized to individual needs (figure 2)
- Proximal length allows for infundibular shaping without patching
- Resilient wall retains suture and supports hemostatic suture line
- No additional material necessary for proximal anastomosis

Convenient

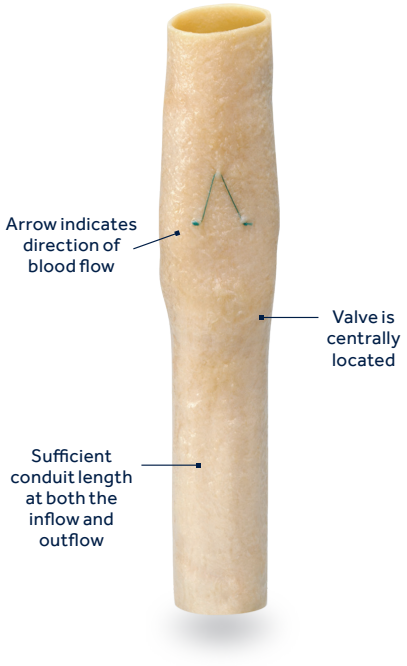
- Preserved in buffered glutaraldehyde
- Readily available — no thawing or preclotting required



(figure 1)



(figure 2)



MEDTRONIC CONTEGRA™ PULMONARY VALVED CONDUIT

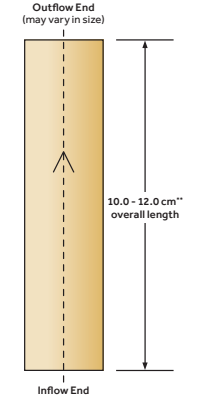
Ordering Information

UNSUPPORTED

PART NUMBER	INTERNAL DIAMETER (Inflow End)
200H12	12 mm
200H14	14 mm
200H16	16 mm
200H18	18 mm
200H20	20 mm

Model 01-0055 - Torque Wrench
Optional, reusable jar opener

Storage Temperature +15 °C +59 °F / +25 °C +77 °F



**7.0 cm length for 12 mm graft.

REFERENCE

1. Brown JW, Ruzmetov M, Rodefeld MD, Vijay P, Darragh RK. Valved bovine jugular vein conduits for right ventricular outflow tract reconstruction in children: an attractive alternative to pulmonary homograft. *Ann Thorac Surg.* September 2006;82(3):909-916.

BIBLIOGRAPHY

1. Bové T, Demanet H, Wauthy P, et al. Early results of valved bovine jugular vein conduit versus bicuspid homograft for right ventricular outflow tract reconstruction. *Ann Thorac Surg.* August 2002;74(2):536-541.
2. Breymann T, Thies WR, Boethig D, et al. Bovine valved xenografts for RVOT reconstruction: results after 71 implantations. *Eur J Cardiothorac Surg.* April 2002;21(4):703-710.
3. Carrel T, Berdat P, Pavlovic M, Pfammatter JP. The bovine jugular vein: a totally integrated valved conduit to repair the right ventricular outflow. *J Heart Valve Dis.* July 2002;11(4):552-556.
4. Corno AF, Hurni M, Griffin H, et al. Bovine jugular vein as right ventricle-to-pulmonary artery valved conduit. *J Heart Valve Dis.* March 2002;11(2):242-247.
5. Corno AF, Hurni M, Griffin H, Jeanrenaud X, von Segesser LK. Glutaraldehyde-fixed bovine jugular vein as a substitute for the pulmonary valve in the Ross operation. *J Thorac Cardiovasc Surg.* September 2001;122(3):493-494.
6. Herijgers P, Ozaki S, Verbeken E, et al. Valved jugular vein segments for right ventricular outflow tract reconstruction in young sheep. *J Thorac Cardiovasc Surg.* October 2002;124(4):798-805.
7. Breymann T, Blanz U, Wojtalik MA, et al. European Contegra multicentre study: 7-year results after 165 valved bovine jugular vein graft implantations. *Thorac Cardiovasc Surg.* August 2009;57(5):257-269.

CONTEGRA (FOR HDE USE)
CONTEGRA™ PULMONARY VALVED CONDUIT

Indications: See *Humanitarian Use Device section below.
Contraindications: None known.
Warnings/Precautions/Adverse Effects: Acceptable clinical performance has been established for the Contegra conduit in pediatric patients under the age of 10. Because of the possibility that complications of the device could become apparent only after extended use, a benefit-risk consideration of the long-term use of the Contegra conduit in pediatric patients over 10 years of age is particularly important. 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, neointimal thickening, neointimal peeling/dehiscence, prosthesis regurgitation, prosthesis structural deterioration (perforation, tear, thickening, dissection, or myxomatous), prosthesis stenosis, prosthesis thrombosis, pulmonary hypertension, thromboembolism, residual or increasing transvalvular pressure gradient, obstruction of implant, pulmonary embolism, coronary artery compression.
For additional information, please refer to the Instructions for Use provided with the product.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

***Humanitarian Use Device:** Authorized by Federal law (USA) for use in patients under 18 years of age for 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.

For a listing of indications, precautions, and potential side effects, please refer to the Instructions For Use provided with the product or contact your local Medtronic representative.

Medtronic

710 Medtronic Parkway
Minneapolis, MN 55432-5604
USA
Tel: (763) 514-4000
Fax: (763) 514-4879
Toll-free: (800) 328-2518

LifeLine
CardioVascular Technical Support
Tel: (877) 526-7890
Fax: (651) 367-0918
rs.structuralheart@medtronic.com

medtronic.com

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