VERSATILE.
CONVENIENT.
THE NATURAL
CHOICE.

Contegra™ Pulmonary Valved Conduit

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

Arrow indicates direction of blood flow
Valve is centrally located
Sufficient conduit length at both the inflow and outflow
CONTEGRA™
PULMONARY VALVED CONDUIT

Ordering Information

<table>
<thead>
<tr>
<th>PART NUMBER</th>
<th>INTERNAL DIAMETER (Inflow End)</th>
</tr>
</thead>
<tbody>
<tr>
<td>200H12</td>
<td>12 mm</td>
</tr>
<tr>
<td>200H14</td>
<td>14 mm</td>
</tr>
<tr>
<td>200H16</td>
<td>16 mm</td>
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<tr>
<td>200H18</td>
<td>18 mm</td>
</tr>
<tr>
<td>200H20</td>
<td>20 mm</td>
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</tbody>
</table>

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

Storage Temperature: 
+15°C to +25°C
+59°F to +77°F

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, Tetrality 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.

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