CryoArtery® Aortoiliac Artery

For Replacing Infected Aortic Grafts
Outline

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• Target Patients
• Clinical Outcomes & Cost Savings
• CryoArtery Aortoiliac Artery vs. Alternative Procedures
• Cryopreserved Aortoiliac Allografts vs. Extra-Anatomic Bypass
• Implant & Post-Op Considerations

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• Wet Lab Resources
• CryoLife Difference
Indications for Use

• Indications for Use
  • Cryopreserved vascular allografts are indicated for use as vascular grafts.

• Contraindications
  • No contraindications for use of CryoArtery Aortoiliac Arterial Allografts are known.
Underlying Need

Aortic Aneurysm Patient 102,256 ('16)¹

Endograft 84,097 ('16)¹

Open Surgery 18,159 ('16)¹

Infection (0.2% to 5%) 204 to 5,112¹⁻³

Treatment Options

CryoArtery

NAIS

Ax-bifem

Rifampin-Soaked Dacron

1. iData 2013.
Target Patients: Abdominal Aortic Infections

**Infected Synthetic Grafts**

The graft infected is typically (woven polyester “Dacron” or ePTFE)

**Aorto-Enteric Fistula**

A fistula is created between the bowel and synthetic graft. This causes sepsis/infection in the blood stream.

**Mycotic Aneurysms**

An infected aneurysm (picture above: an abdominal aorta with a mycotic aneurysm)
Clinical Outcomes & Costs Savings

- 96% Freedom from Infection at 5 years\(^2\)
- “Lower rates of graft rupture, aneurysm formation, recurrent infection and limb loss than other alternatives”\(^2\)
- Potential cost and time savings in OR and ICU\(^2,4\)

The Natural Choice for Infected Fields

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# CryoArtery Aortoiliac Artery vs. Alternative Procedures

<table>
<thead>
<tr>
<th></th>
<th>CryoArtery Aortoiliac Artery 2,5,6,24</th>
<th>NAIS* Procedure7,10</th>
<th>Axillofemoral Reconstruction 2,8,9,11-17</th>
<th>Rifampin-Soaked Synthetic Graft4,9</th>
</tr>
</thead>
<tbody>
<tr>
<td>Graft Re-infection</td>
<td>0% - 9%</td>
<td>10% - 14%</td>
<td>0% - 25%</td>
<td>7% - 47%</td>
</tr>
<tr>
<td>Mortality (30 day)</td>
<td>0% - 17%</td>
<td>0% - 20%</td>
<td>11% - 28%</td>
<td>8% - 18%</td>
</tr>
<tr>
<td>Mean OR Time</td>
<td>4 – 7 hours</td>
<td>5 – 12 hours*</td>
<td>6 – 10 hours*</td>
<td>NR</td>
</tr>
<tr>
<td>Mean Length of Hospital Stay</td>
<td>16.7 – 24 days</td>
<td>21 – 28 days</td>
<td>18 – 33 days</td>
<td>30 days</td>
</tr>
</tbody>
</table>

*Some of these cases may have been performed as staged procedures.

“[…]Cryopreserved aortoiliac allografts should be considered a first line treatment against primary aortic graft infections.” (n=220)²

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Cryopreserved Aortoiliac Allografts vs. Extra-Anatomic Bypass\(^4\)

<table>
<thead>
<tr>
<th></th>
<th>Arterial Allograft</th>
<th>Extra-anatomic Bypass</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgery/ Infection Related Mortality</td>
<td>12%</td>
<td>32%</td>
<td>0.008</td>
</tr>
<tr>
<td>Reoperation</td>
<td>9%</td>
<td>45%</td>
<td>0.001</td>
</tr>
<tr>
<td>Infection Completely Eliminated</td>
<td>91%</td>
<td>53%</td>
<td>0.001</td>
</tr>
<tr>
<td>Time in ICU</td>
<td>Median: 1 day</td>
<td>Median: 11 days</td>
<td>0.002</td>
</tr>
<tr>
<td></td>
<td>Range: 1-42 days</td>
<td>Range: 2-120 days</td>
<td></td>
</tr>
<tr>
<td>Duration of Hospital Stay</td>
<td>Median: 14 days</td>
<td>Median: 30 days</td>
<td>0.02</td>
</tr>
<tr>
<td></td>
<td>Range: 7-150 days</td>
<td>Range: 15-240 days</td>
<td></td>
</tr>
<tr>
<td>Cost</td>
<td>Median: $58,000</td>
<td>Median: $392,000</td>
<td>0.005</td>
</tr>
<tr>
<td></td>
<td>Range: $55,000-$160,000</td>
<td>Range: $89,000-$580,000</td>
<td></td>
</tr>
</tbody>
</table>

“[…]Costs were 40% lower in the group treated by allografts.”\(^4\)

Implant Technique Considerations

Below is information to assist in matching the patient’s pressurized aorta to a healthy unpressurized/undistended CryoArtery Aortoiliac Artery (AI)

<table>
<thead>
<tr>
<th>Unpressurized CryoArtery AI Graft Diameter (mm)</th>
<th>Pressurized Target Vessel Diameter (mm)</th>
<th>Graft Sizing of Undistended CryoArtery Aortoiliac Artery vs. Pressurized Target Vessel</th>
</tr>
</thead>
<tbody>
<tr>
<td>8</td>
<td>8</td>
<td>End to End, Surgical Technique</td>
</tr>
<tr>
<td>9</td>
<td>9</td>
<td>End to End, Surgical Technique</td>
</tr>
<tr>
<td>10</td>
<td>10</td>
<td>End to End, Surgical Technique</td>
</tr>
<tr>
<td>11</td>
<td>11</td>
<td>End to End, Surgical Technique</td>
</tr>
<tr>
<td>12</td>
<td>12</td>
<td>End to End, Surgical Technique</td>
</tr>
</tbody>
</table>

*From measured unpressurized/undistended diameter to 120mmHg, (39% distension)²⁰

Implant Technique Considerations (continued)

Below are illustrations of implant techniques used by vascular surgeons to suture an unpressurized/undistended CryoArtery Aortoiliac Artery to the native aorta to achieve an optimal diameter.29

- Original CryoArtery Aortoiliac Graft
- Use a beveled anastomosis to accommodate the difference in diameters
- Cut across the renal arteries and use the extra tissue as a taper to the native aorta
- More space between suture bites on the native aorta
- “Fish Mouth” the CryoArtery Aortoiliac Graft to match the diameter of the native aorta
- Taper the native aorta to reduce diameter

29. Surgical techniques suggested by CryoLife’s Vascular Advisory Board. This information is provided to medical professionals for your information & education only and is not to be used as a substitute for your medical judgement.
Implant Technique Considerations (continued)

• Check for leaks: distend with D5LR to check & repair leaks (before implantation)\textsuperscript{19}
  • Through and through ligature of the side branches
  • >2cm CryoLife does NOT suture ligate

• Atraumatic vascular clamp or/\& bulldog is/are only what should be used to occlude allograft

• Appropriate Length of Conduit\textsuperscript{18}
  • Avoid kinking the allograft by anticipating the total length the allograft once it is pressurized
  • Absolute tension-free anastomosis

18. Vogt, J Vasc Surg 2002: This study did not use CryoLife tissue.
19. L7092 Thaw and Rinse Procedure.
Implant Technique Considerations
(continued)

- Anastomotic heel enlargement
- Allograft aortic portion distends up to 39% at 120mmHg<sup>20</sup>
  - Begin with aortic anastomosis first**
- Anastomotic reinforcement with allograft strips<sup>18</sup>

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18. Vogt, J Vasc Surg 2002; This study did not use CryoLife tissue.
** Reported from surgeons to CV Reps.
Implant Technique Considerations (continued)

- Implant the posterior side aortoiliac graft to the anterior position to monitor for leaks from the lumbar arteries\(^{28}\)

- End-to-end 90° anastomosis when suturing the aortic portion of the allograft to the aorta using a single non-absorbable running polypropylene suture\(^{23}\)

- Spatulated 45° anastomosis when suturing the allograft iliac branches to the autologous iliac arteries\(^{23}\)

- Omentum wrapping around anastomosis to prevent fistula formation\(^ {22}\)

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Post-Op Protocol Considerations

• Antibiotics:
  • When bacteria was identified, patients received pathogen-specific postoperative antibiotics for a minimum of 6 weeks\textsuperscript{24}

• Follow-Up:
  • Annual evaluation: to include imaging study (CT, MRA, Angiography, Doppler US)\textsuperscript{24}

• Aggressive wound drainage\textsuperscript{18}

\textsuperscript{18} Vogt, J Vasc Surg 2002: This study did not use CryoLife tissue.
Additional Benefits

- Natural Suturability$^{25}$
- Compliance at the Anastomosis

- Natural Pulsatile Flow$^{26}$

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# Arterial Allograft Configurations

<table>
<thead>
<tr>
<th>Allograft Type</th>
<th>Diameter</th>
<th>Length</th>
<th>Catalog #</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aortoiliac Artery</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aorta</td>
<td>8 mm – 15 mm*</td>
<td>6 cm – 11+ cm</td>
<td>R010</td>
</tr>
<tr>
<td>Iliac</td>
<td>4 mm – 5+ mm</td>
<td>4 cm – 11+ cm</td>
<td></td>
</tr>
<tr>
<td>Descending Thoracic Artery</td>
<td>8 mm – 15mm^</td>
<td>6 cm – 11+ cm</td>
<td>A020</td>
</tr>
</tbody>
</table>

*Diameter distends up to 39% at 120mmHg[20]*

^Diameter distends up to 60% at 120mmHg[27]

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Extensions: Allograft Configurations

**CryoVein®**

<table>
<thead>
<tr>
<th>Allograft Type</th>
<th>Diameter*</th>
<th>Length</th>
<th>Catalog #</th>
</tr>
</thead>
<tbody>
<tr>
<td>Femoral Vein</td>
<td>6 mm – 15 mm</td>
<td>10 cm – 30+ cm</td>
<td>V060</td>
</tr>
</tbody>
</table>

**CryoArtery®**

<table>
<thead>
<tr>
<th>Allograft Type</th>
<th>Diameter*</th>
<th>Length</th>
<th>Catalog #</th>
</tr>
</thead>
<tbody>
<tr>
<td>Femoral Artery</td>
<td>4 mm – 5+ mm</td>
<td>10 cm – 30+ cm</td>
<td>R020</td>
</tr>
</tbody>
</table>

*Diameter: label changes as of June 15, 2015*

- Beginning Monday, June 15, 2015, the following CryoLife cryopreserved femoral allografts mentioned above have been packaged and labeled with only the outer diameter on the package label and Certificate of Assurance (Note: the internal diameter is not referenced).
- Prior to Monday, June 15, 2015, the allografts listed above were labeled with only the internal diameter. The internal diameter was determined by measuring the outer diameter of the allograft and subtracting the estimated thickness for the vessel wall.
- In the future, customers may receive allografts that are labeled with the internal diameter or outer diameter (depending on the date the allografts were labeled).
- The Certificate of Assurance is the suggested reference document to review prior to ordering any of the allografts mentioned above to verify that the tissues meet your expectations.
Wet Lab Resources

Aortoiliac Implant Simulator
Used in CryoLife Wet Labs
The CryoLife Difference

Experience
• Over 30 years of expertise in cryopreserving allografts (founded: 1984)
• Over 84,000 CryoLife vascular allografts shipped

Data
• 49 published clinical papers

Service
• Direct Representatives
• Hands-on Wet Labs

Quality
• Certified to be compliant with the ISO Quality System for Tissue Processing & Distribution
• Polypropylene monofilament suture for ligations (which does not harbor infection)
• Packaging: may be submerged in liquid nitrogen*
• CryoFreezers: available to hospitals for allograft storage
• AATB Accredited

*Prior to exposing the allograft to liquid nitrogen, allow the allograft to equilibrate with the liquid nitrogen vapor for a minimum of two (2) hours. After the equilibration period, the allograft may be submerged in liquid nitrogen for long-term storage. See Unpacking and Repacking Instructions for full details.
Surgical technique is at the discretion of the surgeon. Variations in technique will inevitably and appropriately occur when clinicians take into account the needs of the individual patients.