CardioGRAFT®-MC by LifeNet Health®

Decellularized Cardiac Bio-Implants

Thaw & Dilution Instructions

Decellularized using our patented Matracell technology.
CardioGRAFT®-MC Pulmonary Artery Patch Allograft

Decellularized

Thaw & Dilution Instructions

Key Notes:

- Use aseptic technique at all times. Thaw and dilute each device individually.
- If implantation is delayed, cover basin with sterile towel and place basin in larger basin of sterile slush.
- When the allograft bio-implant is removed from the freezer or dry ice equivalent, the thawing procedure must begin without delay.
- Make sure that the outer and inner packaging are intact and not damaged (contact LifeNet Health Client Services if packaging is damaged, 1-888-847-7831).
- This allograft bio-implant must be thawed and rinsed in normal saline within an initial temperature range of 37–42°C.
- Do not manipulate the allograft bio-implant until it is completely thawed.
- The allograft bio-implant must be continuously stirred during initial rinse for one (1) minute to ensure proper amount of glycerol removal.
- Remove outer gloves after transferring allograft bio-implant from initial one (1) minute rinse to fifteen (15) minute rinse.

Step 1 Non-Sterile Team Member
-40° to -100°C Freezer or Dry Ice Storage
Using insulated gloves, retrieve boxed device from freezer or dry ice equivalent. Immediately transport the device to the operating room.

Step 2 Non-Sterile Team Member
Open box and retrieve device pouch. Check package for integrity. Do not use this device if package integrity has been compromised. Aseptically open the outer peel pack and present inner pouch to the Sterile Team Member.

Step 3 Double-glove and aseptically remove inner pouch from outer pouch with clamp, holding package firmly by its sealed edge. Slowly lower inner pouch into 37–42°C normal saline in the first 1,000 ml basin. CAUTION: DO NOT SQUEEZE THE DEVICE. Allow device to thaw for approximately five (5) minutes.

Step 4 Sterile Team Member
Once the device is aseptically thawed, dry the outside of the inner pouch thoroughly. Open inner pouch with scissors at the square end.

Step 5 Sterile Team Member
Remove slip sheet and device slowly from inner pouch. By hand, carefully remove device from slip sheet and transfer into the second 1,000 ml basin filled with 37–42°C normal saline.

Step 6 Sterile Team Member
Gently hand stir solution surrounding device for a minimum of one (1) minute. Warning: Stirring the solution is essential for removing the glycerol from the tissue prior to implantation. Failure to do so may negatively affect the patient’s clinical outcome.

Step 7 Sterile Team Member
Gently transfer graft into the -37° to -42°C normal saline 5,000 ml basin, using hand, and soak for a minimum of fifteen (15) minutes prior to implantation. Remove outer gloves. The device is now ready for implantation. Keep the device completely immersed until needed.

Required Sterile Supplies:

- One thermometer
- One large (5,000 ml+) basin
- Two 1,000 ml basins
- One clamp
- One pair of scissors
- Thawing solution: 1,000 ml of warm (37–42°C) 0.9%/normal saline
- Rinse solution: 5,000 ml of warm (37–42°C) 0.9%/normal saline

Step 6 Sterile Team Member
Gently hand stir solution surrounding device for a minimum of one (1) minute. Warning: Stirring the solution is essential for removing the glycerol from the tissue prior to implantation. Failure to do so may negatively affect the patient’s clinical outcome.
### Repair Grafts | **CardioGRAFT®-MC**

<table>
<thead>
<tr>
<th>Decellularized Pulmonary Patch Graft</th>
<th>Size</th>
<th>Order Codes</th>
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</thead>
<tbody>
<tr>
<td>Thick (Trunk)</td>
<td>W=25–50 mm, <em>L=30–60 mm</em></td>
<td>DPPGK</td>
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<tr>
<td>Thin (Branch)</td>
<td>W=25–50 mm, <em>L=30–60 mm</em></td>
<td>DPPGN</td>
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<table>
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<th>Decellularized Hemi Pulmonary Artery</th>
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<tbody>
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<td>DLHPA</td>
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<tr>
<td>Right</td>
<td>Varies</td>
<td>DRHPA</td>
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*In 5 mm increments