**Vascular:** Thaw & Rinse Instructions
(cannulated)

- CryoVein® Saphenous Vein
- CryoVein Femoral Vein
- CryoArtery® Femoral Artery

Other Vascular Allograft included (not pictured): CryoVein Saphenous Vein, Double Graft Pack

**Cardiac:** Thaw & Rinse Instructions

**Aortoiliac Artery:** Thaw & Rinse Instructions
(non-cannulated)

- CryoValve® Aortic Human Heart Valve
- CryoPatch® SG Pulmonary Human Cardiac Patch (Hemi-Artery)
- CryoArtery Aortoiliac Artery

- CryoValve SG Pulmonary Human Heart Valve
- CryoPatch SG Pulmonary Human Cardiac Patch (Trunk and Branch)
- CryoGraft® Descending Thoracic Artery

Other Cardiac Allografts included (not pictured): CryoValve Pulmonary Valve, CryoPatch, CryoGraft Ascending Thoracic Artery, CryoPatch Pericardial Sheet, and CryoGraft Pulmonary Artery.
Vascular: Thaw & Rinse Instructions

Total Estimated Time: 45 minutes

(cannulated allografts)

- CryoVein Saphenous Vein
- CryoVein Femoral Vein
- CryoArtery Femoral Artery

Required Supplies:

Non-Sterile:
- Large basin (5 liters)
- Three (3) liters of water or saline at 98° to 108°F (37° to 42°C)
- Scissors
- Pack of towels
- Insulated gloves
- Protective eyewear
- Thermometer

Required Supplies:

Sterile:
- One (1) liter of 5% Dextrose in Lactated Ringer’s (D5/LR; at room temperature)
- Large basin (5 liters)
- Two (2) small basins (0.5 to 1 liter)
- 60cc Luer-Lok® syringe
- Scissors
- Marking pen
- Heparinized Lactated Ringer’s solution (mixing ratio is at surgeon’s discretion)

Other Vascular Allograft included (not pictured): CryoVein Saphenous Vein, Double Graft Pack
Strict adherence to this protocol is a critical factor to a successful outcome.

**Non-Sterile Field**

**Step 1:**
- Allograft MUST be thawed or stored (at or below -135°C) prior to the shipper time/date stamp otherwise DO NOT USE
- Handle allograft with care
- DO NOT USE if:
  - Allograft is expired
  - Allograft is dropped at cryogenic temperatures
- If the CryoSafe® packaging system is compromised, see Instructions for Use (IFU)
- Refer to the IFU to review other precautions

**Step 2:** Wear eye protection. Using insulated gloves or towels, gently place CryoSafe packaging system on a flat surface and remove from cardboard sleeve. (DO NOT allow tissue to slip off surface). Note the start time. Air thaw for 3 minutes.

**Step 3:** Fill large basin with three (3) liters of warm water or saline and confirm with thermometer the temperature is 98° to 108°F (37° to 42°C). It is not necessary to maintain this elevated temperature.

**Step 4:** Gently place CryoSafe packaging system in large basin and fully submerge by placing towels on top. DO NOT manipulate allograft during thawing. Note the start time. Remove CryoSafe packaging system from basin when ice crystals are not present. Approximate thaw time: 25 minutes.

**Step 5:** When allograft is completely thawed, dry the outside of the CryoSafe packaging system with towel. Open the outer pouch with scissors (DO NOT cut the middle and inner pouches). Remove the middle pouch and the Implant Summary Card.
Step 6: Using a sterile marking pen, label the two (2) small basins: “Discard” and “heparinized Lactated Ringer’s”. Non-sterile team member should aseptically pour heparinized Lactated Ringer’s into the corresponding marked basin in the sterile field.

Step 7: Non-sterile team member should introduce the inner pouch to the sterile team member by aseptically peeling back the middle pouch.

Step 8: Sterile team member should use sterile scissors to open the inner pouch. Gently pour the contents into the discard basin.

Step 9: Note which end cap and cannulae correspond to the inflow and outflow before removing caps (see Legend). Remove the end caps from the allograft cannulae.

NOTE: The CryoVein Saphenous Vein, Double Graft Pack has a connector that allows the two allograft segments to be rinsed simultaneously.

Legend

| Version 1: Saphenous Vein, Femoral Vein, and Femoral Artery |
|---|---|
| Caps: | Blue = Inflow  Red = Outflow |
| Cannulae: | Blue = Inflow  Red = Outflow |

| Version 2: Saphenous Vein and Femoral Artery |
|---|---|
| Caps: | Blue = Inflow  Red = Outflow |
| Cannulae: | White = Inflow  Clear = Outflow |

| Version 3: Femoral Vein |
|---|---|
| Caps: | Blue = Inflow  Red = Outflow |
| Cannulae: | Clear = Inflow  Clear = Outflow |
Step 10: Non-sterile team member should pour one liter of D5/LR into the sterile five liter basin. Gently place the allograft in large basin with D5/LR. Using the Luer-Lok syringe, gently flush 60cc of the D5/LR for a total of three (3) times. Let allograft passively rinse for **15 minutes**.

Step 11: Using the Luer-Lok syringe, the surgeon should gently flush the allograft with 60cc of heparinized Lactated Ringer’s and check for leaks. Surgeon should ligate the allograft as needed. The thaw and rinse are complete.

Step 12: Discard the segments of allograft in contact with the cannulae (including the connector for the CryoVein Saphenous Vein, Double Graft Pack). The allograft(s) is/are ready to implant.

**NOTE:** If more than 30 minutes are expected to elapse before the allograft(s) is/are implanted, place the large basin containing the D5/LR and allograft(s) on ice and cover with sterile drape until ready for use by the physician. Flush with heparinized Lactated Ringer’s prior to implantation.

**NOTE:** DO NOT allow allograft(s) to dry out. Keep the surface of the allograft(s) moist by wetting it with heparinized Lactated Ringer’s if part of it is outside the body during implantation.

**Non-Sterile Field**

**Step 9:** Complete and remove the Implant Summary Card-Patient Copy and provide to patient. Complete the remaining portion of the Implant Summary Card and mail to CryoLife.

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Cardiac: Thaw & Rinse Instructions

Aortoiliac Artery: Thaw & Rinse Instructions

Total Estimated Time: 35 minutes

Required Supplies:

**Non-Sterile:**
- Large basin (5 liters)
- Three (3) liters of water or saline at 98° to 108°F (37° to 42°C)
- Scissors
- Pack of towels
- Insulated gloves
- Protective eyewear
- Thermometer

**Sterile:**
- One (1) liter of 5% Dextrose in Lactated Ringer’s (D5/LR; at room temperature)
- Large basin (5 liters)
- Small basin (0.5 to 1 liter)
- 60cc Luer-Lok syringe
- Scissors

Other Cardiac Allografts included in this protocol (not pictured): CryoValve Pulmonary Valve, CryoPatch, CryoGraft Ascending Thoracic Artery, CryoPatch Pericardial Sheet, and CryoGraft Pulmonary Artery.
Strict adherence to this protocol is a critical factor to a successful outcome.

Non-Sterile Field

**Step 1:**
- Allograft MUST be thawed or stored (at or below -135°C) prior to the shipper time/date stamp otherwise DO NOT USE
- Handle allograft with care
- DO NOT USE if:
  - Allograft is expired
  - Allograft is dropped at cryogenic temperatures
- If the CryoSafe® packaging system is compromised, see Instructions for Use (IFU)
- Refer to the IFU to review other precautions

**Step 2:** Wear eye protection. Using insulated gloves or towels, gently place CryoSafe packaging system on a flat surface and remove from cardboard sleeve. (DO NOT allow tissue to slip off surface). Note the start time. Air thaw for **3 minutes**.

**Step 3:** Fill large basin with three (3) liters of warm water or saline and confirm with thermometer the temperature is 98° to 108°F (37° to 42°C). It is not necessary to maintain this elevated temperature.

**Step 4:** Gently place CryoSafe packaging system in large basin and fully submerge by placing towels on top. DO NOT manipulate the pouch. Note the start time. Remove CryoSafe packaging system from basin when ice crystals are not present. Approximate thaw time: **25 minutes**.

**Step 5:** When allograft is thawed, dry the outside of the CryoSafe packaging system with towel. Open the outer pouch with scissors (DO NOT cut the middle and inner pouches). Remove the middle pouch and the Implant Summary Card. For SynerGraft® tissue, the label adhered to the Implant Summary Card contains a Unique Device Identifier (UDI). If not already scanned, the end-user has the opportunity to scan the UDI at this time.
**Sterile Field**

**Step 6:** Non-sterile team member should introduce the inner pouch to the sterile team member by aseptically peeling back the middle pouch.

**Step 7:** Sterile team member should use sterile scissors to open the inner pouch. Gently pour the contents into the discard basin.

**Step 8:** Non-sterile team member should pour one liter of D5/LR into sterile five liter basin. Gently place the allograft in the large basin with the D5/LR. Let allograft passively rinse for 5 minutes. The thaw and rinse are complete. The allograft is ready to implant.

**Step 9:** Complete and remove the Implant Summary Card-Patient Copy and provide to patient. Complete the remaining portion of the Implant Summary Card and mail to CryoLife.

**Non-Sterile Field**

NOTE: If more than 30 minutes are expected to elapse before the allograft is implanted, place the large basin containing D5/LR and the allograft on ice and cover with sterile drape until ready for use by the physician.

NOTE: DO NOT allow the allograft to dry out. During implantation, use a 60cc Luer-Lok syringe to wet the surface of the allograft with D5/LR and keep it moist.