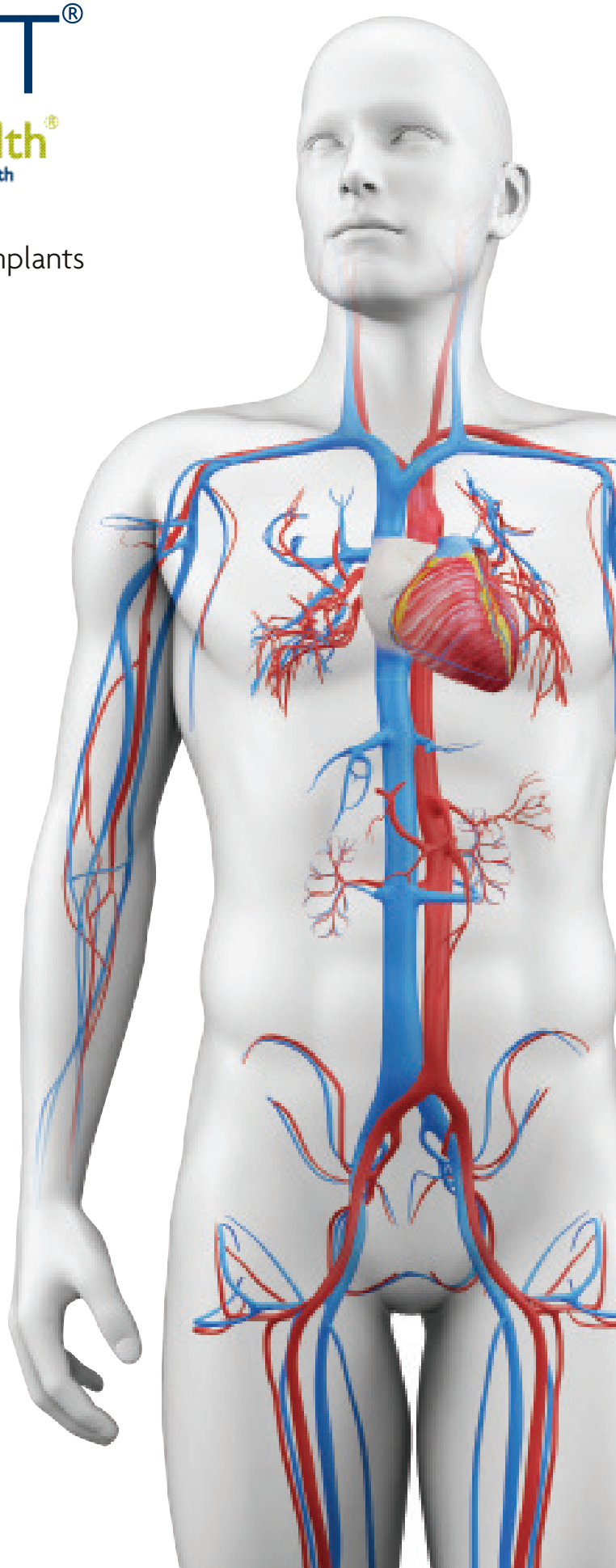
CardioGRAFT®

by LifeNet Health®
Saving Lives, Restoring Health

Decellularized Cardiac Bio-Implants

Thaw & Dilution Instructions



MATRACELL™
The FUTURE of Allograft Bio-Implant DECELLULARIZATION

Decellularized using our patented MatrACELL technology.

Decellularized

CardioGRAFT® Pulmonary Artery Patc

Thaw & Dilution

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

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 mechanical freezer or dry ice equivalent, the thawing procedure must begin without delay. When the allograft bio-implant is removed from vapor phase liquid nitrogen, **open box lid, remove foam and place on a stable surface for seven minutes**, then 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.

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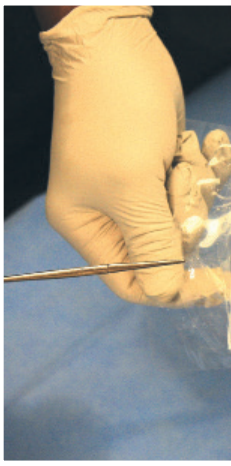
Step 1A
Non-Sterile Team Member
Mechanical Freezer or Dry Ice Storage
Using insulated gloves, retrieve boxed device from mechanical freezer, dry ice container or equivalent. **Immediately transport the device to the operating room.**

Step 1B
Non-Sterile Team Member
Liquid Nitrogen Freezer Vapor Phase Storage
Using insulated gloves, retrieve boxed device from vapor phase liquid nitrogen. **Immediately transport the device to the operating room.** Transport time does not count toward ambient thaw time. **Open box lid, remove foam and place on a stable surface for seven (7) minutes.**



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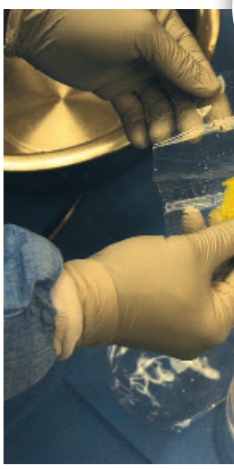

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Instructions

n-Sterile Team Member
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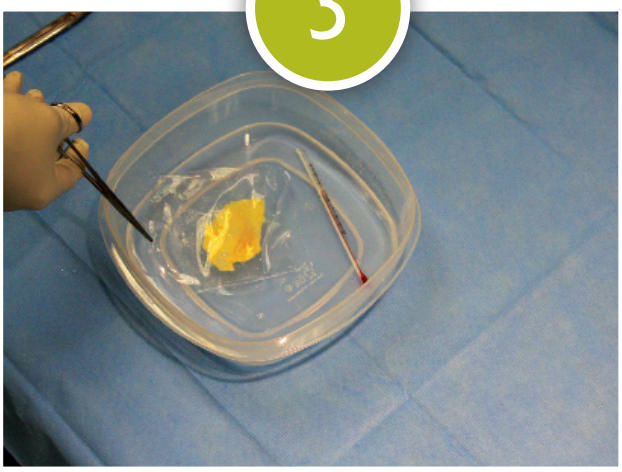
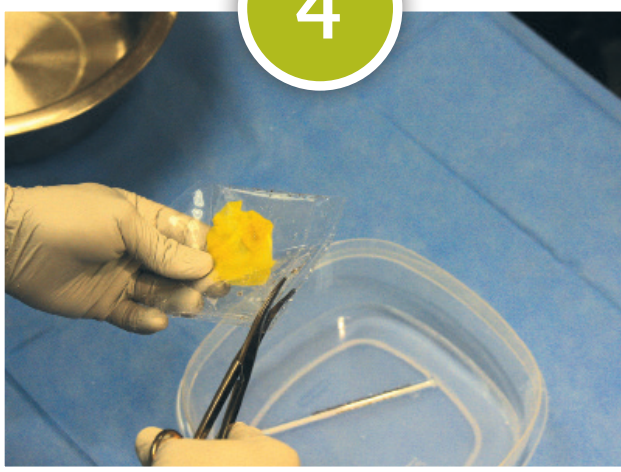
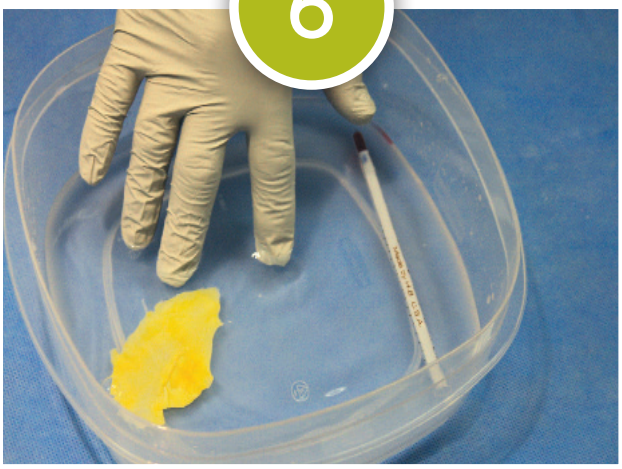


Step 3 Double-glove and aseptically remove inner pouch from outer pouch with clamp, holding package firmly by its sealed edge. Slowly lower inner pouch into 37–42°C normal saline in the first 1,000 ml basin.
CAUTION: DO NOT SQUEEZE THE DEVICE.
Allow device to thaw for approximately five (5) minutes.



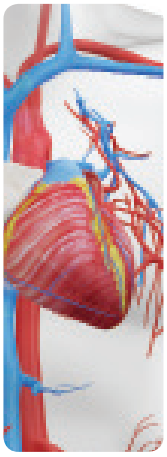
Step 4 Sterile Team Member
Once the device is aseptically thawed, dry the outside of the inner pouch thoroughly. Open inner pouch with scissors at the square end.

terile Team Member
eet and device slowly from By hand, carefully remove o sheet and transfer into the nd 1,000 ml basin.



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 clincial outcome.

Step 7 Sterile Team Member
Gently transfer graft to 5,000 ml basin, using hand, and allow to **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.



LifeNet Health®
Saving Lives, Restoring Health

Cardiac

Repair Grafts | CardioGRAFT®

	Size	Order Codes
DECELLULARIZED PULMONARY PATCH GRAFT		
Thick (Trunk)	W=25–50 mm,* L=30–60 mm*	DPPGK
Thin (Branch)	W=25–50 mm,* L=30–60 mm*	DPPGN
DECELLULARIZED HEMI PULMONARY ARTERY		
Left	Varies	DLHPA
Right	Varies	DRHPA

*in 5 mm increments

Decellularized
Pulmonary Patch
(Thick/Thin)

Decellularized
Hemi Pulmonary Artery
(Right/Left)

www.AccessLifeNetHealth.org 1-888-847-7831 1-757-464-4761 ext. 2000 (OUS)

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