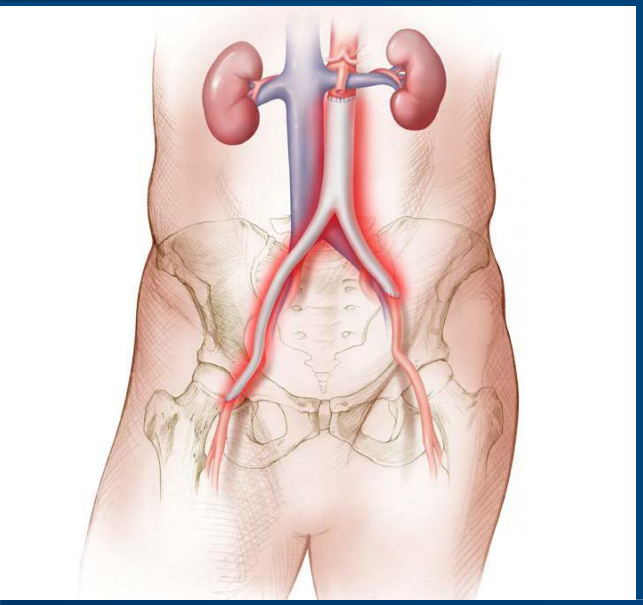
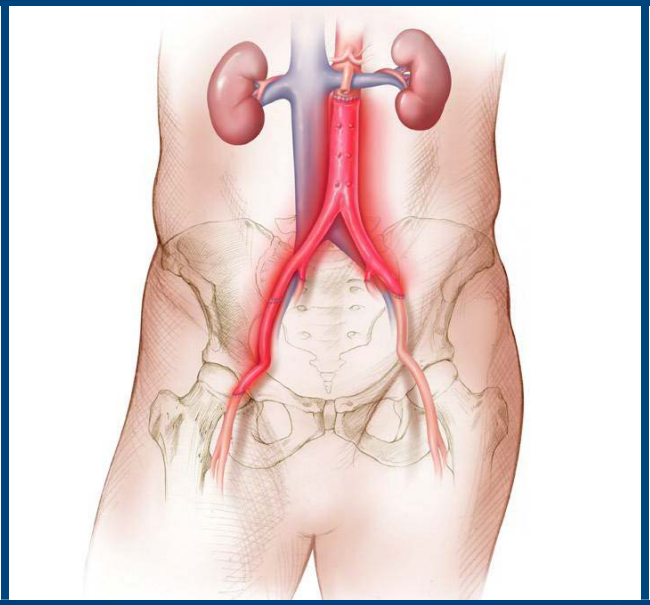
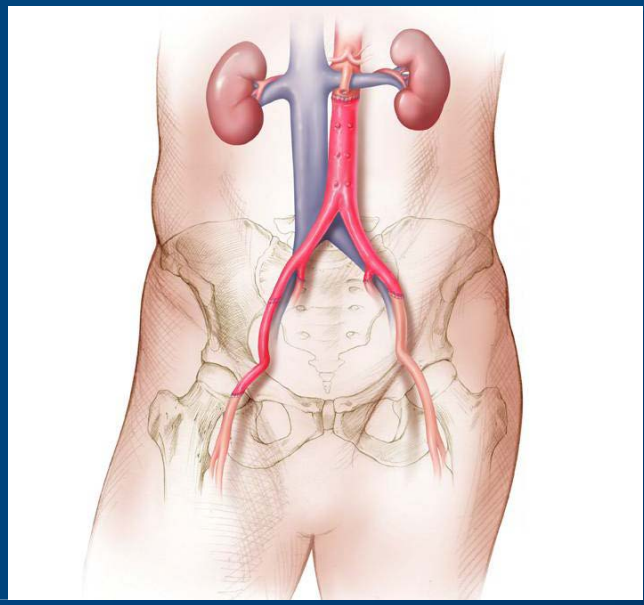






CryoArtery® | Aortoiliac Artery

For Replacing Infected Aortic Grafts

CryoLife®
Life Restoring Technologies®

Outline

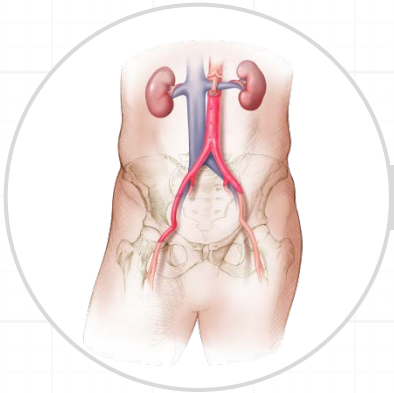
CryoArtery® | Aortoiliac Artery

- Indications for Use
- Underlying Need for CryoArtery Aortoiliac
- Target Patients
- Clinical Outcomes & Cost Savings
- CryoArtery Aortoiliac Artery vs. Alternative Procedures
- Cryopreserved Aortoiliac Allografts vs. Extra-Anatomic Bypass
- Implant & Post-Op Considerations
- Additional Benefits
- Arterial Allograft Configurations
- Extensions: Allograft Configurations
- Wet Lab Resources
- CryoLife Difference

Indications for Use

CryoArtery® | Aortoiliac Artery

- 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.

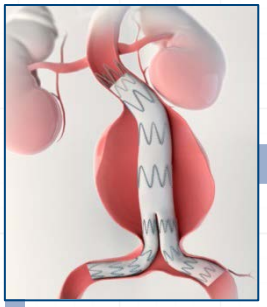


Aortoiliac Arterial Allograft Instructions for Use, L6415.

Underlying Need

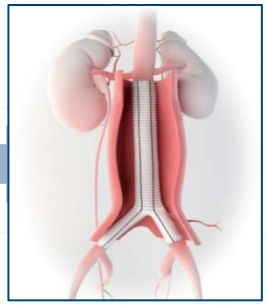
CryoArtery® | Aortoiliac Artery

Aortic Aneurysm Patient
102,256 (‘16)[1]



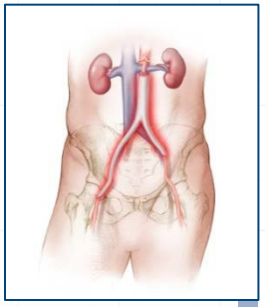
Endograft
84,097 (‘16)[1]

or



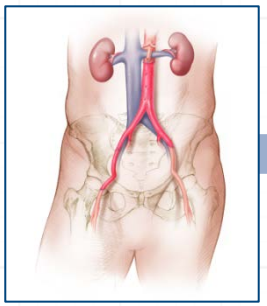
Open Surgery
18,159 (‘16)[1]

=



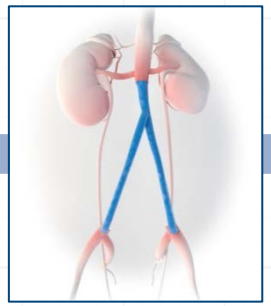
Infection
(0.2% to 5%)
204 to 5,112[1-3]

Treatment Options



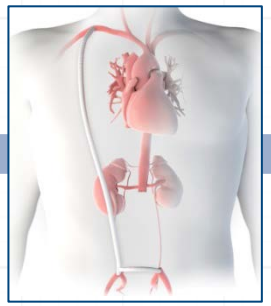
CryoArtery

or



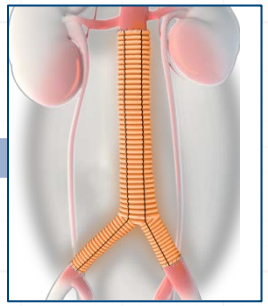
NAIS

or



Ax-bifem

or



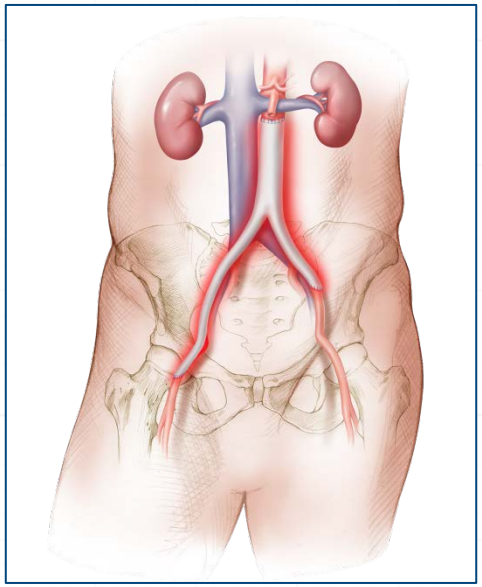
Rifampin-Soaked Dacron

1. iData 2013.
2. Harlander-Locke, et al. JVS 2014.
3. Davila, et al. JVS 2015.

Target Patients: Abdominal Aortic Infections

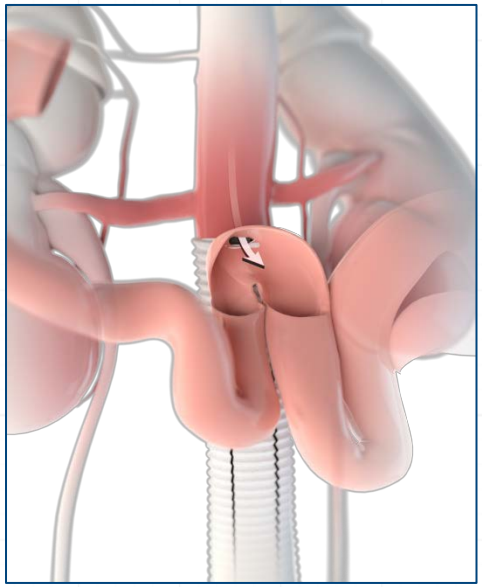
CryoArtery® | Aortoiliac Artery

Infected Synthetic Grafts



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

Aorto-Enteric Fistula



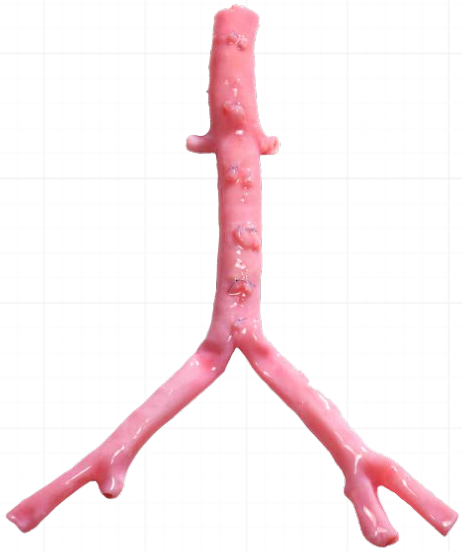
A fistula is created between the bowel and synthetic graft. This causes sepsis/infection in the blood stream.

Mycotic Aneurysms

An infected aneurysm (picture above: an abdominal aorta with a mycotic aneurysm)

Clinical Outcomes & Costs Savings

CryoArtery® | Aortoiliac Artery



The Natural Choice for Infected Fields

- 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]

2. Harlander-Locke, et al. JVS 2014.
4. Vogt et al. JTCS 1998.

CryoArtery Aortoiliac Artery vs. Alternative Procedures

CryoArtery® | Aortoiliac Artery

	CryoArtery Aortoiliac Artery [2,5,6,24]	NAIS* Procedure[7,10]	Axillofemoral Reconstruction [2,8,9,11-17]	Rifampin-Soaked Synthetic Graft[4,9]
Graft Re-infection	0% - 9%	10% - 14%	0% - 25%	7% - 47%
Mortality (30 day)	0% - 17%	0% -20%	11% - 28%	8% - 18%
Mean OR Time	4 – 7 hours	5 – 12 hours*	6 – 10 hours*	NR
Mean Length of Hospital Stay	16.7 – 24 days	21 – 28 days	18 – 33 days	30 days

*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]

2. Harlander-Locke, et al. JVS 2014.
4. Vogt, et al. J Thorasic Cardiovasc 1998.
5. Vardanian, et al. AM Surg 2009.
6. Zhou W, et al. Tex Heart Inst J 2006.
7. Ali, et al. J Vasc Surg 2009.
8. Liedenbaum, et al. Worl J Surg 2009.
9. Bandyk, et al J Surg Res 2001.
10. Claggett, et al. J Vasc Surg 1997.
11. O'Hara, et al. J Vasc Surg 1986.
12. Reilly, et al. J Vasc Surg 1987.
13. Yeager, et al. J Vasc Surg 1999.
14. Seeger, et al. J Vasc Surg 2000.
15. Hart, et al. Ann Vasc Surg 2005.
16. Schmitt, et al. J Vasc Surg (Torino). 1990.
17. Bandyk, et al. J Vasc Surg 2001.
24. Brown KE, et al J Vasc Surg 2009.

Cryopreserved Aortoiliac Allografts vs. Extra-Anatomic Bypass[4]

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

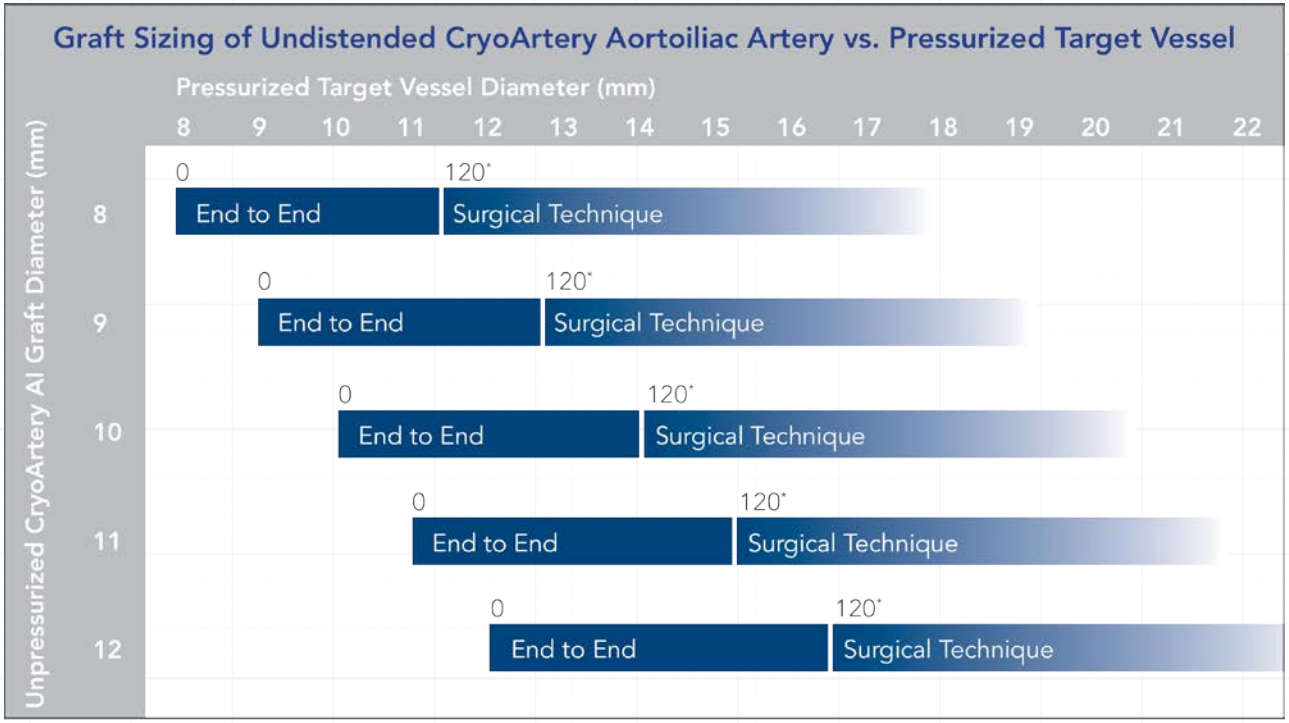
"[…]Costs were 40% lower in the group treated by allografts."[4]

4. Vogt, et al. J Thor Cardiovasc Surg 1998.

Implant Technique Considerations

CryoArtery® | Aortoiliac Artery

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



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

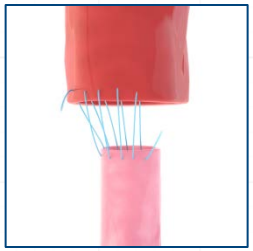
20. CryoLife, data on file.

Implant Technique Considerations (continued)

CryoArtery® | Aortoiliac Artery

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]

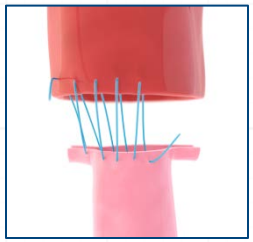
- Original CryoArtery Aortoiliac Graft



- More space between suture bites on the native aorta

- Use a beveled anastomosis to accommodate the difference in diameters

- "Fish Mouth" the CryoArtery Aortoiliac Graft to match the diameter of the native aorta



- Cut across the renal arteries and use the extra tissue as a taper to 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)

CryoArtery® | Aortoiliac Artery

- Check for leaks: distend with D5LR to check & repair leaks (before implantation)[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

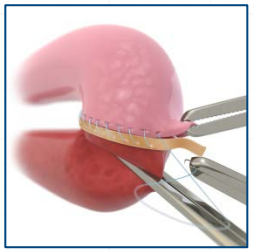
- Appropriate Length of Conduit[18]
  - Avoid kinking the allograft by anticipating the total length the allograft once it is pressurized
  - Absolute tension-free anastomosis

18. Vogt, J Vasc Surg 2002; This study did not use CryoLife tissue.
19. L7092 Thaw and Rinse Procedure.

Implant Technique Considerations
(continued)

CryoArtery® | Aortoiliac Artery

- Anastomotic heel enlargement
- Allograft aortic portion distends up to 39% at 120mmHg[20]
    - Begin with aortic anastomosis first**



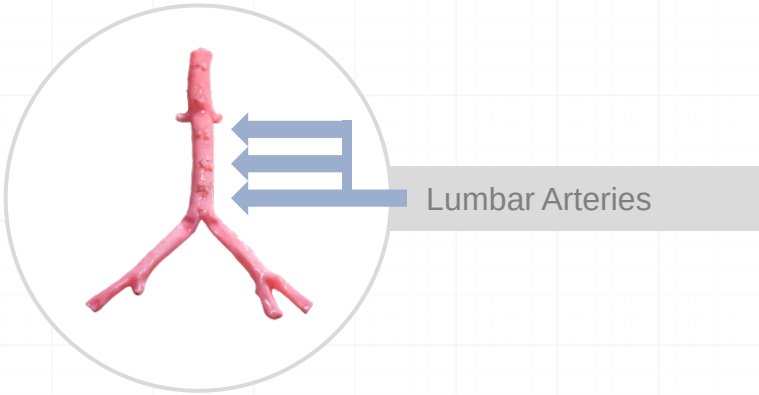
- Anastomotic reinforcement with allograft strips[18]

18. Vogt, J Vasc Surg 2002; This study did not use CryoLife tissue.
20. CryoLife, data on file.
** Reported from surgeons to CV Reps.

Implant Technique Considerations (continued)

CryoArtery® | Aortoiliac Artery

- 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]

22. McCready, et al. J Surg Res 2010.
23. Rutherford's Vascular Surgery. 7th Edition. March 2010.
28. Vogt, et al. J Vasc Surg 1995.

Post-Op Protocol Considerations

CryoArtery® | Aortoiliac Artery

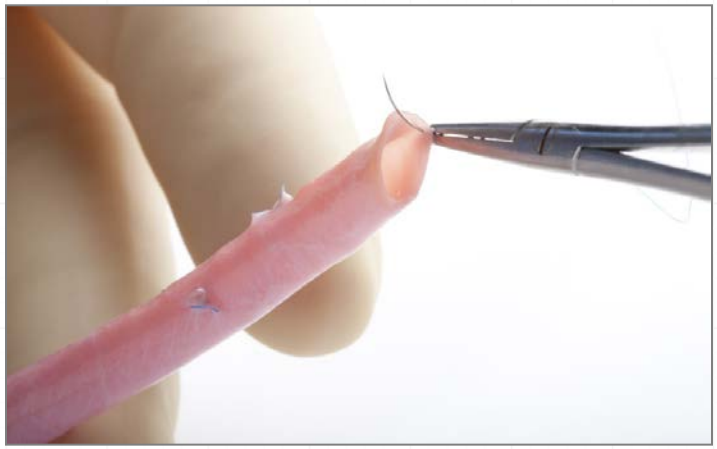
- Antibiotics:
  - When bacteria was identified, patients received pathogen-specific postoperative antibiotics for a minimum of 6 weeks[24]
- Follow-Up:
  - Annual evaluation: to include imaging study (CT, MRA, Angiography, Doppler US)[24]

- Aggressive wound drainage[18]

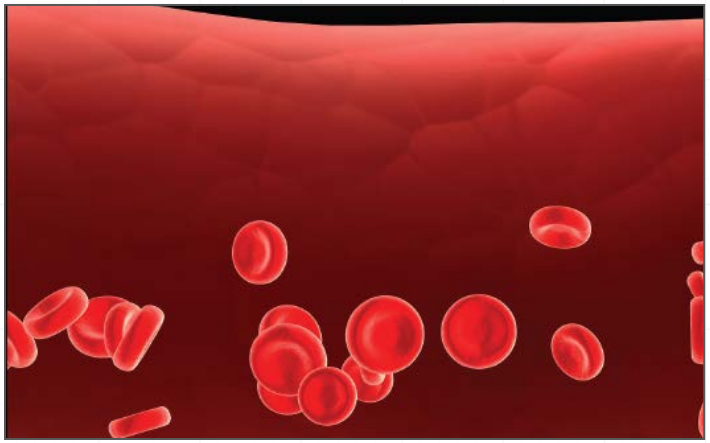
18. Vogt, J Vasc Surg 2002; This study did not use CryoLife tissue.
24. Brown KE, et al. J Vasc Surg 2009.

Additional Benefits

CryoArtery® | Aortoiliac Artery



- Natural Suturability[25]
- Compliance at the Anastomosis



- Natural Pulsatile Flow[26]

25. Martin R, et al. Ann Surg 1994.
26. Bia D, et al. Artif Organs 2007.

Arterial Allograft Configurations

CryoArtery® | Aortoiliac Artery

Allograft Type	Diameter	Length	Catalog #
Aortoiliac Artery 	Aorta: 8 mm – 15 mm*	6 cm – 11+ cm	R010
	Iliac: 4 mm – 5+ mm	4 cm – 11+ cm	
Descending Thoracic Artery 	8 mm – 15mm^	6 cm – 11+ cm	A020

*Diameter distends up to 39% at 120mmHg[20]
^Diameter distends up to 60% at 120mmHg[27]

20. CryoLife, Data on File.
27. Langerak, et al. Transpl Int 2001.

Extensions: Allograft Configurations

CryoVein® | Vascular Allograft CryoArtery® | Vascular Allograft

CryoVein®

Allograft Type	Diameter*	Length	Catalog #
Femoral Vein	6 mm – 15 mm	10 cm – 30+ cm	V060

CryoArtery®

Allograft Type	Diameter*	Length	Catalog #
Femoral Artery	4 mm – 5+ mm	10 cm – 30+ cm	R020

*DIAMETER: label changes as of June 15, 2015

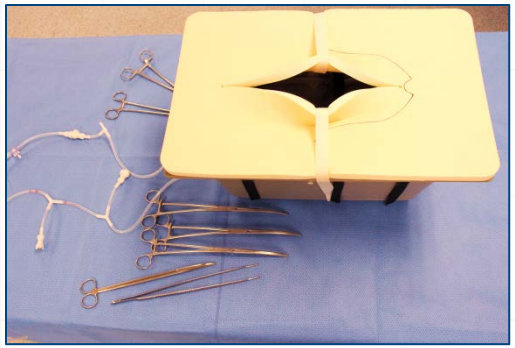
- Beginning Monday, June 15, 2015, the following CryoLife cryopreserved femoral allografts mentioned above have been packaged and labeled with only the outer diameter on the package label and Certificate of Assurance (Note: the internal diameter is not referenced).
- Prior to Monday, June 15, 2015, the 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.

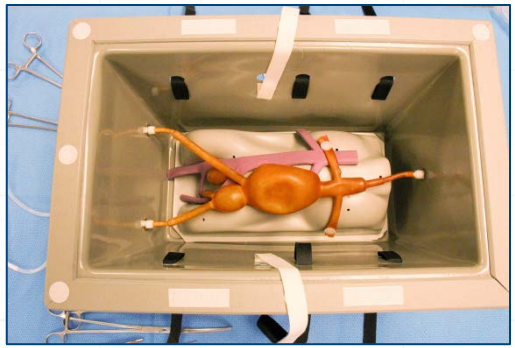
Wet Lab Resources

CryoArtery® | Aortoiliac Artery

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.

Learn more at www.CryoLife.com

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.

CryoLife®
Life Restoring Technologies®

ML1031.000 (07/2016)