



**The
Challenge**



**The
Solution**

CryoVein[®] | Saphenous
Vein

For Peripheral Bypass or Infection Overview



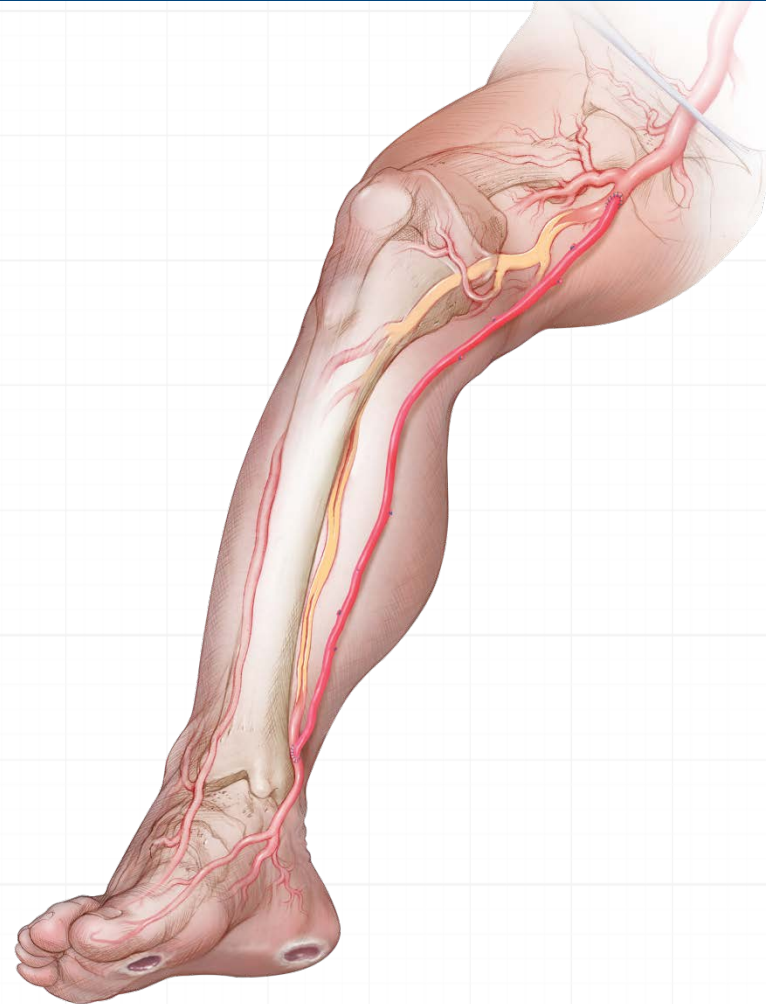
CryoLife[®]
Life Restoring Technologies[®]



Outline

CryoVein® | Saphenous Vein

- Indications for Use
- Underlying Need for CryoVein Saphenous Vein
- Target Patient
- The Challenge and Solution
- Clinical Benefits
- Other Considerations
- Configurations
- CryoLife Difference



Indications for Use

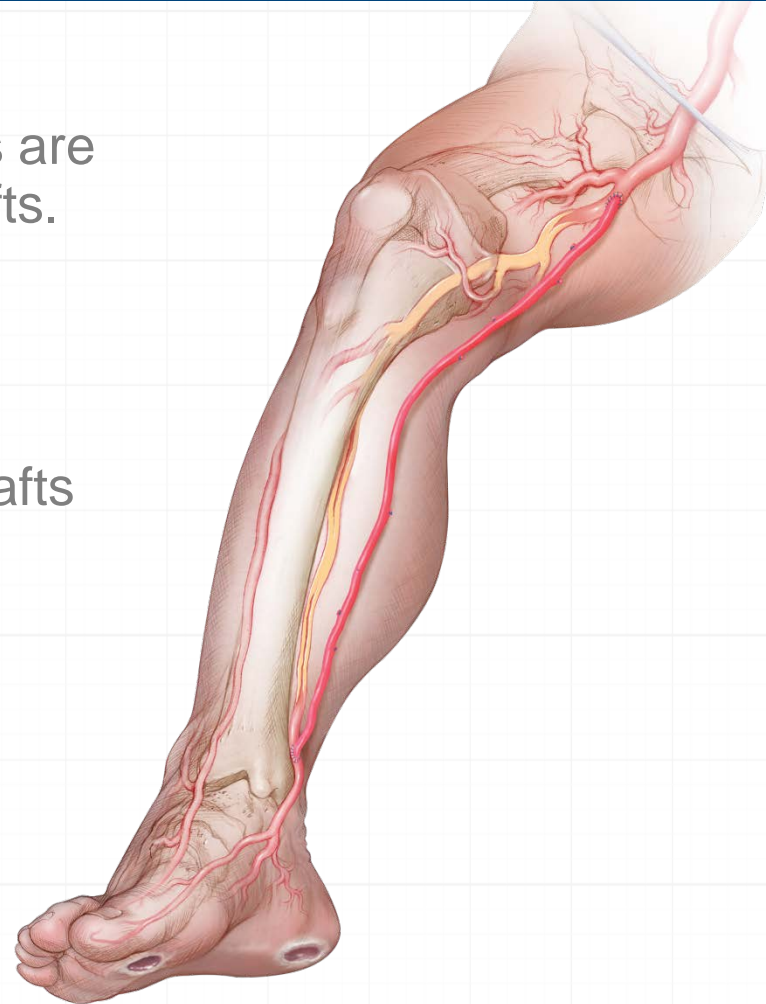
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Indications for Use

- Cryopreserved vascular allografts are indicated for use as vascular grafts.

Contraindications

- No contraindications for use of CryoVein Saphenous Vein Allografts are known.



Underlying Need for CryoVein

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Underlying Need for CryoVein Saphenous Vein¹

- Up to **30% patients** do not have suitable autologous tissue available for bypass¹

Reasons for Unsuitability¹

- Insufficient Quality:
 - Venous Disease
 - Diameter: <3mm
- Not Enough Length
 - Previous CABG, distal bypasses, etc.
 - Varicose vein ablation

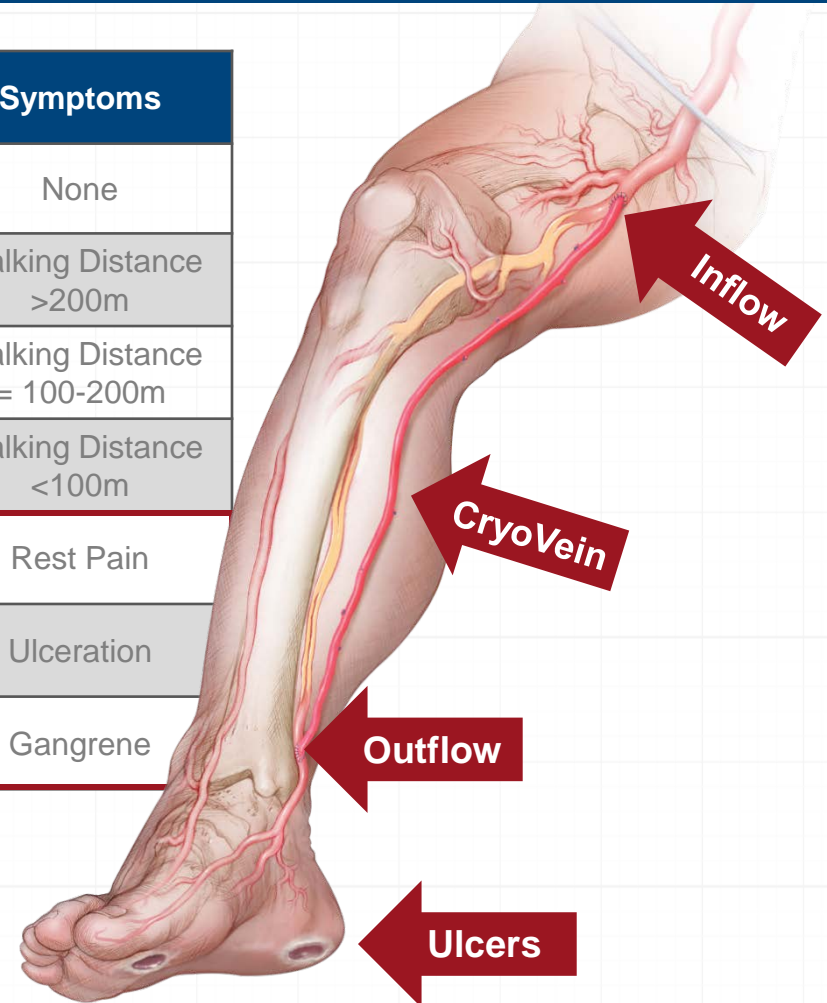


Autograft Vein Harvesting

Target Patient: Below the Knee and Critical Limb Ischemia⁹

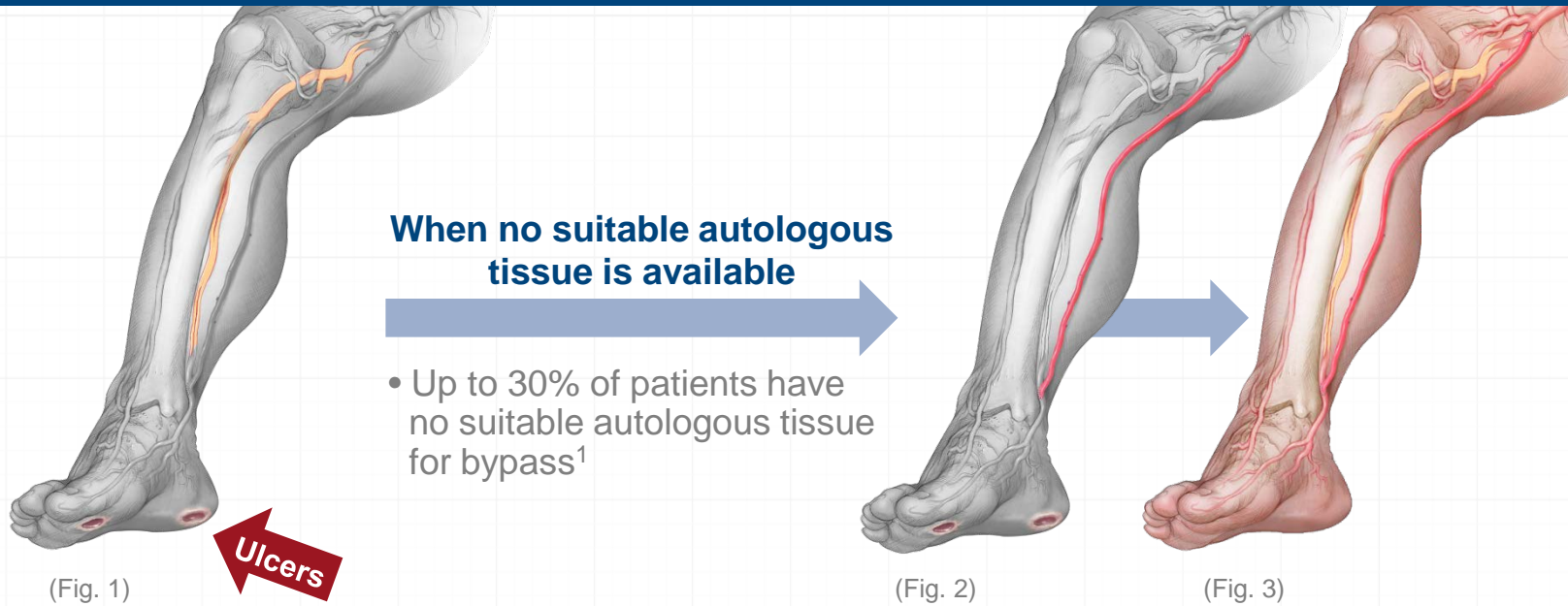
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Classification	Rutherford Category	Symptoms	
Asymptomatic	0	None	
Mild Claudication	1	Walking Distance >200m	
Moderate Claudication	2	Walking Distance = 100-200m	
Severe Claudication	3	Walking Distance <100m	
Critical Limb Ischemia (CLI)	Ischemic Rest Pain	4	Rest Pain
	Minor Tissue Loss	5	Ulceration
	Major Tissue Loss	6	Gangrene



The Challenge & The Solution

CryoVein[®] | Saphenous Vein



The Challenge

- Ulcers >2cm
- Critical limb ischemia (Fig. 1)

The Solution

- Revascularization of diseased limb (Fig. 2)
- The ulcers heal and the limb is saved (Fig. 3)

Clinical Benefits

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- Up to 87% primary patency at 1 year¹⁻⁵
- High limb salvage rates: up to 70% at 4 years^{2,3}
- Excellent resistance to infection⁶



Limb Salvage Rates for CLI Patients with BTK Bypass

Author	# of Patients	% with previous bypass(es)	1 Yr (%)	2 Yr (%)	3 Yr (%)	4 Yr (%)	5 Yr (%)
Randon, et al. ¹	92	62	85	77	70	NR	64
CryoLife Multicenter ²	381	59	73	72	70	70	NR
Martin, et al. ³	82	94	84	81	NR	62	NR
Farber, et al. ⁴	177	50	80	71	NR	NR	NR
Buckley, et al. ⁵	24	27	80	80	NR	NR	NR

1. Randon C, et al. J Vasc Surg 2010.
 2. CryoLife data on file (ML0041).
 3. Martin R, et al. Ann Surg 1994.
 4. Farber A, et al. J Vasc Surg 2003.
 5. Buckley C, et al. J Vasc Surg 2000.
 6. Fujitani R, et al. J Vasc Surg 1992.

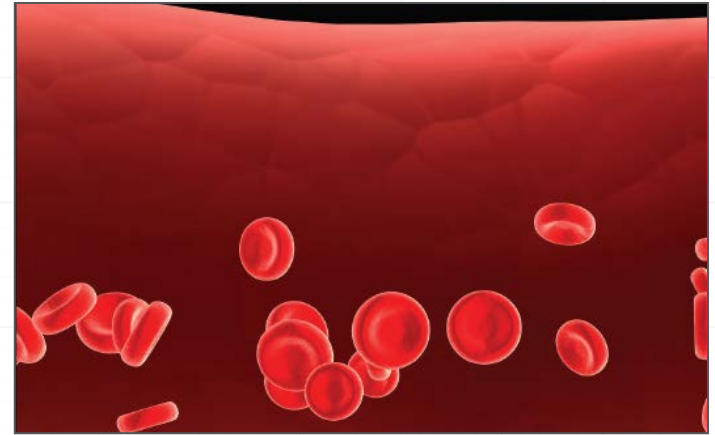
NR: Not Reported

Additional Benefits

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- Natural Suturability³
- Compliance at the Anastomosis



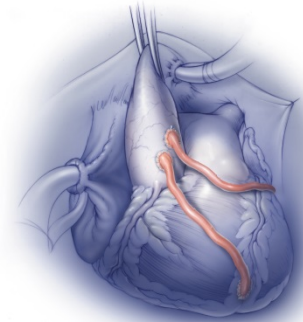
- Natural Pulsatile Flow⁸

Other Considerations: CABG

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An Ideal Choice When

- No suitable autologous tissue is available
- Redo CABG procedures



Clinical Outcomes^{7,10}

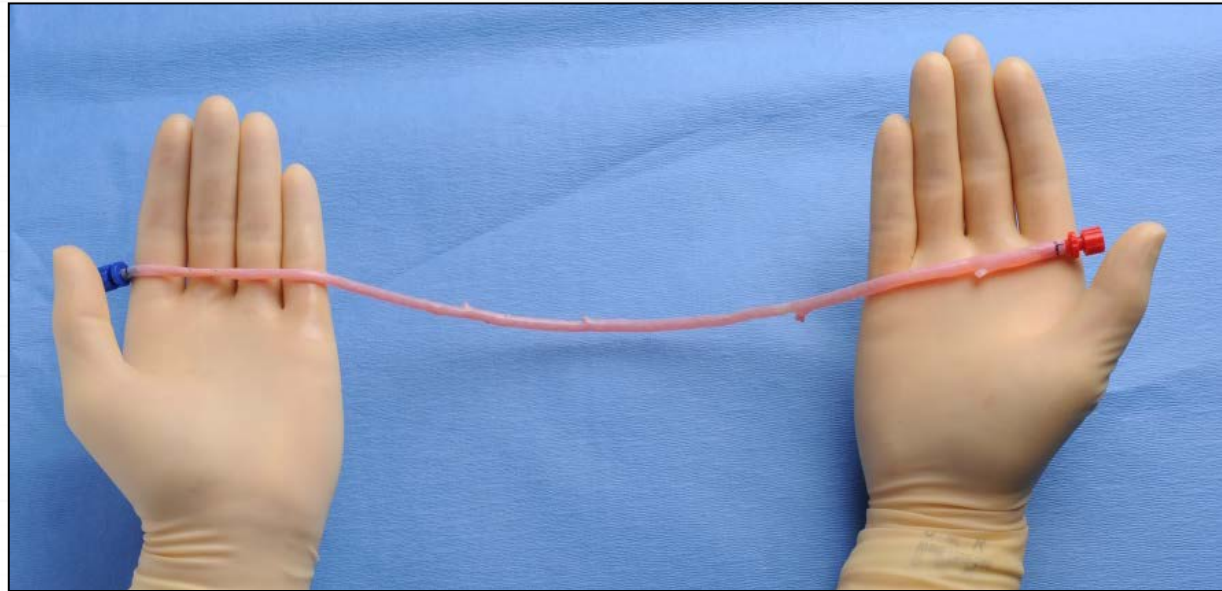
- **Laub, et al.** reports a 41% patency for follow-up between 2 and 16 months for a series of 14 patients with 17 CryoVein Saphenous Vein placed for CABG.
- **Saunders, et al.** reports 60% patency at a mean follow-up of 11.5 months in a subset of five patients with 10 reverse saphenous vein homografts.

Configurations

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Allograft Type	Diameter [^]	Length	Catalog #
Saphenous Vein	3 mm – 6 mm*	30 cm – 80+ cm*	V010

*Pressurized



[^]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, you 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.

The CryoLife Difference

CryoVein[®] | Saphenous
Vein

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 & cannulas (which does not harbor infection)
- Packaging: may be submerged in liquid nitrogen*
- CryoFreezers: available to hospitals for allograft storage
- AATB Accredited

**Learn more at
www.CryoLife.com**



CryoLife[®]
Life Restoring Technologies[®]