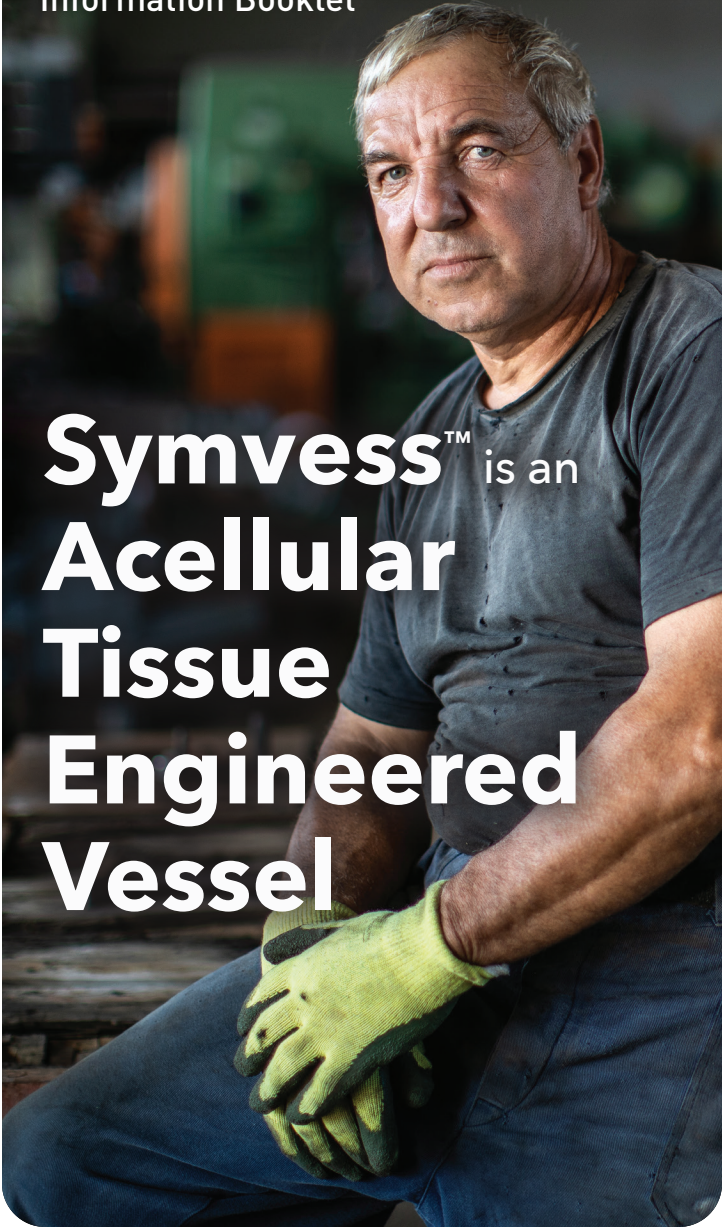


PATIENT AND CAREGIVER

Information Booklet



Symvess™ is an
**Acellular
Tissue
Engineered
Vessel**



acellular tissue engineered vessel-tyod
Symvess™

Introduction to this Guide

This guide is intended to provide you with general information about vascular trauma repair and the Symvess acellular tissue engineered vessel-tyod, which your doctor selected to treat your vascular trauma. Please consult your doctor for any questions you may have about your treatment.



About Your Arteries¹

Your arteries are tubular structures in the body that transport oxygen-rich blood from your heart to every part of your body including your legs and feet.

About Vascular Trauma²

The term “vascular trauma” applies to damage inflicted upon a blood vessel, be it an artery responsible for carrying blood to an extremity or organ, or a vein facilitating the return of blood to the heart. These injuries are classified based on the nature of the trauma incurred: either blunt or penetrating.

- A blunt injury may occur when a blood vessel is crushed or stretched.
- A penetrating injury may occur when a blood vessel is punctured, torn, or severed.

Regardless of the type, vascular trauma can cause bleeding or clot formation within the blood vessel (thrombosis), blocking blood flow to the affected organ or extremity, which could cause loss of the limb or death of the patient.

Treatment of Vascular Trauma²

Surgically repairing an injured blood vessel may include surgical reconstruction or a bypass. This procedure may require using a vein, typically from your lower thigh, a graft (synthetic or non-synthetic), or other types of vessels such as an acellular tissue engineered vessel (Symvess acellular tissue engineered vessel-tyod).

Symvess Description and Indication

Symvess is like a clean, germ-free tube made from materials found in human blood vessels, but without the cells so it does not cause rejection.^{3,4,5}

Symvess is a non-cellular vessel that is tissue engineered and used for repair of an artery, in an extremity after a trauma, when using a patient's own vein is not possible.



PHOTO OF SYMVESS BEING HELD

After Your Vascular Trauma Repair Procedure

Follow your doctor's recommendations for resuming your daily activities.

Important things to keep in mind:

Medications³: You may be prescribed medications to prevent blood clots such as aspirin and/or clopidogrel. Take these as directed by your doctor.

Identification Card: You will receive a Symvess identification card that states that you were implanted with Symvess for vascular replacement or reconstruction due to vascular trauma and that Symvess does not contain ferromagnetic material.

The card also shows the date of your operation, the physician's and hospital's name and phone number, the length and location where Symvess was implanted in your body. You should store the card in a safe place with your medical records and be sure to share the information on the card with your doctor(s). If you have not received an identification card, inform your doctor.

Symvess™ ID Card

The carrier of this card was implanted with Symvess for vascular replacement or reconstruction. The vessel does not contain ferromagnetic material.

**AFFIX PRODUCT IDENTIFICATION
STICKER HERE**

Product Name:
Symvess
acellular tissue engineered vessel-tyod,
6mm x 42cm (40cm usable length)

Patient Name: _____

Implant Date: _____

Physician Name: _____

Hospital Name, City, State: _____

Hospital Telephone: _____

 acellular tissue engineered vessel-tyod
Symvess™

Symvess ID Card

Procedure: ☐ Arterial Bypass ☐ Interposition Implantation
☐ Other _____

Location (check all that apply):

☐ Upper Extremity	☐ Lower Extremity
☐ Brachial Artery (☐ Right ☐ Left)	☐ Popliteal Artery (☐ Right ☐ Left)
☐ Axillary Artery (☐ Right ☐ Left)	☐ Superficial Femoral Artery (☐ Right ☐ Left)
☐ Radial Artery (☐ Right ☐ Left)	☐ Common Femoral Artery (☐ Right ☐ Left)
☐ Ulnar Artery (☐ Right ☐ Left)	☐ Posterior Tibial Artery (☐ Right ☐ Left)

☐ Multiple Repair Sites: _____

☐ Other _____

Symvess Length Implanted:
☐ Full 40cm ☐ Shortened to: _____cm Implanted

☐ Other _____

 acellular tissue engineered vessel-tyod
Symvess™

For medical questions:
1-833-591-0081 or
customer@humacyte.com

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Clinical Studies³

Clinical trials demonstrated Symvess to be effective. The clinical trials studied vascular trauma patients, similar to you, who received Symvess for vascular replacement or reconstruction due to life- or limb-threatening trauma of the extremities. A total of 70 patients were studied at 22 sites in the United States, Israel, and Ukraine.

The Symvess clinical data showed that Symvess had a high rate of staying open to allow blood flow (patency) and low rates of infection and amputations.

INDICATION AND IMPORTANT SAFETY INFORMATION

WHAT IS SYMVESS?

SYMVESS is a tissue engineered vessel that is used for urgent repair of traumatic injury to an artery to avoid imminent limb loss and when using a patient's own vein is not feasible.

WHEN SHOULD SYMVESS NOT BE USED?

IMPORTANT WARNING: Loss of SYMVESS integrity due to mid-graft rupture or failure of the connection point (sutures) where the vessel is sewn into the body can result in life threatening bleeding.

SYMVESS should not be used in patients who cannot use certain long-term blood thinners called antiplatelet therapy (such as aspirin or clopidogrel) after their sudden injuries have resolved.

WHAT IS THE MOST IMPORTANT INFORMATION I SHOULD KNOW ABOUT SYMVESS?

- Some patients have experienced a break in their vascular graft, which can cause dangerous bleeding. This bleeding can be life-threatening, so it's important to get emergency medical help if you notice any signs like bleeding, pain, or swelling in your arm or leg, or if your limb starts feeling unusually cold or pale.
- Some patients have had issues with failure of the connection point (sutures) where the vessel is sewn into the body. If you experience bleeding, swelling, increased pain at the surgery site, or notice changes in the color of your skin around the area, seek emergency help right away.
- Some patients treated with SYMVESS have developed blood clots. If you have SYMVESS implanted, it is recommended you take medication that helps decrease the risk of blood clots. Talk to your surgeon or doctor about using any blood thinners before you start taking them.
- SYMVESS is made from cells and materials that could potentially carry infections or diseases. Although tested and no infections that can be spread from person to person were reported during clinical testing, the risk of transmitting infectious diseases or agents is not eliminated.



WHAT ARE THE MOST COMMON SIDE EFFECTS OF SYMVESS?

The most common side effects seen in patients receiving SYMVESS were thrombosis (blood clots), fever, pain, narrowing of the vessel at the surgical connection point, rupture or failure of the connection point (sutures) where the vessel is sewn into the body, and infection.

Possible Risks of Surgical Repair of Vascular Trauma³

The same medical/surgical conditions or complications that apply to any surgical procedure may occur during or following implantation. Please consult your doctor for any questions you may have about your treatment.

- The risk of infection is similar to any other surgical procedure. Contact your doctor immediately if you develop any symptoms suggestive of infection.
- If you were prescribed antiplatelet medications (aspirin and/or clopidogrel) to prevent blood clots, notify your doctor.

If you have any questions or feel anything abnormal, please contact your doctor.

**PLEASE SEE ACCOMPANYING
FULL PRESCRIBING INFORMATION,
INCLUDING BOXED WARNING.**

REFERENCES: 1. <https://www.webmd.com/heart/difference-between-arteries-and-veins> Accessed 06MAY2024. 2. <https://vascular.org/patients-and-referring-physicians/conditions/vascular-trauma> Accessed 06MAY2024. 3. Symvess U.S. Prescribing Information. Durham, NC. Humacyte Global, Inc. 4. Kirkton RD, et al. Bioengineered human acellular vessels recellularize and evolve into living blood vessels after human implantation. *Sci Transl Med*. 2019;11(485):eaau6934. 5. Moore EE, et al. Bioengineered Human Arteries for the Repair of Vascular Injuries. *JAMA Surg*. 2024 Nov 20:e244893.

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