STORAGE AND HANDLING GUIDE

acellular tissue engineered vessel-tyod Symvess™

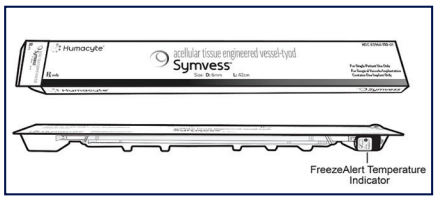
IMPORTANT NOTE This guide summarizes the How Supplied/Storage and Handling section of the U.S. Prescribing Information for Symvess. It is not medical advice. Always consult the full U.S. Prescribing Information for the most accurate, up-to-date information regarding Symvess.

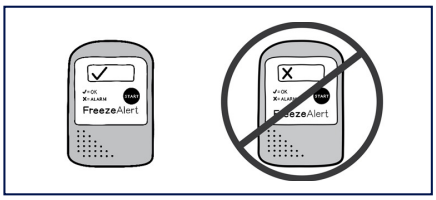
ABOUT SYMVESS PACKAGING[1]

- Symvess is for single patient use only and is supplied in a sealed sterile packaging bag. The packaging bag is contained within a plastic thermoformed tray sealed with a Tyvek®‡ lid, the contents of which are sterile. The sealed plastic thermoformed tray (NDC 83564-110-00) is contained within a non-sterile carton (NDC 83564-110-01).
- Symvess is fixed inside the packaging bag between the endcaps with a supporting silicone tube and is immersed in sterile phosphate buffered saline solution. Symvess, the saline solution, and the outer surface of the packaging bag are sterile.
- Symvess is shipped in an insulated shipping box (between 2° C to 8° C).

STORING & HANDLING SYMVESS[1]

- Store Symvess between 2° C to 8° C (36° F to 46° F). Do not freeze.
- Use Symvess prior to the expiration date printed on the carton.





A FreezeAlert™‡ temperature indicator is attached to the exterior of each thermoformed tray. Prior to preparing Symvess for a procedure, check the FreezeAlert™‡ indicator. A check mark indicates Symvess has not been exposed to freezing temperatures and can be used. **An "X" displayed on the indicator signifies that Symvess has been exposed to freezing temperatures and should NOT be used.**

DO NOT use Symvess

- if expired
- if the carton has been damaged
- if the Tyvek®‡ lid is punctured or detached
- if the thermoformed tray is punctured or compromised
- if there is evidence of fluid leakage from the packaging bag
- if the FreezeAlert™‡ temperature indicator has an "X"

Dispose of unused Symvess and packaging bag using established clinical facility procedures in accordance with local regulatory requirements.

INDICATION

SYMVESS is an acellular tissue engineered vessel indicated for use in adults as a vascular conduit for extremity arterial injury when urgent revascularization is needed to avoid imminent limb loss, and autologous vein graft is not feasible.

IMPORTANT SAFETY INFORMATION

BOXED WARNING: GRAFT FAILURE

- Loss of SYMVESS integrity due to mid-graft rupture or anastomotic failure can result in life threatening hemorrhage.

PLEASE SEE ACCOMPANYING FULL PRESCRIBING INFORMATION, INCLUDING BOXED WARNING

IMPORTANT SAFETY INFORMATION (CONT'D)

CONTRAINDICATIONS

DO NOT use SYMVESS in patients who have a medical condition that would preclude long-term antiplatelet therapy (such as aspirin or clopidogrel) after resolution of acute injuries.

WARNINGS & PRECAUTIONS

- **Graft Rupture:** Vascular graft rupture has occurred in patients treated with SYMVESS. Advise patients that arterial bleeding can be life-threatening and to seek emergent medical evaluation for any signs or symptoms of graft rupture such as bleeding, pain and swelling in the extremity, or signs of extremity ischemia. Follow appropriate procedures for handling and administering SYMVESS.
- **Anastomotic Failure:** Anastomotic failure has occurred in patients treated with SYMVESS. In clinical studies of SYMVESS, anastomotic failure occurred within the first 36 days post-implantation. Monitor patients for signs of anastomotic failure such as pain and swelling at the surgical site, decreasing hemoglobin or other signs and symptoms of bleeding. Advise patients to seek urgent medical evaluation if they have any signs or symptoms that may be indicative of anastomotic failure such as bleeding, swelling or worsening pain at the surgical site or changes in color of overlying skin. Follow appropriate procedures for handling and administering SYMVESS.
- **Thrombosis:** Thrombosis has occurred in patients treated with SYMVESS. In clinical trials of SYMVESS, patients received antiplatelet therapy following implantation of SYMVESS to reduce the risk of thrombosis. The risk of thrombosis may increase in patients who discontinue antiplatelet therapy. Anti-platelet therapy is recommended following treatment with SYMVESS.
- **Transmission of Infectious Diseases:** SYMVESS is manufactured using cells and reagents that may transmit infectious diseases or infectious agents. The cells used in the manufacture of SYMVESS are derived from a donor who met the donor eligibility requirements for transmissible infectious diseases. Animal-derived reagents are tested for animal viruses, bacteria, fungi, and mycoplasma before use, but this does not eliminate the risk of transmitting these or other transmissible infectious diseases and disease agents. No transmissible agent infections have been reported during clinical testing.

ADVERSE REACTIONS

The most common adverse reactions (≥3%) were thrombosis, fever, pain, anastomotic stenosis, rupture or anastomotic failure, and infection.

USE IN SPECIFIC POPULATIONS

Pediatric Use: The safety and effectiveness of SYMVESS in pediatric patients (0 to 17 years old) have not been established.

Geriatric Use: Two patients out of the 54 Extremity Group implanted with SYMVESS as a conduit in Study 1 were aged ≥65 years. The number of patients aged ≥65 years was not sufficient to determine whether they responded differently than younger patients to SYMVESS.

PLEASE SEE ACCOMPANYING FULL PRESCRIBING INFORMATION, INCLUDING BOXED WARNING.

REFERENCE: 1. Symvess U.S. Prescribing Information. Durham, NC: Humacyte Global, Inc.

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Humacyte®