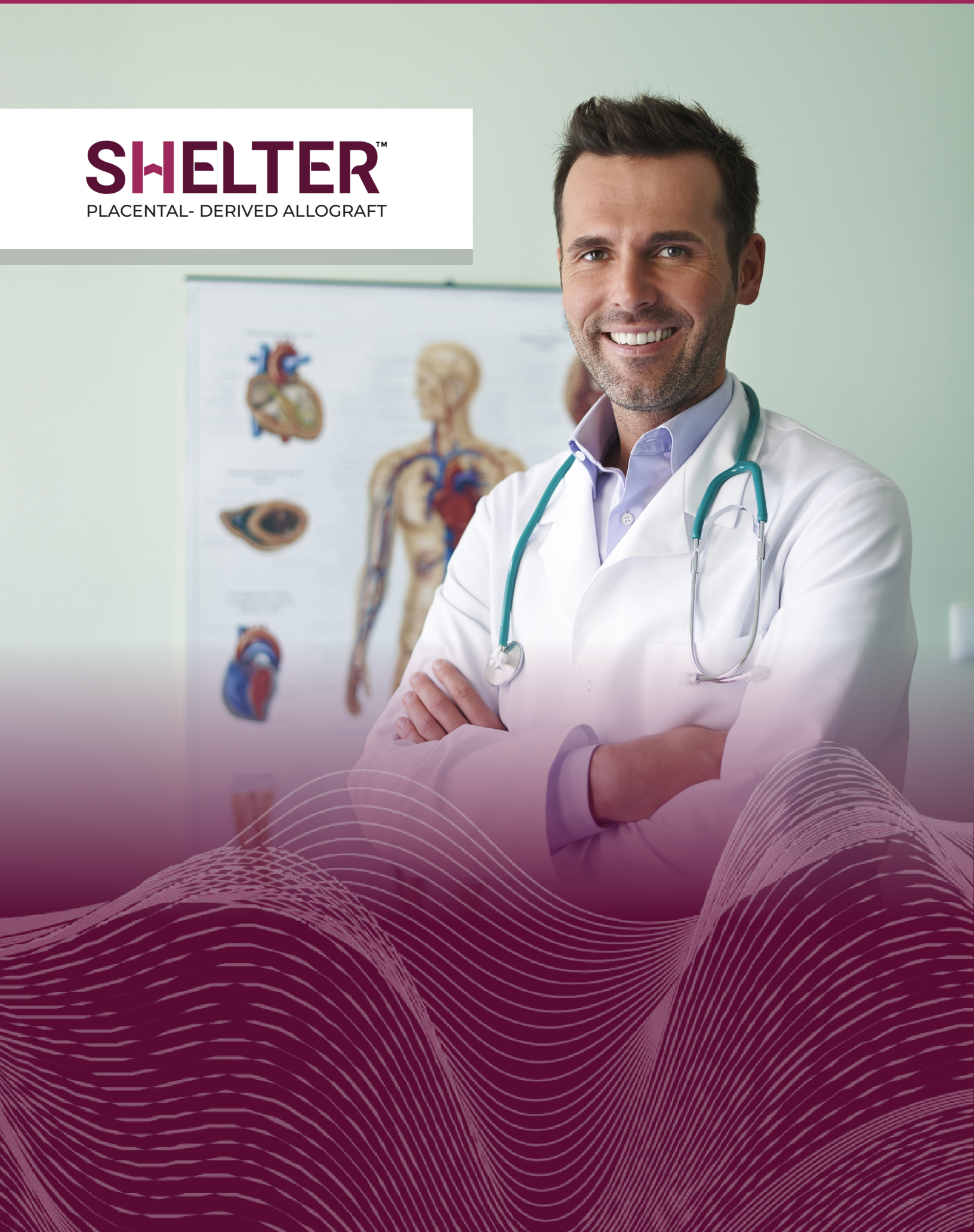
SHELTER™

PLACENTAL- DERIVED ALLOGRAFT



SHELTER™

Shelter™ Placental-Derived Allograft is comprised of the amniotic and chorionic membranes of the placenta. This product is designed as an innovative solution to serve as a barrier or wound cover for acute and chronic wounds. Leveraging the structural and biochemical properties of placental tissue, Shelter™ offers a comprehensive biologic approach for a variety of acute or chronic wound applications.

PLACENTAL TISSUE

Placental tissue, previously considered biologic waste following delivery, is a pristine newly formed extracellular matrix (ECM) to protect and support fetal development. Therefore, this tissue represents an untainted extracellular matrix...essentially a neomatrix.

DESCRIPTIONS OF LAYERS

Broadly, placental tissue includes an internal or fetus facing amnion and an external or maternal facing chorion. The physical and biochemical properties of the two primary membranes are subtly different owing to the position they occupy in the placenta. The amnion is a thinner yet more compact layer of extracellular matrix while the chorion is a slightly thicker but less compact matrix. Both layers are constituted of collagen fibers (predominantly Types I, III, IV and V), along with other ECM proteins (including laminin, fibronectin, proteoglycans and hyaluronic acid).

SAFETY

Donated tissues for Shelter™ products are collected from fully consented mothers undergoing full term c-sections. Each donor is screened according to the strict standards required by the U.S. Food and Drug Administration and the American Association of Tissue Banks. Further, Shelter™ Placental-Derived Allograft products undergo a validated terminal sterilization process to help ensure these products are safe. All donated tissue is obtained in partnership with FDA regulated and accredited recovery organizations. Additional details of screening procedures can be found in the product package insert or Instructions for Use.

PRODUCT SUMMARY

Shelter™ Placental-Derived Allograft products are minimally manipulated and dehydrated and are derived from human amniotic and chorionic membrane. Shelter™ allograft tissues retain the structural and functional characteristics of the starting placental membranes.
The final products are packaged in different sizes and verified to be terminally sterilized to a 10^{-6} SAL.

INSTRUCTION FOR USE

Shelter™ Placental-Derived Allograft (361 HCT/Ps) are intended as a natural biologic wound covering or skin substitute for cutaneous wounds. Use of Shelter™ Placental-Derived Allograft by qualified health care professionals is for application in a physician office, outpatient, or inpatient setting.

ORDERING INFORMATION

Shelter™ tissue is available in the following sizes for a variety of choices depending on the patient and circumstance:
Product HCPCS Level II code Q4346, Shelter™ Matrix, per square centimeter.

Product SKU	Size
SHE-26222	2 X 2 cm
SHE-26224	2 X 4 cm
SHE-26244	4 X 4 cm
SHE-26248	4 X 8 cm

REFERENCES:

1. H. Niknejad, H. Peirovi, M Jorjani, et al, “Properties of the Amniotic Membrane for Potential Use in Tissue Engineering”, Eur Cell Mater, vol. 15, pp 88-99, 2008.
2. A. Roy, M. Mantay, C. Brannan, and S. Griffiths, “Placental Tissues as Biomaterials in Regenerative Medicine” BioMed Research International, vol. 2022, pp. 1-26, 2022.

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