

SimpliMax

Amniotic Membrane Allograft



✉ accounts@alercebiologix.com

ALLOGRAFT MEMBRANES

We Are Pioneering A New Era In Regenerative Medicine,
Leveraging The Potential Of Human Biology To Revolutionize
Healing And Recovery Worldwide.

Why Amniotic Membrane?

Human amniotic membrane forms the innermost layer of placenta tissue.

The avascular membrane acts as a protective barrier for the developing fetus. Its properties provide a wide variety of potential benefits in regenerative medicine.

Protective Covering

The membrane sheet provides a protective covering that may aid in wound management

Immunogenicity

The amniotic membrane has unique non-immunological properties

Scaffold

The extracellular matrix acts as a scaffolding and potentiates the migration and adhesion of resident cells

Growth Factors

Natural cytokines in the membrane

Why SimpliMax?

SimpliMax is intended for the repair, reconstruction, replacement, or supplementation of a patient's injured tissue.

Benefits of SimpliMax:

- Placental tissue allograft composed of dual layer amnion
- Non-side specific orientation for application
- Thicker membrane for deep wounds or exposed anatomy that can be easily positioned or repositioned for improved conformity
- Enhanced tensile strength, adheres well, and easy to apply
- Can be used in a hydrated or dehydrated state
- Retains important major structural proteins and ECM biochemicals that are naturally present in placental tissue

What is SimpliMax?

SimpliMax is a dehydrated, dual-layer amnion membrane allograft. The allograft is derived from human placental membrane collected from a consenting donor and processed aseptically. It is terminally sterilized to achieve a sterility assurance level (SAL) of 1×10^{-6} utilizing gamma irradiation. SimpliMax is packaged as a sterile product in sealed, single-use pouches. SimpliMax is processed in compliance with all current Good Tissue Practices as mandated by the United States Food and Drug Administration and the American Association of Tissue Banks.

Only tissues from donors meeting the prescribed criteria are processed for manufacturing of SimpliMax

Infectious Disease Screened In Blood Specimens Of Donor

| | | |
|-------------------------------------|-------------|-------------|
| • HIV-1/2 antibody | • HTLV I/II | • Malaria |
| • Hepatitis B surface antigen | • HIV (NAT) | • Syphilis |
| • Hepatitis B core antibody (Total) | • HBV (NAT) | • WNV (NAT) |
| • Hepatitis C antibody | • HCV (NAT) | |

Known Presence Of Growth Factors & Cytokines In The Extracellular Matrix Of Human Placental Tissue And Their Functions:

| Growth Factors and Cytokines | Native Function | SimpliMax |
|------------------------------|-------------------|-----------------------------------|
| IL-1ra, IL-4, IL-6, IL-10 | Anti-Inflammatory | ✓ |
| VEGF | Angiogenic | ✓ |
| bFGF | | ✓ |
| TGF-Beta | | ✓ |
| PDGF | | ✓ |
| EGF | | ✓ |
| IGF-1 | | Cell Proliferation and remodeling |
| KGF | ✓ | |
| MIP | Anti-Bacterial | ✓ |

Potential SimpliMax Applications

- + Podiatry/Vascular
- + Wound Management
- + Orthopaedic Surgery
- + Other Surgical Scenarios

Potential SimpliMax Benefits

- + Flexible
- + Protective Covering
- + Non-Steroidal
- + All-Natural

Ordering Information

| Reference Number | Dimension | UPC |
|------------------|-----------|--------------|
| SMAX AA 0202 | 2cmx2cm | 860013115500 |
| SMAX AA 0203 | 2cmx3cm | 860013115517 |
| SMAX AA 0404 | 4cmx4cm | 860013115524 |
| SMAX AA 0406 | 4cmx6cm | 860013115531 |
| SMAX AA 0408 | 4cmx8cm | 860013115548 |
| SMAX AA 1010 | 10cmx10cm | 860013115555 |
| SMAX AA 2024 | 20cmx24cm | 860013115562 |

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