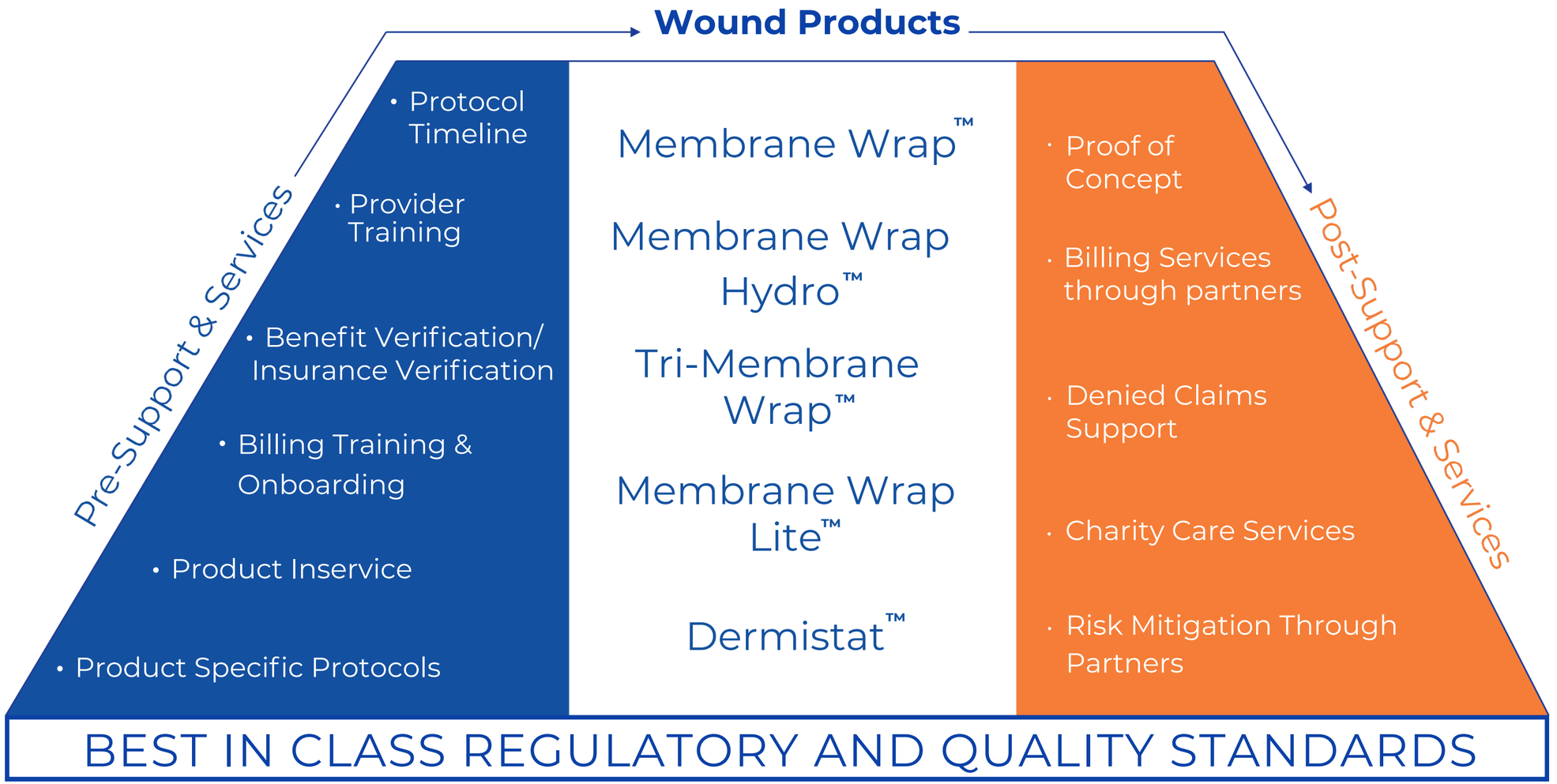
BIOLAB HOLDINGS

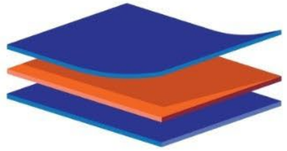
WOUND CARE PORTFOLIO



BEST IN CLASS REGULATORY AND QUALITY STANDARDS

WIN for the Patient, ***WIN*** for the Provider, ***WIN*** for the Payer

Wound Product Matrix

Product	Image	Indications
Membrane Wrap™		• Dehydrated • Dual Layer Amnion • ASP listed • Use in multiple types of wounds • Q-code 4205
Membrane Wrap Hydro™		• Hydrated in saline • ASP listed • More malleable for irregular shaped wounds • Conforms well in Irregular wound beds and wound tunnels • Extra Saline for hydration of dry wounds • Q-code 4290
Tri-Membrane Wrap™		• Dehydrated • Improved tensile strength • Tolerates gentle suturing as needed • Best for difficult location of wounds • More membrane for deeper wounds • Amnion/Chorion/Amnion • Q-code pending
Membrane Wrap Lite™		• Dehydrated • Single Layer Amnion • Use in multiple types of wounds • Q-code 4373
Dermistat™		• 510K device • Contours to the wound • Multiple formats for graft delivery • No donor biopsy needed • Game changer for LCD's in the future • Pending FDA approval & not commercially available in US.

BIOLAB HOLDINGS

Q4205

MEMBRANE WRAP™

DUAL-LAYER AMNIOTIC ALLOGRAFT MEMBRANE

BIOLAB HOLDINGS

Q4205

MEMBRANE WRAP™

DUAL-LAYER AMNIOTIC ALLOGRAFT MEMBRANE

BioLab Membrane Wrap™ is a dual-layer amnion-amnion human tissue allograft derived from the amniotic membrane that serves as a barrier and provides protective covering for the wound. It is minimally manipulated, preserving the properties exhibited in its natural state*, remaining compliant with FDA Regulations.

READILY AVAILABLE

EASY APPLICATION

5-YEAR SHELF LIFE

FDA COMPLIANT

Membrane Wrap Size (cm)	SKU	Wound Coverage
1x1	MW0101	1 cm^2
2x2	MW0202	4 cm^2
2x3	MW0203	6 cm^2
4x4	MW0404	16 cm^2
4x6	MW0406	24 cm^2
4x8	MW0408	32 cm^2
6x8	MW0608	48 cm^2
10x10	MW1010	100 cm^2

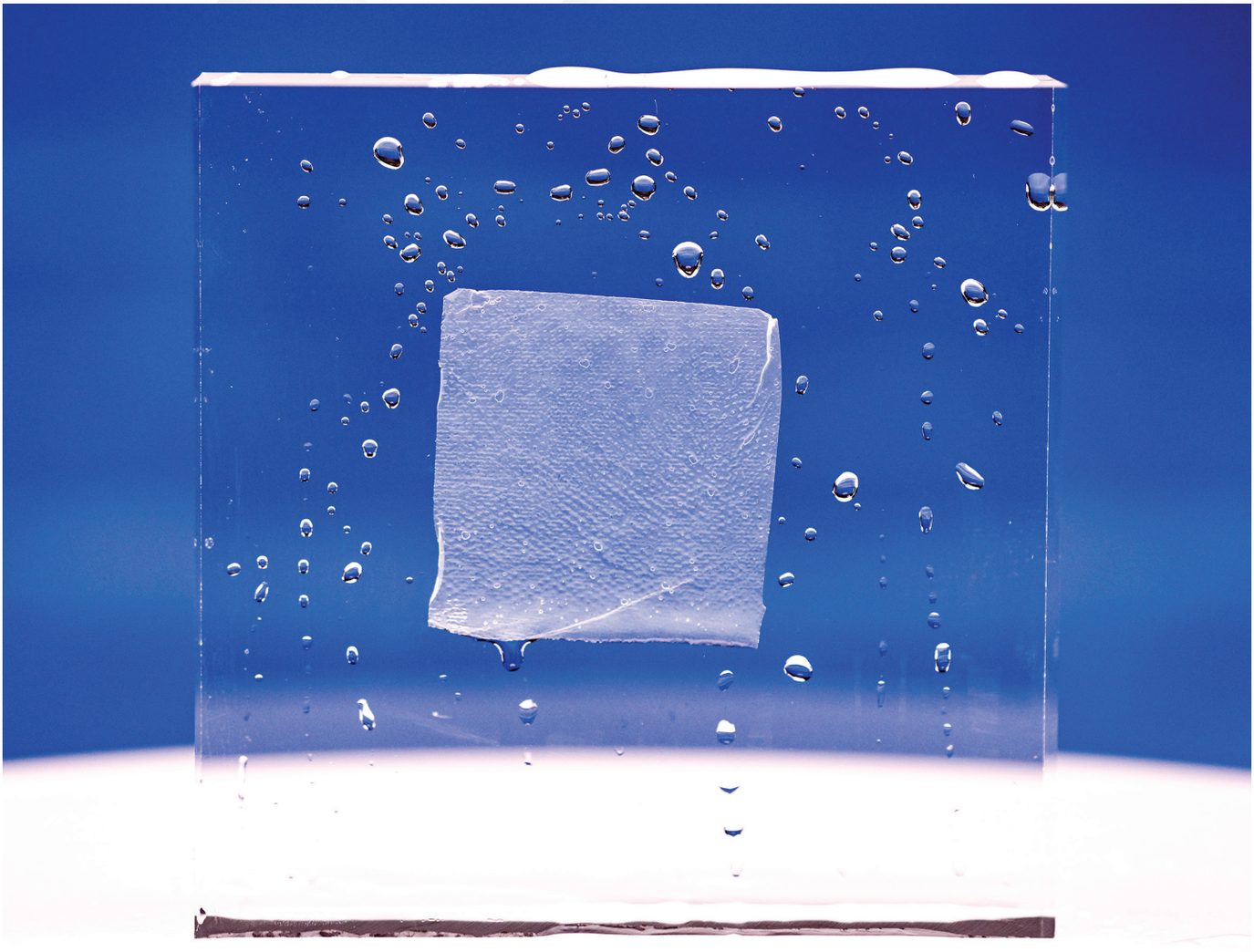
*All BioLab Holdings Membrane Wrap™ allograft tissue products have been tested for potentially infectious diseases and terminally sterilized to ensure the safety of each membrane.

BIOLAB HOLDINGS

Q4290

MEMBRANE WRAP - HYDRO™

HYDRATED DUAL-LAYER AMNIOTIC ALLOGRAFT MEMBRANE



BIOLAB HOLDINGS

Q4290

MEMBRANE WRAP - HYDRO™

HYDRATED DUAL-LAYER AMNIOTIC ALLOGRAFT MEMBRANE

BioLab Membrane Wrap - Hydro™ is a pre-hydrated dual-layer human tissue allograft derived from the amniotic membrane that serves as a barrier and provides protective covering for the wound.
It is minimally manipulated, preserving the properties exhibited in its natural state*, while remaining compliant with FDA Regulations.

CONFORMS TO WOUND

READILY AVAILABLE

2-YEAR SHELF LIFE

FDA COMPLIANT

Membrane Wrap Hydro Size (cm)	SKU	Wound Coverage
2x2	HM0202	4 cm^2
2x3	HM0203	6 cm^2
4x4	HM0404	16 cm^2
4x6	HM0406	24 cm^2
4x8	HM0408	32 cm^2
6x8	HM0608	48 cm^2
10x10	HM1010	100 cm^2

*All BioLab Holdings Membrane Wrap - Hydro™ allograft tissue products have been tested for potentially infectious diseases and terminally sterilized to ensure the safety of each membrane.

BIOLAB HOLDINGS

Q4344

TRI-MEMBRANE WRAP™

TRIPLE-LAYER AMNIOTIC ALLOGRAFT MEMBRANE

BIOLAB HOLDINGS

Q4344

TRI-MEMBRANE WRAP™

TRIPLE-LAYER AMNIOTIC ALLOGRAFT MEMBRANE

BioLab Tri-Membrane Wrap™ is a triple-layer amnion-chorion-amnion human tissue allograft derived from the amniotic membrane that serves as a barrier and provides protective covering for the wound. It is minimally manipulated, preserving the properties exhibited in its natural state*, while remaining compliant with FDA Regulations.

READILY AVAILABLE

EASY APPLICATION

2-YEAR SHELF LIFE

FDA COMPLIANT

Tri-Membrane Wrap Size (cm)	SKU	Wound Coverage
2x2	TM0202	4 cm^2
2x3	TM0203	6 cm^2
4x4	TM0404	16 cm^2
4x6	TM0406	24 cm^2
4x8	TM0408	32 cm^2
6x8	TM0608	48 cm^2
10x10	TM1010	100 cm^2

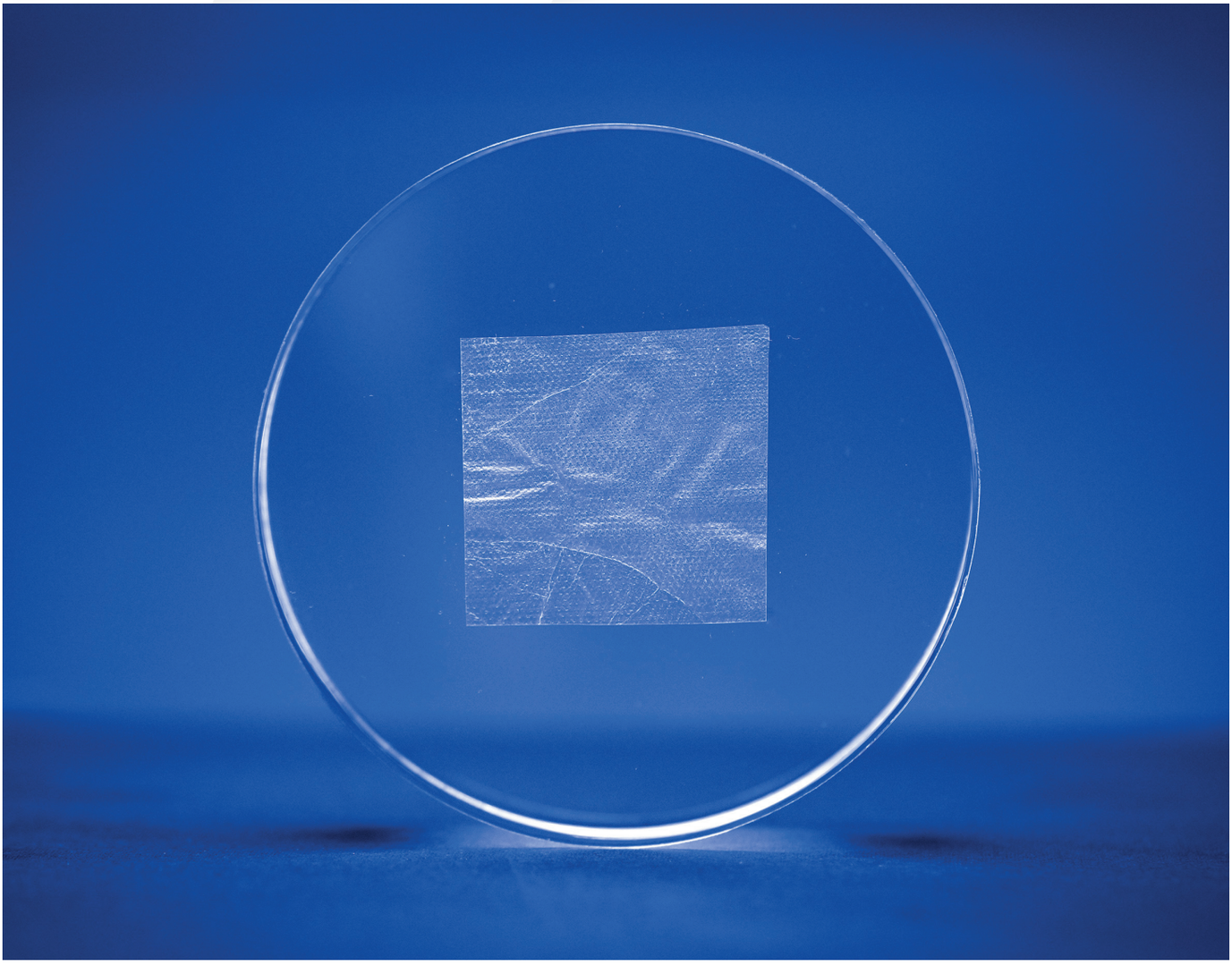
*All BioLab Holdings Tri-Membrane Wrap™ allograft tissue products have been tested for potentially infectious diseases and terminally sterilized to ensure the safety of each membrane.

BIOLAB HOLDINGS

Q4373

MEMBRANE WRAP - LITE™

SINGLE-LAYER AMNIOTIC ALLOGRAFT MEMBRANE



BIOLAB HOLDINGS

Q4373

MEMBRANE WRAP - LITE™

SINGLE-LAYER AMNIOTIC ALLOGRAFT MEMBRANE

BioLab Membrane Wrap - Lite™ is a single-layer amnion human tissue allograft derived from the amniotic membrane that serves as a barrier and provides protective covering for the wound. It is minimally manipulated, preserving the properties exhibited in its natural state*, while remaining compliant with FDA Regulations.

READILY AVAILABLE

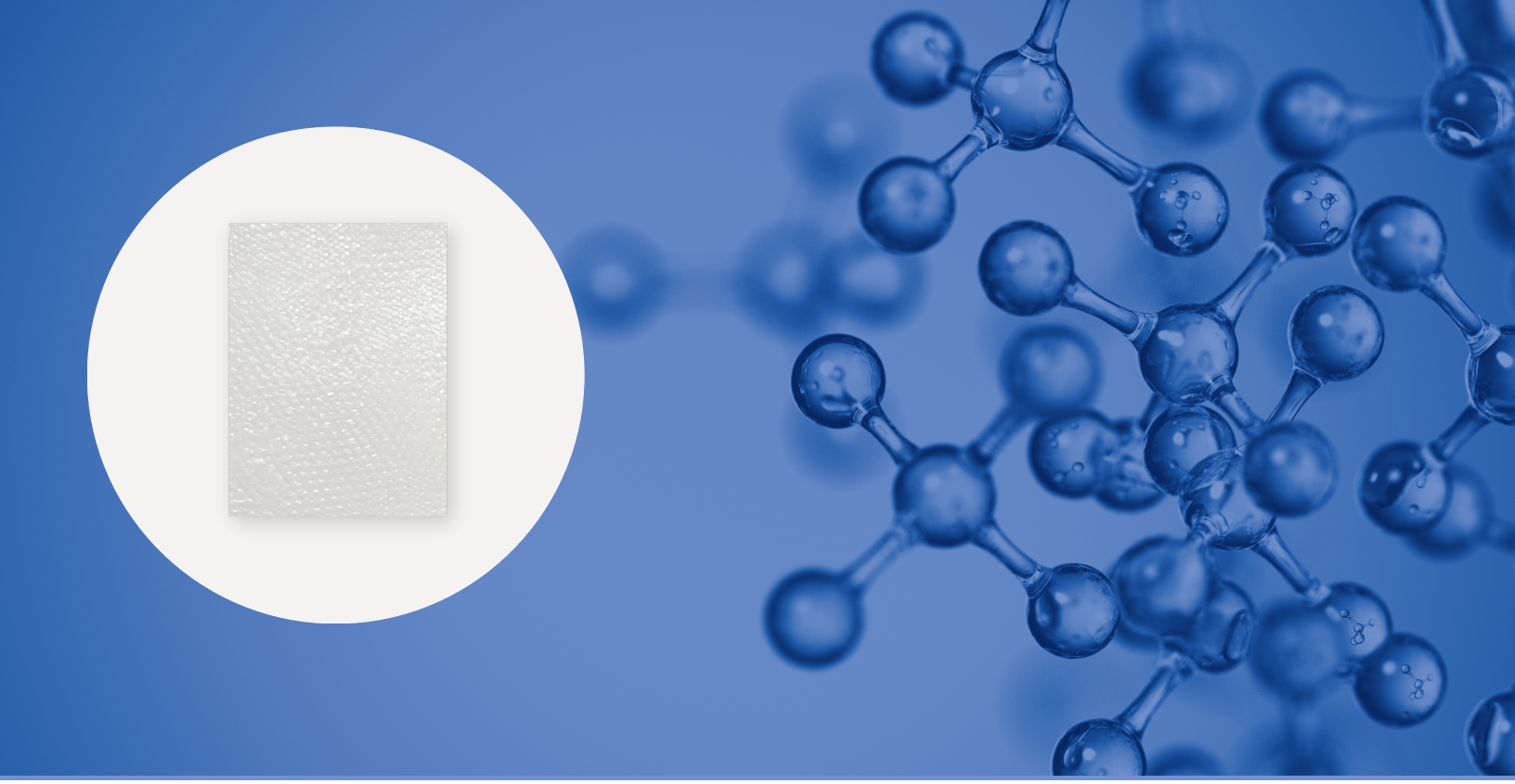
EASY APPLICATION

2-YEAR SHELF LIFE

FDA COMPLIANT

Membrane Wrap LITE Size (cm)	SKU	Wound Coverage
2x2	ML0202	4 cm^2
2x3	ML0203	6 cm^2
4x4	ML0404	16 cm^2
4x6	ML0406	24 cm^2
4x8	ML0408	32 cm^2
6x8	ML0608	48 cm^2
10x10	ML1010	100 cm^2

*All BioLab Holdings Membrane Wrap - LITE™ allograft tissue products have been tested for potentially infectious diseases and terminally sterilized to ensure the safety of each membrane.



CT-SHIELD™

CONNECTIVE TISSUE PRODUCT

CT-Shield™ is a triple-layer amnion-chorion-amnion product. The unique composition of CT-Shield™ provides a supportive barrier and protective cover for soft tissue repair.

CT-Shield™ can be a viable resource for providers in need of a connective tissue product for surgical procedures.*

*All BioLab Sciences CT-Shield™ tissue products have been tested for potentially infectious diseases and terminally sterilized to ensure the safety of each product.

Criteria for treatment with Skin Substitutes:

Diabetic Foot Ulcer (DFU)

- Failed *Conservative Care* for 30 days prior to treatment
- **All Standard of Care needs to be noted in each clinical record for each date of service when skin substitute is being applied. Clarification- ANY standard of care taken place, whether prior or current, needs to be documented**
  - Medical records show that the wound has failed to respond to *Conservative Care* and documents what treatments have been tried and failed. i.e. Wound is not improving after 30 days of conservative care
  - *Conservative Care* includes the following but is not limited to:
    - Control of swelling (edema)
    - Local high blood pressure in the veins (venous hypertension), or type of swelling from blood fluids (lymphedema)
    - Control of infection including infection of the bone (osteomyelitis) and skin (cellulitis)
    - Removal of foreign bodies or cancer if present
    - Surgery to clean foreign material and dead tissue out of the wound (debridement)
    - Appropriate non-weight bearing or off-loading of pressure
    - Adequate blood flow
    - Smoking Cessation
    - Controlled diabetes
    - Wound does not involve tendon, muscle, or joint capsule or exposed bone or sinus tracts
    - Wound is at least 1.0 cm^2 in size
    - The skin substitute product has been cleared for this use by the FDA (check IFU)
    - No active infection present
    - All medical findings and any other documentation to support the claim and medical necessity of the billed services.
    - Note the severity of the wound
    - Notate potential for improvement with Skin Substitute
    - **Records must include a care plan that includes reason for CAMPs (Cellular, Acellular and Matrix like Products), whether current treatment has resulted in healing, and expectation to heal with CAMPs application**

Venous Leg Ulcer (VLU)

- Failed *Conservative Care* for 30 days prior to treatment
- **All Standard of Care needs to be noted in each clinical record for each date of service when skin substitute is being applied. Clarification- ANY standard of care taken place, whether prior or current, needs to be documented**
- Presence of a venous stasis ulcer for at least 90 days prior to skin sub treatment
  - Medical records show that the wound has failed to respond to *Conservative Care* and documents what treatments have been tried and failed. i.e. Wound is not improving after 30 days of conservative care
  - *Conservative Care* includes the following but is not limited to:
    - Control of swelling (edema)
    - Local high blood pressure in the veins (venous hypertension), or type of swelling from blood fluids (lymphedema)
    - Control of infection including infection of the bone (osteomyelitis) and skin (cellulitis)
    - Removal of foreign bodies or cancer if present
    - Surgery to clean foreign material and dead tissue out of the wound (debridement)
    - Compression therapy and limb elevation
    - Adequate blood flow
    - Smoking cessation
    - Wound does not involve tendon, muscle, or joint capsule or exposed bone or sinus tracts
    - Wound is at least 1.0 cm^2 in size
    - The skin substitute product has been cleared for this use by the FDA (check IFU)
    - No active infection present Notate severity of the wound
    - All medical findings and any other documentation to support the claim and medical necessity of the billed services.
    - Note the severity of the wound
    - Notate potential for improvement with Skin Substitute
    - **Records must include a care plan that includes reason for CAMPs (Cellular, Acellular and Matrix like Products), whether current treatment has resulted in healing, and expectation to heal with CAMPs application**

All Other Wounds

- Failed *Conservative Care* for 30 days prior to treatment
- **All Standard of Care needs to be noted in each clinical record for each date of service when skin substitute is being applied. Clarification- ANY standard of care taken place, whether prior or current, needs to be documented**
  - Medical records show that the wound has failed to respond to *Conservative Care* and documents what treatments have been tried and failed. i.e. Wound is not improving after 30 days of conservative care
  - *Conservative Care* includes the following but is not limited to:
    - Wound does not involve tendon, muscle, or joint capsule or exposed bone or sinus tracts
    - Smoking Cessation
    - Wound is at least 1.0 cm^2 in size
    - The skin substitute product has been cleared for this use by the FDA (check IFU)
    - No active infection present
    - All medical findings and any other documentation to support the claim and medical necessity of the billed services.
    - Note the severity of the wound
    - Notate potential for improvement with Skin Substitute
    - While there are no other specific criteria guidelines for other wounds, we would recommend applying all relevant qualifying criteria from DFU and VLU guidelines above
    - **Records must include a care plan that includes reason for CAMPs (Cellular, Acellular and Matrix like Products), whether current treatment has resulted in healing, and expectation to heal with CAMPs application**

Key Points on Medicare Skin Substitute Denials

- Failure to address underlying conditions (diabetes management and HbA1C)
- Fully evaluate and correct poor circulation
- Evaluate and address venous disease
- Excessive applications; exceeding the allowable number of applications
- Inaccurate diagnosis; misdiagnosing diabetic foot ulcers as pressure ulcers
- Failing to complete a comprehensive evaluation and assessment of patient and disease state
- Failure to confirm diagnosis with available testing
- Dopler Ultrasound for Venous Ultrasound
- Failing to complete comprehensive plan documentation in the medical record

Documentation Requirements for Skin Substitutes:

- Consent for treatment
- Signed HIPAA Privacy Notification Forms
- Electronic Signature Policy
- Date, time and location of ulcer treated
- Name of skin substitute
- Amount of product units used
- Amount of product units discarded
    - Reason for the wastage
- Manufacturer's serial/lot/batch or other unit identification number of graft material. When manufacturer does not supply unit identification, record must document such
- Pictures **(NOT REQUIRED BUT HIGHLY RECOMMENDED)**
    - Pre-debridement (with measurements)
    - Post-debridement (with measurements)
    - Post-graft application (with measurements)
- A list of any abbreviations and symbols used in documentation
- Copies of licenses and/or certifications for all personnel documenting in the beneficiary chart and/or performing services, including Physician, Nurse Practitioner and Nursing

Skin Substitute Treatment Limitations:

- Treatment will not exceed 10 applications and will not last longer than 12 weeks from the start of treatment (exceptions exist)
    - Additional treatments beyond 10 applications will require medical justification of necessity
    - For Medicare Advantage, prior authorization is required
- Re-treatment of any given course of skin substitute for venous stasis ulcer or diabetic (neuropathic) foot ulcer does not occur within one year, as it is considered treatment failure
- Use of more than one skin substitute product at a time for the same wound is not permitted
- Continued use on wounds that are smaller than 0.5 cm^2 is not permitted
- Continued use of the same or alternate skin substitute for wounds that have no improvement in size or depth, after four weeks from the start of therapy is not permitted

Novitas or FCSO policies are referenced as a standard since the criteria in those LCDs are very comprehensive and apply to nearly all scenarios when using skins subs for DFU or for VLU conditions. It's important to read through the ENTIRE LCD including the article link as the criteria points are what need to be documented for all skin subs.

These are the 3 available MAC policies, and all have very similar if not identical criteria for use:

1. **FCSO LCD**: https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=36377
2. **NOVITAS LCD**: https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=35041&ver=113&articleId=57023&name=331*1&UpdatePeriod=852&bc=AAAAEAAAAAAA&
3. **CGS LCD:** LCD - Wound Application of Cellular and/or Tissue Based Products (CTPs), Lower Extremities (L36690) (cms.gov)
4. **Palmetto, Noridian, NGS, WPS do NOT have LCD Guidelines. Reference Novitas or FCSO**