Clinical UM Guideline

Subject:	Products for Wound Healing and Soft Tissue Grafting: Medically Necessary Uses		
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Description

This document addresses the use of soft tissue (e.g., skin, ligament, cartilage, etc.) substitutes in wound healing and surgical procedures.

Note: This document does not address:
- The use of fresh, unfrozen, unprocessed allogeneic cadaver-derived skin grafts (see definition section); or
- The use of meshes or patches when used for hernia repair procedures; or
- Products used to treat osteochondral defects (for information on such products, please refer to the applicable guidelines used by the plan).

Note: For additional information please see:
- ANC.00007 Cosmetic and Reconstructive Services: Skin Related
- ANC.00008 Cosmetic and Reconstructive Services of the Head and Neck
- CG-SURG-123-Autologous Fat Grafting and Injectable Soft Tissue Fillers
- MED.00110 Silver-based Products for Wound and Soft Tissue Applications
- MED.00132 Autologous Adipose-derived Regenerative Cell Therapy
- SURG.00011 Products for Wound Healing and Soft Tissue Grafting: Investigational
- SURG.00023 Breast Procedures; including Reconstructive Surgery, Implants and Other Breast Procedures
- TRANS.00035 Therapeutic use of Stem Cells, Blood and Bone Marrow Products

Note: See definition section for information on The Women's Health and Cancer Rights Act of 1998 (WHCRA).

Clinical Indications

Medically Necessary:

I. *Breast Reconstruction Surgery*

The following products are considered **medically necessary** when used for breast reconstruction surgery:
A. AlloDerm Regenerative Tissue Matrix (aseptic or sterile); **or**
B. Cortiva®; **or**

C. DermACELL™; **or**
D. DermaMatrix®; **or**
E. FlexHD®; **or**
F. SimpliDerm™; **or**
G. Strattice™; **or**
H. SurgiMend®.

II. *Burns*

The following products are considered **medically necessary** when used for the treatment of full-thickness or deep partial-thickness burns:

A. Biobrane; **or**
B. Epicel®; **or**
C. EZ Derm™; **or**
D. Fresh frozen unprocessed allograft skin products (for example, AlloSkin™*, TheraSkin®); **or**
E. Integra™ Bilayer Matrix Wound Dressing; **or**
F. Integra® Omnigraft Dermal Regeneration Template; **or**
G. ReCell™ Autologous Harvesting Device; **or**
H. StrataGraft®.

***Note:** "AlloSkin," "AlloSkin RT™," and "Alloskin™ AC" are different products. AlloSkin is a fresh-frozen product, AlloSkin RT is a fresh irradiated product (not frozen) and Alloskin AC is an acellular dermal matrix product. Please see SURG.00011 investigational and not medically necessary statement for the position on AlloSkin RT™ and Alloskin™ AC.

III. Complex Abdominal Wall *Reconstruction*

The following products are considered **medically necessary** for complex abdominal wall reconstruction:

A. AlloDerm Regenerative Tissue Matrix (aseptic or sterile); **or**
B. Strattice; **or**
C. OviTex™; **or**
D. Phasix™ Mesh; **or**
E. Phasix™ ST Mesh.

IV. *Diabetic Foot Ulcers*

The following products are considered **medically necessary** for the treatment of diabetic foot ulcers when the clinical criteria below have been met:

A. Products:
   1. AmnioBand®, sheet or membrane form; **or**
   2. Apligraf®; **or**

3. Biovance®; **or**
4. DermACELL™; **or**
5. Dermagraft®; **or**
6. EpiCord®; **or**
7. EpiFix™; **or**
8. Grafix® PRIME; **or**
9. Kerecis®; **or**
10. mVASC; **or**
11. NuShield®; **or**
12. Oasis® Ultra Tri-Layer Wound Matrix; **or**
13. Oasis® Wound Matrix; **or**
14. TheraSkin®;

and

B. Clinical Criteria:

1. Ulcers that have not healed with standard conservative therapy (such as surgical debridement, complete off-loading, and standard dressing changes) attempted for at least 1 month.

V. *Dystrophic Epidermolysis Bullosa*

The following products are considered **medically necessary** for the treatment dystrophic epidermolysis bullosa:

A. Dermagraft®; **or**
B. OrCel™.

VI. *Non-healing Wounds*

The following products are considered **medically necessary** for the treatment of non-healing wounds (for example but not limited to; dermal wounds, pressure ulcers, surgical wounds, traumatic wounds, vascular ischemic ulcers, venous stasis ulcers) when the clinical criteria below have been met:

A. Products:
   1. AmnioBand, sheet or membrane form; **or**
   2. Apligraf®; **or**
   3. EpiFix™; **or**
   4. GraftJacket™, sheet or membrane form; **or**
   5. Oasis® Ultra Tri-Layer Wound Matrix; **or**
   6. Oasis® Wound Matrix; **or**
   7. PriMatrix™; **or**
   8. TheraSkin®;

   and

B. Clinical Criteria:

1. Wounds that have not healed with standard conservative therapy (such as surgical debridement, complete off-loading, standard dressing changes, and compression therapy) attempted for at least 1 month.

VI. *Ocular Indications*

Amniotic membrane-derived graft or wound covering products are considered **medically necessary** for any of the following ocular indications:

A. To facilitate reconstruction of large conjunctival or corneal resections (for example, pterygium excision or excision of conjunctiva related to disease processes); **or**
B. As therapy for corneal injuries (for example, thermal, chemical, physical trauma); **or**
C. As treatment for non-healing or persistent corneal epithelial defects including ulcers or melts, which have not responded to conservative therapy*, including those due to any of the following conditions:
   1. Bullous keratopathy; **or**
   2. Dry eye; **or**
   3. Limbal stem cell deficiency; **or**
   4. Neurotrophic keratitis; **or**
   5. Recurrent pterygium; **or**
   6. Stevens-Johnson syndrome.

*Conservative therapies for corneal epithelial defects may include frequent topical lubrication, pressure patching, and bandage contact lenses.

Note: Examples of amniotic membrane-derived grafts include AmbioDisk, AmnioGraft, AmnioPlast, Artacent Ocular, Biovance 3L Ocular, Omnigen, Opticyte, Prokera, SurSight, and Vendaje Optic.

Not Medically Necessary:

For each proposed use above (Breast Reconstruction, Burns, Diabetic Foot Ulcers, Dystrophic Epidermolysis Bullosa, Non-Healing Wounds, and Ocular Indications), use of products other than those explicitly listed for the indication is considered **not medically necessary**. (For example, use of an amniotic membrane-derived product considered medically necessary in the Ocular Indications section above is considered **not medically necessary** for the use in breast reconstructive surgery, treatment of dystrophic epidermolysis bullosa, or other non-ocular indications).

Coding

The following codes for treatments and procedures applicable to this guideline are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

I. Application of skin substitutes and soft tissue grafts:

When services may be Medically Necessary when product criteria are met:

CPT	
15150	Tissue cultured skin autograft, trunk, arms, legs; first 25 sq cm or less
15151	Tissue cultured skin autograft, trunk, arms, legs; additional 1 sq cm to 75 sq cm
15152	Tissue cultured skin autograft, trunk, arms, legs; each additional 100 sq cm, or each additional 1% of body area of infants and children, or part thereof
15155	Tissue cultured skin autograft, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; first 25 sq cm or less
15156	Tissue cultured skin autograft, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; additional 1 sq cm to 75 sq cm
15157	Tissue cultured skin autograft, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; each additional 100 sq cm, or each additional 1% of body area of infants and children, or part thereof
15271	Application of skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm; first 25 sq cm or less wound surface area
15272	Application of skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm; each additional 25 sq cm wound surface area, or part thereof
15273	Application of skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children
15274	Application of skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq cm; each additional 100 sq cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof
15275	Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq cm; first 25 sq cm or less wound surface area
15276	Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq cm; each additional 25 sq cm wound surface area, or part thereof
15277	Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children
15278	Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq cm; each additional 100 sq cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof

15777	Implantation of biologic implant (eg, acellular dermal matrix) for soft tissue reinforcement (i.e., breast, trunk)
17999	Unlisted procedure, skin, mucous membrane and subcutaneous tissue [when specified as implantation of biologic implants for soft tissue reinforcement in tissues other than breast and trunk]

HCPCS

C5271	Application of low cost skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm; first 25 sq cm or less wound surface area
C5272	Application of low cost skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm; each additional 25 sq cm wound surface area, or part thereof
C5273	Application of low cost skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children
C5274	Application of low cost skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq cm; each additional 100 sq cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof
C5275	Application of low cost skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq cm; first 25 sq cm or less wound surface area
C5276	Application of low cost skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq cm; each additional 25 sq cm wound surface area, or part thereof
C5277	Application of low cost skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children
C5278	Application of low cost skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq cm; each additional 100 sq cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof

ICD-10 Diagnosis

All diagnoses

When services are Not Medically Necessary:
For the procedure codes listed above when product criteria are not met.

II. Products

When services may be Medically Necessary when criteria are met for breast reconstruction:

HCPCS	
A4100	Skin substitute, FDA cleared as a device, not otherwise specified [when specified as Cortiva, DermaMatrix, SimpliDerm or SurgiMend]
C9358	Dermal substitute, native, non-denatured collagen, fetal bovine origin (SurgiMend Collagen Matrix), per 0.5 square centimeters
C9360	Dermal substitute, native, nondenatured collagen, neonatal bovine origin (SurgiMend Collagen Matrix), per 0.5 sq cm
C9399	Unclassified drugs or biologicals [when specified as Cortiva, DermaMatrix or SimpliDerm]
Q4100	Skin substitute, not otherwise specified [when specified as Cortiva, DermaMatrix, SimpliDerm or SurgiMend]
Q4116	AlloDerm, per square centimeter [AlloDerm Regenerative Tissue Matrix (aseptic or sterile)
Q4122	Dermacell, Dermacell AWM or Dermacell AWM porous, per square centimeter
Q4128	FlexHD, or Allopatch HD, per sq cm [only **when specified as FlexHD**]
Q4130	Strattice, per square centimeter
ICD-10 Diagnosis	
	All diagnoses

When services may be Medically Necessary when criteria are met for burns:

CPT	
	For the following CPT codes for RECELL System:
15011	Harvest of skin for skin cell suspension autograft; first 25 sq cm or less
15012	Harvest of skin for skin cell suspension autograft; each additional 25 sq cm or part thereof
15013	Preparation of skin cell suspension autograft, requiring enzymatic processing, manual mechanical disaggregation of skin cells, and filtration; first 25 sq cm or less of harvested skin
15014	Preparation of skin cell suspension autograft, requiring enzymatic processing, manual mechanical disaggregation of skin cells, and filtration; each additional 25 sq cm of harvested skin or part thereof
15015	Application of skin cell suspension autograft to wound and donor sites, including application of primary dressing, trunk, arms, legs; first 480 sq cm or less
15016	Application of skin cell suspension autograft to wound and donor sites, including application of primary dressing, trunk, arms, legs; each additional 480 sq cm or part thereof

15017	Application of skin cell suspension autograft to wound and donor sites, including application of primary dressing, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; first 480 sq cm or less
15018	Application of skin cell suspension autograft to wound and donor sites, including application of primary dressing, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; each additional 480 sq cm or part thereof

HCPCS

A4100	Skin substitute, FDA cleared as a device, not otherwise specified [when specified as Biobrane, EpiCel or StrataGraft]
C1832	Autograft suspension, including cell processing and application, and all system components [RECELL System]
C8002	Preparation of skin cell suspension autograft, automated, including all enzymatic processing and device components [RECELL System]
C9363	Skin substitute, Integra Meshed Bilayer Wound Matrix, per square centimeter
C9399	Unclassified drugs or biologicals [when specified as Biobrane, EpiCel or StrataGraft]
Q4100	Skin substitute, not otherwise specified [when specified as Biobrane, EpiCel or StrataGraft]
Q4104	Integra Bilayer Matrix Wound Dressing (BMWD), per square centimeter
Q4105	Integra Dermal Regeneration Template (DRT) or Integra Omnigraft dermal regeneration matrix, per square centimeter
Q4115	AlloSkin, per square centimeter
Q4121	TheraSkin, per square centimeter
Q4136	EZ-derm, per square centimeter

ICD-10 Diagnosis

T20.20XA-T20.39XS	Burn of second or third degree of head, face, and neck
T20.60XA-T20.79XS	Corrosion of second or third degree of head, face, and neck
T21.20XA-T21.39XS	Burn of second or third degree of trunk
T21.60XA-T21.79XS	Corrosion of second or third degree of trunk
T22.20XA-T22.399S	Burn of second or third degree of shoulder and upper limb, except wrist and hand
T22.60XA-T22.799S	Corrosion of second or third degree of shoulder and upper limb, except wrist and hand
T23.201A-T23.399S	Burn of second or third degree of wrist and hand
T23.601A-T23.799S	Corrosion of second or third degree of wrist and hand
T24.201A-T24.399S	Burn of second or third degree of lower limb, except ankle and foot
T24.601A-T24.799S	Corrosion of second or third degree of lower limb, except ankle and foot
T25.211A-T25.399S	Burn of second or third degree of ankle and foot
T25.611A-T25.799S	Corrosion of second or third degree of ankle and foot
T31.0-T31.99	Burns classified according to extent of body surface involved
T32.0-T32.99	Corrosions classified according to extent of body surface involved

When services may be Medically Necessary for complex abdominal wall reconstruction:

HCPCS	
A4100	Skin substitute, FDA cleared as a device, not otherwise specified [when specified as OviTex or Phasix/Phasix ST Mesh]
C9399	Skin substitute, FDA cleared as a device, not otherwise specified [when specified as OviTex or Phasix/Phasix ST Mesh]
Q4100	Skin substitute, FDA cleared as a device, not otherwise specified [when specified as OviTex or Phasix/Phasix ST Mesh]
Q4116	AlloDerm, per square centimeter [AlloDerm Regenerative Tissue Matrix (aseptic or sterile)]
Q4130	Strattice, per square centimeter

ICD-10 Diagnosis	
	All diagnoses

When services may be Medically Necessary when criteria are met for diabetic foot ulcers:

HCPCS	
A4100	Skin substitute, FDA cleared as a device, not otherwise specified [when specified as mVASC]
C9399	Unclassified drugs or biologicals [when specified as mVASC]
Q4100	Skin substitute, not otherwise classified [when specified as mVASC]
Q4101	Apligraf, per square centimeter
Q4102	Oasis Wound Matrix, per square centimeter
Q4106	Dermagraft, per square centimeter
Q4121	TheraSkin, per square centimeter
Q4122	Dermacell, Dermacell AWM or Dermacell AWM porous, per square centimeter
Q4124	Oasis Ultra Tri-Layer Wound Matrix, per square centimeter
Q4133	Grafix PRIME, GrafixPL PRIME, Stravix and StravixPL, per square centimeter [only **when specified as Grafix PRIME**]
Q4151	AmnioBand or Guardian, per sq cm
Q4154	Biovance, per square centimeter
Q4158	Kerecis Omega3, per square centimeter
Q4160	NuShield, per square centimeter
Q4186	EpiFix, per square centimeter
Q4187	EpiCord, per square centimeter
Q4283	Biovance Tri-layer or Biovance 3L, per square centimeter

ICD-10 Diagnosis	
E08.00-E13.9	Diabetes mellitus

When services may be Medically Necessary when criteria are met for epidermolysis bullosa:

HCPCS	
A4100	Skin substitute, FDA cleared as a device, not otherwise specified [when specified as OrCel]
C9399	Unclassified drugs or biologicals [when specified as OrCel]
Q4100	Skin substitute, not otherwise classified [when specified as OrCel]
Q4106	Dermagraft, per square centimeter

ICD-10 Diagnosis	
Q81.0-Q81.9	Epidermolysis bullosa

When services may be Medically Necessary when criteria are met for nonhealing wounds

HCPCS	
Q4101	Apligraf, per square centimeter
Q4102	Oasis Wound Matrix, per square centimeter
Q4107	GraftJacket, per square centimeter
Q4110	PriMatrix, per square centimeter
Q4121	TheraSkin, per square centimeter
Q4124	Oasis Ultra Tri-Layer Wound Matrix, per square centimeter
Q4151	AmnioBand or Guardian, per sq cm
Q4186	EpiFix, per square centimeter

ICD-10 Diagnosis	
	All diagnoses

When services are Not Medically Necessary:
For the product codes listed above when criteria are not met, or when the code describes a procedure indicated in the Clinical Indications section as not medically necessary.

III. Application of amniotic membrane-derived grafts or wound coverings for ophthalmologic conditions:

When services may be Medically Necessary when criteria are met:

CPT	
65778	Placement of amniotic membrane on the ocular surface; without sutures
65779	Placement of amniotic membrane on the ocular surface; single layer, sutured
65780	Ocular surface reconstruction; amniotic membrane transplantation, multiple layers

HCPCS

Q4283	Biovance Tri-layer or Biovance 3L, per square centimeter
Q4334	AmnioPlast 1, per square centimeter
Q4335	AmnioPlast 2, per square centimeter
Q4369	AmnioPlast 3, per square centimeter [**Note:** code effective 07/01/2025]
V2790	Amniotic membrane for surgical reconstruction, per procedure

ICD-10 Diagnosis

C69.00-C69.02	Malignant neoplasm of conjunctiva
C69.10-C69.12	Malignant neoplasm of cornea
H11.001-H11.069	Pterygium of eye
H16.001-H16.079	Corneal ulcer
H16.231-H16.239	Neurotrophic keratoconjunctivitis
H18.10-H18.13	Bullous keratopathy
H18.40-H18.599	Corneal degeneration, hereditary corneal dystrophies
H18.831-H18.839	Recurrent erosion of cornea
H59.091-H59.099	Other disorders of the eye following cataract surgery
L51.1	Stevens-Johnson syndrome
T26.10XA-T26.12XS	Burn of cornea and conjunctival sac
T26.60XA-T26.62XS	Corrosion of cornea and conjunctival sac

When services are Not Medically Necessary:
For the procedure codes listed above when criteria are not met.

Discussion/General Information

General considerations

There are many different products (see definition section for product types) available for soft tissue grafting and wound treatment. These products differ in source (e.g., human cadaveric, synthetic, bovine, porcine, equine, a combination of several types, etc.), tissue (e.g., dermis, pericardium, intestinal mucosa, etc.), bioburden reduction (e.g., nonsterile, sterile), additives (e.g., antibiotics, surfactants), delivery formats (e.g., wet packaged, freeze-dried), and preparation requirements (e.g., multiple rinses, rehydration). Additionally, products are often procured, produced, manufactured, or processed in sufficiently different manners such that product are evaluated based on product specific evidence rather than as a category or class of equivalent products. Products for which there is a lack of published and peer-reviewed evidence showing material improvement to the net health outcome are addressed in a related document: SURG.00011 Products for Wound Healing: Investigational.

Unlike products approved through the PMA process or authorized under the 510K process which are assigned specific indications for use by the U.S. Food and Drug Administration (FDA), there are no authorized indications for products regulated through the FDA Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/P)

process as human tissue for transplantation. Use of HCT/P products is therefore guided by the available published and peer reviewed literature among other factors.

Wound products as part of the treatment of DFUs or non-healing wounds are used when standard therapy has not resulted in wound healing. Standard therapy generally includes debridement as appropriate to a clean granular base, offloading for DFUs, compression dressings for VLUs, infection control with removal of foreign body or focus of infection, and management of exudate with maintenance of a moist environment. In addition, attention should be paid to other factors impacting wound healing including smoking.

Wound care should be well documented and include objective measurements of wound size and depth before, during and after treatment. Wound measurements should be documented before and after each application of a wound product. Clinical records should describe the planned skin replacement with choice of skin substitute graft/CTP.

Breast Reconstructive Surgery

In breast reconstruction, tissue substitutes are utilized to replace or supplement natural tissue, typically after mastectomy or lumpectomy, to restore breast appearance. They provide volume, shape, and support while aiding healing and enhancing cosmetic results. These substitutes are particularly useful when there is insufficient natural tissue available or a less invasive procedure is desired. Options include acellular dermal matrices, synthetic meshes, and fat grafting, with selection influenced by individual needs, surgical objectives, and surgeon preferences. Relevant citations for each listed product can be found in the bibliography section of this document.

Product	Description and FDA Status
AlloDerm Regenerative Tissue Matrix (RTM)	An acellular human dermis product regulated through the HCT/P process as human tissue for transplantation process. This product comes in over 30 forms that are marketed in several sub-brands, including AlloDerm Select and AlloDerm Select RESTORE. These products are all based on the same sheet form of AlloDerm, but are supplied in various sizes, shapes, thicknesses, and textures.
Cortiva	An acellular human dermis product that was granted investigational Device Exemption (IDE) approval for a clinical study designed to confirm the safety and effectiveness in implant-based breast reconstruction. It is regulated through the FDA's HCT/P process.
DermACELL	An acellular human dermis product regulated through the FDA's HCT/P process. DermACELL AWM and DermACELL AWM Porous are two products also available on the market that are substantially the same as the original DermACELL product, having the same tissue origin and processing but are provided in different formats.
DermaMatrix	An acellular human dermis product which is regulated through the FDA's HCT/P process.

FlexHD	An acellular human dermis product which is regulated through the FDA's HCT/P process.
SimpliDerm	An acellular human dermis product which is regulated through the FDA's HCT/P process.
Strattice	An acellular porcine dermal collagen product cleared under the FDA's 510k process and is intended for use as a soft tissue patch to reinforce soft tissue where weakness exists and for the surgical repair of damaged or ruptured soft tissue membranes. Indications for use include the repair of hernias and/or body wall defects which require the use of reinforcing or bridging material to obtain the desired surgical outcome.
SurgiMend	An acellular fetal bovine dermis product cleared under the FDA's 510k process and indicated for implantation to reinforce soft tissue where weakness exists and for surgical repair of damaged or ruptured soft tissue membranes. SurgiMend is specifically indicated for: plastic and reconstructive surgery, muscle flap reinforcement, and hernia repair including abdominal, inguinal, femoral, diaphragmatic, scrotal, umbilical, and incisional hernias.

(Return to Clinical Indications)

Burns

Tissue substitutes play a crucial role in burn treatment by offering wound coverage and promoting healing. They protect wounds from infection and injury, maintain moisture, alleviate pain by limiting air exposure, and support tissue growth for functional and cosmetic skin restoration. In severe cases, they serve as temporary covers until natural healing or skin grafts are viable. These substitutes can be synthetic or biological, with choice influenced by burn severity, wound location, the individual's condition, and treatment objectives. Relevant citations for each listed product can be found in the bibliography section of this document.

Product	Description and FDA Status
Biobrane	A synthetic product composed of a silicone film bonded to a nylon fabric base and approved through the FDA's PMA process for the treatment of burns, dermal donor sites, and as a protective covering for meshed autografts.
Epicel	A cultured epidermal autograft (CEA) approved in 2007 by the FDA via the Humanitarian Device Exemption (HDE) process. The authorization was for use in adult and pediatric individuals who have deep dermal or full thickness burns with a total body surface area (TBSA) greater than or equal to 30%.
EZ Derm	A porcine acellular dermis product cleared through the FDA's 510K process to treat partial-thickness burns, venous, diabetic, and pressure ulcers. It may also be used as a temporary cover and test graft.
Fresh frozen unprocessed allograft skin products (for	There are several brands of fresh, frozen, unprocessed including AlloSkin and TheraSkin. These products are regulated through the FDA HCT/P process.

example, AlloSkin*, TheraSkin)	
Integra Bilayer Matrix Wound Dressing	A composite grafting material made from cross-linked bovine tendon collagen and glycosaminoglycan and a semi-permeable polysiloxane (silicone) layer cleared through the FDA's 510K process and indicated for the management of wounds, including: partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, surgical wounds (donor sites/ grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns, and skin tears) and draining wounds.
Integra Omnigraft Dermal Regeneration Template	A composite graft material made from bovine collagen, chondroitin-6-sulfate (C6S), and a semi-permeable polysiloxane (silicone) layer cleared through the FDA's 510K process and indicated for use in the treatment of partial and full-thickness neuropathic diabetic foot ulcers that are greater than six weeks in duration, with no capsule, tendon or bone exposed, when used in conjunction with standard diabetic ulcer care.
ReCell Autologous Harvesting Device	An autologous cell harvesting device used at point of care to prepare an autologous skin cell suspension which is sprayed directly on second-degree burns or applied in combination with meshed autografts for third-degree burns. It received FDA approval through the PMA process and is indicated for treatment of acute partial thickness burns in adults 18 years and older.
StrataGraft	A product made from an acellular murine collagen base impregnated with allogeneic cultured keratinocytes and dermal fibroblasts. It is regulated through the FDA's Biologics License Application process and indicated for the treatment of adults with thermal burns containing intact dermal elements for which surgical intervention is clinically indicated (deep partial-thickness burns).

(Return to Clinical Indications)

Complex Abdominal Wall Reconstruction

Abdominal wall reconstruction procedures are performed to repair extensive or recurrent hernias, hernias resulting from previous surgeries, those affecting multiple areas of the abdominal wall, or associated with complicating factors like infections, compromised or damaged tissues, or contamination. The purpose of the procedure is to restore functional and structural integrity of the abdominal wall, it may involve moving muscles and skin flaps, implantation of synthetic, biologic, or composite mesh, and may require surgical component separation techniques to ensure a tension-free repair to reduce the risk of failure and recurrence.

Product	Description and FDA Status

AlloDerm Regenerative Tissue Matrix (aseptic or sterile);	A decellularized grafting product derived from donated cadaveric dermis and sterilized with electron beam radiation. It is regulated through the FDA HCT/P process. This product comes in over 30 forms and are marketed in several sub-brands, including AlloDerm Select and AlloDerm Select RESTORE. These products are all basically the same sheet form of AlloDerm, but are supplied in various sizes, shapes, thicknesses, and textures.
OviTex	An acellular ovine forestomach extracellular matrix mesh reinforced with five percent polymer fiber cleared through the FDA's 510k process for implantation to reinforce soft tissue where weakness exists in patients requiring soft tissue repair or reinforcement in plastic and reconstructive surgery. This product is also available in long-term resorbable for marketed as OviTex PRS.
Phasix Mesh and Phasix ST Mesh	Phasix Mesh is a biosynthetic monofilament mesh product composed of poly-4-hydroxybutyrate cleared through the FDA's 510K process and indicated for use in the reinforcement of soft tissue where weakness exists in patients undergoing plastic and reconstructive surgery, or for use in procedures involving soft tissue repair, such as the repair is hernia or other fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result. Phasix ST Mesh is a product that combines the Phasix Mesh product with a hydrogel barrier purported to minimize tissue attachment on the visceral side of the mesh for use in hernia repair. It is cleared through the FDA's 510K process and indicated for use in the reinforcement of soft tissue, where weakness exists, in procedures involving soft tissue repair, such as for the repair of hernias.
Strattice	An acellular porcine dermal collagen product cleared under the FDA's 510k process and is intended for use as a soft tissue patch to reinforce soft tissue where weakness exists and for the surgical repair of damaged or ruptured soft tissue membranes. Indications for use include the repair of hernias and/or body wall defects which require the use of reinforcing or bridging material to obtain the desired surgical outcome.

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Diabetic Foot Ulcers (DFUs)

Tissue substitutes are used to treat DFUs to aid in healing and provide benefits addressing the unique challenges posed by these types of wounds. Tissue substitutes can provide a scaffold that supports cell migration and tissue

regeneration, promoting faster healing, they are a protective barrier, reducing the risk of infection due to impaired immune responses, and they can help keep the wound environment conducive to healing by preventing excessive dryness or moisture. Some tissue substitutes contain growth factors or are designed to elicit the body's own healing response and speed up the tissue regeneration process. Products vary in composition, including synthetic materials and bioengineered skin equivalents, each chosen based on the specific needs of the wound and overall management strategy. Relevant citations for each listed product can be found in the bibliography section of this document.

Product	Description and FDA Status
AmnioBand, sheet or membrane form	A human placental membrane comprised of amnion and chorion regulated through the FDA's HCT/P process. This product is available in both sheet and membrane form. Also see SURG.00011 Products for Wound Healing and Soft Tissue Grafting: Investigational.
Apligraf	A composite product composed of human fibroblasts in a matrix of bovine dermal collagen covered by a layer of human keratinocytes approved through the FDA's PMA process for the treatment of non-infected partial and full thickness skin ulcers due to venous insufficiency of greater than 1 month duration and which have not adequately responded to conventional ulcer therapy. It is also FDA indicated for the treatment of full-thickness neuropathic diabetic foot ulcers of greater than three weeks duration which have not adequately responded to conventional ulcer therapy and which extend through the dermis but without tendon, muscle, capsule or bone exposure.
Biovance Biovance3L	A decellularized human amniotic membrane regulated through the FDA's HCT/P process.
DermACELL	An acellular human dermis product regulated through the FDA's HCT/P process. DermACELL AWM and DermACELL AWM Porous are two products also available on the market that are not substantially different from the original DermACELL product, having the same tissue origin and processing but are provided in different formats. They are considered equivalent for the purposes of this document.
Dermagraft	A composite grafting product composed of cryopreserved human fibroblastin and allograft collagen scaffold approved through the FDA's PMA process and indicated for the treatment of full-thickness diabetic foot ulcers greater than six weeks duration which extend through the dermis, but without tendon, muscle, joint capsule or bone exposure.
EpiCord	A human umbilical cord graft product regulated through the FDA's HCT/P process.
EpiFix	An amniotic human membrane regulated by the FDA's HCT/P process. It is available in sheet and mesh/fenestrated configurations in a variety of sizes.
Grafix PRIME	An amniotic human membrane regulated through the FDA's HCT/P process. A similar product, GrafixPL Prime, is also available. The difference between these

	products is that Grafix Prime is cryopreserved, and GrafixPL Prime is lyopreserved (a method of dehydration).
Kerecis	An acellular dermal matrix derived from fish skin and cleared through the FDA's 510K process for the management acute and chronic wounds, trauma wounds (second degree burn, abrasions, lacerations, skin tears), surgical wounds, and draining wounds.
mVASC	A product derived from processed subcutaneous allogenic microvascular tissue regulated through the FDA's HCT/P process. It is derived from the structural elements of microvascular tissue of human donors and includes inherent non-viable cells and signaling factors.
NuShield	A human placental allograft regulated through the FDA's HTC/P process.
Oasis Ultra Tri-Layer Wound Matrix Oasis Wound Matrix	A suite of grafting products composed of decellularized porcine intestinal mucosa cleared through the FDA's 510K process for the management acute and chronic wounds, trauma wounds (second degree burn, abrasions, lacerations, skin tears), surgical wounds, and draining wounds.
TheraSkin	A fresh, frozen, unprocessed allograft regulated through the FDA's HTC/P process.

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Dystrophic Epidermolysis Bullosa

Tissue substitutes are employed in managing Epidermolysis Bullosa (EB), a genetic condition causing fragile, blistering skin. They provide benefits including protecting the underlying skin from further trauma and infection, promoting more efficient wound healing by providing a scaffold for cell growth and aiding in the regeneration of tissue, reduced pain, and maintaining a moist wound environment for healing which can help prevent scab formation and subsequent blistering. They may also reduce scar formation which helps maintain skin function and appearance. While primarily therapeutic, tissue substitutes may also help achieve a more normal skin appearance and functionality and can improve the quality of life by reducing the frequency of wound dressing changes, promoting better healing, and minimizing complications associated with chronic wounds. Relevant citations for each listed product can be found in the bibliography section of this document.

Product	Description and FDA Status
Dermagraft	A composite grafting product composed of cryopreserved human fibroblastin and allograft collagen scaffold approved through the FDA's PMA process and indicated for the treatment of full-thickness diabetic foot ulcers greater than six weeks duration which extend through the dermis, but without tendon, muscle, joint capsule or bone exposure.
OrCel	A living skin equivalent (composite cultured skin) composed of human allogeneic skin cells cultured in layers of Type I bovine collagen approved through the FDA's PMA process for the treatment of fresh, clean split thickness donor site wounds in

	burn patients. This product was also granted an FDA HDE for use in children with recessive dystrophic epidermolysis bullosa (RDEB), who are undergoing reconstructive hand surgery.

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Non-Healing Wounds

Tissue substitutes are used for non-healing wounds to facilitate the healing process. They provide a scaffold that supports cell migration and new tissue growth, function as a barrier to help protect the wound from bacterial exposure, thereby reducing the risk of infection, they help maintain an optimal moisture balance, and may reduce pain associated with dryness and exposure to environmental factors. Some tissue substitutes include components that actively support and enhance the body's own regenerative processes. Tissue substitute products can be derived from natural materials, synthetic sources, or a combination of both. Product selection depends on the wound's specific characteristics and the individual's needs. Tissue substitutes are often used when traditional treatments, like dressings and topical therapies, have not been successful in promoting healing. Relevant citations for each listed product can be found in the bibliography section of this document.

Product	Description and FDA Status
AmnioBand, sheet or membrane form	A human placental membrane comprised of amnion and chorion regulated through the FDA's HCT/P process. This product is available in both sheet and membrane form. Also see SURG.00011 Products for Wound Healing and Soft Tissue Grafting: Investigational.
Apligraf	A composite product composed of human fibroblasts in a matrix of bovine dermal collagen covered by a layer of human keratinocytes approved through the FDA's PMA process for the treatment of non-infected partial and full thickness skin ulcers due to venous insufficiency of greater than 1 month duration and which have not adequately responded to conventional ulcer therapy. It is also FDA indicated for the treatment of full-thickness neuropathic diabetic foot ulcers of greater than three weeks duration which have not adequately responded to conventional ulcer therapy and which extend through the dermis but without tendon, muscle, capsule or bone exposure.
EpiFix	An amniotic human membrane regulated by the FDA's HCT/P process. It is available in sheet and mesh/fenestrated configurations in a variety of sizes.
GraftJacket sheet or membrane form	An acellular human skin-derived product regulated through the FDA's HCT/P process.
Oasis Ultra Tri-Layer Wound Matrix	A suite of grafting products composed of decellularized porcine intestinal mucosa cleared through the FDA's 510K process for the

Oasis Wound Matrix	management acute and chronic wounds, trauma wounds (second degree burn, abrasions, lacerations, skin tears), surgical wounds, and draining wounds.
PriMatrix	An acellular bovine dermis product that been cleared through the FDA's 510K process for the management of wounds that include partial and full thickness wounds; pressure, diabetic, and venous ulcers; second-degree burns; surgical wounds-donor sites/grafts; post-Mohs surgery; post-laser surgery; podiatric, wound dehiscence; trauma wounds-abrasions, lacerations, and skin tears; tunneled/undermined wounds; and draining wounds.
TheraSkin	A fresh, frozen, unprocessed human dermal allograft regulated through the FDA's HTC/P process.

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Ocular Indications

Amniotic membrane-based wound products are used for the management of select ophthalmologic wounds and reconstruction of large conjunctival resections where there is limited access to autologous tissue for transplant, or when allogeneic transplant is not appropriate. Some amniotic membrane based wound products used are obtained directly from tissue banks while others are commercially available products.

Indication	Clinical Rationale
To facilitate reconstruction of large conjunctival or corneal resections (for example, pterygium excision or excision of conjunctiva related to disease processes)	A pterygium is a triangular, fleshy fold of tissue that extends from the conjunctiva and encroaches onto the cornea. The size and growth rate of pterygia vary, and when vision is affected, surgery is often indicated. Pterygium is generally treated with autograft or bare scleral techniques, however, when there is extensive, double, or recurrent pterygium in individuals who have insufficient healthy tissue to create a conjunctival autograft, the amniotic membrane-derived products may be used.
Corneal injuries, including acute thermal, mechanical, and chemical injuries	Thermal, mechanical or chemical trauma may produce corneal injury. Use of amniotic membrane-derived products as an adjunct to corneal transplantation in individuals with active inflammation has been shown to reduce inflammation and promote healing.
As treatment for non-healing or persistent corneal epithelial defects including ulcers or melts, which have not responded to conservative therapy	Bullous keratopathy - amniotic membrane-derived products are used for treatment of bullous keratopathy due to corneal endothelial dysfunction. These products are often used as an alternative for individuals who are not candidates for curative endothelial or penetrating keratoplasty.

Indication	Clinical Rationale
	Dry eye - first-line treatment of corneal defects include topical lubricants, antibiotics, therapeutic contact lenses and patching. When these methods fail, amniotic membrane-derived products may be used in lieu of corneal transplantation. Partial limbal stem cell deficiency - limbal stem cell deficiency is characterized by a loss or deficiency of the stem cells in the limbus that are vital for re-population of the corneal epithelium. Total limbal stem cell deficiency is commonly treated with limbal cell transplantation; partial limbal stem cell deficiency is commonly treated with an approach which includes grafting with amniotic membrane-derived products in conjunction with superficial keratectomy to remove the diseased tissue. Neurotrophic keratitis - neurotrophic keratitis can result in persistent corneal epithelial defects, ulcers, and melts. Amniotic membrane derived products may be used when unresponsive to conservative therapy such as topical lubricants, antibiotics, therapeutic contact lenses and patching. Moderate or severe Stevens-Johnson syndrome - for moderate or severe Stevens-Johnson syndrome (SJS) involving the eye, there are few treatment options, and the use of amniotic membrane-derived products has been widely accepted as the standard of care.

Several branded amniotic-membrane derived products have been used to treat ocular conditions due to their unique biological properties. These products are regulated through the FDA HCT/P process as human tissue for transplantation. Some examples of such products are AmbioDisk, AmnioGraft, AmnioPlast, Artacent, Biovance 3L Ocular, Omnigen Ocular, and Opticyte.

Prokera is a amniotic product device that is intended to treat ocular surface diseases such as dry eye syndrome, corneal scars, and chemical burns. It is for use in eyes in which the ocular surface cells have been damaged, or the underlying stroma is inflamed and scarred. Prokera is a biologic corneal bandage that's made from amniotic tissue. It is composed of amniotic-membrane fastened to a synthetic ring, the device is inserted in between the eyeball and eyelid to maintain space in the orbital cavity and prevent closure or adhesions. Prokera was cleared through the FDA's 510K process.

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Other Proposed uses of Wound Products:

Additional uses for wound products continue to be investigated. As evidence is developed showing additional products or additional uses are in accordance with generally accepted standards of medical practice (for these purposes, "generally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, national physician specialty society recommendations and the views of medical practitioners practicing in relevant clinical areas and any other relevant factors) these products and uses will be added to the those identified above as medically necessary.

AlloDerm for Graves' Disease

In the one available clinical trial of aseptic AlloDerm in people with lid retraction due to Graves' disease, only 14 participants were studied in a non-blinded fashion (Sullivan, 2003).

A retrospective non-randomized case series involving 54 participants (95 eyes) with Graves' orbitopathy who underwent swinging eyelid orbital decompression was reported by Kim (2017). The participants were divided into 3 groups: 1) conjunctival lengthening using AlloDerm (36 eyes), 2) inferior retractor recession (33 eyes), and 3) decompression only (26 eyes). Participants in groups 1 and 2 showed correction of eyelid retraction at 4 to 6 months (2.7 mm and 1.8 mm, respectively). Mean improvement in margin reflex distance-2 at 4 to 6 months was significantly better in the AlloDerm group vs. the other two groups ($p<0.001$). Similarly, the mean reduction in inferior scleral show at baseline to 4 to 6 months after surgery was also significantly better in group 1 vs. group 2 and group 3 ($p<0.001$). All 3 groups achieved good surgical results. The author concluded that the use of AlloDerm resulted in better outcomes when compared to inferior retraction recession or decompression only. While promising, further controlled studies with larger numbers of participants are needed to confirm these findings.

AlloDerm for Burns

There are currently two studies available in the peer-reviewed literature addressing the use of aseptic AlloDerm for treatment of burns. The first study involved 19 participants randomized to aseptic AlloDerm with an *autograft* overgraft vs. aseptic AlloDerm with an *allograft* overgraft which was replaced with an autograft overgraft after 1 week (Munster, 2001). Graft uptake was not different between groups. Immediate use of aseptic AlloDerm with thin autograft was associated with more healing than spilt thickness grafts. The second study involved 52 nonrandomized participants all of whom received aseptic AlloDerm covering to radial arm free flap donor sites (Sinha, 2003). The results of this study indicated that there were minimal contractures or restrictions to the healed graft. While these studies suggest some benefit from the use of aseptic AlloDerm for burns, larger randomized trials are needed to confirm efficacy of this procedure.

AlloDerm for Frey's Syndrome

At this time, there are two available studies in the peer-reviewed literature regarding the use of aseptic AlloDerm to treat Frey's syndrome. The first involved 64 participants randomly assigned to the use of aseptic AlloDerm placement in the parotid bed following removal of the parotid gland vs. no aseptic AlloDerm (Govindaraj, 2001).

While the rate of gustatory sweating in the aseptic AlloDerm group was found to be statistically lower than the control group, the aseptic AlloDerm group also had an almost three-fold increase in complications, including both a higher frequency of seroma as well as one wound infection. In a second study, 30 participants were randomized into 3 groups; (1) superficial parotidectomy with placement of aseptic AlloDerm, (2) superficial parotidectomy without placement, and (3) deep-plane rhytidectomy (Sinha, 2003). The incidence of both subjective and objective Frey's syndrome was significantly higher in group 2 when compared to both groups 1 and 3. However, given the small numbers of participants in each group, the results of this study do not allow strong conclusions to be drawn as to the effectiveness of this procedure.

While AlloDerm has been used for a wide variety of other indications, including insufficient conjunctiva (Park, 2017), such uses have been poorly studied and are not widely accepted by the practicing community.

Biobrane for Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis (SJS-TEN)

The use of Biobrane has been reported in a case series study of 18 participants with SJS-TEN (Rogers, 2017). The authors reported that there were no complications, infections, premature removals, or Biobrane-associated sepsis in 24/25 applications (96%). Time to healing was 13 (12-16) days, and mean burn center length of stay was 34 days. This study demonstrates promising data regarding the safety and efficacy of Biobrane for SJS and other conditions.

Cortiva for abdominal wall reconstruction

The use of Cortiva for abdominal wall reconstruction was reported by Lindsey in 2020. This retrospective chart review involved 82 participants who underwent abdominal wall reconstruction with either AlloDerm (n=53) or Cortiva (n=29). The overall complication rate was found to be not significantly different between groups (51.92% in the AlloDerm group vs. 72.41% in the Cortiva group, p=0.099). No explantations were reported. This was the first peer-reviewed, published description of Cortiva for the treatment of abdominal wall reconstruction procedures. Additional data is needed to fully evaluate the clinical utility of this technique

DermaMatrix for Parotid Surgery

DermaMatrix, a product composed of acellular human dermis, has been studied for a variety of indications. It is treated as human tissue for transplantation under the FDA's HCT/P process.

Athavale published the results of a retrospective, non-controlled study of the complication rate for parotid reconstruction surgery involving 100 participants who received treatment with either aseptic AlloDerm (n=69) or DermaMatrix (n=31) (2012). Sixty-nine AlloDerm implants were associated with a total of 5 complications (7%), whereas 31 DermaMatrix implants were associated with a total of 8 complications (26%) (p=0.0107). Subgroup analyses found that for subtotal parotidectomies, the incidence of complications was found to be 8% for the AlloDerm group and 37% for the DermaMatrix group (p=0.004). The authors conclude that:

> …this study suggests that DermaMatrix was associated with increased postoperative complications compared with AlloDerm when used for reconstruction of parotidectomy defects. To better define the complication profile of AlloDerm versus DermaMatrix in the postoperative parotid bed, a prospective study should be considered to determine implant performance following parotidectomy reconstruction.

EpiFix for Neurovascular Bundle Surgery

In 2015, Patel and others published the first study to address the use of EpiFix as a protective measure for the prostatic neurovascular bundle during nerve-sparing robot-assisted prostatectomy. This prospective study involved 58 potent and continent participants who underwent the procedure compared to 58 propensity-matched participants who underwent the same procedure without the use of EpiFix. It was reported that continence at 8 weeks returned in 81.0% of the EpiFix participants vs 74.1% of the control participants (p=0.373). Mean time to continence was enhanced in the EpiFix participants vs. controls (1.21 months vs. 1.83 months; p=0.033). Potency at 8 weeks returned in 65.5% of the EpiFix participants vs. 51.7% of the controls (p=0.132). Mean time to potency was enhanced in the EpiFix group vs. controls (1.34 months vs. 3.39 months; p=0.007). The authors concluded that the use of EpiFix appeared to hasten the early return of continence and potency in participants following nerve-sparing robot-assisted prostatectomy. However, the results of this unblinded nonrandomized study need to be further investigated and a large well-controlled blinded trial is warranted.

EpiFix for Mohs Micrographic Surgery

Toman (2021) published the results of a retrospective case-control study involving 286 participants who underwent Mohs micrographic surgery of the face, head, or neck with the use of EpiFix or autologous tissue-based procedures, including full-thickness skin grafts (FTSG) and flaps (n=143, respectively). In univariate analysis, the authors reported that participants in the EpiFix group had no postoperative complications vs. the autologous tissue group participants (97.9% vs. 71.3%, p<0.0001, RR=13.67). The EpiFix group also experienced significantly fewer infections (p=0.004), better scar cosmesis (p<0.0001), fewer scar revisions (p<0.0001), and fewer surgical reinterventions at the index site (p=0.0007). The autologous tissue group required fewer mean (SD) follow-up visits (2.5 vs. 3.4, p<0.0001). In a multivariate analysis controlling for defect surface area, operation time, age, medical history, and gender, use of autologous tissue remained an independent significant risk factor for infection or additional operation (OR, 11.71, p<0.0001). The authors also reported the results of an analysis that included cosmetic outcomes. The results indicated that the odds of infection, additional operation, poor scar cosmesis, or scar revision were 19-times higher in autologous group (OR,18.76, p<0.0001). Finally, they found that being a natal female was also associated with 3-times greater odds of having a cosmetic complication (OR, 2.84, p=0.010).

Fresh Frozen Unprocessed Allograft Skin for non-healing DFU's and Dermal Wounds

Towler, 2018 Apligraf (n=12) to TheraSkin (n=15) for the treatment of VSUs. The authors reported no statistical differences between groups with regard to time to complete healing at 12 or 20 weeks (p=0.294 and p=0.569, respectively). Additionally, no differences were noted between groups with regard to the number of grafts needed (p=0.119). No adverse events were reported for either group. The authors concluded that both products are safe and

effective to treat VSUs. However, the study was limited by small sample size, lack of blinding and other methodological issues.

Armstrong (2022) conducted a randomized, prospective, evaluator-blinded study which compared the response of 100 participants with non-healing DFU's, 50 of which were treated with TheraSkin and 50 treated with SOC. A total of 23 participants withdrew from the trial, 4 in the TheraSkin group and 19 in the control group. In the TheraSkin group 1 was removed for not achieving > 50% area reduction by 6 weeks, 1 for wound worsening, and 2 due to adverse events, 1 potentially related to the study treatment and the other not related. In the control group, 11 participants were removed for not achieving > 50% area reduction by 6 weeks, 1 due to reopened wound, 3 due to serious adverse events, 2 which were potentially treatment related, and 4 due to adverse events, 1 of which was possibly related to study treatment. In the ITT analysis the results at 12 weeks showed that 76% (38/50) of the TheraSkin-treated DFUs healed compared to 36% (18/50) of controls treated with SOC (adjusted p=0.00056). The mean percent area reduction at 12 weeks was 77.8% in the TheraSkin group vs. 49.6% in the SOC group (adjusted p=0.0019). The average time for closure within the 12-week period was 46.9 days for the TheraSkin group vs. 65.3 days for controls (p=0.0019). The authors concluded that wounds treated with TheraSkin in addition to SOC improved wound healing compared to SOC alone.

Grafix PRIME for Non-DFU Dermal Wounds

In 2017, Johnson and others published a report of a retrospective nonrandomized study comparing the outcomes from two separate cohort studies involving Grafix PRIME (n=40) or Epifix (n=39) for the treatment of a variety of wounds including VSUs, surgical wounds, DFUs, arterial ulcers, pressure ulcers, and 'other' wounds. The authors reported that the proportion of wounds achieving complete wound closure was 63.0% (29/46) for the Grafix group and 18.2% (10/55) for the Epifix group (OR=7.5, p<0.0001) for all treated wounds combined. When analyzed by wound type, the results indicated that treatment with Grafix group had a significantly higher rate of completely closed VSUs (70% vs. 7%, p=0.0024) and surgical wounds (81.9 vs. 18.2%, p=0.009). The small number of participants, and retrospective, non-random, and unblinded methodology used in this study impair the generalizability of the results.

Another published case series study addressed the use of Grafix PRIME and included 67 wounds in 66 participants with either DFUs (n=27), VSUs (n=34), or other chronic wounds (n=6) (Regulski, 2013). At 12 weeks, 51 of 67 wounds (76.1%) were healed. By wound type, 23 of 34 (67.6%) VSUs and 23 of 27 (85.2%) DFUs were healed at 12 weeks. The average time to closure in these wounds was 5.8 (± 2.5) weeks. No significant differences were reported between the two wound type groups, and no adverse events or recurrences were reported.

GraftJacket for DFUs

One randomized controlled trial compared the use of standard surgical debridement of DFUs followed by GraftJacket placement vs. standard surgical debridement alone (20 participants in each group) (Brigido, 2004). The findings of the study demonstrated significant differences between the two groups, with the experimental group demonstrating much faster healing progression. While the results of this study are promising, the small sample size,

as well as its single-blind design, limits its utility. The same authors conducted a second RCT with 28 participants with chronic DFUs who were assigned to receive either GraftJacket (n=14) or standard care (n=14) (Brigido, 2006). At 16 weeks, 12 of 14 (85.7%) of the GraftJacket participants demonstrated complete wound closure, compared with 4 of 14 (28.6%) in the control group (p value not provided). Participants treated with GraftJacket demonstrated a statistically significant higher percentage of wound healing with respect to wound area, and clinically significant differences in wound depth and wound volume ($p<0.001$).

Reyzelman (2009) reported the results of an RCT involving 85 participants with DFUs assigned to receive treatment with either GraftJacket (n=46) or standard care (n=39). The authors reported significantly better complete and mean healing times in the GraftJacket group (69.6% and 5.7 weeks) compared to the controls (46.2% and 6.8 weeks) who received standard care ($p=0.029$). Furthermore, there was a significantly higher non-healing rate for the control group (53.9%) compared with the study group (30.4%) at 12 weeks ($p=0.015$). Neither the participants nor the investigators were blind to group assignment.

A prospective non-blind RCT involving 168 participants with DFUs assigned in a 2:2:1 fashion to treatment with DermACELL (n=71), conventional care (n=69), or Graftjacket (n=28) (Walters, 2016). At 16 weeks post intimal treatment, no significant differences in the proportion of completely healed ulcers vs. the conventional care group was found (67.9% vs 47.8%; $p=0.1149$). No differences between groups were reported with regard to severe adverse events ($p\geq0.05$).

Cazzell (2017) conducted an RCT involving 132 participants with chronic DFUs undergoing treatment in 2:2:1 fashion with either DermACELL (n=53), conventional care (n=56), or GraftJacket (n=23). Participants were followed through 24 weeks, with endpoint measurement at 12, 16, and 24 weeks. GraftJacket did not show a significantly greater healing rate over conventional care at any of these time points. No significant difference was noted between the GraftJacket group vs. the conventional care group for healed wounds remaining closed. However, as noted above, the results of this comparison for GraftJacket are significantly hampered by small numbers of participants, and the results should be viewed with that in mind.

GraftJacket for Tendon Injuries (e.g., rotator cuff)

GraftJacket has also been proposed for use in shoulder surgery to repair soft tissue injuries. Barber (2012) reported on an RCT involving 42 participants with rotator cuff injuries randomized to undergo repair with GraftJacket (n=20) or standard surgical procedures (n=22). At the 2-year follow-up period, significant benefits were noted on several scales, including the American Shoulder and Elbow Surgeons (ASES) ($p=0.035$) and Constant ($p=0.008$) assessment tools. No significant difference was seen on the University of California, Los Angeles (UCLA) tool ($p=0.43$). Imaging studies found that at 2 years, 85% of the GraftJacket group had intact grafts, compared to only 40% in the standard care group ($p<0.01$). A prospective case series study by Gupta and others (2012) involved 24 participants with rotator cuff tears treated with GraftJacket and followed for 3 years postoperatively. The authors report significant improvements with regard to pain, ($p=0.002$), mean active forward flexion and external rotation ($p=0.002$), mean shoulder abduction ($p=0.0001$), supraspinus strength ($p=0.0003$), and ASES scores ($p=0.0003$).

Ultrasonography showed 76% of repairs were fully intact, with the remainder of participants with partially intact repairs.

GraftJacket for Osteoarthritis

Marks (2017) reported on a study involving the use of GraftJacket for the treatment of 60 participants with osteoarthritis at the first carpometacarpal (CMC I) joint who underwent treatment with either trapeziectomy with suspension-interposition arthroplasty using the flexor carpi radialis (FCR) tendon (n=29) or GraftJacket (n=31). They reported that baseline Michigan Hand Outcomes Questionnaire (MHQ) total scores significantly increased from 51 to 83 in the FCR group and 53 to 76 in the GraftJacket group by 12 months ($p<0.05$ for both). No differences between groups were reported ($p>0.05$). Complications were reported in 5 FCR-related participants, and 10 in the GraftJacket group ($p=0.24$). Revision surgery was required for 1 allograft recipient. They concluded that the use of the FCR tendon or GraftJacket for trapeziectomy with suspension-interposition arthroplasty leads to similar outcomes, but with more complications, mainly tendon irritations, associated with GraftJacket. They noted that they "only use the allograft in cases of severe instability requiring a larger amount of suspension-interposition material or for revision procedures after failed suspension-interposition with the FCR tendon."

Integra Bilayer Matrix Wound Dressing for Cutaneous Scalp Defects

Othman (2021) reported the results of a retrospective case series study involving the use of Integra Bilayer Matrix Wound Dressing for the treatment of cutaneous scalp defects in 127 participants older than 60 years of age. The reconstructive procedures were conducted in a 2-stage fashion, with the wound first being treated with Integra followed by STSG between 3-4 weeks afterwards. A total of 107 (84%) participants were successfully reconstructed. The 20 participants who had treatment failure were more likely to have a history of radiotherapy (30% in the failure group vs. 12% in the success group, $p<0.04$). Place of service was noted as a significant factor in treatment failure, with 25% of participants treated in the inpatient setting having failure vs. 8% of participants treated in the outpatient setting ($p<0.034$). The authors noted that postoperative wound infection was significantly associated with reconstructive failure (30% vs. 6.5%, respectively; OR, 6.4, $p<0.006$). The results of this study are promising, but the methodology used does not allow generalization of these findings to a wider population.

Integra OmniGraft Dermal Regeneration Template for DFUs

In 2015, Driver reported the results of an RCT involving 307 participants with DFUs assigned to treatment with either standard care (n=153) or treatment with Omnigraft (n=154) and followed initially for 16 weeks or until confirmation of complete wound closure, and then for a further 12 weeks. The investigators reported that complete DFU closure during the treatment phase was significantly greater with Omnigraft vs. control treatment (51% vs. 32%; $p=0.001$). The median time to complete DFU closure was 43 days for Omnigraft participants vs. 78 days for controls, in wounds that healed. The rate of wound size reduction was significantly better in the Omnigraft participants (7.2% per week vs. 4.8% per week, $p=0.012$). They concluded that for the treatment of chronic DFUs, Omnigraft treatment decreased the time to complete wound closure, increased the rate of wound closure, improved components of quality of life and had less adverse events compared with the standard of care treatment.

Hicks and others (2020) reported the results of a case series study that included 85 participants treated with Omnigraft who underwent surgical procedures for debridement of a DFU or gangrene resulting in complex post-surgical DFUs. Overall, 107 wounds were treated, with 45.8% involving the forefoot, 23.4% the heel, 19.6% the midfoot, 5.6% the ankle, and 5.6% the lower leg/Achilles tendon. Bone involvement due to acute or chronic osteomyelitis occurred in 71.7%. Most participants were at high risk for amputation based on Society for Vascular Surgery Wound, Ischemia, and foot Infection (WIfI) classification score (6.4% were WIfI classification score 4). Overall success rate for all initial dermal regeneration template applications was 66.7%, with the majority of wounds (81.3%) receiving one dermal regeneration template application. Two applications were reported in 15.9% of cases and three applications in 2.8%. Mean time to complete healing was 198 ± 18 days. Location of the wound on the forefoot was associated with significantly better healing (HR, 5.2) as was the presence of bone involvement (HR, 1.86). While these results are promising, the lack of a comparison group and other methodological weaknesses limit their generalizability.

Integra OmniGraft Dermal Regeneration Template for Cutaneous Scalp Defects

In 2021 Mogedas-Vergara described a retrospective cohort study involving 70 participants with skin cancer undergoing scalp reconstruction procedures. All participants were over 65 years or age. Each participant underwent 2-stage procedures involving the first stage where Integra Derma Regeneration Template was used followed by the application of a STSG after 3-4 weeks. The mean surface area treated was 23 cm^2 and the mean interval between stages was 30.6 days. Seven participants (10%) did not undergo a second-phase procedure due to rapid wound epithelialization. The Integra and skin graft success rates were 87.1% and 100%, respectively. A total of 13 participants (18.6%) developed infections. In 4 participants (5.7%) the infection caused partial Integra loss, which was treated via debridement and antibiotics and no need to reconsider placement of the graft. Infection resulted in total loss of the Integra graft in in 9 participants (12.9%) and healing was completed by second intention without major complications. Mean wound epithelization in this subgroup of 13 participants was 60.33 days and no other complications were recorded. The results of this study are promising, but the methodology used does not allow generalization of these findings to a wider population.

Integra OmniGraft Dermal Regeneration Template for Skin Donor Site Sites

Falcone (2023) reported on the results of a retrospective comparative study involving the use of single-layer Integra to treat allogenic radial artery forearm free-flap skin donor site sites during total phallic construction. A total of 34 participants were included, 18 who received FTSG alone and 16 who received Integra covered by a STSG. The authors reported significantly better healing time in the Integra group vs. the FTSG group (24 days vs. 30 days, p=0.003). Similarly, the Integra group had significantly better complete graft take (93.8% vs. 27.8%, p=0.001), shorter operative times (310 min vs. 447 min, p=0.001), and median hospital stay (8 days vs. 10 days, p=0.001). This was the first study of its kind to be published. The results are promising, but additional data from more robustly designed and conducted trials is warranted to better understand the role of Integra for the treatment of free-flap donor sites.

Kerecis™ Omega3 for Surgical Wounds

The available evidence addressing the clinical safety and efficacy of Kerecis is limited. A double-blind, parallel-group non-inferiority RCT involving 81 participants with 162 full-thickness surgical wounds was reported by Baldursson in 2015. Each participant underwent the creation of two 4 mm full thickness wounds made on the proximal anteriolateral aspect of their non-dominant arm, 2 cm apart. Each participant had one wound treated with Kerecis and the other wound with Oasis porcine-derived graft product and were followed for 28 days. At the study endpoint, 95% (76/80) of wounds in the Kerecis group and 96.3% (79/82) of wounds in the Oasis group were healed. The authors reported that this result was within the 95% two-sided confidence interval for non-inferiority margin of 0.1. They also noted that the OR of a Kerecis-treated wound being healed vs. an Oasis-treated wound was 4.75 (p=0.041), indicating that Kerecis added significantly faster wound healing vs. Oasis. No significant immunological responses were noted in the Kerecis group. While the findings of this study are interesting, they do not provide data regarding performance of the product in the populations for which they are proposed, specifically, those with impaired healing and chronic wounds. The results involving experimentally created wounds are not useful in informing the discussion of the clinical utility of Kerecis Omega3 in the real-world setting for the treatment of individuals with impaired healing function.

Another study addressing the clinical outcomes of Kerecis has been published (Yang, 2016). However, this study involved only 5 participants, limiting the generalizability of the results, and did not involve any comparison group. The value of this publication in understanding the generalizable safety and efficacy of Kerecis is limited.

Kirsner (2020) published the results of a double blind RCT involving 85 healthy participants who had two investigator-created full thickness punch biopsy wounds randomly assigned to treatment with either Kerecis or EpiFix. A total of 170 wounds were treated. The authors stated that the Kerecis-treated wounds healed significantly faster than the EpiFix-treated wounds (HR, 2.37, p=0.0014). No differences between groups were reported with regard to adverse or serious adverse events. These results indicate that Kerecis is similar to EpiFix in the treatment of acute surgical wounds. However, as with the Baldursson study previously discussed, this study did not adequately reflect the actual real-world use of these products, such as for the treatment of refractory DFUs.

Kerecis™ Omega3 for Chronic Deep Dermal Wounds

Kim (2021) reported the results of a retrospective non-randomized controlled study involving f56 participants with acute or chronic deep dermal wounds who were treated once with Kerecis (n=16) vs. daily standard dressings (n=41). Choice of group was at the participants preference. The control group had 9 participants convert to surgical treatment before the end of the trial, for a total of 32 participants (78%) completing the trial period. In the Kerecis group, 8 participants had acute burns, 5 had acute traumatic wounds, and 1 DFU, 1 VSU and 1 pressure ulcer. In the control group, 15 participants had acute burns, 11 had acute traumatic wounds, and 6 had other unspecified wounds. In the Kerecis group, it was reported that the graft was fully absorbed at an average of 5.56 ± 1.60 days following application, with an average healing rate of 77.7% at 2 weeks. There were no significant differences in wound healing rates between groups for participants with traumatic wounds. For burn participants, the mean healing rate was 86.5% in the Kerecis group vs. 61.1% in the control group (p=0.021). The overall average healing

rate of all wound types treated with Kerecis was 77.7% vs. 53.3% for the control group ($p<0.05$). These results are promising in aggregate, but limited sample sizes limit generalizability, including how Kerecis preforms for certain wound types.

Kerecis™ Omega3 for Non-healing Wounds

Lee (2024) conducted a single-center, prospective RCT study regarding ischemic hard-to-heal wounds below the knee that were unresponsive to 3 weeks of standard care. The study included participants over 18 with specific wound criteria and vessel impairments. Additional inclusion criteria were having a subcutaneous or deep wound; a wound surface area of 4–250 cm in an ischemic state during wound assessment; showing below-knee vessel impairment by CTA; and demonstrating decreased tissue perfusion, with a transcutaneous oxygen pressure (TcPO2) value of ≤ 40mmHg at the ankle. Participants were randomized into either Kerecis dressing (n=28) or standard dressing (n=22) groups. The outcomes measured were weekly decrease in wound area over 12 weeks, and the number of participants that achieved complete wound closure. The findings demonstrated that in participants with DFUs and wounds predominantly on the foot and pretibial area, the Kerecis dressing led to a more rapid decrease in wound area compared to the standard dressing. Additionally, complete wound healing was greater in the Kerecis group (82%) compared to the standard group (45%). In severe ischemic wounds with TcPO2 < 32mmHg, the Kerecis group re-epithelialization rates were 80.24% compared to 57.44%, respectively. The authors concluded that application of Kerecis is a promising treatment option for lower-extremity hard-to-heal wounds, particularly those with impaired vascularity. However, the study's small sample size and limit its generalizability. Large-scale studies are needed to confirm these findings and further investigate the use of Kerecis for the treatment of ischemic non-healing wounds.

Oasis for Burns

Additionally, several studies have been published addressing the use of Oasis products for the treatment of burns. The first (Salgado, 2014) involved a total of 5 participants treated with both Oasis and silver-containing cellulose hydrofiber (Aquacel AG) at different burn sites on the same individual. This study reported on the histomorphometric outcomes, which demonstrated favorable results in favor of the Oasis product. Measurement of epithelial maturation within the repair areas were considered significantly more phenotypically structured after 7 days of treatment with Oasis vs. the Aquacel-treated wounds at 7 days (6.2 vs. 3.2, p=0.029). No infections or "irritation" were reported. Both products were naturally expelled in all participants by 7 days. The Vancouver Scar Scale score for vascularity, pigmentation, and pliability indicated more favorable results in the Oasis group (3.6 vs. 7.2, p=0.025). The unblinded nature of the study, in addition to the low power and other methodological weaknesses do not allow generalization of the findings across larger populations.

A retrospective unblinded case-control study was reported published by Glik in 2017. This study involved 30 participants with burns treated with either Oasis (n=6) or Suprathel (n=24). Histopathological specimens were harvested for evaluation from the participants at 14 and 21 days. The authors provide qualitative observations of the healing process, including comments regarding product adherence to the wound, progression of epithelialization, and pain levels. However, no quantitative data in these factors were reported. While the authors state that Oasis

provides clinical benefit in the treatment of burn wounds, their report is of little value due to the lack of quantitative data to support their findings. Additionally, as with the Salgado study above, significant methodological weaknesses in this study do not allow generalization of the findings across larger populations.

PriMatrix for DFUs

Primatrix is a product derived from acellular bovine dermis and has been cleared through the FDA's 510K process. To date, there are only a limited number of small studies addressing its use in humans. One retrospective, nonrandomized controlled series involved 68 participants with either DFUs (n=40) or VSUs (n=28) who received treatment with either Apligraf (n=34) or PriMatrix (n=34) (Karr, 2011). The number of participants with each type of wound receiving treatment with Apligraf or PriMatrix was equal, with 20 diabetic foot wounds and 14 VSUs in each group. For diabetic foot ulcers, the Apligraf-treated group's time to complete healing was 87 days, the PriMatrix was 37 days. The average number of graft applications was 2 in the Apligraf group and 1.5 in the PriMatrix group. For VSUs, the time to complete healing was 63 days in the Apligraf group and 32 days in the PriMatrix group. The Apligraf group had 1.7 graft applications compared to 1.3 in the PriMatrix group.

Lantis and others (2021) reported the results of an unblinded RCT involving 226 participants with treatment resistant DFUs treated with either PriMatrix plus standard care or standard care. The authors state that the study was terminated early due to the COVID-19 pandemic. They conducted a modified intent-to-treat analysis on a total of 207 participants, 103 in the PriMatrix group and 104 in the standard care group. Additionally, a total of 161 participants completed the study per modified protocol, with 79 receiving PriMatrix and 82 standard care. The modified intent-to-treat analysis found that PriMatrix treated participants had a significantly greater number of wounds achieve complete wound closure vs. those treated with standard care (45.6% vs. 27.9%, p=0.008). Similar findings were reported in the modified per-protocol analysis (59.5% vs. 35.4%, p=0.002). The odds of complete wound closure at 12 weeks were reported to be 2.2 times greater in the PriMatrix group (p=0.008). No significant differences were noted with regard to median time to closure within 12 weeks (43 days vs. 57, p=0.36). The mean and median number of PriMatrix applications to achieve closure per wound was 1.4 and 1. No adverse events or serious adverse events related to the use of PriMatrix or the procedure were reported. The authors concluded that a single application of PriMatrix plus standard care offers a safe, faster, and more effective treatment of DFUs than standard care alone.

SurgiMend diaphragmatic and/or chest wall reconstruction

Lampridis, 2023 described the results of a non-randomized comparative study of 66 participants who underwent diaphragmatic and/or chest wall reconstruction for a malignant (74.2%) or benign (25.8%) disease with SurgiMend (n=26, 39.4%) or synthetic expanded polytetrafluoro ethylene mesh (Gore-Tex, n=40, 60.6%). The Gore-Tex group experienced a significantly higher rate of surgical site complications vs. the SurgiMend group (n=6 [37.5%] vs. 2 [11.5%]; p=0.025). Readmission rates were significantly higher in the Gore-Tex group (17.5% vs. 0%; p=0.037), with causes including pleural effusion (n=3), pneumothorax (n=2), empyema (n=1), and pneumonia (n=1). Among the study cohort, only 1 participant with a synthetic mesh underwent reoperation (p>0.99). There were no differences between groups with regard to medical complications or 90-day mortality. This study demonstrates

beneficial results with regard to the use of SurgiMend vs. Gore-Tex for diaphragmatic and/or chest wall reconstruction. However, the low power and other methodological issues impair the generalizability of these findings.

Definitions

510k process: The FDA process used to clear Class I and II medical devices prior to marketing in the U.S. Also referred to as the premarket notification process. This process does not require the review of safety or efficacy data for the products reviewed. Devices considered via this process are deemed "cleared" by the FDA.
Allogeneic*:* A product derived from humans, other than the individual being treated.

Autologous*:* A product derived from the individual's own body or body products.

Bioengineered: A product derived from cultured and processed cells.

Bullous keratopathy: A condition where small fluid-filled vesicles, or bullae, form within the cornea.

Complex Abdominal Wall Reconstruction: A surgical procedure to repair extensive or recurrent hernias, hernias resulting from previous surgeries, those affecting multiple areas of the abdominal wall, or associated with complicating factors like infections, compromised or damaged tissues, or contamination. The purpose of the procedure is to restore functional and structural integrity of the abdominal wall. It may involve moving muscles and skin flaps, implantation of synthetic, biologic, or composite mesh, and may require surgical component separation techniques to ensure a tension-free repair to reduce the risk of failure and recurrence.

Composite: A product derived from a mix of materials of various origins.

Conjunctiva: A clear, thin membrane that covers part of the front of the eye and lines the inside of the eyelids.

Corneal melt: Keratolysis, or sterile melting of the cornea, is a condition characterized by a progressing thinning of the cornea, leading to perforation.

Diabetic foot ulcer (DFU): A potential complication of diabetes due to prolonged elevated blood sugar levels which can damage blood vessels and nerves throughout the body. A DFU is a slow healing full-thickness wound, through the dermis, below the ankle on a weight-bearing or exposed surface in an individual with diabetes. DFUs are categorized as being neuropathic, ischemic, or neuroischemic (mixed). The most common sites are the plantar surface of foot and the toes. DFUs are caused by repetitive injury to an insensate or vascularly compromised foot and may lead to amputation.

Epidermolysis bullosa (EB): A disease characterized by the presence of extremely fragile skin and recurrent blister formation, resulting from minor mechanical friction or trauma.

HCT/P: The FDA's review process for 'Human Cells, Tissues, and Cellular and Tissue-Based Products' human tissue transplantation.

Hernia meshes of non-biologic origin: These products are either synthetic or biosynthetic:

Biosynthetic: Mesh products are made from resorbable synthetically derived meshes with resorption profiles between 6 and 36 months. Theoretically, this allows native collagen deposition for wound strength and durability while reducing the risks of chronic mesh infection affiliated with permanent synthetic alternatives.

Synthetic: Mesh products are made from either woven extruded monofilament (for example, polypropylene or polyester) or created from expanded polytetrafluoroethylene. They may be subcategorized by; weight/density, material, composition, pore characteristics, and mechanical parameters. Products in this category are permanent and are not absorbed by the body.

Humanitarian Device Exemption (HDE): This is an FDA pathway for devices intended to treat or diagnose a disease or condition that affects fewer than 4,000 people per year and such conditions purportedly make it difficult to gather enough clinical evidence to meet the FDA standards for other pathways. Applicants must demonstrate that there are no similar, legally approved devices on the market and that there is no other way to bring a Humanitarian Use Device to market. The law exempts HDE devices from demonstrating a reasonable assurance of effectiveness, and instead requires demonstration of probable benefit, and is subject to certain profit and use restrictions. HDE devices must be used only with prior approval and strict observation of an Institutional Review Board (IRB) or appropriate local committee serving a similar function.

Limbal stem cell deficiency: A condition characterized by decreasing function of the stem cells within the epithelial layer of the cornea.

Neurotrophic keratitis: A degenerative disease of the eye due to a loss of corneal sensation leading to progressive damage to the top layer of the cornea.

Penetrating keratoplasty: A surgical procedure that is conducted during corneal transplantation.

Plant based: A product derived from plant sources.

Premarket Approval (PMA): The FDA process used to clear Class III medical devices prior to marketing in the U.S. This process requires the review of safety or efficacy data for the products reviewed. Devices considered via this process are deemed "approved" by the FDA.

Pterygium: A growth involving the conjunctiva of the eye that appears as a growth or bump on the side of the eye near the nose.

Stevens-Johnson syndrome: Also known as toxic epidermal necrolysis, is a rare, serious disorder of the skin and mucous membranes that is characterized by painful rash in its mild form and severe blisters and skin peeling in its more advanced form.

Superficial punctate keratitis (SPK): An inflammation of the upper layers of the cornea with white opacities present below the surface of the cornea, a characteristic negative fluorescein staining pattern may be present. Symptoms include recurrent burning, tearing, light sensitivity, and a sensation of a foreign body in the eyes. Symptoms are usually self-limiting and can be treated with steroids in severe cases.

Synthetic: A product derived from manufactured materials.
Vancouver scar scale: An objective and validated method for describing burn scars that includes a summation of scar characteristics including pigmentation [0-2], vascularity [0-3], pliability [0-5], and height [0-3], normal skin is given a score of 0 for each category.

WHCRA: The Women's Health and Cancer Rights Act of 1998 (WHCRA) is federal legislation that provides that any individual, with insurance coverage who is receiving benefits in connection with a mastectomy covered by their benefit plan (whether or not for cancer) who elects breast reconstruction, must receive coverage for the reconstructive services as provided by WHCRA. This includes reconstruction of the breast on which the mastectomy has been performed, surgery and reconstruction of the other breast to produce a symmetrical appearance and prostheses and treatment of physical complications of all stages of the mastectomy including lymphedemas. If additional surgery is required for either breast for treatment of physical complications of the implant or reconstruction, surgery on the other breast to produce a symmetrical appearance is reconstructive at that point as well. The name of this law is misleading because: 1) cancer does not have to be the reason for the mastectomy; and 2) the mandate applies to men, as well as women. WHCRA does not address lumpectomies. Some states have enacted similar legislation, and some states include mandated benefits for reconstructive services after lumpectomy.

Xenographic*:* A product derived from non-human organisms (e.g., cows, pigs, horses, etc.).

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Index

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

History

Status	Date	Action
Revised	05/08/2025	Medical Policy & Technology Assessment Committee (MPTAC) review. Revised Description/Scope section. Removed content related to complex abdominal wall reconstruction from non-healing wound section. Added separate MN statement for complex abdominal wall reconstruction. Revised list of products in non-healing wound section. Revised formatting in Clinical

		Indications section. Revised Definitions, References, and Websites sections. Revised Coding section and updated to include 07/01/2025 HCPCS changes, added Q4369.
New	02/20/2025	MPTAC review. Initial document development. Moved MN and NMN criteria for breast reconstruction, burns, complex abdominal wall wounds, dermal wounds, diabetic foot ulcers, venous stasis ulcers, and ocular indications from SURG.00011. Added NuSheild and Oasis Ultra Tri-Layer Wound Matrix as MN for diabetic foot ulcers. Added Oasis Ultra Tri-Layer Wound Matrix as MN for chronic wounds. Removed limit of "not more than 52 weeks" from DFU and non-healing wound criteria. Revised ocular indications to be agnostic to specific product, as long as it is amnion-derived. Reformatted and updated Coding section, added Q4160, Q4334, and Q4335 with MN indications.