Bioengineered Skin and Soft Tissue Substitutes

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

Injuries and damage to the skin or underlying soft tissue can occur through a number of different mechanisms. Common causes may include severe burns, accidents, surgical procedures, and ulcers (e.g., diabetic or venous stasis ulcers). In most cases, conservative treatment, such as optimizing blood flow, preventing or treating infections, keeping the tissue moist, and clearing any dead tissue is adequate. However, some wounds require more advanced techniques to promote wound healing in the presence of other comorbidities or due to the extent of the damage. In such cases, biologic or synthetic skin/tissue products may be grafted to the wound. These skin/tissue products can provide living cells and/or a scaffold to encourage wound closure, promote tissue regeneration, or provide structural support. They can be "donated" from another site on the member's body or bioengineered depending on the specific indication. Such procedures are often part of a multidisciplinary wound care treatment plan.

This guideline outlines the clinical criteria, indications, and exclusions for bioengineered skin and soft tissue substitutes. This document does *not* address cosmetic or reconstructive skin procedures, blood-derived products for chronic wound healing, hyperbaric oxygen therapy, negative pressure wound therapy, suction devices, infrared or electrical stimulation, or other types of wound management.

Certain skin and soft tissue substitutes may be considered as part of medically necessary breast reconstruction as per the Plan Clinical Guideline: Breast Procedures (CG036).

Definitions

"Allograft (allogeneic transplant)" is the transfer of tissue from a genetically non-identical donor of the same species.

"Bioengineered skin substitutes," also referred to as "human skin equivalents (HSE)," are engineered artificial skin products or combinations of skin products and other materials. They can be acellular or cellular, as defined below, and may be contained within a framework called a matrix, which can be synthetic or natural.

"Cellular dressing" refers to a bioengineered skin substitute containing at least one layer of live cells (e.g., fibroblasts, keratinocytes, epidermal cells, dermal cells, etc.). The cells can be derived from the member's own body (i.e., autologous), a human donor (i.e., allogeneic), or from another species (i.e., xenographic). They can also be derived from tissues other than skin, such as placenta, intestine, or synthetic/composite materials. Cellular dressings provide a framework for the body to begin wound healing, as well as growth factors and cells to facilitate this process. Some examples include, but are not limited to:

- AmnioBand/Guardian (Q4151) - an allograft placental matrix comprised of donated human amnion and chorion
- Apligraf (Q4101) - a living, bilayered (epidermal and dermal) skin substitute derived from human keratinocytes and fibroblasts
- Dermagraft (Q4106) - a human fibroblast-derived dermal substitute
- Epicel (Q4100) - a cultured epidermal autograft
- Epicord (Q4187) - a dehydrated human umbilical cord allograft composed of an extracellular matrix of hyaluronic acid (HA) and collagen
- Epifix (Q4186) - a multilayer biologic allograft derived from human amniotic membrane
- Grafix Core and Grafix PRIME (Q4132-Q4133) - extracellular matrix containing growth factors designed as allografts with endogenous mesenchymal stem cells; Grafix Core is derived from chorionic placental tissue and Grafix PRIME is derived from the amniotic membrane of placental tissue
- OrCel (Q4100) - a bilayered skin substitute consisting of epidermal keratinocytes and dermal fibroblasts in two layers of bovine collagen
- StrataGraft (Q4100) - is a bi-layered construct made from allogeneic (human) cultured keratinocytes and dermal fibroblasts in murine (rodent) collagen
- Theraskin (Q4121) - a biologically active epidermal and dermal skin substitute consisting of cryopreserved human skin allograft, fibroblasts, keratinocytes, and extracellular matrix
- TransCyte (Q4100) - a biosynthetic dressing consisting of allogeneic human dermal fibroblasts

"Acellular dressing" refers to a bioengineered skin substitute containing matrix or scaffold materials (e.g., collagen, hyaluronic acid) but without any living cells. An acellular matrix provides a foundation for the member's cells to begin wound healing. Some examples include, but are not limited to:

- Allopatch (Q4128)- a hydrated allograft acellular dermal matrix uniquely derived from human tissue processed to remove epidermal and dermal cells
- Biobrane/Biobrane-L (Q4100) - a biosynthetic wound dressing constructed from a silicon film with nylon impregnated into the dressing
- Cortiva (Allomax/NeoForm) (Q4100), Alloderm (Q4116), FlexHD (Q4128)
- DermACELL (Q4122) - human acellular dermal matrix with ≥97% of donor DNA removed.
- Integra Bilayer Matrix Wound Dressing (Q4104), Integra Meshed Bilayer Wound Matrix (C9363 or Q4105), and Integra Dermal Regeneration Template (Q4105) or Integra Omnigraft Dermal Regeneration Matrix (Q4105) - cross-linked bovine tendon collagen and glycosaminoglycan and a semi-permeable polysiloxane (silicone) layers
- Graftjacket Regenerative Tissue Matrix (Q4107) - a cadaveric dermal and epidermal skin substitute
- Oasis Wound Matrix (Q4102) - an extracellular matrix material derived from the submucosal layer of porcine small intestine

"Grafting" is when a material (whether organic or synthetic) is transplanted to cover an injury or wound. There are several graft types:

- "Autologous" grafting (i.e., autograft) refers to a graft derived from the patient's own skin/tissue, and can be referred to as partial- or split-thickness depending on how it is harvested.
- "Allogeneic" grafting (i.e., allograft) refers to a graft derived from another human other than the member (e.g., cadaver).
- "Xenographic" grafting refers to a graft derived from non-human organisms (e.g., cows, pigs, etc.).
- "Synthetic" grafting refers to a graft that is derived from man-made materials.
- "Composite" grafting refers to a graft derived from various materials or organisms that can be interlinked to create a final product, such as a combination of human cells and synthetic matrix.

"Epidermolysis bullosa (EB)" is a rare disease characterized by fragile skin and recurrent blisters resulting from minor irritation or trauma, typically presenting in early childhood. The resulting blisters may form large, painful wounds that resemble severe burns, and may require extensive grafting. Epidermolysis Bullosa can be categorized as Epidermolysis Bullosa Simplex (most common type with majority of mutations in the keratin genes KRT5 and KRT14), Junctional Epidermolysis Bullosa (majority of mutations in the laminin-332 genes), and Dystrophic Epidermolysis Bullosa (mutations in the COL7A1 gene).

A. Clinical Indications

1. Medical Necessity Criteria for Clinical Review

a. General Medical Necessity Criteria

b. Indication-Specific Criteria

Medical Necessity Criteria for Clinical Review

General Medical Necessity Criteria

In addition to the Indication-Specific Criteria, ALL of the following criteria must be met:

1. The procedure is performed by a licensed practitioner per state and federal law; *and*
2. Members using tobacco products have received cessation counseling and been informed of the impact of smoking on surgical outcomes prior to the procedure; *and*
3. Medical records document ALL of the following (unless the review of request is upon prior auth and wound characteristics are not available until after surgery, the surgery must meet medical necessity and the planned brand of tissue must be identified in request):
    a. Medical necessity for the skin/tissue substitute; *and*
    b. Wound characteristics, including the size, location, depth, underlying conditions; *and*
    c. Previous methods, response, and duration of conservative therapy; *and*
    d. Full treatment plan that accompanies the bioengineered skin/tissue substitute.
4. The duration and frequency of the treatment plan is ordered as follows:
    a. Treatment is limited to one initial application; *and*
    b. Additional applications may occur at a minimum of 1 week intervals up to a maximum of 12 weeks (specific number of treatments may vary) *and* only when there is evidence of wound healing (e.g., reduced ulcer size, increasing epithelialization).

Indication-Specific Criteria

<u>Alginate or Other Fiber Gelling Dressing (A6196 - A6199)</u>

Alginate or other fiber gelling dressing (A6196 - A6199) is considered medically necessary when the following criteria are met:

1. For moderate to heavy exudating partial- and full-thickness wounds (e.g., pressure ulcers, venous ulcers, diabetic ulcers, donor and graft sites, traumatic and surgical wounds, and 1st and 2nd degree burns).

<u>AmnioBand/Guardian (Q4151), AlloPatch (AllopatchHD) (Q4128)</u>

AmnioBand/Guardian (Q4151) or AlloPatchHD (Q4128) are considered medically necessary when ALL of the following criteria are met:

2. For diabetic foot ulcers, when the following characteristics are present:
    a. Ulcer has no evidence of infection; *and*
    b. Full-thickness (i.e., extends through the dermis) neuropathic diabetic foot ulcer; *and*
    c. Ulcer does not expose bone, tendon, muscle, or joint capsule; *and*
3. A minimum of 4 weeks of appropriate conventional therapy has failed or been ineffective, defined by standard dressing changes, debridement as necessary, and off-loading of pressure/weight: *and*

4. Current diagnosis of type 1 or type 2 diabetes, with hemoglobin A1C less than 12%; *and*
5. Adequate circulation to the affected extremity, defined by ONE of the following:
    a. Transcutaneous oxygen test (TcPO2) ≥30 mmHg; *or*
    b. Ankle-brachial index (ABI) between 0.7 and 1.2; *or*
    c. Triphasic or biphasic Doppler arterial waveforms at the ankle of the affected leg; *or*
    d. Palpable foot pulses (e.g., dorsalis pedis or posterior tibial pulses).

Artiss (C9250)

Artiss (C9250) is considered medically necessary when BOTH of the following criteria are met:

1. Age 1 year or older with severe burns undergoing autologous skin grafting; *and*
2. Body surface area of burn(s) ≤40%.

Breast Reconstructive Surgery

Cortiva (AlloMax/NeoForm) (Q4100), Alloderm/Alloderm RTU (Q4116), DermACELL (Q4122), or FlexHD (Q4128) are considered medically necessary when BOTH of the following criteria are met:

1. For use in members in conjunction with medically necessary breast reconstructive surgery*; and*
2. Member has completed discussion with the provider about the risks and benefits of implant-based breast reconstruction with or without these acellular dermal matrices. (Note: In general, the FDA has provided a safety communication that acellular dermal matrix products have not been approved/cleared for breast reconstruction. These matrices can be ordered for members unless explicitly stated in a black box warning or contraindication).

Biobrane/Biobrane-L (Q4100)

Biobrane/Biobrane-L (Q4100) is considered medically necessary when ONE of the following criteria is met:

1. Biobrane: For the temporary covering of superficial, partial-thickness thermal injury; *or*
2. Biobrane-L: Covered when the criteria for Biobrane are met AND the dressing is used as an adjunct to a meshed autograft.

Dermagraft (Q4106)

Dermagraft (Q4106) is considered medically necessary when ALL of the following criteria are met:

1. Dermagraft is not being used in conjunction with Dakin's solution, chlorhexidine, polymyxin/nystatin, or any other cytotoxic solution due to breakdown and loss of effectiveness as demonstrated in clinical studies; *and*
2. Dermagraft is not ordered for members under the age of 18, pregnant women, members receiving immunosuppressive therapy (e.g., steroids, chemotherapy), or members with ulcers overlying Charcot's deformity; *and*
3. Treatment strictly adheres to FDA labeling guidelines, as documented by the 24-step procedure; *and*
4. For dystrophic epidermolysis bullosa wounds; *or*
5. For diabetic foot ulcers, when the following characteristics are present:

a. Full-thickness (i.e., extends through the dermis) neuropathic diabetic foot ulcer; *and*
b. Ulcer does not expose bone, tendon, muscle, or joint capsule; *and*
c. Ulcer has no evidence of infection or a sinus tract; *and*
d. Adequate circulation to the affected extremity, defined by ONE of the following:
    i. Transcutaneous oxygen test (TcPO2) ≥30 mmHg; *or*
    ii. Ankle-brachial index (ABI) between 0.7 and 1.2; *or*
    iii. Triphasic or biphasic Doppler arterial waveforms at the ankle of the affected leg; *or*
    iv. Palpable foot pulses (e.g., dorsalis pedis or posterior tibial pulses); *or*
    v. No clinically significant stenosis in a major feeding blood vessel as demonstrated by advanced imaging (MRA, CTA, or angiography).
e. A minimum of 6 weeks of appropriate conventional therapy has failed or been ineffective, as defined by standard dressing changes, debridement as necessary, and off-loading of pressure/weight; *and*
f. Current diagnosis of type 1 or type 2 diabetes, with hemoglobin A1C less than 12%.

<u>DermACELL (Q4122)</u>

DermACELL (Q4122) is considered medically necessary when ALL of the following criteria are met:

1. For diabetic foot ulcers, when ALL the following characteristics are present:
    a. Full-thickness (i.e., extends through the dermis) diabetic foot ulcer; *and*
    b. Ulcer does not expose bone, tendon, muscle, or joint capsule; *and*
    c. Ulcer has no evidence of infection or a sinus tract; *and*
    d. Adequate circulation to the affected extremity, defined by ONE of the following:
        i. Transcutaneous oxygen test (TcPO2) ≥30 mmHg; *or*
        ii. Ankle-brachial index (ABI) between 0.8 and 1.2; *or*
        iii. Triphasic or biphasic Doppler arterial waveforms at the ankle of the affected leg; *or*
        iv. Palpable foot pulses (e.g., dorsalis pedis or posterior tibial pulses); *and*
    e. A minimum of 4 weeks of appropriate conventional therapy has failed or been ineffective, as defined by standard dressing changes, debridement as necessary, and off-loading of pressure/weight; *and*
    f. Current diagnosis of type 1 or type 2 diabetes, with hemoglobin A1C less than 12%.

<u>Epicel (Q4100)</u>

Epicel (Q4100) is considered medically necessary per FDA-approved Humanitarian Device Exemption (HDE) when ONE of the following criteria is met:

1. For deep-dermal or full-thickness burns reaching a total body surface area (BSA) ≥ 30%; *or*
2. For use in conjunction with split-thickness autografts or alone in members who are not candidates for autografting given the severity and/or extent of the thermal injury or the instability of the current overall condition.

Epicord (Q4187)

Epicord (Q4187) is considered medically necessary for diabetic foot ulcers when ALL of the following criteria are met:

1. Full-thickness (e.g. extends through the dermis) non-healing diabetic foot ulcer; *and*
2. Ulcer does not expose bone, tendon, muscle, or joint capsule; *and*
3. A minimum of 4 weeks, and a maximum of 52 weeks, of appropriate conventional therapy has failed or been ineffective, defined as standard dressing changes, debridement as necessary, and off-loading of pressure/weight; *and*
4. Ulcer has no evidence of infection; *and*
5. Current diagnosis of type 1 or type 2 diabetes, with hemoglobin A1C less than 12%; *and*
6. Adequate circulation to the affected extremity, defined by ONE of the following:
    a. Transcutaneous oxygen test (TcPO2) ≥30 mmHg; *or*
    b. Ankle-brachial index (ABI) between 0.7 and 1.2; *or*
    c. Triphasic or biphasic Doppler arterial waveforms at the ankle of the affected leg; *or*
    d. Palpable foot pulses (e.g., dorsalis pedis or posterior tibial pulses).

Epifix (Q4186) Dehydrated Human Amnion/Chorion Membrane (dHACM)

Epifix (Q4186) is considered medically necessary when ALL of the following criteria are met:

1. Ulcer has no evidence of infection or malignancy; *and*
2. Member does not have an autoimmune connective tissue disease; *and*
3. Member is not being treated with radiation, chemotherapy, or COX-2 inhibitors; *and*
4. One of the following:
    a. For diabetic foot ulcers, when the following characteristics are present:
        i. Full-thickness (e.g. extends through the dermis) neuropathic diabetic foot ulcer; *and*
        ii. Ulcer does not expose bone, tendon, muscle, or joint capsule; *and*
        iii. A minimum of 4 weeks, and a maximum of 52 weeks, of appropriate conventional therapy has failed or been ineffective, as defined by standard dressing changes, debridement as necessary, and off-loading of pressure/weight: *and*
        iv. Current diagnosis of type 1 or type 2 diabetes, with hemoglobin A1C less than 12%; *and*
        v. Adequate circulation to the affected extremity, defined by ONE of the following:
            1. Transcutaneous oxygen test (TcPO2) ≥30 mmHg; *or*
            2. Ankle-brachial index (ABI) between 0.7 and 1.2; *or*
            3. Triphasic or biphasic Doppler arterial waveforms at the ankle of the affected leg; *or*
            4. Palpable foot pulses (e.g., dorsalis pedis or posterior tibial pulses).
        vi. Wound is between 1cm^2 and 25cm^2; *or*
    b. For venous insufficiency skin ulcers, when the following characteristics are present:

i. Ulcer must be chronic, non-infected, partial- or full-thickness and due to venous insufficiency; *and*
ii. A minimum of *4 weeks* of appropriate conventional therapy has failed or been ineffective; *and*
iii. Conventional therapy must have included at least 14 days of standard therapeutic compression; *and*
iv. Adequate circulation to the affected extremity, defined by ONE of the following:
    1. Transcutaneous oxygen test (TcPO2) ≥30 mmHg; *or*
    2. Ankle-brachial index (ABI) between 0.7 and 1.2; *or*
    3. Triphasic or biphasic Doppler arterial waveforms at the ankle of the affected leg; *or*
    4. Palpable foot pulses (e.g., dorsalis pedis or posterior tibial pulses).
v. Wound is between 2cm^2 and 20cm^2; *and*
vi. If the member has diabetes, the hemoglobin A1C is less than 10%; *and*
vii. Ulcer is not on the dorsum of the foot or at least 50% of the ulcer is below the malleolus.

<u>Grafix Core and Grafix PRIME (Q4132-Q4133) or Graftjacket Regenerative Tissue Matrix (Q4107)</u>

Grafix Core and Grafix PRIME (Q4132-Q4133) or Graftjacket Regenerative Tissue Matrix (Q4107) is considered medically necessary when ALL of the following criteria are met:

1. ONE of the following:
    a. For Grafix Core and Grafix PRIME, the ulcer has no evidence of infection; *or*
    b. For Graftjacket Regenerative Tissue Matrix, treatment is limited to ONE application; *and*
2. For diabetic foot ulcers, when the following characteristics are present:
    a. Full-thickness (i.e., extends through the dermis) neuropathic diabetic foot ulcer; *and*
    b. Ulcer does not expose bone, tendon, muscle, or joint capsule; *and*
    c. A minimum of 4 weeks of appropriate conventional therapy has failed or been ineffective, as defined by standard dressing changes, debridement as necessary, and off-loading of pressure/weight: *and*
    d. Current diagnosis of type 1 or type 2 diabetes, with hemoglobin A1C less than 12%; *and*
    e. Adequate circulation to the affected extremity, defined by ONE of the following:
        i. Transcutaneous oxygen test (TcPO2) ≥30 mmHg; *or*
        ii. Ankle-brachial index (ABI) between 0.7 and 1.2; *or*
        iii. Triphasic or biphasic Doppler arterial waveforms at the ankle of the affected leg; *or*
        iv. Palpable foot pulses (e.g., dorsalis pedis or posterior tibial pulses).

Integra Bilayer Matrix Wound Dressing (Q4104), Integra Meshed Bilayer Wound Matrix (C9363 or Q4105), Integra Dermal Regeneration Template (Q4105), or Integra Omnigraft Dermal Regeneration Matrix (Q4105)

Integra Bilayer Matrix Wound Dressing (Q4104), Integra Meshed Bilayer Wound Matrix (C9363 or Q4105), Integra Dermal Regeneration Template (Q4105), or Integra Omnigraft Dermal Regeneration Matrix (Q4105) are considered medically necessary when the following criteria are met:

1. Hemostasis must be obtained prior to application, as blood products may interfere with application; *and*
2. ONE of the following:
    a. Integra Bilayer Matrix Wound Dressing or Integra Meshed Bilayer Wound Matrix:
        i. For deep partial- and full-thickness thermal injury (i.e., second and third degree burns), when applied on the day of excision and when ONE of the following characteristics is present:
            1. There is inadequate remaining skin to perform autografting; *or*
            2. The member is too ill for further autografting; *or*
        ii. For chronic pressure ulcers, venous ulcers, trauma wounds, or surgical wounds that have been treated for a minimum of *6 weeks* with appropriate conventional therapy that has tried and failed or been ineffective, as defined by standard dressing changes, debridement as necessary, and off-loading of pressure/weight; *and*
            1. Ulcer does not expose bone, joint capsule, or tendon; *or*
        iii. For diabetic ulcers when ALL of the following characteristics are present:
            1. Partial- and full-thickness (e.g. extends through the dermis) diabetic ulcer; *and*
            2. Ulcer does not expose bone, tendon, muscle, or joint capsule; *and*
            3. Adequate circulation to the affected extremity, defined by ONE of the following:
                a. Transcutaneous oxygen test (TcPO2) ≥30 mmHg; *or*
                b. Ankle-brachial index (ABI) between 0.7 and 1.2; *or*
                c. Triphasic or biphasic Doppler arterial waveforms at the ankle of the affected leg; *or*
                d. Palpable foot pulses (e.g., dorsalis pedis or posterior tibial pulses).
            4. A minimum of 6 weeks of appropriate conventional therapy has failed or been ineffective, as defined by standard dressing changes, debridement as necessary, and off-loading of pressure/weight; *and*
            5. Current diagnosis of type 1 or type 2 diabetes, with hemoglobin A1C less than 12%; *or*
    b. Integra Dermal Regeneration Template or Integra Omnigraft Dermal Regeneration Matrix:

i. For deep partial- and full-thickness thermal injury (i.e., second and third degree burns), when applied on the day of excision and when ONE of the following characteristics is present:
    1. There is inadequate remaining skin to perform autografting; or
    2. The member is too ill for further autografting; *or*

ii. For diabetic foot ulcers when ALL of the following characteristics are present:
    1. Full-thickness (e.g. extends through the dermis) neuropathic diabetic foot ulcer; *and*
    2. Ulcer does not expose bone, tendon, muscle, or joint capsule; *and*
    3. Adequate circulation to the affected extremity, defined by ONE of the following:
        a. Transcutaneous oxygen test (TcPO2) ≥30 mmHg; *or*
        b. Ankle-brachial index (ABI) between 0.7 and 1.2; *or*
        c. Triphasic or biphasic Doppler arterial waveforms at the ankle of the affected leg; *or*
        d. Palpable foot pulses (e.g., dorsalis pedis or posterior tibial pulses).
    4. A minimum of 6 weeks of appropriate conventional therapy has failed or been ineffective, as defined by standard dressing changes, debridement as necessary, and off-loading of pressure/weight; *and*
    5. Current diagnosis of type 1 or type 2 diabetes, with hemoglobin A1C less than 12%.

<u>OrCel (Q4100)</u>

OrCel (Q4100) is considered medically necessary when ONE of the following criteria is met:

1. To close and heal wounds in children with dystrophic epidermolysis bullosa who are undergoing hand surgery, including donor sites; *or*
2. To be applied to donor sites in members who have been burned and required autografting.

<u>StrataGraft (Q4100)</u>

StrataGraft (Q4100) is considered medically necessary when BOTH of the following criteria are met:

1. Adult with deep partial-thickness burns; *and*
2. No known allergy to any similar or specific implanted material in this product.

<u>Apligraf (Q4101), Oasis Wound Matrix (Q4102), or Theraskin (Q4121)</u>

Apligraf (Q4101), Oasis Wound Matrix (Q4102), or Theraskin (Q4121) is considered medically necessary when ALL of the following criteria are met:

1. Apligraf is not being used in conjunction with Dakin's solution, chlorhexidine, polymyxin/nystatin, or any other cytotoxic solution due to breakdown and loss of effectiveness as demonstrated in clinical studies; *and*
2. One of the following:

a. For diabetic foot ulcers, when all of the following characteristics are present:
    i. Full-thickness (e.g., extends through the dermis) neuropathic diabetic foot ulcer; *and*
    ii. The ulcer does not expose bone, tendon, muscle, or joint capsule; *and*
    iii. The member must have adequate circulation to the affected extremity, and may be defined by:
        1. Transcutaneous oxygen test (TcPO2) ≥30 mmHg; *or*
        2. Ankle-brachial index (ABI) between 0.7 and 1.2; *or*
        3. Triphasic or biphasic Doppler arterial waveforms at the ankle of the affected leg; *or*
        4. Palpable foot pulses (e.g., dorsalis pedis or posterior tibial pulses).
    iv. Appropriate conventional therapy has failed or been ineffective, as defined by standard dressing changes, debridement as necessary, and off-loading of pressure/weight
        1. For Apligraf, a minimum of 3 weeks; *or*
        2. For Oasis Wound Matrix or Theraskin, a minimum of 4 weeks; *and*
    v. Current diagnosis of type 1 or type 2 diabetes, with hemoglobin A1C less than 12%; *or*
b. For venous insufficiency skin ulcers, when all of the following characteristics are present:
    i. Ulcer must be chronic, non-infected, partial- or full-thickness and due to venous insufficiency; *and*
    ii. A minimum of *4 weeks* of appropriate conventional therapy has failed or been ineffective; *and*
    iii. Adequate circulation to the affected extremity, defined by ONE of the following:
        1. Transcutaneous oxygen test (TcPO2) ≥30 mmHg; *or*
        2. Ankle-brachial index (ABI) between 0.7 and 1.2; *or*
        3. Triphasic or biphasic Doppler arterial waveforms at the ankle of the affected leg; *or*
        4. Palpable foot pulses (e.g., dorsalis pedis or posterior tibial pulses).
    iv. Conventional therapy must have included standard therapeutic compression.

<u>TransCyte (Q4182)</u>

TransCyte (Q4182) is considered medically necessary when ONE of the following criteria is met:

1. For deep partial- and full-thickness thermal injury (i.e., second and third degree burns) after surgical excision has been performed, in members who need temporary wound covering prior to autografting; *or*
2. For mid-dermal burns or those of an indeterminate depth that are expected to heal without autografting.

Experimental or Investigational / Not Medically Necessary

Wound applications beyond 12 weeks of therapy are not considered medically necessary. Retreatment of a successfully treated, healed ulcer is generally not medically necessary.

Intra-abdominal and pelvic adhesion prevention (including gynecologic adhesion prevention) with biologic or bioengineered materials is considered experimental or investigational (some examples are, but not limited to: amniotic, placental, stem cell) have not been shown scientifically to be of clinical significance. This does not apply to hyaluronic acid or cellulose derived adhesion barrier films, gels, or liquids.

3D bioprinted skin substitutes are considered experimental or investigational, as there is insufficient scientific evidence to evaluate its clinical safety and efficacy.

Skin/tissue substitutes or wound care treatments ordered for any indication not listed in the General Medical Necessity Criteria or Indication-Specific Criteria are considered experimental, investigational or unproven. The following skin/tissue substitutes or other wound care treatments are considered experimental, investigational or unproven (not all inclusive):

- Affinity®
- AlloMend® Acellular Dermal Matrix
- AlloSkin™
- AlloSkin™ AC
- AlloSkin™ RT
- AlloWrap®
- AlloWrap™ Dry
- AlloWrap™ DS
- AmnioArmor®
- AmnioCare®
- AmnioCore, AmnioCore Pro, and AmnioCore Pro+
- AmnioClear®
- AmnioExcel® (also known as BioDExcel) Amniotic Allograft Membrane and AmnioExcel® Plus Placental Allograft Membrane
- AmnioFix®
- AmnioGraft® for any indication other than ocular surgery
- Amniomatrix® and BioDMatrix™
- Amnio-Maxx™
- AmnioMTM™
- AmnioShield®
- Amnio Wound
- Aongen™ Collagen Matrix
- Architect® Stabilized Collagen Matrix (ECM), Architect PX, and Architect FX
- Artacent® Wound, Artacent® AC, and Artacent AC Powder
- Artacent AC Cord
- Artacent Connect®
- Artacent Flex®
- Artacent Trident
- Artacent Velos
- Artacent Vericlen
- Artelon® (CMC and TMC)
- ArthroFLEX® Decellularized Dermal Allograft
- Atlas Wound Matrix
- Avance® Nerve Graft
- AxoGuard Nerve Connector®
- AxoGuard Nerve Protector®
- Axolotl Graft and Axolotl DualGraft™
- Belladerm®
- Bio-ConneKt®
- BioDDryFlex® Amniotic Tissue Membrane (formerly BioDFence DryFlex)

- BioDfactor®
- BioDFence®
- BioDOptix® Amniotic Extracellular Membrane
- Biovance® Amniotic Membrane Allograft
- Biovance Tri-layer, Biovance 3L
- CellerateRX®
- Cellesta® Cord
- Cellesta® and Cellesta® Duo
- Cellesta® Flowable Amnion
- CG CryoDerm™ and CGDerm™
- CLARIX® 100 Quick-Peel Wound Matrix
- CLARIX® Cord 1k
- CLARIX™ FLO
- CollaFix™
- CollaGUARD®
- CollaMend™
- CollaSorb™
- CollaWound™
- Coll-e-Derm RT™
- Collexa®
- Complete FT™
- Conexa™
- CorMatrix®
- C-QUR™
- CryoSkin®
- Cuffpatch™
- Cymetra®
- Cygnus® Dual
- Cygnus® Matrix
- Cygnus Max and Cygnus Max XL
- Cygnus® and Cygnus® Solo
- Cytal® Wound Matrix and Cytal® Burn Matrix (formerly MatriStem®)
- DeNovo® NT Graft
- Dermadapt™ Wound Dressing
- Derma-Gide®
- DermaPure®
- DermaSpan™ Acellular Dermal Matrix
- Dermavest®
- Duragen® Plus Dural Regeneration Matrix
- Duragen® XS
- DuraMatrix™
- Durepair® Regeneration Matrix
- Endoform™
- ENDURAgen™
- Enverse®
- EpiBurn®
- EpiDex®
- EpiFix™, particulate or injectable form
- Excellagen®
- E-Z Derm™
- FloGraft®
- FlowerAmnioFlo™ and FlowerFlo™
- FlowerAmnioPatch™ and FlowerPatch™
- FlowerDerm™
- Fortiva™ Porcine Dermis
- GalaFLEX™ Scaffold, GalaFLEX LITE™ Scaffold, GalaFLEX 3D™ Scaffold, and GalaFLEX 3DR™ Scaffold
- GammaGraft™
- Genesis Amniotic Membrane
- Gentrix® Surgical Matrix (formerly MatriStem® Surgical Matrix)
- GORE® Preclude® Pericardial Membrane
- Graftjacket™ Xpress injectable
- Helicoll®
- hMatrix® ADM
- Hyalomatrix®
- InnovaMatrix AC® and InnovaMatrix® FS
- Integra® Matrix Wound Dressing
- Integra® Flowable Wound Matrix
- IntéguPly™ (formerly TranzGraft)
- Jaloskin®
- Kerecis MariGen® and Kerecis Shield® Adhesive
- Keroxx® Flowable Wound Matrix
- MatriDerm®
- Matrion™ Placental Membrane
- MicroMatrix® UBM Particulate (formerly MatriStem® MicroMatrix)

- Matrix™ HD Allograft Dermis
- Medeor® Matrix Surgical Mesh
- MediHoney®
- Mediskin®
- MemoDerm™
- Menaflex™ Collagen Meniscus Implant
- Meso BioMatrix® Acellular Peritoneum Matrix
- Microlyte® Matrix
- NeoPatch™
- NEOX® 100 Quick-Peel Wound Matrix
- NEOX® 1k Wound Matrix
- NEOX® FLO
- NeuraGen® Nerve Guide
- NeuraWrap® Nerve Protector
- Neuroflex™
- NeuroMatrix™
- NeuroMend™
- Novachor®
- NovoSorb® BTM and NovoSorb® SynPath™
- NuCel®
- NuShield®
- OrthADAPT™
- OsseoGuard®
- OviTex® Reinforced Tissue Matrix
- PalinGen® Flow
- PalinGen® Hydromembrane
- PalinGen® Membrane
- PalinGen® XPlus Hydromembrane
- PalinGen® XPlus Membrane
- Pelvicol®
- Pelvisoft®
- Peri-Guard® Repair Patch
- Peri-Strips Dry with Veritas Collagen Matrix
- Permacol™
- Phasix Mesh™
- Phasix™ ST Mesh and Phasix™ Plug and Patch
- Primatrix® Dermal Repair Scaffold (formerly DressSkin)
- Procenta®
- Puracol® Collagen Wound Dressings
- Puraply®, Puraply® AM (formerly Fortaderm), and PuraPly® XT
- PureSkin™ and PureSkin XL
- Puros® Dermis
- PX50® and PX50® Plus
- Repliform®
- Repriza™
- Restore® Orthobiologic Soft Tissue Implant
- Restorigin™ Amnion Patch and Restorigin™ Amniotic Fluid Therapy
- Restrata®
- Restrata® MiniMatrix™
- Revita®
- Revitalon™ Amnion Chorion Membrane
- SERI® Surgical Scaffold
- Signature APatch
- SIS Wound Dressing II
- SJM™ Pericardial Patch
- SkinTE™
- Sterishield II® Dual Layer Amnion
- Stimulen Collagen Wound Care Formula
- Strattice™ Reconstructive Tissue Matrix (RTM)
- Stravix® and StravixPL
- Suprathel®
- SurgiGRAFT™, SurgiGRAFT nano, and SurgiGRAFT-Dual
- SurgiMend®
- Symphony™
- Talymed®
- TenoGlide® Tendon Protector Sheet
- TenSIX™ Acellular Dermal Matrix
- TEXAGEN® Amniotic Membrane Allograft

- TheraForm™ Standard/Sheet Absorbable Collagen Membrane
- TheraGenesis Bilayer Wound Matrix
- TissueMend Soft Tissue Repair Matrix
- Tornier® BioFiber Absorbable Biological Scaffold
- Tutomesh® Fenestrated Bovine Pericardium
- Tutopatch® Bovine Pericardium
- Unite® Biomatrix
- Vascu-Guard®
- Veritas® Collagen Matrix
- VIM Amniotic Membrane
- WoundEx® Flow
- WoundEx® Membrane
- XCelliStem Wound Powder
- XCM Biologic™ Tissue Matrix
- Xelma®
- XenMatrix™ Surgical Graft
- XenoSure® Biologic Patch
- X-Repair
- XWRAP® (Hydro, DRY, and ECM)

Applicable Billing Codes

Table 1	
CPT/HCPCS codes considered medically necessary if criteria are met:	
Code	*Description*
15002-15003	Surgical preparation or creation of recipient site by excision of open wounds, burn eschar, or scar (including subcutaneous tissues), or incisional release of scar contracture, trunk, arms, legs; first 100 sq cm or 1% of body area of infants and children. Or each additional 100 sq cm.
15004-15005	Surgical preparation or creation of recipient site by excision of open wounds, burn eschar, or scar (including subcutaneous tissues), or incisional release of scar contracture, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet and/or multiple digits; first 100 sq cm or 1% of body area of infants and children. Or each additional 100 sq cm.

Table 1	
CPT/HCPCS codes considered medically necessary if criteria are met:	
Code	*Description*
15100-15101	Split-thickness autograft, trunk, arms, legs; first 100 sq cm or less, or 1% of body area of infants and children (except 15050). Or each additional 100 sq cm.
15120-15121	Split-thickness autograft, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; first 100 sq cm or less, or 1% of body area of infants and children (except 15050). Or each additional 100 sq cm.
15220-15221	Full thickness graft, free, including direct closure of donor site, scalp, arms, and/or legs; 20 sq cm or less. Or each additional 20 sq cm.
15240-15241	Full thickness graft, free, including direct closure of donor site, forehead, cheeks, chin, mouth, neck, axillae, genitalia, hands, and/or feet; 20 sq cm or less. Or each additional 20 sq cm.
15260-15261	Full thickness graft, free, including direct closure of donor site, nose, ears, eyelids, and/or lips; 20 sq cm or less. Or each additional 20 sq cm.
15271-15278	Application of skin substitute
15760	Graft; composite (eg, full thickness of external ear or nasal ala), including primary closure, donor area
15777	Implantation of biologic implant (eg, acellular dermal matrix) for soft tissue reinforcement (ie, breast, trunk) (List separately in addition to code for primary procedure)
A6196 - A6199	Alginate or other fiber gelling dressing, wound cover, sterile
C5271 - C5274	Application of low cost skin substitute graft to trunk, arms, legs
C5275 - C5278	Application of low cost skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits
C9250	Human plasma fibrin sealant, vapor-heated, solvent-detergent (Artiss), 2ml
C9363	Skin substitute, Integra Meshed Bilayer Wound Matrix, per square centimeter
Q4100	Skin substitute, not otherwise specified ● Due to multiple products represented by this CPT/HCPCS code, specific indications are provided: ● When this code is billed for Orcel®, Biobrane Biosynthetic Dressing®, Epicel®, Cortiva® (AlloMax/NeoForm), or Stratagraft, it is considered medically necessary

Table 1	
CPT/HCPCS codes considered medically necessary if criteria are met:	
Code	*Description*
Q4101	Apligraf, per sq cm
Q4102	Oasis Wound Matrix, per sq cm
Q4104	Integra Bilayer Matrix Wound Dressing (BMWD), per sq sm
Q4105	Integra Dermal Regeneration Template (DRT), per sq cm
Q4106	Dermagraft, per sq cm
Q4107	Graftjacket, per sq cm
Q4116	Alloderm, per square centimeter
Q4121	TheraSkin, per sq cm
Q4122	DermACELL, DermACELL AWM or DermACELL AWM Porous, per sq cm
Q4128	FlexHD,Allopatch HD, per sq cm
Q4132	Grafix core, per sq cm
Q4133	Grafix PRIME, GrafixPL PRIME, Stravix and StravixPL, per sq cm • Due to multiple products represented by this CPT/HCPCS code, specific indications are provided: • When this code is billed for Grafix PRIME or GrafixPL PRIME, it is considered medically necessary.
Q4151	Amnioband or guardian, per sq cm
Q4182	Transcyte, per square centimeter
Q4186	Epifix, per square centimeter
Q4187	Epicord, per sq cm

Table 2	
CPT/HCPCS codes considered experimental or investigational:	
Code	*Description*
A2001	InnovaMatrix AC, per sq cm
A2004	XCelliStem, 1 mg

Table 2	
CPT/HCPCS codes considered experimental or investigational:	
Code	*Description*
A2005	Microlyte Matrix, per sq cm
A2006	NovoSorb SynPath dermal matrix, per sq cm
A2007	Restrata, per sq cm
A2008	TheraGenesis, per sq cm
A2009	Symphony, per sq cm
A2012	SUPRATHEL, per sq cm
A2013	Innovamatrix FS, per sq cm
A2019	Kerecis Omega3 MariGen Shield, per sq cm
A2026	Restrata MiniMatrix, 5 mg
A2027	Matriderm, per square centimeter
A2028	Micromatrix flex, per mg
C9352	Microporous collagen implantable tube (NeuraGen Nerve Guide), per cm length
C9353	Microporous collagen implantable slit tube (NeuraWrap Nerve Protector), per cm length
C9354	Acellular pericardial tissue matrix of nonhuman origin (Veritas), per sq cm
C9355	Collagen nerve cuff (NeuroMatrix), per 0.5 cm length
C9356	Tendon, porous matrix of cross-linked collagen and glycosaminoglycan matrix (Tenoglide Tendon Protector Sheet), per square centimeter
C9358	Dermal substitute, native, non-denatured collagen (SurgiMend Collagen Matrix), per 0.5 square centimeters
C9360	Dermal substitute, native, non-denatured collagen, neonatal bovine origin (SurgiMend Collagen Matrix), per 0.5 square centimeters
C9361	Collagen matrix nerve wrap (NeuroMend Collagen Nerve Wrap), per 0.5 cm length
C9364	Porcine implant, Permacol, per square centimeter
G0428	Collagen meniscus implant procedure for filling meniscal defects (e.g., CMI, collagen scaffold, Menaflex)
Q4100	Skin substitute, not otherwise specified *(use assigned code for covered product)*

Table 2	
CPT/HCPCS codes considered experimental or investigational:	
Code	*Description*
Q4103	Oasis Burn Matrix, per sq cm
Q4108	Integra Matrix Wound Dressing
Q4110	PriMatrix, per sq cm
Q4111	GammaGraft, per sq cm
Q4112	Cymetra, injectable, 1 cc
Q4113	GRAFTJACKET XPRESS, injectable, 1cc
Q4114	Integra Flowable Wound Matrix, injectable, 1 cc
Q4115	AlloSkin, per square centimeter
Q4117	HYALOMATRIX, per sq cm
Q4118	MatriStem micromatrix, 1 mg
Q4123	AlloSkin RT, per square centimeter
Q4124	OASIS ultra tri-layer wound matrix, per sq cm
Q4125	Arthroflex, per sq cm
Q4126	MemoDerm, DermaSpan, TranZgraft or IntéguPly, per square centimeter
Q4127	Talymed, per sq cm
Q4130	Strattice, per sq cm
Q4133	Grafix PRIME, GrafixPL PRIME, Stravix and StravixPL, per sq cm ● Due to multiple products represented by this CPT/HCPCS code, specific exclusions are indicated: ● When this code is billed for Stravix and StravixPL, it is considered experimental or investigational.
Q4134	hMatrix, per sq cm
Q4135	Mediskin, per sq cm
Q4136	E-Z Derm, per sq cm
Q4137	AmnioExcel, AmnioExcel Plus or BioDExcel, per sq cm
Q4138	Biodfence dryflex, per sq cm
Q4139	Amniomatrix or bioDMatrix, injectable, 1 cc

Table 2	
CPT/HCPCS codes considered experimental or investigational:	
Code	*Description*
Q4140	Biodfence, per sq cm
Q4141	AlloSkin AC, per square centimeter
Q4142	XCM biologic tissue matrix, per sq cm
Q4143	Repriza, per sq cm
Q4145	Epifix, injectable, 1 mg
Q4146	TENSIX, per sq cm
Q4147	Architect, architect PX, or architect FX, extracellular matrix, per sq cm
Q4148	Neox Cord 1K, Neox Cord RT, or Clarix Cord 1K, per sq cm
Q4149	Excellagen, 0.1 cc
Q4150	Allowrap DS or dry, per sq cm
Q4152	Dermapure, per sq cm
Q4153	Dermavest and Plurivest, per sq cm
Q4154	Biovance, per sq cm
Q4155	Neoxflo or clarixflo 1 mg
Q4156	Neox 100, per sq cm
Q4157	Revitalon, per sq cm
Q4158	Kerecis Omega3, per sq cm
Q4159	Affinity, per sq cm
Q4160	Nushield, per square centimeter
Q4161	Bio-connekt wound matrix, per square centimeter
Q4162	WoundEx Flow, BioSkin Flow, 0.5 cc
Q4163	WoundEx, BioSkin, per sq cm
Q4164	Helicoll, per square centimeter
Q4165	Keramatrix, per square centimeter
Q4166	Cytal, per square centimeter
Q4167	Truskin, per square centimeter

Table 2	
CPT/HCPCS codes considered experimental or investigational:	
Code	*Description*
Q4168	Amnioband, 1 mg
Q4169	Artacent wound, per square centimeter
Q4170	Cygnus, per square centimeter
Q4171	Interfyl, 1 mg
Q4173	Palingen or Palingen XPlus, per square centimeter
Q4174	Palingen or Promatrix, 0.36 mg per 0.25 cc
Q4175	Miroderm, per square centimeter
Q4176	NeoPatch, per sq cm
Q4177	FlowerAmnioFlo, 0.1 cc
Q4178	Floweramniopatch, per square centimeter
Q4179	FlowerDerm, per sq cm
Q4180	Revita, per sq cm
Q4181	Amnio wound, per square centimeter
Q4183	Surgigraft, per sq cm
Q4184	Cellesta or Cellesta Duo, per sq cm
Q4185	Cellesta Flowable Amnion (25 mg per cc); per 0.5 cc
Q4188	AmnioArmor, per sq cm
Q4189	Artacent AC, 1 mg
Q4190	Artacent AC, per sq cm
Q4191	Restorigin, per sq cm
Q4192	Restorigin, 1 cc
Q4193	Coll-e-Derm, per sq cm
Q4194	Novachor, per sq cm
Q4195	PuraPly, per sq cm
Q4196	PuraPly AM, per sq cm
Q4197	PuraPly XT, per sq cm

Table 2	
CPT/HCPCS codes considered experimental or investigational:	
Code	*Description*
Q4198	Genesis Amniotic Membrane, per sq cm
Q4199	Cygnus matrix, per sq cm
Q4200	SkinTE, per sq cm
Q4201	Matrion, per sq cm
Q4202	Keroxx (2.5 g/cc), 1 cc
Q4203	Derma-Gide, per sq cm
Q4204	XWRAP, per sq cm
Q4214	Cellesta Cord, per sq cm
Q4216	Artacent Cord, per sq cm
Q4219	SurgiGRAFT-Dual, per sq centimeter
Q4227	AmnioCore, per sq cm
Q4239	Amnio-Maxx or Amnio-Maxx Lite, per sq cm
Q4251	Vim, per sq cm
Q4258	Enverse, per sq cm
Q4260	Signature apatch, per square centimeter
Q4271	Complete FT, per sq cm
Q4282	Cygnus Dual, per sq cm
Q4283	Biovance Tri-Layer or Biovance 3L, per sq cm
Q4298	AmniCore Pro, per sq cm
Q4299	AmniCore Pro+, per sq cm
Q4310	Procenta, per 100 mg
Q4331	Axolotl Graft, per sq cm
Q4332	Axolotl DualGraft, per sq cm
Q4336	Artacent c, per square centimeter
Q4337	Artacent trident, per square centimeter
Q4338	Artacent velos, per square centimeter
Q4339	Artacent vericlen, per square centimeter

Table 2	
CPT/HCPCS codes considered experimental or investigational:	
Code	*Description*
Q4345	Matrix hd allograft dermis, per square centimeter
S9055	Procuren or other growth factor preparation to promote wound healing

References

1. Abston, S., Blakeney, P., Desai, M., Edgar, P., Heggers, J. P., & Herndon, D. N. (2016). 8. Surgical management of the burn wound. *ISBI Practice Guidelines for Burn Care*, 2, 981.
2. ACeLL®, Inc. Cytal® Burn Matrix Devices. Accessed May 22, 2023 https://www.acell.com/products/cytal-burn-matrix/
3. ACeLL®, Inc. Cytal® Wound Matrix Devices. Accessed May 22, 2023 https://www.acell.com/products/cytal-wound-matrix-devices/
4. ACeLL®, Inc. Gentrix® Surgical Matrix Devices. Accessed May 22, 2023 https://www.acell.com/products/gentrix-surgical-matrix/
5. ACeLL®, Inc. MicroMatrix®. Accessed May 22, 2023 https://www.acell.com/products/micromatrix-matrix/
6. Adams Jr, W. P., Baxter, R., Glicksman, C., Mast, B. A., Tantillo, M., & Van Natta, B. W. (2018). The use of poly-4-hydroxybutyrate (P4HB) scaffold in the ptotic breast: a multicenter clinical study. *Aesthetic Surgery Journal*, 38(5), 502-518.
7. Ahuja, N., Jin, R., Powers, C., Billi, A., & Bass, K. (2020). Dehydrated human amnion chorion membrane as treatment for pediatric burns. *Advances in Wound Care*, 9(11), 602–611. https://doi.org/10.1089/wound.2019.0983
8. Alam, K., & Jeffery, S. L. A. (2019). Acellular fish skin grafts for management of split thickness donor sites and partial thickness burns: A case series. *Military Medicine*, 184(Suppl 1), 16–20. https://doi.org/10.1093/milmed/usy280
9. Alkhonizy, S. W., Sabbah, B. N., Khader, M. S., Abdul Rab, S., Chaudhri, E. N., Safar Alsofyani, K. M., Raheel, H. M., Alhassoun, M., & Alabdulkarim, A. (2024). Effectiveness of dermal regeneration templates in managing acute full-thickness and deep dermal burn injuries: A comparison with split-thickness skin grafts. *Plastic and Reconstructive Surgery–Global Open*, 12(2), e5572. https://doi.org/10.1097/GOX.0000000000005572
10. Alvarez, O. M., Makowitz, L., & Patel, M. (2017). Venous ulcers treated with a hyaluronic acid extracellular matrix and compression therapy: Interim analysis of a randomized controlled trial. *Wounds: A Compendium of Clinical Research and Practice*, 29(7), E51–E54.
11. Aiolfi, A., Gagner, M., Zappa, M. A., Lastraioli, C., Lombardo, F., Panizzo, V., Bonitta, G., Cavalli, M., Campanelli, G., & Bona, D. (2022). Staple line reinforcement during laparoscopic sleeve

gastrectomy: Systematic review and network meta-analysis of randomized controlled trials. *Obesity Surgery*, 32(5), 1466–1478. https://doi.org/10.1007/s11695-022-05950-z

12. American Diabetes Association. (2025). Standards of Care in Diabetes—2025. https://diabetesjournals.org/care/issue/48/Supplement_1
13. American Diabetes Association Professional Practice Committee (2024). 12. Retinopathy, Neuropathy, and Foot Care: Standards of Care in Diabetes—2025. *Diabetes Care*, 48(Supplement_1), S252–S265. https://doi.org/10.2337/dc25-s012
14. Armstrong, D.G., & Meyr, A.J. (2025). Basic principles of wound healing. *UpToDate*. Retrieved from https://www.uptodate.com/contents/basic-principles-of-wound-healing
15. Armstrong, D. G., Tan, T., Boulton, A. J. M., & Bus, S. A. (2023). Diabetic foot ulcers. *JAMA*, 330(1), 62. https://doi.org/10.1001/jama.2023.10578
16. Armstrong, D. G., Tettelbach, W. H., Chang, T. J., De Jong, J. L., Glat, P. M., Hsu, J. H., Kelso, M. R., Niezgoda, J. A., Tucker, T. L., & Labovitz, J. M. (2021). Observed impact of skin substitutes in lower extremity diabetic ulcers: lessons from the Medicare Database (2015–2018). *Journal of Wound Care*, 30(Sup7), S5–S16. https://doi.org/10.12968/jowc.2021.30.Sup7.S5
17. Ball, C. G., Kirkpatrick, A. W., Stuleanu, T., Rosen, M. J., & Eberle, T. L. (2022). Is the type of biomesh relevant in the prevention of recurrence following abdominal wall reconstruction? A randomized controlled trial. *Canadian Journal of Surgery*, 65(4), E541–E549. https://doi.org/10.1503/cjs.020621
18. Ball, J.F., Sheena, Y., Saleh, D.M.T., et al. (2017). A direct comparison of porcine (Strattice™) and bovine (Surgimend™) acellular dermal matrices in implant-based immediate breast reconstruction. *J Plast Reconstr Aesthet Surg, 70* (8),1076-1082. doi: 10.1016/j.bjps.2017.05.015.
19. Bakri M, Lovato FC, Diosti GM, Salles YLSG, Moreira PHB, Collaço LM, Czeczko NG, Malafaia O, Kubrusly LF. Comparative Analysis of Tissular Response After AbdominalL Wall Repair Using Polypropylene Mesh and Bovine Pericardium Mesh. Arq Bras Cir Dig. 2022 Jan 5;34(3):e1527.
20. Bairagi A, Griffin B, Banani T, McPhail SM, Kimble R, Tyack Z. A systematic review and meta-analysis of randomized trials evaluating the efficacy of autologous skin cell suspensions for re-epithelialization of acute partial thickness burn injuries and split-thickness skin graft donor sites. Burns. 2021 Sep;47(6):1225-1240.
21. Barbul A, Gurtner GC, Gordon H, Bakewell K, Carter MJ. Matched-cohort study comparing bioactive human split-thickness skin allograft plus standard of care to standard of care alone in the treatment of diabetic ulcers: A retrospective analysis across 470 institutions. Wound Repair Regen. 2020 Jan;28(1):81-89.
22. Barmettler A, Heo M. A Prospective, Randomized Comparison of Lower Eyelid Retraction Repair With Autologous Auricular Cartilage, Bovine Acellular Dermal Matrix (Surgimend), and Porcine Acellular Dermal Matrix (Enduragen) Spacer Grafts. Ophthalmic Plast Reconstr Surg. 2018 May/Jun;34(3):266-273.
23. Barski D, Gerullis H, Ecke T, Boros M, Brune J, Beutner U, Tsaur I, Ramon A, Otto T. Application of Dried Human Amnion Graft to Improve Post-Prostatectomy Incontinence and Potency: A Randomized Exploration Study Protocol. Adv Ther. 2020 Jan;37(1):592-602. doi: 10.1007/s12325-019-01158-3. Epub 2019 Nov 28.

24. Benitez-Sanchez, S., Rao, A., & Oropallo, A. (2023). Fetal bovine acellular dermal matrix in the management of chronic nonhealing lower extremity wounds. Wound Management & Prevention, 69(4). https://doi.org/10.25270/wmp.23031
25. Bervoets, A., & Aerts, O. (2016). Polyhexamethylene biguanide in wound care products: A non-negligible cause of peri-ulcer dermatitis. *Contact Dermatitis*, 74(1), 53–55. https://doi.org/10.1111/cod.12469
26. Bianchi, C., Cazzell, S., Vayser, D., Reyzelman, A. M., Dosluoglu, H., Tovmassian, G., & EpiFix VLU Study Group (2018). A multicentre randomised controlled trial evaluating the efficacy of dehydrated human amnion/chorion membrane (EpiFix®) allograft for the treatment of venous leg ulcers. *International Wound Journal*, 15(1), 114–122. https://doi.org/10.1111/iwj.12843
27. Blomström-Lundqvist C, Traykov V, Erba PA, et al. European Heart Rhythm Association (EHRA) international consensus document on how to prevent, diagnose, and treat cardiac implantable electronic device infections-endorsed by the Heart Rhythm Society (HRS), the Asia Pacific Heart Rhythm Society (APHRS), the Latin American Heart Rhythm Society (LAHRS), International Society for Cardiovascular Infectious Diseases (ISCVID) and the European Society of Clinical Microbiology and Infectious Diseases (ESCMID) in collaboration with the European Association for Cardio-Thoracic Surgery (EACTS). Europace. 2020;22(4):515-549.
28. Bullard, J. D., Lei, J., Lim, J. J., Massee, M., Fallon, A. M., & Koob, T. J. (2019). Evaluation of dehydrated human umbilical cord biological properties for wound care and soft tissue healing. Journal of Biomedical Materials Research. Part B, Applied Biomaterials, 107(4), 1035–1046. https://doi.org/10.1002/jbm.b.34196
29. Cai, S. S., Gowda, A. U., Chopra, K., Waldman, R., Silverman, R. P., & Rasko, Y. M. (2016). A case series of complex recalcitrant wounds treated with epidermal grafts harvested from an automated device. Cureus, 8(10), e853. https://doi.org/10.7759/cureus.853
30. Carsin H, Ainaud P, Le Bever H, et al. Cultured epithelial autografts in extensive burn coverage of severely traumatized patients: a five year single-center experience with 30 patients. Burns. 2000;26(4):379-387.
31. Cazzell S. A Randomized Controlled Trial Comparing a Human Acellular Dermal Matrix Versus Conventional Care for the Treatment of Venous Leg Ulcers. Wounds. 2019 Mar;31(3):68-74. Epub 2019 Jan 31.
32. Cazell S, Vayser D, Pham H, et al. A randomized clinical trial of a human acellular dermal matrix demonstrated superior healing rates for chronic diabetic foot ulcers over conventional care and an active acellular dermal matrix comparator. *The International Journal of Tissue Repair and Regeneration.* 2017;25(3):483-497. doi:https://doi.org/10.1111/wrr.12551
33. Campitiello, F., Mancone, M., Della Corte, A., Guerniero, R., & Canonico, S. (2017). To evaluate the efficacy of an acellular flowable matrix in comparison with a wet dressing for the treatment of patients with diabetic foot ulcers: a randomized clinical trial. Updates in surgery, 69, 523-529.
34. Capella-Monsonís H, Tilbury MA, Wall JG, Zeugolis DI. Porcine mesothelium matrix as a biomaterial for wound healing applications. Mater Today Bio. 2020 May 17;7:100057.

35. Carmichael SP 2nd, Shin J, Vaughan JW, Chandra PK, Holcomb JB, Atala AJ. Regenerative Medicine Therapies for Prevention of Abdominal Adhesions: A Scoping Review. J Surg Res. 2022 Jul;275:252-264.
36. Chang, E.I. & Liu, J. (2017). Prospective unbiased experience with three acellular dermal matrices in breast reconstruction. *J Surg Oncol, 116*(3):365-370. doi: 10.1002/jso.24656.
37. Chen H, Cheng Y, Tian J, Yang P, Zhang X, Chen Y, Hu Y, Wu J. Dissolved oxygen from microalgae-gel patch promotes chronic wound healing in diabetes. Sci Adv. 2020 May 15;6(20):eaba4311.
38. Chopra S, Al-Ishaq Z, Vidya R. The Journey of Prepectoral Breast Reconstruction through Time. World J Plast Surg. 2021;10(2):3-13. doi:10.29252/wjps.10.2.3
39. Costa A, Adamo S, Gossetti F, D'Amore L, Ceci F, Negro P, Bruzzone P. Biological Scaffolds for Abdominal Wall Repair: Future in Clinical Application? Materials (Basel). 2019 Jul 25;12(15):2375.
40. Cottler PS, Kang H, Nash V, Salopek L, Bruce AC, Spiller KL, Campbell CA. Immunomodulation of Acellular Dermal Matrix Through Interleukin 4 Enhances Vascular Infiltration. Ann Plast Surg. 2022 Jun 1;88(5 Suppl 5):S466-S472.
41. Cottone G, Amendola F, Strada C, et al. Comparison of efficacy among three dermal substitutes in the management of critical lower-limb wounds: The largest biases-reduced single-center retrospective cohort study in literature. Medicina (Kaunas). 2021;57(12). doi:10.3390/medicina57121367.
42. DeNoto G, 3rd, Ceppa EP, Pacella SJ, et al. 24-month results of the BRAVO study: A prospective, multi-center study evaluating the clinical outcomes of a ventral hernia cohort treated with OviTex® 1S permanent reinforced tissue matrix. Ann Med Surg (Lond). 2022;83:104745.
43. Dikmans RE, El Morabit F, Ottenhof MJ, et al. Single-stage breast reconstruction using Strattice™: a retrospective study. J Plast Reconstr Aesthet Surg. 2016; 69(2):227-233.
44. Duisit J, Maistriaux L, Taddeo A, Orlando G, Joris V, Coche E, Behets C, Lerut J, Dessy C, Cossu G, Vögelin E, Rieben R, Gianello P, Lengelé B. Bioengineering a Human Face Graft: The Matrix of Identity. Ann Surg. 2017 Nov;266(5):754-764.
45. Egozi D, Allwies TM, Fishel R, Jacobi E, Lemberger M. Free Nipple Grafting and Nipple Sharing in Autologous Breast Reconstruction after Mastectomy. Plast Reconstr Surg Glob Open. 2020 Sep 28;8(9):e3138.
46. Elassal AA, Al-Radi OO, Zaher ZF, Dohain AM, Abdelmohsen GA, Mohamed RS, Fatani MA, Abdelmotaleb ME, Noaman NA, Elmeligy MA, Eldib OS. Equine pericardium: a versatile alternative reconstructive material in congenital cardiac surgery. J Cardiothorac Surg. 2021 Apr 23;16(1):110.
47. Ellis CR, Greenspon AJ, Andriulli JA, Gould PA, Carillo RG, Kolek MJ, Donegan R, Amaral AP, Mittal S. Randomized Trial of Stand-Alone Use of the Antimicrobial Envelope in High-Risk Cardiac Device Patients. Circ Arrhythm Electrophysiol. 2023 May;16(5):e011740.
48. Espinosa-de-Los-Monteros A, Avendano-Peza H, Novitsky YW. Abdominal Closure after TRAM Flap Breast Reconstruction with Transversus Abdominis Muscle Release and Mesh. Plast Reconstr Surg Glob Open. 2016 Sep 21;4(9):

49. Farag, S., Padilla, P. F., Smith, K. A., Sprague, M. L., & Zimberg, S. E. (2018). Management, prevention, and sequelae of adhesions in women undergoing laparoscopic gynecologic surgery: a systematic review. Journal of Minimally Invasive Gynecology, 25(7), 1194-1216.
50. Fearmonti RM. Efficacy of Epidermal Skin Grafts Over Complex, Chronic Wounds in Patients With Multiple Comorbidities. Wounds. 2016 Jul;28(7):226-32.
51. Finger PT, Jain P, Mukkamala SK. Super-Thick Amniotic Membrane Graft for Ocular Surface Reconstruction. Am J Ophthalmol. 2019 Feb;198:45-53.
52. Flutur I-M, Păduraru DN, Bolocan A, Palcău AC, Ion D, Andronic O. Postsurgical Adhesions: Is There Any Prophylactic Strategy Really Working? *Journal of Clinical Medicine*. 2023; 12(12):3931.
53. Formica, F., & Hsia, T. Y. (2020). Commentary: "CorMatrix: If it is too good to be true, …". *The Journal of Thoracic and Cardiovascular Surgery*, 160(4), e222–e223. https://doi.org/10.1016/j.jtcvs.2019.11.043
54. Franceschini, G., & Masetti, R. (2021). Acellular dermal matrix as filler in breast-conserving surgery: Warnings for a careful use. *World Journal of Surgical Oncology*, 19(1), 1. https://doi.org/10.1186/s12957-020-02109-x
55. Frykberg, R. G., Cazzell, S. M., Arroyo-Rivera, J., Tallis, A., Reyzelman, A. M., Saba, F., Warren, L., Stouch, B. C., & Gilbert, T. W. (2016). Evaluation of tissue engineering products for the management of neuropathic diabetic foot ulcers: An interim analysis. *Journal of Wound Care*, 25(Sup7), S18–S25. https://doi.org/10.12968/jowc.2016.25.Sup7.S18
56. Frykberg, R. G., Gibbons, G. W., Walters, J. L., Wukich, D. K., & Milstein, F. C. (2017). A prospective, multicentre, open-label, single-arm clinical trial for treatment of chronic complex diabetic foot wounds with exposed tendon and/or bone: Positive clinical outcomes of viable cryopreserved human placental membrane. *International Wound Journal*, 14(3), 569–577. https://doi.org/10.1111/iwj.12649
57. Galati, V., Vonthein, R., Stang, F., Mailaender, P., & Kisch, T. (2021). Split thickness skin graft versus application of the temporary skin substitute suprathel in the treatment of deep dermal hand burns: A retrospective cohort study of scar elasticity and perfusion. *International Journal of Burns and Trauma*, 11(4), 312–320.
58. Gibson, A. L. F., Holmes, J. H., 4th, Shupp, J. W., Smith, D., Joe, V., Carson, J., Litt, J., Kahn, S., Short, T., Cancio, L., Rizzo, J., Carter, J. E., Foster, K., Lokuta, M. A., Comer, A. R., Smiell, J. M., & Allen-Hoffmann, B. L. (2021). A phase 3, open-label, controlled, randomized, multicenter trial evaluating the efficacy and safety of StrataGraft® construct in patients with deep partial-thickness thermal burns. *Burns*, 47(5), 1024–1037. https://doi.org/10.1016/j.burns.2021.04.021
59. Glat, P., Orgill, D.P., Galiano, R., et al. (August 2019). Placental Membrane Provides Improved Healing Efficacy and Lower Cost Versus a Tissue-Engineered Human Skin in the Treatment of Diabetic Foot Ulcerations. *Plastic and Reconstructive Surgery - Global Open*, 7(8), e2371. doi: 10.1097/GOX.0000000000002371
60. Gould LJ. Topical Collagen-Based Biomaterials for Chronic Wounds: Rationale and Clinical Application. Adv Wound Care (New Rochelle). 2016 Jan 1;5(1):19-31.

61. Grassi A, Lucidi GA, Filardo G, Agostinone P, Macchiarola L, Bulgheroni P, Bulgheroni E, Zaffagnini S. Minimum 10-Year Clinical Outcome of Lateral Collagen Meniscal Implants for the Replacement of Partial Lateral Meniscal Defects: Further Results From a Prospective Multicenter Study. Orthop J Sports Med. 2021 May 25;9(5):2325967121994919.
62. Graziano, F. D., Plotsker, E. L., Rubenstein, R. N., Haglich, K., Stern, C. S., Matros, E., & Nelson, J. A. (2024). National trends in acellular dermal matrix utilization in immediate breast reconstruction. *Plastic and Reconstructive Surgery*, 153(1), 25e–36e. https://doi.org/10.1097/PRS.0000000000010575
63. Gossetti F, Zuegel N, Giordano P, Pullan R, Schuld J, Delrio P, Montorsi M, van Kerschaver O, Lemaitre J, Griffiths B, D'Amore L. A Biologic Surgical Implant in Complex Abdominal Wall Repair: 3-Year FollowUp Results of a Multicentric Prospective Study. Med Devices (Auckl). 2021 Aug 25;14:257-264. Doi: 10.2147/MDER.S297897. PMID: 34471389; PMCID: PMC8403569.
64. Guest JF, Weidlich D, Singh H, La Fontaine J, Garrett A, Abularrage CJ, Waycaster CR. Cost-effectiveness of using adjunctive porcine small intestine submucosa tri-layer matrix compared with standard care in managing diabetic foot ulcers in the US. J Wound Care. 2017 Jan 2;26(Sup1):S12-S24.
65. Gupta S, Mohapatra DP, Chittoria RK, Subbarayan E, Reddy SK, Chavan V, Aggarwal A, Reddy LC. Human Skin Allograft: Is it a Viable Option in Management of Burn Patients? J Cutan Aesthet Surg. 2019 Apr-Jun;12(2):132-135. doi: 10.4103/JCAS.JCAS_83_18. PMID: 31413483; PMCID: PMC6676815.
66. Gurtner GC, Garcia AD, Bakewell K, Alarcon JB. A retrospective matched-cohort study of 3994 lower extremity wounds of multiple etiologies across 644 institutions comparing a bioactive human skin allograft, TheraSkin, plus standard of care, to standard of care alone. Int Wound J. 2020 Feb;17(1):55-64.
67. Haller HL, Blome-Eberwein SE, Branski LK, Carson JS, Crombie RE, Hickerson WL, Kamolz LP, King BT, Nischwitz SP, Popp D, Shupp JW, Wolf SE. Porcine Xenograft and Epidermal Fully Synthetic Skin Substitutes in the Treatment of Partial-Thickness Burns: A Literature Review. Medicina (Kaunas). 2021 Apr 30;57(5):432.
68. Han HH, Jun D, Moon SH, Kang IS, Kim MC. Fixation of split-thickness skin graft using fast-clotting fibrin glue containing undiluted high-concentration thrombin or sutures: a comparison study. Springerplus. 2016 Nov 2;5(1):1902.
69. Hassan, A. M., Asaad, M., Brook, D. S., Shah, N. R., Kumar, S. C., Liu, J., Adelman, D. M., Clemens, M. W., Selber, J. C., & Butler, C. E. (2023). Outcomes of abdominal wall reconstruction with a bovine versus a porcine acellular dermal matrix: A propensity score-matched analysis. *Plastic and Reconstructive Surgery*, 152(4), 872–881. https://doi.org/10.1097/PRS.0000000000010292
70. Hayes, Inc. 3D Bioprinted Skin Substitutes for Treatment of Burns. Search & Summary. Prepared by Hayes, Inc. Publication Date: May 13, 2019.
71. Hayes, Inc. Evidence Analysis Research Brief. Skin Substitutes for Treatment of Acute Wounds. Prepared by Hayes, Inc. Publication Date: Jan 31, 2024

72. Hayes, Inc., Evidence Analysis Research Brief. Antibacterial Envelopes for the Prevention of Cardiac Implantable Electronic Device (CIED) Infections. Prepared by Hayes, Inc. Publication Date: May 19, 2023.
73. Hayes, Inc. Evidence Analysis Research Brief. *bio-ConneKt Wound Matrix (MLM Biologics Inc.) for Treatment of Wounds*. Lansdale, PA: Hayes, Inc., Jan 20, 2023.
74. Hayes, Inc. Evidence Analysis Research Brief. *Enverse (StimLabs LLC) for Treatment of Wounds.* Lansdale, PA: Hayes, Inc.; July 2023.
75. Hayes, Inc. Evidence Analysis Research Brief. I*nnovaMatrix AC (Triad Life Sciences Inc.) for Treatment of Wounds*. Lansdale, PA: Hayes, Inc.; January 2023.
76. Hayes, Inc., Evidence Analysis Research Brief. *NovoSorb (PolyNovo Pty. Ltd.) for Treatment of Wounds*. Lansdale, PA: Hayes, Inc.; February 2023.
77. Hayes, Inc. Evidence Analysis Research Brief. *Microlyte Matrix (Imbed Biosciences) for Treatment of Wounds*. Lansdale, PA: Hayes, Inc.; March 2023.
78. Hayes, Inc. Evidence Analysis Research Brief. *SurgiMend (Integra Life Sciences) for Postmastectomy Breast Reconstruction*. Lansdale, PA: Hayes, Inc.; March 2023.
79. Hayes, Inc. Evidence Analysis Research Brief. *Symphony (Aroa Biosurgery Ltd.) for Treatment of Wounds*. Lansdale, PA: Hayes, Inc.; March 2023.
80. Hayes, Inc. Evidence Analysis Research Brief. *TheraGenesis (Bioventus LLC) for Treatment of Wounds*. Lansdale, PA: Hayes, Inc.; March 2023.
81. Hayes, Inc. Evidence Analysis Research Brief. *Vim Amniotic Membrane (Cook Biotech) for Treatment of Surgical and Nonsurgical Wounds*. Lansdale, PA: Hayes, Inc.; February 2023.
82. Hayes, Inc. Evidence Analysis Research Brief. *XCelliStem Wound Powder (Stemsys) for Treatment of Wounds*. Lansdale, PA: Hayes, Inc.; January 2023.
83. Hayes Inc. Evidence Analysis Research Brief. *Stravix and Stravix PL (Osiris Therapeutics) for the Treatment of Nonhealing Wounds.* Lansdale, PA: Hayes, Inc.; September 2019.
84. Hayes Inc. Evolving Evidence Review. *Kerecis Omega3 Wound (Kerecis Limited) for the Management of Chronic Lower Extremity Wounds.* Lansdale, PA: Hayes, Inc.,: February 2022.
85. Hayes, Inc. Evolving Evidence Review. *PuraPly AM Antimicrobial Wound Matrix (Organogenesis) for Treatment of Wounds*. Lansdale, PA: Hayes, Inc.: December 2022
86. Hayes, Inc. Health Technology Assessment. *Amniotic Allografts for Tendon and Ligament Injuries*. Lansdale, PA: Hayes, Inc.; September 2022.
87. Hayes, Inc. Health Technology Assessment. *Human Amniotic Membrane Injections for Treatment of Chronic Plantar Fasciitis*. Lansdale, PA: Hayes, Inc.; December 2022.
88. Hayes, Inc. Health Technology Assessment. *Comparative Effectiveness Review Of Human Acellular Dermal Matrix For Breast Reconstruction*. Lansdale, PA: Hayes, Inc.: February 2022
89. Hayes, Inc. Health Technology Assessment. *Processed Nerve Allografts with the Avance Nerve Graft (Axogen Corporation) for Peripheral Nerve Discontinuities*. Lansdale, PA: Hayes, Inc.; May 2023.
90. HerniaSurge Group. International guidelines for groin hernia management. Hernia. 2018 Feb;22(1):1-165. doi: 10.1007/s10029-017-1668-x. Epub 2018 Jan 12.

91. Holmes, J. H., Cancio, L. C., Carter, J. E., Faucher, L. D., Foster, K., Hahn, H. D., King, B. T., Rutan, R., Smiell, J. M., Wu, R., & Gibson, A. L. F. (2022). Pooled safety analysis of STRATA2011 and STRATA2016 clinical trials evaluating the use of StrataGraft® in patients with deep partial-thickness thermal burns. *Burns*, 48(8), 1816–1824. https://doi.org/10.1016/j.burns.2022.07.013
92. Hoogewerf CJ, Hop MJ, Nieuwenhuis MK, Oen IM, Middelkoop E, Van Baar ME. Topical treatment for facial burns. Cochrane Database Syst Rev. 2020 Jul 29;7(7):CD008058.
93. Huang W, Chen Y, Wang N, Yin G, Wei C, Xu W. Effectiveness and safety of human amnion/chorion membrane therapy for diabetic foot ulcers: An updated meta-analysis of randomized clinical trials. Wound Repair Regen. 2020 Nov;28(6):739-750. doi: 10.1111/wrr.12851. Epub 2020 Aug 11.
94. Husain, Khalid, et al. "A prospective, blinded, randomized controlled clinical trial evaluating the effect of the synthetic electrospun fiber matrix in the treatment of chronic diabetic foot ulcers." Foot & Ankle Surgery: Techniques, Reports & Cases 4.1 (2024): 100362.
95. Hyland EJ, D'Cruz R, Menon S, Harvey JG, La Hei E, Lawrence T, Waddell K, Nash M, Holland AJ. Biobrane™ versus acticoat™ for the treatment of mid-dermal pediatric burns: a prospective randomized controlled pilot study. Int J Burns Trauma. 2018 Jun 20;8(3):63-67.
96. Hicks KE, Huynh MN, Jeschke M, Malic C. Dermal regenerative matrix use in burn patients: A systematic review. J Plast Reconstr Aesthet Surg. 2019 Nov;72(11):1741-1751. doi: 10.1016/j.bjps.2019.07.021. Epub 2019 Aug 8.
97. Ilic D, Vicovac L, Nikolic M, Ilic E. Human amniotic membrane grafts in therapy of chronic non-healing wounds. Br Med Bull. 2016 Mar;117(1):59-67. doi:10.1093/bmb/ldv053.
98. Jabarkhyl, D., Perusseau-Lambert, A., Fasuyi, J., Kostova, M., Anetekhai, C., Mistry, D., Harris, S., Yoshida, H., & Rahman, S. (2025). The efficacy of Biobrane in managing superficial paediatric burn Injuries: A systematic review and meta-analysis. Cureus. https://doi.org/10.7759/cureus.78508
99. James, WD, Elston D, Treat JR, et al. *Andrews' Diseases of the Skin, 13th Edition.* USA: Elsevier; 2019.
100. Jaseem M, Alungal S, Dhiyaneswaran, Shamsudeen J. Effectiveness of autologous PRP therapy in chronic nonhealing ulcer: A 2-year retrospective descriptive study. J Family Med Prim Care. 2020 Jun 30;9(6):2818-2822.
101. Johnson, A., Gyurdieva, A., Dhall, S., Danilkovitch, A., & Duan-Arnold, Y. (2017). Understanding the impact of preservation methods on the integrity and functionality of placental allografts. *Annals of Plastic Surgery*, 79(2), 203–213. https://doi.org/10.1097/SAP.0000000000001101
102. Johnston M, McBride M, Dahiya D, Owusu-Apenten R, Nigam PS. Antibacterial activity of Manuka honey and its components: An overview. AIMS Microbiol. 2018 Nov 27;4(4):655-664
103. Joshi, C. J., Hassan, A., Carabano, M., & Galiano, R. D. (2020). Up-to-date role of the dehydrated human amnion/chorion membrane (AMNIOFIX) for wound healing. *Expert Opinion on Biological Therapy*, 20(10), 1125–1131. https://doi.org/10.1080/14712598.2020.1787979

104. Kalaiselvan R, Carlson GL, Hayes S, et al. Recurrent intestinal fistulation after porcine acellular dermal matrix reinforcement in enteric fistula takedown and simultaneous abdominal wall reconstruction. Hernia. 2020; 24(3):537-543.
105. Kallis, P. J., Friedman, A. J., & Lev-Tov, H. (2018). A guide to tissue-engineered skin substitutes. *Journal of Drugs in Dermatology*, 17(1), 57–64.
106. Kanapathy M, et al. Epidermal grafting versus split-thickness skin grafting for wound healing (EPIGRAAFT): study protocol for a randomised controlled trial. Trials. 2016 May 17;17(1):245.
107. Kashimura T, Nagasaki K, Horigome M, Yoshida K, Soejima K. Selection of Artificial Dermis for Shortening Treatment Period: Integra versus Pelnac. Plast Reconstr Surg Glob Open. 2021 Jun 10;9(6):e3599.
108. Keane, A. M., Chiang, S. N., Tao, Y., Pierce, A., Gagne, J., Margenthaler, J. A., Tenenbaum, M. M., & Myckatyn, T. M. (2024). Cortiva versus AlloDerm in prepectoral and partial submuscular implant-based breast reconstruction: A randomized clinical trial. *Plastic and Reconstructive Surgery*, 154(4S), 13S–26S. https://doi.org/10.1097/PRS.0000000000011244
109. Khan MA, Javed AA, Rao DJ, Corner JA, Rosenfield P. Pediatric Traumatic Limb Amputation: The Principles of Management and Optimal Residual Limb Lengths. World J Plast Surg. 2016 Jan;5(1):7-14.
110. Kim JH, Kim DH, Lee YP. Long-term comparison of physiologic anorectal changes and recurrence between transanal repair and transanal repair with posterior colporrhaphy in rectocele. Asian J Surg. 2020 Jan;43(1):265-271.
111. Kirsner, R. S., Bohn, G., Driver, V. R., Mills, J. L., Sr, Nanney, L. B., Williams, M. L., & Wu, S. C. (2015). Human acellular dermal wound matrix: Evidence and experience. *International Wound Journal*, 12(6), 646–654. https://doi.org/10.1111/iwj.12185
112. Kogan S, Sood A, Granick MS. Amniotic Membrane Adjuncts and Clinical Applications in Wound Healing: A Review of the Literature. Wounds. 2018 Jun;30(6):168-173.
113. Kumar, N.G., Berlin, N.L., Kim, H.M., et al. (Jan 2021). Development of an evidence-based approach to the use of acellular dermal matrix in immediate expander-implant-based breast reconstruction. *J Plast Reconstr Aesthet Surg,* 74(1), 30-40. doi: 10.1016/j.bjps.2020.10.005.
114. Lakmal K, Basnayake O, Hettiarachchi D. Systematic review on the rational use of amniotic membrane allografts in diabetic foot ulcer treatment. BMC Surg. 2021 Feb 15;21(1):87.
115. Laimer, M., Bauer, J., & Murrell, D.F. (2021). Epidermolysis bullosa: Epidemiology, pathogenesis, classification, and clinical features. *UpToDate*. Retrieved from https://www.uptodate.com/contents/epidermolysis-bullosa-epidemiology-pathogenesis-classification-and-clinical-features
116. Lakmal K, Basnayake O, Hettiarachchi D. Systematic review on the rational use of amniotic membrane allografts in diabetic foot ulcer treatment. BMC Surg. 2021 Feb 15;21(1):87.
117. Landsman A, Rosines E, Houck A, et al. Characterization of a cryopreserved split-thickness human skin allograft - TheraSkin. Adv Skin Wound Care. 2016;29(9):399-406.
118. Lantis, J. C., Snyder, R., Reyzelman, A. M., Van Gils, C. C., Sigal, F., Vayser, D., Caporusso, J. M., Cazzell, S., Lavery, L. A., & PriMatrix Study Group (2021). Fetal bovine acellular dermal matrix

for the closure of diabetic foot ulcers: A prospective randomised controlled trial. *Journal of Wound Care*, 30(Sup7), S18–S27. https://doi.org/10.12968/jowc.2021.30.Sup7.S18

119. Latifi, R., Samson, D. J., Gogna, S., & Joseph, B. A. (2020). Perioperative complications of complex abdominal wall reconstruction with biologic mesh: A pooled retrospective cohort analysis of 220 patients from two academic centers. International Journal of Surgery, 74, 94–99. https://doi.org/10.1016/j.ijsu.2019.12.035
120. Lavery, L., Fulmer, J., Shebetka, K. A., Regulski, M., Vayser, D., Fried, D., Kashefsky, H., Owings, T. M., Nadarajah, J., & Hesp, Z. (2018). Open-label extension phase of a chronic diabetic foot ulcer multicenter, controlled, randomized clinical trial using cryopreserved placental membrane. *Wounds*, 30(9), 283–289.
121. Lei, J., Priddy, L. B., Lim, J. J., Massee, M., & Koob, T. J. (2017). Identification of extracellular matrix components and biological factors in micronized dehydrated human amnion/chorion membrane. *Advances in Wound Care*, 6(2), 43–53. https://doi.org/10.1089/wound.2016.0699
122. Lim JZ, Ng NS, Thomas C. Prevention and treatment of diabetic foot ulcers. J R Soc Med. 2017;110(3):104-109. Doi: 10.1177/0141076816688346.
123. Lintzeris D, et al. Effect of a New Purified Collagen Matrix With Polyhexamethylene Biguanide on Recalcitrant Wounds of Various Etiologies: A Case Series. Wounds. 2018 Mar;30(3):72-78.
124. Luo, X., Kulig, K. M., Finkelstein, E. B., Nicholson, M. F., Liu, X. H., Goldman, S. M., Vacanti, J. P., Grottkau, B. E., Pomerantseva, I., Sundback, C. A., & Neville, C. M. (2017). In vitro evaluation of decellularized ECM-derived surgical scaffold biomaterials. *Journal of Biomedical Materials Research*. Part B, Applied biomaterials, 105(3), 585–593. https://doi.org/10.1002/jbm.b.33572
125. MacCraith, E., Joyce, M., do Amaral, R. J. F. C., O'Brien, F. J., & Davis, N. F. (2022). Development and in vitro investigation of a biodegradable mesh for the treatment of stress urinary incontinence. *International Urogynecology Journal*, 33(8), 2177–2184. https://doi.org/10.1007/s00192-022-05160-2
126. MacEwan, Matthew R., et al. "Comparison of a fully synthetic electrospun matrix to a bi-layered xenograft in healing full thickness cutaneous wounds in a porcine model." Cureus 9.8 (2017).
127. MacEwan, Matthew R., et al. "Efficacy of a Nanofabricated Electrospun Wound Matrix in Treating Full-thickness Cutaneous Wounds in a Porcine Model." Wounds: a compendium of clinical research and practice 30.2 (2018): E21-E24.
128. Magnusson S, et al. Regenerative and Antibacterial Properties of Acellular Fish Skin Grafts and Human Amnion/Chorion Membrane: Implications for Tissue Preservation in Combat Casualty Care. Mil Med. 2017 Mar;182(S1):383-388.
129. Mallucci, P., & Bistoni, G. (2022). Experience and indications for the use of the P4HB scaffold (GalaFLEX) in aesthetic breast surgery: a 100-case experience. Aesthetic Surgery Journal, 42(12), 1394-1405.

130. Marra, C., Cuomo, R., Ceccaroni, A., Pentangelo, P., & Alfano, C. (2024). Acellular dermal matrix in breast augmentation surgery: A systematic review. JPRAS Open, 40, 111–117. https://doi.org/10.1016/j.jpra.2024.02.004
131. Martinez-Zapata, M. J., Martí-Carvajal, A. J., Solà, I., Expósito, J. A., Bolíbar, I., Rodríguez, L., Garcia, J., & Zaror, C. (2016). Autologous platelet-rich plasma for treating chronic wounds. *The Cochrane Database of Systematic Reviews*, 2016(5), CD006899. https://doi.org/10.1002/14651858.CD006899.pub3
132. Martinson, M., & Martinson, N. (2016). A comparative analysis of skin substitutes used in the management of diabetic foot ulcers. J Wound Care, 25(Sup10), S8–S17. https://doi.org/10.12968/jowc.2016.25.Sup10.S8
133. Massand, S., Lewcun, J. A., & LaRosa, C. A. (2021). Clinical and cost efficacy of advanced wound care matrices in the treatment of venous leg ulcers: A systematic review. *Journal of Wound Care*, 30(7), 553–561. https://doi.org/10.12968/jowc.2021.30.7.553
134. Massee M, Chinn K, Lei J, et al. Dehydrated human amnion/chorion membrane regulates stem cell activity in vitro. J Biomed Mater Res B Appl Biomater. 2016;104(7):1495-1503.
135. Mayer, T & Glat, P.M. The Use of Dehydrated Human Amnion/Chorion Membranes in the Treatment of Burns and Complex Wounds. Annals of Plastic Surgery. 2017; 78 (2):pS11-S13. doi: 10.1097/SAP.0000000000000983
136. Mazari FAK, Wattoo GM, Kazzazi NH, et al. The comparison of Strattice and SurgiMend in acellular dermal matrix-assisted, implant-based immediate breast reconstruction. Plast Reconstr Surg. 2018; 141(2):283-293.
137. Mendenhall SD, Anderson LA, Ying J, Boucher KM, Neumayer LA, Agarwal JP. The BREASTrial Stage II: ADM Breast Reconstruction Outcomes from Definitive Reconstruction to 3 Months Postoperative. Plast Reconstr Surg Glob Open. 2017 Jan 25;5(1):e1209.
138. Mohammed Y, Farouk H, Gbreel M, et al. Human amniotic membrane products for patients with diabetic foot ulcers. Do they help? A systematic review and meta-analysis. J Foot Ankle Res. 2022 Sep 14;15(1):71. doi:10.1186/s13047-022-00575-y.
139. Moravvej H, Hormozi AK, Hosseini SN, et al. Comparison of the application of allogeneic fibroblast and autologous mesh grafting with the conventional method in the treatment of third-degree burns. J Burn Care Res. 2016;37(1):e90-e95.
140. Narang SK, Alam NN, Köckerling F, Daniels IR, Smart NJ. Repair of Perineal Hernia Following Abdominoperineal Excision with Biological Mesh: A Systematic Review. Front Surg. 2016 Sep 5;3:49.
141. Nasso G, Di Bari N, Moscarelli M, Fiore F, Condello I, Santarpino G, Speziale G. A modified technique for aortic prosthesis implantation after prosthetic valve endocarditis complicated by complex paraannular aortic abscess. Rev Cardiovasc Med. 2021 Dec 22;22(4):1621-1627.
142. National Institute for Health and Care Excellence (NICE). (2023, January 18). Diabetic foot problems: prevention and management. NCBI Bookshelf. https://www.ncbi.nlm.nih.gov/books/NBK553608/

143. National Institute for Health and Care Excellence (NICE). (2020, December 11). *Peripheral arterial disease: Diagnosis and management*. NCBI Bookshelf. https://www.ncbi.nlm.nih.gov/books/NBK553733/
144. Noël J, Mascarenhas A, Patel E, Reddy S, Sandri M, Bhat S, Moschovas M, Rogers T, Ahmed S, Stirt D, Patel V. Nerve spare robot assisted laparoscopic prostatectomy with amniotic membranes: medium term outcomes. J Robot Surg. 2022 Oct;16(5):1219-1224. doi: 10.1007/s11701-022-01370-4. Epub 2022 Jan 11.
145. Ogaya-Pinies G, Palayapalam-Ganapathi H, Rogers T, Hernandez-Cardona E, Rocco B, Coelho RF, Jenson C, Patel VR. Can dehydrated human amnion/chorion membrane accelerate the return to potency after a nerve-sparing robotic-assisted radical prostatectomy? Propensity score-matched analysis. J Robot Surg. 2018 Jun;12(2):235-243. doi: 10.1007/s11701-017-0719-8. Epub 2017 Jun 27. PMID: 28656504.
146. Ontario Health (Quality). Skin Substitutes for Adults With Diabetic Foot Ulcers and Venous Leg Ulcers: A Health Technology Assessment. Ont Health Technol Assess Ser. 2021 Jun 4;21(7):1-165.
147. Osorio CC, Escobar LM, González MC, Gamboa LF, Chambrone L. Evaluation of density, volume, height and rate of bone resorption of substitutes of autologous bone grafts for the repair of alveolar clefts in humans: A systematic review. Heliyon. 2020 Sep 4;6(9):e04646.
148. Osugi I, Inagawa K, Ebisudani S, Hara N. Usefulness of a Skin Graft Obtained from the Bilateral Nasolabial Folds for a Skin Defect following Resection of a Malignant Tumor at the Nasal Tip. Plast Reconstr Surg Glob Open. 2021 Mar 26;9(3):e3481.
149. Pasqualini, I., Menendez, M. E., Ardebol, J., & Denard, P. J. (2022). Dermal allograft augmentation for rotator cuff tears. *Arthroscopy*, 38(11), 2957–2959. https://doi.org/10.1016/j.arthro.2022.08.004
150. Pittman, T.A., Fan, K.L., Knapp, A., et al. (March 2017). Comparison of Different Acellular Dermal Matrices in Breast Reconstruction: The 50/50 Study. Plast Reconstr Surg,139(3), 521-528. doi: 10.1097/PRS.0000000000003048.
151. Piejko M, Radziun K, Bobis-Wozowicz S, Waligórska A, Zimoląg E, Nessler M, Chrapusta A, Madeja Z, Drukała J. Adipose-Derived Stromal Cells Seeded on Integra® Dermal Regeneration Template Improve Post-Burn Wound Reconstruction. Bioengineering (Basel). 2020 Jul 2;7(3):67.
152. Poppler LH, Mundschenk MB, Linkugel A, Zubovic E, Dolen UC, Myckatyn TM. Tissue Expander Complications Do Not Preclude a Second Successful Implant-Based Breast Reconstruction. Plast Reconstr Surg. 2019 Jan;143(1):24-34.
153. Primous, N. R., Elvin, P. T., Carter, K. V., Andrade, H. L., La Fontaine, J., Shibuya, N., & Biguetti, C. C. (2024). Bioengineered skin for diabetic foot ulcers: A scoping review. *Journal of Clinical Medicine*, 13(5), 1221. https://doi.org/10.3390/jcm13051221
154. Reilly, DA, Hickey S, Glat P, et al. Using Dehydrated Human Amnion/Chorion Membrane Allografts for Acute and Reconstructive Burn Care. Annals of Plastic Surgery. 2017; 78(1):S19-S26. DOI: 10.1097/SAP.0000000000000981
155. Regulski MJ, MacEwan MR. Implantable nanomedical scaffold facilitates healing of chronic lower extremity wounds. Wounds. 2018;30(8):E77-E80. PMID: 30212370.

156. Robb GL, Gurtner GC. Letter to the editor. Healing rates in a multicenter assessment of a sterile, room temperature, acellular dermal matrix versus conventional care wound management and an active comparator in the treatment of full-thickness diabetic foot ulcers. ePlasty. 2016;16:229.
157. Romain, B., Story, F., Meyer, N., et al. (Jun 2016). Comparative study between biologic porcine dermal meshes: risk factors of postoperative morbidity and recurrence. *J Wound Care, 25*(6), 320-5. doi: 10.12968/jowc.2016.25.6.320.
158. Roshangar L, Soleimani Rad J, Kheirjou R, Reza Ranjkesh M, Ferdowsi Khosroshahi A. Skin Burns: Review of Molecular Mechanisms and Therapeutic Approaches. Wounds. 2019 Dec;31(12):308-315.
159. Royal Biologics. Amnio-Maxx™. 2022. Accessed May 18, 2023. Available at URL address: https://royalbiologics.com/amnio-maxx-dual-layer-patch
160. Santema TB, Poyck PP, Ubbink DT. Skin grafting and tissue replacement for treating foot ulcers in people with diabetes. Cochrane Database Syst Rev. 2016 Feb 11;2(2):CD011255.
161. Schmiedova I, Dembickaja A, Kiselakova L, Nowakova B, Slama P. Using of amniotic membrane derivatives for the treatment of chronic wounds. Membranes (Basel). 2021 Nov 29;11(12):941. doi:10.3390/membranes11120941.
162. Scott JR, Deeken CR, Martindale RG, Rosen MJ. Evaluation of a fully absorbable poly-4-hydroxybutyrate/absorbable barrier composite mesh in a porcine model of ventral hernia repair. Surg Endosc. 2016;30(9):3691-3701. doi:10.1007/s00464-016-5057-9
163. Senneville, É., Albalawi, Z., Van Asten, S. A., Abbas, Z. G., Allison, G., Aragón-Sánchez, J., Embil, J. M., Lavery, L. A., Alhasan, M., Oz, O., Uçkay, I., Urbančič-Rovan, V., Xu, Z., & Peters, E. J. G. (2023). IWGDF/IDSA guidelines on the diagnosis and treatment of diabetes-related foot infections (IWGDF/IDSA 2023). *Clinical Infectious Diseases*. https://doi.org/10.1093/cid/ciad527
164. Sharma, A., Sharma, D., & Zhao, F. (2023). Updates on recent clinical assessment of commercial chronic wound care products. *Advanced Healthcare Materials*, 12(25), e2300556. https://doi.org/10.1002/adhm.202300556
165. Shawa, H., Kaur, R., Tchanque-Fossuo, C., Lev-Tov, H., West, K., Lim, P. S., Yang, N. T., Dafinone, M., Lyle, R. E., Li, C. S., Rocke, D., Dahle, S., & Isseroff, R. R. (2025). Cellular versus acellular matrix products for diabetic foot ulcer treatment: The Dermagraft and Oasis Longitudinal Comparative Efficacy Study (DOLCE)-A randomized clinical trial. *Diabetes Care*, 48(6), 966–973. https://doi.org/10.2337/dc24-1233
166. Sigalove, S., O'Rorke, E., Maxwell, G. P., & Gabriel, A. (2022). Evaluation of the safety of a GalaFLEX-AlloDerm construct in prepectoral breast reconstruction. *Plastic and Reconstructive Surgery*, 150, 75S-81S.
167. Selvarajah D, Bollu BK, Harvey J, Jacques M, Jehangir S, Fuller ES, La Hei E, Bertinetti M, Lawrence T, Holland AJ. Acticoat versus biobrane: a retrospective review on the treatment of paediatric mid-dermal torso burns. Int J Burns Trauma. 2019 Aug 15;9(4):82-87.
168. Shakir, S., Messa, C. A., Broach, R. B., Rhemtulla, I. A., Chatman, B., D'Angelantonio, A., Levin, L. S., Kovach, S. J., Serletti, J. M., & Fischer, J. P. (2020). Indications and limitations of bilayer wound matrix-based lower extremity reconstruction: A multidisciplinary case-control

study of 191 wounds. *Plastic and Reconstructive Surgery*, 145(3), 813–822. https://doi.org/10.1097/PRS.0000000000006609

169. Simman, R., Mari, W., Younes, S., & Wilson, M. (2018). Use of hyaluronic acid-based biological bilaminar matrix in wound bed preparation: A case series. *Eplasty*, 18, e17.
170. Smith OJ, et al. The CelluTome epidermal graft-harvesting system: a patient-reported outcome measure and cost evaluation study. Int Wound J. 2016 Aug 4.
171. Sobti N, Liao EC. Surgeon-controlled study and meta-analysis comparing FlexHD and AlloDerm in immediate breast reconstruction outcomes. Plast Reconstr Surg. 2016;138(5):959-967.
172. Srivastava, Akanksha, et al. "Reconstruction of intraoral oncologic surgical defects with Integra® bilayer wound matrix." Clinical Case Reports (2021): 213-219.
173. Su Y, Zhao D, Li Y, et al. Human amniotic membrane allograft, a novel treatment for chronic diabetic foot ulcers: a systematic review and meta-analysis of randomised controlled trials. Int Wound J. 2020 Jun;17(3):753-764. doi:10.1111/iwj.13318.
174. Tan, A. P. P., & Chng, J. K. (2025). Fish skin acellular dermal matrix combined with negative pressure wound therapy for diabetic foot ulcers. Cureus. https://doi.org/10.7759/cureus.80488
175. Tanas, Y., Gasper, G., Tanas, J., Swed, S., & De Sario Velasquez, G. (2025). Comparative outcomes of human acellular dermal matrices in breast reconstruction: A systematic review and meta-analysis framework. *Systematic Reviews*, 14(1), 157. https://doi.org/10.1186/s13643-025-02915-y
176. Tarakji, K. G., Mittal, S., Kennergren, C., Corey, R., Poole, J. E., Schloss, E., ... & Wilkoff, B. L. (2019). Antibacterial envelope to prevent cardiac implantable device infection. New England Journal of Medicine, 380(20), 1895-1905.
177. Taupin, P., Gandhi, A., & Saini, S. (2023). Integra® Dermal Regeneration Template: From design to clinical use. Cureus. https://doi.org/10.7759/cureus.38608
178. Tchero, H., Herlin, C., Bekara, F., Kangambega, P., Sergiu, F., & Teot, L. (2017). Failure rates of artificial dermis products in treatment of diabetic foot ulcer: A systematic review and network meta-analysis. *Wound Repair and Regeneration*, 25(4), 691–696. https://doi.org/10.1111/wrr.12554
179. Tettelbach, W., Cazzell, S., Sigal, F., Caporusso, J. M., Agnew, P. S., Hanft, J., & Dove, C. (2018). A multicentre prospective randomised controlled comparative parallel study of dehydrated human umbilical cord (EpiCord) allograft for the treatment of diabetic foot ulcers. International Wound Journal, 16(1), 122–130. https://doi.org/10.1111/iwj.13001
180. Tettelbach, W. H., Armstrong, D. G., Chang, T. J., De Jong, J. L., Glat, P. M., Hsu, J. H., Kelso, M. R., Niezgoda, J. A., Labovitz, J. M., Hubbs, B., Forsyth, R. A., Cohen, B. G., Reid, N. M., & Padula, W. V. (2022). Cost-effectiveness of dehydrated human amnion/chorion membrane allografts in lower extremity diabetic ulcer treatment. Journal of Wound Care, 31(Sup2), S10–S31. https://doi.org/10.12968/jowc.2022.31.sup2.s10
181. Tettelbach, W., Cazzell, S., Reyzelman, A. M., Sigal, F., Caporusso, J. M., & Agnew, P. S. (2019). A confirmatory study on the efficacy of dehydrated human amnion/chorion membrane dHACM allograft in the management of diabetic foot ulcers: A prospective, multicentre,

randomised, controlled study of 110 patients from 14 wound clinics. *International Wound Journal.*, 16(1), 19–29. https://doi.org/10.1111/iwj.12976

182. Thomson, S. E., Ng, N. Y., Riehle, M. O., Kingham, P. J., Dahlin, L. B., Wiberg, M., & Hart, A. M. (2022). Bioengineered nerve conduits and wraps for peripheral nerve repair of the upper limb. *Cochrane Database of Systematic Reviews*, 12(12), CD012574. https://doi.org/10.1002/14651858.CD012574.pub2

183. Tian, J., Yao, G., Tian, T., Li, X., Li, S., Wu, C., & Zhang, S. (2025). Comparison of the efficacy and safety of different growth factors in the treatment of diabetic foot ulcers: An updated network meta-analysis. *Frontiers in Endocrinology*, 16, 1614597. https://doi.org/10.3389/fendo.2025.1614597

184. Towler, M. A., Rush, E. W., Richardson, M. K., & Williams, C. L. (2018). Randomized, prospective, blinded-enrollment, head-to-head venous leg ulcer healing trial comparing living, bioengineered skin graft substitute (Apligraf) with living, cryopreserved, human skin allograft (Theraskin). *Clinics in Podiatric Medicine and Surgery*, 35(3), 357–365. https://doi.org/10.1016/j.cpm.2018.02.006

185. Trippoli, S., Caccese, E., Tulli, G., Ipponi, P., Marinai, C., & Messori, A. (2018). Biological meshes for abdominal hernia: Lack of evidence-based recommendations for clinical use. *International Journal of Surgery* (London, England), 52, 278–284. https://doi.org/10.1016/j.ijsu.2018.02.046

186. U.S. Food & Drug Administration. Acellular Dermal Matrix (ADM) Products Used in Implant-Based Breast Reconstruction Differ in Complication Rates: FDA Safety Communication. FDA.gov. Issued March 31, 2021.

187. U.S. Food & Drug Administration. (2024). STRATAGRAFT (allogeneic cultured keratinocytes and dermal fibroblasts in murine collagen-dsat), for topical use. Full Prescribing Information. Initial U.S. Approval 2021. Revised: 1/2024. Retrieved from https://www.mallinckrodt.com/globalassets/documents/products/brands/stratagraft-full-uspi.pdf

188. Vaishya R, Agarwal AK, Tiwari M, Vaish A, Vijay V, Nigam Y. Medical textiles in orthopedics: An overview. J Clin Orthop Trauma. 2018 Mar;9(Suppl 1):S26-S33. doi: 10.1016/j.jcot.2017.10.016.

189. van de Warenburg, M. S., Teeuwen, B., Hummelink, S., Ulrich, D. J., & Vehmeijer-Heeman, M. L. (2025). Does the dressing matter in pediatric partial-thickness burns: A systematic review and meta-analysis. *Burns*, 51(4), 107428. https://doi.org/10.1016/j.burns.2025.107428

190. van den Beukel, B. A., de Ree, R., van Leuven, S., Bakkum, E. A., Strik, C., van Goor, H., & Ten Broek, R. P. (2017). Surgical treatment of adhesion-related chronic abdominal and pelvic pain after gynaecological and general surgery: a systematic review and meta-analysis. Human Reproduction Update, 23(3), 276-288.

191. van Doormaal TPC, Germans MR, Sie M, Brouwers B, Fierstra J, Depauw PRAM, Robe PA, Regli L. Single-Arm, Open-Label, Multicenter Study to Evaluate the Safety and Performance of Dura Sealant Patch in Reducing Cerebrospinal Fluid Leakage Following Elective Cranial Surgery: The ENCASE Trial Study Protocol. Neurosurgery. 2020 Feb 1;86(2):E203-E208.

192. Vasanthan, V., Biglioli, M., Hassanabad, A. F., Dundas, J., Matheny, R. G., & Fedak, P. W. (2021). The CorMatrix Cor™ PATCH for epicardial infarct repair. Future Cardiology, 17(8), 1297-1305.
193. Vecin, N. M., & Kirsner, R. S. (2023). Skin substitutes as treatment for chronic wounds: Current and future directions. *Frontiers in Medicine*, 10, 1154567. https://doi.org/10.3389/fmed.2023.1154567
194. Ventris Medical. Cellesta™. 2020. Accessed May 15, 2023. Available at URL address: https://www.ventrismedical.com/products/amniotic-tissue/
195. Veit-Rubin N, Cartwright R. Sacrocolpopexy tends to be superior to transvaginal mesh surgery. BJOG. 2021 Jan;128(1):24.
196. Vu, T. V. A., Lorizio, D., Vuerich, R., Lippi, M., Nascimento, D. S., & Zacchigna, S. (2022). Extracellular matrix-based approaches in cardiac regeneration: Challenges and opportunities. *International Journal of Molecular Sciences*, 23(24), 15783. https://doi.org/10.3390/ijms232415783
197. Walters J, Cazzell S, Pham H, et al. Healing rates in a multicenter assessment of a sterile, room temperature, acellular dermal matrix versus conventional care wound management and an active comparator in the treatment of full-thickness diabetic foot ulcers. *Eplasty*. 2016;16(10).
198. Wang L, Yan X, Zhao J, Chen C, et al. Expert consensus on resection of chest wall tumors and chest wall reconstruction. Transl Lung Cancer Res. 2021 Nov;10(11):4057-4083.
199. Wazir U, Mokbel K. The Evolving Role of Pre-pectoral ADM-assisted Approach in Implant-based Immediate Breast Reconstruction Following Conservative Mastectomy: An Overview of the Literature and Description of Technique. In Vivo. 2018 Nov-Dec;32(6):1477-1480.
200. Wen Z, Lu T, Wang Y, Liang H, Gao Z, He X. Anterior Cervical Corpectomy and Fusion and Anterior Cervical Discectomy and Fusion Using Titanium Mesh Cages for Treatment of Degenerative Cervical Pathologies: A Literature Review. Med Sci Monit. 2018 Sep 12;24:6398-6404.
201. Woodrow T, Chant T, Chant H. Treatment of diabetic foot wounds with acellular fish skin graft rich in omega-3: a prospective evaluation. J Wound Care. 2019 Feb 2;28(2):76-80.
202. Xu R, Xie ME, Jackson CM. Trigeminal Neuralgia: Current Approaches and Emerging Interventions. J Pain Res. 2021 Nov 3;14:3437-3463.
203. Yang CK, Polanco TO, Lantis JC. A Prospective, Postmarket, Compassionate Clinical Evaluation of a Novel Acellular Fish-skin Graft Which Contains Omega-3 Fatty Acids for the Closure of Hard-to-heal Lower Extremity Chronic Ulcers. Wounds. 2016 Apr;28(4):112-8.
204. Yeung, D. A., & Kelly, N. H. (2021). The role of collagen-based biomaterials in chronic wound healing and sports medicine applications. *Bioengineering* (Basel, Switzerland), 8(1), 8. https://doi.org/10.3390/bioengineering8010008
205. Zelen, C.M., Orgill, D.P., Serena T.E., et al. (2018). An aseptically processed, acellular, reticular, allogenic human dermis improves healing in diabetic foot ulcers: A prospective, randomised, controlled, multicentre follow-up trial. *International Wound Journal,* 15(5), 731-739. doi: https://doi.org/10.1111/iwj.12920

206. Zelen CM, Serena TE, Gould L, Le L, Carter MJ, Keller J, Li WW. Treatment of chronic diabetic lower extremity ulcers with advanced therapies: a prospective, randomised, controlled, multi-centre comparative study examining clinical efficacy and cost. Int Wound J. 2016 Apr;13(2):272-82.
207. Zenn, M.R., & Salzberg, C.A., (Aug 2016). A Direct Comparison of Alloderm-Ready to Use (RTU) and DermACELL in Immediate Breast Implant Reconstruction. *Eplasty, 16*: e23.
208. Zhou, H., Shen, Y., Zhang, Z., Liu, X., Zhang, J., & Chen, J. (2022). Comparison of outcomes of ventral hernia repair using different meshes: A systematic review and network meta-analysis. *Hernia*, 26(6), 1561–1571. https://doi.org/10.1007/s10029-022-02652-4
209. Zhu T, Wang H, Jing Z, Fan D, Liu Z, Wang X, Tian Y. High efficacy of tetra-PEG hydrogel sealants for sutureless dural closure. Bioact Mater. 2021 Jun 27;8:12-19.
210. Zografakis J, Johnston G, Haas J, Berbiglia L, Bedford T, Spear J, Dan A, Pozsgay M. Urinary Bladder Matrix Reinforcement for Laparoscopic Hiatal Hernia Repair. JSLS. 2018 Apr-Jun;22(2):e2017.00060.

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