Integra® LifeSciences

COMPLEX WOUND RECONSTRUCTION PORTFOLIO

INTEGRA®
LIMIT UNCERTAINTY

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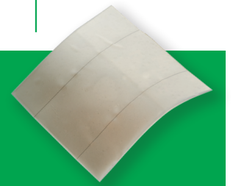
Wounds come in a multitude of shapes and sizes. Fortunately, so does our wound reconstruction portfolio.

Comprehensive solutions in tissue regeneration for acute and chronic complex wounds and burns.

BROAD CLINICAL REACH



Integra®
Dermal Regeneration Template (IDRT)

Helps restore lost function and joint mobility

Where: Wounds in areas where functionality* is critical.

Why: The Integra technology is specifically engineered as a 3D matrix with an optimized design to regenerate high-quality dermal tissue, and the clinical data helps demonstrate improvement in function in critical areas that matter most. IDRT is indicated for the treatment of third-degree burn injury.

PriMatrix®
Dermal Repair Scaffold

An adaptable solution for challenging wounds

Where: Wounds with high potential shearing forces,[1-3] elevated risk of infection,†[4] and/or increased areas of pressure and friction.[1-3]

Why: Derived from fetal bovine dermis, PriMatrix retains a robust structure that helps resist breakdown in challenging wounds while allowing the cells and vessels to infiltrate the matrix.[5]

AmnioExcel® Plus
Placental Allograft Membrane

Strong enough to go the distance

Where: Wounds at high risk of stalling where a strong amniotic product is needed.

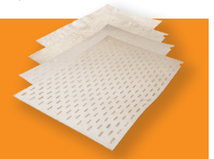
Why: AmnioExcel Plus is the only tri-layer placental allograft consisting of amnion-chorion-amnion. Its unique configuration and processing provide the strength needed in the operating room or anywhere improved handling is needed.

MicroMatrix®
UBM Particulate

Quick wound modification to support healing

Where: Tunneling, undermining or irregular wounds requiring quick tissue formation.

Why: Upon application, MicroMatrix has been shown to support a shift from an inflammatory wound environment to one that facilitates rapid revascularization and may allow for quick wound remodeling.[6-8] Because it is a powder, MicroMatrix provides thorough contact with the wound bed.



Cytal®
Wound Matrix

Addressing challenging wound microenvironments

Where: Traumatic full-thickness wounds where there may be barriers to healing.

Why: Cytal is a non-crosslinked scaffold that provides an environment where the body is more likely to exhibit a higher ratio of M2 (pro-remodeling) to M1 (pro-inflammatory) macrophages.[6,7] Cytal offers flexible wound management options with 4 pre-fenestrated layering configurations.

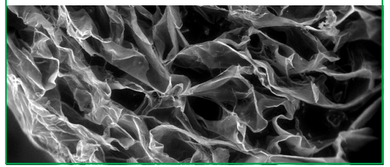
* Functionality refers to cushion from stress and strain, elasticity, and mobility.
† PriMatrix should be used with caution in regions where an infection exists or is suspected. Treat any existing infection appropriately.

Integra Dermal Matrices

Helps Restore Lost Function* and Joint Mobility

Functional* Dermal Regeneration

- Engineered to promote the regeneration of dermal tissue
- Minimal inflammatory response[9]
- Pore structure permits cellular ingrowth[10]
- Resorption occurs at rate of new tissue formation[11]



Proven Clinical Excellence

- The most extensive body of research of any dermal matrix with over 300 published studies
- Studied in over 3,600 patients in Level I – III clinical evidence[12]
- Demonstrated health-economic outcomes in total cost and length of stay.[12–14]

Successful Patient Outcomes

- Over 30 years of restoring patient functionality
- Demonstrated long-term outcomes leading to improved quality of life

*Function refers to cushion from stress and strain, elasticity, and mobility.

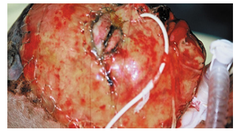
Integra Clinical Outcomes

Over 30 Years of Successful Patient Outcomes

Condition: Full-Thickness Burns to the Face

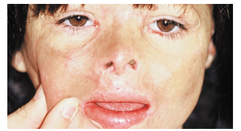
Photos courtesy of Jean-Michel Rives, MD

Situation
Young girl with extensive full-thickness facial burns.



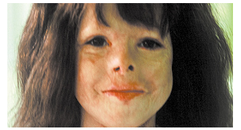
Revascularization of IDRT

Approach
Burn wound excision on the lower cheek was to the fat; higher on the cheekbone, excision was to the muscle; on the forehead, excision was to the periosteum. Following wound excision, Integra Dermal Regeneration Template (IDRT) was applied. Once the neodermis was revascularized, the silicone layer was removed and a split-thickness skin graft was performed.



Follow-up after 6 months

Outcome
Three years later, the patient experienced no hypertrophic scarring, and had facial suppleness, good motor function, and restoration of the facial contours.



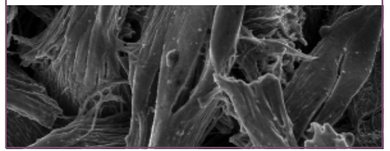
Follow-up after 3 years

PriMatrix Acellular Bovine Dermal Matrix

An Adaptable Solution for the Most Challenging Wounds

Robust Architectural Design

- Preserved architecture provides a cell-friendly environment to support dermal tissue repair[5,15,16]
- Porosity provides the foundation for rapid cellular repopulation and tissue revascularization[5,15]
- Retains a robust structure that helps resist breakdown in challenging wounds[5]



Successful Clinical Results

- Clinically studied in diverse wound types, surgical conditions, and anatomic locations[4,17,18]
- Demonstrated clinical success in a series of peer-reviewed prospective, retrospective, and case studies[1,4,16-24]

Broad Family of Product Offerings

- Twelve different sizes to manage multiple wound types
- Three configurations: solid, meshed, or fenestrated
- Ionic silver option

PriMatrix Clinical Outcomes

Managing Challenging Wounds for Over a Decade[18,24]

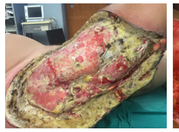
Condition: The Treatment and Reconstruction of Soft Tissue Following Cutaneous Mucormycosis

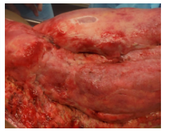
Sean O'Connor, MD; James H Holmes IV, MD, FACS; and Jeffrey E Carter, MD, FACS

Situation

18-year-old female sustained a closed degloving lesion of the thigh and an open tibial fracture. On post-op day 5, she developed a necrotizing fungal infection and septic shock caused by mucormycosis.

Hospital Day 1

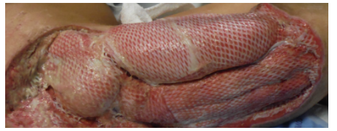




Day 16: s/p 7 debridements, 4 days wound VAC

Approach

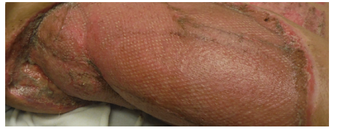
The wound area at 2,250 cm^2 with exposed nerve and femur and no remaining fascia. NPWT was applied. After 6 days, PriMatrix was placed. At 2 weeks, there was 100% take with a well-vascularized wound bed amenable to autograft, followed by negative pressure wound therapy (NPWT*).



Day 31: POD 13 from PriMatrix

Outcome

Five days after the autograft, she had 99% take and discharged to rehab, ambulating with assistance. Resumed playing golf within 8 months.



Day 51: POD 13 from Autograft

* The use of PriMatrix with NPWT in this publication reflects surgeon preference. The safety and effectiveness of concomitant use of PriMatrix with negative pressure wound therapy has not been established or cleared by the FDA.

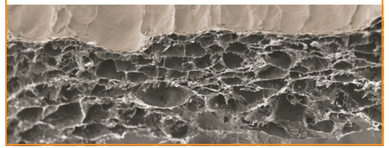
VAC = Vacuum-assisted closure
POD = Post operative day

MicroMatrix

Quick Wound Modification to Support Healing

Thorough Contact with the Wound Bed

- Particulate configuration offers a wound management solution for irregular, tunneled, or undermined wounds.
- May be applied as a powder or a paste for ease of use in a variety of wound geometries.



Bimodal scaffold with intact epithelial basement membrane

Fast Revascularization

- Provides an open, porous structure which permits cell infiltration and neovascularization.
- Facilitates ingrowth of vascular tissue over avascular structures.[8,25,26]
- Supports the development of a vascular wound environment that may allow for follow-up management via additional sheet products, skin grafting, or flap reconstruction.[27]

Modified Inflammatory Response

- Provides an environment where the body is more likely to exhibit a higher ratio of M2 (pro-remodeling) to M1 (pro-inflammatory) macrophages.[6,7]
- In a prospective case control study, wound management with UBM resulted in a statistically significant decrease in M1 to M2 scores for both diabetic and non-diabetic patients which correlated with the rate of wound area reduction.[6]

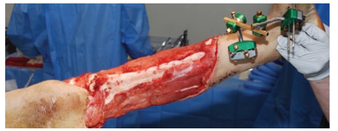
MicroMatrix Patient Outcomes

Proven Clinical Track Record

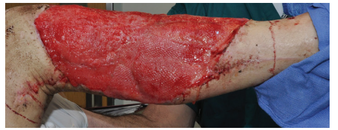
Condition: LLE Blast-Related Trauma

Images reprinted with permission from Future Medicine

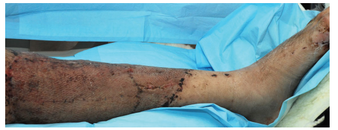
Situation
Gustilo-Anderson 3B LLE injury with severe degloving and exposed tibial fracture.



Approach
LLE reconstruction: free latissimus flap covers proximal 2/3, and MicroMatrix/Cytal scaffold covers the distal 1/3 of wound. After 3 applications of MicroMatrix/Cytal combination, the wound bed was adequately vascularized for skin grafting.



Outcome
One month later: STSG over hybrid reconstruction salvage and remodeled MicroMatrix/Cytal.



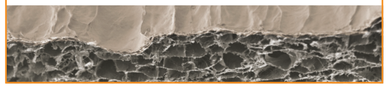
Valerio et al.

Cytal Wound Matrix

Addressing Challenging Wound Microenvironments

Supports a Shift in Inflammatory Response

- Provides an environment where the body is more likely to exhibit a higher ratio of M2 (pro-remodeling) to M1 (pro-inflammatory) macrophages.[6,7]
- In a prospective case control study, wound management with UBM resulted in a statistically significant decrease in M1 to M2 scores for both diabetic and non-diabetic patients which correlated with the rate of wound area reduction.[6]



Bimodal scaffold with intact epithelial basement membrane

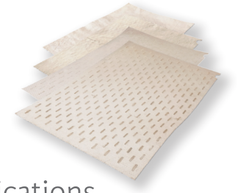
Provides Flexible Treatment Options

- Supports the development of a vascular wound environment that may allow for follow-up management via additional sheet products, skin grafting, or flap reconstruction.[27]
- Available in a variety of sizes and layering configurations.

Facilitates Fast Revascularization and Formation of Site-Appropriate TIssue

- Provides an open, porous structure which permits cell infiltration and neovascularization.
- Supports ingrowth of vascular tissue over avascular structures.[8,25,26]
- Facilitates formation of site-appropriate tissue remodeling.[7,28]

Cytal Patient Outcomes

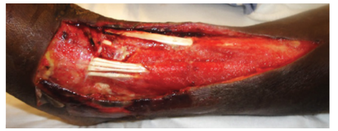


Over 25 Clinical Publications on Successful Use in Wound Management Applications

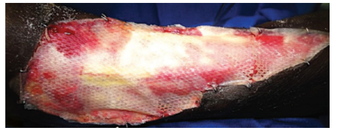
Condition: Open LE Wound After Tissue Necrosis

Images reprinted with permission from Geiger et al.

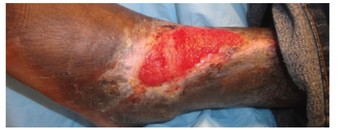
Situation
Open lower extremity wound after tissue necrosis from narcotic injection.



Approach
Wound was managed with MicroMatrix and Cytal Wound Matrix.



Outcome
Wound healing after 3 months of hydrogel, prior to skin grafting, demonstrating robust, vascularized wound bed.

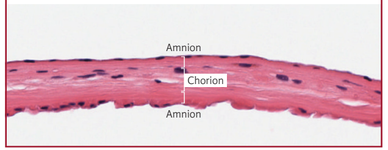


AmnioExcel Plus

Strong Enough to Go the Distance

Strong Enough to Go the Distance

- AmnioExcel Plus was shown to be 100% stronger than EpiFix®, even when wet.*[29]
- Tri-layer membrane with non-side specific application.*[29]
- Strong enough to be picked up and repositioned at the time of application—even when wet.



AmnioExcel Family Evidence

- The processing of AmnioExcel Plus preserves the inherent growth factors, cytokines and ECM (extracellular matrix) found in native placental tissue.[29]
- The first-generation AmnioExcel, amnion-only membrane, is supported by Level 1 clinical evidence supporting its use on DFUs[30] and numerous other peer-reviewed papers.[29-38]

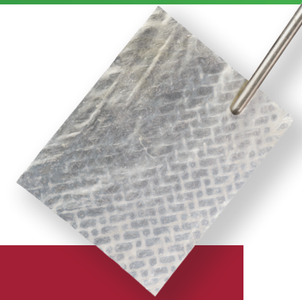
The AmnioExcel Family Offering

- AmnioExcel and AmnioExcel Plus both utilize DryFlex processing.
- AmnioExcel amniotic tissue membrane is made with the amnion layer only. It quickly integrates into the wound bed.
- With AmnioExcel and AmnioExcel Plus, you can have access to 17 SKUs from 1 cm^2 to 100 cm^2.
- Dehydrated and terminally sterilized.
- Off-the-shelf: room temperature storage with a 5-year shelf life.

* Laboratory and preclinical studies are not necessarily indicative of clinical outcomes.

AmnioExcel Plus Patient Outcomes

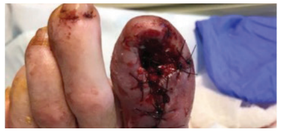
Aiding in Closing Complex and Stalled Wounds



Condition: Dehisced Onychectomy Site

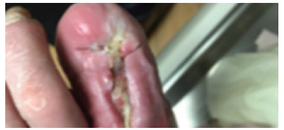
Photos courtesy of Anthony Tickner, DPM

Situation
60-year-old non-compliant male with poorly controlled diabetes mellitus, hypertension and HIV+. The initial surface area of the wound was measured at 2.8 cm^2.



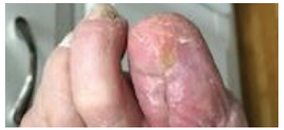
Day 0

Approach
AmnioExcel Plus was applied every 1-2 weeks in addition to standard of care, which includes debridement, infection control, and use of dressings.



Week 2

Outcome
Complete closure was obtained on Day 35 following 2 applications of AmnioExcel Plus.



Week 5

Ordering Information

Full Ordering Information

Web Link:
http://app.sales.integralife.com/surgical-reconstruction/tissue-technologies-sku-list.pdf

Integra Reimbursement Hotline Services

For assistance with the following:

- Insurance benefits verification
- Prior authorizations
- Predeterminations
- Claims review
- Navigating the approval process

Phone: 1-877-444-1122, option 3

Fax: 1-888-807-0571

Email: smartreimbursement@integralife.com

Web: integralife.com

Disclaimer: Integra intends to use reasonable efforts to provide insurance coding advice, but this advice should not be construed as providing clinical advice, dictating reimbursement policy or substituting for the judgment of a practitioner. It is always the provider's responsibility to determine and submit appropriate codes, charges, and modifiers for services that are rendered. Provider is responsible for verifying coverage with the patient's insurance carrier. Integra LifeSciences Corporation assumes no responsiblity for the timeliness, accuracy and completeness of the information contained herein. Since reimbursement laws, regulations, and policies change frequently, it is recommended that providers consult with their payers, coding specialists and/or legal counsel regarding coverage, coding, and payment issues.

Indications

Brief Summary
Consult Package Insert for Full Prescribing Information

Integra® Dermal Regeneration Template
Integra® Meshed Dermal Regeneration Template

Description
Integra® Dermal Regeneration Template, available in Meshed and Non-Meshed configurations (Integra template), is a bilayer membrane system for skin replacement. The dermal replacement layer is made of a porous matrix of fibers of cross-linked bovine tendon collagen and glycosaminoglycan (chondroitin-6-sulfate) that is manufactured with a controlled porosity and defined degradation rate. The epidermal substitute layer is made of a thin polysiloxane (silicone) layer to control moisture loss from the wound.

Integra template is provided sterile and non-pyrogenic. The inner foil pouch and product should be handled using sterile technique. Integra template should not be re-sterilized.

Indications
Integra template is indicated for the postexcisional treatment of life-threatening full-thickness or deep partial-thickness thermal injuries where sufficient autograft is not available at the time of excision or not desirable due to the physiological condition of the patient. Integra template is also indicated for the repair of scar contractures when other therapies have failed or when donor sites for repair are not sufficient or desirable due to the physiological condition of the patient.

Integra template is also marketed as Integra® Omnigraft® Dermal Regeneration Matrix. Omnigraft is indicated for the use in the treatment of partial and full-thickness neuropathic diabetic foot ulcers that are greater than six weeks in duration, with no capsule, tendon or bone exposed, when used in conjunction with standard diabetic care.

Contraindications
Use of Integra template is contraindicated in patients with known hypersensitivity to bovine collagen or chondroitin materials.

Integra template should not be used on clinically diagnosed infected wounds.

Warnings and Precautions
Excision of the wound must be performed thoroughly to remove all coagulation eschar and nonviable tissue. Integra template will not "take" to nonviable tissue. Leaving any remaining nonviable tissue may create an environment for bacterial growth.

Hemostasis must be achieved prior to applying Integra template. Inadequate control of bleeding will interfere with the incorporation of Integra template.

Precautions
There have been no clinical studies evaluating Integra template in pregnant women. Caution should be exercised before using Integra template in pregnant women. Such use should occur only when the anticipated benefit clearly outweighs the risk.

In clinical trials, the use of Integra template was evaluated in a small number of patients with chemical, radiation, or electrical burns. A surgeon's decision to use Integra template on these wounds should be based on their evaluation of the wound and its suitability to excisional therapy, the likelihood that a viable wound bed will be created by excision, and whether the possible benefit outweighs the risk in this patient population. The extent of scarring associated with the use of this product has not been determined.

Adverse Events

Burn Patients
Integra template has been found to be well tolerated in 4 prospective clinical trials involving 444 burn patients. There were no reports of clinically significant immunological or histological responses to the implantation of Integra template. There were no reports of rejection of Integra template.

Adverse events reported in the Integra template clinical trials include death, sepsis, apnea, heart arrest, pneumonia, kidney failure, multisystem failure, and respiratory distress. With the exception of wound fluid accumulation, positive wound cultures, and clinical wound infection, none were directly related to the use of Integra template.

In these clinical trials, data were collected regarding wound infection. The consequences of infection at sites treated with Integra template included partial or complete loss of take (incorporation into the wound bed) of Integra template. Infection rates in sites treated with Integra template in these three clinical trials supporting the PMA ranged from 14 to 55%. The overall infection rate for the Postapproval Study was 16.3%.

Adverse events in the Postapproval study were similar to those observed in the previous clinical trials and are common in populations of critically ill burn patients regardless of type of treatment used. There were no trends noted. There were six adverse events which were rated by the investigator as being related. These events were all single occurrences except for sepsis (2). These adverse events occurred in <1% of the safety population.

Incidence of adverse events occurring in >1% of the safety population in the Post-approval Study are as follows: Sepsis (23.1%), Death (13.9%), Infection (2.8%), Thrombophlebitis (2.8%), Kidney Failure (2.8%), Necrosis (2.3%), Hemorrhage (2.3%), Heart Arrest (1.9%), Apnea (1.9%), Pneumonia (1.9%), Allergic Reaction (1.4%), Fever (1.4%), Multisystem Failure (1.4%), Atrial Fibrillation (1.4%), Gastrointestinal Hemorrhage (1.4%), Kidney Abnormal Function (1.4%).

Contracture Release Patients
The following adverse events were reported in a Reconstructive Surgery Study involving 20 patients with 30 anatomical sites and a Retrospective Reconstruction Contracture Survey involving 89 patients and 127 anatomic sites.

Incidence of adverse events in the Reconstructive Contracture Surgery Study and Retrospective Contracture Reconstruction Survey is as follows: Infection (0.0%), Fluid under Silicone Layer (0.0%), Partial graft loss (Integra) (0.0%), Failure to take (Integra) (0.0%), Shearing/Mechanical shift (3.3%), Hematoma (16.7%),

Granulation tissue formation (0.0%), Delayed Healing (0.0%), Separation of the Silicone Layer (0.0%), Seroma (0.0%), Pruritis (0.0%), Epidermal autograft loss >15% (6.7%), Epidermal autograft loss <15% (23.3).

There were no infections reported in the Reconstructive Surgery Study and the reported infection rate was 20.5% in the Retrospective Contracture Reconstruction Survey. No deaths were reported.

Diabetic Foot Ulcer Patients

All adverse events that were reported in the study evaluating Omnigraft for the treatment of diabetic foot ulcers at a frequency of ≥ 1% in either cohort are presented in Table 1 in the Instructions for Use. This table includes adverse events that were both attributed to and not attributed to treatment. The most common adverse events experienced by patients treated with Omnigraft were: wound infection (15%); new, worsening, or recurring wounds (14%); pain around the wound (9%); infection beyond the wound (either cellulitis or osteomyelitis, 14%); swelling (5%); nausea (5%); worsening health condition (4%). These adverse events occurred in a similar or lower percentage of patients treated with Omnigraft compared to patients treated with standard wound care alone. The sale of Integra template is restricted to clinicians who have completed a company sponsored training program. Product training is available at ilstraining.com.

PriMatrix® Dermal Repair Scaffold

Description

PriMatrix is an acellular dermal tissue matrix derived from fetal bovine dermis. The device is supplied sterile in a variety of sizes to be trimmed by the surgeon to meet the individual patient's needs.

Indications

PriMatrix is intended for the management of wounds that include:

- Partial and full thickness wounds
- Pressure, diabetic, and venous ulcers
- Second-degree burns
- Surgical wounds—donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence
- Trauma wounds—abrasions, lacerations, and skin tears
- Tunneled/undermined wounds
- Draining wounds

Contraindications

PriMatrix should not be used for patients with a known history of hypersensitivity to collagen or bovine products.

Warnings and Precautions

- Do not expose to chemicals or substances other than sterile, room temperature 0.9% saline.
- Excessive heat can damage collagen. Do not hydrate in 0.9% saline warmed above room temperature. If, when hydrated, the product shrinks in size, DO NOT use the product as it may be damaged.
- PriMatrix should be used with caution in regions where an infection exists or is suspected. Treat any existing infection appropriately.
- PriMatrix should not be applied directly on third-degree burns.

Potential Complications

The following complications are possible. If any of these conditions occur, the device should be removed.

- Infection
- Chronic inflammation
- Allergic reaction
- Excessive redness, pain, swelling, or blistering

PriMatrix® Ag Antimicrobial Dermal Repair Scaffold

Description

PriMatrix® Ag Antimicrobial is an acellular dermal tissue matrix derived from fetal bovine dermis. The device is supplied sterile in a variety of sizes to be trimmed by the surgeon to meet the individual patient's needs. The Ionic Silver content is intended to prevent microbial colonization of the device. Ionic silver is a broad spectrum antimicrobial. PriMatrix® Ag Antimicrobial has been shown in CLSI Disc Susceptibility testing to be effective against a range of bacteria, including: Staphylococcus aureus, Staphylococcus epidermidis, Escherichia coli, Methicillin-Resistant Staphylococcus aureus (MRSA), Enterococcus faecium, Klebsiella pneumoniae, Listeria monocytogenes, Vancomycin-Resistant Enterococcus faecalis (VRE), Acinetobacter baumannii, and Streptococcus pyrogenes (Group A).

Indications

PriMatrix® Ag Antimicrobial is intended for the management of wounds that include:

- Partial and full thickness wounds
- Pressure, diabetic, and venous ulcers
- Second-degree burns
- Surgical wounds—donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence
- Trauma wounds—abrasions, lacerations, and skin tears
- Tunneled/undermined wounds
- Draining wounds

Contraindications

PriMatrix® Ag Antimicrobial should not be used for patients with a known history of hypersensitivity to silver, collagen, or bovine products. This device is not indicated for use in third-degree burns.

Warnings and Precautions

Silver-containing compounds are known to cause a condition known as argyria, a silver-induced darkening of the skin. Frequent or prolonged use of PriMatrix® Ag Antimicrobial may result in skin discoloration.

Potential Complications

The following complications are possible. If any of these conditions occur, the device should be removed.

- Infection
- Chronic Inflammation
- Allergic reaction
- Excessive redness, pain, swelling, or blistering

MicroMatrix®

Description

Intended for the management of wounds including: partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns, skin tears), and draining wounds. The device is intended for one-time use.

Contraindications

1. Known sensitivity or allergy to porcine materials.
2. Third-degree burns.

Warnings

- If active infection is present, treat patient to resolve infection prior to device application.
- Do not use glass vial if cracked, broken, or otherwise damaged.
- MicroMatrix is not indicated for treatment of alopecia.

Precautions

Do not tap glass vial with metal objects or handle in a way that may cause glass to break and contaminate wound.

Cytal® Wound Matrix

Description

Intended for the management of wounds including: partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns, skin tears), and draining wounds. The device is intended for one-time use.

Contraindications

1. Patients with known sensitivity or allergy to porcine materials.
2. Third-degree burns.

Warnings

Exposure to contaminated or infected field can lead to rapid breakdown of device.
If active infection is present, treat patient to resolve infection prior to device application.
Do not use if cracked, broken, or otherwise damaged.

Precautions

Always use aseptic technique when handling device.

AmnioExcel® and AmnioExcel® Plus

AmnioExcel and AmnioExcel Plus are regulated as Human Cellular and Tissue-Based Products (HCT/P) under Section 361 of the Public Health Service Act and as such are governed by the FDA Center for Biologics Evaluation and Research (CBER).

General Use

AmnioExcel and AmnioExcel Plus Membranes are intended for use as a wound covering. This product is an allograft tissue intended for homologous use as a protective barrier covering during the repair of soft tissue wounds at the direction of a physician.

Precautions

1. AmnioExcel and AmnioExcel Plus Membranes contain trace amounts of ethanol. They should not be used in patients with known sensitivity to ethanol. 2. In order to reduce the risk of complications, AmnioExcel and AmnioExcel Plus Membranes should not be used in the presence of active infection. 3. Although donor tissue is evaluated and processed following strict FDA guidelines, the donor screening methods are limited and may not detect all diseases. As with any allograft, complications at the graft site may occur postoperatively that are not readily apparent. Availability of these products might vary from a given country or region to another, as a result of specific local regulatory approval or clearance requirements for sale in such country or region.

- Non contractual document. The manufacturer reserves the right, without prior notice, to modify the products in order to improve their quality.
- Warning: Applicable laws restrict these products to sale by or on the order of a physician.
- Consult product labels and inserts for any indication, contraindications, hazards, warnings, precautions, and instructions for use.

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AmnioExcel and AmnioExcel Plus are regulated as Human Cellular and Tissue-Based Products (HCT/P) under Section 361 of the Public Health Service Act and as such are governed by the FDA Center for Biologics Evaluation and Research (CBER).

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Availability of these products might vary from a given country or region to another, as a result of specific local regulatory approval or clearance requirements for sale in such country or region.

- Non contractual document. The manufacturer reserves the right, without prior notice, to modify the products in order to improve their quality.
- Warning: Applicable laws restrict these products to sale by or on the order of a physician.
- Consult product labels and inserts for complete indications, contraindications, warnings, precautions, and instructions for use.

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