

In partnership with Extremity Care.



WOUND CARE SOLUTIONS

Product Catalog

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Potential Clinical Applications

Diabetic Foot Ulcers Partial and Full-Thickness Wounds Trauma wounds (including second degree burns)

Venous Leg Ulcers Pressure Ulcers **Draining Wounds**

Chronic Vascular Ulcers Surgical Wounds Tunneled/Undermined Wounds



Welcome to Parametrics Medical

Parametrics Medical provides the latest advancements in allograft tissue, biologic implants, and regenerative medicine designed to enhance surgical outcomes and improve patient quality of life while honoring the gift of donated human tissue.

Our Mission

Ensuring physicians have the best solutions for their patients.

Partnership with Extremity Care

Through our exclusive relationship, we offer a comprehensive portfolio of wound care solutions designed to meet the clinical needs of physicians and patients across the reimbursement spectrum, providing stability and continuity in a dynamic environment.



Contact Us



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1.800.917.4880



www.parametricsmedical.com

RESTORIGIN™

DUAL LAYER AMNIOTIC MEMBRANE ALLOGRAFT

Restorigin is a placental tissue allograft that may be used as a protective barrier in wound care applications. The natural properties of amniotic tissue provide mechanical protection and growth factors to aid in the management of acute and chronic wounds.^{1,2,3}

About Restorigin[™]

Non-Oriented

Restorigin is a dual layer amnion that offers the flexibility of placing either side toward the wound

Optimal Handling Characteristics Easily controlled during application due to dual layer technology and 60 micron thickness

Natural Adherence

Adheres naturally to the patient's tissue without the need for sutures or other fixation

Safety and Processing

Gentle Processing

Minimally manipulated and processed using gentle detergents and water rinses

Gentle Sterility

Terminally sterilized with electron beam which has shorter exposure times and produces less free radicals, resulting in less deterioration to tissue structures

Versatility and Ease-of-Use

Convenient Storage
 Restorigin is delivered
 and stored at room temperature with a 5-year
 shelf life

Preparation

Requires no up front preparation or hydration

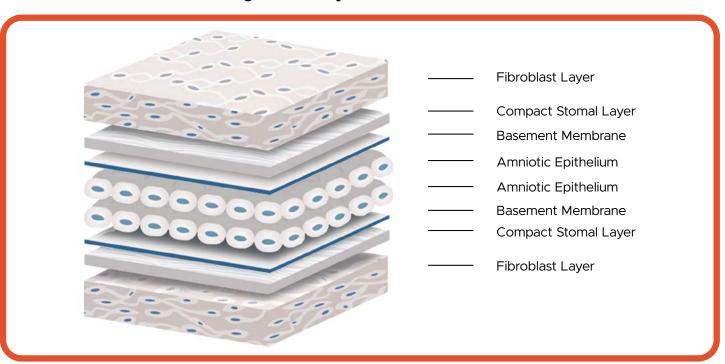
Dual Layer Technology

Provides orientation placement flexibility

Multiple Sizes

Available in a variety of sizes to accommodate physician preferences

Restorigin[™] **Dual Layer Amnion Membrane**



RESTORIGIN

DUAL LAYER AMNIOTIC MEMBRANE ALLOGRAFT

Why Restorigin™?

Proven Results

Restorigin has been shown to be effective in the management of chronic, non-healing wounds including diabetic and venous leg ulcers.

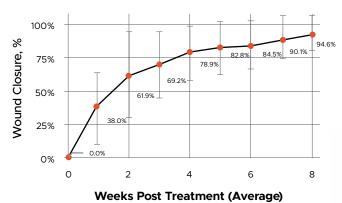


Figure 1. An average of 94.6% of wound area reduction was observed after 8 weeks of HAM sheet therapy.

In a 10 patient case series, 95% of wound closure was achieved after 8 weeks of treatment in patients who previously failed standard care protocols.⁴

Healing Progression - Before and After Treatment

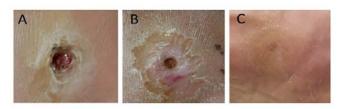


Figure 2. Healing progression is shown for a 42-year-old female patient from before the treatment (A) to complete closure after 4.5 weeks of Human Amniotic Membrane therapy and a single graft application (C).



RESTORIGIN

DUAL LAYER AMNIOTIC MEMBRANE ALLOGRAFT

| SKU | Product Description | Size | Units | HCPCS | SKU |
|-------------|---|-------|-------|-------|--------------|
| RGN-AM-0202 | Restorigin [™] Amnion Membrane | 2x2cm | 4 | Q4191 | 382567000830 |
| RGN-AM-0203 | Restorigin™ Amnion Membrane | 2x3cm | 6 | Q4191 | 382567000847 |
| RGN-AM-0204 | Restorigin™ Amnion Membrane | 2x4cm | 8 | Q4191 | 382567000854 |
| RGN-AM-0404 | Restorigin™ Amnion Membrane | 4x4cm | 16 | Q4191 | 382567000861 |
| RGN-AM-0406 | Restorigin [™] Amnion Membrane | 4x6cm | 24 | Q4191 | 382567000878 |
| RGN-AM-0408 | Restorigin™ Amnion Membrane | 4x8cm | 32 | Q4191 | 382567000885 |

- 1. Rowlatt, U. (1979). Intrauterine wound healing in a 20-week human fetus. Virchows Arch A Pathol Anat Histol, 381(3), 353-361.
- 2. Coolen, N.A. et al. (2010). Comparison between human fetal and adult skin. Archives of Dermatological Research, 302(1), 47–55.
- 3. Niknejad H, Peirovi H, Jorjani M, et al. Properties of the amniotic membrane for potential use in tissue engineering. Eur Cell Mater. 2008;15:88-89.
- 4. Zakharova M, Hall B, Schallenberger M, Bangart K, Bangart D, Moore S, Thomas J: Case study report of chronic non-healing foot ulcers treated with dehydrated human amniotic membrane sheet. SAWC Spring 2020.



Tissue Characteristics

- · Dual-layer amniotic membrane.
- Intended for homologous use only. Acts as a wound cover, that is a natural bandage shielding wounds from its external environment.
- Proprietary processing of the tissue ensures that the natural structure and relevant characteristics are preserved.
- Dehydrated, packaged, and terminally sterilized with a 2-year shelf life. Stored at ambient temperature.

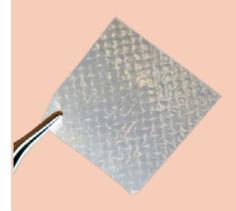
Configurations



Square sizes: 2x2cm, 4x4cm Rectangular sizes:

2x3cm, 2x4cm, 4x6cm, 4x8cm

Tissue Processing - Amniotic Membrane Barrier



- The amniotic membrane for barrera[™] is sourced from healthy deliveries of placental tissue with maternal consent.
- Processed using minimally manipulated amniotic membrane in a dual layer composition to retain the amniotic membrane's original relevant characteristics of the placental extracellular matrix (ECM).
- The amniotic membrane's key structural components, specifically the epithelium layer, as well as the basement layer of the placental tissue, are retained to allow the membrane its utility to serve as a barrier.
- May adhere to the underlying wound surface as a cover protecting wounds and may help prevent formation of dead space on wounds.^{1,2}
- May prevent infiltration and adhesion of microorganisms to wounds.^{1,2}

| SKU | Product Description | Size | Units | HCPCS | UPC |
|---------|---------------------------------------|-------|-------|-------|--------------|
| BRD-022 | Barrera™ Dual Layer Amniotic Membrane | 2x2cm | 4 | Q4281 | 382567000137 |
| BRD-023 | Barrera™ Dual Layer Amniotic Membrane | 2x3cm | 6 | Q4281 | 382567000144 |
| BRD-024 | Barrera™ Dual Layer Amniotic Membrane | 2x4cm | 8 | Q4281 | 382567000151 |
| BRD-044 | Barrera™ Dual Layer Amniotic Membrane | 4x4cm | 16 | Q4281 | 382567000168 |
| BRD-046 | Barrera™ Dual Layer Amniotic Membrane | 4x6cm | 24 | Q4281 | 382567000175 |
| BRD-048 | Barrera™ Dual Layer Amniotic Membrane | 4x8cm | 32 | Q4281 | 382567000182 |

^{1.} Malhotra C, Jain AK. Human amniotic membrane transplantation: Different modalities of its use in ophthalmology. World J Transplant. 2014 Jun 24;4(2):111-21. doi: 10.5500/wjt.v4.i2.111. PMID: 25032100; PMCID: PMC4094946.

^{2.} Gupta A, Kedige SD, Jain K. Amnion and Chorion Membranes: Potential Stem Cell Reservoir with Wide Applications in Periodontics. Int J Biomater. 2015;2015:274082. doi: 10.1155/2015/274082. Epub 2015 Dec 6. PMID: 26770199; PMCID: PMC4684856.

carePATCH[™]

DUAL LAYER AMNIOTIC MEMBRANE ALLOGRAFT

Tissue Characteristics

- carePATCH™ is a dehydrated tissue product stored at ambient temperature with a 2 YearShelf Life.
- carePATCH™ retains amniotic membrane's natural structure and relevant characteristics including epithelium and basement membrane layers.
- carePATCH™ acts as a wound cover, that is a natural bandage shielding wounds from its external environment.

Configurations

These different configurations serve as barriers for different types of wounds.



Square sizes: 2x2cm, 4x4cm

Rectangular sizes: 2x3cm, 2x4cm, 4x6cm, 4x8cm

Amniotic Tissue as a Barrier

- Amniotic membrane adheres closely to its underlying surface as a cover protecting wounds and may help prevent formation of dead space on wound.^{1,2}
- Amniotic membrane's barrier function may help prevent infiltration and adhesion of microorganisms to wounds.



Figure 3 Amniotic membrane of carePATCH™ where epithelial layer is in purple/blue areas and basement membrane is in pink.

Tissue Processing

- The amniotic membrane for carePATCH™ is sourced from healthy deliveries of placental tissue with maternal consent.
- carePATCH™ is produced using minimally manipulated amniotic membrane in a dual layer composition.
- Through minimally manipulated methods carePATCH™ retains amniotic membrane's original relevant characteristics relating to its utility to serve as a barrier, specifically its physical integrity, tensile strength, and elasticity.
- carePATCH™ retains the amniotic membrane's key structural components related to its utility to serve as a barrier, specifically:
 - Epithelium Layer Basement Membrane
- carePATCH™ is dehydrated, packaged, and terminally sterilized with a 2 year shelf life.

| Product Description | Size | Units | HCPCS | UPC |
|------------------------------|--|--|--|---|
| carePATCH™ Amniotic Membrane | 2x2cm | 4 | Q4236 | 382567000014 |
| carePATCH™ Amniotic Membrane | 2x3cm | 6 | Q4236 | 382567000090 |
| carePATCH™ Amniotic Membrane | 2x4cm | 8 | Q4236 | 382567000021 |
| carePATCH™ Amniotic Membrane | 4x4cm | 16 | Q4236 | 382567000038 |
| carePATCH™ Amniotic Membrane | 4x6cm | 24 | Q4236 | 382567000045 |
| carePATCH™ Amniotic Membrane | 4x8cm | 32 | Q4236 | 382567000059 |
| | carePATCH™ Amniotic Membrane | carePATCH™ Amniotic Membrane 2x2cm carePATCH™ Amniotic Membrane 2x3cm carePATCH™ Amniotic Membrane 2x4cm carePATCH™ Amniotic Membrane 4x4cm carePATCH™ Amniotic Membrane 4x6cm | carePATCH™ Amniotic Membrane2x2cm4carePATCH™ Amniotic Membrane2x3cm6carePATCH™ Amniotic Membrane2x4cm8carePATCH™ Amniotic Membrane4x4cm16carePATCH™ Amniotic Membrane4x6cm24 | carePATCH™ Amniotic Membrane2x2cm4Q4236carePATCH™ Amniotic Membrane2x3cm6Q4236carePATCH™ Amniotic Membrane2x4cm8Q4236carePATCH™ Amniotic Membrane4x4cm16Q4236carePATCH™ Amniotic Membrane4x6cm24Q4236 |

^{1.} Malhotra C, Jain AK. Human amniotic membrane transplantation: Different modalities of its use in ophthalmology. World J Transplant. 2014 Jun 24;4(2):111-21. doi: 10.5500/wjt.v4.i2.111. PMID: 25032100; PMCID: PMC4094946.

^{2.} Gupta A, Kedige SD, Jain K. Amnion and Chorion Membranes: Potential Stem Cell Reservoir with Wide Applications in Periodontics. Int J Biomater. 2015;2015:274082. doi: 10.1155/2015/274082. Epub 2015 Dec 6. PMID: 26770199; PMCID: PMC4684856.



FULL THICKNESS PLACENTAL MEMBRANE ALLOGRAFT

Tissue Characteristics

- Multi-Layer graft processed using a proprietary processing technology to ensure all naturally occurring components of birth tissue remain intact through processing.
- Contains the Amnion, Chorion as well as the important Intermediate Layer (IL)/Spongy layer of the placenta.
- Amber color comes from advanced preservation of placental structures and layers.
- Intended for homologous use only. May act as a wound cover, that is a natural bandage shielding wounds from its external environment.
- Dehydrated, packaged, and terminally sterilized with a 2-year shelf life. Stored at ambient temperature.

Configurations



Square sizes: 2x2cm, 4x4cm Rectangular sizes: 2x4cm, 3x6cm, 4x8cm

Tissue Processing - Placental Membrane Barrier



- The placental tissue for completeFT™ is sourced from healthy deliveries of placental tissue with maternal consent.
- Processed using minimally manipulated placental tissue in a full thickness composition to retain the native characteristics of the placental extracellular matrix (ECM).
- The placental tissue's key structural components, specifically the chorionic, amniotic as well as the spongy layers are retained to allow the membrane its utility to serve as a barrier.
- May adhere to the underlying wound surface as a cover protecting wounds and may help prevent formation of dead space on wounds.^{1,2}
- May prevent infiltration and adhesion of microorganisms to wounds.^{1,2}

| SKU | Product Description | Size | Units | HCPCS | UPC |
|-------|---|-------|-------|-------|--------------|
| EFT22 | Complete FT™ Placental Allograft Membrane | | 4 | Q4271 | 382567000311 |
| EFT24 | Complete FT™ Placental Allograft Membrane | 2x4cm | 8 | Q4271 | 382567000328 |
| EFT44 | T44 Complete FT™ Placental Allograft Membrane | | 16 | Q4271 | 382567000335 |
| EFT36 | Complete FT™ Placental Allograft Membrane | 3x6cm | 18 | Q4271 | 382567000342 |
| EFT48 | Complete FT™ Placental Allograft Membrane | 4x8cm | 32 | Q4271 | 382567000359 |

^{1.} Malhotra C, Jain AK. Human amniotic membrane transplantation: Different modalities of its use in ophthalmology. World J Transplant. 2014 Jun 24;4(2):111-21. doi: 10.5500/wjt.v4.i2.111. PMID: 25032100; PMCID: PMC4094946.

^{2.} Gupta A, Kedige SD, Jain K. Amnion and Chorion Membranes: Potential Stem Cell Reservoir with Wide Applications in Periodontics. Int J Biomater. 2015;2015:274082. doi: 10.1155/2015/274082. Epub 2015 Dec 6. PMID: 26770199; PMCID: PMC4684856.

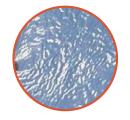
LYOPHOLIZED PLACENTAL MEMBRANE ALLOGRAFT

XCELLERATE™

- An acellular amniotic allograft barrier/membrane that supports an environment for wound healing.
- Aseptically processed to preserve extracellular matrix, growth factors and cytokines native to amniotic tissue.
- Indicated for use as a protective barrier in wound care applications

XCELLERATE™ has two distinct sides: an epithelial side and a stromal side. The epithelial side is smooth while the stromal side is dull.

In addition, the graft has a 2-3 mm vertical orientation guide slit that when in the upper right corner, the epithelial side is facing upward.





EPITHELIAL

STROMAL

Possible Applications for Amniotic Membranes (Please see Instruction for Use for more details)





NON-HEALING WOUNDS

WOUND COVER

- Certain placental allografts attempt to utilize acellular, minimally manipulated tissues intended for homologous use to supplement patients' own tissues.
- Placental membranes may create an environment that includes growth factors to support wound protection.

Amniotic Membrane/Barrier





Human-derived barrier

Preservation of endogenous growth factors¹

- Shelf-stable, amniotic allograft
- 4-year shelf-life, stored at room temperature
- Usable as a protective barrier in wound care applications
- Intended for homologous use only to supplement patients' own tissue

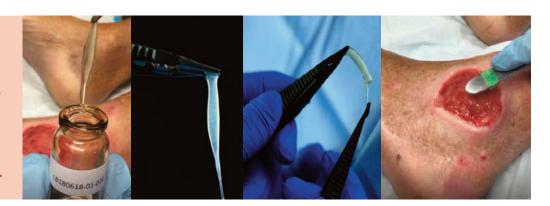
| SKU | Product Description | Size | Units | HCPCS | UPC |
|------------|---|-------|-------|-------|--------------|
| XCELL-0202 | XCELLERATE™ Lyophilized Amniotic Membrane | 2x2cm | 4 | Q4234 | 860004706533 |
| XCELL-0204 | XCELLERATE™ Lyophilized Amniotic Membrane | 2x4cm | 8 | Q4234 | 860004706540 |
| XCELL-0404 | 4O4 XCELLERATE™ Lyophilized Amniotic Membrane | | 16 | Q4234 | 860004706557 |
| XCELL-0407 | XCELLERATE™ Lyophilized Amniotic Membrane | 4x7cm | 28 | Q4234 | 860004706564 |

^{1.} Barrientos, S., et al. Growth factors and cytokines in wound healing. Wound Repair and Regeneration. 16: 585-601, 2008.

Procenta[®]

PLACENTAL-DERIVED ALLOGRAFT

Procenta® is an acellular placental-derived graft made from soft connective tissue that is hydrophilic, sterile and requires no re-hydration or orientation.



Procenta's Features

- Provides a conformable, adherent scaffold that may be used in wound care applications
- Protects application area from surrounding environment
- Retains fluid in application area



Tissue Characteristics

- Procenta® is an acellular, highly hydrophilic, structural extracellular matrix derived from placental connective tissue.
- Structural, human tissue allograft (FDA/TRG recommendation letter received).
- Comprised of extracellular matrix scaffold that serves as a cover, to offer protection from the surrounding environment, and to retain fluid.
- Allograft produced from donated human placental tissue.
 Intended for homologous use to supplement or replace damaged or inadequate connective tissue.
- Stored at ambient temperature, ready for application in a sterile vial.
- Terminally sterilized with a 4 year shelf life.

Product Packaging & Content



Outer Box that contains sterile packaged Procenta* vial.



Vial is packaged in a single pouch.



Allograft Tracking Card that must be completed and returned to Extremity Care.



Allograft Return Card must be completed and sent back to Extremity Care in case product is returned.

Procenta[®]

Product Application



Open product package & remove the Tyvek peel pouch containing the vial.



Using aseptic technique, peel open the Tyvek peel pouch and present sterile vial onto sterile field.



Open the vial and apply product as needed.







Ambient Storage

Directly Applied

4-Year Shelf Life

Ordering Information

| SKU | Product Description | Size | HCPCS | UPC |
|-------|---------------------------------------|-------|-------|--------------|
| PC100 | Procenta™ Placental-Derived Allograft | 100mg | Q4310 | 382567001752 |
| PC200 | Procenta™ Placental-Derived Allograft | 200mg | Q4310 | 382567001769 |
| PC300 | Procenta™ Placental-Derived Allograft | 300mg | Q4310 | 382567001776 |
| PC400 | Procenta™ Placental-Derived Allograft | 400mg | Q4310 | 382567001783 |

Tissue Processing

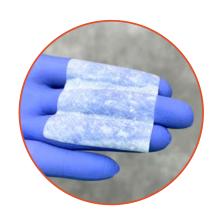
- The manufacturing of Procenta® Tissue-based Allograft does not involve the combination of the placental tissue with another article, except for preservation media.
- After minimally manipulated processing, Procenta® is terminally sterilized using E-beam irradiation to ensure recipient safety.
- The Procenta® Allograft manufacturer is Lucina BioSciences, LLC. A proprietary, minimally manipulative manufacturing process (Nativus) ensures the original relevant characteristics of the tissue are retained.
- The tissue bank is registered with the Food and Drug Administration (FDA).

RESOLVE MATRIX™

EXTRACELLULAR MATRIX FOR THE MANAGEMENT OF WOUNDS

Harnessing the Body's Power to Heal

Resolve Matrix[™] is a thin, flexible, yet strong acellular wound dressing designed to support the body's repair process during wound healing. It is uniquely derived from porcine peritoneum membrane and processed using the Optrix[™] tissue cleansing methodology, which is optimized to remove antigens while preserving desirable tissue scaffold properties and components. Both its source material and unique cleansing process, provide a combination of highly desirable attributes that are appreciated during its clinical application and supporting role in the healing of wounds.

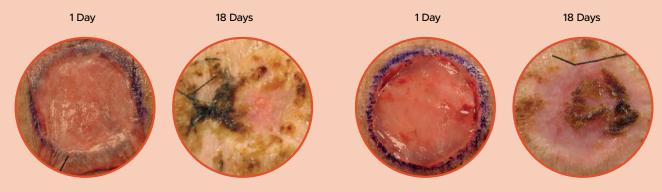


| FEATURES | BENEFITS |
|--|---|
| Derived from porcine peritoneum membrane Targeted for its thickness and desirable properties in the management of wounds Thinner than many dermal derived scaffolds, yet thicker than single layer amniotic or small intestine submucosa (SIS) | A thin, flexible, yet strong biologic collagen matrix that's suturable, with good handling properties that aid its application¹ Highly conformable to the wound bed, allowing for good contact during the healing process² |
| Optrix™ Tissue Process, designed to: Remove antigens (DNA, epitopes) Maintain native structures including the natural tissue porosity Maintain high levels of extracellular components | Preserves natural components such as growth factors, proteins, proteoglycans and glycosaminoglycans³ Provides an environment for cellular infiltration and migration² Scaffold is not crosslinked |
| Terminally sterilized • 10 ⁻⁶ Sterility Assurance Level (SAL) | Terminal sterility means that there is a 1 in 1,000,000 probability that any bacteria or viable microorganisms survived the sterilization process. |
| Non-human derived biologic tissue matrix | Convenience: Unlike Allografts, Xenografts are regulated as a medical device and not a tissue, and thus do not require special handling or refrigerated storage. |
| Ready-to-use | Convenience: room temperature storage with a three-year shelf life from time of sterilization May be applied dry, or hydrated in sterile saline or autologous body fluids ⁴ |

EXTRACELLULAR MATRIX FOR THE MANAGEMENT OF WOUNDS

Efficacy in Wound Management

Results from 22-day porcine wound pilot study



Resolve Matrix™ Scaffold

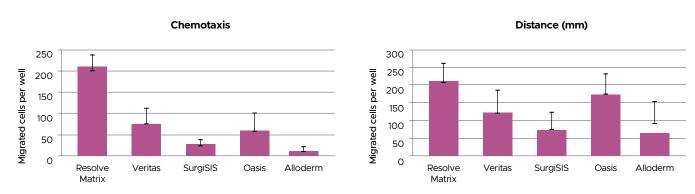
Antibiotic Ointment

When compared to empty defect, full thickness defects treated with Resolve Matrix[™] showed improvement over untreated control.²

- Reduced fibrosis (Days 4 & 8)
- Increased angiogenesis (Day 4)

Note: Data may not be indicative of clinical results. Study was not conducted within GLP requirements.

Resolve Matrix™ is cell friendly 5



In-Vitro studies with fibroblasts and conditioned media show Resolve Matrix™ allows for cellular migration. ⁵

Resolve Matrix™ is a trademark of Parametrics Medical.

OPTRIX™ is a trademark of DSM Biomedical, Inc. or its affiliates.

- 1. ETF-03525 Data on File at DSM Biomedical, Inc. The effect of these components on the performance of Resolve MatrixTM has not been clinically evaluated.
- 2. Data on file at DSM Biomedical, Inc. Pilot study in pigs. Full thickness wound with n=16 test and 8 empty defect sites tested for up to 22 days. Study was not conducted within GLP requirements.
- 3. Hoganson, David M., Gwen E. Owens, Elisabeth M. O'Doherty, Chris M. Bowley, Scott M. Goldman, Dina O. Harilal, Craig M. Neville, Russell T. Kronengold, and Joseph P. Vacanti. «Preserved Extracellular Matrix Components and Retained Biological Activity in Decellularized Porcine Mesothelium.» Biomaterials 31.27 (2010): 6934-940. The effect of these components on the performance of Resolve MatrixTM has not been clinically evaluated
- 4. ETF-03307 on file at DSM Biomedical, Inc. The effect of these components on Resolve MatrixTM has not been clinically evaluated.
- 5. Luo, Xiao ; Kulig, Katherine M. ; Finkelstein, Eric B. et al. / In vitro evaluation of decellularized ECM-derived surgical scaffold biomaterials. In: Journal of Biomedical Materials Research Part B Applied Biomaterials. 2017 ; Vol. 105, No. 3. pp. 585-593.

EXTRACELLULAR MATRIX FOR RESOLVE MATRIX TOR THE MANAGEMENT OF WOUNDS

| Product Description | Size | Units | HCPCS | UPC |
|--|--|---|--|--|
| Resolve Matrix™ Biologic Membrane | 2x2cm | 4 | A2024 | 382567000953 |
| Resolve Matrix™ Biologic Membrane | 2x3cm | 6 | A2024 | 382567000960 |
| Resolve Matrix™ Biologic Membrane | 2x4cm | 8 | A2024 | 382567000977 |
| Resolve Matrix™ Biologic Membrane | 3.5x3.5cm | 12.25 | A2024 | 382567000984 |
| AD45 Resolve Matrix™ Biologic Membrane | | 20 | A2024 | 382567000991 |
| Resolve Matrix™ Biologic Membrane | 5x5cm | 25 | A2024 | 382567001004 |
| Resolve Matrix™ Biologic Membrane | 6x8cm | 48 | A2024 | 382567001011 |
| | Resolve Matrix™ Biologic Membrane Resolve Matrix™ Biologic Membrane | Resolve Matrix™ Biologic Membrane 2x2cm Resolve Matrix™ Biologic Membrane 2x3cm Resolve Matrix™ Biologic Membrane 2x4cm Resolve Matrix™ Biologic Membrane 3.5x3.5cm Resolve Matrix™ Biologic Membrane 4x5cm Resolve Matrix™ Biologic Membrane 5x5cm | Resolve Matrix™ Biologic Membrane2x2cm4Resolve Matrix™ Biologic Membrane2x3cm6Resolve Matrix™ Biologic Membrane2x4cm8Resolve Matrix™ Biologic Membrane3.5x3.5cm12.25Resolve Matrix™ Biologic Membrane4x5cm20Resolve Matrix™ Biologic Membrane5x5cm25 | Resolve Matrix™ Biologic Membrane2x2cm4A2024Resolve Matrix™ Biologic Membrane2x3cm6A2024Resolve Matrix™ Biologic Membrane2x4cm8A2024Resolve Matrix™ Biologic Membrane3.5x3.5cm12.25A2024Resolve Matrix™ Biologic Membrane4x5cm20A2024Resolve Matrix™ Biologic Membrane5x5cm25A2024 |





What is Coll-e-Derm?

Coll-e-Derm is a prehydrated human acellular dermal matrix that retains angiogenin and collagen type IV. Angiogenin and collagen type IV may play a key role in supporting revascularization.¹



What Advantages Does Coll-e-Derm Offer?

Using a proprietary, patented and gentle process, a sterility assurance level (SAL) of 10⁻⁶ is achieved, while retaining angiogenin and collagen type IV of native dermis.¹

By preserving a more intact matrix, Coll-e-Derm maintains similar biomechanics to native dermis.¹

| Features ^{1,2} | Advantages ^{1, 2} |
|--|---|
| Proprietary and patented gentle processing | Retains angiogenin and collagen type IV |
| Intact Matrix | Revascularization |
| Pre-hydrated | Ready-to-use |
| Sterility Assurance Level (SAL) 10 ⁻⁶ | Favorable safety profile |

^{1.} Testing performed by independent laboratory. Data on file, Berkeley Biologics, LLC. Animal and bench testing results may not necessarily be indicative of clinical performance.

^{2.} Coll-e-Derm Hydrated Instructions for Use. Coll-e-Derm Hydrated is to be used for the repair or replacement of damaged or insufficient integumental tissue or for other homologous uses of human integument.

HYDRATED ACELLULAR DERMAL MATRIX

Coll-e-Derm is proven to retain angiogenin and collagen type IV1

Coll-e-Derm maintains structural integrity, mechanical strength, and collagen stability similar to native dermis.¹

Figure 1. The brown staining identifies collagen type IV, which is present in the basement membrane at the epidermisdermis junction and around blood vessels. Collagen type IV is known to be involved in pathways that support blood vessel formation such as angiogenesis. Angiogenesis is the physiological process through which new blood vessels form from pre-existing vessels.





Collagen IV staining

Mechanical Strength¹

Collagen Stability¹

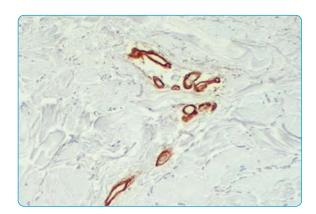
| | Suture retention strength (N/mm) | Onset T ^m (°C) | % Soluble Col (w/w) | % Digested Col (w/w) |
|-------------|-------------------------------------|------------------------------|------------------------|-------------------------|
| Native | 61.0 ± 4.1 | 64.2 ± 0.2 | 47.6 ± 1.3 | 21.9 |
| Coll-e-Derm | 61.1 ± 12.2 | 61.3 ± 0.9 | 62.6 ± 1.2 | 26.7 |

Figure 2.

- Onset Tm: Temperature where a substance starts to melt
- % Soluble Collagen (w/w): Percentage of collagen fiber that can be dissolved in acid
- % Digested Collagen (w/w): Percentage of collagen fiber that is unraveled (in this case by collagenase type I)

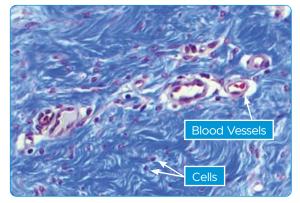
Tissue Integration

Coll-e-Derm demonstrated robust tissue regeneration at 12 weeks¹



Type IV Collagen

Figure 4. The brown staining identifies collagen type IV. Coll-e-Derm preserves the basement complex (BMC) of blood vessels preimplantation that allows angiogenesis. Angiogenesis is the physiological process through which new blood vessels form from pre-existing vessels.



Masson's Trichrome

Figure 4. Masson's Trichrome staining shows robust tissue regeneration is evident for Coll-e-Derm at 12 weeks with new collagen formation, revascularization, and host cell repopulation.¹

^{1.} Testing performed by independent laboratory. Data on file, Berkeley Biologics, LLC. Animal and bench testing results may not necessarily be indicative of clinical performance.



Robust Remodeling

Coll-e-Derm prehydrated Acellular Dermal Matrix (ADM) maintains structural attributes of native dermis that may facilitate remodeling.¹

Similar to native dermis, Coll-e-Derm retains intact collagen, elastin, and vascular structure that may provide a robust platform for allograft integration.¹

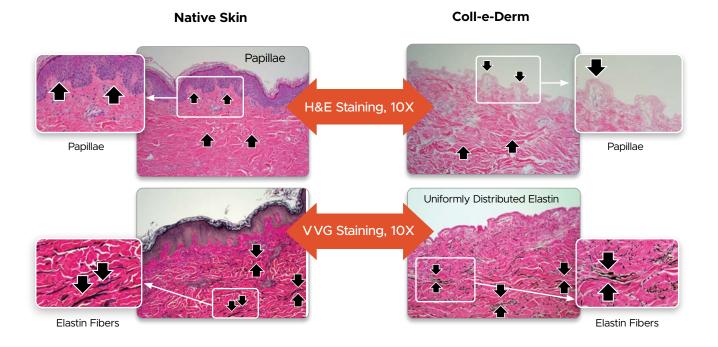


Figure 3. ADM is structurally similar to native dermis.

- Hematoxylin and eosin (H&E) staining shows cellular and tissue structure detail.
- Verhoeff-Van Gieson (VVG) staining differentiates collagen and other connective tissues, and highlights elastin fibers.

^{1.} Testing performed by independent laboratory. Data on file, Berkeley Biologics, LLC. Animal and bench testing results may not necessarily be indicative of clinical performance.



- - Intact extracellular matrix¹
- Retains angiogenin and collagen type IV1
- Collagen stability¹

- Revascularization¹
- Biomechanical properties similar to native dermis¹

Coll-e-Derm is treated with a proprietary, patented and gentle decellularization process which retains structural integrity, mechanical strength, and collagen stability similar to native dermis. Coll-e-Derm retains angiogenin and collagen type IV that may play a role in supporting revascularization.

^{1.} Testing performed by independent laboratory. Data on file, Berkeley Biologics, LLC. Animal and bench testing results may not necessarily be indicative of clinical performance.

^{2.} Coll-e-Derm Hydrated Instructions for Use. Coll-e-Derm Hydrated is to be used for the repair or replacement of damaged or insufficient integumental tissue or for other homologous uses of human integument.





| SKU | Product Description | Size | Units | HCPCS | UPC |
|---------|---|---------|-------|-------|--------------|
| ADT22-M | Coll-e-Derm™ Acellular Dermal Matrix, Meshed | 2x2cm | 4 | Q4193 | 382567001332 |
| ADT23-M | Coll-e-Derm™ Acellular Dermal Matrix, Meshed | 2x3cm | 6 | Q4193 | 382567001233 |
| ADT24-M | Coll-e-Derm™ Acellular Dermal Matrix, Meshed | 2x4cm | 8 | Q4193 | 382567001349 |
| ADT44-M | Coll-e-Derm™ Acellular Dermal Matrix, Meshed | 4x4cm | 16 | Q4193 | 382567001356 |
| ADT46-M | Coll-e-Derm™ Acellular Dermal Matrix, Meshed | 4x6cm | 24 | Q4193 | 382567001363 |
| ADT48-M | Coll-e-Derm™ Acellular Dermal Matrix, Meshed | 4x8cm | 32 | Q4193 | 382567001370 |
| AD146-W | Coll-e-Deliti Aceliaiai Delitiai Matrix, Meshed | 4700111 | 32 | Q+133 | 302307001370 |



Indication Driven Care

carePAC™ are pre-configured pouches that contain indication-relevant wound care components for surgically created wounds. The sealed pouches allow healthcare providers to prescribe their patients the necessary combination of primary and secondary dressings for daily dressing changes. carePAC™ has 3 primary categories allowing for streamlined care and product selection to improve wound care management. carePAC™ is delivered directly to the patient's permanent address in quantities that are predetermined by the patient's healthcare provider.

The carePAC™ is a pre-configured, physician-prescribed, sealed pouch that contains indication-relevant, sterile wound management products.



carePAC™ Options:

- Collagen Powder
- Collagen Matrix 2"x2"
- Collagen Matrix 7"x7"
- Collagen Powder with Antimicrobial Dressing



The carePAC™

- Prescribed by physicians for wounds where continuous wound coverage is medically necessary*.
- Contains everything the patient or caregiver needs to perform proper dressing changes at home.
- Different carePAC configurations contain a variety of primary, secondary and supportive dressing options based on individual wound needs.

Indications for Use**

- Diabetic, Pressure and Stasis Ulcers
- Post-Surgical Wounds
- Donor Sites, Burns
- Lacerations and Abrasions
- Available in a 15 or 30-day supply.
- Please see Extremity Care™ Guidance Document for DME billing recommendations of the carePAC™.
- ** Not all dressings are indicated for all indications shown. Please review IFU carefully for more details.

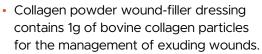




Collagen Powder with Antimicrobial Dressing

ECA-030 (30 day supply)

Primary Dressing: careLAGEN™ Powder





- The dressing is intended for single use only and works by providing collagen to the wound bed to attract cellular components necessary to stimulate the healing process.
- The collagen particles are applied topically and designed to come in contact with wound drainage to help maintain a moist wound bed and to aid in the formation of granulation tissue and epithelialization.

Secondary Dressing: Antimicrobial Gauze Sponge

- Antimicrobial gauze sponges are impregnated with pHMD (polyhexamethylene biguanide), a powerful, yet safe antiseptic that has a broad range of effectiveness against gram positive and gram negative microorganisms including some multidrug resistant strains such as MRSA.
- Resists bacterial colonization within the dressing and reduces bacterial penetration through the dressing.

Conforming Stretch Gauze Bandages

 Sterile stretch gauze bandages are included in order to secure primary and secondary dressing. These wraps offer a gentle compression and form a protective layer over the Dressings.



ORDER CODE:

ECA-030

Collagens

- Create suitable environment for wound healing.
- Dual MMP inhibition to help initiate healing in stalled/chronic wounds and encourage granulation.
- Non-adherent characteristics minimize irritation and trauma when performing dressing changes.

Secondary dressings necessary.

Indications for Use

- Abrasions
- Dehisced surgical wounds
- · Donor and graft sites
- First and second-degree burns
- · Pressure, diabetic, venous ulcers
- Ulcers caused by mixed vascular etiologies

Reimbursement

| DRESSING | HCPCS CODE |
|-----------|------------|
| Primary | A6010 |
| Secondary | A6222 |
| Bandages | A6446 |
| PPE | A4927 |

Personal Protective Equipment





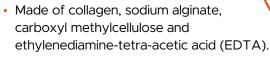


Collagen Dressing 2"x2"

careLAGEN M

ECD-030 (30 day supply)

Primary Dressing: careLAGEN™ Matrix 2"x2"



- Transforms into a soft gel sheet when in contact with wound exudates.
- Maintains a moist wound environment and creates ideal conditions for healing. May be trimmed and layered for management of deep wounds.

Secondary Dressing: careGARD™ 4"x4"

- Absorptive dressing consisting of three layers: low adherent layer protects the wound surface, absorbent gauze layer absorbs exudate, and a non-woven adhesive tape that holds the dressing in place.
- Maintains a moist wound environment. Soft and flexible.
 Easily conforms to wound sites that are difficult to dress.
 Gentle on skin.
- Ideal for daily use as a secondary or supportive dressing.

Conforming Stretch Gauze Bandages

 Sterile stretch gauze bandages are included in order to secure primary and secondary dressing. These wraps offer a gentle compression and form a protective layer over the Dressings.



ORDER CODE:

ECD-030

Collagens

- Create suitable environment for wound healing.
- Dual MMP inhibition to help initiate healing in stalled/chronic wounds and encourage granulation.
- Non-adherent characteristics aid in performing dressing changes.

Secondary dressings necessary.

Indications for Use

- Abrasions
- · Dehisced surgical wounds
- Donor and graft sites
- First and second-degree burns
- Pressure, diabetic, venous ulcers
- Ulcers caused by mixed vascular etiologies

Reimbursement

| DRESSING | HCPCS CODE |
|-----------|------------|
| Primary | A6021 |
| Secondary | A6219 |
| Bandages | A6446 |
| PPE | A4927 |

Personal Protective Equipment





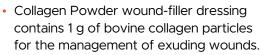


Collagen Powder

ECP-030 (30 day supply)

careLAGEN E

Primary Dressing: careLAGEN™ Powder





- The dressing is intended for single use only and works by providing collagen to the wound bed to attract cellular components necessary to stimulate the healing process.
- · The collagen particles are applied topically and designed to come in contact with wound drainage to help maintain a moist wound bed and to aid in the formation of granulation tissue and epithelialization.

Secondary Dressing: careGARD™ 4"x4"

- · Absorptive dressing consisting of three layers: low adherent layer protects the wound surface, absorbent gauze layer absorbs exudate, and a non-woven adhesive tape that holds the dressing in place.
- Maintains a moist wound environment. Soft and flexible. Easily conforms to wound sites that are difficult to dress. Gentle on skin.
- Ideal for daily use as a secondary or supportive dressing.

Conforming Stretch Gauze Bandages

• Sterile stretch gauze bandages are included in order to secure primary and secondary dressing. These wraps offer a gentle compression and form a protective layer over the Dressings.



ORDER CODE:

ECP-030

Collagens

- Create suitable environment for wound healing.
- Dual MMP inhibition to help initiate healing in stalled/chronic wounds and encourage granulation.
- Non-adherent characteristics aid in performing dressing changes.

Secondary dressings necessary.

Indications for Use

- Abrasions
- · Dehisced surgical wounds
- · Donor and graft sites
- First and second-degree burns
- · Pressure, diabetic, venous ulcers
- · Ulcers caused by mixed vascular etiologies

Reimbursement

| DRESSING | HCPCS CODE |
|-----------|------------|
| Primary | A6010 |
| Secondary | A6219 |
| Bandages | A6446 |
| PPE | A4927 |

Personal Protective Equipment







Collagen Dressing 7"x7"

ECX-015 (15 day supply)

Primary Dressing: careLAGEN™ Matrix 7"x7"

- Made of collagen, sodium alginate, carboxyl methylcellulose and ethylenediamine-tetraacetic acid (EDTA).
- Transforms into a soft gel sheet when in contact with wound exudates.
- Maintains a moist wound environment and creates ideal conditions for healing. May be trimmed and layered for management of deep wounds.

Secondary Dressing: careGARD™ 6"x8"

 Absorptive dressing consisting of three layers: low adherent layer protects the wound surface, absorbent gauze layer absorbs exudate, and a non-woven adhesive tape that holds the dressing in place.



careLAGEN

- Maintains a moist wound environment. Soft and flexible.
 Easily conforms to wound sites that are difficult to dress.
 Gentle on skin.
- Ideal for daily use as a secondary or supportive dressing.

Bulky Gauze Bandages

 Sterile secondary dressing for cushioning, bulk and extra conformability to provide improved wound bed protection. These wraps offer a gentle compression and form a protective layer over the Dressings.



ORDER CODE:

ECX-015

Collagens

- Create suitable environment for wound healing.
- Dual MMP inhibition to help initiate healing in stalled/chronic wounds and encourage granulation.
- Non-adherent characteristics aid in performing dressing changes.

Secondary dressings necessary.

Indications for Use

- Abrasions
- · Dehisced surgical wounds
- · Donor and graft sites
- First and second-degree burns
- Pressure, diabetic, venous ulcers
- Ulcers cause by mixed vascular etiologies

Reimbursement

| DRESSING | HCPCS CODE |
|-----------|------------|
| Primary | A6023 |
| Secondary | A6220 |
| Bandages | A6441 |
| PPE | A4927 |

Personal Protective Equipment





The careBox

The careBOX provides up to 30 carePAC™ pouches and is sent directly to the patient within 36 hours post patient visit.

- Contains up to 30-day carePAC™ supply.
- Shipped to patient's residence directly by Extremity Care™ on behalf of physician.
- Requires patient signature for proof of delivery.



How to prescribe the carePAC™

STEP 1



 Healthcare provider determines that dressing is medically necessary.

STEP 2



- The careBOX is shipped to patient.
- DME Dispensable Wound Care Supply.

careBOX Order Codes

| SKU | Product Description | QTY |
|---------|---|-----|
| ECA-030 | Collagen Powder with Antimicrobial Dressing | 30 |
| ECD-030 | Collagen Dressing 2"x2" | 30 |
| ECP-030 | Collagen Powder | 30 |
| ECX-015 | Collagen Dressing 7"x7" | 15 |



Parametrics Medical // In partnership with Extremity Care.