OMEZA Complete Matrix (OCM™)

OCMTM is an FDA 510(k)-cleared advanced wound care therapy in the “Cellular, Acellular and Matrix-like Products” (CAMPs) category. It enables in situ formation of a scaffolding matrix that integrates into the wound bed to support cellular infiltration and tissue regeneration.

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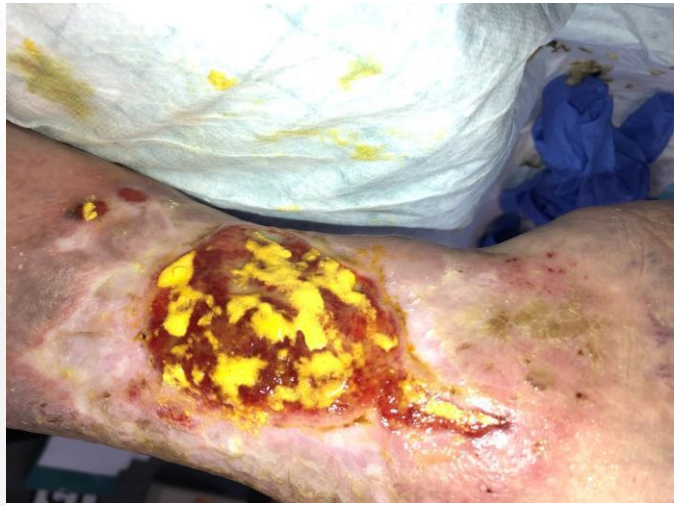
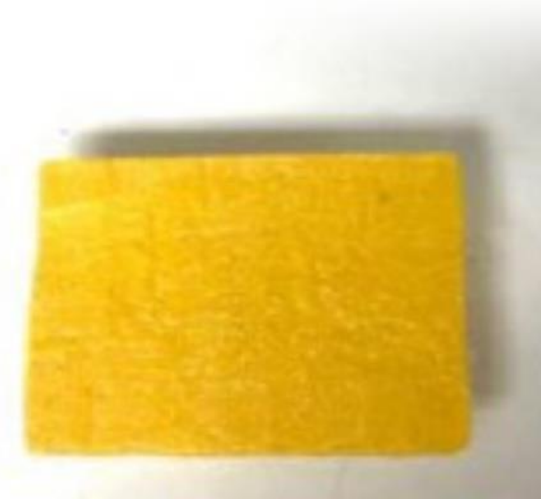
Intended Use

OCM™ is indicated for partial and full-thickness wounds, including:

- **Chronic ulcers**
  - Pressure ulcers
  - Venous ulcers
  - Diabetic ulcers
  - Chronic vascular ulcers
- **Surgical wounds**
  - Donor sites/grafts
  - Post-Moh's surgery
  - Post-laser surgery
  - Podiatric
  - Wound dehiscence
- **Trauma wounds**
  - Abrasions
  - Lacerations
  - Superficial partial thickness burns
  - Skin tears
- **Other**
  - Tunneled/undermined wounds
  - Draining wounds.





Product	Product Number	Total Size	Coverage	Weight	HCPCS Code
OCM™	CM-720.001	18 cm^2	18 cm^2 when applied per IFU	1.6 g	**A2014**

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Amorphous Solid Formulation for Most Effective Wound Bed Coverage, Leading to Better Patient Outcomes

OCM™ is comprised of hydrolyzed fish peptides infused with cod liver oil, which acts as an anhydrous skin protectant. The formulation contains all natural components:

- Hydrolyzed fish peptides - Primary structural component
- Cod liver oil - Anhydrous skin protectant
- Omega fatty acids (3, 6, and 9) - Fish- and plant-derived mono- and polyunsaturated fatty acids
- Tissue-generating signaling molecules
- Essential nutrients - Vitamins A, C, D, and E and minerals

- **Physical Form**
  - Supplied as an amorphous solid
  - Applied in stripes to uniform thickness of ~1.95mm (approximately thickness of a nickel)
  - Conforms to wound bed, providing **18 cm^2 coverage** per single-use vial

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Amorphous Solid Formulation for Most Effective Wound Bed Coverage, Leading to Better Patient Outcomes

Mechanism of Action (MOA)

- When applied to a wound surface, OCM undergoes a significant change in the three-dimensional alignment of molecules. As conformational equilibrium is reached, the molecular structure forms a three-dimensional scaffold that is more crystalline in nature.
- This physical, three-dimensional microstructural framework provides scaffolding that:
  - Promotes host cells to migrate, adhere and proliferate
  - Facilitates tissue regeneration during wound healing
  - Supports cellular invasion- patient's cells begin to proliferate and may remodel the matrix
  - Enables capillary growth in the wound bed to support natural healing (fibroblast migration and epithelialization
- OCM™ peer reviewed publications have also shown significant antimicrobial activity against MRSA and Pseudomonas.

Amorphous Solid Formulation for Most Effective Wound Bed Coverage, Leading to Better Patient Outcomes

- **Addressing Irregularly Shaped Wound Beds:**
  - The amorphous solid formulation of OCM™ provides a critical advantage for irregularly shaped wounds:
    - Superior conformability - Unlike pre-formed sheets, OCM™ conforms intimately to complex wound geometries
    - Complete coverage - Ensures contact with all wound surface areas, including tunneled and undermined regions
    - No gaps or dead space - Reduces risk of incomplete healing or infection in uncovered areas
    - Patient-specific application - Can be customized to each unique wound configuration
- **This complete wound bed coverage is essential for optimal patient outcomes, as incomplete coverage can lead to:**
  - Persistent non-healing areas
  - Increased infection risk
  - Extended healing time
  - Greater risk of recurrence

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Clinical Evidence

As of 2025, **seven peer-reviewed studies** encompassing real-world evidence (RWE), interventional trials, and case series have confirmed the safety and effectiveness of OCM™ in managing hard-to-heal wounds. Studies demonstrate OCM™ provides meaningful benefits for chronic ulcers that have not responded to established methods of healing, including advanced wound therapies.

Study	Design	Sample Size	Population Characteristics	Key Results
Dhillon et al., 2025	Multi-site RWE, prospective trial	53 wounds (18 DFUs, 19 VLUs, 2 PrUs, others)	Avg age 64.3 yrs; all >65 had 2+ comorbidities; wound age 10-304 weeks (avg 38 wks); failed multiple prior therapies including skin substitutes	**34% complete closure** by 12 weeks; **66% mean area reduction**; 42% objective response rate
Simman et al., 2024	Prospective open-label clinical study	19 patients with DFUs	Median age 60 yrs (44-85); median ulcer duration 36 weeks; 5 patients with ≥1-year duration DFUs	**57% achieved 100% wound closure**; **94% mean area reduction**at 12 weeks; 62% PAR at 4 weeks
Swain et al., 2024	RWE case series	63 patients (21 DFUs, 18 VLUs, 10 PrUs, 14 others)	Median age 63 yrs for DFUs; included smokers, opioid users, BMI >40; multiple comorbidities	**78% achieved 100% epithelialization**; 57% PAR at 4 weeks; **86% PAR at 12 weeks**
Bettle et al., 2023	Multi-site RWE	60 chronic wounds	Various chronic/refractory wounds; previous treatment failures	**77% complete closure** in mean 6.5 weeks; 69% area reduction at 4 weeks
Cole et al., 2024	Clinical pilot case series	3 patients (2 VLUs, 1 DFU)	Failed ≥50% reduction after ≥4 weeks SOC	2 VLUs: complete closure (3-4 weeks); **Mean PAR: 82%**; bacterial clearance by week 2
Reinkraut et al., 2024	Case studies	2 patients	>7 months duration; failed advanced skin substitutes + SOC	Both achieved **100% re-epithelialization** (7-11 weeks with OCM)
Gil et al., 2024	In vitro and in vivo lab and animal studies	Bacterial challenge models	Tested for antimicrobial and healing properties against common pathogens	Demonstrated in vitro and in vivo antimicrobial efficacy of OCM, suggesting possible clinical benefit in reducing wound pathogen burden

DETAILED STUDY - DHILLON ET AL., 2025

Title: An Open-Label, Interventional, Prospective, Real-World Evidence Study to Evaluate a Multimodal Wound Matrix in Patients with Refractory Wounds

Study Design:
- Multi-site, real-world, prospective trial
- 111 patients entered screening phase
- 64 treated after exclusion (wounds responding to additional 2 weeks high-quality treatment, or too small)
- **53 wounds eligible for final dataset**

Patient Population Characteristics:
Wound Types:
- 18 Diabetic Foot Ulcers (DFUs)
- 19 Venous Leg Ulcers (VLUs)
- 2 Pressure Injuries
- 1 Surgical Wound
- 13 Unclassified Ulcers

Demographics & Comorbidities:
- Average age: 64.3 years
- All subjects >65 years old: had **2+ comorbidities**
- Represents typical Medicare-eligible population

Wound Characteristics:
- **Size range:** 2.1 cm^2 to 72.0 cm^2 (average 11.7 cm^2, median 5.4 cm^2)
- **Wound age:** 10 to 304 weeks (average 38 weeks, median 22 weeks)
- **6 wounds >1 year old**
- **3 wounds >3 years old**
- Most had **failed multiple prior therapies including skin substitutes**

Results:
Primary Outcomes:
- **34% (18/53) achieved complete closure (100% re-epithelialization) by week 12**
- **66% mean area reduction at 12 weeks**
- **34% PAR at 4 weeks**

Response Metrics:
- **42% objective response rate** (22/53 wounds with >40% reduction after 4 weeks)
- **4 wounds closed 100% after just 4 weeks**
- **55% (29/53) decreased by >40% by week 12**

Non-Responders:
- 32% (16/53) did not respond to treatment (8 were unclassified ulcers)

Clinical Significance:
This study demonstrates OCM™'s effectiveness in the **most difficult-to-heal wounds** - those with extended duration, multiple comorbidities, and previous failure of advanced therapies. The results in this highly refractory population support OCM as a valuable option for patients who have exhausted standard care approaches.

DETAILED STUDY - SIMMAN ET AL., 2024

Title: A Novel Approach for the Treatment of Diabetic Foot Ulcers Using a Multimodal Wound Matrix: a Clinical Study

Study Design:
- Prospective, open-label clinical study
- Focused on diabetic foot ulcers (DFUs)
- **19 patients enrolled**
- **14 patients completed the study**

Patient Population Characteristics:
Demographics:
- Median age: 60 years (range 44-85 years)
- All patients had diabetes with chronic DFUs

Wound Characteristics:
- **Median ulcer duration: 36 weeks** (approximately 9 months)
- Wounds had been **stalled despite previous standard or advanced wound care**
- **5 patients had DFUs of ≥1-year duration** (among the most challenging cases)

Prior Treatment Failures:
- Ulcers persisting for months despite:
  - Standard wound care
  - Advanced wound therapies
  - Appropriate diabetic management
  - Vascular assessment
  - Off-loading interventions

Results:
Primary Outcomes:
- **57% (8/14 completers) achieved 100% wound closure**
  - 3 patients: 100% closure by **4 weeks**
  - 5 additional patients: 100% closure by **12 weeks**

Percent Area Reduction (PAR):
- **4-week PAR: 62%** (average)
- **12-week PAR: 94%** (average)

Long-Standing DFUs (≥1-year duration):
Among the 5 patients with the most challenging wounds:
- **3 patients achieved 100% wound closure by week 12**
- Remaining 2 patients: **73% and 85% PAR** at 12 weeks

Clinical Significance:
This study is particularly notable for demonstrating effectiveness in **long-standing, refractory DFUs**. The fact that 60% (3/5) of patients with ≥1-year duration DFUs achieved complete closure highlights OCM's potential for even the most challenging cases where amputation risk is elevated.
The rapid response in some patients (100% closure by 4 weeks) demonstrates OCM™'s ability to **re-initiate the healing process** in stalled wounds.

DETAILED STUDY - BETTLE ET AL., 2023

Title: A Novel Comprehensive Therapeutic Approach to the Challenges of Chronic Wounds: A Brief Review and Clinical Experience Report

Study Design:
- Multi-site, real-world clinical experience focused on chronic and refractory wounds
- Enrolled **60 patients** who had wounds that persisted despite standard and/or advanced care

Patient Population:
- Wound types included diabetic foot ulcers (DFUs), venous leg ulcers (VLUs), pressure ulcers, and other chronic wounds
- Patients had a history of **treatment failure with conventional or advanced wound products**, representing a high-barrier, clinically challenging population
- Broad, real-world cohort, including those with significant comorbidities and complex wound presentations

Study Protocol:
- All patients were treated with Omeza Complete Matrix (OCM™) applied to wound bed per instructions for use
- Progress was tracked for wound closure, reduction in wound area, and time to healing

Key Results:
- **77% (46/60) of patients achieved complete wound closure** with OCM
- **Mean time to closure was 6.5 weeks**, indicating relatively rapid healing even in chronic, recalcitrant wounds
- In addition to closure rates, a **69% mean reduction in wound surface area was observed after just 4 weeks of treatment**
- Treatment was well tolerated with no notable safety concerns reported

Clinical Significance:
This study validates OCM's efficacy in a truly "real-world" clinical setting, where wounds are often more chronic and patients are more complex than in controlled trials. High closure and area reduction rates show OCM™'s effectiveness where previous treatments had failed, affirming its potential as a vital adjunct for clinicians managing the most challenging wounds. The rapid mean time to closure represents a meaningful impact for both patient quality of life and clinical resource utilization.

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OCM™ Meets Regulatory Standards

FDA 510(k) Clearance:
- OCM™ is an **FDA 510(k)-cleared** medical device
- Predicate device: Apis Collagen Matrix

Classification:
- **Cellular, Acellular and Matrix-like Products (CAMPs)**
- **In situ formation** of sheet-like scaffold aligns with updated AMA CPT® and MAC definitions

HCPCS Code: A2014
- OCM™ is provided in single-use vials, with each vial delivering 18cm2 of coverage when applied per the IFU

Regulatory Distinctions:
Not a Wound Dressing
OCM™ is **NOT** classified as:
- Gel, powder, foam, or liquid dressing
- Temporary collagen-based dressing
- Non-adherent wound covering

✓ Integrates into wound bed (not intended to be removed)
✓ Supports cellular migration and proliferation
✓ Provides extracellular matrix scaffold
✓ Promotes natural tissue regeneration

Medicare Coverage Status:
- Submitted for coverage under LCD L35041 for DFU and VLU indications
- Meets evidence standards with multiple peer-reviewed studies which enrolled Medicare eligible patients
- Demonstrates clinical utility as adjunctive treatment for chronic ulcers that have failed standard and cellular tissue methods

Product Safety:
- **Contents in vials sterilized using irradiation**
- Sterility assurance level (SAL) maintained

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EASE OF USE AND PRODUCT SPECIFICATIONS

Application Process – *Simple 5-Step Application:*

1. Prepare wound bed using standard methods (debridement if necessary)
2. Remove tip of OCM package
3. Slowly squeeze to apply directly to wound bed in stripes OR onto suitable applicator (e.g., tongue depressor)
4. Distribute product evenly across wound bed to uniform thickness of **~1.95mm (thickness of a nickel)**
5. Cover with appropriate dressing to maintain OCM™ adherence and protect wound area

No Preparation Required:

- No rehydration needed before application
- No thawing required
- Ready to use straight from package

Dosage Guidelines: (Institutional protocol or clinical guidance supercedes dosing guidelines)

- Do not apply more than 2 OCM™ devices in one day
- Do not apply more than 4 OCM™ devices in one week

Storage and Handling

Feature	Specification
Storage Temperature	Room temperature 77°F (25°C)
Storage Requirements	Keep away from sunlight
Shelf Life	See product pouch for expiration date
Sterilization	Irradiation sterilized
Packaging	Sterile single-use inner package

Product Specifications

Specification	Details
Product Code	CM-720.001
Coverage Area	18 cm^2 per device
Weight	1.6 g per single-use vial/pouch
Application Thickness	~1.95mm (approximately thickness of a nickel)
Quantity	1 device per pouch
Form	Amorphous solid

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OCM™

℞ Only

Caution: Federal law (USA) restricts this product to sale by or on the order of a physician (or properly licensed healthcare professional).

INSTRUCTIONS FOR USE

PRODUCT DESCRIPTION

OCM™ is a wound care matrix comprised of hydrolyzed fish peptide infused with cod liver oil, which acts as an anhydrous skin protectan When applied to a wound surface, the matrix is naturally incorporate into the wound over time. OCM™ is designed for intimate contact wit both regular and irregular wound beds, to provide a conduciv environment for the patient's natural wound healing process.

OCM™ is supplied in a sterile single use inner package.

INDICATIONS FOR USE

OCM™ is indicated for the management of wounds including: partial an full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers chronic vascular ulcers, tunneled/undermined wounds, surgical wound (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric wound dehiscence), trauma wounds (abrasions, lacerations, superficia partial thickness burns, skin tears) and draining wounds.

CONTRAINDICATIONS

- This product should not be used in patients with known sensitivity to fish collagen or cod liver oil.
- The product is not indicated for use in third degree burns.

PRECAUTIONS

- Each unit of OCM™ is for single use. Discard all opened and unused portions after each treatment session.
- Contents are sterile if the inner package is unopened and undamaged. Do not use if the inner package is broken. Do not re-sterilize.
- Discard product if mishandling has caused possible damage or contamination.
- Excessive exudate, bleeding, acute swelling, and infection should be controlled before OCM™ is applied. Debridement or excision must be done thoroughly to remove any remaining necrotic tissue that may cause infection.
- The following complications are possible with the use of wound management products: infection, chronic inflammation (initial application of wound dressings may be associated with transient, mild, localized inflammation), allergic reaction, excessive redness, pain, or swelling. If any of these conditions occur, the product should be removed.

DIRECTIONS FOR USE

These recommendations are designed to serve only as a genera guideline. They are not intended to supersede institutional protocol or professional clinical judgment concerning patient care.

Dosage

- Do not apply more than 2 OCM™ devices in one day
- Do not apply more than 4 OCM™ devices in one week

Initial application

1. Always handle OCM™ using aseptic techniques. Only inner package content is sterile.
2. Prior to application of OCM™, prepare the wound bed using standard methods to ensure wound is free of debris and necrotic tissue. If necessary, surgically debride the wound to ensure the wound edges contain viable tissue.
3. Remove the tip of the OCM™ package.
4. Slowly squeeze to apply either directly to the wound bed in stripes, or onto a suitable applicator (e.g. a tongue depressor). Use the applicator to distribute product evenly across the wound bed so that is uniformly applied at an approximate thickness of a nickel (~1.95mm).
5. After application, cover with an appropriate dressing to maintain OCM™ adherence and protect the wound area. The optimum dressing is determined by wound location, size, depth, and volume of exudate

Follow-up application

1. Duration of treatment and reapplication frequency is determined by the physician and will depend on the condition of the patient as well as the level of wound exudate.
2. Reapply when OCM™ has been naturally incorporated into the woun bed or as directed by a wound care professional.
3. Remove the dressing from the wound bed gently.
4. Cleanse the wound area and prepare the wound bed prior to application.
5. Distribute product evenly across the wound bed so that it is uniformly applied at an approximate thickness of a nickel (~1.95mm).
6. Cover with an appropriate dressing to maintain OCM™ adherence and protect the wound area.
7. Change the dressing based on physician assessment of patient's individual needs and as consistent with manufacturer's instructions to maintain a moist, clean wound area.

HOW SUPPLIED

Product Codes	*Size*	*Quantity*	*Weight*
CM-720.001	18 cm^2	1 device/pouch	1.6 g

STORAGE

Store at room temperature (77°F/25°C). Keep away from sunlight. See product pouch for expiration date.

SYMBOLS USED IN LABELING

ISO 15223-1: 2016 Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements		
REF	5.1.6	Catalogue Number
LOT	5.1.5	Batch Code
	5.4.2	Do not re-use
	5.2.6	Do not resterilize
	5.2.8	Do not use if package is damaged
	5.1.4	Use-by date
STERILE	5.2.4	Sterilized using irradiation
	5.4.3	Consult instructions for use
	5.3.2	Keep away from sunlight
	5.4.4	Caution
	5.1.1	Manufacturer
	5.3.6	Upper limit of temperature

For product ordering information, further information, or guidance, please contact Omeza for assistance at: 1-888-88OMEZA (1-888-886-6392)

PRODUCT INFORMATION DISCLOSURE

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