A Novel Flowable Gel
for Wound Management

A recombinant human collagen-based matrix for optimal wound healing

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Made of Plant Derived Recombinant Human Collagen

The Ideal Regenerative Building Block for Wound Management

Regenerative Medicine – a new course in wound healing
Recombinant human collagen for optimal wound management

Vergenix™ Flowable Gel (FG) is an innovative bio-degradable wound care device that provides a scaffold for cellular proliferation and capillary growth. It is comprised of a recombinant type I human collagen derived from bioengineered tobacco plants and demonstrates a profile resembling that of the native human collagen.

This charts a new course in the treatment of acute and chronic wounds.

Vergenix™FG is made of type I recombinant human collagen (rhCollagen) and hydroxypropyl methyl cellulose (HPMC). Vergenix™FG is supplied as a lyophilized material contained in a syringe that, when hydrated with saline, forms a gel.

Vergenix™FG is indicated for the management of acute and chronic wounds, including:

- Full thickness and partial thickness wounds
- Pressure ulcers
- Venous ulcers
- Ulcers caused by mixed vascular etiologies
- Diabetic ulcers
- Second degree burns
- Donor sites and other surface bleeding wounds
- Abrasions
- Trauma wounds healing by secondary intention
- Surgical wounds
- Deep and tunneled undermined wounds
Vergenix™FG, made of type I rhCollagen and hydroxypropyl methyl cellulose (HPMC), drives the formation of granulation tissue, one of the most important steps leading to an effective wound closure.
The main property anticipated from a collagen-based scaffold is its ability to attract and trap cells and growth factors to the wound site in order to build and regenerate the missing tissue.

The collagen scaffold, through integrin and fibronectin binding sites, attracts fibroblasts and immune cells to the wound site to form a new granulation tissue. The granulation tissue contracts and reduces the wound size as well as enables keratinocytes to migrate and re-epithelialize, leading to final wound closure.

When selecting an advanced wound care product it is of high importance that the matrix material has the ability to provide the optimal structural support to the abovementioned wound healing process.

Owing to its perfect structure, its undamaged binding sites and non-immunogenic properties, the rhCollagen in Vergenix™FG can provide the optimal scaffold to promote wound healing as demonstrated in both preclinical and clinical studies.
Preclinical evidence

**Vergenix™FG significantly accelerates wound closure**¹

In preclinical studies, Vergenix™FG has shown remarkable ability to regenerate skin tissue in several wound healing models. Specifically, Vergenix™FG has demonstrated its ability to jumpstart the wound healing process.

![Graph showing wound closure and blood vessel score](image)

**Vergenix™FG promotes the creation of new blood vessels at the wound site**¹

Angiogenesis is an important process that has to take place during wound healing. Higher blood vessel score at day 7 and fewer blood vessels at day 21 demonstrate an effective and accelerated healing process. Fully maturated tissue should later present fewer blood vessels.

![Graph showing blood vessel score](image)
Vergenix™FG significantly accelerates wound closure compared to the bovine commercial control¹

![Graph showing wound closure percentage over 21 days with Vergenix™FG and bovine collagen.](image)

* p < 0.05

![Images of tissue sections from Day 0 and Day 21 for Vergenix™FG and bovine collagen.](image)
Clinical evidence
Single arm open label clinical study

Patients: 20 hard-to-heal wounds
Vergenix™FG application: single
Follow up: 4 weeks
Mean age: 63.6 years [36.1–85.3]

Type of wound:

- Neuropatic Ulcer: 10%
- Post Trauma Wound: 10%
- Venous Ulcer: 35%
- Post Operative Wound: 45%
- Other: 10%

79% mean wound size reduction within 4 weeks after a single Vergenix™FG application

By week 4:
Complete wound closure: 45% of patients
Good granulation tissue: 90% of patients
Reduction in pain level: 50% of patients
No inflammatory response, edema or erythema
No serious adverse events
Post Marketing Surveillance

Patients: 75 hard-to-heal wounds
Vergenix™ FG application: single
Follow up: 16 weeks
Mean age: 65.7 years [17.7-92.2]

Type of wound:

Post-Operative Wounds: 25%
Neuropathic Ulcer: 11%
Venous Limb Ulcer: 39%
Post-Trauma Wounds: 12%
Not Reported: 8%
Pressure Ulcer: 5%

88% mean wound size reduction within 16 weeks after a single Vergenix™ FG application

By week 16, wound closure observed in 72% of patients

By week 12:
Vergenix™ FG: wound closure in 69% of patients
Standard of care: wound closure in 24% of patients

*p < .0001

48% 58% 69% 72%
Week 4 Week 8 Week 12 Week 16

Patients with >90% Wound Volume Reduction (%)

*p >90% closure
Case studies
single Vergenix™ FG application

Venous Leg Ulcer

*History:* Male, 82 years old with venous lower limb ulcer with associated peripheral artery disease stage IIB.

*Results:* Wound was in complete resolution within 30 days.

Pressure Ulcer

*History:* Female, 86 years old with large pressure ulcer in sacral area with medium yellow exudation.

*Results:* Patient achieved complete wound closure within in 4 months post treatment.

Diabetic Foot Ulcer

*History:* Male, 64 years old with neuropathic leg ulcer with history of ischemia, angioplasty and infection. Patient underwent weekly dialysis for the last 2 years. Patient did not react to any other wound treatment/materials.

*Results:* Wound fully healed within 3 months.

Post Operative Wound

*History:* Male, 79. Neuropathic ulcer Grade IIB.

*Results:* Wound fully healed within 1 month.
What makes Vergenix™ FG different?

- Made from truly recombinant human collagen
- Wounds heal faster
- 3-dimensional scaffold for deep/irregular shaped wounds
- Promotes new tissue formation
- A single application is sufficient
- Non immunogenic
- Proven in use
- Pure and homogenous

“**It is the most effective filler I used so far. It is easy to use, and in my surgical practice helps me in addressing problems with loss of substance after debridement or bone and joint removal for Osteomyelitis. In 2 words: it works.**”

Prof. Alberto Piaggesi about Vergenix™ FG

Director, Diabetic Foot Section, University of Pisa, Member of Board of Directors of Diabetic Foot Study Group of European Association. Honorary Secretary – EWMA
How to apply Vergenix™ FG?

1. Peel open the blister kit and inspect all packaging integrity. Do not use the kit if packaging is damaged. Visually inspect the empty syringe. Do not use if empty syringe contains cracks or visible particulate matter.

2. Surgically debride the wound bed using standard methods to ensure wound is free of debris and necrotic tissue.

3. Fill a 5 mL empty syringe with 1.6 mL of saline.

4. Connect the luer-lock connector supplied to the saline containing syringe and fill the luer-lock volume with the saline up to 5 mm from its edge.
5 Connect the saline containing syringe to the syringe containing the Vergenix™FG through the luer-lock connector.

6 Hold the two connected syringes in your hands securely and rapidly inject the saline solution into the syringe containing the Vergenix™FG powder.

7 Tap the filled syringe 20 times on the palm of your hand, wait 5 minutes and then tap the syringe additional 20 times.

8 Disconnect the empty syringe and adjust the syringe plunger containing the gel to 2 mL.
9 Fill the luer-lock with the gel solution and reconnect the empty syringe.

10 Mix 15 times back and forth to form a whitish gel.

11 Consider the flowable gel mixed when product appearance is consistent and homogeneous and all the product can be moved from one syringe to the other.

12 Gather the gel to one syringe and disassemble the empty syringe. Withdraw the remaining gel from the luer-lock to the filled syringe and disassemble the luer-lock.
13 When dispensing the Vergenix™FG, first determine the location of the base of the wound bed utilizing the cannula and then fill the tissue voids. Upon dispensing product into the wound, avoid pressing the cannula tip directly against the base of the wound to ensure the product is not prevented from exiting the cannula.

14 After application, use an optimal secondary dressing to maintain the gel adherence and protect the wound area. The optimum dressing is determined by wound location, size, depth and user preference.

2. Itay Wiser, MD, PhD; Eran Tamir, MD; Hanna Kaufman, MD; Elad Keren, MD; Shalom Avshalom, MD; Doron Klein, MD; Lior Heller, MD; and Eyal Shapira, MD. A Novel Recombinant Human Collagen-based Flowable Matrix for Chronic Lower Limb Wound management: First Results of a Clinical Trial. Wounds 2019 February 14

3. Post marketing surveillance - Data on file


CollPlant is an ISO 13485: 2016 certified company. Vegenix™FG is CE marked.