Cutimed®

# CUTIMED® EPIONA CLINICAL STUDY

28 OCTOBER – 11 DECEMBER 2015

*FAST FACTS ON A NEW 3D MATRIX™ TECHNOLOGY THAT FAST-TRACKS HEALING FOR CHRONIC WOUNDS*

## QUICK OVERVIEW

- Study evaluated the effectiveness of Cutimed® Epiona when administered with standard care (debridement, cleaning, cover dressing, compression, off-loading), based on wound etiology of 31 patients
- Study performed up to 4 weeks at wound care centers in the U.S.
- Four patients had multiple wounds
- Wounds were mainly diabetic foot ulcers (DFUs; 42%) and venous leg ulcers (VLUs; 32%); the remainder were other types of chronic wounds
- Mean age of wounds at first visit was 301 days
- 30 of 31 participants completed the study

### PRIMARY ENDPOINT

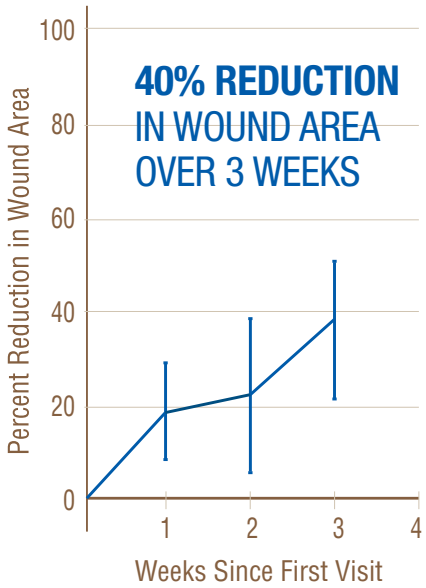
- Reduction in wound area

### SECONDARY ENDPOINTS

- Rate of wound healing over time
- Amount of granulation over time
- Ease of study product application
- Number of dressing changes over time
- Adverse events
- Pain

### COMPELLING RESULTS

- Mean reduction in wound area after 3 weeks was almost 40% in wounds that had stalled with a mean wound age of 301 days
- Fourteen of the wounds were reduced by 50% or more after 3 weeks
- Complete wound healing occurred in 3 wounds, 2 and 3 weeks after the first visit
- No infections or adverse events were reported
- Change in wound area compared at Week 1 and Week 4 was statistically significant (p=.006)




*Percent reduction in wound area by week. Vertical bars represent 95% confidence intervals.*

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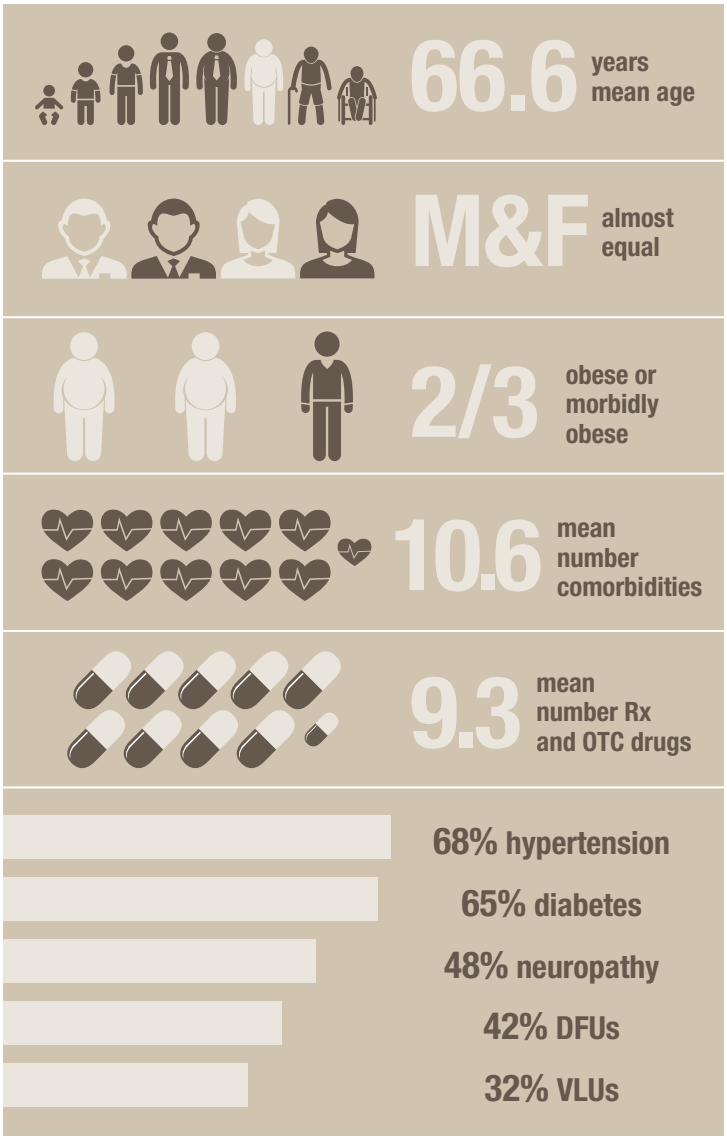
# All Participants Had Multiple Serious Comorbidities Likely to Slow Wound Healing

## SUBJECT SNAPSHOTS




| Patient Variable | Count (%) | Mean/Median (SD) |
|---|---|---|
| Gender | | |
| Male | 15 (48) | |
| Female | 16 (52) | |
| Race | | |
| Caucasian | 28 (90) | |
| African American | 3 (10) | |
| Drug Count | | 9.3/9 (5.64) |
| Selected Drug Categories | | |
| For pain | 19 (61) | |
| For neuropathic pain | 13 (42) | |
| Pain for wound | 1 (3) | |
| For diabetes | 15 (48) | |
| For dyslipidemia/high cholesterol | 15 (48) | |
| For mental illness | 7 (23) | |
| For renal disorders | 2 (7) | |
| For hypertension | 23 (74) | |
| Wound Variable | Count (%) | Mean/Median (SD) |
| Type | | |
| DFU (diabetic foot ulcer) | 13 (42) | |
| VLU (venous leg ulcer) | 10 (32) | |
| Traumatic | 4 (13) | |
| PU (pressure ulcer) | 2 (7) | |
| Mixed | 1 (3) | |
| Surgical | 1 (3) | |
| Initial area (cm2) | | |
| All | | 4.8/1.8 (8.38) |
| DFU (diabetic foot ulcer) | | 2.1/1.5 (1.68) |
| VLU (venous leg ulcer) | | 8.9/2.3 (13.21) |
| Traumatic | | 1.6/1.5 (1.13) |
| PU (pressure ulcer) | | 0.5 |
| Mixed | | 15.8 |
| Surgical | | 11.2 |

## INCLUSION CRITERIA

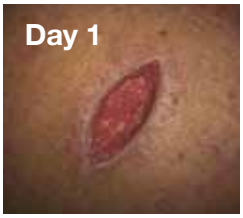
1. Male or female subjects > 18 years old
2. Subjects with a chronic wound (pressure ulcer, diabetic ulcer, venous ulcer, ulcers caused by mixed vascular etiologies, second-degree burns, donor and graft sites, abrasions, dehisced surgical wounds or traumatic wounds healing by secondary intention)
3. Subjects who agreed to participate in the study, including all study-related procedures and evaluations, and documents agreement by signing the IRB-approved informed consent

## EXCLUSION CRITERIA

1. Subjects with a known sensitivity or allergy to bovine collagen or one of the other product contents
2. Subjects whose wounds were third-degree burns, covered in eschar or were dead tissue
3. Subjects who were not willing or able to consent or participate
4. Subjects who received an experimental drug or used an experimental medical device within seven days prior to the planned start of treatment
5. Employees of the Investigator or study center with direct involvement in the proposed study or other studies under the direction of that Investigator or study center

# Rapid Clinical Results on Chronic Wounds

## Patient #1 – Surgical Wound





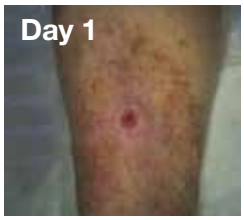
Patient was a 78-year-old male with a chronic ulcer on the upper back (surgical wound), four weeks in duration. Patient presented with a history of hypertension, type II diabetes, melanoma of the upper back (removed) and dyslipidemia. The wound had severe drainage at screening, with a wound area of 11.2 $cm^2$.

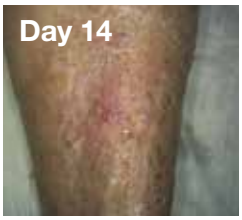
Study evaluated the effectiveness of Cutimed® Epiona Native Collage Dressing. Adjunct therapy included standard care (debridement, cover dressing).

Debridement was performed as needed throughout the study. Patient was seen weekly from Visits 1-4 with wound area decreasing throughout the study duration.

- Day 1 wound area 11.2 $cm^2$
- Day 21 wound area 1.4 $cm^2$
- Total Wound Area Reduction 87.1% from day 1

## Patient #2 – Venous Leg Ulcer




Patient was a 73-year-old female with a venous leg ulcer on the right leg, nine months in duration. Patient presented with a history of hypertension, type II diabetes and diabetic neuropathy. The wound had moderate drainage at screening with a wound area of 1.1 cm2.

Study evaluated the effectiveness of Cutimed® Epiona Native Collage Dressing. Adjunct therapy included standard care (debridement, cover dressing and compression).

Patient was seen weekly from Visits 1-4 and presented with a closed wound at Visit 3, which remained closed at final Visit 4.

- Day 1 wound area 1.1 $cm^2$
- Day 14 wound area completely closed
- Total Wound Area Reduction 100% from day 1

## Patient #3 – Diabetic Foot Ulcer



Patient was a 53-year-old male with a right, distal, plantar diabetic foot ulcer, four months in duration. Patient presented with a history or type II diabetes, diabetic neuropathy, hypertension, transmetatarsal amputation (TMA), cholecystectomy, tubes in ears, left knee meniscus repair and vasectomy. The wound had mild drainage at screening (Visit 1) with a wound area of 1.8 cm2.

Study evaluated the effectiveness of Cutimed® Epiona Native Collage Dressing. Adjunct therapy included standard care (debridement, cover dressing, TCC).

The patient was seen weekly from Visits 1-4 with wound area decreasing throughout the study duration.

- Day 1 wound area 1.8 $cm^2$
- Day 21 wound area 0.5 $cm^2$
- Total Wound Area Reduction 71.8% from day 1

## Change in wound exudate level by week:

| Week | None | Minimal | Moderate | Heavy |
|---|---|---|---|---|
| 1 | 0 (0) | 18 (58) | 11 (35) | 2 (7) |
| 3 | 5 (16) | 18 (58) | 8 (26) | 0 (0) |

# Cutimed® Epiona: Helps Speed Healing for Chronic Wounds

- The mean age of the wounds at first visit was 301 days
- Three weeks into the study, 14 of the 31 patients' wounds (45%) were reduced by 50% or more
- Cutimed® Epiona's native collagen provides structural support with an ECM-like scaffold to enhance tissue generation and promote healing of stalled wounds
  - It transforms into a flexible, moist gel covering when exposed to wound exudate or blood
  - Its unique and flexible 3D Matrix™ Technology provides an open, porous structure to help capture and bind excessive proteases and inflammation inducing elements
  - Because it acts like an ECM scaffold, the collagen fiber network encourages rapid cell proliferation and tissue growth
  - Cutimed® Epiona helps put chronic wounds on the fast track to healing; safely and inexpensively

# Study Methodology

An intent-to-treat (ITT) approach was used for analyses. For missing observations, the last observation carried forward (LOCF) principle was used. For wounds that healed, the following variables were set to 0 at Week 4: area, pain, exudate level. Study variables were summarized as means and standard deviations (SDs) for continuous variables unless data were non-normal, as determined by the Shapiro-Wilk test, in which case medians were also reported, and proportions or percentages of categorical variables. Paired t tests were used to compare trial endpoints if data were normal, and the Wilcoxon signed rank test is data were non-normal, and differences existed. To adjust for the family-wise error rate (FWER), p values were reported using the Hochberg step-up procedure. Adjusted two-side p values $< 0.05$ were considered significant. PASW 19 (IBM, Chicago, IL) was used to perform the statistical testing.

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