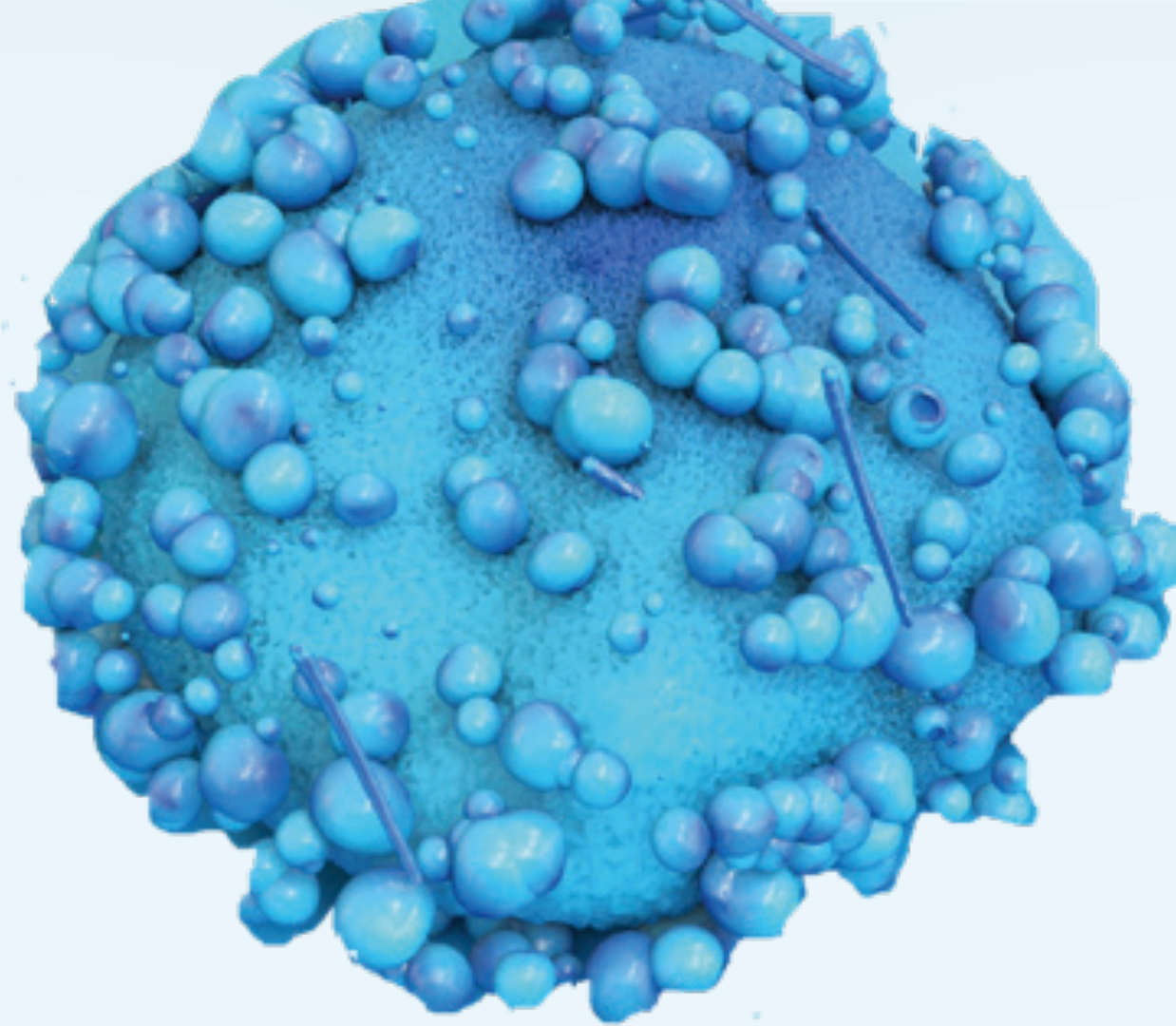




A Better Solution to Wound Care

- Amnion/Chorion
 - Umbilical Cord
 - Placental Disc
-



- **Safe & effective**
- **Easy to use**
- **Case studies**

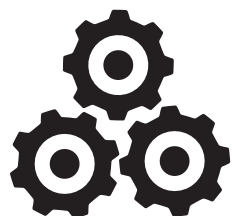
Meticulously Processed and Tested



- Normal, Healthy full Term Pregnancies.
- Every lot tested for Cytotoxicity and Endotoxin..

PROCESS:

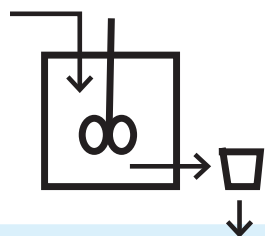
1



Gently Grind

Amnion / Chorion, Umbilical Cord and Placental Disc

2



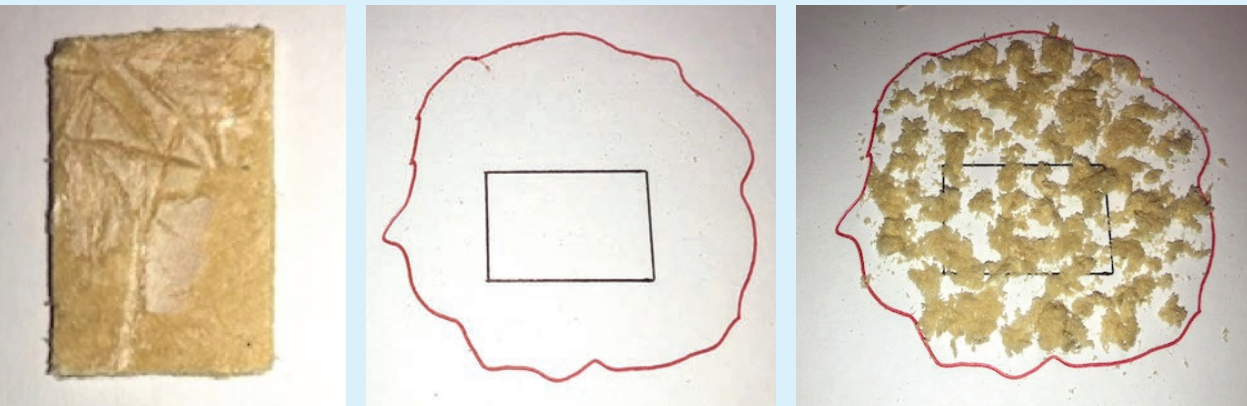
Decontaminate & Capture

3



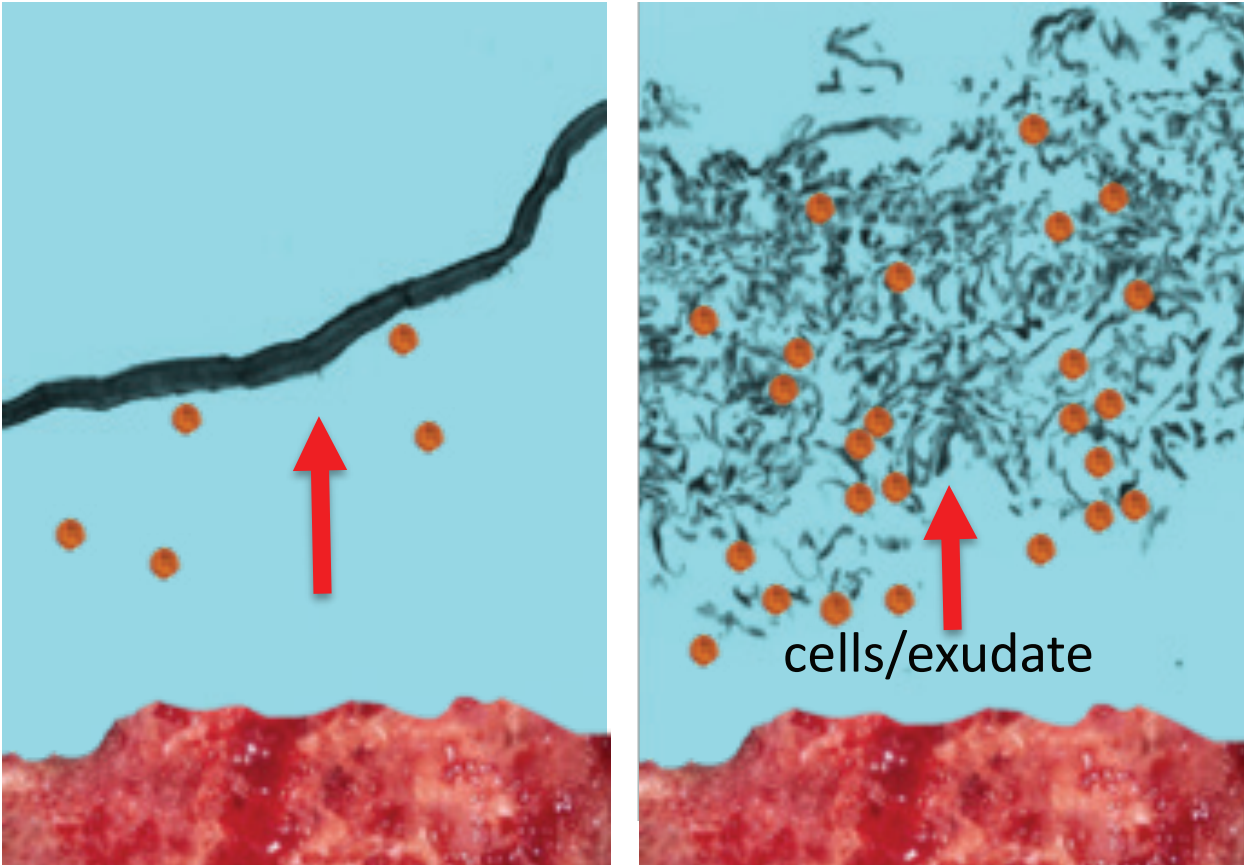
Lyophilize & Validated 17kGy Irradiation

3-DIMENSIONAL PRODUCTS FOR 3-DIMENSIONAL PROBLEMS



Safe & effective

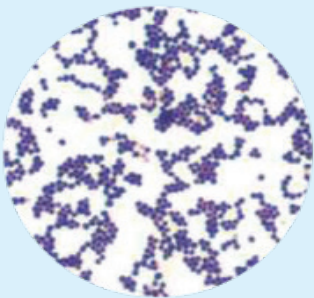
MORE TISSUE AND A PARTICULATE SHEET ENABLES CELL MIGRATION



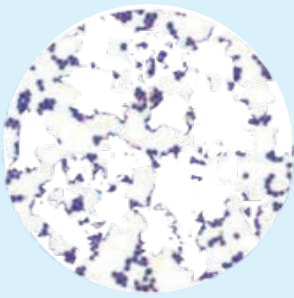
Amnion / chorion

Plurivest / Dermavest

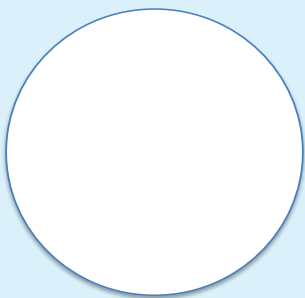
BACTERIAL RESISTANCE (Staph Aureus 4 hour co-culture)



Negative control
(cotton bandage)



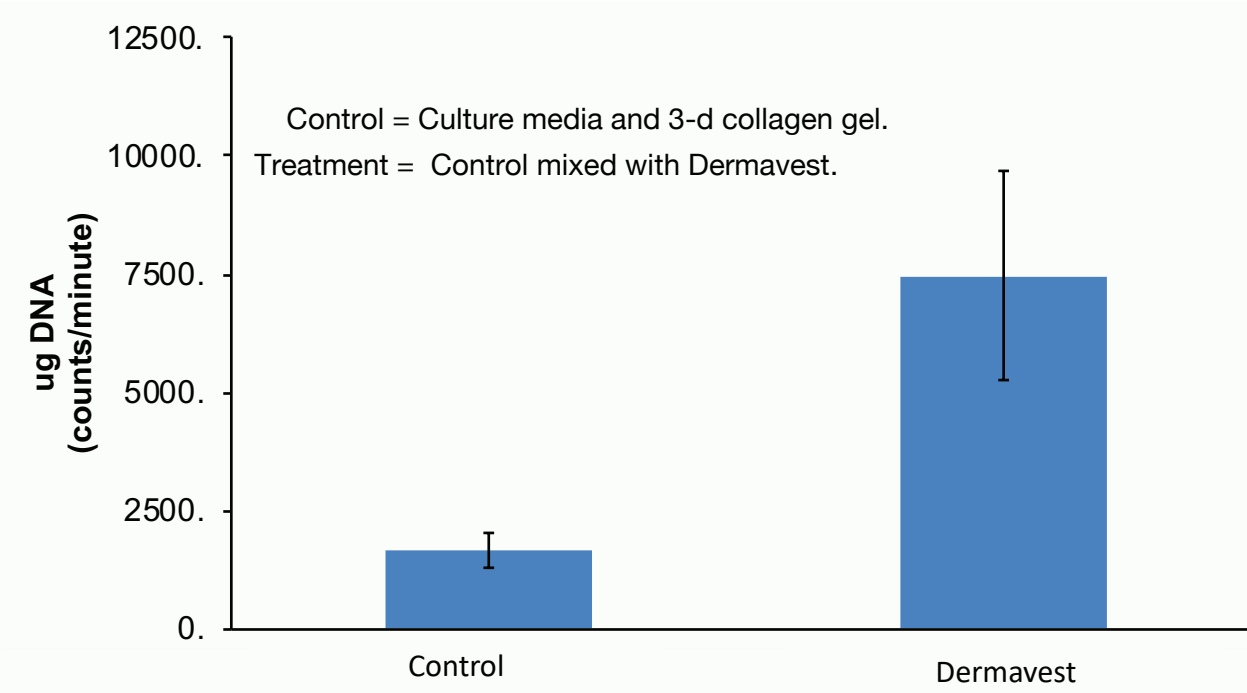
Dermavest 55%
reduction



Positive control (Acticoat
7 silver dressing >99.9%
reduction)

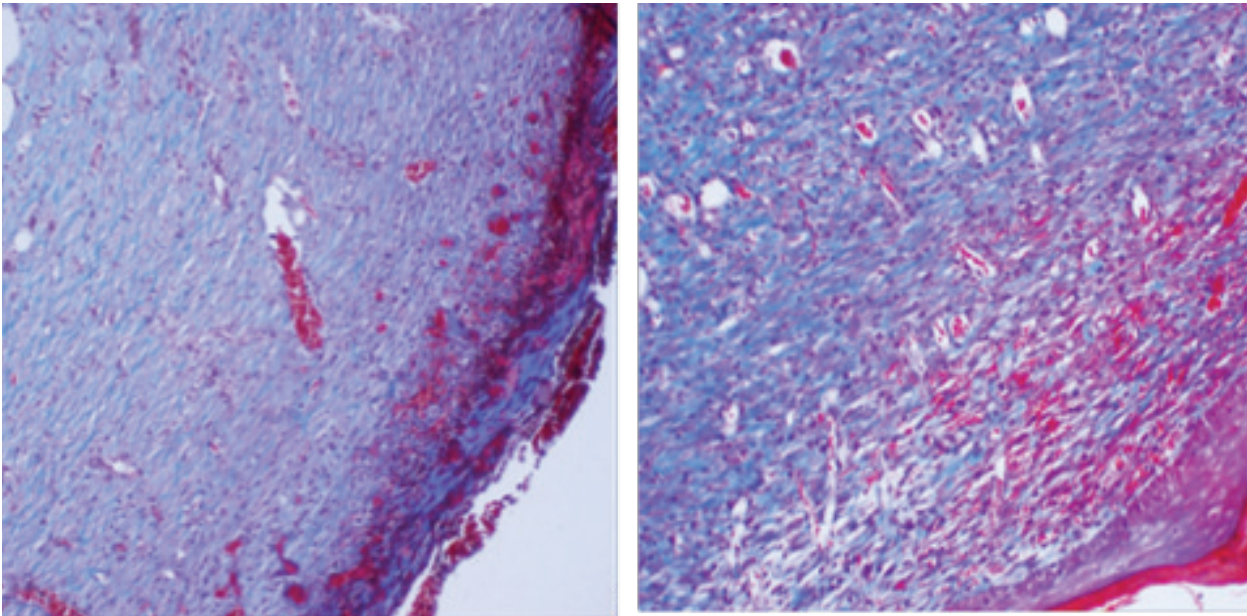
Placental Disc extracts are known to be antimicrobial

MESENCHYMAL STEM CELL GROWTH IN CULTURE (72 hours)



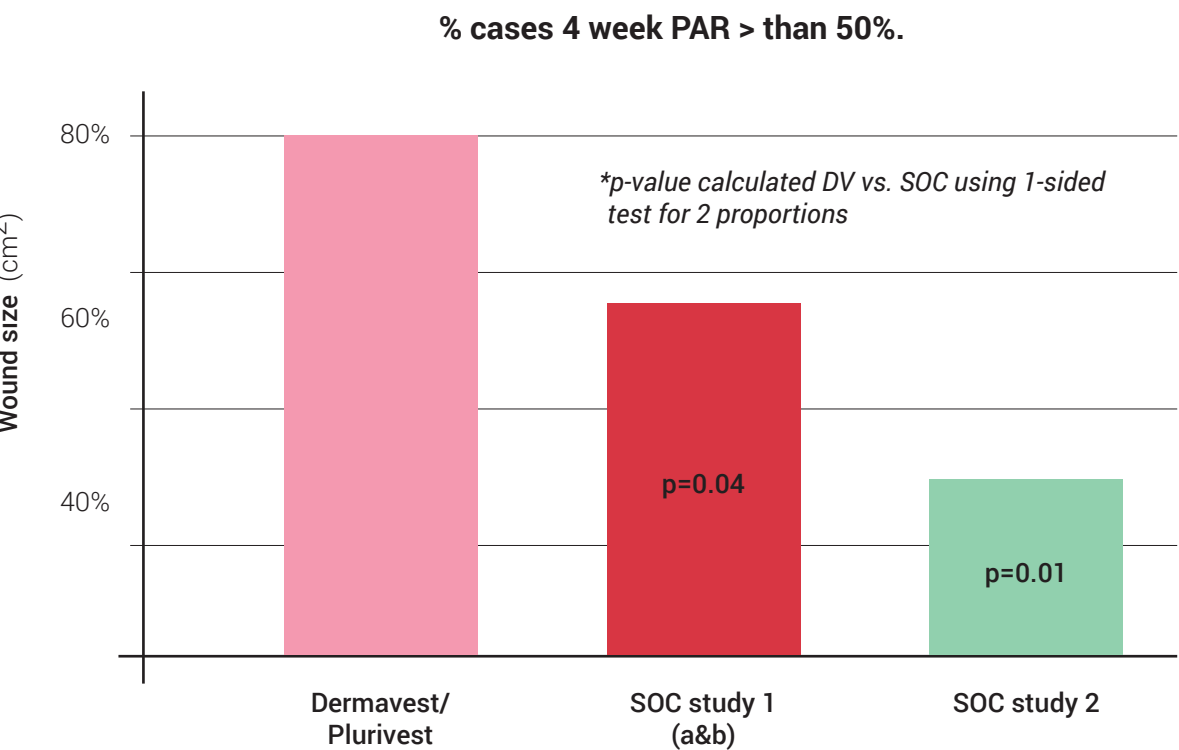
MSC'S - key to effective wound healing

ANGIOGENESIS (Diabetic Rat Model)



Dermavest induces vascularization

DIABETIC ULCER STATISTICS



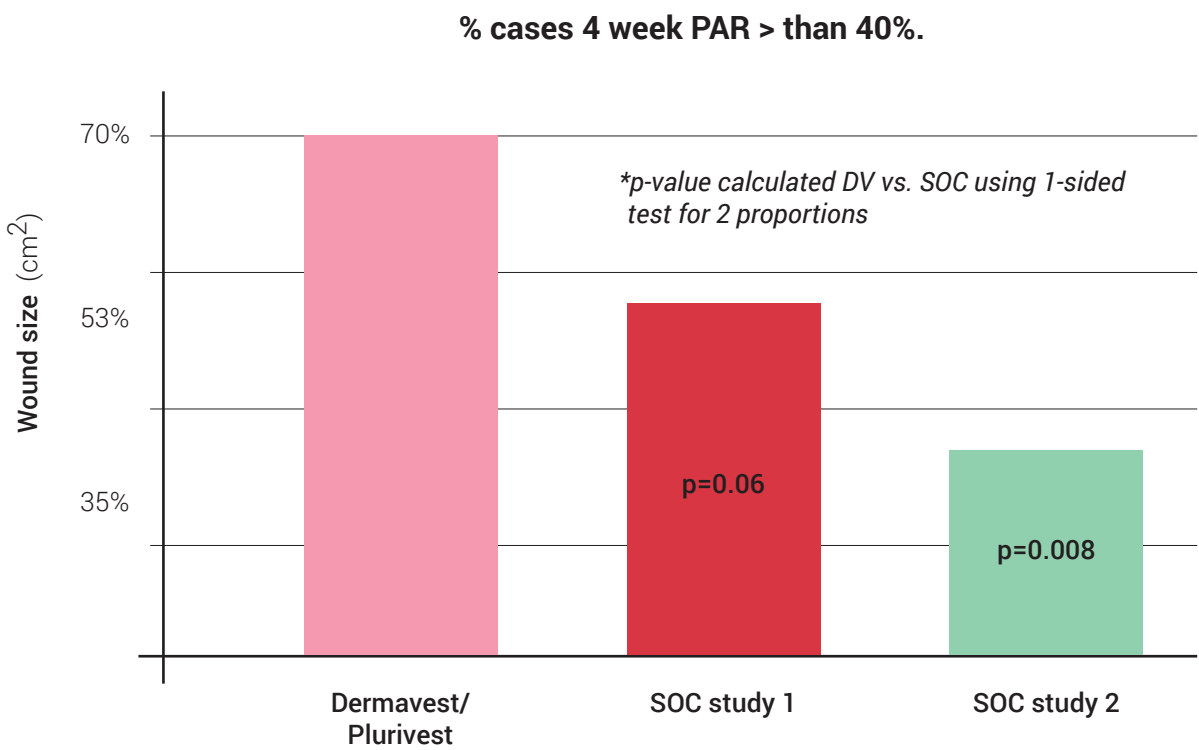
	Dermavest	SOC study 1 (a&b)	SOC study 2
# wounds	10	250	12
Duration: weeks mean (stdev)	42 (11.3)	67 ¹	16.7 (15.5)
Size: cm2 mean (stdev)	4.74 (5.3)	2.53 ¹	3.4 (2.9)
Age: mean (stdev)	60.5 (11.3)	55.3 ¹	61.7 (10.3)
# cases PAR>50%	8	142	4

1. Dermavest data compiled from two case series presented at the society of advanced wound care (SAWC) annual meeting.

2. SOC Study 1 data derived from Snyder RJ, Cardinal M, Dauphinee DM, Stavosky J, "A Post-hoc Analysis of Reduction in Diabetic Foot Ulcer Size at 4 Weeks as a Predictor of Healing by 12 weeks ", Ostomy wound Management 2010; 56 (3); 44-50.

3. SOC study 2 data derived from Zelen CM, Serena TE, Denoziere G, Fetterolf D "A prospective

VENOUS ULCER STATISTICS



	Dermavest	SOC study 1	SOC study 2
# wounds	13	25,406	31
Duration: weeks mean (stdev)	85 (72)	16	16.7 (15.5)
Size: cm2 mean (stdev)	3.73 (4.4)	3.2	6.3 (5.3)
Age: mean (stdev)	66 (88)	68.5	63.6 (61.1)
# cases PAR>50%	9	12,542	10

1. Dermavest data compiled from two case series presented at the society of advanced wound care (SAWC) annual meeting.

2. SOC Study 1 data derived from Gelfand JM, Hoffstad O, Margolius D, "Surrogate Endpoints for the Treatment of Venous Leg Ulcers", J Invest Dermatol 119:1420-1425, 2002

3. SOC study 2 data derived from Serena TE, Carter MJ, Lam TE, DSabo MJ, and DiMarco DT "A Multicenter, randomized, controlled clinical trial evaluating the use of dehydrated human amnion/

Comparison of the concentration (pg/cm²) of cytokine and growth factor (GF) content in Plurivest, Dermavest, dehydrated Amnion and Chorion*

Cytokine/GF	Dermavest (12.5 mg/cm ²)	Amnion (1.2* mg/cm ²)	Chorion (2.7 * gm/cm ²)
TIMP (1+)	1,272	284	1,060
HGF	4,253	161	395
PDGF-BB	744	101	405
PIG-F	415	145	306
SDF-1	141	33	71
TGF-b1	14,000	20	69
VEGF	968	36	498

1. Cytokine/GF concentration values (pg/mg) for amnion and amnion/chorion layer analyzed from samples as cited by: Koob TJ, Lim JJ, Zabek N, Massee M. 2015. Cytokines in single layer amnion allografts compared to multilayer amnion/chorion allografts for wound healing. J Biomed Mater Res Part B 2015: 103B:1133-1140.
2. The Dermavest, amnion and amnion/chorion samples were all measured with multiples ELISA arrays (RayBiotech, Inc.). All testing and Cytokine/GF analysis for Dermavest, , amnion and amnion/chorion samples were performed by the independent CRO, Ray-Biotech, Norcross, GA using, assumedly the same standard Ray-Biotech extraction and testing protocols..
3. The density of dehydrated amnion layer (mg/cm²). that is used to translate cytokine/GF concentration on a mass basis (pg/mg) to an area basis. (pg/ cm²), is conservatively drawn from non-processed membrane values in: Halaburt JT et al. *The concentration of collagen and the*

Main Growth Factors Involved in Ocular Scarring, Suggesting Common Functions of Each of the Main Growth Factors

Growth factor	Primary sources	Roles
TGF-β	Platelets, mast cells, macrophages, endothelial cells, epithelial cells, fibroblasts	Chemotaxis, inhibition of endothelial proliferation, stimulation of fibroblastic and epithelial proliferation, activation of extracellular cytokines, TIMP synthesis, angiogenesis
PDGF	Platelets, mast cells, macrophages	Fibroblast, epithelial and endothelial proliferation and chemotaxis, angiogenesis, keratinocyte migration, wound contraction
EGF	Platelets, macrophages	Fibroblast proliferation and migration
VEGF	Platelets, mast cells, astrocytes, macrophages, Muller cells	Stimulation of endothelial and fibroblastic proliferation, granulation tissue formation, neovascularisation
FGF	Platelets, mast cells, macrophages	Cellular proliferation and chemotaxis
CTGF	Macrophages, ECM, fibroblasts	Proliferation, migration, wound contraction

CTGF = Connective tissue growth factor

EGF = Epidermal growth factor

ECM = Extracellular matrix

FGF = Fibroblast growth factor

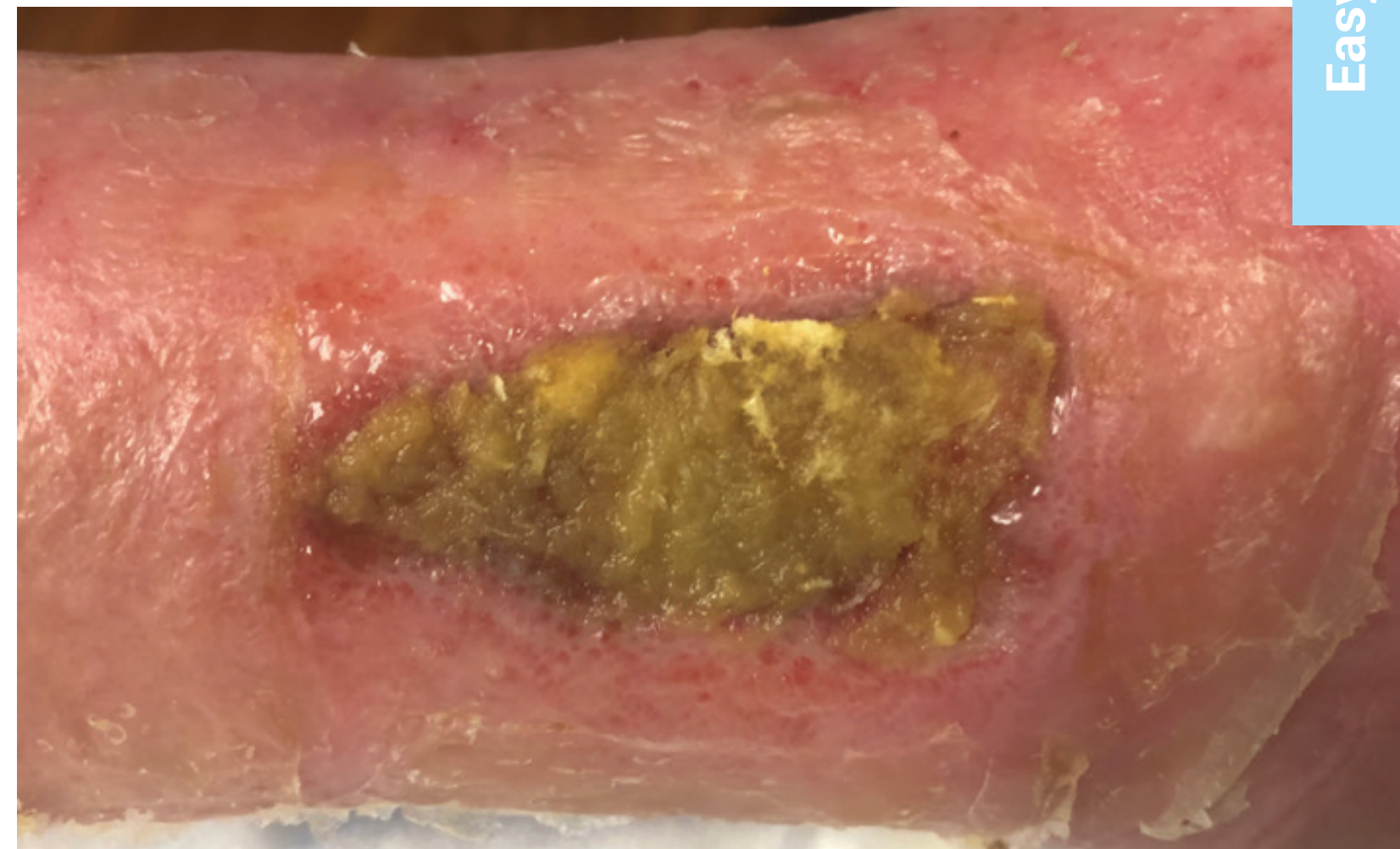
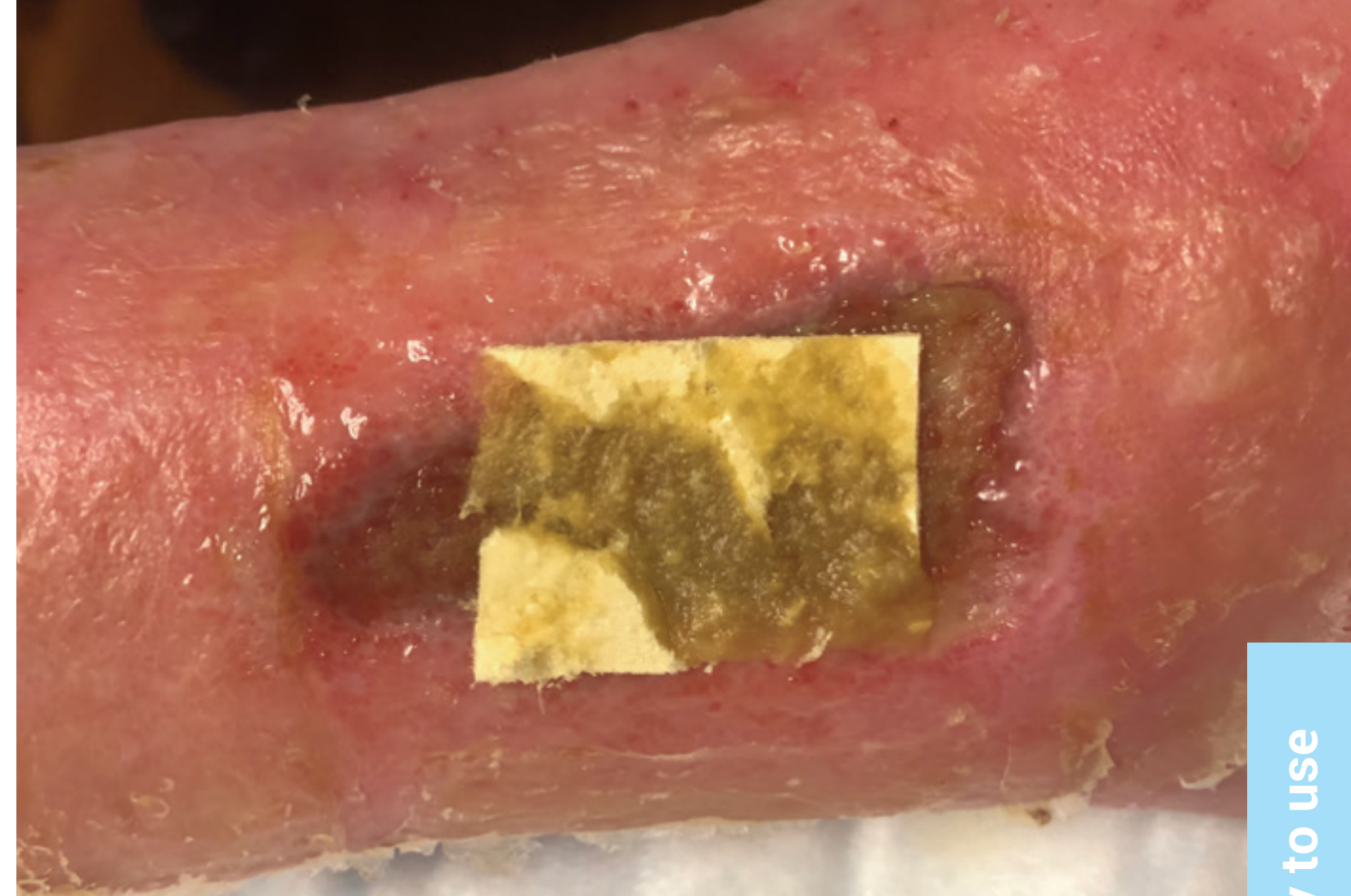
PDGF = Platelet-derived growth factor

TGF = Transforming growth factor

Easy to use.

Room
temperature
storage.

- Shelf stable particulate in contiguous sheet
- 3 year room temperature shelf life
- Spreads to cover over 2x listed size
- Can be molded to fit deep and tunneled wounds



Easy to use

Effectiveness case studies.

CASE STUDY 1

Wound with significant undermining and little to no blood flow. Physician had previously applied a tube of regranix and then apligraf - neither worked as the wound became deeper and more necrotic.

These images represent 6 applications over 8 weeks.



CASE STUDY 2

87 year old patient with sacral pressure ulcer treated with santyl and dressing change for 7 months (about 50% reduction) then stalled for 6 weeks. Then Dermavest applied.

11/28



DV applied.

12/16



Filled in.

1/20



1.08 cm2. Using Allevyn only.

2/4

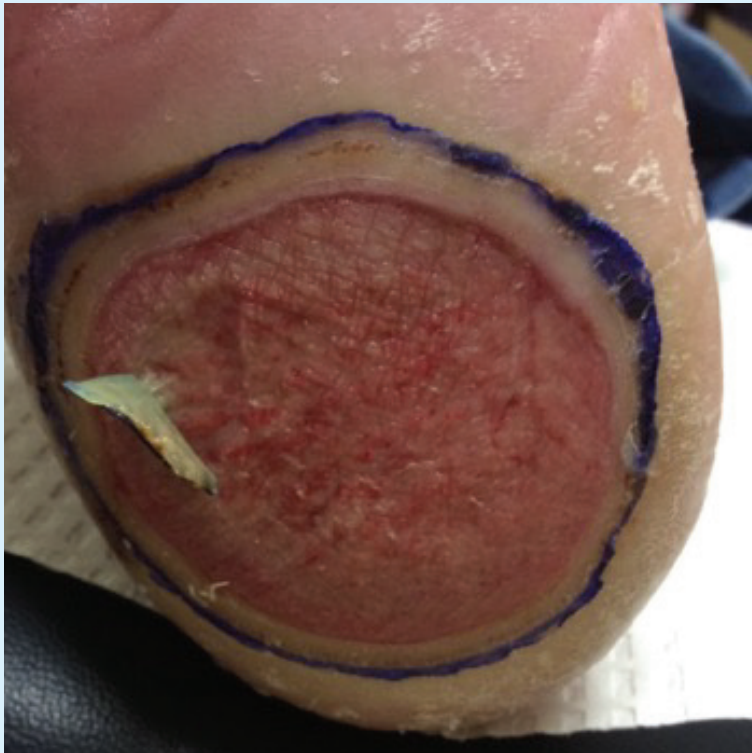


Healed.

CASE STUDY 3

Large diabetic ulcer hard to off-load..

10/24/17



1/9/18



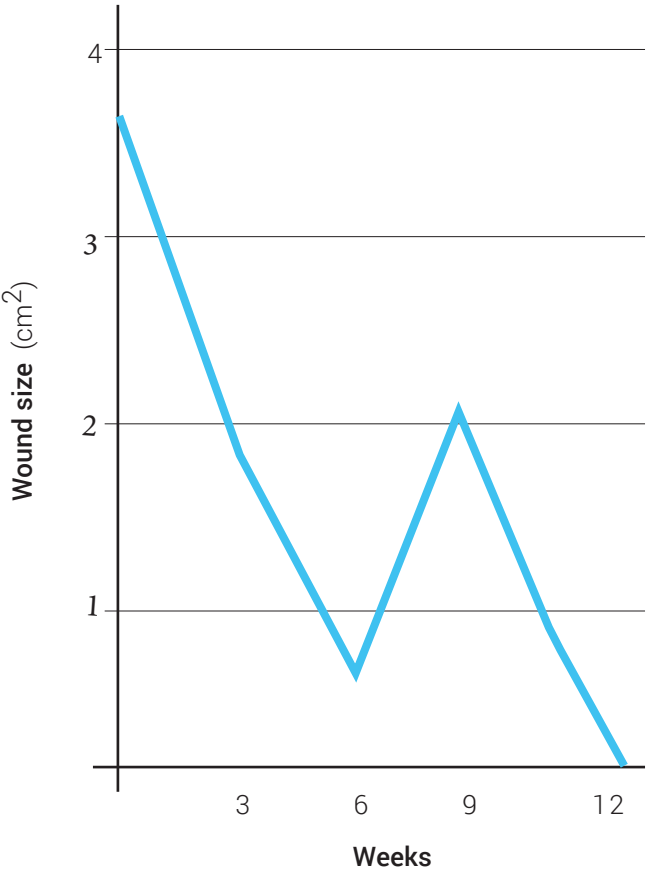
CASE STUDY 4: :

Diabetic Foot Ulcer (3.8 cm²)

Wound location:
Left Hallux Distal Tip

Previous treatments:
Pomogram/Prisma

Treatment:
4 applications of 2x3 cm
Dermavest



RESULTS:



CASE STUDY 5:

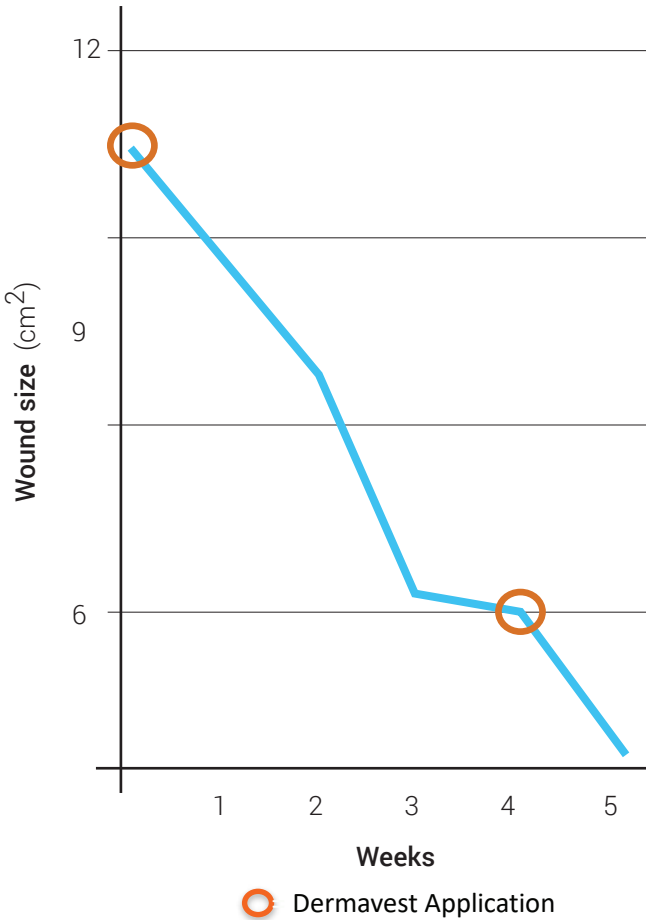
Venous/Arterial Foot Ulcer (10 cm²)

Wound location:
Right medial ankle.

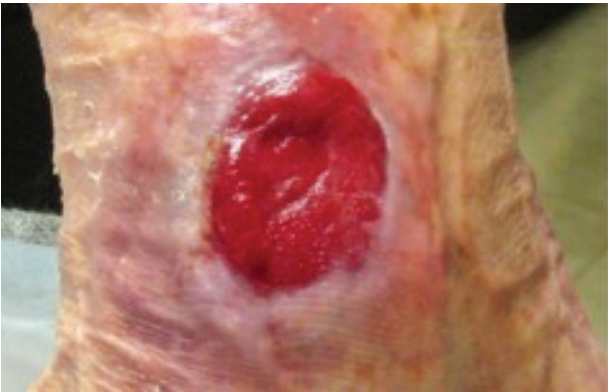
Age of wound:
2 years – difficult to treat due to health conditions.

Previous treatments:
Oasis, Endoform, Promogran, Xeroform and compression with no reduction in wound size.

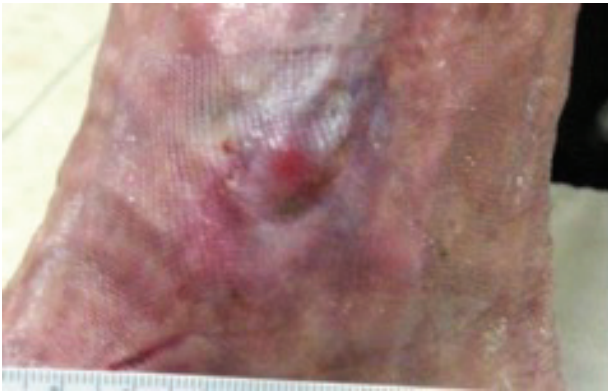
Treatment:
2 applications of one, 2x3 cm Dermavest with compression.



RESULTS:



Day 0
5-week % area reduction: 100%



Day 39

CASE STUDY 6:

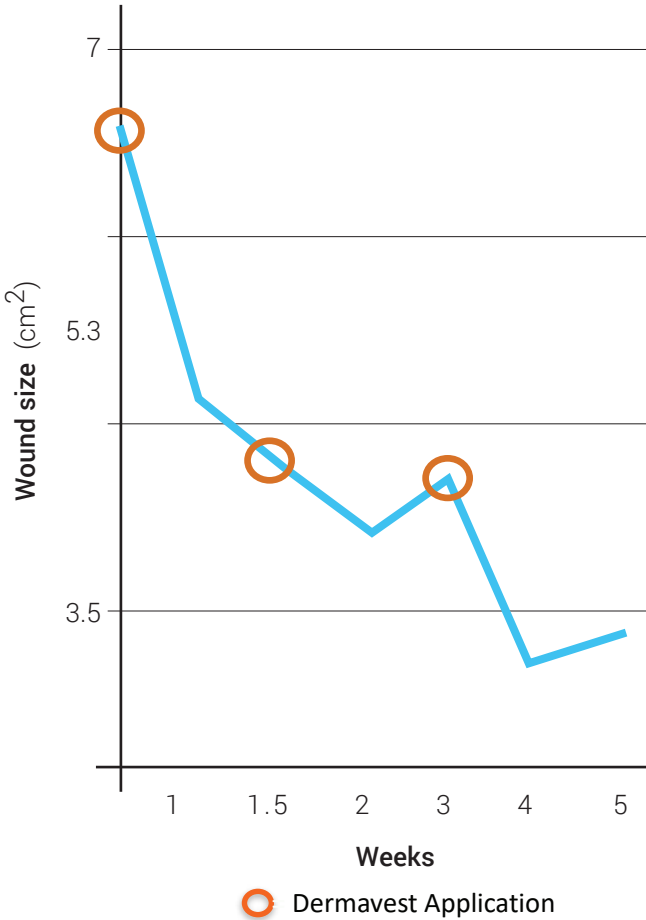
4-week Study: Diabetic Foot Ulcer (6cm²)

Wound location:
Right plantar heel.

Age of wound:
3 years

Previous treatments:
HBO, Epifix, Deramgraft, Cellutome, Endoform, Promogran, Prisma, Crow-walker, NPWT, IV antibiotics.

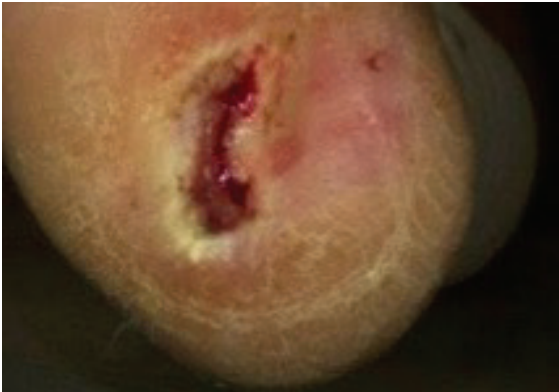
Treatment:
2 applications of **ONE** 2x3 cm Dermavest with adaptic, foam and TCC.



RESULTS:



4 week % area reduction = 80%



CASE STUDY 7:

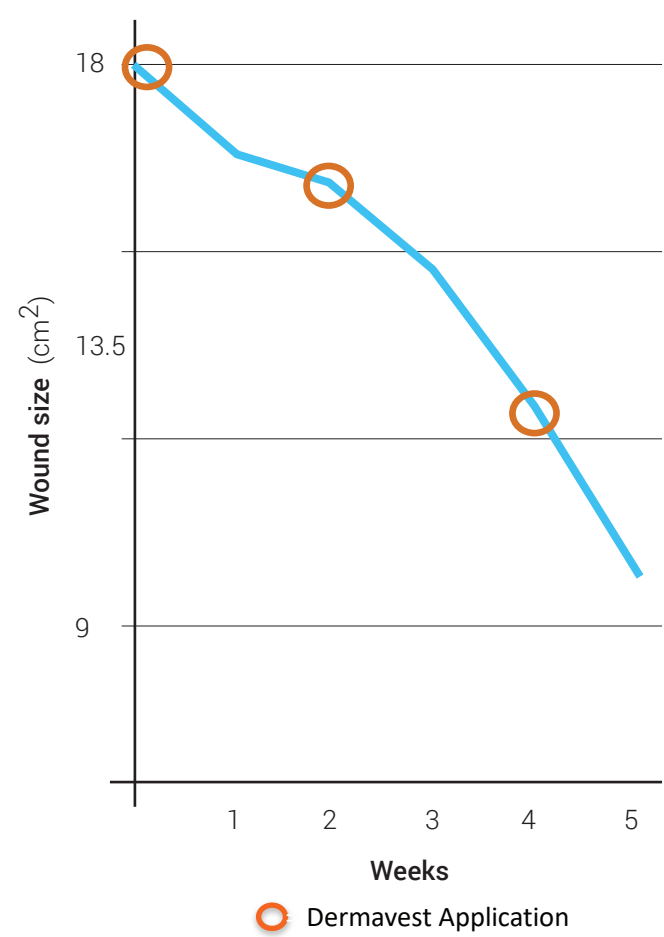
4-week Study: Diabetic Foot Ulcer (18 cm²) Treated with 6 cm² Dermavest

Wound location:
Left foot amputation site.

Age of wound:
2.5 months

Previous treatments:
Debridement HBO, NPWT, Hypochlorous acid wash.

Treatment:
3 applications of **ONE**, 2x3 cm Dermavest, Hypochlorous, GranufFoam and NPWT.



RESULTS:



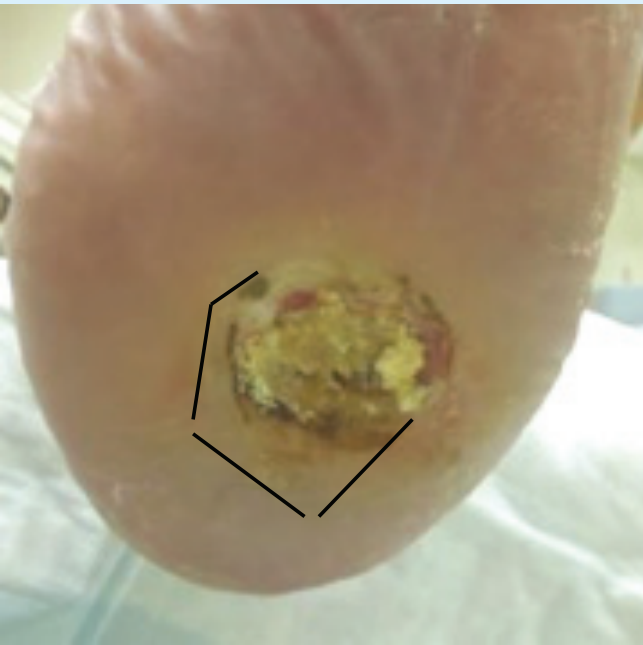
Day 0
4-week % area reduction: 47%



Day 35

CASE STUDY 8

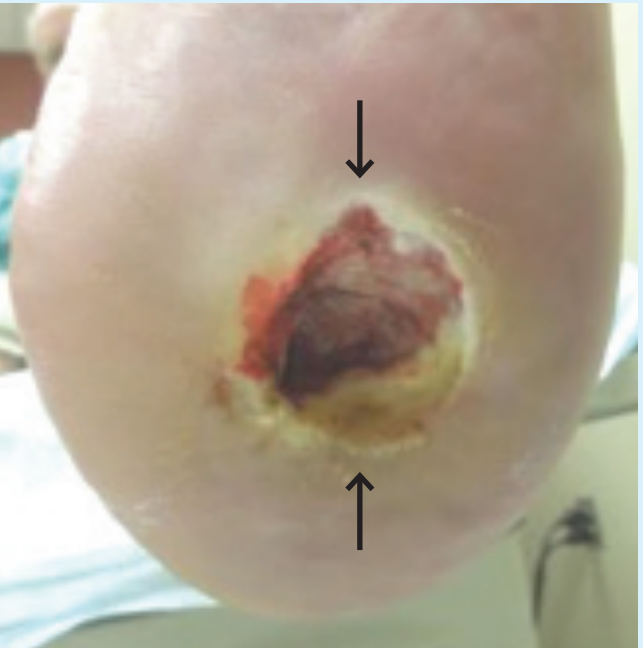
Diabetic ulcer. Significantly undermined, and failed treatment with just about everything.



At the time of first treatment (black line shows extent of undermining).



Two weeks after first treatment.



Three weeks after first treatment (ulcer debrided undermining gone - arrows show edge of new skin ingrowth).

Product Comaprison

Product	Amnion	Chorion	Umbilical Cord	Placental Disc	Spreadable
Affinity	✓	✗	✗	✗	✗
Amniofix	✓	✓	✗	✗	✗
Artacent	✓	✗	✗	✗	✗
Biofix	✓	✗	✗	✗	✗
Biovance	✓	✗	✗	✗	✗
EpiCord	✗	✗	✓	✗	✗
EpiFix	✓	✓	✗	✗	✗
GraFix Core	✗	✓	✗	✗	✗
GraFix Prime	✓	✗	✗	✗	✗
Nushield	✓	✓	✗	✗	✗
Dermavest	✓	✓	✓	✓	✓

