

dermaPACE®

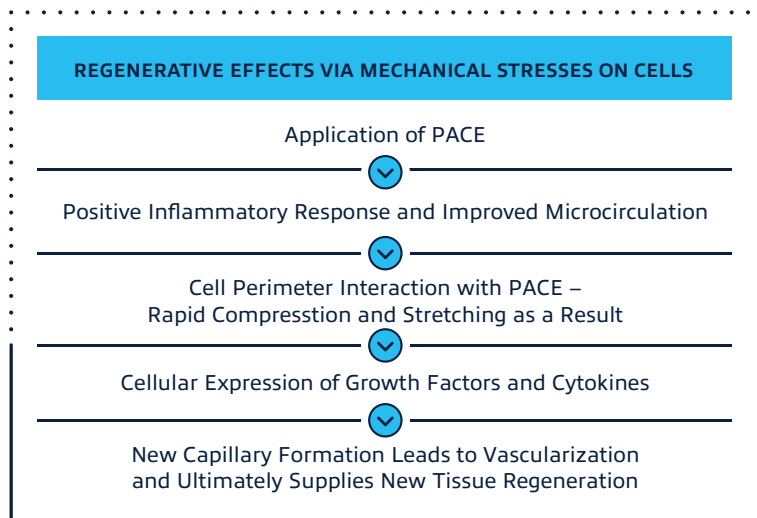
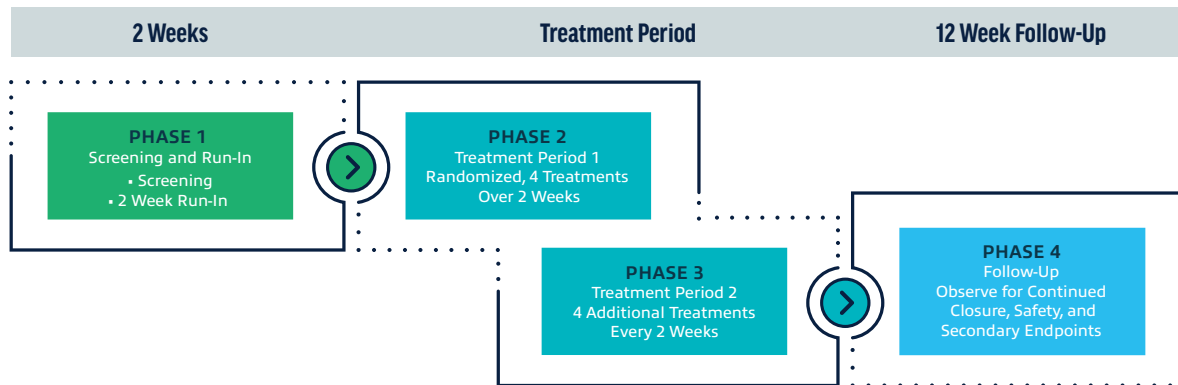
Technological Advancement in Wound Care



The dermaPACE® System is based upon SANUWAVE®'s proprietary Pulsed Acoustic Cellular Expression (PACE®) technology. PACE technology is the newest generation of shockwave technology utilizing electrohydraulic shockwave principles. It has been developed via scientific and clinical evidence to provide beneficial wound healing effects of acoustic pressure focused shockwaves. The precise shockwave parameters generated by the dermaPACE System optimize safety and effectiveness in the treatment of diabetic foot ulcers. High-energy acoustic pressure waves elicit a cellular response that initiates healing in wounds.

PULSED ACOUSTIC CELLULAR EXPRESSION TECHNOLOGY IN THE TREATMENT OF DIABETIC FOOT ULCERS: A Randomized, Sham-Controlled, Double-Blinded, Multicenter, Pivotal Phase III Clinical Trial

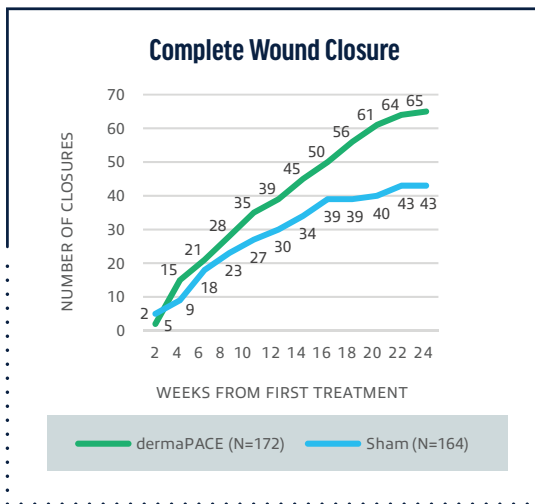
The dermaPACE System was evaluated using two studies under IDE G070103 (U.S. FDA). The studies were designed as prospective, randomized, double-blind, parallel-group, sham-controlled, multicenter 24-week studies at 39 centers. A total of 336 subjects were enrolled and treated with either dermaPACE plus conventional therapy or conventional therapy (a.k.a. standard of care) alone. The study allowed up to eight (8) device applications (four within the first two weeks of randomization, and one treatment every two weeks thereafter up to a total of eight treatments over a 10-week period).



CLINICAL RESULTS: Pulsed Acoustic Cellular Expression Technology in the Treatment of Diabetic Foot Ulcers: A Randomized, Sham-Controlled, Double-Blinded, Multicenter, Pivotal Phase III Clinical Trial

Complete Closure:

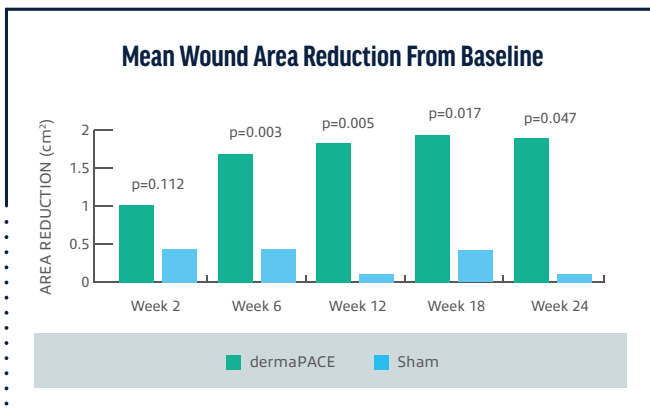
Statistical significance was achieved at the $p=0.050$ level at the 20-week time point and was maintained through the end of the study. A trend toward significance was shown at earlier times. At the 20-week endpoint, the rate of wound closure in the dermaPACE cohort was 35.4% compared to 24.39% for the control group, resulting in a p -value of 0.027. At the 24-week endpoint, the rate of wound closure in the dermaPACE cohort was 37.8% compared to 26.2% for the control group, resulting in a p -value of 0.023.



Study Visit	dermaPACE (N=172)		Sham Control (N=164)		X ² p-value
	n	%	n	%	
Week 12	39	22.67	30	18.29	0.320
Week 14	45	26.16	34	20.73	0.241
Week 16	50	29.07	39	23.78	0.272
Week 18	56	32.56	39	23.78	0.074
Week 20	61	35.47	40	24.39	0.027
Week 22	64	37.21	43	26.22	0.031
Week 24	65	37.79	43	26.22	0.023

Wound Area Reduction:

The mean wound area reduction for both cohorts was analyzed. The mean wound reduction for dermaPACE subjects at 24 weeks was 1.92 cm² compared to 0.16 cm² in the control group. There was a statistically significant difference between the wound area reductions of the two cohorts from the six-week follow-up visit through the end of the study. Because means can be influenced by outliers in the data, the median wound reduction was also reported and favored dermaPACE.



Study Visit	dermaPACE	Sham Control	T-test p-value
Week 2	1.05 cm ²	0.49 cm ²	0.112
Week 6	1.77 cm ²	0.49 cm ²	0.003
Week 12	1.9 cm ²	0.16 cm ²	0.005
Week 18	1.99 cm ²	0.54 cm ²	0.017
Week 24	1.92 cm ²	0.16 cm ²	0.047

Results Stratified by Demographic Characteristics by 24 Weeks:

Several demographic subgroups presented with very interesting results. There appears to be an interaction involving weight and height. There was a statistically significant difference between the weight (< 220 lbs., $p=0.063$) and height (≥ 70 inches, $p=0.0002$) of the two cohorts in favor of dermaPACE®. This also manifests in wound closure rates in the dermaPACE arm being significantly higher for patients with BMI <32 ($p=0.006$). Additionally, the wound closure rates in dermaPACE patients with baseline HbA1c levels ≥ 7 was significantly higher than the control group ($p=0.021$).

Demographic		dermaPACE			Sham Control			χ^2 p-value
		N	N	%	N	N	%	
Age Years	<65	120	45	37.5	129	33	25.6	0.043
	≥ 65	52	20	38.5	35	10	28.6	0.341
Sex	Male	137	55	40.1	132	10	25.0	0.008
	Female	35	10	28.6	32	10	31.3	0.811
Smoking Status	Non-Users	146	54	37.0	133	35	26.3	0.056
	Users	26	11	42.3	31	8	25.8	0.188
BMI (kg/m ²)	<32	84	38	45.2	87	22	25.3	0.006
	≥ 32	88	27	30.7	77	21	27.3	0.631
Weight (lbs.)	<220	86	35	40.7	78	21	26.9	0.063
	≥ 220	86	30	34.9	86	22	25.6	0.184
Height (in.)	<70	72	20	27.8	72	25	34.7	0.369
	≥ 70	100	45	45.0	92	18	19.6	0.0002
HbA1c	<7	55	20	11.6	46	14	8.5	0.581
	≥ 7	155	45	26.2	116	29	17.7	0.021

Safety:

Throughout the 24-week follow-up, the adverse event rates between the dermaPACE and control subjects were similar with no statistical significance between the two cohorts in treatment-emergent adverse events (55.8% vs. 51.2%), device-related treatment emergent adverse events (5.2% vs. 2.4%), or all adverse events (73.2% vs. 68.9%).

The percentage of patients that had to undergo full or partial amputation of the target ulcer was lower in dermaPACE, when compared to the control (2.3% vs. 6.63%, p -value=0.066, respectively). The reoccurrence rate for dermaPACE patients was 7.7% compared to 11.6% in the control group (p -value=0.490).

For device and supply ordering, refurbishments, technical support, and customer service, please email order@sanuwave.com or call 770-419-7525.