SANLIVAVE[®] Healing today. Curing tomorrow.

The Pulse

Newsletter, Summer 2019



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Happy Summer SANUWAVE® Community

The graph to the right is what drives our bold goal to "have our dermaPACE® System available anywhere and everywhere a diabetic foot ulcer (DFU) is treated". As shown, ~70% of patients that have an amputation due to DFU die within 5 years. This is simply unacceptable! SANUWAVE® is committed to changing this trend and we are well on our way towards achieving.



-Shri Parikh, President

Our Growing SANUWAVE® Family



Pictured, left to right: Anthony Stegagno, Cary McGhin, Sharon Grantham, Andre Mouton, Mary Beth Rogers, Jan Prainito, Shri Parikh, Pete Stegagno, Alina Clerie, Lisa Sundstrom, David Cummings, John Jackson, Kevin Richardson II, Richard Johnston, Susan Weins, Lorraine Bittinger, Patrik Bordovsky.

SANUWAVE® EVENTS

October 12-14, 2019 SAWC FALL

October 17-19, 2019 DFCON

December 5-8, 2019 Innovations in Wound Care

An Update on SANUWAVE®-sponsored Clinical Investigations

The dermaPACE[®] System is by far the most studied shockwave device on the market. Beginning in the early 2000's, animal and lab studies were prolific and helped to establish our early understanding of the dermaPACE[®] System's effects on blood perfusion, inflammatory effects, and upregulation of growth factors to name just some of the more important effects of treatment. This all led to our two Phase III U.S. clinical trials comparing the effects of the dermaPACE[®] System and Standard of Care vs. Standard of Care only in the treatment of diabetic foot ulcers (DFU).

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Clinical Update, continued

...Continued from front page

These trials helped us gain a solid understanding of how DFU respond to Pulsed Acoustic Cellular Expression (PACE[®]) treatment: increased perfusion, reduction in inflammation, accelerated wound area reduction and wound healing. With these results, we are now able to offer the dermaPACE[®] System to you. But we are far from finished. In fact, we've just scratched the surface in our plans for clinical investigations. Currently, we have three case series projects underway.

System to you. But we are far from finished. In fact, we've just scratched the surface in our plans for clinical investigations. Currently, we have three case series projects underway. SANUWAVE® is sponsoring a set of case series, currently being conducted at two sites, to specifically measure and monitor oxyhemoglobin and de-oxy hebased upon wound are duction and healing rate study and is expected to 2019.

moglobin levels before, during, and after a treatment regimen using the dermaPACE[®] System on DFU. Measurement of hemoglobin levels is via the Hyper-View device from HyperMed. We are currently about 50% complete in enrollment.

- University Hospital/Rutgers University (Newark, NJ) with <u>Dr. Mark Granick</u> and <u>Dr. Oscar Alvarez</u> as Principal Investigators.
- UCLA/Olive View (Sylmar, CA) with Dr. Aksone Nouvong as the Principal Investigator.

Concurrently, a similar case series is being conducted using the Kent Imaging device to measure perfusion levels. The study has enrolled approximately 50% of its target numbers.

• Kent State University (Kent, Ohio) with <u>Dr. Windy Cole</u> as the Principal Investigator.

In Poland, we are currently conducting an expansive evaluation on how varying the number of shocks,

based upon wound area, affects the wound area reduction and healing rates of DFU. This is a 60 patient study and is expected to be completed by the end of 2019.

All of this work is expected to springboard us into major follow-on work in 2020 including an advanced trial to further support treatment of DFU as well as early work for expansion of wound indications beyond DFU.

Finally, we are in the early stages of planning our Clinical Plate for 2020. Projects will include, but not limited to the following:

- \Rightarrow DFU 2
- \Rightarrow VLU 1
- \Rightarrow Combination therapies
- \Rightarrow Biofilm work
- \Rightarrow Inflamation work
- \Rightarrow Cosmetic
- \Rightarrow Cardiac animal work

Exciting developments are right around the corner. Stay tuned!

- Pete Stegagno, Chief Operating Officer



Spring 2019 Shows and Conferences

If you've been to any of the major medical shows and conferences in 2019, you may have seen SANUWAVE's exhibits. We have been very active in attending shows and symposiums, telling all interested about the benefits of the dermaPACE[®] System (and the orthoPACE[®] System in some international markets):

Korea International Medical and Hospital Equipment Show (KIMES, March 14—17, 2019): In March, SANUWAVE®, in cooperation with our exclusive Korean distributor, exhibited the orthoPACE® System at the Korea International Medical and Hospital Equipment Show (KIMES) in Seoul, South Korea. South Korea is a major market for SANUWAVE's orthoPACE® System. Our

presence in support of the distributors was greatly appreciated.

- Modern Wound Care Management, Greensboro, NC (April 26 -27, 2019): This event is a true interdisciplinary approach to wound care with input from multiple specialties. It is designed for more proactive audience participation and interaction with national experts in wound care, including physicians, podiatrists, nurses, physical therapists and other wound care modality providers.
- Symposium of Advanced Care (SAWC) Spring, San Antonio, TX (May 7 – 11, 2019): Traffic at our booth was high and our staff were eager and excited to talk to and educate the visitors on the dermaPACE[®] System.



Spring 2019 Shows and Conferences

Dr. Mark Granick and Dr. Oscar Alvarez (University Hospital, Rutgers University) presented in an Industry Supported Symposium at the Symposium of Advanced Wound Care. The title of the presentation was: "Explore the effects of high-energy acoustic shockwave therapy on local skin perfusion and healing of diabetic foot ulcers". This symposium addressed SANUWAVE's dermaPACE® System and:

- Investigated results of late-breaking clinical studies designed to observe/measure oxygen saturation levels in the area of treated wound before initiation of focused, high-energy acoustic shockwave therapy treatment, during treatment period, and post treatment
- Explored cases on the use of high-energy acoustic shockwave therapy for healing of diabetic foot ulcers (DFU)

This was well attended and audience participation in the Q&A section was high. We wish to thank both Drs. Granick and Alvarez for their enthusiastic support.

 International Symposium on the Diabetic Foot (ISDF), The Hague, The Netherlands (May 22 – 25, 2019). This quadrennial event is the largest and most prestigious meeting devoted to lower extremity problems in diabetes. Our participation in this event allowed us the unique opportunity to communicate with world renowned experts in wound care.

- European Wound Management Association (EWMA) Gothenburg, Sweden (June 5 - 7, 2019): The EWMA conference offered high-level scientific presentations, networking activities and was an excellent opportunity to exchange knowledge and experiences with international colleagues. We were fortunate in that many contacts made at ISDF were able to follow up with us a few weeks later here in Sweden.
- "The National" American Podiatric Medical Association (APMA), Salt Lake City, UT (July 11 14, 2019: This is "The National" for thousands of foot and ankle physicians, assistants, and related professionals. While providing diverse educational programs, the show also offered SANUWAVE® the opportunity to showcase the dermaPACE® System. Additionally, Dr. Windy Cole presented the dermaPACE® System in a didactic discussion and Drs. Cole and James McGuire performed a live demonstration.

Finally, SANUWAVE[®] will be announcing attendance at shows further into 2019, including Wounds Canada, SAWC Fall, DFCon, and Innovations in Wound Healing, among others.

- Pete Stegagno, Chief Operating Officer



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SANUWAVE[®] Customers Making News

Dr. Jayesh B. Shah discusses the dermaPACE® System in published and televised interviews

Recently, residents of multiple states, including Texas, Indiana, Michigan, Wisconsin and others, have had opportunity to catch a glimpse of SANUWAVE's dermaPACE[®] System in newspapers and online news sites, and on their local television stations. Thanks in large part to Northeast Baptist Wound Care Center Medical Director Dr. Jayesh B. Shah, who graciously sat down with San Antonio Express News for interviews spotlighting the dermaPACE® System, the story has been picked up by numerous other affiliate stations and their respective YouTube channels, including:

- * WNDU16 in South Bend, Indiana
- * News8000 in La Crosse, Wisconsin
- * ABC12 in Flint, Michigan
- * ABC's KSAT12, in San Antonio, Texas
- * WQAD Channel 8, in Moline, Illinois
- * 9&10 News in Northern Michigan
- * Local 3 (now known as upmatters), in Marquette, Michigan
- * Ivanhoe Broadcast News





Dr. Jayesh B Shah, Medical Director, Northeast Baptist Wound Care Center, San Antonio, TX

Over the course of the interview, Dr. Shah shares his views on the dermaPACE® System and the beneficial effects of SANUWAVE's proprietary Pulsed Acoustic Cellular Expression (PACE®) technology, stating, "This is a good alternative for patients who are not healing. ... You basically give 360 shocks for a minute, and it lasts two to four minutes, so it's not really complicated, it's pretty easy. It's completely brandnew technology. It's kind of breakthrough compared to what we had so far in wound care."

For now, Shah is one of a handful of physicians nationwide clinically evaluating the dermaPACE® System.



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SANUWAVE[®] Customers Making News

AZH President Dr. Niezgoda profiles the dermaPACE System

Dr. Jeffrey Alan Niezgoda, President, Chief Executive Officer and Corporate Medical Director of AZH, LLC, along with special guest, Ms. Sharon Baranoski, coeditor of Wound Care Essentials: Practice Principles, and author of more than 100 published nursing articles, profiled the dermaPACE® System as part of WebCME's Wound Information Network video series. The informative video is also available to view on the WebCME YouTube channel.

With the assistance of a technician, Dr. Niezgoda demonstrates the application of the dermaPACE® System's Pulsed Acoustic Cellular Expression (PACE®) technology on two diabetic foot ulcers (DFU) and a pressure ulcer (Note: at this time in the U.S., the dermaPACE[®] System is FDA cleared only for treating DFU. Treatment of other types of chronic wounds is currently off-label).

In the video, the dermaPACE® System is used in conjunction with a Kent Imaging Snapshot, a Near Infra-Red Spectroscopy (NIRS) imaging device used to measure the amount of oxygenated v. deoxygenated hemoglobin in the area of injury.



Kent Snapshot, comparing tissue oxygenation of wound after (left image) and before (right image) treatment with the dermaPACE[®] System.



Dr. Jeffrey Niezgoda, President, CEO and Corporate Medical Director of AZH, LLC

Images of the treated area were taken pre and post treatment with the dermaPACE® System. In the image prior to treatment, tissue oxygenation of the wound area was measured at 44%. Post-treatment, the same region displayed oxygenation level at 58%, showing an immediate, post-treatment increase of 14%! This is significant, because increases in tissue oxygenation and hemoglobin saturation have been shown to correlate with tissue perfusion and wound healing.

Dr. Niezgoda also believes that in addition to stimulating angiogenic factors and tissue perfusion, dermaPACE® treatment may also support antiinflammatory benefits, stating: "We've noticed overall reduction in wound inflammation when treating with the dermaPACE[®] system".

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SANUWAVE[®] Customers Making News



Eric J. Hanson, SANUWAVE® Patent attorney

SANUWAVE[®] patent attorney Eric Hanson interviewed on LAW360

SANUWAVE® patent attorney and all-around veteran patent expert Eric Hanson recently provided an interview for Law360 (a Lexis Nexis company), discussing his recent addition to Polsinelli PC. In the interview Hanson discusses representing SANUWAVE® and his role in the company obtaining more than 100 patents related to shockwave technology over a period of 10+ years.

To access the full Law360 interview, please click here.

Testimonials from the field

The dermaPACE[®] System, in the hands of clinicians

When Drs. Olson, Tomassi and Weily, of Bay City Associates in Erie, Pennsylvania read about the dermaPACE[®] System, they immediately wanted it for their clinic as their patient population has a tremendous prevalence of diabetic foot ulcers (DFU).

The physicians have been using the device since early June and as you can see, Dr. Olson gives the dermaPACE[®] System the Thumbs up! The doctors are "PACE-ing" every DFU they see and are extremely impressed with how quickly every wound responds.

In addition to his private practice, Dr. Weily is also working on placing the dermaPACE® System at a local clinic so he can further use PACE® technology to promote faster healing on his DFU population.

- Lorraine Bittinger, Clinical Affairs Manager - Mary Beth Rogers, Area Sales Manager, PA



Dr. David Olson and RN Constantino, of Bay City Associates in Erie, PA, aiving an enthusiastic thumbs up review to the dermaPACE[®] system

Employee Spotlight



Mary Beth Rogers Area Sales Manager PA

Mary Beth Rogers is a veteran of wound care sales. She began her career at Healthpoint, where she excelled selling into both long term care and acute care markets. She also has experience with other well-known companies,

including SteadMed Medical, Mimedx and Hollister. Having a passion for new technology and always up for a challenge, she was immediately drawn to SANUWAVE[®] and has been quoted as saying "you had me at perfusion"!

She is most excited about the dermaPACE[®] System and its ability to help the body heal itself and confident that this technology will soon change the standard of care.

"The most exciting and encouraging things about being part of SANUWAVE® is the absolute commitment the company has made to help the millions of people suffering with chronic wounds and the integrity of the people who work there. This company is doing things the right way for the right reasons and the team is made of solid professionals.

In 17 years of sales, I have never seen such a positive and quick reaction to a device. Physicians and clinicians are tired of using outdated and over-priced technology that doesn't really do anything. Patients, physicians and clinicians are so excited to see results in as little as 1 treatment and they are telling their friends. This is a total game changer!"



Sharon Grantham Clinical Trainer NC & SC

Sharon has been a nurse for over 32 years, and has held many different roles within the industry; however, throughout each role she has taken on, the irreplaceable connection to the pa-

tient has stayed consistent. It is this connection that has brought her to SANUWAVE® and its flagship product, the dermaPACE® System. As she explains, "Each year due to diabetic foot ulcers (DFU), there is a loss of two million workdays per year, at a cost of approximately <u>\$300 million in lost productivity</u>. SANUWAVE's focused shockwave therapy can significantly reduce that number".

Sharon continues, "There is an indescribable feeling of accomplishment when I hear one of our evaluating physicians say, 'Hey, you all have something here'. While laud from physicians is encouraging, what keeps me determined is when patients who have been treated with our technology say, 'every Tuesday morning feels like Christmas morning because that is when the nurses unwrap my bandages and I see that my foot ulcer for so many years is finally healing'. It is statements such as these that motivate me to place the dermaPACE[®] System into as many doctor's offices and wound care clinics as possible. My dream for those suffering from DFU is for SANUWAVE's Pulse Acoustic Cellular Expression (PACE®) technology to be synonymous with 'Standard of Care' for chronic wound treatment."

Employee Spotlight



David Cummings Area Sales Manager NC & SC

David has been in medical device sales since graduating college and in wound care for the past 12 years. He believes that wound care has been where he has been able to make the most impact on patient

outcomes.

Asked about his thoughts on the dermaPACE[®] System, he replied, "SANUWAVE[®] can make a real difference in treatment of diabetic foot ulcers (DFU) and help not only to close the wound faster but save lives. Most people are not aware that the fiveyear mortality rate for a patient with a DFU is greater than one with many types of cancer. It is vitally important to get the wound closed quickly. If you can reduce the wound size by 50% in 4 weeks, that wound is much more likely to go on to heal. If a wound remains open for longer, it is more likely to get infected and could lead to amputation.

The key here is to understand that SANUWAVE's dermaPACE[®] System is a tool that can help assist in wound closure. When used in conjunction with offloading and other advanced modalities it will help get the wound healed faster. Studies show we are on a time clock to heal, and the faster we can achieve wound closure the better the chance is that the patient goes on to live a more fulfilled life."



Craig Jones Sales Consultant TX

Craig is an independent representative in Texas who works with companies in the podiatry, wound care and orthopedic markets. He has tremendous experience in both the wound care and shockwave therapy markets for musculo-

skeletal pain.

With over thirty years of experience with medical devices, Craig is well positioned to aid SANUWAVE[®] in its efforts to commercialize its novel Pulsed Acoustic Cellular Expression (PACE[®]) technology.

Asked about his recent addition to SANUWAVE[®] and his role in expanding the dermaPACE[®] System in the Lone Star State, he says, "I am very excited to be able to help bring this technology to the market. It's rare that you get the opportunity to introduce something so novel that is supported with published clinical proof of efficacy. With this technology, SANUWAVE[®] will play a major role in the wound care market and establish itself as a lead influencer of patient treatment far beyond Diabetic Foot Ulcers (DFU)".



SANUWAVE[®] HR Corner—Open Positions



SANUWAVE® IS HIRING!

SANUWAVE[®] is looking for experienced and driven professionals to join our growing team. If you have energy, passion and experience improving healthcare results for patients and clinicians alike then we'd love to hear from you!

SANUWAVE[®] offers employees a competitive total rewards package, an innovative experience and a dynamic team in the field! Additionally, we offer:

- Comprehensive Medical, Prescription Drug, Eye and Dental Coverage
- Company-provided Life Insurance, Long Term and Short Term Disability Insurance
- 401(k) Plan
- Paid Vacations
- 9 Paid Holidays

If this sounds like the right culture for you, we invite you to apply with us by sending your resume to <u>recruiting@sanuwave.com</u>.

Open Positions:

(Click on Position Title for in-depth description)

- Area Sales Manager
 - * Chicago, Illinois
 - * New York
 - * Massachusetts/New England
- <u>Clinical Account Manager</u>
 - Houston TX
 - * Dallas, TX
 - Chicago, Illinois
 - New York
 - Massachusetts/New England
- Software Engineer

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