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UPCOMING EVENTS CALENDAR

NYSPMA "NY20"
January 24-26, 2020

2020 PRESENT Treasure Hunt, Los Angeles, CA
Feb 8 -9, 2020

AAWC Pressure Ulcer Summit, Atlanta, GA
March 26-28, 2020



The Holiday Issue



To our loyal SANUWAVE Friends,

Greetings and Happy Holidays! As we welcome and celebrate the start of a new decade, SANUWAVE is positioned well for continued channel growth and success. Much of 2019 was focused on commercialization in the US and select international markets, where DFUs continue to climb stressing why the urgency of our dermaPACE® technology is needed. Many of our investments in processes, in areas of Quality, Systems Management, Manufacturing and Distribution position SANUWAVE for disciplined growth moving forward. This *Pulse* newsletter shares specifics in these respective areas. 2019 was a foundational year, where commercially we clarified and proved the merits of our technology and the cost-effectiveness of it. Looking forward to 2020, our learnings to date, improved market access and reimbursement channels will further support our expansion and road to profitability.

Hope you enjoy this edition of *The Pulse*. All of us here at SANUWAVE thank you for your loyalty, support and for being a part of our growing community. Best wishes for through the holidays and CHEERS to 2020.

- Shri Parikh, President



Clinical Update



SANUWAVE is in full commercialization of the dermaPACE® System

We've swung full circle and are now laying out our clinical research pathways for the near and long term. The dermaPACE® System is by far the most studied shockwave device on the market. We have a comfortable understanding of the product's mechanism of action in wound healing thanks to ground breaking work performed by Dr. CJ Wang at Kaohsiung Medical Center in Taiwan and by a team led by Dr. Maria Siemionow at Cleveland Clinic. These works - encompassing lab, animal and human 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.

In consultation with key opinion leaders (KOLs), we are continuing to further quantify the effects

that Pulsed Acoustic Cellular Expression (PACE®) technology has on wound healing.

SANUWAVE is sponsoring a set of case series to specifically measure and monitor oxyhemoglobin and de-oxy hemoglobin levels before, during, and after a treatment regimen using the dermaPACE® System on diabetic foot ulcers (DFU). Measurement of hemoglobin levels is via the HyperView device from HyperMed.

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

Preliminary findings suggest that treating chronic DFUs with the dermaPACE® System induces an acute inflammatory response leading to an increase in periwound skin temperature combined with a spike in Oxy-Hb and O2Sat 60 minutes following treatment.

Clinical Update, continued

A trend showing rise in TcPO₂ and O₂sat is also evident as early as the first treatment and out through the 8th and last treatment.

Concurrently, Dr. Windy Cole at Kent State University is conducting a case series to similarly measure and monitor tissue oxygen saturation levels before and after a treatment regimen using the dermaPACE[®] System on DFUs. In this case, measurement of hemoglobin levels is via the Snapshot NIRS device from Kent Imaging. The ongoing series reported wound improvement as measure by wound area reduction and increased granulation while also exhibiting an improvement in tissue oxygenation by 17.3%. To date, 10 patients have been treated, 4 with complete healing during the 5-week period and 6 with substantial wound area reduction.

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 DFUs. This is a 40-patient study. Professor Doctor Tomasz Banasiewicz from the Department and Clinic of General, Endocrinological and Gastroenterological Oncology, Poznan University of Medical Sciences, Poznan, Poland is leading this study to assess in DFU patients the effects of three (3) different regimens of shockwave pulses delivered in up to ten (10) treatment sessions. The early results have shown strong wound area improvement in 16 of the 19 enrolled patients. The study is expected to enroll over 40 patients when com-

pleted and assist in an optimized dosage to be used by dermaPACE[®] System for the treatment of DFU patients.

At Northwestern University, Dr. Robert Galiano and Dr. Chitang Joshi are developing models to study the effect of PACE[®] technology in the reduction of hypertrophic scarring. This work is expected to begin in earnest in early 2020.

Just as exciting is the enthusiasm we are seeing from our early adopters in the commercialization/placement program for the dermaPACE[®] System. Early feedback is showing that the dermaPACE[®] System is performing even better than seen in the earlier Phase III trials. We have a band of KOLs who are proposing a wide range a new and innovative investigative work to better understand. In early 2020, SANUWAVE will be developing a comprehensive investigative program encompassing the furthering of our understanding of the mechanism of action in wound healing, expanding our understanding of the effects on DFU, looking at expanding our indications into other types of wounds as well as other types of skin conditions. We are fortunate to have over 100 current sites using dermaPACE[®], many of whom will also be excellent research sites. If you haven't yet jumped onto the dermaPACE[®] bandwagon, it's never too late to start. See you in 2020!

Pete Stegagno - Chief Operating Officer

SANUWAVE[®]

Healing today. Curing tomorrow.

International Update

SANUWAVE has had an exciting quarter on the international front.

Brazilian Joint Venture

In early November, SANUWAVE signed a term sheet for a Brazilian joint venture for the dermaPACE® System with IDIC Group of São Paulo, Brazil and the deal is expected to close in December 2019.

The joint venture anticipates receiving regulatory approval for the dermaPACE® System from ANVISA (Agência Nacional de Vigilância Sanitária), the National Health Surveillance Agency of Brazil, in the third quarter of 2020. Shipment of the first dermaPACE® Systems will occur shortly and training will occur in January 2020. shortly and in the fourth quarter of 2019, to be followed by local KOL case work in early 2020. In fact, IDIC Group recently received a commitment for dermaPACE® System case work and publications

from one of the most important DFU specialist in Brazil, [Dr. Luis Clemente Rolim](#), professor and head of the DFU Ambulatory at the UNIFESP School of Medicine and the leader of the DFU section of the Brazilian Society of Diabetes.

IDIC Group is a group of primarily senior pharmaceutical and medical device industry executives and investors from Brazil, the United Kingdom and the Czech Republic that was formed to create and finance the local partner operation for the SANUWAVE Brazil joint venture. The group includes Morningside Holdings Pharmaceuticals Ltd., the investment division of the Morningside group of companies in the U.K. and is led Daniel Feliciano Ferreira. Mr. Ferreira possesses 20 years of experience in the pharmaceutical industry and most recently served as the Portfolio and Alliances Director Latin America for Abbott, where he was responsible for product introductions and alliance management in Latin America. He is also Managing Director of Synova Licensing



Left to right: Daniel Feliciano Ferreira, Lilliane Victoria, Mauricio Grimoni, Kevin Richardson, Dr. Luis Clemente Rolim

International Update, continued

and Access, a Synova Health business unit. Synova Health is a leading CRO in Latin America.

Partnership in Oman

In October, SANUWAVE entered a distribution partnership with Taiba Healthcare (“Taiba”), a leading healthcare marketing, distribution and retail pharmacies group in the Sultanate of Oman with regional operations, Taiba ME and Taiba KSA that serve the Middle East markets.

SANUWAVE sponsored and attended the Global Diabetic Foot Course in Muscat, Oman from November 7-10, 2019 with our partners in the region, Taiba Healthcare and MenaCare.



The dermaPACE® System Approved by Costa Rican Ministry of Health

The dermaPACE® System was recently approved for use by The Costa Rican Ministry of Health. SANUWAVE’s joint venture partner for Central America, Tarbaca Lightning, managed the registration process and is now preparing to commence KOL case work in January.

Tarbaca is the distribution company in Costa Rica for Latin America Pharma Supply Inc., a company that was formed in 2005. Latin America Pharma Supply specializes in the distribution, import and export of medical devices and pharmaceutical products in the Latin American region. Latin America Pharma Supply is a consolidated company which possesses its own sale force, marketing personnel and customer service. Latin America Pharma Supply is led by Gustavo Di Mare who possesses over 20 years of experience in the Latin American medical markets. He has held senior executive positions with several multinational companies, such as Bristol Myers Squibb’s ConvaTec division, holding the office of General Director of the Latin American region.

- Michael Hubert, VP of Strategy, Business Development, & International Partnerships

R&D Update

SANUWAVE Makes Significant Strides in 2019 in Continuously Growing Its Patent Portfolio

Innovation is a proud trait and competency we aim to foster here at SANUWAVE. The company continued to improve its patent portfolio with important additions in both medical and non-medical arenas. The new patents that were approved this year are:

US 10,238,405 titled “Blood Vessel Treatment with Intracorporeal Pressure Shockwaves” that has 8 claims related to the construction of a catheter-based shockwave system for intracorporeal use. The target market for such system is for cardiovascular and endovascular applications to treat blood vessels plaques, to stabilize vulnerable plaques, to promote accelerated blood vessel wall healing after angioplasty or stenting, to treat in-stent restenosis, and aneurysms, to name just a few.

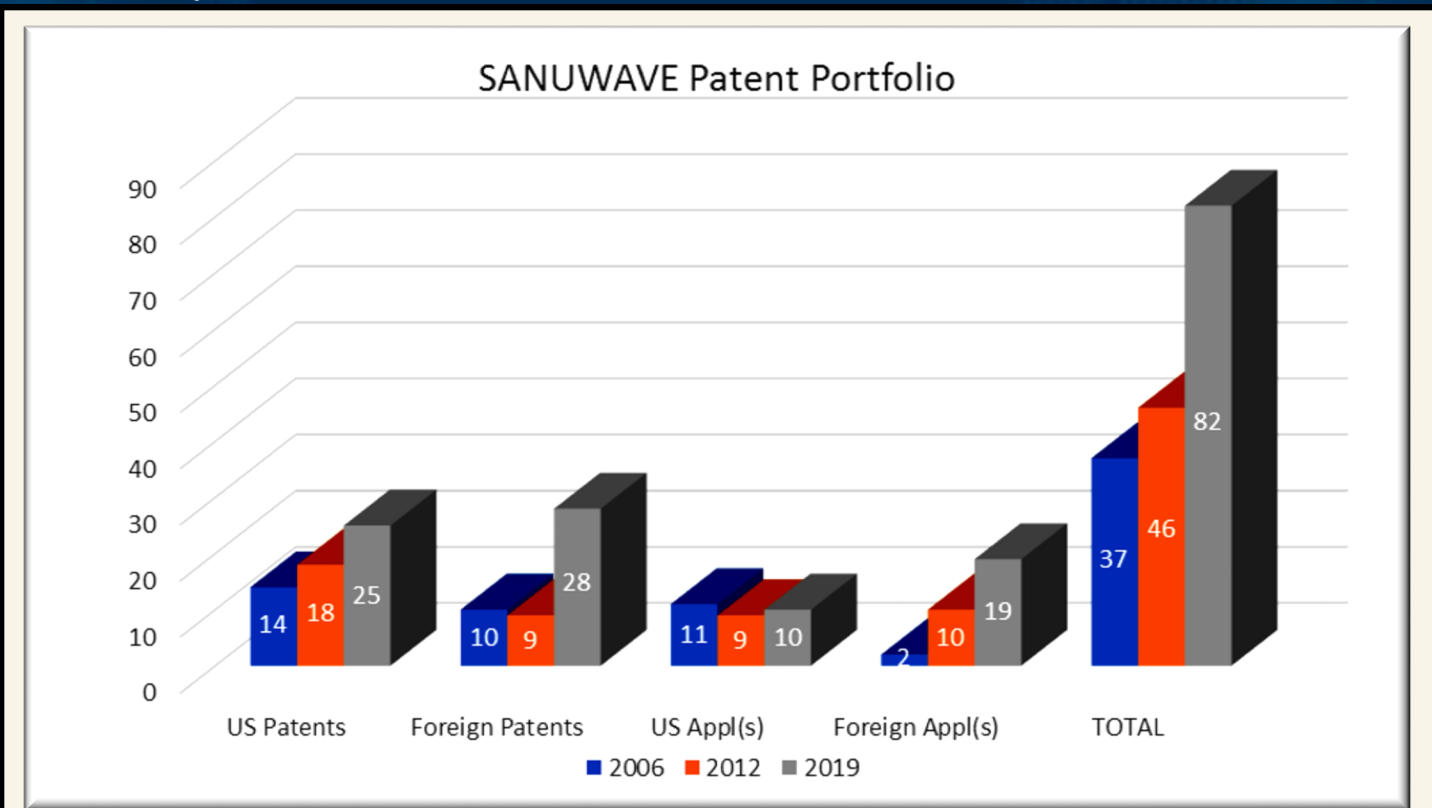


- *US 10,246,349 titled “Water Desalination Using Freeze Crystallization and Acoustic Pressure Shock Waves” that has 13 claims related to the system and method used to desalinate salt water by cooling the salt water to produce slush and then apply*

shockwaves to rapidly move upwards the ice crystals containing pure water from the slush and thus recovering water from the brine. The shockwaves are used to expedite the process of ice crystals separation from brine using shockwaves unidirectional acoustic streaming forces, which make the process feasible and cost-effective to be applied on a large industrial scale.

- *US 10,378,314 titled “Shock Waves for Pipe Cleaning” that has 19 claims related to the methods of cleaning internal deposits, occlusions, and ice plugs on the interior of pipelines for oil, gas, and water, when a shockwave system is moved internally through the pipeline or externally on the outside of the pipeline. This patent covers the use of shockwaves as part of a pig system modules that can be used to clean the pipeline by moving the pig inside of it. The external approach is about a robotic system that moves outside a pipeline and send shockwaves through its wall to clean deposits, occlusions, and ice plugs, especially for the underwater pipelines.*
- *US 10,457,571 titled “Membrane Cleaning and Desalination with a Membrane Using Acoustic Pressure Shock Waves” that has 20 claims related to the system and method used to unclog or prevent clogging of the membranes in general and specifically for those used in desalination processes. Applying shockwaves continuously or intermittently to the membranes, can extend their operation life with significant implications in reducing process time, diminishing of necessary infrastructure, reducing installation maintenance costs, with an environmentally friendly approach.*

R&D Update, continued



- For the patent application US 15/353,216 titled “Systems and Methods for Separating Heavy Water from Normal Water Using Acoustic Pressure Shock Waves” SANUWAVE recently received the notice of allowance from US Patent Office. This has 20 claims allowed related to the system and method used to separate nuclear plant heavy water from a mixture of heavy water and normal water. The actual separation is done by cooling the mixture to produce a slush and then apply shockwaves to rapidly move heavy water ice crystals downwards from the slush and thus recovering the normal water on the top and the heavy water at the bottom of a dedicated process container/tank..

SANUWAVE was founded in 2006 and started with a total of 37 patents and patent applications. In 2012 the active patent portfolio increased to 46, which represents a 24% increase.

In 2019 SANUWAVE’s active patent portfolio reached a total of 82, which represents an increase of 2.22 times from 2006 and 78% from 2012. The distribution among US patents, foreign patents, US patent applications, and foreign patent applications is presented in the following graph.

Interesting to note that SANUWAVE from its incorporation until now constantly increased the US patent presence and lately is getting a much better coverage of international markets such as Canada, South America, Europe, Middle East, and Far East/Asia.

For the future, SANUWAVE will continue to be committed to the effort of protecting its technology for diverse applications in the medical and non-medical fields, which significantly enhances the intangible assets of the company.

Regulatory Update

SANUWAVE's 2019 Year End Focus on Quality

2019 has been an exciting year for all of us here at SANUWAVE. We started the year 2019 by re-vamping our Quality Policy with superior quality being our focus. With our focus centered around providing a superior product and experience to our customers, investing in our employees, and organically growing, we set our sights on and accomplished the following tasks:

- The company, The communalization and placement of the dermaPACE® System in the United States,
- Increased employee headcount and retention
- Successfully completed the certification process to obtain the ISO 13485:2016 Medical Device International Certification.
- Successfully completed a week-long Korean FDA Inspection, and
- Successfully Certified to the MEDICAL DEVICE SINGLE AUDIT PROGRAM (MDSAP).

All these achievements support our commitment to and focus on "SUPERIOR QUALITY".

Leon Lambry: Director of Quality and Regulatory Affairs, SANUWAVE, INC.



Clinic Spotlight

Dr. Anna Sanchez & Dr. Michael Roth, NEW STEP PODIATRY

SANUWAVE is proud to spotlight New Step Podiatry, in San Antonio, TX. <https://sanewstep.com/> The clinic's two locations have been using the dermaPACE® System to treat patients with diabetic foot ulcers for over 7 months with remarkable success.

New Step Podiatry is owned by Drs. Anna Sanchez and Michael Roth, both of whom have been practicing podiatrists for over 20 years.

Dr. Anna Sanchez specializes in wound care with a primary focus on diabetic foot wounds. When you meet Dr. Sanchez, the passion for her work and the compassion for her patients is awe inspiring and highly infectious. Whether through research, websites, vendors or just plain word of mouth, Dr. Sanchez is always searching for the next technology, product or therapy that will benefit her patients. She says, "I could have owned 3 homes with as much money as I have spent on equipment, devices, therapies and products for my patients. But I like it this way and wouldn't have it any other way. It is ALWAYS about the patient. We have to stop the high rate of amputations."

SANUWAVE did not call on Dr. Sanchez; She researched SANUWAVE and wanted to use the dermaPACE® System right away. She had used SANUWAVE's orthopedic device years ago and knew of the amazing benefits of focused shock-wave technology.

Dr. Sanchez and her incredible staff were the first physician office in the U.S. to successfully com-



plete SANUWAVE's Foundational Competency in the Safe Use of the dermaPACE® System. I was honored and proud to present the clinical staff with Certificates of Evaluation during their Annual Employee Appreciation Luncheon.

Dr. Sanchez has built a large referral network, with over 100 physicians that refer their patients to her with many different foot and ankle conditions such as bunions, hammertoes, plantar fasciitis, and more. However, most of her clinic time is spent treating patients with diabetic foot ulcers where she continues to implement a patient specific plan of care that is healing wounds at a phenomenal rate. She credits this increase in healing rates to using the dermaPACE® System and its ability to increase modulate inflammation, increase perfusion and new capillary formation. As per Dr. Sanchez, dermaPACE is revolutionary!

Currently, Dr. Sanchez is treating over 70 patients with diabetic foot ulcers weekly with the dermaPACE® System.

- Ellen (Lorraine) Bittinger, Clinical Manager

SANUWAVE New Hire Spotlight



*Gloria Keehn
Clinical Account
Manager, PA*

Gloria started at SANUWAVE in mid-August as a Clinical Account Manager. Gloria's passion is wound care, having spent most of her career working as a Certified Wound, Ostomy and Conti-

nence Nurse.

Since becoming a WOCN, she has gained wide-ranging experience from working in various roles both in healthcare and industry. She has garnered experience at ConvaTec in clinical research, project management and clinical sales support. Her most recent position as a program director at a busy outpatient wound care center provided additional preparation for her new role at SANUWAVE.

Gloria is most excited about being at SANUWAVE because she believes that the dermaPACE® System will be life changing for diabetic patients. Given the results of the clinical trials on the dermaPACE® System and the anecdotal clinical results we are seeing today, patients will be able to return to their normal quality of life quicker with fewer reoccurrences. It is so gratifying to be part of a company whose mission statement speaks of a commitment to create a brighter future by providing novel and cost-effective solutions, focused on societal needs with the sole purpose of bettering lives everywhere. It's an exciting time in wound care".



*Michael Hubert
VP of Strategy, Busi-
ness Development &
international part-
nerships*

Michael came on board in September, and joins us from Universus Global Advisors, a firm he founded in 2014, that provided strate-

gic solutions to medical product companies seeking market entry and growth in Brazil and other Latin American markets.

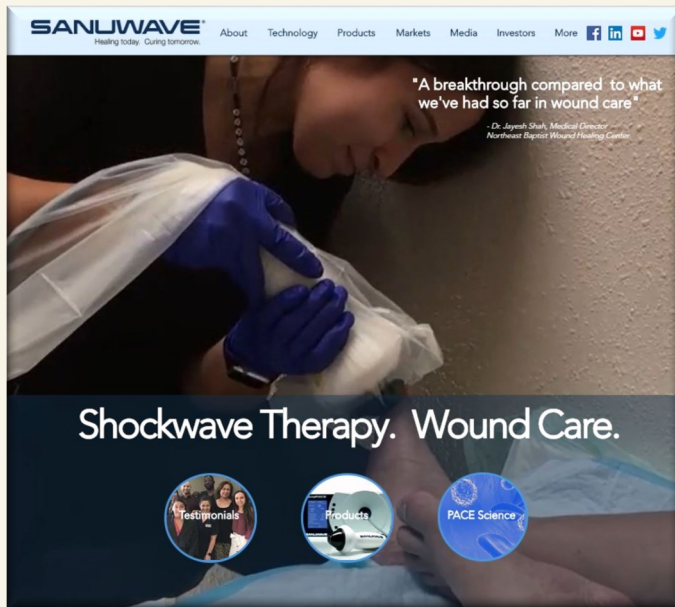
Michael possesses over fifteen years of strategy and transactional experience across Fortune 100, startup and early-stage company settings. He has cultivated, structured and negotiated numerous domestic and international transactions including licensing agreements, joint venture partnerships, distribution alliances and strategic equity investments.

Born and raised in Chicago, Illinois, Michael holds a Bachelor of Science degree in Finance from Arizona State University and a Master of Business Administration degree from Southern Methodist University. An avid sports fan, Michael now lives in Atlanta with his fiancée Ingrid and his two children, Zach, 19 years old who is a sophomore at the University of Georgia and Elena, age 16, who is a junior at Grady High School in Atlanta.

SANUWAVE Marketing Update

SANUWAVE Website Redesign

SANUWAVE is excited to announce the upcoming launch of its updated and fully revised website! The community spoke, and we Listened!



Starting in early January 2020, visitors to www.sanuwave.com will enjoy a wholly redesigned digital user experience that promises a smoother, simplified layout, intuitive navigation, responsive pages permitting viewing on both mobile and PC platforms, and several new, prominent, previously unavailable features, such as:

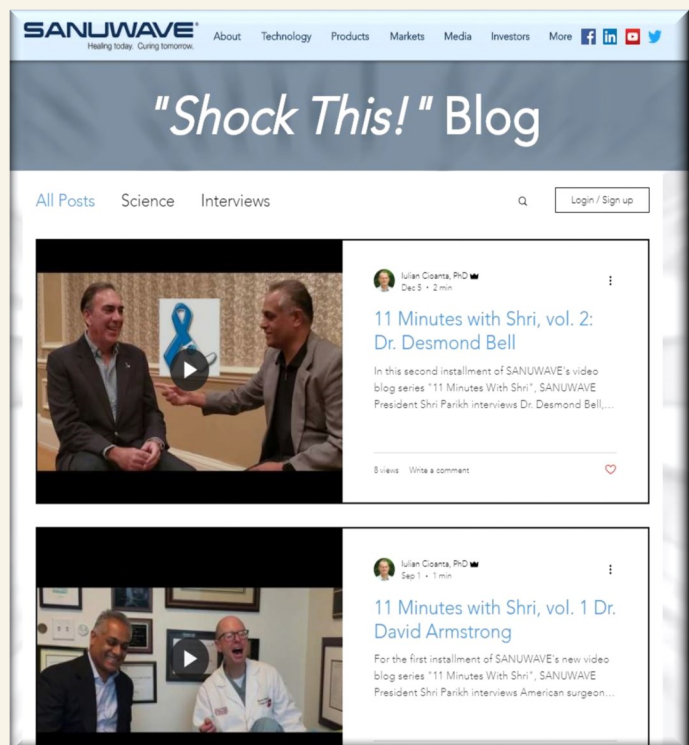
- Revamped Executive Management, Board of Directors and SANUWAVE Staff pages, enabling visitors to view the many real people and faces that make up the SANUWAVE family
- Dedicated Company News, Industry News, & Social Media News Feeds and Social Media Integration (Facebook, LinkedIn, Youtube, Twitter)
- Revised and updated Shock This! Blog with log-

in & comments option

- Interactive real-time map and location finder of U.S.-based clinics and wound centers providing treatment with the dermaPACE® System
- Clinicians and Key Opinion Leaders (KOLs) testimonials page
- 'Products' and 'Markets' tabs providing easy to follow information on SANUWAVE products and services
- Publications library and Poster Room, offering visitors access to SANUWAVE's robust archive of scientific literature on Shockwaves, PACE® Technology, and the dermaPACE® System.

And Much More!

The current redesign is slated to go live in a few short weeks, so be sure to check in to www.sanuwave.com often. We hope to see you there!



SANUWAVE® CEO Corner

Dear Santa,

We have been a good company this year. We met all our corporate goals. We have treated thousands of patients including many who would have had an amputation but the dermaPACE® System prevented that from happening.

We did all our chores like training, educating, and certifying users, attending tradeshows, and publishing peer reviewed articles.

For Christmas we don't want a whole lot as a company but here is our list:

5. Industry partners to work on combination therapies to help wounds heal better and faster
4. A new 3D printer for our R&D team
3. A heating and A/C system that works on the weekends
2. International deals that close when expected
1. One of those baby Yoda dolls. For the office.



From all of us at SANUWAVE, wishing you a wonderful holiday season and a happy new year!

SANUWAVE

Kevin A. Richardson II, Chairman & Chief Executive Officer, SANUWAVE