

AVACEN Medical is bringing to market their FDA-cleared Class II Thermo-Therapy Medical Device that Increases Systemic Microcirculation and provides Pain Relief



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Interview conducted by:
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CEOCFO: *Mr. Muehlbauer, what is the idea behind AVACEN® Medical?*

Mr. Muehlbauer: AVACEN Medical has developed and manufactures a unique FDA-cleared Class II medical device that increases systemic microcirculation in the human body. **AVACEN** stands for **Advanced VAscular Circulation ENhancement**.

CEOCFO: *Why do we want to do that?*

Mr. Muehlbauer: When you are over forty years old, it is said that about eighty percent of people have a compromised microcirculatory system. The vessels comprising microcirculation are between 100 and 10 micrometers in diameter and make up around eighty five percent of the vascular network in your entire body, so it is a very important network. As you get older, the amount of blood, or the profusion, in the microvascular system declines and it continues to decline until you die. Microcirculation is the final step to delivering oxygen and nutrients and removing waste from the cells.

CEOCFO: *What have you developed to help in this process?*

Mr. Muehlbauer: We have developed a patented process called **The AVACEN Treatment Method**. It is used by a family of devices called the AVACEN 100 and the AVACEN PRO, which infuse heat into a circulatory system to elicit capillary function. By getting the capillary function to engage we can increase microcirculation throughout the entire body.

CEOCFO: *How would someone use the devices?*

Mr. Muehlbauer: The AVACEN device is easy to operate. Even though it takes a single button push, the device has an operating system made up of over 4,000 instructions which controls and monitors the highly complex AVACEN Treatment Method. Either hand is placed into the device which is actually a small vacuum chamber and rests palm down on a thermal exchange pad for 10-30 minutes.

Most regimen protocols suggest use after waking and prior to going to bed, or when needed for pain. Our recommended wellness protocol is fifteen to twenty minutes twice a day; first thing in the morning and then at night before you go to bed. Because you can multitask using our device you can work at your computer, drink your tea or read a book while enjoying our relaxing treatment.

CEOCFO: *Would this affect various areas in the body that hurt?*

Mr. Muehlbauer: Because we are increasing the temperature of the blood, it is also warming muscles allowing them to become more relaxed. Therefore, in areas where muscles are tight and pinching on nerves or vascular systems, when those muscles relax then the pain associated with those pinched nerves will normally dissipate.

Microcirculation is highly responsive to, and a vital participant in, the inflammatory response, enhancing the delivery of inflammatory cells to the injured/infected tissue setting the stage for tissue repair and regeneration. Because we increase microcirculation, we can reduce the pain from areas of the body that are in need of healing.

CEOFCO: *Is this something people use at home or is this done in a doctor's office?*

Mr. Muehlbauer: Right now, approximately twenty percent of our clients are medical clinics, doctor's offices, chiropractors, homeopathic and natural medicine doctors and the other eighty percent are people who have devices in their homes. We have the AVACEN-PRO device, which is a device that is used by healthcare professionals. The AVACEN 100 is our consumer device, which is priced much less.

CEOFCO: *For how long of a period of time will the AVACEN relieve the pain for example?*

Mr. Muehlbauer: It really varies according to the condition that the person has. In most cases it will last twenty-four hours or more. We had a lady in our office the other day and she used it at about one o'clock. She had just had an operation the day before and her pain immediately went away, but it came back at about ten o'clock at night. For people who are recovering from surgery, we recommend that they use the device every other hour for a half hour. On the first day after their operation they get by with just an over the counter pain reliever, so it is eliminating the need for opioids. Then the next day, if they continue to use our device, they will normally not need any pain meds.

I received an email last week from a seventy-two-year-old veteran, and he said he uses our device for thirty minutes, three times a day. Before he got our device, his mobility was restricted from bed to wheelchair and from his wheelchair back to the bed. The reason he wrote me was that he was able to again drive his car for the first time in a year after using our device for only two months. Therefore, it really varies for each person and what is causing their problem.

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CEOFCO: *I am guessing that you cannot over use it?*

Mr. Muehlbauer: You cannot over use it. That is the beauty of our device. We have people that use it, as I said, after surgery, for pain reduction. They use it every other hour for thirty minutes while awake.

CEOFCO: *What is the opinion of the medical community?*

Mr. Muehlbauer: It is much better than it was three years ago. Three years ago, when we introduced our device to the medical community, it was overlooked, because it was a concept that you have to take a little bit of time to understand; how can you put your hand in a device and have an effect in thirty minutes on plantar fasciitis in the foot. Unless you are willing to take time to understand our mechanism of action, it will be hard to believe. When their patients relay stories of how they have been helped by our device, the doctor will basically say, "Yes, go ahead, keep using it," but they do not bother to try and understand it. Now in the homeopathic area, we have got a great following. I continually get calls from homeopathic professionals who have heard about our device and they understand it right away! They always open to evaluating new and innovative processes.

CEOFCO: *What care do you have to take with the device?*

Mr. Muehlbauer: As long as you wear the hand mitt and protect the special sealing cuff there is really no special care or maintenance necessary. The mitt keeps the oil in your palm off the heat transfer pad, which will build up over time keeping the heat transfer pad clean and efficient. The mitt also keeps inside of the device clean and it because it covers the wrist, the sealing bladder that closes around your wrist to make a vacuum also stays clean and oil free which extends the bladder life.

CEOFCO: *What has changed as people have used it? Is it essentially the same device from day one or have you made some tweaks or learned a little bit over time?*

Mr. Muehlbauer: Yes, we are in version number seven. That came out at the end of 2016. Almost all the changes made to the device over the years have been to make it easier to operate. A one button push operation for an extremely complex methodology, or mechanism of action, is not an easy task. Today the device has over four thousand firmware instructions which is over 30% more than before. One of the bigger changes is that we moved from using heated water to electricity back in 2014.

CEOFCO: *Are you seeing more interest due to the opioid crisis?*

Mr. Muehlbauer: Everyone wants a drug free solution to pain and I think they are all very worried about becoming addicted to opioids. Those people who have been using opioids for their pain are seeing their prescriptions being reduced and they need another way to get relief for their pain. Therefore yes, when I think about it, that is correct. We do not

market the device for opioid reduction, but I think that most people who are looking for a drug free solution to resolve their pain issues understand that we fit that requirement.

CEOFO: *How do you market the device?*

Mr. Muehlbauer: That is a timely question! Up until last year, we marketed the device over the internet. To do this we had to go through a process with the FDA to get the device cleared as an over the counter (OTC) product whereby customers did not need a prescription before they could purchase. However, because it is an expensive product that goes from around four thousand dollars to seven thousand dollars for the professional version, we found it difficult to market it over the internet.

We ended up finding a group of healthcare professionals that had worked together in the past and they came together to form a company (NuLife Ventures) that only markets our device. I did not go with an existing medical device distributor because I wanted a one hundred percent focus on marketing our device. Not having to worry about marketing, releases me to concentrate on the six clinical studies we want to do. So now AVACEN Medical is a manufacturing, medical research and new product development company.

CEOFO: *How is business?*

Mr. Muehlbauer: Actually, it is great! We have two shifts working right now. Last Memorial Day people had to work all day to keep up with the demand, so business is great!

CEOFO: *Is this reimbursable or still not there yet?*

Mr. Muehlbauer: It is currently not reimbursable. There are some CPT codes that are used to get certain aspects for treatment reimbursed, but as for being able to have CMS pay for eighty percent of the device or third-party payers pay for 50 %; we are not there yet. The problem being that there is no predicate device that we can point to that does what we do. That is what the reimbursement people always look at. It is easy when they approve reimbursement for a device that is substantially equivalent to a currently reimbursed device. However, when it is something totally brand new like our device it creates a difficult challenge with obtaining reimbursement.

CEOFO: *Is cost an issue for potential customers?*

Mr. Muehlbauer: Yes, for some it is. But... almost everyone has a credit card and monthly payments are quite reasonable when compared to money they are spending on drugs and/or treatments that don't help. Even if they have spent all their money trying to resolve their pain issues, and there sure are a lot of people who have done that, when they find something that works, they will go out and they will find the money. They will go to their parents, they will go to their grandparents; they will even go to their neighbors to borrow the money if it will get them out of pain or drug free. What's a good night's pain free sleep worth... or just a good night's sleep?

CEOFO: *Would you tell us about your geographic reach today?*

Mr. Muehlbauer: We have product, in maybe thirty different countries right now. Distributor sales are primarily in the US and they are growing very quickly in Canada.

CEOFO: *What will we see a year from now?*

Mr. Muehlbauer: We will have a very large independent brand partner network globally and a new device for the EMS market.

CEOFO: *What, if anything, might our readers miss when they first look at AVACEN Medical?*

Mr. Muehlbauer: When we do our annual customer surveys, the quality of sleep is one of the highest benefits we get rated on! After that people miss that it's a family device with many great benefits. And finally, it's a wellness device with no side effects.

CEOFO: *Other than helping with various chronic and acute medical symptoms, what are you most proud of accomplishing with the AVACEN device?*

Mr. Muehlbauer: Achieving the 2017 European OTC Fibromyalgia Pain Management New Product Innovation Award alongside numerous Fortune 100 product innovation companies.

