

AVACEN 100 – A Drug-Free Alternative for Temporary Relief of Pain Associated with Chronic and Acute Medical Conditions



Thomas G. Muehlbauer
CEO

Interview conducted by:
Lynn Fosse, Senior Editor, CEOCFO Magazine

CEOCFO: Mr. Muehlbauer, what was the concept when you founded AVACEN Medical?

Mr. Muehlbauer: The concept for AVACEN, which is an acronym for **Advanced VAscular Circulation Enhancement**, grew out of doing research on migraines for my sister in law. My sister in law was one of many unfortunate people who suffer from migraines that are absolutely debilitating. While looking into ways to help her, I discovered a thyroid treatment protocol being used by a doctor that was raising core body temperature using T3 hormones, and the unexpected result was that his patients with migraines had some amazing relief. That put me on the track of understanding core body temperature which led me to some other research whereby putting the hand in a slight vacuum and transferring heat or cold into the circulatory system could influence core body temperature. I then found that for normothermic people, introducing heat into the circulatory system had some pretty widespread and exciting results. That led me on a journey trying to understand why nobody in medicine had figured this out. I came to realize that the primary purpose of raising core body temperature was to treat hypothermic people and get them to normothermia. When the body got to normothermia the job was done and there was no need for further research. Our AVACEN Treatment Method starts at normothermia, and that method has been

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AVACEN Medical

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patented. The good news was that I was able to help my sister in law while discovering a valuable technology at the same time.

CEOCFO: *What have you developed? What are you able to offer people right now?*

Mr. Muehlbauer: Today we have an FDA cleared class II medical device called the AVACEN 100 that is indicated for helping people with the temporary relief of minor muscle and joint pain and stiffness; the temporary relief of joint pain associated with arthritis, muscle spasms, minor strains and sprains; and muscular relaxation. We have just started marketing the AVACEN 100 which is taking us from a developmental stage company to a growth stage company.

CEOCFO: *Are there any potential side effects?*

Mr. Muehlbauer: The AVACEN 100 noninvasive treatment method, sanitary mitt and the relatively low heat transfer temperature minimizes potential safety problems. No serious negative side effects have been observed using the AVACEN Treatment Method (ATM) in over 60,000 treatments. We just finished a clinical trial about a year ago for fibromyalgia, and none of the patients in that trial reported any negative effects either. It's important to note that we cannot induce hyperthermia. The amount of heat that we infuse into the circulatory system is at a level that the body can naturally dissipate it.

CEOCFO: *Why would anyone hesitate?*

Mr. Muehlbauer: Our device is relatively expensive at \$3995 . But when you consider that the average health care costs for rheumatoid arthritis is \$8,700 annually it becomes inexpensive. Especially when you factor in the fact that the useful life of our device is five to ten years and it can treat more than one family member. Besides the cost, our mechanism of action is a concept that people do not really understand. The sales to date are a result of word of mouth from those who were introduced to our device by their doctor. Also it is not unusual to get an order from those reading the testimonials on our website. To be successful it's our job to educate our huge potential customer base. Even though we have just started our marketing there are days when we will get up to 4 orders.

CEOCFO: *How do the machines work?*

Mr. Muehlbauer: Simply place your hand into the AVACEN 100 for a comfortable treatment session. Session duration can range from ten to thirty minutes depending on needs. Easy to understand instructions are presented on the LED Display Screen. If you use the preset defaults, only a single button press is required! The AVACEN 100 works with the body's natural adaptations. It's easy to use, and noninvasive. It incorporates heat therapy and negative pressure to increase local circulation and infuse heat into a unique vascular network, located in the palm of the hand. Raising the blood temperature at this "single point treatment" (the palm) increases blood temperature throughout the body naturally via the circulatory system. This can benefit the entire body.

CEOCFO: *Would it be appropriate for a machine to be in a therapist's office for someone to go in and use?*

Mr. Muehlbauer: Absolutely. We have what we call AVACEN Treatment Providers. The device was actually developed and calibrated to use a patented mitt that you wear. For a clinic, you can enforce a sanitary protocol by having numerous people use the machine using the mitt. We have one cosmetic surgery clinic in Beverly Hills has every one of its patients use the AVACEN machine. We ship hundreds of mitts to this clinic every so often.

CEOCFO: *Are you working on reimbursement?*

Mr. Muehlbauer: Yes. The direction of reimbursement has really changed over the last couple years to focus on cost effective treatment versus a prescription for a non-experimental device. Economic benefits are king today. The good news for us is that is where we shine. Why wouldn't an insurance company with an arthritic patient reimburse a one-time cost of \$3995 for the AVACEN 100 versus paying about \$4,500 every year for medications, doctor visits and specialized treatments? Although this sounds like common sense, we know it will take a while to get our device approved.

CEOCFO: *You offer the first medical device with an internal game mode. Would you explain that?*

Mr. Muehlbauer: The AVACEN 100 is a sophisticated medical device incorporating over 3,000 firmware instructions supporting numerous innovations including an internal "Game Mode". This mode encourages users to complete their 10-30 minute therapy session, and also allows a therapist to monitor for proper device use during self-administered therapy. We designed this feature for a family member with attention challenges. The goal was to help him remain engaged while completing an unexciting 20 minute therapy session. Later we determined that this was also an ideal way to monitor the unattended use by therapy patients. In 'normal' mode, the device automatically turns off at the end of each session. In 'Game Mode', the therapist can simply look at the points accumulated to determine if the device was properly used. This optional Game Mode awards real-time points when the user keeps their hand properly positioned on the hand pad during the therapy session. Accumulated points are shown on the display panel. The better the hand position, the more points earned. If the patient's hand drifts too far off target, an alarm goes off and 10,000 points are lost. At the end of the therapy session the final score is displayed, along with the previous high score and a random encouragement message which relates to the performance achieved e.g. "*Major league performance! Wow*".

CEOCFO: *Are you funded for the rollout and push you would like to make, or will you be seeking partners or investment?*

Mr. Muehlbauer: We have moved from a development stage company where we were fully funded to a growth stage company where it is much more difficult to bootstrap. Over 90 percent of our \$3 million in development funding came from our customers. They would try the device, have impressive results, and their next question was if we needed any investment capital. Because these were mainly physicians, they had the money to invest and understood the value of what we had. Now that we have moved to a growth stage company, I will be looking for a more strategic investor although I still expect some level of investment

from new and existing customers. With FDA clearance, approved patents in the U.S. and Europe and inventory that we are selling. I hope the Angel community will reward us for the significant completed milestones we have under our belt.

CEOCFO: *What is the strategy?*

Mr. Muehlbauer: We see social media as a very efficient way to educate our market. Right now, we are trying out several different customer acquisition models and are looking at several national markets. One of them is in the chiropractic business, and another is assisted living. In the case of assisted living, we have found that people with arthritis pain will usually sleep much better if they use our machine before retiring for the night. Not only can the treatment provider charge a fee for treatments but they may experience a reduction in nighttime staff workload if their residents are resting more peacefully. The third area is in the massage area. In the last couple of years arthritis pain relief using massage has become very popular. We provide an additional low cost treatment method that can be implemented without additional staff or office space. While addressing the arthritis market we plan to work on getting FDA clearance for migraines and fibromyalgia (areas where we have some great anecdotal results). To do this we will need to conduct strong clinical studies in the areas of migraines and fibromyalgia. A recent AVACEN sponsored Fibromyalgia Study using 22 subjects showed a significant reduction in fibromyalgia tender point count, widespread pain index and symptom severity score after one month of treatment using our AVACEN Treatment Method (ATM).

CEOCFO: *How important is the drug-free aspect?*

Mr. Muehlbauer: The AVACEN 100 may be the answer for many people who need or prefer an easy to use, drug-free alternative for temporary relief of pain, which might be associated with a variety of chronic and acute medical conditions such as Arthritis. Besides avoiding the detrimental effect of possible damage to the heart or liver by some pain medications, additional reasons for this preference may include:

- Values or philosophical orientations
- Insufficient response to pain medications
- Pregnancy, nursing, or pre-pregnancy
- A history of pain medication overuse
- Age, specifically youth
- Insurance company dosage restrictions

CEOCFO: *Put it all together for our readers. Why pay attention today to AVACEN Medical?*

Mr. Muehlbauer: First of all, we have an enormous market. It is estimated that a total of one billion people suffer from pain associated with arthritis, fibromyalgia and migraines. Second, we can significantly reduce annual healthcare costs. And third, we have an innovative proprietary product. Our patents are very strong, and they are very broad allowing multiple therapeutic uses to alleviate symptoms associated with a circulatory, neurological, lymphatic, or endocrinal dysfunction, or any combination thereof.