

Non-Drug Treatment for Restless Legs Syndrome



Dr. Fred Burbank, M.D.
CEO

About Sensory Medical Inc.

Sensory Medical, Inc. (Sensory) was formed in 2009 after CEO, Fred Burbank, M.D., began to experience symptoms of restless legs syndrome (RLS). Dr. Burbank found relief from his RLS symptoms by getting out of bed, standing, and walking. Although his symptoms were gone, the physical act of standing and walking left him wide awake.

Dr. Burbank postulated that a device that could provide a counter stimulus to the dysphoric sensations of RLS - while a patient was still in bed - might relieve RLS symptoms and allow quick return to sleep.

Sensory developed the Relaxis™ vibrating pad and has tested the device in two clinical studies of 158 patients. The results of these two clinical trials are available in four medical journal publications at: <http://sensorymedical.com/clinical-results/>

Until the Sensory Relaxis vibrating pad was cleared for commercial use in late 2013 by the U.S. Food and Drug Administration (FDA), only drug treatments were approved by the FDA for the treatment of RLS.

Sensory has the “First in Class” - and only - device that the FDA states is “indicated to improve the quality of sleep in patients with primary Restless Legs Syndrome (RLS) through the use of vibratory counterstimulation.”

The Relaxis vibrating pad is a device, not a drug, and has none of the adverse effects of drug treatments. The only adverse effects reported for our device were a temporary worsening of RLS symptoms, leg cramping, tingling, soreness, pain and motion sickness, all of which resolved on their own.

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

CEOCFO: Dr. Burbank, what is the concept at Sensory Medical?

Dr. Burbank: Sensory Medical, Inc. (Sensory) was started to develop a non-drug method of treating restless legs syndrome, commonly referred to as RLS. The disorder has been known in the medical literature since 1672 when it was described by Sir Thomas Willis. It was further characterized by Karl-Axel Ekbom in 1945. As a result the syndrome is sometimes known as “Willis-Ekbom” disease.

The disorder comes on as an “attack.” I believe that these attacks originate in the brain when one is sleepy or asleep. When one is sleepy or asleep, awareness of the world outside the brain diminishes and internal communications between the thalamus and the sensory cortex begin. Attacks occur either at the time a patient is trying to go to sleep or when a patient is asleep and wants to stay asleep.

CEOCFO: How did you become interested in that area?

Dr. Burbank: I have the disorder myself, and I do not like drugs that influence brain chemistry. Therefore, I developed Relaxis to give my legs real sensations (vibration) at the time of an RLS attack. Vibratory sensations are sufficient sensory input to allow me to focus my attention on vibration and extinguish the unpleasant feelings of RLS that are occurring inside my brain.

CEOCFO: When you start to get an attack, are you able to get up and put on the device? How do the attacks occur and how easy is to get the solution in place on your legs to make a difference?

Dr. Burbank: The syndrome comes on as an attack of unpleasant sensations that originate in the brain and are projected by the brain to the legs. The legs of RLS sufferers are fine - their bones are fine, their arteries are fine, their muscles are fine. Their legs are not the problem.

When they are sleeping, the brain begins to disconnect from the outside world. One actually has very little sensory input coming into your brain when one is asleep or is about to go to sleep.

The dysphoric sensations of RLS arise in the brain and are projected by the brain to the legs. RLS sensations are difficult to describe. They are relieved momentarily by twisting, bending, flexing or rubbing the legs. They are relieved substantially by standing up. If, during an attack, one stands up and walks around a bit, the bad sensations just go away. But of course, then you are standing up, wide awake, looking at your bed.

I wanted to develop a device that generated real sensations that one could experience while almost asleep and still in bed.

We developed a pad that vibrates at different patient-controlled intensity levels. Vibration provides real sensations to allow the brain to focus on vibration and focus attention away from the bad sensations that are occurring in the brain during a restless leg attack.

To use the device, which is a pad about the size of the pillow but which is flat, one pulls it in the bed, placing it underneath one's thighs or calves, and turns Relaxis on.

The pad vibrates at whatever level the patient previously set it. After 30 minutes, vibration very slowly and gently turns off. It slows down gradually in order not to disturb and wake the patient.

The device is quite simple to use. You note that you are having an attack. You pull the pad under your legs, just push a button, and it starts. Then you focus your attention on the feelings coming from the pad instead of the feelings you are having from RLS.

People do not experience an attack from the syndrome every night; they get it some number 4 times per week. So some nights they do not need it and some nights they do.

“RLS is a very common disorder that robs people of sleep. It affects five to ten percent of the population. It is a very common problem. Relaxis pad had been cleared by the FDA as a safe and effective device for improving sleep. Relaxis does not involve drugs - so it has no drug side effects. The device is now being introduced in to the U.S. marketplace.”
- Dr. Fred Burbank, M.D.

CEOCFO: *Why is 30 minutes the optimal time?*

Dr. Burbank: We do not know if that is the optimal time or not. We chose that time based on preliminary work and on our clinical studies. We have four published papers in the medical literature. The studies all use 30 minutes of treatment followed by a ramp down period. There is nothing magic about 30 minutes, and there may be a better time frame, but that is the time frame we have studied.

CEOCFO: *What are the numbers? How many people tend to suffer RLS?*

Dr. Burbank: The syndrome is present in between five and ten percent of the population in the United States and about the same thing in Europe. We have the most information from those two large areas, so it is a large number of people. Ten percent of 300 million is 30 million and is the size of the entire population of Canada.

CEOCFO: *Have similar approaches to Relaxis been tried in the past?*

Dr. Burbank: There have been no approaches similar to our Relaxis device. No one else has proposed or studied the use of a counter stimulation device applied at the time of an RLS attack.

Some have thought that RLS is a disorder that requires brain drugs and chemicals, so that has been the primary direction for treatment research. We thought that something that would emulate or act like standing up and provide real sensory input during an attack, could work.

CEOCFO: *Did you test it on yourself first?*

Dr. Burbank: Oh yeah! I was the first subject in the world. I determined vibration intensity levels - how many and the type of motors needed to create vibration, and how it was controlled. I was the initial guinea pig.

CEOCFO: *How long has Relaxis been available?*

Dr. Burbank: We have finished the studies for our Relaxis device and finished our FDA clearance at the end of last year. Therefore, it is just now becoming available and we will begin to see commercial sales in September.

CEOFCO: *What segment of the medical community would typically treat RLS and are they on board with your solution?*

Dr. Burbank: There are two general areas of medicine that see patients with RLS. One of them is doctors who specialize in sleep medicine and operate overnight sleep centers. The other is general practitioners who have a number of patients in their practice that they have prescribed medicines for but who might prescribe a physical device in the future.

CEOFCO: *How do you reach the right people?*

Dr. Burbank: That is going to be a slow uphill journey for us. We need to deal with the doctors who are interested in sleep disorders. We also need to inform the public about alternatives of medication. We have professional education and public education to do.

CEOFCO: *You have certainly been involved in a number of ventures. What have you learned as to what to do and what not to do when you are bringing out a new product?*

Dr. Burbank: The first thing that is really required on a new product is to have clinical data that shows that the new device works and how well it works. We performed two double blind prospective clinical trials, compared our device to two different shams, and also used statistical methods to compare our device to the current drugs that are approved by the FDA. The bare minimum is one has to have clinical data that shows that the device works well and we in fact show that our device works and that it works to about the same degree at improving sleep as current RLS drugs work. The bare minimum needed is clinical proof that the device is effective. We also showed that our device is safe.

CEOFCO: *Do many people take drugs for RLS?*

Dr. Burbank: I do not know the frequency of drug use or whether there are folks out there who need help and do not get it. I believe that many RLS patients will seek a non-drug method of treatment. What happened was when the drugs were first introduced, there was a substantial amount of television advertising and that advertising helped a great deal in alerting the public to the fact that this is a distinct disorder and that may require treatment to improve sleep.

CEOFCO: *Will you be approaching the public directly with your product?*

Dr. Burbank: We will probably have ads directed to the public that are educational and that promote our product as a potential treatment.

CEOFCO: *What do you see as potential challenges?*

Dr. Burbank: One of the challenges is that since drugs have been shown to help RLS, people may think that RLS is exclusively a drug treatment disorder.

We need to teach them that a device can also help improve sleep.

CEOFCO: *Are you funded?*

Dr. Burbank: We have been funded from the beginning by the Salt Creek I fund, of which I am also a director.

CEOFCO: *Will you be working with partners, distributors or marketing firms and will you be handling it direct through Sensory Medical? What is your strategy?*

Dr. Burbank: We are just now developing our strategy and there will be different levels of marketing because there is not a single, simple marketplace in the sleep world. We are just developing our marketing plan. Once developed, we will work out a strategy for sales execution.

CEOFCO: *Put it all together for our readers, why pay attention to Sensory Medical and your Relaxis?*

Dr. Burbank: RLS is a very common disorder that robs people of sleep. It affects five to ten percent of the population. It is a very common problem. Relaxis pad had been cleared by the FDA as a safe and effective device for improving sleep. Relaxis does not involve drugs - so it has no drug side effects. The device is now being introduced in to the U.S. marketplace.

BIO: Fred Burbank, M.D. received his medical degree from Stanford University in 1968. He was an epidemiologist at the National Institutes of Health. He learned the principles of sleep medicine from Dr. William Dement, M.D., Ph.D. (the father of sleep medicine) during his Psychiatry Residency at Stanford University. Later, Dr. Burbank completed a residency in Diagnostic Radiology and a two-year fellowship in Cardiovascular and Interventional Radiology, both at Stanford.

He began developing medical devices in 1993 with the invention of a image-guided probe for extracting diagnostic quantities of breast tissue through a tiny skin opening – the Mammotome™. (Formerly Biopsys Medical, Inc., San Juan Capistrano, CA; then Johnson & Johnson, Inc., New Brunswick, NJ; currently, Devicor Medical Products, Inc., Cincinnati, OH).

He is an inventor and has many patents. His full CV is available at:
http://www.saltcreekmedical.com/images/profile/fred_burbank_cv.pdf



Sensory Medical Inc.

1235 Puerta del Sol #600

San Clemente, CA 92673

888-721-1117

www.sensorymedical.com