

Q&A with Dr. Leonard Schultz, Founder and CEO of Nascent Surgical, LLC bringing to market their marketed miniSQUAIR® that Captures Smoke, Nanoparticles and Bioaerosols in the Operating Room and now with a Smaller Footprint



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CEOCFO: *Dr. Schultz, it has been about a year since we have spoken, would you bring us up to date about what is happening now at Nascent Surgical?*

Dr. Schultz: Probably the most significant thing that I have noticed in the last year is that the source of requests for clinical trials and further information about our product is coming not so much from physician advocates or even individual nurses, but rather from the executive level, notably the strategic material managers. They seem to be the ones that are calling us now. It seems as though we have reached a new plateau in the healthcare industry as far as recognition of the importance of smoke evacuation and there are multiple reasons for this. The first is that the ISO community got together in 2014 and published the first guideline on smoke evacuation in the operating room, which had never been done before and it was designated as ISO 16571: 2014. Soon thereafter, Medtronic provided a fair amount of funding, primarily dispersed through AORN (Association of periOperative Registered Nurses), who support smoke evacuation policy development within healthcare institutions. The next thing that happened was that California, through the efforts of the California Nurses Association, developed potential legislation that was actually vetoed twice by the governor of California in 2015 and 2016, but the second time around Governor Brown suggested that the California Nurses Association, send a petition to the Standards Board at Cal/OSHA, requesting them to take up the topic of smoke evacuation in the operating rooms in the state which they did successfully. The Standards Board accepted the petition and passed it on to the Rules Committee and the Cal/OSHA Rules Committee is currently about to discuss statewide mandatory smoke evacuation in the operating rooms.

CEOCFO: *Would you explain the problem with getting rid of smoke and why the problem has been ignored?*

Dr. Schultz: I think the biggest problem with getting rid of smoke in the operating room is a lack of education of the surgeons. The nurses have been educated by their nursing associations primarily AORN, for a number of years. AORN also has a journal of its own that has published multiple times on why smoke should be eliminated from the operating room. From the point of view of a surgeon, I dare say, there have been no articles on smoke evacuation, either the reasons for it or methodology to actually evacuate smoke in any surgical journal. In other words, the surgeons have largely been uneducated and the efforts of industry and the professional organizations have been focused on nurses because they are the ones that live in the coal mine 24/7 whereas surgeons may take one and a half to two hours per case so their time in the OR is limited. Plus, they see no economic advantage or even health advantage to it. Why should that be? Because surgeons have not been educated to the fact that the ill health effects of chronic inhalation of surgical smoke is dependent upon genetics, preexisting illnesses, and dose/duration of exposure. To give you an idea of the contrast that we deal with, surgeons that do orthopedic and spine surgery are well aware of the dangers of radiation because they have had cases coming out one after the other of thyroid carcinoma because most of the participants in those surgeries have avoided the use of a lead-lined neck protector. Today you cannot find a lead-shield apron without an attached neck protector. The doctors have become well aware of the dangers of radiation but not of surgical smoke. Lack of education is the primary problem.

CEOCFO: *What have you developed at Nascent Surgical?*

Dr. Schultz: The product that is currently being marketed is called miniSQUAIR®, which suggests a smaller footprint than the parent product which we called SQUAIR primarily because of its square shape and the fact that we promised clean air in the operating room, thus the name is spelled SQUAIR. After two to three years of clinical trials with this product, we realized that the first thing the surgeons did was cut it down to size because they thought it was too big and that is where the miniSquare came from which has been a stable product for us now for about four and a half years. The purpose of this product is literally to remove surgical smoke and its components which include bioaerosols. In order to be able to say we do this, we have been able to document the claims through a number of laboratory tests and now clinical studies. For example, we went to the University of Minnesota that has a world class air quality laboratory called the Particle Calibration Lab in the Department of Mechanical Engineering. They tested our product at 98-99.5% smoke capture efficiency. We said that if it is that efficient, what is it really capturing? Well it just so happens that they measured not only the percentage and efficiency but also the components of the smoke which were 80% nanoparticles. That was back in 2011 and just because the surgeons are not educated does not mean the manufacturers aren't educated either. From that point on we started to learn about nanoparticles and that the chronic inhalation of those nanoparticles can produce a real health hazard just like radiation does to people who use x-rays. Nanoparticles represent a danger to the long-term health of the perioperative team and they do this by accumulating in the lungs and passing through the lung capillaries to distant organs, the results of which are neurodegenerative, cardiac diseases, cancers, all sorts of illnesses that have been well documented but not in the surgeon's literature. There has been very little interest in the surgeon's literature. For that reason, to find out what chronic inhalation will do to an individual's health, we had to go to environmental and occupational

health literature where there are hundreds and hundreds and hundreds of articles. The information was there but it was not in the surgical journals.

CEOCFO: *Once you have captured the nanoparticles, what do you do with them?*

Dr. Schultz: Once we have captured the nanoparticles and other particulates in smoke, including bioaerosols, they enter into our product which is a capture device. It passes through tubing and then goes through an air filter system, known as the ULPA (Ultra Low Particulate Air) filter, which is the standard in the industry. Another filter that you are more familiar with is the Hepa filter, but Hepa filters do not filter to the same degree as the ULPA filter does. So that is the best filter we have on the market. Supposedly it is capable of filtering out 99.999% of particles down to the nanoparticle level. But the nanoparticles are the problem child, so does that mean the filters are ineffective? The answer is no because although the air flow that we use clinically is much greater than the specifications originally described for an ULPA filter manufacturer, the airflow means that more air and impurities are coming to the filter than it was specified for, but the process known as diffusion still allows the absorption of most of these nanoparticles onto the filter material. Still, about 5% of them get through the filter. Why is that an issue?

First of all it means that we are not really purifying the air that is returned back into the operating room. The second problem is that the filtration systems that we currently have which filter the air about twenty times an hour, are not sufficient to rid the air of the nanoparticles, which are constantly being added to during the course of the surgery, so the filters are needed but they do not do the kind of job we want them to do, and that is why I proposed that ultimately we will be having a distant site removal through central vacuum systems.

CEOCFO: *So, you need to go a step at a time?*

Dr. Schultz: The standard in the industry is some form of capture device held close to the smoke, tubing to transfer the smoke to the ULPA filter, which is currently the state-of-the-art for us, to getting rid of the impurities from the operating room. It is not perfect but it does a pretty good job.

CEOCFO: *How does manufacturing work for Nascent Surgical?*

Dr. Schultz: We are a virtual reality company. By that I mean the FDA calls us a specification and design company. We develop the specifications for our product, we go to subcontractors and they put it together for us. In this particular case, that is Medline Industries in Northbrook, Illinois. They are a huge company and they really added a big dimension for us because as our business has been growing, it allows us a limitless supply of product, constructed quickly, and inventory storage. These are advantages that companies like ours need as we grow our business. They are the ones that put our product together for us and return it to our warehouse or in certain instances can ship directly to our customer.

CEOCFO: *Is it a separate kit for each procedure, or are there some permanent pieces and then disposables?*

Dr. Schultz: Our product is classified as a disposable with a 510 (k) clearance from the FDA and a CE Mark from a notified body in Europe called NSAI which is the Irish notified body; they are the ones who look after our product and make sure it is made properly and documented

properly. Our sales are in the United States primarily, but we also sell in Europe and we are actually increasing our sales in Europe rather surprisingly, primarily in the Nordic countries where they really care about their individual health. Remember, these people cross-country ski everywhere and they are really into personal health responsibility. As it is turning out, UK is becoming another site for us. We also sell in Canada which has been a little slow because there the contracts, or “tenders” that the government gives out do not come at a fast pace. In essence we sell in Canada and throughout Europe.

CEOCFO: *What does it take to show proof to an organization that is looking at what you do?*

Dr. Schultz: Every organization that we sell to all want pretty much the same thing. First, they want proof that we are FDA 510 (k) cleared or have some other avenue of approval by the FDA, which we have had for a long time. The CE Mark in the US is unimportant but the CE Mark is pivotal outside the United States because most countries want to see the CE Mark, and secondarily they will accept FDA approval. That is the most important part that they want, otherwise we have to be registered every year with the FDA which we of course do and if there are specific things that they are after they may ask for proof of validation and sterilization processes. Those are primarily validations and verifications of product materials and how we put it together for the marketplace that are audited by the FDA and by the CE Mark authorities.

CEOCFO: *When you start a trial with an organization, who is in charge?*

Dr. Schultz: I would say that the strategic material managers are in charge of what large healthcare organizations do. If they are just individual small hospitals, O.R. directors or material managers are primary contacts. Right now we have a big clinical trial at four or five of the hospitals of Northwest University Medical System in Illinois. Those folks want a lot of free samples, which is pretty expensive to do because it also involves on-site teaching as well as travel and staying at the institutions for a minimum of one week. We just got done with two weeks at the University Hospital. There are three or four other hospitals and we stay at each one for a week at a time. These are expenses that the companies have to bear. Some of the large companies like Medtronic actually charge the hospitals for the time spent, at least this how one of the contracts appeared to me that I was able to see. We do not charge them, and it may vary from three or four boxes of product samples to one or two boxes of product depending on the size of the hospital, the number of doctors that we would like to have trial the product. That is an expense born by the companies.

CEOCFO: *How do they check that the room is clear; is there a way to measure?*

Dr. Schultz: We have an ongoing study now at Stanford done by a Dr. Kirkham Wood, in which they are measuring the particulates in the operating room, and he is telling me that they are finding an extraordinary decrease in the particulates using the particle sensors that actually count the particles in the air. We will let his study be complete and he will publish it. That is how you can measure the effect of use of a capture device such as ours. You can do it by particle counts in the air during the case to see whether or not the product that you are using is effective. Some have said that particle counts are not all that useful. Instead, they want culture results but that brings up the other topic and

that is that there are viable bacteria in the air most commonly the source of which is the patient themselves. What we are learning is that during elective surgery the patients are releasing the bacteria in the smoke which then carries the bacteria into the room and this is the reason why bacteria are present on surfaces in the operating room on lights, ceiling and so forth and why chemical decontaminants, and more recently ultraviolet light is being used to decontaminate the rooms. What they are really doing is destroying the bacteria that most commonly come from the patients themselves.

CEOCFO: *How does cost come into play for a hospital? Why does miniSQUAIR make financial as well as health sense?*

Dr. Schultz: What the hospitals have to deal with is whether they want compliance or value and can they have both. I can tell you that our product offers value; I know that because we documented our percent of capture efficiency, nanoparticle capture, bioaerosol capture, and more recently a clinical study of over a thousand spine fusion cases that pointed out a major drop in infection rates. I can tell you that this data is documented, whereas our competitors, as far as I know, have no documentation of any functionality or benefit of their product. However, is it easier to get people to comply with holding onto an electrosurgical pencil, defined as an electrode with an embedded tubing to remove smoke, or is it easier to use our product which requires a certain degree of education and time to learn how to use it most effectively to achieve what we have shown it can achieve? So the hospitals have an issue. They want compliance which they need, because internal auditing is now emphasized by all certifying bodies, so the hospitals say we have a smoke capture policy, we do audits and those audits are reviewed by The Joint Commission, the group that gives the hospital certification for their insurance and functioning in the subsequent year. Audits that show continuous improvement are the key. Audits mean compliance and compliance has to increase with time if they are going to be quality improvement audits which they almost all are. What is it that the hospital wants? Do they want the number of people to increase that are using a certain product which they are auditing, or do they want value based outcomes because another product that is not as easy to learn such as ours, would give better outcomes? This is the biggest issue I see today in the hospital and why we are now being called on by the executive group to do serious clinical trials, because what they are finding is the "pencils" that have been around for twenty years are being disregarded by the surgeons. Why? Because in order to capture smoke with a pencil to any degree, you have to have the end of the tube right close to the tip of the electrode and most surgeons are operating below the level of the skin and cannot see the tip of the electrode as they look down the vertical axis of the pencil, so they pull the tube all the way back so they can see what they are doing. Or now I have noticed even more, they are all asking for these long-stemmed electrodes. The suction tube does not go down to the tip of a long-stemmed electrode. So in other words the pencils are being put aside because the surgeons do not want them. That is another reason we are being called. The hospitals need an alternative to achieve compliance, and compliance is the key to sales today because of the fact that pencils had a good run and a new technology needs to come to the fore and we hope our technology will be that choice.