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Issue: August 21, 2023



Histologics' New Patented Kylon® Compassionate Tissue Removal Technology is Making a Difference in Diagnostics and Therapeutics for Gynecology and Wound Care



Neal Lonky MD MPH
Founder/CEO

Histologics LLC
<https://histologics.com/index.php> - Gyn
<https://www.histologicswc.com/> - Wound Care
<https://www.histologicsvet.com/> - Emerging Veterinary Division

Contact:
Jannalee Johnson - Business Development
(480) 710-9322
jjohnson@histologics.com

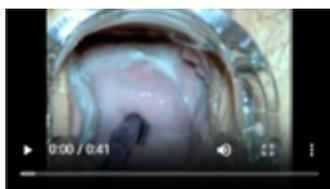
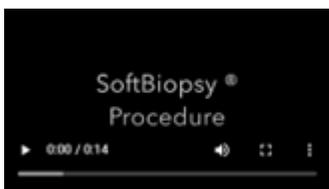
Interview conducted by:
Lynn Fosse, Senior Editor
CEOCFO Magazine

Histologics' new Kylon® patented tissue removal technology in Gynecology and Wound Care "did not exist, and now it is used routinely in the market and making a difference in diagnostics, therapeutics, and with a gentle approach"
Neal Lonky MD MPH

CEOCFO: Dr. Lonky, what is Histologics LLC?

Dr. Lonky: Histologics LLC grew out of a need to approach the removal of tissue from the body in a compassionate, efficient, and safe way. From my observation, we were using late nineteenth-century/early twentieth-century, instruments to do that at the clinical sites. I am not only a developer but a provider of health care. I see gaps and try to fill them. I am a Board-Certified Obstetrician, Gynecologist, and an expert in lower genital tract disease. My first impression of the procedure I did to rule out cervical cancer, led me to believe that there could be a better way to remove tissue in that scenario.

The technology we developed is a multipatented medical fabric called Kylon® that lends itself to many other areas in medicine where we need to remove tissue from the body predominantly for patients that are not under general anesthesia.

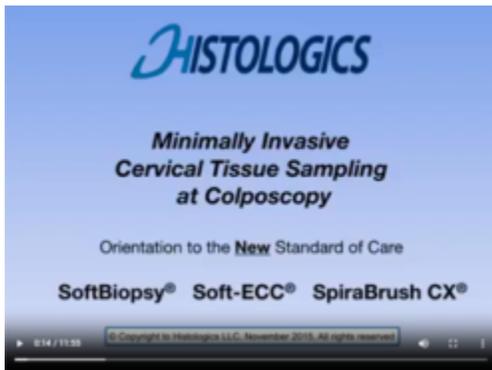


CEOCFO: How did it go on for so long in an antiquated method before you realized that something should be done?

Dr. Lonky: Yes, there has been a historical movement to make medical procedures minimally invasive. However, there has been some neglect in doing that in more outpatient procedure settings that require instrumentation that physicians and nurses train to use, and they get protective of their methodology. To be able to transform something that is being taught in medical and specialty nursing schools and certification courses, and to transfer from something sharp to something less invasive, is a paradigm shift. For diagnostics, they have to trust the sample they receive is valid for laboratory pathologic testing. For therapeutics, it has to remove the abnormal tissue safely, compassionately, and efficiently.

CEO CFO: *Would you tell us more about Kylon® and how you were able to come up with that?*

Dr. Lonky: In the 1990s, I was the inventor behind a procedure called Speculoscopy, which was a bedside specialized chemiluminescent magnified inspection of the cervix and vagina to disclose lesions that could be precancerous. That procedure along with the pap smear, at the same time, became PapSure®, that was FDA-cleared. Many clinicians remarked that they were seeing things but they were primary care physicians or internists or non-surgical providers and did not have the equipment to take biopsies. They were concerned about people leaving their office with precancerous lesions.



My first invention for outer cervical biopsy was called Spirobrush®, which we still sell today. It is a stiff spiral bristle brush technology to remove tissue from the body. It is a single-use sterile disposable device and it evolved into the more versatile and easy to handle Kylon® fabric later on with this new company, Histologics. The Kylon® lends itself to be very adaptive to remove tissue from the body and to more efficiently trap, transport, and handle the sample when it is removed at the lab. All versions for biopsy are extremely patient-friendly.

CEO CFO: *Are potential patients aware that they should be looking for better procedures?*

Dr. Lonky: I am a clinician myself, a physician, and a Board Certified OB/GYN. When companies try to promote things that are novel and maybe have some minimally invasive approach or some other unique feature, if it is removing tissue from the body you want to get the clinicians first. You have to get the clinician who is doing the procedure and the pathologist who is reading the sample to agree that this is of

substantial significant quality, that it has an efficient, effective pathway to use, and that it is patient-friendly and affordable.

The first leg on the wrung of the ladder is to make sure there are a lot of providers out there that are capable and embracing the new technology. Then, I think it is natural for women seeking OB/GYN care and other markets that we are in such as wound care, to seek it out the “adopters” of new technology. At the very end, you promote it to the public market because you have a capability to provide it in nearly any setting.

We are getting to that tipping point in women’s health where women call Histologics for providers. Wound care is a little bit of an earlier market approach for us and evolving into that. We have been in the gynecologic field broadly for over seven years, so we are getting toward that tipping point.

CEOCFO: What about medical schools; how do you approach them?

Dr. Lonky: I think the key to success for any technology is to have the trainers in the schools on board and passionate about transformation and welcome it into the curriculum as the next new way. We have done that with societies in OB/GYN with the wound care and formal training programs when the faculty who are training them are passionate about Compassionate Colposcopy®, which is the procedure to diagnose cervical dysplasia and cancer after a screening test. Regarding Compassionate Debridement at your Fingertips®, or tissue biopsy for wounds those who try it convert and are passionate, thus they transfer that to their curriculum.

Of course, you have to have the evidence behind it which we do. We have peer-reviewed publications or peer-reviewed abstracts from presentations that are in the body of medical literature that explain why the Kylon® fabric or the minimally invasive approach has some unique advantages to the patient, to the provider, to the payer, whether it be the government or insurance companies or the patient.

CEOCFO: How measurable are the results in comparison to what is being done now? How do you assess the difference?

Dr. Lonky: What you do is prove it takes a true biopsy and you go back and do a randomized clinical trial to show that the patient does not perceive the discomfort at the higher level that the stainless-steel instruments do. Then you show that they are still as diagnostic and sometimes provide an even more abundant or topically wider specimen because people have errors in aiming for lesions that might be abnormal, and with the broader face of this device that excavates off a wider area, you can overcome some mistargeting areas that is at-risk. For a debridement and cleaning of wounds you show how Kylon® is more precise going layer by layer not traumatizing the patient.

We make an analogy to something like Mohs surgery for dermatology where you are removing the tissue layer by layer precisely until you reach the normal area and you stop. With the sharp instruments, there is some traumatic deeper excavation that may not be as easily controlled that causes some pain and bleeding at times and we try to avoid that, so that is another advantage of the technology. How you prove it is through

evidence-based research, clinical trials, case studies, case series, and testimonials. We have done that.

CEOCFO: *Do customers use a wide range of your products and possibly mix them with other products they are using?*

Dr. Lonky: It depends on the level of expertise of the provider. For example, with wound care, one of the biggest drawbacks to helping wounds heal is the aversion of mid-level healthcare providers who may or may not be advanced wound care trained, to be able to maintain or clean the wound at regular intervals, or clean the wound of the necrotic tissue, and creating a small level of inflammation in the area triggers the healing process. If it is left to fester it is not going to heal because of the presence of biofilm in the base of the wound. You need something that can either hygienically do this or do it using a surgical excision technique, and the versatility of the Kylon® being able to do both is a unique attribute of the fabric-based technology. It simply is modulated by the pressure applied to the Kylon® hook tips. If twisted with pressure, it deploys a curette function to the device for deeper debridement.

CEOCFO: *What is involved in manufacturing?*

Dr. Lonky: We have two manufacturing facilities that predominantly manufacture in the USA. We do not have a supply chain issue or problem with our inventory. We can source it at a decent enough price to still be able to bring this to the market at an affordable price. Our products are all \$5.50 when sold retail. If they are bought through distribution, it could be higher.

CEOCFO: *Histologics recently added a new development consultant for expansion. Why expansion at this juncture?*

Dr. Lonky: Not only are we in these two spaces but we are heavily integrated with diagnostics and therapeutics. Jannalee Johnson, who we announced on August 4th of this year as our new Business Development Consultant for Gynecologic and Wound Care, has had a lot of experience predominantly in the diagnostic pathology field. I have known her for over a decade and she has developed the respect and admiration of many of the over 50 laboratories we work with, to channel our OB/GYN or wound care diagnostics. We work with all of them in different ways but they are a channel for us or a promoter of compassionate tissue removal, to still bring diagnostic specimens to the lab. Jannalee will enhance the ability of the company to continue to do that and expand into new avenues.

She is also excited about the pipeline of other products in other fields that we premarket and she will help us develop the same kind of relationships with partners for the diagnostics there.

CEOCFO: *Would you tell us about some of those fields?*

Dr. Lonky: Because molecular testing of wounds relates to genomic molecular testing, we have a unique way to take molecular samples from the body. Other cancers in the body would benefit from a minimally invasive approach to tissue sampling. We are focused on predominantly genomics and cancer diagnostics. We have one published paper regarding the therapeutic nature of Kylon® frictional tissue removal

beyond just removing the tissue a-traumatically and precisely. It involves our patented way of frictionally affecting the tissues that may be responsible for the inflammatory immune response in the tissues that are affected. That could be helpful for many conditions.

CEOCFO: *How do you deal with the frustration of knowing you developed something that can help a lot of people, but also knowing it is such a long and arduous process to gain acceptance?*

Dr. Lonky: I have a health policy and management public health background and I write on transformation and how procedures and methodologies are integrated into healthcare in a value-based way, where the quality and health care delivery is enhanced. We aim to do that compassionately. Medicine is going this way finally. As a former member of the board of directors for Southern California (Kaiser) Permanente Medical Group, I was always interested in something that improved quality, did not impact access negatively, and hopefully enhanced it, that was exceptional to the service cost-effectively rendered to the patients. But that takes time to prove, to demonstrate, and everybody needs an assessment of who is going to render into the new technology.

An old joke, "How many psychiatrists would it take to change a light bulb?" The answer is, "one, but the light bulb has to want to change." That is what bringing new technology into more routine healthcare, entails. All stakeholders have to want to be ready for it. The patients are certainly ready for it, they want a more compassionate approach. The physicians have already bought the metal instruments, so to get them to say they are ready for the new thing means they have to be willing to try it.

A very high percentage of people who venture into something new which are called the early adopters, reorder our product once they try it. The key is making that initial curiosity and looking under the hood and saying this is going to be something of very high value and I am going to give it a chance. Once they do that for Kylon® products, it is very successful with a high re-order rate.

CEOCFO: *What have you learned along the way about how to get doctors to try your advances?*

Dr. Lonky: I break the population into three segments. The early adopters are easy and usually looking for things, and they are in markets where there is some pricing that allows them to get a significant reimbursement related to the procedures we bring. They are seeing that our products can be used in reimbursable procedures, which is a help.

The middle is the on-the-fence type of people who are looking for early adopters to tout it to them, and we are into that group heavily now with OB/GYN. Then there are the naysayers, in other words, they did it this way their whole life and if it is not broken it does not need fixing. There are some of those that are coming around too.

Sometimes what happens is naysayers start losing patients to more compassion-approach physicians in their market or they finally see it for

what it is and they want to learn. We are into some of that as well. Once you are in the training programs, the next thing people realize is that it is valuable.

CEOCFO: *Are you seeking funding, investment, and partnerships?*

Dr. Lonky: We are ripe for merger and acquisition because we are already post-revenue in OB/GYN and have grown at a significant pace, and in wound care as well, where we are just getting off the launching pad and doing pretty well. There is a lot to do. If we were to incrementally take investments, I think it would go slower at this point. We are in the process of candidates for that and I think with the right partner, this can be accelerated at a much higher pace. We are still a small footprint-company.

CEOCFO: *Is there anything we should know about Histologics that we have discussed?*

Dr. Lonky: We have a wonderful small group of dedicated people who work in Histologics as employees or consultants. They bought into the compassionate approach as being our foundation. We love getting calls from patients to find places they can go that we sell, so they can get that kind of approach in their procedure. It gives us energy.

As you know, transforming healthcare is a challenge. You have to have a group of people who are dedicated to it and can listen to those that say they do not need it yet and ultimately, they call us. It is very energy-producing for mission-driven Histologics LLC.

I am the patented inventor of all of the technologies. It is very rewarding to see something that did not exist that is now used routinely in the market and making a difference in diagnostics, therapeutics, and with a gentle approach.

