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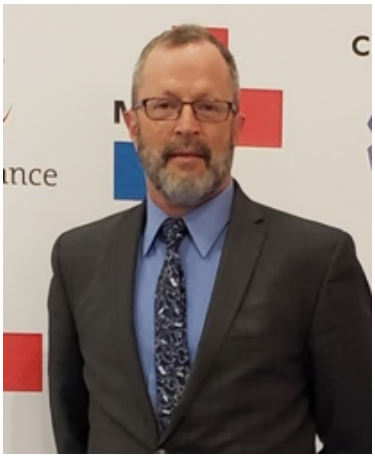
SUTUREGARD® Medical's HEMIGARD® is the First Device to Show Significant Reduction in Lower Leg Wound Dehiscence



Dan Ladizinsky, MD
CEO and Co-Founder

SUTUREGARD® Medical, Inc.
Https://suturegard.com/

Contact:
Jen Akeroyd
Jen@suturegard.com
1-844-585-8421

Interview conducted by:
Bud Wayne, Editorial Executive
CEOCFO Magazine

"We are addressing an unmet need by bringing a product that is the first of its kind that actually creates a new category of wound closure device. Traditionally wound closure has been staples, sutures, tape and glue. HEMIGARD is a hybrid of adhesive and suture technology, and is a load-transferring skin anchor that allows you to close high-risk, high-tension, wounds without skin tearing." Dan Ladizinsky, MD

CEOCFO: ***Dr. Ladizinsky, would you tell us about the founding of SUTUREGARD® Medical? Which came first, the product or the company?***
Dr. Ladizinsky: The company was started in 2016 by Dr. Bill Lear and his wife Dr. Jen Akeroyd. Bill had just finished writing a book chapter on wound closure in dermatology and noted that there was still no effective dehiscence reduction device. He was looking at things that would be less traumatic to the skin and would disperse tension because either a suture or a staple focuses a lot of force on a powerful filament or a piece of metal. When it comes up against tension or swelling, against skin which is much more delicate, it can be traumatic. The driving force was the unmet need for some kind of a wound closure device that is gentler on the skin and can withstand the forces that can occur during healing due to motion or swelling, or tension.

CEOCFO: ***The original company name before being changed to SUTUREGARD was Julvia Technologies. How did the original name come about?***
Dr. Ladizinsky: The company was named after their two children. It came by combining their children's two first names: Julia and Olivia, so the original company name was Julvia, which was subsequently changed to SUTUREGARD after our first product.

CEOCFO: ***You currently have two products. Were either through acquisition or both through inhouse product development?***
Dr. Ladizinsky: The product came from a bedside sketch done by Dr. Lear. Therefore, what came first was the product idea, then the company and the actual product. Bill and Jen worked with engineers and veterinary surgeons at Oregon State University to do both computer

modeling and an animal study of the prototypes. Jen joined the Oregon State University Advantage Accelerator and did customer discovery with our early prototypes and then refined them further.

Our first product was SUTUREGARD®, which is based on suture cushioning and spreading of tension. It is used more particularly on the scalp and other areas where you cannot apply an adhesive device because where there is hair you cannot really stick tape on the wound.

SUTUREGARD went through 12 prototypes to get to the final product. There was a similar process with HEMIGARD®, our second product. Though HEMIGARD is physically a simpler product it still required very much hands on involvement from the founding team. Dr Lear's early clinical use was crucial in refining the approach. Therefore, both of our products came from in-house product development; not through acquisition.

CEOCFO: ***You have a distinguished career as a surgeon, consulting to the medical technology and biotechnology, as an inventor and author, with multiple patents. How did you come to join the team of founders and then become CEO of the company?***

Dr. Ladizinsky: They were working with some preliminary models and prototypes, and had something going with this cushioning concept for how to lessen the traumatic effects of the suture. They were looking for help on how it could be applied surgically. Bill is a Mohs Dermatologic surgeon, so he knows a lot about skin surgery. My background is reconstructive plastic surgery, so I worked with all inpatient surgical specialties - a different perspective. They were looking at the broader impact and wanted to talk to a surgeon that had some experience in product development, patenting and bringing products to market. They got connected to me by a mutual friend who was in the Oregon medtech scene. I consulted with Julvia for several months, helping them with their intellectual property, strategy and prototype development. I retired from clinical practice in February 2018, at which point they asked me to be the CEO of the company and become a Co-founder. I thought the concept was valid and there was an unmet need, because sutures and staples are too crude for the reasons previously cited.

CEOCFO: ***Was there a key moment in the development of either of your products?***

Dr. Ladizinsky: A key moment in the development of HEMIGARD occurred when Dr Bill Lear placed a plastic insert that he, 3D printed himself into an adhesive tape and then placed suture through that, creating a suture/tape hybrid that could allowed the skin to withstand higher tension than normal. That was great! Another key moment occurred because we were going to the manufacturer and looking at how the machinery actually assembles medical adhesive devices. It is very interesting. There are multiple layers that are on spools. In a sequence, these are all fed into a common entry point on the machine, at which point they get laminated together in a certain order at certain widths. Then you got this big sheet of laminated materials and then you have a metal die-cutting machine that cuts out the shape that you need of that construct.

Many times, in inventions, people are inventing things in a vacuum, not aware what the manufacturing capabilities are. If you can invent something that is already aligned with current manufacturing technology and machining, that is way simpler and you get a much lower cost of goods. We used concepts from Design for Manufacturing from the beginning of the company.

CEOCFO: ***Would you tell us your role as CEO? Is it raising funds, product development, developing partnerships, attending conferences to explain the value of what you are doing?***
Dr. Ladizinsky: I have pretty much been the sole fundraiser for the company. Bill and Jen recruited one institutional investor early on, Oregon State University Accelerator, which gave us a boost early on before I joined. We got a non dilutive grant from Business Oregon. We did friends and family rounds thereafter. Most of the fundraising has been through private investors and I have been the one raising the money. In the most recent round, most investors were from the foot and ankle surgery ecosystem.

I am a surgeon by trade and when you do surgery, you are embarking on a trust-based partnership. You do not have a certainty of an outcome and you present the best possible scenario for your patient but realistically. That for me was kind of hard to become a fundraiser after being a surgeon. As a surgeon, you pitch to what you can deliver or maybe a little below because it is better to under-promise and over-deliver. As a CEO, I would go to these pitch competitions and at times to me these guys were just blowing smoke up there and showing these revenue trajectories of what is going to happen two years from now, it's the next great product and we are going to do an IPO like Apple. I was like what the heck is he talking about, you are selling a left-handed monkey wrench, how is that going to become a unicorn?

It is very hard for a surgeon to pitch in the traditional biotech, med-tech CEO role. However, I think that worked in my favor because I am selling medical devices to surgeons and surgeons are skeptical people. I know because I am one and I have been on both sides of the buying and the selling side, going to tradeshows as a practicing surgeon and listening to reps of companies. We have a high level of skepticism. If you pitch in a strident and extreme way and over-promise, that becomes very apparent to the listener. A lot of my investors turned out to be surgeons and people involved in the supply-chain within foot and ankle, orthopedic surgery. I was saying realistically what I thought this would and could do. I think that the frankness of it resonated. I let them know this would take a while and they respected that.

Right now an important role for me is sales – I think the CEO has to be able to sell the product to optimize the sales process, which is always evolving. We are fortunate to have Alex Morse on the team as National Sales Director, and his energy and social media savvy have been vital in raising our profile and getting our messaging properly tuned. Since COVID, access to hospitals and offices was restricted and Alex and I began to do one on one Zoom calls daily with surgeons to inform them of the benefits of HEMIGARD and share best practices. This has worked well.

CEOCFO: ***What types of surgery is your SUTUREGARD used for and how does it improve results?***

Dr. Ladizinsky: It is applicable to pretty much any skin surgery closure where you expect that there is either going to be tension in the wound due to swelling or motion, or if the skin quality is poor due to thinness of the skin be it from aging, kidney failure which reduces body protein levels and thins the skin, be it from chronic steroid use which also thins the skin, or other co-morbidities like diabetes or obesity. When you start adding all those categories into a pot, those are people that are at-risk for skin healing complications, it is a pretty big group. There are 100 million surgeries done in the US annually. It turns out that half of them are done in people over 65 years of age.

In people who are 65 and older, there is a condition called dermatoporosis, which is something I just learned about a few years ago from a dermatologist. You have heard of osteoporosis and that is when the bones become porous and weaker. Dermatoporosis is the same thing, just of the skin. It is a weakening of the skin due to thinning which can be from multiple factors but 30% of people over 65 have this skin fragility and here they are getting tens of millions of surgeries a year. They are in an at-risk bucket. I think prudent health systems doing higher value surgery where the risk of complication is huge, like a knee or hip replacement, must consider the potential risk of wound dehiscence, as it can be a real disaster for the patient and extremely costly for the system and so on. If you are looking at patient safety as an overriding issue, here is a way to bolster the surgical outcome, to improve the patient's safety. It is more like a risk mitigation tool for at-risk closures, which could be anywhere on the body. We feel it is valid to think of this as a multi-specialty technology.

The people that use it the most right now are foot and ankle surgeons. We focused on that because the foot and ankle suffers from being the farthest from the heart, so it has the weakest blood-flow both in and out. You are supposed to elevate your foot after foot surgery, well people have to get up and go to the bathroom and they may not be as diligent as after let's say hand surgery where it is less debilitating to keep a hand elevated postop, but having a foot elevated all the time is not really possible, so they swell more. They might bear weight and the incision might be on or near a weight-bearing surface or joint. Those surgeries have a higher complication rate. It is no fault of the surgeon; they are just operating on the toughest part of the body to heal. We are proud to point out that we have 3 clinical studies in lower leg surgery showing 80% reduction in wound dehiscence when HEMIGARD is used (diabetic amputations, skin cancer excisions and repair of ankle fractures). As such we focused on foot and ankle surgery as a key market for us.

CEOCFO: ***Is ease of use a factor? Does the surgeon need much training to use it and if so, how does the surgeon learn to use the device; special classes, videos, online?***

Dr. Ladizinsky: Ease of use is a huge factor because surgeons do not have to change their technique at all. This is a huge selling point. We actually launched HEMIGARD product in January of 2020. That was right when COVID started. It turns out we were able to train our surgeons with a brief Zoom call and that became our sales model. We would

explain the product, show how it was being used and then do this brief training and they were able to use it right out of the box because it is really a simple product to use. You just apply an adhesive device on either side of the skin wound before you close, and then suture through the device and then through the tissue as you normally would. You go through the device on entrance and exit of the suture. That is very easy for surgeons to adopt because that does not change your technique at all. We have online videos that show surgeons do not have to change their skin suturing technique. HEMIGARD also reduces the need for deep sutures and the closures are therefore faster.

There is also another time saving aspect to HEMIGARD. Because you can apply high tension on a HEMIGARD suture, you can pull together wounds without having to resort to a surgical technique known as undermining. When we do undermining, that is when you lift the skin away from the overlying muscle layer. If you imagine, it is like you are trying to get a wrinkle out of the middle of your rug, you have to lift the whole rug up there. Then you can slide it over better. It is kind of like that when you are trying to pull skin together. If you lift it away from the underlying muscle, there are ligaments that are released and the skin can slide better. That is not a risk-free technique.

When you do that undermining maneuver, you create actually a bigger wound underneath the skin that can form a pocket, which can gather blood which is called a hematoma and that is a significant complication. HEMIGARD improves patient safety by reducing the need for that undermining maneuver. It allows you to close wounds that are fairly high-tension without having to use undermining. HEMIGARD also speeds the surgery up by eliminating the need for undermining and reducing the need for deep sutures.

CEOCFO: ***Is HEMIGARD your biggest selling product today?***
Dr. Ladizinsky: Yes, HEMIGARD is our biggest selling product. It is outselling our other products by over ten to one.

CEOCFO: ***Do you have any product demonstration videos that you present at trade shows?***
Dr. Ladizinsky: We have a video that shows how HEMIGARD prevents skin tearing. In the video it shows that with suture alone it rips at low tension. With retention tape it rips at somewhat higher tension. However, with HEMIGARD, the skin does not rip; 0 nylon breaks. This video is what we show surgeons at trade shows. Our sales guys show this to surgeons and ask if it can help some of their patient. Invariably they say, "Yes."

CEOCFO: ***How is skin tearing addressed today outside of your device?***
Dr. Ladizinsky: Skin tearing is a real problem with fragile skin patients. Conventional suture and staples tear fragile skin. Medical Adhesive Related Skin Injury (MARSI) is a patient safety issue where the overlying tape can have a mismatch to underlying skin in terms of elasticity, resulting in shear injury and blistering. HEMIGARD has a zonal progressive elasticity specifically designed to address this problem. There are no other products purposefully designed this way as far as I know.

Skin tearing from traditional retention sutures in abdominal trauma is a different kind of problem. Severe abdominal swelling can cause tremendous tension on the suture and those sutures can cut through even normal skin. Right now there is a lack of tools for this problem since Ethicon stopped manufacturing their retention suture bridges a few years ago. Star Surgical sells a foam/plastic pad with two holes that can work well with a horizontal mattress suture pattern. We also make a product (SUTUREGARD ISR) that can be used this way. But after that, there are only solutions you MacGyver in the OR from red rubber catheters or vaseline gauze that work like pledgets.

CEOCFO: ***Are you funded for future initiatives or will you be reaching out to partners or potential investors?***
Dr. Ladizinsky: It is a timely question because we were just picked for something called Medtech Innovator. It is the leading accelerator incubator program in the world. There were 1200 companies plus that filed an application. There were 28 companies picked and we were one of them for this year's cohort. We were in there with companies from Austria, Israel, Singapore, Ireland, and United States. These were all medtech companies that were going through a several-month accelerator program that will culminate with the AdvaMed MedTech Conference in Boston, in October of this year, at which point we will have an opportunity to present at AdvaMed and meet strategics.

Between now and then we are getting mentoring contacts from potential strategic partners. We are reaching out to partners all the time now and we have very high-level access through the MedTech Innovator Network and that has been a big boon to us. We are looking to accelerate our growth through strategic partnership and that might take the shape of mutual investment, it could take multiple shapes depending on what the priorities are from the partner.

We are a small company. What we cannot do is develop a multi-specialty salesforce on our own. We see a path to partner with somebody who already has a multi-specialty presence in surgery and then have them scale it with us.

CEOCFO: ***In closing, why is SUTUREGARD Medical an important company?***
Dr. Ladizinsky: We are addressing an unmet need by bringing a product that is the first of its kind that actually creates a new category of wound closure device. Traditionally wound closure has been staples, sutures, tape and glue. HEMIGARD is a hybrid of adhesive and suture technology, and is a load-transferring skin anchor that allows you to close high-risk, high-tension, wounds without skin tearing. As such, it has been the first device to show a really significant improvement in wound dehiscence, which is where wounds breakdown post-op. We have three studies now showing 80% reduction in wound dehiscence and they are all lower lead studies, the most difficult area on the body to close.

We are offering a first solution to an unmet need. Huge companies like 3M are doing negative pressure wound therapy with wound V.A.C.®, which has not shown much effect in reducing wound dehiscence in the lower leg. These other adhesive based products that are used as adjunct wound closure devices such as ZipLine have not shown a reduction in

wound dehiscence rate. However, we are. It is a breakthrough! It is novel platform technology that is broadly applicable in surgery and it already is improving surgical outcomes significantly and will continue to do so.