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The Ergosuture Drive’N Roll with Advanced Suturing Capabilities and new X-Needle allows Surgeons to Tie Knots and Manipulate the Needle Safer in the Body



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CEOCFO: *Mr. Nogard, it has been about a year since we have talked with you about Ergosuture and your Drive 'N Roll. For people who may not be familiar with the company, what is Ergosuture?*

Mr. Nogard: ErgoSuture is a med tech company specializing in surgeons-driven innovations, and our goal is to develop solutions that will enable surgeons to do surgical tasks easier, better, and faster. Our roller-based technology is cost-effective, easy to use, and enables suturing tasks only possible by skilled surgeons or robots.

The main idea behind the company's creation was that technology had a more significant role to play to meet surgical care demands worldwide.



CEOCFO: *Where are you today? Your site tagline is "for surgeons by surgeons." Has it been a challenge to get interest? Where do you stand right now?*

Mr. Nogard: Our product is a class II 510K device. Hence, we are currently engaging with experts and the FDA to define testing and studies requirements ahead of our application, scheduled for 2024.

Our seed investors, whose majority are surgeons, continue to support our development effort. For example, they have allowed us to advance in developing our proprietary needles. Our initial objective was to optimize the needle architecture for use with the Drive'N Roll; we have now expanded application to all types of needle holders using flat tips, more than 98% of the market.

CEOCFO: *What is different from one needle to another? What have you recognized can make the difference for your product?*

Mr. Nogard: This new needle, which we call the "X-Needle", allows surgeons to manipulate the needle safer in the body and tie knots with much less effort than commercially available needles. This needle differs from current needles because it contains a flexible extension that confers more control during the manipulation without affecting the path of the tip of the needle through tissue. For the Drive'N Roll, we have also modified the geometry of the half-circle part of the needle to allow surgeons to choose the necessary angle to complete the suture.

CEOCFO: *Are there many needle manufacturers today? Where can you fit into the mix, or would it be just for your own product?*

Mr. Nogard: Multiple manufacturers produce needles for a handful of companies that commercialize them. Also, needles are sold as consumables and follow a selling model very different from medical devices such as needle drivers. Hence our goal is to find a partner to maximize the opportunity. We are looking for manufacturers interested in strengthening their position in the needle business; ideally, they would have the global reach and capabilities to take on such innovation.

"Our roller-based technology is cost-effective, easy to use, and enables suturing tasks only possible by skilled surgeons or robots." Claude C. Nogard

CEOCFO: *What else have you learned over the past year?*

Mr. Nogard: As many entrepreneurs have experienced and continue to experience, raising funds to launch your first product gets harder as you approach the goal line. More specifically, we intend to enter the US market, shifting from handheld devices to automated systems such as surgical robots. Hence the burden of proof stands substantially higher. The good news is that the data we are collecting through our product testing continues to validate our product and technology. For example, we have demonstrated how the use of the Drive'N Roll can improve a surgeon's proficiency and speed of suturing compared to traditional straight shaft needle drivers, widely used in laparoscopic surgery.



CEOCFO: *What have you incorporated in the model you are working on today, that was learned from surgeon input? What might be one of the things you changed or tweaked a little?*

Mr. Nogard: We have learned from them that when you drive a needle using rollers, the slower the increment of the needles moving through the tissue, the more control and the faster they will do the procedure. That translated into less hand movement, minor needle driver's distal end movement, and faster suturing. There is no movement amplification at the needle driver tips when using the rollers. To date, the only way to achieve such control of the tips is to use a surgical robot.

This data has led us to evaluate further surgeons' cognitive efforts when using the Drive'N Roll compared to the commercially available needle drivers. This finding is one of our clinical studies' objectives.

CEOCFO: *You mentioned that people, other than surgeons, could be able to use what you have developed. Are you reaching out globally? Are you reaching out to those communities, or is it too early to actively do something to go beyond surgeons?*

Mr. Nogard:

There are two parts to this question. For the first part, the Drive'N Roll, in its current architecture, is designed primarily for minimally invasive surgery, such as laparoscopic surgery. In this case, we have had tractions with potential partners outside the US, looking to find more accessible tools to expand the use of laparoscopic surgery in their markets. We are already evaluating collaborations outside the US by integrating Drive'N Roll into their portfolio or creating stand-alone companies to commercialize it.

The second part of the question addresses future applications that cater to surgeons and non-surgeon-users. For example, we intend to develop a product that will use the same roller-based technology to enable EMTs or field specialists to close wounds on-site, such as in the military. The same device could also be used in high throughput suturing situations, such as reconstructive surgery or ER.

CEO CFO: *What does the timetable look like for you? You mentioned the FDA.*

Mr. Nogard: We have learned that the Drive'N Roll was a class II 510 K device and would require more data such as human factors tests before submission, which leads to some delays. However, we expect to apply by late next year, or early 2024, with the first entry in the market by the end of 2024.

CEO CFO: *That is not atypical for your industry.*

Mr. Nogard: No.

CEO CFO: *Is it easy to get surgeons to try and to provide feedback? How do you get them to recognize it is important for them to incorporate Drive 'N Roll into their activity?*

Mr. Nogard: Getting surgeons to try our device has not been difficult. However, COVID lockdowns have made it more difficult for surgeons to have hands-on experience with the device in the lab.

CEO CFO: *Are they willing to give you enough feedback? I understand that they might try it and like it, but are you getting the feedback you need? Are there ways to encourage them to be more detailed or do something, not just "Hey, we think it is great," but here are the reasons why?*

Mr. Nogard: Surgeons generally feel at ease providing us with positive and negative feedback. We try to integrate most feedback we receive; doing this and showing surgeons how we have used or not their input goes a long way in building trust.

We do not get feedback from one surgeon but multiple surgeons, and that has given us tremendous insight into what works and does not work.

CEO CFO: *Are there particular surgical procedures that make more sense for the device, or is it more or less across the board?*

Mr. Nogard: The current design targets intra-abdominal, urological and gynecological surgeries. This design also fits novices and average surgeons looking for less strenuous efforts while suturing in hard-to-reach locations. We expect that we will identify other applications post-launch as we collect feedback about the Drive'N Roll.

CEO CFO: *What has changed in how to talk to potential investors?*

Mr. Nogard: I have learned that it takes a team to connect to the right investors. I have also learned that trust and familiarity are paramount to having a meaningful engagement with an investor. Investors tend to have so many requests from companies from all around the world. Hence, it would be best to surround yourself with people part of their investor ecosystem and, more importantly, people they trust. Trust is not something that happens overnight.

CEO CFO: *How do you deal with some of the frustration when you are working on something that could really help so much, and yet it is a long and arduous process to get to where you need to be, so that people can actually use it?*

Mr. Nogard: The good news is that we are not unique. Most successful companies faced multiple rejections. However, we try to keep in mind that frustration is part of being an entrepreneur.

CEO CFO: *Are you looking at manufacturing yet? Are you looking at distributors?*

Mr. Nogard: We are indeed looking at manufacturing. Part of the regulatory submission requires testing the final product, so we are looking into both outsourced and in-house manufacturing.

From a distributor's standpoint, we have been fortunate outside the US. Distributors have been reaching out to us for the last three years, so we have an initial list of distributors. However, we are just starting to reach out to these distributors to evaluate the volumes required to meet their market demand.

CEOCFO: *Why both from the medical side and the investment side, to Ergosuture? What, if anything might people miss, about the importance of Drive 'N Roll?*

Mr. Nogard: ErgoSuture is a medical device startup that strives to close the surgical care gap through surgeon-driven innovations. In addition, we are trying to solve a bigger problem: how we can improve proficiency in the operating room across multiple applications and surgical platforms. Our goal is to make every surgeon better at what they do to improve outputs for both patients and hospitals.

