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Single Pass – Improving the Safety of Biopsy Procedures with Their Revolutionary Cautery Device

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CEOCFO: ***Mr. Colone, what is the idea behind Single Pass?***
Mr. Colone: The idea behind Single Pass is very simple and straightforward. It is to improve the safety of biopsy procedures. We have developed a cautery device that prevents and stops bleeding caused by the biopsy tools.

"We have developed a cautery device that prevents and stops bleeding caused by the biopsy tools." Bill Colone

CEOCFO: ***How has the bleeding been handled before Single Pass?***
Mr. Colone: Right now, no method or device can effectively prevent bleeding. Thus, physicians may try different self-taught remedies based on their personal experience. They will try anything from pressure bandages to sometimes shooting a hemostatic agent in liquid form into the biopsy channel to try to prevent bleeding. No method or technique is 100% effective so literally there is no known prevention. Prevention has instead been replaced by lengthy monitoring after biopsy procedures in hope of catching and treating adverse events quickly.

Currently, no standard method or product can prevent or stop bleeding that is caused by biopsy procedures.

CEOCFO: ***What are the challenges and what led you to take a look at this problem?***
Mr. Colone: I was introduced to two physicians by a hand surgeon in Phoenix, Arizona. I previously developed a product for him, and he sold it to a large company. So now when his physician friends have product

ideas, he has them reach out to me. He introduced me to two radiologists who did a lot of biopsies every day because they worked out of a liver transplant hospital. They frequently saw bleeding problems in biopsy procedures for which they had no solution, so they were motivated to create a solution. They came up with the concept, created the device, filed some patents, and even made working prototypes before they were introduced to me. I co-formed a company with those physicians along with a couple of partners that I have in Orange County, California and we raised the seed funding for the company.

We then hired a CMO to finish the design, development, and testing before we did a clinical study in Europe and the US. We recently received the CE Mark which means we have approval to sell the Single Pass device in Europe. We already submitted to the FDA and hopefully, we will have approval sometime in Q-1 to be able to commercialize in the US.

CEOCFO: ***What is happening during the procedure; how does your device make a difference?***
Mr. Colone: Right now, we do not change anything about the current biopsy procedure. They start these procedures by identifying a tissue target. Usually, it is a tumor or mass of concern. Under ultrasound guidance, they will poke through the skin with a large hollow needle and keep pushing it deeper into the body, sometimes four to six inches, until they reach the target tissue area. They then reach in through the hollow needle with a tissue extractor to remove a solid core of tissue. They put the tissue sample on a glass slide that is given to the pathologist. Normally, the guide needle would be removed, and the procedure ended.

However, before they remove the guide needle, they put our device probe all the way through the guide needle to reach the area where the tissue sample was extracted. The Single Pass probe extends beyond the end of the guide needle and the probe tip gets very hot when the power button is depressed. The hot probe tip heat seals and cauterizes the tissue that was damaged by the tissue extractor. When the Single Pass device is removed, it also removes the guide needle with it, so we essentially cauterize the entire tissue channel that has been damaged by the guide needle and tissue extractor.

CEOCFO: ***Would this be done with every procedure?***
Mr. Colone: We prefer that our device be used on all the procedures and that this becomes the standard of care. From what the published data reveals, it is very difficult to predict who may potentially have a bleeding problem. Kidney biopsies bleed almost every time because the kidney is a blood filter. Liver, breast, and lung biopsy procedures may also be problematic.

From what we have gathered from market feedback, some clinicians will use our device only for kidney biopsies and selectively for other cases. Other physicians may use it all the time.

CEOCFO: ***Is there any potential downside?***

Mr. Colone: No, we do not believe we create any additional damage beyond what is caused by the biopsy tools. There potentially would only be upside or a neutral benefit to using the Single Pass device.

CEOCFO: ***Is this a disposable device?***
Mr. Colone: The device is single use and disposable. It is a hand-held unit that utilizes two AA batteries that send enough current to the tip for it to reach an effective cautery temperature. We designed the device to be disposable based on feedback we received from hospitals. They preferred that the entire device be single-use and disposable to avoid inventory management and resterilization issues. We also have another design where the handle is reusable and only the probes are changed, but cleaning, re-sterilizing, and recharging of the handle was viewed as problematic.

CEOCFO: ***Where does the potential cost of the product come into play?***
Mr. Colone: It comes into play significantly because we certainly are adding cost to the procedure. Biopsy tools are typically inexpensive, and this is a premium product. However, significant cost savings are realized by reducing the after-procedure care and potentially eliminating adverse events that require secondary procedures.

Currently, patients are held for up to 8 hours, and sometimes overnight, after the biopsy simply for observation for bleeding issues. We believe we can reduce that observation time significantly by ensuring there is no bleeding at the procedure conclusion.

A single reintervention, or hospital admission, due to a bleeding adverse event, creates thousands of dollars, and sometimes tens of thousands of dollars, in new healthcare costs. We can reduce those costs significantly each time we prevent an adverse event.

CEOCFO: ***I would imagine that would be easy for a hospital to understand the ROI?***
Mr. Colone: We are working to create a formal economic benefit analysis based on published rates of adverse events and their associated costs. The benefit analysis will reveal that an average volume biopsy center will enjoy significant cost savings by reducing the nursing time currently required and eliminating reinterventions due to adverse events.

CEOCFO: ***Will you be marketing in Europe or will you wait until you are established in the US?***
Mr. Colone: Europe will be first because we already received the CE Mark under EU MDR. Unfortunately, we are right up against the holidays, so we will launch in Europe in January of 2024. Our application with the FDA is pending and we are hopeful of FDA clearance in Q1 of 2024.

CEOCFO: ***What is your manufacturing situation?***
Mr. Colone: We use a well-known contract manufacturing company in Orange County, California. The company is called M4D and they are ISO Certified and FDA registered. It is also very convenient because they are right across the street from my office.

CEOCFO: ***Are you looking for funding, investors, or partnerships?***
Mr. Colone: We just opened a new round for Insiders to fund the global commercial launch. If not filled by Insiders, we may open the round to others sometime in January.

CEOCFO: ***What have you learned from experience that might have helped you get this far with Single Pass?***
Mr. Colone: I think we learned to pivot. Very rarely is there a straightforward path for a medical device startup company. Something inevitably comes up that has not happened before that creates tough decision making. We simply have to be ready when we come to a fork in the road and make the best choice possible with the available information. Also, none of these things runs perfectly smoothly, so we need to be patient with vendors, the supply chain, and other aspects that frequently cause delay. In spite of this, Single Pass was able to receive the CE Mark under EU MDR in less than 30 months.

CEOCFO: ***When did you know that you had figured out the best way and a workable way?***
Mr. Colone: The moment we started to treat patients. About a year ago, we did a clinical study and started with patients in Europe. It was under an approved protocol, informed consent, and ethics committee approval. The physicians had never seen anything like this before and they were skeptical. Before the study began, they informed us that they were probably not going to do kidney biopsies because they bleed too much. They said they would only do liver and lung biopsies.

The first day we did two liver biopsies and the device worked beautifully. When we arrived the next morning, we were informed that they wanted to use it on kidneys. In the end, they treated thirty patients and thirteen of them ended up being kidney biopsy patients. They were quickly convinced once they were able to use the device and see how well it worked. That is the moment we knew had something valuable.

CEOCFO: ***What does the next year look like?***
Mr. Colone: The desire would be to be acquired by a strategic partner because they have such large sales forces and marketing power that we do not have. We will perform a limited market release in Europe, and we will do a limited market release in the United States as well. Along the way we will collect more clinical data and put some of our physician advocates on the podium.

CEOCFO: ***Final thoughts, what makes Single Pass special and why should it standout?***
Mr. Colone: I think because we have created the only solution for a large unmet clinical need.

Beyond the clinical data, we also saw a human kindness benefit. Biopsy patients are already anxious about the nature of the procedure and the potential complications due to bleeding. We saw a significant relief of anxiety when study patients were informed that there was assurance post procedure that they did not have to be concerned about any bleeding complications.