

Propel paper - Challenges Within the Industry

Have you ever seen the videos of the once deaf kids being able to hear their parents voices for the first time? If not, they are the most wholesome videos, and if you have you can confirm the joy. These pure moments are all accredited to one device, the cochlear implant. It is a small biomedical device that is inserted behind the ear into the cochlea which is the part of your ear that plays a vital role in the sense of hearing. Iota Motion is a small medical device company that is paving the way for technological advances in the Ear, Nose, and Throat (ENT) division of the medical device industry. They manufacture a device that physicians use to insert the implant into the cochlea slower than the human hand as to lessen the trauma of the insertion and aid in faster healing for the patients. Being the first to do anything comes with challenges such as FDA approval, funding, and credibility.

When starting a company there are many hurdles to jump over but there are especially more when you are in a medical setting because it is a regulated industry. Technology in the surgical field is by no means a new concept, but in the ENT division this is an unheard of concept. This means that Iota has to “train the FDA” to be open to the integration of robots. When you are first to market you have to educate people and convince them that your ideas are different which is where Iota’s struggle began with the FDA. To my mentor Marie’s surprise, who is a cofounder of Iota, the people at the FDA were “actually very willing to learn” and government agencies are sort of known for saying “the answer is no until you convince me otherwise”. Although they were willing to

learn and accept new ideas there was also the legal aspect that had to be hashed out. It took over a year for Iota to get approval and it even took some intervention from them to achieve this. They had to bring their device concept all the way to the head of the ENT department of the FDA. All in all it proves a great struggle to pave the way for new technology because of the FDA regulations in place for the medical device industry.

The next big challenge for Iota was the limited funds. Being a start up you have to engineer a device, test the device, get FDA approval, then get marketing approval all on a very limited budget. "You have to be as prudent as possible and get as far as you can with the funds that you have," Marie told us. After they achieved approval from De Novo, who grants the permission to go on the market, Marie told us there was not much money left so it became a challenge to launch the device and the company with the little means they had. They persevered through the struggles of being a small start up company and are now the first to market a device anything like the one they have created. As of right now Iota's primary market has been the US because of the way our country does health care. As for the future they are onto their next project of trying to market internationally and grow their company.

The final challenge that Iota faced was the fact that they were first to market a device like theirs. Being a trailblazer means you are navigating uncharted territory which can be daunting to a small business because there is a lot on the line and a lot to lose. Because they are the first to market they needed to make extremely careful decisions. In Marie's words, "if you screw up and go down in flames nobody's ever going to forget

that". In other words they had to be very cautious with their reputation to achieve success. Thankfully, because of their hard work, they had great success. The first few physicians that used the device expressed a great liking toward it and led Iota to getting on podiums and panels that aided in spreading the word about their company. Iota has been on the market for just three years and nobody as of now is doing anything like what they are. They have no competition. Marie says it is a "good place to be, lonely place to be" which isn't a bad thing.

In conclusion, these challenges of FDA approval, funding, and credibility have not been holding this small company back. Iota has persevered and thrived. They continue to set their sights on bigger and better things and will proceed to grow their company. But, to the community of Iota employees, this all means nothing without the thought of bringing loving parents voices to the ears of their newly hearing children.

[Watch](#) skip to 1:40