

They sold their company to Boston Scientific and then reacquired the technology years later - the unique story of NuCryo Vascular

Because of diminishing margins, a lot of major medical device companies continue to add products to their sales bag in hopes of meeting top-line revenue goals. But successfully selling the entire bag can be challenging.

When the bag gets too big, a typical sales force will usually focus only on products that generate the most revenue. So what about the products that don't product much revenue? Well, they're sometimes just lost in the dust.

In the following interview with Kevin Beedon, General Manager of NuCryo Vascular, we learn how their team is taking advantage of this very scenario as they look to commercialize the newly redesigned PolarCath device.

Scott Nelson: Let's start with NuCryo because it's an an interesting story. And by the way, congrats on your recent 510(k) clearance. The cryo-catheter device that you're commercializing has a storied history with the likes of Dr. James Joye, who initially founded CryoVascular Systems, the acquisition by Boston Scientific, and so on. Can you provide a high-level overview of the history, and then we'll dig into the details later on in our conversation.

Kevin Beedon: I do think it's a great story and it's a pretty unique opportunity because of the history of cryoplasty and the previous proven customer base that we've had. But back in the day, Boston Scientific acquired the PolarCath line from CryoVascular Systems, which was a startup formed and created by Dr. Joye. In its heyday, there was over \$40 million in revenue from this product line, over 350 accounts, and approximately 900 to 1,000 physicians that had been trained on the product. But Boston Scientific went through a reorganization back in 2012. And it was their decision at the time to eliminate some products that they perceived to be costly too make, that weren't within their core focus areas, had a small revenue stream compared to the larger coronary and CRM product lines that they offered. So at that time, they decided to stop manufacturing the product and it was deemphasized from the perspective of their sales force. So in 2014, the cryoplasty balloon, PolarCath, still had about \$5.3 million in

revenue and over 100 accounts using it, but sales were dwindling along with Boston Scientific's inventory.

Dr. Joye and a few of the early investors in cryoplasty decided to create a company called Gemini NuCryo to buy back the rights from Boston Scientific with the intent to do some engineering modifications and bring it back to market. And that's where we are in the present day. We did have an exclusive distribution deal last year with Vascular Solutions. But that was terminated in December of 2015 and we're now moving forward with a direct sales force model for Gemini NuCryo.

Scott Nelson:

Certainly an interesting story, and to set the stage for those that are reading, this was a really successful product. In fact, I remember competing against the PolarCath device, and then it seemed like it just disappeared. There wasn't a major recall. There wasn't any data that was released that suggested it didn't work. It just sort of, like I said, kind of disappeared. On that note, what's your take on the reason for Boston Scientific deemphasizing it? It makes you wonder how often this really happens with large strategics like Boston Scientific, Medtronic, Stryker, etc.

Kevin Beedon:

I think that's a great question, and obviously, I'm not going to speak on behalf of Boston Scientific. But I think back in the 2012 timeframe when these decisions were being made, post Boston's acquisition of Guidant, there was a lot of change taking place in the industry. And so I believe they just made a decision that it was a smaller product line within the peripheral space and they decided to divest and stop manufacturing the product. But there never was a recall. In fact, in 2011 at TCT, there was very positive data to support cryoplasty, which was later published in 2012. It was called the COBRA study, which was a randomized prospective multicenter study comparing cryoplasty versus PTA in the post dilation of nitinol stents in the diabetic patient population. So it's very, very positive data that a lot of physicians aren't familiar with. In fact, a lot of physicians were also disappointed that the product went away. And so when we started reviving cryoplasty last year, physicians were surprised, but also very happy that they would have the opportunity to put PolarCath or cryoplasty back in their treatment algorithm for peripheral vascular disease.

Scott Nelson:

During my time at Covidien and Medtronic, there was a similar situation with one of our devices. It was relatively expensive to manufacture and sales were relatively low in comparison to other product franchises. So

the decision was made to stop, not discontinue it per se, but really just stop selling it. And I know physicians weren't very enthused about that decision. As I said earlier, you just wonder how often this really takes place with other companies. Regardless, it seems like a great opportunity for NuCryo.

Kevin Beedon: I agree 100%. And I think what it comes down to is larger companies have such a breadth of product lines, or a large sales bag, that sometimes the smaller revenue-generating products are dismissed discontinued. And I believe that's what happened with cryoplasty. But for our company, which is Gemini NuCryo, it's a great opportunity because we've, in a relatively short period of time, reengineered the product twice from the inflation perspective and we've eliminated a ton of costs.

Scott Nelson: To finish up on the story, you mentioned that back in 2014, Dr. Joye reacquired the assets from Boston Scientific. Do you know the underlying rationale? Was it based on the fact that he was involved initially with this product through Cryovascular?

Kevin Beedon: Dr. Jooye was the founder of cryoplasty back in 1999. He's always believed in the technology in addition to a lot of other physicians. So when the opportunity to buy back the assets came up, he jumped on it. And the team that we have today are individuals that were originally involved with Cryovascular as well as some other folks from Boston Scientific. The team that was formed were people that had experience with cryoplasty and they, along with Dr. Joye, were excited to work on it. So it was an opportunity to buy back the assets, reengineer it, make it more cost-effective in the market in order to compete head-to-head with other technologies. Plus, there's some nice clinical data too.

Scott Nelson: When you put all those pieces together, it really does make for an interesting opportunity on a lot of different fronts. Before we get into how you were able to move so fast from an R&D perspective, I want to ask you about the distribution agreement you had in place with Vascular Solutions. There are probably pros and cons with both avenues, so can you take us through the rationale to go direct versus continuing through a distribution channel?

Kevin Beedon: First of all, Vascular Solutions is a great company with a proven track record of success. They have an impressive product portfolio and a specific sales model that's worked very well for them. However, it was a mutual decision for us to part ways. We're very excited about moving forward in this way because it gives us the opportunity to be in complete

control of our future from both a sales perspective and from an engineering perspective. There are a lot of physicians that have used cryoplasty, it's got a proven mechanism of action, it's differentiated. We believe that going direct will allow us to engage the physicians and sort of reconnect them to this technology. It's somewhat of a different sales model where we're not trying to sell people on the data or sell someone on the device. What we're really trying to do is reengage them and bring awareness to the COBRA study. Let them know that we're back and they now have an opportunity to add cryoplasty back to their treatment algorithm. And because we're such a small company, we're very efficient and we're super lean. And one of the things we emphasize is our cost control and our cost structure. Because we're so lean and efficient, we can capitalize with a direct sales force in a market that's ready and has been waiting for cryoplasty to come back.

Scott Nelson: Makes a lot of sense when you explain the rationale because it would probably be entirely different story if you had to approach this more from a market development standpoint. Where you had to educate physicians not only on the product, but also on the disease state or maybe even the patient pathway. In your scenario, the device is proven and a lot of physicians are fond of it. So it allows for a lot of efficiency from a commercialization perspective.

Kevin Beedon: Exactly.

Scott Nelson: While on the topic of being lean and being able to iterate quickly at a lower cost, you were able to make changes to the product very quickly. In addition, your team was able to get regulatory clearance in short order as well. Things that are almost unheard of within large device companies. So are there some key takeaways that we can learn from in regards to how you approached this from a R&D and regulatory perspective?

Kevin Beedon: I think it's a real testament to the engineering team that was put together because the rights were acquired in August of 2014, and in a relatively short period of time, we had to find a facility, set up a clean room, create a manufacturing line, and start production. Remember, NuCryo Vascular went to market with the distribution model in early 2015. So all those steps had been completed within that timeframe. Also, the 510(k) submission only took 40 days for approval. Because we have a lean team, we can get the engineering folks to do their work, we can analyze it and provide feedback very quickly. Dr. Joye can provide his

input from the end-user's perspective. And then we can go back and do it again. Not a lot of bureaucracy and a total team effort allowed us to really do something relatively quickly in today's world.

Scott Nelson: Regarding the regulatory submission taking only 40 days, does that speak to how it was initially submitted or the relationship with a particular FDA reviewer? Can you provide us with some additional details?

Kevin Beedon: I think it was a combination of the history of cryoplasty as well as the modifications we made. There were modifications to the inflation unit that allowed it to be more effective and more cost-effective. The FDA asked a few questions and we responded relatively quickly. So the turnaround time from their response to ours was also something that we could do really fast because of the team we had in place. We try to be very efficient in all of our activities.

Scott Nelson: I've got a friend that's a regulatory consultant and she always scoffs at this notion that the FDA is always to blame. Maybe that's the case in some scenarios. But she has mentioned to me several times that if the submission is tight and well done, that will save a ton of back and forth dialogue between the device company and the FDA. Seems like regulatory approvals can happen fast if they're done well. So again, congratulations on how fast your team was able to accomplish that. Before we transition to your career experiences, Kevin, let's discuss the changes you've made to the PolarCath device and why a physician might be interested in using it now.

Kevin Beedon: I think the basis for cryoplasty is its mechanism of action and apoptosis, or the biological effect that it provides. There's not another balloon in the peripheral space that treats with the -10 degree Celsius cooling impact of apoptosis. So I think that's critical for why physicians are excited that it's back and why we're excited to bring it back to market. But with the importance of price in today's market, with our next-generation unit that we just got 510(k) approval for, it's a nonsterile reusable device for up to 100 inflations. Prior to that, every time an inflation unit was used, it was disposed of after the case. And there was a cost associated with that for both the manufacturer as well as the hospital. By introducing this next-generation unit, it significantly lowers the cost per procedure for PolarCath. So now we can talk to physicians, hospitals, office-based labs, office administrators, etc. and we have an economic story that will compete in today's market. And again, we have proven data, the COBRA study, as well as an existing customer base. But it was

absolutely critical for us to get the 510(k) approval to compete in today's market.

Scott Nelson: So the balloon itself is disposable, but the inflation device that allows for the cooling effect, that itself is reusable now.

Kevin Beedon: Yes, you're correct. The reusable inflation device is going to be significantly less per case because you can amortize the initial cost over 100 cases, or 100 inflations, which will allow us to compete with other specialty balloons on the market.

Scott Nelson: Let's now transition to your career, Kevin. You came up through the ranks on the sales side with Boston Scientific and Spectranetics. Focusing on your most recent move from Spectranetics to Gemini and NuCryo, can you explain that transition in your career?

Kevin Beedon: First of all, Spectranetics is a great company. I really enjoyed my time there. But when the opportunity with Gemini came to my attention, it was something I couldn't turn down. It was a startup with great people, people that I admire and people that I knew I'd really enjoy working with. It was also based on a technology that I used to sell at Boston Scientific back in 2006. And I really believe there's a market out there for it. With the COBRA study and the changes that I knew that were forthcoming, it seemed like a great opportunity to take a chance at a startup with a great team. It was almost too good to turn down and that's why I eventually left Spectranetics,

Scott Nelson: I'm sure some people would analyze that move and say, "Really exciting opportunity, but you're taking a big risk." So how did you justify balancing the pros and cons of making that move from Spectranetics to NuCryo and Gemini?

Kevin Beedon: That's a great question. Something my wife and I talked about. I certainly talked with my friends and some of my mentors about it. I did the analysis. Spoke with Dr. Joye and the team at NuCryo and Gemini. And once again, it came down to the opportunity that's ahead of us as well my passion for the product.

I honestly don't think there is another opportunity in the medical device space that we have right now at NuCryo Gemini. And it all comes down to the proven track record of the device, the data, the next-generation unit, etc. We don't have to be everywhere in the market, we just have to be part of the algorithm for PAD and we will be successful. We also have a strong future at Gemini NuCryo from a product perspective. I get to

work with really good people, like Dr. Joye, who I admire and I respect. I just had to say yes and I'm very happy that I did.

Scott Nelson:

As I mentioned before, you came up through the sales ranks and have held various sales leadership positions at Boston Scientific, Spectranetics, etc. But your undergrad is in chemical engineering, you've got an MBA in finance, so I'm curious as to why you stayed on the sales side through your career versus other positions that you probably could have taken within the medical device space that were maybe closer to your background. Whether it was a marketing position or whether it was something else. So why sales and how do you think that's helped you along the way?

Kevin Beedon:

That's a great question. After graduating with a chemical engineering degree, I worked for Dell Corning in the engineering space for three-plus years and then I transitioned over to marketing, I think that's given me a broad foundation that applies to the medical device space. So there's a technical component that I believe I bring to the sales model that's helped me in my career. But more importantly, one thing that I truly love and enjoy is building teams. I love the human element. And so with sales, it allows me to engage physicians. To have difficult conversations about a technology that might be misunderstood or how they might consider it within their treatment algorithm. Sales is challenging, but also allows you to engage people, to build relationships with them, and provide them a product that will service them and their patients. So that's why I've always enjoyed sales and that's why I love the position I'm in right now.

Scott Nelson:

As you think back to your sales experiences versus what you're doing now in your role as GM of NuCryo, are there things that you wish you had more experience in? People reading this interview might have opportunities to zig and zag throughout their career, to go from sales to marketing, marketing to medical education, etc. What are your thoughts about that?

Kevin Beedon:

First, I think you always have to surround yourself with good mentors that you trust. And for me, I'm fortunate my wife is also in the medical device space and so she's a great sounding board. But I think at the end of the day, you always have to have a story. I get phone calls from a lot of people now that ask about making a career move and they always ask about their résumé. It's definitely a critical component and one that people look at. But I think you always have to have a story to tell. And so if you look at mine, I've been very fortunate. My first medical device job

was with Boston Scientific, as a peripheral sales rep, which happened to include cryoplasty. And that connected me with Dr. Joye and I believe this is one of the reasons why I'm here today. I was also allowed to launch a coronary stent before transitioning to Spectranetics. So as long as you make a change that makes sense to you and there's a story behind it, I don't think you should be afraid to take risks or to make certain changes. Just believe in that path and stay true to it. Change is inevitable but you have to manage through it and believe in the path that you're on.

Scott Nelson: So what's next with NuCryo? You're clearly excited about the opportunity you have with the new PolarCath device, but can you tell us a little bit more about what's ahead for the company?

Kevin Beedon: One of the great things about Gemini is that we're really a medical device startup that was created to develop, engineer, manufacture, and distribute novel or new medical devices that are differentiated for the treatment of PAD. We already have prototypes and IP that we're working on. And our goal is to develop them through collaboration with other entrepreneurs. In fact, other physicians have already contacted us about ideas they have. Because we're such a small shop and we're so efficient, we can take an idea, build a prototype, get voice-of-the-customer feedback, and then build a marketing plan around it. So that's the future. Stay small, have a direct sales force, grow a little bit here and there, but always be nimble enough to adapt. We're going to continue this process of bringing out new technology year after year after year.

Scott Nelson: Is it safe to say that Gemini acts a little bit like an incubator or an accelerator specific to the peripheral vascular market?

Kevin Beedon: Absolutely. That's one way to look at it. There are various ideas and thoughts behind an incubator, but right now we have a business plan that's lined up with a product we already want to bring to market in a few years. But first and foremost, our goal is get cryoplasty off the ground, get it back to where it was, produce a nice revenue stream, and then build off of that with the products that we already have in our pipeline.

Scott Nelson: You obviously have a lot of experience in the peripheral vascular market. And as you know, it's one that's pretty competitive with a lot of different players that have solid sales forces and quality products. So when you look at how competitive this particular market is, what thoughts come to mind?

Kevin Beedon: T peripheral space is highly competitive and there's new competitors coming to market almost every day it seems like. But the one thing that I

really appreciate when I talk to other sales reps at other companies is the focus that we're going to have within our bag. With a lot of larger companies, they have to continue to add products because to the bag because their margins are dropping due to increased competition. But for us, we're extremely focused. We have one product right now and we have a direct sales team that's going to target a proven customer base. So I think that gives us a competitive advantage, which will hopefully prove to be true in the coming years.

Scott Nelson: Let's transition to one of my favorite parts of these interviews, which is more personal in nature. With that said, what's your favorite nonfiction business book?

Kevin Beedon: Thinking off the top of my head, it's probably 'Into Thin Air', about the Mount Everest story. It's a great story about survival. One that's very engaging conquering Mount Everest.

Scott Nelson: Second question, is there is a business leader, whether it's a CEO or anyone else for that matter, that you're following right now? Or maybe one that inspires you?

Kevin Beedon: I'm a Michigan State grad and I'm a big Tom Izzo fan. I really respect what Tom Izzo has done. He's built an amazing program. And I think that's really critical in today's medical device space. You have to build a program. That's what really defines success. I think Tom Izzo has done that at Michigan State. He's a motivator, a mentor, a teacher, and an absolute disciplinarian. He's built a program that has a great culture where his players have fun. I'm a big fan of working hard, but at the end of the day, if you're not having fun, I think you really have to look in the mirror and figure out, "Is this the opportunity for me?" It's never going to be easy, but you have to enjoy what you're doing. And I think that's what Tom Izzo has done at Michigan Stae.

Scott Nelson: Okay, so last question. When thinking about your career, even back to your days at Dell Corning, is there something that you would tell your 30-year-old self?

Kevin Beedon: There's probably a lot I would tell myself. But for the sake of this interview, I would tell myself to not be afraid to take some risks. Also, I think you need to surround yourself with good people that have your best intentions in mind. And that's not easy, but I think it's critical. When I decided to make the move to Gemini, I talked to my peers inside the industry as well as friends and family outside the industry. I think you have to have a sounding board of people that have your back and will

give you straight advice. Sometimes it hurts, but I think it's important to hear. Change is important and it helps you grow. So take risks, but make sure you analyze everything appropriately.

Scott Nelson: Great advice. To end our conversation, for people that want to learn more about Gemini Interventional or NuCryo, where would you direct them to?

Kevin Beedon: I'd direct them to NuCryoVascular.com. They can also visit PolarCath.com or Cryoplasty.com if that's easier to remember.

Scott Nelson: Thanks so much for your time, Kevin.

Kevin Beedon: Thanks Scott. I appreciate the opportunity.