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Editorial

"In My Experience...Medical Device Design & Innovation in Shoulder Replacements"

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The author reviews his experience with a novel process of designing and bringing a medical device to market.

I was fortunate about seven years ago to work with a start-up group called Ignite Orthopaedics. We were a small group with two main people, an engineer, a marketing person, a business expert, and six design surgeons. We were able to develop a full shoulder arthroplasty platform with our own investments and equity in ourselves. We were able, over a five-year span, to then license this to Johnson and Johnson DePuy Synthes, which has now become the Inhance Shoulder Arthroplasty System. This is a full system with stemless, reverse, revision, hybrid and convertible glenoids. We gained a lot of experience with design and working with engineers, especially at the beginning.

This was a particularly satisfying experience. Traditionally, when working with the big orthopaedic companies on a new design, the issues have always been speed and efficiency to design and to production. In this case we worked with a start-up company that has all the engineering, business, and legal resources in place. The Ignite Orthopaedics team were all from Warsaw. We were able to prototype, design, and have a finished product literally in two years. Then, they had the internal experience to do the nuances to prepare to sell it or license it to a large orthopaedic company. It's faster. We're able to make our own changes. We could 3D-print a prototypes in a day versus two years with a large company. And I think this sort of design outsourcing will now be the standard. We have seen that now asthe large companies are outsourcing to smaller companies to bring products to market faster.

The ability of Ignite to find a large strategic orthopaedic company, like Depuy, was crucial. The shopping around of these designs was done by Brian Hodorek and Matt Purdy from Ignite. This was a skill set that we, as surgeons, clearly did not have. They were ableto construct a deal with J&J Depuy/Synthes that was a great sale due to their worldwide distribution market. You can have the greatest product you want, but it can also be a great product that no one's ever seen.

The ability of Brian and Matt, who have worked in the shoulder replacement space was critical due to the wide range of resources they had at their disposal They knew hey were going to use Paragon for 3D printing, they were going to use a certain company for the polyethylene. You have to have those resources if you have an idea. Just having an idea is not enough. You have to have the ability to do something with it, to bring it to fruition.

It would take me a lot of time from clinical practice to work in my garage and design a new replacement system. So, you have to partner with people who have their skill set, and even the design students will each have their own skill set. Some are engineers, some are social media and marketing experts, and more. Before you move ahead, you have to have have those pieces in place.

Throughout this entire experience, I also learned about the process of taking an idea to market. I mean, we went to all these companies, negotiating the deal, what they own, streams of royalties, royalty amounts, what you own, and the role of keeping your intellectual property. So, the experience itself, I love that it came to a sale, but the experience itself was awesome.

Once you design something and take it to market, seeing it help patients is very satisfying. We've been putting the

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implant in for about four years now. I think 2021 was the first stemless design implantation.

I think the implant matched and surpassed our expectations. And just the efficiency of it, and now, at the same time, we're transitioning to ASCs, with the two-tray system, which was also kind of a big deal, because it normally is so many more trays for ambulatory surgery centers. These team had that all in mind. We had the forethought to know that "Hey, we're going to be doing these in surgery centers" We're also coming out with disposable instrumentation as well, so that saves money on the sterile processing. So, all of that I've learned, and it's been an incredible experience.

What is particularly satisfying, even after the sale to Depuy is that we are still involved in the thinking part of the process. We plan to add add extensions, different liners, or revisions. Working with Ignite will let you do that and it's just so much more efficient. Couple that with having the distribution power of DePuy and you have a great business model.

What is unique about my experience with Ignite Orthopaedics is that the model is transferrable to other surgeons and other subspecialties of orthopaedics. They are doing knee, elbow, soft tissue products, and more. It's like a think tank. They hired a lot of interns, and engineers out of Purdue. So, we're working with 21-year-old kids who are extremely focused.

I think if you're a creative surgeon, I have learned you have to protect your intellectual property (IP), especially if you're going to shop things around, make sure you get a non-disclosure agreement signed. But that IP is the most powerful thing we have because it comes from our minds. And now with this type of model, it's so much easier to bring things to market now. You can have Zoom calls, telemedicine, you can design things in a day, and use 3D printing. You can design anchors, in a day. Besides the ability of bringing this to market, I feel that financially this works out well for designing surgeons with novel ideas and we certainly need a lot of solutions in orthopaedics. The horizon is incredible.

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