MEDTECH

Spinal Motion Preservation

Ted Bird
Dymicron, Chief Strategy Officer
Interview by Darwin Shurig
CEO/Founder, Shurig Solutions Inc.

Do you have a challenge currently with a strategic initiative relevant to RA, Quality, Engineering, Clinical, Operations or Marketing talent?

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DARWIN SHURIG

PRESIDENT - SHURIG SOLUTIONS INC.

Darwin Shurig understands the key qualities that companies look for in candidates to grow market share, while enhancing their positive culture and team environment. He has a clinical background of over 20 years, including 15 years of sales experience within: medical device, diagnostics, medical distribution, and sleep therapy; 8 years in sales management success; 3 years in operations; and extensive experience in negotiations and business development.

SSI has been growing for over 6 years with a focus on RA, Quality and Engineering within the Medical Device and Pharma industries. With over $3 Million in revenue and a 91% offer acceptance rate, SSI is helping companies find unique talent that makes a difference, brings value, and decreases the risk of a mis-hire.

Ted Bird

Chief Strategy Officer - DYMICRON

Ted Bird has over 35 years of global commercial and executive leadership experience in the medical device industry. Ted is currently Chief Strategy Officer with Dymicron, a pre-commercial startup with a breakthrough next generation artificial cervical disc; and Principal of Bird Medical Group, a strategic management consulting and go-to-market Medtech commercialization solutions provider. Ted is also currently on the Board of Novum Medical, a pre-commercial startup company with a proprietary bio-regenerative material for implantable musculoskeletal devices. He was previously the Chief Commercial Officer for Titan Spine, helping them achieve market-leading growth in the interbody spine fusion segment with a unique nano-textured titanium surface technology prior to an acquisition by Medtronic. Ted also served as Chairman of the Board for ApiFix, Ltd., a commercial stage Israeli startup company with a novel fusionless minimally invasive treatment alternative for Adolescent Idiopathic Scoliosis (AIS). ApiFix was acquired by Orthopediatrics in 2020. Mr. Bird also held key executive and management leadership positions at Orthofix, Depuy Spine, Medtronic Sofamor Danek, Johnson & Johnson Orthopedics, Microvasive, (Division of Boston Scientific) and Dyonics, (now Smith & Nephew). Ted graduated from Brown University in Providence, RI, with Bachelor's Degrees in International Relations and Political Science.

[Link to Full Webinar]

DYMICRON STORY

Ted: The history of the company begins with the founder, Dr. Pope, a professor of biomaterials at Brigham Young University; was a pioneer in the manufacturing and application of man-made diamond, (called polycrystalline diamond), which he applied very successfully for industrial applications in deep earth mining. His work resulted in revolutionary changes in the oil drilling and recovery industry where these polycrystalline diamond drill bits were manufactured by Dr. Pope and his team at a company called U.S. Synthetic. The story of Dymicron began when Dr. Pope had a good friend who told him he had to go back to the hospital to undergo surgery for a failed hip implant**.**

Video Link 1

Video Link 2

It was the material that allowed a Ph.D. Engineer in Utah, to look at all the other artificial implants that were on the market and see a theme. They are all ball and socket design; which rotate around a central core. He matched that up with his Ph.D. experience in human anatomy/kinematics and discovered that it doesn't replicate the normal spinal motion. So, he developed a new design, which was a tri-lobe, three-ball and three-pockets, in order to more closely mimic the normal motion.

That design would not be possible with today's material of PEEK polyethylene, cobalt chrome, or titanium because they would just wear out. Polycrystalline diamond was perfect because it was the material that allowed that very innovative breakthrough design to come together. (Continue to video links)

Big Company vs Small Company

Darwin: Speak a little bit about your perspective of the larger company versus the smaller and how you make those types of decisions.

Ted: I have a passion for knowing that I'm working with an organization or on a project that is making a difference. It's not just another commodity or widget with a different color that we're just trying to sell. I do appreciate the big company experience, as you get tremendous training and professional development opportunities at companies like Johnson & Johnson, Medtronic, Stryker, etc. because they have tremendous resources to invest in their people.

Video Link 1

Video Link 2

The frustration people have with bigger companies is that they move slowly. Also, many people stay too long with a bigger company because they think it is more stable than a start-up. That's not the case anymore with larger companies doing consolidations regularly, and sometimes you have to re-interview for your own position!

Darwin: Whatever they want to call it, Rightsizing, Downsizing.

Ted: With small companies, you get the flexibility, speed, and autonomy to move your career very quickly because you are given so much opportunity to gain experience. You can see tremendous career growth.

(Continue to video links)

Product Leading Spinal Motion Market

Darwin: Let's talk about the Spinal Motion Market. Design and material and some of the things that affect and differentiate Dymicron's product from the marketplace.

Ted: Dymicron is focused on the cervical total disc replacement market, and it's one of the hottest segments in the spine right now. Cervical disc degeneration is absolutely debilitating. Cervical TDR is now growing at double digits, almost 20% a year. There are over 350,000 cervical fixation procedures just in the US alone and only 10-15% of those are being addressed by artificial discs today. At least 80% of these procedures are suitable and can be done by discs, as there's more experience in multi-levels, hybrid constructs, etc. It's a very attractive growth space in spine.

Video Link 1

Video Link 2

Video Link 3

Darwin: The fusion oftentimes results in another surgery, so in terms of benefit not only in the cost of motion vs fusion, but in the long run it's potentially less expensive vs fusion.

Ted: Currently, there are five products in the US Market approved by the FDA. These are all what I would call first-generation ball and socket designs that are performing well. Medtronic's Prestige is a metal-on-metal device. Centinel Spine is a metal on plastic with a fixed core design. Then there is Zimmer Biomet with its acquisition of LDR for their Mobi-C Disc that is a metal on plastic mobile core design. Orthofix acquired the M6-C Disc, which is viscoelastic type design but also with a ceramic core that has a cushioning effect. The big news in 2021 was the acquisition of Simplify Medical Disc by NuVasive, which is an MRI-friendly design comprised of PEEK on ceramic and with some unique implant dimensions.

Darwin: In terms of ball and socket you get more motion, less stability, so the challenge with the ball and socket, Dymicron solves.

Ted: Correct. Our product called Triadyme, (Tri for the tri-lobe and dyme for the polycrystalline diamond), is a revolutionary biomaterial and is a dual innovation device. Polycrystalline Diamond is almost entirely comprised of carbon and it's the strongest material in the universe. It doesn't wear, which means it's going to last; you're not going to have the wear debris, which leads to complications. The design mimics healthy spinal motion that can't be replicated by a simple geometric ball and socket design. The primary advantages are the virtual elimination of wear debris and superior kinematics.
(Continue to video links)

Wear Debris

Darwin: Dymicron has a photo on the website that talks about the 14 million cycles of these different materials and shows the size of the breakdown in comparison and it's an amazing photo.

Ted: We did this test in a special lab in Germany and it confirmed that this biocompatible polycrystalline diamond at those high levels of motion will last beyond a patient's lifetime.

Video Link

Darwin: When you look at hip and knee replacements, you get concerned that you might have to have them replaced again, so having this product where it's once in a lifetime is incredible.

Ted: It meets Dr. Pope's original vision when he started the company to provide a Medtech implant for the lifetime of the patients.
(Continue to video links)

Wear Debris & Competition

Ted: The FDA is concerned about wear debris. They had a special panel in 2019, the Immunology Devices Panel, that discussed the topic of immunological responses to metal-containing products regulated as medical devices. They are very interested in what we're doing here at Dymicron.

The problem with implants, in general, is wear debris. 2-10% of the problems are from infections in patients. Fracture failure or bone fracture is another 5-10%. Over 50-70% is because the implant gets loose because of the inflammation from the debris created by wear, called Aseptic Osteolysis.

Video Link

Darwin: Wear debris is such a huge challenge in terms of polyethylene, about 70% of the wear debris comes from those types of materials. When you look at inflammation, what it does at a cellular level, the complications there, and the loosening of the implant from the Osteolysis, the fact that Dymicron is eliminating that risk is such a huge benefit to patients.
(Continue to video link)

Career Advice

Darwin: Talk a little about how important it is to have a plan for your career and how you manage that process. Share how you made some of those decisions in your career progression.

Ted: My plan was to dive in, not just sit back and scratch my head. When you get an opportunity, I advise you to take it, especially if it's international. When you look at taking responsibility outside the US, it's such a great opportunity for you to learn different cultures and different ways of doing business. My definition of a true leader is getting others to follow voluntarily, and that is through earning trust.

Video Link 1

My advice to those starting their careers is don't look sideways, continue to look down the road. Fill your career with as much experience as you can. Volunteer, sign up for projects, reach out to other departments. If you are in marketing, spend time with the engineers. If you're in engineering spend time with the sales and marketing team and get into the field. Understand what goes on in the sales force. If you're with a bigger company, sign up for all those great management training opportunities.

Video Link 2

My focus was to learn as much as I could to add to my experience with the goal of being well-rounded so that one day, I would be well equipped as a CEO or President.

My advice is to have a plan and focus on serving others. I'm a big believer in Servant Leadership.

Darwin: I always say our goal every day is to bring other people value. If you focus on bringing people value and you're genuine, it's going to be a win-win situation.
(Continue to video links)

Career Advice

Dymicron Next Steps

Darwin: What are the next steps for Dymicron after getting the CE mark? What does the next 1-3 years look like?

Ted: The top 2 priorities for Dymicron is first getting FDA clearance to commercialize this product in the US, which is the biggest market in the world and expanding our commercial efforts in countries where the CE Mark is recognized. Cervical TDR is a class III device, so a full PMA is required, which is an expensive venture. We are at the point now where we expect to finish our application to the FDA by the end of this year; get the green light and start our study. We will need to get the 185 patients enrolled and follow them for two years, so the earliest for this product to be commercialized would be 2025. In the meantime, we're seeing great success in Germany, and other key markets in Europe.

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Video Link

Dymicron Moving Forward

Ted: We implanted the first disc in 2015 at an Ambulatory Surgery Center in Cyprus, Greece. That patient is doing phenomenally well six years later. We learned from the first round of experience that we needed some design changes based on feedback from the surgeons primarily in Germany. So, in 2018-19, we took some time to change and improve the design and came out with a smaller 5 mm disc, which we didn't have for the first launch. We acquired a new CE mark in March 2020, just when the pandemic hit. We were all excited to hit the ground running with a limited controlled release, but because of COVID 19 restrictions, we didn't start until about fourth quarter of last year. We're now making great progress and moving into other key markets in Europe.

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Video Link

Full Webinar

Do you have a unique product? Are you in a growth phase or lead a company disrupting the MedTech market?

Reach out to see about setting up a webinar for your company to promote your product.

Video Link

If you have an inquiry for Darwin, you may reach him at:
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