

The Most Powerful Name in Corporate News

Engineering Solutions for Surgical Procedures



Joseph C. McGinley, MD, PhD
Founder | CEO

CEOCFO: *Dr. McGinley, what is the idea behind McGinley Orthopaedic Innovations?*

Dr. McGinley: McGinley Orthopaedic Innovations, LLC (MOI) develops innovative engineering solutions for surgical procedures. MOI strives to engineer medical technologies which improve patient care by reducing costs and improving safety. The Company recently received FDA Clearance on a small-bone version of its IntelliSense Drill.

CEOCFO: *What are you working on?*

Dr. McGinley: We recently received FDA clearance for our first product, the IntelliSense Drill™. The IntelliSense Drill™ is now fully tested, developed and on the market. Our technology has auto-stop at the far side of the bone, an automatic depth gauge that gives the surgeon an instantaneous measurement for screw sizing and integrated In-Sight Surgical Lighting™ that illuminates the surgical field. Essentially our drill senses the bone as the surgeon is drilling. Then when it gets to the far side of the bone the drill system turns off so that the surgeon does not plunge beyond the bone into the soft tissues. By doing that, you can safely do the surgeries without damaging tissue, nerves, and blood vessels on the far side. The depth measurement of the bone replaces the need for a depth gauge and is very accurate, to tenths of a millimeter. This could potentially save the surgeon time in the operating room and more importantly, help ensure the correct screw size. This could greatly reduce the number of surgeries needed to replace misplaced screws.

CEOCFO: *Is it common to go too far?*

Dr. McGinley: There is a lot of research in published literature that states plunging is a problem. As you can imagine, it can be a significant problem in spine surgery. In spine surgery, if a surgeon plunges beyond the far side of the bone, they can damage critical structures. In worse case scenarios, over plunging in the spine could lead to nerve damage, paralysis or even death. Plunging is one issue, but the more favorable feature to the surgeons is the automatic depth measurement.

CEOCFO: *How are you able to measure?*

Dr. McGinley: Right now depth measurement is performed manually, using a hand held depth gauge. Studies have shown it is fairly inaccurate to measure depth with a hand held device. It may be hard to believe but right now surgical drills are no more advanced than a drill you would find in a hardware store. Surgeons use their “feel” to drill through the bone, and then physically stop drilling when they “feel” like they have passed through the far side of the bone. Then they use this little device that has a small hook on the end of it called a depth gauge. They place that through the hole they just drilled and try to grab the far side of the bone. It can be a tedious and inaccurate process. We put sensors inside of our drill which does all of that automatically. Our drill will turn off when it gets to the far side of the bone and then a number pops up on the screen that shows exactly what depth they have drilled through to tenths of a millimeter. It can hopefully improve safety for the patient and save the surgeon time.



CEOCFO: Will doctors be more confident using this device?

Dr. McGinley: We cannot say that for sure yet, but that is what we hope will be the outcome once surgeons start using this in the operating room. It is meant to be an assist device for the surgeon to improve their technique. It is not meant to replace surgeons nor is it robotics. It is a smart drill to enhance the process for the surgeons. We are not changing how the surgeon operates; we are just making it more efficient and improving the process with the technology.

CEOCFO: Have surgeons been looking for a better way?

Dr. McGinley: Honestly, some have and others haven't. Problem recognition is always difficult. If someone has been doing a technique for decades, they may not see the problem or think it only applies to others. However, with our technology, surgeons see that it is possible to improve upon current techniques and then they do recognize the problem. Even if they did not see the plunging as a problem, the time saving and the improved efficiency by eliminating depth measurement has been universally well received by most surgeons.

CEOCFO: Now that you have FDA clearance, what are the next steps?

Dr. McGinley: The next step for our process is commercializing our device. We are in the process of manufacturing right now, and we expect to have first delivery of products by June of 2015. Sales are well underway and distribution will shortly follow. We are also working on many products with other technologies. It is an exciting time.

**"We believe in using the latest technologies and innovative engineering to solve problems and improve patient care."
- Joseph C. McGinley, MD, PhD**

CEOCFO: How will you reach out to potential users, such as doctors or hospitals? What do you understand about the process, it is not always easy?

Dr. McGinley: It is complex, that is for sure! We are going to take a multifaceted approach to introducing this technology. We obviously plan to attend trade shows where there is a high concentration of surgeons and hospital administrators to demonstrate the technology. We are working with many surgical groups and research centers to publish papers demonstrating the efficacy of our technology and the change from what they are currently using. We will also go the traditional route with sales and distribution with established distributors that can get this product in front of hospital administrators and surgeons. We also plan to do direct to patient marketing to alert them that there is something better out there that could make their surgery safer and less costly. It is a multifaceted approach. Many of these processes are underway right now. We are making inroads with a lot of facilities already.

CEOCFO: Why the decision to go directly to patients?

Dr. McGinley: I am a practicing physician. I always believed that patient education is primary. I believe in making sure the patient is well aware of all of the options they have. Since this is new technology, patients may not even be aware that this is an option for them. In turn, they could bring it to the attention of their surgeons, who may not know that it exists either. Patients are the ones undergoing the surgeries, and if there are technologies out there that can make their procedure safer and more cost effective, then they should be able to find that information and learn about it. That is how I practice medicine and plan to continue that philosophy with the IntelliSense Drill™.

CEOCFO: Were you looking for a solution to this problem or did you come upon a technology and think this was the right place to apply it?

Dr. McGinley: This technology started with a real patient case. A colleague of mine was discussing a case where a screw was placed to fix a fracture that ended up being too long and projecting into the soft tissues beyond the bone. That screw, because it was too long, eroded and tore through a tendon in this patient's wrist. I thought I could solve this common problem. I knew that sensors could take the guess work out of the process and improve the potential of the outcomes for the patient.

CEOCFO: Are you funded for the phase? Will you be seeking investment or partnerships?

Dr. McGinley: Yes. We are currently funded, but we do have an open investment round for company growth and manufacturing. Interested investors can go to our contact page at www.intellisensedrill.com. We are always open for discussions on partnerships as well. We are not closed to any options or any ideas. You never know what is going to be best path unless you listen to what someone has to offer.

CEOCFO: What is involved in training for the doctor?

Dr. McGinley: It is fairly simple. The drill still functions like a current drill. The software that is associated with our drill walks the surgeon step by step through the entire process. We can literally train someone to do this in less than five minutes.

CEOFCO: *What is next? What is in the pipeline?*

Dr. McGinley: We are currently working on the IntelliSense Bone Saw™ with similar technology that would be used for joint replacements (knee, hip, shoulder and ankle replacements). When it cuts through the far side of the bone, the saw turns off so that you do not damage tissue. It also gives the surgeon an assessment of depth, although that is not as important as it is with the drill. The auto-stop feature becomes more important with the bone saw for obvious safety reasons. We are pretty far along on development of the bone saw. We also have a few other products in the pipe line that I cannot really discuss publicly; but we are working on several additional technologies and products.

CEOFCO: *What surprised you as you started to work on the business and on the development side as opposed to practicing as a physician?*

Dr. McGinley: I took this from business plan to FDA clearance in less than two years. We have had to learn a great deal along the way, it was surely a team effort. There is the complexity of all the testing required for FDA clearance, the factors involved in setting up manufacturing, the factors involved in setting up sales—all of that is fairly complex. I have learned a lot over the past few years and have been fortunate to be surrounded by many talented and knowledgeable people. I will admit when I first started, I think I did not have a full appreciation of all the intricacies and complexities of the development process. It has been a wonderful experience, that is for sure!

CEOFCO: *Would you tell us about the McGinley Orthopedic Innovations Race Team?*

Dr. McGinley: We have local sponsors and myself personally support the team. We post race team information on www.mcginleyinnovations.com. I have been an adventure racer now for the past ten to fifteen years. Adventure racing is essentially an off road triathlon, for the most part, over a long distance. Our big race is called the Cowboy Tough Adventure Race held here in Wyoming where we are based. It is a four day, about three to four hundred mile race, over some of the most beautiful landscape you could imagine. This is something I love to do. It is one of the reasons that I moved to Wyoming and live in Wyoming. It is a great sport and the best way to relax—if you call 400 mile race relaxing!

CEOFCO: *Why should people take note of McGinley Orthopedic Innovations today?*

Dr. McGinley: Our company's goals are to innovate technologies in orthopedics to improve patient outcomes and decrease costs. There are many areas in orthopedics where the technologies have been unchanged for decades. I believe there is a lot of room for improvement. I am proud to be part of something that will greatly impact patients' lives for the better. We believe in using the latest technologies and innovative engineering to solve problems and improve patient care. As a physician, my code is first "do no harm". McGinley Orthopaedic Innovations is a way to do just that for many patients.

Interview conducted by: Lynn Fosse, Senior Editor, CEOFCO Magazine



McGinley Orthopaedic Innovations

For more information visit:

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