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Innovative Spine Surgery Platform Wins FDA Clearance

by Brian Bossetta

The US FDA recently cleared Paradigm, a new surgical platform from Seattle-based Proprio that could change the landscape of spine surgery through the use of light field technology.

The Food and Drug Administration has cleared a new platform that will enable spine surgeons to operate more efficiently, manufacturer Proprio says.

According to the company, Proprio's Paradigm platform is the first of its type to use "light field technology" in spine surgery.

Light field technology captures every ray of light traveling through every pixel in a scene, thus creating a live, 3D immersive rendering of the entire surgical field, Gabriel Jones, Proprio's CEO and co-founder, explained to *Medtech Insight*.

"You can fly through that world embedded with other types of information, like CT and MRI scans, to get a more complete view and understanding of everything happening with the patient and anatomy in real-time. The effect is like being able to see around corners."

Jones further explained that light field technology uses multiple cameras to capture the angle and intensity of light, after which the 3D images are generated. The platform's sensor suite consists of four RGB (red, green, and blue wavelengths) cameras that deliver full-color images of the surgical field by capturing these spectrums.

The fusion of the images from the sensors and depth camera is what creates the light field technology. "Light field creates an understanding of the entire operative scene, location, depth, color, and texture," Jones added. "It allows for more precise and dynamic registration by continuously seeing and sampling the scene."

The platform's sensor suite, Jones said, might be the "most sophisticated sensor suite that has ever been placed in the operating room." This is because company has taken what each sensor does best and fused it into a seamless experience for the surgeon, he explained.

"Depth sensors provide a topological map of the anatomy in infrared, while RGB cameras layer on the colors from multiple different views, while tracking cameras see and track the instruments used in the surgery," he said.

In practical terms, the platform provides surgeons with tools that alleviate many of the challenges they face in traditional surgery.

"As the operative scene is captured digitally and fuses with preoperative scans, the surgeon can see the combined data sets in high definition, from any perspective, for the first time," Jones said. "Paradigm provides an unprecedented understanding of the entire operative scene including location, depth, color and texture."

> *"Clinicians are very excited about this technology and want to bring it into virtually every clinical setting." – Gabriel Jones*

While in its current form the surgeon using the platform operates with his or her own hands, Jones added that in the near future Proprio's technology will guide robots in the performance of surgery as well.

"Both humans and robots need to see what they're doing," he said.

Another benefit to Paradigm, Jones noted, was the potential for the platform to reduce radiation exposure – by as much as 10 times – by removing the need for high-radiation intraoperative scans throughout the procedure.

Removing intraoperative scans could also result in an accelerated workflow. Previously, according to Proprio, the registration process for these scans could take up to 30 minutes. Proprio says Paradigm registration can be completed in seconds.

And through continuous data capture, Paradigm can collect a high volume of data – as much as 250GB per hour – which drives Proprio's product development process and informs advanced models for future applications.

GABRIEL JONES

But the most significant upside is what it means for patients.

As Jones explained, utilizing navigation in spine surgery is widely accepted as a method to reduce the incidence of misplaced implants, which can lead to improved post-surgery outcomes.

“Proprio’s targets include addressing some of the biggest unmet clinical needs in orthopedic surgery, including the ability to get the patient and the anatomy into a healthier alignment as a result of the surgery,” Jones said. “This post-operative alignment is known to be one of the biggest drivers of outcomes.”

The FDA’s clearance also comes at a good time.

As Jones noted, there are 1.6 million spine procedures in the US annually – and that number is increasing 10% per year as the population ages. On top of that, the US is facing a shortage of surgeons to address this growing need.

And it’s not just a problem in the US. Many patients across the globe are unable to access high quality clinical care, as well as the technologies that enable that care.

Jones also pointed out that while the FDA’s clearance is for spine surgery, future applications of the technology will be used in a variety of other therapeutic areas.

“Clinicians are very excited about this technology and want to bring it into virtually every clinical setting,” he said. “They also see huge opportunities to revolutionize medical training and education globally.”