

**FOR IMMEDIATE RELEASE:**



**Spinal Elements® Announces FDA Clearance of Sapphire® X Anterior Cervical Fixation System**

A graphic for a Spinal Elements advertisement. On the left is a grayscale illustration of a human torso showing the spine, overlaid with a red abstract shape. On the right, the Spinal Elements logo is at the top right. Below it is the text "MIS Ultra" in large bold letters, followed by "Transforming MIS Beyond Small Incisions." and a paragraph of text. At the bottom right is an image of the Sapphire X device and its name.

**MIS Ultra**

Transforming MIS  
Beyond Small Incisions.

Every MIS Ultra spine surgery solution is designed to preserve and protect patient anatomy, minimize unintended consequences, and make surgery safe and more efficient.

**Sapphire® X**  
Anterior Cervical Fixation System  
An MIS Ultra Solution

**Carlsbad, CA – July 2, 2020** - Spinal Elements, a Carlsbad, CA-based medical device company focused on spine surgery procedures, today announced the FDA clearance of Sapphire® X for anterior cervical fixation. Sapphire X is the newest product in its MIS Ultra™ suite of products aiming to minimize the unintended consequences of traditional spine surgery.

The Sapphire X Anterior Cervical Fixation System features unique integrated instrumentation and high angulation screws designed to help surgeons perform the procedure while preserving the patient's skeletal and muscle tissue. Beyond a smaller incision is the expectation that the streamlined integrated instrumentation will reduce procedural steps and complexity. After the procedure has taken place, the low-overhang

implant is designed to minimize disruption to the patient's nearby healthy anatomy, a feature that has been shown in studies to reduce the incidence adjacent level ossification.

Orthopedic surgeon John Devine, M.D., Professor and Chief of Spine Surgery at Augusta University Medical Center in Augusta, GA said, "The Sapphire X system is going to allow me to secure the smallest possible anterior plate after an anterior cervical discectomy and fusion which may decrease the risk of iatrogenic adjacent segment disease that is often seen associated with longer anterior plates. Additionally, the instrumentation will allow a single step insertion of both the interbody spacer and anterior plate, improving my efficiency while decreasing the exposure needed for traditional plating systems."

Commercial introduction of the Sapphire X system is expected in the coming months. "We are thrilled that Sapphire X, another organically developed MIS Ultra solution, is one step closer to clinical use and commercial introduction," stated Jason Blain, President and CEO of Spinal Elements. "We believe Sapphire X has the potential to improve the intra-operative experience while reducing long-term adjacent level degeneration, one of the recognized unintended consequences in this application."

Spinal Elements announced its MIS Ultra platform in June of this year. Traditionally, MIS procedures have been focused on the size of the incision required for access to the spine. The MIS Ultra product suite goes beyond small incisions to consider the implications of spine surgery after the procedure has taken place. The surgical instruments of the MIS Ultra platform have been designed to reduce the disruption of the patient's skeletal and muscle tissue, and the implants have been designed to balance the loads shared between the implants and the body while not disrupting the patient's surrounding healthy anatomy.

Spinal Elements is a Carlsbad, California based medical device company focused on the design, development and commercialization of a comprehensive portfolio of systems, products and technologies for spine surgery procedures. A leading designer, developer, manufacturer and marketer of innovative medical devices used in spinal surgical procedures, Spinal Elements combines leading medical device technologies, biologics and instrumentation to create positive surgical outcomes that exceed surgeon and patient expectations. Spinal Elements has built a reputation delivering innovative and differentiated technologies that enable fundamental shifts in solutions for spine surgery. The company markets a complete portfolio of advanced spinal implant technologies. For more information, please visit [www.spinalelements.com](http://www.spinalelements.com).

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