

Shoulder Innovations Announces FDA 510(k) Clearance For InSet™ Reverse Shoulder Platform Technology



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HOLLAND, Mich., Aug. 23, 2021 /PRNewswire/ -- Shoulder Innovations Inc, a leading innovator in the development of shoulder replacement systems, announced today that they have received FDA clearance for their InSet™ Reverse Shoulder Arthroplasty System.

The InSet™ Reverse Shoulder system seamlessly integrates and rounds out a best in class product line for shoulder arthroplasty including:

- Class leading AI enabled 3D PreView Software Planning solution to help ensure a more precise implant selection and placement.
- Broad range of implant types representing 6 different products, seamlessly integrated into one instrument tray allowing efficient treatment of patients with the simplest to the most complex pathologies, optimized for ASC environments,
- Convertible humeral platform demonstrating best in class fixation, the only true fully convertible humeral inlay system, and surprising minimally invasive bone preservation.
- Highly innovative instrumentation providing the simplest possible surgery.
- Published long term clinical data proving the effectiveness of the InSet system.

David Blue, Chief Commercialization Officer for Shoulder Innovations, said, "Our surgeon customers value having all possible shoulder surgery implants and instruments available in one tray. Not only does our system provide a reduced implant and instrument footprint, but more importantly, the surgeon has access to our primary total shoulder and reverse shoulder including our innovative primary InSet™ and InSet™ Plus glenoid technology all in one place. This convertible system is game-changing and efficient. The InSet™ Platform simplifies shoulder replacement technology in order to improve outcomes."

Matt Ahearn, Chief Operating Officer for Shoulder Innovations, said, "Shoulder Innovations has been preparing for this product release for many months. The FDA clearance and upcoming launch of the InSet™ Reverse Shoulder represent a significant inflection point for all aspects of the Shoulder Innovations business. Early indications of customer demand for this technology have been very high, and we're ready to deliver this unique product to our clinical partners to enable excellent patient care."

Brandon Florence, Director of Education & Product Management added, "The InSet™ Reverse Shoulder system continues to follow the "Simple, Yet Significant" approach as is seen with our proven InSet™ Total Shoulder System. This approach gives our surgeon customers a dynamic range of surgical options to help deliver better outcomes to their patients in an efficient manner. It is a truly convertible platform system that won't overstuff the joint. Having this entire SI shoulder system all interact and work seamlessly with our latest and most innovative 3-D PreView Software Planning System, makes this complete shoulder system even that much more compelling."

Rob Ball, CEO of Shoulder Innovations said, "Our team is very excited to bring the Reverse system to market. While it indeed provides for game-changing simplicity, it simultaneously resolves many significant technical and clinical challenges faced by orthopedic specialists seeking to offer optimal outcomes to their patients. We've been able to package not 2, but 6 products in one instrument tray, an unmatched efficiency in the marketplace. This includes all options necessary to treat glenoid deformity from simple to complex. This comes with published long-term proof of excellent outcomes for our InSet technology. Our humeral fixation is unmatched and offers the simplest technique on the market. Our technical team working with our clinical team has assembled a truly special solution, and together with our recent equity financing, Shoulder Innovations is very well positioned to bring value for all stakeholders in the care event."

The Reverse Shoulder was developed in conjunction with a team of specialist trained shoulder surgeons and will begin surgical cases in the coming days.

Additional information about Shoulder Innovations and its Total Shoulder Replacement System is available at <https://shoulderinnovations.com>

About Shoulder Innovations:

Shoulder Innovations, LLC is a medical device development company that designs and commercializes innovative products which demonstrate the potential for improved patient care and reduced overall cost to the healthcare system.

Leveraging its breakthrough, patented, inset glenoid design, Shoulder Innovations is commercializing a shoulder replacement implant system focused on improving outcomes related to the greatest cause of shoulder replacement failure: glenoid loosening.

The InSet™ technology has been shown in testing to significantly reduce glenoid implant micro-motion and simplifies surgical the surgical technique, potentially reducing complications or increase implant longevity.

Shoulder Innovations is based in Holland, Mich.

Learn more about Shoulder Innovations and its Total Shoulder Replacement System at shoulderinnovations.com.

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