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Shoulder Innovations Announces FDA 510(k) Clearance For InSet Plus™ Augmented Glenoids For Total Shoulder System

HOLLAND, Mich., Dec, 10, 2019 /PRNewswire/ -- [Shoulder Innovations](#), (SI), a leading innovator in the development of shoulder replacement systems, announced today that they have received FDA clearance for their InSet Plus™ augmented glenoids for the InSet™ Total Shoulder System.



The InSet™ Total Shoulder System is used to treat significant disability in degenerative, rheumatoid and traumatic disease of the glenohumeral joint and avascular necrosis of the humeral head. The InSet™ System includes patented inset glenoid technology, [originally innovated by Stephen Gunther, M.D.](#) The new InSet Plus™ glenoids feature an angled articular surface and are available in both 5° and 10° variants with multiple diameters.

David Blue, Chief Commercialization Officer for Shoulder Innovations said, "In the United States, there are more than 100,000 total shoulder patients operated on annually, with demand for the procedure growing at approximately 10% per year. Surgeons are seeking implant systems that can help to reduce implant loosening and revision rates, therefore increasing patient satisfaction and reducing overall healthcare costs."

[Results published in the Journal of Shoulder and Elbow Surgery \(JSES\)](#) show improved implant stability with the Shoulder Innovations InSet™ Shoulder System, demonstrating an 87 percent reduction in implant micro-motion as compared to conventional glenoid design. Additional results published in JSES show there were no complications, no cases of glenoid implant loosening and no revision surgeries performed in the series at a mean 8.7 year follow-up.

Don Running, Vice President, Research and Development for Shoulder Innovations explained, "The key to the long-term clinical success of the InSet™ glenoid has been both the unique flat back design and novel bone pocket created in the fossa to allow for a secure fixation that is "set in" the subchondral bone. With the new InSet Plus™ design, surgeons have the ability to create optimal pocket depths on more eroded glenoid faces while still providing significant version correction. In addition, due to the circular nature of the implant design, surgeons are able to dial the augmentation to provide stability in multiple positions."

The Shoulder Innovations InSet™ System simplifies shoulder replacement technology in order to improve patient outcomes.

Mr. Blue added, "We are excited to see the InSet™ glenoid product line expanded to include our InSet Plus™ glenoid. This innovation shares the same simplicity of our primary InSet™ glenoid, while offering surgeons the opportunity to simply "dial-in" the desired correction.

Surgeons appreciate the fact that they don't have to commit to a specific configuration until they are at the trial stage and no new instrumentation is required for this benefit. The long-term vision of Shoulder Innovations is to offer a complete leading technology shoulder arthroplasty product line and the addition of the InSet Plus™ is another step in that direction."

Additional details on Shoulder Innovations and its Total Shoulder Replacement System are available at shoulderinnovations.com.

About Shoulder Innovations

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Shoulder Innovations, LLC is a medical device development company which 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.

View original content to download multimedia:<http://www.prnewswire.com/news-releases/shoulder-innovations-announces-fda-510k-clearance-for-inset-plus-augmented-glenoids-for-total-shoulder-system-300971389.html>

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