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Shoulder Innovations Announces FDA Clearance of New InSet™ Stemless Humeral Implant

GRAND RAPIDS, Mich., March 14, 2022 /PRNewswire/ -- Shoulder Innovations Inc., (SI), a leading innovator in the development of shoulder replacement systems, announces the FDA Clearance of their latest component of the InSet™ Total Shoulder System, the InSet™ Stemless Humeral System. The InSet™ Stemless implant is the latest addition to the innovative and integrated InSet™ system, which already includes the successful InSet™ Glenoid, Humeral Short Stem and Reverse components.

Shoulder Surgery, InSet, Glenoid, Humeral Head, Humeral Stem, Shoulder Innovations.

The new Stemless device is a component of the first truly integrated shoulder system in the world, combining stemless and stemmed, in both anatomic and reverse configurations in the same platform.   This platform makes use of the identical instruments and surgical techniques as the existing InSet™ Humeral Short stem, allowing flexibility for intraoperative decision-making with no cost in time or any additional instruments or bone preparation required.   Previously surgeons had to choose—stem or stemless—for each surgical case without the option to easily change from one to the other. This concise configuration, the first of its kind, is also expected to help reduce O.R. time and reflect savings related to cleaning and sterilization processing costs. The unique design for the humeral preparation allows for the least amount of bone removal while the implant's curved fin design maximizes axial and rotational fixation surface area.

Rob Ball, CEO of Shoulder Innovations said, "This most recent product clearance from the FDA is a key component to our multi product strategy to provide the simplest and most elegant solutions on the market for shoulder surgery. We have packaged the equivalent of six innovative products in this simple instrumentation set. We refer to this is as **The Power of One**, and are proud to bring unmatched efficiency to the market."

Matt Ahearn, Chief Operations Officer for Shoulder Innovations said, "The addition of the Stemless system expands the clinical options available to our surgeon partners, with the same anatomic surgical technique and no incremental instrumentation. This is extremely exciting for Shoulder Innovations, as we have significant demand from clinicians who want to pair a Stemless implant with our InSet™ Glenoid technology.

David Blue, Chief Commercial Officer at Shoulder Innovations said, "The Stemless implant is another transformational addition to the [InSet™ Shoulder System](), where we continue to transcend shoulder science."

The InSet™ Stemless device will be available at select U.S. sites in the coming weeks.

About Shoulder Innovations:
[Shoulder Innovations, LLC]() is a medical device development company that designs and commercializes innovative products that 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 the surgical technique, potentially reducing complications or increasing implant longevity.

For more information about Shoulder Innovations and the *Power of One™* visit [www.shoulderinnovations.com]().

Please note that the InSet™ Stemless Humeral Implant is not yet cleared for use in the United States in a reverse articular configuration.

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