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Shoulder Innovations Receives FDA 510(k) Clearance for N-22 Humeral Head and Initiates Full Commercial Launch

Second Product Introduction on New Line of Technologies for Metal-Sensitive Patients

GRAND RAPIDS, Mich., Sept. 10, 2026 /PRNewswire/ -- Shoulder Innovations, Inc. ("Shoulder Innovations", or "the company") (NYSE: SI), a commercial-stage medical technology company exclusively focused on transforming the shoulder surgical care market, today announced it has received U.S. Food and Drug Administration (FDA) 510(k) clearance for the N-22 Humeral Head, a titanium implant option for patients with metal hypersensitivity. Alongside the clearance, the company also announced the product's full commercial launch.

Approximately 10% to 15% of the general population test positively for metal hypersensitivity and may experience persistent pain, or other symptoms associated with allergic reactions from metal implants. The N-22 Humeral Head is designed for use in anatomic total shoulder arthroplasty procedures involving patients with these complications and complements the company's N-22 Glenosphere implant, cleared in January 2026, which is used in reverse total shoulder arthroplasty procedures involving the same patient population.

"The N-22 Humeral Head augments our line of technologies for patients with metal hypersensitivity, now providing surgeons with a metal-sensitive option across both shoulder arthroplasty configurations," said Rob Ball, CEO of Shoulder Innovations. "As we continue to expand our commercial footprint across the U.S., even small incremental additions to our product line can have a meaningful impact on our relationships with surgeons and operating centers."

About Shoulder Innovations
Shoulder Innovations is a commercial-stage medical technology company exclusively focused on transforming the shoulder surgical care market, with a current offering of advanced implant systems for shoulder arthroplasty. These systems are a core element of Shoulder Innovations' ecosystem, which is designed to improve core components of shoulder surgical care – preoperative planning, implant design and procedural efficiency – to benefit each stakeholder in the care chain. Shoulder Innovations' ecosystem is also comprised of enabling technologies, efficient instrument systems, specialized support and surgeon-to-surgeon collaboration. Together, these elements seek to address the long-

standing clinical and operational challenges in the shoulder surgical care market by delivering predictable outcomes, procedural simplicity, and efficiency across all sites of care.

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