



Anika Announces First Surgeries Performed using the Integrity™ Implant System, a Regenerative Hyaluronic Acid-Based Patch System for Rotator Cuff Repairs, Commencing Limited Market Release

Integrity marks Anika's entrance into the fast-growing \$150 million+² U.S. rotator cuff augmentation market and expansion of its proprietary hyaluronic acid (HA) regenerative portfolio

BEDFORD, Mass., November 28, 2023—[Anika Therapeutics, Inc.](#) (NASDAQ: ANIK), a global joint preservation company focused on early intervention orthopedics, today announced that the first surgeries using the Integrity Implant System were successfully performed by Dr. Christopher Baker at the Florida Orthopaedic Institute in Tampa, FL. Integrity, comprised of a hyaluronic acid-based scaffold with bone and tendon fixation components and single use arthroscopic delivery instruments, is designed to protect an injured tendon and promote healing in rotator cuff repair and other tendon procedures. The system was fully cleared by the FDA in August of 2023. This marks the beginning of the limited U.S. market release ahead of schedule that will ramp to a full market release during the first quarter of 2024.

“The successful first surgeries using Anika’s new Integrity Implant System mark another key milestone in the build out of our regenerative product portfolio as we continue to provide differentiated solutions to surgeons for rotator cuff procedures,” said Cheryl R. Blanchard, Ph.D., Anika’s President and CEO. “The HA-based scaffold, together with the instrumentation and fixation components, provide a seamless, efficient, and elegant rotator cuff repair solution. While having a strong implant at time zero is critically important in rotator cuff repairs, the instrumentation and delivery are just as important, and we believe we have nailed it. The feedback received after the procedure exceeded our expectations highlighting the system’s ease of use and strength of the HA-based scaffold. We believe that Integrity is truly a game changer for surgeons and their patients and look forward to extending this exciting technology to other tendon repairs, for example, in the foot and ankle.”

The Integrity implant itself is a flexible, knitted, HA-based scaffold that provides improved dry and wet strength and regenerative capacity over first generation collagen patches¹, and supports regenerative healing through improved cell infiltration¹, tissue remodeling¹, and tendon thickening¹. In an independent head-to-head animal study¹ comparing Anika’s Integrity system and the market leading collagen implant, fibroblast infiltration and regularly oriented new collagenous tissue formation had occurred within the Integrity repair, demonstrating greater regenerative capacity as early as 12 weeks post-implantation. At 26 weeks, within the resorbing Integrity structure, new collagenous tissue infiltration had occurred, forming a new network of tendon tissue. This resulted in an average repaired tendon thickness nearly three times greater than with the market-leading collagen device. The scaffold component of the Integrity system is a porous, knitted, flexible construct combining Anika’s proprietary HYAFF® fibers with polyethylene terephthalate (PET) and is designed to support cell infiltration and regenerative healing. Integrity is inherently strong and can be confidently manipulated arthroscopically, which offers a truly unique and differentiated solution for shoulder surgeons to treat rotator cuff tears. Integrity is fixated using PEEK bone staples, resorbable PLGA soft tissue tendon tacks or suture fixation, as desired, at the site of the rotator cuff repair. The fixation components and instrumentation are delivered single-use and sterile for added efficiency.

Christopher Baker, MD, of the Florida Orthopaedic Institute commented, “The hybrid, multifilament structure provides superior implant handling and strength when compared to collagen-based products alone. This combination of materials is comprised of 80% HYAFF, a hyaluronic acid-based material in clinical use for more than 20 years, and 20% PET fiber, i.e. surgical suture, which also has a long and established clinical history. The

material and knitted structure result in a compelling blend of strength and healing that stands out from other products. The suture material remaining after full resorption of the HYAFF component is less than 30% of the total amount of suture used in a typical double-row repair. Handling of the implant has met every expectation that I had for this new device.”

Timothy Codd, MD, of the University of Maryland St. Joseph Medical Center stated, “Integrity’s instrumentation, delivery and surgical technique are a game changer. Securing the implant laterally first helps ensure proper coverage across the repair site and the rolling deployment tool provides consistent and repeatable implant placement.”

The U.S. rotator cuff augmentation market is currently over \$150 million² and is estimated to grow at a nearly 7% CAGR² over the next 5 years, representing one of the high opportunity spaces in orthopedics. The Integrity Implant System continues Anika’s focus on delivering new, differentiated shoulder solutions, with a specific focus on the intersection of regenerative solutions and sports medicine. The launch of Integrity continues Anika’s release of differentiated products to support shoulder surgeons and a portfolio built around rotator cuff disease. Integrity, combined with recent product launches including X-Twist™ Fixation System, RevoMotion™ Reverse Total Arthroplasty System, and Tactoset® Injectable Bone Substitute for hardware augmentation, provide a truly innovative and comprehensive rotator cuff solution portfolio that is unmatched in the industry. These solutions position Anika to be a compelling partner for surgeons and facilities when treating all types of rotator cuff pathologies.

¹Data on File

²2023 SmartTRAK

About Anika

[Anika Therapeutics, Inc.](https://www.anika.com) (NASDAQ: ANIK), is a global joint preservation company that creates and delivers meaningful advancements in early intervention orthopedic care. Leveraging our core expertise in hyaluronic acid and implant solutions, we partner with clinicians to provide minimally invasive products that restore active living for people around the world. Our focus is on high opportunity spaces within orthopedics, including Osteoarthritis Pain Management, Regenerative Solutions, Sports Medicine and Arthroscopic Joint Solutions, and our products are efficiently delivered in key sites of care, including ambulatory surgery centers. Anika’s global operations are headquartered outside of Boston, Massachusetts. For more information about Anika, please visit www.anika.com.

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This press release may contain forward-looking statements, within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, concerning the Company's expectations, anticipations, intentions, beliefs or strategies regarding the future which are not statements of historical fact, including statements regarding the planned launch and future expansion of Integrity, the potential expansion of Integrity to treat other tendon repairs, and the potential growth of the rotator cuff augmentation market. These statements are based upon the current beliefs and expectations of the Company's management and are subject to significant risks, uncertainties, and other factors. The Company's actual results could differ materially from any anticipated future results, performance, or achievements described in the forward-looking statements as a result of a number of factors including, but not limited to, (i) the Company's ability to successfully commence and/or complete clinical trials of its products on a timely basis or at all; (ii) the Company's ability to obtain pre-clinical or clinical data to support domestic and international pre-market approval applications, 510(k) applications, or new drug applications, or to timely file and receive FDA or other regulatory approvals or clearances of its products; (iii) that such approvals will not be obtained in a timely manner or without the need for additional clinical trials, other testing or regulatory submissions, as applicable; (iv) the Company's research and product development efforts and their relative success, including whether we have any meaningful sales of any new products resulting from such efforts; (v) the cost effectiveness and efficiency of the Company's clinical studies, manufacturing operations, and production planning; (vi) the strength of the economies in which the Company operates or will be operating, as well as the political stability of any of those geographic areas; (vii) future determinations by the Company to allocate resources to products and in directions not presently contemplated; (viii) the Company's ability to successfully commercialize its products, in the U.S. and abroad; (ix) the Company's ability to provide an adequate and timely supply of its products to its customers; and (x) the Company's ability to achieve its growth targets. Additional factors and risks are described in the Company's periodic reports filed with the Securities and Exchange Commission, and they are available on the SEC's website at www.sec.gov. Forward-looking statements are made based on information available to the Company on the date of this press release, and the Company

assumes no obligation to update the information contained in this press release.

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