



Anika Receives 510(k) Clearance for Integrity™ Implant System, a Regenerative Hyaluronic Acid-Based Patch System for Augmentation of Rotator Cuff Repairs

Complete Integrity Implant System is now fully cleared; targeting launch in Q1-2024

Integrity is highly differentiated by its knitted structure, resulting in higher strength and greater regenerative capacity compared to first generation bovine collagen patches¹

Integrity marks Anika's expansion of its proprietary regenerative portfolio and entrance into the over \$150 million² U.S. rotator cuff augmentation market

BEDFORD, Mass., August 17, 2023—[Anika Therapeutics, Inc.](#) (NASDAQ: ANIK), a global joint preservation company focused on early intervention orthopedics, today announced that it has received the final 510(k) clearance from the FDA for the Integrity™ Implant System. The system is designed to augment an injured tendon to promote healing in rotator cuff repair procedures. Clearance of the hyaluronic acid (HA) based patch component joins the prior 510(k)s received for the associated fixation devices and instrumentation. The Integrity implant is a flexible, knitted, HA-based scaffold that provides improved strength and regenerative capacity over first generation collagen patches¹, and supports regenerative healing through improved cell infiltration¹, tissue remodeling¹, and tendon thickening¹.

“The clearance of Integrity is a key milestone in the continued build-out of Anika’s proprietary HA-based regenerative portfolio and underscores our commitment to helping surgeons improve outcomes in rotator cuff repair procedures through biologic healing,” said Cheryl R. Blanchard, Ph.D., Anika’s President and CEO. “Integrity, named for its structural integrity compared with first-generation collagen patches, is a key value driver for Anika and was developed internally using our proprietary HA technology that has demonstrated differentiated regenerative performance characteristics. The HA-based patch, together with the instrumentation and fixation, provide a seamless, efficient, and elegant rotator cuff repair solution. This clearance opens significant opportunities in the shoulder and we see future expansion for this innovative technology in other anatomies. Integrity enhances the breadth and depth of our regenerative offering, adding critical mass to a growing portfolio that provides meaningful solutions to unmet needs in early intervention orthopedics that restore active living for patients around the world.”

The Integrity Implant System is comprised of the HA-based patch implant, fixation implants, and single use arthroscopic delivery instruments. The patch component of the system is a porous, flexible construct knitted using HYAFF® fibers and designed to support cell infiltration and regenerative healing. HYAFF is Anika’s proven and proprietary esterified HA technology that resorbs over time as tissue remodels. 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. The Integrity patch implant is fixed using PEEK bone staples, resorbable PLGA soft tissue tendon tacks, or suture fixation, as desired, at the site of the rotator cuff augmentation. The fixation components and instrumentation are delivered single use and sterile for added efficiency.

Christopher Baker, MD, of the Florida Orthopedic Institute commented, “I’m excited to see Anika working to improve the biologic augmentation market starting with rotator cuff repair. While some collagen products on the market are showing promising results with biological incorporation, in animal studies, Integrity facilitated improved biological healing without the use of animal collagen, while also providing a scaffold that can add strength to the construct at the time of implantation. In addition to improving the patch itself, they have also identified a more streamlined surgical technique. This product could improve patient outcomes and reduce the likelihood of future failures of rotator cuff repair.”

In an independent head-to-head animal study comparing Anika’s Integrity system and the leading competitive collagen device, 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 forming a new network of tendon tissue had occurred. This resulted in the repaired tendon thickness being nearly 3 times greater than with the competitive collagen device. Tendon thickness is thought to improve the local biomechanical environment of the tear by reducing tendon strain, thus optimizing its healing potential³.

Timothy Codd, MD, of the University of Maryland St. Joseph Medical Center stated, "Building on previous work with biological augmentation, the new Integrity system will be the next step forward in improving tendon healing and patient outcomes, with refined and more precise delivery. With the ability to augment and improve tendon healing along with increased structural support for early tendon repairs, Integrity should be the next big advance in improving patient outcomes in rotator cuff disease."

The U.S. rotator cuff augmentation market is currently estimated at \$150 million², growing 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 Integrity clearance, and upcoming launch, continues Anika's release of unique products to support shoulder surgeons and a portfolio built around rotator cuff disease. Recent launches include Tactoset with hardware augmentation and with bone marrow aspirate, the X-Twist suture anchor fixation system, and the RevoMotion Reverse Shoulder System. These new products allow Anika to expand deeper into the shoulder market by offering regenerative, sports medicine, and reconstructive solutions.

Anika expects to commence a limited market release of Integrity in the United States in the first quarter of 2024 with a full U.S. market release and expansion into international markets to follow.

¹Data on File

² 2023 SmartTrak

³ Schlegal, T. F., M.D. (2017). Radiologic and clinical evaluation of a bioabsorbable collagen implant to treat partial-thickness tears: A prospective multicenter study. *Journal of Shoulder and Elbow Surgery*. <https://doi.org/10.1016/j.jse.2017.08.023>

About Anika

Anika Therapeutics, Inc. (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.

ANIKA, ANIKA THERAPEUTICS, HYAFF, INTEGRITY, REVOMOTION, TACTOSET, X-TWIST, and the Anika logo are trademarks of Anika Therapeutics, Inc. or its subsidiaries or are licensed to Anika Therapeutics, Inc. for its use.

Forward-Looking Statements

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 success of Integrity in improving the treatment of rotator cuff disease 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.

For Investor Inquiries:

Anika Therapeutics, Inc.

Mark Namaroff, 781-457-9287

Vice President, Investor Relations, ESG and Corporate Communications

investorrelations@anika.com

For Media Inquiries:

Greenough

Christine Williamson, 617-922-1289

Senior Vice President

cwilliamson@greenough.biz

<https://ir.anika.com/2023-08-17-Anika-Receives-510-k-Clearance-for-Integrity-TM-Implant-System,-a-Regenerative-Hyaluronic-Acid-Based-Patch-System-for-Augmentation-of-Rotator-Cuff-Repairs>