



Anika Receives FDA 510(k) Clearance for the X-Twist™ Knotless Fixation System, Expanding its Sports Medicine Soft Tissue Portfolio

X-Twist provides a simple, versatile knotless suture anchor system ideal for key repairs in the shoulder, foot and ankle, and other extremities

BEDFORD, Mass., May 19, 2022-- [Anika Therapeutics, Inc.](#) (NASDAQ: ANIK), a global joint preservation company focused on early intervention orthopedics, today announced that it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for the X-Twist™ Knotless Fixation System. The X-Twist Knotless Fixation system is a platform of suture anchors designed to be mechanically strong¹, easy to use, and support healing for key repairs such as rotator cuff repair. According to SmartTRAK, there were nearly 670,000 rotator cuff procedures performed in 2021, with the majority of these being performed in the ambulatory surgery center (ASC)².

“The clearance of the X-Twist Knotless Fixation System is another step forward in establishing Anika as a preferred partner within the ASC,” said Kevin Stone, Vice President and General Manager, Sports Medicine. “Feedback from our surgeon thought leaders has been very positive with a specific focus on the versatility of the anchor and the fixation it provides in both soft and hard bone conditions. Surgeons can use the X-Twist in rotator cuff repair for both medial and lateral row applications, as well as other soft tissue procedures where a knotless anchor is desired. This clearance adds to the family of innovative new products to address high opportunity spaces, such as the shoulder market, that will drive accelerated growth for Anika Sports Medicine and our overall joint preservation portfolio.”

The X-Twist Knotless Fixation System affords surgeons a variety of knotless and knotted soft tissue fixation options in a single anchor platform. The feature-rich design includes venting, intended to support cellular infiltration through the anchor; a double helix thread that allows fast and easy deployment; the ability to support the surgeon’s preferred combination of multiple sliding suture or tape configurations; and the unique X-Spline™ drive technology which provides more torque transfer for easy anchor insertion. In addition to the shoulder, X-Twist has direct applications in a variety of procedures, including in the foot and ankle, and will initially be available in PEEK-Optima®.

The X-Twist represents the newest innovation within Anika’s Sports Medicine segment focused on the ASC. Combined with Anika’s recent hardware augmentation indication for Tactoset®, its proprietary hyaluronic acid-enhanced injectable bone substitute, the X-Twist clearance differentiates Anika among its competition by enabling it to offer a knotless fixation solution for rotator cuff repair in patients with insufficient bone quality.

Anika expects to begin commercializing the X-Twist Knotless Fixation System in the second half of 2022 within the United States.

¹ Competitive pull-out data on file.

² SmartTrak 2022

PEEK-Optima is a registered trademark of Invibio Limited Corporation

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 the last sentence of the quotation from Kevin Stone and the fourth paragraph. 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.

About Anika

[Anika Therapeutics, Inc.](http://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 soft tissue repair and bone preserving joint technologies, 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.

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/news-releases?item=279>