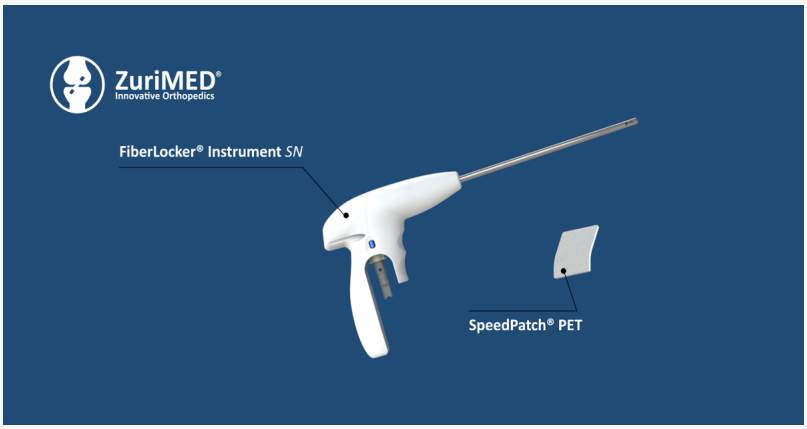
ZuriMED Secures FDA Clearance for the FiberLocker® System

BOSTON, MA, UNITED STATES, December 20, 2024 / EINPresswire.com/ -- The Swiss MedTech startup ZuriMED Technologies AG announces FDA clearance of its FiberLocker® System, a cutting-edge solution for rotator cuff repair reinforcement. This milestone marks the upcoming U.S. launch in early 2025 and enables surgeons to leverage this novel technology for rotator cuff repair procedures.



The FiberLocker® System

Just in time for the holiday season, ZuriMED celebrated the FDA clearance of its 510(k) submission for the FiberLocker® System, the first clinical indication of its pioneering Surgical-Fiberlock® technology.
Rotator cuff tears are among the most prevalent shoulder-related ailments, affecting a vast segment of the population.[1] Traditional repair techniques often fail at the suture-tendon interface[2], leading to retears, further surgeries, and longer recoveries. ZuriMED's FiberLocker® System addresses these issues by reinforcing repairs at the time of surgery in an effort to improve traditional repair techniques.[3]

The FiberLocker® System: Felting is the Solution:

The FDA-cleared device combines two components:
1. SpeedPatch® PET – a non-woven polyethylene terephthalate (PET) patch implanted onto the repaired tendon.
2. FiberLocker® Instrument SN – a single-use device attaching the patch to the tendon.
Translating felting technology from the textile industry into medicine, the FiberLocker® Instrument SN employs a reciprocating needle that pushes the fibers into the underlying tendon tissue, creating an interwoven construct that securely integrates the implant to the tendon. Unlike traditional augmentation methods, the FiberLocker® System simplifies the fixation process while providing immediate biomechanical support.[2] Prof. Dr. Karl Wieser, Head of Shoulder and Elbow Surgery at Balgrist University Hospital stated: "I truly believe that ZuriMED's

unique technology has the potential to become a game changer in shoulder surgery by helping us to improve patient's outcomes. The application of the device is simple and fast and has shown to reinforce traditional repair techniques."

Pre-Clinical Data: A Robust Foundation for FDA Clearance:

Comprehensive ex vivo biomechanical testing has supported the enhanced suture retention and even load distribution across the implant achieved with the FiberLocker® System.[3] The arthroscopic procedure streamlines the surgical process, with a rapid, 90-second patch-to-tendon fixation.[3]
Further validation through in vivo animal studies confirmed the excellent biocompatibility of the implant, with no adverse effects noted up to 13 weeks post-implantation. The patch was well integrated with the tendon, evidenced by a smooth transition between the patch and tendon tissues and cellular ingrowth into the porous scaffold. [3,4]

Mission Statement: Innovation Rooted in Zurich's Health Cluster:

The FiberLocker® System is the fruit of five years of dedicated effort by the team at ZuriMED, situated within Zurich's premier health care cluster and supported by the Balgrist Beteiligungs AG. Originating from the Laboratory of Orthopedic Biomechanics at ETH Zurich and the University of Zurich, the startup has capitalized on direct access to leading-edge research labs at Balgrist Campus and top-tier orthopedic clinics like Balgrist University Hospital. These collaborations have accelerated the system's journey from concept to clinical application.
Professor Jess Snedeker, co-founder of ZuriMED and professor of orthopedic biomechanics, commented: "The challenges of traditional rotator cuff repair, long a source of frustration for both patients and surgeons, are addressed head-on with our FiberLocker® System. This FDA clearance represents a significant leap forward in surgical technology. Our system, born from pioneering research and clinical collaborations, has the potential to enhance patient outcomes. With the U.S. launch on the near horizon, we are poised to set new benchmarks in soft tissue repair."
ZuriMED is driven by the ambition to leave a long-lasting impact on the medical technology landscape. The company anticipates a limited U.S. market release of the FiberLocker® System in early 2025, allowing patients to soon benefit from this new technology.

[1] Zumstein MA, Künzler M, Hatta T, Galatz LM, Itoi E. Rotator cuff pathology: state of the art. Journal of ISAKOS. 2017 July, 213-221
[2] Cummins CA, Murrell GA. Mode of failure for rotator cuff repair with suture anchors identified at revision surgery. J Shoulder Elbow Surg. 2003 Mar-Apr, 128-33
[3] Meyer DC, Bachmann E, Darwiche S, Moehl A, von Rechenberg B, Gerber C, Snedeker JG. Rotator Cuff Repair and Overlay Augmentation by Direct Interlocking of a Nonwoven Polyethylene Terephthalate Patch Into the Tendon: Evaluation in an Ovine Model. Am J Sports Med. 2023 Oct, 3235-3242.

[4] Data on File

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