



Winter Innovations Receives 510(k) Clearance for EasyWhip™ Suturing Needle

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For Immediate Release

Knoxville, Tennessee – Winter Innovations, Inc., a medical device startup company, announced that it has received 510(k) clearance from the Food and Drug Administration (FDA) for its EasyWhip™ suturing needle product. EasyWhip™ is a non-absorbable suture with specialized needle that simplifies and standardizes suturing techniques. Its primary application is for orthopedic procedures to repair torn ligaments and tendons, like the anterior cruciate ligament (ACL), Achilles tendon, and distal biceps tendon.

The innovation in EasyWhip™ is the patented two-part needle, which has a needle tip and a connectable rod/insert. The two needle components are fixed to ends of a length of ultra-high strength orthopedic suture. They can be connected to create a continuous loop of suture and disconnected to create a straight length of suture, which facilitates faster, easier stitching and creation of patterns that cannot be made with conventional needles.

“The beauty of EasyWhip™ is that it’s sophisticated, yet so simple. And it’s reproducible,” stated Dr. James Bradley, MD, an orthopedic surgeon in Pittsburgh, PA and the team physician for the Pittsburgh Steelers. “Because of its configuration, there are three or four different stitch patterns that you can make with EasyWhip™. Timing-wise, I’m much faster with this product than I am using a traditional whip stitch needle.”

“We are extremely pleased to have received 510(k) clearance for EasyWhip™ and believe that the ease of use and time savings benefits will be attractive for our orthopedic surgeon and physician assistant end users,” said Lia Winter, co-founder and CEO of Winter Innovations.

Winter Innovations received clearance from the FDA less than two months after submitting their 510(k) application. “The speed at which we were able to navigate this regulatory hurdle is a testament to the strong team and ecosystem that we have supporting us,” said Preston Dishner, the company’s co-founder and COO. “Our focus now is on ramping up production and preparing for limited market release. We are excited to deliver a new and innovative suturing system that can raise the operating efficiency for hospital and surgery center customers.”

EasyWhip™ is the first FDA-cleared product for Winter Innovations. It is indicated for use in approximation and/or ligation of soft tissues, including the use of allograft tissue for orthopedic surgeries. Winter Innovations also recently announced that it received a \$256,000 Small Business Innovation Research (SBIR) grant from the National Science Foundation. This funding will allow Winter Innovations to perform research and development on the two-part needle technology for orthopedic applications and provide a basis for additional research for other surgical applications.

About Winter Innovations: *Winter Innovations is an award-winning medical device startup developing innovative tools for overlooked areas in orthopedic surgery. Founded in 2018 by Lia Winter (BS/MS Engineering, MBA) and Preston Dishner, (BS/MS Data Science, MBA), Winter Innovations' mission is to create products that improve outcomes for patients in sports medicine. The company's first product is EasyWhip™, a patented surgical needle designed to simplify and standardize stitching in orthopedic ligament and tendon reconstruction surgeries. Winter Innovations has won awards in numerous competitions and been selected to participate in national accelerator programs including [Tampa Bay Wave](#), [Springboard Enterprises Health Innovation Hub](#), and [ZeroTo510](#).*

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