



**Knotless Tissue Repair and  
Attachment Devices**

**\$5,000,000 Series "A" Offering**



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## Offering

Ziptek LLC is a Limited Liability Company (LLC), based in Sarasota, Florida, and has been incorporated since 2012. The Company is seeking \$5,000,000 - series "A" Offering.

## Capital Raised and Background of Founder and Company

To date, Ziptek LLC has raised \$500,000 in exchange for equity and has a \$300,000 convertible loan at a 20 percent discount, with a 3 percent simple interest rate, and an expiration date of March 2018.

From 1996 - 2012, the precursor development of the company was funded by the Founder, William F Bennett MD, an orthopedic surgeon with 26 years of experience, (see CV [bennettorthopedics.com](http://bennettorthopedics.com)) and continued to fund its development until an investor joined him in 2014 investing \$500,000 in exchange for 12.5 percent equity. An estimated \$500,000 - \$750,000 of personal funds were used to fuel Ziptek LLC's birth and evolution through 2012, by Dr. Bennett who holds 81.5 percent equity in the Company.

William F Bennett MD has also founded Ziptek Mexico SA De CV, 60 percent equity, based in Hermosillo, Sonora, Mexico, where much of the engineering and testing work has been and continues to be produced on location. Ziptek Mexico SA De CV employs numerous biomedical engineers, mechanical engineers and others with non-investor money. Ramses Galaz PhD is a partner in both the U.S. and Mexican companies – holding 40 percent equity in the latter. He is a Professor, PhD biomedical engineer at Mexico's Monterrey Tech and teaches both in Mexico City and Monterrey. Valuation of engineering, prototype development, biomechanical testing, degradation testing are just a few benefits coming to Ziptek LLC, from Ziptek Mexico Sa De CV , and may to date, exceed \$500,000 from non-investor or founder funds, but from Mexican grants.

Ziptek LLC uses a 13485:2003 TÜV Süd certified contract manufacturer located in Charlotte, NC and Chicago, Illinois for production, assembly, packaging and assures our quality system.

## What Do We Make and Our Commercial Assessment

Ziptek LLC makes ZipE® (trademark accepted-say Zip and then say the word "e") knotless tissue repair and attachment devices. These devices are developed for tissue to tissue and tissue to bone repair and can be used in minimally invasive techniques or open surgery. The device utilizes an engineered mechanism whereby a surgical button or "capture" slides along the suture with protuberances and is kept from moving back along its path. It uses a technology similar to a Zip-Tie. This avoids the need to tie knots in small spaces and creates a superior contact of the tissue to be repaired compared to all other devices on the market.

This device falls in the general category of bone anchors: regular bone anchors require a surgeon to place a knot, newer knotless devices engage the suture by friction hold. Ziptek LLC's technology does not crimp the suture but employs a Zip-Tie, type mechanism, found in a surgical button. The surgical button disperses pressure across a larger surface area and helps prevent the suture from tearing out through the tissue. This is the MOST common failure mechanism found with all devices on the market. Studies have shown that the addition of the button to the rotator cuff repair device stabilizes the tissue and helps prevent this form of failure. Additionally, it creates increased contact surface area which should allow for better and improved tissue healing and should decrease the rate of non-healing and re-tears.

The device is initially being optimized for the rotator cuff repair market, roughly a 500-600,000, reimbursed cases per year in the United States. With average implant revenue of \$1,000/case, this correlates to a

\$500-\$600,000,000 per year revenue alone in the United States in a domain with a growth rate of 10-12 percent.

There are numerous further indications for use in orthopedic surgery alone, outlined in the Indications For Use (IFU) and filed with the U.S. Food and Drug Administration, that span multiple different joints and tissues beyond rotator cuff repairs-see 21 CFR §807.92(a)(3) . The device's engineering can be utilized in many other surgical disciplines with small changes to the introducer. Countries beyond the United States are embracing minimally invasive rotator cuff repair devices.

Ziptek LLC is aggressively interacting with various well-known national and international orthopedic training centers - funded through its Mexican grants - which continues real-time research that defines the ZipE® device's superiority for tissue repair. Specifically, a contact surface area study with a well-known orthopedic training department in Florida has been started. Preliminary testing with a Teckscan machine illustrates the superior contact area afforded by the ZipE® surgical button/capture, and supports previous studies that show the addition of a surgical button to rotator cuff repair devices prevents the suture from pulling through the tissue and actually provides a compressive force at the surgical button site. The final results of this study should be available in 6-8 weeks.

Additionally, the Chairman of the orthopedic training program at the National Institute for Rehabilitation in Mexico City, a Federal program, and Ziptek LLC are planning on corroborating on an animal study to further support ZipE® claims of superior contact surface area and healing rates.

(Please note, that none of these studies cited above are needed for FDA approval, 21 CFR §807.92(a) (3). See below for finished testing requirements for FDA submission that have all been passed by Ziptek LLC.)

As such, the management team anticipates a swift growth rate and are optimistic to capture 10 percent of the market by the end of the second year – equating to nearly \$50,000,000 in revenue in the United States alone. A growing list of distributors are waiting for Ziptek LLC to notify them immediately upon FDA approval and can be provided upon request. These distributors are not located simply in the United States but also across Europe, Gulf Arab states (Dubai), Brazil, and Columbia, to name a few.

## Assets

Ziptek LLC has over 7 patents issued and expects another 3 within 6-12 months. Additionally, patentable material is filed in 36 countries and one of these foreign patents has already been issued.

Indirectly through Ziptek Mexico SA De CV, Ziptek LLC has access to and owns® numerous testing, manufacturing and packaging machines.

## Regulatory and FDA

Ziptek LLC utilizes various contract manufacturers that are located from Chicago, Charlotte, Naples to Mexico. Our quality system is maintained by our contract manufacturer who is 13485:2003 TÜV Süd certified. With this certification and with a CE mark, the ZipE® products can be sold in Europe. The Gulf Arab states, Mexico, Central America and most of South America accept FDA approval.

In preparation for regulatory approval, 510k premarket notification, substantial equivalence, 21 CFR §807.92(a)(3), Ziptek LLC has been performing years of and is continuing in real time to do - biomechanical, biocompatibility and degradation study testing. All testing to date shows that the ZipE® device is at least equivalent or better than comparable devices on the market. This is how the FDA will evaluate the

Company's testing. However, beyond being substantially equivalent in the eyes of the FDA, there are numerous areas that the ZipE® device exceeds other devices and brings advantages to tissue repair NOT found anywhere in this device domain. Preliminary contact studies show the superiority of the ZipE® to other devices on the market - these studies are not needed for FDA approval. With FDA approval the ZipE® device can be immediately marketed for sale - turn-around time is approximately 132 days from submission.

Specific testing categories that have been performed and passed include:

Test	Certification	Status
Biocompatibility	21 CFR Part 58 Compliance	
	Good Laboratory Practice for Nonclinical / Lab Studies	
	ISO 10993-13 tests	Passed
Performance testing	Biomechanical- static and cyclic loading	
	USP 39-NF 33:2016 <881> Tensile Strength	Passed
Degradation Studies	ASTM F1635	Passed
Sterilization Validation	ISO 11135	Passed
EO Residuals	ISO 11135	Passed
Shelf life -post accelerated aging	ASTM F1980	Passed*
	ASTM 2096 – 11	Passed
Seal Package Validation	ISO 11607 -1:2006	
	ASTM F88/F88M-15	Passed
Finalizing bubble burst testing	ASTM 2096 – 11	Passed

\*1 year passed

Ziptek LLC has FDA consultants that include:

- An attorney with 20 years of experience with bone anchor submissions and engineering background
- A Toxicologist with 40 years of submitting applications and interacting with the FDA
- A former bone anchor FDA reviewer

The application to the FDA was submitted on August 29, 2016 and Ziptek LLC expects to hear initial feedback as soon as 90 days from the submission date. With FDA approval the ZipE® device can be sold immediately, 21 CFR §807.92(a) (3).

\*update- on 09/06/2016, Ziptek LLC received notification that its application had passed the administrative checklist and would be undergo substantial examination.

William F Bennett MD

Founder - Ziptek LLC

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