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Orthopaedic

CASE STUDY

Collagen Matrix: Crucial partner in the development and manufacturing of a revolutionary implant for tissue repair and regeneration

- **Advances in biomaterials support the body's natural ability to regenerate.**
- **An experienced, fast-moving contract development and manufacturing partner is critical.**
- **Predicate technologies and regulatory know-how are invaluable for 510(k) approval.**

Opportunity

Orthopedic surgeons specializing in sports medicine often see patients with a partial tear in a tendon.This puts surgeons in a quandary. If they don't operate, the partial tear will propagate to a full thickness tear. If they cut the tendon and reattach it, the patient is faced with a many months-long recovery.

Fortunately, advanced biomaterials are making this cut-and-reattach standard of care obsolete. Surgeons can now apply collagen-based implants on top of partial tears to create a healing environment for the tendon. The downside: placing a biomaterial implant arthroscopically can require a high degree of skill, and the complexity of the procedure also means that it takes a long time, posing a greater risk of complications for the patient.

Challenge

A medical device maker took the initiative to develop and patent a delivery and fixation system, but required a biomaterial partner to develop and manufacture the most important component, the implant itself. They began their search by defining a set of properties for an implant that would induce the production of tendon-like tissue. The biomaterial would need to meet stringent specifications for tear strength and composition. The partner had to bring both high-caliber expertise and the facilities required to consistently deliver top-quality material for regenerative results.

Historically, inducing the production of collagen-like tissue or tendon-like tissue in humans or animals has proven to be incredibly difficult. The medical device maker explored approximately 30 different materials, from various providers, many of them synthetic. They knew from past research experiences that animal or human collagen-based implants were far more likely to be successful.

Solution

Collagen Matrix was one of the few companies that had a collagen-based material option. More significantly, Collagen Matrix had many products already in market, including a similar device. This predicate device would be invaluable in obtaining 510(k) clearance for the new implant system.

"The amount of work Collagen Matrix put in to help support our FDA submission was a ten out of ten. Collagen Matrix had a predicate technology that enabled us to get 510(k) approval very quickly."

As a partner, Collagen Matrix possessed the biologic expertise and regulatory knowledge to deliver speed to market and a high-quality supply of the product in the long term. Together, the medical device company and Collagen Matrix succeeded in developing an FDA-approved technology that has good patent protection and is very effective for its intended clinical application. The medical device maker developed all the instrumentation. The implant and its fabrication were done by Collagen Matrix.

"The thickness of the implant and the mechanical strength are different than what Collagen Matrix had done in the past. Collagen Matrix did custom development for our clinical application, and they did it very well."

The collagen-based implant helps the tendon heal from within. Rather than a matrix substrate that merely houses tissue, the implant induces new tissue to grow and become tendon-like.[1] This implant is now benefiting hundreds of thousands of patients around the world.

"We have had experiences where a patient had the procedure, and then had a fall six or 12 months later, so they had to re-operate. We biopsied some of those patients. The quality of the tissue that was generated was the most striking thing. No one had ever demonstrated healing a tendon. It gives you goose bumps. You can't believe this works as well as it does."

The device maker's delivery-and-fixation system makes it possible to complete the procedure in five to ten minutes—a boon to surgeon adoption and patient access.

Benefits

In choosing a contract development and manufacturing partner, the quality of Collagen Matrix's leadership was also a deciding factor for the medical device maker. They found the Collagen Matrix team to be "very smart, experienced, capable people" who understood the clinical need and collaborated to achieve their specific goals. Best-in-class infrastructure and the ability to adapt also strengthened the working relationship.

"Collagen Matrix did a very good job of investing in their own business during our time of development. Their operative capacity was never in the way of our technology, even though it had an exponential growth curve."

In addition to improving patient outcomes, the partnership of Collagen Matrix and the medical device maker was a commercial success, sparking investment and inspiring more biologics development in the orthopedic space. Contract development and manufacturing partners like Collagen Matrix are helping to bring those ideas to fruition.

"I would tell any colleague that was looking at partnering, that in a 510(k) world, the breadth of experience and the patent portfolio is a very important and valuable part of what Collagen Matrix brings to the table."

Consider Collagen Matrix for your contract development and manufacturing needs.

Collagen Matrix offers a full line of collagen- and mineral-based medical devices to support the body's natural ability to regenerate. Our TruSource™ process guarantees the highest level of biomaterial quality to enable peak performance from your finished product. To learn more about Collagen Matrix and the TruSource™ process, visit **collagenmatrix.com.**

References

1. Arnoczky SP, Bishai SK, Schofield B, et al. Histologic evaluation of biopsy specimens obtained after rotator cuff repair augmented with a highly porous collagen implant. Arthroscopy 2017;33:278-83.

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