CASE STUDY

OEM | Medical Grade Collagen

“First, and foremost, it allowed us to optimize product handling.”

How medical device manufacturer, Xenco Medical, optimized product performance through the selection of an OEM collagen partner.

About Xenco Medical

- Headquarters, San Diego, CA
- Founded 2011
- >50 employees
- Privately held

The power of partnership

Helping to improve patient outcomes

The landscape for medical device development is not getting any easier. The pressure to create more innovative, less expensive devices while minimizing development costs and getting a product to market faster – especially in the face of a rigorous regulatory environment – has never been more challenging.

The challenge

The pressure to navigate this commercialization challenge is placed directly on the product innovators to find new solutions. Working with trusted, reliable, proven partners, across every aspect of the development lifecycle and supply chain spectrum – from raw materials to regulatory support and beyond – can help minimize the risk of false starts, accelerate time to market and optimize return on investment of both time and money.

Xenco Medical's relationship with Getinge and their OEM collagen portfolio is proof of how the power of partnership, the power of access to material scientists, the power of expert regulatory support and the power of proactive customer service, helped provide the power to improve patient outcomes.

Uncompromising confidence

When Xenco Medical Founder and CEO, Jason Haider, was in the early-stage development of the Xenco Sorrento™ Bone Graft Substitute, he was convinced (after conversations with surgeon design partners) that selecting the right collagen partner would be crucial to the product's success.

Incorporating collagen as a key component would provide better product handling and absorption and, ultimately, fast and effective fusion and healthy bone growth during the healing process – all critical attributes that would ensure the product performed at a level equal to or better than the market leader.

Based upon the recommendation of a contract manufacturing partner, Xenco approached the material science experts at Getinge to determine whether the properties of Getinge OEM Collagen would support the product attributes Xenco was seeking to achieve successful surgeon adoption and, ultimately, patient safety and positive patient outcomes.

Xenco Medical's Sorrento™ Osteoconductive Bone Graft Substitute is indicated for use as a bone void filler to fill voids or gaps of the skeletal system not intrinsic to the stability of the bony structure (extremities, pelvis, posterior lateral spine) and in the treatment of surgically created osseous defects or osseous defects created from traumatic injury to the bone.

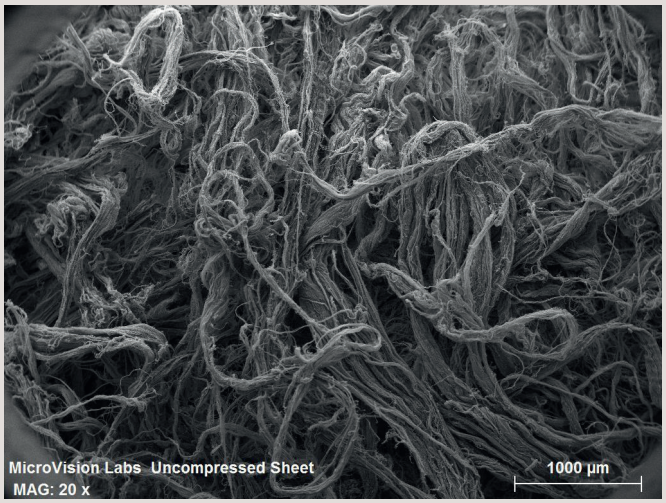
"It certainly helps to work with a materials partner who has been there, seen it, done it, and Getinge was just that."

Jason Haider
Founder and CEO
Xenco Medical

Proven collagen properties

Getinge has been manufacturing Bovine Type I collagen for over 30 years and Getinge's collagen is known for its pure and naturally long fiber content. Based upon the Getinge collagen samples provided for early product development, Xenco knew immediately that this differentiating feature would prove to be beneficial to product performance and adoption.

"I think one of the reasons we're proven to outperform competitors such as Vitoss, is because of Getinge collagen's interwoven strong fibers," Haider said. "First and foremost, it allowed us to optimize product handling – which we knew was a real issue with competitive graft substitutes."



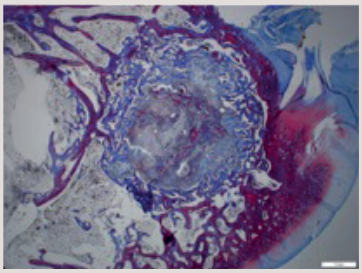
Getinge OEM collagen – microscopic view of fibers

Improved handling provides the surgeon with better control over where the graft is placed, and also facilitates easier tearing – allowing surgeons to split or cut the graft to accommodate various locations in the surgical area where fusion is needed without the concern of the collagen dissolving.

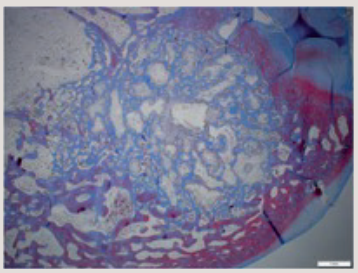
Beyond its handling properties, Getinge collagen offered better absorption, enabling a lower percentage of collagen to be used in the product formulation. This allowed for an increase in the percentage of beta tricalcium nitrate (B-TCP). B-TCP is both osteoconductive and osteoinductive and carries significant bone growth characteristics. The proprietary mix of Xenco's high-performing synthetic creates a structure and porosity that resembles natural human bone with a pore size optimized for revascularization and bone regeneration.

"In surgical applications, especially those involving the posterolateral spine, surgeons don't compromise. Bottom line, because of the quality profile and properties of Getinge collagen we didn't have to compromise on any of the product features we were looking to deliver," Haider continued.

Femur Defect Validation – Histology



Vitoss Strip + BMA: Little to no bone formation in the middle of the defect after 3 weeks, mainly at the margins.



Sorrento™ Strip + BMA: Evidence of new bone formulation even at 3 weeks at the margins and in the middle of the defect.

Highly regarded regulatory support

For Xenco Medical, the product development process didn't stop with a great graft substitute prototype in hand. In fact, it had only just begun. As most MedTech and pharma companies have realized, the regulatory process to secure FDA clearance for a medical device can be every bit as rigorous as developing the product itself.

While Xenco was pursuing regulatory clearance for general orthopedic use – foot, hand, and pelvis – FDA approval gets more difficult when a company is also seeking clearance for applications that can have a significant impact on patient safety. Such was the case with Xenco's bone graft substitute for use in spinal surgery – a critical clearance demanded by spinal surgeons yet, based upon the difficulty of regulatory approval, not often, or easily secured by most bone graft substitutes.

Throughout the extensive regulatory process, however, the one thing that the Xenco Medical R&D team didn't have to worry about was providing the clinical evidence – that the Getinge collagen component would deliver the highest level of patient safety. From biocompatibility testing and material toxicology assessments to gel electrophoresis studies and traceability mapping, Getinge had all of the required clinical documentation and knew how to best present the data – and defend the data, as necessary – to ensure clearance success. Beyond this pre-clinical and predicate evidence, direct access to Getinge's regulatory team ensured every FDA question would be answered, thoroughly and in a timely fashion.

Getinge's close collaboration – from support with the product design to the development of the design dossier – provided the in-depth knowledge to arm Xenco with the documentation and certifications they would need.

"They provided outstanding support, delivering everything we needed for submission within days of the request. That didn't happen with some of our other materials providers," Haider said, "Honestly, the product is so good and since there are predicate products already in the market – that prove its safety and effectiveness – that had to have an impact on the FDA's confidence in our product design."

So much of the cost of the R&D process is associated with the trial and error of sourcing various vendors and trying to bridge together materials, knowledge and information from those external companies. Between product development and regulatory, Xenco significantly accelerated the entire development process and reduced project and business risk by selecting Getinge as their OEM collagen partner.

»Getinge provided outstanding support, delivering everything we needed for submission within days of the request.«

Jason Haider

Global reach. Local touch.

The material science, product design and regulatory support provided by Getinge were certainly critical to the successful clearance and ultimate commercialization of Xenco's Sorrento™ Bone Graft Substitute. But how did they extend the partnership beyond initial product launch?

"Anytime we need anything from Getinge they connect us with just the right players on the team to meet our need. As our product sales continue to improve, Getinge has been proactive in making sure that we have the collagen components we need to meet the growing demand."

Getinge's partnership with Xenco Medical extends beyond what is typically seen between most raw material suppliers and med device developers. Getinge has connected Xenco Medical with its global distributor network with the goal of helping them introduce the Sorrento™ Osteoconductive Bone Graft Substitute to neurosurgeons and orthopedic spine surgeons around the world.

"It's like working with a close friend who just happens to have a network of resources that spans the globe," Haider said.

»Getinge offers the reach and resources of a global company with a sense of community, collaboration, and partnership that you would get from a small company.«

Jason Haider

The bottom line

Medical device developers today – whether it's a start-up or an established industry player – can't afford false starts. Lost time on restarts in any aspect of the product development process means time and money lost in re-engineering, which equates to being late to market. Bottom line, you must mitigate any risks that can derail product commercialization.

"In the end, our selection of Getinge as our collagen materials provider helped us eliminate any risk with a crucial aspect of our design," Haider said. "The confidence in Getinge from a product and a customer support standpoint allowed us to concentrate on aspects of the design and regulatory processes that we knew were critical to clearance. That's the true definition of a partner."

Let Getinge help you with your medical device development.

For more information about the Getinge OEM collagen portfolio, please send us a message on **getinge.com/collagen**

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