Evergen™

Lenoss Medical

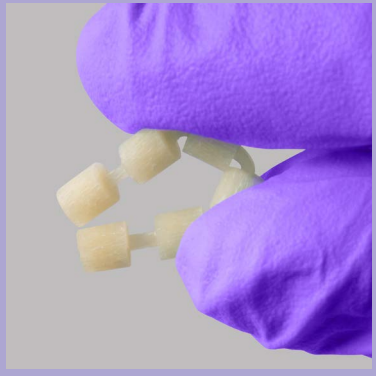
CASE STUDY

Executive summary

Founded on the belief that natural solutions can improve patient outcomes, Lenoss Medical Inc. created the OsteoPearl® Biological Augmentation Implant, which is osteoconductive and made of 100% cortical bone. This provides a scaffold for the ongrowth and/or ingrowth of newly formed bone, allowing for natural fracture repair.

Lenoss developed an efficient, high-volume processing method to create the OsteoPearl® allograft implant. In its search for a contract development and manufacturing organization (CDMO) partner, Lenoss sought a forward-thinking team that recognized the value of its newly developed method and could contribute new ideas to drive additional processing innovation and optimization. Evergen, a leading CDMO with a similar vision and full suite of end-to-end capabilities, emerged as the perfect fit.

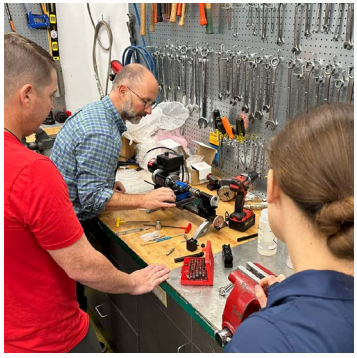
Together, Lenoss and Evergen collaborated on design for manufacturability, optimizing equipment and reimagining processes to streamline workflows and maximize output. The result was scalable processing for the OsteoPearl® allograft implant that improved operational efficiency and significantly increased tissue utilization to meet market demands. This solution positions Lenoss for growth, enabling them to deliver reliable implants to more patients than ever before.



OsteoPearl® Allograft Biological Augmentation Implant

What problems did Lenoss aim to solve through a CDMO partnership?

When Lenoss approached Evergen, it was facing a series of challenges common to many companies, including:



- **Supply uncertainty:** As an emerging business, Lenoss needed a consistent supply of the OsteoPearl® allograft to meet growing demand from the physicians and patients who rely on this implant option.
- **Processing limitations and scalability constraints:** Existing processes were not optimized for scalability, making it difficult to expand from pilot to commercial volumes. Lenoss sought a partner capable of optimizing processes to scale production while maintaining high quality and operational effectiveness.
- **Low yield and high fallout:** A significant amount of valuable donor tissue was being lost during processing. This underscored the need for changes that maximize tissue utilization.
- **Limited agility:** Difficulty adapting current processing approaches to shifting requirements and long-term goals highlighted the importance of a collaborative partner capable of evolving processes over time.
- **Strategic fit:** As a smaller, developing company, Lenoss needed a partner that shared its long-term vision and would prioritize innovation and collaboration regardless of company size.

Addressing these challenges required not only technical expertise but also a partner committed to flexibility, transparency and innovation throughout the development and scale-up process.

WHAT STOOD OUT IMMEDIATELY WAS LENOSS'S URGENCY TO GET THIS RIGHT FOR PATIENTS. THE EVERGEN TEAM BOUGHT IN EARLY—RETHINKING PROCESSES, CHALLENGING ASSUMPTIONS AND WORKING SIDE BY SIDE TO BUILD A PROCESSING SOLUTION THAT COULD SCALE.

–Steve Szabo, Business Development Director at Evergen

What made Evergen the CDMO of choice?

Evergen distinguished itself as the ideal partner for Lenoss through a combination of advanced technical capabilities, resourcefulness and a deeply collaborative mindset.

- **Transparency and collaboration:** Evergen quickly established trust through open and frequent communication, keeping Lenoss informed and involved throughout feasibility and beyond. The teams met regularly to address technical and business challenges together, ensuring alignment and quick resolution of issues.
- **Supply assurance:** Evergen was forthcoming about tissue procurement and supply. As Kevin Cooney, Executive Director, Marketing and Product Management at Lenoss, recalls, "I remember the way Steve [Business Development Director at Evergen] talked about the different procurement partners and relationships Evergen has. He spoke about the gift of tissue in an elegant and compassionate way, and the transparency was very reassuring. It cleared any doubt in our minds in terms of tissue supply."
- **Flexibility and resourcefulness:** Working in close collaboration, Evergen and Lenoss adapted to shifting project requirements. The teams were proactive in exploring alternative approaches, optimizing equipment and evolving processes to overcome unforeseen challenges and meet ambitious goals.
- **Commitment to quality:** Both teams worked continuously to refine processing approaches, recognizing that rigorous standards are critical to ensuring patient safety. Dom Messerli, Lenoss President and CEO, states "Graft quality is always number one. As we continue to make improvements and get better with the process, all parties benefit."

IT ALWAYS FELT LIKE EVERGEN WAS OUR PARTNER. FROM THE VERY FIRST MEETING THERE WAS A STRONG CULTURE OF COLLABORATION AND AN EMPHASIS ON WORKING TOGETHER AS A TEAM TO MOVE FORWARD.

–John Williams, Executive Director, Sales Strategy and Operations at Lenoss

These qualities made Evergen the clear choice for Lenoss, solidifying a partnership built on trust, creativity and a shared commitment to improving patient outcomes.

How did Evergen and Lenoss bring a solution to life?

- **Feasibility:** Evergen began with rigorous feasibility testing, evaluating possible processing methods for the OsteoPearl® allograft. In frequent meetings marked by open dialogue and transparency, Evergen and Lenoss brainstormed potential solutions and quickly iterated on new ideas. This approach allowed for rapid feedback and creative problem solving.
- **Alternatives analysis:** Once initial feasibility was established, each potential pathway was assessed for quality, efficiency, scalability and cost-effectiveness. This process narrowed the options down to a select few that were clinically, technically and commercially viable.
- **Process innovation and iteration:** Together, Evergen and Lenoss drove process innovation by combining fresh engineering approaches with the strategic adaptation of advanced equipment. The Evergen team applied its cross-functional expertise to tailor these technologies, refining bone handling, shaping and graft dimensions to meet the OsteoPearl® allograft's requirements.

  For example, to shape the bone, the teams replaced a manual process with an automated system. These process and equipment adaptations resulted in streamlined operations, reduced processing time and increased yield.

  In parallel, Lenoss designed and developed specialized tooling capable of batch processing, further accelerating production. Building on these improvements, the teams also designed custom workstations to optimize production flow, delivering consistent quality and efficient output.

WE NEEDED ONE MORE PIECE TO RUN ADDITIONAL GRAFT IN THE TEST LAB, AND AN EVERGEN EMPLOYEE PULLED AN ALL-NIGHTER TO MAKE IT HAPPEN. WE CAME IN AT 7:00 AM THE NEXT MORNING AND EVERYTHING WAS READY FOR US TO RUN TRIAL MACHINE PARTS. IT WAS INCREDIBLE.

–Dom Messerli, President and CEO at Lenoss, on Evergen's dedication to innovation and collaboration

What were the outcomes of the Lenoss and Evergen partnership?

Together, Lenoss and Evergen reimagined the processing of the OsteoPearl® allograft, making significant improvements to enable scalable growth. Such advancements include:

- **Increased donor availability:** Enhanced processing now allows for a wider range of high-quality donor tissue to be used for the OsteoPearl® allograft implant, increasing potential supply, which ultimately supports Lenoss's goal of making this implant option more widely available.
- **Higher yield:** Improved processes preserve more usable tissue from each donation. Early data suggests that these improvements led to a significant increase in yield per donation, maximizing the value of each precious donation. Ultimately, higher yield also reduces economic pressure for Lenoss.

EVERGEN IS A TRUE CDMO. THEY HELP THEIR CUSTOMERS NAVIGATE A GRAFT FROM A NAPKIN SKETCH ALL THE WAY TO THE OPERATING ROOM.

–Dom Messerli, President and CEO at Lenoss

- **Improved efficiency:** The OsteoPearl® allograft workflow was compartmentalized, allowing multiple operations—cutting, shaping, sterilization and chemical processing—to run concurrently. This increases donor tissue utilization and enables higher-volume processing that powers scalability.
- **Trusted partnership:** Lenoss and Evergen built a partnership rooted in collaboration, innovation, strategic alignment and cultural fit, establishing a strong foundation for continued success in the future.

This collaboration reflects Lenoss and Evergen's shared commitment to advancing biomaterial processing and making a meaningful difference in the lives of patients.

Evergen™

Are you looking to launch, scale or optimize a high-impact medical innovation? **Learn how our technical expertise and collaborative approach can support your goals.**

CONNECT WITH THE EVERGEN TEAM

†Data on file at Evergen.

Allografts processed by RTI Surgical, Inc. Please refer to the labeling for complete instructions for use. Regulatory approvals vary by country.

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Evergen
11621 Research Circle
Alachua, FL 32615 USA
T 877.343.6832
evergenbio.com
13918 R00