

Engineered Bone Graft

A BioFabUSA Project / Department of Defense Manufacturing Innovation Institutes



Technology: Engineered Bone Graft

Project Participants: EpiBone, DEKA Integrated Solutions Corp.

Institutes' Role: The institute is leading the development of a scalable, modular, automated and closed manufacturing line to support the production of patient-specific bone implants. The institute is adapting the open, manual manufacturing process to automated subsystems, which are being integrated for end-to-end production.

Technology Description: The technology developed by EpiBone is a living, tissue engineered anatomical bone graft comprising a patient's own fat-derived stem cells and a decellularized bovine bone scaffold. EpiBone's first product is indicated for the treatment of craniomaxillofacial (CMF) bone defects that arise from traumatic injury, cancer, disease, or congenital anomalies. Cell culture optimizations carried out by the institute will reduce materials costs and automation will reduce labor costs and operator-induced variability in production. Closing the system will reduce the requirements for manufacturing in a low-particulate environment, thereby lowering final product cost of goods. The system is applicable to the production of a wide variety of patient-specific, grafts, including a muscle cell-containing patch for the repair of cleft palate.

Impact: The use of bovine scaffolds and minimally-invasive harvest of stem cells from liposuction aspirates obviates the need for bone harvest from donor sites elsewhere on the body, which eliminates donor site morbidity and other risks associated with a second surgical site. EpiBone's bovine bone scaffolds are customized to the patient's CMF anatomy prior to seeding with cells, reducing surgical times and the risk of contamination of the implant.

