

Clinical Validation of Adipose-derived Regenerative Cells for Tissue Repair

Harnesses the power of stem cells from the patient's own fat tissue

The Tissue Genesis Icellator[®] is an automated system that isolates adipose-derived stem cells (ASCs), which can be delivered directly to damaged or diseased tissue. The key intellectual property has been issued 20 patents, with more than 100 patents pending. Patients are currently being enrolled in the first and only FDA-approved clinical trial treating Critical Limb Ischemia with the patient's own ASCs. These are otherwise no-option patients facing amputation. Patients receive multiple injections of their own stem cells into their ischemic leg at the time of treatment. The primary outcome is amputation-free survival at six months' post cell therapy.



Supporting the Continuum of Care



y Role 1 er First Aid Posts

Project directly supports specific Continuum of Care Stage



Role 3 Division Level Facility (i.e., Multinational Medical Unit Kandahar Airfield)

Project does not directly support specific Continuum of Care Stage

Role 4 Definitive Medical/Surgical Rehabilitative Care (i.e., Landstuhl, VA poly-trauma)

Key Features

- Autologous stem cells available for multiple clinical uses in about 1 hour
- 50 million nucleated cells from the Stromal Vascular Fraction of fat
- Counter-top technology suitable for the Operating Room
- 5 ongoing FDA-approved cell therapy trials to treat:
 - Critical Limb Ischemia
 - Peripheral Vascular Disease
 - Amputation
 - Facial Reconstruction
 - Erectile Dysfunction
- More than 700 patients treated world-wide
- Clinical and regulatory success
- Device master file enables quick approval of clinical trials by FDA



This project is managed by the **Pacific Joint Information Technology Center**, which focuses on rapidly researching, testing, and developing warfighter medical solutions and products, through pilots or prototypes in support of the DOD.