



AN ALLOGRAFT
WITH VIABLE CELLS.

Trinity[®]Evolution[™]

Redefining your bone grafting options through stem cell technology.

Long considered the best source of tissue for grafting, autograft has limitations. Age and health of the patient can compromise the quantity and quality of cells recovered, and a second surgical procedure can extend healing time and present lingering complications. Trinity Evolution provides a viable alternative to autograft with none of the drawbacks. Trinity Evolution is the next step forward.

The potential of adult stem cells, realized today

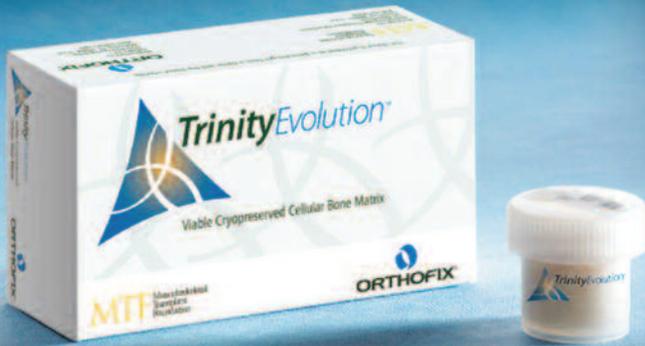
Stem cell technology has opened up a world of possibilities in science and health care. Adult mesenchymal stem cells (MSCs) are capable of responding to their environment to differentiate into a variety of cells as needed, making them an ideal alternative to autograft and other bone grafting options.

- MSCs are multipotential, capable of differentiating into muscle, cartilage, fat or bone
- MSCs and osteoprogenitor cells (OPCs) do not express the Class II and co-stimulatory antigens required to provoke a T-cell response (Fig. 4)

A comprehensive foundation for bone growth

Trinity Evolution supplies the three essential components for robust bone formation:

- Osteoconductive scaffold
- Verified osteoinductive potential
- A reliable number of viable osteogenic cells retained within the cancellous matrix (Figs. 1, 3, 5, 6)



Trinity Evolution is the new standard in bone grafting.

Preserving cell health for successful grafting

Every step in the processing of Trinity Evolution is designed to maximize the health of mesenchymal stem cells and osteoprogenitor cells delivered.

Research shows that available MSCs decline with age (Fig. 2), and that as cells age, there are changes in differentiation and regeneration capacity⁷. In Trinity Evolution, cell health begins with quality cells:

- Strict donor screening
- Average donor age 30 years*

** Historical data based on 2008 recoveries*

Cell health is preserved through careful processing:

- Cells are maintained within the matrix
- Controlled-rate freezing prevents crystallization within cells
- Cryopreservation in vapor-phase liquid nitrogen at -185°C inhibits cell metabolism

Trinity Evolution contains a minimum of 250,000 cells per cc: 50,000 of which are validated to be MSCs and/or OPCs.

Ensuring quality at every step

MTF is committed to excellence in tissue quality

Cell health is maximized through:

- Donor criteria
- Processing
- Vapor-phase liquid nitrogen storage

Improved handling from consistent particle size and specific component ratios

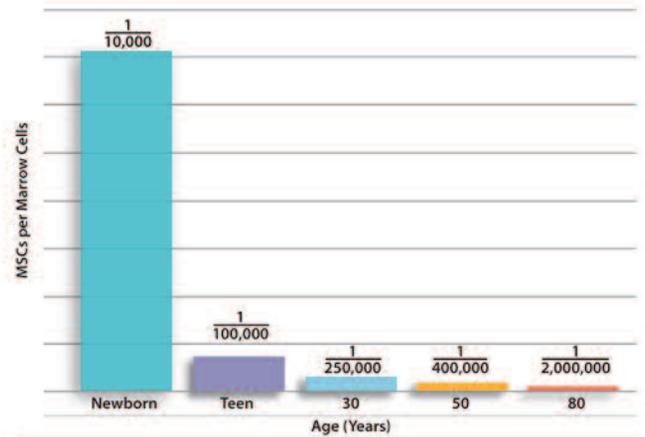


Trinity Evolution Supplies the Three Components Necessary for Bone Growth

	Osteoconductive SCAFFOLD	Osteoinductive GROWTH FACTORS	Osteogenic LIVING CELLS
Synthetic Ceramics	●		
Banked Cancellous Bone	●		
Banked Demineralized Bone	●	●	
BMPs		●	
Autograft	●	●	●
Trinity Evolution	○	○	○

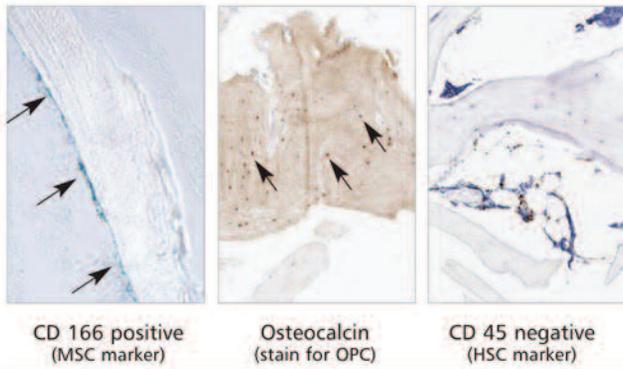
(Fig. 1) All the benefits of autograft, without the risks.

Human MSCs Decline with Age



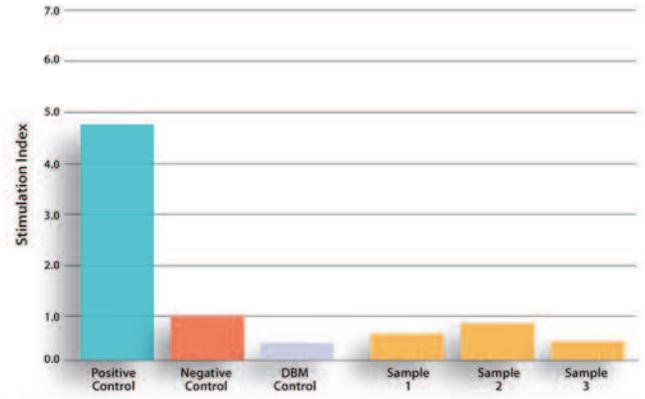
(Fig. 2) Caplan A. Clinics in Plastic Surgery 1994. Estimates obtained by CFU-F assay.

Cell Identification



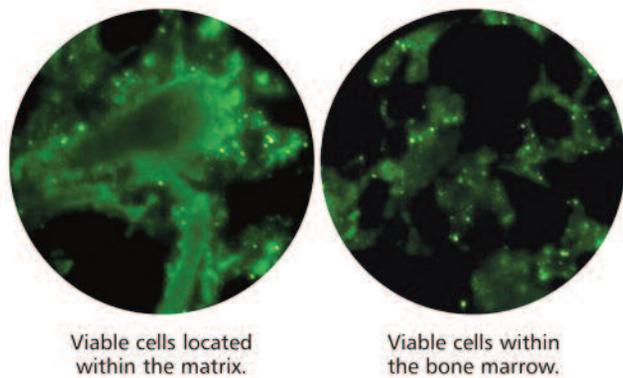
(Fig. 3) Trinity Evolution demonstrates the presence of MSCs and osteoprogenitor cells (OPCs), and the absence of hematopoietic cells (HSCs).

Mixed Lymphocyte Reaction Assays



(Fig. 4) Based on the MLR assay, Trinity Evolution does not stimulate an immune response.

Cell Viability and Location in Trinity Evolution



Viable cells located within the matrix. Viable cells within the bone marrow.

(Fig.5)

Bone Growth Results from Trinity Evolution

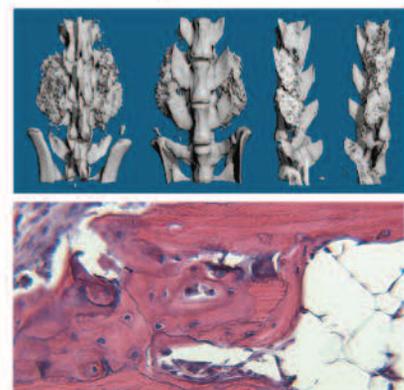


Fig. 6a

Fig. 6b

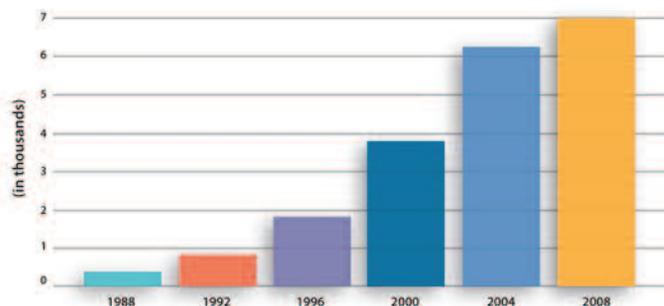
(Fig.6a) MicroCT of rat spinal posterolateral fusion model. (Fig. 6b) Day 28: New bone formation evident in athymic rat intramuscular pouch model.

The better approach. **MTF** Musculoskeletal Transplant Foundation

The Musculoskeletal Transplant Foundation (MTF) is a nonprofit service organization dedicated to providing quality tissue through a commitment to excellence in education, research, recovery and care for recipients, donors and their families.

MTF is distinguished not by just one aspect of operations, but by all facets of the organization, focused on supporting donation, processing, implantation and research. The MTF Medical Board of Trustees includes representatives from more than 40 academic institutions, primarily orthopaedic surgeons, who have established highly stringent donor acceptance criteria. MTF has maintained an exceptional safety record since inception in 1987, with approximately 4.2 million grafts distributed.

Growth in MTF Donor Recoveries



The right of first refusal

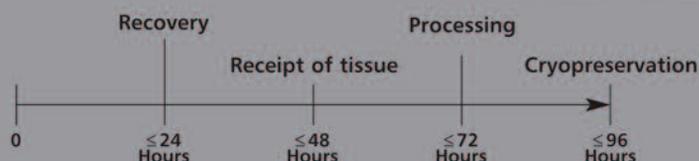
A successful graft is built upon cell health, which can only be as good as the cell health of the donor. MTF has the strongest recovery network in the nation, and maintains exclusive or "right of first refusal" agreements with recovery partners. Rigorous donor screening by highly qualified personnel guarantees that tissue health is optimal.

- Only 3% of all donors referred meet MTFs stringent criteria
- MTF never accepts donors deferred by other tissue banks
- MTF never accepts direct referrals from funeral homes

Safety first and last

With Trinity Evolution, MTF ensures patient safety by adhering to strict standards that include donor screening, timely processing and cryopreservation, and pre-release testing.

MTF Adheres To A Strict Schedule To Optimize Cell Health:



⁷Bonab, Mandana Mohyeddin, Kamran Alimoghaddam, Fatemeh Talebian, and Syed Hamid Ghaffari, "Aging of mesenchymal stem cell in vitro," *BMC Cell Biology* 2006: 7-14 .

Cristofalo, Vincent J., Robert G. Allen, Robert J. Pignolo, Bernard G. Martin, and Jeanne C. Beck, "Relationship between donor age and the replicative lifespan of human cells in culture: A reevaluation," *Proceedings of the National Academy of Sciences, USA* 95 (September 1998): 10614-10619.

Sethe, Sebastian, Andrew Scutt, and Alexandra Stolzing, "Aging of Mesenchymal Stem Cells," *Ageing Research Reviews* 5 (2006): 91-116.

Trinity Evolution is processed by MTF.

⚠ Refer to the package insert supplied with product for specific information on indications for use, contraindications, warnings, precautions, and adverse reaction information.



Tissue Codes

410101 – 1cc

410105 – 5cc

410110 – 10cc

410115 – 15cc

This tissue is provided as a generous gift from a donor and the donor's family.



For more information contact your local representative or call
1.800.266.3349 Orthopedics
1.888.298.5700 Spinal Implants
1.800.946.9008 MTF

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