TRINITY ELITE®

OSTEOCONDUCTIVE · OSTEOINDUCTIVE · OSTEOGENIC

ALLOGRAFT WITH VIABLE CELLS

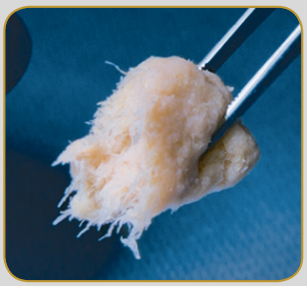
A FULLY MOLDABLE ALLOGRAFT WITH VIABLE CELLS

SHAPE THE POSSIBILITIES

MTF Musculoskeletal Transplant Foundation

ORTHOFIX®

TRINITY ELITE® BRINGS AN ENHANCED HANDLING EXPERIENCE TO YOUR SURGERY



When choosing the optimal graft for surgical demands, **Trinity ELITE®, a third generation allograft with viable cells,** provides a unique alternative to autograft, long considered the standard for bone grafting.

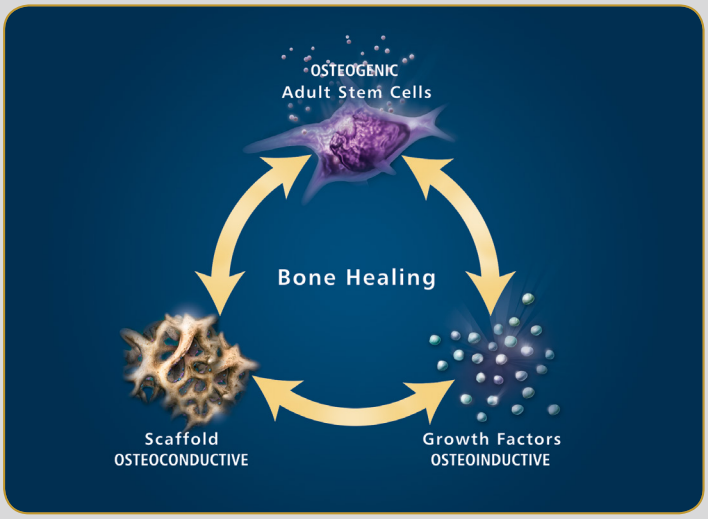
Exclusively processed for Orthofix by our premier partner, the Musculoskeletal Transplant Foundation (MTF), Trinity ELITE builds on the exemplary safety profile of more than 85,000 Trinity Evolution® procedures to date. Trinity ELITE offers an enhanced handling experience, while providing a viable grafting alternative supplying the three physiologic and essential components for robust bone formation:

Osteogenic cells, or adult mesenchymal stem cells (MSCs) and osteoprogenitor cells (OPCs), are native to the cancellous matrix and capable of responding to their environment to differentiate into a variety of cell types as needed. This makes them an ideal osteogenic component of viable allograft. Adult MSCs are non-immunogenic since they do not present the Class II HLA antigens that trigger a T-cell response. Trinity ELITE undergoes a proprietary and selective process that depletes hematopoietic stem cells (HSCs) while maintaining the viable osteogenic cells within the bone matrix.

Osteoinductive potential is derived from the demineralized cortical bone component which has been shown to possess active components of BMP-2, BMP-4, BMP-7, VEGF, TGF-ß, and other essential growth factors.[1,2,3]

Osteoconductive scaffold is provided by the cancellous bone component that serves as a natural trabecular bone matrix. It provides a porous, interconnected scaffold for bone ingrowth.

In addition to providing the three essential elements for robust bone formation, Trinity ELITE provides the unique feature of being fully moldable by the user, which arises from the size and orientation of the demineralized cortical bone component.



	Osteoconductive SCAFFOLD	Osteoinductive GROWTH FACTORS	Osteogenic LIVING CELLS
Synthetic Ceramics	●		
Banked Cancellous Bone	●		
Banked Demineralized Bone	●	●	
BMPs		●	
Autograft	●	●	●
TRINITY ELITE	●	●	●

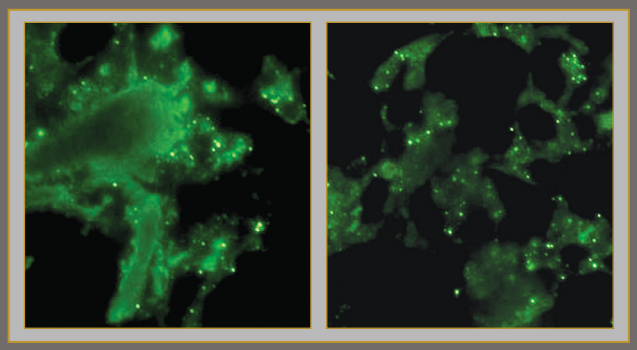
Trinity ELITE supplies the three components necessary for bone growth.

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 and differentiate into a variety of cell types, as needed—making them an ideal alternative to other bone grafting options.

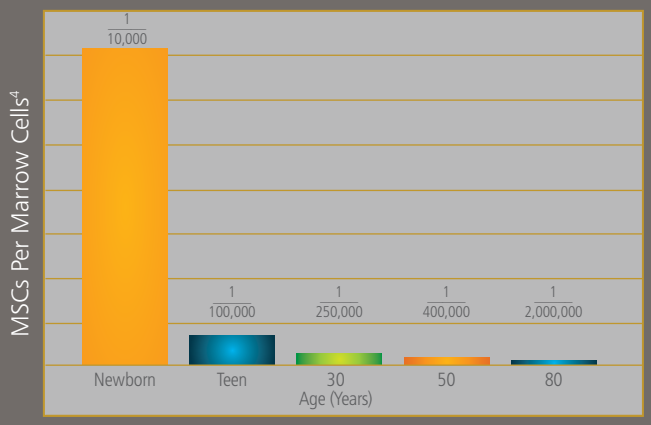
- MSCs are multipotential, capable of differentiating into bone, muscle, cartilage, or fat
- MSCs do not express the Class II and co-stimulatory antigens which provoke a T-cell response

Cell viability and location in Trinity ELITE within the cancellous matrix



Viable cells adherent to the cancellous bone matrix are represented by bright green fluorescent dot markers.

Human MSCs Decline with Age



Graph depicts the decline of human MSCs with age. Estimates were obtained by performing a CFU-F assay. [4]

Preserving cell health for successful grafting. Ensuring quality at every step.

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

Research shows that available MSCs decline with age, and as cells age, there are changes in differentiation and regeneration capacity.[4] In Trinity ELITE, cell health begins with quality cells:

- Stringent donor screening standards
- Time-sensitive processing & controlled rate of freezing for optimal cell viability
- Cryopreservation and storage in vapor-phase liquid nitrogen at -185° C limits cell metabolism
- Expiration dating, that reflects real time testing and must pass MTF's stringent release criteria

Trinity ELITE contains a minimum of 500,000 cells per cc; 100,000 of which are validated to be adult mesenchymal stem cells (MSCs) and/or osteoprogenitor cells (OPCs).[5]

When you start with better tissue, you end with better tissue.

The allograft material used for Trinity ELITE is processed exclusively by MTF. As evidenced in the accompanying charts, MTF's safety and quality are industry leading. MTF always has, and always will, take the better approach.

MTF Musculoskeletal Transplant Foundation

The most stringent donor criteria in the industry

SCREENING CRITERIA	MTF	INDUSTRY*	FDA
Hepatitis B virus	X	X	X
Hepatitis C virus	X	X	X
HIV 1/2	X	X	X
Malaria	X	X	X
Sepsis	X	X	X
Syphilis	X	X	X
Transmission spongiform encephalopathy (TSE)	X	X	X
Vaccinia	X	X	X
West Nile Virus (WNV)	X	X	X
Clinically significant metabolic bone disease	X	X	
Gonorrhea (clinically active)	X	X	
Illicit drug use, injected drugs	X	X	
Leprosy (Hansen's disease)	X	X	
Polyarteritis nodosa	X	X	
Rabies	X	X	
Rheumatoid arthritis	X	X	
Sarcoidosis	X	X	
Systemic lupus erythematosus	X	X	
Systemic mycosis	X	X	
Tuberculosis (clinically active)	X	X	
Active genital herpes	X		
Acute infectious/septic illness	X		
Ankylosing spondylitis	X		
Antiphospholipid syndrome	X		
Autoimmune hemolytic anemia	X		
Autoimmune lymphoproliferative syndrome	X		
Autoimmune thrombocytopenic purpura	X		
Autoimmune vasculitis	X		
Cancer (see chart below)	X		
Chagas disease	X		
End stage renal disease/chronic dialysis**	X		
Epstein Barr virus (clinically symptomatic mononucleosis)	X		
Clostridium difficile infection	X		
Cold agglutinin disease	X		
Encephalitis (clinically active)	X		
Endocarditis (clinically active)	X		
Guillain-Barre syndrome (clinically active)	X		
High risk behavior	X		
Illicit drug use, non-injected drugs	X		
Meningitis (clinically active)	X		
Methicillin resistant staphylococcus aureus (MRSA)	X		
Mixed connective tissue disease	X		
Multiple sclerosis	X		
Myasthenia gravis	X		
Osteoporosis, clinically diagnosed**	X		
Peritonitis	X		
Poliomyelitis	X		
Pyelonephritis	X		
Reactive arthritis (Reiter's syndrome)	X		
Rheumatic fever	X		
Steroid use/Treatment Chronic	X		
Vancomycin resistant enterococcus (VRE)	X		
Varicella zoster	X		
Wegener's granulomatosis	X		

*Generally recognized industry standards, although some tissue banks may vary
**Not an automatic rule-out for skin donors

The toughest criteria on cancer…

	MTF	BANK A	BANK B	BANK C	BANK D
Melanoma	Defer	Accept (if no recurrence in 5 yrs)	Defer	Accept (if no recurrence in 5 yrs)	Accept (if no recurrence in 5 yrs)
Cancer, Metastatic	Defer	Defer	Accept (if no recurrence in 5 yrs)	Defer	Defer
Cancer, Infiltrating	Defer	Accept (if no recurrence in 5 yrs)	Accept (after MD review)	Accept (if no recurrence in 3 yrs, 5 yrs for Br/Pr)	Accept (if no recurrence in 5 yrs)
Cancer, Heme	Defer	Defer	Accept (if no recurrence in 5 yrs)	Defer	Defer
Cancer, Brain	Defer	Defer GBM Accept Grade 1 & 2	Defer GBM Accept if no shunt/surgery	Accept if no shunt/ surgery	Accept (if no mets)
Cancer, Skin	Accept BCC (if no reccurence in 6 mos)	Accept	Accept	Accept SCC after excision	Accept

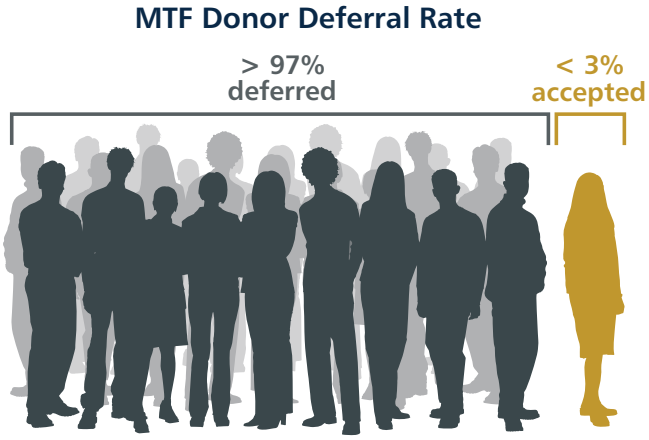
MTF Musculoskeletal Transplant Foundation
the better approach

MTF is the *exclusive* supplier of Trinity ELITE® — for all the right reasons

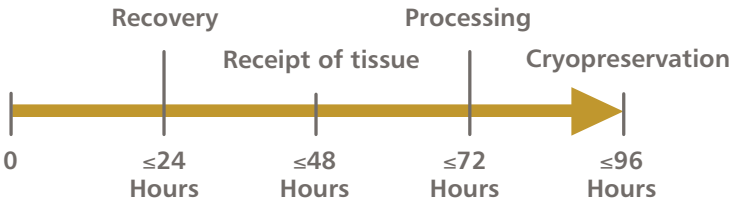
The Musculoskeletal Transplant Foundation (MTF) is the nation's premier tissue bank, dedicated to providing allografts of high quality. In fact, MTF's tissue exceeds the standards set by the industry*, the FDA, and other competing tissue banks *(See inside for a chart comparing MTF's standards to industry).*

Governed by physicians, not shareholders.
As a non-profit organization, MTF is governed by a surgeon based board of directors and by its medical board of trustees, comprised of more than 40 orthopaedic surgeons from academic institutions. Their goal is simple: do what's right for patients, surgeons, tissue donors and their families.

Stringent criteria results in optimal tissue health.
In addition to the strongest recovery network in the industry, MTF maintains a "right of first refusal" with most of its recovery partners. Rigorous donor screening by highly qualified personnel guarantees the quality and cell health of MTF allografts. MTF's quality control also extends to its tissue processing and delivery — to ensure a high level of safety, without compromising biological integrity.



Less than 3% of donors accepted. Unlike most other tissue banks, MTF defers 97% of donors for such conditions as cancer, illegal drug use, infection, high-risk behavior, age, osteoporosis, steroid use and more.



MTF's schedule is carefully timed and optimized for cell health by utilizing timely processing, cryopreservation, and more.

With Trinity ELITE, MTF ensures your patient's safety by adhering to the industry's most demanding standards in donor selection and pre-release testing.

*Generally recognized industry standards, although some tissue banks may vary

For more information contact
your local representative or call
1.888.298.5700 Orthofix
1.800.946.9008 MTF

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

TRINITY ELITE	
Order Number	Sizes
410001	**Small**
410002	**Medium**
410003	**Large**
410004	**Extra-Large**

1 Bostrom MPG, and Seigerman DA. The clinical use of allografts, demineralized bone matrices, synthetic bone graft substitutes and osteoinductive growth factors: A survey study. 2005. HSS Journal 1(1):9-18.
2 Pacaccio DJ, and Stern SF. Demineralized bone matrix: Basic science and clinical applications. 2005. Clin Podiatr Med Surg 22:599-606.
3 Wildermann B, Kadow-Romacker A, Haas NP, Schmidmaier G. Quantification of various growth factors in different demineralized bone matrix preparations. 2007. J Biomed Mater Res A 81(2):437-442.
4 Caplan, AI. The Mesengenic Process. Clin Plast Surg, 1994 Jul; 21(3); p.429-35.
5 Data on File (MTF).

Trinity ELITE is processed by MTF.

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

1.888.298.5700
www.mtf.com
www.orthofix.com

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