

Trinity Elite™

Allograft With Viable Cells

Trinity ELITE™ is a natural bone graft substitute; containing the three essential components autograft has to offer to support bone regeneration.¹



Osteoconductive.

The cancellous bone component serves as a natural porous scaffold. This trabecular matrix is the optimal micro environment for bone cells to attach, proliferate and remodel.²



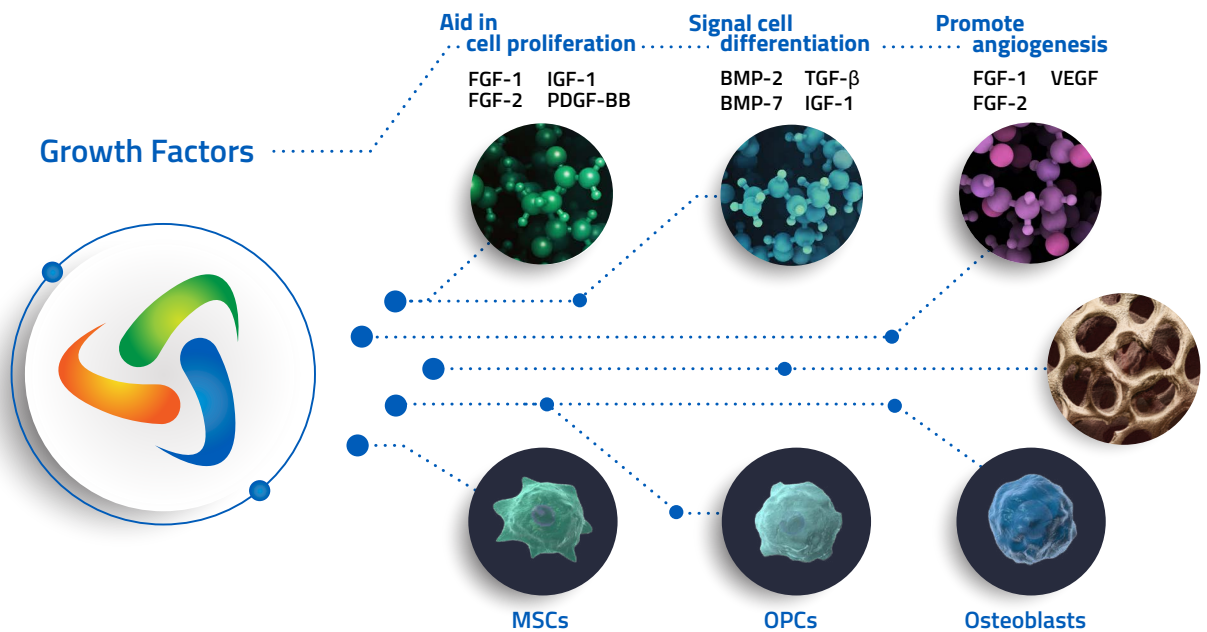
Osteoinductive.

Growth factors inherent in the demineralized cortical fibers (DBF) are necessary in the bone healing cascade. These proteins are known to induce bone formation by recruiting progenitor cells, differentiating cells down the bone forming pathway, and promoting angiogenesis.³⁻⁶



Osteogenic.

Viable adult mesenchymal stem cells (MSCs), osteoprogenitor cells (OPCs) and bone forming cells, such as osteoblasts, are native to the cancellous matrix.⁷ Cells which attach to the DBF surface are able to interface with the growth factors, resulting in a positive effect on bone formation.⁸



FIBERLOCK TECHNOLOGY

Trinity ELITE is a third generation allograft processed using FiberLock™ technology. The interconnected cortical fibers provide moldable handling with no carrier added.

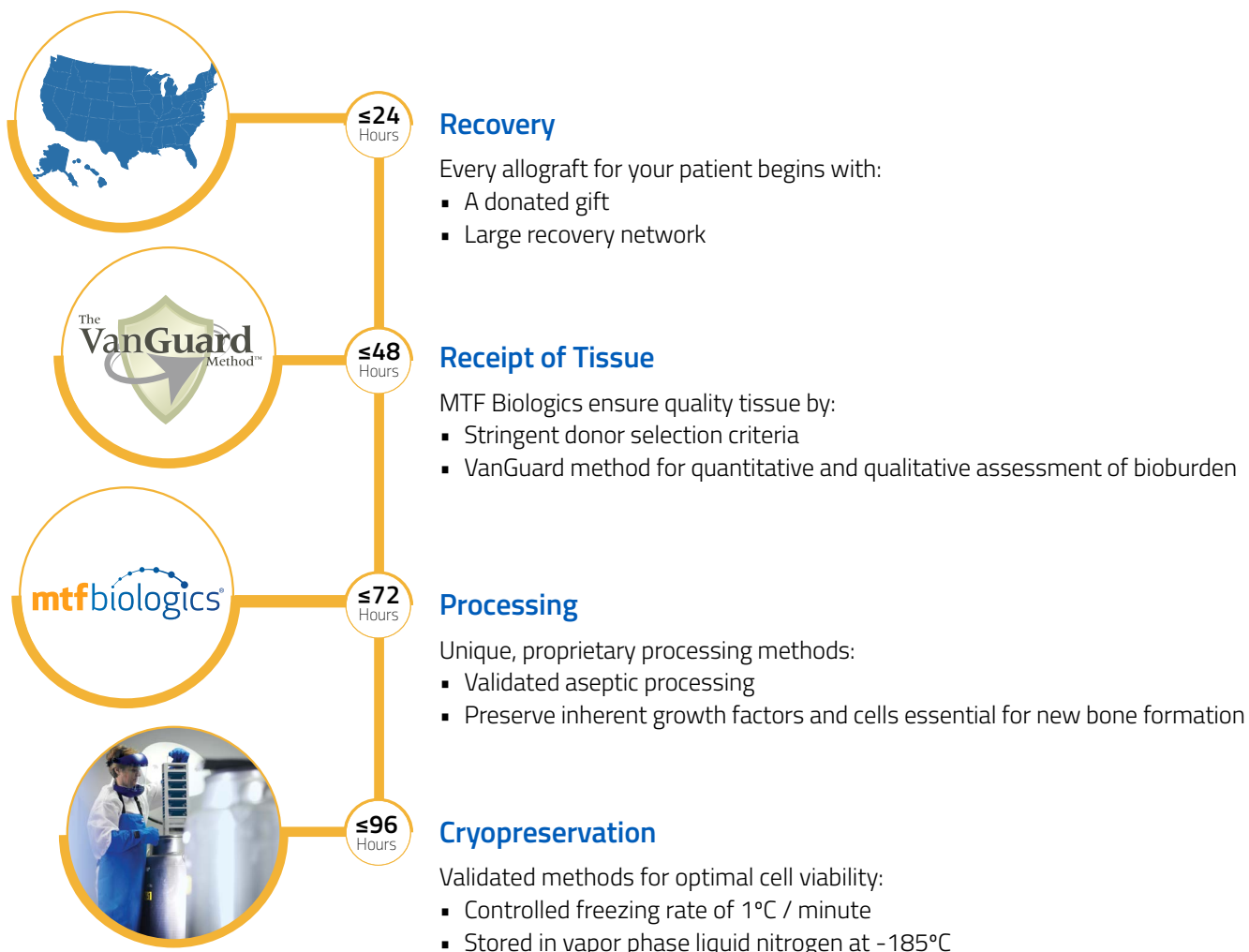
- 100% bone
- Versatile handling and application
- Stays where implanted; provides bone to bone contact
- Withstands irrigation and blood flow



FIBERLOCK™
TECHNOLOGY

ELITE PROCESSING

Trinity ELITE is exclusively processed by MTF Biologics. A sole provider ensures the same high standards of donor recovery and processing, delivering a consistent graft for you and your patients. Every step in the processing of Trinity ELITE is tailored to maintain the biochemical integrity; preserving the endogenous growth factors and viable cells naturally found in the bony matrix.⁷



Validated Quality Test Methods Establish:⁷

- ✓ Presence of BMP-2
- ✓ ≥ 70% Cell Viability
- ✓ A minimum of 750,000 cells/cc of which 250,000 are MSCs, OPCs and bone forming cells
- ✓ Compliance with USP <71> Sterility

ELITE RESULTS

Trinity Allograft Clinical Data Summary

10+ YEARS
ON THE MARKET

350,000+
PATIENTS IMPLANTED

0.00 %
SERIOUS ADVERSE EVENTS

Trinity ELITE has been clinically shown to be safe and efficacious in aiding in bone repair, including successful outcomes in patients with multiple co-morbidities.⁹⁻¹⁵

Trinity ELITE allograft can eliminate the need for harvesting autograft, reducing operative time, expense and complications for the patient.^{4,13}

Study	# of Patients	Fusion at 12 Months
One-Level Cervical ⁹	31	93.5%
Two-Level Cervical ¹⁰	40	93.4%
One & Two-Level PLF ¹¹	43	90.7%
One & Two-Level PLIF ¹²	103	89.5%
One & Multi-Level Lumbar Fusion ¹³	201	90.5%
Foot & Ankle Study 1 ¹⁴	92	86.8%
Foot & Ankle Study 2 ¹⁵	75	93.3%
Study		Fusion at 6 Months
Triple Arthrodesis ¹⁶	15	93.3%
TOTAL		
600		

The ELITE Choice.

Leading the Industry with STRINGENT Donor Criteria



With a large recovery network, MTF Biologics accepts less than 2% of all donor referrals. MTF Biologics exceeds industry standards with strict donor selection criteria.

SCREENING CRITERIA	MTF BIOLOGICS	INDUSTRY	FDA
Hepatitis B virus	X	X	X
Hepatitis C virus	X	X	X
HIV 1/2	X	X	X
Illicit drug use, injection drugs	X	X	X
Malaria	X	X	X
Sepsis	X	X	X
Syphilis	X	X	X
Transmissible 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	
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 mycoses	X	X	
Tuberculosis	X	X	
Active genital herpes	X		
Ankylosing spondylitis	X		
Autoimmune hemolytic anemia	X		
Autoimmune hepatitis	X		
Bacteremia/systemic infection	X		
Cancer	X		
Chagas disease	X		
End stage renal disease/chronic dialysis*	X		
Encephalitis (clinically active)	X		
Endocarditis (clinically active)	X		
Epstein Barr virus (clinically symptomatic mononucleosis)	X		
Guillain-Barre syndrome (clinically active)	X		
Hematologic malignancies	X		
Illicit drug use, non-injection drugs	X		
Melanoma	X		
Meningitis (clinically active)	X		
Metastatic disease (any history)	X		
Mixed connective tissue disease*	X		
Multiple sclerosis	X		
Myasthenia gravis*	X		
Osteoporosis*	X		
Peritonitis	X		
Poliomyelitis	X		
Pyelonephritis	X		
Progressive systemic sclerosis (scleroderma)	X		
Reactive arthritis (Reiter's syndrome)	X		
Rheumatic fever	X		
Steroid Treatment, (chronic)	X		
Varicella zoster	X		
Vasculitis	X		
Wegener's granulomatosis	X		

*Not an automatic rule-out for skin donors

Please visit [Orthofix.com/IFU](https://www.Orthofix.com/IFU) for full information on indications for use, contraindications, warnings, precautions, adverse reactions information and sterilization.

Order Number	Size	Volume
410001	Small	1.2cc
410002	Medium	5.3cc
410003	Large	10.6cc
410004	Extra-Large	16.0cc

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