

The logo features three interlocking, curved bands in orange, green, and blue, forming a stylized 'S' or 'T' shape.

**Trinity** **ELITE**<sup>TM</sup>  
ALLOGRAFT WITH VIABLE CELLS

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



### 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.<sup>2</sup>



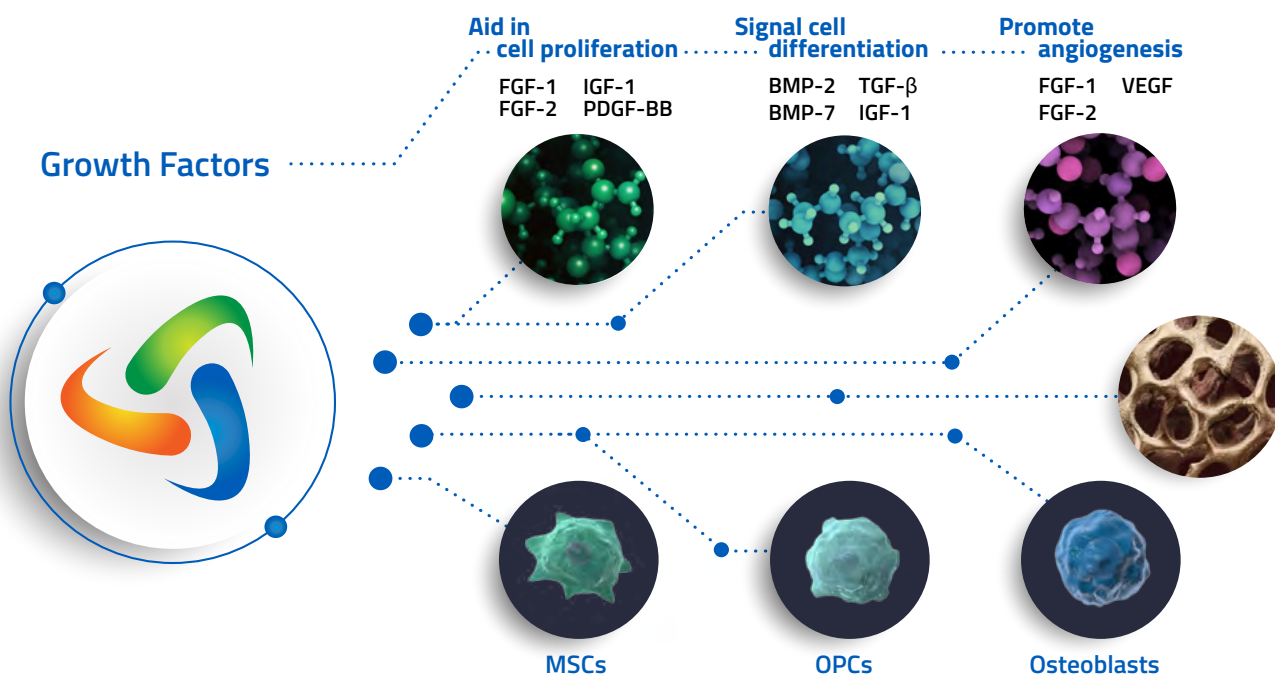
### Osteoinductive.

Growth factors inherent in the demineralized cortical fibers (DBF) are necessary in the bone healing cascade; inducing bone formation by recruiting progenitor cells, differentiating cells down the bone forming pathway, and promoting angiogenesis.<sup>3-6</sup>



### Osteogenic.

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



## FIBERLOCK TECHNOLOGY

Trinity ELITE allograft 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



# ELITE PROCESSING

Trinity ELITE allograft 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.<sup>8</sup>



≤24  
Hours

## Recovery

Every allograft for your patient begins with:

- A donated gift
- Large recovery network



≤48  
Hours

## Receipt of Tissue

MTF Biologics ensure quality tissue by:

- Stringent donor selection criteria
- VanGuard method for quantitative and qualitative assessment of bioburden



≤72  
Hours

## Processing

Unique, proprietary processing methods:

- Validated aseptic processing
- Preserve inherent growth factors and cells essential for new bone formation



≤96  
Hours

## Cryopreservation

Validated methods for optimal cell viability:

- Controlled freezing rate of 1°C / minute
- Stored in vapor phase liquid nitrogen at -185°C

## Validated Quality Test Methods Establish:<sup>8</sup>

- ✓ 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



## The most STRINGENT Donor Criteria in the Industry



With a large recovery network, MTF Biologics accepts less than 2% of donated tissue. MTF Biologics exceeds industry standards with strict donor selection criteria, and will not accept any donors deferred by another tissue bank.

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 (clinically active)	X	X	
Active genital herpes	X		
Acute infectious illness, systemic	X		
Acute Epstein Barr virus (clinically symptomatic mononucleosis)	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 inside)	X		
Chagas disease	X		
End stage renal disease/chronic dialysis*	X		
Cold agglutinin disease	X		
Encephalitis (clinically active)	X		
Endocarditis (clinically active)	X		
Guillain-Barre syndrome (clinically active)	X		
Illicit drug use, non-injection drugs	X		
Meningitis (clinically active)	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 Treatment, chronic	X		
Varicella zoster	X		
Wegener's granulomatosis	X		

\*Not an automatic rule-out for skin donors

# ELITE RESULTS

## Trinity Allograft Clinical Data Summary

**10+ YEARS**  
ON THE MARKET

**200,000+**  
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.<sup>9-15</sup>

Trinity ELITE allograft can eliminate the need for harvesting autograft, reducing operative time, expense and complications for the patient.<sup>4,13</sup>

Study	# of Patients	Fusion at 12 Months
One Level Cervical <sup>9</sup>	31	93.5%
Two Level Cervical <sup>10</sup>	76	93.4%
One & Two Level PLF <sup>11</sup>	43	90.7%
One & Two Level PLIF <sup>12</sup>	103	89.5%
Foot & Ankle Study 1 <sup>13</sup>	103	86.8%
Foot & Ankle Study 2 <sup>14</sup>	75	84.0%
Study		Fusion at 6 Months
Triple Arthrodesis <sup>15</sup>	15	93.3%
<b>TOTAL</b>		
<b>446</b>		

The ELITE Choice.

Please visit [Orthofix.com/IFU](http://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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