MTF BIOLOGICS
SOFT TISSUE PROCESS

mtfbiologics®
Science Driven. Patient Focused.

What makes us unique, and why do we have the best outcomes?[1]

SELECTING THE IDEAL DONOR | OUR ASEPTIC PROCESS | CLINICAL OUTCOMES

Do you know where your tissue comes from?

MTF Biologics exceeds industry standards with stricter donor acceptance criteria.

Screening for 115 clinically relevant criteria, compared to the industry norm of 20, and the 10 criteria categories required by the FDA.

SCREENING CRITERIA	MTF Biologics	INDUSTRY	FDA
Hepatitis B virus	X	X	X
Hepatitis C virus	X	X	X
HIV 1/2	X	X	X
Non-medical injection drug use	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

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

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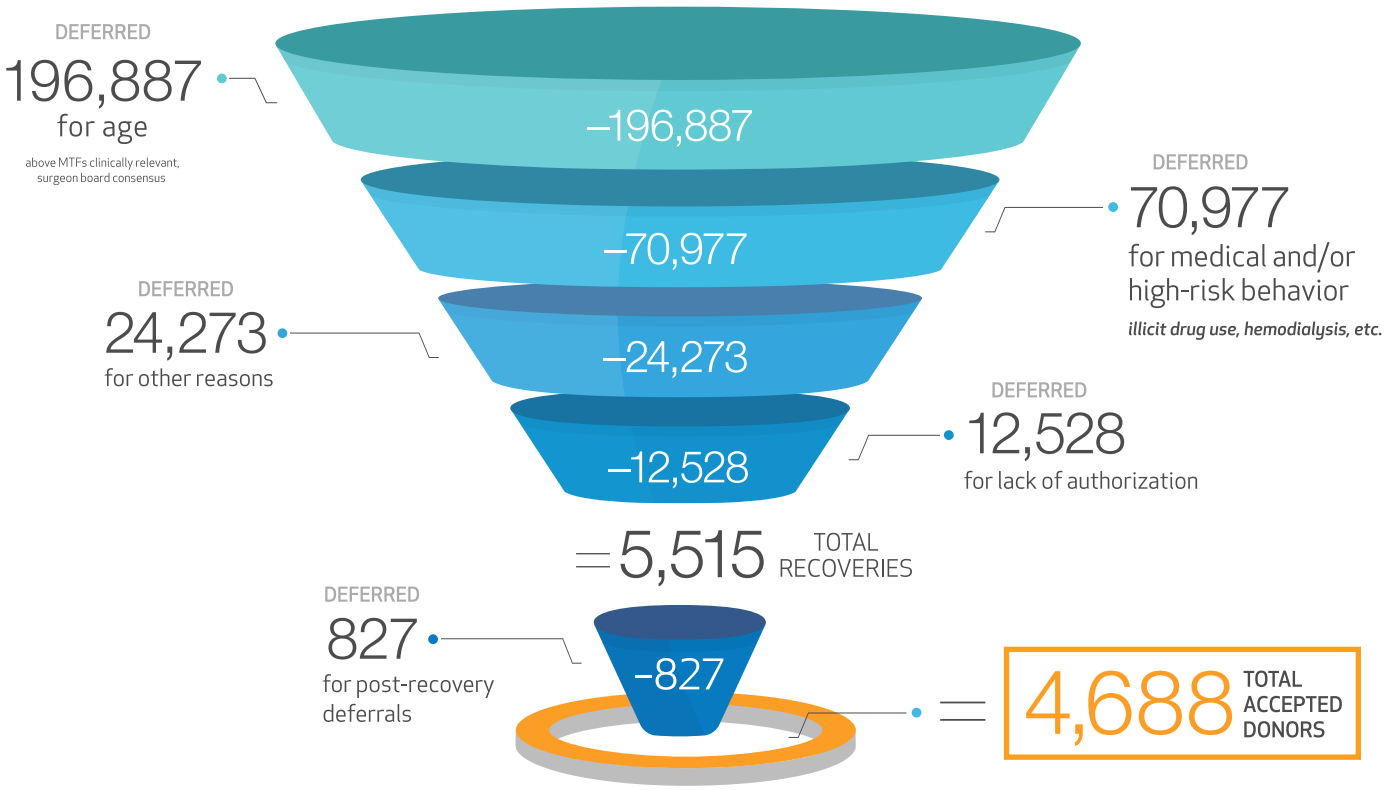
310,180
DONOR REFERRALS

Stricter criteria...
Better clinical outcomes.

Selecting the **ideal donor** (2%).

MTF Biologics accepts less than 2% of donated tissue.[1]



100% aseptic processing
NO terminal sterilization

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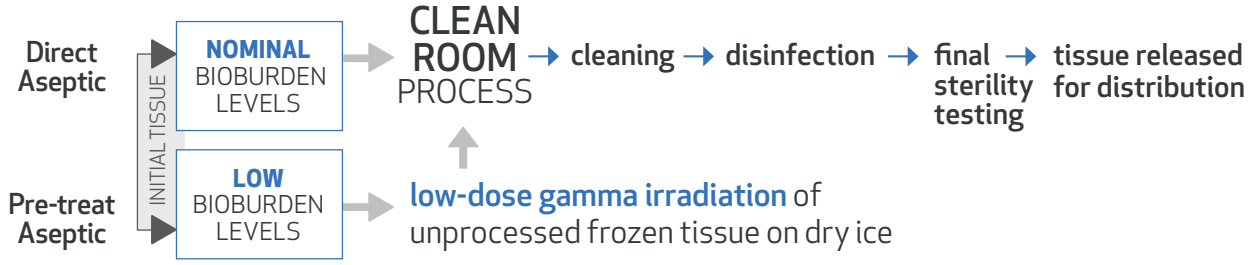
With strict donor criteria, we aim to minimize potential bioburden on the tissue, thus eliminating the need for harsh chemical disinfection or terminal sterilization. After being initially assessed for bioburden levels, most incoming donor tissues directly follow our aseptic processing methods. On a minority of donors, bioburden levels are detected that require an additional pre-processing decontamination step prior to subsequent processing. This step involves subjecting unprocessed, frozen tissue to a low-dose of gamma irradiation before any dissection, debridement, trimming or chemical processing is performed and is designed to eliminate microorganisms without adversely impacting tissue quality.

MTF BIOLOGICS ASEPTIC PROCESSING METHODS



PROCESSING PHILOSOPHY

MAINTAIN NATURAL BIOMECHANICAL PROPERTIES OF EVERY GRAFT

Proven clinical results

Recovered Aseptically

- Only recovered in a sterile environment (ISO 8) equivalent to OR or class 1,000

Processed Aseptically

- Processed in ISO 4 room (Class 10)
- Proprietary antibiotic soaks and agitation w/o harsh chemicals
- Sterility testing performed on all tissue

Packaged Aseptically

- No terminal sterilization
- Visual inspection of every graft
- Packaged in ISO 4 room (Class 10)

Quality Verification

- Final sterility
- Final donor chart review
- Processing suite verification

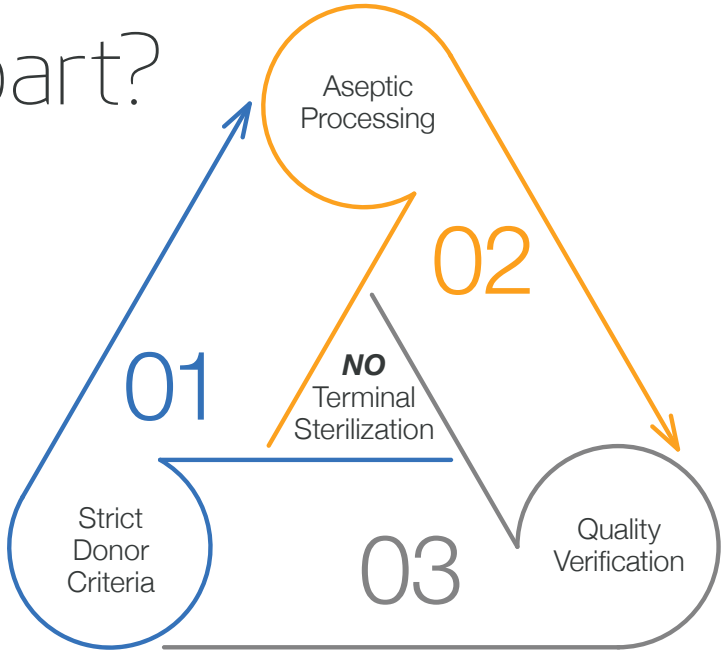
MTF Biologic's ISO 4 / class 10 processing eliminates the need for terminal sterilization.

	class	maximum particles/ft³					ISO equivalent		
		≥0.1 µm	≥0.2 µm	≥0.3 µm	≥0.5 µm	≥5 µm			
CLEANER	**10**	**350**	**75**	**30**	**10**	**0.07**	**ISO 4**	**→ MTF BIOLOGICS**	
	100	3,500	750	300	100	0.07	ISO 5	→ TISSUE BANK B	
	1,000	35,000	7,500	3,000	1,000	7.00	ISO 6	→ TISSUE BANK C	
	10,000	350,000	75,000	30,000	10,000	70.00	ISO 7	→ TISSUE BANK D	standard operating room
	100,000	3.5 X 10^6	750,000	300,000	100,000	700.00	ISO 8		

At MTF Biologics, we **save and heal lives.**

What sets us apart?

Best outcomes among all sports tissue graft providers backed by the largest set of clinical data[2]



Clinical Outcomes Comparable to Autograft

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- **The most stringent donor acceptance criteria** and bioburden screening method
- **100%** aseptic processing
- ISO Class 4 clean rooms are **1,000x cleaner** than standard operating room environment
- **An unrivaled safety record** with **10 million allografts** distributed since inception

Success Rate at 3 Years[3]

AUTOGRAFT
96.5%

↓

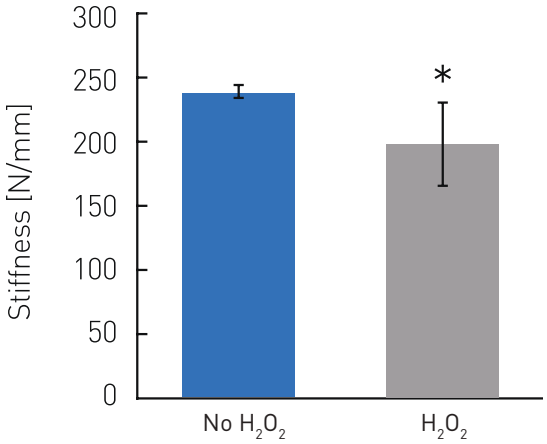
MTF BIOLOGICS
ASEPTIC PROCESSING
98%

Why we **don't** use hydrogen peroxide[4]

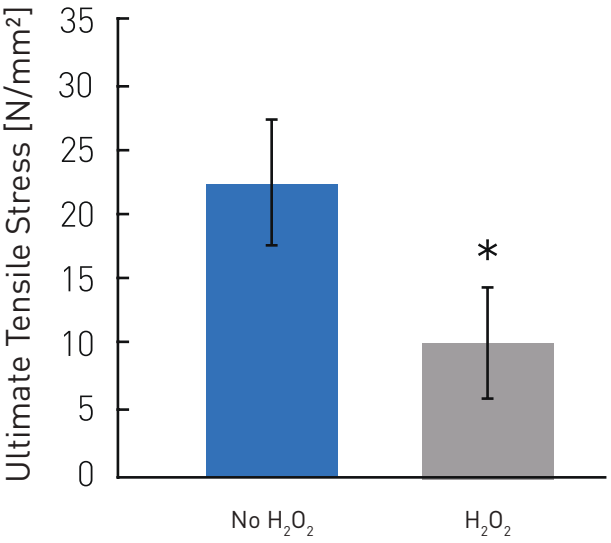
Our process does not use chemicals that have a negative impact on soft tissue quality

Hydrogen Peroxide

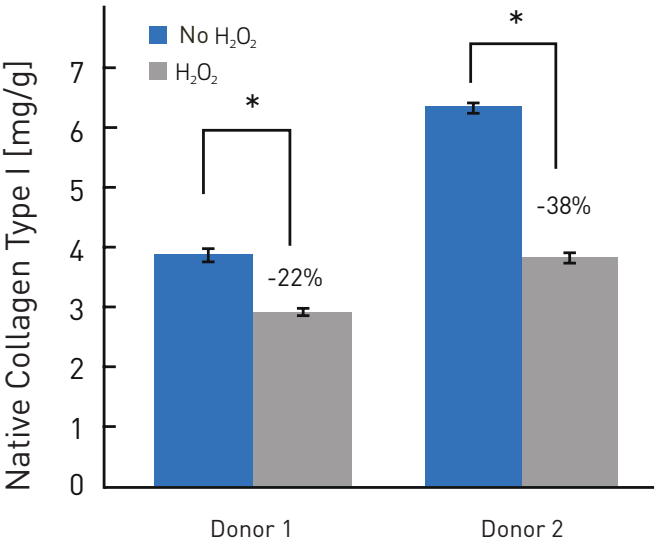
Hydrogen peroxide (H_2O_2) is commonly used in the treatment of allograft bone and soft tissue due to its potent disinfectant and antibacterial properties. MTF Biologics has investigated the effects of H_2O_2 exposure on tendon biomechanical and biochemical properties (H_2O_2 exposure was for 0.5hr at 3% concentration followed by 2.0 hr at 6% concentration, using published methods). Exposure of hemi-bone-patellar tendon bone grafts (hemi-BPTBs) to H_2O_2 resulted in significant reductions in stiffness (Figure 1), ultimate tensile stress (Figure 2), and native collagen type I levels (Figure 3) relative to aseptically processed grafts which were not exposed to H_2O_2 [data on file]. Due to the detrimental effect of H_2O_2 on hemi-BPTB properties, MTF Biologics does not utilize H_2O_2 during processing of soft tissue allografts.



(Figure 1) Stiffness of hemi-BPTBs was significantly decreased following exposure to H_2O_2. (*p=0.022; general linear model).



(Figure 2) Ultimate tensile stress of hemi-BPTBs was significantly decreased following exposure to H_2O_2 (*p<0.001; general linear model).

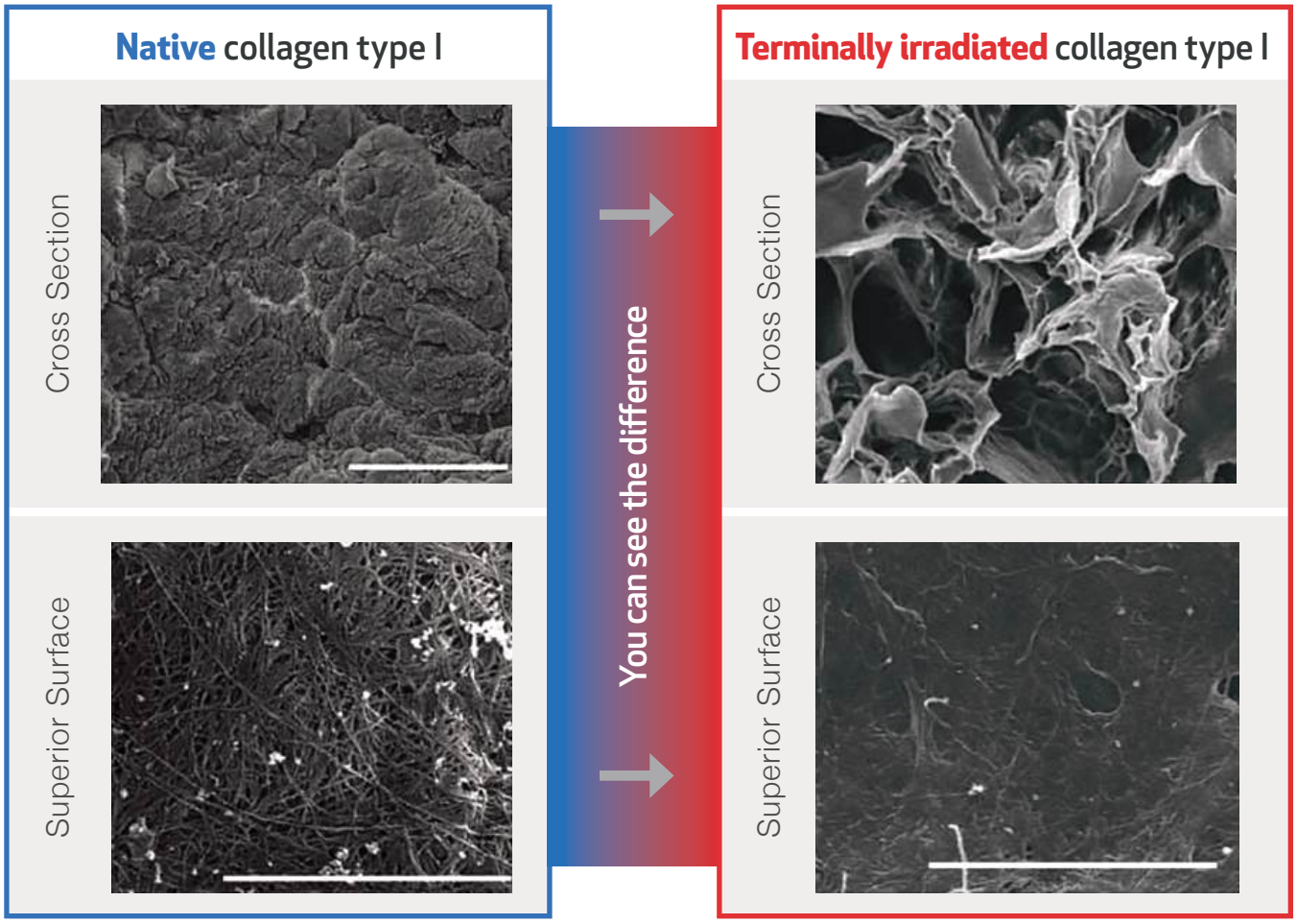


(Figure 3) Native Type I Collagen is significantly decreased in hemi-BPTB following H_2O_2 exposure (*p<0.05; one-way ANOVA).

Why we **don't** use terminal irradiation

Grafts treated with terminal irradiation **elongated 27% more**[6] and have been shown to have a **33%** failure rate.

Effects of terminal irradiation on tissues



- Intact collagen fibrils are visible and distinct in non-irradiated tendons[7]
- Exposure of individual fibrils in normal collagen is beneficial for ingrowth and remodeling
- Tissue microstructure showed extensive alterations when exposed to terminal irradiation
- Terminally irradiated collagen bundles appear smeared and there is a loss of fibril definition in superior surface imaging

The difference is clear

There are **over 100 peer-reviewed publications** on the use of MTF tissues. Many have demonstrated equivalent performance to autograft as well as **superiority** to tissues prepared using other processing methods. Ask your current provider for a list of their studies.

Do you know who your tissue processor is?

Here are questions to ask...

1. Does your tissue bank terminally sterilize their tissues using one of the following the methods:

- Gamma Irradiation
- E-Beam
- Hydrogen Peroxide
- Critical CO_2

2. Does your tissue bank have a clinical compendium available with studies validating their outcomes?

3. Is your tissue bank an AATB accredited tissue bank for the following ***specific*** designations?

- Recovery
- Processing
- Distribution

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REFERENCES

1 This information is based on 2019 data on file MTF Biologics.

2 Tejwani SG, Chen J, Funahashi TT, Maletis GB, Love R. Revision Risk After Allograft Anterior Cruciate Ligament Reconstruction: Association With Graft Processing Techniques, Patient Characteristics, and Graft Type. AAOS presentation 2015. AJSM 2015

3 Maletis G, Chen J, Inacio M, Love R, Funahashi T. Increased Risk of Revision After ACLR with Soft Tissue Allograft Compared to Hamstring Allograft. ISAKOS Presentation, 2015.

4 Effect of Hydrogen Peroxide Treatment on the Biomechanical and Biochemical Properties of Soft Tissue Allografts - Data on file MTF Biologics

5 Matthew Rappé, MD, MaryBeth Horodyski, EdD, ATC, LAT, Keith Meister, MD, Peter Indelicato, MD. Nonirradiated Versus Irradiated Achilles Allograft In Vivo Failure Comparison. The American Journal of Sports Medicine, Vol. 35, No. 10.

6 Andrew R. Curran,*† DO, Douglas J. Adams,‡ PhD, Julie L. Gill,† PA-C, Mark E. Steiner,† MD, and Arnold D. Scheller,† MD. The Biomechanical Effects of Low-Dose Irradiation on Bone–Patellar Tendon–Bone Allografts. The American Journal of Sports Medicine, Vol. 32, No. 5

7 Matuska M, McFetridge PS. The Effect of Terminal Sterilization on Structural and Biophysical Properties of A Decellularized Collagen-Based Scaffold; Implications for Stem Cell Adhesion. J. Crayton Pruitt Family, Department of Biomedical Engineering, University of Florida, Florida. June 2014 in Wiley Online Library (wileyonlinelibrary.com). DOI: 10.1002/jbm.b.33213