## **All allograft tissue is the same.** *Isn't it?*

Actually, you'd be very surprised.

There are national standards for tissue banks, set by the AATB and FDA. But they set only a minimal baseline for the industry. Beyond the basics, most regulations are left to interpretation. As a result, tissue quality, consistency and performance can change—drastically—from bank to bank.

The real question is, how do you get safe allografts, without sacrificing quality?

## The simple answer is MTF.

MTF's process—in its entirety—is centered on bringing you the highest quality tissue available in the industry. Our standards, set by a medical board of trustees from the world's finest healthcare institutions, exceed those set by the AATB and FDA.

Creating and meeting the industry's highest standards is not easy. It's an approach, and commitment, that takes place in every step of the process—from donor selection to delivery. You won't find a more comprehensive, thorough, medically founded process than ours.

## We invite you to see for yourself...


References:

1. www. nof.org; About Osteoporosis, Bone Basics, Why Bone Health.

2. Vigorita, VJ. (2008). Metabolic Bone Disease: Part I, Orthopedic Pathology, Second Edition. pp. 104-143. Philadelphia: Lippincott Williams and Wilkins.

3. Coco M, Rush H. Increased incidence of hip fractures in dialysis patients with low serum parathyroid hormone. Am J Kidney Dis. 36: 1115-1121, 2000.

4. Rillo, et al. Tendinous and ligamentous hyperlaxity in patients receiving longterm hemodialysis. J of Rheumatology. 18:8, 1227-1231, 1991.

5. Laan RF, et al. Low dose prednisone induces rapid reversible axial bone loss in patients with rhuematoid arthritis: A randomized, controlled study. Ann Intern Med. 119:963-968, 1993.

6. Poehling et al. Analysis of outcomes of anterior cruciate ligament repair with 5-year follow-up: allograft vs autograft. J Artho Rel Res 21(7): 774-785, 2005.

7. Shah AA, et al. Failure rate of Achilles tendon allograft in primary anterior cruciate ligament reconstruction. J Arthroscopic and Rel Surg. 26(5), 667-674, 2010.

8. Barber et al. Anterior cruciate ligament reconstruction using patellar tendon allograft: an age-dependent outcome evaluation. J Artho Rel Surg 26(4): 488-493, 2010.

9. Shaieb M, et al. A prospective randomized comparison of patellar tendon vs. semitendinosus and gracilis tendon autografts for anterior cruciate ligament reconstruction. Am J Sports Med. 2:214-220, 2002.

10. Salmon LJ, et al. Long term outcome of endoscopic anterior cruciate ligament reconstruction with patellar tendon autograft: Minimum 13 year review. Am J Sports Med. 34: 721-732, 2006.

11. DePaula et al. Effects of hydrogen peroxide cleaning procedures on bone graft osteoinductivity and mechanical properties. Cell and Tissue Banking. 6:287-298, 2005.

12. Dunn et al. Effect of allograft bone processing on structural cortical grafts: a comparison of three proprietary processing methods. Proc of NASS 23rd Annual Meeting/The Spine Journal 8 138S: 78, 2008.

13.Gertzman et al. (2005) The effect of cold gamma radiation sterilization on the properties of demineralized bone matrix. In Kennedy JF, Philips GO, Williams PA, editors. Sterilization of tissues using ionizing radiations: CRC Press. pp 151-156l.

14. Han et al. Effects of gamma irradiation on osteoinduction associated with demineralized bone matrix. JOR 26(1): 75-82, 2008.

15. Freytes (2006) Sterilization of Biologic Scaffold Materials. Encyclopedia of Medical Devices and Instrumentation, Second Edition. pp 273-283.

16. Huang et al. Use of peracetic acid to sterilize human donor skin for production of acellular dermal matrices for clinical use. Wound Repair Regen. 12(3): 276-287, 2004.

17. Analysis of extracellular matrix (ECM) characteristics via enzyme degradation assay. Data on file, MTF. Feb 20, 2010. LE-282.


MTF Musculoskeletal Transplant Foundation

the better approach


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# The MTF Quality Method


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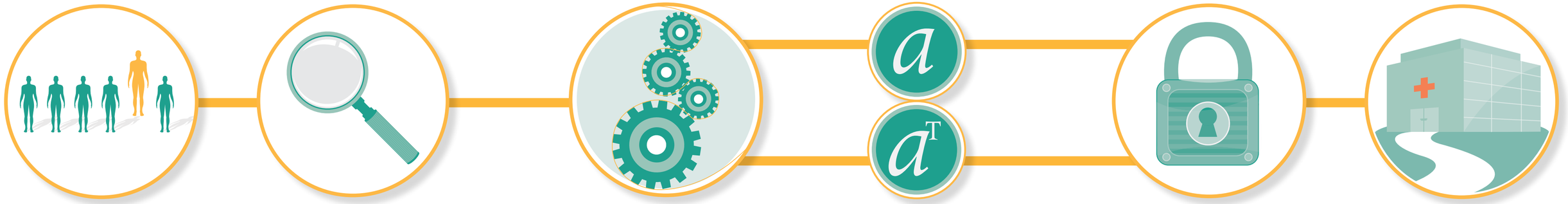
# The better approach to... *quality*.



## Donor Selection

### MTF accepts less than 3% of potential donors.

***Why?***

1. ***10 million Americans*** suffer from osteoporosis, which is responsible for more than 2 million fractures per year.[1]
2. Over a lifetime, a woman loses approximately ***35%*** of her cortical bone and ***50%*** of her trabecular bone.[2]
3. People being treated for end-stage renal disease with hemodialysis are 17 times more susceptible to fracture.[3]
4. Tendon and ligament laxity occurs in ***74%*** of patients undergoing hemodialysis.[4]
5. During the first year of steroid treatment, ***bone loss amounts to 4% to 8%.***[5]

The decision to accept or defer a donor with these conditions is at the discretion of each individual tissue bank.

## Test Method

### MTF is the only tissue bank to use The VanGuard Method™ to customize final tissue pathway.

By employing this state-of-the-art test method, MTF is able to avoid harsh processing and sterilization techniques.

**The VanGuard Method™ far exceeds the industry standard and is defined by the following characteristics:**

- Direct tissue testing
- Qualitative and quantitative assessment
- Close representation of final graft form
- Highly reproducible
- Highly accurate

The VanGuard Method™

## Aseptic Processing and Sterilization

### Depending on the results of the VanGuard Method™, a validated pathway is selected to ensure sterility.

**a Aseptic:** Donor tissue with results that comply with aseptic parameters is sent down this pathway.

**a<sup>T</sup> Aseptic with treatment:** Low dose gamma radiation is used on some tissue during processing or as a terminal sterilization step.

**Not all biological tissues are the same and neither are the processing methods they require.**

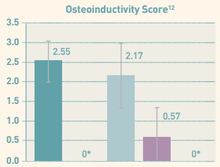
**Soft Tissue:** MTF believes in minimal processing to maintain the biomechanical integrity and biochemistry of every graft. Recent clinical data suggests equivalence between MTF soft tissue allografts and autografts for ACL reconstruction[6], and demonstrates no difference in outcome between younger and older patients.[7,8]

ACL Reconstruction

| Failure Rates | Graft Source |
|---|---|
| 5.6%[7] | MTF Allograft |
| 5% - 13%[9,10] | Autograft |

**Available in:** a a<sup>T</sup>

**Bone Tissue:** At certain exposure times, hydrogen peroxide is known to impair the integrity of bone.[11] MTF uses a validated process that results in tissue with biological activity that exceeds tissue from other banks.[12]

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**Viable Cell Tissues:** MTF ensures optimal cell retention and guarantees > 70% cell viability by controlling variables affecting cell health such as age and cryopreservation method.

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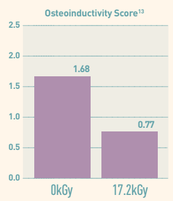
**DBX:** It is well documented that certain processing and sterilization techniques can impair the osteoinductivity of DBM.[13,14] MTF's validated process preserves the biological integrity of the tissue and terminal radiation is never used.

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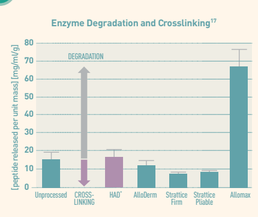
**Dermal Tissues:** Harsh chemical processing and various methods of sterilization have detrimental effects on the material properties of dermal tissues.[15,16] MTF dermal tissues are processed using techniques that yield grafts that mimic native tissue and meet sterility standards.

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## Quality Verification

### All MTF tissues undergo a series of review steps prior to release.

- ✓ Final sterility results
- ✓ Visual inspection of tissue
- ✓ Three levels of tissue specification verification
- ✓ Final donor chart review
- ✓ Processing documentation verification
- ✓ Processing suite environmental verification
- ✓ Packaging/labeling final verification
- ✓ Frequent internal audits

## Delivery

### MTF offers a broad tissue portfolio and extensive inventory.

**Services We Provide**

- Inventory Management Program
- Tissue Tracking System
- Large Graft Matching
- Tissue for Research and Charitable Outreach
- In-Services
- Professional Education Services

**Our Corporate Partners**

- Synthes
- Ethicon, Inc.
- Orthofix
- Dentsply Tulsa Dental
- Mentor
- Spineology