

Safety

1. Tissue Bank

HRT is an **FDA registered** and **AATB accredited** tissue bank since 2014, and is one of the nation's leading tissue banks specializing in regenerative human tissues. Along with its quality advantages, HRT's stringent safety standards are setting a new standard in the industry for tissue processing.

2. Tissue Source

All of HRT's donated placental tissues are obtained from **healthy mothers** who are under the care of a licensed OB/GYN physician at a partner facility. All donations are sourced from U.S.-based donors, and only after **live, healthy, successful cesarean birth delivery**. No maternal or fetal tissues are collected during the process.

3. Donor Screening

HRT employs stringent donor screening criteria in compliance with FDA HCT/P regulations and American Association of Tissue Banks (AATB) standards. See attached abbreviated Donor Screening Criteria.

As an integral part of donor screening, HRT screens the living donor for communicable disease (serologic and nucleic acid amplification) test markers for human immunodeficiency virus 1 & 2, hepatitis B virus, hepatitis C virus, human T cell lymphotropic virus I/II and causative agent of syphilis in accordance to FDA regulations and AATB standards. The employed testing laboratory is FDA registered and CLIA certified to perform such tests. All test kits are FDA approved and cleared for living donor testing.

4. Tissue Recovery

HRT strictly controls the entire tissue process and does not rely on outside recovery agencies that may not operate at HRT's level of strict process control. HRT runs its own placental donation program, PlacentaDonor.org, to connect donors with partner donation sites. All donated tissues are recovered aseptically in an operating room environment of a Joint Commission accredited hospital. For sanitary reasons, donated tissues are not obtained from birth deliveries performed at birthing centers. Each recovered tissue is placed on wet ice and maintained at wet ice temperature range within the hour of recovery to prevent growth of microorganisms (maintain the low bioburden of the tissue) and preserve the biologic properties of the tissue.

5. Collection and Processing

Tissues are processed aseptically and subjected to minimal processing to maintain the biologic properties and biomechanical integrity of the tissue. HRT HydraTek® technology is a proprietary preservation system which encapsulates the biologic components and preserve the natural fluid consistency of the connective tissue. Other processing methods utilize harsh chemicals, high-heat baking or lyophilization which have been shown to denature proteins, cause collagen collapse, and/or disrupt the delicate tissue matrix and protein structure of the tissues.*

6. Sterility

HydraTek® Process utilizes a cutting edge sterility system which enables our grafts to be preserved throughout the entire process and achieve sterility without harming the integrity of our grafts. We are leading the industry by testing our products post-processing to ensure effective preservation of the biologic viability and biomechanical integrity.

HRT sets the new standard in biologic safety through its ability to offer its finished products in a terminally sterilized form by a validated precise and low-dose E-Beam derived Technological method (in compliance to ANSI/AAMI/ISO11137-2: 2013 Method VDmax15 Dose Substantiation), and are "Sterile" with a 10⁻⁶ Sterility Assurance Level (SAL).

Donor Screening Criteria	HRT	FDA
Hepatitis B Virus	•	•
Hepatitis C Virus	•	•
HIV 1/2	•	•
Malaria	•	•
Sepsis	•	•
Syphilis	•	•
Transmission Spongiform Encephalopathy (TSE)*	•	•
Vaccinia	•	•
West Nile Virus (WNV)	•	•
Ebola Virus	•	
Zika Virus	•	
Clinically significant metabolic bone disease	•	
Illicit drug use, injected drugs	•	
Leprosy (Hansen's disease)	•	
Polyarteritis nodosa	•	
Rabies	•	
Rheumatoid arthritis	•	
Sarcoidosis	•	
Systemic lupus erythematosus	•	
Systemic mycosis	•	
Tuberculosis (clinically active)	•	
Active genital herpes	•	
Acute infection / septic illness	•	
Alzheimers Disease	•	•
Ankylosing spondylitis	•	
Autoimmune hemolytic anemia	•	
Autoimmune thrombocytopenia purpura	•	
Autoimmune vasculitis	•	
Cancer (MDD)	•	
Chagas Disease	•	
Degenerative Disease of CNS	•	•
Dementia	•	•
End stage renal disease / chronic dialysis	•	
Epstein Barr Virus (clinically symptomatic mononucleosis)	•	
Gonorrhea (clinically active)	•	
Encephalitis (clinically active)	•	
Endocarditis (clinically active)	•	
Guillain-Barre syndrome (clinically active)	•	
High risk behavior	•	
Illicit drug use, non-injected drugs	•	
Meningitis (clinically active)	•	
Mixed connective tissue disease	•	
Multiple sclerosis	•	
Myasthenia gravis	•	
Neurological Diseases	•	•
Peritonitis	•	
Poliomyelitis	•	
Pyelonephritis	•	
Reactive arthritis (Reiter's syndrome)	•	
Rheumatic fever	•	
Steroid use / Treatment Chronic	•	
HTLV I/II Virus	•	
Vaginal delivery	•	
Human Papilloma Virus (HPV)	•	

*Including CJD & VCJD

Safety

HRT strives to provide the highest quality, safest amniotic and placental tissues available, and maintains an **outstanding safety record**.

Our stringent donor screening criteria surpasses AATB standards, for improved tissue safety.