
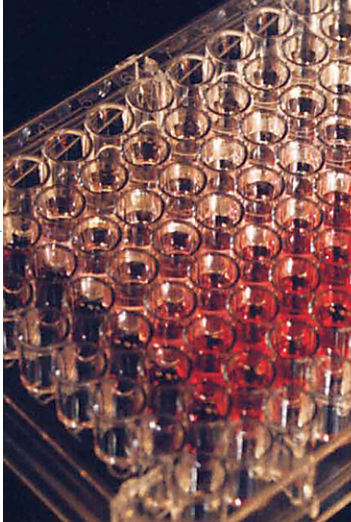




Patient Safety Through Redundant Safeguards

The safety of tissue implants is contingent on three stages – donor screening, laboratory testing and processing methods validated to address potential disease transmission. In the event that one of these stages is challenged, RTI's built-in redundancies continue to ensure a high level of patient safety.

STAGE 1 Donor Screening	<p>After consent for donation is obtained, potential donors are screened for risk factors associated with infectious diseases and medical conditions that would rule out donation.</p>	<p>Screening includes, but is not limited to:</p> <ul style="list-style-type: none"> • Family/next-of-kin interview • Medical/hospital record review • Behavioral/lifestyle risk assessment • Medical examiner/coroner's report (autopsy report, when available) • Laboratory, pathology and radiology reports 	
STAGE 2 Donor Testing	<p>An extensive panel of serological infectious disease tests is performed on each donor. The testing is done in a CLIA certified laboratory using test kits cleared, approved or licensed by the United States Food and Drug Administration (FDA) for donor testing. The results are subject to stringent acceptance criteria in order to release the donor tissue to the processing stage.</p>	<p>Serological Testing</p> <ul style="list-style-type: none"> • HCV Antibody • HBV Surface Antigen • HIV 1 & 2 Antibody • HBV Total Core Antibody • HTLV I & II Antibody • Syphilis • HIV-I/NAT • HCV/NAT 	
STAGE 2 Donor Testing	<p>Microbiological testing is used appropriately throughout the process to screen for potential contamination and to provide confirmation of tissue suitability for transplant.</p> <p>The final determination of donor eligibility is made by RTI's medical director—a licensed physician—utilizing all available, relevant screening and testing information.</p>	<p>Microbiological Testing</p> <ul style="list-style-type: none"> • Pre-processing culturing: Performed before processing begins to remove potentially unsuitable tissue • Sterility culturing: Performed at packaging for products that are not terminally sterilized • Environmental controls: Monitors cleanliness of processing environment 	
STAGE 3 Validated Tissue Processing	<p>Tissue processing is performed in certified ISO Class 5 to Class 7 clean rooms to prevent environmental contamination of the tissue.</p> <p>Where possible, RTI has advanced beyond the sole use of aseptic processing, which does not ensure the removal or inactivation of microorganisms inherent to the donor or tissue. RTI's scientifically proven and clinically successful tissue sterilization processes (BioCleanse®, Tutoplast® and Canceled™ SP DBM) inactivate or remove bacteria, viruses, fungi and spores. These validated chemical sterilization processes thoroughly penetrate tissue while preserving the biomechanical properties, biochemical integrity and collagen structure of a particular tissue type.</p>	<p>Following processing, grafts undergo one of the following final steps to confirm safety:</p> <ul style="list-style-type: none"> • Post-processing sterility culturing: Grafts subject to sterility cultures before final release • Terminal sterilization through Sterrad®: Grafts sterilized in final package to achieve 10⁻⁶ sterility level • Low-dose gamma sterilization: Grafts sterilized in final package to achieve 10⁻⁶ sterility level 	

Ensuring Patient Safety

RTI's primary goal is to ensure patient safety. To fulfill this goal, RTI employs stringent donor screening, laboratory testing and tissue preparation validated to inactivate or remove pathogens. These redundant safeguards provide the highest level of confidence that patients will receive safe, high quality tissue.

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