

# The RTI Donor Services Difference

## Our Commitment to Patient Safety



Tissue donation is a gift of life—a gift that allows recipients to move without pain, to play with their children and grandchildren, and to participate in activities they thought were lost forever. As an organization that participates in a donation program, you have the opportunity to offer more families the chance to give this special gift and make a difference in the lives of many.

### Working Together: Donation to Transplantation.

#### Two Philosophies Serving One Mission.

RTI Donor Services provides donation opportunities to your families and community. Through our affiliation with RTI Biologics, you will also receive the advantage of having tissues transformed into safe and innovative biologic solutions for patients in need. The confidence you can have in how your tissues are handled and subsequently utilized to mitigate pain and provide increased quality of life for so many can be assured by knowing that these two organizations work in synergy to maximize each gift.



#### Brandon Sack, Recipient

*While wakeboarding, Brandon Sack suddenly felt his knee twist and pop. Brandon said it was horrible timing because the weather had just warmed up enough for him to stop using his wetsuit while on the water. He thought about all of the warm spring days to come that he would not be able to enjoy.*

*After a visit to the doctor, Brandon found out that he had torn his anterior cruciate ligament (ACL) and feared that his injury would keep him from returning to his wakeboard.*

*"I knew I needed corrective surgery because I wanted to be able to return to wakeboarding and not have to worry about my knee," says Brandon.*

*Almost two months after his injury, Brandon received a donated Achilles tendon to replace the torn ligament in his knee. He had to undergo physical therapy two or three times a week to strengthen the muscles around his knee and was soon able to return to the sport he enjoyed so much.*

### Our Credentials

The organization that you select to work with for donation and/or distribution programs should have credentials that demonstrate their commitment to patient safety. RTI Donor Services and RTI Biologics are committed to providing this evidence through a robust credentialing process and providing those certifications to your facility for review.

- RTI Donor Services is accredited by the American Association of Tissue Banks (AATB) for screening and recovery of donated skin, pericardium and musculoskeletal tissue for transplantation and research.
- RTI Biologics is accredited by the American Association of Tissue Banks (AATB) for processing, storage and distribution of skin, pericardium and musculoskeletal tissue for transplantation and research.
- Both RTI Donor Services and RTI Biologics are registered as Tissue Establishments with the Food and Drug Administration (FDA).
- RTI Biologics is registered as a Medical Device Manufacturer with the FDA.
- RTI Biologics' quality system is certified to ISO 13485:2003 (with CMDCAS for Canada) Medical Devices Quality Management Systems.
- RTI Biologics is registered with Health Canada for Human Cells, Tissue and Organs for Transplantation (CTO).
- RTI Biologics' State Tissue Bank Licensure includes:
  - Florida
  - Maryland
  - California
  - New York
  - Other state registrations as applicable: (Delaware, Illinois and Oregon)
- RTI Biologics is licensed as a Medical Device Manufacturer with the State of Florida.
- RTI Biologics' Biomedical Laboratory:
  - FDA Registration
  - Clinical Laboratory Improvement Amendments (CLIA) Certificate of Compliance (Federal)
  - State of Florida Clinical Laboratory Licensed
  - New York State Department of Health Clinical Laboratory Permit


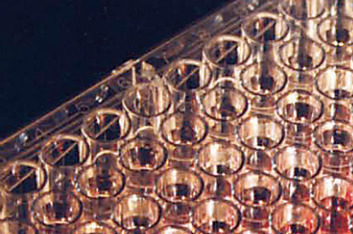
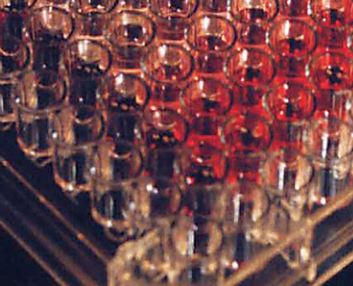

# Redundant Safeguards – The RTI Difference

The safety of any tissue is contingent upon three stages – donor screening, laboratory testing and tissue preparation validated to address potential disease transmission.

For surgeries involving tissue implants, RTI Biologics has developed methodologies to address the risk of infection that could be caused by the implants themselves. Where possible, we use validated, proprietary sterilization processes—such as BioCleanse®, Tutoplast® and Cancellle™ SP—to provide safe tissue implants that have enhanced the lives of patients around the world.

Each individual tissue donor is evaluated for multiple factors that determine the type of implant that can be processed from the tissue based upon the defined implant specification. Donor and/or tissue requirements are established through scientific methods such as biological properties, biomechanical testing and clinical evaluations and not based solely on donor age or other arbitrary criteria.

RTI has provided more than two million tissue implants with zero incidence of allograft-associated infection. At RTI, that’s our track record, and we’re proud of it.

<b>STAGE 1</b> <b>Donor Screening</b>	<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><b>Screening includes, but is not limited to:</b></p> <ul style="list-style-type: none"> <li>• Family/next-of-kin interview</li> <li>• Medical/hospital record review</li> <li>• Behavioral/lifestyle risk assessment</li> <li>• Medical examiner/coroner’s report (autopsy report, when available)</li> <li>• Laboratory, pathology and radiology reports</li> </ul>	
<b>STAGE 2</b> <b>Donor Testing</b>	<p>An extensive panel of 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><b>Tests Performed</b></p> <ul style="list-style-type: none"> <li>• HCV Antibody</li> <li>• HBV Surface Antigen</li> <li>• HIV 1 &amp; 2 Antibody</li> <li>• HBV Total Core Antibody</li> <li>• HTLV I &amp; II Antibody</li> <li>• Syphilis</li> <li>• HIV-I/NAT</li> <li>• HCV/NAT</li> </ul>	
<b>STAGE 2</b> <b>Donor Testing</b>	<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><b>Microbiological Testing</b></p> <ul style="list-style-type: none"> <li>• Pre-processing culturing: Performed before processing begins to remove potentially unsuitable tissue</li> <li>• Sterility culturing: Performed at packaging for products that are not terminally sterilized</li> <li>• Environmental controls: Monitors cleanliness of processing environment</li> </ul>	
<b>STAGE 3</b> <b>Validated Tissue Processing</b>	<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 Cancellle™ 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><b>Following processing, grafts undergo one of the following final steps to confirm safety:</b></p> <ul style="list-style-type: none"> <li>• <b>Post-processing sterility culturing:</b> Grafts subject to sterility cultures before final release</li> <li>• <b>Terminal sterilization through Sterrad®:</b> Grafts sterilized in final package to achieve 10<sup>-6</sup> sterility assurance level (SAL)</li> <li>• <b>Terminal low-dose gamma sterilization:</b> Grafts sterilized in final package to achieve 10<sup>-6</sup> SAL</li> </ul>	

**RTI Donor Services**

[www.rtidonorservices.org](http://www.rtidonorservices.org)