

Welcome to the  
*Community*

***Allograft Awareness***



Community Tissue Services®  
*Commitment • Technology • Safety*

## Selecting the right allograft

for your patients is much like choosing the best community in which to live. Not all neighborhoods or tissue providers offer the same benefits, amenities, or services, but asking the correct questions can help in making the right choice. At Community Tissue Services, our commitment to our donors, their families, and tissue recipients, combined with innovative technology, safety, and trusted leadership, have allowed us to be an allograft provider of choice for over 20 years.

## Licenses & Accreditation

All Community Tissue Services' (Community) locations are registered with the Food and Drug Administration (FDA), accredited by the American Association of Tissue Banks (AATB) and maintain all applicable state licenses. Community is ISO 9001:2000 registered. For access to all of our licenses and certificates, please visit: <http://www.communitytissue.org/distribution/accreditation.html>

## Industry Leaders

Elected by a vote of industry peers, **Diane Wilson**, Community's Chief Operating Officer, is the current President of AATB while **Dr. David Smith**, Community's Chief Executive Officer, is the President-Elect. Consecutive elections from the same tissue bank are unprecedented in the industry and speak strongly of the respect earned by Community's leadership.

## Innovative Research & Product Development

Community has committed resources and undertaken the construction of a new Research & Development, Manufacturing and Distribution facility. Scheduled to open in early 2011, this 90,000 square foot, state-of-the-art facility will allow us to extend our abilities to service the orthobiologic needs within communities around the world.

A large, stylized graphic of the word "Community" in a teal, serif font, partially visible within a white oval shape that is part of a larger teal and white swoosh design.

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## The Community Experience



**David M. Smith, MD** is the Chief Executive Officer of Community Tissue Services. Dr. Smith earned a Bachelor of Science degree in Biology from Wright State University in Dayton, Ohio. In 1983 he earned a Medical Doctor degree from the Wright State University

School of Medicine. Dr. Smith served his Anatomic and Clinical Pathology residency at Kettering Medical Center in Dayton, Ohio, followed by a fellowship in Forensic Pathology at the Institute of Forensic Medicine, Toxicology and Criminalistics in Cincinnati, Ohio. He is Board certified in Anatomic and Clinical Pathology, as well as Forensic Pathology.

Prior to joining Community Tissue Services, Dr. Smith was a staff Pathologist and Director of Autopsy Services at Ball Memorial Hospital in Muncie, Indiana. Dr. Smith began his career as a Forensic Pathologist with the Montgomery County Coroner's Office in Dayton, Ohio.

He is an Associate Clinical Professor of Pathology at the Wright State University Boonshoft School of Medicine. Dr. Smith is President-Elect of the American Association of Tissue Banks' (AATB), having been elected for a two year term that begins in 2011. Other positions that he has held within AATB are: Board of Governors, Chair of Physicians Council, Chair of Tissue Transmitted Diseases (TTD) Advisory Group, member of the Medical Advisory Committee, and member of the Standards Committee.

*"Commitment to Technology and Safety drives our organization of extraordinary people saving and enhancing lives. I am grateful to tissue donors and their families for their compassion and generosity."*



**Diane L. Wilson, BSN, MSN/MHA** is the Chief Operating Officer for Community Tissue Services. Mrs. Wilson received her Associates Degree in Nursing from Everett Community College in Everett, Washington and later earned her Bachelors and Masters degrees in Science

in Nursing and Health from the University of Phoenix. Mrs. Wilson's 20+ years in tissue banking started in 1988, when she became the first Director of the Dayton Regional Tissue Bank, which later became the first Community Tissue Services. Mrs. Wilson has served on most AATB committees and has Chaired the Standards Committee. In 2005, she was the first woman to be honored with the prestigious Kenneth Sell Award, which is given to individuals who have made a significant contribution to the field of tissue banking. In 2009, Mrs. Wilson was elected President of AATB. She is currently the Chairman of the Board for the Joint Restoration Foundation (JRF), which is the nation's leader in fresh cartilage distribution. She has co-authored tissue bank standards for the Association of Orthopedic Nurses (AORN) and the American Association of Blood Banks (AABB).

*"In 1999, my youngest daughter's boyfriend died in a car accident and became one of our donors. The feelings that our family experienced were ones that most families feel during a tragedy. In knowing that we could improve the quality of life for someone by donation of a bone graft or repair a fallen athlete's tendon, we viewed Brian's life not as a loss, but as an opportunity to make him a lasting hero."*



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## About Our Donors

In 2009, Community Tissue Services recovered tissues from nearly 4,000 donors and returned more than 130,000 grafts to communities around the world.

Community is committed to honoring the last wish of each donor while providing recipients and surgeons with a trusted source for allograft implants. As part of this commitment, Community only accepts tissue donors that meet or exceed the donor eligibility requirements set in place by the FDA, AATB, state regulations, and Community's in-house Medical Directors. To this end, Community uses the experience of licensed Medical Doctors to assist in the donor screening process prior to recovery.

More than two-thirds of the tissue processed by Community is recovered directly by our employees at branches located throughout the United States. The remaining tissue is recovered by our partner Organ Procurement Organizations (OPOs). All of Community's valued OPO partners

are trained and audited by Community to ensure recovery operations are compliant with all applicable regulations.

- All partners performing recoveries for Community are registered with the FDA as an HCT/P establishment
- All donors are recovered using aseptic technique in an environment that meets or exceeds the standards set by the FDA, AATB, and Community's Standard Operating Procedures

Prior to clearance for processing, donor medical records, including the donor's medical and social history, physical assessment and autopsy results (if performed), as well as all other recovery documentation are reviewed by Community's Medical Directors.

All Community donors are tested for transmissible diseases using FDA-licensed, approved, or cleared donor screening test kits. Additionally, each individually recovered tissue undergoes pre-processing microbiological cultures to ensure pathogenic organisms are not introduced to the processing environment.

As an added measure of safety, and to reduce the risk of transmission of Creutzfeldt-Jakob disease (CJD), Community does not recover tissue from the spinal column or Dura, as these areas have a higher potential for carrying the prion associated with CJD transmission.



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## The Community Experience



**James L. Alexander, MD** is the Medical Director of the Community Blood Center (CBC), Community Tissue Services. He serves CBC as the Director of the Human Leukocyte Antigen laboratory. The laboratory provides compatibility testing for the Miami Valley Kidney

Transplant Services. Dr. Alexander started his professional career as a Chemical Engineer in 1981, working in numerical simulation of oil reservoirs and aquifers. He started medical school in Oklahoma and completed his residency in Anatomic and Clinical Pathology in 1994 at Baylor University Medical Center in Dallas, Texas. Dr. Alexander worked as a hospital-based pathologist for two years before entering a Transfusion Medicine fellowship at the University of Texas, Southwestern Medical School. After completing his fellowship, Dr. Alexander worked as the Medical Director for the American Red Cross in Texas before joining Community in 2003.

*"I am constantly amazed by the altruism exhibited by our donors and their families across the entire country."*



**Shawn A. Hunter, PhD** is the Director of Research and Development for Community Tissue Services. Dr. Hunter received his Ph.D. in Engineering Mechanics from the University of Cincinnati in 2002. His expertise in musculoskeletal tissue biomechanics was

cultivated through the study of various tissue and whole joint models along with collagen matrix stabilization aimed at developing knee meniscus allografts. Dr. Hunter expanded his research to cartilage tissue engineering during his post-doctoral fellowship, where he gained experience in bioreactor design, transgenic stem cell creation and culture, and biomaterial scaffold evaluation. Dr. Hunter currently leads Community's efforts in developing new allografts and combination devices directed toward use in regenerative medicine applications. Dr. Hunter is responsible for establishing an Advanced Tissue Biomechanics Laboratory. Dr. Hunter is a member of the Orthopaedic Research Society (ORS) and American Association of Tissue Banks (AATB), and he serves on the AATB Scientific and Technical Affairs Committee.

*"Allografts possess many characteristics that potentially make them the ideal scaffolds for growing new and/or regenerating injured tissues. Our goal at Community is to advance tissue banking in this area to produce effective treatment solutions for our patients and thereby further realize the gift of our donors and donor families."*



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## Product Sterility

Community has validated a  $10^{-6}$  Sterility Assurance Level (SAL) for musculoskeletal grafts in their final packaging following ISO 11137 Method 2B. A  $10^{-6}$  SAL means the probability of a graft being non-sterile is 1 in 1,000,000.

Community chose Method 2B and employed a two-media approach for conducting sterility testing because it represents a conservative methodology, well suited for the variations of bioburden inherent in human tissue.



The STERILE R logo is an international symbol indicating a product has been sterilized using gamma radiation.

## Community Fees

Community Tissue Services is a not-for-profit organization. Fees associated with our products and services are established based on our ability to control Recovery, Manufacturing, Distribution, Research and Product Development expenses. Effective planning, solid execution, and responsible resource management have allowed Community to continue to educate and support our communities, enhance our research efforts, develop our infrastructure and human resources, and to provide quality allograft products under one of the most competitive and value-added fee structures in the industry.



Community Tissue Services Center for Tissue, Innovation and Research

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