

## An Inside Look at LifeLink Tissue Bank's Quality Assurance Department

By Brandy Keech

In its simplest terms, quality assurance is prevention and quality control is detection. These are crucial parts of a program essential for providing safe, effective tissue to surgeons and their patients.



LifeLink Tissue Bank's Quality Assurance Department

The LifeLink Quality Assurance Department (QA) is led by its Vice President,

Elizabeth Horn-Brinson, who works diligently with the team to ensure the safety of tissue provided by LifeLink. The department's commitment is based on the recipient's safety. LifeLink always leans on the side of caution in order to provide the highest quality of tissue to the patient out of respect for the donor families whose generous gifts make tissue transplants possible.

*"A crucial part of QA involves an understanding of the Food and Drug Administration, American Association of Tissue Banks and LifeLink's Standards of Procedure."*



"Safety from the Beginning" is LifeLink's philosophy. To illustrate the value LifeLink places on safety, I visited the QA department which includes recovery review coordinators, process review coordinators, validation coordinators, microbiology technicians and support coordinators.

**Recovery Review Coordinators** are responsible for donor review and verification of medical records to help determine donor suitability. Numerous hours are spent reviewing medical and social history records, hemodilution calculations, and results of serological testing. "We must coordinate the tests performed on each donor to make sure there is no duplicate testing," said Dayna Zavaglia, recovery review coordinator.

According to Patricia Fiedler, recovery review coordinator, a crucial part of QA involves an understanding of the Food

and Drug Administration, American Association of Tissue Banks and LifeLink's Standards of Procedure. The staff must continually assess tissue procurement documentation to ensure all procedures are followed correctly.

In addition, the staff works closely with the Associate Medical Director, Daniel Schultz, M.D., a forensic pathologist who determines final donor suitability.

**Process Review Coordinators** review each step in the processing of allograft tissue to ensure that all cultures are performed and required documentation has been completed. The staff is responsible for the review of processing records as well as temperature, disinfection and room cleaning logs. Working closely with the processing staff, the coordinators frequently conduct audits and investigations of internal processes.

**Validation Coordinators** focus on validating processes and equipment, and environmental monitoring. Responsibilities include installation, operational and performance

qualifications on all validated equipment as well as the coordination of all calibration activities.

**Microbiology Laboratory personnel** test cultures collected from tissue samples pre and post processing. In addition, ten percent of all allografts produced from one donor are randomly selected and destructively tested for the presence of microorganisms.

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### Tissue Connection Trivia

Correctly answer this quarter's question and you'll be entered to win a \$25 gift certificate to Best Buy.

To enter, e-mail your answer to: [contactinfo@lifelinkfound.org](mailto:contactinfo@lifelinkfound.org). Please provide your full name, hospital and phone number.

**When did the FDA begin regulating the recovery, processing and distribution of tissue intended for transplantation in the United States?**

Only correct answers will be entered into the drawing. One winner per quarter. The winner will be notified and posted in the next Tissue Connection.

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LifeLink's microbiology laboratory is accredited by the College of American Pathologists and certified by the Clinical Laboratory Improvement Amendment.

**Support Coordinators** act as a "clearing house" for QA. Their primary responsibilities include organizing and placing all documentation in the donor's chart. In addition, these coordinators enter all recovery information into a computerized tracking system to help facilitate traceability of the tissue.



In summary, the LifeLink Quality Assurance Department is responsible for monitoring all of the tissue bank operations to prevent the introduction, transmission or spread of communicable diseases. Q.A. regularly audits other departments to ensure all requirements are met.

I have learned that an experienced quality assurance program is an essential foundation for allograft safety. The LifeLink Quality Assurance Department's knowledge, hard work and dedication lives the philosophy of "Safety from the Beginning." ■

## LifeLink Tissue Bank Nurse's Tissue Council

LifeLink is excited to announce the development of a nurse's tissue council. Members will consist of operating room and blood bank management from Florida, Georgia and Alabama as well as select LifeLink personnel. Objectives of the council include:

- Identify healthcare industry issues pertaining to the handling of human tissue
- Address current issues in the tissue banking industry
- Review technical advances in the tissue banking industry
- Analyze compliance requirements of the FDA and Joint Commission
- Identify cost containment issues pertaining to human tissue

The nurse's tissue council will network with colleagues and jointly recommend solutions to some of these issues. In addition, a representative from the committee will have the opportunity to present issues and solutions to the LifeLink Tissue Advisory Council which consists of surgeons from across the nation.

If you are interested in becoming a member or require further information, please contact Dawn Carney at 800-683-2400 ext. 4144.

## Introducing... The Tricortical Cancellous Wedge



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Please contact LifeLink at 800-683-2400 for more information. ■

# Seven Answers to Dr. Joyce's Simple Questions

In June 2005, the AAOS bulletin published an article written by Michael J. Joyce, M.D.\* in which he posed seven questions for hospitals and practicing surgeons who work with allografts to ask their tissue processors to ensure they are meeting the regulations for tissue procurement and processing. In addition to becoming thoroughly familiar with the tissue processor that provides your allograft tissue, Dr. Joyce also highlighted the importance of becoming knowledgeable about the FDA's regulations.

As your tissue processor, LifeLink Tissue Bank would like to provide their answers to Dr. Joyce's excellent questions:

## 1. What are your standard procedures for evaluating potential contaminants on incoming tissue?

During the recovery process, the entire surface of each tissue recovered is swab cultured. These pre-processing swab cultures are then inoculated into the appropriate media for isolation of aerobic, anaerobic, and fungal organisms. Strict aseptic technique is utilized throughout the recovery of tissue. Tissue is excised following zone recovery and tissue sequencing methods as recommended by the American Association of Tissue Banks to help prevent contamination/cross contamination of tissue during recovery.

## 2. What procedures do you use to detect microorganisms?

Prior to exposure to antibiotics or other processing reagents, a surface swab culture is taken on 100% of incoming tissue and inoculated into Thioglycollate broth for 14 days. At packaging, 50% of each allograft type is again swab cultured. For Freeze-Dried allografts, samples representing 10% of the total number of allografts produced from each donor are destructively tested for the presence of microorganisms. For frozen allografts, 100% of the allografts are swab cultured and inoculated into Thioglycollate and TSB along with a piece of the allograft. The inoculated tubes are then incubated for 14 days at 37°C and 25°C respectively.

## 3. What in-process steps do you use to reduce the biological contamination of processed allografts?

LifeLink processes all bone and soft tissue utilizing aseptic technique in a climate controlled ISO Class 5 (Class 100) Cleanroom environment. Tissue from only one donor is processed in a room at a time; pooling of tissue from multiple donors is strictly prohibited. LifeLink utilizes Allowash® Technology to process the allografts. Allowash® Technology involves a series of mechanical and reagent cleaning and disinfection steps to reduce any potential bioburden. This process includes the use of Allowash® solution, a combination of biological detergents that work in conjunction with traditional treatments such as alcohol and hydrogen peroxide to enhance the solubilization and removal of bone marrow, blood, and lipids (elements that may possibly act as a reservoir for disease transmission).

In addition, antibiotics (Bacitracin and Polymyxin B) are also utilized in the processing of allografts. Tissue to be demineralized is further processed using Hydrochloric Acid and Sodium Phosphate Buffer.

## 4. Do medical professionals make the final determination on the release of allografts?

LifeLink's medical director or physician designee review the donor's medical and social history, physical assessment findings, serology testing, pre-processing culture results, autopsy findings (if performed) and other relevant medical records (i.e. hospital records) to determine donor eligibility.

## 5. How do you address adverse event complaint reports from surgeons?

All adverse event complaints are documented, investigated and reported to the appropriate agencies by the Quality Assurance Department in accordance with applicable state and federal regulations and AATB standards.

Each investigation determines whether associated tissue may be affected. If it is determined that associated tissue may be affected, the tissue is located and quarantined until the investigation is completed.

The QA director or designee evaluates complaints to determine if any information pertaining to the possible contamination of tissue or potential for disease transmission needs to be forwarded to other establishments known to have recovered tissue from the same donor and other establishments known to have received tissue from the same donor (such as other processors, consignees).

The Quality Assurance director or designee in conjunction with the executive director and medical director determines if a recall of tissue is warranted. If warranted, a recall is initiated. The recall includes notification and communication with affected physicians.

If the adverse event is attributed to tissue recovery or processing, a Corrective Action Request is generated to determine the cause and identify corrective actions to be taken.

## 6. Are you in compliance with FDA regulations and accredited by the American Association of Tissue Banks?

LifeLink Tissue Bank was re-accredited by the AATB in December of 2004 and was last inspected by the FDA in February of 2007 with no 483's noted.

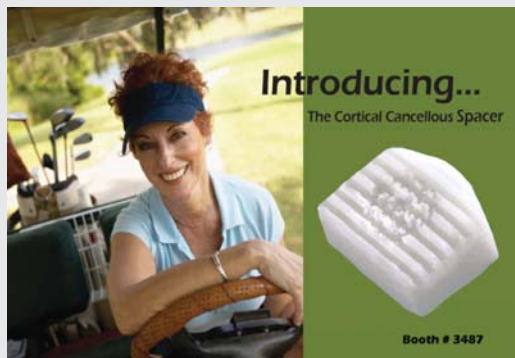
## 7. Does your serological evaluation of tissue include nucleic acid testing (NAT) for HIV and HCV?

The Nucleic Acid Test for detection of HIV-1 and Hepatitis C Virus was implemented by LifeLink on February 21, 2005.

\*Michael J. Joyce, MD, is an orthopedic surgeon at The Cleveland Clinic and is also a past-president of the AATB. ■

## AORN CORNER

AORN's 54th Congress had another successful year this past March in Orlando. LifeLink Tissue Bank would like to thank all the nurses who stopped by our booth and participated in our putting contest. Thank you also to the Florida Council of periOperative Registered Nurses (FCORN) for giving us the opportunity to support their annual dinner. The fashion show was awesome. We had a blast!



## Did you Know?

People with tattoo(s), ear or body piercings and who undergo acupuncture therapy with unsterilized (shared) instruments cannot be donors within 12 months of their procedure.

Congratulations to Martha Howell, Nurse Manager from the Methodist Medical Center in Oak Ridge, TN. Martha won LifeLink's drawing at the AORN 54th Congress—a \$250 gift certificate to Best Buy! Martha was among thousands of attendees at the AORN Congress.

## Special Announcements:

### Tissue Connection Trivia Winner:

The Tissue Connection Trivia winner from last quarter's newsletter was Rusty Jackson from Gwinnett Medical Center in Lawrenceville, GA. He was randomly picked out of 25 entries with the correct response. Rusty received a \$25 Best Buy gift certificate. Congratulations Rusty! Rusty is a Surgical Tech Educator for 40 surgical technologists and has worked at Gwinnett M. C. for 7 years.

The answer was "LifeLink performs the following serological donor screening tests in addition to those required by the FDA: HTLV I/II Ab, HIV1/HCV NAT, HbCAbtI, ABO/Rh, and Chagas Ab."

### The Joint Commission Introduces New Brand Identity

The new website for the Joint Commission, formerly called "The Joint Commission on Accreditation of Healthcare Organizations (JCAHO)" reflects the new name with a new logo and a new tagline, "Helping Health Care Organizations Help Patients." The new brand reflects The Joint Commission's continuing efforts to improve the value of accreditation and its utility as a mechanism for improving the quality and safety of patient care. For more information please visit their new website at: <http://www.jointcommission.org>.

## TAMPA SYMPOSIUM WAS A HUGE SUCCESS



Technological Advancements in Tissue Transplantation, a symposium held in Tampa on June 9th at the Westshore Marriott, was a huge success with 100 people in attendance. The morning was filled with a variety of engaging and informative presentations: applications of autopsy and biopsy in determining tissue donor suitability, stem cell therapy in orthopedics, tissue intermediaries, the past and present of allograft skin transplantation, a local organ and tissue donation update, and a heartfelt recipient story. Some of the out of town guest speakers included Ernest K. Manders, MD from Pittsburg, PA and Dr. Dayna Buskirk from Gainesville, FL. The success of the program's content and speaker quality was evident from the responses on the program evaluations. A similar program took place in Mobile, Alabama on July 28. Please check our website for upcoming programs and to register at [www.lifelinktb.org/symposium](http://www.lifelinktb.org/symposium).



### Excerpts from the program evaluations:

"You supplied excellent information with the utmost compassion. You brought it home."

"Fabulous program. This demonstrates your commitment to accurate dissemination of vital info. Amazing data!"



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