The Tissue Connection
Volume 1, Issue 1, Autumn 2006
A LifeLink Tissue Bank Newsletter

Kristin Green (middle) with husband Bradley and mother Dorothy

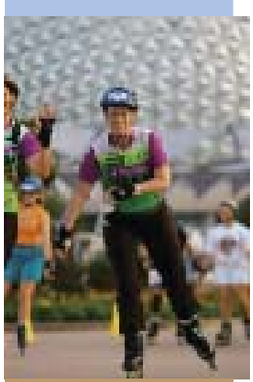
Kristin's life will never be the same

An allograft recipient's courageous story

By Regina Grisales

A lifelong dream of running a marathon was shattered in the blink of an eye when Kristin Green was in a terrible car accident. A young, inexperienced driver ran a stop sign, launching herself and three other teens into Kristin's path. Luckily, the teens walked away without injuries. Kristin, on the other hand, suffered major neck injuries that changed her life and altered her dreams.

Kristin couldn't move in certain directions and was out of work for over a week. After several months of treatment her pain worsened. She couldn't turn her head without pain, she couldn't lift her arms to reach things, Kristin, a teacher, couldn't get dressed or write on the blackboard at work. Driving was also difficult because she had to rest her head every so often. Four months after the accident she was diagnosed with severe spinal stenosis and neural foramen narrowing, produced by cervical disc protrusion at C5-6. In addition, her doctors found disc bulges and narrowing at multiple levels.



Kristin competing in Walt Disney's Inline Marathon

An avid jogger and normally an optimistic person, she found little to be positive about, even in the midst of planning her wedding. She often wondered if she would ever be able to run a marathon, or lift and carry a future child. Her doctor discussed surgery but Kristin and her husband Bradley, who provided amazing support, were not convinced. Kristin spent hours online to learn whether surgery would be a quick fix or a long term therapy. When the pain reached its maximum, she knew it was time to do something. They scheduled the surgery after they returned from their honeymoon in Tahiti. Dr. Jed Weber performed an anterior cervical disectomy, utilizing plating instrumentation, replacing discs C4-5 and C5-6 with allografts. "Dr. Weber was excellent and since I wasn't familiar with the process, it was so refreshing to find a doctor who was emphatic, confident and knowledgeable about donated bone grafts. He went over all of the benefits and risks in detail, I knew I was in good hands," she said.

After the surgery Kristin did not have to wear a brace however, she received physical therapy for one year accompanied by massage therapy and pain management. After the pain from the neck surgery subsided in about 1½ weeks, she could already tell the difference. The pain down her arm was gone. She couldn't move her neck much because she was limited by the healing process. It would take several more weeks before she could turn her head. By Christmas Kristin made a full recovery and began to take her life back. "I never thought I could lift my arm again, now I can lift my child!" In December of 2003, Kristin focused toward a new challenge—competing in an inline marathon. Although her doctors advised against it, she began training 4-5 times a week; 10 miles a day from January until the beginning of May. She completed the 26.2 miles at the Walt Disney World Inline Marathon successfully. Kristin was told not to run again but rollerblading and inline marathons fulfilled her desire for physical activity and competition. She is a busy stay at home mom with Spencer and looks forward to the birth of her second child in October.

> *"When the pain reached its maximum, she knew it was time to do something."*

"I was given a gift. This gift allowed me to avoid additional postoperative pain and recovery from an additional surgical procedure because I would have utilized autograft bone. It has given me the ability to focus on my neck injury and begin regaining control of my life, Kristin shared." ■

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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. Please provide your full name, hospital and phone number.

How often must ambient temperature be documented for freeze dried allograft tissue per FDA and JCAHO regulations?

You must provide the correct answer to enter. All correct answers will be entered into a drawing. One winner per quarter. The winner will be notified and posted in the next Tissue Connection.

How well do you know your tissue source facilities?

By Linda Humphries

Since October, 2005, print and broadcast media have reported the indictments of four men accused of recovering tissues from deceased donors without family consent. An investigation by the Food and Drug Administration (FDA) resulted in the October 25, 2005 recall of all tissues from 761 donors procured by Biomedical Tissue Services (BTS) of Ft. Lee, New Jersey. The circumstances under which these tissues—some possibly implanted as far back as early 2004—were procured have given rise to FDA concerns that the donors "may not have met FDA donor eligibility requirements" and "may not have been properly screened for certain infectious diseases."

The implicated tissues were distributed throughout the country by five tissue processing facilities. Those tissue processors are notifying the hospitals which received the recalled tissues. The hospitals in turn are notifying surgeons.

FDA and the Centers for Disease Control and Prevention (CDC) believe the risks from these tissues are low because the tissues were routinely processed using methods that help to reduce the risk of infectious disease; however because many thousands of grafts were implanted and the actual infectious risk is unknown, the FDA recommended recipients of the implicated grafts be tested for HIV, hepatitis B and C, and syphilis, the relevant infectious disease agents for which all tissue donors are to be tested according to FDA regulations.

In order to help protect your patients who will receive allograft implants in the future, learn all you can about the facilities which supply allograft tissue to your hospital. Inquire about the specifics of all your allograft tissue source facilities' quality control programs for ensuring the safety of the tissues they procure, process and distribute, as well as those tissues they may receive for processing and distribution from outside entities.

"Learn all you can about the facilities that supply allograft tissue to your hospital."

Below is a list of recommendations for hospitals to follow:
It is important to learn who recovers the tissue distributed by source facilities. If the tissue was provided by an independent procurement agency, determine how the tissue distributor ensures that legal consent for donation and complete, reliable donor medical and social history is obtained.

Continued on page 3

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Continued from page 2

Find out what mechanisms are in the distributor's quality assurance program for oversight, training, and inspection of any independent procurement agency that supplies them tissue. How does the distributor know the procurement agency is handling the tissue according to the FDA's requirements?

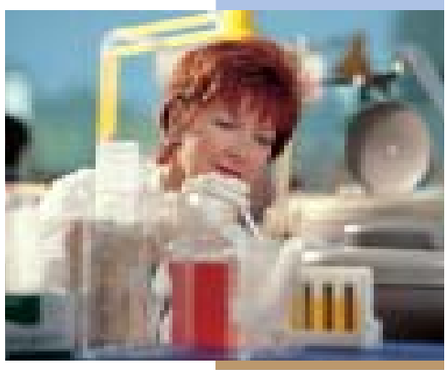
Inquire about tissue recovery conditions. Are donor recoveries made in operating rooms settings using strict aseptic technique? Or, are they done in a morgue, funeral home, or autopsy suite under clean conditions? If the latter is the case, secondary sterilization such as irradiation is required to ensure the safety of the tissue. However, hospitals should be aware of the possibility of biomechanical damage to the grafts from irradiation.

"It is important to learn who recovers the tissue distributed by source facilities"

Determine the extent of the tissue source facility's cleaning and processing protocols. Do they use advanced cleaning methodologies employing both mechanical and chemical processes to reduce microbial and viral burden in the tissue? Is the cleaning and processing done in the most advanced setting, an air quality environment certified to be equal to or cleaner than a Class 100 environment?

Establish the extent of the donor testing done by the tissue source facilities. Are only the FDA-required tests performed or are they supplemented with Nucleic Acid testing (NAT) for HIV-1 and HCV? Has the donor been tested for human T-cell lymphotropic viruses (HTLV-1 & 2), precursors to disease manifestations including adult T-cell leukemia?

Ensure tissue cultures are obtained before the tissue is placed in antimicrobial solutions. Are process validations performed to ensure residual antimicrobials in treatment solutions do not result in false negative culture results? Is a representative sample of the donor's tissue destructively sampled as further confirmation of the safety of the tissue? Does the tissue source facility utilize other information sources such as autopsy results on their donors?



Learn the tissue source facilities' age restrictions for donors. Tissue recovery organizations set age limits for different kinds of tissues (e.g. bone, skin, tendons). Ask the age limits for each kind of tissue to make sure they are within acceptable ranges for your surgeons' needs.

Your hospital and patients are entitled to know what has transpired with allograft tissues before they reach your operating room. For more information on the recall and a list of the specific tissue distributors involved, go to http://www.fda.gov/cber/recall.htm or call 800-835-4709. If you would like to learn ways to help protect your hospital and your surgical patients from incidents like the one described above, contact LifeLink Tissue Bank's Education Department for materials or Continuing Education programs on effective

AORN CORNER

What's wrong with this picture? If you're a perioperative nurse, AORN hopes you immediately cringe at the sight of the OR in this illustration. Now, take time to circle at least 25 things that violate AORN's recommended practices for appropriate technique in the operating room.

The Center for Nursing Practice developed this cartoon before the 2004 Congress in San Diego. AORN held a contest at the 2005 Congress in New Orleans, asking members to find all of the breaks in technique in the illustration. After receiving more than 1,600 entries, the Center for Nursing Practice identified two winners who found all of the 25 technique violations — Gwendolyn P. Jackson, RN, BSN, CNOR, Morris Plains, N.J., and Tim Loosbrock, RN, BSN, CNOR, Sanford, N.C.

The cartoon was published in the May 2005 *AORN Connection* and re-printed with permission from AORN Connection. ■

Did you Know?

LifeLink does not procure tissue in morgues, autopsy suites or funeral homes and all of LifeLink's recovery partners are organ procurement organization based.

Due to contamination concerns, LifeLink does not allow the recovery of tissue after autopsy.

Educational Programs:

LifeLink Tissue Bank's Education Department holds accredited continuing education programs throughout the year in different states we serve. The goal of these programs is to educate the medical community about new developments in the tissue banking industry, including new federal regulations and JCAHO standards regarding the use of implantable tissues. If you are interested in learning more about tissue donation and transplantation and need CNE credits, these programs are a perfect opportunity for you. If you would like to schedule a program for your facility please contact your professional services representative.

Programs may also be custom designed to meet the needs of your medical staff. Please e-mail us with topic and location suggestions at ontactinfo@lifelinkfound.org. ■

Tissue Banking Program held in Tampa on June 10.

Scheduled Accredited Continuing Education Programs

Look for the September issue of The AORN Journal which will contain a Home Study Course about the Massive FDA Tissue Recall titled Quality Control in Tissue Banking—Ensuring the Safety of Allograft Tissues, based on an article authored by LifeLink Tissue Bank executives. Don't miss this opportunity to receive CNE credits from the comfort of your own home or office! For more details visit their website at www.aornjounal.org

October 14, 2006 - Safety without Compromise: The Secret to Successful Tissue Banking, Clarion Hotel, Ft. Myers, Florida. Registration is free and open for the first 120 registrants. You can register online at www.lifelinktb.org/symposium. Four(4) contact hours for this continuing nursing education activity have been applied for through the Association of periOperative Registered Nurses, Inc. AORN is accredited as an approver of continuing nursing education by the American Nurses Credentialing Center's Commission on Accreditation.

Other Scheduled Programs:

Dec 2, 2006 - Tallahassee, FL
February 10, 2007 - Mobile, AL
March 29, 2007 - Atlanta, GA
May 17, 2007 - Dallas, TX
June 9, 2007 - Tampa, FL

Program details will soon be posted on our website. Please check it periodically for details and to register.

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