



EDCO FORUM[®]

PRESENTING INNOVATIVE PRODUCTS & SERVICES TO HEALTHCARE PROFESSIONALS

VOLUME 11 NUMBER 53

OCTOBER 2004

REPRINT

How Confident are You in Your Tissue Bank?

When a hospital begins the process of choosing a provider of allograft tissue, there are many questions to ask and elements to consider. The following questions will outline some of the fundamental elements that should be considered when selecting a tissue bank.

Is the tissue bank registered with the FDA, accredited by the AATB and ISO certified?

Though not an accrediting agency, tissue banks are required to register with the Food & Drug Administration (FDA). Certification through the International Organization for Standardization (ISO) is not required, but assures that a quality system is in place and functioning. In addition, the facility should also confirm that the tissue bank is accredited by the American Association of Tissue Banks (AATB). While not required, this accreditation can offer the hospital a significantly higher level of confidence regarding the tissue bank's processes and procedures. LifeNet (Virginia Beach, VA), is registered with the FDA regulations and ISO 9001:2000 certified. The company has held AATB accreditation since its first inspection in 1986. This marks the longest running continuous accreditation in AATB history. Going above and beyond, LifeNet also strives to assist hospitals in following guidelines set forth by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) as they pertain to tissue banking.

Is the tissue bank licensed to do business in the state of your facility (if applicable)?

While most states require tissue banks to only register with the FDA, there are a few states that require license documentation in order to do business in that state, such as California, Florida, New York, and Maryland. LifeNet holds licenses in all of these states

Does your tissue bank screen all potential donors using strict donor criteria?

Both the FDA and the AATB provide guidelines for screening potential donors. Adhering to these guidelines is paramount in providing safer tissue for processing. LifeNet donors undergo a rigorous screening process that includes a medical history

and behavioral risk assessment that mirrors the requirements set forth by the AATB and the FDA.

Does your bank recover tissue aseptically?

Aseptic recovery provides additional measures to ensure the tissue processed by the tissue bank will be suitable for transplant use. LifeNet utilizes stringent aseptic recovery techniques and follows strict aseptic procedures during the processing and preserving of allograft tissue. Trained and skilled professionals process tissue from individual donors under strict aseptic conditions according to AATB standards in a controlled environment. Cultures are taken at each step to check for fungal or bacterial contamination.

Does your tissue bank perform serological tests that meet and exceed FDA and AATB standards?

It is important to understand the testing standards utilized by your hospital's allograft tissue supplier. The AATB and FDA require a battery of tests, including HIV1/2Ab (the primary marker for the Human Immunodeficiency Virus), HBsAg (testing for current Hepatitis B infection), and HCVAb (testing for the virus causing Hepatitis C) among others. LifeNet takes its testing protocols beyond those of the AATB and FDA (See Table) by also performing HIV NAT (a type of testing used for early detection of the HIV virus) and HBcAb (a test for antibodies to Hepatitis B). These tests assure that only tissue from suitable donors is made available for transplant. In addition, LifeNet's microbiology laboratory is CLIA certified.

Does the tissue bank utilize any cleaning methodology for its grafts to minimize the possibility of disease transmission?

In addition to strict donor screening, testing and aseptic recovery, many tissue banks use different methodologies in processing grafts for transplant use. LifeNet's patented Allowash[®] Technology is specially designed to facilitate the removal of cellular elements from musculoskeletal tissue while maintaining structural integrity. The Allowash process utilizes both mechanical and chemical methodologies to reduce the potential danger of disease transmission. This technology, along with a

Microbiologic and Serological Testing Performed by LifeNet	Required by LifeNet	Required by AATB	Required by FDA
Testing to identify bacteria and fungi	✓	✓	
HIV1/2Ab – detects antibody response to HIV 1 and 2 – the causative agents of AIDS	✓	✓	✓
HIV NAT – test used for early detection of HIV	✓		
HTLV1/2Ab – detects antibody response to human T-cell Lymphotropic viruses 1 and 2	✓	✓	
HBsAg – detects Hepatitis B virus	✓	✓	✓
HBcAb – detects antibody response to Hepatitis B virus	✓		
HCVAb – detects antibody response to Hepatitis C virus	✓	✓	✓
RPR or equivalent – detects potential exposure to the causative agent of syphilis	✓	✓	

rigorous donor screening process, has been designed and validated to increase the safety of LifeNet's allograft tissue.

Can the tissue bank assist with helping the hospital adhere to JCAHO regulations as they pertain to tissue banks?

When tissue is received in the hospital, JCAHO standards require a concurrent system to log the receipt, storage and ultimate disposition of the tissue regardless of its preservation method. This system should track tissue supplier, a description of the specific tissue, date of receipt, and patient information. When LifeNet enters into a relationship with a hospital, their trained staff will assist the facility in establishing such a tracking system. In addition to appropriate tracking systems, hospitals must also provide for the proper storage of tissue prior to use in the operating room. The requirements for storage are provided in advance, as well as on the package inserts for all forms of tissue distributed by LifeNet. Again, LifeNet's staff are available to advise and assist the hospital in establishing tissue tracking and storage systems.

In the event of an adverse reaction or recall situation, does the tissue bank have a procedure in place for tracking the tissue?

The tissue bank must monitor, track and report any adverse reactions resulting from the use of its tissue. If it were ever to become necessary to recall tissue for any reason, LifeNet has written procedures in place. LifeNet places a strong emphasis on this responsibility and maintains an exhaustive database of complaints/concerns expressed by clients. These data are reviewed on a continuous basis for trend analysis and early intervention.

Does your tissue bank provide patient education literature? Does your tissue bank provide training to hospital personnel such as in-service meetings or continuing education programs?

It is important that tissue banks provide literature for tissue recipients to better understand the process, as well as training opportunities for hospital personnel. LifeNet is a leader in the education and training of both the medical professionals who utilize allograft tissue and the patients who receive the transplants. Printed materi-

als detailing the entire donation and transplant cycle are provided for patients. In addition, LifeNet offers a wide array of training and in-service programs for professionals, ranging from reconstitution of human tissue to proper use and handling of tissue. Specific training programs can be designed and/or facilitated to meet the individual hospital staff's needs.

LifeNet's Web site, www.accesslifenet.org, also contains a wealth of information regarding donor screening, testing, and processing as well as pictures and descriptions of grafts for clinical use.

Is someone from the tissue bank available when you need assistance?

As with any relationship, it is important to know that your needs are being met. At LifeNet, orders may be placed 24 hours per day, 365 days per year via either direct telephone ordering, fax ordering systems, or in the case of emergencies, on-call order processing. LifeNet's Customer Service Representatives are available weekdays from 7:00 a.m. until 7:00 p.m. Eastern Time to assist hospitals with placing orders and to provide information on product availability. When selecting a tissue bank to supply your facility's needs, the primary focus must be on providing high quality, safe allograft tissue to meet your patient's needs. At LifeNet, these are the company's goals as well. Establishing a partnership with LifeNet to supply your tissue needs will allow you to proceed with confidence.

Allowash is a Registered trademark of LifeNet



For more information call LifeNet at 1-888-847-7831, or visit the company Web site at www.accesslifenet.org.