

FREQUENTLY ASKED QUESTIONS

What is Zika virus disease?

Zika virus disease (Zika) is a disease caused by the Zika virus, which is spread to people primarily through the bite of an infected *Aedes* species mosquito. The most common symptoms of Zika are fever, rash, joint pain, and conjunctivitis (red eyes). The illness is usually mild with symptoms lasting for several days to a week after being bitten by an infected mosquito. People usually don't get sick enough to go to the hospital, and they very rarely die of Zika. For this reason, many people might not realize they have been infected.*

Has tissue donor screening changed in light of Zika virus?

LifeNet Health tissue donor screening has, for many years, incorporated review of all available information, and our Criteria Policy precludes acceptance of a donor with any systemic viral disease.

LifeNet Health has added to the existing screening several additional questions specifically aimed at evaluating risk for Zika virus infection. The criteria are in accordance with Food and Drug Administration (FDA) Guidance for Industry "Donor Screening Recommendations to Reduce the Risk of Transmission of Zika Virus by Human Cells, Tissues, and Cellular and Tissue-Based Products," and the questions are recommended by the American Association of Tissue Banks (AATB).

Any person who has been diagnosed with Zika virus within the past six months (prior to death) will be deferred. People who have visited an area where Zika is known to be active within the past six months (prior to death) will be carefully evaluated. Any recent symptoms such as joint pain and/or conjunctivitis will also be carefully evaluated by the medical director in conjunction with other known facts regarding the individual's medical history, gathered from multiple sources.

How does LifeNet Health's Allowash XG® process reduce the risk of Zika virus transmission?

All donors accepted for tissue recovery are subjected to a rigorous screening and testing process that exceeds FDA and AATB requirements. LifeNet Health utilizes the Donor Risk Assessment Interview, which is comprised of more than 30 categories of questions designed to uncover criteria in any potential donor that would preclude the donation process. When administered by a properly trained medical professional, the likelihood of transmission of viral, bacterial, fungal, prion, and other pathogens becomes remote.

LifeNet Health's Allowash XG technology, utilized for most types of grafts we prepare, encompasses a comprehensive, patented and validated process during which greater than 99% of bone marrow and blood elements are removed from the internal matrix. This process, along with subsequent chemical treatment and sterilization steps, has been shown to render tissue sterile to a Sterility Assurance Level (SAL) of 10^{-6} , the same standard as required for medical devices. It also inactivates all viruses (enveloped and non-enveloped), without compromising the biomechanical or biochemical properties of the tissue as needed for its intended surgical application.

Since 1995, LifeNet Health has distributed more than 5 million bio-implants processed using Allowash technology, with no disease transmission. LifeNet Health remains strongly committed to ensuring the safety of grafts we provide for patient use.

LifeNet Health can be contacted at any time at 1-888-847-7831 or (757)-464-4761 should questions arise regarding screening of donors for potential viral and bacterial diseases.

*<http://www.cdc.gov/zika/about>