

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 MATRACELL® process reduce the risk of Zika virus transmission in DermACELL®?

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 has more than 30 years of experience in tissue regeneration including expertise in advanced decellularization and sterilization techniques for biologic matrices. After being rendered acellular via Matracell, a patented and proprietary technology that removes at least 97% of donor DNA, Dermacell undergoes a terminal sterilization step to ensure a SAL of 10^{-6} . Low-dose gamma irradiation performed at ultra-low temperatures is used to reach surgical device-grade sterility, which lowers the probability of an active organism in the graft to 1 in 1,000,000 – lower than 10^{-3} or, a 1 in a 1,000 chance. All of this is achieved without compromising the desired biomechanical structures or biochemical properties (i.e. cross-linking) of the biologic matrix.

Matracell was first introduced in 2009 as a processing technology for neonatal cardiac patches and has since been used in thousands of dental, craniomaxillofacial, sports medicine, advanced wound management, and plastic reconstruction procedures with no disease transmission.

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>