

## What is syphilis?

Syphilis is a sexually transmitted disease caused by the bacterium *Treponema pallidum*. It is passed from person to person through direct contact with a syphilis sore.

## Is transmission of syphilis through an allograft possible?

Although there is no evidence that syphilis has ever been transmitted by banked tissue transplantation, syphilis infection is considered a marker for high-risk behavior, and is addressed in LifeNet Health's current medical and behavioral examination.

## Does LifeNet Health's screening, physical exam and testing for non-viral pathogens include syphilis?

For **screening** LifeNet Health utilizes the Donor Risk Assessment Interview, which is comprised of more than 30 categories of questions. These questions include an extensive sexual history that is designed to uncover situations in which a potential donor may be found not to be eligible for 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. All donors accepted for tissue recovery are subjected to a rigorous screening and testing process that exceeds the requirements set forth by the U.S. Food and Drug Administration (FDA) and the American Association of Tissue Banks (AATB).

Prior to tissue recovery a complete **physical examination** of the donor documents any and all suspicious lesions. These include lesions that may be indicative of a sexually transmitted disease. A LifeNet Health Medical Director and Recovery Technical Director are on-call to evaluate the findings and make a determination of eligibility to continue with the donation process or not.

**Testing** for potential exposure of each tissue donor to the causative agent of syphilis is required by the American Association of Tissue Banks (AATB) and the U.S. Food and Drug Administration (FDA). **Testing for syphilis is performed on all LifeNet Health tissue donors in FDA registered and CLIA certified laboratories.** A positive test for syphilis prohibits distribution of any donor grafts for clinical use.

## How does LifeNet Health's Allowash XG<sup>®</sup> process reduce the potential risk of syphilis transmission?

LifeNet Health's Allowash XG<sup>®</sup> technology encompasses a comprehensive patented and validated process during which greater than 99% of bone marrow and blood elements are removed from the internal bone 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  $10^{-6}$ . It also inactivates enveloped and non-enveloped viruses, without compromising the biomechanical or biochemical properties of the tissue as needed for its intended surgical application.

Since 1995, millions of bio-implants processed using Allowash Technology have been distributed by LifeNet Health, with no disease transmission.