

What is Cytomegalovirus (CMV)?

Cytomegalovirus (CMV) is a common virus that infects most individuals at some time during their lifetime, but rarely causes any obvious symptoms. The virus is widespread, and 60 to 90 percent of adults in the general population have been exposed to CMV.

The virus is not highly communicable, and rapidly becomes inactive once outside the human body. It can be spread from person to person by direct contact. CMV is a member of the herpes virus family. Other members of this family cause such diseases as chickenpox, infectious mononucleosis, fever blisters (herpes I), and genital herpes (herpes II). All the members of the herpes virus family have the ability to remain latent, that is, to be present but inactive, in the body for long periods of time. To date, an effective vaccine has not been developed.

Is transmission of CMV through an allograft possible?

Complications due to CMV infection are not a concern in the transplantation of tissue allografts, because tissue recipients are generally not immunosuppressed. Transmission of the Cytomegalovirus to an immunosuppressed individual during organ transplantation is a risk, particularly for recipients who were not previously infected and receive an organ from a donor who carried the virus. Nevertheless, the high prevalence of CMV in the population makes it impractical to rule out all CMV infected organ donors, and new treatment strategies have been developed to decrease the rate of complications in organ recipients.

Does LifeNet Health ensure the safety of its allografts?

LifeNet Health uses a safety strategy that involves screening, testing and medical records review for each donor. Screening for LifeNet Health utilizes the Donor Risk Assessment Interview (DRAI), which is comprised of more than 30 categories of questions designed to uncover any risk of the donor having a disease that could be transmitted thru transplantation. Testing of blood and all recovered tissues for infectious agents meets or exceeds the requirements set forth by the U.S. Food and Drug Administration (FDA) and the American Association of Tissue Banks (AATB). Finally a licensed physician must review all relevant medical records and test results before making a final determination as to whether the grafts are safe to release for transplantation or not. This safety strategy minimizes the likelihood of transmission by any viral, bacterial, fungal or parasitic pathogen including prion disease.

How does LifeNet Health minimize the risk of CMV transmission?

LifeNet Health's Allowash XG[®] 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 have been processed and distributed using Allowash XG[®] Technology with no disease transmission.