



## Dedicated to Safety

*LifeNet Health's Commitment to Patient Health*

*There is no margin for error when it comes to patient safety. That's why LifeNet Health developed a comprehensive protocol — from screening and recovery to graft preparation and clearance for implantation — designed to eliminate to the risk of disease transmission, including COVID-19, in allograft tissue. Our industry-leading processes and technologies have stood the test of time, proving effective even as new diseases emerge. This commitment is part of how we honor the selfless gift of donation, and it's why clinicians and patients have trusted the safety of LifeNet Health allografts for nearly 40 years.*

### **Protecting Patients from Recovery to Implantation**

LifeNet Health has been providing allograft tissues since the 1980s, establishing an unparalleled record of safety while revolutionizing allograft preparation. Since 1995, we have distributed more than seven million implants cleaned with our patented sterilization technology, without a single case of disease transmission.

Before tissue preparation is even initiated, we go beyond industry standards with rigorous donor screening, stringent tissue-recovery protocols, and testing of all recovered tissue for bacteria and fungi. Additionally, state-of-the-art nucleic acid testing is performed to detect the presence of specific viruses. Together, these steps minimize the chance that infected tissue would even be processed. As further assurance, a physician medical director assesses all medical and testing records to affirm that each donor's gifts are safe for transplant.

### **Virtually Eliminating the Threat of Disease Transmission**

LifeNet Health applies a range of processing techniques that are customized to each tissue type to mitigate the risk of viral and bacterial transmission. This includes Allowash XG<sup>®</sup>, a six-step process that kills or removes microorganisms such as bacteria to render tissue sterile to the same standard as medical devices. This process also has been shown to inactivate and remove viruses, and our Matracell<sup>®</sup> decellularization technology has been demonstrated to degrade a virus's genetic material and dissolve its protective envelope, allowing the virus's remnant fragments to be removed from tissue along with the donor's cells. In fact, studies have shown that our processes are robust enough to inactivate DNA, RNA, enveloped and non-enveloped viruses, assurance that they can effectively nullify any type of virus.

### **Protecting Against COVID-19**

Every donor whose gifts are processed by LifeNet Health is screened for potential risks to patient safety, including viral and bacterial infections, and there have been no cases of respiratory viruses being transmitted through human cells or tissues. However, in light of COVID-19, our screening protocols have been enhanced to detect the presence of SARS-CoV-2 — the virus that causes COVID-19 — and to identify even the potential for a donor to carry the virus based on their medical history or social activities such as travel.

Terminal sterilization utilizing gamma irradiation, which is performed on the majority of allografts provided by LifeNet Health, has been demonstrated to inactivate viruses like SARS-CoV-2. For donors of special tissue types that cannot be sterilized, such as most cardiovascular tissue and other grafts with viable cells, we conduct testing specifically for SARS-CoV-2. Our physician medical directors use these test results alongside the medical and social history to determine the safety of each individual donor's gifts. Gifts from any donor who tests positive for the virus or who is suspected of having it are not able to be transplanted.