

An Unmatched Standard

in Donor Screening, Selection & Safety

We care about quality, and our safety record is unmatched. Learn more about how (and why) our screening criteria and standards exceed those required by the American Association of Tissue Banks (AATB) and federal regulations.



- Burn & Wound
- Cardiac
- Craniomaxillofacial
- Dental
- General Orthopedics
- Spine
- Sports Medicine
- Vascular

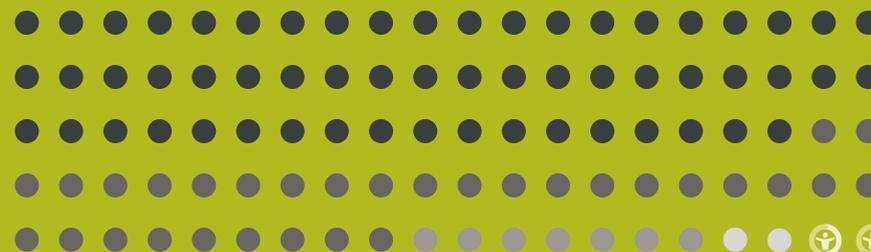
LifeNet Health Products

A PROVEN SAFETY RECORD

LifeNet Health's guidelines for donor suitability are based on FDA requirements and AATB guidelines and in some cases are even more stringent than those required. When combined with LifeNet Health's proprietary and patented Allowash XG® sterilization technology, aseptic recovery techniques, and donor screening process, these policies help to assure that only safe and effective tissue is released for transplantation.

ONLY 2%
are accepted
by LifeNet Health
of total donors screened for transplantation.

- 58% Age
- 31% Medical History and/or High Risk Behavior
- 7% Lack of Consent
- 2% Other + Post Recovery Rejections
- ⊕ 2% Accepted Donors



ABOUT LIFENET HEALTH

LifeNet Health helps save lives and restore health for thousands of patients each year. We are the world's most trusted provider of transplant solutions, from organ procurement to new innovations in bio-implant technologies and cellular therapies—a leader in the field of regenerative medicine, while always honoring the donors and healthcare professionals that allow the healing process.

LifeNet Health is a leader in the engineering and processing of dental, cardiovascular, spinal, and orthopedic bio-implants and distributes more than 300,000 bio-implants every year to restore health to patients around the world.



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Donor Criteria



We take donor quality control very seriously. The table at right shows all of the screening criteria we are obligated to follow, but more importantly, the additional criteria that we choose to screen for as we lead the way in this field.

“Throughout our process, LifeNet Health leaves no room for error.”

ILLEGAL DRUGS

On top of a life-time deferral for Intravenous Drug Abuse, LifeNet Health rejects non-IVDA drugs such as heroin, crack, cocaine, methamphetamine, and ecstasy within 12 months of death. Also, all known gang members are deferred due to their high risk association with drugs.

CANCER

All LifeNet Health donors must have finished treatment and been cancer free for at least three years prior to death and have had routine follow-up exams with their primary care physician. Exceptions include melanoma, breast cancer and prostate cancer, which are deferred for at least five years. LifeNet Health follows AATB regulations for primary brain cancer.

INFECTION

LifeNet Health does not accept any donors with evidence of active

systemic infection (sepsis), bacteremia, viremia or parasitemia, or in which infection was the cause of death. If infection is a contributing factor to death, then it is a case by case determination by the LifeNet Health Medical Director. Tuberculosis: If a Purified Protein Derivative (PPD) tuberculosis test is positive, a negative chest x-ray is required for acceptance.

HIGH RISK BEHAVIOR

We follow Food and Drug Administration (FDA) and AATB regulations regarding incarceration, although anyone receiving a tattoo while incarcerated is a lifetime deferral. Donor historians (those who provide information regarding donors) are evaluated on the likelihood of knowledge of sexual activity and drug use, to ensure that LifeNet Health receives the most accurate information on potential donors. We defer potential

donors with tattoos or piercings received within four months prior to death.

AGE

All tissue is evaluated to meet age limit standards. Constraints are placed on specific allograft bio-implant types that would require optimal properties.

OSTEOPOROSIS

LifeNet Health accepts donors with osteoporosis. Though the bone is not suitable for weight-bearing allograft bio-implants, it provides excellent properties and it can be used in the production of dental products. Numerous donors with osteoporosis take medications, such as bisphosphonate, to strengthen bones. A recent AATB study demonstrates that residual bisphosphonates are removed from the tissue through the decalcification processing of bones. Allograft bio-implants from donors using bisphosphonates

perform equally as well as bone from donors not taking bisphosphonates.¹

STEROIDS

Chronic steroid use is sometimes associated with active infection; therefore, LifeNet Health evaluates all donors for active infection. For hospitalized patients, LifeNet Health also seeks the physician's opinion on systemic infection of the patient.

SKIN BIOPSY

A biopsy report identifying occult malignancy or a possible relevant infection eliminates the potential risk for transmission of disease. A 2010 study published by the AATB found that out of 561 biopsies revealed no effect on medical suitability in 98.4% of the cases.²

END STAGE RENAL DISEASE

End stage renal disease donors are acceptable if the underlying disease is acceptable and there

is no evidence of cancer or pyelonephritis (renal infection). Several donors with end stage renal disease demonstrate bone disease (renal osteodystrophy). All recovered bones are evaluated for density by a bone scanner. All must meet minimum density standards in order to be processed and distributed. Donors with end stage renal disease may also be on hemo-dialysis or peritoneal dialysis. Since they are at risk for infections such as Hepatitis B, LifeNet Health investigates any serology testing that might have been done prior to death.

1. Hunter S, Orheim R, Sazon M, Newman H, Woll J, Bergavin M. Demineralization Removes Residual Alendronate in Allograft Bone Procured from Donors with a History of Bisphosphonate use. *Journal of Periodontology*. 23 August 2010: 1-8.

2. Singh S, Blevins M, Wakeman M, Bergevin M. The Utility of Recovery Biopsies in Determining Donor Eligibility and Suitability. Presented at: American Association of Tissue Banks Annual Meeting, National Harbor, MD; September 2010.

Screening Criteria

Screening Criteria	LifeNet Health	AATB	FDA
Encephalitis (clinically active)	×	•	•
Gonorrhea (within the past year)	×	•	•
Hepatitis B	×	•	•
Hepatitis C	×	•	•
HIV 1/2	×	•	•
Malaria	×	•	•
Meningitis (clinically active)	×	•	•
Sepsis	×	•	•
Syphilis	×	•	•
Transmission spongiform encephalopathy (TSE)	×	•	•
Vaccinia	×	•	•
West Nile Virus (WNV, 4 month exclusion from the time of onset)	×	•	•
Clinically significant metabolic bone disease	×	•	•
Leprosy (Hansen's disease)	×	•	•
Polyarteritis nodosa	×	•	•
Rabies	×	•	•
Rheumatoid arthritis (musculoskeletal deferral)	×	•	•
Sarcoidosis	×	•	•
Systemic lupus erythematosus	×	•	•
Systemic mycosis	×	•	•
Tuberculosis (clinically active or treated in the past 5 years)	×	•	•
Ankylosing spondylitis	×	•	•
Autoimmune vasculitis if type is not known	×	•	•
Cancer	×	•	•
Chagas disease	×	•	•
Epstein Barr virus (clinically active)	×	•	•
Clostridium difficile infection (defer if occurred during present hospitalization)	×	•	•
Cold agglutinin disease	×	•	•
Endocarditis (clinically active)	×	•	•
Guillain-Barre syndrome (clinically active)	×	•	•
Herpes (any evidence of active herpes infection is a deferral)	×	•	•
Illicit drug use (see Illegal Drugs)	×	•	•
Mixed connective tissue disease	×	•	•
Multiple sclerosis	×	•	•
Peritonitis (clinically active)	×	•	•
Poliomyelitis (clinically active or untreated)	×	•	•
Pyelonephritis (clinically active)	×	•	•
Reactive arthritis (must be asymptomatic for 6 months for musculoskeletal deferral)	×	•	•
Rheumatic fever (defer all tissues if clinically active, defer heart valves for any history)	×	•	•
Wegener's granulomatosis	×	•	•