

LifeNet Health Corporate Profile

Cardiac & Vascular Surgery

Quality, Innovation and Safety You Can Trust



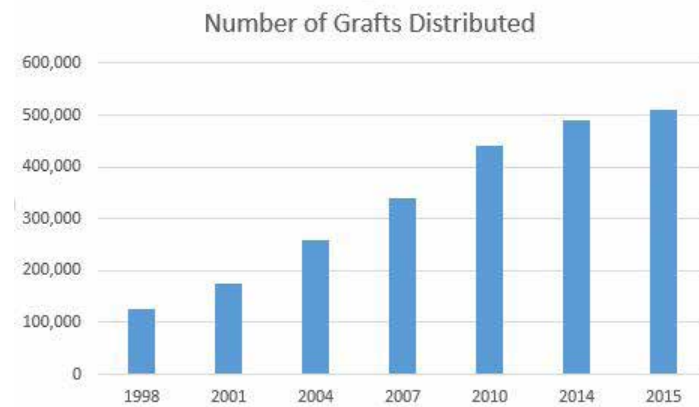
About LifeNet Health

WORLD'S

MOST TRUSTED

LifeNet Health is a **non-profit organization** whose mission is **Saving Lives. Restoring Health. Giving Hope.** We are the **world's most trusted provider** of transplant solutions, from organ procurement to innovative bio-implant technologies and cellular therapies. Last year, we delivered nearly **500,000** allograft bio-implants, and have distributed tens of thousands of cardiac and vascular implants since 1986.

With LifeNet Health as your primary bio-implant supplier, you are investing in the best possible partner to ensure the well-being of your patients. Our record of safety, quality, innovation, and experience enables us to produce the highest quality bio-implants. The service and accessibility that we provide to clinicians and hospitals is unmatched in the industry.



Surgical Applications

- Cardiac
- Sports Medicine
- Plastic and Reconstructive
- Vascular
- Spine
- Wound Management
- Orthopaedics
- Craniomaxillofacial



Corporate headquarters

Our **Donor Family Services** program is an expression of that purpose. The program is staffed by bereavement specialists dedicated to honoring donors and their families through ongoing support that promotes peace and healing. Our **Thanks 2 You** program enables implant recipients to contact their tissue donor family to thank them for their loved one's gift. In addition to individual family communication and online resources, LifeNet Health hosts several events and workshops throughout the year to aid in the healing process and provide a meaningful way for families to celebrate the gift of life.



A donor's daughter listening to her father's heartbeat, now in a grateful recipient.



“Please know I will always cherish the gift and remember your loved one. Because of this gift, my three month old baby girl was able to have her heart repaired.”

—Brittany & daughter Krisalyn

QUALITY

LifeNet Health cardiovascular bio-implants are designed and produced to ensure the highest possible quality – allowing you to focus on the procedure and your patients to focus on healing.

At both our Virginia Beach, Virginia and Renton, Washington facilities, we consistently apply systems, controls and processes that produce the highest quality bio-implants on the market.

Controlled Environment

- Our state-of-the-art clean room facilities are engineered to eliminate the possibility of cross-contamination.
- We adhere to strict hygiene and sterile techniques.
- We meet or exceed all regulatory requirements.



Focused Product Development and Quality Control

- We ensure all products meet specific surgical needs and preferences.
- All bio-implants undergo a 100% visual inspection before release.
- Microbiologic testing is performed on tissue to ensure it is free from contamination.
- We require a multidisciplinary review on each bio-implant before its release.

Validated Storage and Shipping Methods

- We have precise requirements for storage, packaging and shipping.
- All products include detailed instructions for safe storage.

Registrations and Accreditations

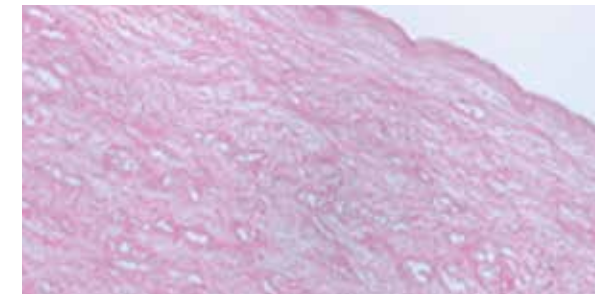
- American Association of Tissue Banks (AATB) accreditation
- Food and Drug Administration (FDA) registration
- United Network for Organ Sharing (UNOS) member
- Licensed in all required states
- International Organization for Standardization (ISO) 13485: 2003 certified
- CLIA certified
- Association of Organ Procurement Organizations (AOPO)

INNOVATION

Our **Institute of Regenerative Medicine (IRM)** is equipped and staffed to develop innovative allograft tissue-based products designed with surgeons and their patients in mind. New life-saving technologies are being developed with leading surgeons and scientists around the world from our state-of-the-art innovation center.

Matracell® is one of these proprietary technologies. It is a validated, patented process unique to LifeNet Health that renders tissue acellular, without compromising the native scaffold or desired biohospitable properties of the graft.

Donor tissue decellularized using our patented Matracell technology.



Process Validation

Implant Preservation

Decellular Technology

Over 50 Patents

LifeNet Health cardiac and vascular grafts are implanted in all of the top ten pediatric cardiology and heart surgery hospitals nationwide.

–US News and World Report (2014-2015)

Institute of Regenerative Medicine



LEADERS IN SAFETY

Our safety and regulatory compliance record is unmatched. Our highly refined processes, quality control systems and proprietary disinfection protocols **ensure the highest level of safety, reduced risk, and better outcomes.** This includes reducing the probability of post-implant infection for your patients and unexpected costs to your institution.

Our CLIA-certified laboratory performs required FDA and AATB tests. We adhere to the highest safety standards at every step of the donation process, including:

Pre-Process Assessment Testing

Medical Suitability Assessment	Mitigates the possible transmission of viral, bacterial, fungal and prion pathogens
Serologic Testing	Tests donor blood samples for evidence of infectious agents, including human immunodeficiency virus (HIV), hepatitis and syphilis
Microbiologic Testing	Pre disinfection microbial samples tested to detect and indentify a wide array of micro organisms

Post-Process Testing

Microbiologic Testing	Tissue is deemed suitable for transplantation only if ALL post-processing microbiologic testing is negative
Quality Assurance Review	Ensures all required donor documentation and test results are documented, complete and meets acceptability requirements



Going Above and Beyond on Safety: Industry-Leading Screening and Recovery Processes

At LifeNet Health, we use every tool available to ensure that we meet or exceed FDA Regulations and AATB Standards. We are leaders in developing new tests to ensure the safest implants for your patients and the best possible outcomes. The following are industry-leading safety tests that have been implemented at LifeNet Health.

National Recovery Biopsy Program*

Our industry-leading program screens donated tissue for unknown infections and cancer.

Incidence-Window Period Method**

We have led the way in adopting the Incidence-Window Period Method to identify donors who are at risk of having a recent viral infection that may not be detected by routine serology or NAT testing.

Medical Director's Advisory Group

Our independently formed cross-departmental team meets quarterly to review and improve donor suitability criteria.

Antibiotic Protocol Enhancement

We continually assess our antibiotic protocol and revise it as needed.

Pathologic Examination of Hearts

More than 50 percent of our recovered hearts are sent to an independent pathology laboratory for further examination.

*The Utility of Recovery Biopsies in Determining Donor Suitability, Singh, S., et.al. Cell and Tissue Banking, Vol. 13, Issue 4 (December), 2012: pp565-567.

**The Incidence/Window Period Model and its Use to Assess the Risk of Transfusion-Transmitted Human Immunodeficiency Virus and Hepatitis C Infection. Kleinman, S., et.al. Transfusion Medicine Reviews, Vol. 11, No 3 (July), 1997: pp155-172.





LifeNet Health employees on National Donate Life® Blue & Green Day

Thank you for putting your trust in us.

At LifeNet Health, we are driven by innovation and grounded by our mission to save lives, restore health and give hope. Since our formation in 1982, LifeNet Health has pioneered technologies designed to ensure safety in allograft screening, recovery, cleaning, and delivery. Our innovative processes have been benchmarks for the industry. We are the largest non-profit, full-service organ and tissue grafts provider in the United States. We are also 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, committed to honoring the donors and healthcare professionals that make the healing process possible.



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