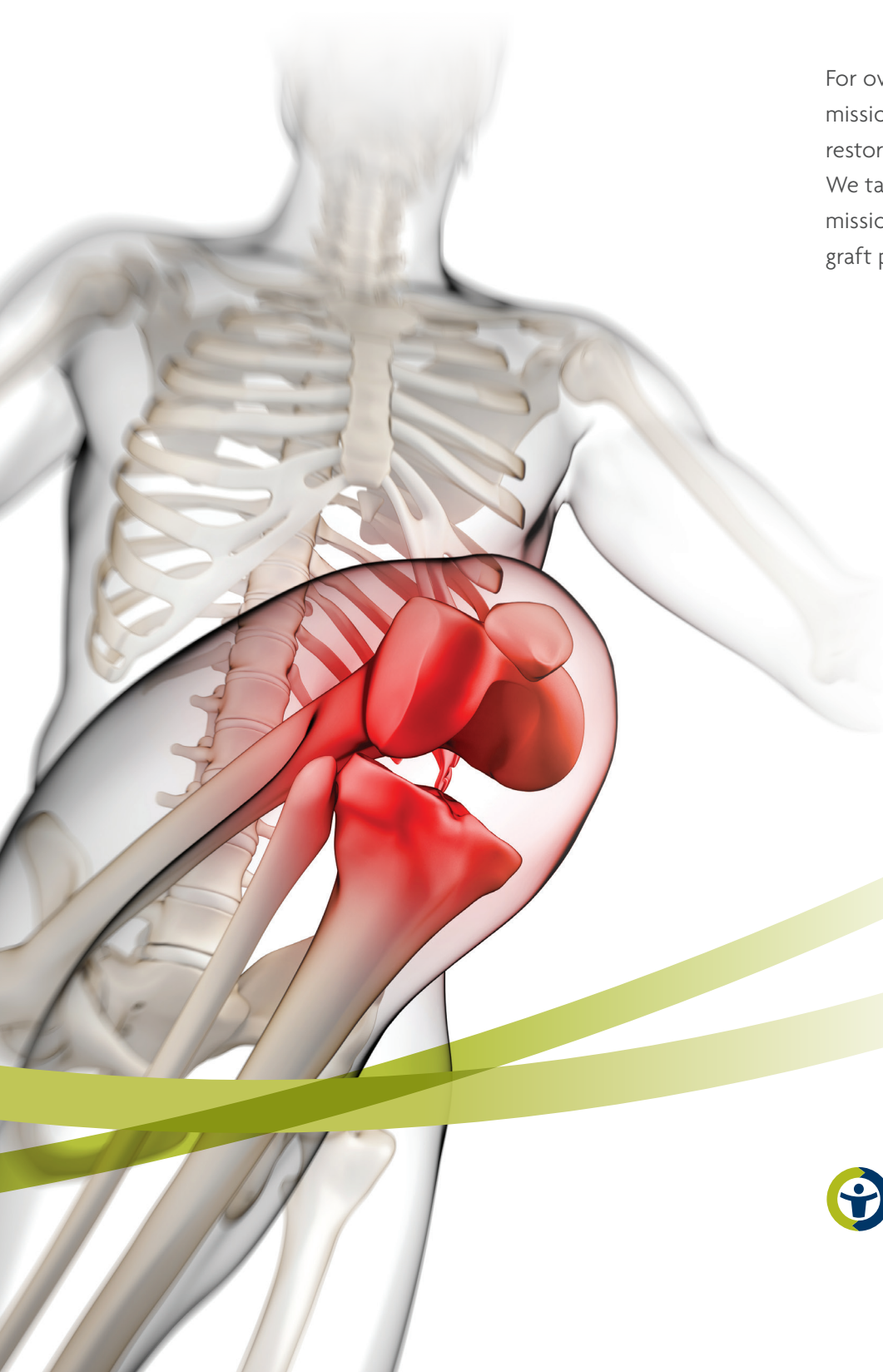


Fresh Osteochondral Grafts

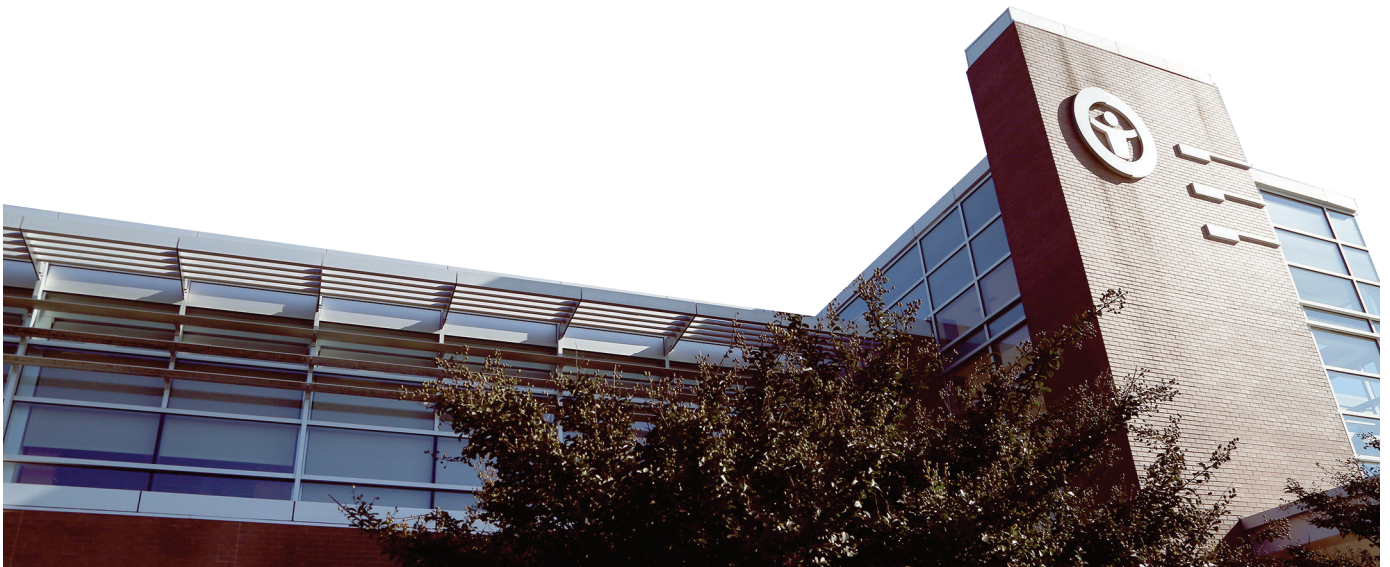
Reference Manual

For over 35 years, LifeNet Health's mission has been saving lives, restoring health, and giving hope. We take another step in that mission with our Osteochondral graft product offerings.



About LifeNet Health

Saving Lives, Restoring Health, and Giving Hope is Our Business.



Safety

Our record speaks for itself. By using a network of qualified and trained recovery partners, one of the most stringent screening and recovery protocols, patented tissue cleaning and sterilization processes, and a highly controlled processing environment, we counter the risks of disease transmission at every step.

Quality

LifeNet Health's controlled tissue grafts processing environment is designed to ensure tissue allograft bio-implant quality and safety. Through the consistent application of quality systems, quality control, and design control processes, LifeNet Health tissue graft are designed and manufactured to ensure highest possible quality. Year after year, this dedication to quality is validated internally and vetted by your peers as well as government and industry regulators. LifeNet Health holds the longest running current accreditation by the American Association of Tissue Banks (AATB). Our certifications and memberships include AATB, CLIA (Clinical Laboratory Improvement Amendments), FDA registration, ISO 13485 (Standard for medical devices) and UNOS (United Network of Organ Sharing).

Innovation

In keeping with the mission of saving lives, restoring health and giving hope, LifeNet Health's focus on research and development has resulted in many U.S. issued patents. As part of its commitment to advancing tissue grafts and regenerative medicine, LifeNet Health has developed key innovations such as proprietary and patented cleaning, demineralization, and composite allograft technologies. A leader in its field, LifeNet Health continually works on innovations to advance tissue grafts safety and efficacy

Service

Customer service and on-call support is provided 24 hours a day. Technical Implant Specialists are also available during select business hours. With LifeNet Health as your primary bio-implant supplier, you are investing in the best possible value to ensure the well-being of your patients and the reputation of your hospital.



Fresh Osteochondral Grafts

Our Fresh Osteochondral Graft Program is designed to offer a variety of allograft choices for joint reconstruction procedures to repair articular cartilage and subchondral bone defects. These osteochondral bio-implants allow orthopedic surgeons to transplant mature hyaline cartilage with viable chondrocytes and subchondral bone into recipients' damaged articular surfaces.

LifeNet Health ensures the quality and safety of our Fresh Osteochondral Grafts through stringent donor screening, cleansing, processing, and preservation procedures designed to produce safe and high quality allograft bio-implants. We have been an industry leader for over 35 years; developing innovative technologies and providing bio-implants that are proven in more applications than any other.

Unlike most frozen grafts, fresh grafts are customized and require advanced planning due to their short expiration period. Our facility in Renton, Washington, has been processing and distributing Fresh Osteochondral Allograft bio-implants for more than ten years. We are confident in our ability to meet the demands of those physicians seeking allografts of the highest quality for their patients.

Fresh Osteochondral Bio-Implants from LifeNet Health are:

- Aseptically processed from carefully selected donors.
- Cleared via serology and microbial testing through a CLIA Certified Laboratory.
- Provided with detailed dissection sheets and photographs.
- Preserved in a serum-free nutrient medium with antibiotics to maintain chondrocyte viability.
- Placed in an advanced shipper system that suspends the graft, designed to reduce the peak impact loads during shipment.¹
- Radiographically sized and matched using the recipient's x-rays or MRI films. Our electronic File Transfer System allows quick uploading of files without the need to mail in a CDROM or forms.
- Stored at refrigerated temperatures 1°C to 10°C, NOT Frozen.

¹ Data on file at LifeNet Health.

“We offer you knowledgeable service professionals who are committed to providing technical expertise and ongoing, responsive support. We’ll also partner with you to help you stay on schedule. **It’s all part of the LifeNet Health experience.**”



Fresh Osteochondral Grafts

Order Code	Product Description
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Femoral



FHL80 Femoral Head (Left)

FHR80 Femoral Head (Right)

FCA80 Femoral Condyle Hemi (Left Lateral)

FCB80 Femoral Condyle Hemi (Left Medial)

FCC80 Femoral Condyle Hemi (Right Medial)

FCD80 Femoral Condyle Hemi (Right Lateral)

PCA80 Partial Condyle (Left Lateral)

PCB80 Partial Condyle (Left Medial)

PCC80 Partial Condyle (Right Medial)

PCD80 Partial Condyle (Right Lateral)

FCL80 Femoral Condyle Whole (Left)

FCR80 Femoral Condyle Whole (Right)

FTR80 Femoral Trochlea (Right)

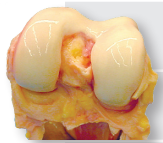
FTL80 Femoral Trochlea (Left)

FTD80 Bi-Compartment (Right Lateral & Trochlea)

FTC80 Bi-Compartment (Right Medial & Trochlea)

FTA80 Bi-Compartment (Left Lateral & Trochlea)

FTB80 Bi-Compartment (Left Medial & Trochlea)



Order Code	Product Description
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Ankle



ATL80 Ankle Talus (Left)

ATR80 Ankle Talus (Right)

Patellar



PAL80 Patella bone with Attachments (Left)

PAR80 Patella bone with Attachments (Right)

Tibial



TDL80 Tibia Distal (Left)

TDR80 Tibia Distal (Right)

TFL80 Tibial Plateau with Meniscus (Left)

TFR80 Tibial Plateau with Meniscus (Right)

Humeral



HHL80 Humeral Head (Left)

HHR80 Humeral Head (Right)

Plugs



RFPI0 10 mm Plug

RFPI6 16 mm Plug

Ordering Fresh Osteochondral Grafts

Special Ordering and processing procedures are as follow:

1. The surgeon, hospital or sales representative contacts their local LifeNet Health representative. The surgeon or hospital receives, completes, and returns the Patient Consent Form (if applicable) and the Fresh Osteochondral Graft Order Form along with MRI or Lateral and A/P X-ray films to LifeNet Health. X-rays must have magnification marker, please see below for more information. Films will be returned upon request after they have been measured for the size specifications needed.

Films and order form can be electronically uploaded by contacting freshorders@lifenethealth.org

Films and forms can be mailed to:

LifeNet Health

Attn: Technical Service Representative

501 SW 39th Street, Renton, WA 98057

2. When a suitable match is found; the surgeon, hospital, and/or sales representatives will be contacted.
3. The surgeon will be provided a dissection description for review, along with any available photographs of the graft and donor information for evaluation and final approval. This form should be signed and returned within 48 hours, or the graft can potentially be offered elsewhere.

4. Once the form is returned, an estimated surgery window will be provided. When all of the donor and processing evaluations are complete and acceptable; the surgeon, hospital, and sales representative will be notified to confirm the surgery date and shipping instructions.

Key points:

- Utilize the LifeNet Health Fresh Osteochondral Graft Order form.
- Have a PO or equivalent ready, when the graft is available. We cannot ship without a PO.
- Do not schedule the surgery until the graft availability is confirmed.
- If applicable, the hospital should get insurance approval before placing an order, especially in the US.
- **If an order is filled elsewhere or no longer needed, please contact us so that we can offer the allograft to another surgeon and honor our mission: Saving Lives, restoring health and giving hope.**
- **All Fresh osteochondral bio-implants are shipped on wet ice in a validated shipper.**

Matching Fresh Osteochondral Grafts

Matching Fresh Osteochondral Grafts to the recipient is key to the success of the procedure. We collect patient information such as height, weight, age and gender; as well as measurements from their X-ray or MRI films to find the best match possible. We will offer on a graft that comes within +/- 3 mm of the measurements taken from the patient's films.

When using pre-operative X-ray films for graft-sizing measurements, a magnification marker must be used in the X-ray. A marker of known size should be utilized in order to properly determine magnification of the X-ray in order to accurately determine the size of the graft the recipient will need. During the X-ray, the magnification marker should be

placed at the level of the bone being examined. For example, use a rubber band to hold the magnification marker along-side the patient's joint versus setting the marker on the table to avoid a skewed reading that will result in incorrect sizing. For Anterior/Posterior (A/P) views, place the marker medially or laterally. For Lateral views, place the marker anteriorly.

LifeNet Health has access to proper magnification markers, and can arrange to have one sent to your facility. Contact the Technical Implant Specialist at freshorders@lifenethealth.org with any questions or to have a magnification marker shipped to you.

Ordering Fresh Osteochondral Allografts

Health care facilities, approved distributors and authorized tissue dispensing intermediaries are permitted to order allograft bio-implants from LifeNet Health. Only licensed clinical professionals may actually transplant tissue.

Orders may be placed by e-mail, phone and/or fax or e-mail at freshorders@lifenethealth.org. A valid purchase order or equivalent number must be provided for all orders. All phone calls to LifeNet Health's Client Services department are recorded for quality control purposes.

Title to LifeNet Health products passes from LifeNet Health to the customer once the shipment leaves our facility.

Delivery

All Fresh Osteochondral Bio-Implants are shipped on wet ice in a validated shipper. Any Fresh grafts shipped by special courier may incur additional charges.

Early AM Delivery (US only)

LifeNet Health requires a \$35.00 surcharge for any Early AM (before 10:30 am) shipment. Special delivery requests utilizes courier will incur additional charges.

Storage Requirements

Grafts must be stored at 1°C to 10°C, in a refrigerator.

DO NOT FREEZE OR STORE BELOW 1°C.

Return Policy

Due to their short expiration period, Fresh grafts are non-returnable.

LifeNet Health Vendor Information

Company:

LifeNet Health
 Address: 1864 Concert Drive Virginia Beach, VA 23453

North America

1.888.847.7831
orders@lifenethealth.org

Latin America Asia Middle East

1.757.464.4761 ext. 2000
internat.orders@lifenethealth.org

Europe

Address: LifeNet Health Europe GmbH

Dietrichgasse 25, 1030 Wien, Austria

Österreich / Austria

+ 43 1 375002710
eu_orders@lifenethealth.eu

Summary Of LifeNet Health Accreditations/Certifications

- ✓ AATB ACCREDITATION
- ✓ FDA REGISTRATION
- ✓ UNOS MEMBER
- ✓ AOPO MEMBER
- ✓ ISO 13485 CERTIFIED
- ✓ CLIA CERTIFIED
- ✓ LICENSED IN REQUIRED STATES
- ✓ HEALTH CANADA CTO
10038 & 100001

Fresh Osteochondral Grafts

Reference Manual

LifeNet Health helps to save lives, restore health and give hope to 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.

www.LifeNetHealth.org

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