

# FRESH OSTEOCHONDRAL ALLOGRAFT FREQUENTLY ASKED QUESTIONS

## **Frequently Asked Questions**

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### **1. What are Fresh Osteochondral Allografts?**

Fresh Osteochondral Allografts have mature hyaline cartilage with viable chondrocytes and subchondral bone intended for joint reconstruction procedures to repair articular cartilage and subchondral bone defects.

### **2. How are Fresh Osteochondral Allografts deemed suitable for transplant?<sup>1-3</sup>**

#### **Pre-Process Assessment and Testing**

##### **Medical Suitability Assessment**

Tissue is designated as suitable or unsuitable for transplantation in accordance with all applicable laws and regulatory requirements, and as determined by LifeNet Health's Medical Director. LifeNet Health's Donor Medical History & Behavioral Risk Assessment questionnaire is comprised of more than 30 types of questions, designed to identify behavioral and medical situations that can result in increased risk of disease transmission for allografts. Additionally, LifeNet Health acquires information from the healthcare professionals and relevant portions of the donor's medical record, including the autopsy report if applicable/available. A properly administered Risk Assessment, including serologic and microbiologic testing results, ensures that transmission of viral, bacterial, fungal, prion, and other pathogens is a remote risk to any recipient.

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### Serologic Testing

All donor blood samples used for required infectious disease testing are evaluated and qualified for acceptability regarding the potential for hemodilution. **Qualified donor blood samples are tested for evidence of infectious agents, including Human Immunodeficiency Virus (HIV), Hepatitis B/C, and syphilis. Additional testing is performed as required according to country eligibility criteria (i.e., HTLV).** All required serologic testing is performed by a CLIA certified laboratory, registered with the FDA to perform donor testing. Lastly, donors for Fresh osteochondral allografts are also tested for COVID-19 via nasopharyngeal swab (RT-PCR) **FDA-licensed or approved donor screening tests are used when available. The donation is accepted or rejected in accordance with applicable regulatory requirements.**

### Microbiology Testing

Each tissue is swabbed at recovery using a 100% swabbing method (prior to coming into contact with antibiotics). Swabs have been validated to maintain the viability of aerobic, anaerobic, and fungal microorganisms of concern. The swabs are individually wrapped, packed with ice, and transported to LifeNet Health's CLIA-certified QC Laboratory for testing. Standard microbiologic methods are employed to detect and identify a wide array of microorganisms.

### Quality Assurance (QA) Review

QA staff review the donor record in detail to ensure that all required documentation is present, complete, and meets acceptability requirements before being sent for review and final medical suitability determination by LifeNet Health's Medical Director.

### Post-Process Testing

To microbiologically evaluate Fresh Osteochondral Allografts, representative samples of co-processed tissue and processing solutions undergo robust microbiologic testing to evaluate and detect the presence of bacteria and fungi in the processed grafts. Test methods are validated and adapted from USP <71> volume 36.

**Fresh Osteochondral Allograft tissue is released for transplant only if ALL post-process testing is negative, and ALL donor suitability criteria are met\*.**

- \* **After release, additional information may become available and if this additional information has an impact on donor suitability, the surgeon will be notified by LifeNet Health.**

### 3. What is a Utility-Based Release (UBR)?

Typically, allografts are deemed suitable by the Medical Director after reviewing documentation associated with a donor.

Utility Based Tissue Release is a defined procedure whereby specific types of grafts (i.e., Refrigerated Fresh Osteochondral Allografts) may be released for implantation using the alternative criteria and processes as described in LifeNet Health policy. This release process is in accordance with applicable

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laws and regulation when permitted. These are allografts whose clinical utility has a narrow timeframe from recovery to implantation, and where the clinical benefit has been determined to outweigh the risks associated with this alternative approval procedure.

All available donor medical records, laboratory reports and medical/social history have been, or will have been, reviewed and donor suitability established by the Medical Director based on this information prior to release of this allograft. All microbiology and serological testing must have negative/nonreactive results prior to release. If an autopsy was performed, the final report may not yet be available, but the preliminary information is also reviewed prior to release. Should any information associated with the donor become available and indicate the donor may be unsuitable, the surgeon will be notified immediately. It is the sole responsibility of the surgeon to ensure that the patient is aware of and consents to the risks of Fresh Osteochondral Allograft transplantation.

#### **4. How are Fresh Osteochondral Allografts measured?**

During production, the graft's cartilage surface is measured by hand using digital calipers and only the usable cartilage surface is measured. Arthrex sizers are then held up against the graft and photographed to demonstrate size.

#### **5. What is the shelf life for a Fresh Osteochondral Allograft?**

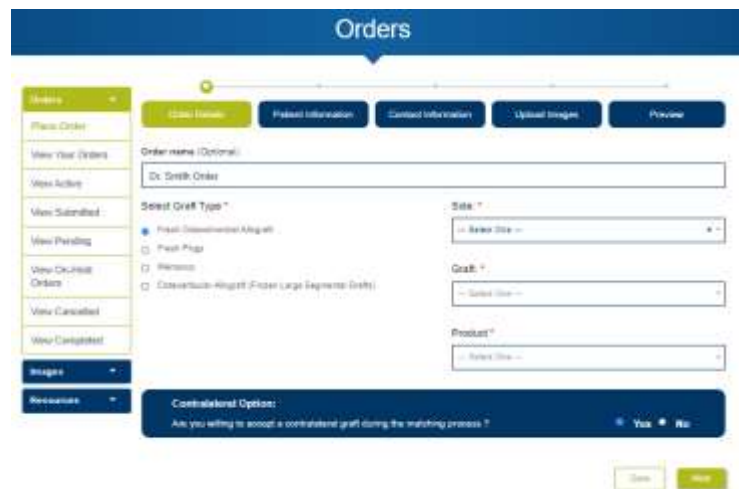
LifeNet Health has validated the viability of Fresh tissue for 45 days. Grafts typically get released between days 16-18, allowing ample time for surgical planning and shipping.

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6. **How do I order a Fresh Osteochondral Allograft?** If in the EU, please skip down to question seven below.

### Special Ordering and Processing Procedures:

- a) In nearly all cases, the customer or sales representative can visit [fresh.lifenethealth.org](http://fresh.lifenethealth.org) and create an account in the Specialty Graft Online Portal to enter and update orders. Once an account is created, orders can be submitted and viewed in the portal.

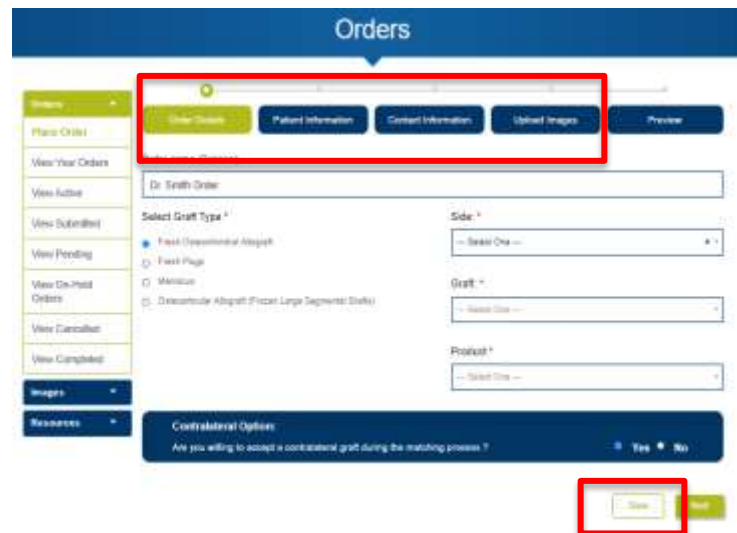


The screenshot shows the 'Orders' section of the LifeNet Health portal. It features a navigation menu on the left with options like 'Place Order', 'View Your Orders', and 'View Submitted'. The main content area includes a 'Status Overview' tab, a 'Patient Information' section with an 'Order name (Optional)' field containing 'Dr. Smith Order', and a 'Select Graft Type' section with radio buttons for 'Fresh Osteochondral Allograft', 'Fresh Plug', 'Wetcast', and 'Cryopreserved Allograft (Frozen Large Segments - Grafts)'. There are also dropdown menus for 'Site', 'Graft', and 'Product'. At the bottom, there is a 'Contraindication Option' section with a question: 'Are you willing to accept a contraindicated graft during the matching process?' and 'Yes'/'No' radio buttons.

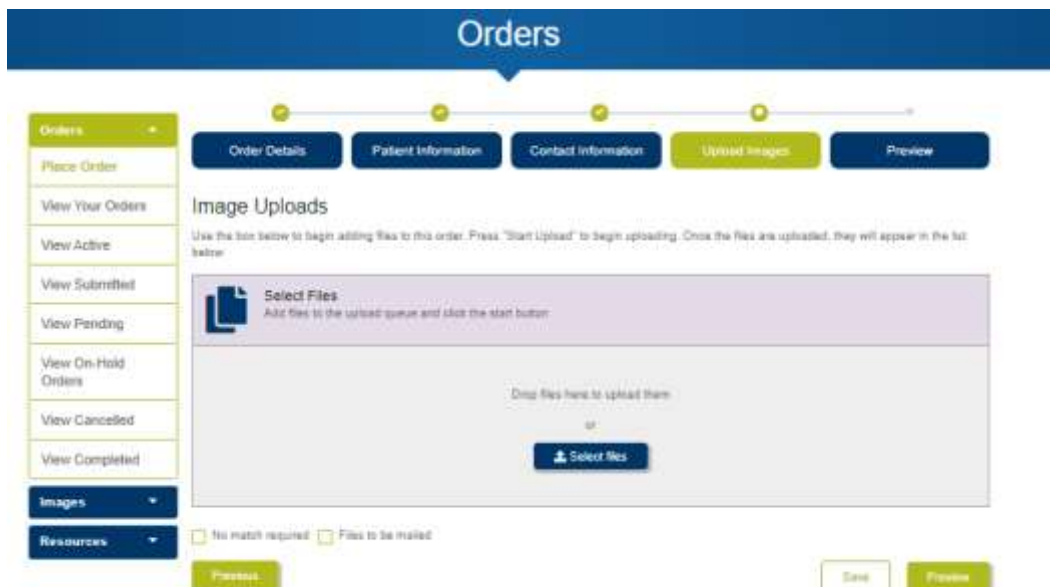
- b) If the surgeon, hospital or sales representative has any questions about ordering through the portal, they may contact LifeNet Health's Client Services Department by calling 1-888-847-7831 or 1-757-464-4761 and ask for a Fresh Technical Specialist or by emailing [freshorders@lifenethealth.org](mailto:freshorders@lifenethealth.org).

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- c) All order information must be provided in the portal to submit a new order. You can save your order at any time by clicking “Save” and view your pending orders in the “View Pending” section.



- d) All matched Fresh allografts will need patient images submitted as well. This may include an MRI or Lateral and A/P X-ray images with magnification marker. In the LifeNet Health Specialty Graft Portal on the “Upload Images” tab, simply drag the zip file into the box or click “Select Files” to find the zip file on your computer. See question eight below for detailed information regarding acceptable imaging for graft matching.



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- e) A status bar appears to show the file is uploading. Once the file is uploaded, click preview and then submit.

**PLEASE NOTE:** Fresh plugs do not require custom matching; therefore, films are not required as part of the order process.


- f) All order information must be provided in the portal to submit a new order; however, patient images can be mailed if preferred. In the LifeNet Health Specialty Graft Portal on the “Upload Images” tab, please select “Files to be Mailed.” Images should be mailed to:

Attn: Technical Specialist / Graft Matching  
501 SW 39th Street • Renton, WA 98057  
Phone: (888) 847-7831 • Fax: (425) 981-8986  
[freshorders@lifenethealth.org](mailto:freshorders@lifenethealth.org)

**PLEASE NOTE:** If films need to be returned, please notify the Fresh Technical Specialist at the time of ordering. If the request for films is made later, there is no guarantee that the films can be returned.


### Medical Image Uploads

Use the box below to drag and drop your zip file into the box. Once the file is uploaded, it will appear in the box below. If you are not uploading, check one of the options below.

 **Select Files**  
Drag and drop zipped files here or “Select files” Button.  
[View instructions](#)




Drop files here to upload them

or



Maximum 5 files.  
1 GB limit.  
Allowed types: zip, dicom, dcm

Image Uploaded  **Files to be mailed**  No match required



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- g) When a suitable match is found, the surgeon, hospital, and sales representatives are contacted. For orders placed in the Specialty Graft Portal, the contacts noted in the portal will also be emailed a copy of the offer packet. The offer packer will include an offer letter with patient specifications and estimated surgery window, dissection description for review, along with any available photographs of the graft. The offer letter should be signed and returned within 48 hours, or the graft will potentially be offered elsewhere. A Utility-Based Release (UBR) form may also be included in the offer packet if not already on file during the current calendar year. See question three for more information about a UBR. Once the form is returned, a quote will be provided, and shipping can be arranged.

### **Key points:**

- **Do not schedule the surgery until graft availability is confirmed.**
- Graft release dates are estimated and may change depending on the release process.
- Utilize the LifeNet Health Specialty Graft Portal or Fresh Osteochondral Graft Order form.
- Please have a billable PO or equivalent ready when the graft is available. We cannot ship the graft without a billable PO or equivalent.
- The hospital should obtain insurance approval (if applicable) before placing an order.
- **All Fresh Osteochondral Allografts are shipped on wet ice in a validated shipper and use expedited services for outside the US.**

### **7. How do I order a Fresh Osteochondral Allograft in the European Union (EU)?**

#### **Special Ordering and processing procedures are as follow:**

- a) The surgeon, hospital, or sales representative may contact LifeNet Health Europe Client Services by calling +43 1 375002710 or emailing [eu\\_orders@lifenethealth.eu](mailto:eu_orders@lifenethealth.eu). A representative will provide the patient consent form and order form to be filled out and returned.
- b) **The patient consent form must first be submitted before the order form and patient imaging films can be provided.**

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- c) The surgeon, hospital, or sales representative completes and submits the order form along with any patient imaging films to LifeNet Health via the contact information below:

LifeNet Health Europe GmbH  
Attn: Client Services  
Dietrichgasse 25, 1030 Wien, Austria  
Österreich / Austria  
Phone: +43 1 375002710 | Fax: +43 1 375002790  
[eu\\_orders@lifenethealth.eu](mailto:eu_orders@lifenethealth.eu)

- d) All matched Fresh allografts will need patient images submitted as well. This may include an MRI or Lateral and A/P X-ray images with magnification marker. See question eight below for detailed information regarding acceptable imaging for graft matching.

**PLEASE NOTE:** *If films need to be returned, please notify the Client Services Representative at the time of ordering. If the request for films is made later, there is no guarantee that the films can be returned. Fresh plugs do not require custom matching; therefore, films are not required as part of the order process.*

- e) When a suitable match is found, the surgeon, hospital, and/or sales representatives are contacted. The offer packet will include an offer letter with patient specifications and estimated surgery window, dissection description for review, along with any available photographs of the graft. The offer letter should be signed and returned within 48 hours, or the graft will potentially be offered elsewhere. Once the Graft Acceptance Form is returned, a quote will be provided, and shipping can be arranged.

### **Key points:**

- **Do not schedule the surgery until graft availability is confirmed.**
- Graft release dates are estimated and may change depending on the release process.
- Utilize the LifeNet Health Fresh Osteochondral Graft Order form.
- Please have a billable PO or equivalent ready when the graft is available. We cannot ship the graft without a billable PO.
- **All Fresh Osteochondral Allografts are shipped on wet ice in a validated shipper and uses expedited services for outside the US.**



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### 8. What images are acceptable for patient matching?

All matched Fresh allografts will need patient images submitted. This may include an MRI or CT scan, which are preferred, or Lateral and A/P X-ray images with proper magnification marker.

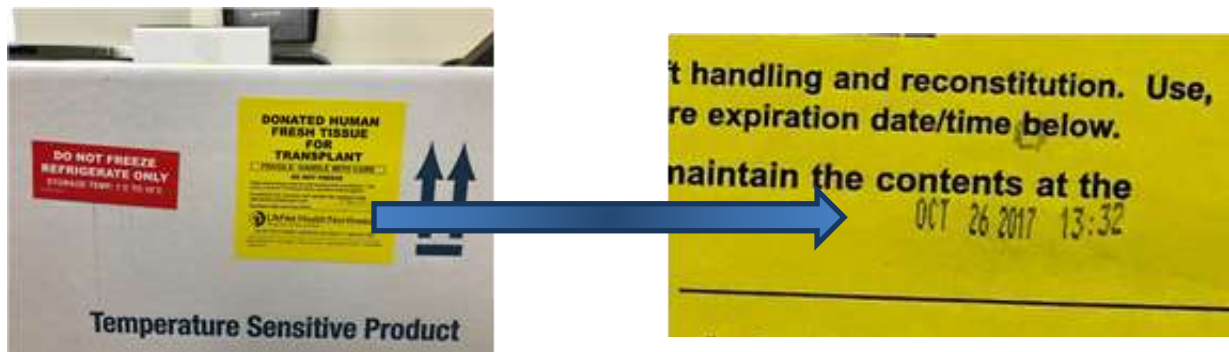
When using pre-operative X-ray images for graft-sizing measurements, a magnification marker must be used in the X-ray. During the X-ray, the magnification marker should be placed at the level of the bone being examined. See examples below.



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### 9. How are Fresh Osteochondral Allografts shipped?

All Fresh Osteochondral Allografts are shipped on wet ice in a validated shipper. Expedited Services are utilized for shipments outside of the US. Any Fresh Osteochondral Allograft shipped by special courier in the United States may incur additional charges. Please refer to label/seal on shipper for the date and time of shipper expiration (Times are US PST). See example below.



### 10. Are Fresh Osteochondral Allografts returnable?

Due to their short expiration period, Fresh grafts are non-returnable. Please refer to the LifeNet Health Return Policy or email [freshorders@lifenethealth.org](mailto:freshorders@lifenethealth.org) or [eu\\_orders@lifenethealth.eu](mailto:eu_orders@lifenethealth.eu) with questions.

### 11. What are the storage requirements?

Fresh Osteochondral Allografts must be stored between **1-10° C, refrigerated**. **DO NOT FREEZE**.<sup>4</sup>

### 12. What if a Fresh Osteochondral Allograft is accidentally placed in the freezer?

Freezing a Fresh Osteochondral Allograft has a negative effect on the viability of chondrocytes and may possibly affect general biomechanical properties of the cartilage. Fresh Osteochondral Allografts should NOT be frozen and use after accidental freezing is not recommended.

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### **13. What is the storage media?**

LifeNet Health's Fresh Osteochondral Allografts are stored in either Dulbecco's Modified Eagle's Medium (DMEM) or X-VIVO™ 10 media amended with antibiotics. DMEM and X-VIVO 10 are both chemically defined, serum-free, xeno-free cell culture media that can provide a nutritionally complete and balanced environment for the in vitro culture and maintenance of cells including chondrocytes. Either media is used to provide nutritionally complete and balanced environments for a variety of cells, such as chondrocytes. X-VIVO™ 10 and DMEM are manufactured under current good manufacturing practices (cGMP) at cGMP-compliant facilities in the United States and Europe. These facilities are registered with the FDA as a medical device manufacturer and are certified to ISO 13485 standards.<sup>5,6</sup>

### **14. Is there any potential for allergic reactions due to use of antibiotics or other reagents?**

Yes, LifeNet Health's Fresh Osteochondral Allografts may contain residuals of antibiotics (Gentamicin and Vancomycin). The graft is stored in either DMEM or X-VIVO media amended with these two antibiotics. Caution should be exercised if the patient has a known sensitivity to any of these antibiotics and/or reagents. Please refer to the instructions for use included in the bio-implant packaging.<sup>4</sup>

### **15. Where can I access the Instructions for Use (IFU)?**

The IFU is included with the shipped allograft. A copy can be found on the website. Visit <https://www.lifenethealth.org/instructions-use>  
For customers with an account in the Specialty Graft Ordering Portal, the IFU can also be found in the Resources Menu.

### **16. What is the risk of graft rejection?**

Cartilage is avascular and has been shown to have little to no immune response. The bone segment used in osteochondral transplant procedures is usually trimmed down to the minimal amount needed by the implanting surgeon. Additionally, the surgeon often performs additional graft lavage to remove bone marrow and lipids prior to implantation that minimizes the potential presence of immunogenic cells and proteins. After several months, many studies have shown that the bony segment is being remodeled and replaced with host tissue.<sup>7</sup> It is the decision of the implanting surgeon to determine graft suitability.

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## References

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2. Title 21, Code of Federal Regulations, Parts 1270 & 1271, Human Tissue Intended for Transplantation, Food and Drug Administration, Department of Health and Human Services, Current Edition.
3. Guidance for Industry, Screening and Testing of Donors of Human Tissue Intended for Transplantation, U.S. Department of Health and Human Services, Food and Drug Administration, Center for Biologics Evaluation and Research. 2007.
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7. Bugbee, W. Cavallo M and Gianni S. Osteochondral Allograft Transplantation in the Knee. J Knee Surg. 2021. 25:109-116.