Orthobiologics Samples

A Comprehensive Portfolio

Armeto

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Orthobiologics Samples— Providing Awareness and Clarity

As the need for biologics within orthopedics and sports medicine continues to become more evident, it is important for our agencies to have a comprehensive understanding of allograft tissue and its availability as sample product. The goal of this portfolio is to create a one-stop resource for orthobiologic sample information.

This portfolio provides information on the life cycle of allograft tissue, the gift of donation, important American Association of Tissue Banks (AATB) policies, which allograft tissues are available for sample (and which are not), the process for expired tissue and our current return field policy, and any available demo kits, instruments, and accessories related to our current orthobiologics product line.

Overview

At Arthrex, we are committed to honoring the gift of donated human tissue. This includes ensuring that all donated tissue is handled with the utmost respect and used according to each donor's wishes.

Arthrex has partnered with some of the most respected tissue banks in the world to provide our surgeons with the highest quality allograft tissue. To ensure that our partners uphold the highest standards with regard to tissue banking, each of our tissue partners must be accredited with the AATB. With this accreditation, they are required to comply with the AATB Standards for Tissue Banking. As their partners and marketers of donated human tissue, we must also comply with these standards.

The AATB Standards for Tissue Banking outline the general polices surrounding tissue banking, including the requirements for authorization to acquire tissues and make them available for transplantation.

During the authorization process for tissue donation, donors and/or their loved ones are able to determine the permitted use of the recovered tissues (ie, transplant, therapy, research, or education). For this reason, we must be very mindful of our use of donated human tissue as samples. Any expired tissue in your agency's tissue bank must be authorized for research or education uses prior to use as a sample.

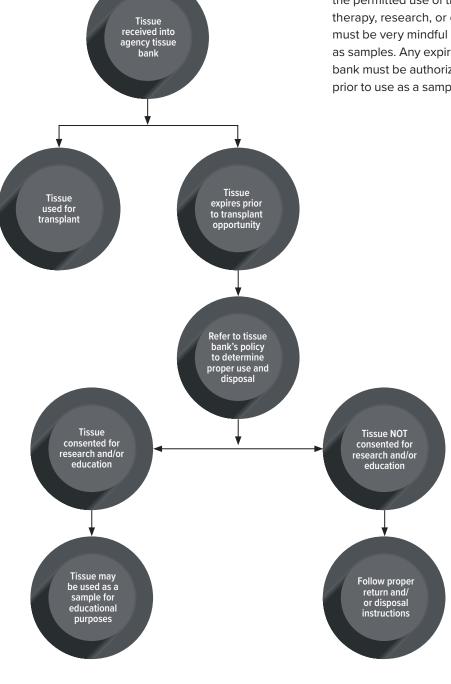


Figure 1. Overview process of allograft tissue and life cycle

AATB Policies to Know

D1.000 General Policies for Tissue Recovery or Collection Organizations

D1.200 Tissue for Research

Facilities providing tissue for research and other nontransplantation purposes shall develop detailed, relevant specific policies and procedures. Informed consent or authorization for research and/or education shall be obtained. See the series of standards at D2.000 and D3.000.

D1.300 Consideration for the Donor

A policy shall be established requiring the donor always be treated with dignity and respect.

D2.000 Authorization

D2.100 Requirements

Authorization to acquire tissues and make them available for transplantation, therapy, research, or education shall be obtained from a donor or authorizing person in accordance with applicable anatomical gift acts and other laws or regulations. This authorization shall be expressed in a document of gift/authorization, the original or a copy of which shall be maintained in the donor's record at the tissue bank responsible for recovery, as well as in the donor's record at the tissue bank whose medical director is responsible for the donor eligibility determination. In the case of an electronic or voice recorded document of gift/authorization, the original recording should be maintained in reproducible form.

D2.400 Core Elements for Authorization

The document of authorization shall contain adequate information. No document of authorization from an authorizing person shall be acted upon if it does not contain the following core elements. These core elements also apply to D2.500.

Core Elements:

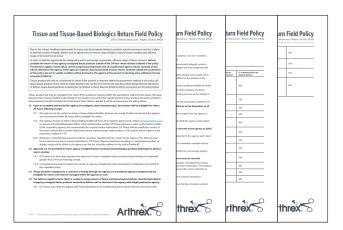
- The name of the donor
- The name, mailing address, and telephone number of the authorizing person, and his/her relationship to the donor
- An explanation that the tissue is a gift, and that neither the donor's estate nor the authorizing person will receive monetary compensation or valuable consideration for it
- A description of the general types of tissue to be recovered
- A description of the permitted use(s) of the recovered tissues (ie, transplant, therapy, research, or education)
- An explanation that recovery of tissue requires the following actions, and the document of gift/ authorization thus specifically authorizes:
 - Access to, and required disclosure of, the donor's medical and other relevant records
 - Testing and reporting for transmissible diseases
 - The removal of specimens which may include, but are not limited to, blood or tissue samples for the purposes of biopsy or other testing necessary for determination of donor eligibility
 - The release to the tissue bank of any and all records and reports of a medical examiner, coroner, or pathologist (eg, autopsy report); and such other requirements as may be applicable for the specific donation or tissue bank, such as transport of the donor's body, archiving of samples, photographic or other imaging, etc
- Contact information for the organization represented by the donation coordinator and any additional information required by laws or regulations

Return Field Policy

Due to the unique handling requirements for tissue and tissue-based biologics products, special processes must be in place to maintain product integrity. Arthrex and its agents have an ethical responsibility to ensure proper handling and efficient usage of donated human tissue.

The return field policy is specific to to Arthrex tissuebased products listed out in Exhibit A of the Return Field Policy. All other tissue and/or tissue-based products from partnering tissue banks must follow the expired tissue protocols outlined in the next section.

For more information, please reference the <u>Arthrex</u> <u>Tissue and Tissue-Based Biologics Return Field Policy.</u>



Expired Tissue Protocols

LifeNet Health

Any expired clinical grafts must be checked to see if they are marked for either research or universal consent. Please reach out to SM_sample@lifenethealth.org and quarantine the expired graft away from clinical tissue. LifeNet Health will notify you if the expired graft has donor consent for research use and will send a chain of custody form for you to fill out. If consented for research use, please label the expired tissue "not for clinical use—educational purposes only." If the graft does not have consent for research use, it can be properly discarded or sent back to LifeNet Health for proper disposal.

JRF Ortho

In the event tissue expires, the facility should follow its standard processes for expired tissue.

SeaSpine

In the event tissue expires, the facility should follow its standard processes for expired tissue. If the facility wishes to use expired tissue for sample, please contact SeaSpine at 1 (866) 942-8698 to have the tissue properly relabeled.

Osiris

In the event tissue expires, the facility should follow its standard processes to discard the tissue.

Vivex

For expired samples to be used as demo/educational purposes, we will need to verify the serial numbers with our quality department. Please send the full tissue ID of the grafts requested to be used as demo/educational purposes and we will respond with confirmation of the approval. The turnaround time for responses is 48 hours (business days). Expired samples sent from Vivex to Arthrex have already been checked for this use and new requests will only apply to outside agencies/ distributors/customers. All requests should be sent to customercare@vivex.com.

Allosource

In the event tissue expires, the facility should follow its standard processes for expired tissue. If the facility wishes to use the expired tissue for sample, please contact Allosource at 1 (800) 557-3587 to have the tissue properly relabeled.

CellRight

Please use the <u>Arthrex Return Field Policy</u> to initiate the return of the expired tissue to CellRight. CellRight will complete documentation and send the expired product back to the designated person, if the graft is consented for research.

Available Tissue Samples

LifeNet Health

All sample requests can be sent to <u>sm_samples@lifenethealth.org</u>. In the request, please include the specific request, the date the sample is needed, and any shipping information. Please provide these requests at least 7 business days in advance.



ArthroFLEX® Dermal Allograft

| Product Description | Size | Item Number |
|--------------------------------------|-----------------------------|-------------|
| Decellularized dermis patch | 1.5 mm × 35 mm × 35 mm | AFLEX100 |
| Decellularized dermis patch | 1.5 mm × 40 mm × 70 mm | AFLEX101 |
| Decellularized dermis patch | 1.5 mm × 50 mm × 90 mm | AFLEX103 |
| Decellularized dermis patch | 1.5 mm × 15 mm × 140 mm | AFLEX150 |
| Decellularized dermis patch | 2 mm × 35 mm × 35 mm | AFLEX200 |
| Decellularized dermis patch | 2 mm × 40 mm × 70 mm | AFLEX201 |
| Decellularized dermis patch | 2 mm × 25 mm × 30 mm | AFLEX202 |
| Decellularized dermis patch | 3 mm × 40 mm × 50 mm | AFLEX300 |
| Decellularized dermis patch | 3 mm × 40 mm × 70 mm | AFLEX301 |
| Decellularized dermis patch | 3 mm × 50 mm × 60 mm | AFLEX302 |
| Decellularized dermis patch | 1 mm × 40 mm × 40 mm | AFLEX400 |
| Decellularized dermis patch | 1 mm × 40 mm × 70 mm | AFLEX401 |
| Decellularized dermis patch | 1 mm × 20 mm × 25 mm | AFLEX402 |
| Decellularized dermis patch | 1 mm × 25 mm × 30 mm | AFLEX403 |
| Decellularized dermis patch | 0.5 mm × 30 mm × 40 mm | AFLEX500 |
| Decellularized dermis patch (2 pack) | 2 mm × 10 mm × 14 mm (each) | AFLEX822 |

Tendon Allografts

| Product Description | Size | Item Number |
|--------------------------------|--------------------------------------|-------------|
| Tibialis tendon, anterior | L ≥ 230 mm; D ≥ 7.5 mm | FANT/TIB/T |
| Achilles tendon w/ bone block | L ≥ 160 mm | FATB |
| Patellar tendon, bisected/hemi | | FBPL |
| Gracilis tendon, small joint | $L \ge 230$ mm; $D \ge 4$ mm minimum | FGRACILIS |
| Preshaped patellar tendon | 10 mm | FPL10 |
| Peroneus tendon | L ≥ 23 cm; D ≥ 7.5 mm | FPLT |
| Quadriceps tendon w/ bone | | FQUADB |
| Semitendinosus tendon | Min L = 230 mm; min D > 4.0 mm | FST |
| Patellar tendon, whole | | FWPL |

For any questions about allograft tissue samples from LifeNet Health, email SM_sample@lifenethealth.org

Presutured Tendons

| Product Description | Size | Item Number |
|--|---|-------------|
| Allograft GraftLink [®] tendon | L= 60 mm-80 mm; D= 7.5-10.5 mm | FGL |
| Allograft GraftLink triple strand tendon | L= 65 mm-95 mm; D= 8.5 mm-12.5 mm | FGLTS |
| QuadLink [™] construct tendon | L= 60 mm-75 mm; D= 9 mm-11 mm | FQL |
| FlexiGRAFT [®] connect tendon | L= 150 mm-250 mm; D= 4 mm, 4.5 mm, 5 mm | FCON |
| FlexiGRAFT connect EXT tendon | L= 140 mm-200 mm, D= 3 mm | FCONEXT |

Precut Fresh Osteochondral Allograft Cores

| Product Description | Size | Item Number |
|----------------------------------|-------|-------------|
| Precut osteochondral core, fresh | 10 mm | RFP10 |
| Precut osteochondral core, fresh | 16 mm | RFP16 |

Fresh Cartilage

| Product Description | Size | Item Number |
|---|--------|-------------|
| Talus, left | Varies | ATL80 |
| Talus, right | Varies | ATR80 |
| Femoral head, left | Varies | FHL80 |
| Femoral head, right | Varies | FHR80 |
| Distal tibia, left | Varies | TDL80 |
| Distal tibia, right | Varies | TDR80 |
| Whole tibial plateau w/ meniscus, left | Varies | TFL80 |
| Whole tibial plateau w/ meniscus, right | Varies | TFR80 |

Meniscus Allografts

| Product Description | Size | Item Number |
|-------------------------|----------------|-------------|
| Lateral meniscus, right | Custom-matched | FMN R |
| Lateral meniscus, left | Custom-matched | FMN LL |
| Medial meniscus, right | Custom-matched | FMN RM |
| Medial meniscus, left | Custom-matched | FMN LM |

Cancellous Plugs

| Product Description | Size | Item Number |
|---|-------|-------------|
| FlexiGraft [®] cancellous plug | 6 mm | PCPD6 |
| FlexiGraft cancellous plug | 7 mm | PCPD7 |
| FlexiGraft cancellous plug | 8 mm | PCPD8 |
| FlexiGraft cancellous plug | 9 mm | PCPD9 |
| FlexiGraft cancellous plug | 10 mm | PCPD10 |
| FlexiGraft cancellous plug | 11 mm | PCPD11 |

Revision Dowels

| Product Description | Size | Item Number |
|--|--------------------------|-------------|
| Cannulated revision bone dowel | L= 25 mm-29 mm; D= 10 mm | PCD10 |
| Cannulated revision bone dowel | L= 25 mm-29 mm; D= 12 mm | PCD12 |
| Cannulated revision bone dowel, extended | L= 30 mm-35 mm; D= 10 mm | PCDXL10 |
| Cannulated revision bone dowel, extended | L= 30 mm-35 mm; D= 12 mm | PCDXL12 |

For any questions about allograft tissue samples from JRF Ortho, email jbrownlee@jrfortho.org

For any lab/medical education tissue, please submit requests through the JRF Ortho Educational Allograft Request Application.

If you have any expired tissue on hand, please follow the guidelines stated in the section Expired Tissue and Return Field Policy.

Osteochondral Allografts

| Product Description | |
|------------------------|---------------------------|
| Femoral condyle: | Humeral head: |
| Left lateral | Left w/ lateral meniscus |
| Left medial | Left w/ medial meniscus |
| Right lateral | Right w/ lateral meniscus |
| Right medial | Right w/ medial meniscus |
| Meniscus: | Metatarsal |
| Left lateral | Metacarpal |
| Left medial | Patella: |
| Right lateral | Left |
| Right medial | Right |
| OCA core: | Talus: |
| 10 mm | Left |
| 16 mm | Right |
| Distal tibia: | Tibial plateau: |
| Left | Left |
| Right | Right |
| Femoral head: | Trochlea: |
| Left | Left |
| Right | Right |
| Whole femoral condyle: | |
| .eft | |
| Right | |

Presutured Tendons

| Product Description | |
|--------------------------------|--|
| VersaGraft [®] tendon | |
| SpeedGraft [®] tendon | |
| GraftLink® XL tendon | |

Tendon Allografts

| Product Description | |
|--------------------------|----------------|
| Achilles | Tibialis: |
| Quadriceps | Anterior |
| Patellar Ligament (BTB): | Posterior |
| Preshaped | Peroneous |
| Hemi | Semitendinosus |
| Whole | Gracilis |
| | Fascia lata |



Cartiform[®] Viable Osteochondral Allograft Bovine Samples

Please reach out to a member of the Biologics Product Management Team for samples. There is a limited inventory on these samples, so please be cognizant of order quantity.

Cartiform Rubber Samples

Please place your order through the <u>Arthrex Business</u> <u>Portal</u>; these samples are free of charge. Your agency will only need to pay for shipping costs. For additional questions and general assistance, please contact your regional manager or email Customer Service at <u>samples@arthrex.com</u>.

| Available Sizes (Bovine, Rubber) | Item Number | |
|----------------------------------|-------------|--------------------|
| 10 mm disc | 1 | AS- 1101-10 |
| 12 mm × 19 mm disc | 2 | AS- 1102-19 |
| 20 mm disc | 3 | AS- 1101-20 |
| 20 mm × 25 mm disc | 4 | AS- 1102-25 |

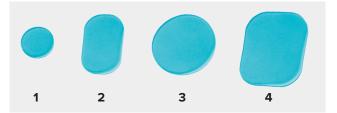
BioCartilage® Allograft Samples

Please email Customer Service at <u>cstissue@arthrex.com</u> with requests for nonclinical allograft tissue at a discounted rate for product demonstrations. For additional questions and general assistance, please contact your regional manager.

| Available Sizes | Item Number | Fee |
|-----------------|--------------------|------|
| 1 cc | AS- 1010-BC | \$25 |









Unavailable Tissue Samples

Please note that the following allograft tissue samples are NOT readily available for sample.

| AlloSync [™] Product Line | ArthroCell [™] Product Line |
|---|--|
| AlloSync putty | ArthroCell allograft |
| AlloSync gel | |
| AlloSync paste | Arthrex Amnion [™] Product Line |
| AlloSync Cotton wedge | Arthrex Amnion matrix |
| AlloSync Evans wedge | |
| AlloSync chips | |
| AlloSync fibers | |
| AlloSync Expand demineralized cortical fibers | |
| AlloSync bone PIP dart | |
| AlloSync strips | |
| AlloSync button | |
| AlloSync cubes | |
| AlloSync Pure DBM | |

Demo Kits Available to Order

If ordering a demo kit, please call Customer Service at 1 (800) 934-4404.

| Product Description | Item Number | Stocking Price |
|---|-------------|----------------|
| AlloSync strip/block demo kit | DS-249 | \$375 |
| AlloSync Pure DBM demo kit | DS-250 | \$109 |
| IOBP [®] closed tip demo kit | DS-247CT | \$75 |
| IOBP open tip demo kit | DS-2470T | \$75 |
| IOBP foot and ankle demo kit w/ sawbone | DS-269 | \$95 |
| OCA cutter, 16 mm | DS-267 | \$140 |
| Cartiform [®] implant, sawbones | DS-229 | \$30 |
| ACP Max [™] platelet-rich plasma system | DS-ACP Max | \$80.75 |

Ordering Information for Instruments and Accessories

If ordering a sample, please place your order through the <u>Arthrex Business Portal</u>. Please note that there are monthly allotments for some of the items listed below. Note: All samples available for order through the Arthrex Business Portal are free of charge. Your agency will only need to pay for shipping costs.

For additional questions and general assistance, please contact your regional manager or email Customer Service at samples@arthrex.com.

Bone

| Product Description | Item Number |
|---|--------------------|
| Quickset [™] cement sample, delivery gun | AS- 3001 |
| Quickset cement sample, cylinder | AS- 3003 |
| Quickset cement sample, syringe | AS- 3004 |
| BoneSync [™] cement, 1 cc | AS- 3101 |
| BoneSync cement sample kit, 3 cc | AS- 3103 |
| OsteoAuger™ bone graft harvester, 6 mm | AS- 8000-06 |
| OsteoAuger bone graft harvester, 8 mm | AS- 8000-08 |
| OsteoAuger bone graft harvester, 10 mm | AS- 8000-10 |
| BoneSync BioActive strip, 5 cc | AS- 3500-05 |
| BoneSync BioActive strip, 10 cc | AS- 3500-10 |
| BoneSync BioActive strip, 20 cc | AS- 3500-20 |
| BoneSync BioActive strip, 40 cc | AS- 3500-40 |
| BoneSync BioActive putty, 2.5 cc | AS- 3400-02 |
| BoneSync BioActive putty, 5 cc | AS- 3400-05 |
| BoneSync BioActive putty, 10 cc | AS- 3400-10 |
| BoneSync BioActive putty, 20 cc | AS- 3400-20 |
| Arthrex Calcium Sulfate BioBeads, 5 cc | AS- 3000-05 |

Cellular and Molecular

| Product Description | Item Number |
|---|-----------------------|
| ACP® Double-Syringe, unsterile, bulk | AS- 10014 |
| ACP Max [™] platelet-rich plasma system | AS- 10013 |
| Thrombinator [™] system | AS- 10080 |
| Fenestrated delivery needle | AS- 20000 |
| Tuohy delivery needle | AS- 21000 |
| Applicator w/ mixer and spray tip kit | AS- 10051 |
| Angel® BMA kit | AS- 10062 |
| AutoPose [™] Access device | AS-101024-1 |
| AutoPose Restore syringe | AS-101035-1 |
| Vortex [™] threaded BMA recovery needle, 13 ga, closed tip | AS-1101TH-13CT |
| Vortex threaded BMA recovery needle, 13 ga, open tip | AS-1101TH-130T |
| Vortex threaded BMA recovery needle, 8 ga, closed tip | AS- 1101TH-8CT |
| Vortex threaded BMA recovery needle, 8 ga, open tip | AS-1101TH-80T |

Soft Tissue

| Product Description | Item Number |
|--|------------------|
| TenoWrap™ collagen tendon wrap, 16 mm × 2.5 cm | AS- 16025 |
| TenoWrap [™] collagen tendon wrap, 16 mm × 5 cm | AS- 16050 |

Wound

| Product Description | Item Number |
|---|-----------------|
| JumpStart [®] wound dressing, 2 in \times 2 in | AS- 4002 |
| JumpStart pin site dressing | AS- 4059 |

Cartilage and Meniscus

| Product Description | Item Number |
|--|---------------------|
| BioCartilage® kit, large joint | AS- 1000-L |
| BioCartilage kit, hip | AS- 1000-H |
| BioCartilage kit, small joint | AS- 1000-S |
| Tuohy needle w/ obturator | AS- 1001 |
| Tuohy needle, long | AS- 1001-L |
| Tuohy needle, short | AS- 1001-S |
| Tuohy needle, straight, w/ obturator | AS- 1002 |
| Funnel | AS- 1003 |
| BioCartilage straight needle w/ obturator | AS- 1004 |
| GraftNet [™] device | AS- 1050 |
| Cartiform [®] viable osteochondral allograft, 10 mm rubber disc | AS- 1101-10 |
| Cartiform viable osteochondral allograft, 20 mm rubber disc | AS- 1101-20 |
| Cartiform viable osteochondral allograft, 12 mm × 19 mm rubber disc | AS- 1102-19 |
| Cartiform viable osteochondral allograft, 20 mm × 25 mm rubber disc | AS- 1102-25 |
| IOBP® knee kit, open tip, w/ 7 mm reamer | AS- 2000-OT |
| IOBP knee kit, open tip, w/ decompression device | AS- 2001-0T |
| IOBP knee kit, closed tip | AS- 2000-CT |
| IOBP hip kit, open tip, w/ decompression device | AS- 2010-OT |
| IOBP hip kit, closed tip | AS- 2010-OT |
| IOBP foot and ankle kit | AS- 2020-OT |
| OATS [®] 2.0 set, 10 mm | AS- 8981-105 |
| OATS 2.0 set, 12 mm | AS- 8981-12S |



This description of technique is provided as an educational tool and clinical aid to assist properly licensed medical professionals in the usage of specific Arthrex products. As part of this professional usage, the medical professional must use their professional judgment in making any final determinations in product usage and technique. In doing so, the medical professional should rely on their own training and experience, and should conduct a thorough review of pertinent medical literature and the product's directions for use. Postoperative management is patient-specific and dependent on the treating professional's assessment. Individual results will vary and not all patients will experience the same postoperative activity level or outcomes.



Arthrex manufacturer, authorized representative, and importer information (Arthrex eIFUs)



US patent information

arthrex.com

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