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.

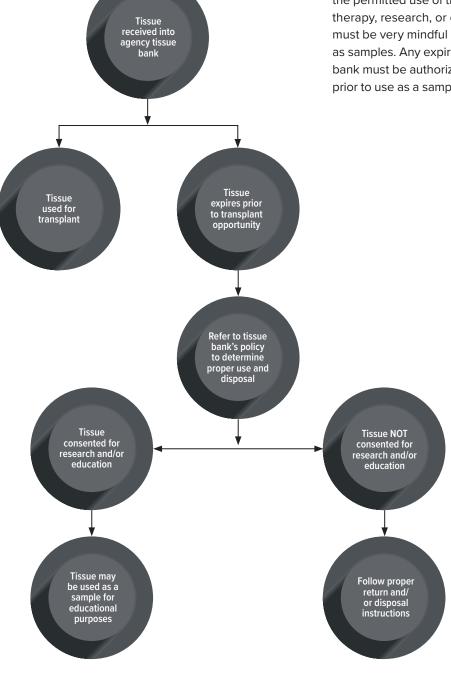


Figure 1. Overview process of allograft tissue and life cycle

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:

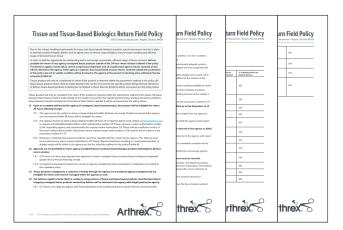
- The name of the donor
- The name, mailing address, and telephone number of the authorizing person, and his/her relationship to the donor
- An explanation that the tissue is a gift, and that neither the donor's estate nor the authorizing person will receive monetary compensation or valuable consideration 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

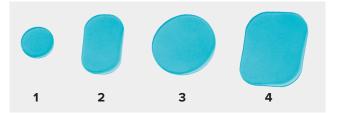
BioCartilage® Allograft Samples

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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