

LifeLink Tissue Bank Allograft Catalog



Your Global Link to the Future

**We Connect Healthcare
Professionals with a
World Class Tissue Bank**




We've helped surgeons and hospitals provide a multitude of second chances.

LifeLink is the largest not-for-profit tissue bank in the Southeastern United States providing more than 50,000 allografts each year to many surgical specialists. Over one million LifeLink allografts have been implanted since the tissue bank's inception. This amount is a direct result of our unwavering commitment to exceeding all FDA and industry standards.

It is our obligation to hospitals, surgeons and patients to provide the safest, highest quality allografts available. We accomplish this through a guiding conviction of respect, integrity, quality and safety.

For many people an allograft transplant presents the opportunity to walk or run again, to live pain free and in some cases the chance to simply live a normal life.

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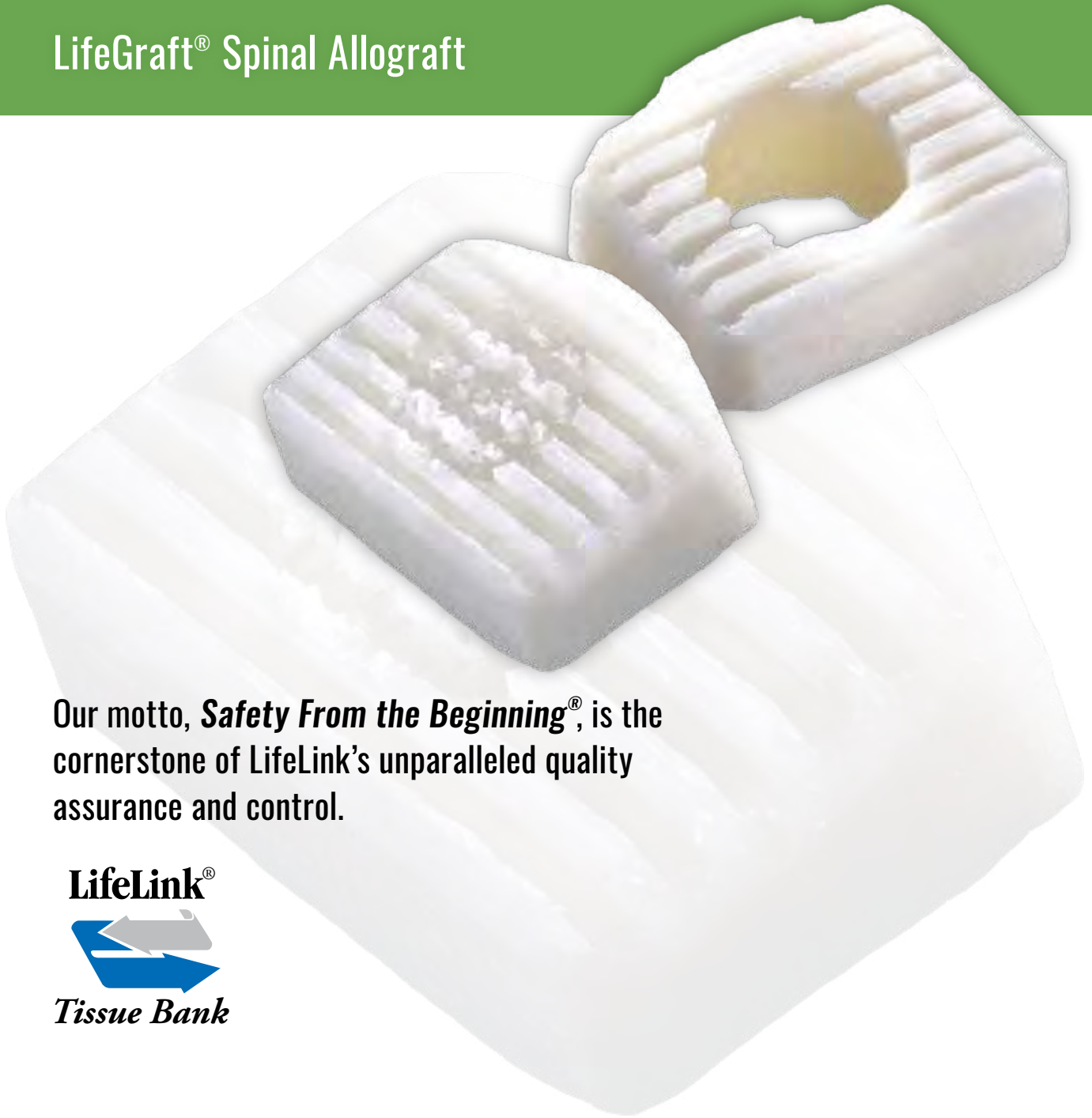
 **NOVUTECH**
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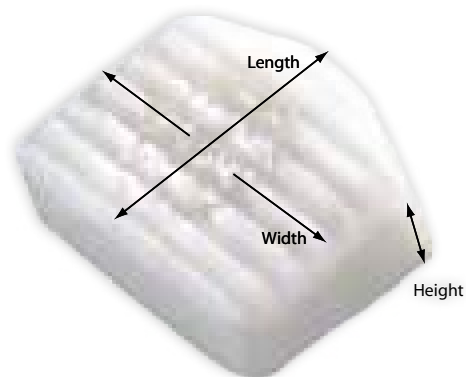
LifeGraft® Spinal Allograft



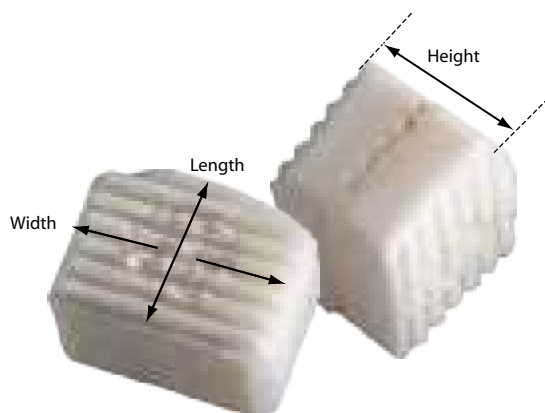
Our motto, ***Safety From the Beginning®***, is the cornerstone of LifeLink's unparalleled quality assurance and control.



Cortical Cancellous Spacer



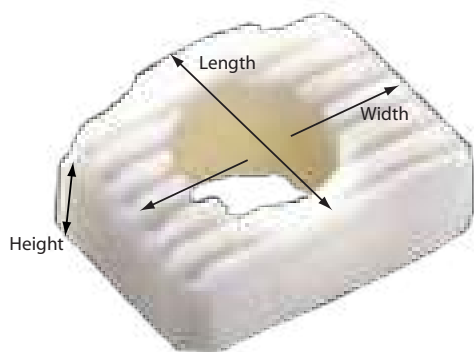
Dimensions			Catalog #	
Width	Length	Height	Freeze-Dried	
			Parallel	Lordotic
14.5mm	11.5mm	5mm	LGAP905	LGAL905
		6mm	LGAP906	LGAL906
		7mm	LGAP907	LGAL907
		8mm	LGAP908	LGAL908
		9mm	LGAP909	LGAL909
14mm	14mm	6mm	-	LGAL956
		7mm	-	LGAL957
		8mm	-	LGAL958



Cortical Cancellous Spacer-C

Dimensions			Catalog #	
Width	Length	Height	Freeze-Dried	
			Parallel	Lordotic
14.5mm	11.5mm	10mm	-	LGAL910

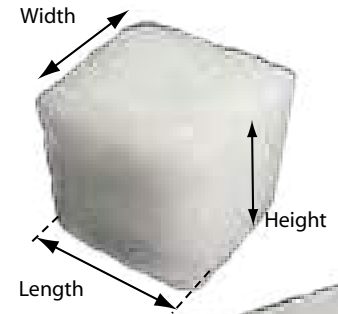
Cortical Spacer



Dimensions			Catalog #	
Width	Length	Height	Freeze-Dried	
			Parallel	Lordotic
14.5mm	11.5mm	5mm	LGAP915	LGAL915
		6mm	LGAP916	LGAL916
		7mm	LGAP917	LGAL917
		8mm	LGAP918	LGAL918
		9mm	LGAP919	LGAL919
14mm	14mm	6mm	-	LGAL946
		7mm	-	LGAL947
		8mm	-	LGAL948

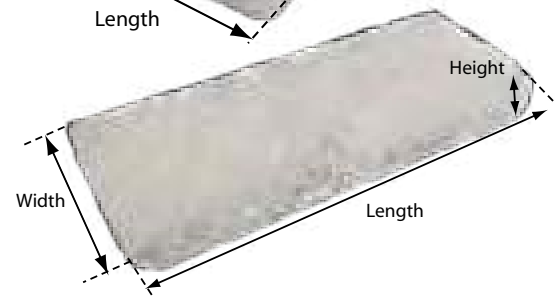
LifeFlex® Demineralized Cancellous Cube

Specifications			Catalog #
Height	Width	Length	Freeze-Dried
8mm	8mm	8mm	15A008
10mm	10mm	10mm	15A010
12mm	12mm	12mm	15A012
14mm	14mm	14mm	15A014



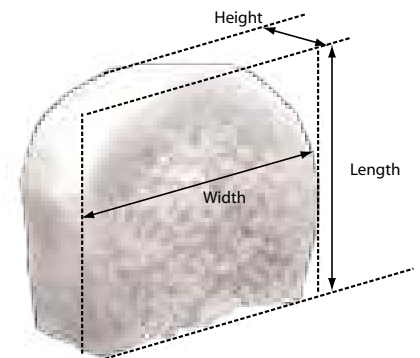
LifeFlex® Demineralized Cancellous Strip

Specifications			Catalog #
Height	Width	Length	Freeze-Dried
5mm	20mm	50mm	15A040
8mm	25mm	50mm	15A050



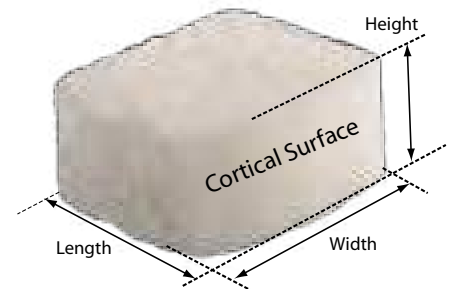
Tricortical Cancellous Wedge

Dimensions			Catalog #	
Width M/L	Length A/P	Height	Freeze-Dried	
			Parallel	Lordotic
13 - 15mm	13 - 15mm	5mm	LGAP705	LGAL705
		6mm	LGAP706	LGAL706
		7mm	LGAP707	LGAL707
		8mm	LGAP708	LGAL708
		9mm	LGAP709	LGAL709
		10mm	LGAP710	LGAL710



Unicortical Cancellous Spacer

Dimensions			Catalog #
Width	Length	Height	Freeze-Dried
14mm	11mm	5mm	LGAP505
		6mm	LGAP506
		7mm	LGAP507
		8mm	LGAP508
		9mm	LGAP509
		10mm	LGAP510



Spinal Contract Allograft



Indux™ Cancellous Strip

Dimensions	Catalog #
	Freeze-Dried
5 x 20 x 50mm	45-3250
8 x 25 x 50mm	45-3208

Tissue represented by Zimmer Biomet Spine, Inc.



Osteoamp® Compressible Sponge Strip

Dimensions	Catalog #
	Freeze-Dried
7 x 10 x 50mm, Large	13812209
7 x 20 x 50mm, XL	13812509

Tissue represented by Bioventus Surgical.



SiJoin Sacroiliac Joint Fusion Implant

Dimensions	Catalog #
	Freeze-Dried
6 x 11 x 15mm	VG-SJ-AG-11511
6 x 11 x 20mm	VG-SJ-AG-TS-12011

Tissue represented by VGI Medical, LLC.



NuFix® I Cortical Dowel

Dimensions	Catalog #
	Freeze-Dried
5.0 x 9mm	10050
5.5 x 9mm	10055

Tissue represented by Nutech Spine.

Spinal Contract Allograft

NuFix® II Cortical Dowel

Dimensions	Catalog #
	Freeze-Dried
5.0 x 10 x 10.5mm	20050

Tissue represented by Nutech Spine.



SIFix® Sacroiliac Intra-Articular Fusion Allograft (Cancellous)

Dimensions	Catalog #
	Freeze-Dried
11 x 22mm	1743011

Tissue represented by Nutech Spine.



SIFix® Sacroiliac Intra-Articular Fusion Allograft (Cortical)

Dimensions	Catalog #
	Frozen
11 x 22mm	3743011

Tissue represented by Nutech Spine.



Sports Tissue Allograft



LifeLink goes to great lengths to ensure the safety of our allograft bone and tissue.

LifeLink[®]



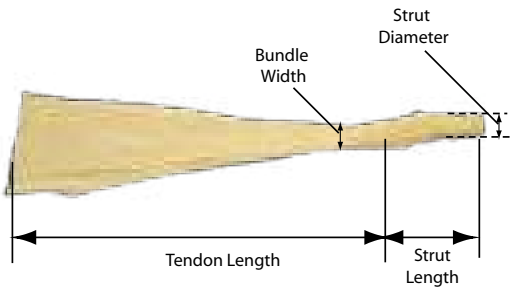
Tissue Bank

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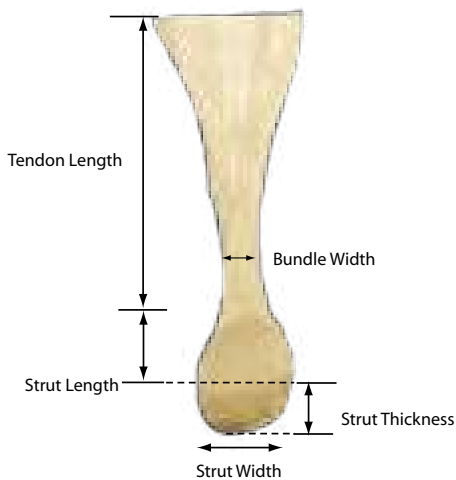
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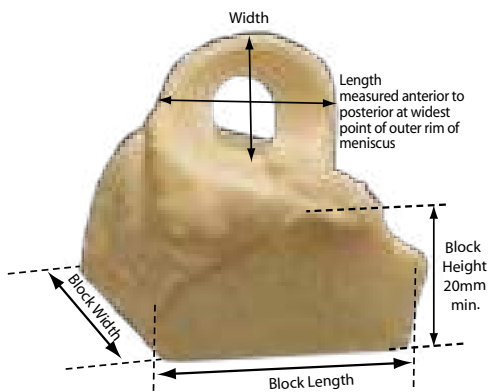
Achilles Tendon Preshaped

Specifications				Catalog #	
	Diameter	Width	Length	Aseptically Processed	Gamma Irradiated
Strut	10mm	-	25mm min.	02B003	50R102
Tendon	-	-	160mm min.		
Bundle	-	Measure	-		



Achilles Tendon with Strut

Specifications				Catalog #	
	Diameter	Width	Length	Aseptically Processed	Gamma Irradiated
Strut	Measure	12mm min.	25mm min.	02B002	50R103
Tendon	-	-	160mm min.		
Bundle	-	Measure	-		

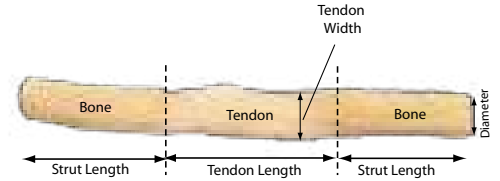


Meniscus Half

Specifications		Catalog #	
Graft	Size	Aseptically Processed	Patient Matched Aseptically Processed
Left Medial	Measure	90B007-X	90B007
Left Lateral	Measure	90B008-X	90B008
Right Medial	Measure	90B010-X	90B010
Right Lateral	Measure	90B011-X	90B011

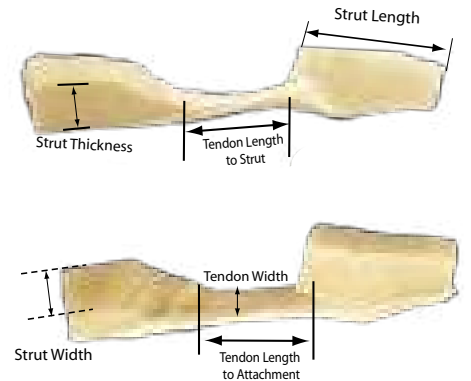
Patella Tendon Preshaped

Specifications				Catalog #	
Struts		Tendon		Aseptically Processed	Gamma Irradiated
Diameter	Length	Width	Length		
10mm	25mm min.	10mm min.	30 - 50mm	47B010	50R301



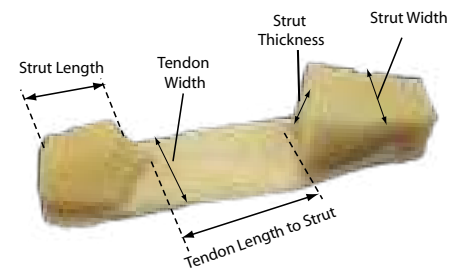
Patella Tendon with Strut- Half

Specifications				Catalog #		
	Thickness	Width	Length		Aseptically Processed	Gamma Irradiated
Tendon	-	10mm min.	To Strut	To Attachment		
			Measure	35mm min.		
Struts	12mm min.	10mm min.	25mm min.			

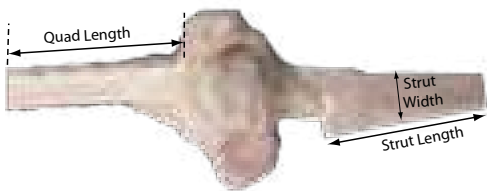


Patella Tendon with Strut- Whole

Specifications				Catalog #		
	Thickness	Width	Length		Aseptically Processed	Gamma Irradiated
Tendon	-	15mm min.	To top of Strut	To Attachment		
			Measure	35mm min.		
Struts	15mm min.	15mm min.	25mm min.			
w/ Quad	-	-	50mm min.		46B006	50R304



Sports Tissue Allograft

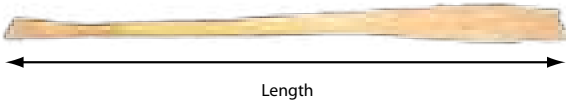


Patella Tendon w/Extensor Mechanism

Specifications				Catalog #
	Thickness	Width	Length	Aseptically Processed
Quad Tendon	-	-	120mm min.	46B020
Patella Tendon	-	Measure	35mm min. to attachment	
Tibial Strut	25mm min.	25mm min.	100mm min.	

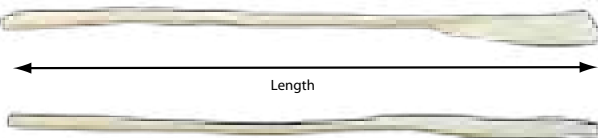
Peroneus Longus Tendon

Dimensions		Catalog #	
Diameter	Length	Aseptically Processed	Gamma Irradiated
8mm min. (Folded)*	240mm min.	81B006	50R401



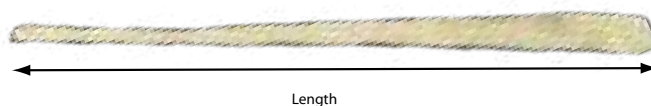
Semitendinosus/Gracilis

Dimensions		Catalog #		
Diameter	Minimum Length	Allograft Type	Aseptically Processed	Gamma Irradiated
4mm min. (Folded)*	200mm	Semitendinosus	81B003	50R502
3mm min. (Folded)*	200mm	Gracilis	81B004	50R501
8mm min. (Folded)*	200mm	Semitendinosus with Gracilis	81B005	50R503



Tibialis Tendon

Dimensions			Catalog #	
Diameter	Length	Allograft Type	Aseptically Processed	Gamma Irradiated
8mm min. (Folded)*	240mm min.	Anterior	81B001	50R601
		Posterior	81B002	50R602



How we measure our soft tissue allografts



*The diameter is determined by pulling the folded tendon through the appropriate channel of the sizing block smoothly and without excessive force.

Fresh Osteochondral Allograft



Over one million LifeLink allografts have been implanted since the tissue bank's inception. This amount is a direct result of our unwavering commitment to exceeding all FDA and industry standards.



Fresh Osteochondral Allograft

Our Fresh Osteochondral Allograft Program provides a variety of choices for repair of articular cartilage and subchondral bone defects. Osteochondral allografts eliminate the discomfort and morbidity associated with autogenous grafting. These allografts restore mobility to patients who suffer from pain and limited movement preventing them from enjoying daily activities. By transplanting mature hyaline cartilage with viable chondrocytes, patients may return to a more active lifestyle and prevent or delay more complicated and invasive joint replacement surgeries.

Fresh grafts have a short expiration time which requires detailed, coordinated planning in order to offer custom options for each qualifying patient. Microbiological testing is performed by our in-house CAP Accredited and CLIA Certified Laboratory. These Bio-Implants are only cleared for release after serology results are finalized.



Fresh Osteochondral Allograft

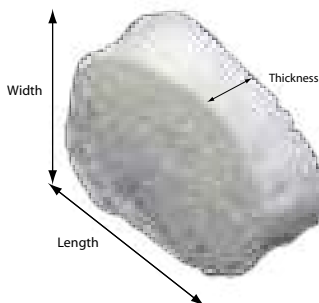
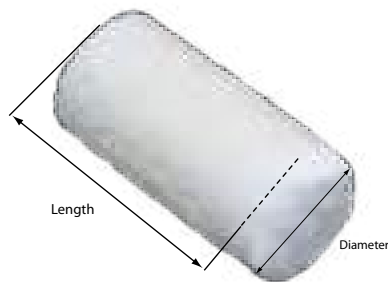
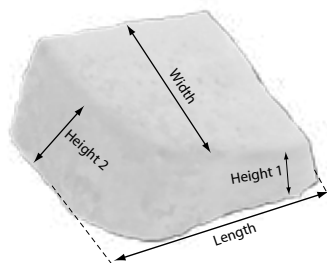
Description	Catalog #
Fresh Lateral Hemi Condyle, Left	98F001
Fresh Lateral Hemi Condyle, Right	98F002
Fresh Medial Hemi Condyle, Left	98F003
Fresh Medial Hemi Condyle, Right	98F004
Fresh Talus, Left	97F001
Fresh Talus, Right	97F002

General Orthopedic Allograft



Our continuous focus on service ensures that surgeons receive the allografts they need when they need them.





Bicortical Foot Wedge

	Specifications				Catalog #
	Height 1	Height 2	Width	Length	Freeze-Dried
6mm COTTON	2.5mm	6mm	14mm	24mm	67A006
8mm EVANS	3.5mm	8mm	22mm	20mm	67A008
10mm EVANS	5.5mm	10mm	22mm	20mm	67A010
12mm EVANS	7.5mm	12mm	22mm	20mm	67A012

Bone Plug

Diameter	Specifications	Catalog #
	Length	Freeze-Dried
12mm	18 mm min. - 25mm max.	03A003
13mm	18 mm min. - 25mm max.	03A006
14mm	18 mm min. - 25mm max.	03A004
16mm	18 mm min. - 25mm max.	03A005

Calcaneus Wedge

Thickness	Specifications		Catalog #
	Width	Length	Freeze-Dried
10mm	30mm min.	40mm min.	04A002

Cancellous 1-4mm

Specifications	Catalog #	
	Freeze-Dried	Frozen
5cc	05A101	05B101
15cc	05A001	05B005
30cc	05A002	05B006
60cc	05A008	05B009
90cc	05A010	05B007

General Orthopedic Allograft



Cancellous 4-10mm

Specifications	Catalog #	
	Freeze-Dried	Frozen
5cc	08A024	-
15cc	08A022	08B023
30cc	08A020	08B024
60cc	08A021	08B025
90cc	08A023	-



Cancellous 250-850µm

Specifications	Catalog #
	Freeze-Dried
15cc	07A001
30cc	07A004



Cancellous Block

Dimensions			Catalog #
Thickness	Width	Length	Freeze-Dried
20mm	20mm	40mm	09A004



Cancellous Cortical 1-4mm

Specifications	Catalog #
	Freeze-Dried
15cc	10A002
30cc	10A001

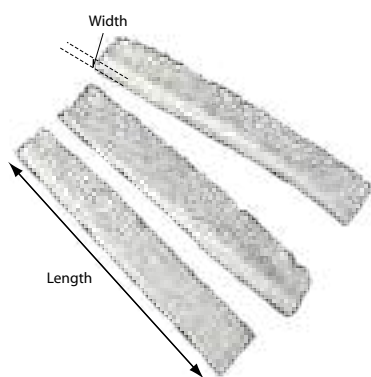


General Orthopedic Allograft



Cancellous Cortical 4-10mm

Specifications	Catalog #
	Freeze-Dried
15cc	19A002
30cc	19A001



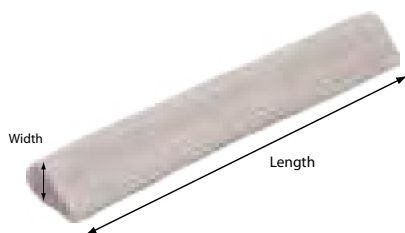
Cancellous Cortical Matchsticks

Specifications			Catalog #	
	Width	Length	Quantity	Freeze-Dried
Small	3 - 6mm	60mm	3 / Pack	18A008
			6 / Pack	18A006
Large	3 - 6mm	80mm	3 / Pack	18A009
			6 / Pack	18A005



Cancellous Cubes

Dimensions			Catalog #	
Thickness	Width	Length	Freeze-Dried	
10mm	10mm	10mm	13A001	4 pack
10mm	10mm	10mm	13A002	1 pack



Cortical Segment

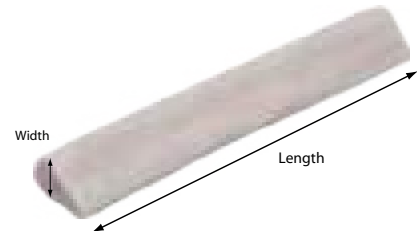
Specifications			Catalog #	
	Width	Length	Freeze-Dried	Frozen
Small	Measure	40 - 65mm	71A003	71B004
Large	Measure	66 - 99mm	71A004	71B005

General Orthopedic Allograft



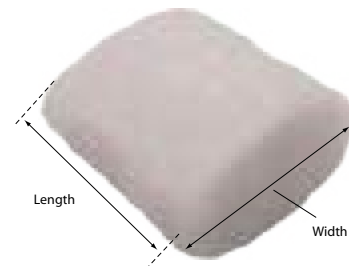
Cortical Shaft

Specifications			Catalog #	
	Width	Length	Freeze-Dried	Frozen
Small	Measure	100 - 125mm	72A002	72B005
Large	Measure	126mm min.	72A003	72B006



Costal Cartilage

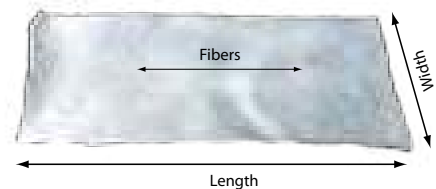
Dimensions		Catalog #
Width	Length	Frozen
10mm min.	30mm min.	70B001



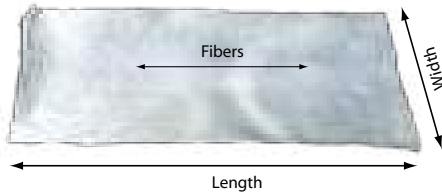
Fascia

Dimensions		Catalog #
Width	Length	Freeze-Dried
60mm min.	140mm min.	21A001

Dimensions		Catalog #
Width	Length	Frozen
80mm	80mm	21B007

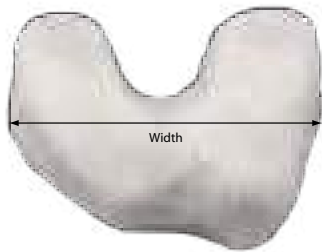


General Orthopedic Allograft



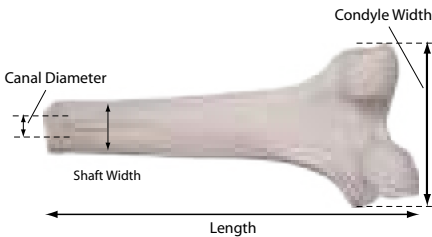
Fascia Strip

Dimensions		Catalog #
Width	Length	Freeze-Dried
40 - 60mm	50 - 140mm	21A005



Femur Condyle

Specifications		Catalog #	
Width		Freeze-Dried	Frozen
Measure Medial to Lateral	Whole	22A003	22B004
	Half	22A001	22B002



Femur Distal with Condyle

Specifications				Catalog #	
Overall Length	Condyle Width	Shaft Width	Canal Diameter	Frozen	
200mm min.	Measure	25mm min.	Measure	LEFT	23B002
	Measure	25mm min.	Measure	RIGHT	23B004



Femur Head

Specifications	Catalog #	
Diameter	Freeze-Dried	Frozen
40mm min.	24A001	24B002

General Orthopedic Allograft



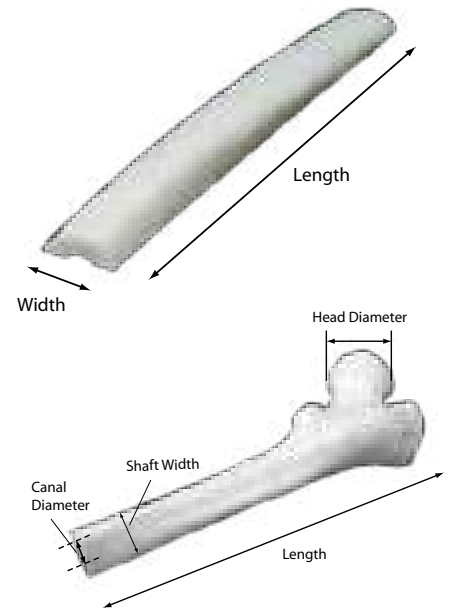
Femur Plate

Specifications		Catalog #	
Width*	Length	Freeze-Dried	Frozen
20mm min.	150mm min.	25A001	25B003

*Width is measured on smallest end of shaft

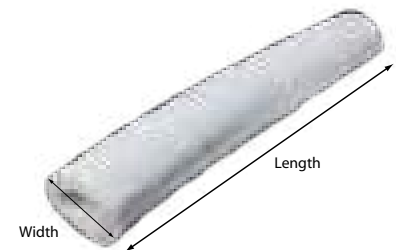
Femur Proximal with Head

Specifications				Catalog #	
Length	Head Diameter	Shaft Width	Canal Diameter	Frozen	
200mm min.	Measure	25mm min.	Measure	LEFT	30B002
	Measure		Measure	RIGHT	30B003



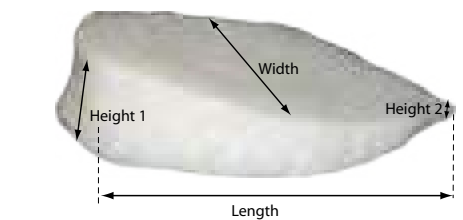
Femur Shaft

Specifications		Catalog #	
Width	Length	Freeze-Dried	Frozen
25mm min.	150mm min.	27A005	27B006



HTO Wedge

Specifications					Catalog #
Description	Height 1 +0 / -2.0mm	Width	Length	Height 2	Freeze-Dried
HTO Wedge 6°	7.5mm	Measure	Measure 35mm min. 50mm max.	Measure 3mm min.	64A106
HTO Wedge 8°	10.0mm	Measure			64A108
HTO Wedge 10°	12.5mm	Measure			64A110
HTO Wedge 12°	15.0mm	Measure			64A112
HTO Wedge 14°	17.5mm	Measure			64A114

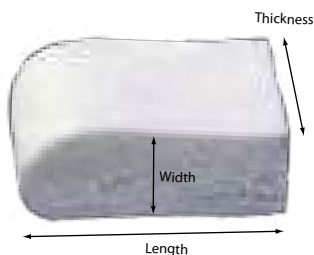
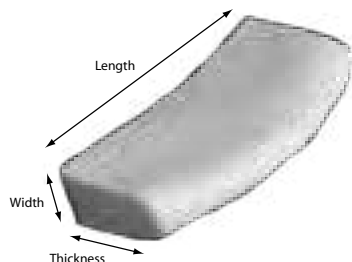
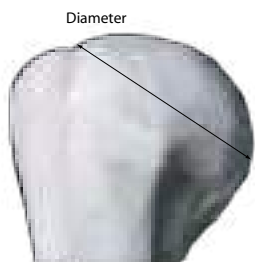


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Humerus Head

Specifications	Catalog #	
Diameter	Freeze-Dried	Frozen
40mm min.	34A001	34B002

Humerus Shaft

Specifications		Catalog #	
Width*	Length	Freeze-Dried	Frozen
15mm min.	100mm min.	37A002	37B003

*Width is measured on smallest end of shaft

Iliac Crest Strip

Specifications			Catalog #
Thickness	Width	Length	Freeze-Dried
15mm min.	9mm min.	50 - 80mm	40A003

Iliac Crest Wedge

Specifications				Catalog #	
	Thickness	Width	Length*	Freeze-Dried	Frozen
Sm.	7mm min. 14mm max.	9mm min.	18mm min. 25mm max.	40A002	N/A
Lg.	15mm min. 25mm max.	10mm min.	25mm min. 30mm max.	40A001	40B004

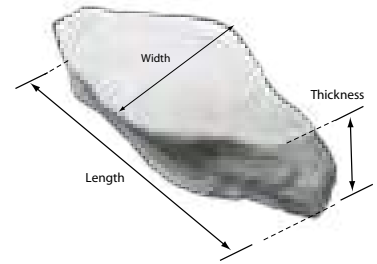
*No more than 3mm variance on length from side to side

General Orthopedic Allograft



Ilium Block Tricortical

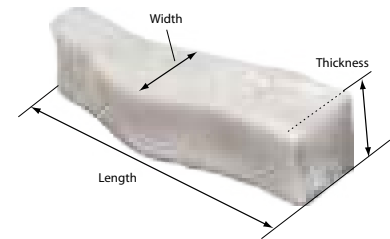
Specifications			Catalog #
Thickness	Width	Length	Freeze-Dried
15mm min. 25mm max.	20mm min.	75mm min.	39A002



Ilium Strip Tricortical

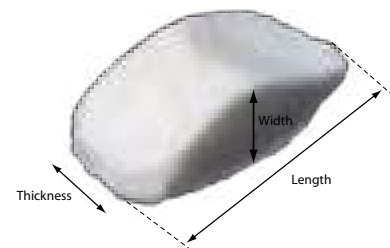
Specifications			Catalog #
Thickness	Width*	Length	Freeze-Dried
15mm min. 25mm max.	10mm min.	65mm min.	42A001

*Width is measured at centerline of graft

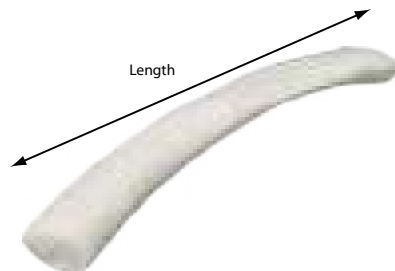


Patella Wedge

Specifications			Catalog #
Thickness	Width	Length	Freeze-Dried
15mm min.	13mm min.	30mm min.	46A005

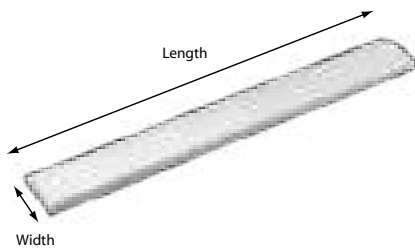


General Orthopedic Allograft



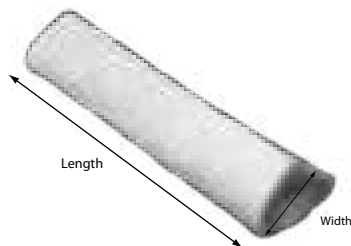
Rib Whole

Specifications	Catalog #
Length	Freeze-Dried
80mm min.	51A001



Tibia Plate

Specifications		Catalog #	
Width	Length	Freeze-Dried	Frozen
20mm min. - 30mm max.	150mm min.	56A001	56B002



Tibia Shaft

Specifications		Catalog #	
Width*	Length	Freeze-Dried	Frozen
Measure	150mm min.	59A002	59B003

*Width is measured on smallest end of shaft

Our formula for success is simple, unique and amazingly effective. We provide safe, superior allografts through an uncompromising series of processes.

A full service tissue bank since 1985, LifeLink ensures that all established state and federal standards for recovery, processing, packaging and distribution of human allograft tissue are met. Our motto, *Safety From The Beginning*®, is the cornerstone of LifeLink's unparalleled quality assurance and control. From using donor screening criteria that is among the strictest in the nation, to processing all bone and soft tissue utilizing cleanroom technology, we have earned a reputation in the surgical community for providing allografts of unsurpassed safety and quality.

The following are a few of the standards that set LifeLink apart:

- Our tissue comes strictly from federally designated OPOs (organ procurement organizations) including three LifeLink OPOs. We only recover tissue in a qualified recovery environment.
- All tissue is recovered and processed under aseptic conditions. All LifeLink musculoskeletal tissue is processed using Allowash® technology. While most of our grafts receive low dose gamma irradiation, the majority of all sports and demineralized allografts are non-irradiated.
- On-site CAP accredited microbiology laboratory.
- In-house Medical Directors available to tissue bank staff and medical screening personnel 24 hours a day, 7 days a week, 365 day a year.



We perform an average of 48 cultures per donation, because safety is in the details.

LifeLink goes to great lengths to ensure the safety of our allografts. In addition to evaluating the donor's medical and social history, relevant medical records and autopsy (if performed), comprehensive serologic testing is performed. An average of 48 microbiologic cultures are also performed from aseptic recovery through final allograft packaging. As a final safety measure, test samples equaling 10 percent of the non-irradiated allografts generated from each donor are destructively tested for the presence of microorganisms.

Blood screening includes the following:

- HIV1/HIV2 AB ■ HBsAg ■ HBcAb ■ HCVAb ■ *STS ■ HIV1/HCV/**HBV NAT
- *STS Serologic Test for Syphilis **HBV NAT performed on cases 016691 and higher

All tissue is determined to be suitable for transplantation after LifeLink Tissue Bank's Medical Directors perform a thorough review of all the items listed above in addition to toxicology (if applicable) and any other relevant medical/investigative records.

Our continuous focus on service ensures that surgeons receive the allografts they need when they need them.

Life changing allografts are of no use if they are not in the right place at the right time, delivered into a surgeon's hands. Understanding the timely importance of this process, LifeLink's highly trained customer service team is ready to respond 24/7, 365 days a year.

- All staff members have extensive knowledge of allograft tissue and their numerous surgical applications
- We are available to assist your hospital and surgeons with technical support, cost containment strategies and graft selection
- We can assist with consignment and inventory management
- We will work with your hospital to ensure that surgeons' allograft needs are fulfilled
- Joint Commission compliance and continuing education
- Service is available 24 hours a day, 7 days a week, 365 days a year



Emergency Requests:

- Staff is available 24 hours a day to handle any emergency
- Overnight express delivery is utilized for out-of-town orders
- Same day delivery arrangements are made for local emergency orders

Consignment Program:

- Wide range of grafts constantly available in the OR
- Hospital pays for allografts only after implantation
- Hospital does not bear loss from expired allografts
- Shipping, handling and restocking fees are eliminated on consigned allografts, including returns

Licenses and Certifications



LifeLink's ultimate goal is to preserve and improve a patient's quality of life.

LifeLink Tissue Bank is a division of the LifeLink Foundation, an independent not-for-profit organization, dedicated to the recovery and transplantation of organs and tissue. Since 1982, the Foundation has worked in a sensitive, diligent and compassionate manner to help save and improve lives. LifeLink Foundation consists of five divisions, which includes the tissue bank, three organ procurement organizations, and an immunology laboratory.

Licenses and Certifications

- LifeLink Tissue Bank is accredited by the American Association of Tissue Banks
- Registered with the FDA (FEI: 3008286876)
- Registered with Health Canada (CTO Certificate# 100144)
- Licensed by the States of Florida, California, and New York
- Holds a permit to distribute in Maryland and is registered in Delaware, Oregon and Illinois

Copies of LifeLink Tissue Bank's current licenses and accreditations can be obtained at <http://www.lifelinktissuebank.org/physicians-hospitals/certifications/>

Ordering LifeLink Allografts



LifeLink's Hospital Services department is available to answer questions and process requests Monday through Friday from 8:00 a.m. until 5:00 p.m. EST. On-call service is also available for emergencies after hours. Staff is available 24 hours a day, 7 days a week, 365 days a year.

Advanced ordering is recommended to ensure prompt delivery. A purchase order number is always required prior to shipment to effectively process an order.



To place an order call **1-800-683-2400** or email hs.orders@lifelinkfound.org

Shipping

All local orders are handled by an established courier service or FedEx. We utilize FedEx Priority for all orders outside the LifeLink service area. Same day delivery arrangements are made for emergency orders.

Packaging and Preservation

State-of-the-art techniques are utilized to package and preserve tissue. All packaging is completed in continuously monitored cleanrooms and placed in double heat sealed envelopes. Allografts are then preserved utilizing one of the following commonly accepted methods:

- **Freeze-drying or lyophilization:** This is the most commonly applied preservation method for tissues. Specific freeze-drying cycles are utilized to ensure a residual moisture level of 6% or less.
- **Freezing:** A method in which allograft tissue is packaged and then stored at -40 degrees celsius or colder.

Recommended Procedure for Handling and Reconstitution of Freeze-Dried Allografts

Freeze-dried allografts are stored at ambient temperature (11°C-25°C; 52°F-77°F). Rehydration time varies with the type of allograft. Freeze-dried weight bearing bone allografts that are to be sawed, drilled, or shaped should be rehydrated to ensure that the tissue will not be brittle. If the allograft is to be rehydrated longer than two hours, it should be refrigerated until use. Smaller non-weight bearing bone allografts generally do not require rehydration.

Once removed from the package, the allograft should be implanted immediately or refrigerated and used within 24 hours (if stored with proper precautions to prevent contamination).

Please refer to package insert for detailed instructions.

Recommended Procedure for Thawing Frozen Allografts

To prepare the allograft for use, it must be thawed. Thawing time for most frozen allografts is about 15-30 minutes at room temperature. For larger structural grafts, thaw for up to one hour. Soft tissue allografts must be thawed until they become soft and pliable.

Once thawed, the allograft should be implanted immediately or refrigerated and used within 24 hours (from start of thawing) if stored with proper precautions to prevent contamination.

Please refer to package insert for detailed instructions.

Transit and Storage Temperatures

Frozen allografts are shipped to the hospital on dry ice and should be stored at -40° Celsius or colder until use. Temperatures between -20° Celsius and -40° Celsius are acceptable for short-term storage (six months or less). For returns however, LifeLink only accepts frozen tissue that has been stored at -40° Celsius or colder. Unless it is being thawed for implantation, a graft removed from the freezer should be maintained in a transport container with dry ice completely surrounding the allograft. The time the graft is removed from and returned to the freezer should be documented in the Allograft Management Log. Care should be taken when working with dry ice, as burns may result from contact with unprotected skin.

Freeze-dried allografts do not have a specific required environmental temperature during shipping and are shipped at ambient temperature. Upon receipt, freeze-dried allografts should be stored at ambient temperature (11°-25°C; 52°F-77°F).

The methods of processing and storage utilized by LifeLink Tissue Bank are well documented and have been proven effective by many years of clinical experience.

Tracking

Traceability of each allograft is maintained by means of an automated system. Each allograft is assigned a unique identifying number that allows complete traceability from the donor through each stage in processing, storage and shipment to the end user. Included with each packaged allograft is an Allograft Implant Record which must be completed and returned to LifeLink Tissue Bank upon implantation. This information is essential for maintaining a complete record of all allografts shipped from LifeLink Tissue Bank.

Return Policies

This return policy is intended to allow return of certain allografts while at the same time ensuring adequate control of those factors that affect allograft safety and clinical effectiveness.

1. LifeLink Tissue Bank reserves the right to refuse to issue credit if return criteria have not been met. A \$25 handling fee will be charged for each allograft returned unless the reason for return is due to the result of an error for which the hospital or surgeon is not at fault.
2. If you encounter any problem with an allograft, have any questions, or if there is a patient complication possibly related to an allograft, please contact LifeLink Tissue Bank immediately at (800) 683-2400.
3. For consignment accounts, please contact the LifeLink Tissue Bank distribution location from which the allograft was ordered for return instructions.

Return Authorization

A Return Authorization Form and number must be obtained from LifeLink Tissue Bank. This completed form must accompany returned allografts in the transport container.

Criteria for Return of Human Allograft Tissue

Allograft must be stored in accordance with the temperatures defined in the LifeLink package insert.

Frozen Tissue

Frozen allograft tissue that has been stored in a monitored freezer maintained at -40°C or colder may be accepted for return within 5 days of shipment from LifeLink. A signed Tissue Storage Certification for Return must be on file with LifeLink Tissue Bank. If this form has not been completed, please call the LifeLink Distribution location from which the allograft was ordered to have the form faxed or sent to you:

Tampa (800-683-2400), **Norcross** (800-683-2400), and **Orlando** (800-781-3066).


Frozen allograft tissue that has not been stored in a monitored freezer maintained at -40°C or colder, must have been maintained on a minimum amount of dry ice in the original LifeLink transport package and packed so that the dry ice surrounds the allograft(s). In addition, return authorization must be obtained from LifeLink within 24 hours of receipt of the tissue at your facility. Tissue must be received by LifeLink within 48 hours of the return packaging date and time and no more than 3 days from when your facility initially received the tissue.

Freeze-Dried Tissue

- Allograft tissue must be returned within 30 days of receipt at facility.
- Integrity of allograft package must be intact. Return allografts in their original dust cover if possible.

For detailed information about returning allograft, please contact the LifeLink Tissue Bank Hospital Services department at 800-683-2400 or refer to LifeLink Tissue Bank's return policy.

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