

Sports Medicine

Allograft Solutions

Reference Manual



High-performance allograft solutions
for your active patients.



THE **VALUE** OF WORKING WITH LIFENET HEALTH

“My orthopedic surgeon suggested allograft fusion, which spared me a second surgery that would have been necessary to take bone from my body to complete the fusion.”

Safety

We have refined and defined safety in the allograft industry. Our validated processes, quality systems, and technologies are designed to ensure patient safety — reducing the probability of infection that could be caused by an allograft implant. In fact, since 1995, more than 7 million allografts processed using Allowash technology have been distributed by LifeNet Health with no disease transmission.

The thread of safety is woven through every step of the donation process, including:

- Stringent Donor Screening and Review
- Bacteria & Serology Testing
- Controlled Processing & Terminal Sterilization
- Medical Director Review & Release
- Physical Examination & Recovery Protocols

Quality

LifeNet Health's tissue-processing environment is designed to ensure allograft quality and safety. Through the consistent application of quality systems, quality control, and design control processes, LifeNet Health is both a medical device company and a tissue bank, and our allografts are designed and manufactured to ensure the highest possible quality. LifeNet Health grafts consistently perform as they should, allowing medical professionals to focus on the procedure, and patients to focus on healing. Year after year, this dedication to quality is validated internally and vetted by health-care organizations and industry partners, as well as government and industry regulators. The thread of safety is woven through every step of the donation process, including:

- Extraordinary Design Control Processes
- Validated Processes
- Quality Control Post-Processing Testing
- A product complaint rate of approximately 0.1%
- ISO, AATB, FDA, CLIA accreditations, registrations and certifications

Innovation

LifeNet Health is a leader in our industry, bringing clinicians, patients and researchers the most up-to-date solutions. LifeNet Health consistently provides the products, technologies, and services designed to improve safety, clinical effectiveness, ease of use and, ultimately, cost. Since opening its doors in 2012, the Institute of Regenerative Medicine has been a hub of research and development activity, dedicated to meeting clinical and scientific needs now — and in the future.



THE **VALUE** OF WORKING WITH LIFENET HEALTH

“Not only have you given my child health, you have taught her the most important lesson of life. To heal her own soul by looking beyond her own pain and thinking of what she can do for others.”

Service

LifeNet Health works with best-in-class distribution partners who are dedicated to meeting surgeon and patient needs and saving valuable time. LifeNet Health supports hospital staff by working with helping provide educational materials and customer support services. The thread of safety is woven through every step of the donation process, including:

- Dedicated Local Partner
- Scientific Expert Support
- Technical Support Services
- Clinical Education Services

Clinical Effectiveness

Our extensive portfolio of implants consistently performs at the highest level. LifeNet Health has invested considerable resources performing multiple clinical studies to ensure patients' outcomes are positive.

- More than 100 Published Studies
- More than 100 Patented Innovations

Supply Chain & Reliability

LifeNet Health has among the world's largest access to donor tissue through our dedicated recovery teams and partnerships with world-class, non-profit recovery agencies. Our global production and distribution infrastructure ensures uninterrupted distribution of our comprehensive portfolio of allograft implants.

- Multiple Processing Centers in U.S.
- Global Distribution Infrastructure
- Nationwide Recovery Network

Experience:

Many of the world's largest orthopedics companies rely on LifeNet Health's expertise and experience. As a non-profit organization, LifeNet Health is able to focus our energies and passion to our mission of saving lives and restoring health -- not shareholders' concerns for the bottom line.

- Over 35-Year Record of Success
- First ISO-Certified Tissue Bank
- Preferred allograft provider to six of *US News & World Report's* top 10 hospitals
- Longest-running AATB certification



INNOVATIVE TECHNOLOGIES



LifeNet Health has fundamentally changed how allografts are recovered and prepared, developing new technologies that make implants safer, easier to use and clinically effective. We continually invest in research and development to push through barriers and ensure that each donated gift has the greatest possible impact. These efforts have resulted in more than 100 patents to date.



Innovation in Sterilization Processes

Our patented Allowash XG sterilization process renders allograft bio-implants sterile, without compromising biomechanical or biochemical properties.



Innovation in Preservation Technology

Our proprietary Preservon technology allows bio-implants to be stored in a fully hydrated state at ambient temperature. This eliminates the need for lengthy rehydration and saves valuable operating room time.



Innovation in Demineralization Technology

Patented PAD Demineralization technology provides precise bone demineralization to target the ideal residual calcium level of 1-4 percent. This controlled process protects bone morphogenetic proteins (BMPs) while ensuring optimal osteoinductivity.

Innovation in Decellularization Technology

Matracell® decellularization renders allografts acellular, without compromising the biomechanical or desired biochemical properties of an allograft bio-implant for its intended surgical application



SPORTS MEDICINE SURGICAL SOLUTIONS

LifeNet Health's portfolio of allograft bio-implants most often used in sports medicine surgeries, such as knee and shoulder applications, are available in many different sizes to fit various applications. Your active patients require high performance solutions. And so do the surgeries you offer them. From routine ACL to complex reconstructions, LifeNet Health has high-quality allograft bio-implants with the biomechanical specifications you need to perform successful sports medicine surgeries.

Our Portfolio of Solutions

Osteobiologics

- FlexiGraft® Demineralized Cancellous Sponge
- FlexiGraft Demineralized Cortical Fibers

Acellular Dermal Matrix

- ArthroFlex®

Ligaments/Tendons

- FlexiGraft
- Patellar Ligaments
- Achilles Tendons
- Tibialis Tendons
- Peroneus Tendons
- Hamstrings
- Double Bundle None-Bone Tendons
- Quadriceps Tendon

Fresh Osteochondral Grafts

Constructs

- GraftLink®
- Connect
- QuadLink™

Other Grafts

- FlexiGraft Meniscus
- FlexiGraft Cancellous Plugs
- FlexiGraft Revision Dowels

Commitment to Quality

LifeNet Health's expertise in allograft tissue processing spans more than 35 years. Our refined processes, quality-control systems and proprietary disinfection protocols ensure the highest level of safety, reduced risk and better outcomes.

Multiple Processing & Distribution Locations

LifeNet Health has processing and distribution centers serve the entire country efficiently and reliably – minimizing the impact of uncontrollable events like weather.

Tissue Availability

We collaborate with more than 50 recovery partners across the US, all of whom are required to adhere to our strict standards of donor screening and recovery techniques. This enables us to maintain a ready supply of grafts for your hospital's needs.

Experience & Knowledge

Our staff brings more than 200 years experience in cardiac and vascular tissue processing, and we hold the longest-running American Association of Tissue Banks accreditation. In the latest US News "2017-2018 Best Hospitals for Pediatric Cardiology and Heart Surgery" report, LifeNet Health provides life-saving donor gifts to 9 of the Top 10 noted centers.



"People are saved in many different ways, not just through organs, but through tissues and tendons as well. I had the surgery in January 2016, and now have a new ACL from the tendon of your loved one."

Diane, ACL recipient

Osteobiologics


Surgical applications that require a bone void filler.

- Osteoconductive
- Osteoinductive potential
- Biocompatible
- Sterility Assurance Level (SAL) 10^{-6}
- Malleable, elastic, compressible after hydration
- Hydrophilic—naturally absorbs bioactive fluids like blood, PRP, and BMA
- No carrier or fillers like those found in putties or gels
- Will not migrate
- Room temperature storage

Demineralized Cancellous Sponge | FlexiGRAFT®

CUBES	Size	Freeze-Dried
	8 x 8 x 8 mm	BL-1100-001
	10 x 10 x 10 mm	BL-1100-003
	12 x 12 x 12 mm	BL-1100-002
STRIPS	Size	Freeze-Dried
	10 x 20 x 2 mm	BL-1300-001
	15 x 40 x 2 mm	BL-1300-002
	20 x 25 x 6 mm	BL-1300-003
	10 x 20 x 8 mm	BL-1300-004
CHIPS, 1 - 4 mm	Volume	Freeze-Dried
	1 cc	BL-1200-001
	2.5 cc	BL-1200-002
	5 cc	BL-1200-003

Demineralized Cortical Fibers | FlexiGRAFT®

FIBERS	Volume	Freeze-Dried
	1 cc	BL-1000-001
	2.5 cc	BL-1000-002
	5 cc	BL-1000-003
	10 cc	BL-1000-004

Ligaments/Tendons

Patellar Ligaments | FlexiGRAFT®

FlexiGraft tendons can be used for ACL or PCL Reconstruction procedures.



- Allows for bone-to-bone interface within tunnels
- Provided either whole, bisected or pre-shaped
- Tendon lengths vary
- Store frozen at -40° C to -80° C

PATELLAR LIGAMENTS	Size	Frozen
BISECTED PATELLAR LIGAMENT	10 mm Min. Insertion Width	FBPL
BISECTED PATELLAR LIGAMENT W/SMALLER BLOCK	10 mm Min. Insertion Width	FBPLSB
WHOLE PATELLAR W/SMALLER BLOCK	20 mm Min. Insertion Width	FWPLSB
WHOLE PATELLAR LIGAMENT	20 mm Min. Insertion Width	FWPL
WHOLE PATELLAR W/EXTRA QUAD	20 mm Min. Insertion Width Quad Length > 6.0 cm	FWPLQ

PRE-SHAPED PATELLAR	Size	Frozen
	10 mm Diameter Dowel	FPL10
	11 mm Diameter Dowel	FPL11



- ACL/PCL reconstruction
- Allows for bone-to-bone interface
- Tendon lengths vary
- Store frozen at -40° C to -80° C

Quadriceps Tendon | FlexiGRAFT®

QUADRICEPS TENDON	Size	Frozen
	10 – 12 mm Insertion Width	
QUADRICEPS TENDON W/BONE BLOCK	Bone Block Length = ≥ 20mm Quad Length 65-95 mm	FQUADB



- Can be used for multi-ligament surgery
- Can be trimmed to accommodate surgical procedure
- Allows for bone-to-bone interface
- Provided either whole or pre-shaped
- Store frozen at -40° C to -80° C

Achilles Tendons | FlexiGRAFT®

ACHILLES TENDON	Size	Frozen
W/OUT BONE BLOCK	> 160 mm	FAT
W/BONE BLOCK	> 160 mm	FATB

PRE-SHAPED ACHILLES	Size	Frozen
	10 mm Diameter Dowel	FATB10
	11 mm Diameter Dowel	FATB11

Tendons

Tibialis Tendons | FlexiGRAFT®



- Tunnel size can be predetermined
- Graft length for procedure can be predetermined
- Allows for various fixation techniques
- Available in short length configurations
- Diameters are measured as a double strand
- Store frozen at -40° C to -80° C

	Size	Frozen
ANTERIOR TIBIALIS TENDON: Short Length	Length 170 – 225 mm; Diameter 7.5 mm or >	FANT - SL
POSTERIOR TIBIALIS TENDON: Short Length	Length 170 – 225 mm; Diameter 7.5 mm or >	FPOST - SL
ANTERIOR TIBIALIS TENDON	Min. Length 230 mm; Min. Diameter 7.5 mm or >	FANT/TIB/T
POSTERIOR TIBIALIS TENDON	Min. Length 230 mm; Min. Diameter 7.5 mm or >	FPOST.TIBIAL

Peroneus Tendons | FlexiGRAFT®



- Store frozen at -40° C to -80° C

	Size	Frozen
PERONEUS LONGUS TENDON: Short Length	Length 170 – 225 mm; Diameter 7.5 mm or >	FPLT - SL
PERONEUS LONGUS TENDON	Min. Length 230 mm; Min. Diameter 7.5 mm or >	FPLT

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



Tendons



- ACL/PCL reconstruction
- Soft tissue applications
- Tendon-to-bone interface in femoral and tibial tunnel
- Diameter size of tunnels and length can be predetermined by physician
- Allows for various fixation techniques
- Diameters are measured as a double strand (except for FSTP)
- Store frozen at -40° C to -80° C

Hamstrings | FlexiGRAFT®

	Size	Frozen
SEMI-TENDINOSUS TENDON	Length 150 mm or > ; Diameter 4.0 – 5.5 mm	FROPE
SEMI-TENDINOSUS TENDON OR GRACILIS TENDON	Length 160 – 180 mm; Diameter 4.0 – 6.0 mm	FSTP
GRACILIS TENDON	Min. Length 230 mm; Min. Diameter 4.0 mm or >	FGRACILIS
SEMI-TENDINOSUS TENDON	Min. Length 230 mm; Min. Diameter 4.0 mm or >	FST

Two Posterior/Anterior/Peroneus Longus Tendons per pack.



- Allows for tendon to bone interface
- ACL/PCL reconstruction
- Store frozen at -40° C to -80° C

Double Bundle Non-Bone Tendons | FlexiGRAFT®

	Size	Frozen
2 POSTERIOR/ANTERIOR/PERONEUS LONGUS	Min. Length 230 mm; Min. Diameter 7.5 mm or >	FDBLTEND

Constructs



Preconstructed allograft tendons designed to be used with Arthrex® implants for ACL and PCL reconstructions.

- Triple or Quadruple strand construct
- Pre-assembled with Arthrex® FiberWire®
- ACL and PCL reconstruction
- Store frozen at -40°C to -80°C

GraftLink® | FlexiGRAFT®

	Size	Frozen
QUAD-STRAND	Length 60 – 80 mm Diameter 7.5 – 10.5 mm	FGL
TRI-STRAND	Length = 65 – 95 mm Diameter = 8.5 – 12.5 mm	FGLTS



- Single Strand Construct
- Pre-assembled with Arthrex® FiberWire®
- ACL reconstruction
- Store frozen at -40°C to -80°C

QuadLink™ | FlexiGRAFT®

	Size	Frozen
PRE-SUTURED QUADRICEPS TENDON	Length 60 – 75 mm Diameter 9.0 – 11.0 mm	FQL



A pre-sutured, pre-sized allograft construct designed for use in various ligament reconstructions.

- Single Strand Construct
- Pre-assembled with Arthrex® FiberWire®
- Store frozen at -40°C to -80°C

Connect | FlexiGRAFT®

	Size	Frozen
PRE-SUTURED LATERAL ANKLE TENDON	Length = 150 – 160 mm Diameter 4.0 – 5.0 mm	FPSST
CONNECT	Length = 150 – 250 mm Diameter = 4.0 – 5.0 mm	FCON
CONNECT EXTREMITY	Length = 140 – 200 mm Diameter = 3.0 mm	FCONEXT

CONNECT, GRAFTLINK, QUADLINK, and Lateral Ankle may not be approved for use in all markets

Soft Tissue



Decellularized dermis for use in soft tissue repair applications.

- Superior capsular reconstruction
- Rotator cuff and tendon augmentation applications
- Retains native growth factors, collagen and elastin*
- $\geq 97\%$ donor DNA removed for biocompatibility
- Room temperature storage for excellent handling and minimal prep time
- Sterile, SAL 10^{-6}

* Data on file at LifeNet Health, TR-0292.



Decellularized Dermis | ArthroFLEX®

0.5 mm (Thickness = 0.3 mm - 1.0 mm)	Size	Room Temperature
	30 x 40 mm	AFLEX500
1.0 mm (Thickness = 0.76 mm - 1.24 mm)	Size	Room Temperature
	40 x 40 mm	AFLEX400
	40 x 70 mm	AFLEX401
1.5 mm (Thickness = 1.26 mm - 1.74 mm)	Size	Room Temperature
	35 x 35 mm	AFLEX100
	40 x 70 mm	AFLEX101
	50 x 90 mm	AFLEX103
	15 x 140 mm	AFLEX150
2.0 mm (Thickness = 1.76 mm - 2.24 mm)	Size	Room Temperature
	35 x 35 mm	AFLEX200
	40 x 70 mm	AFLEX201
	25 x 30 mm	AFLEX202
2.0 mm (Thickness = 1.76 mm - 2.24 mm)	Size	Room Temperature
BioWasher®, 2 pack	10 x 14 mm	AFLEX822
3.0 mm (Thickness = 2.5 mm - 3.5 mm)	Size	Room Temperature
SCR	40 x 50 mm	AFLEX300
	40 x 70 mm	AFLEX301
	50 x 60 mm	AFLEX302

Fresh Osteochondral Allografts

Fresh osteochondral allografts are used for repair of articular cartilage and subchondral bone defects.

- Repair of articular cartilage and subchondral bone defects
- Stored at 1 – 10°C in nutrient rich media with antibiotics
- Custom/special grafts also available

Order Code	Product Description
ATL80	Ankle Talus (Left)
ATR80	Ankle Talus (Right)
FCA80	Fem Condyle Hemi (Left Lateral)
FCB80	Fem Condyle Hemi (Left Medial)
FCC80	Fem Condyle Hemi (Right Medial)
FCD80	Fem Condyle Hemi (Right Lateral)
FCL80	Fem Condyle Whole (Left)
FCR80	Fem Condyle Whole (Right)
FHL80	Femoral Head (Left)
FHR80	Femoral Head (Right)
HHL80	Humeral Head (Left)
HHR80	Humeral Head (Right)
TDL80	Tibia Distal (Left)
TDR80	Tibia Distal (Right)
TFL80	Tibial Plateau with Meniscus (Left)
TFR80	Tibial Plateau with Meniscus (Right)
PAL80	Patella bone with Attachments (Left)
PAR80	Patella bone with Attachments (Right)
PCA80	Partial Condyle (Left Lateral)
PCB80	Partial Condyle (Left Medial)
PCC80	Partial Condyle (Right Medial)
PCD80	Partial Condyle (Right Lateral)
FTR80	Femoral Trochlea (Right)
FTL80	Femoral Trochlea (Left)
FTD80	Bi-Compartment (Right Lateral & Trochlea)
FTC80	Bi-Compartment (Right Medial & Trochlea)
FTA80	Bi-Compartment (Left Lateral & Trochlea)
FTB80	Bi-Compartment (Left Medial & Trochlea)
RFPI0	10 mm Diameter Plug
RFPI6	16 mm Diameter Plug

Fresh grafts are available on a special order basis only. Please contact LifeNet Health Client Services at **1-888-847-7831** or email **freshorders@lifenethealth.org** for special ordering and processing procedures.


Other Grafts

Meniscus | FlexiGRAFT®

Meniscal transplant processed with tibial bone block to allow for surgical technique flexibility such as double bone plug technique, keyhole technique or dove tail technique.

- Custom Sizing Our extensive measurement parameters are designed to find the most precise fit for the patient
- Allows for various surgical techniques
- Store frozen at -40° C to -80° C

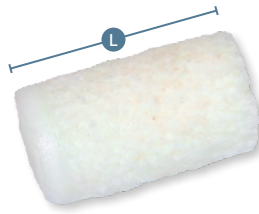


	Size	Frozen
	Left Lateral Meniscus (Varies)	FMN LL
	Left Medial Meniscus (Varies)	FMN LM
	Right Lateral Meniscus (Varies)	FMN RL
	Right Medial Meniscus (Varies)	FMN RM

Cancellous Plugs | FlexiGRAFT®

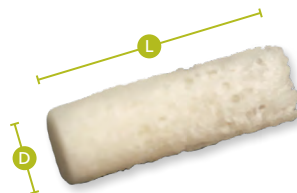
FlexiGraft Cancellous Plugs are sterile plugs of 100% cancellous bone for use in backfilling autograft OATS® procedures.

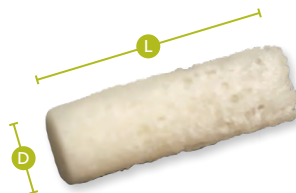
- 16 mm length
- Store frozen at -40° C to -80° C



WITH CARTILAGE	Diameter	Frozen
	7 mm	FCPD7
	8 mm	FCPD8
	9 mm	FCPD9
	10 mm	FCPD10
	11 mm	FCPD11

WITHOUT CARTILAGE



WITHOUT CARTILAGE	Diameter	Preservon
	6 mm	PCPD6
	7 mm	PCPD7
	8 mm	PCPD8
	9 mm	PCPD9
	10 mm	PCPD10
	11 mm	PCPD11

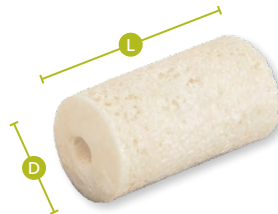
- Room temperature storage

Other Grafts

Revision Dowels | FlexiGRAFT®

FlexiGraft Revision Dowels are 100% cancellous bone with a thin cortical plate for use in backfilling tunnels created during ACL/PCL procedures.

- Does not have cartilage
- Fully cannulated with chamfered tip for easy insertion
- Room temperature storage



Standard Length 25 - 29 mm

Diameter

Fully Cannulated

9 mm

PCD9

10 mm

PCD10

11 mm

PCD11

12 mm

PCD12

13 mm

PCD13

14 mm

PCD14

16 mm

PCD16

18 mm

PCD18

20 mm

PCD20

22 mm

PCD22

Extra Long Length 30 - 35 mm

Diameter

Fully Cannulated

9 mm

PCDXL9

10 mm

PCDXL10

11 mm

PCDXL11

12 mm

PCDXL12

13 mm

PCDXL13

14 mm

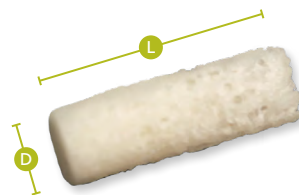
PCDXL14

16 mm

PCDXL16

18 mm

PCDXL18



Notes

LifeNet Health helps to save lives, restore health and give hope to thousands of patients each year. We are the world's most trusted provider of transplant solutions, from organ procurement to new innovations in bio-implant technologies and cellular therapies—a leader in the field of regenerative medicine, while always honoring the donors and healthcare professionals that allow the healing process.

LifeNet Health, the LifeNet Health logo, Allowash, Allowash XG, ArthroFlex, FlexiGraft, and Preservon are registered trademarks of LifeNet Health.

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