



ReadiGRAFT BLX Sponge

Demineralized Cancellous Cubes, Strips, and Chips for
Spine & Orthopedic Procedures

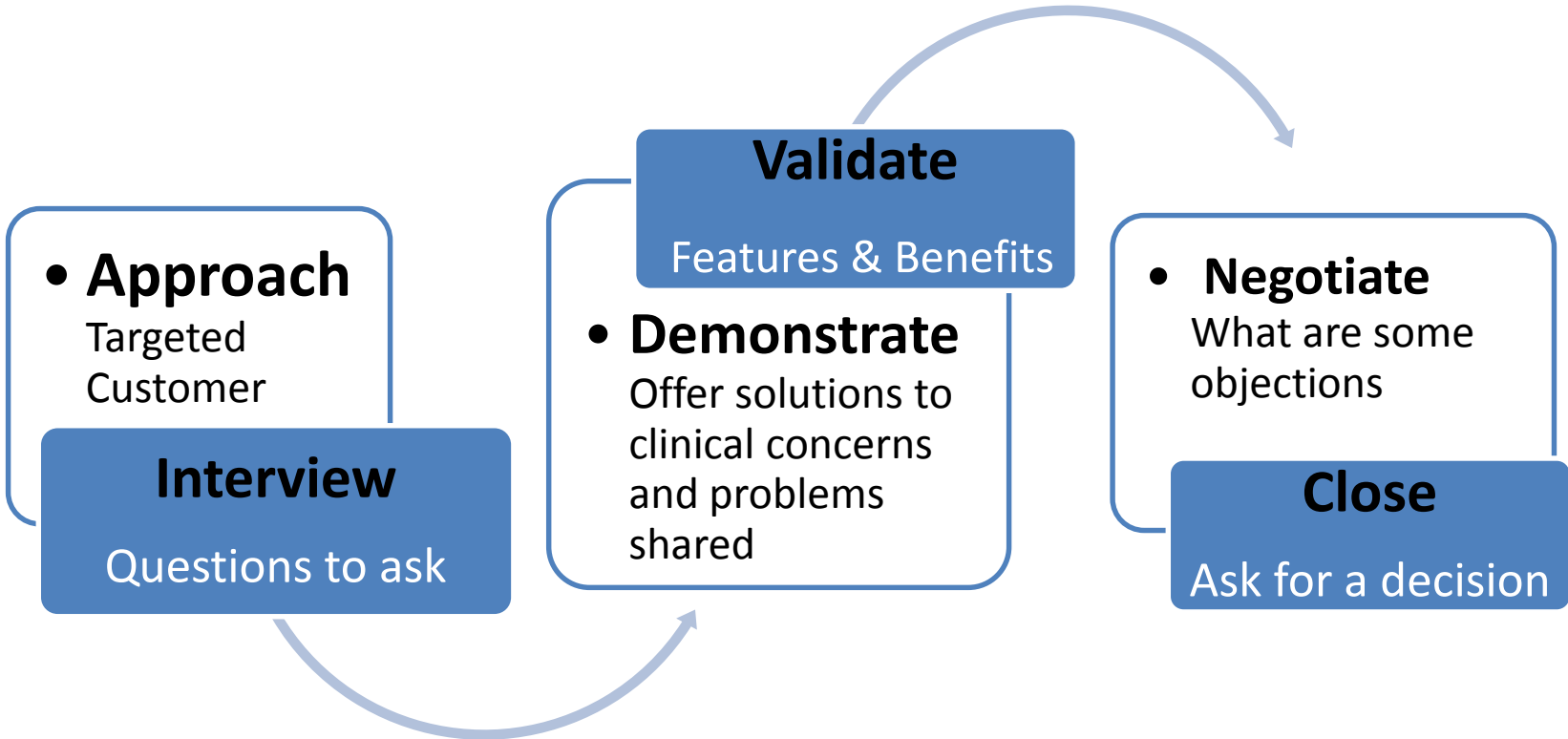


Objectives

- Summarize the product overview of ReadiGraft BLX Sponge
- Identify the types of product application
- Outline the features & benefits of ReadiGraft BLX Sponge
- Describe the clinical data for ReadiGraft BLX Sponge
- Identify the available marketing tools
- Outline product logistics



Integrity Selling



ReadiGRAFT BLX Sponge Overview & Description

- Demineralized cancellous cubes, strips, and chips
- Provides a natural osteoconductive scaffold for new bone growth
- Demineralization exposes natural growth factors with osteoinductive potential
- Compressible graft conforms to the defect site and resists migration under irrigation
- **Targeted Customer:** Spine, orthopedic, oncology, and trauma surgeons who use bone void fillers



Approach
Who is your Targeted Customer?



Uncovering the Clinical Need

- To fill the void and promote bone healing of an osseous defect that isn't intrinsic to the structural stability of the bone
- Used when:
 - A patient requires an augmented solution to promote healing
 - Autograft is insufficient
 - Additional volume is needed

Interview

What does the clinician need?





Clinical Solutions

- Used to fill osseous defects caused by trauma or created during surgical procedures
 - Minimize need for a secondary surgical site
 - Provide a natural osteoconductive scaffold that allows cell infiltration and vascular ingrowth which helps promote natural bone healing
 - Demineralization exposes natural growth factors with osteoinductive potential to promote bone remodeling and growth

Demonstrate

Can you offer solutions to clinical concerns and problems shared?



Clinical Applications: Spine



- Fill interbody spacers



- Bridge transverse processes

Demonstrate

*Which application is best
for your customers
practice?*



Clinical Applications: Orthopedics-Osteotomy



- Promote healing after a knee osteotomy



- Fill corrective osteotomy void after a fracture

Demonstrate
*Which application is best
for your customers
practice?*



Clinical Applications: Orthopedics – Ankle Fusion



- Used to augment ankle arthrodesis

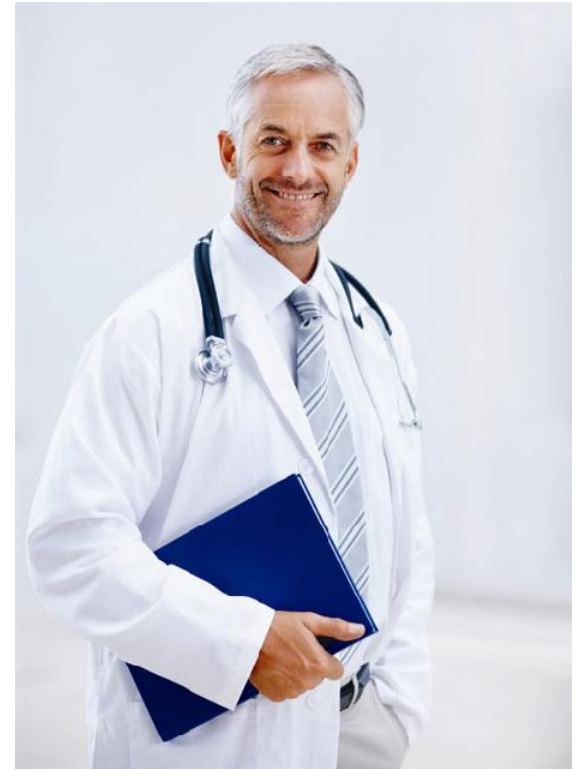
Demonstrate
*Which application is best
for your customers
practice?*





Clinical Applications

Clinician preference and practice will dictate what size and configuration of grafts are needed as multiple configurations can be used in each of these procedures



Comparison of graft types offered

	Advantages	Disadvantages
ReadiGraft BLX Sponge	<ul style="list-style-type: none"> ✓ Demineralization exposes natural growth factors with osteoinductive potential ✓ Excellent handling after rehydration to conform and fill defect ✓ Surgeon may hydrate with fluids of choice ✓ Sterile – Sterility Assurance Level (SAL) 10⁻⁶ 	<ul style="list-style-type: none"> ✓ Concerns about disease transmission ✓ Requires hydration for optimal handling
Mineralized Allograft	<ul style="list-style-type: none"> ✓ Strong clinical efficacy ✓ Readily available ✓ Room temperature storage (freeze dried) ✓ Natural matrix – closely resembles autograft 	<ul style="list-style-type: none"> ✓ Concerns about disease transmission ✓ Preparation time required ✓ Growth factors are not readily accessible
Autograft	<ul style="list-style-type: none"> ✓ No immunogenicity issues ✓ Contains growth factors ✓ Long history of use 	<ul style="list-style-type: none"> ✓ Limited availability ✓ Requires second site surgery ✓ Increased patient morbidity
Xenograft	<ul style="list-style-type: none"> ✓ Readily available 	<ul style="list-style-type: none"> ✓ Low biocompatibility profile ✓ Increased risk of immunogenicity¹⁻⁸ ✓ Limited safety & efficacy research
Synthetic	<ul style="list-style-type: none"> ✓ Readily available 	<ul style="list-style-type: none"> ✓ Low biocompatibility profile ✓ Increased risk of immunogenicity⁴⁻⁵ ✓ Less safety & efficacy research



Features & Benefits

	Feature	Benefit
Performance	Compressible properties when rehydrated	Graft can conform to defect and resist migration under irrigation
	Demineralization exposes natural growth factors	Promotes natural bone healing
	Natural osteoconductive scaffold	Allows for cellular attachment and vascular ingrowth
	Absorbs and retains bio-active fluid	Surgeon can customize hydration to meet intraoperative needs
Biocompatibility	100% human bone	Will remodel alongside patient's own tissue during healing process
Safety	Medical device grade sterility (SAL 10 ⁻⁶)	Reduced risk of disease transmission

Validate
What features and benefits will support the clinician's needs?



Supporting Documents

- Clinical Publications
 - White Paper: Histological Evaluation of Demineralized Cancellous Sponge (68-20-051)



Validate

What clinical data would you want them to know?



Marketing Tools

- Spec Sheet: ReadiGRAFT BLX Sponge (68-60-025)
- VAC Package: ReadiGRAFT BLX Sponge (68-80-015-02)

Contact LifeNet Health for available marketing tools and other supporting documents.



Logistics - Sizes Available

RediGraft BLX Sponge Cubes	
Order Code	Size
OSC1003	8 x 8 x 8 mm
OSC1000	10 x 10 x 10 mm
OSC1001	12 x 12 x 12 mm
OSC1002	14 x 14 x 14 mm

RediGraft BLX Sponge Chips (1-8 mm grind)	
Order Code	Volume
OSF2000	2.5 cc
OSF2001	5 cc
OSF2002	10 cc

RediGraft BLX Sponge Strips	
Order Code	Size
OSS3001	10 x 20 x 2 mm
OSS3002	15 x 40 x 2 mm
OSS3003	20 x 50 x 2 mm
OSS3004	20 x 25 x 6 mm
OSS3005	15 x 20 x 6 mm
OSS3006	10 x 20 x 8 mm



Logistics – Packaging

- Packaged in clear tray within a larger clear tray
 - Double sterile barrier
- External packaging features:
 - Shipped in corrugated cardboard box (ambient storage)
 - Cutout window to allow label to clearly show through
 - Outer package dimensions
 - 3.08 x 1.19 x 4.37 cm (Cubes)
 - 4.63 x 1.31 x 5.75 cm (Strips and Filler)



Logistics - Labeling

- The label states the:
 - Order code
 - Volume
 - Graft ID
 - Storage requirements
 - Expiration date



Logistics – Instructions for Use

- Shelf life of up to 5 years
- Allograft Bio-Implant Instructions for Use (63-0116)
 - Rehydrate until required consistency and handling are achieved

Allograft Bio-Implant
Instructions for Use

LifeNet Health

1384 Concert Drive | Virginia Beach, VA 23462, USA
1-800-447-1100 (inside the US) | 1-757-464-4760 (outside the US)
www.LifeNetHealth.org
Source: SmithKlineBeecham LifeNet Health CTO #00038

Allograft Bio-Implant

Read this entire package insert carefully prior to use.

Federal law (FDA) restricts this Allograft Bio-Implant for use by a licensed health care provider.

DESCRIPTION
This allograft bio-implant was processed from donated human tissue, resulting from the generous gift of an individual or his/her family. The bio-implant was cleaned and disinfected through a proprietary process.

There are three preservation methods included in these instructions: frozen, freeze-dried, and packaged with Resorcinol. Please refer to the label to identify which preservation method was utilized for this bio-implant.

WARNING
Bio-implants that are red, pink or white in color on the label are red, pink or white in color and adhere a white substance (SAL) if dry.

INDICATIONS FOR USE
This allograft bio-implant is intended for implantation.

CONTRAINDICATIONS
The contraindications include, but are not limited to:
- Use in any patient who has a known or suspected allergy to any of the antibiotics and/or preservative agents listed in the package insert.

WARNINGS AND PRECAUTIONS
The same medical/surgical conditions or complications that apply to any surgical procedure may occur during or following implantation. The surgeon is responsible for informing the patient of the risks associated with their treatment and the possibility of complications or adverse reactions. As with any allograft bio-implant, the potential for transmission of infectious agents exists.

The bio-implant may contain residual antibiotics (Bacitracin, Gentamicin and/or Polymyxin B sulfate), alcohol, surfactants, and/or glycerol. Caution should be exercised if the patient has a known sensitivity to any of these antibiotics and/or agents.

POTENTIAL ADVERSE EVENTS
Potential adverse events or outcomes include, but are not limited to, infection, allograft tissue rejection, allergic reaction to residual preservative agents, rejection and/or death.

Promptly report any adverse event(s) or outcome(s) potentially attributable to the allograft bio-implant (see **COMPLAINTS AND RETURNS** section).

STERILIZATION AND TESTING
All devices have been opened and issues reviewed, processed, stored, tested and distributed in accordance with current US federal regulations as promulgated in 21 CFR 312.62 and 312.71, current standards for Tissue Banking set forth by the American Association of Tissue Banks (AATB) and international laws and regulations as required.

This allograft bio-implant was deemed suitable for implantation by LifeNet Health. A physician medical director evaluated the following donor variables to determine donor suitability: infectious disease test results, current donor medical history, behavioral risk assessment interview, physical assessment, relevant medical records, including previous medical history, laboratory test results, and autopsy or cancer reports (if performed).

All devices are tested for relevant infectious diseases. Testing is performed by laboratories that are certified with the ISO 9001 and ISO 13485 certifications.

INSTRUCTIONS FOR USE
It is important to read and understand the following instructions prior to clinical use. Improper preparation technique may adversely affect handling properties and/or performance.

GENERAL INSTRUCTIONS:

- Use on a single occasion for a single patient only.
- Once the packaging is opened, the bio-implant must be used for the current procedure or discarded.
- Inspect the bio-implant, inner and outer packaging, and labels carefully.
 - Do not use past the expiration date as indicated on the label.
 - Do not use if the bio-implant is damaged or the packaging integrity is compromised.
 - Do not use if there are discrepancies in label information.
- Use aseptic technique at all times.
- Do not use dry.
- Keep the bio-implant stored according to recommended storage instructions until preparing for the implantation.

PREPARED / PRECISEM BIO-IMPLANTS

OPENING INSTRUCTIONS:

1. **New Sterile Team Member:** Peel open outer tray lid & break and present inner contents to the Sterile Team Member.
2. **Sterile Team Member:**
 - a. If the bio-implant is packaged in a plastic tray, firmly grasp the "Red View" tab and remove from outer tray. If rehydration is performed by the physician, place the bio-implant in a sterile basin and follow the appropriate preparation for use below.
 - b. If the bio-implant is packaged in a jar, firmly grasp the jar and remove from outer tray. If rehydration is performed by the physician, keep the bio-implant in the jar and follow the appropriate preparation for use below.

PREPARATION FOR USE:

- 3a. **Rehydration:** It is recommended to rehydrate the bio-implant in sterile irrigant per physician preference.
- 3b. **Storage:** After rehydrating, refer to the table below for the recommended rehydration solutions. Rehydration media may include antibiotic solution, sterile saline, 1% NaCl, blood, plasma, bone marrow, or other specific blood components.

Allograft Bio-Implant Type	Recommended Rehydration Instructions
Soft-Tissue Femur, Humerus, Radius, Carp	Submerge for a minimum of 20 minutes.
All Other Allograft Bio-Implants	Submerge until required consistency and handling are achieved as per physician preference.

PRECISEM BIO-IMPLANTS

OPENING INSTRUCTIONS:

1. **New Sterile Team Member:** Open the outer pack and present the inner pouch to the Sterile Team Member.
2. **Sterile Team Member:** Firmly grasp the inner pouch and remove from outer pack. Peel open inner bag and place the bio-implant in a sterile basin.
3. **New Sterile Team Member:** Open the outer pack and present the inner bag. Do NOT present the inner or outer bag to the Sterile Field.
4. **Sterile Team Member:** Open the inner bag and present the bio-implant to the Sterile Field.

PREPARATION FOR USE:

Rehydration Solutions & Bagging:

1. Refer to the table below for the recommended rehydration time based on bio-implant type. Rehydration times are provided for three different rehydration techniques.
2. If solution soak technique is utilized, the following solutions may be used for rehydrating antibiotic solution, sterile saline, 1% NaCl, blood, plasma, bone marrow, or other specific blood components.

WARNING: Once the bio-implant is opened, it must be used during the current procedure or discarded. Do not rehydrate or rehydrate the bio-implant after rehydration has begun.

Allograft Bio-Implant Type	Soak Rehydration (Submerge)	Flow Rehydration (100% - 40%)	Soak Rehydration (Soak Bag)
Soft-Tissue (Femur)	5 minutes	20 seconds	20 seconds
Soft-Tissue (Femur)	10 minutes	10 seconds	2 minutes
Radius, Humerus, Femoral	15 minutes	10 seconds	2 minutes
Other Allograft Tissue	30 minutes	5 minutes	10 minutes

RELIABILITY
It is the responsibility of the end-user to maintain accurate records for the purpose of tracking tissue post-implantation. As a courtesy to the end-user clinician or facility, LifeNet Health has included a Graph Implant Tracking Card to assist in the post-implantation tracking. Please refer to the enclosed card for additional information.

COMPLAINTS AND RETURNS
If you have a complaint or issue, or to report a complaint or issue, please contact your authorized distributor or LifeNet Health Client Services. You may contact your distributor at 1-800-447-1100 (inside the US) or 1-757-464-4760 (outside the US), and have the following information ready: (1) your name, (2) your facility name, (3) your contact information, and (4) the date of the complaint.

WARRANTY STATEMENT
Due to the inherent variability of allograft tissue, biological and mechanical performance cannot be guaranteed.





Knowledge Check

RadiGraft BLX Sponge is osteoconductive and has exposed growth factors.

- A. True
- B. False





Knowledge Check

To prepare REDIgraft BLX Sponge:

- A. Thaw the graft for 5-10 minutes.
- B. Rehydrate the graft until desired consistency is achieved.
- C. Rinse in sterile irrigant per surgeon preference prior to use.





Knowledge Check

Which clinical application is **not** indicated for REDIgraft BLX Sponge on its own?

- A. Filling a vertebral spacer to promote fusion
- B. Fracture repair that requires structural support
- C. Filling a biopsy defect





Knowledge Check

ReadiGraft BLX Sponge is available as:

- A. Cubes
- B. Strips
- C. Filler
- D. All of the above





Knowledge Check

Which of the following is **not** true about REDIgraft BLX Sponge grafts?

- A. They retain and absorb bioactive fluid
- B. They contain materials derived from animal tissue.
- C. They have a SAL of 10^{-6} .



References

¹Aurora A, McCarron J, Ianotti J, Derwin K. Commercially available extracellular matrix materials for rotator cuff repairs: State of the art and future trends. *J Shoulder Elbow Surg* 2007;16(5 Suppl):S171-178.

²Iannotti JP, Codsì MJ, Kwon YW, et al. Porcine small intestine submucosa augmentation of surgical repair of chronic two-tendon rotator cuff tears. A randomized, controlled trial. *J Bone Joint Surg Am* 2006;88(6):1238-1244.

³Miller L, Block J. Perspectives on the clinical utility of allografts for bone regeneration within osseous defects: a narrative review. *Orthop Res Rev* 2011;3:31-37.

⁴Giannoudis P, Dinopoulos H, Tsiridis E. Bone substitutes: an update. *Injury* 2005;36: S20-27.

⁵Halim AS, Khoo TL, Mohd Yussof SJ. Biologic and synthetic skin substitutes: an overview.

