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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

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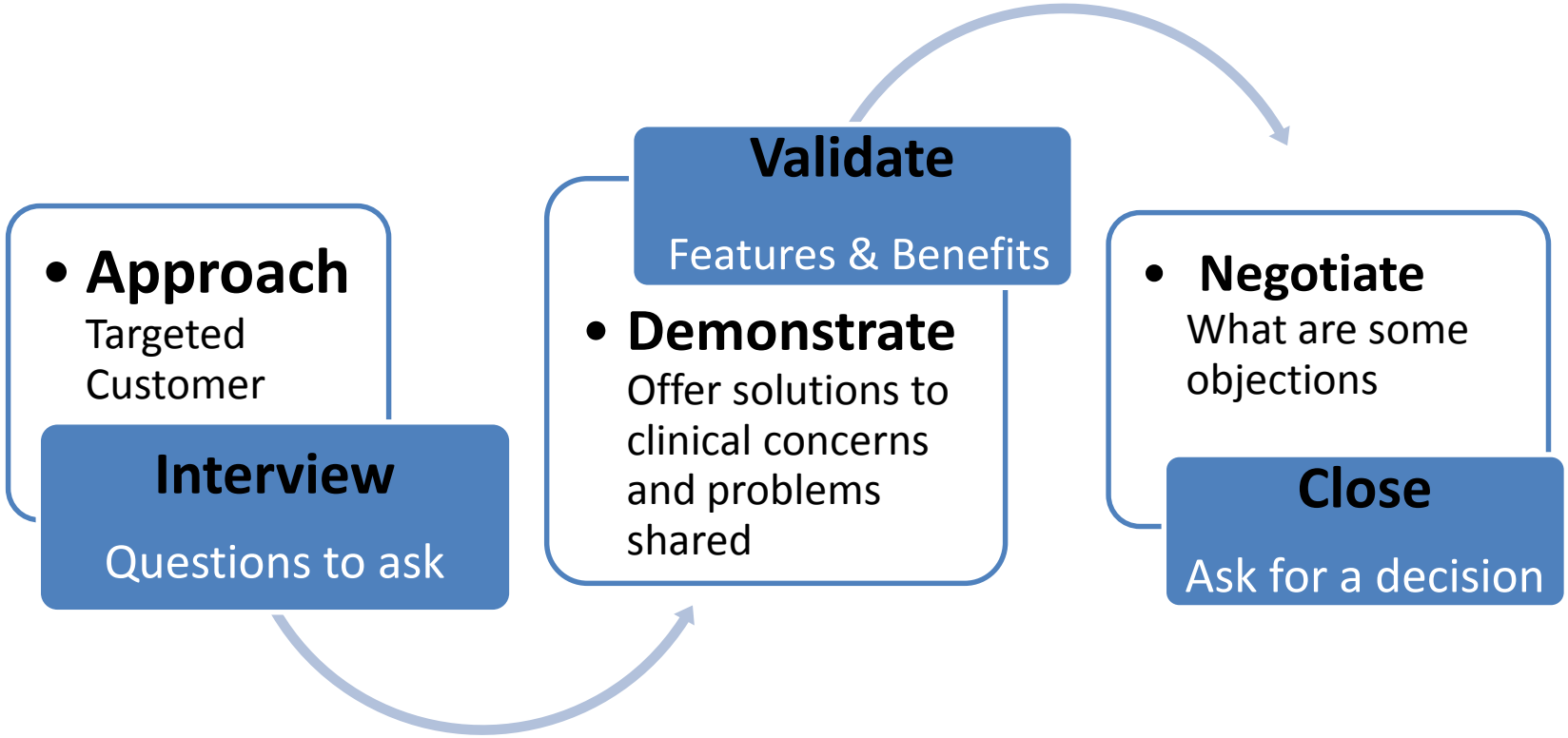
Integrity Selling



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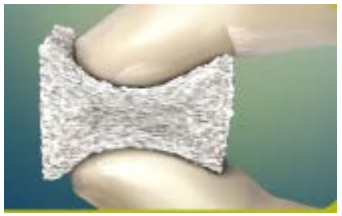
ReadiGRAFT BLX Sponge Overview & Description

- 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?

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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?

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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?

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Clinical Applications: Spine

- Fill interbody spacers

- Bridge transverse processes

Demonstrate

Which application is best for your customers practice?

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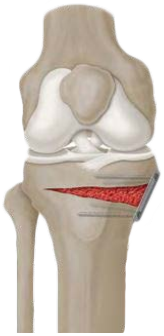
Clinical Applications: Orthopedics-Osteotomy



- Promote healing after a knee osteotomy

- Fill corrective osteotomy void after a fracture

Demonstrate

Which application is best for your customers practice?

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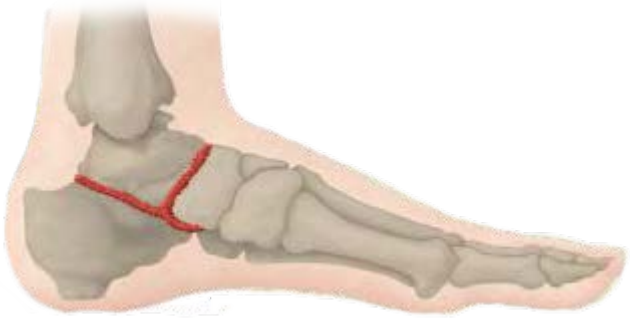
Clinical Applications: Orthopedics – Ankle Fusion



- 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	✓ 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}	✓ Concerns about disease transmission ✓ Requires hydration for optimal handling
Mineralized Allograft	✓ Strong clinical efficacy ✓ Readily available ✓ Room temperature storage (freeze dried) ✓ Natural matrix – closely resembles autograft	✓ Concerns about disease transmission ✓ Preparation time required ✓ Growth factors are not readily accessible
Autograft	✓ No immunogenicity issues ✓ Contains growth factors ✓ Long history of use	✓ Limited availability ✓ Requires second site surgery ✓ Increased patient morbidity
Xenograft	✓ Readily available	✓ Low biocompatibility profile ✓ Increased risk of immunogenicity[1-8] ✓ Limited safety & efficacy research
Synthetic	✓ Readily available	✓ Low biocompatibility profile ✓ Increased risk of immunogenicity[4-5] ✓ Less safety & efficacy research

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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?

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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?

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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.

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Logistics - Sizes Available

ReadiGraft 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

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

ReadiGraft 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

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Logistics – Packaging

- Packaged in clear tray within a larger clear tray
  - Double sterile barrier

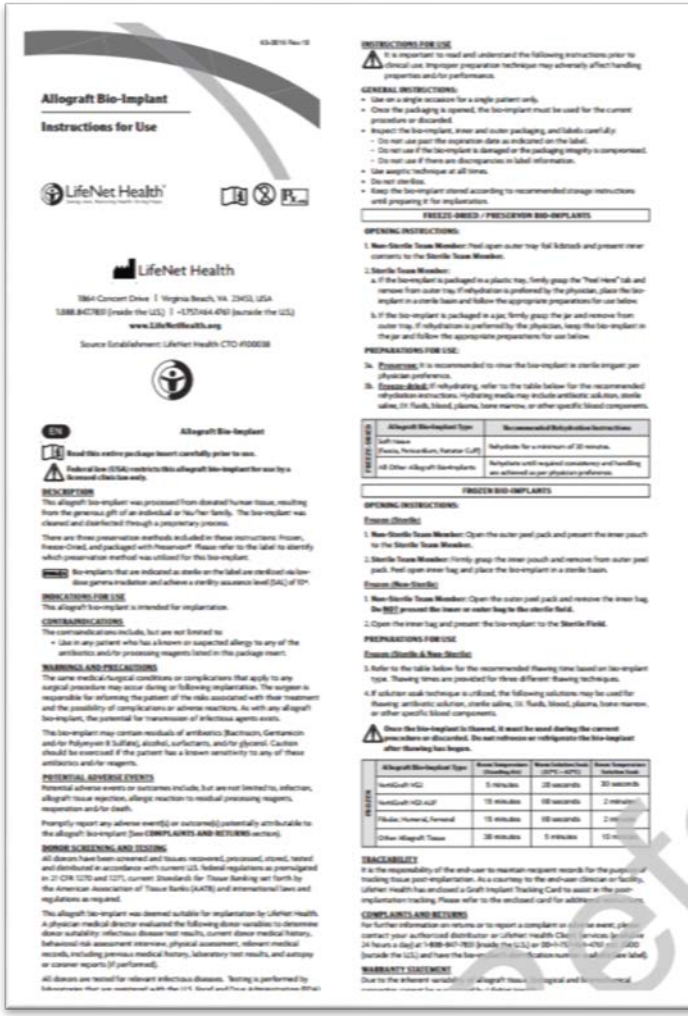
- External packaging features:
  - Shipped in corrugated cardboard box (ambient storage)
  - Cutout window to allow label to clearly show through
  - Outer package dimensions
    - 3.08 x 1.19 x 4.37 cm (Cubes)
    - 4.63 x 1.31 x 5.75 cm (Strips and Filler)

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

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Allograft Bio-Implant

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Knowledge Check

ReadiGraft BLX Sponge is osteoconductive and has exposed growth factors.

A. True

B. False

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Knowledge Check

To prepare ReadiGraft 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.

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Knowledge Check

Which clinical application is ***not*** indicated for ReadiGraft 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

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Knowledge Check

ReadiGraft BLX Sponge is available as:

A. Cubes

B. Strips

C. Filler

D. All of the above

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Knowledge Check

Which of the following is ***not*** true about ReadiGraft 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}.

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References

[1]Aurora 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.

[2]Iannotti JP, Codsi 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.

[3]Miller 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.

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

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

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