



ReadiGRAFT

Bone Void Filler Solutions

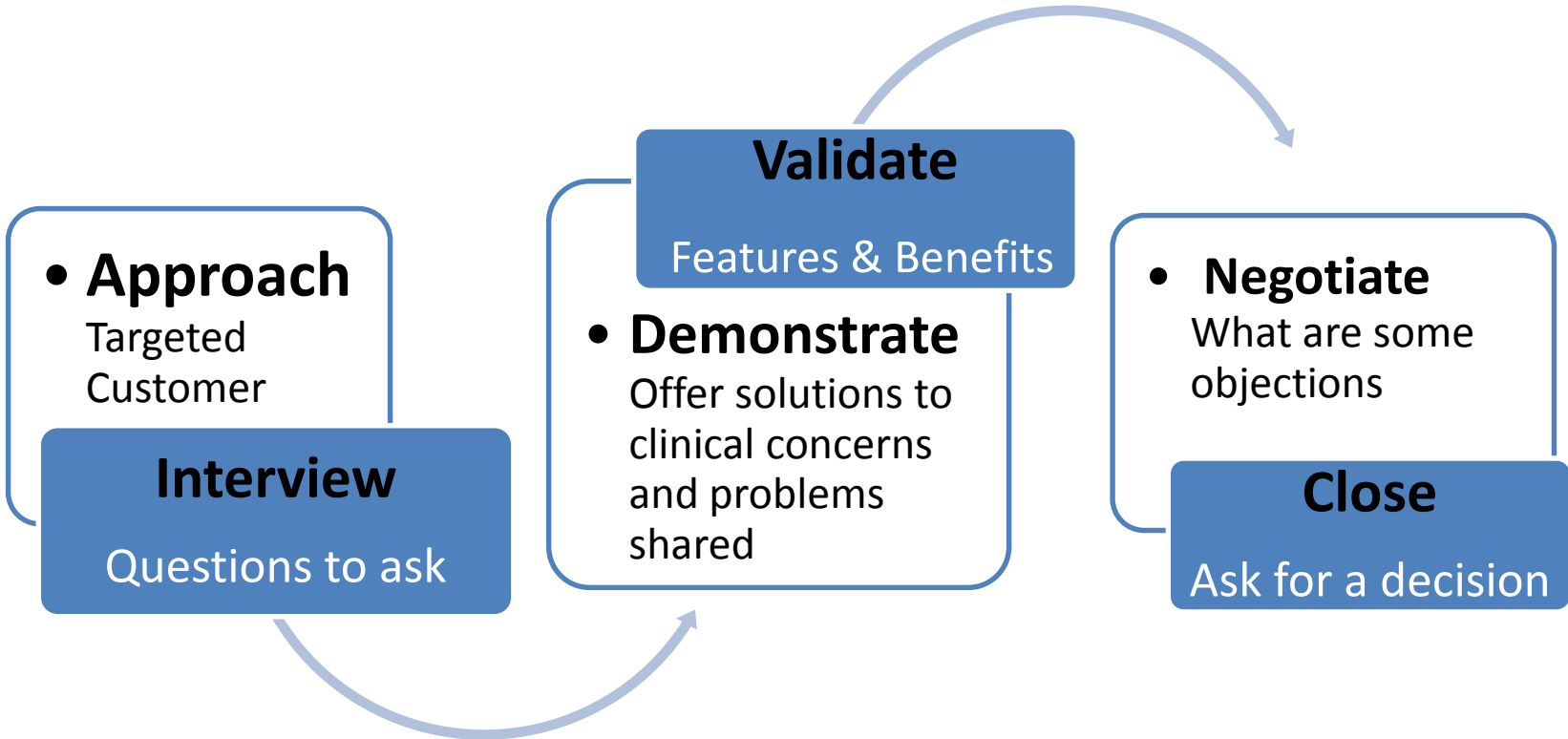


Objectives

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



Integrity Selling





Overview & Description



- Sterile cancellous and cortical/cancellous bone chips, cubes, and blocks



- Used for general orthopedic and spinal grafting procedures



- Provides a natural osteoconductive scaffold for new bone growth



Approach

Who is your Targeted Customer?





Overview & Description



- Available in multiple sizes and volumes for various surgical techniques



- Available in Preservon

- Pre-hydrated to minimize preparation time



- **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 of an osseous defect that isn't intrinsic to the structural stability of the bone
- When the patient is:
 - Relatively healthy
 - Doesn't need an augmented solution
 - i.e. demineralized bone matrix (DBM)

Interview

What does the clinician need?



Uncovering the Clinical Need



Cancellous and Cortical/Cancellous Chips

- Used when:
 - Autograft is insufficient
 - Additional volume is needed



Cancellous Cubes and Blocks

- Used in well-defined defects where the implant can be custom-matched to the space

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 encourages cell infiltration and vascular ingrowth to promote bone healing

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



- Fill knee osteotomy void in an arthritic patient



- Fill corrective osteotomy void after a radius fracture

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



Clinical Applications: Orthopedics – Knee and Hip Revision



- Fill osseous defects after knee revision



- Impaction grafting of the acetabulum and femur during hip revision

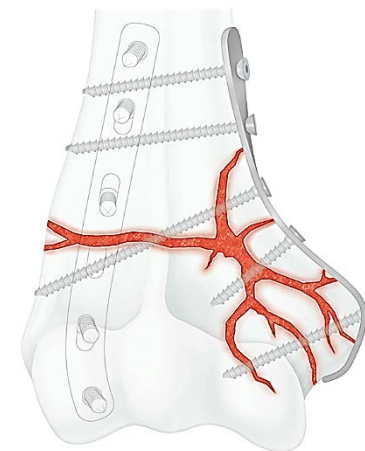
Demonstrate
*Which application is best
for your customers
practice?*



Clinical Applications: Trauma – Fracture Repair



- Fill irregular void in a tibial plateau fracture
- Fill a segmented defect in a humerus fracture



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



Clinical Applications: Orthopedics – Ankle Fusion



Augment fixation of the tibial and calcaneal joints during ankle fusion

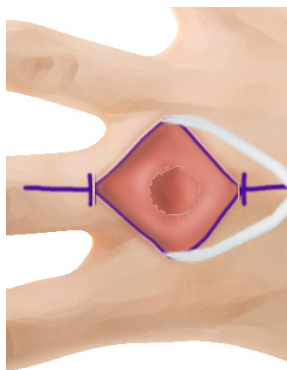
Demonstrate
*Which application is best
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practice?*



Clinical Applications: Oncology



- Fill biopsy defect



- Fill void after tumor excision

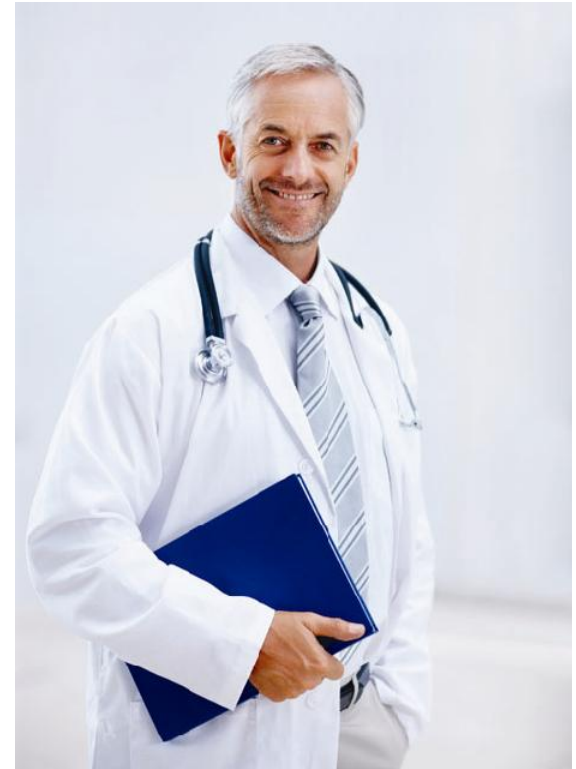
Demonstrate
*Which application is best
for your customers
practice?*





Clinical Applications

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



Comparison of Graft Types

	Advantages	Disadvantages
ReadiGRAFT	<ul style="list-style-type: none"> ✓ Pre-measured sizes and volumes ✓ Sterile - Sterility Assurance Level (SAL) of 10^{-6} ✓ Available pre-hydrated and ready to use (Preservon-treated grafts) 	<ul style="list-style-type: none"> ✓ Concerns about disease transmission
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
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 immunogenicity¹⁻³ ✓ 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
Convenience	Pre-hydrated, ready to use (Preservon)	No freezer storage, thawing, or rehydration needed
	Available in a variety of sizes and configurations	Eliminates graft preparation time in the operating room (OR)
Safety	Medical device grade sterility (SAL 10^{-6})	Reduced risk of disease transmission
Biocompatibility	Natural osteoconductive scaffold	Allows for cellular attachment and vascular ingrowth
	100% human bone	Will remodel alongside patient's own tissue during healing process

Validate

What features and benefits will support the clinicians needs?



Supporting Documents

- Clinical Publications
 - Over twenty years of published cases
 - Demonstrated clinical success case series
- Refer to the Clinical Compendium for a list of publications



Validate

What clinical data would you want them to know?



Marketing Tools

- ReadiGRAFT Cancellous Chips Spec Sheet (68-60-21)
- ReadiGRAFT Cortical/Cancellous Chips Spec Sheet (68-60-019)
- ReadiGRAFT Cancellous Cubes Spec Sheet (68-60-20)
- ReadiGRAFT Cancellous Block Spec Sheet (68-60-22)
- ReadiGRAFT Bone Void Fillers VAC Package (68-80-014)

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

ReadiGraft® Bone Void Filler Overview
for Value Analysis Committee Review



The image shows a preview of a spec sheet for ReadiGRAFT Cancellous Chips. The document features a title 'ReadiGRAFT® Cancellous Chips' and a photograph of the product. Below the title, there is a table with four rows: 'Brand', 'Clinical Applications', 'Features And Benefits', and 'Alternative Products'. The 'Brand' row lists 'ReadiGraft'. The 'Clinical Applications' row lists 'Any surgical application that requires bone void filler'. The 'Features And Benefits' row lists three bullet points: 'Natural Osteoconductive Scaffold', 'Hydrogel-like', and 'Sterile'. The 'Alternative Products' row lists 'Cancellous Cubes', 'Cortical Cancellous Chips', and 'Femoral Head (Grinder)'. At the bottom of the page, there is contact information for LifeNet Health, including phone numbers and the website URL.

Brand	• ReadiGraft
Clinical Applications	• Any surgical application that requires bone void filler
Features And Benefits	• Natural Osteoconductive Scaffold: The natural interconnected porous architecture provides an optimal scaffold for cellular attachment, proliferation, and vascular ingrowth. • Hydrogel-like: Absorbs and retains bioactive fluids like blood, Platelet Rich Plasma (PRP), and Bone Marrow Aspirate (BMA). • Sterile: The implant is sterilized using proprietary and patented Aseptic SIP technology. This technology provides a sterility assurance level of 10 ⁻⁶ , without compromising the implant's inherent osteoconductivity or osteoconductive potential.
Alternative Products	• Cancellous Cubes • Cortical Cancellous Chips • Femoral Head (Grinder)

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Logistics - Sizes Available*

Cancellous Chips			
Grind	Frozen	Freeze-Dried	PRESERVON
0.1 – 2 mm	-	-	5, 15, 30 cc
1 – 4 mm	15, 30, 60, 90 cc	15, 20, 30, 40, 60, 80, 90 cc	5, 15, 20, 30, 40, 60, 80, 90 cc
1 – 8 mm	15, 20, 30, 40, 80, 90, 160 cc	5, 10, 15, 20, 30, 40, 60, 80, 90 cc	5, 10, 15, 20, 30, 40, 60, 80, 90 cc
1.7 – 10 mm	-	-	15, 30, 60, 90 cc
3 – 6 mm	-	-	30 cc
4 – 10 mm	15, 30, 60, 90 cc	15, 30, 60, 90 cc	15, 30, 60, 90 cc

Cancellous Cubes		
Size	Freeze-Dried	PRESERVON
0.5 x 0.5 x 0.5 cm	5, 15 cc	5, 15 cc
1 x 1 x 1 cm	20, 30, 40 cc	20, 30, 40 cc

Cancellous Blocks	
Freeze-Dried	PRESERVON
2 x 2 x 3 cm	20 x 20 x 30 cm
1.5 x 1.5 x 3 cm	1.5 x 1.5 x 3 cm

Cortical/Cancellous Chips		
Grind	Freeze-Dried	PRESERVON
0.1 – 2 mm	-	5, 15, 30 cc
1 – 4 mm	-	15, 30, 60, 90 cc
1 – 8 mm	10, 20, 30, 40, 60, 90 cc	10, 15, 20, 30, 40, 60, 90 cc

*Not all configurations are available in all countries



Logistics – Packaging (Ambient)

- Double sterile barrier - packaged in a clear tray within a larger clear tray
- Label states order code, grind size, volume, graft ID, storage requirements, and expiration date
- External packaging features:
 - Cutout window to allow label to clearly show through
 - Corrugated cardboard box, no temperature control needed (ambient storage)
 - Outer package dimensions
 - 4.6 x 1.3 x 5.75 cm (up to 80 cc)
 - 4.6 x 2.2 x 5.75 cm (80 cc or more)



Logistics – Packaging (Frozen)

- Double sterile barrier - packaged in a clear pouch within a larger clear pouch
- Label states order code, grind size, volume, graft ID, storage requirements, and expiration date
- External packaging features:
 - Shipped on dry ice in a validated shipper
 - Outer package dimensions
 - 6 x 9 cm pouch (up to 60 cc)
 - 9 x 12 cm pouch (60 cc or more)



Logistics – IFU



- Shelf life of up to 5 years
- Allograft Bio-Implant Instructions for Use (IFU 63-0016)
 - Preservation graft preparation: recommended to rinse in sterile irrigant per surgeon preference prior to use
 - Freeze-dried graft rehydration: rehydrate until required consistency and handling are achieved
 - Frozen graft thawing: 5-10 minutes in solution soak





Knowledge Check

ReadiGraft Bone Void Fillers are a natural osteoconductive scaffold.

- A. True
- B. False





Knowledge Check

ReadiGraft Cancellous Cubes and Blocks are available in which preservation method(s)?

- A. Preservon only
- B. Preservon and freeze-dried
- C. Preservon, freeze-dried, and frozen





Knowledge Check

Which clinical application is not indicated for ReadiGraft Bone Void Fillers on their own?

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





Knowledge Check

ReadiGraft Bone Void Fillers may not be combined with other bone graft substitutes, such as autologous tissue or DBMs.

- A. True
- B. False





Knowledge Check

Which statement is true about REDIgraft Bone Void Fillers treated with Preservon technology?

- A. They must be stored in a freezer and thawed before use.
- B. They can be stored at room temperature but require rehydration before use.
- C. They can be stored at room temperature and are ready to use off of the shelf.



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.

