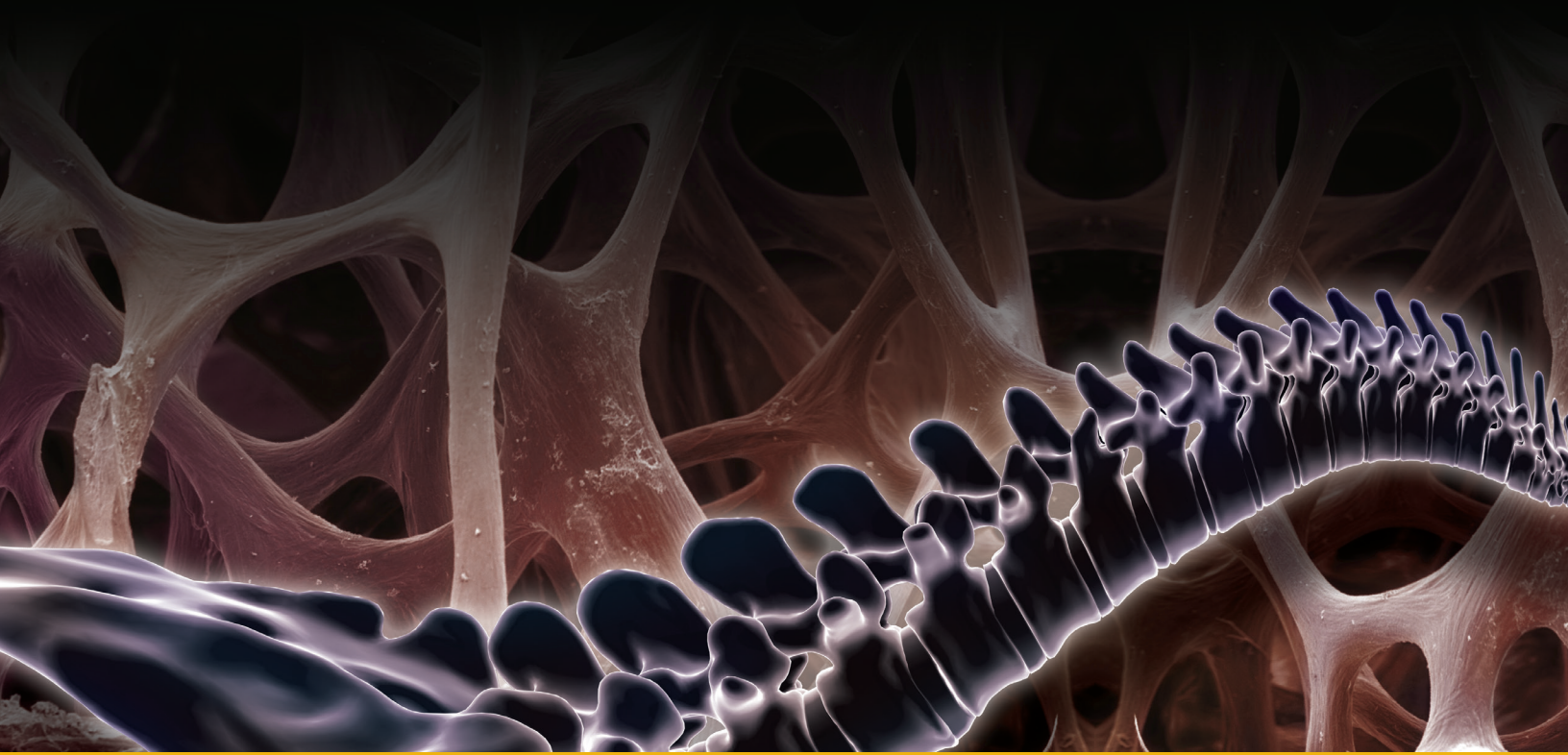


stryker[®]

Spine



Stryker Biologics

Product Catalog

Introduction

Stryker Spine

Stryker is one of the world's leading medical technology companies and together with our customers, we are driven to make healthcare better. Stryker has collaborated with the nation's industry-leading tissue organizations to offer a comprehensive portfolio consisting of traditional and proprietary spinal grafts and viable bone matrix, as well as demineralized bone matrix products and synthetic bone grafting substitutes. Our focus on bringing progressive, compelling products to market is guided by our quality first foundation—Stryker fulfills the rigorous certification requirements of the American Association of Tissue Banks and complies with the U.S. Food and Drug Administration regulations for tissue management.

Our spectrum of orthobiologic products for neurosurgical and orthopedic spine procedures is the result of Stryker's responsiveness and commitment to both surgeon and patient needs. Our comprehensive portfolio offers surgeons the right product for each surgical situation.

Stryker offers one of the most comprehensive and diverse spine portfolios to treat a variety of pathologies through a less or minimally invasive surgical approach. Stryker's breadth of offering includes components for every part of the procedure to deliver to you a complete solution.

Stryker offers one of the most comprehensive and diverse spine portfolios.

Biologics



Viable Bone Matrix



Synthetic



DBM

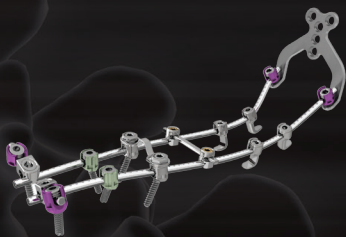


Allograft

Cervical



Aviator



Oasys



Pedicule Based Retractor



LiTe Plate System



ES2

Less Invasive/Instruments

Thoracolumbar Fixation



Xia 3



Xia 4.5



Radius



Trio

Products

Table of Contents

Allograft BIO-Implants

Preservon® Technology	6
BIO AVS	
C-Open	7
C-Plug	7
UniLif Short	8
UniLif Long	8
BIO AVS AL	9
BIO Wedge	
Unicortical	10
Tricortical	10
Iliac Crest	11
BIO Shaft	
Femoral	12
Fibular	12
BIOExpand	13
BIO Chips	
Cancellous	14
Cortico-Cancellous	14
DBM with Chips	14
AlloCraft Line	
PL	15
TL	15
CS	16
CL	16
CP	16
CA	17

Demineralized Bone Matrix

Putty	18
Gel	18
Plus Putty	18
Shapes	19
Boats	19

Viable Bone Matrix

BIO ⁴	20
------------------	----

Synthetics

Vitoss	22
Vitoss BA	26
Vitoss BA2x	26
Vitoss BiModal	27

Bone Marrow Aspiration and Delivery

Imbibe	28
--------	----

Ordering Information

30

References

42

Product Overview

Viable Bone Matrix



Demineralized Bone Matrix (DBM)



Allograft BIO-Implants



Synthetic Bone Graft



Allograft BIO-Implants

Featuring Preservon Technology

Why Choose Preservon Allograft BIO-Implants?

Preservon Allograft BIO-Implants are more efficiently and conveniently stored and handled than grafts treated with conventional preservation methods.

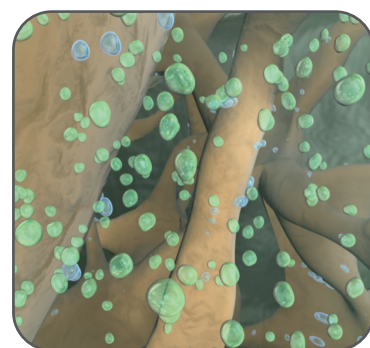
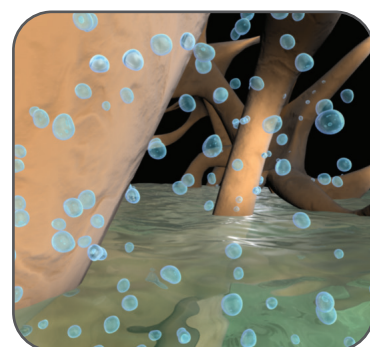
Frozen or freeze-dried allografts can require up to 60 minutes to thaw or re-hydrate, compared to as little as 30 seconds for Preservon treated Allograft BIO-Implants.

The Future of Allograft BIO-Implant Preservation

Preservon is a proprietary and patented glycerol-based preservation technology that allows allograft BIO-implants to be stored in a fully hydrated state at an ambient temperature. This eliminates the need to freeze or freeze-dry allograft BIO-implants, which helps eliminate prolonged thawing and rehydration times.

How does it work?

Glycerol, the active ingredient in Preservon, acts as a humectant to maintain both the moisture within the allograft, as well as a bacteriostatic environment. These properties allow ambient temperature storage of the allograft without decay. Widely used as a food additive, glycerol has been used since 1991 as a carrier in commercially available osteobiologics products to enhance handling characteristics.



What are the potential benefits to my patients, hospitals and me?

Convenient ambient temperature storage and no rehydration	May help increase OR efficiency
Lower possibility of brittle product associated with freeze-drying ¹	Helps preserve product integrity
Consistent osteoconductive properties and compressive strength ¹	May help optimize performance
No inflammatory response ¹	Can help optimize safety

C-Open and C-Plug

Description

The BIO AVS C-Open and C-Plug implants are monolithic cortical constructs with open and cancellous plug design options. BIO AVS implants are machined from femoral and tibial allograft and are designed for cervical procedures.

Technical Specifications

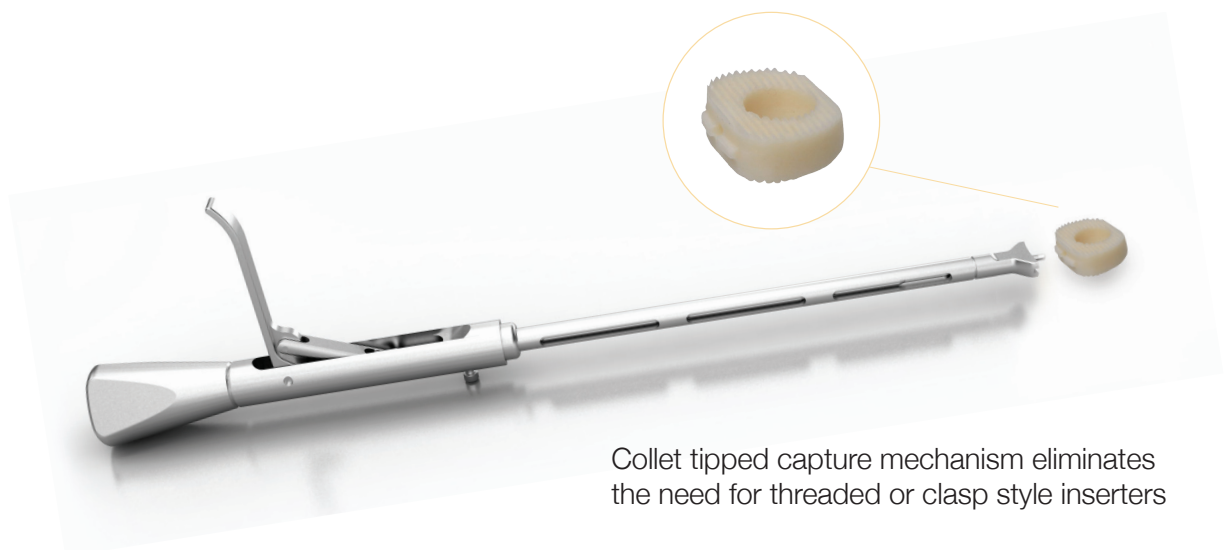
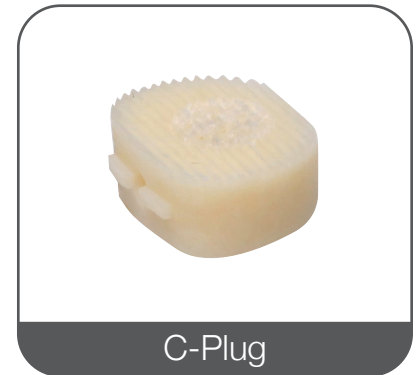
- 12mm anterior-posterior depth
- 14mm medial-lateral width
- 5-10mm heights
- Parallel and 4° lordotic options

Product Features

- One-piece cortical construction for optimized biomechanical strength and load dispersion
- Textured surface area helps minimize risk of implant migration and displacement
- Machined to precise dimensions for consistent fit and functionality
- Open and cancellous plug design options
- Chamfered leading edge for ease of insertion
- No rehydration required
- 5-10mm heights
- Preservon treated for fully hydrated ambient temperature storage
- Processed with Allowash XG to achieve a Sterility Assurance Level to 10^{-6} (SAL)²

Intuitive Instrumentation

- Simplified lever-lock handle allows for rapid assembly/disassembly
- Ridged graft capture mechanism provides more control and tactility during insertion



UniLIF Description

The BIO AVS UniLIF is an allograft posterior lumbar interbody spacer system, designed for both bilateral PLIF and oblique TLIF surgical approaches. Machined from femoral and tibial allograft.

Technical Specifications

BIO AVS UniLIF (Short)

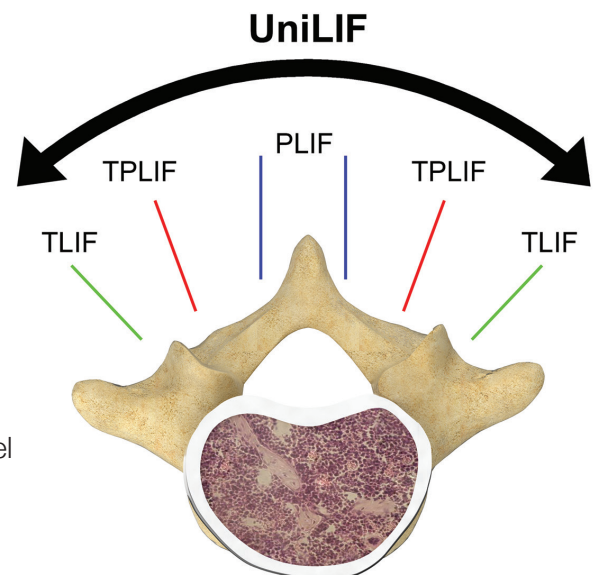
- Length: 25mm
- Width: 9mm
- 7-15mm Heights (2mm increments)

BIO AVS UniLIF (Long)

- Length: 30mm
- Width: 11mm
- 7-15mm Heights (2mm increments)

Product Features

- 25mm and 30mm lengths for PLIF and TLIF approaches
- Full cortical parameter for structural support
- Cancellous center to facilitate fusion through graft
- Self-distracting wedge nose to ease insertion
- 1mm isometric serrations on superior and inferior surfaces to help resist expulsion
- Preservon treated for fully hydrated ambient temperature storage
- Processed with Allowash XG to achieve a Sterility Assurance Level to 10^{-6} (SAL)²



Description

The BIO AVS AL implant is a monolithic, cortical construct machined from femoral allograft. Designed for Anterior Lumbar Interbody Fusion (ALIF) procedures.

Technical Specifications

- Anterior posterior depth - 23mm minimum; 27mm maximum
- Medial lateral width - 23mm minimum; 30 mm maximum
- 10-18mm heights (2mm increments)
- 4°, 8°, and 12° lordotic options

Product Features

- One-piece cortical ring for optimized biomechanical strength and load dispersion
- Textured surface area helps minimize risk of implant migration and displacement
- Machined to precise dimensions for consistent fit and functionality
- Open design to accommodate bone graft material of choice
- Chamfered leading edge for ease of insertion
- Preservon treated for fully hydrated ambient temperature storage
- Processed with Allowash XG to achieve a Sterility Assurance Level to 10^{-6} (SAL)²



BIO AVS AL is ONLY compatible with SLIDE Instrumentation.

Unicortical

Description

Precision cut cancellous block with a single cortical face. Recovered from the femoral condyles, femoral heads, distal tibia, and talus.

Technical Specifications

- 11mm anterior-posterior depth
- 14mm medial-lateral width
- 5-10mm heights
- Parallel

Clinical Applications

- Anterior Cervical Fusion

Product Features

- Preservon treated for fully hydrated ambient temperature storage
- Provides an osteoconductive matrix for incorporation
- Pre-sized for convenience and intraoperative efficiency
- Processed with Allowash XG to achieve a Sterility Assurance Level to 10^{-6} (SAL)²



Tricortical

Description

Tricortical graft processed from the patella.

Technical Specifications

- 11-17mm anterior-posterior depth
- 12-15mm medial-lateral width
- 5-10mm heights
- Parallel

Clinical Applications

- Anterior Cervical Fusion

Product Features

- Preservon treated for fully hydrated ambient temperature storage
- Structural support provided by cortical aspects
- Provides an osteoconductive matrix for incorporation
- Pre-sized for convenience and intraoperative efficiency
- Processed with Allowash XG to achieve a Sterility Assurance Level to 10^{-6} (SAL)²



Description

Tricortical graft recovered from the crest of the ilium.

Technical Specifications

- Minimum 25mm anterior-posterior depth
- Minimum 8mm medial-lateral width
- 6-10mm and 18mm heights
- Parallel

Clinical Applications

- Anterior Cervical Fusion
- Corpectomy
- Ankle Fusion

Product Features

- Preservon treated for fully hydrated ambient temperature storage
- Structural support provided by cortical aspects
- Provides an osteoconductive matrix for incorporation
- Pre-sized for convenience and intraoperative efficiency
- Processed with Allowash XG to achieve a Sterility Assurance Level to 10^{-6} (SAL)²



Femoral

Description

BIO Shaft Femoral grafts are precision cut segments of the femoral diaphysis.

Technical Specifications

- 23-27mm anterior-posterior diameter
- 23-30mm medial-lateral diameter
- 60 and 100mm lengths

Applications

- Corpectomy
- Fracture Management
- Tumor Resection

Product Features

- Preservon treated for fully hydrated ambient temperature storage
- Monolithic structural support provided by cortical ring
- Can be customized to the specific needs of the patient
- Provides an osteoconductive matrix for incorporation
- Processed with Allowash XG to achieve a Sterility Assurance Level to 10^{-6} (SAL)²



Fibular

Description

BIO Shaft Fibular grafts are precision cut segments of the fibular diaphysis.

Technical Specifications

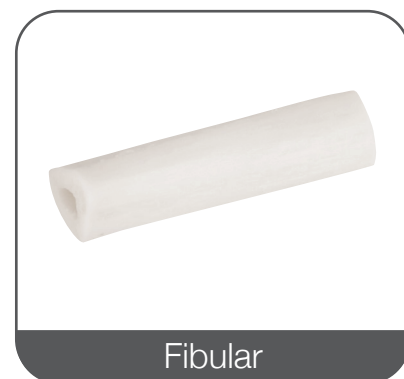
- 8-15mm diameter
- 40, 60, and 100mm lengths

Applications

- Corpectomy
- Anterior Cervical Fusion
- Fracture Management
- Tumor Resection

Product Features

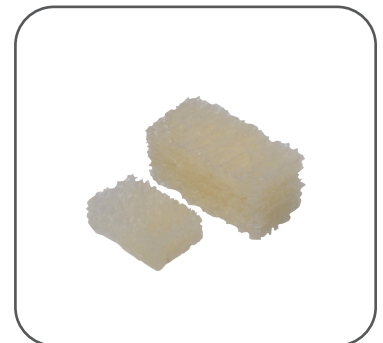
- Preservon treated for fully hydrated ambient temperature storage
- Monolithic structural support provided by cortical ring
- Can be customized to the specific needs of the patient
- Provides an osteoconductive matrix for incorporation
- Processed with Allowash XG to achieve a Sterility Assurance Level to 10^{-6} (SAL)²



BIOExpand is comprised of 100% demineralized cancellous bone providing an osteoconductive scaffold for cell attachment that, when rehydrated, produces a sponge-like effect allowing the graft to be compressed to fit in and around a variety of bony defects.

Product features³:

- Natural osteoconductive scaffold for cell attachment
- Osteoinductive potential by exposed natural growth factors through the demineralization process.
- Malleable, elastic, compressible when rehydrated
- Ambient temperature storage
- Naturally absorbs and retains bioactive fluids like blood and Bone Marrow Aspirate (BMA)
- Sterilized using Allowash XG technology achieving sterility without compromising the inherent osteoconductive or osteoinductive potential.
- 6 sizes available



BIO Chips

Cancellous

Product Features

- Provides osteoconductive matrix
- Offered in two particle size ranges: 1-4mm and 1-8mm
- Offered in four sizes: 5cc, 15cc, 30cc, and 60cc
- Preservon treated for fully hydrated ambient temperature storage
- Processed with Allowash XG to achieve a Sterility Assurance Level to 10^{-6} (SAL)²



Cortico-Cancellous

Product Features

- Provides osteoconductive matrix
- Approximately equal amounts of crushed cortical and crushed cancellous
- Offered in two particle size ranges: 1-4mm and 1-8mm
- Offered in two sizes: 30cc and 60cc
- Preservon treated for fully hydrated ambient temperature storage
- Processed with Allowash XG to achieve a Sterility Assurance Level to 10^{-6} (SAL)²



BIO DBM with Chips

DBM with Cancellous

Product Features

- A mix of demineralized bone material and cancellous chips
- Cancellous particle size 1-8mm
- Provides an osteoinductive component and osteoconductive matrix
- Easily mixed with autograft
- 100% allograft
- Demineralized with patented PAD process targeting 1-4% residual calcium³
- Processed with Allowash XG to achieve a Sterility Assurance Level to 10^{-6} (SAL)²



Description

The AlloCraft PL implant is a monolithic, cortical construct machined from femoral allograft. Designed for use in Posterior Lumbar Interbody Fusion (PLIF) procedures.

Technical Specifications

- 8mm width x 22mm lengths
- 8-16mm heights (2mm increments)
- 5° posterior lordosis

Product Features

- One-piece cortical construction for optimized biomechanical strength and load dispersion
- Textured surface area helps minimize risk of implant migration and displacement
- Machined to precise dimensions for consistent fit and functionality
- Bullet-shaped nose facilitates insertion into the disc space
- Freeze dried. Ambient temperature storage.



Description

The AlloCraft TL implant is a monolithic, cortical construct machined from femoral allograft. Designed for use in Transforaminal Lumbar Interbody Fusion (TLIF) procedures.

Technical Specifications

- 8mm width x 26mm length
- 8-16mm heights (2mm increments)
- Parallel

Product Features

- One-piece cortical construction for optimized biomechanical strength and load dispersion
- Textured surface area helps minimize risk of implant migration and displacement
- Machined to precise dimensions for consistent fit and functionality
- Bullet-shaped nose facilitates insertion into the disc space
- Freeze dried. Ambient temperature storage.



CS

Description

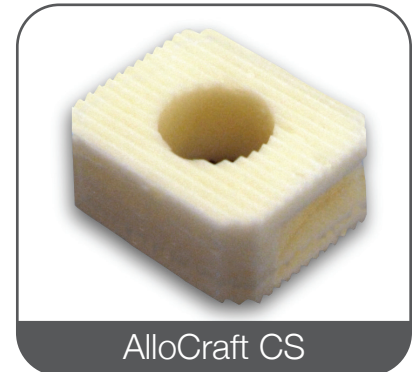
The AlloCraft CS implant is a monolithic, cortical construct machined from femoral or tibial allograft. Designed for cervical procedures.

Technical Specifications

- 14mm medial-lateral width x 12mm anterior-posterior depth
- 5-9mm heights
- 6.5mm lumen
- Parallel

Product Features

- One-piece cortical construction for optimized biomechanical strength and load dispersion
- Textured surface area helps minimize risk of implant migration and displacement
- Machined to precise dimension for consistent fit and functionality
- Open design to accommodate bone graft material of choice
- Chamfered leading edge for ease of insertion
- Freeze dried. Ambient temperature storage.



CL & CP

Description

The AlloCraft CP and CL implants are monolithic cortical constructs with cancellous plugs. Machined from femoral or tibial allograft. Designed for cervical procedures.

Technical Specifications

- 14mm medial-lateral width x 12mm anterior-posterior depth
- 5-9mm heights
- 6.5mm lumen
- Parallel (CP) and 5° lordotic (CL) options

Product Features

- One-piece cortical ring for optimized biomechanical strength and load dispersion
- Textured surface area helps minimize risk of implant migration and displacement
- Machined to precise dimension for consistent fit and functionality
- Central cancellous plug facilitates fusion through the graft
- Chamfered leading edge for ease of insertion
- Freeze dried. Ambient temperature storage.



Description

The AlloCraft CA implant is a three-piece, cortico-cancellous graft machined from femoral or tibial allograft. Designed for cervical procedures.

Technical Specifications

- 14mm medial-lateral width x 12mm anterior-posterior depth
- 5-10mm heights
- 5° lordosis

Product Features

- Proprietary cortico-cancellous assembly is designed to provide load-bearing strength and stability
- Textured surface area helps minimize risk of implant migration and displacement
- Machined to precise dimensions for consistent fit and functionality
- Chamfered leading edge for ease of insertion
- Freeze dried. Ambient temperature storage.



Demineralized Bone Matrix

Gel, Putty and Putty Plus

- Demonstrated equivalent bone formation results to autograft in standard posterolateral fusion model in adult rabbits⁴
- Reversed Phase Medium Carrier is designed to provide excellent handling
- Formulated to resist irrigation
- Every lot is tested to confirm osteoinductive potential⁵
- Putty Plus configurations contain cancellous bone⁵



Gel

- Syringe container
- 1, 5 and 10cc

Putty

- Vial container
- 1, 2.5, 5 and 10cc

Putty Plus

- Vial container
- Contains cancellous bone
- 5 and 10cc



Shapes

BIO DBM Shape

Easily molded into small anatomy applications

- Designed for rapid hydration and high volume retention of blood or saline
- Pliable consistency allows for easy integration of local bone/allograft chips
- 1, 2.5, and 5cc sizes



Boats

BIO DBM Boat

- Deep trough-like design engineered to deliver local bone/allograft chips
- Designed for rapid hydration and high volume retention of blood or saline
- Long and short sizes to address single and multi-level placement as part of posterolateral fusion procedures
- 10, 20, and 40cc sizes



Viable Bone Matrix

BIO⁴

BIO⁴ is a viable bone matrix containing endogenous bone forming cells including mesenchymal stem cells, osteoprogenitor cells and osteoblasts as well as osteoinductive and angiogenic growth factors. BIO⁴ possesses all four characteristics involved in bone repair and regeneration: osteoconductive, osteoinductive, osteogenic, and angiogenic.^{6, 7, 8} It is an alternative to autograft that minimizes the potential for harvest site co-morbidities. BIO⁴ was developed by Osiris Therapeutics, the creators of the original allograft cellular bone matrix. Features for BIO⁴ include:

- Next generation viable bone matrix
- Lot tested for the presence of VEGF (vascular endothelial growth factors)⁷
- Ready to use out of the package; no decanting is required and thaws in 15 minutes
- Differentiated handling compared to the competition
- Contains $\geq 600,000$ cells (endogenous bone forming cells) per cc⁷
- Lot tested for $\geq 70\%$ cell viability post-thaw⁷
- Non-immunogenic⁷

BIO⁴ is processed utilizing proprietary methods. Each BIO⁴ lot is processed from a qualified single donor that undergoes extensive serology, sterility and bioburden testing and a full review of medical records by the tissue bank Medical Director.



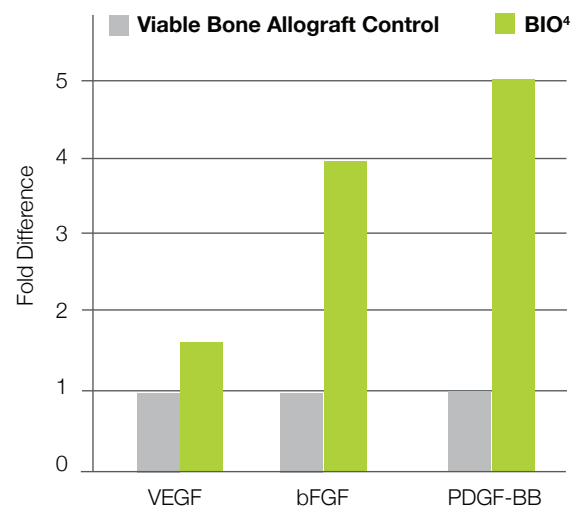
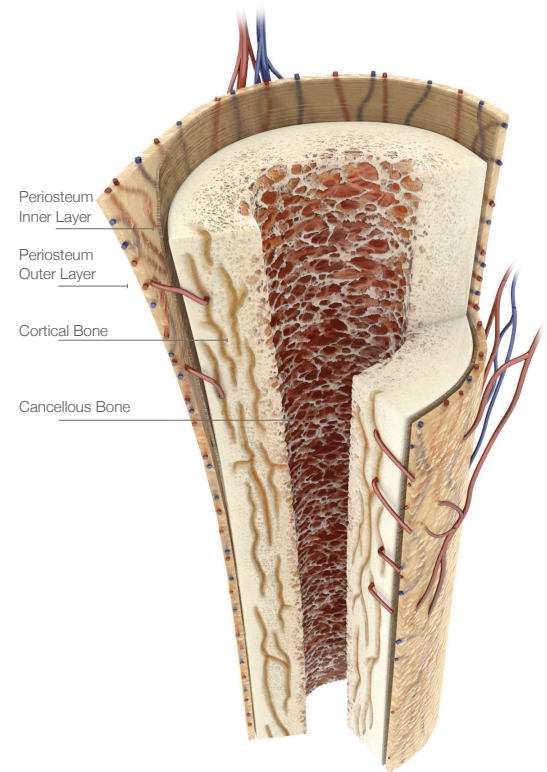
BIO⁴ Composition

BIO⁴'s proprietary formulation includes all components of bone – cancellous and cortical bone and periosteum. Careful processing preserves these components needed for bone formation while removing the elements that might elicit an immunogenic response.

The scaffold, cells and signals are derived from cancellous bone, bone chips and demineralized cortical bone. Bone periosteum is carefully processed to preserve angiogenic growth factors. The presence of periosteum further improves handling properties.⁷

All components of BIO⁴ are from allograft tissue: cancellous bone, cortical bone and periosteum. Processing of the bone periosteum retains growth factors that support angiogenesis, such as the vascular endothelial growth factor VEGF⁸.

As shown in the accompanying chart, the presence of angiogenic signals in BIO⁴ was confirmed using ELISA. BIO⁴ showed higher presence of endogenous angiogenic growth factors compared to a similar bone allograft formulation lacking the periosteum (viable bone allograft control). VEGF, bFGF, and PDGF-BB are detectable to higher degree in BIO⁴ due to the presence of periosteum.⁷



BIO⁴ showed higher presence of angiogenic signals compared to similar bone allograft formulations⁷ using ELISA.

Synthetics

Vitoss Product Platform

The #1 Selling Synthetic Bone Graft⁹

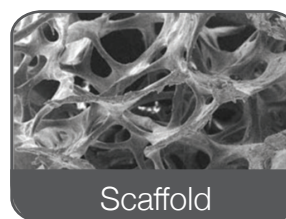
Vitoss continues to be the #1 selling synthetic graft for the simplest reason... it works and has human clinical data to support its efficacy. Vitoss has been implanted over 600,000 times worldwide.¹⁰ Vitoss has been studied in multiple clinical evaluations including the two prospective and peer reviewed studies highlighted below.

	The Spine Journal, February 2008 Epstein, N.E., An Analysis of Noninstrumented Posterolateral Lumbar Fusions Performed in Predominantly Geriatric Patients Using Lamina Autograft and Beta-Tricalcium Phosphate.	The Spine Journal, June 2009 Epstein, N.E., Beta-Tricalcium Phosphate: Observation of Use in 100 Posterolateral Lumbar Instrumented Fusions.
Study Design	Prospective; 60 patients using Noninstrumented PLF; Average age = 70 years	Prospective; 100 patients with lumbar spinal stenosis; Multisegment laminectomies (avg. 3.6 segments) and one segment (78 patients) or two segment (22 patients) instrumented PLF
Outcome Measures	CT scans - Fusion assessment; Dynamic X-rays; Fusion assessed separately by 2 neuro-radiologists blinded to the treatment; Post-operative outcomes using SF-36; 3, 6, 12, and 24 months follow up	Dynamic X-rays; 2D-CT Scans; Post-operative outcomes using SF-36; Fusion assessed separately by 2 neuroradiologists blinded to the treatment; 3, 4, 5, 6, and 12 month follow up with a minimum of 2.5 years and maximum of 5.0 years (avg. 3.1 years)
Results	Successful fusion in 85% of patients (51/60) when judged by CT and F/E	Successful fusion in 95% of patients (95/100) when judged by CT and Dynamic X-ray

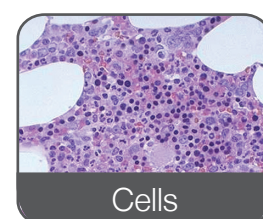
The Gold Standard

Iliac Crest Bone Graft (ICBG) has a Calcium Phosphate (CaP) surface with an open, inter-connected structure that serves as a scaffold.

ICBG contains bone marrow rich with mesenchymal stem cells and hematopoietic stem cells that facilitate bone regeneration and neo-vascularization. In addition, ICBG provides signals that help drive bone formation.

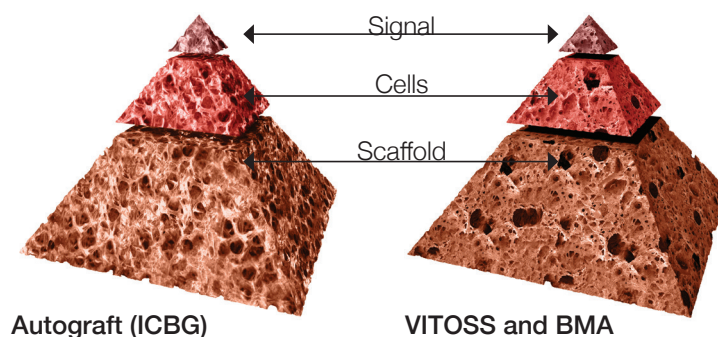


Scaffold



Cells

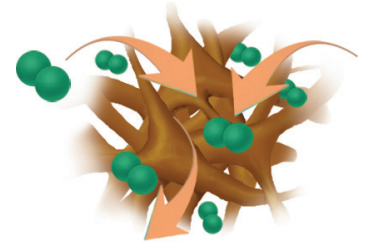
VITOSS + BMA (Bone Marrow Aspirate) resembles ICBG, the gold standard, in that it has the same three components: SCAFFOLD, CELLS and SIGNALS.¹¹



Autograft (ICBG)

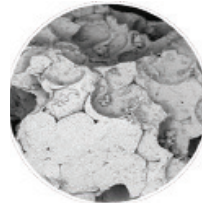
VITOSS and BMA

Despite having similar chemistries, many products perform differently due to different structure. Vitoss has an open-interconnected structure that facilitates 3-D bone regeneration.¹²

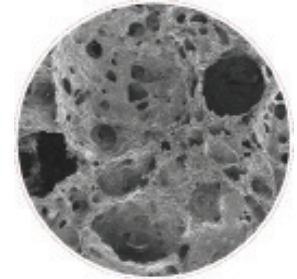


3D Regeneration of Bone

Only materials with interconnected porosity will allow for 3-D regeneration of bone as opposed to creeping substitution. Additionally, increased porosity has been shown to lead to higher rates of bony ingrowth (in an animal model).⁴ Vitoss is a highly porous calcium-phosphate (up to 90% porous).¹³

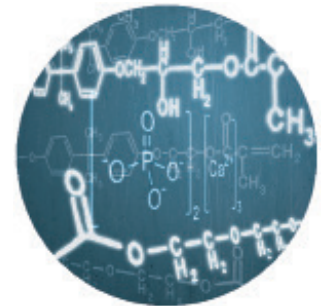


Other scaffolds



Vitoss viewed under scanning electron microscope

Chemistry affects the rate of resorption. Bone grafts should resorb as new bone forms in a physiologic time frame. Vitoss is composed of β -TCP and is stable at physiologic pH. It resorbs during the natural remodeling process of bone. Evidence suggests that β -TCP resorbs in a clinically relevant time frame.¹⁴



Physical Characteristics

Vitoss is a versatile material that comes in various forms to meet your bone grafting needs.

Foam Pack

Description

- Stable in a fluid environment
- Soaks and holds bone marrow
- Moldable
- Available in Vitoss, Vitoss BA, Vitoss BA2X, and Vitoss BiModal



Foam Strip

Description

- Flexible pre-formed Strip (when wet)
- Soaks and holds bone marrow
- Compression resistant
- Easily cut
- Available in Vitoss, Vitoss BA

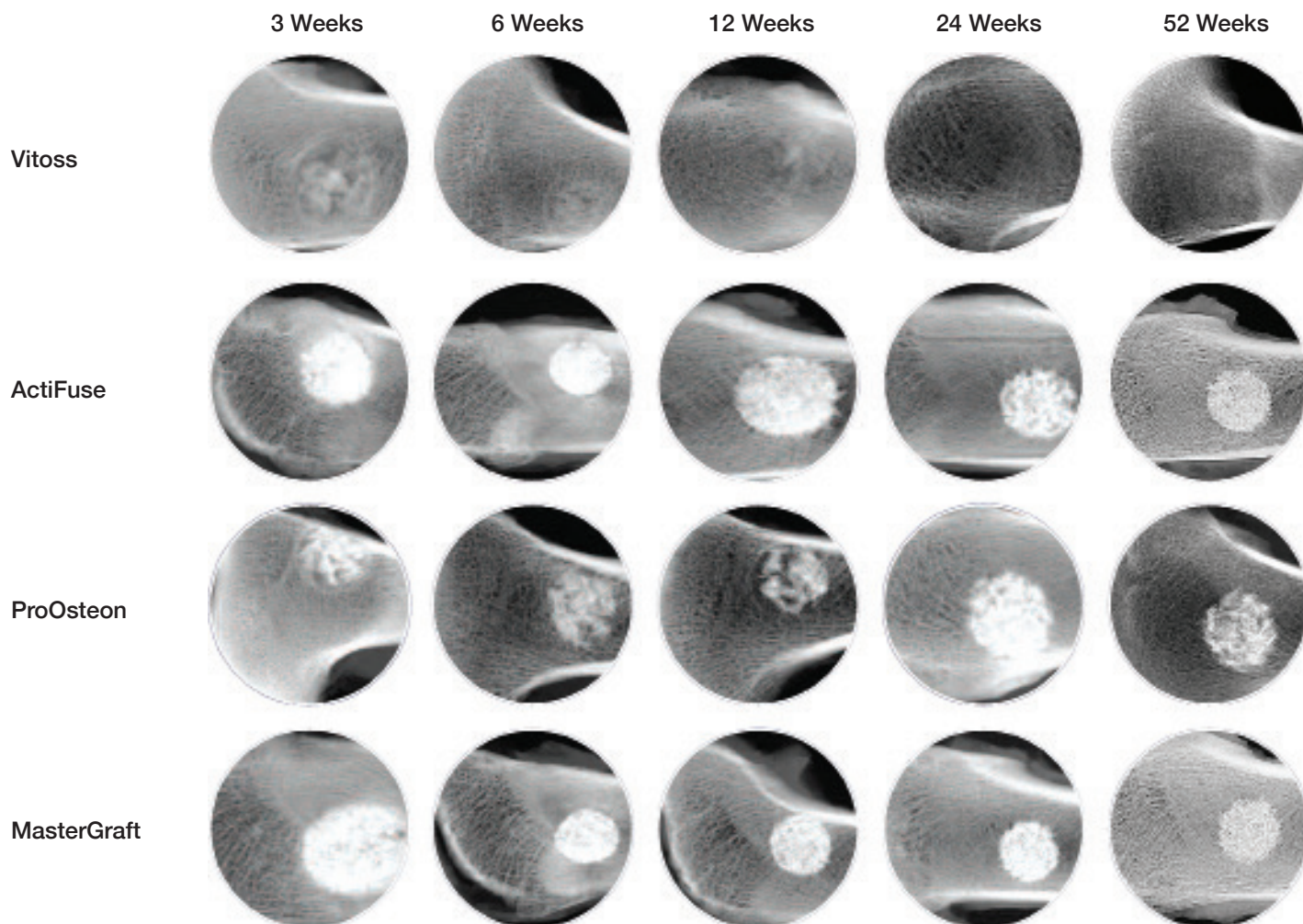
Morsels and Blocks

Description

- Good for large graft volume applications
- Cost comparative to cancellous chips
- Available in Vitoss



Not All Scaffolds are Created Equal



Comparison of Vitoss to ActiFuse, ProOsteon, and MasterGraft in a canine metaphyseal study in order to radiologically compare healing at 3, 6, 12, 24, and 52 weeks. A 10mm x 22mm drill defect was created in the proximal humerus and filled with 2cc of bone graft.¹⁵

Vitoss BA

Bioactive Glass - Mechanism of Action

Literature shows that bioactive glass exhibits good bonding-to-bone properties in animal models.¹⁶⁻¹⁸ Upon implantation, the ionic constituents (Silicon, Sodium, and Calcium) of bioactive glass are released into the surrounding environment and react with bodily fluids.¹⁹⁻²² This reaction produces the deposition of a thin layer of physiologic calcium phosphate at its surface, favorable for osteoblast attachment.²³ This is commonly referred to as a bioactive effect.^{16-18, 21, 24-26} This may lead to the bonding of new bone to the scaffold.

Vitoss BA has a unique porosity, structure, and chemistry to drive 3D regeneration of bone. The addition of bioactive glass helps create a surface favorable for osteoblast attachment and assists the host to regenerate new bone.^{16-18, 21, 24-26}



Figure 1

Hematoxylin and Eosin stained sample of Vitoss BA at 6 weeks of implantation in a canine metaphyseal defect. New bone is forming between morsels of the Vitoss scaffold, resulting in an interconnected trabecular unit.

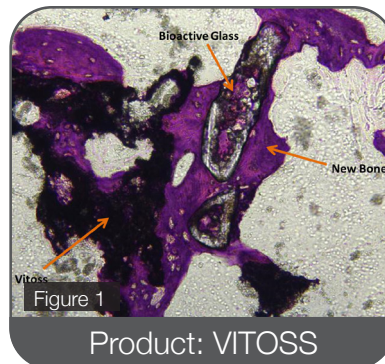
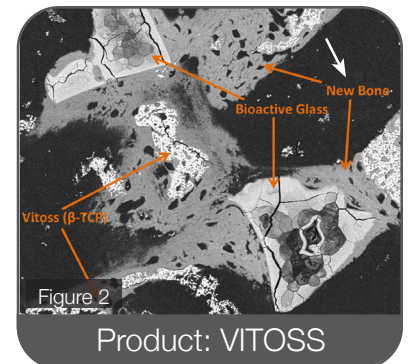


Figure 2

Backscattered electron (BSE) image of an unstained histology slide from Vitoss BA at 6 weeks of implantation in a canine metaphyseal defect. New bone can be seen enveloping the glass particle and bridging the Vitoss scaffold.



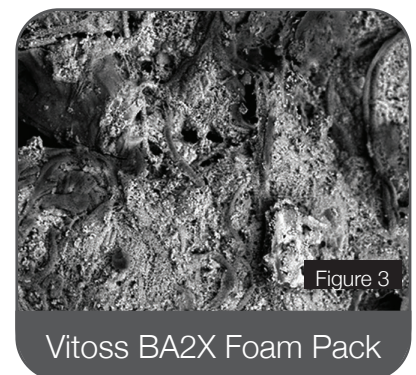
Vitoss BA2X

A little extra can make a difference

Vitoss BA2X Bioactive Bone Graft Substitute, which contains increased levels of bioactive glass, has been shown through in-vitro testing to induce two times the deposition of calcium phosphate onto the surface of the implant while retaining the same handling properties.²⁷

Figure 3

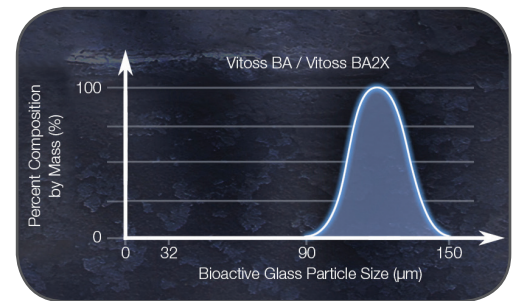
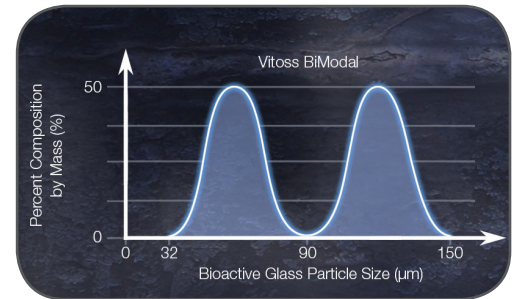
SEM Image of the bioactivity of Vitoss BA2X after 7 days in Simulated Body Fluid. A calcium phosphate layer is seen deposited on the surface of the beta-TCP and collagen matrix.



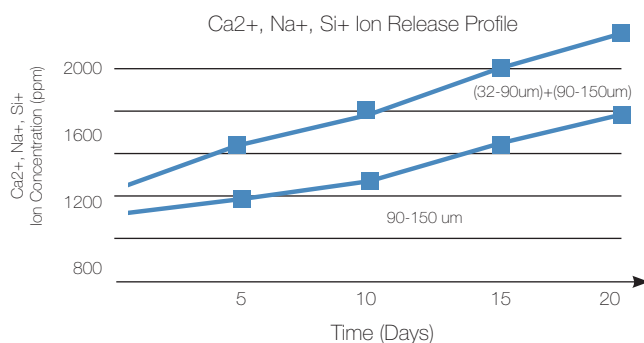
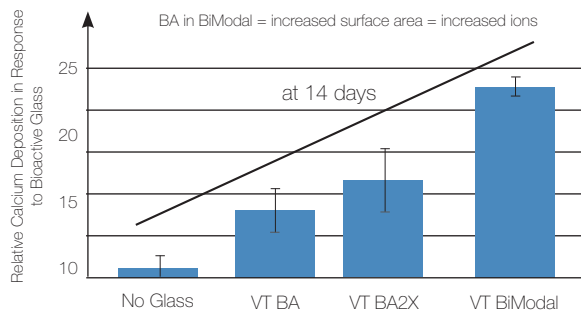
Enhance bioactivity through bimodal technology development

Vitoss BiModal features:

- An ultraporous, open inter-connected structure which guides the 3-dimensional regeneration of bone¹²
- Bimodal bioactive glass particles which promote the deposition of calcium phosphate on the implant surface²⁸
- A broader range of particle size distribution leading to an increased surface area of bioactive glass and both an immediate burst and sustained release of Ca^{2+} , Na^{+} , Si^{+} ions²⁹



Relative Cellular Calcium Deposition Between Vitoss Products



Increased calcium phosphate deposition with Vitoss BiModal

*Greater Initial Burst

The 32-90 µm bioactive glass particles kickstart the Ca^{2+} , Na^{+} , and Si^{+} ion release. Bioactive glass leads to a gel-like surface layer that mineralizes and promotes the deposition of calcium phosphate on the implant surface favorable for osteoblast attachment and bone formation.^{23, 29}

**Sustained Release

In-vitro and animal studies have shown that upon contact with bodily fluid, bioactive glass particles:

- Release ions into the immediate environment²³
- Induce deposition of calcium phosphate on the implant¹²
- Create a surface favorable for osteoblast attachment and bone formation²³

* As shown in in-vitro studies

** The response of bioactive forms of Vitoss has not been assessed in any animal study or clinical investigation and the results from laboratory testing may not be predictive of human clinical experience.

Bone Marrow Aspiration and Delivery

Imbibe Bone Marrow Aspiration and Delivery System

Bone Marrow

Less invasive —————

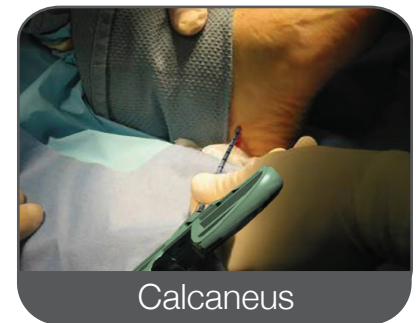
BMA is a safe alternative to iliac crest harvest without associated complications or morbidity. 900(+) patients with bone marrow aspiration (16-200mL) showed no infection, no hematoma, no chronic pain, and only 2 bruises.³⁰

BMA enhances fusion over ICBG alone ———

A pre-clinical evaluation (posterolateral fusion) showed 61% fusion in ICBG + BMA versus 25% fusion in ICBG + blood at 12 weeks.³¹

BMA enhances graft incorporation —————

There was a statistically significant decrease in radioluscent lines on x-rays of knees grafted with marrow versus those without. "Iliac marrow is useful as a bone grafting material to enhance the biological formation in porous coated implants."³²



BMA Harvesting Sites

Bone marrow can easily be aspirated from several anatomical locations throughout the body. Vitoss can be used with or without bone marrow aspirate.

Bone Marrow Aspiration and Delivery

Imbibe Bone Marrow Aspiration and Delivery System

Description

The Imbibe bone marrow aspiration needles provide a minimally invasive way to harvest bone marrow. These needles come with both sharp beveled or trocar stylets, which are color coded to distinguish each needle.

Product Features:

- Bullet-tip stylet design for controlled navigation
- Trocar and bevel cutting stylet to penetrate cortical bone
- Color-coded stylets to quickly and easily identify sharp-tip vs. bullet-tip design
- Optimized fenestrated hole design and placement
- Ergonomic handle for surgeon control and comfort
- Unique snap-lock design promotes a secure connection between stylet and handle
- Hammering platform
- 8 needle sizes / styles available
- Versatility, useful for multiple anatomic locations



Needles Sizes:

- 11 gauge x 4 inch
- 11 gauge x 6 inch
- 8 gauge x 6 inch
- 8 gauge x 8 inch
- Fenestrated 8 gauge x 6 inch

Syringes Sizes:

- 10cc
- 20cc
- 30cc

Allograft BIO-Implants

BIO AVS C-Open, C-Plug

BIO AVS C-Open				
Description	Reference #	Sizing		
BIO AVS C-Open 4°	77101054	H=5mm	4° Lordosis	14(w) x 12(d)
BIO AVS C-Open 4°	77101064	H=6mm	4° Lordosis	14(w) x 12(d)
BIO AVS C-Open 4°	77101074	H=7mm	4° Lordosis	14(w) x 12(d)
BIO AVS C-Open 4°	77101084	H=8mm	4° Lordosis	14(w) x 12(d)
BIO AVS C-Open 4°	77101094	H=9mm	4° Lordosis	14(w) x 12(d)
BIO AVS C-Open 4°	77101104	H=10mm	4° Lordosis	14(w) x 12(d)
BIO AVS C-Open 0°	77101050	H=5mm	0° Lordosis	14(w) x 12(d)
BIO AVS C-Open 0°	77101060	H=6mm	0° Lordosis	14(w) x 12(d)
BIO AVS C-Open 0°	77101070	H=7mm	0° Lordosis	14(w) x 12(d)
BIO AVS C-Open 0°	77101080	H=8mm	0° Lordosis	14(w) x 12(d)
BIO AVS C-Open 0°	77101090	H=9mm	0° Lordosis	14(w) x 12(d)
BIO AVS C-Open 0°	77101100	H=10mm	0° Lordosis	14(w) x 12(d)

BIO AVS C-Plug				
Description	Reference #	Sizing		
BIO AVS C-Plug 4°	77102054	H=5mm	4° Lordosis	14(w) x 12(d)
BIO AVS C-Plug 4°	77102064	H=6mm	4° Lordosis	14(w) x 12(d)
BIO AVS C-Plug 4°	77102074	H=7mm	4° Lordosis	14(w) x 12(d)
BIO AVS C-Plug 4°	77102084	H=8mm	4° Lordosis	14(w) x 12(d)
BIO AVS C-Plug 4°	77102094	H=9mm	4° Lordosis	14(w) x 12(d)
BIO AVS C-Plug 4°	77102104	H=10mm	4° Lordosis	14(w) x 12(d)
BIO AVS C-Plug 0°	77102050	H=5mm	0° Lordosis	14(w) x 12(d)
BIO AVS C-Plug 0°	77102060	H=6mm	0° Lordosis	14(w) x 12(d)
BIO AVS C-Plug 0°	77102070	H=7mm	0° Lordosis	14(w) x 12(d)
BIO AVS C-Plug 0°	77102080	H=8mm	0° Lordosis	14(w) x 12(d)
BIO AVS C-Plug 0°	77102090	H=9mm	0° Lordosis	14(w) x 12(d)
BIO AVS C-Plug 0°	77102100	H=10mm	0° Lordosis	14(w) x 12(d)

Long: 11mm (W) x 30mm (L)

Description	Reference #	Sizing
BIO AVS UniLIF 7mm	96007	7mm (H) x 30mm (L) x 11mm (W)
BIO AVS UniLIF 9mm	96009	9mm (H) x 30mm (L) x 11mm (W)
BIO AVS UniLIF 11mm	96011	11mm (H) x 30mm (L) x 11mm (W)
BIO AVS UniLIF 13mm	96013	13mm (H) x 30mm (L) x 11mm (W)
BIO AVS UniLIF 15mm	96015	15mm (H) x 30mm (L) x 11mm (W)

Short: 9mm (W) x 25mm (L)

Description	Reference #	Sizing
BIO AVS UniLIF 7mm	95007	7mm (H) x 25mm (L) x 9mm (W)
BIO AVS UniLIF 9mm	95009	9mm (H) x 25mm (L) x 9mm (W)
BIO AVS UniLIF 11mm	95011	11mm (H) x 25mm (L) x 9mm (W)
BIO AVS UniLIF 13mm	95013	13mm (H) x 25mm (L) x 9mm (W)
BIO AVS UniLIF 15mm	95015	15mm (H) x 25mm (L) x 9mm (W)

BIO AVS AL

Description	Reference #	Sizing
BIO AVS AL	77701004	10mm
BIO AVS AL	77701204	12mm
BIO AVS AL	77701404	14mm
BIO AVS AL	77701604	16mm
BIO AVS AL	77701804	18mm
BIO AVS AL	77701008	10mm
BIO AVS AL	77701208	12mm
BIO AVS AL	77701408	14mm
BIO AVS AL	77701608	16mm
BIO AVS AL	77701808	18mm
BIO AVS AL	77701012	10mm
BIO AVS AL	77701212	12mm
BIO AVS AL	77701412	14mm

Unicortical

Description	Reference #	Sizing
BIO Wedge Unicortical	7770605	14x11 Height=5mm
BIO Wedge Unicortical	7770606	14x11 Height=6mm
BIO Wedge Unicortical	7770607	14x11 Height=7mm
BIO Wedge Unicortical	7770608	14x11 Height=8mm
BIO Wedge Unicortical	7770609	14x11 Height=9mm
BIO Wedge Unicortical	7770610	14x11 Height=10mm

*11mm Anterior-Posterior Depth, 14mm Medial-Lateral Width

Tricortical

Description	Reference #	Sizing
BIO Wedge Tricortical	7770705	Height=5mm
BIO Wedge Tricortical	7770706	Height=6mm
BIO Wedge Tricortical	7770707	Height=7mm
BIO Wedge Tricortical	7770708	Height=8mm
BIO Wedge Tricortical	7770709	Height=9mm
BIO Wedge Tricortical	7770710	Height=10mm

*11-17mm Anterior-Posterior Depth, 12-15mm Medial-Lateral Width

Iliac Crest

Description	Reference #	Sizing
BIO Wedge Iliac Crest	7770806	Height=6mm
BIO Wedge Iliac Crest	7770807	Height=7mm
BIO Wedge Iliac Crest	7770808	Height=8mm
BIO Wedge Iliac Crest	7770809	Height=9mm
BIO Wedge Iliac Crest	7770810	Height=10mm
BIO Wedge Iliac Crest	7770818	Height=18mm

*Minimum 25mm Anterior-Posterior Depth, Minimum 8mm Medial-Lateral Width

BIO Shaft

Femoral		
Description	Reference #	Sizing
BIO Shaft Femoral	77711060	Length=60mm
BIO Shaft Femoral	77711100	Length=100mm

*23-27mm Anterior-Posterior Diameter, 23-30mm Medial-Lateral Diameter

Fibular		
Description	Reference #	Sizing
BIO Shaft Fibular	77712040	Length=40mm
BIO Shaft Fibular	77712060	Length=60mm
BIO Shaft Fibular	77712100	Length=100mm

*Minimum 8-15mm Diameter

BIOExpand

BIOExpand		
Description	Reference #	Sizing
BIOExpand	77040813	4x8x13
BIOExpand	77040816	4x8x16
BIOExpand	77040820	4x8x20
BIOExpand	77101013	10x10x13
BIOExpand	77101016	10x10x16
BIOExpand	77101020	10x10x20

Cancellous (1-8mm)

Description	Reference #	Sizing
BIO Chips Cancellous 5cc	7770105	5cc 1-8mm particle range
BIO Chips Cancellous 15cc	7770115	15cc 1-8mm particle range
BIO Chips Cancellous 30cc	7770130	30cc 1-8mm particle range
BIO Chips Cancellous 60cc	7770160	60cc 1-8mm particle range

Cancellous (1-4mm)

Description	Reference #	Sizing
BIO Chips Cancellous 5cc	7770205	5cc 1-4mm particle range
BIO Chips Cancellous 15cc	7770215	15cc 1-4mm particle range
BIO Chips Cancellous 30cc	7770230	30cc 1-4mm particle range
BIO Chips Cancellous 60cc	7770260	60cc 1-4mm particle range

Cortico-Cancellous (1-8mm)

Description	Reference #	Sizing
BIO Chips Cortico-Cancellous 30cc	7770430	30cc 1-8mm particle range
BIO Chips Cortico-Cancellous 60cc	7770460	60cc 1-8mm particle range

Cortico-Cancellous (1-4mm)

Description	Reference #	Sizing
BIO Chips Cortico-Cancellous 30cc	7770530	30cc 1-4mm particle range
BIO Chips Cortico-Cancellous 60cc	7770560	60cc 1-4mm particle range

BIO DBM with Chips

Description	Reference #	Sizing
Bio DBM with Chips 5cc	7771305	5cc 1-8mm Cancellous with DBM Powder
Bio DBM with Chips 10cc	7771310	10cc 1-8mm Cancellous with DBM Powder
Bio DBM with Chips 15cc	7771315	15cc 1-8mm Cancellous with DBM Powder

AlloCraft PL

Description	Reference #	Sizing
AlloCraft PL	87008	8 x 22 H=8mm 5° Lordosis
AlloCraft PL	87010	8 x 22 H=10mm 5° Lordosis
AlloCraft PL	87012	8 x 22 H=12mm 5° Lordosis
AlloCraft PL	87014	8 x 22 H=14mm 5° Lordosis
AlloCraft PL	87016	8 x 22 H=16mm 5° Lordosis

AlloCraft TL

Description	Reference #	Sizing
AlloCraft TL	75008	8 x 26 H=8mm 0° Lordosis
AlloCraft TL	75010	8 x 26 H=10mm 0° Lordosis
AlloCraft TL	75012	8 x 26 H=12mm 0° Lordosis
AlloCraft TL	75014	8 x 26 H=14mm 0° Lordosis
AlloCraft TL	75016	8 x 26 H=16mm 0° Lordosis

Cervical Square Monolithic

Description	Reference #	Sizing
AlloCraft CS	6183-6-005	H=5mm 0° Lordosis 14(w) x 12(d)
AlloCraft CS	6183-6-006	H=6mm 0° Lordosis 14(w) x 12(d)
AlloCraft CS	6183-6-007	H=7mm 0° Lordosis 14(w) x 12(d)
AlloCraft CS	6183-6-008	H=8mm 0° Lordosis 14(w) x 12(d)
AlloCraft CS	6183-6-009	H=9mm 0° Lordosis 14(w) x 12(d)
Insertter	6183-0-902	

AlloCraft CL

Cervical Square Monolithic with Plug 4°

Description	Reference #	Sizing
AlloCraft CL	6183-5-005	H=5mm 5° Lordosis 14(w) x 12(d)
AlloCraft CL	6183-5-006	H=6mm 5° Lordosis 14(w) x 12(d)
AlloCraft CL	6183-5-007	H=7mm 5° Lordosis 14(w) x 12(d)
AlloCraft CL	6183-5-008	H=8mm 5° Lordosis 14(w) x 12(d)
AlloCraft CL	6183-5-009	H=9mm 5° Lordosis 14(w) x 12(d)
AlloCraft CL	6183-5-010	H=10mm 5° Lordosis 14(w) x 12(d)

AlloCraft CP

Cervical Square Monolithic with Plug 0°

Description	Reference #	Sizing
AlloCraft CP	6183-4-005	H=5mm 0° Lordosis 14(w) x 12(d)
AlloCraft CP	6183-4-006	H=6mm 0° Lordosis 14(w) x 12(d)
AlloCraft CP	6183-4-007	H=7mm 0° Lordosis 14(w) x 12(d)
AlloCraft CP	6183-4-008	H=8mm 0° Lordosis 14(w) x 12(d)
AlloCraft CP	6183-4-009	H=9mm 0° Lordosis 14(w) x 12(d)

AlloCraft CA

Cervical Assembled 5°

Description	Reference #	Sizing
AlloCraft CA	6183-7-005	H=5mm 5° Lordosis 14(w) x 11(d)
AlloCraft CA	6183-7-006	H=6mm 5° Lordosis 14(w) x 11(d)
AlloCraft CA	6183-7-007	H=7mm 5° Lordosis 14(w) x 11(d)
AlloCraft CA	6183-7-008	H=8mm 5° Lordosis 14(w) x 11(d)
AlloCraft CA	6183-7-009	H=9mm 5° Lordosis 14(w) x 11(d)
AlloCraft CA	6183-7-010	H=10mm 5° Lordosis 14(w) x 11(d)

Demineralized Bone Matrix

DBM Solutions

DBM		
Description	Reference #	Sizing
BIO DBM Putty	7775001	1cc Vial
BIO DBM Putty	7775025	2.5cc Vial
BIO DBM Putty	7775005	5cc Vial
BIO DBM Putty	7775010	10cc Vial
BIO DBM Gel	7776001	1cc Syringe
BIO DBM Gel	7776005	5cc Syringe
BIO DBM Gel	7776010	10cc Syringe
BIO DBM Putty Plus	7777005	5cc Vial
BIO DBM Putty Plus	7777010	10cc Vial

BIO DBM Boat		
Description	Reference #	Sizing
BIO DBM Boat (Single)	65305001	Equiv 10cc Length=5cm
BIO DBM Boat (Short)	653050	Equiv 20cc Length=5cm
BIO DBM Boat (Long)	653100	Equiv 40cc Length=10cm

BIO DBM Shape		
Description	Reference #	Sizing
BIO DBM Shape 1cc	65401	Equiv 1cc
BIO DBM Shape 2.5cc	65402	Equiv 2.5cc
BIO DBM Shape 5cc	65405	Equiv 5cc

Viable Bone Matrix

BIO⁴

BIO ⁴		
Description	Reference #	Sizing
BIO4	PS51001	1cc
BIO4	PS51002	2.5cc
BIO4	PS51005	5cc
BIO4	PS51001	10cc

Synthetics

Vitoss

Vitoss

Description	Reference #	Sizing
Vitoss Foam Pack	2102-1401	Foam Pack 1.2cc
Vitoss Foam Pack	2102-1402	Foam Pack 2.5cc
Vitoss Foam Pack	2102-1405	Foam Pack 5cc
Vitoss Foam Pack	2102-1410	Foam Pack 10cc
Vitoss Foam Strip	2102-1100	Foam Strip 25 x 100 x 4mm 10cc
Vitoss Foam Strip	2102-1101	Foam Strip 25 x 240 x 4mm 24cc
Vitoss Foam Strip	2102-1105	Foam Strip 25 x 50 x 4mm 5cc
Vitoss Foam Strip	2102-1110	Foam Strip 25 x 50 x 8mm 10cc
Vitoss Foam Strip	2102-1120	Foam Strip 25 x 100 x 8mm 20cc
Vitoss Micro-Morsel Canister	2102-0026	Micro-Morsel Canister 5cc 1-2mm morsel range
Vitoss Micro-Morsel Canister	2102-0027	Micro-Morsel Canister 10cc 1-2mm morsel range
Vitoss Micro-Morsel Canister	2102-0028	Micro-Morsel Canister 15cc 1-2mm morsel range
Vitoss Micro-Morsel Canister	2102-0029	Micro-Morsel Canister 30cc 1-2mm morsel range
Vitoss Standard Morsel Canister	2102-0030	Standard Morsel Canister 5cc 1-4mm morsel range
Vitoss Standard Morsel Canister	2102-0031	Standard Morsel Canister 10cc 1-4mm morsel range
Vitoss Standard Morsel Canister	2102-0032	Standard Morsel Canister 15cc 1-4mm morsel range
Vitoss Standard Morsel Canister	2102-0033	Standard Morsel Canister 30cc 1-4mm morsel range
Vitoss Macro-Morsels	2102-0020	Macro-Morsels 15cc 4-7mm morsel range
Vitoss Macro-Morsels	2102-0021	Macro-Morsels 30cc 4-7mm morsel range
Vitoss Block	2102-0013	Block 1.2cc
Vitoss Block	2102-0006	Block 10cc
Vitoss Macro Morsel Tower	2102-0131	Macro Morsel Tower 30 cc (10 pack)

Vitoss BA, BA2X, BiModal

Vitoss BA

Description	Reference #	Sizing
Vitoss BA Bioactive Foam Pack	2102-1601	Bioactive Foam Pack 1.2cc
Vitoss BA Bioactive Foam Pack	2102-1602	Bioactive Foam Pack 2.5cc
Vitoss BA Bioactive Foam Pack	2102-1605	Bioactive Foam Pack 5cc
Vitoss BA Bioactive Foam Pack	2102-1610	Bioactive Foam Pack 10cc
Vitoss BA Bioactive Foam Strip	2102-1500	Bioactive Foam Strip 25 x 100 x 4mm 10cc
Vitoss BA Bioactive Foam Strip	2102-1505	Bioactive Foam Strip 25 x 50 x 4mm 5cc
Vitoss BA Bioactive Foam Strip	2102-1510	Bioactive Foam Strip 25 x 50 x 8mm 10cc
Vitoss BA Bioactive Foam Strip	2102-1520	Bioactive Foam Strip 25 x 100 x 8mm 20cc

Vitoss BA2X

Description	Reference #	Sizing
Vitoss BA 2X Bioactive Foam Pack	2102-2101	Bioactive Foam Pack 1.2cc
Vitoss BA 2X Bioactive Foam Pack	2102-2102	Bioactive Foam Pack 2.5cc
Vitoss BA 2X Bioactive Foam Pack	2102-2105	Bioactive Foam Pack 5cc
Vitoss BA 2X Bioactive Foam Pack	2102-2110	Bioactive Foam Pack 10cc

Vitoss BiModal

Description	Reference #	Sizing
Vitoss BA BiModal Foam Pack	2102-1901	Bioactive Foam Pack 1.2cc
Vitoss BA BiModal Foam Pack	2102-1902	Bioactive Foam Pack 2.5cc
Vitoss BA BiModal Foam Pack	2102-1905	Bioactive Foam Pack 5cc
Vitoss BA BiModal Foam Pack	2102-1910	Bioactive Foam Pack 10cc

Bone Marrow Aspiration and Delivery

Imbibe Bone Marrow Aspiration and Delivery System

Imbibe Needle		
Description	Reference #	Sizing
Beveled Needle	2090-9051	11 gauge x 6 inch
Beveled Needle	2090-9052	8 gauge x 6 inch
Beveled Fenestrated Needle	2090-9053	8 gauge x 6 inch
Diamond Tip Needle	2090-9027	11 gauge x 4 inch
Diamond Tip Needle	2090-9028	11 gauge x 6 inch
Diamond Tip Needle	2090-9029	8 gauge x 6 inch
Diamond Tip Fenestrated Needle	2090-9030	8 gauge x 6 inch
Diamond Tip Needle	2090-9047	8 gauge x 8 inch
Imbibe Syringe	2105-0010	Syringe 10cc
Imbibe Syringe	2105-0020	Syringe 20cc
Imbibe Syringe	2105-0030	Syringe 30cc

Stryker Comprehensive Biologic

Spine



Trauma and Extremities



s Portfolio

Craniomaxillofacial



Demineralized Cancellous Cube



Demineralized Cancellous Fillers



Demineralized Cancellous Sponge Ship



DirectInject HA Cement

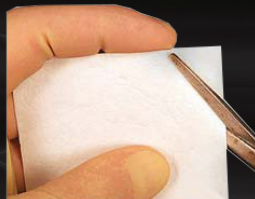


Demineralized Cancellous Particulate

Sports Medicine



Allogratts



Soft Tissue Repair



Autologous Platelet Rich Plasma



Acellular Dermis

Endnotes

1. Independent sources include the Virginia Commonwealth University Medical Center and the American Association of Mechanical Engineers. Data on file at LifeNet Health.
2. Moore M, Linthurst Jones A, Gaskins B et al. Adaptation of ANSI/AAMI/ISO 11137 method 2B Sterilization validation for medical devices to tissue banking. Presented at: American Association of Tissue Banks Annual Meeting; Chicago, IL August 2004.
3. Data on file. LifeNet Health.
4. Walsh WR, Oliver R, Yu Y, et al., Demineralized Bone Matrix provides equivalent results to autograft in standard posterolateral fusion model in adult rabbits. AlloSource White Paper, 2012.
5. Data on file Allosource.
6. Roberts and Rosenbaum, "Bone grafts, bone substitutes and orthobiologics," Organogenesis (2012).
7. Osiris Therapeutics - Data on File.
8. Bourke et al., "Vascular Endothelial Growth Factor (VEGF) in Human Periosteum - Normal Expression and Response to Fracture," Journal of Bone & Joint Surgery, British Volume (2003).
9. Millennium Research Group: US Markets for Orthopedic Biomaterials 2014.
10. Stryker Orthobiologics Internal Sales Data, July 2014.
11. Bellincampi, L., Clineff, T., Erbe, E., Osteoinductivity of Vitoss with Isologous Bone Marrow in Urist Rat Pouch Model. Society for Biomaterials, Tampa, FL, April 24-27, 2002 (Podium).
12. Orthovita Test Report P/N 1050-0003R.
13. Orthovita Test Report P/N 1070-0008R.
14. Anker et al, Ultraporous Beta-Tricalcium Phosphate is Well Incorporated in Small Cavitary Defects. Clinical Orthopaedics and Related Research, 2005 May; 434: 251-7.
15. Havener, MB, Clineff, TD, Darmoc, MM, Brown, LS, Owsiany, R, A Comparative Study of Synthetic Bone Graft Substitutes in a Canine Metaphyseal Defect. 54th Annual Meeting of the Orthopaedic Research Society, 2008.
16. Hench, L.L., Splinter, R.J., and Allen, W.C., Bonding Mechanisms at the Interface of Ceramic Prosthetic Materials. Journal of Biomedical Materials Research, 1971; 2(1): 117-141.
17. Hench, L.L., Paschall, H.A., Direct Chemical Bond of Bioactive Glass-Ceramic Materials to Bone and Muscle. Journal of Biomedical Materials Research, 1973; 4: 25-42.
18. Gross, U., The Interface of Various Glasses and Glass Ceramics with a Bony Implantation Bed. Journal of Biomedical Materials Research, 1985; 19: 251-271.
19. Hench, L.L., The Story of Bioglass. Journal of Materials Science: Materials in Medicine, 2006 Nov; 17(11): 967-78.
20. Oonishi, H., et al., Particulate Bioglass Compared with Hydroxyapatite as a Bone Graft Substitute. Clinical Orthopaedics and Related Research, 1997 Jan; 334: 316-25.
21. Vrouwenvelder, W.C.A., Histological and Biochemical Evaluation of Osteoblasts Cultured on Bioactive Glass, Hydroxyapatite, Titanium Alloy, and Stainless Steel. Journal of Biomedical Materials Research, 1993 Apr; 27(4): 465-75.
22. Xynos, I.D., Edgar, A.J., Buttery, L.D.K., Hench, L.L., and Polak, J.M., Ionic Products of Bioactive Glass Dissolution Increase Proliferation of Human Osteoblasts and Induce Insulin-like Growth Factor II mRNA Expression and Protein.
23. Hench, L.L., Polak, J.M., Xynos, I.D., Buttery, L.D.K., Bioactive Materials to Control Cell Cycle. Materials Research Innovations, 2000; 3(6): 313-323.
24. Sanders, D.M., Hench, L.L., Mechanisms of Glass Corrosion. Journal of American Ceramic Society. 1973; 56(7): 373-377.
25. Hench, L.L., Characterization of Glass Corrosion and Durability. Journal of Non-Crystalline Solids, 1975; 19: 27-39.
26. Ogino, M., Hench, L.L., Formation of Calcium Phosphate Films on Silicate Glasses. Journal of Non-Crystalline Solids, 1980; 38 and 39: 673-678.
27. Orthovita Test Report P/N 1000-2024R.
28. Orthovita Test Report 1010-0117R.
29. Orthovita Test Report 1015-0083.
30. Muschler, G.F., Nakamoto, C., Griffith, L.G., Engineering Principles of Clinical Cell-Based Tissue Engineering. Journal of Bone and Joint Surgery, 2004; 86(7): 1541.
31. Curylo, L.J., et al., Augmentation of Spinal Arthrodesis With Autologous Bone Marrow in a Rabbit Posterolateral Spine Fusion Model. Spine, 1999 March 1, 24(5): 434-8.
32. Kim, K.J., et al., Effect of Bone Marrow Grafting on the Titanium Porous-Coated Implant in Bilateral Total Knee Arthroplasty. Acta Orthopaedica, 2007 February; 78(1): 116-22.

Vitoss Indications for Use

Vitoss Bone Graft Substitute is intended for use as a bone void filler for voids or gaps that are not intrinsic to the stability of the bony structure. Vitoss Bone Graft Substitute is indicated for use in the treatment of surgically created osseous defects or osseous defects created from traumatic injury to the bone.

Vitoss Bone Graft Substitute is intended to be used for filling bony voids or gaps of the skeletal system (i.e., the extremities, pelvis and posterolateral spine) and may be combined with autogenous blood and/or bone marrow. Following placement in the bony void or gap, the scaffold resorbs and is replaced with bone during the healing process.

Vitoss Contraindications

Use of Vitoss Bone Graft Substitute is contraindicated in the presence of one or more of the following clinical situations: Growth plate fractures, segmental defects, conditions where the surgical site may be subjected to excessive impact or stresses, including those beyond the load strength of fixation hardware, significant vascular impairment proximal to the graft site, metabolic or systemic bone disorders that affect bone or wound healing, infected sites, osteomyelitis at the operative site, defect site stabilization is not possible, intraoperative soft tissue coverage is not planned or possible, in direct contact with the articular space, conditions in which general bone grafting is not advisable.

Vitoss Foam, Vitoss BA, Vitoss BA2X, and Vitoss BiModal Foam Bone Graft Substitutes must not be used in patients with a history of anaphylaxis, history of multiple allergies, known allergies to bovine collagen, or who are being treated for desensitization to meat products because this product contains bovine collagen.

Imbibe Needle Indications for Use

The Imbibe Needle is for use in aspirating bone marrow or autologous blood by use of a syringe. The bone marrow or autologous blood may be combined with bone graft or bone void filler. The Imbibe Needle is also for use in the placement of guidewires (e.g. kwires) during orthopedic surgery.

Imbibe Needle Contraindications

Intended for use only by a licensed physician. The physician should be familiar with contraindications of performing a bone marrow aspiration procedure. Physician's judgment is required to consider patient's risk factors such as anticoagulant therapy or clotting disorders, prior to aspirating bone marrow.

Imbibe Syringe Indications for Use:

The Imbibe Bone Marrow Aspiration Syringe is intended for use as a piston syringe for the aspiration of bone marrow, autologous blood, plasma or other blood components. Prior to use, the syringe can be filled with the surgeon's choice of bone void filler (allograft, autograft, or synthetic bone graft material). This syringe provides the surgeon with a convenient way to mix autologous blood or bone marrow with bone void filler (bone graft) and deliver the material to the orthopaedic surgical site.



Reconstructive

Hips
Knees
Trauma & Extremities
Joint Preservation
Orthobiologics

Medical & Surgical

Power Tools & Surgical Accessories
Image Guided Navigation
Endoscopy & Arthroscopy
Integrated Communications
Beds, Stretchers & EMS
Sustainability Solutions

Neurotechnology & Spine

Craniomaxillofacial
Interventional Spine
Neurosurgical, Spine & ENT
Neurovascular
Spinal Implants

A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Stryker does not dispense medical advice and recommends that surgeons be trained in the use of any particular product before using it in surgery.

The information presented is intended to demonstrate the breadth of Stryker product offerings. Caution: Federal Law restrict these devices to sale by or on the order of a physician. A surgeon must always refer to the package insert, product label and/or instructions for use before using any Stryker product. Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Stryker representative if you have questions about the availability of Stryker products in your area.

Stryker Corporation or its divisions or other corporate affiliated entities own, use or have applied for the following trademarks or service marks: AlloCraft, Aviator, AVS, BIO4, Bio AVS, Bio DBM, Bio DBM Boat, BIO Chips, Bio DBM Gel, Bio DBM Putty, Bio DBM Shape, BIOExpand, BIO Shaft, BIO Wedge, ES2, Hydroset, Imbibe, LiTe, Oasys, Radius, SLIDE, Stryker, Trio, UniLIF, Vitoss, Xia. All other trademarks are trademarks of their respective owners or holders.

Allowash XG and Preservon are registered trademarks of Lifenet Health.
Actifuse is a registered trademark of Apatech LTD.
Neuroflex is a trademark of Collagen Matrix, Inc.

Content ID - PRTBI-BR-1
ddm/SC/GS

Copyright © 2015 Stryker
Printed in USA

2 Pearl Court
Allendale, NJ 07401
t: 201-479-8000

www.stryker.com