stryker

Spine
Product Catalog

Introduction

Our Spine division offers a comprehensive portfolio for orthopaedic surgeons and neurosurgeons specializing in the surgical treatment of a broad range of spinal pathologies.

Our continually expanding portfolio features complete procedural solutions for the spine spanning from the occiput to the pelvis, including a full suite of LITe (Less Invasive Technology) procedures such as the LITe TLIF, LITe LIF and LITe ALIF. By teaming up with our sister divisions, we have been able to add navigation and power capabilities to many of our spinal fixation systems including Serrato, Xia 3, Xia 4.5 and ES2. In addition to these solutions, we have collaborated with the nation's industry-leading tissue organizations to offer a comprehensive portfolio consisting of traditional and proprietary spinal grafts as well as demineralized bone matrix products. We also offer a viable bone matrix in BIO[4] as well as a full line of synthetic bone grafting substitutes in Vitoss.

We recently launched our first 3D printed porous titanium interbody devices, the Tritanium PL, TL and C Cages. These cages are manufactured using our proprietary Tritanium In-Growth Technology, a novel highly porous titanium material designed for bone in-growth and biological fixation[1]. We plan to expand the use of this unique technology over the next few years.

Biologics

Viable Bone Matrix

Synthetic

DBM

Allograft

Cervical

Aviator

Oasys

Aero C

Less invasive/instruments

Pedicle Based Retractor

LITe Plate System

ES2

Thoracolumbar fixation

Xia 3

Xia 4.5

Serrato

Xia CT

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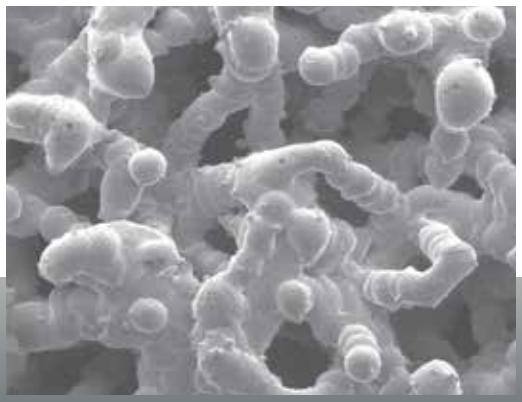
Tritanium In-Growth Technology[1]



Tritanium In-Growth **Technology**[1]

Our proprietary Tritanium In-Growth Technology, used to build the Tritanium PL and C Cages, has been designed for bone in-growth[1] and biological fixation. The unique porous structure is designed to create a favorable environment for cell attachment and proliferation[2,3] and may be able to wick or retain fluid when compared to traditional titanium material.[4, 5] Inspired by the microstructure of cancellous bone,[3] and enabled by AMagine, our proprietary approach to implant creation using additive manufacturing, this technology is deliberately designed for fusion.

Constructed to wick[4, 5]*

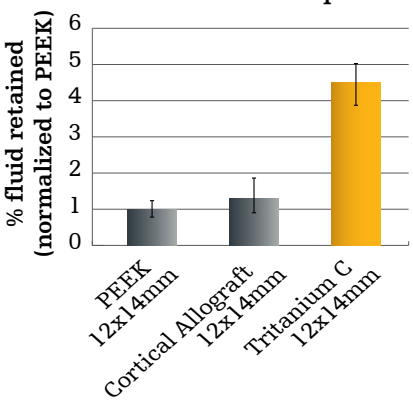
Tritanium material may be able to wick or retain fluid in comparison to traditional titanium material.[5] Tritanium material demonstrated the ability to wick fluid into the porous structure under specified conditions during an experiment. It also absorbed and held fluid inside the porous structure.[5]

- Wicking, synonymous with capillary action, allows for the distribution of nutrients throughout the cage, even against gravity[6, 7]
- Wicking, synonymous with capillary action, may lead to the migration and attachment of cells[7]

The Tritanium C Cage demonstrated it absorbed 3 times more bone marrow aspirate (BMA) than allograft and 4 times more BMA than PEEK, in an in vitro study.[8]

*As compared to traditional titanium material.

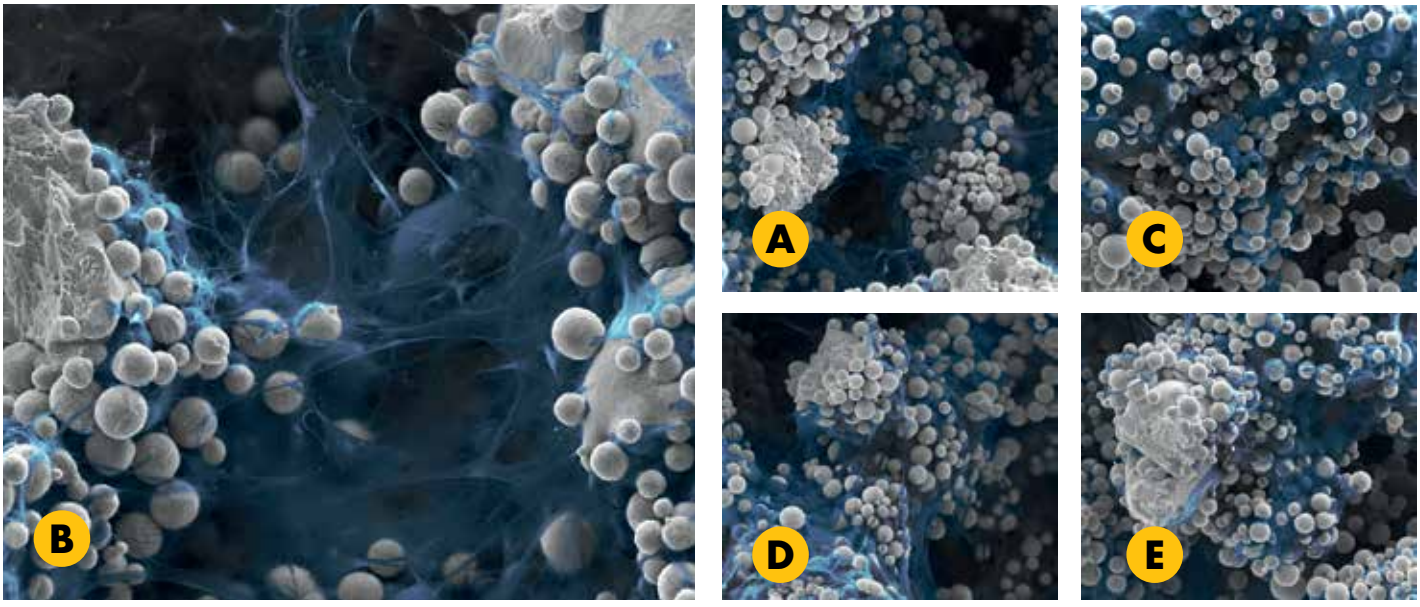
Fluid retention versus material and footprint[8†]



†This experiment was performed using heparinized porcine bone marrow aspirate. No correlation to human clinical outcomes has been demonstrated or established.

Designed to create a favorable environment for cells[2, 3]

A coupon built with Tritanium In-Growth Technology demonstrated that osteoblasts (bone cells) infiltrated, attached to and proliferated on the porosity of the Tritanium technology.[2] The unique porous structure is designed to create a favorable environment for cell attachment.[2,3]



Osteoblasts
Tritanium In-Growth Technology

Normal human osteoblast cells were used for in-vitro cell studies. No correlation to human clinical outcomes has been demonstrated or established.

Image depicts a sample built with Tritanium Technology used for in vitro cell studies. The sample was designed to mimic a generic interbody cage with an open graft window. This is not an implantable device.

Designed for in-growth[1]

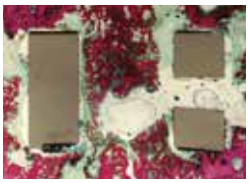
Tritanium technology has been designed for bone in-growth and biological fixation.[1]

8 weeks post-op
in an ovine model[9]

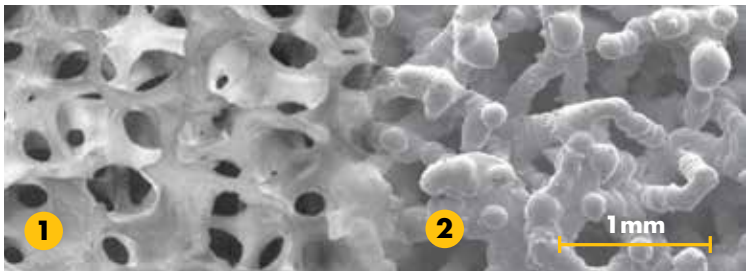
16 weeks post-op
in an ovine model[9]

PEEK Cage


Ti Plasma Sprayed PEEK Cage




Tritanium PL Cage

1 Cancellous bone characteristics[3]

- Average pore diameter of cancellous bone = 1mm
- Average porosity of cancellous bone = 50-90%

2 Tritanium material characteristics[10†]

- Randomized pore sizing designed to mimic cancellous bone
  - Pore size range: 100-700μm
  - Mean pore size: 400-500μm
- Interconnected pore structure from endplate to endplate
  - Mean porosity: 55-65%

†In spinal implants

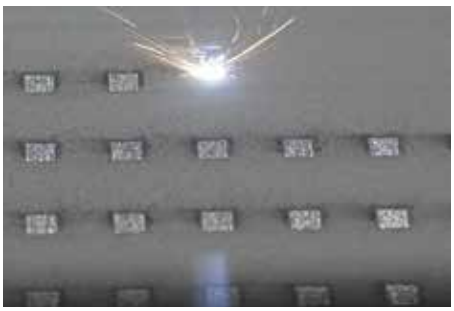
Empowered by AMagine

AMagine is our proprietary approach to implant creation using additive manufacturing (AM). Additive manufacturing allows us to push beyond conventional manufacturing techniques to address design complexity and achieve previously unmanufacturable geometries, but also to deliver the performance, reproducibility and quality you expect from our products.

Our investment in additive manufacturing began in 2001 and, since then, we have collaborated with leading universities in Ireland and the UK to industrialize 3D printing for the healthcare industry.

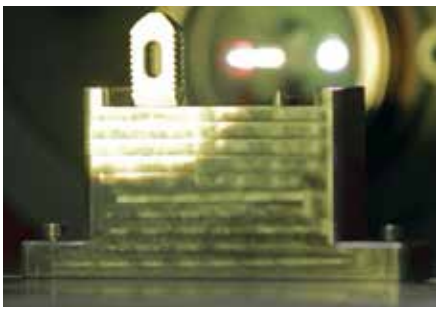
The AMagine Institute, our new global technology development center/hub located in Cork, Ireland, is the world's largest additive manufacturing facility for orthopaedic implants. Among the most advanced AM facilities of its kind, it is where bright ideas are transformed into exciting new implants. AMagine, which incorporates hundreds of quality checks per batch, enables us to design and build Tritanium devices with pinpoint precision, optimizing device characteristics from pore size and porosity to shape and surgical features, for use in spinal surgery.[11]

Originally launched for hip and knee implants, our Tritanium technology has been proven in over 10 years of clinical experience with more than 300,000 orthopaedic devices implanted.[11]



Built with laser precision, layer by layer[11]

AMagine Institute

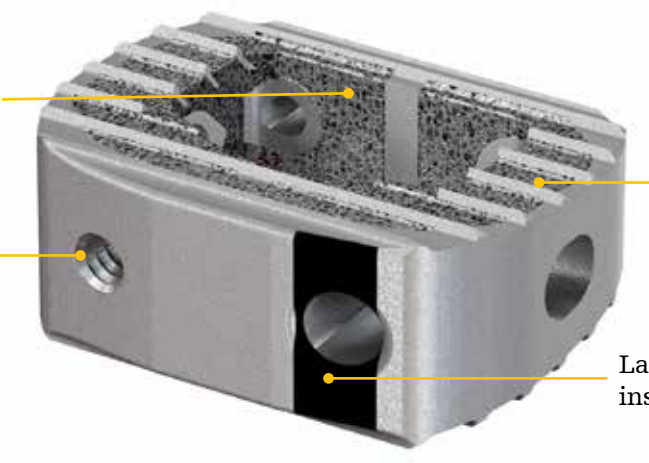


Hundreds of quality checks are utilized to ensure precise design in every batch[11]

For more information please visit www.stryker.com/builttofuse

Tritanium C
Anterior Cervical Cage

Tritanium C Anterior Cervical Cage design

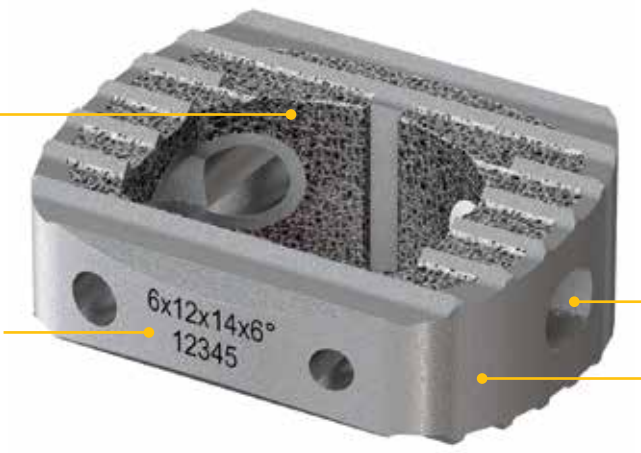


Large central graft window maximizes bone graft volume

Threaded inserter attachment for rigid inserter-to-cage connection

Solid-tipped, precisely angled serrations designed for bidirectional fixation and to maximize surface area for endplate contact with the cage

Laser marking verifies proper inserter attachment



Highly porous titanium alloy material throughout cage

Smooth posterior nose facilitates cage insertion

Lateral windows to reduce stiffness of cage and aid in visualization of fusion

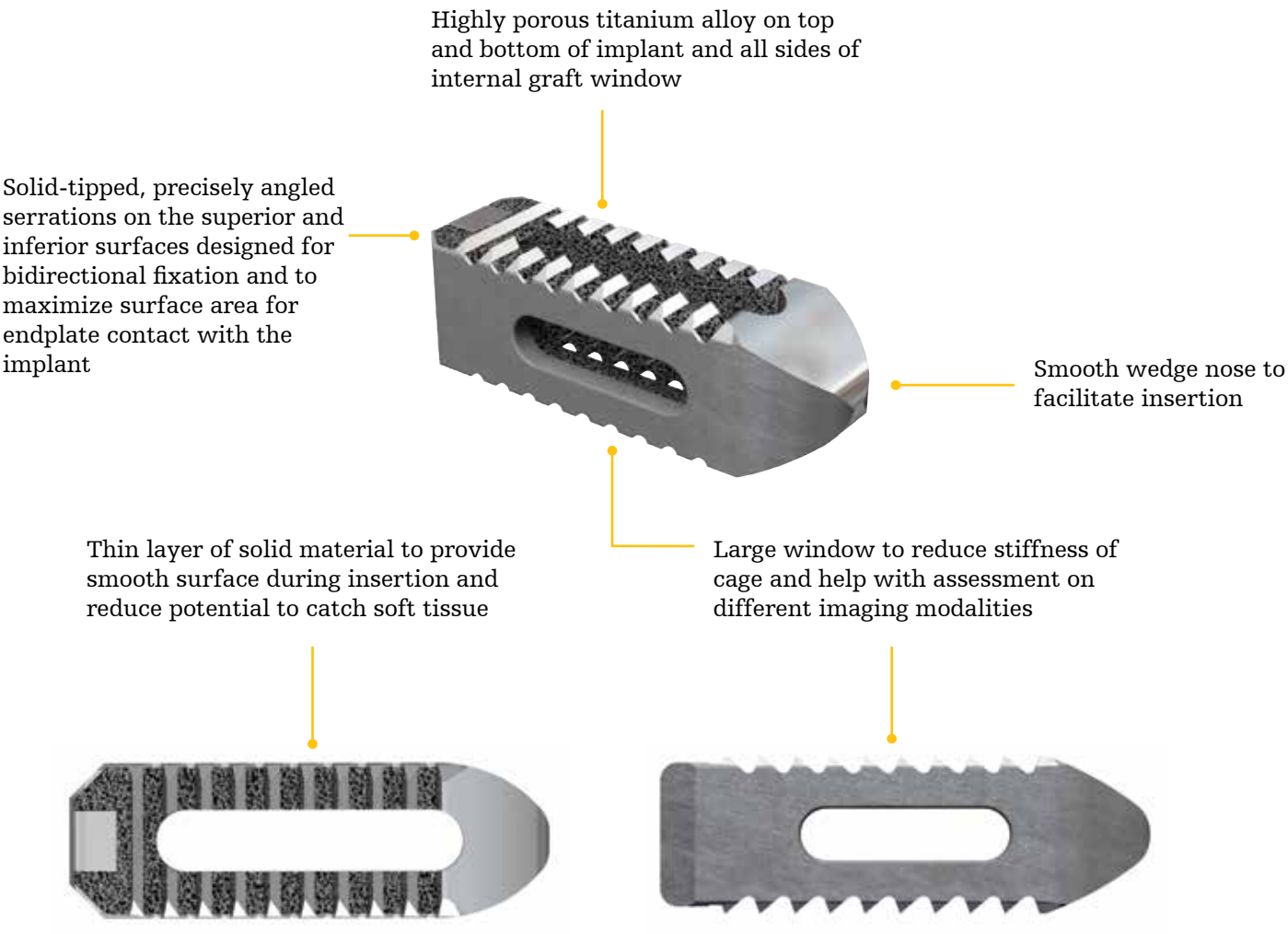
Thin layer of solid material surrounding cage provides smooth insertion

Sizing options

Footprint (W x L)	12 x 14mm	14 x 17mm
Lordosis	**Height**	
6°	5-9mm	5-9mm
10°		6-8mm

Tritanium PL
Posterior Lumbar Cage

Tritanium PL Posterior Lumbar Cage design

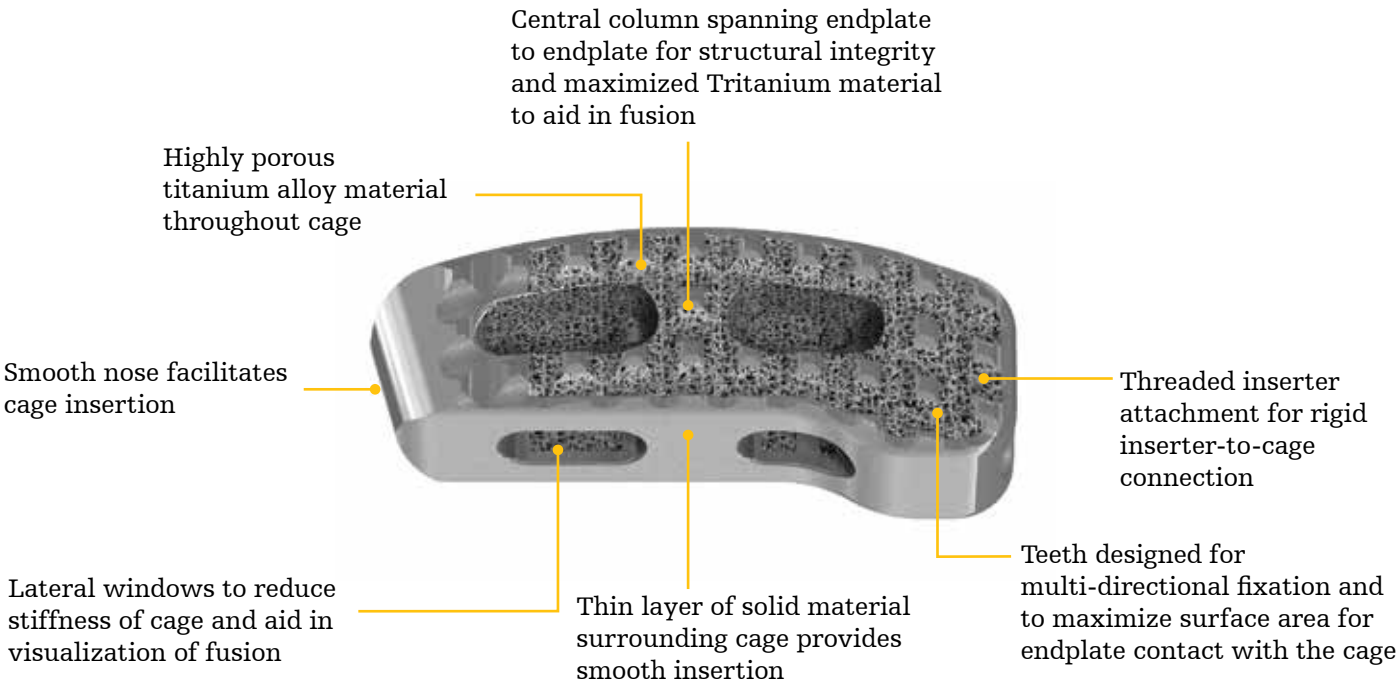


Sizing options

Footprint (W x L)	9 x 23mm	11 x 23mm	9 x 28mm	11 x 28mm
Lordosis	**Height**			
0°	7-14mm	7-14mm	7-14mm	7-14mm
6°	7-14mm	7-14mm	7-14mm	7-14mm
12°	9-14mm	9-14mm	9, 11, 13mm	9-14mm

Tritanium TL
Curved Posterior Lumbar Cage

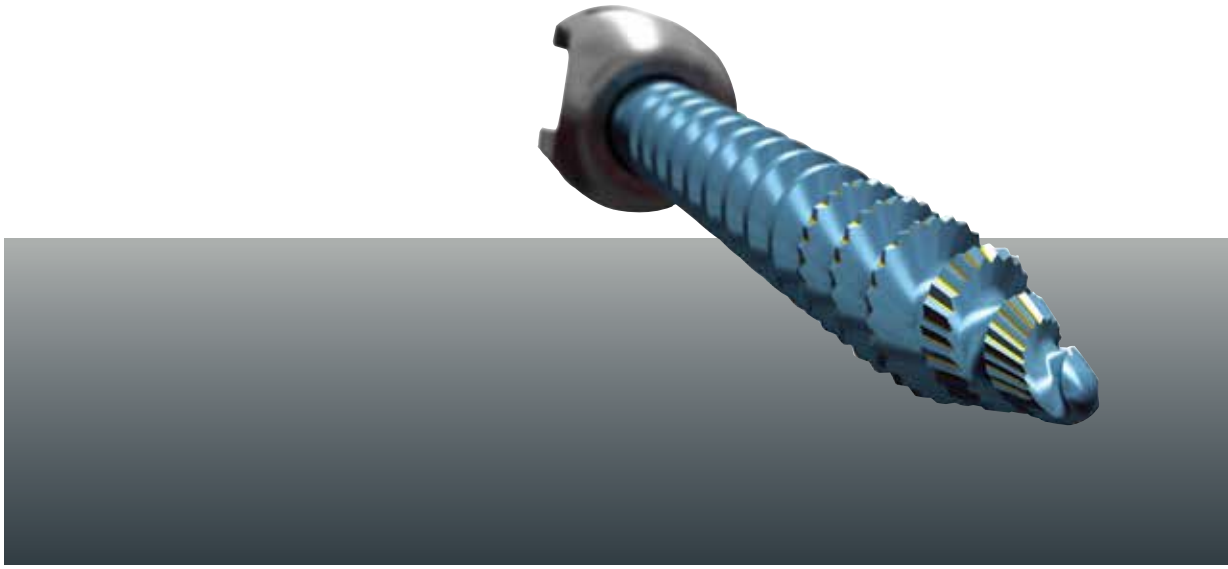
Tritanium TL Curved Posterior Lumbar Cage design



Sizing options

Footprint (W x L)	10 x 27mm	10 x 31mm	10 x 35mm
Lordosis	Height		
0°	7mm	7mm	7mm
6°	8-12mm	8-14mm	8-14mm
12°	9-14mm	9-14mm	9-14mm

Serrato Polyaxial Screw



Serrato

Allowing you to work less and accomplish more.

Description:

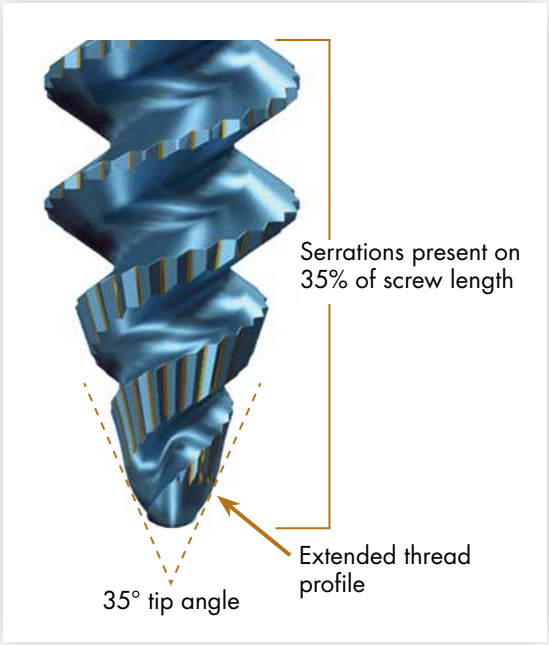
Serrato is designed to increase efficiency in your operating room by decreasing insertion time and energy, and increasing pull-out strength retention and resistance to screw migration.[12,13]

The newly designed Serrato pedicle screws feature **True-Tip** geometry, market-differentiating **serrations** and a **dual-lead** thread, to help achieve accurate screw placement in a more efficient way.

True-Tip technology

The 35° conical tip and extended thread profile are designed to increase OR efficiency by allowing for:

- Immediate engagement with bone[14]
- Reliable insertion and accurate control starting from the screw tip[14]
- Ability to self-center and self-tap in bone[12]



Serrations designed to decrease work

Serrato is the **only available** pedicle screw with serrations designed to reduce work by decreasing the amount of energy needed for screw insertion.[14,15]

Screw to screwdriver interface

6-point star engagement between the screwdriver and screws is designed to decrease toggle, intuitively align when loading and re-engage for screw adjustments.

The 6-point star screw head is designed:

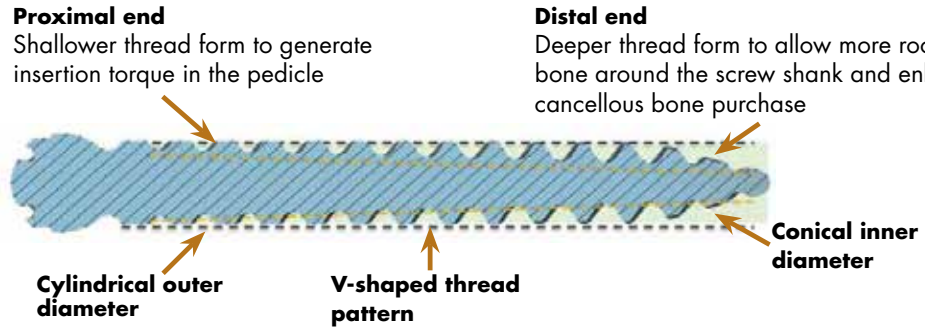
- **For faster and more intuitive engagement with the screwdriver**
- **To prevent screw head stripping**
- **For reengagement during screw adjustments**

Polyaxial screws / cannulated polyaxial screws

Medial biased screws

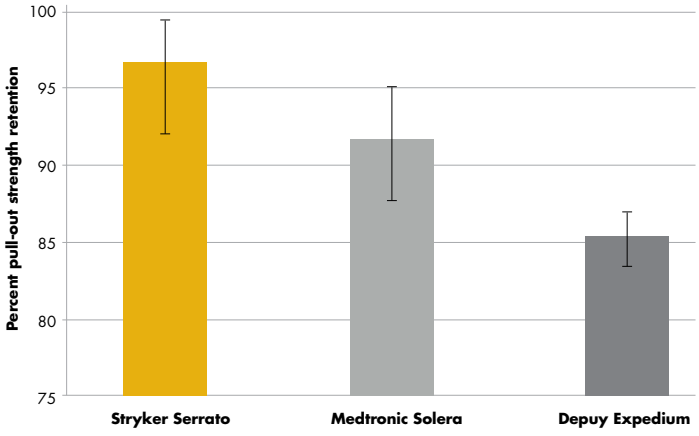
Reduction screws

Cortical cancellous thread pattern



Feature	Location on screw	Reason for design
Shallow thread form	Proximal end	To generate insertion torque in cortical (pedicle) bone
Deep thread form	Distal end	To allow more room for bone around the screw shank and to enhance cancellous (vertebral body) bone purchase
V-shaped thread	Entire shank	Offers potential for enhanced fixation as compared to other thread shapes[16]
Constant pitch	Entire shank	Each full rotation of the screw will move it the same distance into the hole for the entire duration of insertion

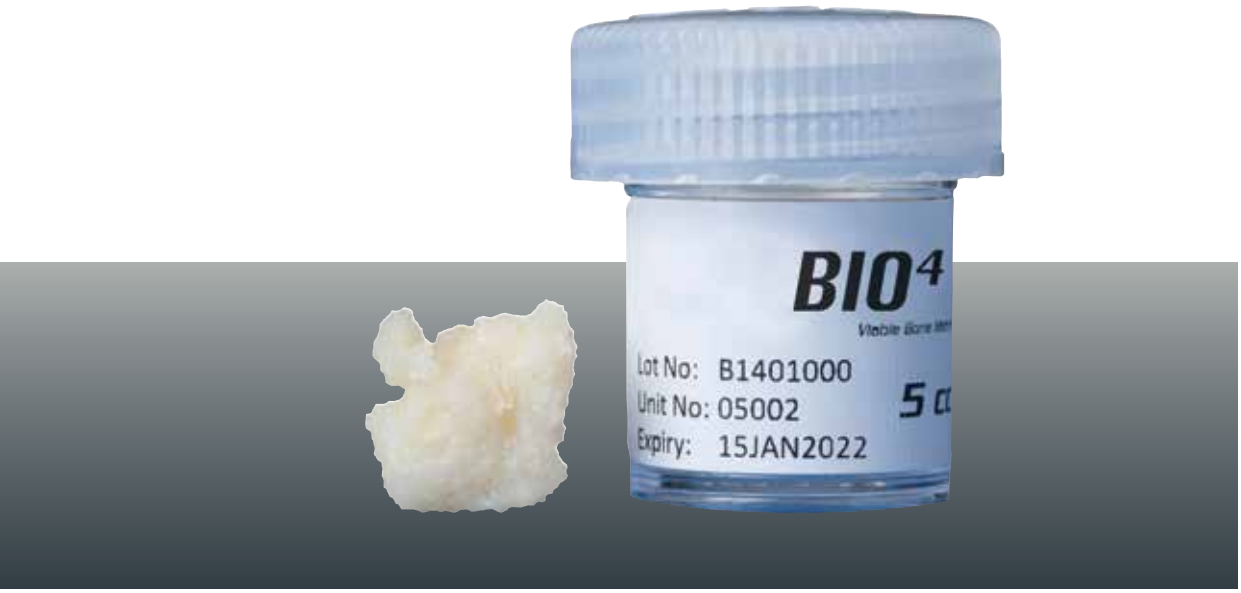
Pull-out strength retention post-toggle[13]



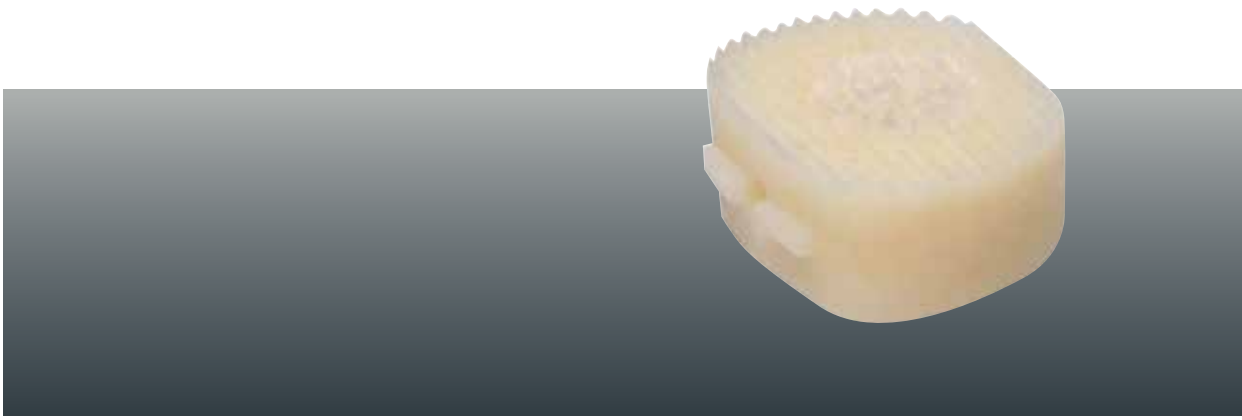
- In addition to a smaller amount of micro-motion, Serrato **demonstrated an improved ability to retain its pull-out strength** compared with other screw designs[13]

Note: this testing was completed in a laboratory setting per ASTM 543-17

Biologics



Allograft Implants

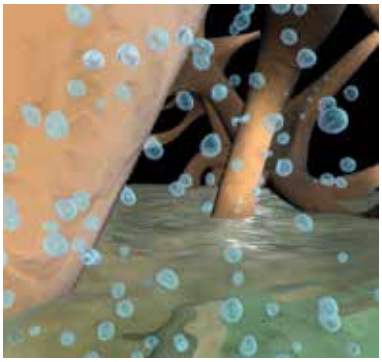


Preservon Technology

Why choose Preservon allograft BIO Implants?

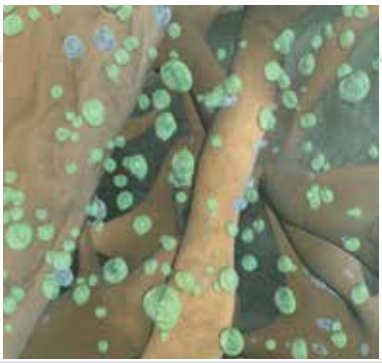
Preservon allograft BIO Implants are more efficiently and conveniently stored and handled than grafts treated with conventional preservation methods.

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[17]	Helps preserve product integrity
Consistent osteoconductive properties and compressive strength[17]	May help optimize performance
No inflammatory response[17]	Can help optimize safety

BIO AVS
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.

BIO AVS C-Open

Technical specifications

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

BIO AVS C-Plug

Product features[18, 19]

- 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
- Preservon treated for fully hydrated ambient temperature storage
- Processed with Allowash XG to achieve a Sterility Assurance Level to 10^{-6} (SAL)[20]

Intuitive instrumentation

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

BIO AVS C-Open

Reference number	Description (height x depth x width x lordosis)*
77101054	5H x 12D x 14 x 4° Lordosis
77101064	6H x 12D x 14 x 4° Lordosis
77101074	7H x 12D x 14 x 4° Lordosis
77101084	8H x 12D x 14 x 4° Lordosis
77101094	9H x 12D x 14 x 4° Lordosis
77101104	10H x 12D x 14 x 4° Lordosis
77101050	5H x 12D x 14 x 0° Lordosis
77101060	6H x 12D x 14 x 0° Lordosis
77101070	7H x 12D x 14 x 0° Lordosis
77101080	8H x 12D x 14 x 0° Lordosis
77101090	9H x 12D x 14 x 0° Lordosis
77101100	10H x 12D x 14 x 0° Lordosis

*height, depth and width measurements in mm

BIO AVS C-Plug

Reference number	Description (height x depth x width x lordosis)*
77102054	5H x 12D x 14 x 4° Lordosis
77102064	6H x 12D x 14 x 4° Lordosis
77102074	7H x 12D x 14 x 4° Lordosis
77102084	8H x 12D x 14 x 4° Lordosis
77102094	9H x 12D x 14 x 4° Lordosis
77102104	10H x 12D x 14 x 4° Lordosis
77102050	5H x 12D x 14 x 0° Lordosis
77102060	6H x 12D x 14 x 0° Lordosis
77102070	7H x 12D x 14 x 0° Lordosis
77102080	8H x 12D x 14 x 0° Lordosis
77102090	9H x 12D x 14 x 0° Lordosis
77102100	10H x 12D x 14 x 0° Lordosis

*height, depth and width measurements in mm

BIO AVS
UniLIF

Description

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

BIO AVS UniLIF

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[18]

- 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)[20]

BIO AVS UniLIF Long

Reference number	Description (height x length x width)*
96007	7H x 30L x 11W
96009	9H x 30L x 11W
96011	11H x 30L x 11W
96013	13H x 30L x 11W
96015	15H x 30L x 11W

*height, length and width measurements in mm

BIO AVS UniLIF Short

Reference number	Description (height x length x width)*
95007	7H x 25L x 9W
95009	9H x 25L x 9W
95011	11H x 25L x 9W
95013	13H x 25L x 9W
95015	15H x 25L x 9W

*height, length and width measurements in mm

BIO AVS
AL

Description

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

BIO AVS AL

Technical specifications

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

Product features[18]

- 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)[20]

BIO AVS AL

Reference number	Description (height x lordosis)*
77701004	10H x 4° Lordosis
77701204	12H x 4° Lordosis
77701404	14H x 4° Lordosis
77701604	16H x 4° Lordosis
77701804	18H x 4° Lordosis
77701008	10H x 8° Lordosis
77701208	12H x 8° Lordosis
77701408	14H x 8° Lordosis
77701608	16H x 8° Lordosis
77701808	18H x 8° Lordosis
77701012	10H x 12° Lordosis
77701212	12H x 12° Lordosis
77701412	14H x 12° Lordosis
77701612	16H x 12° Lordosis
77701812	18H x 12° Lordosis

*height measurements in mm

BIO AVS AL is only compatible with SLIDE Instrumentation

BIO AVS
TL

Description

The BIO AVS TL implants are machined cortical constructs from femur, tibia and humerus allograft bone. They are designed for use in Transforaminal Lumbar Interbody Fusion (TLIF) procedures.

BIO AVS TL

Technical specifications

- Length: 30mm
- Width: 11mm
- Anterior height: Ranging from 7-17mm in 2mm increments

Product features[18]

- Preservon treated for fully hydrated ambient temperature storage
- Machined to precise dimensions for consistent fit and functionality
- Chamfered leading edge for ease of insertion
- Textured surface area helps minimize risk of implant migration and displacement
- Processed with Allowash XG to achieve a Sterility Assurance Level to 10^{-6} (SAL)[20]
- Machined from femur, tibia and humerus cortical bone

BIO AVS TL

Reference number	Description (height x length x width)**
77701070	7H x 30L x 11W
77701090	9H x 30L x 11W
77701110	11H x 30L x 11W
77701130	13H x 30L x 11W
77701150	15H x 30L x 11W
77701170	17H x 30L x 11W
483600100	Allocraft TL inserter

**height, length and width measurements in mm

BIO Wedge
Unicortical

Description

The BIO Wedge Unicortical allografts are recovered from femoral condyles, femoral heads, distal tibia and talus allografts, and designed for use in anterior cervical procedures.

BIO Wedge Unicortical

Technical specifications

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

Product features[18]

- 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)[20]

BIO Wedge Unicortical

Reference number	Description (height x depth x width)*
7770605	5H x 11D x 14W
7770606	6H x 11D x 14W
7770607	7H x 11D x 14W
7770608	8H x 11D x 14W
7770609	9H x 11D x 14W
7770610	10H x 11D x 14W

*height, length and width measurements in mm

BIO Wedge
Tricortical

Description

The BIO Wedge Tricortical allografts are processed from patella allograft, and designed for use in anterior cervical procedures.

BIO Wedge Tricortical

Technical specifications

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

Product features[18]

- 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)[20]

BIO Wedge Tricortical

Reference number	Description (height)*
7770705	5H
7770706	6H
7770707	7H
7770708	8H
7770709	9H
7770710	10H

*height measurements in mm

BIO Wedge
Iliac Crest

Description

The BIO Wedge Iliac Crest allografts are recovered from the crest from the ilium, and designed for use in anterior cervical procedures, corpectomy and ankle fusions.

BIO Wedge Iliac Crest

Technical specifications

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

Product features[18]

- 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)[20]

BIO Wedge Iliac Crest

Reference number	Description (height)*
7770806	6H
7770807	7H
7770808	8H
7770809	9H
7770810	10H
7770818	18H

*height measurements in mm

BIO Shaft
Femoral

Description

The BIO Shaft femoral allografts are precision cut segments of the femoral diaphysis, and designed for use for multiple applications including corpectomy, fracture management and tumor resection procedures.

BIO Shaft Femoral

Technical specifications

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

Product features[18]

- 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)[20]

BIO Shaft Femoral

Reference number	Description (length)*
77711060	60L
77711100	100L

*length measurements in mm

BIO Shaft
Fibular

Description

The BIO Shaft femoral allografts are precision cut segments of the fibular diaphysis, and designed for use for multiple applications including corpectomy, fracture management, and tumor resection and anterior cervical fusion procedures.

BIO Shaft Fibular

Technical specifications

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

Product features[18]

- 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)[20]

BIO Shaft Fibular

Reference number	Description (length)*
77712040	40L
77712060	60L
77712100	100L

*length measurements in mm

BIOExpand

Description

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.

BIOExpand

Product features[18]

- 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
- Six sizes available

BIOExpand

Reference number	Description (height x length x width)*
77040813	13H x 4L x 8W (0.4cc)
77040816	16H x 4L x 8W (0.5cc)
77040820	20H x 4L x 8W (0.6cc)
77101013	13H x 10L x 10W (1.3cc)
77101016	16H x 10L x 10W (1.6cc)
77101020	20H x 10L x 10W (2.0cc)

*height, length and width measurements in mm

BIO Chips

Product features[18]

- Provides osteoconductive matrix
- Preservon treated for fully hydrated ambient temperature storage
- Processed with Allowash XG to achieve a Sterility Assurance Level to 10^{-6} (SAL)[20]
- Easily mixed with autograft
- 100% allograft

BIO Chips Cancellous

Cancellous

- Offered in two particle size ranges: 1-4mm and 1-8mm
- Offered in four sizes: 5cc, 15cc, 30cc and 60cc

BIO Chips Cortico-cancellous

Cortico-cancellous

- 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

Cancellous with DBM Powder

- A mix of demineralized bone material and cancellous chips
- Cancellous particle size 1-8mm
- Offered in three sizes: 5cc, 10cc and 15cc
- Provides an osteoinductive component and osteoconductive matrix
- Demineralized with patented PAD process targeting 1-4% residual calcium[18]

BIO Chips Cancellous with DBM Powder

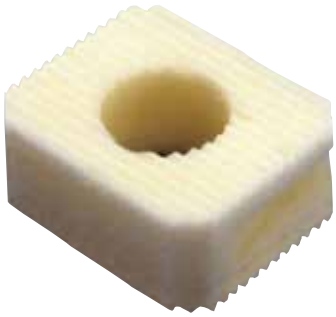
BIO Chips

Reference number	Description
7770205	BIO Chips Cancellous (1-4mm particle range), 5cc
7770215	BIO Chips Cancellous (1-4mm particle range), 15cc
7770230	BIO Chips Cancellous (1-4mm particle range), 30cc
7770260	BIO Chips Cancellous (1-4mm particle range), 60cc
7770105	BIO Chips Cancellous (1-8mm particle range), 5cc
7770115	BIO Chips Cancellous (1-8mm particle range), 15cc
7770130	BIO Chips Cancellous (1-8mm particle range), 30cc
7770160	BIO Chips Cancellous (1-8mm particle range), 60cc
7770530	BIO Chips Cortico-cancellous (1-4mm particle range), 30cc
7770560	BIO Chips Cortico-cancellous (1-4mm particle range), 60cc
7770430	BIO Chips Cortico-cancellous (1-8mm particle range), 30cc
7770460	BIO Chips Cortico-cancellous (1-8mm particle range), 60cc
7771305	BIO Chips Cancellous with DBM Powder (1-8mm particle range), 5cc
7771310	BIO Chips Cancellous with DBM Powder (1-8mm particle range), 10cc
7771315	BIO Chips Cancellous with DBM Powder (1-8mm particle range), 15cc

AlloCraft
CS

Description

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



AlloCraft CS

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

AlloCraft CS
Cervical Square Monolithic

Reference number	Description (height x length x width x lordosis)*
6183-6-005	5H x 12L x 14W x 0° Lordosis
6183-6-006	6H x 12L x 14W x 0° Lordosis
6183-6-007	7H x 12L x 14W x 0° Lordosis
6183-6-008	8H x 12L x 14W x 0° Lordosis
6183-6-009	9H x 12L x 14W x 0° Lordosis
6183-0-902	Inserter

*height, length and width measurements in mm

AlloCraft
CL and CP

Description

The AlloCraft CL and CP implants are monolithic cortical constructs with cancellous plugs that are machined from femoral or tibial allograft, and designed for cervical procedures.

AlloCraft CL and CP

Technical specifications

- 14mm medial-lateral width x 12mm anterior-posterior depth
- CL: 5-10mm heights
- CP: 5-9mm heights
- 6.5mm lumen
- 5° lordotic (CL) and parallel (CP) 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

AlloCraft CL
Cervical Square Monolithic with Plug 4°

Reference number	Description (height x length x width x lordosis)*
6183-5-005	5H x 12L x 14W x 5° Lordosis
6183-5-006	6H x 12L x 14W x 5° Lordosis
6183-5-007	7H x 12L x 14W x 5° Lordosis
6183-5-008	8H x 12L x 14W x 5° Lordosis
6183-5-009	9H x 12L x 14W x 5° Lordosis
6183-5-010	10H x 12L x 14W x 5° Lordosis

*height, length and width measurements in mm

AlloCraft CP
Cervical Square Monolithic with Plug 0°

Reference number	Description (height x length x width x lordosis)*
6183-4-005	5H x 12L x 14W x 0° Lordosis
6183-4-006	6H x 12L x 14W x 0° Lordosis
6183-4-007	7H x 12L x 14W x 0° Lordosis
6183-4-008	8H x 12L x 14W x 0° Lordosis
6183-4-009	9H x 12L x 14W x 0° Lordosis

*height, length and width measurements in mm

AlloCraft
CA

Description

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

AlloCraft CA

Technical specifications

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

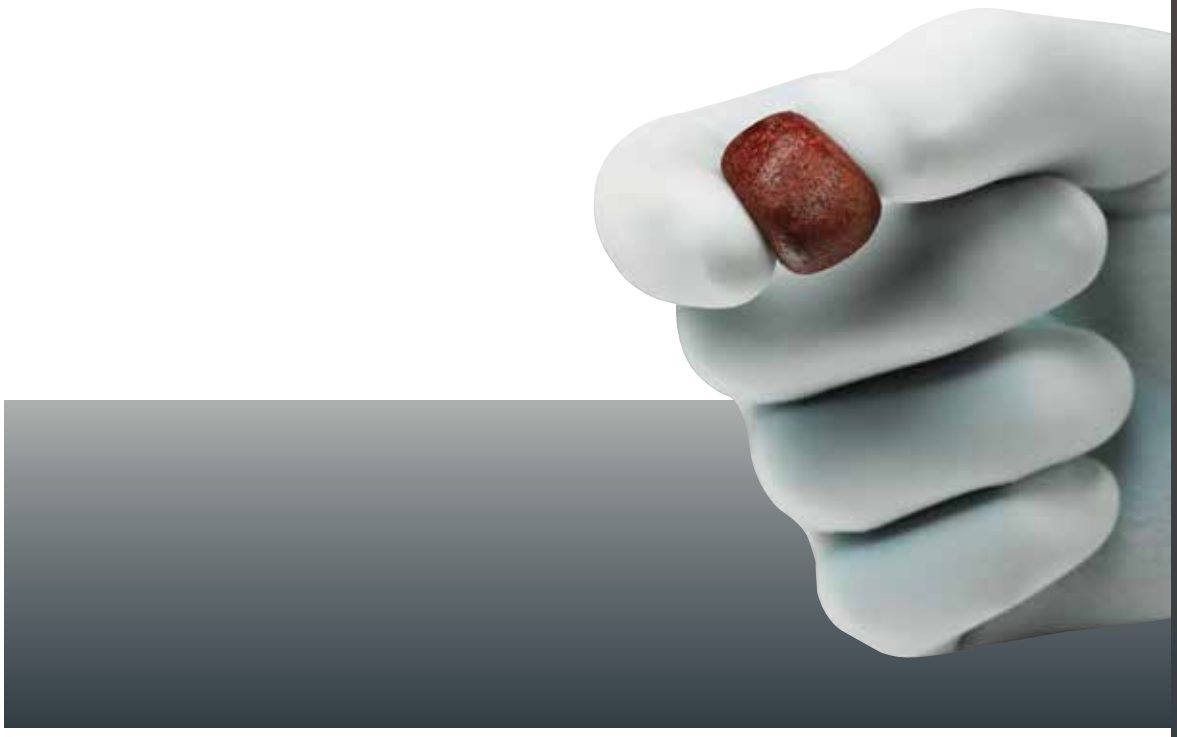
Product features

- 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

AlloCraft CA
Cervical Assembled 5°

Reference number	Description (height x length x width x lordosis)*
6183-7-005	5H x 11L x 14W x 5° Lordosis
6183-7-006	6H x 11L x 14W x 5° Lordosis
6183-7-007	7H x 11L x 14W x 5° Lordosis
6183-7-008	8H x 11L x 14W x 5° Lordosis
6183-7-009	9H x 11L x 14W x 5° Lordosis
6183-7-010	10H x 11L x 14W x 5° Lordosis

*height, length and width measurements in mm



Demineralized Bone Matrix

BIO DBM
Gel, Putty and Putty Plus

Description

- Demonstrated equivalent bone formation results to autograft in standard posterolateral fusion model in adult rabbits[21]
- Reversed phase medium carrier is designed to provide excellent handling
- Formulated to resist irrigation
- Every lot is tested to confirm osteoinductive potential[22]
- Putty Plus configurations contains cancellous bone[22]

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

BIO DBM Putty/Putty Plus

BIO DBM Gel, Putty and Putty Plus

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

BIO DBM
Shape

Description

- 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

BIO DBM Shape

BIO DBM Shape

Reference number	Description
65401	Equiv, 1cc
65402	Equiv, 2.5cc
65405	Equiv, 5cc

BIO DBM
Boat

Description

- 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

BIO DBM Boat

BIO DBM Boat

Reference number	Description
65305001	Equiv 10cc Length=5cm (single)
653050	Equiv 20cc Length=5cm (short)
653100	Equiv 40cc Length=10cm (long)

Viable Bone Matrix

BIO^4

Description

BIO^4 is a minimally manipulated viable bone matrix processed from human cadaveric bone to retain endogenous bone forming cells including mesenchymal stem cells, osteoprogenitor cells and osteoblasts, as well as osteoinductive and angiogenic growth factors.[23] The innovative principle behind BIO^4 is to provide the next generation viable bone matrix that retains not only osteoconductive, osteoinductive and osteogenic properties of bone, but also preserves the endogenous signals (growth factors) for supporting angiogenesis. It is an alternative to autograft that minimizes the potential for harvest site comorbidities. BIO^4 was developed by Osiris Therapeutics, Inc.

BIO^4

Product features[23]

- A viable bone matrix that has been uniquely processed to retain the cancellous bone (scaffold and cells), cortical bone (signals) and periosteum (signals).[23,24,25]
- Lot tested for the presence of VEGF (vascular endothelial growth factor)
- Ready to use out of the package; no decanting is required and thaws in 15 minutes
- Differentiated handling compared to the competition
- Lot tested for ≥ 600,000 viable cells per cc post-thaw
- Lot tested for ≥ 70% cell viability post-thaw
- Validated for up to a 6-hour window of post-thaw viability
- Non-immunogenic[23]
- Lot tested for Bioburden and Sterility per USP 71.

BIO^4 is processed utilizing proprietary methods. Each BIO^4 lot is processed from a qualified single donor who undergoes extensive testing and full review of medical records by the tissue bank medical director.

BIO^4

Reference number	Description
PS51001	1cc
PS51002	2.5cc
PS51005	5cc
PS51010	10cc

BIO^4
composition

BIO^4's proprietary formulation includes all components of bone (Figure 1), which are processed from allograft tissue. Careful processing preserves these components needed for bone formation. Testing has shown that there are no elements that may elicit an immunogenic response.[23]

The scaffold, cells and signals are derived from cancellous bone chips and demineralized cortical bone. Bone periosteum is carefully processed to retain growth factors that support angiogenesis, such as VEGF.[25] Additionally, the presence of periosteum further improves handling properties.[23]

Angiogenesis, the formation of new vasculature from existing blood vessels, is important for bone repair and development, and bone graft integration. Nutrients and oxygen, which are delivered through blood vessels, are required for tissue repair.[26, 27]

The presence of angiogenic signals in BIO^4 were detected using ELISA, as seen in Figure 2. BIO^4 showed higher presence of endogenous angiogenic growth factors compared to a similar bone allograft formulation lacking the periosteum (viable bone allograft control). VEGF, basic fibroblast growth factor (bFGF) and Platelet Derived Growth Factor-BB (PDGF-BB) are detectable to higher degree in BIO^4 due to the presence of periosteum.[23]

In a pre-clinical animal in vivo study it was confirmed that BIO^4 induces angiogenesis within 14 days of implantation, as supported by the new blood vessel formation seen in Figure 3.[28]

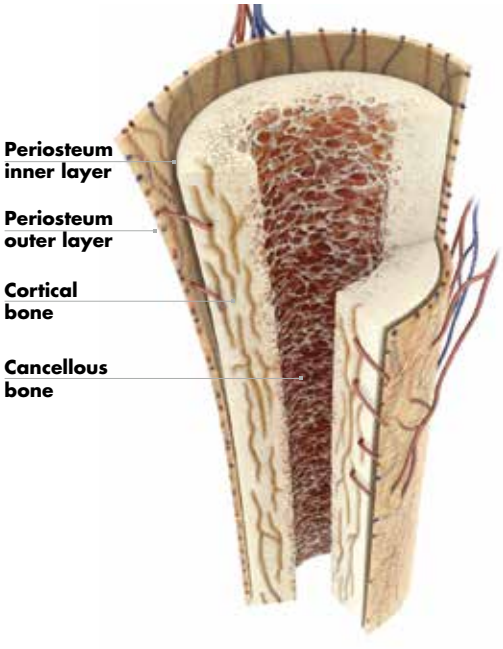


Figure 1: Components of Bone

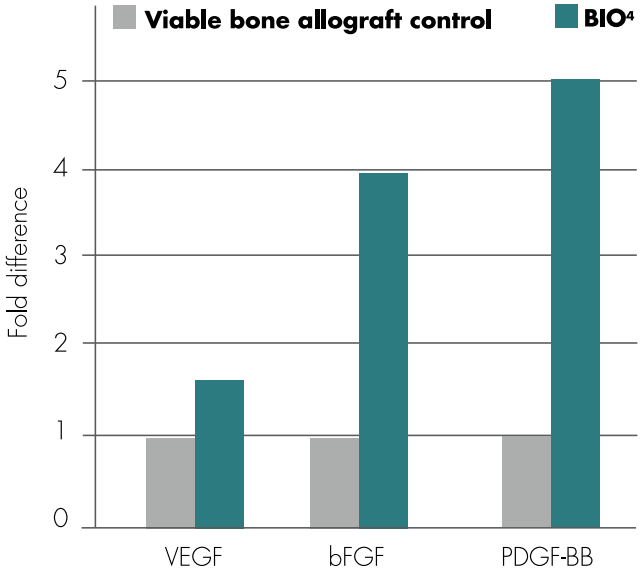


Figure 2: BIO^4 showed higher presence of angiogenic signals compared to similar bone allograft formulations[23] using ELISA.

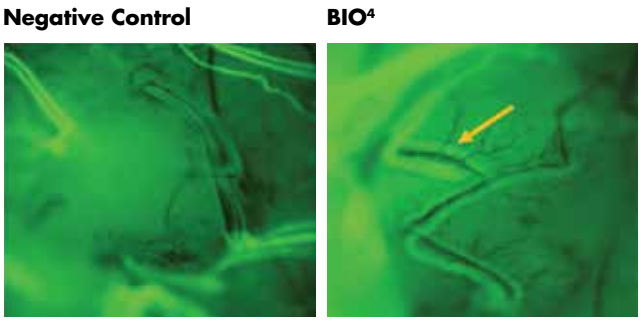


Figure 3: BIO^4-soaked collagen sponge and collagen sponge alone (negative control) were implanted in a nude mouse model of angiogenesis and the formation of blood vessels was monitored over time. New blood vessel formation was qualitatively observed on sponge surfaces, with more vessels seen on the BIO^4 samples compared to negative control.

Synthetics

Vitoss
product platform

The #1 selling synthetic bone graft[29]

Vitoss continues to be the number one 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.[30] 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 two 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 two 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

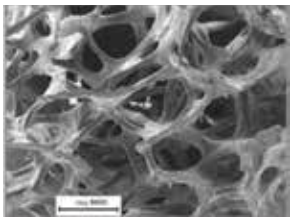
Vitoss
physical characteristics

The gold standard

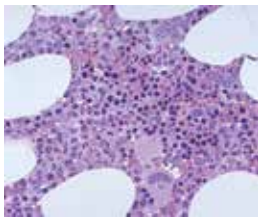
Iliac Crest Bone Graft (ICBG) has a Calcium Phosphate (CaP) surface with an open, inter-connected structure that serves as a scaffold.

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

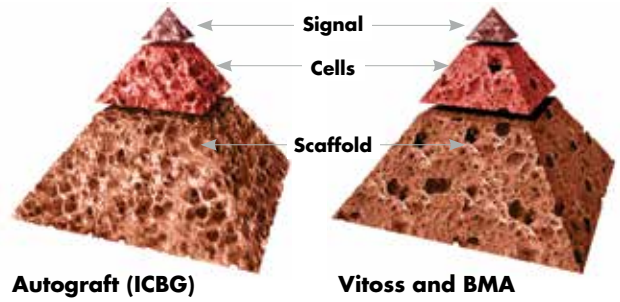
Vitoss + BMA (Bone Marrow Aspirate) resembles ICBG, the gold standard, in that it has the same three components: scaffold, cells and signals.[31]



Scaffold



Cells



Autograft (ICBG) **Vitoss and BMA**

Structure

Despite having similar chemistries, many products perform differently due to different structure. Vitoss has an open-interconnected structure that facilitates 3-D bone regeneration.[32]

Porosity

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).[33] Vitoss is a highly porous calcium-phosphate (up to 90% porous).[34]

Chemistry

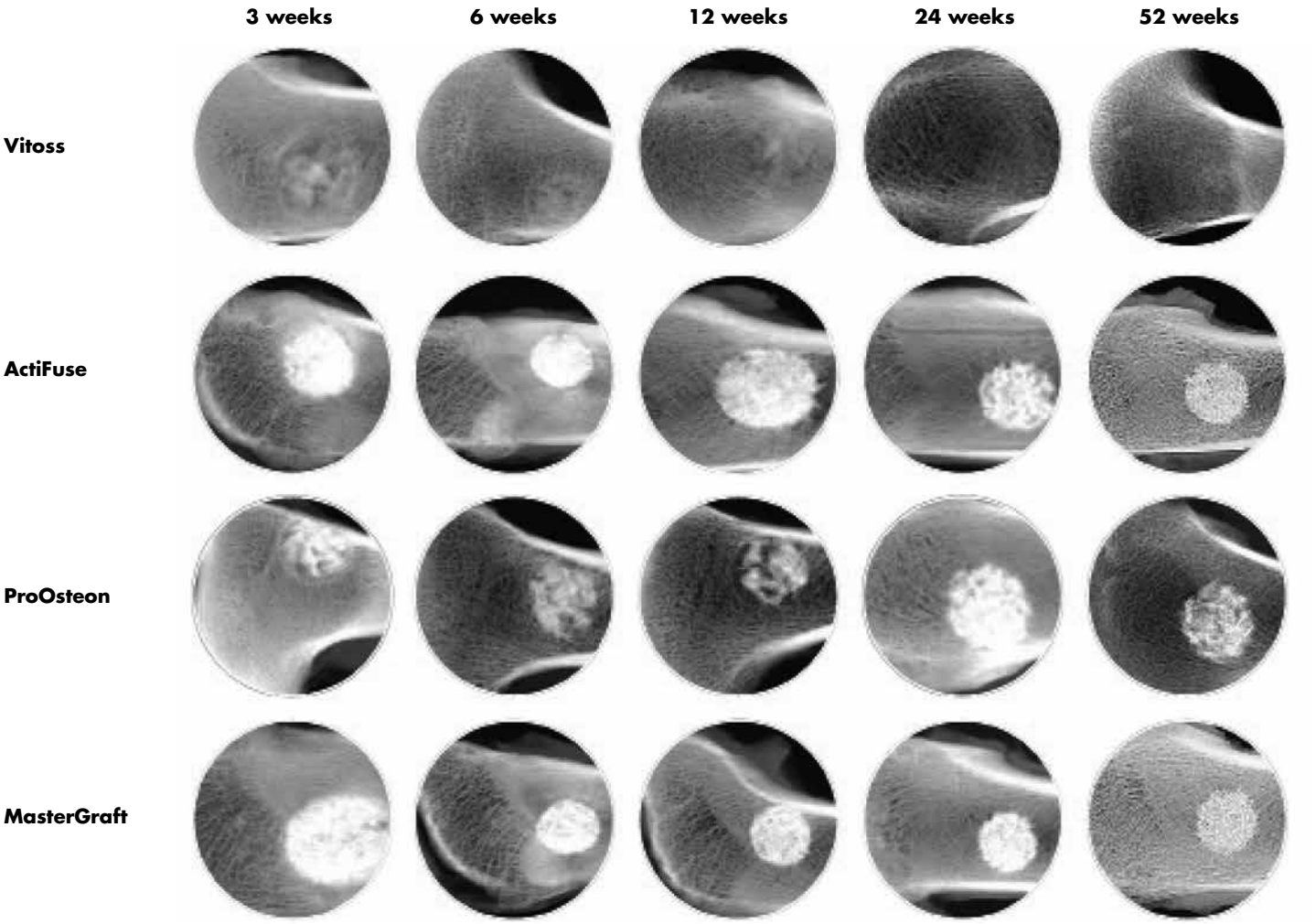
Chemistry affects the rate of resorption. Bone grafts should resorb as new bone forms in a physiologic time frame. Vitoss is composed of ß-TCP and is stable at physiologic pH. It resorbs during the natural remodeling process of bone. Evidence suggests that ß-TCP resorbs in a clinically relevant time frame.[35]

Vitoss viewed under scanning electron microscope

Other scaffolds

Vitoss
physical characteristics

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.[36]

Vitoss

physical characteristics

Description

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

Foam pack

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

Foam strip

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

Morsels

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

Foam pack

Foam strip

Vitoss

Reference number	Description
2102-1401	Foam Pack, 1.2cc
2102-1402	Foam Pack, 2.5cc
2102-1405	Foam Pack, 5cc
2102-1410	Foam Pack, 10cc
2102-1100	Foam Strip 25 x 100 x 4mm, 10cc
2102-1101	Foam Strip 25 x 240 x 4mm, 24cc
2102-1105	Foam Strip 25 x 50 x 4mm, 5cc
2102-1110	Foam Strip 25 x 50 x 8mm, 10cc
2102-1120	Foam Strip 25 x 100 x 8mm, 20cc
2102-0026	Micro-Morsel Canister 1-2mm morsel range, 5cc
2102-0027	Micro-Morsel Canister 1-2mm morsel range, 10cc
2102-0028	Micro-Morsel Canister 1-2mm morsel range, 15cc
2102-0029	Micro-Morsel Canister 1-2mm morsel range, 30cc

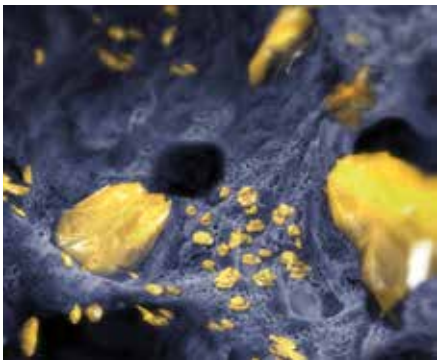
Vitoss

Reference number	Description
2102-0030	Standard-Morsel Canister 1-4mm morsel range, 5cc
2102-0031	Standard-Morsel Canister 1-4mm morsel range, 10cc
2102-0032	Standard-Morsel Canister 1-4mm morsel range, 15cc
2102-0033	Standard-Morsel Canister 1-4mm morsel range, 30cc
2102-0020	Macro-Morsels 4-7mm morsel range, 15cc
2102-0021	Macro-Morsels 4-7mm morsel range, 30cc
2102-0131	Macro Morsel Tower, 30cc (10 pack)

Vitoss
BA

Bioactive glass - mechanism of action

Literature shows that bioactive glass exhibits good bonding-to-bone properties in animal models.[37-39] Upon implantation, the ionic constituents (silicon, sodium and calcium) of bioactive glass are released into the surrounding environment and react with bodily fluids.[40-43] This reaction produces the deposition of a thin layer of physiologic calcium phosphate at its surface, favorable for osteoblast attachment.[44] This is commonly referred to as a bioactive effect.[37-39, 42, 45-47] This may lead to the bonding of new bone to the scaffold.



Bioactive glass

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.[37-39, 42, 45-47]

Figure 1[48]

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

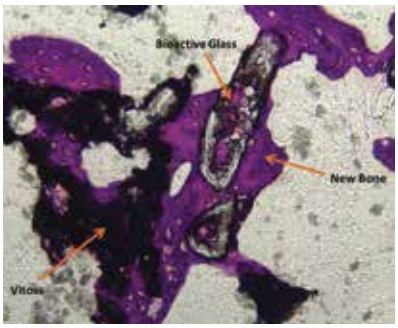


Figure 1
Product: Vitoss

Figure 2[48]

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

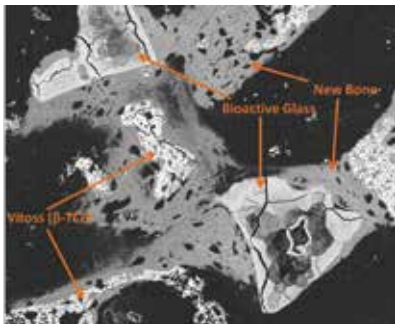


Figure 2
Product: Vitoss

Vitoss BA

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

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.[49]

Figure 3:

SEM Image of the bioactivity of Vitoss BA2X after seven days in simulated body fluid. A calcium phosphate layer is seen deposited on the surface of the beta-TCP and collagen matrix.

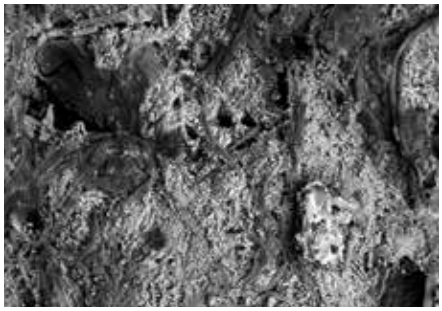


Figure 3
Vitoss BA2X Foam Pack

Vitoss BA2X

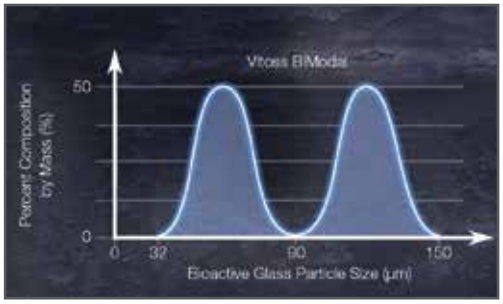
Reference number	Description
2102-2101	2X Bioactive Foam Pack, 1.2cc
2102-2102	2X Bioactive Foam Pack, 2.5cc
2102-2105	2X Bioactive Foam Pack, 5cc
2102-2110	2X Bioactive Foam Pack, 10cc

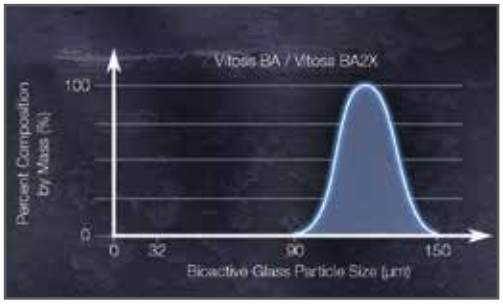
Vitoss
BiModal

Enhance bioactivity through bimodal technology development

Features

- An ultraporous, open inter-connected structure which guides the 3-dimensional regeneration of bone[32]
- Bimodal bioactive glass particles which promote the deposition of calcium phosphate on the implant surface and increased cellular calcium deposition [50, 51]
- 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^{+} ions.[52]





Greater initial burst*

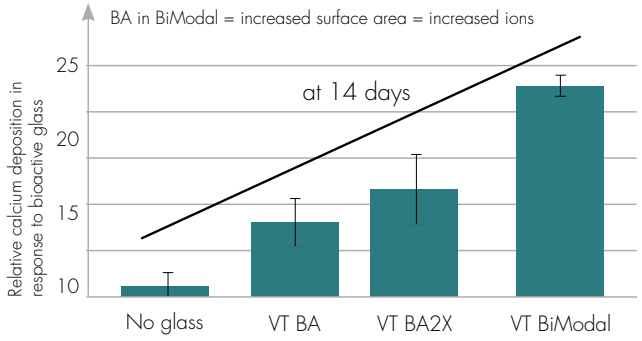
The 32-90μm bioactive glass particles kick start the Ca^{2+}, Na^{+} and Si^{+} ion release. Bioactive glass leads to a gel-like surface layer that mineralizes and promotes the deposition of calcium phosphate on the implant surface favorable for osteoblast attachment and bone formation.[44, 52]

Sustained release**

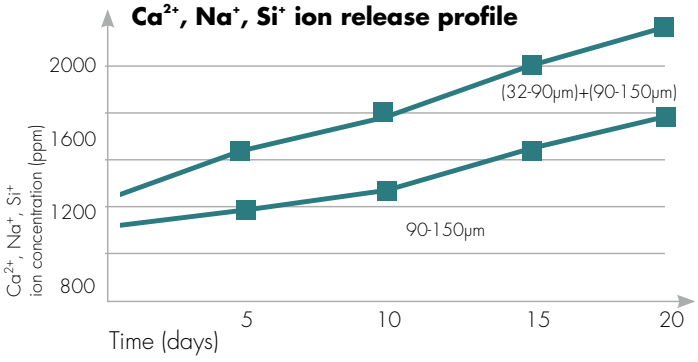
In-vitro and animal studies have shown that upon contact with bodily fluid, bioactive glass particles:

- Release ions into the immediate environment[44]
- Induce deposition of calcium phosphate on the implant[50]
- Create a surface favorable for osteoblast attachment and bone formation[44]

Relative cellular calcium deposition between Vitoss Products [51]



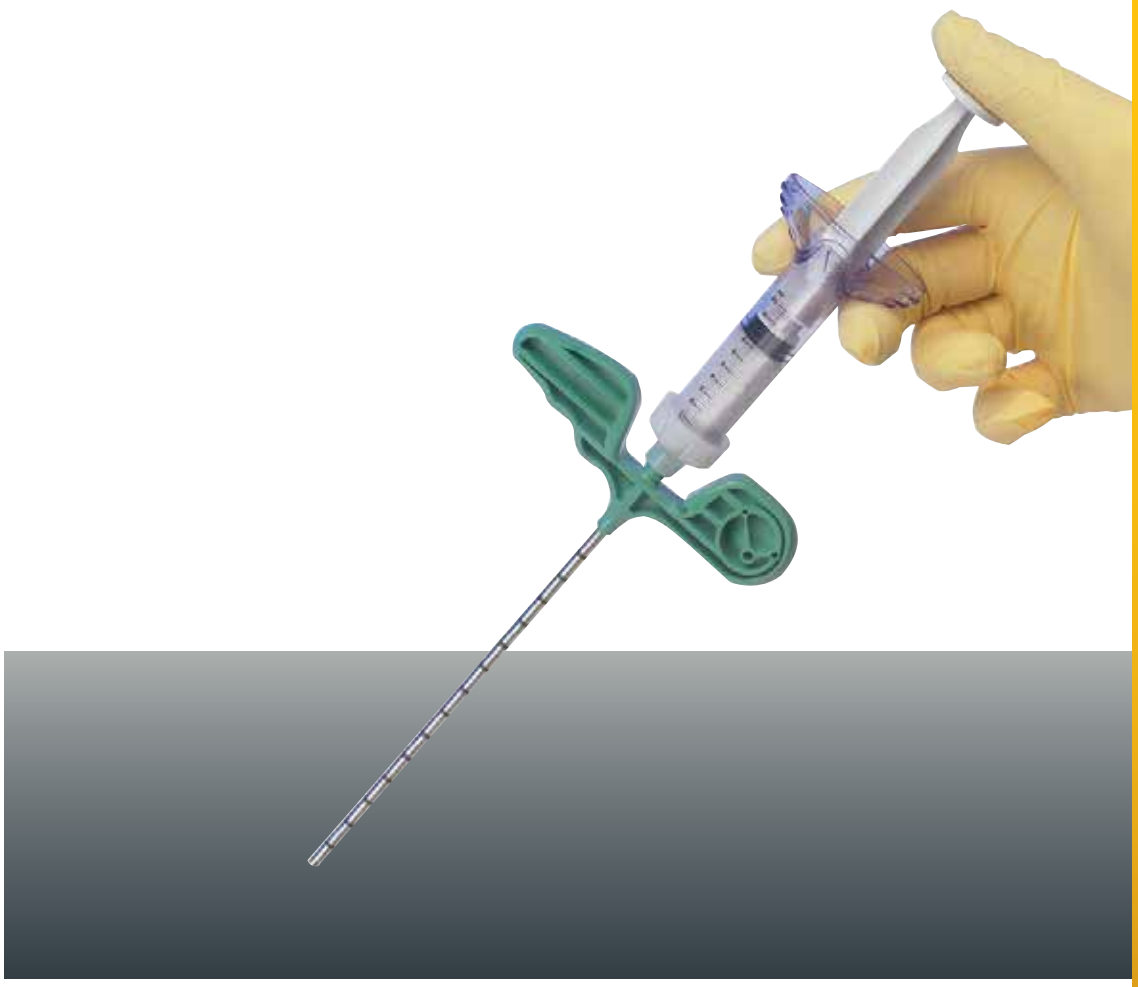
Ca^{2+}, Na^{+}, Si^{+} ion release profile



Vitoss BiModal

Reference number	Description
2102-1901	Bioactive Foam Pack, 1.2cc
2102-1902	Bioactive Foam Pack, 2.5cc
2102-1905	Bioactive Foam Pack, 5cc
2102-1910	Bioactive Foam Pack, 10cc
2102-1800	Bioactive Foam Strip 25 x 100 x 4mm, 10cc
2102-1805	Bioactive Foam Strip 25 x 50 x 4mm, 5cc
2102-1810	Bioactive Foam Strip 25 x 50 x 8mm, 10cc
2102-1820	Bioactive Foam Strip 25 x 100 x 8mm, 20cc

* 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.



Biologic instrumentation

Imbibe

bone marrow aspiration

Less invasive

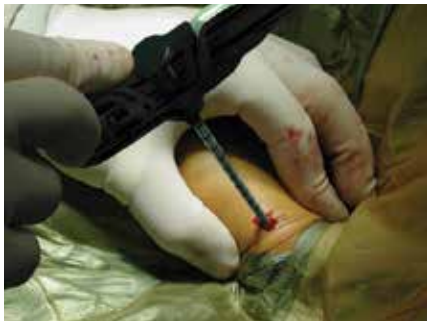
BMA is a safe alternative to iliac crest harvest without associated complications or morbidity. 900(+) patients with bone marrow aspiration (16-200mL) showed no infection, no hematoma, no chronic pain and only two bruises.[53]

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.[54]

BMA enhances graft incorporation

There was a statistically significant decrease in radiolucent 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."[55]



Iliac crest (PSIS, ASIS)

Vertebral body (via pedicle)

Calcaneus

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.

Imbibe

bone marrow aspiration

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.

Imbibe

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
- Eight needle sizes/styles available
- Versatility, useful for multiple anatomic locations

Needles

Needle 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

Syringe sizes:

- 10cc
- 20cc
- 30cc

Syringes

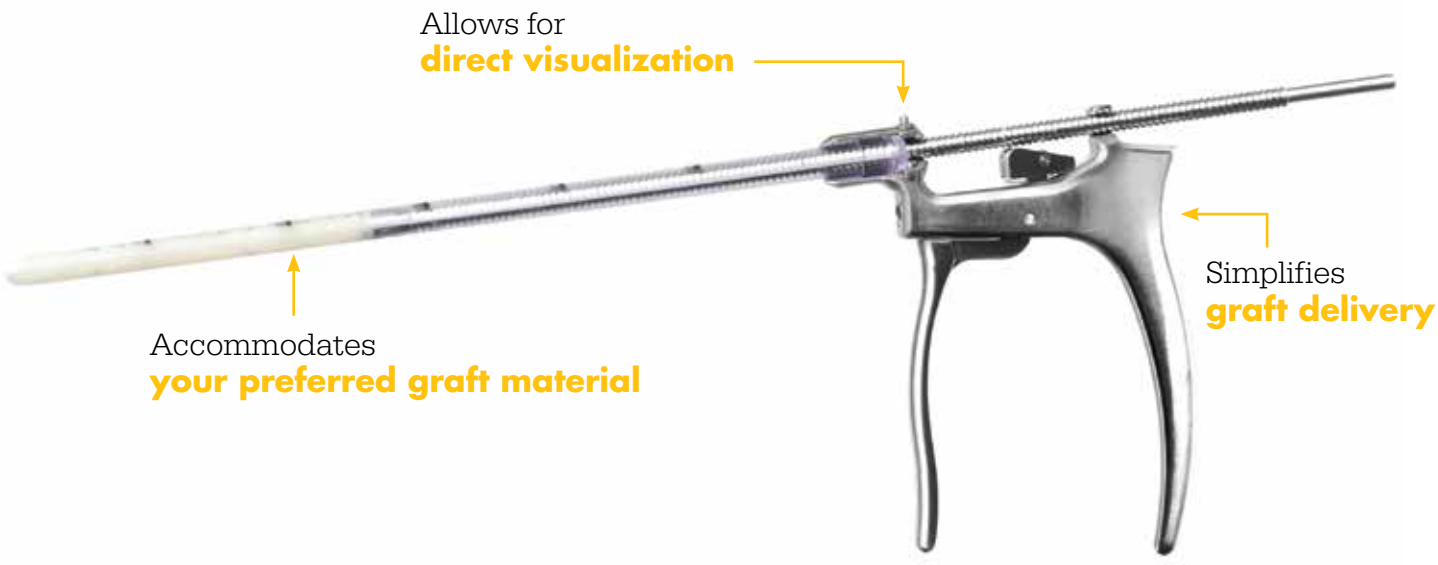
Imbibe bone marrow aspiration and delivery system

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

LITe BIO Delivery System[56]

Description

The LITe BIO Delivery System provides surgeons with a single handed, mallet free method to deliver allograft, autograft or synthetic bone graft material without obstructing direct visualization of the surgical site. The LITe BIO Delivery System may also be used to deliver bone graft material lateral, ventral and/or dorsal to the implant.



Cannula

- Length: 232mm
- Outer diameter: 8.5mm
- Inner diameter: 6.0mm
- Volume: Holds 5cc of graft material
- Tapers down at the distal end to 6.25mm

Delivery Handle

- Width: 10mm
- Length: 95mm
- Height: 113mm

Plunger

- Length: 300mm

Allows for direct visualization

- Low profile instrument designed for less invasive procedures
- Visibility through a decompression tube without obstructing view
- Radiolucent strip allows for visualization under fluoroscopy

Accommodates your preferred graft material

- Compatible with various bone graft materials including allograft, autograft and synthetic bone graft
- Disposable cannulas allow for up to 5cc of bone graft at one time

Simplifies graft delivery

- Single handed, ratcheting handle provides tactile, visual and audible confirmation during bone graft delivery
- Mallet free system eliminates impaction of bone graft during delivery

LITe BIO Delivery System

	Reference number	Description
	48288214	LITe BIO Delivery Sterile Package with Cannula Delivery Cannula* Loading Syringe* Plunger Seals* *Included in LITe BIO Delivery Sterile Package
	48288210	Sterilization Tray and Lid
	48288211	Loading Funnel
	48288212	Loading Tool
	48288213	Delivery Handle
	48288215	Delivery Plunger

References

1. PROJ43909 | Tritanium technology claim support memo.
2. RD0000053710 | Tritanium cell infiltration and attachment experiment.
3. Karageorgiou V, Kaplan D. Porosity of 3D biomaterial scaffolds and osteogenesis. Biomaterials 2005;26:5474–91.
4. RD0000050927 | Tritanium material capillary evaluation.
5. TREP0000053045 | Tritanium Wicking Verification Test Report.
6. Hong MH, Kim YH, Ganbat D, et al. Capillary action: enrichment of retention and habitation of cells via micro-channeled scaffolds for massive bone defect regeneration. J Mater Sci: Mater Med 2014;25:1991–2001.
7. Oh DS, Koch A, Eisig S, et al. Distinctive Capillary Action by Micro-channels in Bone-like Templates can Enhance Recruitment of Cells for Restoration of Large Bony Defect. Journal of Visualized Experiments 2015;103:e52947.
8. RD0000053906 | Tritanium cervical competitive wicking.
9. Pre-clinical study final report, SRL 15-02/Stryker 02-15.
10. DHF0000053171.
11. Data on file, Stryker's Spine division.
12. PROJ 53783.
13. TLSER-WP-1-15845.
14. DHF 52658.
15. DHF 53892.
16. Inceoglu, S., L. Ferrara, and R.F. McLain, Pedicle screw fixation strength: pullout versus insertional torque. Spine J, 2004. 4(5): p. 513-8.
17. Independent sources include the Virginia Commonwealth University Medical Center and the American Association of Mechanical Engineers. Data on file at LifeNet Health.
18. Data on file. LifeNet Health.
19. DHF 09-006.
20. Moore M, Linthurst Jones A, Gaskins B et al. Adapation 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.
21. Walsh WR, Oiliver 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.
22. Data on file Allosource.
23. Osiris Therapeutics, Inc. - Data on File.
24. Roberts and Rosenbaum, "Bone grafts, bone substitutes and orthobiologics," Organogenesis (2012); 8: 114–124.
25. 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).
26. Street et al., "Vascular endothelial growth factor stimulates bone repair by promoting angiogenesis and bone turnover," Proc. Natl Acad. Sci. USA (2002).
27. Khan et al., "An Osteoconductive, Osteoinductive, and Osteogenic Tissue-Engineered Product for Trauma and Orthopaedic Surgery: How Far Are We?," Stem Cells International (2012).
28. Angiogenic Study - BIBI4-JA-5_12553.
29. Millennium Research Group: US Markets for Orthopedic Biomaterials 2014.
30. Stryker Orthobiologics Internal Sales Data, July 2014.

31. 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).

32. Stryker Test Report 1050-0003R - Internal Final Report-VT 800 degree C Block Canine Model.

33. Motomiya, M., et al., Effect of Hydroxyapatite Porous Characteristics on Healing Outcomes in Rabbit Posterolateral Spinal Fusion Model. European Spine Journal, 2007; 16: 2215-2224.

34. Stryker Test Report 1070-0008R - VT Real-Time Stability.

35. Anker et al, Ultraporous Beta-Tricalcium Phosphate is Well Incorporated in Small Cavitary Defects. Clinical Orthopaedics and Related Research, 2005 May; 434: 251-7.

36. 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.

37. 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.

38. 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.

39. Gross, U., The Interface of Various Glasses and Glass Ceramics with a Bony Implantation Bed. Journal of Biomedical Materials Research, 1985; 19: 251-271.

40. Hench, L.L., The Story of Bioglass. Journal of Materials Science: Materials in Medicine, 2006 Nov; 17(11): 967-78.

41. Oonishi, H., et al., Particulate Bioglass Compared with Hydroxyapatite as a Bone Graft Substitute. Clinical Orthopaedics and Related Research, 1997 Jan; 334: 316-25.

42. 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.

43. 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 Biochemical and Biophysical Research Communications, 2000; 276: 461–465.

44. 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.

45. Sanders, D.M., Hench, L.L., Mechanisms of Glass Corrosion. Journal of American Ceramic Society.1973; 56(7): 373-377.

46. Hench, L.L., Characterization of Glass Corrosion and Durability. Journal of Non-Crystalline Solids, 1975; 19: 27-39.

47. Ogino, M., Hench, L.L., Formation of Calcium Phosphate Films on Silicate Glasses. Journal of Non-Crystalline Solids, 1980; 38 and 39: 673-678.

48. Havener, MB, Brown, LS, Darmoc, MM, Owsiany, RS, Clineff, TD. Improvements in Healing with a Bioactive Bone Graft Substitute in a Canine Metaphyseal Defect. 55th Annual Meeting of the Orthopaedic Research Society, 2009.

49. Stryker Test Report 1000-2024R - FM-02 Physical Master Plan Report.

50. Stryker Test Report 1000-2028R FM-03 Physical Master Plan Report.

51. Stryker Test Report 1010-0117R FM-03 in vitro Mineralization Analysis.

52. Stryker Test Report 1015-0083 - FM-03 In-Vitro Dissolution Study.

53. 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.

54. 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.

55. 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.

56. FDA Cleared Indications for Use: The LITe BIO Delivery System is intended to deliver autograft, allograft or synthetic bone graft materials to all orthopaedic surgical sites.

Spine Division

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.

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