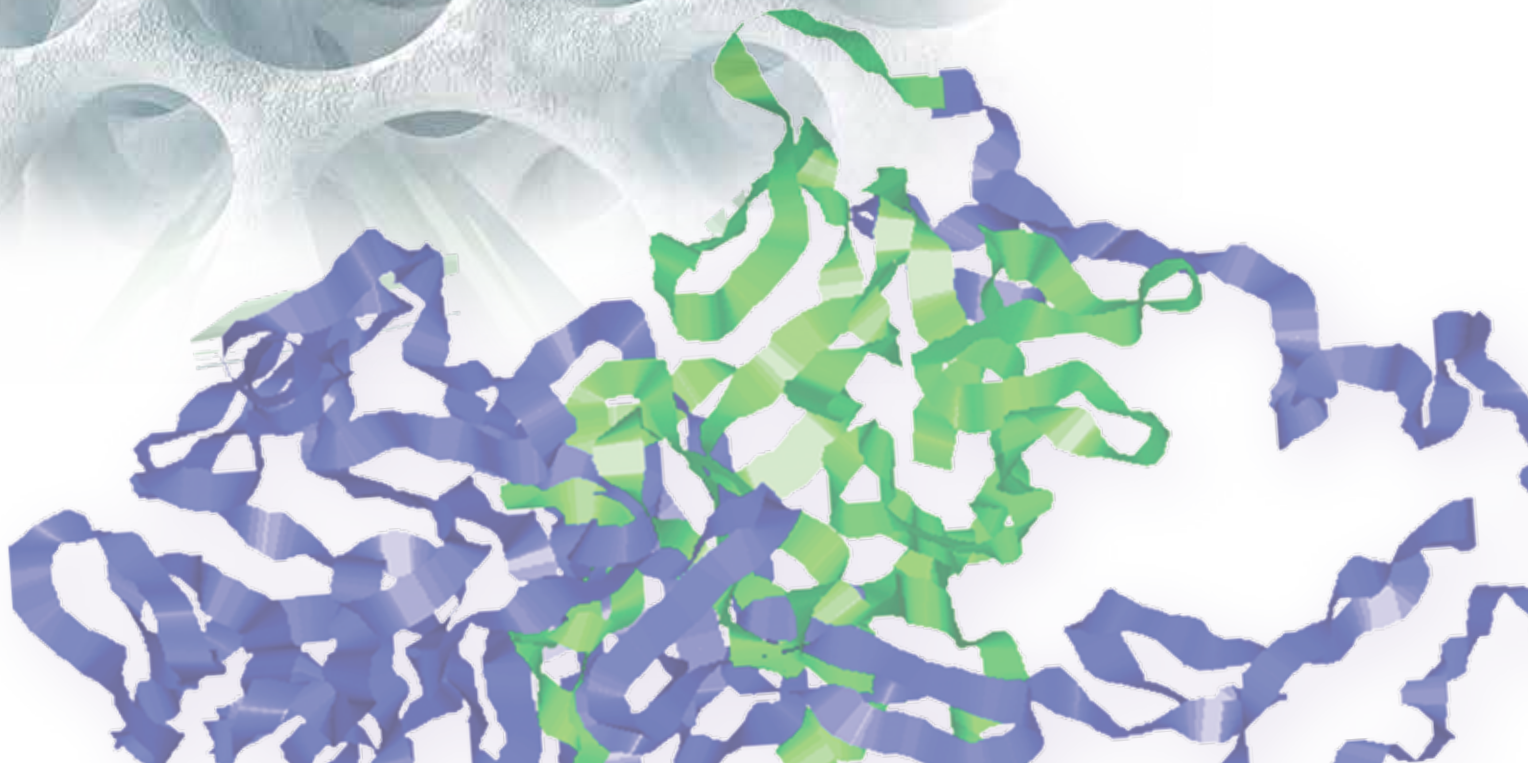
ZIMMER BIOMET
Your progress. Our promise.™

Biologics U.S. Product Portfolio



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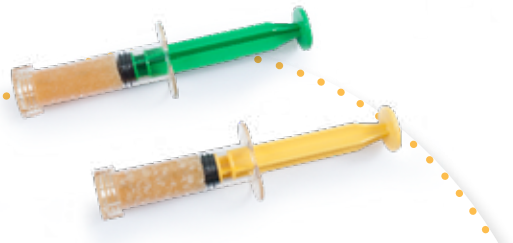
Our Philosophy

The Zimmer Biomet Biologics Product Portfolio represents the passionate pursuit of the most innovative and clinically relevant solutions addressing the needs of surgeons and their patients. Zimmer Biomet Biologics offers a myriad of solutions for both hard and soft tissue applications, including bone grafting products, platelet and plasma concentration systems, a *B*BMA (blood and bone marrow aspirate) concentration system, an autologous activation system and bone marrow aspiration needles. Also offered are: cartilage, soft tissue reinforcement, and wound covering products.

The philosophy defining our hard tissue products is based on the complex process involved in tissue repair, wherein the matrix/scaffold (osteoconductive), signaling proteins (osteopromotive* and/or osteoinductive), and tissue forming cells (osteogenic) work in concert to form new tissue (bone).

This "Essentials of Bone Remodeling Triad" (osteoconductive, osteoinductive, osteogenic) is the cornerstone of the Zimmer Biomet Biologics Product Portfolio, which is one of the broadest portfolios in the market today.



StaGraft DBM Putty & PLUS

EquivaBone
Bone Graft Substitute

StaGraft Canc. DBM
Sponge/Strips

Stagraft BSM

These products also exhibit Osteoconductive properties

Osteoinductive

Plasmax
Plasma Concentration System

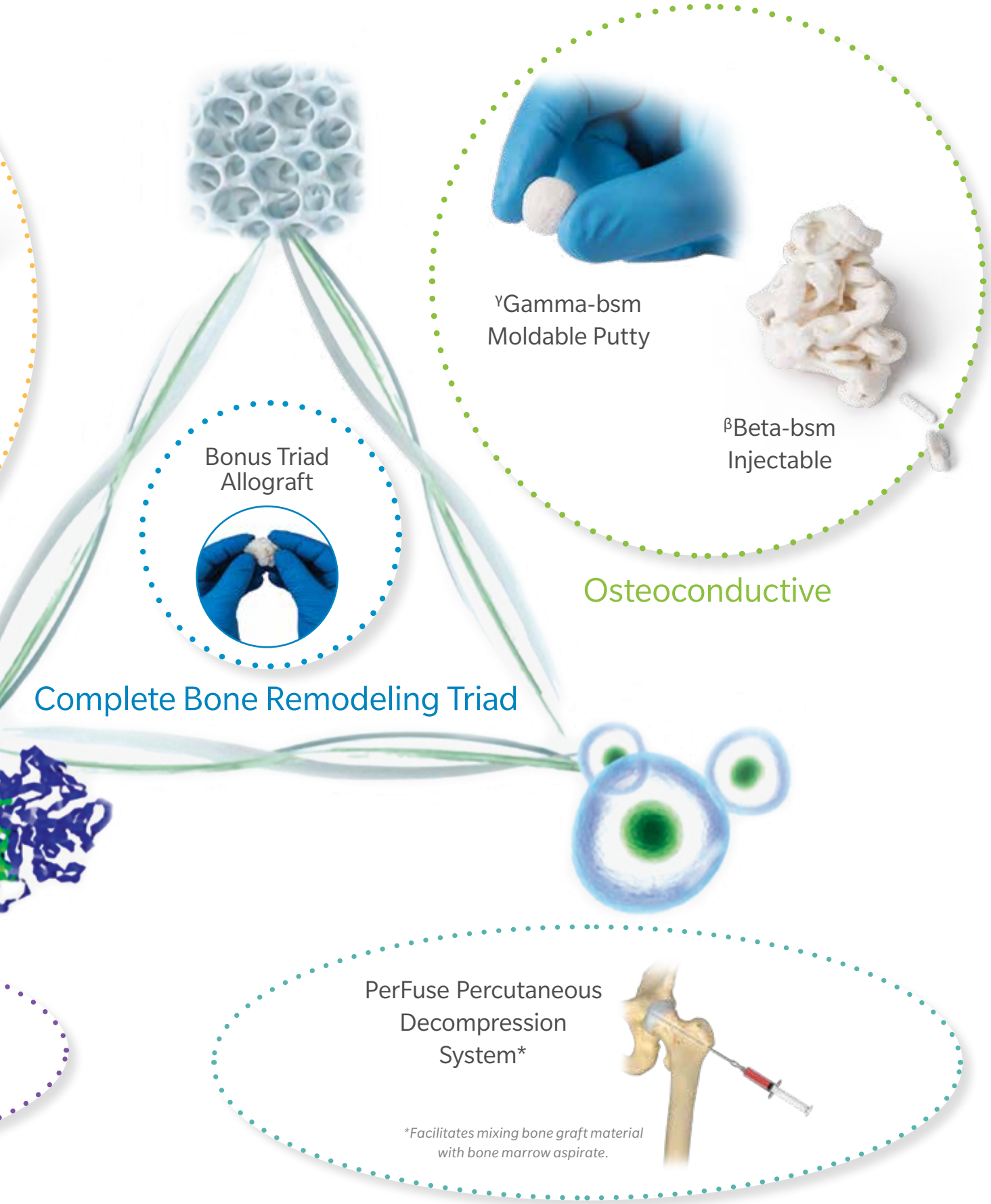
BioCUE
*B*BMA
Concentration System

GPS III
Platelet Concentration System

Mixed with autograft and/or allograft bone

Osteopromotive

*Products that produce a PRP output do not currently have FDA clearance to be characterized with a specific mechanism of action. PRP, in and of itself (i.e., without the autograft or allograft), is not FDA cleared as "osteopromotive."


ᵞGamma-bsm
Moldable Putty
ᵝBeta-bsm
Injectable
Osteoconductive
Bonus Triad
Allograft
Complete Bone Remodeling Triad
PerFuse Percutaneous
Decompression
System*
*Facilitates mixing bone graft material
with bone marrow aspirate.
Osteogenic

Osteoconductive Materials

Osteoconductive materials provide the framework or scaffolding within a bony environment for cells to infiltrate and attach. They also offer porosity for vascular pathways and cell migration. Materials generally referred to as osteoconductive include certain calcium phosphate/calcium sulfate based synthetics and allograft cortical as well as cancellous chips, sponges, and strips.[1, 2]

Although autograft is considered the gold standard for orthopedic procedures requiring graft material, it has known limitations with associated donor site morbidity and limited availability.[2] Synthetic bone graft substitutes have been developed to overcome these limitations, and the emergence of biomaterials, such as ᵝBeta-bsm Injectable and ᵞGamma-bsm Moldable Putty offer many advantages for both the surgeon and the patient.

Self-setting paste options provide the surgeon flexibility to pack, mold, and inject these materials to the defect site.

Calcigen® S

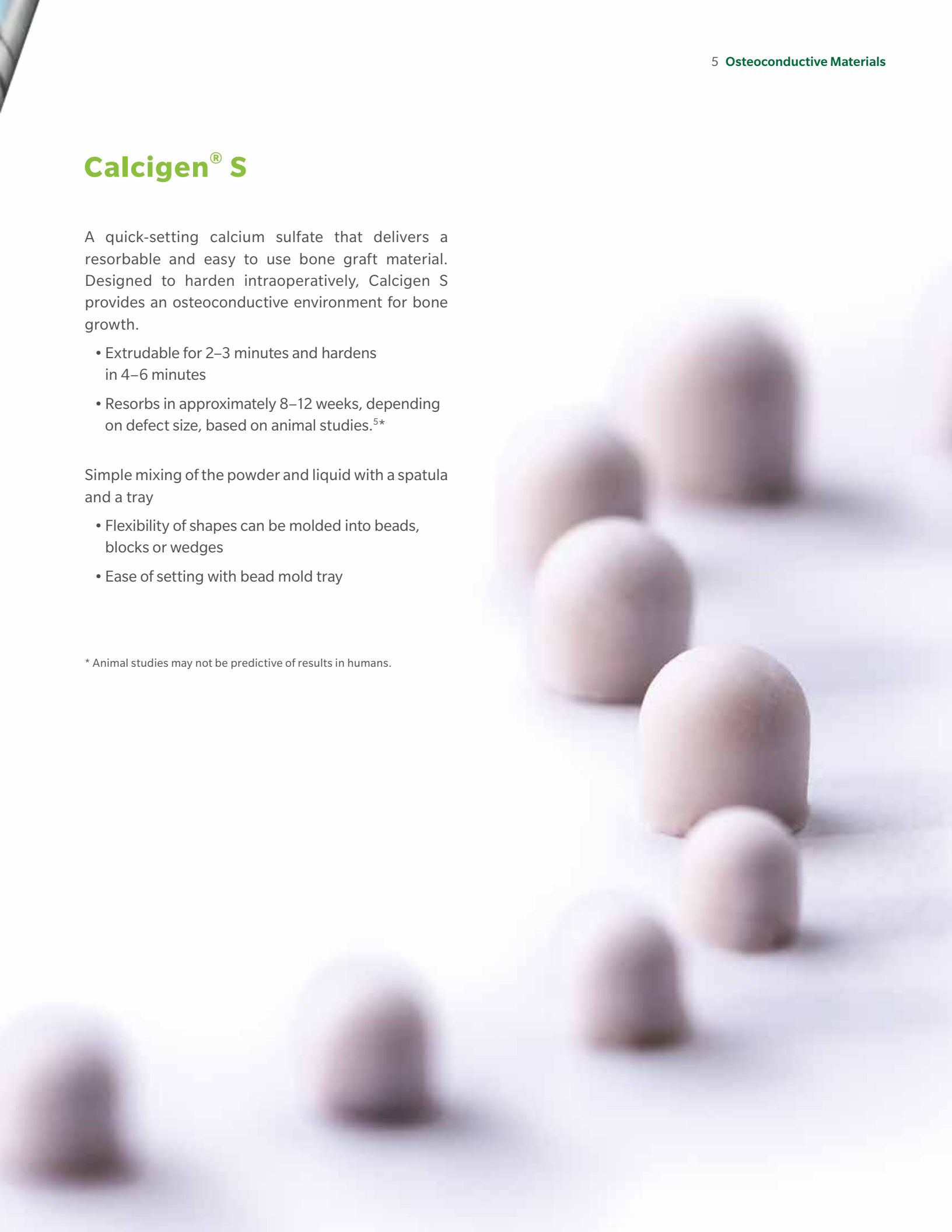
A quick-setting calcium sulfate that delivers a resorbable and easy to use bone graft material. Designed to harden intraoperatively, Calcigen S provides an osteoconductive environment for bone growth.

- Extrudable for 2–3 minutes and hardens in 4–6 minutes
- Resorbs in approximately 8–12 weeks, depending on defect size, based on animal studies.[5]*

Simple mixing of the powder and liquid with a spatula and a tray

- Flexibility of shapes can be molded into beads, blocks or wedges
- Ease of setting with bead mold tray

* Animal studies may not be predictive of results in humans.



Subchondroplasty® (SCP®) Procedure

The Subchondroplasty Procedure is a minimally-invasive fluoroscopically-assisted intervention that targets and fills subchondral bone defects, often called Bone Marrow Lesions (BML) with AccuFill® Bone Substitute Material. AccuFill BSM is an engineered calcium phosphate mineral compound, a bone graft substitute, that resorbs and is replaced with new bone during the healing process.

AccuFill BSM is an optimal material for the Subchondroplasty Procedure:

- Flows readily into closed trabecular bone[6]
- Sets hard within 10 minutes of implantation at 37° C, with properties comparable to healthy cancellous bone[7]
- Undergoes cell-mediated remodeling as the bone heals[8]

ᵝBeta-bsm® Injectable

ᵝBeta-bsm Injectable is engineered using ETEX's proprietary nanocrystalline* calcium phosphate technology that mimics the mineral composition of human bone to provide a scaffold for new bone growth.[7] It is mixed in a closed syringe to syringe system and is delivered in minimally invasive procedures via a needle as small as 16 g.

- User friendly closed mixing system for minimally invasive delivery
- Becomes solid in a wet environment to allow for irrigation after setting
- Osteoconductive scaffold
- 2 minute working time; sets in 3-5 minutes at 37° C
- Average compressive strength of 30MPa; 3x cancellous bone[3,7]
- Available in 2.5 and 5 cc to accommodate a variety of applications

*The grain size of the hydroxyapatite (HA) crystals that form as part of the amorphous and crystalline mixture of calcium phosphate sets are on the nanometer scale. The size of crystalline structures were measured by x-ray diffraction to be less than 100 nanometers.

ᵞGamma-bsm® Moldable Putty

ᵞGamma-bsm Moldable Putty is engineered using ETEX's proprietary nanocrystalline* calcium phosphate technology that mimics the mineral composition of human bone to provide a scaffold for new bone growth.[7] It addresses the need for hard setting, bone substitute materials that are implanted in a wet environment.

- User friendly, moldable putty mixed in an open system (blood or saline)
- Osteoconductive scaffold
- 15 minute working time
- Sets in 3-5 minutes at 37° C; sets in wet environment to allow for irrigation after setting
- Average compressive strength of 46 MPa; 4x cancellous bone[4]
- Available in 2.5, 5, and 10cc to accommodate a variety of applications

*The grain size of the hydroxyapatite (HA) crystals that form as part of the amorphous and crystalline mixture of calcium phosphate sets are on the nanometer scale. The size of crystalline structures were measured by x-ray diffraction to be less than 100 nanometers.

Osteoinductive Materials

Osteoinductive materials induce bone formation in a bony or non-bony environment via the action of growth factors or signaling proteins, including Bone Morphogenetic Proteins (BMPs). These proteins stimulate the conversion of progenitor cells into bone forming osteoblasts.[2,9] Materials that are generally referred to as osteoinductive in nature include demineralized bone matrix (DBM) and BMP products. Zimmer Biomet Biologics products that fit this category include: StaGraft DBM products (Putty*, PLUS,* Cancellous DBM Sponge and Strips), Bonus CC Matrix Bone Graft System, and EquivaBone Bone Graft Substitute. In addition, these products also exhibit osteoconductive properties.

DBM bone void fillers have been developed to overcome the limitations of autograft, and the emergence of biomaterials such as StaGraft DBM, and EquivaBone Bone Graft Substitute offer many advantages for both the surgeon and the patient. Ready-to-use DBM Putty and PLUS (combined with ceramic osteoconductive granules) options provide the surgeon flexibility to pack and mold these materials into the defect site. Cancellous/cortical chips along with cancellous strips and sponges enable the surgeon to hydrate the materials with biologic fluids, such as blood, PRP, or bone marrow aspirate.

Stagraft Fiber

* Each lot of DBM incorporated into StaGraft Putty and Plus is assayed for its osteoinductive potential.
The combination of DBM, the carrier, and, in some formulations, ceramic granules has not been evaluated for osteoinductivity.

EquivaBone® Bone Graft Substitute

EquivaBone Bone Graft Substitute combines the osteoinductivity of demineralized bone matrix with the osteoconductivity, moldability, structure, and hard-setting characteristics of ETEX's proprietary nanocrystalline* calcium phosphate technology. ETEX nanocrystalline* calcium phosphate mimics the mineral composition of human bone, providing a scaffold for new bone growth.[7]

- Osteoconductive scaffold and osteoinductive stimulus
- Each lot of DBM certified osteoinductive prior to release
- DBM promotes bone formation
- Open mixing system with multiple delivery options (moldable or injectable putty)
- 15 minute working time
- Sets in 10 minutes at 37° C; sets in a wet environment to allow for irrigation after setting
- Available in 2.5, 5 and 10cc to accommodate a variety of applications

* The grain size of the hydroxyapatite (HA) crystals that form as part of the amorphous and crystalline mixture of calcium phosphate sets are on the nanometer scale. The size of crystalline structures were measured by x-ray diffraction to be less than 100 nanometers.

StaGraft™ Cancellous DBM Sponge and Strips

The StaGraft Cancellous DBM sponge and strips are machined from a single piece of cancellous bone. The cancellous bone is demineralized, exposing the inherent growth factors that are essential for new bone formation.

Rehydration can be achieved with isotonic solution including blood, bone marrow aspirate (BMA), or saline solution.[10] The demineralization process and trabecular structure provide sponge-like handling, which allows the grafts to fit into a variety of bone voids or spinal cavities.

If compressed, these products will expand to fill the contours of a void, thereby minimizing the space between the graft and the host bone.

- Osteoinductive: Bone fully demineralized to optimize inherent growth factors that are essential for new bone formation.
- Sponge-Like Handling: When compressed, the grafts will naturally expand back to their original state, allowing them to fill the contours of a void, thereby minimizing the space between the graft and the host bone.
- Trabecular Structure: The interconnected porosity of cancellous bone allows for cellular infiltration.

StaGraft™ DBM Putty, PLUS and Paste

StaGraft DBM is an osteoinductive* demineralized bone matrix in a natural lecithin carrier, and is available as a 40% DBM Putty, 35% DBM PLUS pre-mixed with resorbable coralline hydroxyapatite calcium carbonate granules or 35% DBM Paste. The natural quality of the carrier and its outstanding containment and handling characteristics enable the surgeon to mold it to surgical sites, even in the presence of excessive fluids and under lavage.

- Excellent handling and performance characteristics – tolerates lavage/irrigation
- DBM-to-carrier ratio engineered for optimized osteoinductivity[11]
- StaGraft PLUS with resorbable granules has excellent handling properties
- Easy to use – pre-loaded in a syringe; stored at room temperature
- 2cc DBM Paste available with straight or curved injectors

* Each lot of DBM incorporated into StaGraft DBM is assayed for its osteoinductive potential. The combination of DBM, the carrier, and, in some formulations, ceramic granules has not been evaluated for osteoinductivity.

** StaGraft DBM is intended for use in bone voids and gaps in the extremities or pelvis that is not intrinsic to the stability of the structure

Osteopromotive Materials

Osteopromotive* materials enhance the natural bone healing process.[12,13] PRP is mixed with autograft or allograft materials to impart better graft-handling characteristics.[15]

Zimmer Biomet Biologics products that fit this category include the GPS III Platelet Concentration System, BioCUE Blood and Bone Marrow Aspirate (ʙBMA) Concentration System, and Plasmax Plasma Concentration System.

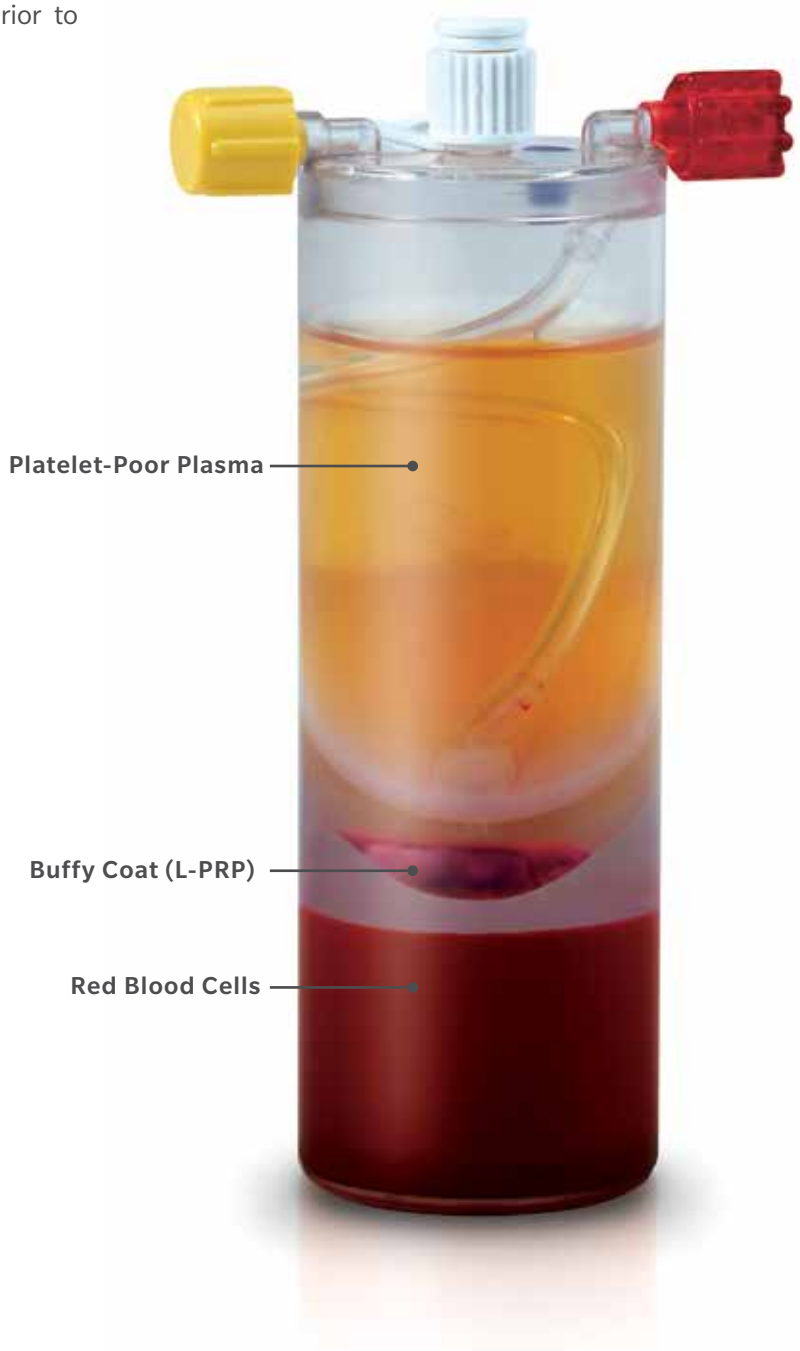
*Products that produce a PRP output do not currently have FDA clearance to be characterized with a specific mechanism of action. PRP, in and of itself (i.e., without the autograft or allograft), is not FDA cleared as "osteopromotive."

GPS® III Platelet Concentration System

Whole blood contains several components that can be concentrated during centrifugation to form a buffy coat layer or leukocyte-rich platelet-rich plasma (L-PRP). By utilizing the GPS III Platelet Concentration System, the patient's own platelets can be separated into a highly concentrated formula. The PRP can be mixed with autograft or allograft bone prior to application at an orthopedic surgical site.

Average L-PRP Output Concentrations

- **90%** recovery of available platelets[15]
- **9.3x** platelet increase over baseline[15]
- **5x** white blood cell increase over baseline[16]
- **6 ml** of autologous PRP output[16]
- **15 minutes** centrifuge process[16]

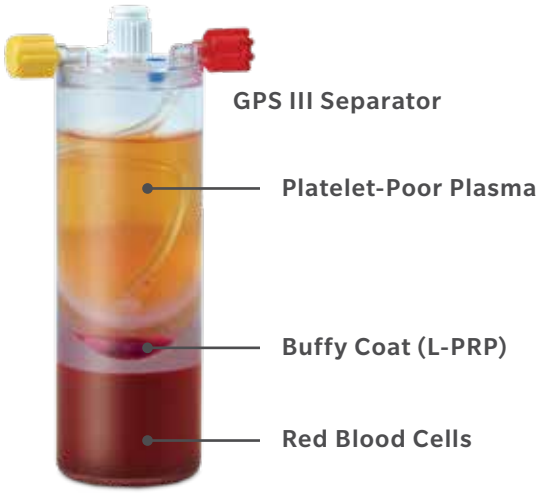


Plasmax® Plasma Concentration System

The Plasmax Plasma Concentration System is comprised of two distinct parts, the GPS III Separator and the Plasmax Concentrator. The GPS III Separator produces leukocyte-rich platelet-rich plasma (L-PRP) from a small sample of the patient's own blood. The Plasmax Concentrator produces autologous fibrinogen-rich platelet-poor plasma concentrate (PPPc)* utilizing polyacrylamide beads to remove excess water.

- 3x increase in plasma proteins (on average) including fibrinogen[17]
- Outputs up to 10 cc of rapidly polymerizing autologous plasma concentrate
- Outputs up to 6 cc of platelet-rich plasma (from GPS III Separator)
- Total centrifugation time is less than 20 minutes
- Point-of-care preparation
- No refrigeration required

Plasmax Concentrator



*Autologous output from the Plasmax Plasma Concentration System eliminates concern regarding pooled blood sources. Pooled plasma sources found in donor-based fibrin sealants carry the risk of transmitting infectious diseases and viruses.

BioCUE® Blood and Bone Marrow Aspirate (*B*BMA) Concentration System

Designed to process a mixture of autologous whole blood and bone marrow aspirate, the BioCUE *B*BMA Concentration System represents an evolution in this technique. The system includes all the components to DRAW blood, ASPIRATE bone marrow, easily PROCESS the disposable system, and produce an autologous PRP output to HYDRATE the surgeon's choice of autograft and/or allograft bone.

Average PRP Output Concentrations

- **77.5%** recovery of nucleated cells[18]
- **71%** recovery of available platelets[18]
- **7.2x** concentration of available platelets[18]
- **7.9x** concentration of available nucleated cells[18]

Technique Matters

When aspirating bone marrow with the BMA needle provided with the BioCUE System, keep these best practices in mind:

- The 6 holes at the distal tip allow for more efficient collection of aspirate from different angles within the bone inside the cortical wall.[19]
- While maintaining a 1:5 ratio of ACD-A to BMA in the aspirating syringe, add a little extra anticoagulant to flush the BMA needle with ACD-A as well.

Each needle comes with a trocar point and blunt tip for surgeon options

OCA Kit

BioCUE
*B*BMA
Concentration System

GPS Platelet
Concentration System

Autologous

Amniorepair

Soft Tissue

DermaSpan
Acellular Dermal Matrix

Calcigen S
Synthetic Bone Graft

Bonus Triad Allograft

Stagraft BSM

Viable Cell

Allograft

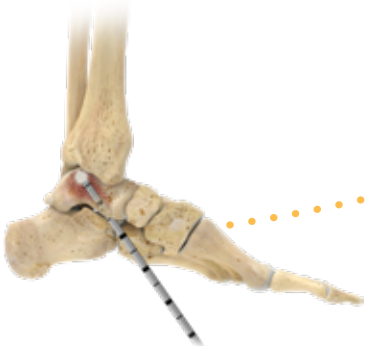
StaGraft DBM Putty & PLUS

EquivaBone
Bone Graft Substitute

Synthetic Allograft

Synthetic

ᵞGamma-bsm Moldable Putty



Subchondroplasty (SCP)
Procedure

ᵝBeta-bsm Injectable

Osteogenic materials, such as autograft and/or bone marrow aspirate (BMA) and live allograft tissue contain viable cells, such as mesenchymal stem cells, osteoprogenitor cells, or osteoblasts, which are capable of synthesizing new bone.[2,9] BMA is typically combined with osteoconductive and osteoinductive materials for bone grafting purposes.

Zimmer Biomet has two systems that help obtain and prepare these osteogenic materials. The bone marrow aspiration kit procures bone marrow aspirate while the PerFuse System facilitates mixing bone graft material with bone marrow aspirate.

BOS Bone Marrow Aspiration Kit

- Aspirate can be obtained from a variety of anatomical locations including the illiac crest, tibia, and calcaneous
- Six holes placed at distal tip, allowing for efficient aspiration[19]
- One stylet with trocar point for penetration of the cortical bone into the bone marrow cavity
- One stylet with blunt tip for easy movement of the needle within the bone marrow cavity

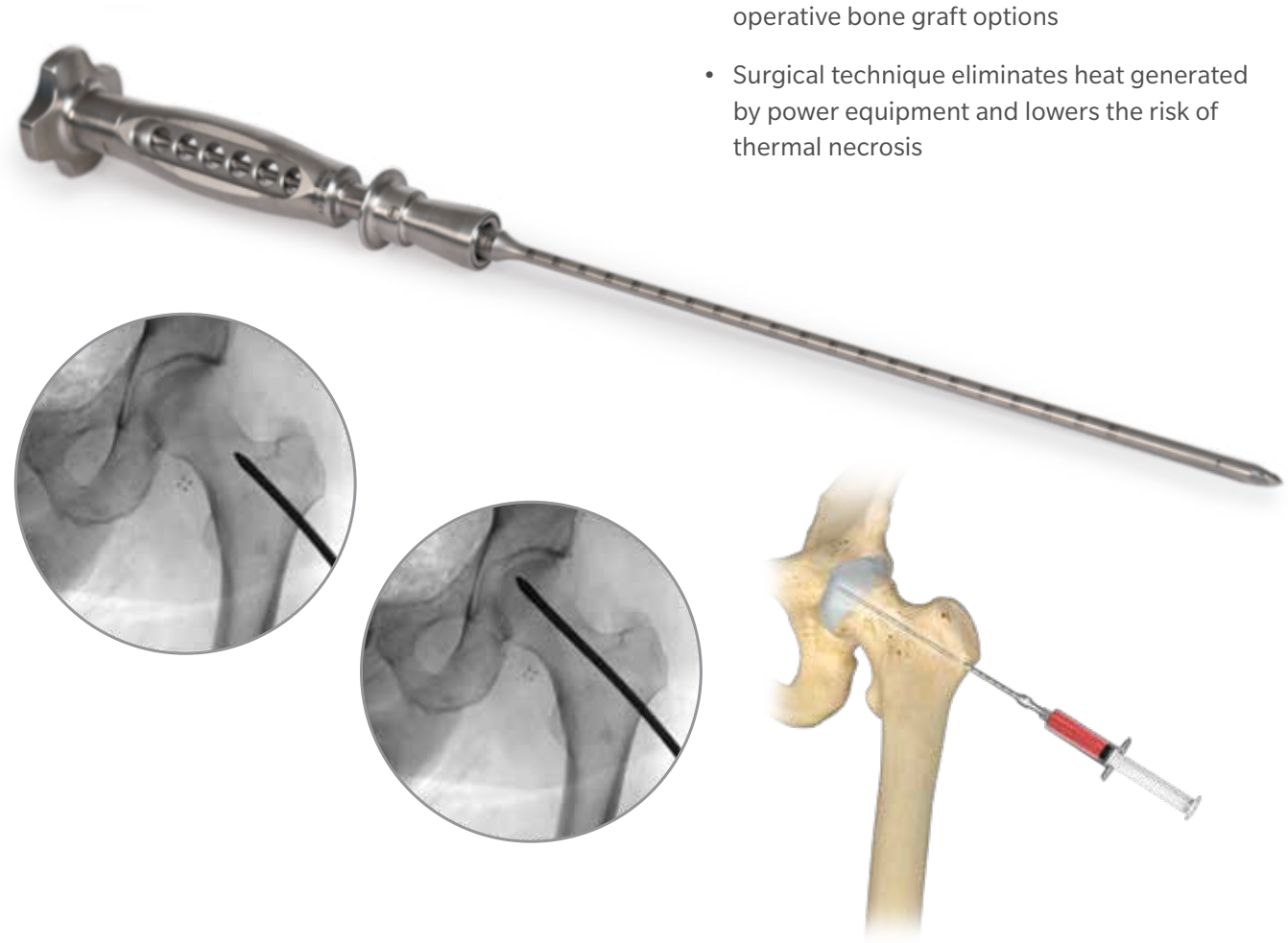
PerFuse™ Percutaneous Decompression System

Zimmer Biomet's PerFuse Percutaneous Decompression System is designed to access the femoral head or humeral head for core decompression. The PerFuse System facilitates mixing and pre-mixing of bone graft material with I.V. fluids, blood, plasma, bone marrow, or other specified blood components deemed necessary by the clinical use requirements.

Core Decompression is a surgical technique to treat Avascular Necrosis involving drilling one or more channels into the dead bone (necrotic lesion). Creating a channel into the necrotic lesion is intended to relieve intraosseous pressure within the bone and provide a channel to restore blood flow to the diseased bone.[20]

Multiple approaches have been employed to augment core decompression (e.g. autologous bone marrow aspirate, synthetic bone graft substitutes, and allograft products including milled trabecular bone and vascularized fibular grafts).

- PerFuse System Cannula creates 6 mm hole, which offers post-op flexibility for physician
- Simple ease of use:
  - Disposable components are always sharp
  - 6 mm in diameter with two options in length: Large (295 mm) and Small (161 mm)
  - Loaner program lowers facility initial investment
- Disposable tamp allows for multiple intra-operative bone graft options
- Surgical technique eliminates heat generated by power equipment and lowers the risk of thermal necrosis



Complete Bone Remodeling Triad

Many currently available bone grafting materials have some of the features necessary for successful bone healing, but few possess all three of the components of the bone remodeling triad: osteoconductivity, osteoinductivity and osteogenicity. In an effort to provide a graft material that contains all three components without the need to harvest autograft, advanced fresh-frozen allografts were developed from cadaveric tissue to meet this medical need. These allografts retain naturally inherent osteogenic cells as well as osteoconductive and osteoinductive properties.

Bonus Triad® Allograft

Bonus Triad Allograft is a cryopreserved human tissue allograft consisting of cancellous bone combined with demineralized cortical bone matrix in uniform granule particle size. This unique combination provides all three components of the bone remodeling triad: osteoconductive, osteoinductive, and osteogenic.

Bonus Triad Allograft has been developed to overcome the limitations of some bone graft substitutes and designed to offer a real alternative to autograft.

Bonus Triad Allograft contains at least 750,000 cells/cc of cancellous tissue with at least 70% cell viability.[21] These cells include MSCs, osteoprogenitor cells and pre-osteoblasts.

Osteoconductive

- Cancellous bone matrix offers an interconnected trabecular structure. This allows for bone in-growth and graft remodeling

Osteoinductive

- Demineralized component provides additional inherent growth factors

Osteogenic

- Provides live osteogenic cells that are critical to the bone healing process

Thorough Processing

- Processed via stringent donor screening, testing and sterility procedures (aseptic processing)
- Test samples of Bonus Triad Allograft were shown to be immune-protective[22,*]

Excellent Handling

- Graft composition designed to provide excellent handling: allows for dense graft packing and placement at surgical site

*Laboratory results are not necessarily indicative of clinical performance

OCA Kit Natural Tissue Graft

The OCA Kit is used for the repair repair of osteochondral defects and articular cartliage damage. Addressing cartilage lesions through cartilage repair can limit the need for further surgical intervention and potentially divert the progression of these lesions to osteoarthritis.

The OCA Kit is a convenient osteochondral allograft (OCA) kit packaged with cancellous chips. This configuration offers surgeons flexibility in addressing multiple types of osteochondral and cartilage defects.

- Cells derived from juvenile donor tissue are 100-fold more active than their adult counterparts at producing cartilagenous tissue in vitro[23]
- Juvenile allograft contains 10x the number of chondrocytes compared to adult tissue
- The OCA Kit includes 5cc of 1-4 mm cancellous chips
- Does not elicit an allogeneic immune response[23]
- The graft is implanted in a single stage procedure with fibrin fixation
- No need to harvest tissue or cells from areas of undamaged cartilage, thereby saving time in the OR

DermaSpan™ Acellular Dermal Matrix

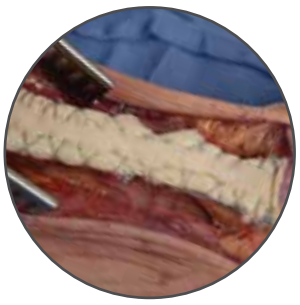
DermaSpan Acellular Dermal Matrix is carefully processed to be used for the repair or replacement of damaged or inadequate integumental tissue or for other homologous uses of human integument.

DermaSpan™ Meshed ACD is to be used as a covering for skin wounds (e.g. burns, ulcers) and should not be used in load-bearing applications. The standard allograft (non-meshed) may also be used for supplemental support, protection, reinforcement or covering of tendon or ligament, but is not intended to bear the load.

Through a unique, proprietary process DermaSpan Acellular Dermal Matrix is supplied sterile (SAL-10-6). Histology studies have shown Precision Dose Sterilization allows the graft to be sterilized while maintaining integrity.[24]

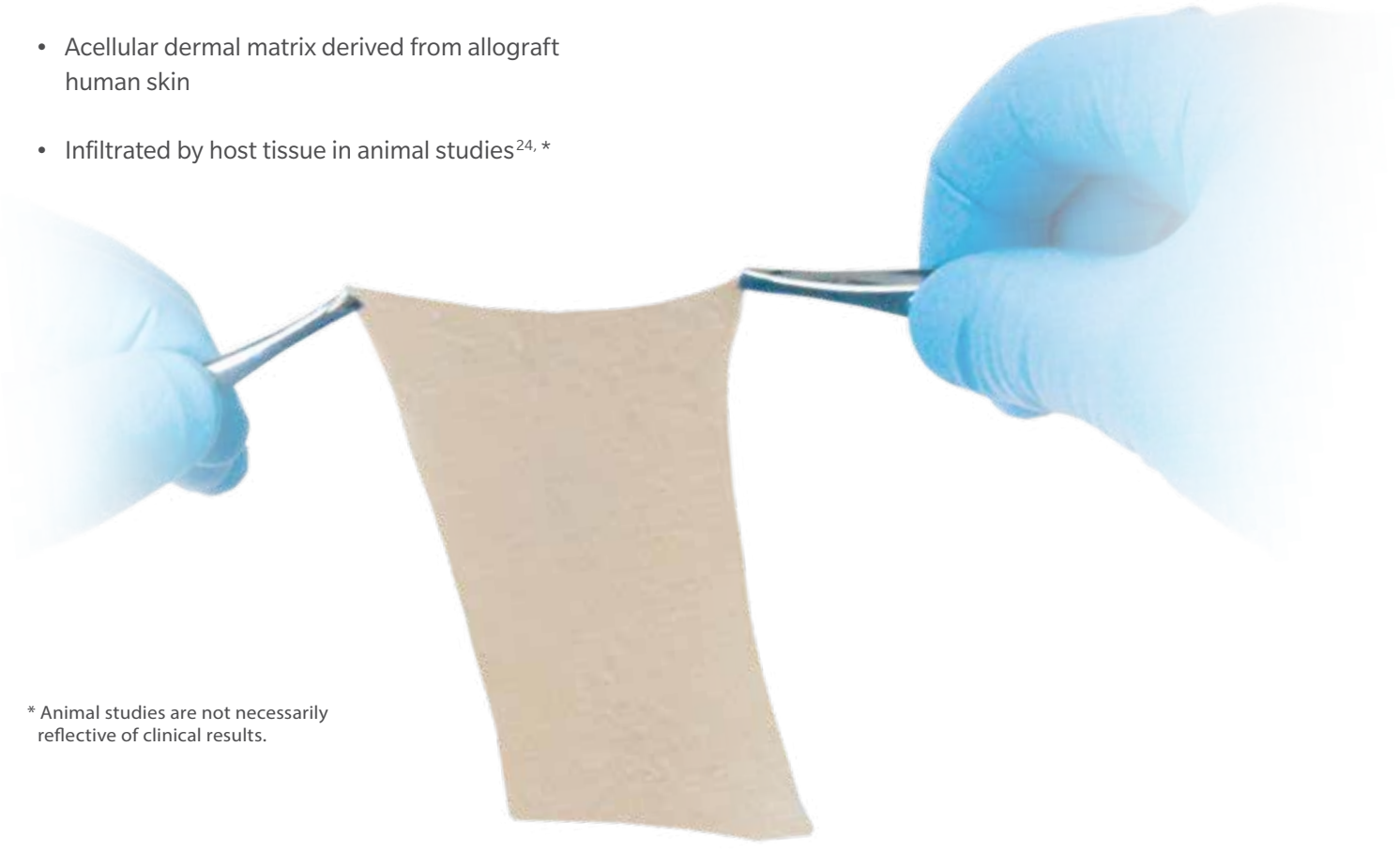
- Acellular dermal matrix derived from allograft human skin
- Infiltrated by host tissue in animal studies[24, *]

Examples of Non-Load Bearing Potential Applications:



Achilles Tendon Reinforcement

Wound Coverage



* Animal studies are not necessarily reflective of clinical results.

AmnioRepair™ Amniotic Membrane Allograft

Structural proteins act as a scaffold for cellular attachment and migration. Placental tissue has several structural matrix components that aid in cell migration and attachment including Collagen type IV, Fibronectin, Laminin, and Glycosaminoglycans (GAGs).

AmnioRepair Allograft is a lyophilized placental membrane allograft that is aseptically processed to preserve the native extracellular matrix and endogenous proteins. Amniorepair Allograft is intended for homologous use as a barrier, forming a protective cover for a variety of acute and chronic wounds.

- Clinical cases include wound cover of the foot and ankle.[25]
- AmnioRepair Allograft uses a proprietary freeze-drying solution during lyophilization, which preserves key growth factors.[26]

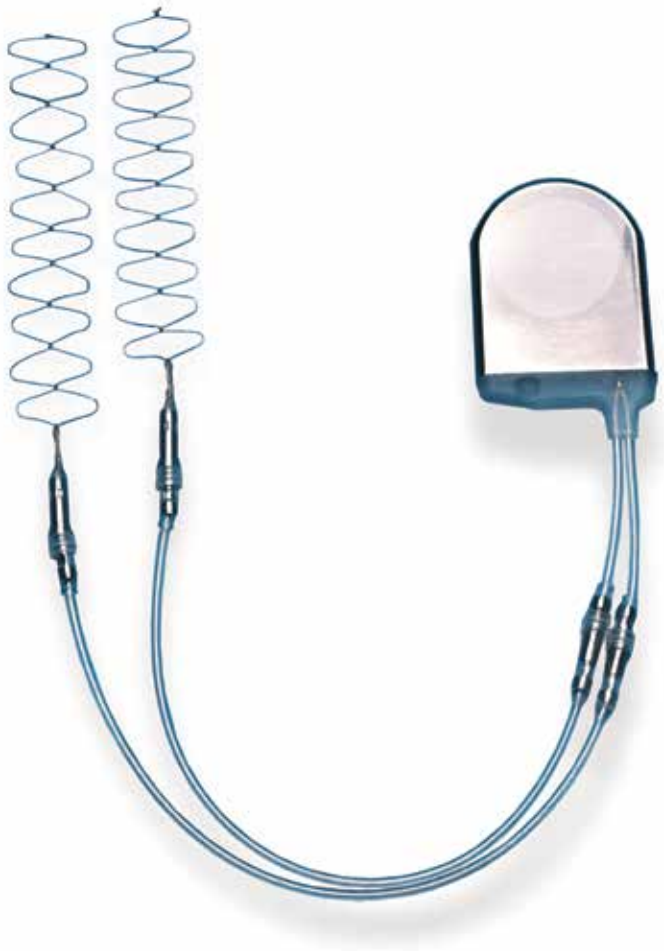
*In- vitro and animal studies are not necessarily indicative of clinical performance.

OsteoGen™ Bone Stimulation

The OsteoGen™ Surgically Implantable Bone Growth Stimulator is a useful adjunct for treating nonunions where surgery is already planned or where patient noncompliance may be a factor with pulsed electromagnetic fields (PEMF). Because the OsteoGen is totally implanted, your patient is assured of the therapeutic treatment at the nonunion site.

OsteoGen is compatible with the surgical treatment commonly used for management of transverse, segmented, and comminuted nonunions of the femur, tibia, fibula, humerus, clavicle, ulna and radius. The OsteoGen Stimulator may be used as an adjunct to internal/external fixation and autograft.

- EBI OsteoGen Implantable Stimulator is clinically proven. In one 10 year follow-up clinical study, the OsteoGen Implantable Stimulator achieved an 85% success rate in healing tibia nonunions.[27]
- Direct current stimulation has been shown in various *in vitro* and animal studies to upregulate gene expression for multiple growth factors including Bone Morphogenic Proteins (BMP) -2,-6, and -7[28]*



*Pre-Clinical studies involve scientific testing of a drug/device to evaluate its feasibility prior to being studied in humans. This testing is often performed utilizing *in vitro* cell cultures and/or animal models. The results of pre-clinical studies may not be indicative of human clinical outcomes.

Indications for Use

Please see package inserts for additional device information/labeling.

Product	Clinical Indications
GPS III Platelet Concentrate Separation Kit with ACD-A	The GPS III Platelet Concentrate Separation Kit with ACD-A is designed to be used for the safe and rapid preparation of autologous platelet-rich plasma (PRP) from a small sample of the patient's blood at the point of care. The PRP can be mixed with autograft and allograft bone prior to application to an orthopedic surgical site as deemed necessary by the clinical use requirements.
Plasmax Plasma Concentrator	The Plasmax Plasma Concentrator Accessory aids in the concentration of the patient's own plasma proteins by centrifugation utilizing a Biomet Biologics centrifuge. Excess water is removed from the platelet-poor plasma (PPP) with desalting beads. GPS III Mini Platelet Concentrate Separation Kit with ACD-A. The GPS III Mini Platelet Concentrate Separation Kit with ACD-A aids separation of the patient's own blood components by density through the use of a Biomet Biologics centrifuge.
BioCUE Platelet Concentration System	The BioCUE Platelet Concentration System consists of a standard (containing 60 ml separator) or a mini (containing 30 ml separator) kit. The kit separates a mixture of the patient's blood and bone marrow components by density through the use of the BioCUE Separator and a Biomet Biologics centrifuge. The system contains syringes, blood draw components, a separator, and bone marrow aspiration (BMA) needle. The BioCUE Separator permits platelet poor plasma (PPP) and platelet rich plasma (PRP) to be rapidly prepared from a small volume of a mixture of the patient's blood and bone marrow that is drawn at the time of treatment.
AccuFill SCP	AccuFill Bone Substitute Material is an injectable, self-setting, macroporous, osteoconductive, calcium phosphate bone graft substitute material that is intended for us to fill bony voids or gaps of the skeletal system of the extremities, spine (ie, posterolateral spine), and the pelvis that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. AccuFill BSM is a bone graft substitute that resorbs and is replaced with new bone during the healing process.
$^{\beta}$Beta-bsm Injectable	$^{\beta}$Beta-bsm Injectable bone Substitute Material is an implantable bone graft that is a synthetic calcium phosphate, poorly crystalline hydroxyapatite material intended for use in filling bone voids or defects of the skeletal system (i.e. the extremities, posterolateral spine and pelvis) that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. $^{\beta}$Beta-bsm Injectable Bone Substitute Material is a bone graft substitute that resorbs and is replaced with new bone during the healing process.
$^{\beta}$Gamma-bsm Moldable Bone Substitute Material	$^{\gamma}$Gamma-bsm Moldable Bone Substitute Material is an implantable bone graft that is a synthetic calcium phosphate, poorly crystalline hydroxyapatite material intended for use in filling bone voids or defects of the skeletal system (i.e. the extremities, posterolateral spine and pelvis) that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. $^{\gamma}$Gamma-bsm Moldable Bone Substitute Material is a bone graft substitute that resorbs and is replaced with new bone during the healing process.

Indications for Use (cont.)

Please see package inserts for additional device information/labeling.

Product	Clinical Indications
DeNovo NT Natural Tissue Graft	361 HCT/P Tissue (Human Tissue) DeNovo NT Graft is intended as a surgical implant to repair damaged articular cartilage.
Chondrofix Osteochondral Allograft	Chondrofix Osteochondral Allograft is intended for the repair of osteochondral lesions in diarthrodial joints. Fresh osteochondral tissue is used to repair Grade III or Grade IV defects in the knee; therefore, Chondrofix Allograft is recommended to repair Grade III and Grade IV osteochondral lesions, including those that are surgically created. It is well suited for a wide range of patient populations experiencing osteochondral lesions and concomitant injuries. The product may be an attractive option for active patients. Chondrofix Allograft is a donated human tissue graft that is regulated by the FDA in the same manner as other orthopedic allograft materials such as meniscus allografts, bone allografts and fresh osteochondral allografts for cartilage repair. It is designated as a '361' HCT/P as specified in 21 CFR §1271.10.
DermaSpan Acellular Dermal Matrix 361 HCT/P Tissue (Human Tissue)	DermaSpan ACD is to be used for the repair or replacement of damaged or inadequate integumental tissue or for other homologous uses of human integument. DermaSpan Meshed ACD is to be used as a covering for skin wounds (e.g. burns, ulcers) and should not be used in load-bearing applications. The standard allograft (non-meshed) may also be used for supplemental support, protection, reinforcement or covering of tendon or ligament, but is not intended to bear the load. Each package of DermaSpan ACD is intended for use in one patient on a single occasion by a licensed physician, surgeon, dentist or podiatrist.
AmnioRepair Amniotic Membrane Allograft 361 HCT/P Tissue (Human Tissue)	AmnioRepair Allograft is a lyophilized placental membrane allograft that is aseptically processed to preserve the native extracellular matrix and endogenous proteins. AmnioRepair is indicated for use as a biological barrier or wound cover. AmnioRepair is a Human Cellular and Tissue Based Product (HCT/P) per 21 CFR Part 1271. Each allograft is restricted to homologous use for use in procedures on a single occasion by a licensed physician or surgeon.
EquivaBone Bone Graft Substitute	EquivaBone is a bone graft substitute that combines synthetic calcium phosphate and demineralized bone. It is resorbed and replace with new bone during the healing process. It is intended for use to fill bony voids or gaps of the skeletal system of the extremities, spine (i.e. posterolateral spine) and pelvis that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone.
StaGraft Cancellous Graft 361 HCT/P Tissue (Human Tissue)	These allografts meet the definition of a tissue-based product as defined in 21 CFR Part 1271, Human Cells, Tissues and Cellular and Tissue-based products (HCT/Ps) and are solely regulated under Section 361 of the Public Health Services Act. Tissue-based products regulated as 361 HCT/Ps are exempt from premarket requirements.

Please see package inserts for additional device information/labeling.

Product	Clinical Indications
StaGraft DBM (Putty, Paste, Plus) also known as InterGro DBM (Putty, Paste, Plus)	StaGraft DBM products are to be used for filling bony voids or gaps in the extremities and pelvis that are not intrinsic to the bony stability of the structure, and as an autograft extender in the spine. StaGraft Plus may also be used as a bone void filler in the spine (posterolateral spine). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to bone. StaGraft DBM may also be used for filling craniofacial defects and craniotomies that are no larger than 25cm^2. The amount of StaGraft DBM products to be used should be based on the type of procedure and size of the graft site.
PerFuse Percutaneous Decompression System	The PerFuse Percutaneous Decompression System is intended to be used for the delivery of allograft, autograft, or synthentic bone graft material to an orthopedic surgical site. In addition, it is designed to facilitate mixing and pre-mixing of bone graft material with I.V. fluids, blood, plasma concentrate, platelet-rich plasma, bone marrow or other specified blood components deemed necessary by the clinical use requirements
BMA Kit	The Bone Marrow Aspiration Needle is intended for use in aspirating bone marrow.
Calcigen S	Calcigen S Bone Void Filler is indicated to be injected into open voids or gaps of the skeletal system (ie, the extremities, spine, and pelvis). These open bone voids may be surgically created osseous defects or osseous defects created from trumatic injury to the bone. Calcigen S Bone Void Filler is indicated only for bone voids or gaps that are not intrinsic to the stability of the bone structure (ie the etremities, spine and pelvis). The device is limited to be used in posterolateral spinal fusion procedures only.
Bonus Triad Allograft 361 HCT/P Tissue (Human Tissue)	Bonus Triad is an allogeneic bone graft substitute containing viable donor cells intended for homologous use in the repair, replacement, reconstruction, or supplementation of the recipient's tissue in musculoskeletal defects. These defects may be surgically created defects or defects created from traumatic injury to bone.
OsteoGen Implantable Bone Stimulator	INDICATIONS The OsteoGen-20/S, OsteoGen- 20/M, OsteoGen -20/F OsteoGen-40/S, OsteoGen-40/M, OsteoGen-40/SL and OsteoGen-40/ML are constant direct current implantable generators indicated in the treatment of long bone nonunions - P790005/S044. The OsteoGen-40/S, OsteoGen-40/M, OsteoGen-40/SL and OsteoGen-40/ML are only to be used to treat multiple nonunions or in a severely comminuted nonunion where a single cathode cannot span the entire breadth of the nonunion site. The OsteoGen-40/S, OsteoGen-40/M, OsteoGen-40/SL and OsteoGen-40/ML must be used with both leads in place, each delivering 20 microamperes per lead - P790005/S042. A nonunion is considered to be established when the fracture site shows no visibly progressive signs of healing - P790005/S041. CONTRAINDICATIONS There are no known contraindications regarding the use of these devices, however, due to insufficient clinical experience; it is not recommended that they be used in the following conditions: pathological fractures due to malignant tumors or in the presence of active osteomyelitis. USAGE: Federal Law (U.S.A.) restricts these devices to sale by or on the order of a physician. Rx Only - Prescription Only - Single Patient Use Only - Not for Re-Sale or Re-Distribution - Do Not Reuse. Complete prescribing information including warnings and precautions associated with the use of these devices may be found online at

Catalog Part Numbers

CopiOs

00110301001	1 cc Sponge
00110301005	5 cc Sponge
00110301010	10 cc Sponge
00110302001	1 cc Paste
00110302005	5 cc Paste
00110302010	10 cc Paste

βBeta-bsm Injectable

76-6025	2.5 cc kit
76-6016	5 cc kit
76-6047	PDMS 14 cc w/ MA
76-6049	PDMS 40 cc w/ MA
76-6054	Precision Cannula 150 mm
76-6055	Precision Cannula 200 mm

γGamma–bsm Moldable Putty

76-6001	1 cc kit
76-6023	2.5 cc kit
76-6005	5 cc kit
76-6010	10 cc kit
76-6047	PDMS 14cc w/ MA
76-6049	PDMS 40cc w/ MA

Calcigen S

348010	5 gram kit
348012	10 gram kit
348014	25 gram kit

SCP

414.502	SCP Complete Knee Kit; 5 cc, Side-Delivery, 11 ga x 120 mm
414.503	SCP Complete Knee Kit; 5 cc, End-Delivery, 11 ga x 120 mm
514.302	SCP Complete Foot & Ankle Kit; 3 cc, Side-Delivery, 11 ga. (3.0 mm OD) x 120 mm
514.303	SCP Complete Foot & Ankle Kit; 3 cc, End-Delivery, 11 ga (3.0 mm OD) x 120 mm
514.315	SCP Complete Foot & Ankle Kit; 3 cc, End-Delivery, 15 ga (1.8 mm OD) x 60 mm
514.502	SCP Complete Foot & Ankle Kit; 5 cc, Side-Delivery, 11 ga (3.0 mm OD) x 120 mm
514.502	SCP Complete Foot & Ankle Kit; 5 cc, End-Delivery, 11 ga (3.0 mm OD) x 120 mm

EquivaBone Bone Graft Substitute

76-6027	2.5 cc kit
76-6021	5 cc kit
76-6022	10 cc kit
76-6047	PDMS 14 cc w/ MA
76-6049	PDMS 40 cc w/ MA
76-6054	Precision Cannula 150 mm
76-6055	Precision Cannula 200 mm

StaGraft Cancellous DBM

92-3250	Cancellous Strip, 20 x 50 x 5 mm
92-3230	Cancellous Strip, 20 x 30 x 5 mm
92-3214	Cancellous Sponge, 14 mm (cube)
92-3214S	Cancellous Sponge, 14 mm (cube) (Sample)
92-3230S	Cancellous Strip, 20 x 30 x 5 mm (Sample)

StaGraft Demineralized Bone

92-2000	Putty, 0.5 cc
92-2001	Putty, 1 cc
92-2002	Putty, 2 cc
92-2003	Putty, 5 cc
92-2004	Putty, 10 cc
92-2005	Plus +500R, 2 cc
92-2006	Plus +500R, 5 cc
92-2007	Plus +500R, 10 cc
92-2003S	Putty (Sample), 5 cc
92-2006S	Plus +500R (Sample), 5 cc
92-2022	Paste, 2 cc

GPS III Platelet Concentration System

800-0505A	GPS III Mini Kit w/ACD-A & BD
800-1003A	GPS III Single Kit w/Blood Draw
800-1004A	GPS III Double Kit w/BD & ACD-A
800-1006A	GPS Standard 6–Pack
800-1007A	GPS Mini 6-Pack
800-0505	Biomet Biologics Mini Ctr Bal
800-0508	Biomet Biologics Counter Bal

Bonus Triad

48-6001	1 cc kit
48-6005	5 cc kit
48-6010	10 cc kit
48-6015	15 cc kit

Plasmax Plasma Concentration System

800-0516	Plasmax W/GPS III Mini & 30 ml ACD-A
800-0517	Plasmax Plus W/GPS III Single & 30 ml ACD-A
800-0510	Plasmax Concentrator C-Bal
800-0512	Counterbalance Plasmax Plus

BioCUE *β*BMA Concentration System

800-0610A	BioCUE Mini Kit
800-0611A	BioCUE Std Kit Domestic
800-0534	Bone Graft Convenience Kit with BioCUE Mini Disposable
800-0536	Bone Graft Convenience Kit with BioCUE Standard Disposable
800-0300	Graft Preparation System
800-0705	BOS Bone Marrow Asp Kit

PerFuse Percutaneous Decompression System

800-0541	Perfuse Hip Single-Use Cannula/Trochar
800-0542	Perfuse Small Joint Single-Use Cannula/ Trochar
800-0543	Perfuse Slide Hammer Adapter
800-0544	Perfuse Handle Strike Cap
800-0545	Perfuse Handle
800-0546	Perfuse Instrumentation Tray

DeNovo NT Natural Tissue Graft

00560600010	DeNovo NT Graft 1 Unit

OCA Kit

00560600030	Osteochondral Allograft (OCA) Kit
00-5604-004-07	OC Drill Bit, 7 mm
00-5604-004-09	OC Drill Bit, 9 mm
00-5604-004-11	OC Drill Bit, 11 mm
00-5604-004-15	OC Drill Bit, 15 mm
00-5604-011-07	Punch, 7 mm
00-5604-011-09	Punch, 9 mm
00-5604-011-11	Punch, 11 mm
00-5604-013-07	Impaction Cap, 7 mm
00-5604-013-09	Impaction Cap, 9 mm
00-5604-013-11	Impaction Cap, 11 mm
00-5604-014-07	Tamp, 7 mm
00-5604-014-09	Tamp, 9 mm
00-5604-014-11	Tamp, 11 mm
00-5604-014-15	Tamp, 15 mm
00-5604-015-07	Delivery Device, 7 mm
00-5604-015-09	Delivery Device, 9 mm
00-5604-015-11	Delivery Device, 11 mm
00-5604-015-15	Delivery Device, 15 mm

DermaSpan Acellular Dermal Matrix

48-0400404M	0.4 mm – 0.8 mm thick, 4 cm x 4 cm (meshed)
48-0400408M	0.4 mm – 0.8 mm thick, 4 cm x 8 cm (meshed)
48-0401012M	0.4 mm - 0.8 mm thick, 10 cm x 12 cm (meshed)
48-0901114M	0.9mm – 1.99 mm thick, 11 cm x 14 cm
48-0901219M	0.9 mm – 1.99 mm thick, 12 cm x 19 cm
48-0401012	0.4 mm - 0.8 mm thick, 10 cm x 12 cm
48-0500202	0.5 mm – 0.9 mm thick, 2 cm x 2 cm
48-0500203	0.5 mm – 0.9 mm thick, 2 cm x 3 cm
48-0500204	0.5 mm – 0.9 mm thick, 2 cm x 4 cm
48-0500303	0.5 mm – 0.9 mm thick, 3 cm x 3 cm
48-0700404	0.5 mm – 0.9 mm thick, 4 cm x 4 cm
48-0700408	0.5 mm – 0.9 mm thick, 4 cm x 8 cm
48-1100407	0.8 mm – 1.4 mm thick, 4 cm x 7 cm
48-1100510	0.8 mm – 1.4 mm thick, 5 cm x 10 cm
48-1100505	0.8 mm – 1.4 mm thick, 5 cm x 5 cm
48-0900307	0.9 mm – 1.99 mm thick, 3 cm x 7 cm
48-0900407	0.9 mm – 1.99 mm thick, 4 cm x 7 cm
48-0900412	0.9 mm – 1.99 mm thick, 4 cm x 12 cm
48-0900416	0.9 mm – 1.99 mm thick, 4 cm x 16 cm
48-0900510	0.9 mm – 1.99 mm thick, 5 cm x 10 cm
48-0900612	0.9 mm – 1.99 mm thick, 6 cm x 12 cm
48-0900616	0.9 mm – 1.99 mm thick, 6 cm x 16 cm
48-0900812	0.9 mm – 1.99 mm thick, 8 cm x 12 cm
48-0900813	0.9 mm – 1.9 mm thick, 8 cm x 13 cm
48-0900816	0.9 mm – 1.99 mm thick, 8 cm x 16 cm
48-0901114	0.9 mm – 1.99 mm thick, 11 cm x 14 cm

Catalog Part Numbers (cont.)

48-0901212	0.9 mm – 1.99 mm thick, 12 cm x 12 cm
48-0901219	0.9 mm – 1.99 mm thick, 12 cm x 19 cm
48-0901620	0.9 mm – 1.99 mm thick, 16 cm x 20 cm
48-2000307	2.0 mm – 3.5 mm thick, 3 cm x 7 cm
48-2000407	2.0 mm – 3.5 mm thick, 4 cm x 7 cm
48-2000412	2.0 mm – 3.5 mm thick, 4 cm x 12 cm
48-2000510	2.0 mm – 3.5 mm thick, 5 cm x 10 cm
48-2000612	2.0 mm – 3.5 mm thick, 6 cm x 12 cm
48-2000616	2.0 mm – 3.5 mm thick, 6 cm x 16 cm
48-2000812	2.0 mm – 3.5 mm thick, 8 cm x 12 cm
48-2000816	2.0 mm – 3.5 mm thick, 8 cm x 16 cm
48-2001212	2.0 mm – 3.5 mm thick, 12 cm x 12 cm
48-2001620	2.0 mm – 3.5 mm thick, 16 cm x 20 cm

AmnioRepair Amniotic Membrane Allograft

00561800416	AmnioRepair 16 mm disk
00561800422	AmnioRepair Sheet 2 cm x 2 cm
00561800423	AmnioRepair Sheet 2 cm x 3 cm
00561800424	AmnioRepair Sheet 2 cm x 4 cm
00561800433	AmnioRepair Sheet 3 cm x 3 cm
00561800444	AmnioRepair Sheet 4 cm x 4 cm
00561800446	AmnioRepair Sheet 4 cm x 6 cm

Tips and Spray Kits

800-0201	Applicator Tip
800-0202	Applicator Tip Dual Cannula, Malleable 20ga X 10 cm (4in)
800-0203	Applicator Tip Dual Cannula, Malleable 20ga X 18 cm (7in)
800-0204	Blending Connector With Single Cannula
800-0207	Applicator Spray Tip Dual Cannula, Malleable 5 mm X 32cm (12.5in)
800-0208	Rigid Endoscopic Tip 1:1 Ratio 5 mm X 40 cm
800-0211	Aerosol Regulator
800-0215	Aerosol Regulator w/Vent
800-0217	Rigid Endoscopic Aerosol Applicator Tip 5 mm X 40 cm (16in), 1:1 Ratio
800-0225	Arthroscopic Delivery Kit
800-0250	Spray Applicator Kit
800-0251	Dual Ratio Applicator Kit
800-0252	Mixing Connector With Spray Tip
800-0260	Aerosol Applicator Kit w/Tips, 11:1 Ratio

Centrifuge and Accessories

755VES	Centrifuge 115V 50/60 HZ Drucker with Cord
7760006	Power Cord for 755VES Centrifuge
7436	Universal GPS Spare Bucket Kit for 755VES 60 mL (2 Green Buckets)
7433	Mini Kit Spare Bucket Centrifuge (Purple Buckets)
800-0401	Universal Blood Draw

OsteoGen Implantable Bone Stimulator

0-1318	OGEN STR CATH/FUSED CONNECTOR
10-1320	OGEN STR CATHODE/DETACHABLE
10-1320M	OGEN MESH CATHRODE/DETACHABLE
10-1322M	OGEN DUAL MESH CATH 30CM LEAD
10-1322S	OGEN DUAL STR CATHOD 30CM LEAD
10-1328M	OGEN MESH CATH/DETAC 30CM LEAD
10-1328S	OGEN STR CATH/DETACH 30CM LEAD
10-1348M	OGEN DUAL MESH CATHODES
10-1348S	OGEN DUAL STRAIGHT CATHODES

Other

92-2010	Supplement Mold Tray

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Success Rates: Proof of efficacy of this treatment for the claimed indication was based on the fact that many patients, who were judged based on the clinical experience of the physician doing the study to be at very high risk of remaining unhealed if left untreated, improved with treatment. The number of patients reaching a functional union divided by the number reaching any definable endpoint. Success rates of this treatment were judged to be approximately equal to, if not higher than, the success rates previously experienced with conventional procedures (i.e., grafting).

The status of the 318 fractures as of August 1978 was 180 functional, 24 partial union, 33 no progress, 46 normal progress, 29 slow progress, and 6 were lost to follow up. That is, of the 318 treated fractures, 235 had reached a definable endpoint, 77 were still in treatment and 6 were lost to follow-up. The success rates of the Bi-Osteogen treatment by analytical site for all investigated fracture types ranged from 57% for adult radius and ulna to 85% for adult tibia.

This material is intended for health care professionals and the Zimmer Biomet sales force. Distribution to any other recipient is prohibited.

ETEX Corporation is the responsible manufacturer of Beta BSM, Gamma BSM, Equivabone BSM, and AccuFill BSM.

For complete product information, including indications, contraindications, warnings, precautions, and potential adverse effects, see the package insert and www.zimmerbiomet.com.

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