LEADER
BIOMEDICAL

Orthobiologics

ORTHOPAEDICS

Perfecting bone regeneration

From trauma and spine surgeries to hip and knee arthroplasties, there is an enormous need for biocompatible grafts with osteoconductive properties.

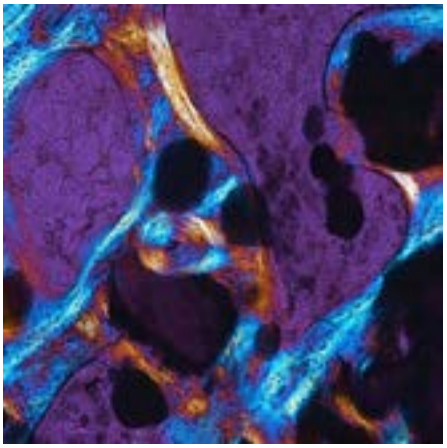
While autografts have historically been the gold standard, their use is subject to availability, safety concerns, and higher morbidity (due to the harvesting process).

Many surgeons prefer to use allografts or synthetic grafts, because they do not require a second surgery site, which would increase the patient's hospital stay and time spent in the OR.

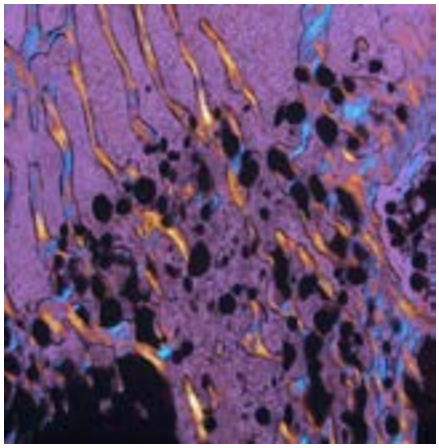
If we are to perfect the art of bone regeneration, we need to ask ourselves:

What would the ideal tissue graft look like?

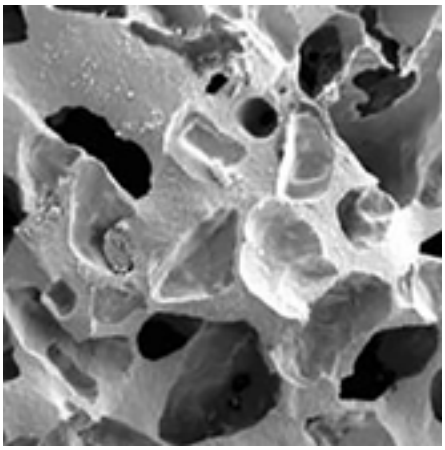
Safety
Designed and manufactured in accordance with excellent safety standards



Biocompatible
To ensure graft acceptance

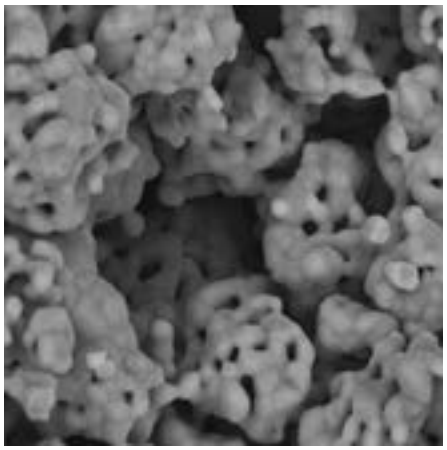


Gradual biodegradation
(bio-dissolution + bioresorption)



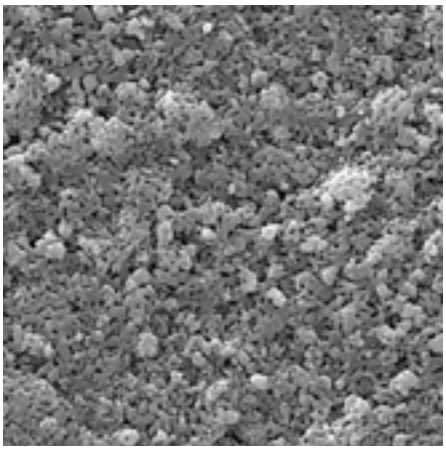
Macroporous

To stimulate cell colonisation and osteoconduction



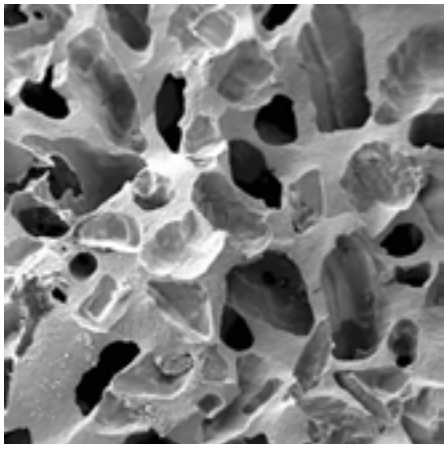
Microporous

To enable biological fluids to pass through the construct



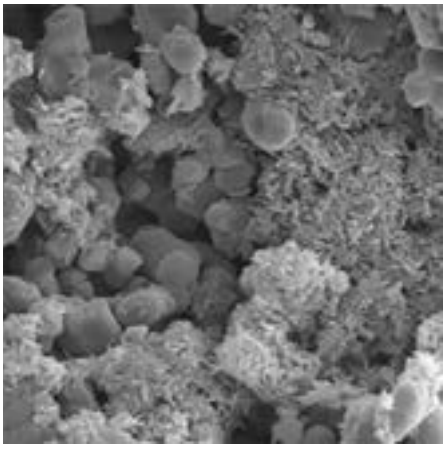
Bioactive

To ensure the tissue graft interacts with patient's body



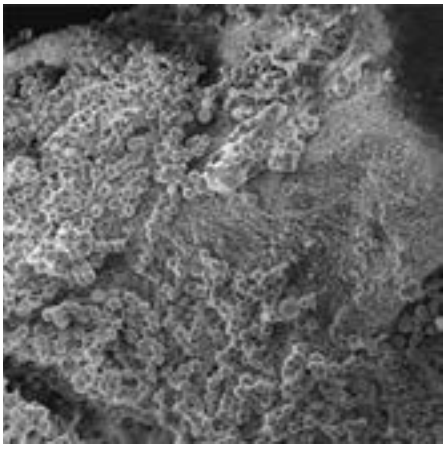
Osteoconductive

To stimulate bone ingrowth



Osteogenetic

To contribute to new bone growth



Osteoinductive

To induce cell differentiation

Allografts

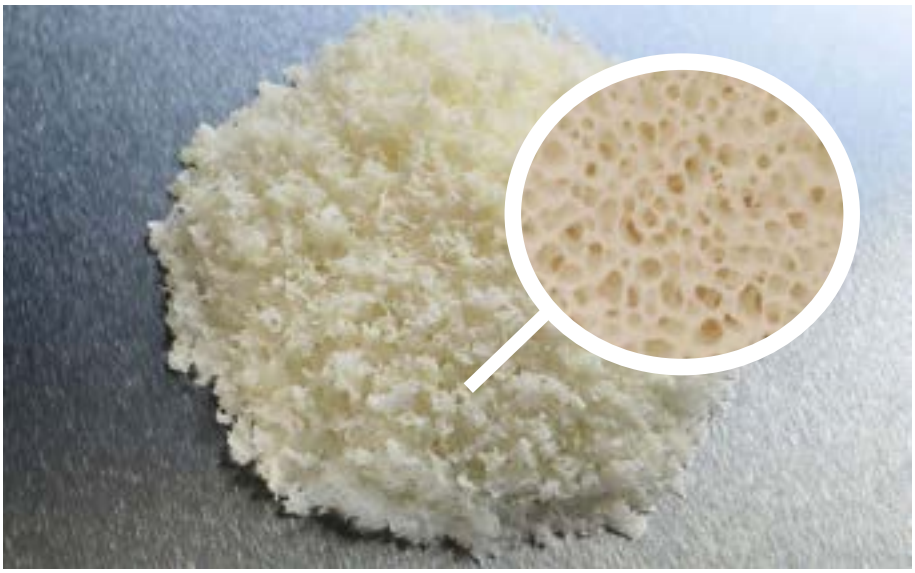
Allografts are the preferred choice for many surgeons, especially in the US. Human bone has the right mineral composition to be easily broken down and allografts' natural micro- and macroporosity are highly osteoconductive.

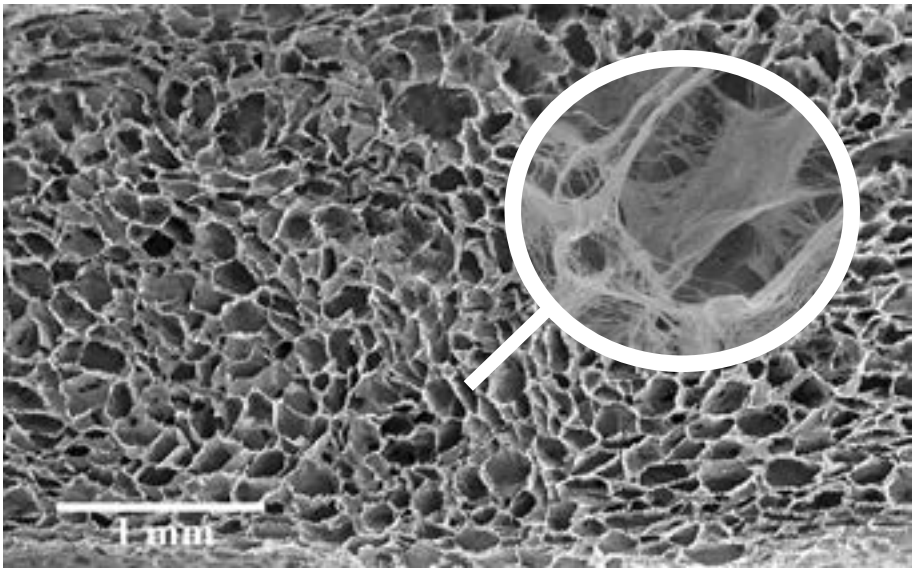
The allograft challenge

Allograft processing typically relies on the use of harsh chemical cleaning agents. These agents weaken the graft and there are some safety concerns. Residual chemical compounds or organic material can lead to its rejection.

Bone cleaned with $scCO_2$

eCOO® | Technology





The eCOO® Technology advantage

All our allografts are processed using our proprietary eCOO® Technology. This technology relies on supercritical CO_2 ($scCO_2$) to clean the grafts with the minimal use of chemicals. This is the ideal cleaning agent, because $scCO_2$ can penetrate matter like a gas and dissolve material like a liquid. Allografts processed with eCOO® Technology exhibit:

Biocompatibility

- Slower protein degradation
- Better cell adhesion

Strength

- Mechanic tests show superior tensile strength and torque
- Favourable primary stability after impaction grafting compared to non-purified fatty implants[1]

Safety

- Minimal risk of toxic residue
- Minimal risk or organic remnants, because of best-in-class cleaning technique
- SAL 6
- Complies to relevant Human Tissue regulations
- Faster more complete integration of graft anticipated[1,2,3,4]

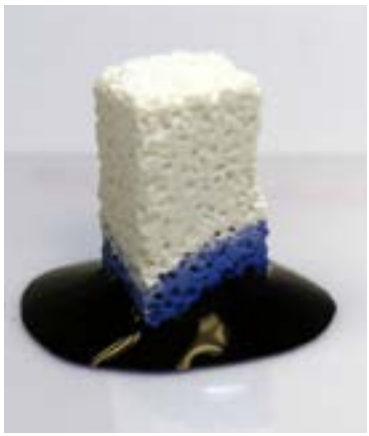
[1] Cornu, O. et al. (2003). Impaction bone grafting with freeze-dried irradiated bone. Part I & II. Acta Orthopaedica, 74(5), pp.547-558.
[2] Frayssinet, P. (1998). Histological integration of allogeneic cancellous bone tissue treated by supercritical CO2 implanted in sheep bones. Biomaterials, 19(24), pp.2247-2253.
[3] Thoren, K. and Aspenberg, P. (1995). Increased bone ingrowth distance into lipid-extracted bank bone at 6 weeks. Arch Orthop Trauma Surg, 114(3), pp.167-171.
[4] Aspenberg, P. and Thoren, K. (1990). Lipid extraction enhances bank bone incorporation: An experiment in rabbits. Acta Orthopaedica, 61(6), pp.546-548.

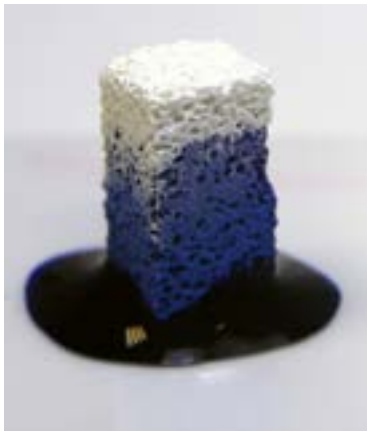
Synthetic grafts

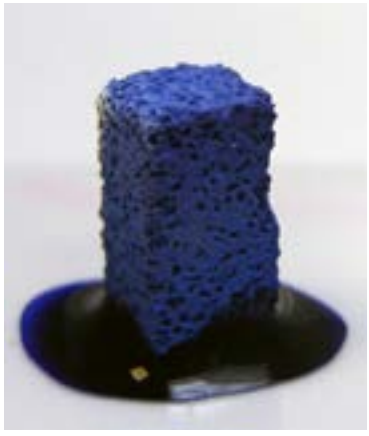
There are no safety concerns or natural constraints to the availability of synthetic grafts and recent developments have greatly improved their efficacy. Widely used in Europe, synthetic grafts have proven to be an excellent alternative, especially when used in conjunction with bone marrow or PRPs, which adds osteoinductive properties to the graft.

The synthetic graft challenge

Most synthetic grafts are made from tricalcium phosphate (TCP) or a combination of TCP and hydroxyapatite (HA). Despite having a comparable chemical composition, there is nonetheless an enormous difference in the quality of available grafts. The majority of synthetic grafts are produced in bulk with cheap, low-quality porogens (the substance used to make pores in a structure). The result is an inferior graft with sub-optimal porosity, which negatively affects both the osteoconductive and bioactive properties of the product.







The MBCP™ advantage

MBCP™ Technology is a proprietary method for producing high quality synthetic grafts composed of 60% HA and 40% βTCP. Unlike other bulk production methodologies, this process relies on a sophisticated process of synthesis with several heating steps. Synthetic grafts produced with MBCP™ Technology exhibit:

Regeneration

- The specific combination of HA and βTCP have a highly regulated resorption rate, mimicking human bone and facilitating bone regeneration

Porosity

- Macro porous structure proven ideal for cell colonisation and improved osteoconductivity
- Micro porosity structure ensures interstitial fluids flow freely to enable growth factors to reach cells

Permeability

- The fully permeable network of interconnected pores absorbs three times the graft's weight in fluids, like bone marrow, in under two minutes

Safety

- No risk of residual chemical or organic material

Availability

- No natural limit on availability

< 2 mn

Overview of grafts per indication

Spine

Indications	Products
Fusion	OssGro® granules, OssGro® Strip, OssGro® stick, eTiss® void fillers, eTiss® DBM
Cage filling	Ossfinity®, eTiss® DBM
Scoliosis	OssGro® granules, OssGro® Strip, eTiss® void fillers
■ Synthetic grafts ■ Allografts	

Trauma

Indications	Products
Fractures	OssGro® granules, OssGro® Strip, eTiss® void fillers
Pseudo fractures	OssGro® granules, OssGro® Strip, eTiss® void fillers
Tumors/bone cysts	Ossfinity®, OssGro® granules, eTiss® DBM, eTiss® void fillers
■ Synthetic grafts ■ Allografts	

Orthopaedics

Indications	Products
Hip Stem revision	OssGro® granules, OssGro® Strip, eTiss® void fillers
Hip Cup revisions	OssGro® granules, OssGro® Strip, eTiss® void fillers, eTiss® femoral heads
Knee Knee revisions	OssGro® granules, eTiss® void fillers
Knee HTO	OssGro® wedges, OssGro® granules, eTiss® femoral heads
■ Synthetic grafts ■ Allografts	

Case Studies

Non-cemented femoral stem revision with OssGro® granules and Ossfinity®

A 16 year old child underwent total hip arthroplasty following epiphyseal slippage. Eight years after the primary surgery, doctors observed a gradual loosening of the femoral stem.

X-ray
Pre-operative

Post-op X-ray
(5 months)

Diagnosis and treatment

During the revision surgery a trochanteric osteotomy was performed to increase the stability of the new implant. OssGro® granules were used to fill the space between the residual bone and the revision stem with Ossfinity® putty securing the granules in place. The use of Ossfinity® ensured proper bone regeneration in the femoral metaphysis.

Results

After five months, the patient had fully recovered and was pain free. As shown in the post-operative X- ray, the new revision stem was stable and regenerated bone can be observed in the remodeled implant area. The OssGro® granules and Ossfinity® putty filled the spaces between the bone and implant perfectly, providing stability.

References:

Uzel AP. Use of In'Oss® and MBCP™ in non-cemented femoral stem revision. Courtesy of Orthopedic Surgeons CUPH.

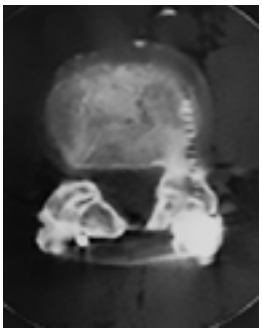
Ossfinity®

Posterolateral spinal fusion with OssGro® granules

A 45 year old male suffering from back pain and unusual leg cramps was diagnosed with degenerative spinal stenosis. Non-surgical treatments did not produce long term pain relief.

CT scan
Pre-operative

X-ray showing the fusion of the articular graft



CT scan confirms fusion of the articular graft

Diagnosis and treatment

The surgeon performed a posterolateral fusion to treat the patient's condition. OssGro® granules were placed on the lateral side of the vertebrates to promote osteointegration. The graft was secured to the vertebrates (lumbar) with spinal wires and screws.

Results

Post-operative X-rays and CT scans showed a successful fusion of the articular graft with no local complications, inflammation, or infection.

References:

Cavagna R. Daculsi G., Bouler JM (1999). Macroporous calcium phosphate ceramic: a prospective study case in lumbar spinal fusion. Long Term Eff Med Implants 9(4): 403-12 .

Treatment of infected non-union with eCOO® Clean cancellous chips

A patient suffered from a femoral non-union after undergoing three unsuccessful surgeries in the wake of a car crash.

X-ray
Pre-operative

Post-op X-ray
(3 months)

Post-op X-ray
(4 years)

Diagnosis and treatment

The surgeon inserted an intramedullary nail into the femur, along with four fixating screws, and treated the infection and fracture with antibiotic-infused cancellous chips cleaned with eCOO® Technology (eCOO® Clean).

Results

The patient could walk again without crutches within two months of the operation. After one year, the two screws serving as the upper lock were removed to facilitate mobility. After four years, the patient suffered no impairment of mobility, and was able to actively participate in many sports, including jogging, biking, and swimming.

References:

Winkler H. One Stage Treatment of Infected Non-Union using Osteomycin I. Courtesy of the Ostetitis Center Privatklinik Döbling

eCOO® | Clean

Bone tumour treatment with OssGro® granules

A 49 year old woman suffered from severe pain in her right ankle, which prevented her from walking unassisted. An X-ray revealed a defect in the anterolateral part of the tibial pilon, which proved to be a benign tumour.

X-ray
Pre-operative

Post-op X-ray
(3 months)

Post-op X-ray
(2.5 years)

Diagnosis and treatment

Anterolateral surgery was performed to remove the tumour. The resulting void was filled with OssGro® granules.

Results

Following surgery, the patient's pain progressively decreased. Three months later, X-rays showed good osteointegration around the surgical site. During the final follow-up, two and a half years later, the patient was pain free and able to walk normally.

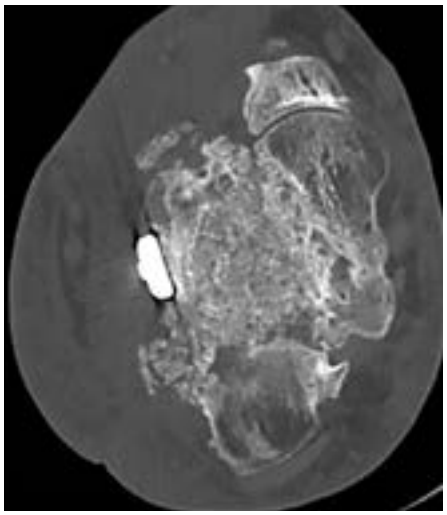
References:

Pierre A. Bone tumour-Case report. Courtesy of Orthapaedic Surgeons CUPH.

Treatment of chronic osteomyelitis after calcaneus fracture with eCOO® Clean cancellous chips

Following multiple operations after a fracture of calcaneus and both malleoli a chronic osteomyelitis was developed.

X-ray
Pre-operative



Post-op X-ray
(1 year)

Diagnosis and treatment

After radical debridement, the fracture was stabilised with a locking plate and screws. The surgeon inserted antibiotic-infused cancellous chips cleaned with eCOO® Technology (eCOO® Clean) was impacted in order to provide an antibiotic scaffold.

Results

The patient received two weeks of bed rest and three months of partial weight bearing. After a year, the graft was fully operated and no recurring osteomyelitis was observed.

References:

Winkler H. One Stage Treatment of Infected Non-Union using Osteomycin II. Courtesy of the Ostetitis Center Privatklinik Döbling

eCOO® | Clean

High Tibial Osteotomy with OssGro® wedges

A patient suffering from chronic knee pain and joint instability.

X-ray
Pre-operative

Post-op X-ray
(1 day)

Post-op X-ray
(1 year)

Diagnosis and treatment

The patient was diagnosed with a varus deformity and surgeons performed an open wedge High Tibial Osteotomy (HTO), inserting an OssGro® wedge into the medial side of the tibia, and securing it with a metal plate and screws.

Results

After one year, the OssGro® wedge was fully integrated, and the metaphyseal triangular space was filled with newly regenerated bone. As seen in the X-ray, the spacing between the tibia and the femur indicates the presence of cartilage.

References:

Rouvillain J.L.; Lavallé F.; Pascal-Mousselard H.; Catonné Y.; Daculsi G. 2008. Clinical, radiological and histological evaluation of biphasic calcium phosphate bioceramic wedges filling medial high tibial valgisation osteotomies. The Knee. 2009; 16(5): 392-397.

Allograft product overview

eTiss® void fillers

Cancellous and cortical bone chips used as void fillers, which require sound structural and mechanical properties

- eCOO® Technology processing ensures excellent osteoconductive properties
- Forms stable complex with patient's adjacent bone
- Wide variety of general orthopaedic and dental applications

eTiss®

eTiss® femoral heads

Femoral heads obtained from donors undergoing hip replacement surgery

- eCOO® Technology processing ensures excellent osteoconductive properties
- Can be modelled and shaped to the patients' individual requirements
- Used in arthroplasty and general orthopaedic surgeries

eTiss®

eTiss® DBM

Cortical bone demineralised with the goal of exposing encapsulated growth factors, such as bone morphogenetic proteins (BMPs)

- The presence of BMPs have proven to result in faster bone regeneration
- Available as putty placed in a syringe for easy application
- Wide range of indications ranging from trauma, periodontology, and spinal surgery

eTiss®

Synthetic grafts product overview

OssGro®

OssGro® granules, sticks, and wedges are bone graft substitutes produced using MBCP™ Technology. The use of this technology ensures good mechanical strength with resorption rates resembling real bone.

- New bone formation promoted by the release of calcium and phosphate ions
- Safe and easy to use
- Effective absorption of osteogenic proteins
- Long term scaffold effect for bone growth
- **OssGro® sticks** are 100% permeable with fluid absorbed in less than two minutes
- **OssGro® granules (syringe)** has improved handling to easily mix with bone marrow
- **OssGro® wedges** available in round and wedge bases with a good compression strength

OssGro®
granules

OssGro®
granules (syringe)

OssGro®
sticks

OssGro®
wedges

OssGro® Strip

OssGro® Strip combines MBCP™ Technology with highly purified Type 1 porcine collagen to optimise handling and containment

- Osteoconductive with osteoinductive properties when used in combination with bone marrow or growth factors
- Can be trimmed for different surgical requirements
- Easy to use
- Highly moldable when hydrated or soaked in blood

Ossfinity®

Ossfinity® combines OssGro® granules and an absorbable hydrogel to create a putty, which acts as a carrier for rapid vascularisation and mineralisation.

- Comes in a syringe for easy handling
- Easily used to different grafting sites
- Hydrogel ensures both containment and structural integrity
- Superior handling characteristics
- Resorbable

Leader Biomedical aims to improve global access to innovative biomaterials and implantable medical devices with a focus on high-growth markets. We contribute to the betterment of the healthcare sector by developing new technologies, delivering world class contract manufacturing services, and providing healthcare solutions.

Orthopaedics

Hips
Knees
Upper Extremities
Trauma
Spine
Orthobiologics

Sports Medicine

ACL

Contact:

info@leaderbiomedical.com
www.leaderbiomedical.com

Not for sale in the US. Refer to IFUs for detailed product information on OssGro®, Ossfinity®, and eTiss® products.

Orthobiologic – LB-BR016-001 Rev.A