



smartbone[®]
ORTHO

**THE NEXT FRONTIER OF
BONE REGENERATION**



 **swiss made**



smartbone[®]
ORTHO

UNIQUE technology...

THE NEXT FRONTIER OF BONE REGENERATION

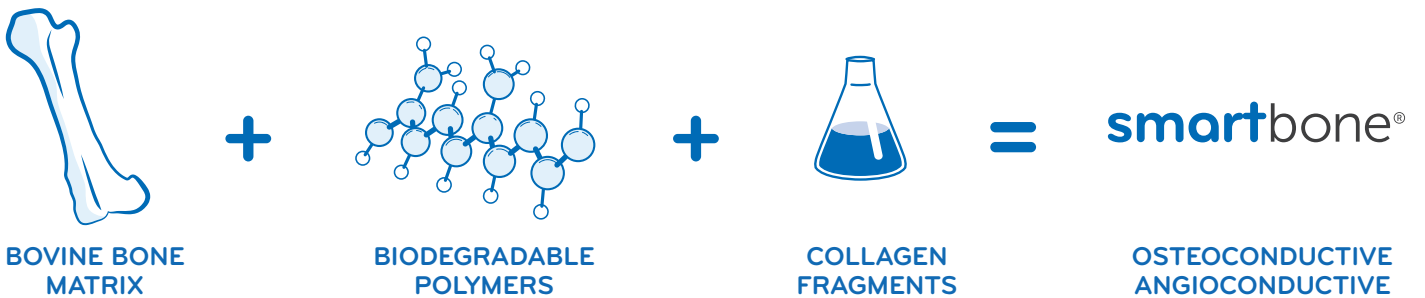
IBI is an innovative hi-tech Swiss biomedical company focused on research, development and production of medical devices for tissue engineering and regenerative medicine: substitutes, grafts, 3D matrixes and 2D scaffolds. IBI believes that regenerative medicine and tissue engineering represent the future in healthcare. IBI has advanced competencies and core skills in processing materials for biomedical applications, which are used to develop proprietary technologies to build new and innovative products. IBI commits to safety and quality management: IBI Quality System is [ISO 13485:2016](#) certificated.

...DIFFERENT indications!



smartbone® ORTHO KEY FEATURES

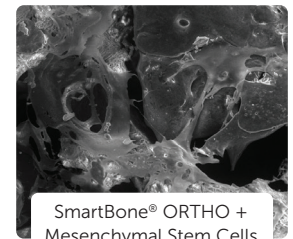
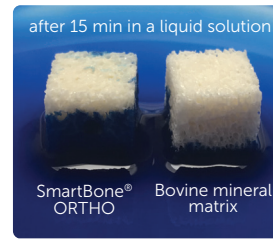
SmartBone® ORTHO is a new hybrid bioactive bone substitutes specifically developed for bone regeneration in reconstructive surgery. SmartBone® ORTHO is suitable for orthopaedic indications such as, traumatology, oncology and spine surgery. SmartBone® ORTHO is produced by combining a bovine mineral bone matrix with resorbable polymers and collagen fragments. This new concept of composite biomaterial promotes a quick growth of the patient's cells into SmartBone® ORTHO while the biopolymers degrade, providing perfect integration and osteogenesis, allowing a final complete remodelling.



BIODEGRADABLE POLYMERS



COLLAGEN FRAGMENTS

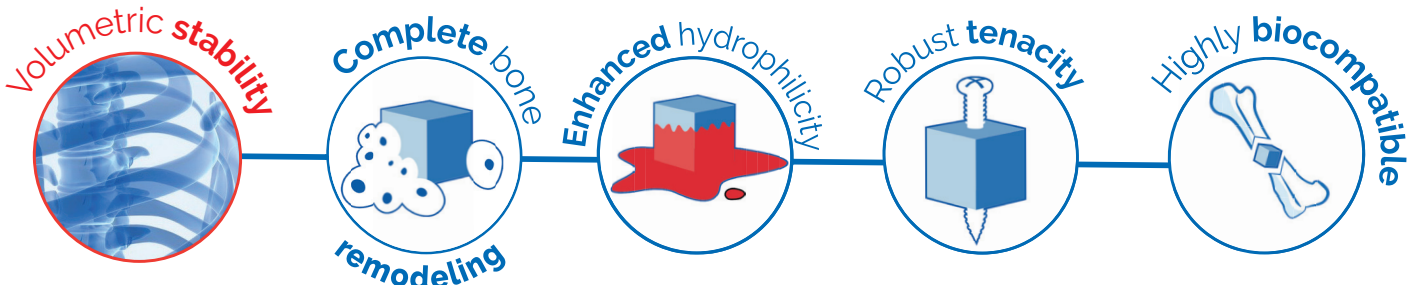


give SmartBone® ORTHO:

- high loading resistance;
- high volumetric stability (>95%), as the polymers protect the bone from early resorption;
- high tenacity to screws fixation.

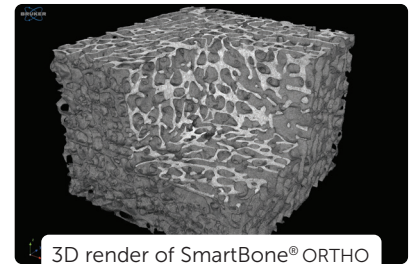
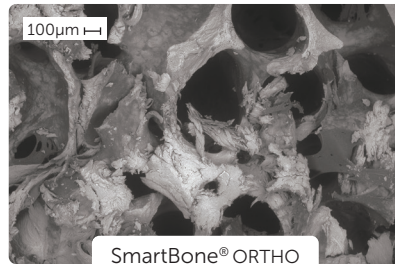
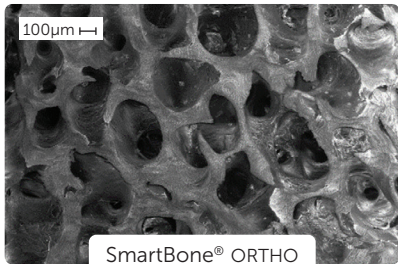
help SmartBone® ORTHO to:

- promote blood cells adhesion and colonization;
- guarantee a high hydrophilicity, thus enhancing the chemical cascade of signals that promotes the overall osteogenic process.



OPEN AND INTERCONNECTED POROSITY

The microstructure of SmartBone® ORTHO's composite matrix strongly resembles the human bone in terms of open, interconnected and mid-sized porosity.



SmartBone® ORTHO is completely resorbed and replaced by the patient's own bone within 1-2 years: this excellent outcome grants a vital, functional bone-implant integration. SmartBone® ORTHO is extremely biocompatible and is fully compliant with ISO 10993-1 requirements.

FROM GRANULES TO BLOCKS AND SPECIAL SHAPES



ADVANTAGES OF SMARTBONE® ORTHO:

- Easy dust free shaping with any type of surgical tool (for example: bone cutter, drill);
- Resistant to heavy loads and to heavy surgical maneuvering;
- Far better stability of the augmented bone graft vs the loose granules;
- Bigger defects do not need autologous bone, thus reducing patient morbidity;
- No resorption: the polymeric coating protects the graft during initial healing/osteointegration period;
- Readily absorbs blood.

PERFECT FOR:

- Filling of bone defects of the skeletal system of traumatic origin when:
 - the trabecular bone architecture is disrupted by impactation forces;
 - when there is a need to implement the bone mass during osteosynthesis;
 - during revision surgeries (delayed unions and non-unions);
 - as a filler at donor sites after harvest of autologous bone;
 - skull bones reconstruction.
- Filling bone defects in elective orthopaedic surgery, in reconstructive applications:
 - during arthroplasty and revision arthroplasty to fill or reconstruct the acetabular bone or for replenishment of the femur in impactation allografting;
 - after wedge or pelvic osteotomies.
- In spine surgery: for vertebral arthrodesis, fusion and vertebral body substitution.
- Filling of bone defects of the skeletal system of oncologic origin:
 - after curettage of benign bone tumors and tumor-like lesions for structural scaffolding of curetted lesions;
 - for reconstruction after geometric osteotomies for benign aggressive tumor resections;
 - for en bloc customized bone reconstructions in malignant tumor resection;
 - skull bones reconstruction after resections.

SMARTBONE® ORTHO MECHANICAL PROPERTIES

Full characterization from a torsional, flexural and compression point of view, have been run on SmartBone® ORTHO showing excellent mechanical response under each of these tests. Results are reported in the following Table.

| Test | Max Stress (MPa) | Max Strain (-) | Elastic Modulus (GPa) |
|-------------|------------------|----------------|-----------------------|
| Compression | 25.8 + 7.9 | 0.024 + 0.005 | 1.2456 + 0.2259 |
| Bending | 23.8 + 4.2 | 0.0765 + 0.009 | 0.3406 + 0.063 |
| Torsion | 25.5 + 4.4 | 0.058 + 0.009 | 0.4906 + 0.1037 |

HIGH MECHANICAL PERFORMANCES

SmartBone® ORTHO bears 3 times the competitor’s maximum load and is 4 times more rigid.

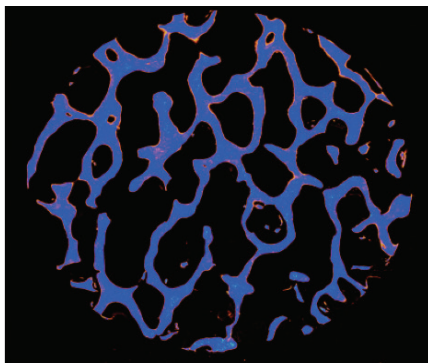
HIGH HYDROPHILICITY

Thanks to its microcomposition, SmartBone® ORTHO quickly reaches an average 38% w/w blood swelling, thereby allowing a robust osteointegration.

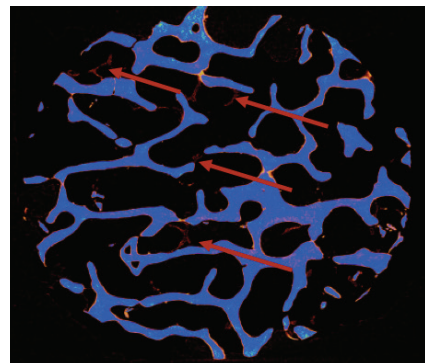
HIGH TISSUE INTEGRATION

SmartBone® ORTHO’s microstructure and composition favour cell colonization. Images collected evidenced the presence of wide and well-structured cell formations inside SmartBone® ORTHO.

IN VITRO CELLULAR CHARACTERIZATION OF SMARTBONE® ORTHO REMODELING MECHANISM



SmartBone®



Stromal Vascular Fraction (SVF)

A reliable in vitro model reproducing the first 60 days post-grafting by using SVF has been developed.

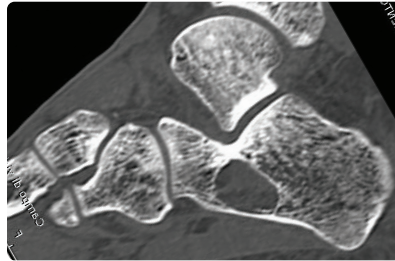
These data proved the dynamics of bone remodeling supported by SmartBone® ORTHO during the very early phase post-surgical grafting. Furthermore, these results strongly support an innovative idea for the use of SVF or other viable adipose tissue extract and SmartBone® ORTHO to promote tissue regeneration and repair, also thanks to an easier cell management preparation that allows a potentially larger use in clinical applications.

CLINICAL CASES

Removal of a calcaneus cist.



SmartBone[®] ORTHO Granules and Block.



CT Scan of the initial situation.



0 Months:
Post operative X-Ray.



5 Months:
Good bone regeneration.



5 1/2 Months:
Good bone regeneration.



6 Months:
Excellent clinical condition good bone remodelling.

Courtesy of Dott. M. Spezia

A decomposed multifragmentary fracture of the distal diaphysis region of the fibula and a decomposed multifragmentary joint fracture of the distal diaphyse-epiphyseal region of the tibia.



SmartBone[®] ORTHO Granules and Block



Rx of the initial situation: fibula and tibial fractures.



1 1/2 Months
Follow-up post-operative with metal and fixation device.



2 1/2 Months
The fixation was removed and presents calcific bone callus signs.



3 1/2 Months:
Callus on the lateral tibial side on the peripheral side is observed.



5 Months:
Increment of the calcified bone callus at the level of the fracture sites.

Courtesy of Prof. Dott. R. Ferracini

Plurifragmentary fracture of the radial epiphysis and detachment of the ulnar styloid.



CT Scan of the multifragmentary radial distal epiphysis fracture.



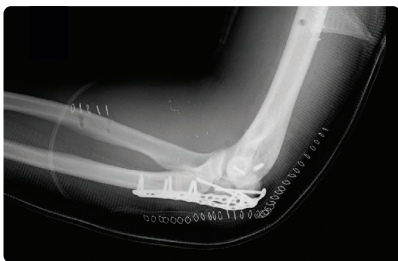
1 Month:
Follow-up after cast removal.



3 Months:
Evidences of callus formation, good bone remodelling.

Courtesy of Dott. B. Battiston

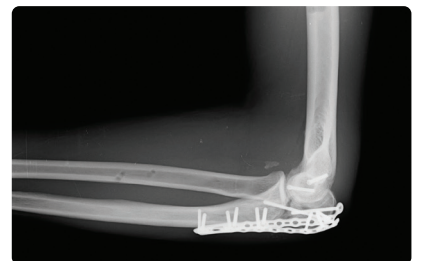
Olecranon multifragmented fracture.



0 Months:
Follow-up immediately after op with fixation device (plates, screws, figure of 8 cerclage wire with pins).



1 Month:
Follow-up of multiple fracture of the olecranon and humeri capitulum fracture synthesized.



2 Months:
Regular evolution of the fracture site reported good bone regeneration.

Courtesy of Dott. A. Bistolfi

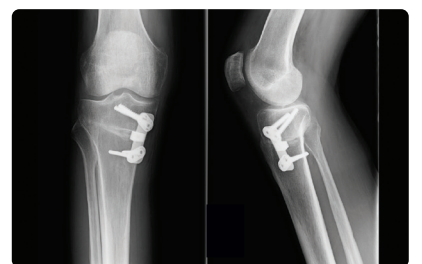
Corrective tibial osteotomy opening.



0 Months:
Post operative X-Ray tibial osteotomy



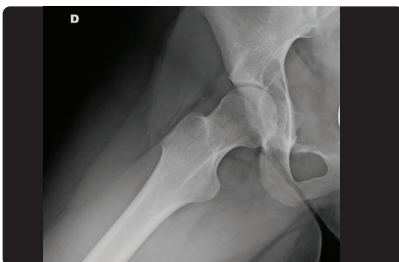
1 Month:
Follow-up of the corrective osteotomy.



4 Months:
Good bone regeneration.

Courtesy of Prof. Dott. R. Ferracini

Aneurysmal bone cysts without osteosynthesis devices.



Pre-op situation with ABC in posterior acetabular and iliac right region.



1 Year:
Evidencing good integration and ongoing bone remodelling.



2 Years:
Good bone regeneration.

Courtesy of Dott. R. Piana

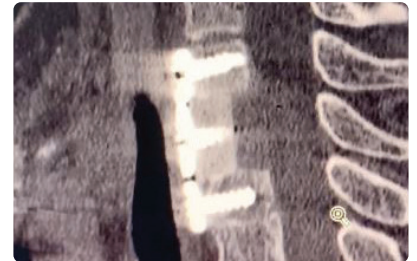
Vertebrectomy for osteoblastoma T2.



SmartBone® ORTHO Block.



CT Scan of the initial situation:
osteoblastoma T2.



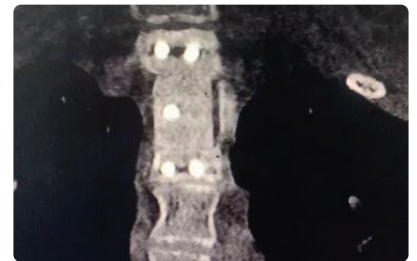
0 Months:
Post operative X-Ray after bone replacement with fixation devices.



6 Months:
Good osteointegration.



1 Year:
Good integration of Block in the vertebrectomy.



1 Year:
Evidencing good integration and ongoing bone remodelling.

Courtesy of Dott. A. Gasbarrini

Emi-vertebrectomy for osteoblastoma L4.



SmartBone® ORTHO Block.



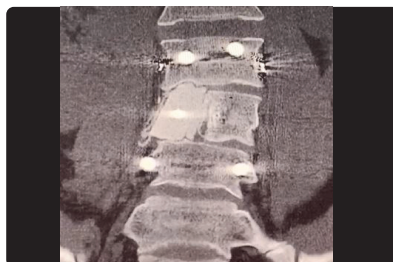
CT Scan of the initial situation:
osteoblastoma L4



0 Months:
Post operative X-Ray with a fixation devices.



1 Month:
Good osteointegration.



8 Months:
Good integration of Block in the partial vertebrectomy.



8 Months:
Evidencing good integration and ongoing bone remodelling.

Courtesy of Dott. A. Gasbarrini



smartbone[®] on demand[™]

CUSTOM MADE GRAFTS FOR RECONSTRUCTIVE SURGERY ARE ONLY FOUR STEPS AWAY

1

Diagnosis prescription

The surgeon sends the patient's CT Scan in *.dicom* format with a brief clinical description.

2

Digital planning

IBI designs the graft in accordance with the surgeon's clinical prescriptions.

3

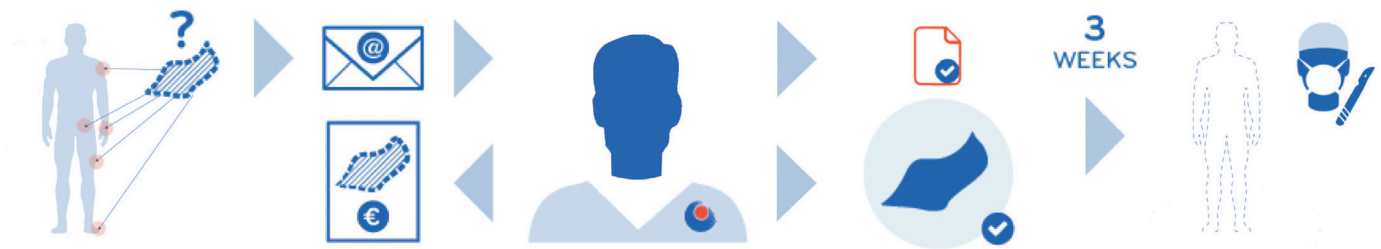
Custom made bone graft

IBI produces the custom made graft in the *.stl* format file.

4

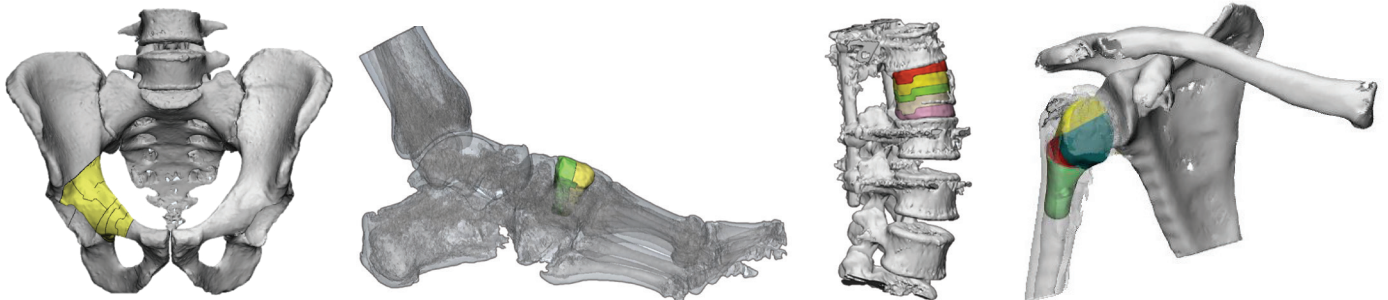
Surgery

3 weeks later you the graft is shipped ready for the surgical operation. No sterilization or extra shaping required.



SMARTBONE[®] ON DEMAND[™]

- is a custom-made bone graft specifically designed on the patient's defect;
- ensures a perfect contact between the graft and the recipient site for improved integration;
- ensures a precise creation of the desired shape;
- helps you to resolve complex situations;
- reduces surgery time;
- reduces patient's risks;
- helps you to reduce surgical costs;
- helps your success.





CATALOGUE

Our most used shapes are available in the following sizes (for other shapes please check our product catalogue as they are available only on request):

smartbone[®] Block
ORTHO

| ITEM | SIZE | Q.TY |
|-----------|-------------|------|
| SBO101010 | 10x10x10 mm | 1 |
| SBO101020 | 10x10x20 mm | 1 |
| SBO102020 | 10x20x20 mm | 1 |
| SBO141208 | 14x12x8 mm | 1 |
| SBO141224 | 14x12x24 mm | 1 |
| SBO153020 | 15x30x20 mm | 1 |
| SBO153060 | 15x30x60 mm | 1 |



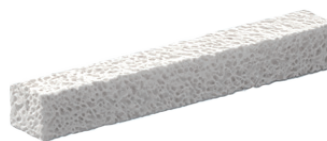
smartbone[®] Wedge
ORTHO

| ITEM | SIZE | Q.TY |
|-----------|-------------|------|
| SBO352510 | 35x25x10 mm | 1 |
| SBO402514 | 40x25x14 mm | 1 |



smartbone[®] Rod
ORTHO

| ITEM | SIZE | Q.TY |
|-----------|-----------|------|
| SBO350403 | 35x4x3 mm | 1 |



smartbone[®] Granules
ORTHO

| ITEM | SIZE | Q.TY |
|-----------|--------|-------|
| SBOG20405 | 2-4 mm | 5 cc |
| SBOG20410 | 2-4 mm | 10 cc |
| SBOG20420 | 2-4 mm | 20 cc |
| SBOG20430 | 2-4 mm | 30 cc |

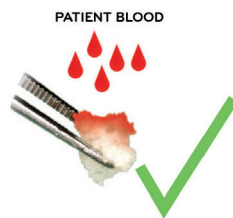


FAQs

- What is SmartBone® ORTHO made of?**
 It's a composite material, made of a bovine derived mineral matrix, reinforced with biopolymers and proteins (collagen fragments of porcine origin).
- What's the biological mechanism of osteointegration of a bone graft?**
 SmartBone® ORTHO as any other bone substitute for that matter, works as a template for bone ingrowth, where the scaffolds of the exogenous bone guide the newly produced bone. As native bone grows, it will generally replace the graft material completely, resulting in a fully integrated region of new bone. The biological mechanisms that provide a rationale for bone grafting with composite grafts and xenografts are osteoconduction (guiding the reparative growth of the natural bone) and osteoinduction (encouraging undifferentiated cells to become active osteoblasts). Only few bone grafts ensure a complete remodeling, SmartBone® ORTHO is among these, together with autografts.
- What are the top mechanical performances of SmartBone® ORTHO?**
 Breaking Stress of about 26MPa (av.)
 Elastic Modulus of about 1,2GPa (av.)
 Breaking torque under screw fixation (screw tenacity) >55Ncm (av.)
- Is SmartBone® ORTHO an open-porous material?**
 Yes! SmartBone® ORTHO has an open interconnected porous structure (see page 4 for further information).
- How is SmartBone® ORTHO 's microstructure?**
 SmartBone® microstructure was specifically designed to mimic natural healthy human bone, in terms of composition and porosity.
- Which is the expected (average) time of resorption of the biopolymers present within SmartBone® ORTHO?**
 They are degraded and resorbed in about 4-6 months: while they degrade and get resorbed, novel bone is formed.
- Is SmartBone® ORTHO hydrophilic?**
 Yes! Due to its composition SmartBone® ORTHO is extremely hydrophilic and can sustain a 38% w/w (av.) swelling in physiologic fluids. This features allow the graft to quickly and massively absorb blood once *in situ*, hence sparking a better and faster integration with the host tissue.
- Which biopolymers are used?**
 We use biodegradable polymers, namely aliphatic polyesters, the same used e.g. in resorbable sutures.
- Where does the bovine derived mineral matrix of SmartBone® ORTHO come from?**
 We supply our production with bovine derived tissues directly from fully certified companies in New Zealand, a "BSE negligible risk Country" (formerly known as "BSE free Country"). We control all our supply chain, according to the most strict norms and highest quality standards, according to the EU Regulation 722/2012 and ISO 22442.
- How is SmartBone® ORTHO produced?**
 IBI applies a proprietary process to produce SmartBone® ORTHO.
- Can the biomaterial be mixed with a saline solution?**
 No. Do not mix SmartBone® ORTHO with any saline solution or saline based preparations or any other salty liquid.
- Once the vial or envelope has been opened, can I close it again, re-sterilise it and, if necessary, within what period of time should I use it?**
 No, once the primary packaging has been opened (in sterile surgical environment), the material must be used immediately on a single patient. The surplus material must be disposed of according to IFU. SMARTBONE® ORTHO IS SINGLE USE.
- Why is SmartBone® ORTHO single use?**
 SmartBone® is provided, in its intact packaging, as a sterile medical device; once opened, it must be used immediately. Storage after opening does NOT ensure safety! SmartBone® is, hence, single use.
- Can I keep the material in the fridge?**
 The material must be stored according to the instructions on the labels, therefore away from light or heat sources, in a dry place and between +2 and +25 °C.



AVOID THE USE OF SALINE SOLUTION



PREFER THE USE OF PATIENT BLOOD



DON'T REUSE



FOR SINGLE USE ONLY

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smartbone® ORTHO



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CAUTION: The law restricts the sales of these devices made by, or on the order of, a surgeon.

Warning: Possible complications that can occur in any surgery might include: swelling of the operative site, intrarticular mobilization, local inflammation, bone loss, infection, pain, lack or incomplete osteointegration, partial or complete graft resorption and/or loss of mechanical performances of graft.