ibi

smartbone®
ORTHO in *SPINAL*

swiss made

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 is a **CE 2797** marked Class III Medical Device

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.

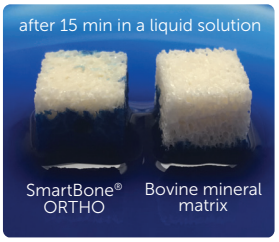
smartbone®

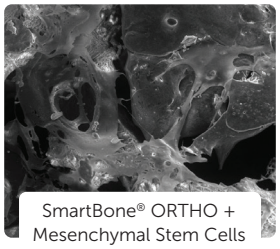
BOVINE BONE MATRIX + **BIODEGRADABLE POLYMERS** + **COLLAGEN FRAGMENTS**

BIODEGRADABLE POLYMERS

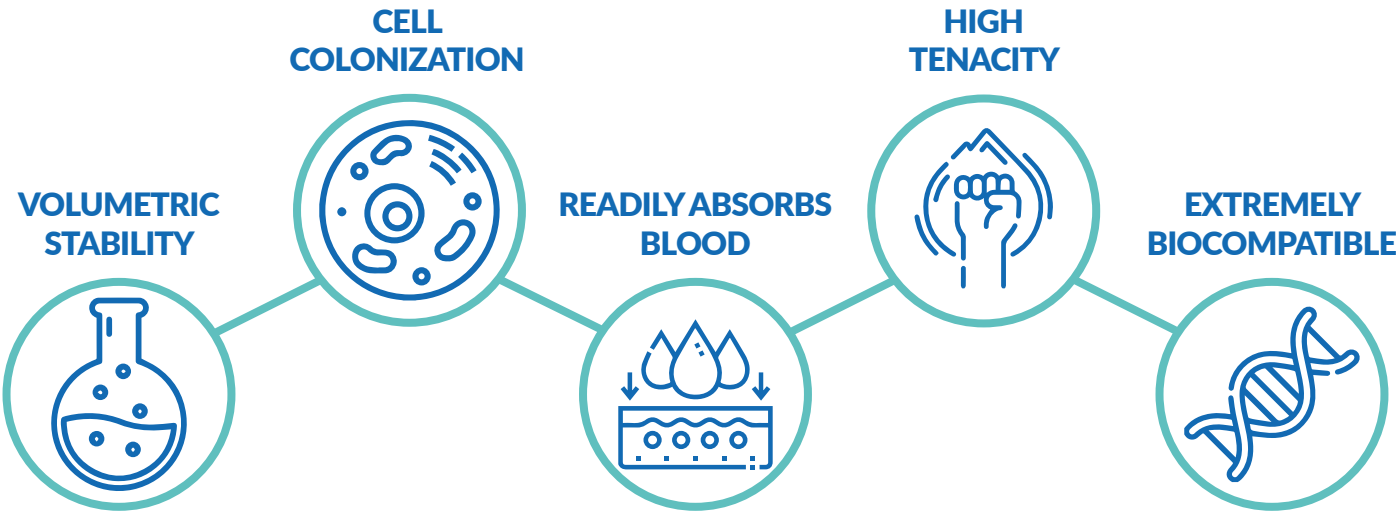
- high loading resistance;
- high volumetric stability (>95%), as the polymers protect the bone from early resorption;
- high tenacity to screws fixation.

COLLAGEN FRAGMENTS





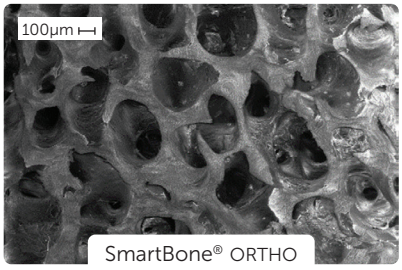
- promote blood cells adhesion and colonization;
- guarantee a high hydrophilicity, thus enhancing the chemical cascade of signals that promotes the overall osteogenic process.



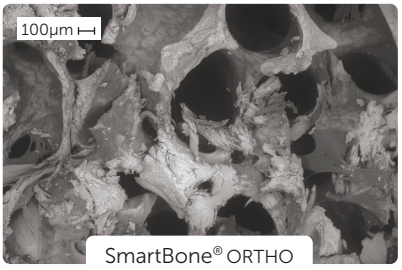
STRUCTURE AND SHAPES

OPEN AND INTERCONNECTED POROSITY

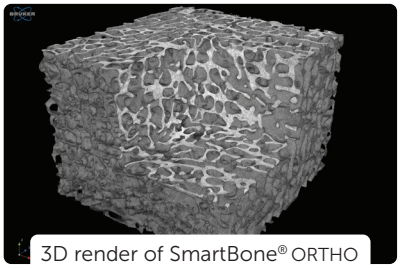
The microstructure of SmartBone® ORTHO's composite matrix strongly resembles the human bone in terms of open, interconnected and mid-sized porosity.



SmartBone® ORTHO



SmartBone® ORTHO


3D render of SmartBone® ORTHO

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:

- Lower arm and wrist- traumatic injuries;
- Iliac crest reconstructions;
- Femur and tibial osteotomies;
- Tibial plateau reconstructions;
- Ankle and foot reconstructions;
- Spinal reconstructions;
- Small segments reconstructions;
- Long bones *en bloc* reconstructions;
- Joint proximal bone reconstructions.

TESTS

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.

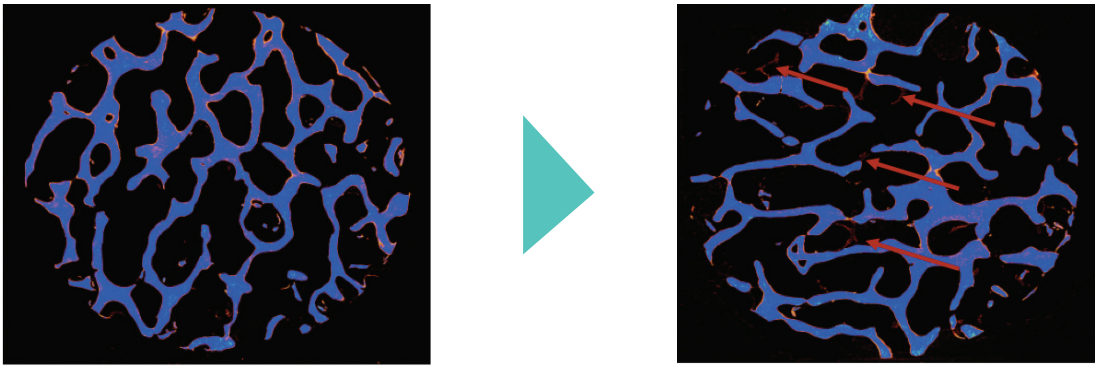
HIGH HYDROPHILICITY

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 microstructure and composition favour cell colonization. Images collected evidenced the presence of wideand 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

CASE 1: OSTEOBLASTOMA L4

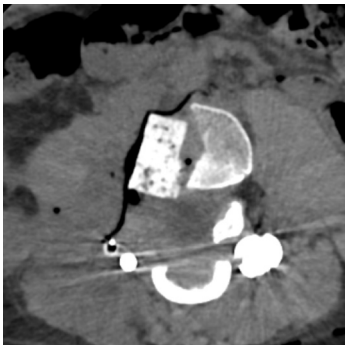
Patient: Male, 20 Years

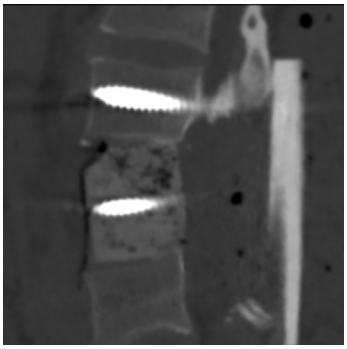
Diagnosis: Osteoblastoma L4

INITIAL CONDITION

CT Scan of the initial situation: osteoblastoma L4.

POST-OP



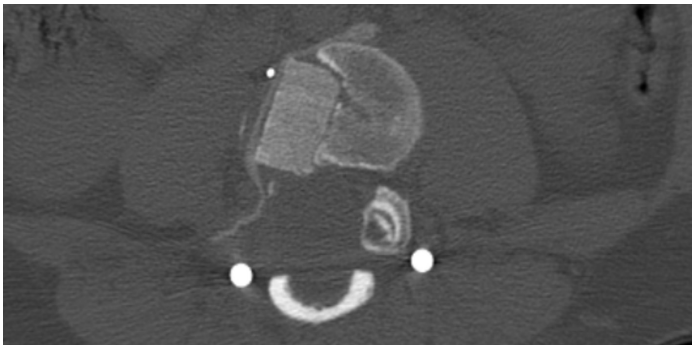


Post operative X-Ray after bone replacement with SmartBone Ortho and fixation devices.

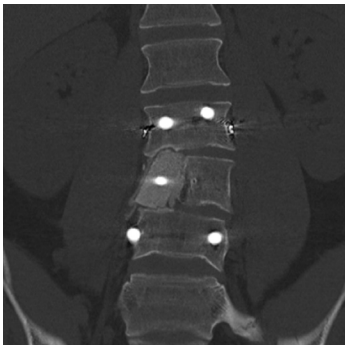
FOLLOW UP

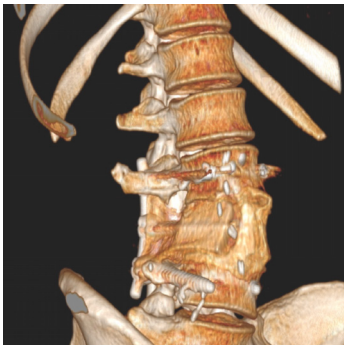
Follow up 1 month

Follow up 8 months



Follow up 14 months





Follow up 23 months

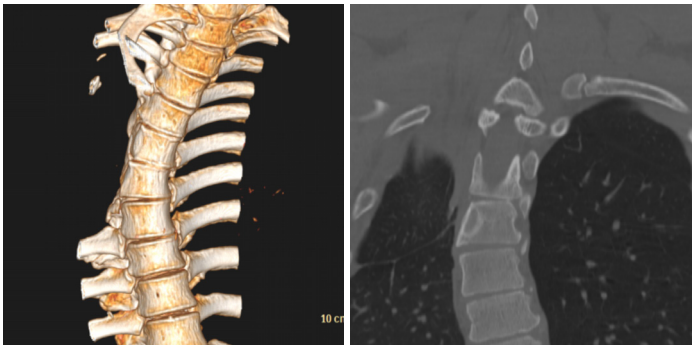
Courtesy of Dr A. Gasbarrini

CASE 1: GIANT CELL TUMOR T6

Patient: Male, 30 Years

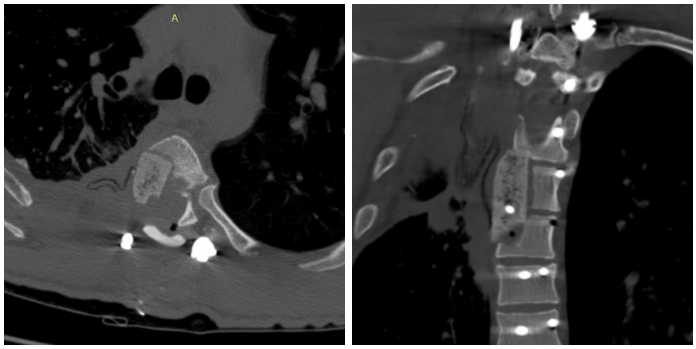
Diagnosis: Giant cell tumour T6

INITIAL CONDITION



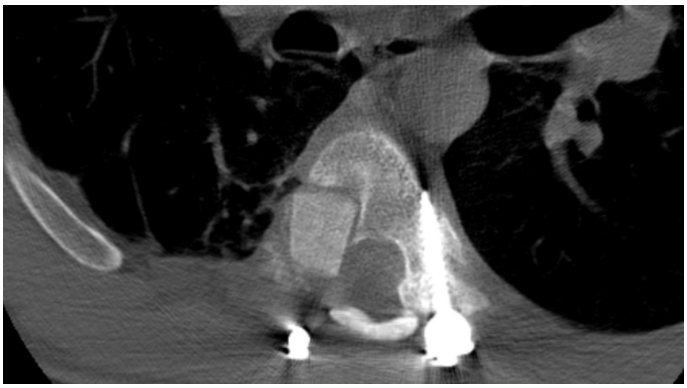
Initial situation: CT Scan and 3D reconstruction

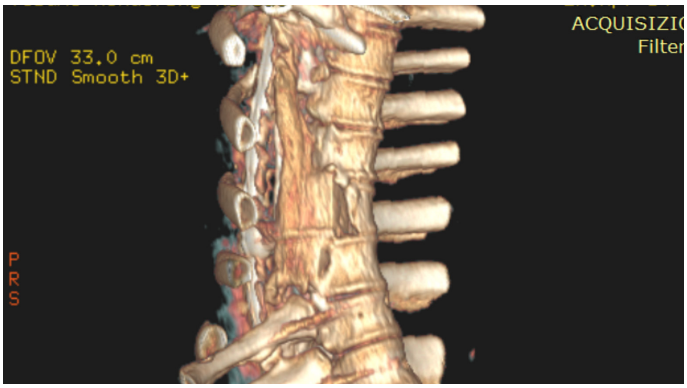
POST-OP



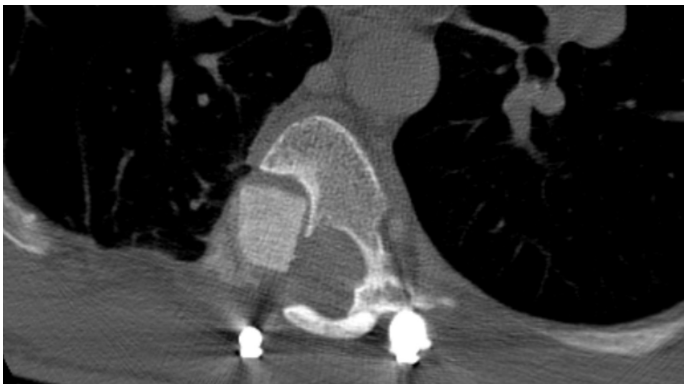
Post operative X-Ray after bone replacement with SmartBone Ortho and fixation devices.

FOLLOW UP





Follow up 9 months



Follow up 21 months

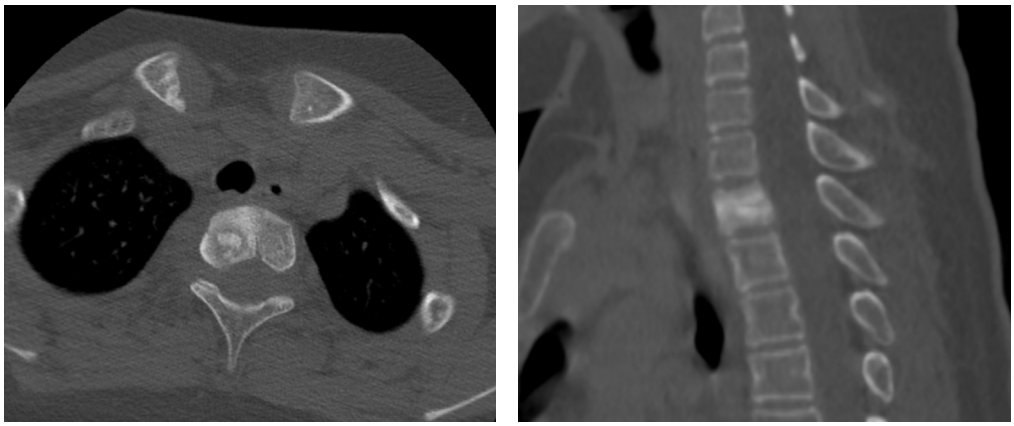
Courtesy of Dr A. Gasbarrini

CASE 3: VERTEBRECTOMY FOR OSTEOBLASTOMA T2

Patient: Male, 18 Years

Diagnosis: Vertebrectomy for osteoblastoma T2

INITIAL CONDITION

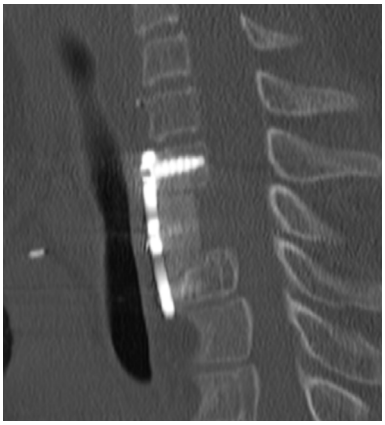


CT Scan of the initial situation: osteoblastoma T2.

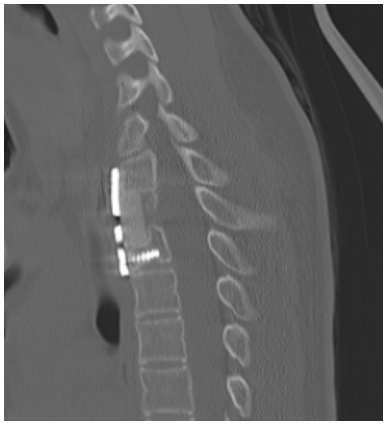
FOLLOW UP

Follow up 13 months

Follow up 19 months



Follow up 25 months

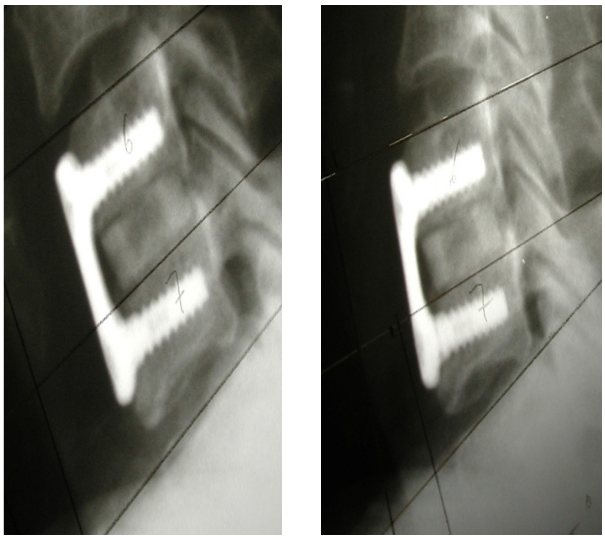


Follow up 32 months

Courtesy of Dr A. Gasbarrini

DISCECTOMY, XENOTRANSPLANT FUSION, PLATE FIXATION:

Cervical disc herniation C4-C5, follow up 12 months



Courtesy of Resorba, Russia

LUMBAR INTERBODY FUSION:

SmartBone block positioned between two vertebrae in percutaneous surgery

Courtesy of Dr M. Ceccarelli

smartbone®on demand™

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.

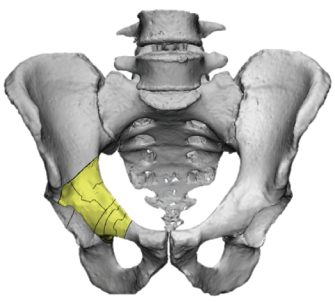
3 Custom made bone graft

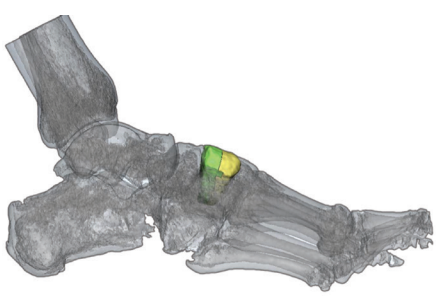
IBI produces the custom made graft in the *.stl* format file.

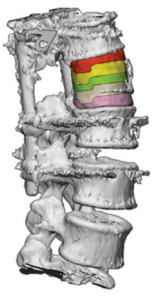
4 Surgery

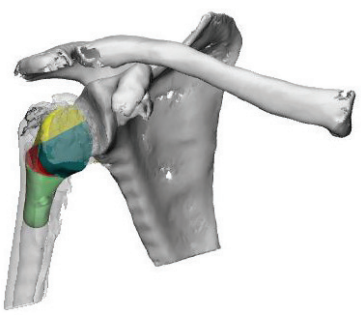
3 weeks later you the graft is shipped ready for the surgical operation. No sterilization or extra shaping required.

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

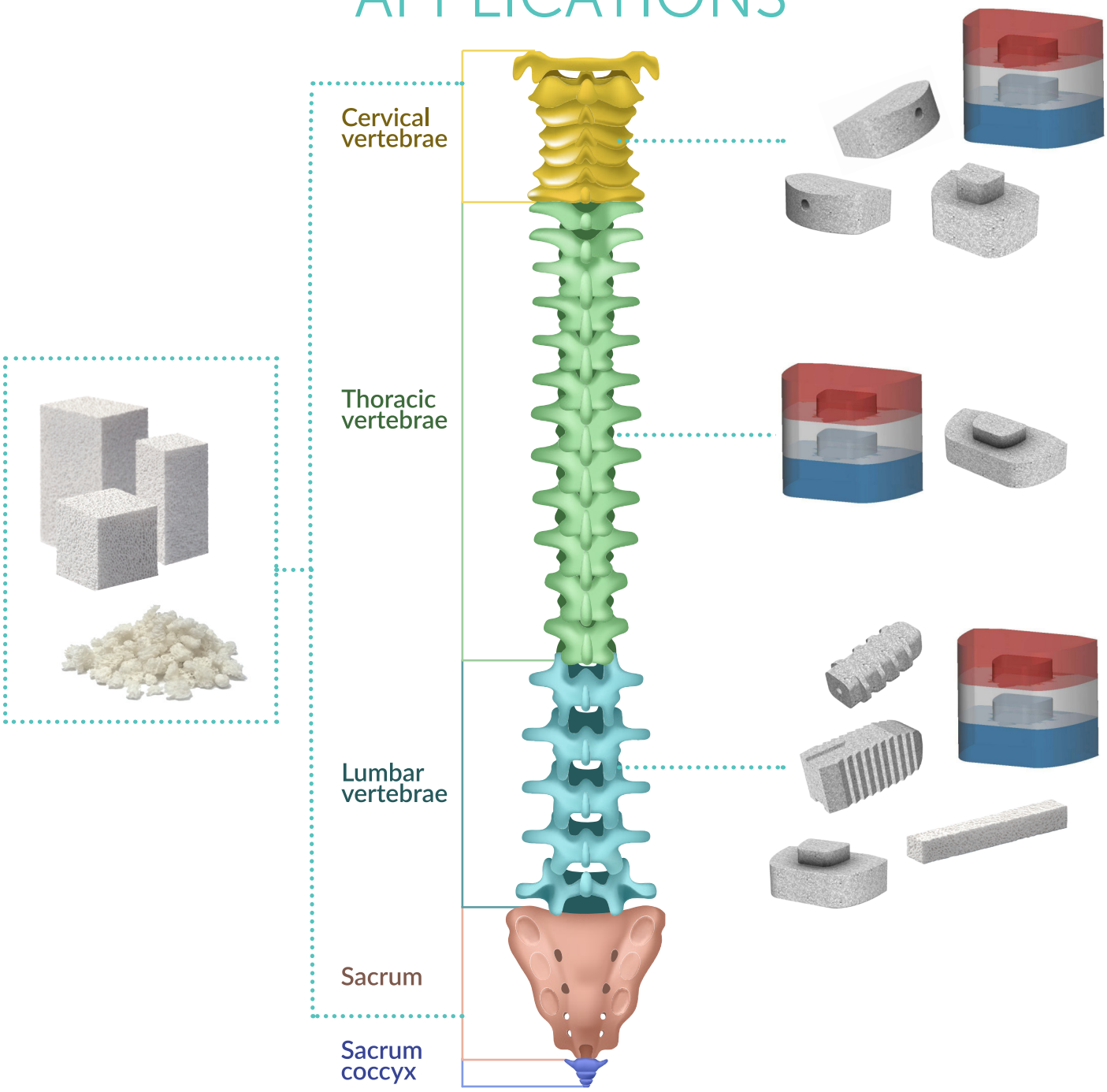








APPLICATIONS



SmartBone Spinal Instrument Surgical KIT

Designed to revolutionize interbody fusion procedures, this cutting-edge kit is set to transform the way spinal cages are inserted, delivering unparalleled precision and patient outcomes.

Key Features of the SmartBone Spinal Instrument Surgical Kit:

Unmatched Precision:
The SmartBone Surgical Kit is engineered to provide surgeons with precise control during interbody fusion surgeries. The instruments' ergonomic design ensures effortless handling and optimal maneuverability, leading to accurate cage placement.

Innovative SmartBone Technology:
Embrace the power of SmartBone, our pioneering bone substitute material. Crafted to mimic the mechanical properties of natural bone, SmartBone encourages rapid integration with the patient's spine, fostering a stable and long-lasting fusion.

Enhanced Patient Recovery:
The fusion of SmartBone with the patient's bone provides exceptional stability and support, reducing the risk of complications and promoting faster patient recovery. Patients can look forward to a quicker return to their daily activities and improved quality of life.

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® ORTHO 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 sparkling 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.

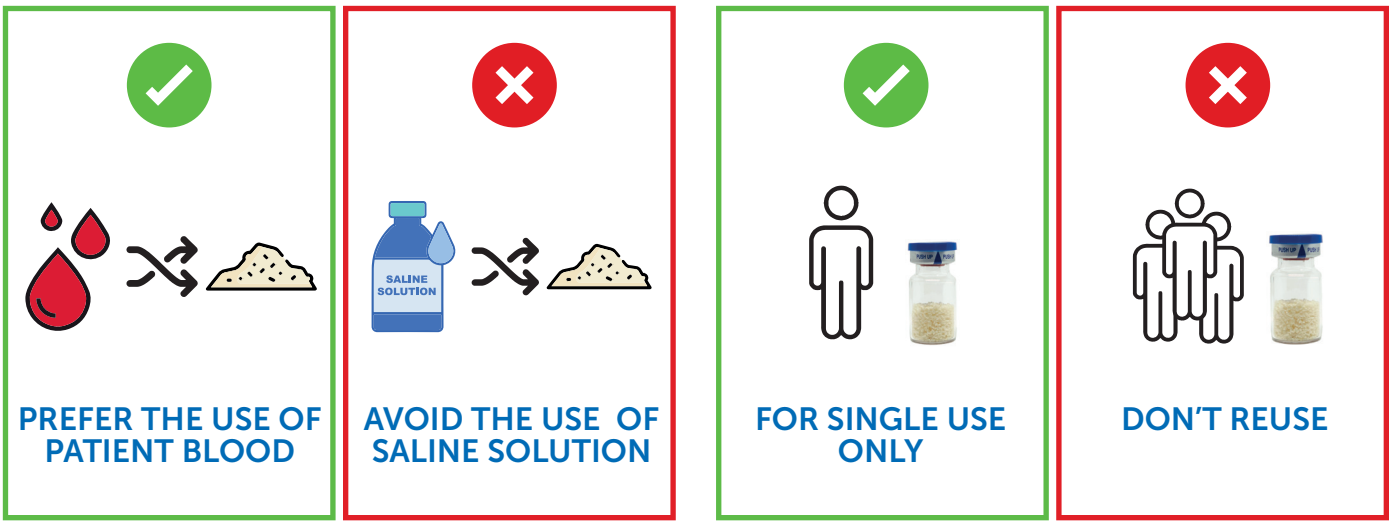
- **How is SmartBone® ORTHO produced?**
  IBI applies a proprietary process to produce SmartBone® ORTHO.

- **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 surgerical 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® ORTHO 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® ORTHO 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.



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smartbone®
ORTHO in *SPINAL*

Industrie Biomediche Insubri SA
Via Cantonale, 67
6805 Mezzovico-Vira
Switzerland

+41 91 93 06 640
www.ibi-sa.com
info@ibi-sa.com

bsi. UKAS MANAGEMENT SYSTEMS 0003 CE 2797

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.
This brochure is for healthcare professionals only, therefore the distribution to the general public is prohibited.

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