ibi

smartbone®

THE NEXT FRONTIER OF BONE REGENERATION

DENTAL

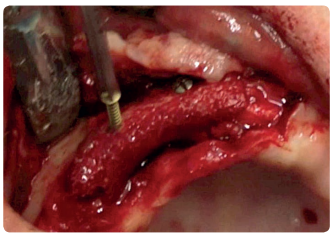
swiss made

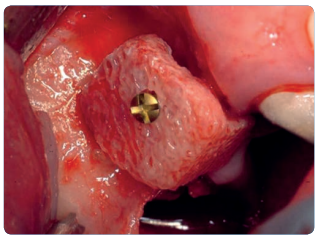
smartbone®

KEY FEATURES

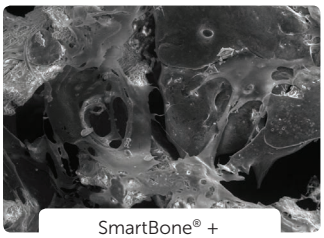
SmartBone® is a new hybrid bioactive bone substitute specifically developed for bone regeneration in reconstructive surgery. SmartBone® is produced by combining a bovine mineral bone matrix with bioactive resorbable polymers and collagen fragments. This new concept of composite biomaterial promotes a quick growth of the patient's cells into SmartBone® while its biopolymers degrade, providing perfect integration and osteogenesis.

BIODEGRADABLE POLYMERS





COLLAGEN FRAGMENTS



SmartBone® + Mesenchymal Stem Cells

Give SmartBone®:

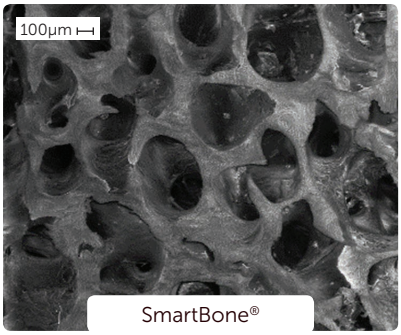
- high loading resistance
- high volumetric stability (>95%); the polymers protect the bone from early resorption
- high tenacity to screws fixation

Help SmartBone® to:

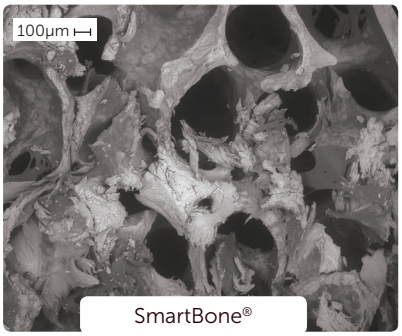
- promote blood cells adhesion and colonization
- guarantee a high hydrophilicity thus enhancing the chemical cascade of signals that promotes the osteogenic process

OPEN AND INTERCONNECTED POROSITY

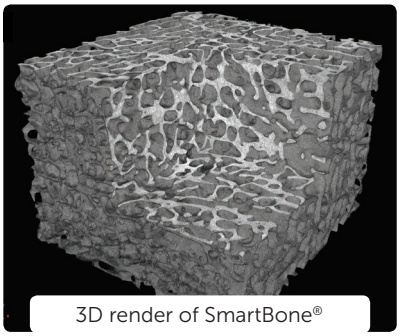
The microstructure of SmartBone®'s composite matrix strongly resembles the human bone in terms of open and mid-sized porosity.



SmartBone®



SmartBone®



3D render of SmartBone®

SmartBone® is a CE 2797 marked Class III Medical Device

smartbone®

SmartBone® 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® is extremely biocompatible and is fully compliant with ISO 10993-1 requirements.

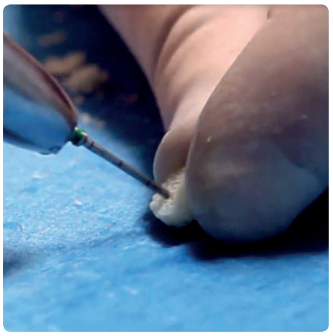
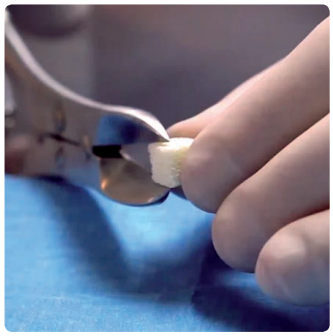
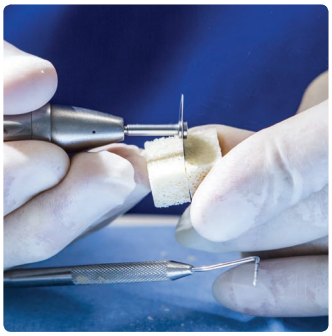
PERFECT FIT:

- Regeneration of periodontal bone defects
- Regeneration of extraction alveoli
- Regeneration of cavities between the alveolar wall and immediate implants
- Horizontal alveolar ridge augmentation
- Sinus lift floor elevation
- Alveolar ridge augmentation at implant sites with sufficient residual bone and a good blood supply

FROM CHIPS TO CUSTOM-MADE GRAFTS

ADVANTAGES OF SMARTBONE®:

- Easy dust free shaping with any type of surgical tool (for example: bone cutter, drill)
- Resistant to extreme 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 avoiding a second surgical site
- No resorption: the polymeric coating protects the graft during initial healing/osteointegration period
- Readily absorbs blood

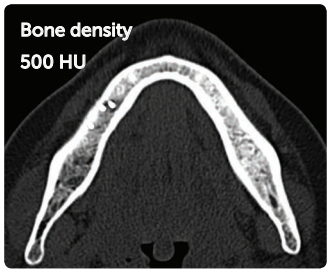




SmartBone® is a CE 2797 marked Class III Medical Device

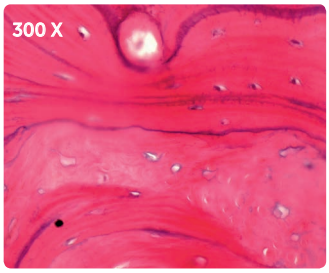
ibi smartbone®

SMARTBONE® PROMOTES OSTEOINTEGRATION AND VASCULARIZATION :

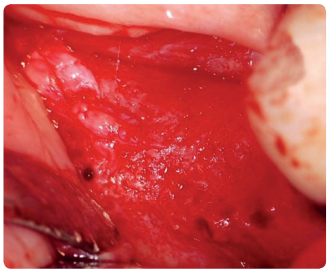
Initial situation



X-Rays after 4 Months



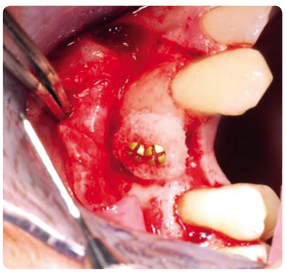
Histological analysis after 4 Months

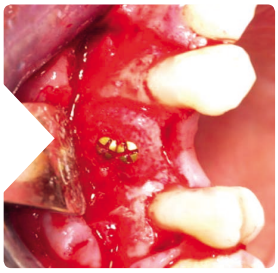


4 Months after surgery

HIGH MECHANICAL PERFORMANCES

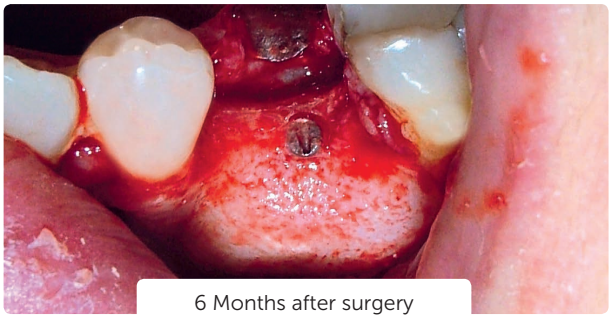
SmartBone® is characterized by an elastoplastic behaviour.
It bears 3 times the competitor's maximum load and is 4 times more rigid.





HIGH HYDROPHILICITY

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

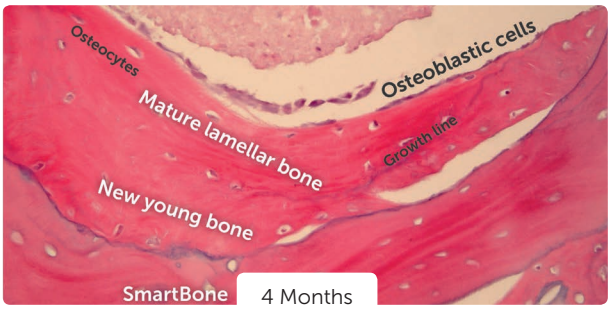


6 Months after surgery

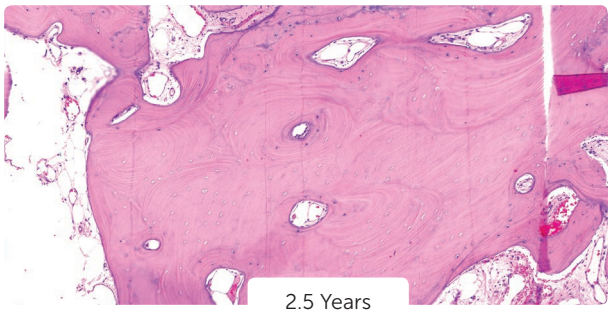
HIGH TISSUE INTEGRATION

SmartBone®'s microstructure and composition favour cell colonization.

Histological analysis evidenced the presence of wide and well-structured cell formations inside SmartBone®.



4 Months



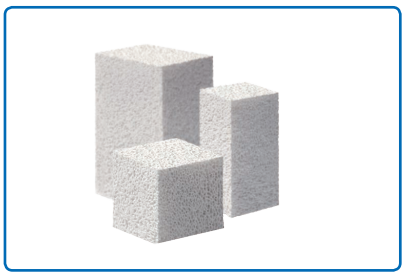
2.5 Years

SmartBone® is progressively replaced by new young bone: osteoblasts are visible both in the active and in the quiescent state, when, after having formed mature lamellar bone, they become osteocytes, as evidenced inside the lacunae. After 2.5 years the graft has been completely replaced and the osteogenesis has formed a lamellar bone with cement lines; there is evidence of a great amount of osteocytes inside the lacunae and of a good angiogenesis. SmartBone®, combined with the native bone, forms an osteoinductive system.

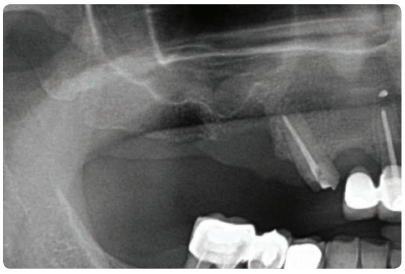
SmartBone® is a CE 2797 marked Class III Medical Device

CLINICAL CASES

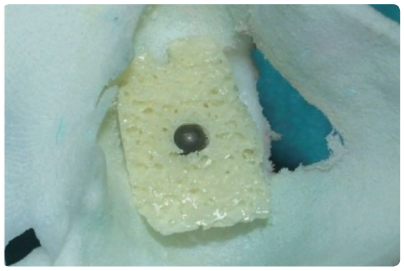
Sinus lift using SmartBone® Block



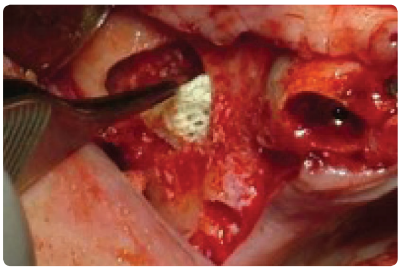
SmartBone® Block.



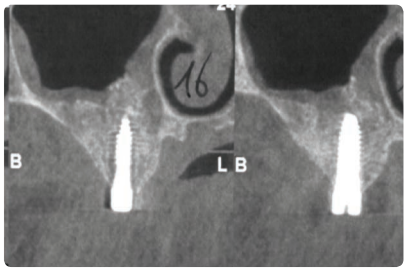
X-Rays of the initial condition.



SmartBone® Block shaped upon the stereolithographic model.



0 Months:
SmartBone® Block placement.



6 Months:
Good bone quality also around the implant and the entire bone volume was maintained.

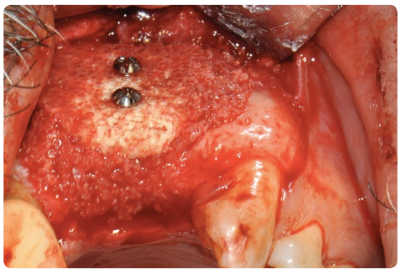
10 Months:
Final result.

Courtesy of Dr. F. Secondo

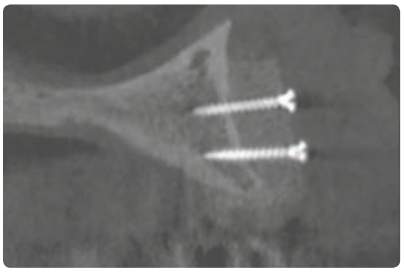
Bone loss due to traumatic event SmartBone® Plate 3x25x15 mm and 0,25 - 1 mm Microchips augmentation.

SmartBone® Plate.

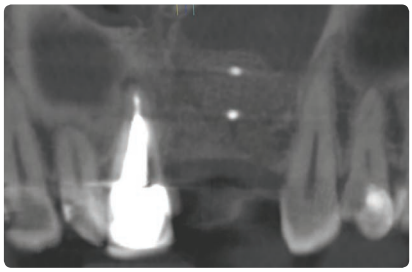
Initial condition.



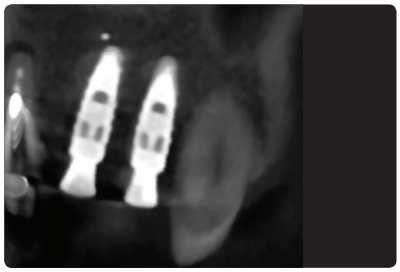
SmartBone® Plate fixed and covered by SmartBone® Microchips mixed with Concentrated Growth Factor (CGF).



0 Months:
X-Rays After Surgery.



6 Months:
Good healing.



10 Months:
Final result with implant placement.

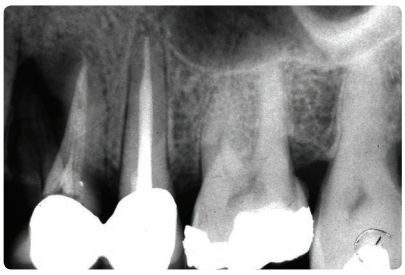
Courtesy of Dr. R. Ghiretti

SmartBone® is a CE 2797 marked Class III Medical Device

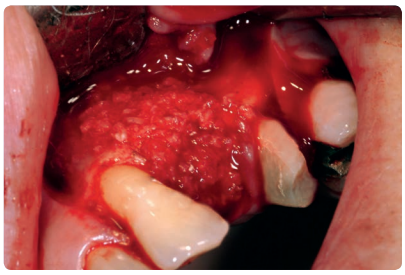
ibi smartbone®

Large bone loss due to fracture treated using SmartBone® Microchips (1-2 mm)

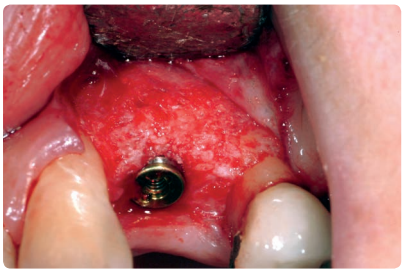
Smartbone® Microchips.



Patient's initial conditions.

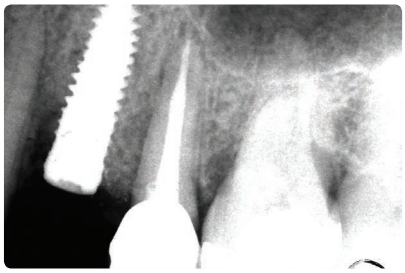


Filling of the defect with SmartBone® Microchips for bone augmentation and fast blood absorption.

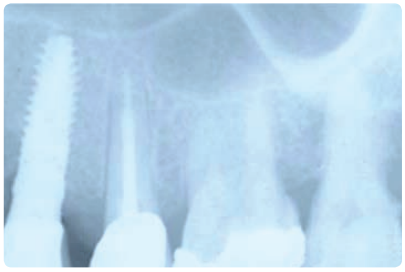


5 Months:
Good bone regeneration for implant placement.

Courtesy of Dr. G. Carusi



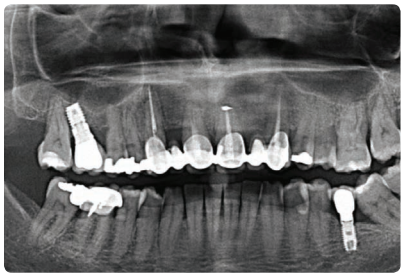
8 Months:
Good osteointegration around the implant.



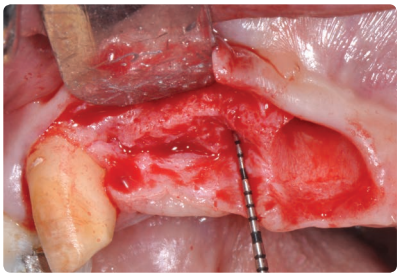
2 Years:
Perfect bone maturation and stable bone volume.

Horizontal bone augmentation with SmartBone® Microchips (1-2 mm)

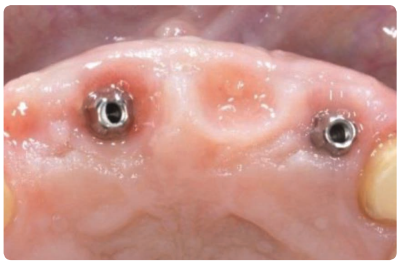
Smartbone® Microchips.



X Rays of the initial condition.



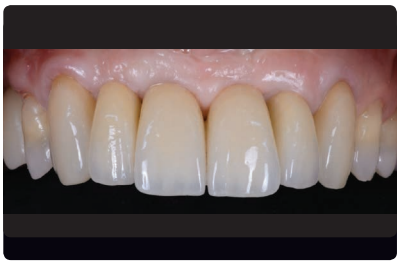
Bone defect.



3.5 Months:
Good keratinized tissue.

Courtesy of Dr. F. Mandelli

6 Months:
Successful bone augmentation in the pontic area.



6 Years:
Complete osteointegration of soft and hard-tissues.

SmartBone® is a CE 2797 marked Class III Medical Device

smartbone®

CATALOGUE

smartbone® Microchips

ITEM	SIZE	QUANTITY
SMG251025	0.25 - 1 mm	0.25 g
SMG251005	0.25 - 1 mm	0.5 g
SMG251010	0.25 - 1 mm	1 g
SMG251020	0.25 - 1 mm	2 g
SMG102005	1 - 2 mm	0.5 g
SMG102010	1 - 2 mm	1 g
SMG102020	1 - 2 mm	2 g

smartbone® Block

ITEM	SIZE	QUANTITY
SMB011005	7 x 7 x 7 mm	1
SMB011010	10 x 10 x 10 mm	1
SMB011020	10 x 10 x 20 mm	1
SMB011030	10 x 20 x 20 mm	1
SMB011110	14 x 12 x 6 mm	1
SMB011130	14 x 12 x 8 mm	1
SMB011160	14 x 12 x 12 mm	1
SMB011310	16 x 14 x 6 mm	1
SMB011330	16 x 14 x 8 mm	1

smartbone® Plate

ITEM	SIZE	QUANTITY
SMP013010	3 x 25 x 15 mm	1
SMP013040	4 x 10 x 10 mm	1

SmartBone® is a CE 2797 marked Class III Medical Device

ibi smartbone®on demand™

CUSTOM MADE GRAFTS FOR RECONSTRUCTIVE SURGERY ARE ONLY FOUR STEPS AWAY

1

Diagnosis prescription

The doctor 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 doctor's clinical prescriptions

3

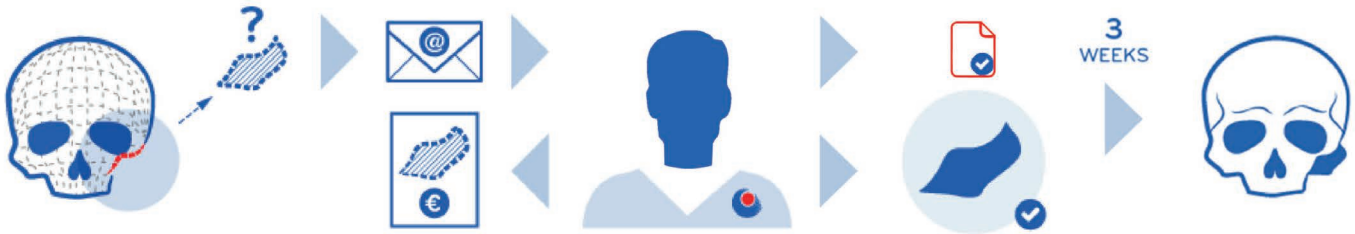
Custom made bone graft

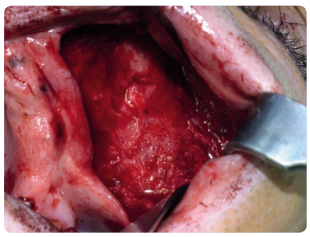
IBI produces the custom made graft based on the .stl file

4

Surgery

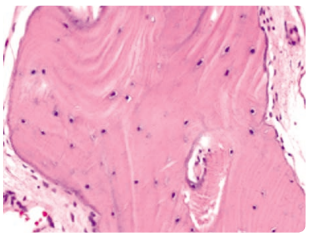
3 weeks later you will receive your graft ready for the surgical operation. No sterilization or extra shaping required





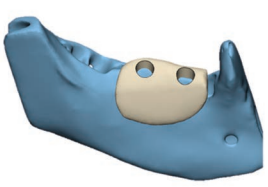
2.5 YEARS AFTER SURGERY

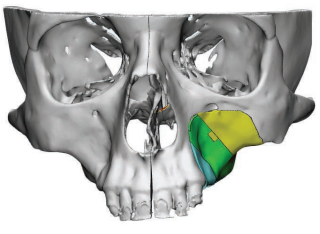
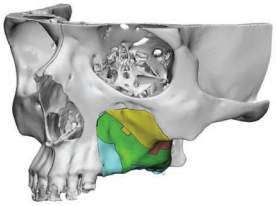
The graft has been completely replaced and a mature lamellar bone has formed



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 improving 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
- guarantees your success



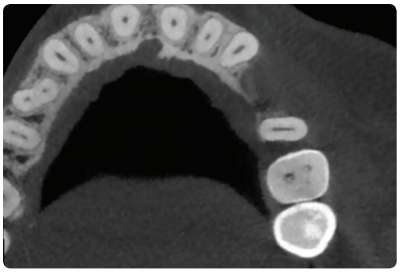



SmartBone® is a CE 2797 marked Class III Medical Device

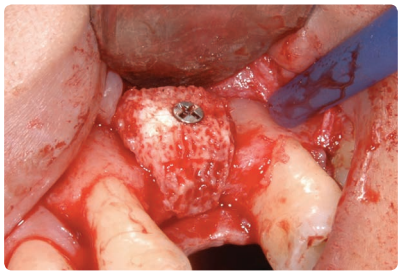
ibi smartbone®on demand™

CLINICAL CASES

Severe resorption, horizontal/vertical augmentation with SmartBone® On Demand™.

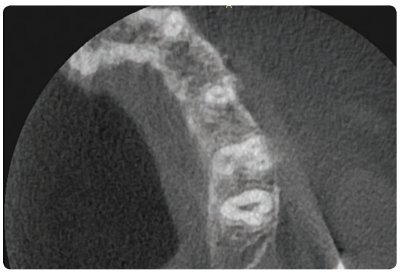


Cone Beam Computed Tomography (CBCT) of the initial condition.

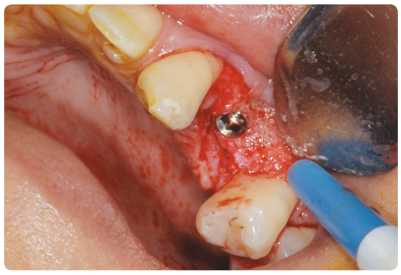


Perfect fitting of the custom graft during fixation.

Sutures.



8 Months:
CBCT section.



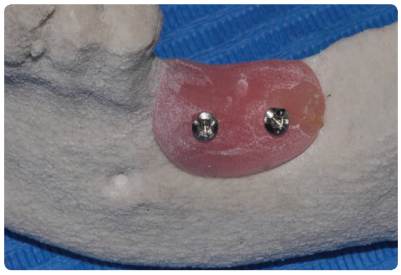
8 Months:
Implant placement.

1 Year:
Final restoration.

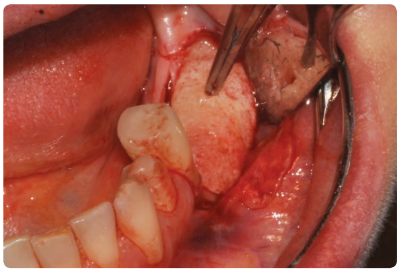
Courtesy of Dr. J. L. Latorre Valenzuela

Horizontal and vertical augmentation with SmartBone® On Demand™

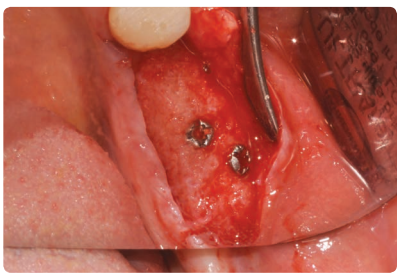
Clinical situation before surgery.



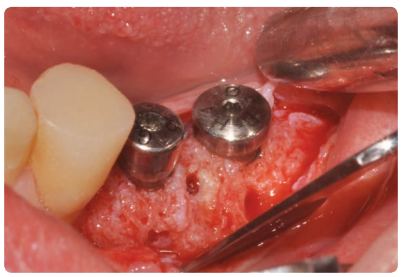
Acrylic resin graft shaped on stereolytgraphic model.



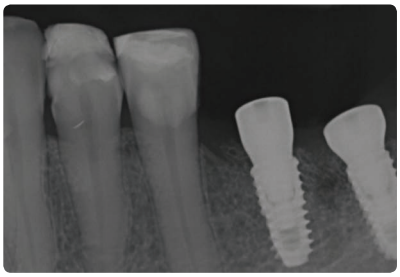
Perfectly matching bone graft placement.



6 Months:
Bone quality.



7 Months:
Implant placement.



7 Months:
X-Rays after implantation.

Courtesy of Dr. M. Martini

SmartBone® is a CE 2797 marked Class III Medical Device

smartbone®

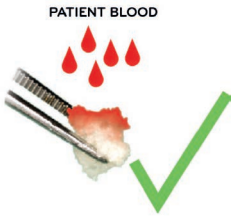
DO

- Prepare the receiving site well
  - properly expand soft tissues
  - properly microdrill native bone
- Ensure a tight contact to host bone
  - appropriate graft shaping
  - firmly tight screws
- Smooth edges and corners
- Use membrane to cover SmartBone® (suggested collagene or pericardium membrane)

DON'T

- Avoid the use of saline solution, mix it with patient blood
- Do not overfill (avoid extra material, it does not shrink)
- Do not mix it with other biomaterials
- Do not reuse the product
- Do not re-sterilise

AVOID THE USE OF SALINE SOLUTION



PREFER THE USE OF PATIENT BLOOD

DON'T REUSE

FOR SINGLE USE ONLY

SmartBone® is a CE 2797 marked Class III Medical Device

FAQs

- **What is SmartBone® 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?**
  Bone generally has the ability to regenerate completely, but it requires a very small fracture space or some sort of scaffold to do so. Indeed, bone grafting is possible because bone tissue has the ability to regenerate completely if provided the space into which to grow.
  As native bone grows, it will generally replace the graft material completely, resulting in a fully integrated region of new bone. The biologic 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® is among these, together with autografts.

- **What are the top mechanical performances of SmartBone®?**
  Braking Stress of about 26MPa (av.)
  Elastic Modulus of about 1,2GPa (av.)
  Breaking torque under screw fixation (screw tenacity) >55Ncm (av.)

- **Is SmartBone® an open-porous material?**
  Yes! SmartBone® has an open interconnected porous structure.

- **How is SmartBone®'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®?**
  They are degraded and resorbed in about 4-6 months: meanwhile they degrade and get resorbed, new born bone is formed.

- **Is SmartBone® hydrophilic?**
  Yes! Due to its composition SmartBone® 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, the same used in resorbable sutures.

- **Where does the bovine derived mineral matrix of SmartBone® 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® produced?**
  IBI applies a proprietary process to produce SmartBone®.

- **Can the biomaterial be mixed with a saline solution?**
  The saline solution is not a fundamental component involved in the regeneration biological process, for this reason the patient's blood is absolutely recommended. The saline solution could extract the proteins addicted onto the trabecular surface of the graft.

- **Do I need to use a membrane?**
  The use of the membrane is recommended in oral surgery, *e.g.* in cases of horizontal augmentations, in order to protect the graft from any dehiscence.

- **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® IS SINGLE USE.

- **Why is SmartBone® 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.

BIBLIOGRAPHY

Carusi, G.; Salin, M.; Scilla, M. Tecnica MISE – procedure chirurgiche; EDRA Ed., 2016.

Cingolani (1), A.; Grottoli, C. F.; Esposito, R.; Villa, T.; Rossi, F.; Perale, G. Improving Bovine Bone Mechanical Characteristics for the Development of Xenohybrid Bone Grafts. Curr. Pharm. Biotechnol. 2018, 19, 1005–1013.

Cingolani (2), A.; Casalini, T.; Caimi, S.; Klaue, A.; Sponchioni, M.; Rossi, F.; Perale, G. A Methodologic Approach for the Selection of Bio-Resorbable Polymers in the Development of Medical Devices: The Case of Poly(l-lactide-co-ε-caprolactone). Polymers (Basel). 2018, 10, 851.

D'Alessandro, D.; Perale, G.; Milazzo, M.; Moscato, S.; Stefanini, C.; Pertici, G.; Danti, S. Bovine bone matrix/poly(L-lactic-co-ε-caprolactone)/gelatin hybrid scaffold (SmartBone®) for maxillary sinus augmentation: A histologic study on bone regeneration. Int. J. Pharm. 2017, 523, 534–544.

Facciuto, E.; Grottoli, C.F.; Mattarocci, M.; Illiano, F.; Compagno, M.; Ferracini, R.; Perale, G. 3D craniofacial bone reconstruction with SmartBone® on demand™. The Journal of Craniofacial Surgery. 2019, 2019, 30(3): 739-741.

Grecchi, F.; Perale, G.; Candotto, V.; Busato, A.; Pascali, M.; Carinci, F. Reconstruction of the Zygomatic Bone with SmartBone®: Case Report. Journal of Biological Regulators and Homeostatic Agents. 2014, 29, 42-47.

Haugen, H.J.; Lyngstadaas, S.P.; Rossi, F.; Perale, G. Bone Grafts: Which is the Ideal Biomaterial? Journal of Clinical Periodontology. 2019, 1, 1–11.

Lanka M.; Poonia N.; Morales H. Management of a Failed Implant Site with Guided Bone Regeneration, Reimplantation, and Root Submergence Technique. International Journal of Oral Implantology and Clinical Research. 2016; 7(2):1-3.

Lanka, M.; Devich, A.S.; Sagrika, S.Socket Preservation Using a Small Particulate Xenograft: A Case Report. The Journal of Implant & Advanced Clinical Dentistry. 2017, 9 (4), 12-17.

Mandelli, F.; Perale, G.; Danti, S.; D'Alessandro, D.; Ghensi, P. Clinical and Histological Evaluation of Socket Preservation using SmartBone®, a Novel Heterologous Bone Substitute: A Case Series Study. Oral & Implantology. 2018, 2, 87-94.

Pertici, G.; Müller, M; Perale, G. Bioresorbable Bioactive Matrix for Bone Regeneration. Tissue Engineering Part A. 2010, 16(8), A-10.

Pertici, G.; Rossi, F.; Casalini, T.; Perale, G. Composite Polymer-Coated Mineral Grafts for Bone Regeneration: Material Characterisation and Model Study. Ann. oral Maxilofac. Surg. 2014, 2, 1–7.

Pertici, G.; Carinci, F.; Carusi, G.; Epistatus, D.; Villa, T.; Crivelli, F.; Rossi, F.; Perale, G. Composite Polymer-Coated Mineral Scaffolds for Bone Regeneration: From Material Characterization To Human Studies. J. Biol. Regul. Homeost. Agents 2015, 29, 136–148.

Poonia N.; Morales H.; Mahesh. L. Management of a failed implant site with guided bone regeneration, reimplantation, and root submergence technique. International Journal of Oral Implantology and Clinical Research. 2016, May-August 7 (2) 1-3.

Roato, I.; Belisario, D. C.; Compagno, M.; Verderio, L.; Sighinolfi, A.; Mussano, F.; Genova, T.; Veneziano, F.; Pertici, G.; Perale, G.; Ferracini, R. Adipose-Derived Stromal Vascular Fraction/Xenohybrid Bone Scaffold: An Alternative Source for Bone Regeneration. Stem Cells Int. 2018, 2018, 1–11.

Rossi, F.; Santoro, M.; Perale, G. Polymeric Scaffolds as Stem Cell Carriers in Bone Repair. J. Tissue Engineering and Regenerative Medicine. 2015, 9, 1093-1119.

Secondo, F.; Grottoli, C. F.; Zollino, I.; Perale, G.; Lauritano, D. Positioning of a Contextual Implant along with a Sinus Lift Anchored with a Block of Heterologous Bone. Oral Implantol. (Rome). 2017, 4, 457–467.

Stacchi, C.; Lombardi, T.; Ottonelli, R.; Berton, F.; Perinetti, G.; Traini, T. New bone formation after transcrestal sinus floor elevation was influenced by sinus cavity dimensions: A prospective histologic and histomorphometric study. Clin. Oral Implants Res. 2018, 465–479.

Zollino, I.; Carusi, G.; Carinci, F.; Perale, G. Positioning of a Contextual Implant Along with a Sinus Lift with Smartbone® Microchips of Composite Heterologous-Synthetic Bone. Indian J. Stomatol. 2015, 6(2), 59-62.

SmartBone® is a CE 2797 marked Class III Medical Device

ibi SA industrie biomediche insubri

Industrie Biomediche Insubri SA
Via Cantonale 67
Mezzovico-Vira
CH-6805
Switzerland
Ph. +41 91 93 06 640

www.ibi-sa.com
info@ibi-sa.com

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.

bsi. UKAS MANAGEMENT SYSTEMS 0003

CE 2797

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

This catalogue is for healthcare professionals only, therefore the distribution to the general public is forbidden.

IBI-BRO011 rev1 October 2019