

Bone void filling

Bioabsorbable synthetic bone substitutes

B_{IO 1}[®]

Bioabsorbable β -TCP



B_{IO 1-S}[®]

Prefilled syringe with β -TCP



B_{IO 1-KIT}[®]

System for β -TCP / bone marrow mix



B_{IO 1-QUICKSET}[®]

Injectable self-hardening paste





SBM: your partner in bone healing

Founded in 1991, SBM is specialized in the design, manufacture and marketing of bone repair systems for use in orthopaedic surgery, traumatology and neurosurgery.

More than 20 years of experience

SBM is an independent company, founded by Denis CLEMENT, PhD in Biomaterials. Based in Lourdes (south-western France), SBM has a subsidiary in Boston, Massachusetts (USA), SBM Inc.

At the heart of innovation

Not only was SBM the first company to introduce tricalcium phosphate to perform bone grafts in Europe, but also was the first, in 1996, to invent implants for valgus-producing open-wedge tibial osteotomies.

Today SBM continues to stand out for its unique know-how in the manufacture of biocomposite implants such as Duosorb, a unique bioabsorbable material which offers mechanical resistance, elasticity, and osteoconduction.

Proven high quality standards

Having expanded into new markets with increasingly strict regulations, SBM has developed a demanding, ISO 9001-13485 (2000) certified quality management approach, which ensures product safety all the way from design to implementation.

Furthermore, SBM was the first European company to obtain CE mark certification, in the 90's, as well as US FDA approval, in 2003, for its line of synthetic bone augmentation implants (in pure tricalcium phosphate - Biosorb).



Worldwide network

- ▶ Over 20% of revenue invested in R&D each year
- ▶ Full range of expertise: implants, instruments & techniques
- ▶ Present in more than 45 countries worldwide



Design

With over 20% of its revenue invested in Research and Development each year, SBM is well positioned for growth through a continued focus on innovation. Renowned for its know-how, the company is also active in the development of OEM products.

SBM designs its own devices, thanks to a research team composed of doctors, engineers, technicians and associated scientists with mutually complementary specialties, such as biology, engineering, ceramics, chemistry, plastics and biostatistics. By developing lasting partnerships with high-level surgeons from all over the world, SBM stays abreast of the most current issues and on the cutting edge of the latest developments in skeletal surgery. Our consultants' competence, clinical experience and reputation enable us to continually improve our products for simplified, repeatable use.

Manufacturing

Over time, SBM has developed specific and original procedures that guarantee high-quality implants. SBM produces a wide variety of implants made of ceramic, composite and metallic materials, as well as associated instruments. Each year over 60,000 SBM implants are manufactured and used in 45 countries.

Certified by independent organizations, the company implements the strictest standards, and is regularly audited to ensure that its methods are in compliance with the regulatory requirements of its foreign increased.

SBM operations are traced throughout all stages of production, distribution and use, which provides increased visibility and significantly contributes to patient safety.

Distribution

SBM is present both in France and abroad, via a network of partners in 45 countries on all 5 continents. Today, 80% of the company's production is intended for export.

Thanks to the many partnerships SBM has developed around the world, permanent postmarket functional and clinical evaluations of SBM devices are carried out to continuously optimize their performance levels.

SBM organizes exhibits each year at major scientific congresses both in France and abroad, in an effort to anticipate future challenges associated with the surgical indications for which we offer solutions.

With its 22 years of experience, the company has built a tight network of partners, surgeons and distributors in France and abroad over the years. SBM's sales team provides attentive customer service which includes, SBM provides support and training to surgeons, hospital staff and distributors.

SBM partnerships are driven by a shared vision of improving patients' well-being, by encouraging exchanges among surgeons from different countries to develop new solutions to promote bone healing.

BIO-1® β -TCP bone substitutes

The original

B_{IO} 1[®]

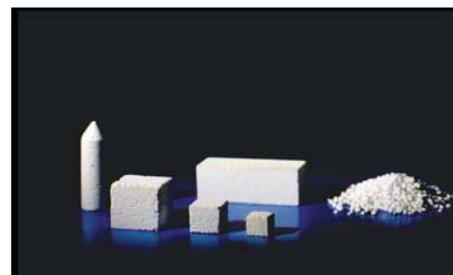
KEY FEATURES

- ▶ **Synthetic**
100% safe and chemically similar to natural bone.
- ▶ **Osteoconductive**
Guides bone cells and creates strong chemical links.
- ▶ **Absorbable**
Resorption occurs simultaneously to bone growth.



INDICATIONS

- ▶ Benign tumors
- ▶ Bone cysts
- ▶ Ankle arthrodesis
- ▶ Metatarsian osteotomy
- ▶ Periprosthetic reconstruction
- ▶ Fracture
- ▶ Pseudarthrosis
- ▶ Osteoporosis



CLINICAL EXAMPLE

Chondroma of the proximal phalanx of the index (8 year-old female)
After resection of the tumor, the bone defect was filled with Biosorb granules.



Fig 1: Pre-op X'Ray



Fig 2: Post-op X'Ray



Fig 3: 4-month Post-operative X'Ray

BIO 1® bioabsorbable implants (β-TCP)

BIO 1® are high purity Tricalcium Phosphate (β-TCP) implants that are ready to use as cancellous or cortico-cancellous bone. Synthetic, bioactive and bioabsorbable, this range is perfectly safe for common bone void filling procedures and promotes bone growth thanks to its osteoconductive properties.

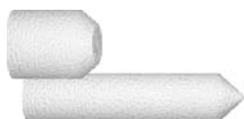
INDICATIONS

Trauma,
Benign Tumors,
Pseudarthrosis,
Intra-articular arthrodesis,
Posterolateral grafts,
Periprosthetic reconstruction.



INDICATION

Circular cavity filling (screw revision...)



INDICATION

Neurosurgery



Granules:

Ø 0,6 mm (20 cc) - P822692228
Ø 1 mm (0.6 cc) - P822692240
Ø 1 mm (2 cc) - P822692243
Ø 1 mm (5 cc) - P822692244
Ø 1 mm (15 cc) - P822692246
Ø 1 mm (20 cc) - P822692249
Ø 1.5 mm (5 cc) - P822692444
Ø 1.5 mm (15 cc) - P822692446
Ø 1.5 mm (20 cc) - P822692451
Ø 3 mm (5 cc) - P822692644
Ø 3 mm (15 cc) - P822692646
Ø 3 mm (20 cc) - P822692649

Macro-porous cubes:

4 x 4 x 4 mm (15 cc) - P822893229
4 x 4 x 4 mm (30 cc) - P822893233
4 x 4 x 4 mm (45 cc) - P822893232

Sticks:

3 x 3 x 10 mm (x 10) - P822634240
5 x 5 x 10 mm (x 5) - P822634440
5 x 5 x 10 mm (x 10) - P822634442
5 x 5 x 10 mm (x 20) - P822634441
5 x 5 x 20 mm (x 1) - P822634446
5 x 5 x 20 mm (x 6) - P822634450
5 x 5 x 20 mm (x 10) - P822634444
5 x 5 x 20 mm (x 20) - P822634445

Cubes:

5 x 5 x 5 mm (x 1) - P822693210
5 x 5 x 5 mm (x 2) - P822693220
5 x 5 x 5 mm (x 5) - P822693221
5 x 5 x 5 mm (x 10) - P822693222
7 x 7 x 7 mm (x 1) - P822693420
7 x 7 x 7 mm (x 2) - P822693421
7 x 7 x 7 mm (x 5) - P822693422
10 x 10 x 10 mm (x 1) - P822693620
10 x 10 x 10 mm (x 2) - P822693622
10 x 10 x 10 mm (x 10) - P822693624

Blocks:

10 x 10 x 25 mm (x 1) - P822694444
30 x 20 x 10 mm (x 1) - P822374400

Cylinders:

Ø 6 mm / L 25 mm (x 2) - P822441442
Ø 6 mm / L 25 mm (x 4) - P822441444
Ø 8 mm / L 10 mm (x 3) - P822661222

Trephine hole filling:

Ø 10 mm (x 2) - P822311244
Ø 10 mm (x 3) - P822311245
Ø 12 mm (x 2) - P822311444
Ø 12 mm (x 3) - P822311445
Ø 14 mm (x 2) - P822311644
Ø 14 mm (x 3) - P822311645

Anatomically-shaped implants:

Ankle arthrodesis 30 x 25 x 7 x 3 mm (x 1) - P822375602
Metatarsian osteotomy 15 x 10 x 4 x 2 mm (x 1) - P822375000
Patellar filling 10 x 10 x 6 mm (x 1) - P822694220

BIO-1 S[®] pre-loaded syringes

Precision in delivery

B_{IO} 1-S[®]

KEY FEATURES

- ▶ **Pre-filled with Biosorb**
Pre-loaded syringe containing bioabsorbable β -TCP (Tricalcium Phosphate).
- ▶ **Easy-to-use**
The use syringe provides enhanced precision and comfort when inserting the granules.
- ▶ **Fast implementation**
Designed for filling small-volume cavities that are not subjected to mechanical stresses.

BIO 1-S[®] pre-loaded syringe with β -TCP granules:

- ∅ 0.6 mm (0.5 cc) x 1 - B1S2692220
- ∅ 1 mm (0.5 cc) x 1 - B1S2692240
- ∅ 1 mm (1 cc) x 1 - B1S2692244
- ∅ 1 mm (1 cc) x 2 - B1S2692246
- ∅ 1.5 mm (2 cc) x 1 - B1S2692440
- ∅ 1.5 mm (2 cc) x 2 - B1S2692442

BIO 1-S[®] syringe cutter

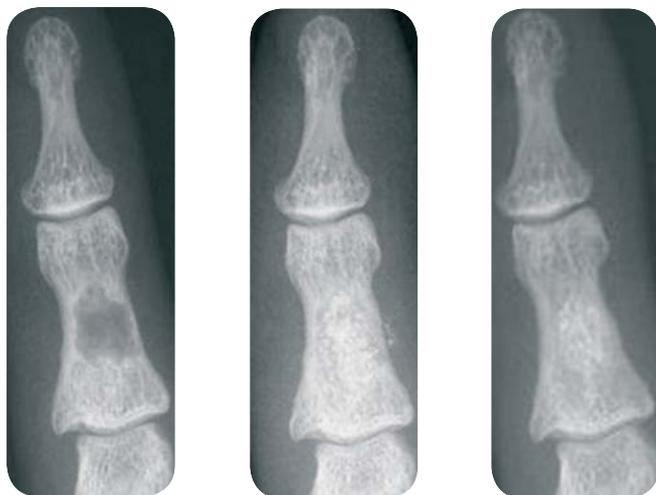
B1S9000001

INDICATIONS

- ▶ Resection - filling of benign tumors (cysts, chondroma...)
- ▶ Post-traumatic reconstruction
- ▶ Foot and hand surgery
- ▶ Filling modular cysts or periodontal bags

Results

Bone void filling using Bio 1-S[®] syringes:



D-0

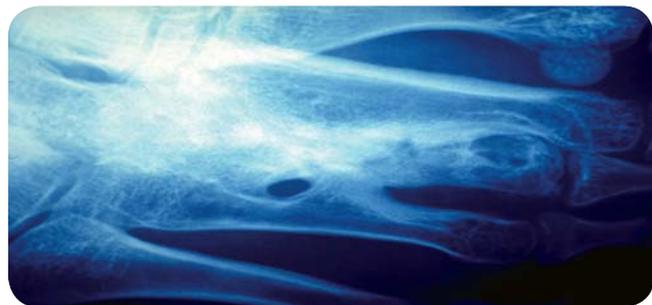
+ 1 year

+ 2 years

Phalanx chondroma



+ 1 year



+ 2 years

Metatarsus chondroma

BIO-1 KIT[®] syringes for bone marrow / TCP mix preparation

The osteoinductive substitute

B_{IO} 1-KIT[®]

KEY FEATURES

- ▶ **Osteoinductive properties**
Quick and easy bone marrow / β -TCP (Tricalcium Phosphate) mix.
- ▶ **Easy-to-use**
Autologous bone marrow is automatically drawn into the syringe to impregnate the granules.
- ▶ **Complete aseptic conditions**
Safe conditions, preservation of the coagulum until implantation.



Jamshidi type trocar

Connector

Pre-loaded vacuum sealed syringe (100% β -TCP)

INDICATIONS

- ▶ Posterolateral graft of the thoracic and lumbar spine
- ▶ Periprosthetic reconstruction
- ▶ Filling of various bone defects and cavities (benign tumors, bone cysts)
- ▶ Pediatric orthopedic surgery
- ▶ Pseudarthrosis
- ▶ Bone substitute for cervical and lumbar cage filling



<http://goo.gl/UsYeMC>

Bio 1-KIT[®] syringe with granules + accessories
Granule sizes:

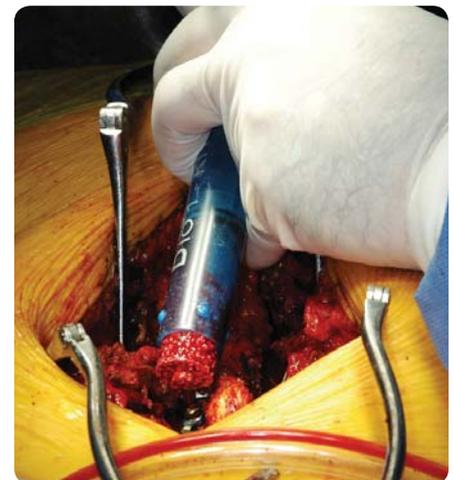
- ø 1.5 mm (5 cc) - SER2692442
- ø 1.5 mm (10 cc) - SER2692444
- ø 1.5 mm (15 cc) - SER2692446
- ø 1.5 mm (30 cc) - SER2692448
- ø 3 mm (5 cc) - SER2692642
- ø 3 mm (10 cc) - SER2692644
- ø 3 mm (15 cc) - SER2692646
- ø 3 mm (30 cc) - SER2692648

Bio 1-KIT[®] syringe with macroporous cubes + accessories
Macro-porous cube sizes:

- 4 x 4 x 4 mm (5 cc) - SER2893222
- 4 x 4 x 4 mm (10 cc) - SER2893224
- 4 x 4 x 4 mm (15 cc) - SER2893226
- 4 x 4 x 4 mm (30 cc) - SER2893228

Included accessories:

Jamshidi type trocar & connector.



BIO 1-QUICKSET® injectable self-hardening filler

Filling irregular bone defects

BIO 1-QUICKSET®



Cannula
Ø 4,25 - L 13 mm

Pre-filled syringe

Cap

Connector & vial of saline solution

Simple

- ▶ All-in-one: no additional items needed.
- ▶ Can be injected in hard-to-reach areas thanks to the cannula.
- ▶ Radiopaque: compatible with MRI & X-ray imaging techniques.

Safe

- ▶ Reputed material: bioabsorbable, bioactive and osseoconductive.
- ▶ Mixture prepared in completely aseptic conditions.
- ▶ Isothermal²: the amount of heat generated is insignificant.

Quick

- ▶ Short mixing time (30 seconds).
- ▶ Fast setting time (8 minutes).
- ▶ Available in different volumes.



<http://goo.gl/RBS0RI>



BIO 1-QUICKSET® injectable self-hardening bone void filler:

- 5 cc - QUICK26220
- 10 cc - QUICK26230
- 15 cc - QUICK26240

Included accessories:

Cannula, Luer connector & vial of saline solution

INDICATIONS



BIO 1-QUICKSET® provides an open void/gap filler that can augment provisional hardware. Indeed, BIO 1-QUICKSET® acts only as a temporary support media, for this same reason, **BIO 1-QUICKSET® cannot be used for vertebroplasty or kyphoplasty.**

Surgical technique

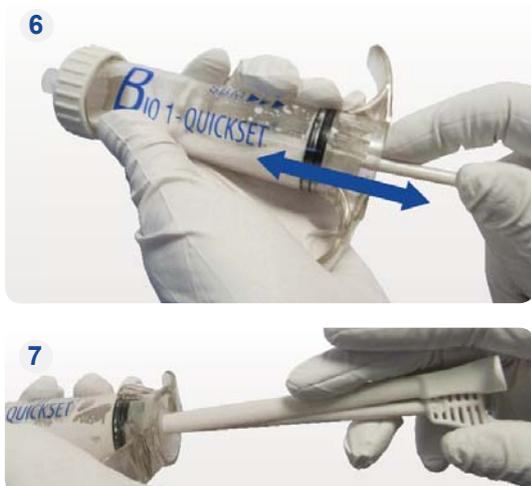
To ensure a homogeneous mixture, it is important to follow the steps below in the order listed:

PREPARATION



- 1 Unscrew the cap from the syringe. Gently tap the syringe extremity to ensure no powder sticks.
- 2 Screw the Luer connector to the syringe until it locks into place to ensure optimal sealing.
- 3 While maintaining the syringe in a vertical position, connect the vial containing the saline solution to the connector and pierce the center of the seal.
- 4 Aspirate the entire content of the vial by pulling straight on the plunger. If needed, repeat the gesture several times until the vial is completely empty.
- 5 Remove the Luer connector and put the syringe cap back on. Remove the spacer from the plunger.

MIXING



- 6 Mix for 30 seconds in order to obtain a homogeneous mixture, by following these steps:
 - Shake the syringe vigorously for 5 seconds.
 - Push the plunger all the way and rotate for 5 seconds to prevent the formation of powder agglomerates.
 - Push the plunger in and out to mix in a back and forth motion for 10 seconds.
 - Repeat the three previous steps, quickly, for 10 seconds.
- 7 Pull the plunger as far as possible in order to lock the spacer into place.

REST



- 8 Allow the syringe to rest for 2 minutes in a slightly inclined position to obtain a pasty texture, then remove the cap.

INJECTION



- 9 Screw the cannula tightly on the Luer tip of the syringe. Verify the consistency of the mixture, the paste should not stick to the glove.
Inject the mixture in a single dose until the osseous defect is filled.

Time scale

Warning
Always respect the injection time.



Clinical examples

A wide variety of indications

Case 1

Filling of the upper part of the femur after essential bone cyst resection (15 year-old male).

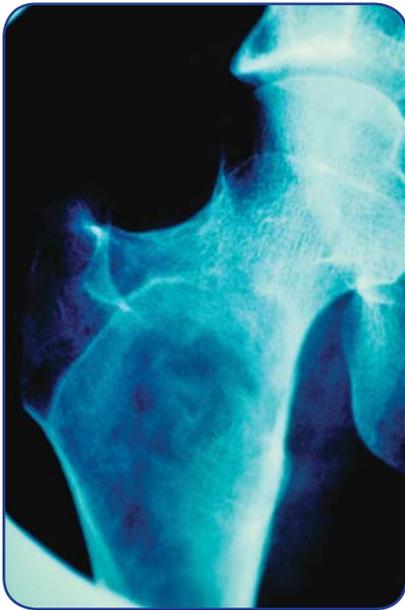


Fig 1: Pre-op X'Ray



Fig 2: 3 months X'Ray

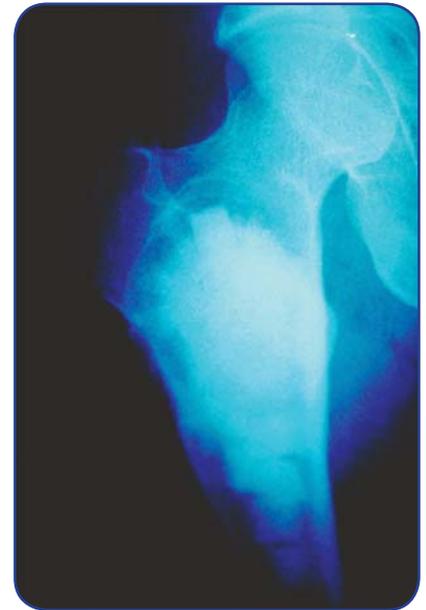


Fig 3: 6 months X'Ray

Fig 1 : Pre-operative X'Ray.

Fig 2 : 3-month post-operative X'Ray. The bone defect resulting from the cyst resection, was filled tightly as possible with Biosorb granules and cubes, avoiding empty contact areas.

The implants were used alone, without autograft. New bone is clearly seen surrounding the implants, without any gaps, as signs of resorption are visible in the upper and lower part of the filled cavity.

Fig 3 : 6-month post-operative X'Ray, showing a good consolidation and satisfying bone volume recovery ; the grafted areas appear more homogenous. The implants are entirely surrounded by bone with the upper and lower ones almost completely resorbed.

Case 2

Astragalus neck fracture (53 year-old man).



Fig 1: 2.5 months Post-op X'Ray



Fig 2: 8 months Post-op X'Ray

Fig 1: X-Ray at 2.5 months after surgery: In order to fill the bone defect due to the fracture and prevent risks of pseudarthrosis, Biosorb cubes were firmly inserted inside the fracture center.

Tightly packing the ceramics inside the defect provided satisfying primary stability. After 2.5 months, as the cubes degraded, fracture consolidation was evident, as well as proper graft integration.

Fig 2: X-Ray at 8 months after surgery: Proper consolidation is obtained, as Biosorb cubes are almost entirely resorbed.

Case 3

Tibial plateau fracture (44 years old female).



Fig 1: 3 months Post-op X'Ray

Fig 1: X-Ray at 3 months after surgery: The fracture was reduced and the bone defect in the cancellous bone was filled with 45% porosity Biosorb cylinders. The patient was allowed to walk immediately after surgery. The borders of the implants seem already weak and signs of the resorption can be seen around the upper portion of the ceramic implant.

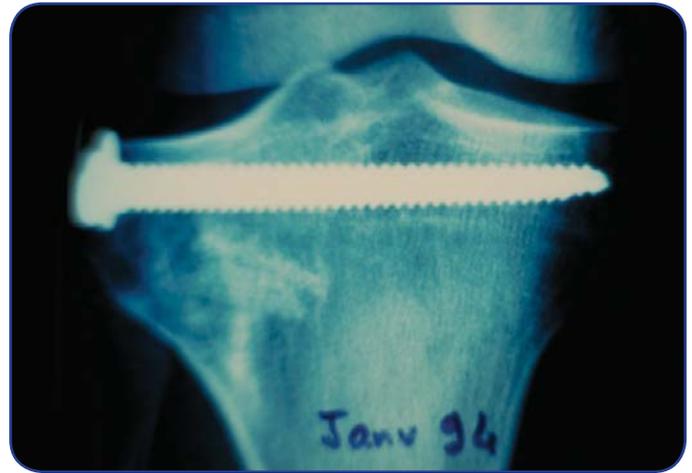


Fig 2: 15 months Post-op X'Ray

Fig 2: X-Ray at 15 months after surgery: The graft is almost entirely resorbed and the the initial bone defect re-stored. Bone trabeculae are visible in place of the ceramics indicating normal bone remodeling.

Case4

Instrumented Idiopathic Scoliosis (CDI). After reducing the deformation, posterolateral bone grafting was performed with Biosorb TCP sticks (5x5x20mm).

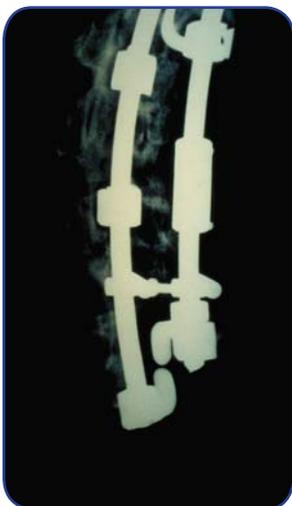


Fig 1: Post-operative



Fig 2: + 3 months



Fig 3: + 7 months



Fig 4: + 11 months

Fig 1: Post-operative X'Ray. Biosorb implants are visible.

Fig 2: 3 months post-operative. The implant progressively loses density. No secondary motion, no radioluscent line is noted.

Fig 3: 7 months post-operative. The implant is almost resorbed.

Fig 4: 11 months post-operative. The implant is totally resorbed and can no longer be observed.

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