BROCHURE

BIO 1®

SYNTHETIC BONE SUBSTITUTES
BONE VOID FILLERS

SBM
Science & Bio Materials

SUMMARY

- Pioneer since 1991 ____ 4
- BIO 1® characteristics ____ 6
- Types of BIO 1® ____ 7
- Traumatology ____ 8
- Benign bone tumors and cysts ____ 10
- Spondylodesis ____ 12
- Chin osteotomy ____ 14
- Crest iliac defects after bone graft harvesting ____ 16
- Bibliography ____ 18

PIONEER SINCE 1995

30 years of experience

Since 1995, SBM has developed a unique material called BIOSORB, composed of pure* Beta-Tricalcium Phosphate (ß-TCP). SBM has created a specific line of products called BIO 1®, designed to safely and effectively fill bone voids or defects due to bone injuries or surgical procedures.

SBM was one of the first manufacturers to offer ß-TCP implants, with CE marking in Europe (1998) and FDA 510K clearance in the United States (2003).
Our commitment at every stage of the manufacturing process is supported by an environmental approach recognized by ECOVADIS certification.

The portfolio adresses many orthopedic indications and plastic surgery with chin osteotomy (genioplasty). Today, more than 145 000 bone void fillers have been implanted, in more than 50 countries worldwide.

Covered indications

TRAUMATOLOGY

BENIGN BONE TUMOR

SPONDYLODESIS

MAXILLOFACIAL OSTEOTOMY

BONE GRAFT HARVESTING SITE

*over 95% according to ASTM F1088-23

Unique savoir-faire

A WELL-KNOWN MATERIAL

Supported by in vivo studies. [7 to 10]
10 years of clinical follow up. [1 to 5]

CONTROLLED MANUFACTURING PROCESSES

With complete in-house control over every step of the BIO 1® manufacturing process, we ensure consistent reliability, safety and traceability of our products.

Chemical synthesis

Sieving

Pressing

Firing

Gamma ray sterilization (minimum dose 25kGy) completes the process.

MADE IN FRANCE

Advantages over therapeutic alternatives

NO DONOR SITE MORBIDITY

Unlike autografts, synthetic grafts eliminate the need for a second surgical site - reducing operative time, patient pain, and the risk of complications.

UNLIMITED AND CONSISTENT SUPPLY

Unlike autografts and allografts, synthetic grafts are always available, with no limitations in volume or donor dependency.

NO RISK OF DISEASE TRANSMISSION

Unlike allografts and xenografts, synthetic materials carry zero risk of viral or prion contamination.

REGULATORY ACCEPTANCE WORLDWIDE

Synthetic grafts avoid the ethical and legal restrictions often associated with allografts or xenografts in many countries.

CONTROLLED COMPOSITION AND PERFORMANCE

Engineered under strict manufacturing protocols, synthetic grafts offer predictable behavior, bioactivity, and safety.

BIO 1® CHARACTERISTICS

Biological properties

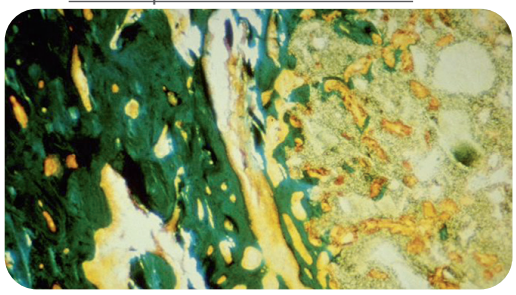
ABSORBABLE

Porous scaffold made of ß-TCP.
Strong chemical link development: rapid bone ingrowth.

OSTEOCONDUCTION

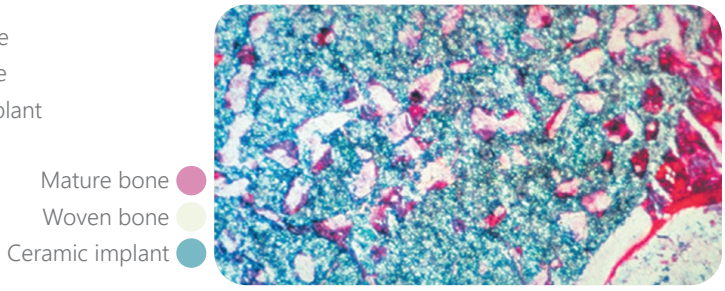
Guide cells penetration.
Improve bone graft integration.

Good biocompatibility between ß-TCP and bone: no interposition of fibrous tissue [11]



2 weeks follow-up

3D electronic microscopy of the porosity of the ceramic (x 1000) [11]

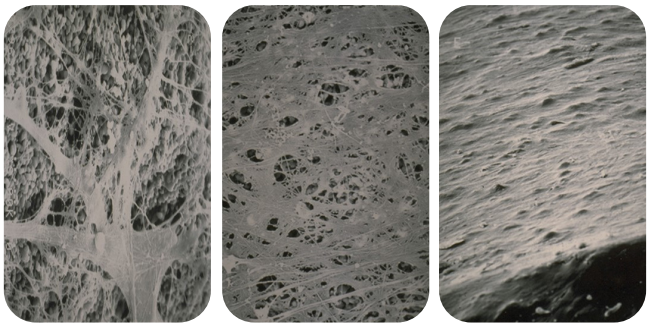


1 month follow-up

OSTEOINTEGRATION

95% pure* ß-TCP.
Excellent cell resorption process.

Cellular growth [11]



24 h | 3 days | 7 days

Physical properties

BIOCOMPATIBLE

Fully biocompatible with excellent tissue tolerance (ISO 10993-1).
No risk of immune rejection.
Completely non-toxic.

CONTROLLED POROSITY

Controlled porosity and mechanical resistance characteristics comparable to human bone grafts.

SYNTHETIC MATERIAL

No risk of viral contamination.

TYPES OF BIO 1®

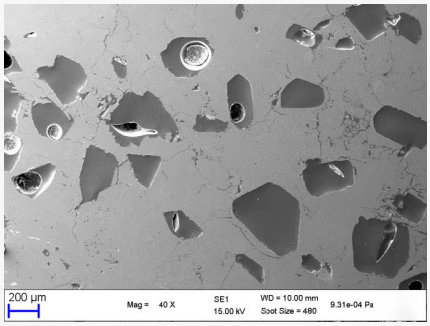
Sticks, blocks and cubes

Porosity: 45%.

Mechanical strength: >15MPa.

Internal porosity (micro- and macropores):
d90 ≈ 300 µm macropores and 1.2 µm micropores.

SEM* of macroporosity [11]

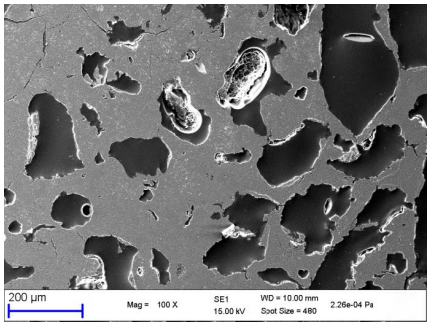


Granules

Porosity: >60%.

Internal porosity (micro- and macropores):
d90 ≈ 300 µm macropores and 1.2 µm micropores.

SEM* of macroporosity [11]

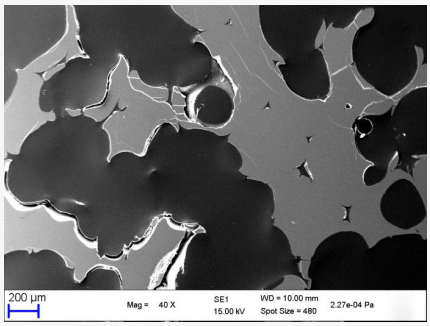


Macroporous

Porosity: > 70%.

Internal porosity (micro- and macropores):
d90 ≈ 640 µm macropores and 0.5 µm micropores.

SEM* of macroporosity [11]



*Scanning Electron Microscopy

TRAUMATOLOGY

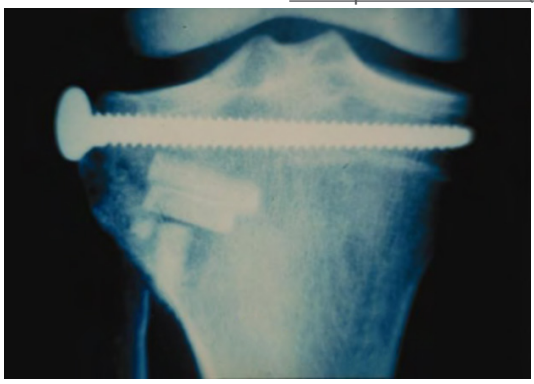
Trauma surgery for fractures
ADULT

Surgical technique

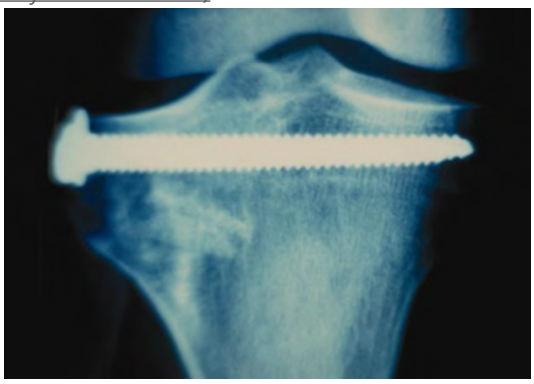
1. Assess the size of the fracture and bone defect.
2. Fracture reduction (surgical procedure independant of BIO 1®).
3. Completely fill and pack the bone defect with the implant. For treatment of larger bone defects, BIO 1® can be mixed with autologous cancellous bone.
4. Complete surgery with a rigid fixation system (such as plate and screws).

Clinical case

Tibial plateau fracture (28 years old female) [11]

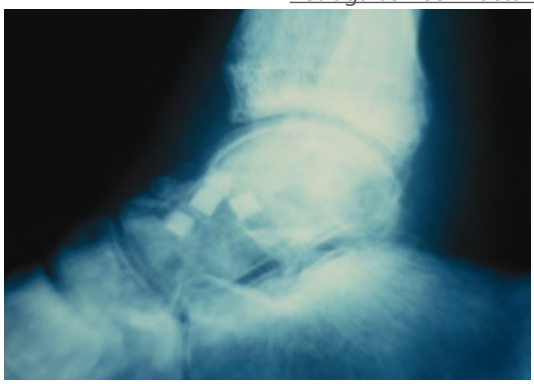


Post-op X-ray

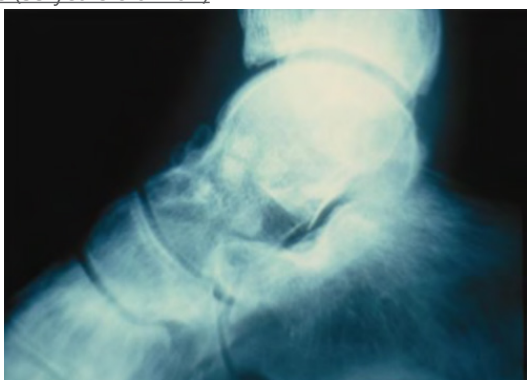


12 months post-op X-ray

Astragalus neck fracture (53 years old man) [11]



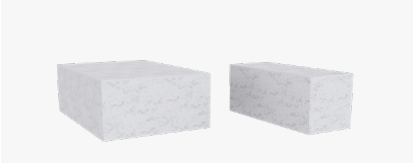
2.5 months post-op X-ray



9 months post-op X-ray

References

Reference	Description	Quantity
P822634240	Sticks for filling - 3 x 3 x 10 mm (0.9 cm³)	x10
P822634460	Sticks for filling - 5 x 5 x 10 mm x5 (Ind.)	x5 (Ind.)
P822634440	Sticks for filling - 5 x 5 x 10 mm (1.25 cm³)	x5
P822634442	Sticks for filling - 5 x 5 x 10 mm (2.5 cm³)	x10
P822634441	Sticks for filling - 5 x 5 x 10 mm (5 cm³)	x20
P822634470	Sticks for filling - 5 x 5 x 20 mm x5 (Ind.)	x5 (Ind.)
P822634446	Sticks for filling - 5 x 5 x 20 mm (0.5 cm³)	x1
P822634450	Sticks for filling - 5 x 5 x 20 mm (3 cm³)	x6
P822634444	Sticks for filling - 5 x 5 x 20 mm (5 cm³)	x10
P822634445	Sticks for filling - 5 x 5 x 20 mm (10 cm³)	x20
P822634548	Sticks for filling - 5 x 5 x 20 mm (20 cm³)	x40
P822694220	Block for filling – 10 x 10 x 6 mm (0.6 cm³)	x1
P822694444	Block for filling – 10 x 10 x 25 mm (2.5 cm³)	x1
P822694446	Block for filling – 10 x 10 x 25 mm (5 cm³)	x2
P822374400	Block for filling - 30 x 20 x 10 mm (6 cm³)	x1
P822693210	Cubes for filling - 5 x 5 x 5 mm (0.12 cm³)	x1
P822693230	Cubes for filling - 5 x 5 x 5 mm (0.62 cm³)	x 5 (Ind.)
P822693221	Cubes for filling - 5 x 5 x 5 mm (0.62 cm³)	x5
P822693222	Cubes for filling - 5 x 5 x 5 mm (1.25 cm³)	x10
P822693225	Cubes for filling - 5 x 5 x 5 mm (2.5 cm³)	x20
P822693420	Cubes for filling - 7 x 7 x 7 mm (0.34 cm³)	x 1
P822693421	Cubes for filling - 7 x 7 x 7 mm (0.69 cm³)	x 2
P822693422	Cubes for filling - 7 x 7 x 7 mm (1.71 cm³)	x 5
P822693430	Cubes for filling - 7 x 7 x 7 mm (1.71 cm³)	x5 (Ind.)
P822693426	Cubes for filling - 7 x 7 x 7 mm (2.40 cm³)	x7
P822693630	Cubes for filling - 10 x 10 x 10 mm (1 cm³)	x5 (Ind.)
P822693620	Cubes for filling - 10 x 10 x 10 mm (1 cm³)	x1
P822693622	Cubes for filling - 10 x 10 x 10 mm (2 cm³)	x2
P822693623	Cubes for filling - 10 x 10 x 10 mm (5 cm³)	x5
P822693624	Cubes for filling - 10 x 10 x 10 mm (10 cm³)	x10
P822693626	Cubes for filling - 10 x 10 x 10 mm (15 cm³)	x15



BENIGN BONE TUMORS OR CYSTS

Shoulder, hand, lower limb and foot
PEDIATRIC (≥8 years old)

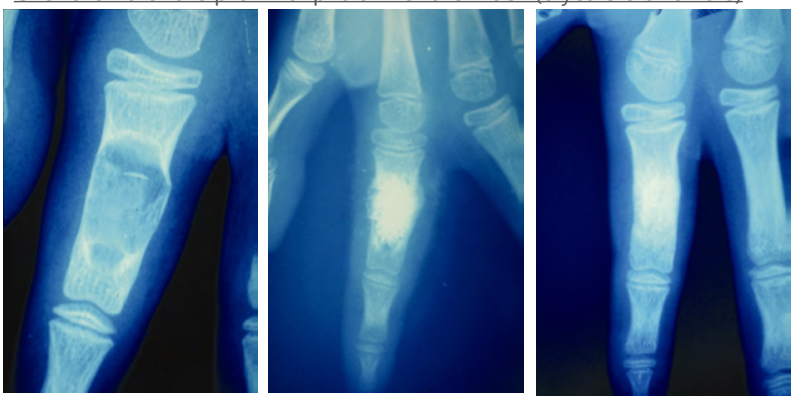
BIO 1® is used to fill a bone void following the curettage of a benign bone tumor or a bone cyst.

Surgical technique

1. Assess the size of the benign bone tumor or cysts and the resulting bone defect after curettage.
2. Pack the sticks, cubes, blocks or granules in the bone defect with patient blood.

Clinical case

Chondroma of the proximal phalanx of the index (8 years old female) [11]



Pre-op X-ray | Post-op X-ray | 4 months post-op X-ray

References

Reference	Description	Quantity
P822634240	Sticks for filling - 3 x 3 x 10 mm (0.9 cm³)	x10
P822634460	Sticks for filling - 5 x 5 x 10 mm x5 (Ind.)	x5 (Ind.)
P822634440	Sticks for filling - 5 x 5 x 10 mm (1.25 cm³)	x5
P822634442	Sticks for filling - 5 x 5 x 10 mm (2.5 cm³)	x10
P822634441	Sticks for filling - 5 x 5 x 10 mm (5 cm³)	x20
P822634470	Sticks for filling - 5 x 5 x 20 mm x5 (Ind.)	x5 (Ind.)
P822634446	Sticks for filling - 5 x 5 x 20 mm (0.5 cm³)	x1
P822634450	Sticks for filling - 5 x 5 x 20 mm (3 cm³)	x6
P822634444	Sticks for filling - 5 x 5 x 20 mm (5 cm³)	x10
P822634445	Sticks for filling - 5 x 5 x 20 mm (10 cm³)	x20
P822634548	Sticks for filling - 5 x 5 x 20 mm (20 cm³)	x40

P822694220	Block for filling – 10 x 10 x 6 mm (0.6 cm³)	x1
P822694444	Block for filling – 10 x 10 x 25 mm (2.5 cm³)	x1
P822694446	Block for filling – 10 x 10 x 25 mm (5 cm³)	x2
P822374400	Block for filling - 30 x 20 x 10 mm (6 cm³)	x1

Reference	Description	Quantity
P822693210	Cubes for filling - 5 x 5 x 5 mm (0.12 cm³)	x1
P822693230	Cubes for filling - 5 x 5 x 5 mm (0.62 cm³)	x 5 (Ind.)
P822693221	Cubes for filling - 5 x 5 x 5 mm (0.62 cm³)	x5
P822693222	Cubes for filling - 5 x 5 x 5 mm (1.25 cm³)	x10
P822693225	Cubes for filling - 5 x 5 x 5 mm (2.5 cm³)	x20
P822693420	Cubes for filling - 7 x 7 x 7 mm (0.34 cm³)	x 1
P822693421	Cubes for filling - 7 x 7 x 7 mm (0.69 cm³)	x 2
P822693422	Cubes for filling - 7 x 7 x 7 mm (1.71 cm³)	x 5
P822693430	Cubes for filling - 7 x 7 x 7 mm (1.71 cm³)	x5 (Ind.)
P822693426	Cubes for filling - 7 x 7 x 7 mm (2.40 cm³)	x7
P822693630	Cubes for filling - 10 x 10 x 10 mm (1 cm³)	x5 (Ind.)
P822693620	Cubes for filling - 10 x 10 x 10 mm (1 cm³)	x1
P822693622	Cubes for filling - 10 x 10 x 10 mm (2 cm³)	x2
P822693623	Cubes for filling - 10 x 10 x 10 mm (5 cm³)	x5
P822693624	Cubes for filling - 10 x 10 x 10 mm (10 cm³)	x10
P822693626	Cubes for filling - 10 x 10 x 10 mm (15 cm³)	x15
P822692240	Granules for filling – Ø 1 mm (0.6 cm³)	x1
P822692243	Granules for filling - Ø 1 mm (2 cm³)	x1
P822692253	Granules for filling - Ø 1 mm (2 cm³)	x5 (Ind.)
P822692244	Granules for filling - Ø 1 mm (5 cm³)	x1
P822692254	Granules for filling - Ø 1 mm (5 cm³)	x3 (Ind.)
P822692245	Granules for filling - Ø 1 mm (10 cm³)	x1
P822692255	Granules for filling Ø 1 mm (10 cm³)	x3 (Ind.)
P822692249	Granules for filling - Ø 1 mm (20 cm³)	x2
P822692444	Granules for filling - Ø 1.5 mm (5 cm³)	x1
P822692453	Granules for filling - Ø 1.5 mm (5 cm³)	x3 (Ind.)
P822692447	Granules for filling - Ø 1.5 mm (10 cm³)	x1
P822692454	Granules for filling - Ø 1.5 mm (10 cm³)	x3 (Ind.)
P822692446	Granules for filling - Ø 1.5 mm (15 cm³)	x1
P822692451	Granules for filling - Ø 1.5 mm (20 cm³)	x2
P822692450	Granules for filling - Ø 1.5 mm (30 cm³)	x2
P822692452	Granules for filling - Ø 1.5 mm (45 cm³)	x3
P822692644	Granules for filling - Ø 3 mm (5 cm³)	x1
P822692653	Granules for filling - Ø 3 mm (5 cm³)	x3 (Ind.)
P822692647	Granules for filling - Ø 3 mm (10 cm³)	x1
P822692654	Granules for filling - Ø 3 mm (10 cm³)	x3 (Ind.)
P822692646	Granules for filling - Ø 3 mm (15 cm³)	x1
P822692649	Granules for filling - Ø 3 mm (20 cm³)	x2
P822692650	Granules for filling - Ø 3 mm (30 cm³)	x2
P822692652	Granules for filling - Ø 3 mm (45 cm³)	x3

SPONDYLODESIS

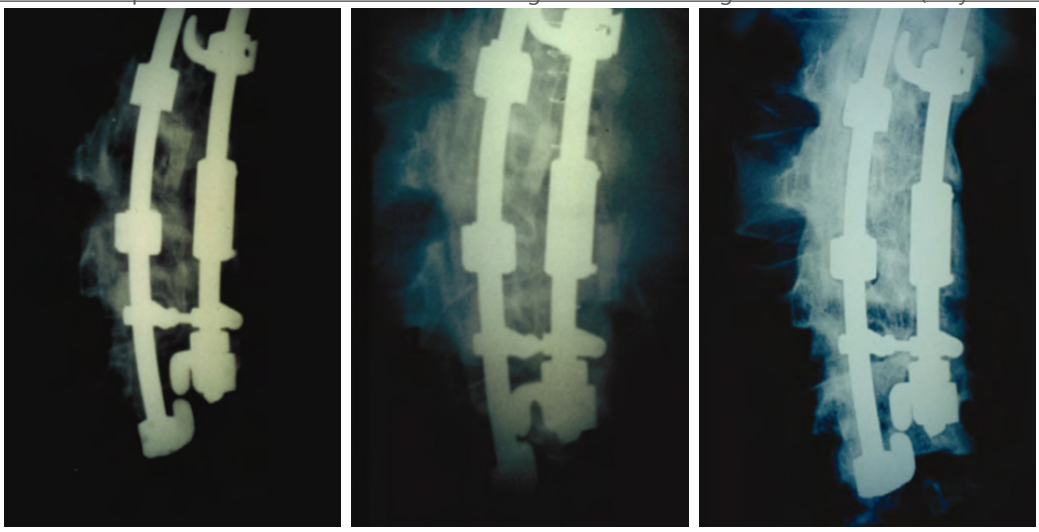
Postero-lateral fusion
ADULT AND PEDIATRIC (≥8 years old)

Surgical technique

1. Prepare bone surface until bleeding.
2. Place a rigid fixation system (surgical procedure independent of BIO 1®).
3. Place granules with autologous cancellous bone and patient blood.

Clinical case

Instrumented Idiopathic Scoliosis. Postero-lateral bone graft after reducing the deformation (20 years old) [11]



3 months post-op X-ray | 6 months post-op X-ray | 11 months post-op X-ray

References

Reference	Description	Quantity
P822692240	Granules for filling – Ø 1 mm (0.6 cm³)	x1
P822692243	Granules for filling - Ø 1 mm (2 cm³)	x1
P822692253	Granules for filling - Ø 1 mm (2 cm³)	x5 (Ind.)
P822692244	Granules for filling - Ø 1 mm (5 cm³)	x1
P822692254	Granules for filling - Ø 1 mm (5 cm³)	x3 (Ind.)
P822692245	Granules for filling - Ø 1 mm (10 cm³)	x1
P822692255	Granules for filling Ø 1 mm (10 cm³)	x3 (Ind.)
P822692249	Granules for filling - Ø 1 mm (20 cm³)	x2
P822692444	Granules for filling - Ø 1.5 mm (5 cm³)	x1
P822692453	Granules for filling - Ø 1.5 mm (5 cm³)	x3 (Ind.)
P822692447	Granules for filling - Ø 1.5 mm (10 cm³)	x1
P822692454	Granules for filling - Ø 1.5 mm (10 cm³)	x3 (Ind.)
P822692446	Granules for filling - Ø 1.5 mm (15 cm³)	x1
P822692451	Granules for filling - Ø 1.5 mm (20 cm³)	x2
P822692450	Granules for filling - Ø 1.5 mm (30 cm³)	x2
P822692452	Granules for filling - Ø 1.5 mm (45 cm³)	x3
P822692644	Granules for filling - Ø 3 mm (5 cm³)	x1
P822692653	Granules for filling - Ø 3 mm (5 cm³)	x3 (Ind.)
P822692647	Granules for filling - Ø 3 mm (10 cm³)	x1
P822692654	Granules for filling - Ø 3 mm (10 cm³)	x3 (Ind.)
P822692646	Granules for filling - Ø 3 mm (15 cm³)	x1
P822692649	Granules for filling - Ø 3 mm (20 cm³)	x2
P822692650	Granules for filling - Ø 3 mm (30 cm³)	x2
P822692652	Granules for filling - Ø 3 mm (45 cm³)	x3

CHIN OSTEOTOMY

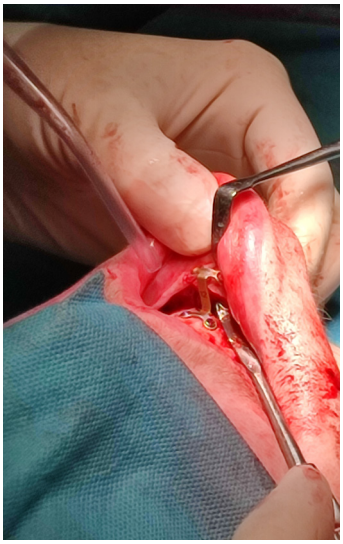
Genioplasty
ADULT AND PEDIATRIC (≥15 years old)

Surgical technique

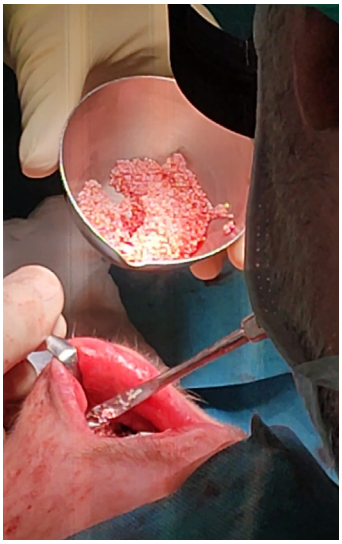
1. Prepare bone site.
2. Place a rigid fixation system (surgical procedure independent of BIO 1®).
3. Place granules with autologous PRF (Platelet-Rich Fibrin) into the void to be filled.
4. Complete the procedure by placing an autologous fibrin membrane to stabilize the granules at the bone site.

Surgical case

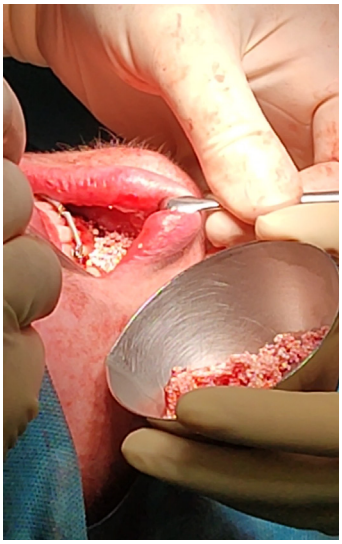
Chin wing genioplasty by Dr Saboye Dr. Saboye*



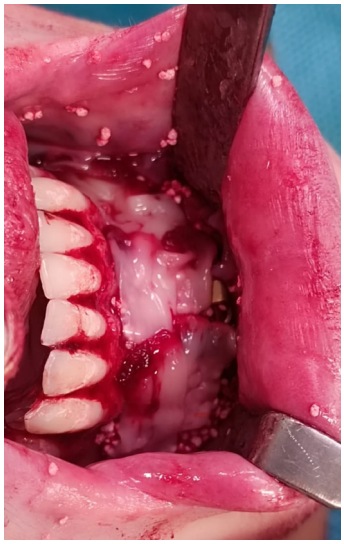
Void before filling



Mix of granules
with autologous PRF



Void filling with BIO 1®
and autologous PRF mix



Placing a PRF membrane to
stabilize fixation

*Clinical case by courtesy of Dr. Saboye

References

Reference	Description	Quantity
P822692240	Granules for filling – Ø 1 mm (0.6 cm³)	x1
P822692243	Granules for filling - Ø 1 mm (2 cm³)	x1
P822692253	Granules for filling - Ø 1 mm (2 cm³)	x5 (Ind.)
P822692244	Granules for filling - Ø 1 mm (5 cm³)	x1
P822692254	Granules for filling - Ø 1 mm (5 cm³)	x3 (Ind.)
P822692245	Granules for filling - Ø 1 mm (10 cm³)	x1
P822692255	Granules for filling Ø 1 mm (10 cm³)	x3 (Ind.)
P822692249	Granules for filling - Ø 1 mm (20 cm³)	x2
P822692444	Granules for filling - Ø 1.5 mm (5 cm³)	x1
P822692453	Granules for filling - Ø 1.5 mm (5 cm³)	x3 (Ind.)
P822692447	Granules for filling - Ø 1.5 mm (10 cm³)	x1
P822692454	Granules for filling - Ø 1.5 mm (10 cm³)	x3 (Ind.)
P822692446	Granules for filling - Ø 1.5 mm (15 cm³)	x1
P822692451	Granules for filling - Ø 1.5 mm (20 cm³)	x2
P822692450	Granules for filling - Ø 1.5 mm (30 cm³)	x2
P822692452	Granules for filling - Ø 1.5 mm (45 cm³)	x3
P822692644	Granules for filling - Ø 3 mm (5 cm³)	x1
P822692653	Granules for filling - Ø 3 mm (5 cm³)	x3 (Ind.)
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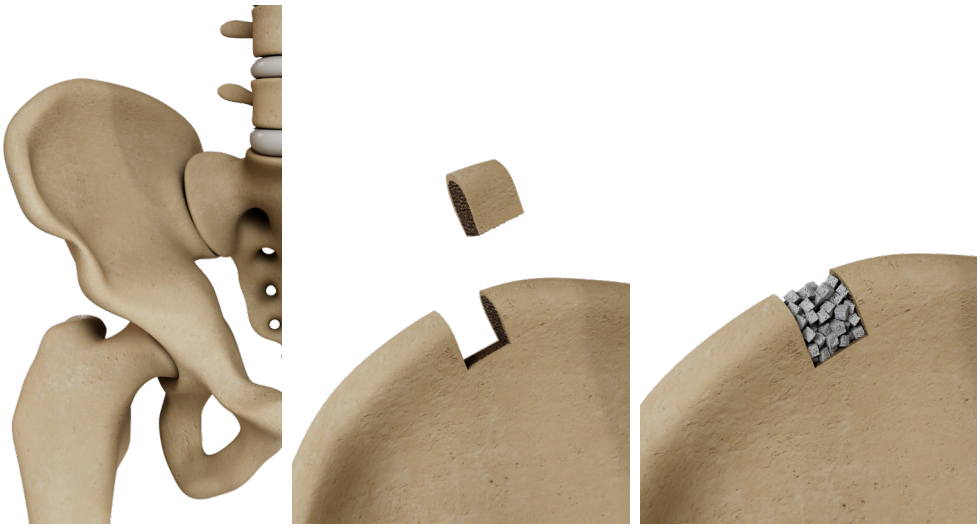
P822692654	Granules for filling - Ø 3 mm (10 cm³)	x3 (Ind.)
P822692646	Granules for filling - Ø 3 mm (15 cm³)	x1
P822692649	Granules for filling - Ø 3 mm (20 cm³)	x2
P822692650	Granules for filling - Ø 3 mm (30 cm³)	x2
P822692652	Granules for filling - Ø 3 mm (45 cm³)	x3

CREST ILIAC DEFECTS AFTER BONE GRAFT HARVESTING

Bone void created by a surgical procedure
ADULT

Surgical technique

1. Assess the size and bone defect.
2. Mix the macroporous cubes with the patient's blood to form a homogeneous coagulum.
3. Pack the mixture into the bone defect.



References

Reference	Description	Quantity
P822893224	Macroporous cubes for filling - 4 x 4 x 4 mm (5 cm³)	x1
P822893229	Macroporous cubes for filling - 4 x 4 x 4 mm (15 cm³)	x1
P822893233	Macroporous cubes for filling - 4 x 4 x 4 mm (30 cm³)	x2

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Carefully read the instructions on the package leaftet that accompanies the medical device or on the label given to the healthcare provider.
Intended use: Intended to fill bony voids or gaps of the skeletal system (i.e.* the extremities, spine and pelvis) caused by trauma or surgery, that are not intrinsic to the stability of the bony structure. BIOSORB® Resorbable Void Filler does not possess sufficient mechanical strength to support reduction of a defect prior to soft and hard tissue ingrowth. Rigid fixation techniques are recommended as needed to assure rigid stabilization of the defect in all planes.

Manufacturer : S.B.M. SAS.

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