Bone void filling

Injectable self-hardening bone substitute

BIO 1-QUICKSET®

- Bioabsorbable and osteoconductive material
- Fast mixing and setting time
- All-in-one pack / Ready to use

SBM
Science & Bio Materials

A simple and fast mix

BIO 1-QUICKSET® is a synthetic bone substitute designed to fill osseous defects that are not subjected to mechanical stresses (< 6 MPa). BIO 1-QUICKSET® is pre-dosed and ready to use which makes it safe, quick and easy.

BIO 1-QUICKSET® comprises a pre-loaded syringe filled with an osteoconductive[1] and bioabsorbable[1] powder made with β-TCP (Tricalcium Phosphate), a vial of saline solution, and a cannula. When the saline solution is added to the contents of the pre-loaded syringe, a self-hardening paste is formed which can be injected *in situ* in hard to reach areas thanks to the cannula. The system ensures optimal filling of irregular bone defects and improves implant-bone contact.

The pack

Bio 1-QUICKSET® is composed of the following items:

Characteristics

Simple
- All-in-one: no additional items needed.
- Can be injected in hard to reach areas thanks to the cannula.
- Radiopaque[2]: compatible with MRI & X-ray imaging techniques

Safe
- Reputed material: bioabsorbable[1], bioactive[1] and osseoconductive[1].
- Mixture prepared in completely aseptic conditions.
- Isothermal[2]: the amount of heat generated is insignificant.

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

Indications

BIO 1-QUICKSET® is indicated for the filling of defects/ gaps (either manually or via injection) that are not intrinsic to the stability of the bony structure (for example the extremities, spine and pelvis). These open bone voids may be the result of benign cysts or bone tumors, they may be surgically created or due to traumatic injury to the bone marrow.

BIO 1-QUICKSET® injectable self-hardening bone substitute provides an open void/gap filler that can augment provisional hardware (e.g. K Wires or other osteosynthetic devices) to help support bone fragments during the surgical procedure. Indeed, BIO 1-QUICKSET® acts only as a temporary support media and is not intended to provide structural support during the healing process. For this same reason, BIO 1-QUICKSET® cannot be used for vertebroplasty or kyphoplasty.

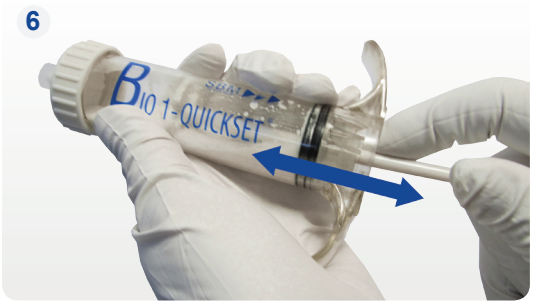
Surgical Technique

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.

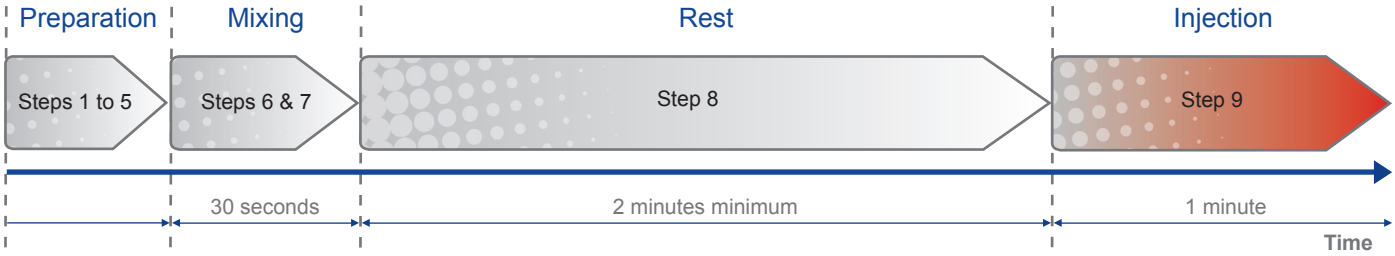
INJECTION

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

Precautions
It is important to always respect the injection time.



Bibliography

[1] **Use of β-tricalcium phosphate in foot and ankle surgery : a report of 20 cases:**
L. Galois, D. Mainard, F. Pfeffer, R. Traversari, J-P Delagoutte. Foot and Ankle Surgery. 2001;7(4):217-27

[2] **Evaluation of a resorbable, In Situ setting bone substitute in a sheep model:**
C. Niedhart, U. Maus, W. Piroth, O. Miltner, B. Schimdt-Rohlfing, C.H. Siebert. J Biomed Mater Res Part B: Appl Biomater 71B: 123–129, 2004

[3] **In vivo testing of a new in situ setting β-tricalcium phosphate cement for osseous reconstruction:**
C. Niedhart, U. Maus, E. Redmann, C.H. Siebert. J Biomed Mater Res 55: 530–537, 2001

[4] **Facts & figures - Bio 1-Quickset - Setting and hardening time, injectability, and compressive strength:**
S. Moisenier, SBM Scientific Research & Development, 2011

Ordering information

Codes	*Designation*	*Packaging*
QUICK26220	Injectable self-hardening bone void filler (5 cm^3 syringe size M + accessories)	1
QUICK26230	Injectable self-hardening bone void filler (10 cm^3 syringe size L + accessories)	1
QUICK26240	Injectable self-hardening bone void filler (15 cm^3 syringe size L + accessories)	1

Bone void filling | ACL reconstruction | Osteotomies around the knee | Cervical spine

About SBM

SBM (Science for BioMaterials) has been specialized in the design, manufacturing and distribution of biomaterials for bone surgery since 1991.

The company's priority is the development and optimization of medical devices in favor of bone healing and human tissue replacement. By completely controlling its technique in biomaterials, the company elaborates a range of innovative, 100% synthetic and absorbable systems along with specific ancillary instrumentation.

Firmly established on the French domestic market, SBM has expanded its activities abroad in more than 40 countries for the sales and development of new products, in order to better meet the demands of the medical industry worldwide.

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CE 0459 ISO 13485

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