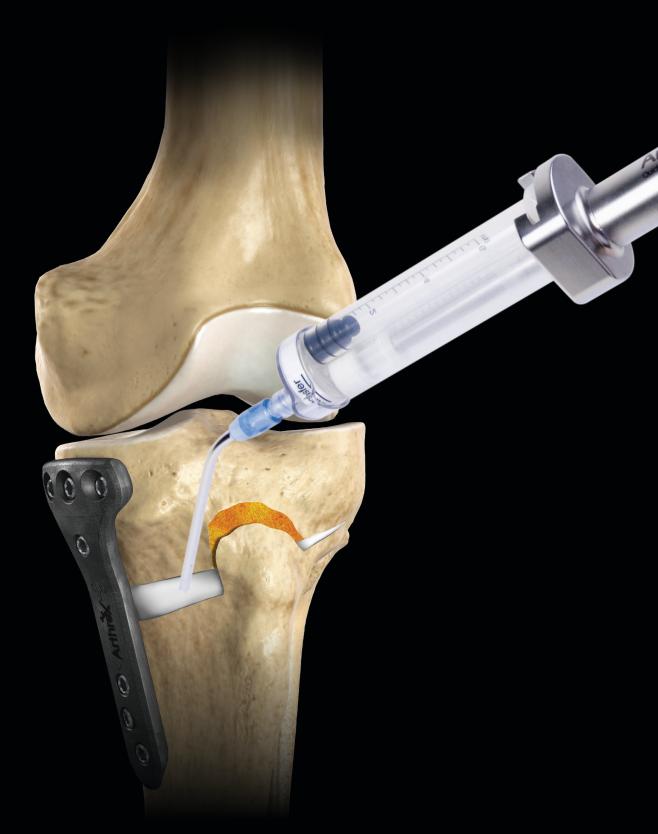
Quickset[™] Bone Cement

Injectable Macroporous Calcium Phosphate





Quickset™ Bone Cement

Features and Benefits

Quickset is a macroporous, injectable, hardening, resorbable bone cement provided in an easy-to-use, closed mixing system.

Composition

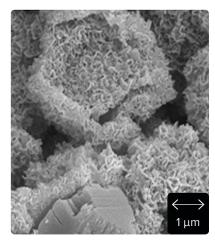
- The mixing system is a dual-chambered syringe containing a powder and mixing liquid
- > The powder chamber contains a mixture of calcium phosphates and an organic polysaccharide polymer
 - The polysaccharide is a highly biocompatible polymer that optimizes the viscosity, cohesiveness, and macroporosity
- > The mixing liquid consists of a sodium phosphate solution which facilitates the setting time (crystallization) of the cement
- The end product is a calcium-deficient apatite very similar to the mineral phase of bone

Physical and Chemical Properties

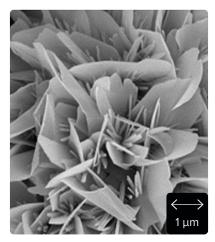
- > Global porosity of 70%
 - > Microporosity (<10 μm): 88%
 - > Mesoporosity (10-100 μm): 2%
 - > Macroporosity (>100 μm): 10%
- Porosity is present by the time it reaches complete hardening (24 hours after implantation)
- Mechanical compressive strength of 24 MPa (24 hours after implantation)
- > Excellent cohesiveness, which prevents wash out by biological fluids
- > No shrinkage during crystallization
- > Nonexothermic reaction
- > Radiopaque

Preparation

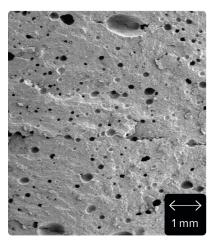
- > Mixing time (room temperature): 2 minutes
- > Injection time (room temperature): 2 minutes
- > Initial setting time (body temperature): 8 minutes (manipulation during this time period is not recommended as it will affect the crystallization process and final strength characteristics)
- > Complete hardening (body temperature): 24 hours



Beginning of crystalization process



Crystalization process completed



Crystalization process completed showing presence of porosity

Scientific Assessment of Quickset™ Bone Cement

The key to bone graft resorption and substitution is the porous nature of the bone graft being used. Quickset cement was designed to maximize porosity on a micro and macro level without compromising its strength characteristics or injectable capabilities. Technical analyses, via a preclinical model and clinical case report, highlight how Quickset cement's porosity contributes toward osteointegration.

Preclinical Scientific Support for Quickset Cement

A critical-sized femoral defect was created in a rabbit model and filled with Quickset cement. At four weeks, these defects were evaluated with scanning electron microscopy (SEM) and histologic assessments. The SEM images demonstrated significant porosity within the implant, along with bone remodeling (Figure 1). The histological staining identified new bone deposition around and within the Quickset cement (Figure 2).

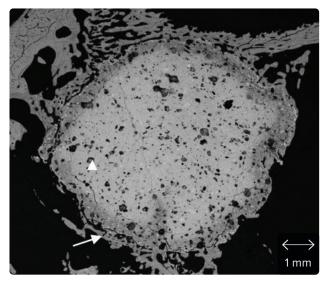
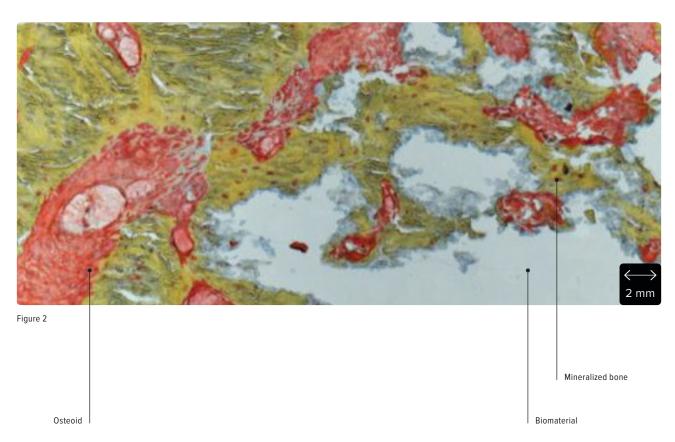


Figure 1



Clinical Case Report Supporting Quickset™ Cement

A complex tibial plateau fracture was treated with ORIF, then Quickset cement was used to fill in the bone voids that remained (Figure 1 and 2). At four months, the wires and a screw were removed and a biopsy was taken. Histological analysis demonstrated good osteointegration of the Quickset cement in direct contact with new bone trabeculae (no fibrous interface). An intertwining network developed as the biomaterial resorbs and mineralized lamellar bone is laid down. Osteoblastic cells were along the osteoid borders going through mineralization; osteoclastic cells were along the borders of the biomaterial representing the resorption process. In addition, numerous blood vessels had been established through the implant (Figure 3). At eight months, fracture healing, along with osteointegration of Quickset, was noted via x-ray evaluation (Figure 4).



Figure 1. Preoperative scan



Figure 2. Immediate postoperative

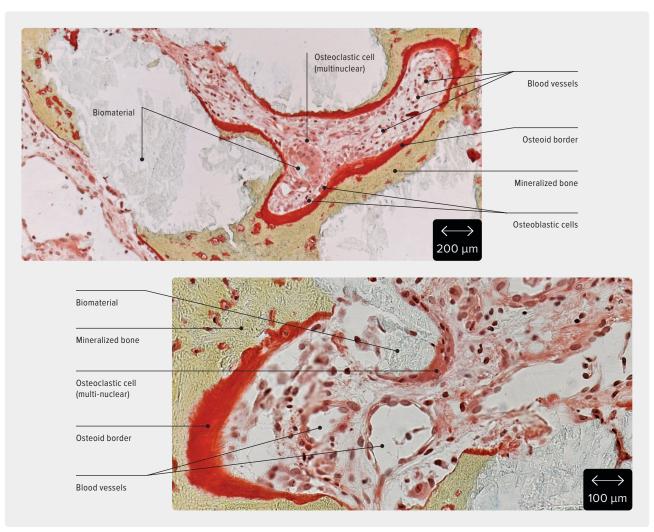


Figure 3. Four months postoperative histology sections at 10× and 20× magnification

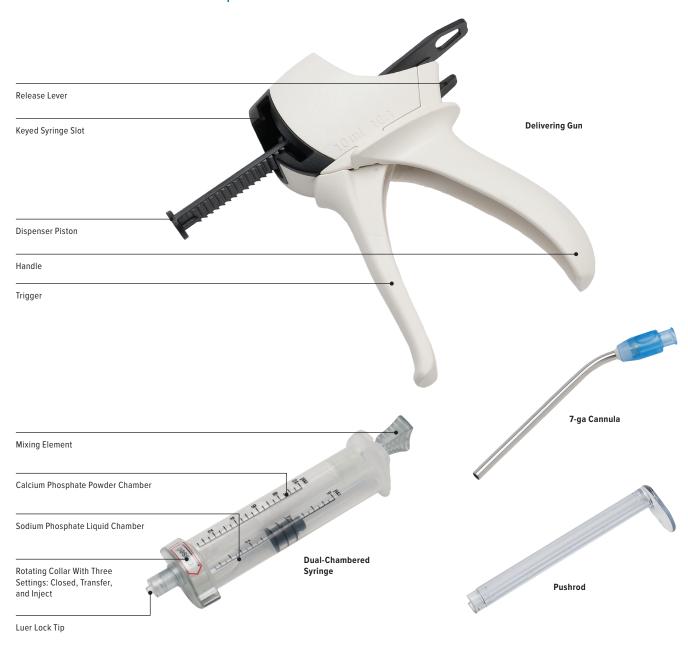
Calcium phosphate bone cements have been demonstrated to play a significant role within orthopaedic surgery. A meta-analysis of randomized trials demonstrated the following: "Patients managed with calcium phosphate had a significantly lower prevalence of loss of fracture reduction in comparison with autograft... and had less pain at the fracture site in comparison with controls managed with no graft..."¹ This study helps to establish the effectiveness calcium phosphate bone cements have within fracture management. When deciding to use a resorbable bone cement, it is important to understand its incorporation capabilities. Quickset™ cement has been shown to have good osteointegration qualities on the periphery and within the biomaterial due to its unique presence of porosity.



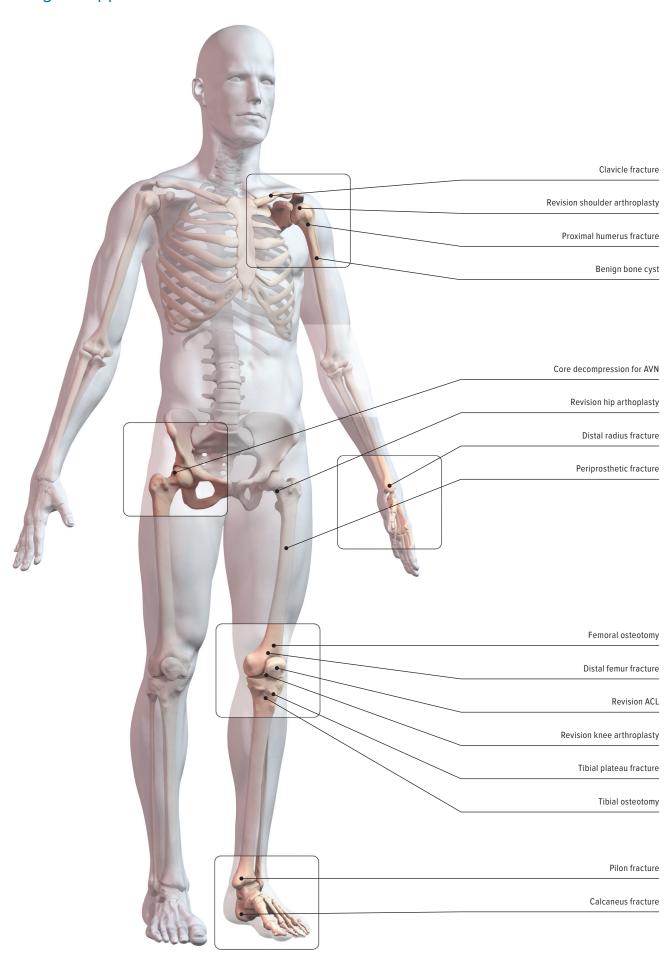


Figure 4. Eight months postoperative AP and ML x-rays

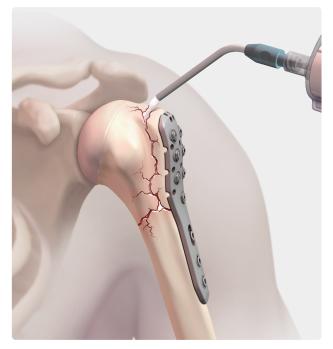
Quickset Cement Kit Components



Surgical Applications



 $\label{eq:Quickset} \text{Quickset}^{\tiny{\mathbb{M}}} \text{ bone cement can be used to help stabilize bone fragments within highly comminuted fractures}.$



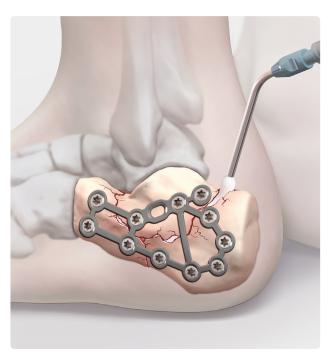
Proximal humerus fracture



Pilon fracture



Distal radius fracture



Calcaneus fracture

Important suggestions to keep in mind when using Quickset cement

- > Use to fill bony voids after initial rigid fixation is obtained; the Quickset bone substitute is not intended to be used as a load-bearing device
- > Prevent unnecessary manipulation during the initial setting time to avoid disruption of the crystallization process
- > Drilling can take place through the bone substitute after the initial setting time is complete

Directions For Use



01

Assemble the gun. Lift up on the release lever and insert the flat end of the dispenser piston (teeth facing down) through the front of the delivering gun. Guide the piston through the gun until the dispensing, circular part is flush against the delivering gun. Set the delivering gun to the side until needed for delivery of Quickset™ cement.



02

Place the syringe selector on "transfer" by rotating the collar clockwise. Hold the syringe with the luer tip facing upwards, connect the pushrod to the piston within the liquid chamber and advance it until all the liquid has passed into the powder chamber. Remove the pushrod.



03

To mix the powder and liquid phases together, push and pull the mixing element back and forth while rotating it in a repeated left-to-right motion.

Note: This process of mixing should continue for 2 minutes.



04

After mixing for 2 minutes, pull the mixing element as far back as possible out of the chamber. Bend the mixing element so that it breaks at its base.



05

Rotate the collar clockwise to "inject". Insert the dual-chambered syringe into the keyed syringe slot on the delivering gun with the markings on the syringe facing upwards. Compress the trigger in order to push the piston forward and expel any excess air.



06

Connect the 7-ga cannula (if needed) to the luer tip portion of the syringe. Dispense Quickset™ resorbable bone cement by compressing the trigger and handle together. To inject a second dose, press up on the release lever, pull back the piston to its starting point, remove the first dual-chambered syringe and insert a second dual-chambered syringe.

Optional Use Without Delivering Gun



07

Pull the mixing element out of the mixing chamber but do not break it off. Use the pushrod from the liquid chamber and clip it onto the rod associated with the mixing element.



08

Rotate the collar to "inject" and slowly apply pressure to the pushrod to expel any excess air. Connect the 7-ga cannula to the luer tip, then apply additional pressure to the pushrod in order to dispense the Quickset resorbable bone cement.

Ordering Information

Quickset™ cement, 5 cc	ABS-3005
Quickset cement, 8 cc	ABS-3008
Quickset cement, 16 cc	ABS-3016

Products advertised in this brochure / surgical technique guide may not be available in all countries. For information on availability, please contact Arthrex Customer Service or your local Arthrex representative.

Reference



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Arthrex manufacturer, authorized representative, and importer information (Arthrex eIFUs)



US patent information