Instructions For Use ARTHREX® QUICKSET
Injectable Macroporous Calcium Phosphate

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DEFINITION

ARTHREX® QUICKSET KIT is a convenience kit intended to be used in orthopaedic surgery. ARTHREX® QUICKSET KIT is composed of 3 devices: ARTHREX® QUICKSET a sterile injectable macroporous calcium phosphate bone void filler available in 5cc, 8cc and 16cc (8cc x2), a sterile delivering gun and a sterile 7G cannula.

DESCRIPTION

ARTHREX® QUICKSET is an injectable self-hardening macroporous synthetic calcium phosphate bone substitutes. It comes in a double-compartment mixing syringe which is pre-filled with a powder (calcium phosphate salts and HPMC) and with a phosphate-based (Na_2HPO_4) aqueous solution. When these two components are mixed in the syringe, 5cc or 8cc of an injectable calcium-deficient apatite is endothermically formed which hardens in vivo, in approximately 8 min.
ARTHREX® QUICKSET is a sterile single-use product.
ARTHREX® QUICKSET Delivering Gun is intended to be used exclusively with the ARTHREX® QUICKSET bone void filler syringe. This device is sterile and single-use.
The cannula is intended to be connected to the ARTHREX® QUICKSET syringe tip. This device is sterile and single-use.

INDICATIONS

ARTHREX® QUICKSET is intended for bony voids or defects that are not intrinsic to the stability of the bony structure. ARTHREX® QUICKSET is intended to be placed or injected into bony voids or gaps of the skeletal system (the extremities and pelvis).These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides bone void filler that resorbs and is replaced with bone during the healing process.

CONTRA-INDICATIONS

ARTHREX® QUICKSET must not be used in the following cases:
• An infected site, or suspected of being so
• A bone site which can lead to the product passing into the joint cavities or into the meningeal spaces
• A site which cannot be stabilised

WARNINGS & PRECAUTIONS

• ARTHREX® QUICKSET must be prepared and implanted under aseptic conditions by qualified personnel who have carefully read these instructions for use. Any product surplus which might be present in the adjacent soft tissues must be removed. Extrusion of the device beyond the site of its intended application could damage the surrounding tissues.
• The ARTHREX® QUICKSET syringe is specifically designed so that a syringe accessory can be fitted to the luer lock tip (catheter or trocar). In order to maintain the injection properties of ARTHREX® QUICKSET, the diameter of the accessory used must be greater than or equal to 7G. When the ARTHREX® QUICKSET syringe is used with an accessory, the loss of useful volume of the injected product must be anticipated.
• The operation site must be cleaned with a sterile saline solution or sterile water. It must be clean and dry, as much as possible and must not be irrigated after the implantation.
• A pre-operative plan which includes the preparation, injection, setting time, and the number of ARTHREX® QUICKSET syringes required to complete the filling operation is recommended.

Device	Mixing time between 20°C-22°C 68°F to 71.6°F	Working time between 20°C-22°C 68°F to 71.6°F	Setting time 37°C ; 98.6°F
ARTHREX® QUICKSET	2min	2min	8min

• ARTHREX® QUICKSET is not intended to be a load-bearing device. Therefore, rigid fixation techniques may often be recommended.
• The setting time in vivo is approximately 8 min for ARTHREX® QUICKSET, provided that during this time the implanted product is neither re-worked nor rinsed.
• In order to provide an optimum mode of action, the implant needs to be in complete and appropriate contact with the bone.
• Caution: injecting ARTHREX® QUICKSET under high pressure in a closely confined and/or highly irrigated bone site is inadvisable due to the risk of embolism.
• The radiopacity of ARTHREX® QUICKSET must be taken into account when taking radiographs.
• The safety and efficacy of ARTHREX® QUICKSET in contact with allografts, or acrylic, silicon, or polymer devices have not been established.
• The safety and efficacy of ARTHREX® QUICKSET when combined with devices with similar indications or medicinal substances have not been established.
• The safety and efficacy of ARTHREX® QUICKSET have not been established in the following populations:

- o Patients with acute or chronic infections, particularly in the implantation site or near to it,
- o Patients with inflammatory bone diseases such as osteomyelitis,
- o Patients with a calcium metabolism anomaly, severe metabolic, vascular or neurological diseases, or immunological deficiencies,
- o Patients not having reached bone maturity,
- o Pregnant or breast-feeding women,
- o Patients undergoing radiotherapy or chemotherapy,

ADVERSE EFFECTS

The adverse effects of ARTHREX® QUICKSET are those related to this type of surgery.
They include but are not restricted to:
• Wound infection
• Non-consolidation
• Wound dehiscence
• Delayed consolidation
• Loss of reduction,
• Re-fracture
The occurrence of any of these effects may require additional surgery and/or removal of the material

PREPARATION (read attentively before using the product)

ARTHREX® QUICKSET is provided in an ancillary device which enables its preparation and injection under ideal conditions.

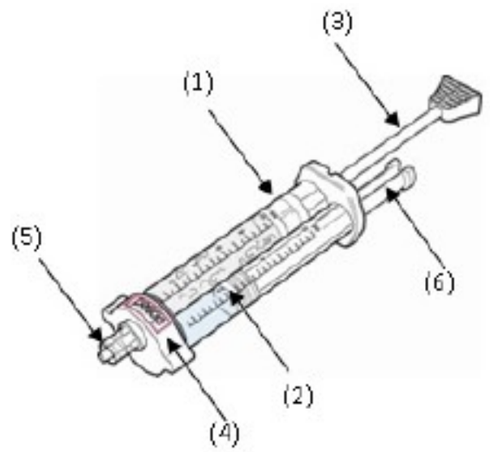


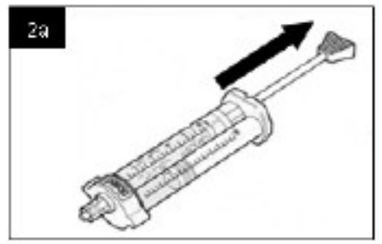
Fig. 1: Ancillary device

The ancillary device shown in figure 1 consists in:
• Two independent chambers, one containing powder (1), and the other containing the hardening liquid (2).
• A mixer placed in the powder compartment (3).
• A multi-position selector which enables the transfer of the hardening liquid into the powder chamber, and then the injection of the cement (4).
• A luer lock tip to which a catheter or trocar can be attached in order to guide the injection (5).
• A pushrod or plunger (6), which enables pressure to be applied to the piston of the chamber containing the liquid in order to transfer it into the compartment containing the powder.

IMPORTANT: to guarantee the optimum properties of the ARTHREX® QUICKSET preparation, the level of the hardening liquid must be between the 3.5 ml and 4 ml graduation marks for the 8cc reference, between 2.5 and 3ml for the 5cc reference. It is important to respect the following stages of ARTHREX® QUICKSET preparation before its injection.

1st stage: Transfer of the hardening liquid

Open the sterile packaging and pull the mixing rod back (fig.2a)



For this stage the tip of the syringe must be held upwards. Place the syringe selector on "transfer" by rotating the collar clockwise (fig 2b).
Connect the plunger (fig 3) to the piston of the hardening liquid chamber and advance it until all the liquid has passed into the chamber containing the powder.

2nd stage: "powder + hardening liquid" mixture

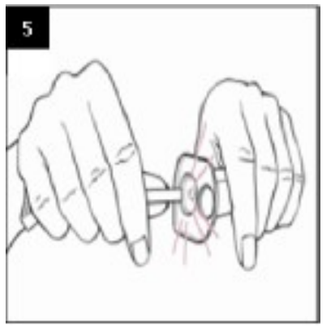
To mix the powder and the hardening liquid, hold the syringe with one hand while holding the end of the mixer with the other hand and rotate in a repeated left-to- right motion until both ends come to a stop (fig 4). At the start of the mixing operation a small amount of powder might escape through the stopper.

IMPORTANT: It is important to repeat these movements for **two (2) minutes** in order to obtain a uniform mixture. Make sure the product is thoroughly mixed at both ends. Without proper mixing, the product cannot be injected.
Once the mixing phase is completed, flow the paste to the extremity opposite to the injection side in order to have all the air ready to be expelled when starting the injection.

3rd stage: Injection

1. Injection using the ARTHREX® QUICKSET Delivering Gun

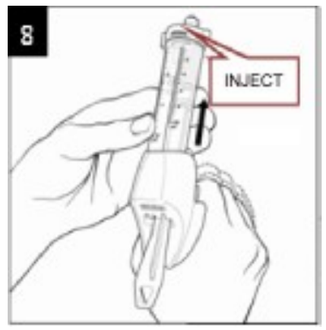
After having prepared ARTHREX® QUICKSET according to the ARTHREX® QUICKSET KIT Instruction for use § Preparation (Fig. 1 to 4), pull and break the mixing rod at its base (Fig.5), after checking that the stopper is at the very back end of the syringe. If not, pull the stopper back into correct position.



Place the syringe selector on "inject" by rotating the collar clockwise (fig 6).

Connect the syringe to the ARTHREX® QUICKSET Delivering Gun (fig 7), ensuring that the graduations of the syringe are facing upwards.

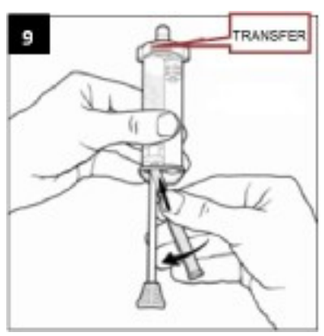
Hold the ARTHREX® QUICKSET Delivering Gun-syringe unit vertically with the syringe tip upwards (fig 8). Connect the cannula to the syringe tip. Slowly press on the trigger in order to push the piston and expel the air. Then, inject the ARTHREX® QUICKSET bone void filler.



To inject a second dose of ARTHREX® QUICKSET, press on the tab at the rear of the ARTHREX® QUICKSET Delivering Gun and pull the black "piston-push device" fully in order to remove the syringe.

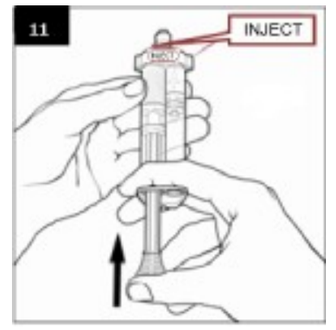
2. ARTHREX® QUICKSET also may be used without the delivering gun by following the next steps

Pull the mixer down to the piston stop. Remove the plunger from the liquid chamber and clip it on to the rod of the mixer (fig 9). The mixer is now stabilized.



Place the syringe selector on "inject" by rotating the collar clockwise (fig 10).

Hold the syringe in a vertical position with the tip upwards. Slowly press the piston in order to expel the air. Then push the plunger and mixer in order to inject the ARTHREX® QUICKSET (fig 11).



STERILIZATION AND STORAGE

ARTHREX® QUICKSET and ARTHREX® QUICKSET Delivering Gun are sterilized by gamma radiation. The cannula is sterilized by ethylene oxide.
ARTHREX® QUICKSET must be kept at room temperature (between 10°C/50° F and 40°C/104°F).
Before use: check the expiration date, ensure that the sterility protector is intact, and that the sterilization indicator is red. DO NOT USE if the product packaging is opened or damaged. Do not use if the sterilization indicator is not red.
ARTHREX® QUICKSET and ARTHREX® QUICKSET Delivering Gun and cannula are single-use products which must be neither re-used nor re-sterilized.

CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN

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