EN – INSTRUCTIONS FOR USE – Injectable Macroporous Calcium Phosphate

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ARTHREX® QUICKSET KIT

NORAKER
THE BIOGLASS® COMPANY
60, Avenue Rockefeller
69008 LYON, France
Tel: +33 (0)4 78 93 30 92
www.noraker.com

Manufactured for
Arthrex, Inc
1370 Creekside Blvd
Naples, FL 34108, USA
Ph. : +1 (800) 934 4404
www.arthrex.com

References	Volume
ABS-3005	5 cc
ABS-3008	8 cc
ABS-3016	16 cc

List of symbols

	Do not use if package is damaged and consult instruction for use
	Manufacturer
2025/12	Last update
REF	Reference
LOT	Batch number
	Use-by date
QTY	Quantity
STERILE EO	Sterilized by ethylene oxide treatment
25°C 15°C	Temperature limit 15-25°C (storage)
	Do not reuse
STERILE R	Sterile, Gamma irradiation
2 STERILIZE	Do not resterilize
	Manufacturing date
MR	MR safe
VOL	Volume (cc / cm^3)
MD	Medical Device
	Single sterile barrier system with protective packaging outside
	Single sterile barrier system
eifu.noraker.com	Consult electronic instructions for use
UDI	Unique Device Identifier

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 cannula.

Description

ARTHREX® QUICKSET is an injectable self-hardening macroporous calcium phosphate bone void filler. It is provided in a double-compartment mixing syringe which is pre-filled with a powder (calcium phosphate salts and HPMC) and with a phosphate-based (Na2HPO4) aqueous solution. Mixing of these two components in the syringe results in an injectable paste, which hardens under in vivo conditions. The final product formed during the setting reaction is a calcium-deficient apatite.

ARTHREX® QUICKSET Delivering Gun is intended to be used exclusively with the ARTHREX® QUICKSET bone void filler syringe. The cannula is intended to be connected to the ARTHREX® QUICKSET syringe tip.

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 (i.e., 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.

Contraindications

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.
• A bone site which can lead to the product passing into the meningeal spaces.
• A site which cannot be stabilized.

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, we recommend using only the accessory supplied. 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 the implant must not be subjected to aggressive lavage during the surgery.
• 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.
• Two minutes of mixing are necessary to reach an homogeneous texture at 20-22°C
• The injection/working time is two minutes to implant or sculpt the product into the defect.
• The injection/working time might be shorter in cases of a room temperature higher than 22°C.
• The product should not be re-worked after the working time.
• The surgical site can be closed and the product will only be fully hardened after 24h at 37°C.

• The setting starts at 37°C within approximately 6-20 min. During the setting reaction, the product keeps a paste-like texture.
• The setting time reaction is strongly temperature dependent and gets longer when temperatures are lower than 37°C.
• In order to provide an optimum mode of action, the implant needs to be in complete and appropriate contact with the bone.
• 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 is slightly higher than the trabecular bone and must be taken into account during radiographic analysis.
• This product is not cleared for use in Vertebroplasty or Kyphoplasty.
• ARTHREX® QUICKSET is not intended to be used as a load-bearing device.
• 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, near to the implantation site,
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.

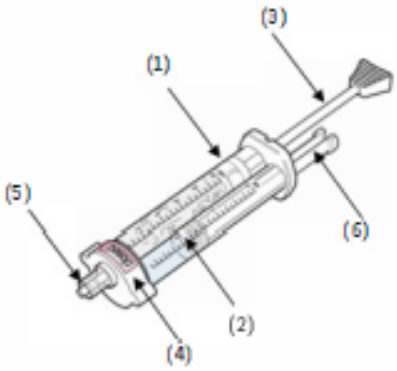


Fig 1: Ancillary device

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

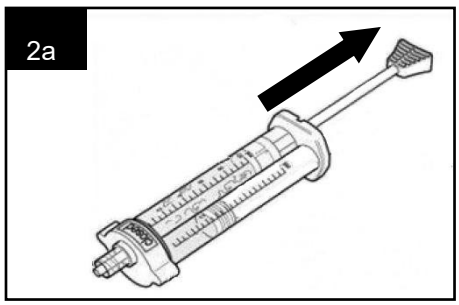
5 cc syringe	8 cc syringe
between 2,5 ml and 3 ml	between 3,5 ml and 4 ml

It is important to respect the following stages of ARTHREX® QUICKSET preparation before its injection.

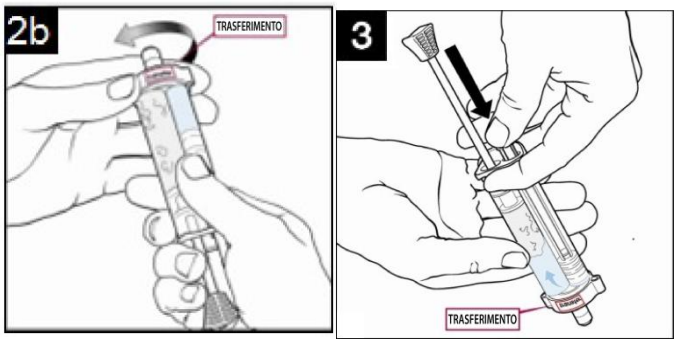
1st stage: Transfer of the hardening liquid

Open the sterile packaging and use the product in aseptic conditions.

Pull the mixing rod and the stopper back (If it is not already at the very back end of the powder chamber) (fig.2a).



Turn the tip of the syringe upwards. Place the syringe selector on "transfer" by rotating the collar clockwise (fig 2b). Turn the tip of the syringe downwards, Connect the plunger (fig 3) to the piston of the hardening liquid chamber and advance it until all the liquid is driven 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 (fig 4). Be certain to reach both extremities of the powder chamber. 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 extremities. Without proper mixing, the product cannot be injected.

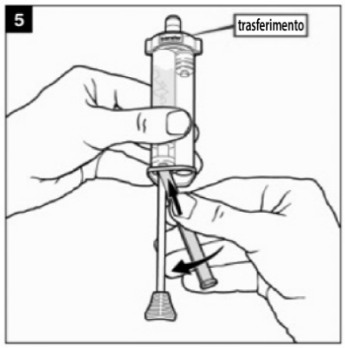
Once the mixing phase is completed, flow the paste to the extremity opposite to the injection side in order to have all the air ready to be expelled when starting the injection.

3rd stage: Injection

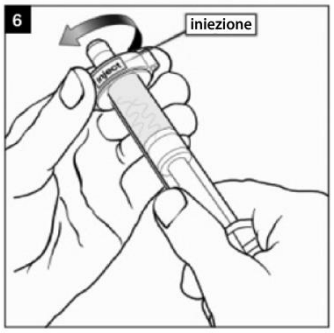
ARTHREX® QUICKSET can be injected by two methods:
- Direct injection
- Injection using the sterile ARTHREX® QUICKSET Delivering Gun

1. Direct injection

Gently pull the mixer rod down to expose the full length of the rod. Remove the plunger from the liquid chamber and snap it over the rod of the mixer (fig. 5) mixing rod + plunger can be now used as an injection piston.



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

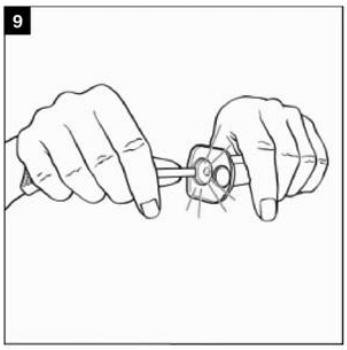


Hold the syringe in a vertical position with the tip upwards. Slowly press the piston in order to expel the air (use a gauze to avoid any projection of the product) until product starts to be extruded. (fig. 7).

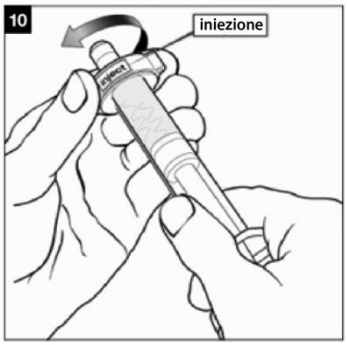
If needed, connect the cannula to the syringe tip (fig 8) and push the injection piston in order to expel the air (use a gauze to avoid any projection of the product) until product starts to be extruded and inject the ARTHREX® QUICKSET. Try to inject in one attempt and discard the rest.

2. Injection using the ARTHREX® QUICKSET Delivering Gun

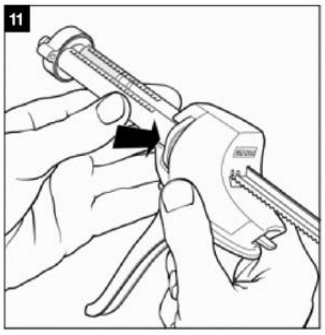
After the hardening liquid has been transferred and mixed with the powder (Fig. 1 to 4), pull and break the mixing rod at its base (fig. 9), after checking that the stopper is at the very back end of the powder chamber. If not, pull the stopper back into correct position.



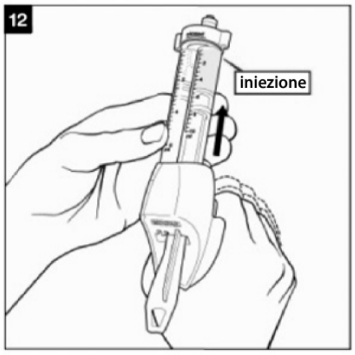
Place the syringe selector on "inject" by rotating the collar clockwise (fig. 10).



Connect the syringe to the ARTHREX® QUICKSET Delivering Gun (fig. 11), 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. 12). Slowly press on the trigger in order to expel the air (use a gauze to avoid any projection of the product) until product starts to be extruded.



If needed, connect the cannula to the syringe tip (fig 13). Slowly press on the trigger in order to expel the air (use a compress to avoid any projections) until product starts to be extruded. Then, inject the ARTHREX® QUICKSET bone void filler. Try to inject in one attempt and discard the rest.

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

This device is MR safe.

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 15°C/59°F and 25°C/77°F).
Before use: check the expiration date. DO NOT USE if the product packaging is opened or damaged. ARTHREX® QUICKSET and ARTHREX® QUICKSET Delivering Gun and cannula are single-use products which must be neither re-used nor re-sterilized.
Reuse could lead to infection or inflammation and would not enable the healing process.

Caution: Federal law restricts this device to sale by or on the order of a physician.

Document update

2025/12