PATIENT INFORMATION LEAFLET

Patient information materials assist patients to:
- understand the medical device being implanted, both prior to and following surgery;
- have informed consent conversations with their health professional; and
- report any adverse events associated with their implanted medical device.

1. Device identification

(a) the name of the device

The device is named ARTHREX® QUICKSET KIT.

(b) the model of the device

They are different references depending on the volume of the product.

Reference	Designation	Volume*
ABS-3005	ARTHREX® QUICKSET KIT	5 cc
ABS-3008		8 cc
ABS-3016		16 cc

*The volume is express in cc, 1cc=1cm^3

2. Intended use

(a) the intended purpose of the device

ARTHREX® QUICKSET is an implant that fills bone defects. Bone defects are also called bone voids. These are areas where bone is missing. This can be in areas like arms, legs and pelvis. The treatment is for bone voids caused by surgery or injury. Surgeons pack ARTHREX® QUICKSET into these bony voids in your skeleton. Over time, the implant resorbs and is replaced with your own bone.

(b) the kind of patient on whom the device is intended to be used

ARTHREX® QUICKSET can be used to fill bone defects in adults.

3. Special operating instruction for the use of the device

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.

4. Intended performance and adverse effects

(a) the intended performance of the device;

ARTHREX® QUICKSET has a structure that resembles the one of human bone. The implant guides the regeneration of bone in all directions in the defect site into which it is implanted. Over time, the implant resorbs and is replaced with bone during the natural healing process.

ARTHREX® QUICKSET is provided sterile and is intended for single patient only. The exact amount of material used in the procedure is determined by the clinician, based on the size of the defect to be filled.

(b) any undesirable side effects that could be caused by use of the device

As with any major surgical procedures, there are risks involved in bone grafting surgery such as:

- Infection,
- Non-consolidation
- Wound dehiscence,
- Delayed or absent bone healing,
- Loss of reduction,
- Re-fracture

The occurrence of any of these effects may require additional surgery and/or removal of the material.

5. Residual risks

There are no residual risks of the device itself, i.e., the risks remaining after the implementation of the risk management measures.

To date, no adverse effects directly related to the device are reported or detected.
The occurrences of risks and damages are 0% directly related to the device.

6. Warning and precautions about interaction of the device with other equipment

The combination of any drug substance with ARTHREX® QUICKSET during implantation is the responsibility of the surgeon.

7. Patient precautions

(a) the nature and frequency of regular or preventative examination, monitoring or maintenance of the device that should be undertaken; and

Regular or preventive examination, monitoring or maintenance of the device are the responsibility of the surgeon.

(b) symptoms that could indicate that the device is malfunctioning; and

See part 4.(b)

(c) precautions and other measures that should be taken by the patient if the performance of the device changes or the patient experiences any of the symptoms mentioned in paragraph (b); and

Contact your doctor or a healthcare professional if you think you have any side effects related to the device, its use or if you are concerned about the risks. This document is not intended to replace a consultation with a professional.

(d) the expected device lifetime; and

After ARTHREX® QUICKSET is implanted in your body, it begins to resorb. It is fully replaced by new bone. This can

take up to 2 years after surgery. The resorption time is different depending on patient metabolism.

(e) anything that could shorten or lengthen the device lifetime; and

Not applicable

(f) precautions and other measures that should be taken at, or near, the end of the expected device lifetime; and

Not applicable

(g) other circumstances in which the patient should contact a health professional in relation to the operation of the device

Not applicable

8. Component

(a) the materials and substances included in the device; and

ARTHREX® QUICKSET is a synthetic, resorbable material. It consists of a powder (calcium phosphate salts and HPMC) and a liquid (phosphate-based solution) that are to be mixed to form a paste which is implanted and hardens into the defect.

The powder is made of 78% of α-Tri-Calcium Phosphate (α-TCP), 10% of Calcium-Deficient Apatite (CDA), 10% (DCPA) and 2% of Hydroxypropyl Methylcellulose (HPMC). The liquid consists of 99,5% of Diammonium Hydrogen Phosphate (DAHP) and 0,5% of Water for Injection (PPI Water). The paste primarily consists of Calcium-Deficient Apatite.

(b) any manufacturing residuals that could pose a risk to the patient

None

9. Incident

Any serious incident which may arise in connection with ARTHREX® QUICKSET must be notified to NORAKER and to the relevant Regulatory Authority.

Manufacturer:

NORAKER
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A	02/12/2025	Creation

The instructions for use is available online at: