

TECHNICAL INFORMATION

- Shelf-life:** 4 years
- Sterilization:** Gamma radiation
- Storage Conditions:** Room Temperature (15°C to 25°C)
- Regulatory Status:**
 - CE marked 0050
 - FDA Cleared - 510(k) K093343



ORDERING INFO

| Reference | Product | Description | Volume |
|-------------|-------------------------------|---|--------|
| GYQSKIT2Q5 | GRAFTYS QuickSet | Pre-filled syringe + cannula | 5cc |
| GYQSKIT2Q8 | | | 8cc |
| GYQSKIT2Q16 | | | 16cc |
| | | | |
| GYQSKIT3Q5 | GRAFTYS QuickSet Full Set Kit | Pre-filled syringe + cannula + Delivery Gun | 5cc |
| GYQSKIT3Q8 | | | 8cc |
| GYQSKIT3Q16 | | | 16cc |
| | | | |
| GYGUN | GRAFTYS Delivering gun | | |

ABOUT GRAFTYS

Graftys is an innovation-driven medtech company committed to the development and manufacturing of synthetic bone biomaterials. Graftys products are registered in more than 30 countries worldwide, including Europe, the USA, and South America. Graftys’ mission is to become a major player in the design, manufacturing & distribution of bone biomaterials, with a solid product portfolio based on clinical evidence to address patients’ /surgeon’s medical needs, sustained by an innovation - driven growing pipeline through partnerships with leading academic research institutions in Europe.

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2022



CALCIUM PHOSPHATE
BONE VOID FILLERS



PRODUCT INTRODUCTION

Graftys® QUICKSET is an injectable, self-hardening, highly porous, calcium phosphate bone void filler

INDICATION

Graftys® QUICKSET is intended for filling or reinforcing bony voids or defects of the skeletal system that are not intrinsic to the stability of the bony structure (extremities and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. Graftys® QUICKSET resorbs and is replaced by natural bone during the healing process.

PRODUCT FACT SHEET

Main Composition

Powder:

A mix of calcium-phosphates and a rheo-fluidifying polymer (HPMC)

Liquid:

Phosphate-based aqueous solution

Final product:

Nano-sized Calcium Deficient Apatite crystals (CDA)

Global porosity

Up to 70% of global porosity.

Microporosity (<10 µm) 88%, mesoporosity (10-100 µm) 2%, macroporosity (>100 µm) 10%

Injectability:

Yes, improved injectability thanks to the rheo-fluidifying polymer

Hydroxypropyl Methyl Cellulose (HPMC)

Benefits of HPMC polymer:

Unique final porosity; Improved injectability; Good cohesion; Optimal filling; No Shrinkage (during hardening process)

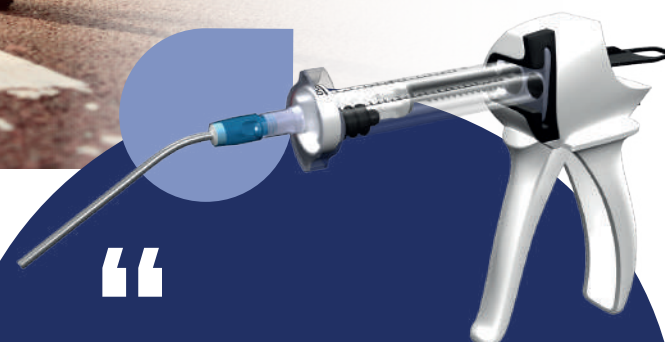
Compressive strength: Within the range of cancellous bone compressive strength (24MPa after 24 hours)



Graftys® QUICKSET Double-compartment Syringe with a Cannula



Graftys® QUICKSET Delivery Gun (Optional)



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DESIGN - AN ALL-IN-ONE CLOSED DEVICE

Graftys® Quickset consists of a double-compartment syringe, a cannula and an optional choice for a delivery gun.

- Safe: closed mixing system;
- Swift: intuitive preparation takes only 2 minutes;
- Simple: no extra tools required.

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The “Diamond concept” is considered as the principles of bone regeneration. It involves four major components for successful fracture healing- osteogenic cell, growth factors, mechanical stability and osteoconductive scaffolds.

Osteogenic Cell (Osteogenesis)

Macroporosity and permeability of Graftys® QUICKSET enhance the penetration and circulation of cells.

Mechanical Stability

It provides a stable enough matrix for secondary bone fixation. Graftys® QUICKSET can also be drilled and screwed. The compressive strength of Graftys® Quickset is similar to cancellous bone.

Growth Factors (Osteoinduction)

Macro and micropores of Graftys® QUICKSET allow the penetration of body fluids and circulation of cells.

Matrix / Scaffold (Osteoconduction)

The similar composition of Graftys® Quickset and natural bone provides a stable osteoconductive scaffold for bone remodeling.

DIAMOND CONCEPT



FIRST STEP

Turn on “Transfer” and push the liquid to the powder chamber.
* No vial to open and empty or syringe to connect.



SECOND STEP

Push and pull the mixing element back and forth for 2 minutes.
* No spatula, bowl and other tools on the edges are needed.



LAST STEP

Turn on “Inject” and connect the provided cannula.
* Graftys® QUICKSET can be injected by hands or with a delivering gun.

TRANSFER

MIX
2 min

INJECT
2 min

SET
8 min

DRILL & SCREW
INSERTION

FULL
HARDEN

Drill & screw can be done during the 2 minutes injecting time or after the 8 minutes setting time.

To reach its full mechanical properties.

0:00-2:00min → 2:00 – 4:00min → 4:00-12:00min → 24h