

User FAQ Graftys® QuickSet & HBS

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Where can I buy Graftys product?

To know if Graftys products are distributed in your country or if you are interested to become a Graftys product distributor, send us an e-mail at contact@graftys.fr

Is the product FDA cleared or CE marked?

Graftys QuickSet and Graftys HBS have FDA 510(K) clearance ([link to 510\(k\) summary](#)):

- Graftys QuickSet 510(k) premarket notification: K093343
- Graftys HBS 510(k) premarket notification: K082498
- Graftys QuickSet and Graftys HBS are CE marked (code 0050):
- Graftys QuickSet and HBS registration number: 252.798

What is shelf life for Graftys® HBS or Graftys® QuickSet?

Graftys® HBS or QuickSet shelf life is 4 years.

What is Graftys® HBS and Graftys® Quickset storage temperature?

Graftys® HBS and QuickSet should be store between 15°C and 25°C.

However, during transportation, temperature can easily exceed that limitation. Graftys® HBS and QuickSet quality has been tested in transportation temperature condition (between 0°C for 72 hours and 60°C for 22 days) without any alteration of the quality of the product. Temperature changes for a short period during transportation do not affect the product properties.

How do I prepare Graftys® HBS or Graftys® Quickset?

Please refer to the user manual inside the product box or on our website:
The preparation is easy: Transfer – Mix – Inject



How should I mix Graftys® QuickSet and Graftys® HBS?

Mix gently while rotating the mixing wand and make sure to fully mix material at both ends of the chamber. This will ensure a homogenous paste.

What happens if I mix...

... 2 min?

The correct mixing time for Graftys® QuickSet and Graftys HBS is 2 minutes.

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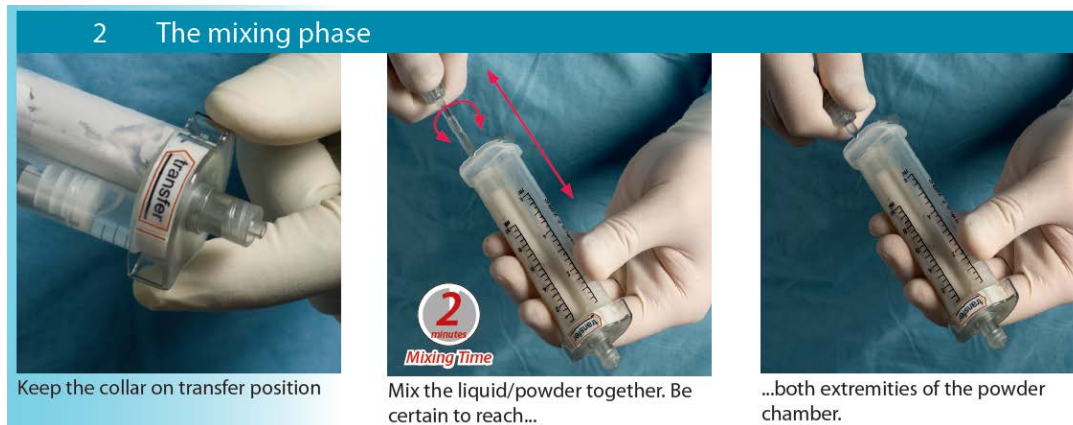
... Less than 2 minutes?

Two minutes mixing time mix will ensure homogeneity and optimal viscosity of the product.

... More than 2 minutes?

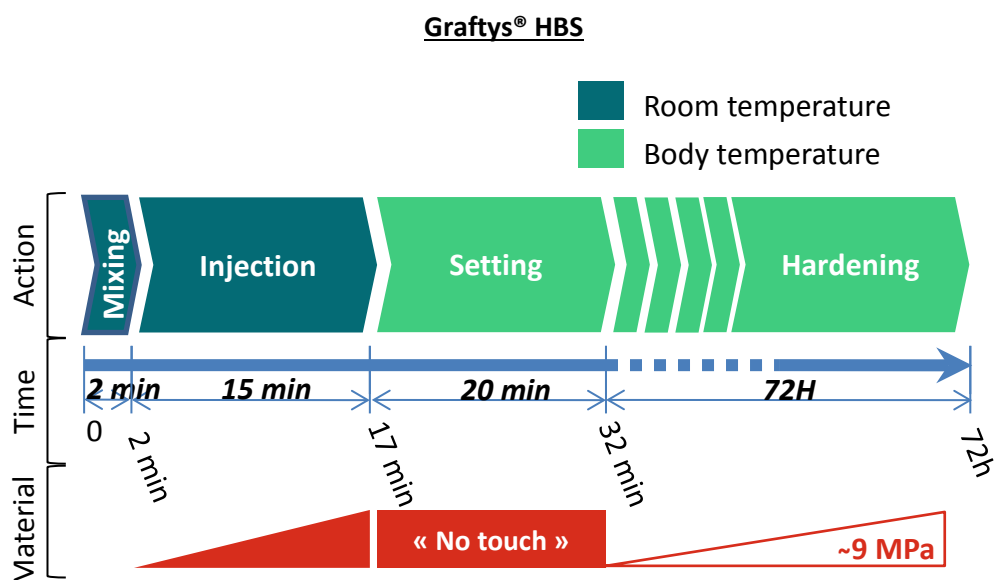
For Graftys® HBS: the product is still injectable,

For Graftys® QuickSet: The product may become difficult to inject.



What is the timing to implant Graftys® HBS or Graftys® Quickset?

Graftys® HBS and Graftys® QuickSet are two different products; the timelines for each are depicted below:

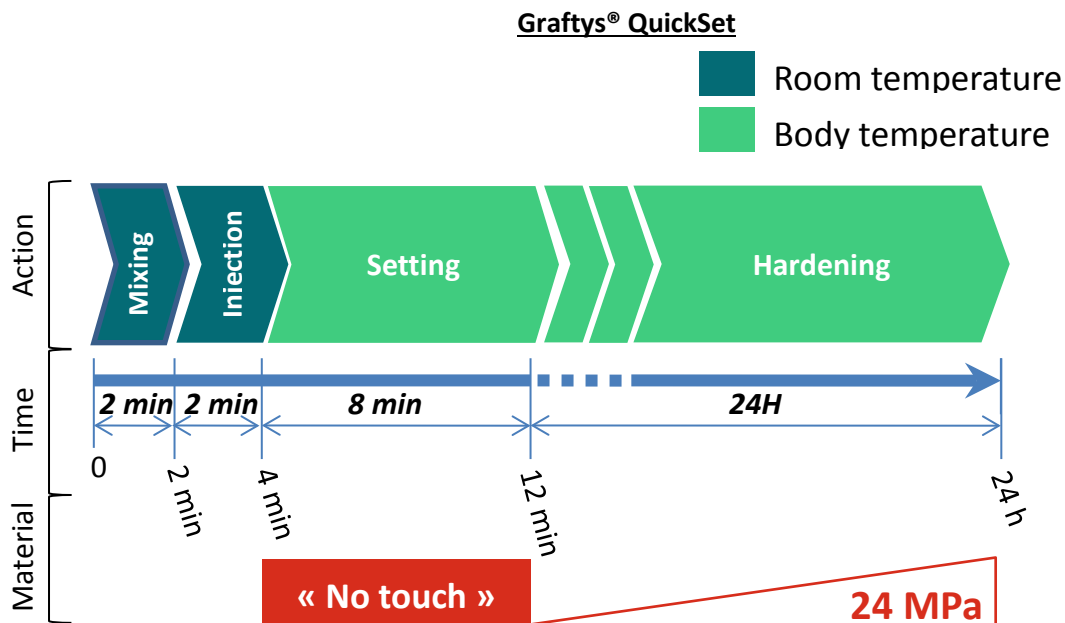


Mixing time: 2 min
Injection time: 15 min

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Initial Setting time: 20 min

Full Hardening time: 72H



Mixing time: 2 min

Injection time: 2min

Setting time: 8 min

Full Hardening time: 24H

Try to inject in one go and throwing away the rest.

What is the setting time?

The setting time differs from the hardening time that is reached after 72 hours for Graftys® HBS and 24 hours for Graftys® QuickSet at body temperature and environment conditions.

The setting time is the time the bone substitute needs (20 minutes for Graftys® HBS and 8 minutes for Graftys® QuickSet) to reach a state of crystallization that gives enough cohesiveness to not leak or deform. The product should not be manipulated from the beginning of the setting time at the risk of delaying the crystallization process and not reaching the expected final properties. (see also : Is it serious if I manipulate the product during the “no touch time period”?)

When and how long can I work on the product?

You can manipulate on the product during the injection time:

- Graftys® HBS: for 15 minutes after mixing the product
- Graftys® QuickSet: for 2 minutes after mixing the product

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When is Graftys Quickset or HBS finally hard?

The product reaches its final hardened state:

- For Graftys® HBS : after 72 hours at 37°C
- For Graftys® QuickSet: after 24 hours at 37°C

I can't break the mixing rod to use the delivery gun, what can I do?

Firmly pull back the mixing rod until the white plunger is closer to the opening. See illustration below.



Wrong position



Right position

What is the exact volume of product available in the syringe?

The volumes of the syringe available are:

- 5cc
- 8cc
- 16cc (2 syringes of 8cc)

Be aware that when you use a cannula to inject the Graftys® QuickSet or HBS a certain volume of bone substitute will be trapped. With the 7G cannula supply in the Graftys® QuickSet packaging approximately 1cc stays in the cannula after injection.

Why can't I inject the product?

If you cannot inject the product there are some things to check:

- The collar is set to « Inject »
- Make sure plunger was not snapped onto the mixing wand shaft
- Make sure that you didn't mix more than 2 minutes
- Make sure that you didn't leave the syringe on the table for more than 2 minutes after mixing for Graftys® QuickSet and 15 minutes after mixing for Graftys® HBS.

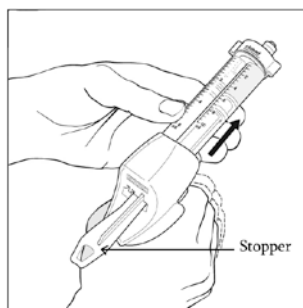
- Make sure that you mix from top to bottom and all the powder has been mixed with the liquid
- Make sure all the liquid has been transferred to the powder chamber
- Make sure you use one syringe with one cannula to inject the bone substitute. Use a new cannula every time you mix a new syringe

If you think there is problem with the product, please refer the incident to your distributor for follow-up.

When have I to stop the injection step?

- With delivering gun,

Check the positioning of the stopper, if it reaches the end, stop compressing the trigger.



- With or without delivering gun,

If you feel an abnormal resistance, stop the injection.

Why the product is going in the liquid chamber when I inject it?

When the pressure is too high at the exit of the syringe, the security valve is mechanically engaged to avoid separation of the powder and liquid. This situation can happen if:

- You are using an incorrect cannula (too long or too small diameter)
- The bone you are filling is already full of bone substitute
- A bone fragment is trapped in the cannula and stops the outflow of the bone substitute

If you think there is problem with the product, please refer the incident to your distributor for follow-up.

Can I mix Graftys® QS or Graftys® HBS with another kind of bone graft?

The safety and efficacy of GRAFTYS® HBS and GRAFTYS®QUICKSET when combined with devices with similar indications have not been established.

Can I mix Graftys® HBS or Graftys® QS with active molecule?

The safety and efficacy of GRAFTYS® HBS and GRAFTYS®QUICKSET when combined with devices with medicinal substances have not been established.

Can a screw be inserted through the Graftys® HBS or Graftys® QS?

You can screw through the biomaterial however Graftys HBS and QuickSet are intended for use in bony voids or defects that are not intrinsic to the stability of the bony structure, so the cement cannot be a source of primary stabilization for any metal implant. (see our clinical case : Graftys HBS used in secondary reinforcement of femoral neck after blade plate removal on <http://www.graftys.com/en/cliniques/>)

Is it serious if I manipulate the product during the “no touch time period”?

It is important not to touch the Graftys® QuickSet during this 8 minutes period and Graftys® HBS during this 20 minutes period after implantation because the product must be undisturbed in order to reach its full properties. If the product is manipulated during this “no touch” period, there is a possibility of interfering with the crystallization process, and extending the setting time.

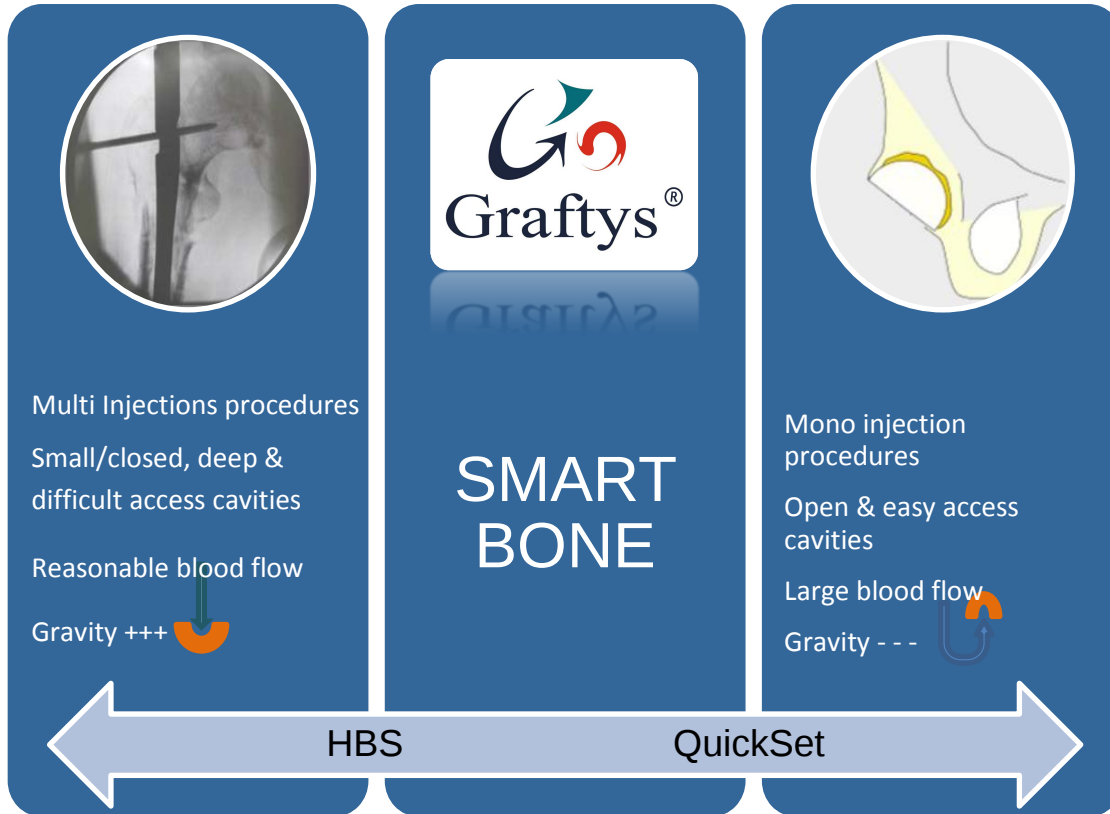
What is the regeneration time of the product?

The regeneration time is depending on several factors like:

- Patient age
- Patient hygiene
- Patient consumption of alcohol or tobacco
- Site of implantation
- Site vascularization
- Primary stability of the site
- Size of the defect to fill
- Surgical technique used

Case reports with Graftys materials demonstrate resorption/regeneration which is aligned with natural bone formation processes.

When should I use Graftys® HBS or Graftys® QuickSet?



Is there any risk of immunologic reaction for my patient?

Graftys products are fully synthetic biomaterial. There are no materials of animal or human origin.

Is there an affinity between radiological bone tracer and Graftys Quickset or HBS?

Yes, there is. The affinity of some radiologic bone tracers with calcium phosphate bone substitutes like Graftys Quickset and HBS must be taken into account during their radiographic analysis.

Is there any risk of inflammatory reaction for my patient?

Harmful inflammatory reaction with Calcium phosphate bone substitute might happen if product was accidentally left in soft tissue. Be careful and wash the soft tissue before closure ^{1, 2, 3}.

What are the indications?

Graftys® QUICKSET and HBS are intended for filling or reinforcing bony voids or defects of the skeletal system that are not intrinsic to the stability of the bony structure (orthopedic, cranio-facial, maxillo-facial, or parodontological). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. These

products provide a bone void filler that resorbs and is replaced with bone during the healing process.

What are the contra-indications?

Graftys® QUICKSET and HBS 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 without appropriate controls (i.e. visual, arthroscopic, lavage....)
- A bone site which can lead to the product passing into the meningeal spaces
- Vertebroplasty and kyphoplasty
- A site which cannot be stabilised
- A cranio-maxillofacial defect with a surface area larger than 25 cm²
- A site exposed to the sinus (lumen) or nasal mucosa.

Graftys® QUICKSET and HBS are not intended to be used as a load-bearing device.

How the product is sterilized?

Gun and doses are sterilized by irradiation

Cannula is sterilized by ethylene oxide

Cannula, dispenser and dose are under sterile protection, do not use them if the sterile protection is damaged and do not resterilize them.

N.B. All the products are single use only

Where are Graftys® QuickSet and HBS made?

All Graftys products are made in France.

Bibliography

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2. E.M. Ooms et al., « Soft-tissue response to injectable calcium phosphate cements », Biomaterials 24 (2003) 749–757
3. Huipin Yuan et al., "Tissue responses of calcium phosphate cement: a study in dogs", Biomaterials 21 (2000) 1283}1290

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