



FIELD SAFETY NOTICE

Date: 15 March 2023

Device Name: **GRAFTYS® QUICKSET** (Graftys Quickset, Graftys Quickset Full Set Kit, Graftys Quickset Kit 2, Axoz Quickset, Arthrex Quickset Kit (EU), Eurobone 2 STD)

Device Type: Injectable Resorbable Calcium Phosphate Bone Void

Device mode: GYQSMV1Q5, GYQSMV1Q8, GYQSMV1Q16, GYQSKIT3Q5, GYQSKIT3Q8, GYQSKIT3Q16, GYQSKIT2Q5, GYQSKIT2Q8, GYQSKIT2Q16, 4922005, 4922008, 4922016, ABS-3005-EH, ABS-3008-EH, ABS-3016-EH, 263666, 263667

Unique Device Identifier(s) (UDI-DI) : 03760177571259, 03760177571266, 03760177571273, 03760177571297, 03760177571303, 03760177571310, 03760177573062, 03760177573079, 03760177573086, 03760177571976, 03760177571983, 03760177571990, 03760177576667, 03760177576735, 03760177570061, 03760177570078, 03760177570085.

Reference: GRAFTYS FSCA_20230313.

For attention of: <Name Title>
<Name>
<Address>

Dear Customers and Users of GRAFTYS® QUICKSET,

As part of our post-marketing surveillance activities, we identified a product deviation that could impact the characteristics of the GRAFTYS® QUICKSET which is an injectable self-hardening macroporous calcium phosphate bone void filler intended for filling or reinforcing bony voids or defects of the skeletal system that are not intrinsic to the stability of the bony structure.

This Field Safety Notice (FSN) include additional precautions and additional information about the product use. Please note that the issuance of this FSN is not in link with any reportable event. Please also note that the relevant Competent Authorities have been advised of this communication to customers.

Issue identified and potential risks

A real-time in-house stability study on the product GRAFTYS® QUICKSET showed non-conforming results on physico-chemical characteristics of the product, at various time point during the storage. These consist in slight deviations from the following properties: injectability, setting time, compressive strength and powder chemical composition.

Based on our risk assessment, the residual risk that could occur is low. These slight deviations might lead to a short delay in surgery.

The purpose of this FSN is to provide precautions and additional information concerning the use of the GRAFTYS® QUICKSET, alongside a reminder concerning the Instructions for Use (IFU) for the product, as preventive action.



We guarantee the safety and performance of the product to be used on the patients, which can continue to be used as such. Moreover, please note that the sterile barrier validation is not concerned by these results and continue to be effective to maintain the sterility of the product during the 4 year-shelf life time.

Actions to be taken

We kindly request you to pay close attention to the following precautions, additional information and IFU reminder below:

▪ **Precautions**

- By following the preparation instructions in the IFU, if difficulties during mixing or injection still occur, do not implant the product;
- The product should not be injected forcefully (with or without gun);
- In case of injection issues, another device should be used to complete procedure. Please ensure that you have two devices available before starting the procedure.

▪ **Information**

- At the end of the mixing stage, the injection can start immediately and should not exceed 2 minutes (no waiting time needed);
- Setting reaction can get longer than the approximate 8 minutes mentioned in the IFU (up to 30 minutes max);
- After implantation, the product keeps a paste-like texture and will only be hardened after 24h at 37°C.

▪ **IFU reminder**

- GRAFTYS® QUICKSET is not intended to be used as a load-bearing device;
- The setting time reaction is strongly temperature dependent and gets longer when temperatures are lower than 37°C;
- Respect the stages of GRAFTYS® QUICKSET preparation before its injection :
 - To guarantee the optimum properties of the GRAFTYS® QUICKSET preparation, the level of the hardening liquid must be verified;
 - Mix for two 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;
 - Put the selector ring on INJECT.

Moreover, we ask you to complete the reply form attached to this notice (importers/distributors and end users). Your reply form should be sent to fannie.reynaud@graftys.com by 24 March 2023.

To this end, please refer to:

- The Customer Reply Form in Annex I to this letter;
- The list of products reference in Annex II to this letter.



Transmission of this Field Safety Notice

This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred. (As appropriate)

Please transfer this notice to other organizations on which this action has an impact. (As appropriate)

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

If you need any further information or support concerning this, please reach out to our company representative:

Fannie REYNAUD – Quality Director : fannie.reynaud@graftys.com

Stéphane PELE – Customer service officer : stephane.pele@graftys.com

Best regards,

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**ANNEX I
CUSTOMER REPLY FORM**

1. Field Safety Notice (FSN) information	
FSN Reference number	[Insert FSN reference number]
FSN Date	15 March 2023
Product/ Device name	GRAFTYS® QUICKSET

2. Customer Details	
Name	
Organization Address	
Department/Unit	
Shipping address if different to above	
Contact Name	
Title or Function	
Telephone number	
Email	

3. Customer action undertaken on behalf of Healthcare Organization		
<input type="checkbox"/>	I confirm receipt of the Field Safety Notice and that I read and understood its content.	Customer to complete or enter N/A
<input type="checkbox"/>	I performed all actions requested by the FSN.	Customer to complete or enter N/A
<input type="checkbox"/>	The information and required actions have been brought to the attention of all relevant users and executed.	Customer to complete or enter N/A
<input type="checkbox"/>	I have a query please contact me.	Customer to enter contact details if different from above and brief description of query
	Print Name	Customer print name here
	Signature	Customer sign here
	Date	



4. Return acknowledgement to sender	
Email	fannie.reynaud@graftys.com
Customer Helpline	0442603000
Postal Address	Eiffel Park – Bât D – 415, rue Claude Nicolas Ledoux - 13 290 AIX ENPROVENCE Cedex 3
Fax	0442603011
Deadline for returning the customer reply form	24/03/2023



ANNEX II
PRODUCTS REFERENCE

GRAFTYS Quickset	GYQSMV1Q5 GYQSMV1Q8 GYQSMV1Q16
GRAFTYS Quickset Full Set Kit	GYQSKIT3Q5 GYQSKIT3Q8 GYQSKIT3Q16
GRAFTYS Quickset Kit 2	GYQSKIT2Q5 GYQSKIT2Q8 GYQSKIT2Q16
Axoz Quickset	4922005 4922008 4922016
Arthrex Quickset kit (EU)	ABS-3005-EH ABS-3008-EH ABS-3016-EH
Eurobone 2 STD	263666 263667