Rev 2: February 2020

FSN Ref: 018-2024
FSCA Ref: 018-2024

Degradable Solutions AG
Wagistrasse 23
8952 Schlieren Switzerland

COLLAGEN MATRIX
SCIENCE • TECHNOLOGY • INNOVATION
15 Thornton Road, Oakland, NJ 07436, USA

Date: 2024/08/21

Field Safety Notice
easy-Graft CRYSTAL

For Attention of*:

Customer	Contact e-mail
Biotech Dental	approvisionnements@biotech-dental.com

Contact details of local representative (name, e-mail, telephone, address etc.)*
For any questions, please contact Leslie McCormick, Lmccormick@regenity.com, Phone: 551-284-7768, Headquarters: Collagen Matrix, Inc. 15 Thornton Road, Oakland NJ 07436.

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Field Safety Notice (FSN)
easy-Graft CRYSTAL
Risk addressed by FSN

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	easy-graft CRYSTAL is a sterile, synthetic bone defect filler. It consists of two components: granules (syringe) and BioLinker (ampulla). After mixing, easy-graft CRYSTAL is putty-like and can be applied directly from the syringe into the bone defect. In contact with blood or other body fluid, easy-graft CRYSTAL hardens within minutes to form a solid but porous implant.
	2. Commercial name(s)*
	GUIDOR® easy-graft® CRYSTAL
	3. Unique Device Identifier(s) (UDI-DI)
	07640164360256 (1 unit – inner package label) 17640164360253 (3 units – outer package label)
	4. Primary clinical purpose of device(s)*
	easy-graft CRYSTAL should be used for the filling of mostly unloaded and preferably multi-walled dental or maxilla-facial bone defects. The implantation site should be free of infections and soft granulation tissue.
	5. Device Model/Catalogue/part number(s)*
	C15-002
	6. Software version
	Not applicable
	7. Affected serial or lot number range
	EGCR40230101
	8. Associated devices
	Not applicable.

2. Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	In certain units, easy-graft CRYSTAL was found to have hardened in the syringe and could not be expressed. Additionally, a few of the syringe plungers broke in the effort to express the product from the syringe.
	2. Hazard giving rise to the FSCA*
	This product problem may result in the inability to use the product. May also result in dispersal of product in undesirable locations due to difficulty in ejecting product.
	3. Probability of problem arising
	If the device problem were to occur the likelihood of injury to the patient is low as the product may be unusable. The probability of the problem arising is low.
	4. Predicted risk to patient/users
	The inability to use the product could affect the outcome of a surgical procedure such as a delay in surgery. The risk of injury to the patient is low.
	5. Further information to help characterise the problem
	Not applicable.
	6. Background on Issue
	The issue was discovered via a customer complaint.
	7. Other information relevant to FSCA
	Not applicable.

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3. Type of Action to mitigate the risk*

3. 1. Action To Be Taken by the User*

☒ Identify Device ☒ Quarantine Device ☒ Return Device ☐ Destroy Device

☐ On-site device modification / inspection

☐ Follow patient management recommendations

☐ Take note of amendment / reinforcement of Instructions For Use (IFU)

☒ Other ☐ None

Identify any customers who received the device and provide them with a copy of this Field Safety Notice.

2. By when should the action be completed?	Please email a completed Field Safety Notice Distributor/Importer Reply Form via email to lmccormick@regenity.com within 5 business days of receipt of this notice.

3. Particular considerations for: Implantable device

Is follow-up of patients or review of patients' previous results recommended?
No

If the product was able to be used, the product should function as normal. Continue regular patient monitoring.

4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes

5. Action Being Taken by the Manufacturer*

☒ Product Removal
☐ Software upgrade
☐ Other
☐ On-site device modification/inspection
☐ IFU or labelling change
☐ None

6. By when should the action be completed?	Please email a completed Field Safety Notice Distributor/Importer Reply Form via email to lmccormick@regenity.com within 5 business days of receipt of this notice.
7. Is the FSN required to be communicated to the patient /lay user?	No

8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?

Choose an item. Choose an item.

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4. General Information*		
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	Not applicable
4.	3. For Updated FSN, key new information as follows:	
	Not applicable	
4.	4. Further advice or information already expected in follow-up FSN? *	Not planned yet
4.	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	Not applicable	
4.	6. Anticipated timescale for follow-up FSN	Not applicable
4.	7. Manufacturer information **(For contact details of local representative refer to page 1 of this FSN)**	
	a. Company Name	**Degradable Solutions AG**
	b. Address	**Wagistrasse 23, 8952, Schlieren, Switzerland**
	c. Website address	**www.regenity.com**
	d. SRN	Manufacturer, CH-MF-000018342, Degradable Solutions AG
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	Attachment 1 – Product Label Images, Attachment 2 – Field Safety Notice Distributor/Importer Reply Form, Attachment 3 – Field Safety Notice Customer Reply Form
4.	10. Name/Signature	Leslie McCormick Program Manager, Regulatory Affairs Collagen Matrix, Inc.

	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations 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. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.*

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.

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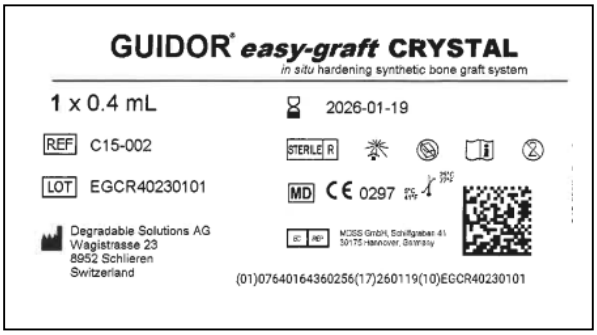
Attachment 1: Product Labelling

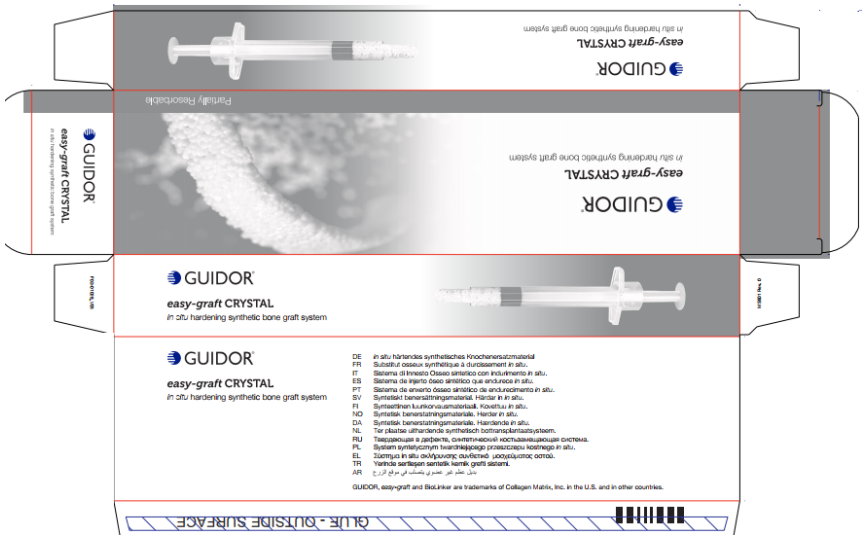
Inner Unit Label



Outer Unit Label

Patient Chart Sticker

Box Image



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Field Safety Notice Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	MD24.174
FSN Date*	2024-08-20
Product/ Device name*	easy-graft Crystal
Product Code(s)	C15-002
Batch/Serial Number (s)	EGCR40230101

2. Customer Details	
Account Number	DHL - 962919307
Healthcare Organisation Name*	Biotech Dental
Organisation Address*	BIOTECH DENTAL 305 ALLEES DE CRAPONNE 13300 SALON DE PROVENCE - France
Department/Unit	N/A
Shipping address if different to above	GANDONNE ZA LA GANDONNE 235 , RUE CANESTEU 13300 SALON DE PROVENCE - France
Contact Name*	Jérôme DARTHOUX
Title or Function	Purchaser (**Approvisionnement)**
Telephone number*	*Tel : +33(0)0490446060*
Email*	*approvisionnements@biotech-dental.com*

3. Customer action undertaken on behalf of Healthcare Organisation				
☐	I confirm receipt of the Field Safety Notice and that I read and understood its content.	Customer to complete or enter N/A		
☐	I performed all actions requested by the FSN.	Customer to complete or enter N/A		
☐	The information and required actions have been brought to the attention of all relevant users and executed.	Customer to complete or enter N/A		
☐	I have returned affected devices - enter number of devices returned and date complete.	Qty:	Lot/Serial Number:	Date Returned (DD/MM/YY):
		Qty:	Lot/Serial Number:	Date Returned(DD/MM/YY):
		N/A	Comments:	
☐	I have destroyed affected devices – enter number destroyed and date	Qty:	Lot/Serial Number:	
		Qty	Lot/Serial Number:	

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	complete.	N/A	Comments:
☐	No affected devices are available for return/ destruction	Customer to complete or enter N/A	
☐	Other Action (Define):		
☐	I do not have any affected devices.	Customer to complete or enter N/A	
☐	I have a query please contact me (e.g. need for replacement of the product).	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	jmabille@regenity.com / contact@regenity.com
Customer Helpline	551-287-2947
Postal Address	10 Industrial Ave, Mahwah N.J. 07430
Web Portal	https://regenity.com/
Fax	N/A
Deadline for returning the customer reply form*	Please return the completed form via email to lmccormick@regenity.com within 5 business days of receipt of this notice.

Mandatory fields are marked with *

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.