Rev 2: February 2020
FSN Ref: ACTION_SL-25-0005
FSCA Ref: ACTION_SL-25-0004

Date: 2025-01-31

Urgent Field Safety Notice
NEVELIA®

For Attention of: Distributors and end users

SYMATESE wants to inform its customers of the implementation of a **Voluntary Field Safety Notice** concerning NEVELIA® products, matrix for dermal regeneration, due to a possible PETG support positioning issue.

SYMATESE informs you that this Field Safety Notice has been communicated to the relevant Health Authorities including ANSM (French Authority).

Upon receipt, we kindly ask you to take note of this Field Safety Notice and to acknowledge receipt of it by returning to us **Appendix 1 completed and signed within 3 working days of receipt** in order to ensure the effectiveness of this corrective action.

SYMATESE would like to assure you that we take the quality of our products very seriously and that all necessary corrective measures will be taken to prevent this problem from recurring.

We apologize for the inconvenience and are available to answer any questions you may have on this matter at the following address: vigilance@symatese.com.

Please accept, dear Madam, Sir, our respectful greetings.

Julien BATY
Quality Director & PRRC
SYMATESE

Electronically signed by:
Julien Baty
Reason: Writer
Date: Jan 31, 2025 12:20
GMT+1

Contact details of local representative (name, e-mail, telephone, address etc.)	
Manufacturer Details	Distributor Details
SYMATESE ZI les Troques 69630 Chaponost – France phone: +33 (0) 4 78 56 72 80 e-mail: vigilance@symatese.com	

Urgent Field Safety Notice (FSN)
NEVELIA®

1. Information on Affected Devices

1. 1. Device Type(s)

Matrix for dermal regeneration:
NEVELIA® bi-layer matrix is a sterile medical device consisting of a collagen layer to promote dermal regeneration and a reinforced silicone layer acting as a pseudo-epidermis.
NEVELIA® bi-layer matrix is supplied hydrated between two protective sheets of plastic (PETG supports) in double pouches. Each pack contains one bi-layer matrix and is radiation-sterilised.

1. 2. Commercial name(s)

NEVELIA®

1. 3. Unique Device Identifier(s) (UDI-DI)

Not applicable

1. 4. Primary clinical purpose of device(s)

NEVELIA® is indicated for dermal regeneration in individuals with skin loss, particularly in the following fields:

- Burns surgery (third and deep second-degree burns),
- Reconstructive plastic surgery,
- Traumatology.

NEVELIA® is used in combination with a thin split thickness skin graft to recreate skin resembling normal skin in terms of function and appearance.

NEVELIA® bi-layer matrix is particularly useful for:

- patients who are unable to supply sufficient donor skin for an autograft at the time of excision
- When the physiological condition of the patient does not allow the autograft

1. 5. Device Model/Catalogue/part number(s)

NEVELIA® References	Width (cm)	Length (cm)	Thickness (cm)	GTIN
MCS0505	5	5	0,2	03760172160076
MCS1015	10	15	0,2	03760172160083
MCS2030	20	30	0,2	03760172160106

1. 6. Software version

Not applicable

1.	7. Affected serial or lot number range

NEVELIA® References	Batch numbers
MCS0505	S2231100069
MCS1015	S2231100070
MCS2030	S2231100072

1.	8. Associated devices
	Not applicable

2. Reason for Field Safety Corrective Action (FSCA)

2.	1. Description of the product problem
	NEVELIA® is supplied between two PETG supports one on each side of the NEVELIA® matrix. The two PETG supports may be both on one side of the matrix.
2.	2. Hazard giving rise to the FSCA
	The defect described affects the positioning of the PETG supports which renders the product unusable. This situation may require the user to open another product. The integrity of the primary packaging (double pouches) is ensured which provides reassurance regarding the direct safety issue (no risk of bacterial/viral infection). The patients who are already implanted with the product affected by this FSCA do not require any follow-up as the product used was therefore conform.
2.	3. Probability of problem arising
	This is the first time since the product CE-marking (2013) that this event is reported. This is an isolated case (2 units from same batch). No element indicates that this could be a systemic issue. However, NEVELIA® products are manufactured by campaign. During, the campaign for S2231100072 batch, the same operator had worked on the following references and batches (MCS0505 - S2231100069 and MCS1015 - S2231100070). Therefore, out of caution, these batches are also part of this FSCA. Finally, as part of its defect trend analysis, SYMATESE will monitor any arising trend.
2.	4. Predicted risk to patient/users
	Unusable device.
2.	5. Further information to help characterise the problem
	None.
2.	6. Background on Issue
	One complaint was received from a user (through the distributor) reporting that the two PETG supports were both on one side of the matrix instead of being one on each side of the matrix. The problem observed comes from a production issue: staff error during the manufacturing step.
2.	7. Other information relevant to FSCA
	None.
2.	8. Types of end recipients in the distribution chain known to the manufacturer
	Pharmacy of internal use (hospitals, clinics)

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

We kindly ask you to:

For Distributors
Upon receipt of this Field Safety Notice, we kindly ask you to:

- consult this Field Safety Notice which lists all the references and batches of products concerned,
- check if any products concerned is in your stock,
- if any, destroy these products,
- to return to us **Appendix 1 completed and signed within 3 working days of receipt**,
- forward this Field Safety Notice **to all your customers** who have already received at least one product concerned by the defect.

For End Users
Upon receipt of this Field Safety Notice, we kindly ask you to:

- consult this Field Safety Notice which lists all the references and batches of products concerned,
- check if any of products concerned is in your stock,
- if any, destroy these products,
- to return to us **Appendix 1 completed and signed within 3 working days of receipt**.

3.	2. By when should the action be completed?	**within 3 working days of receipt**

3. 3. Particular considerations for: Implantable device

Is follow-up of patients or review of patients' previous results recommended?
No. The patients who are already implanted with the product affected by this FSCA do not require any follow-up as the product used was therefore conform.

3.	4. Is customer Reply Required? (If yes, form attached specifying deadline for return)	Yes See Appendix 1 of this FSN To be returned within **3 working days** after receipt.
3.	**5. Action Being Taken by the Manufacturer** ☐ Product Removal ☐ Software upgrade ☒ Other ☐ On-site device modification/inspection ☐ IFU or labelling change ☐ None Update of batch files to integrate a step-by-step method for the concerned manufacturing step.	
3.	6. By when should the action be completed?	2025-02-10
3.	7. Is the FSN required to be communicated to the patient /lay user?	No
3.	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?	
	Not applicable	

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?	No
4.	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	No follow-up FSN expected.	
4.	6. Anticipated timescale for follow-up FSN	No follow-up FSN expected.
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	SYMATESE
	b. Address	ZI les Troques 69630 Chaponost – France
	c. Website address	https://www.symatese-lab.com/nevelia/
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. Yes	
4.	9. List of attachments/appendices:	Appendix 1 (form to return)
4.	10. Name/Signature	Julien BATY Quality Director & PRRC
		Electronically signed by: Julien Baty *Reason: Approver* *Date: Jan 31, 2025 12:20 GMT+1*

	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.

APPENDIX 1 – FORM TO RETURN

PLEASE RETURN A COMPLETED AND SIGNED COPY NO LATER THAN 3 WORKING DAYS AFTER RECEIPT:

By email vigilance@symatese.com

1. Field Safety Notice (FSN) information	
FSN Reference number	ACTION_SL-25-0005
FSN Date	31/01/2025
Product/ Device name	NEVELIA®

Product References/ Batch numbers

NEVELIA® References	Batch numbers
MCS0505	S2231100069
MCS1015	S2231100070
MCS2030	S2231100072

2. Distributor Information	
Company Name	
Address	
Contact Name	
Title or Function	
Telephone number	
Email	

☐ **I am a distributor**

☐ I confirm the receipt, the reading and understanding of this Field Safety Notice.

☐ I have checked the status of my stocks for the concerned batches and the data collected are reported in the table below.

☐ I confirm I have destroyed the products concerned that I have in stock.

☐ I confirm I have identified the customers/organisations that have received or may have received the batches of concerned products.

☐ I undertake to communicate this Field Safety Notice to all the customers/organisations concerned.

☐ **I am an end user**

☐ I confirm the receipt, the reading and understanding of this Field Safety Notice.

☐ I have checked the status of my stocks for the concerned batches and the data collected are reported in the table below.

☐ I confirm I have destroyed the products concerned that I have in stock.

Device	Reference	Batch number	Quantity received	Quantity in stock	Quantity destroyed

Name: Date:

Function:

Signature:

Email: Company Stamp:

Client code:

FSN_NEVELIA_2025.01_EN

Final Audit Report 2025-01-31

Created:	2025-01-31
By:	Mélodie VUARCHEY (m.vuarchey@symatese.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAADf1DAHwii1XGgqp_EvEs07lyBhaYNxmC
Number of Documents:	1
Document page count:	8
Number of supporting files:	0
Supporting files page count:	0

"FSN_NEVELIA_2025.01_EN" History

Document created by Mélodie VUARCHEY (m.vuarchey@symatese.com)
2025-01-31 - 11:18:24 AM GMT

Document emailed to Julien Baty (j.baty@symatese.com) for signature
2025-01-31 - 11:19:34 AM GMT

Email viewed by Julien Baty (j.baty@symatese.com)
2025-01-31 - 11:19:53 AM GMT

Agreement viewed by Julien Baty (j.baty@symatese.com)
2025-01-31 - 11:19:53 AM GMT

Julien Baty (j.baty@symatese.com) authenticated with Adobe Acrobat Sign.
Challenge: The user completed the signing ceremony.
2025-01-31 - 11:20:36 AM GMT

Document e-signed by Julien Baty (j.baty@symatese.com)
Signing Reasons
Writer (Champ de signature 1)
Approver (Champ de signature 2)
Signature Date: 2025-01-31 - 11:20:37 AM GMT - Time Source: server

Agreement completed.
2025-01-31 - 11:20:37 AM GMT