FSN ref : FSN24-001

FSCA ref : FSCA24-001

Urgent Field Safety Notice (FSN)

Date: 11/03/2024

BO MEDICAL TECHNOLOGIES

[redacted]

Urgent Field Safety Notice (FSN)
RECALL OF STYLAGE M LIDOCAINE, **Batch number 232281101**

Dear Customer,

We would like to inform you about a potential issue on **the batch 232281101** of STYLAGE M lidocaine. According to our records, you have received STYLAGE M Lidocaine products from batch 232281101.

Following a customer complaint, a syringe of STYLAGE XL Lidocaine has been detected in the packaging of STYLAGE M lidocaine. Two cases were reported out of 11278 syringes (5639 boxes) placed on the market since September 2023 (i.e. a rate of 0.02% syringes). No injuries to patient or users were reported.

The affected product can be identified by the physician as:

- the syringe of STYLAGE XL Lidocaine is labelled "STYLAGE XL lidocaine."
- the syringe of STYLAGE XL lidocaine is almost not possible to be injected as the combination with the needle provided in the box (30G1/2) requires higher injection force (twice higher than conforming products and out of injection force specifications).

As part of a voluntary recall, we ask you to identify and return the products from the affected batch delivered to you.

The following pages of this letter contain further information on the affected products, the possible risks for patients/users and the measures to be taken on your part.

If you need any further information or support, please do not hesitate to contact Laboratoires VIVACY Vigilance department: vigilance@vivacy.fr - phone call +33 (0)4 84 79 05 03.

We would be much obliged if you could reply to this notice before **March 22nd, 2024**.

We apologize for any inconvenience caused. We thank you in advance for your cooperation to perform this voluntary recall as quickly and efficiently as possible.

Quality is the priority of Laboratoires VIVACY, we want to assure you that all appropriate corrective actions are taken to prevent this issue from recurring.

Yours sincerely.

[redacted]

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1. **Information on Affected Devices**	
Device Type	Facial Tissue Filler: Each box contains 4 sterile needles and two syringes containing a sterile gel of cross-linked sodium hyaluronate (20mg/g) associated with 0,3% of lidocaine hydrochloride and mannitol for intradermal injection.
Commercial name	STYLAGE M LIDOCAINE
Unique Device Identifier(s) (UDI-DI)	UDI-DI 03760208530491
Primary clinical purpose of device	A hyaluronic acid injectable gel designed to fill skin depressions on the face by injection into the dermis. STYLAGE M Lidocaïne is also indicated for the outline of the lips and/or for lips augmentation by injection in the lips mucosa.
Device Model/Catalogue /part number	SPF255 - STYLAGE M LIDOCAINE
Affected serial or lot number range	Batch number: 232281101 – expiry date: 2026-01-18

2. Reason for Field Safety Corrective Action (FSCA)	
Description of the product problem	A syringe of STYLAGE XL Lidocaine is inserted in the packaging of STYLAGE M lidocaine. The labelling of the box, labelling of the blister and packaging items including needles (30G1/2) are those of STYLAGE M lidocaine. The syringe is labelled STYLAGE XL lidocaine and does contain STYLAGE XL lidocaine gel.
Hazard giving rise to the FSCA	The two affected products STYLAGE XL lidocaine and STYLAGE M lidocaine have different indications and different rheology. The discrepancy is likely detectable (refer to section “Probability of problem arising”), nevertheless if it is not detected when preparing the injection, it may lead to the product being used in areas where STYLAGE XL lidocaine is contra-indicated: – area where the skin is thin (e.g. the forehead and the periorbital region, including the eyelids, the under-eye shadows, the crow's feet),

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	– areas where the vascular system is exposed (e.g. the glabellar region) and in the lips. The consequences for the patient depend on the area where the gel is injected and may include the following rare but serious complications such vascular occlusion due to tissue compression leading to necrosis and/or underlying tissue damage, irregular correction, oedema and indurations. As the injection force applied is much higher than usual (the 30G1/2 needle provided in the box is the one for STYLAGE M lidocaine and is not appropriate for injecting higher gel viscosity such as STYLAGE XL lidocaine), there is also a higher risk of needle ejection, due to the higher pressure requested, resulting in a potential injury to the patient or the healthcare professional.
Probability of problem arising	The discrepancy between the name written on the syringe (STYLAGE XL lidocaine) and the name written on the box (STYLAGE M lidocaine) help the user to identify the problem. Furthermore, if the discrepancy is not detected when preparing the injection, the syringe of STYLAGE XL lidocaine is very difficult to be injected as the combination with the needle provided in the box (30G1/2) requires higher injection force (twice higher than conforming products and out of injection force specifications) Based on these two elements, the non-conforming product is likely to be detected by the user. Two incidents were reported out of 11278 syringes (5639 boxes) sold from September 2023 to February 2024 (i.e. a rate of 0.02% syringes). The first case was detected by the practitioner because the product was very difficult to be injected (high injection force required), and for the second case the practitioner detected the discrepancy before injection based on labelled information on the syringe.
Background on Issue	Laboratoires VIVACY was informed by customer complaints about the defective product. Two cases were reported out of 11278 syringes (5639 boxes) placed on the market since September 2023. The internal investigation concludes that a mix-up occurred during the manufacturing process which led to the non-conforming devices.

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3. Type of Action to mitigate the risk	
Action To Be Taken by the User	1. Immediately check your inventory and put in quarantine all devices from batch **232281101.** 2. Disseminate this notice to all relevant individuals in your organization. 3. Return the completed form of **Appendix 1** to the sender (Laboratoires Vivacy France or your Distributor) which confirm the acknowledgement receipt and the quantity put in quarantine, **even if no product identified.** 4. After reception of Appendix 1 and in case you have products to return, Laboratoires VIVACY France or your Distributor will contact you to organize the return of products and proceed with the replacement.
Action To Be Taken by the Distributor / Pharmacy	1. Immediately check your inventory and put in quarantine all devices from batch **232281101.** 2. Disseminate this notice to all relevant individuals in your organization. 3. Identify the users who have received the affected batch and send them the Field Safety Notice (FSN). Ask them to put in Quarantine affected products, to acknowledge receipt and send back affected products to your organization using **Appendix 1**. Please update Appendix 1 (section 4) with your contact details prior sending. 4. When you receive all replies from all customers, fill in the form in **Appendix 2** and send it back to Laboratoires VIVACY. 5. After reception of the form and in case you have products to return, Laboratoires VIVACY will contact you to organize the return of products and proceed with replacement.
By when should the action be completed?	Return acknowledgment of receipt forms in Appendix of the FSN by: **22 March 2024** Return affected products to the manufacturer by : **29 March 2024**

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Is follow-up of patients or review of patients' previous results recommended?	No delayed harm is expected for the patients. The potential hazards identified are immediate harms which would have been identified by the user as part of the usual follow-up of patients. Hence, no specific follow-up of patients or review of patients' previous results is recommended.
Is customer Reply Required?	Yes, using the form attached

4. General Information	
FSN Type	New
Further advice or information already expected in follow-up FSN?	No follow-up FSN is expected
List of attachements/ appendices:	Appendix 1 : CUSTOMER/USER Reply Form Appendix 2 : DISTRIBUTOR Reply Form

The Competent (Regulatory) Authority of your country has been informed about this communication to customers.

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: CUSTOMER/USER Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number	FSN24-001
FSN Date	8 March 2024
Product/ Device name	STYLAGE M LIDOCAINE
Product Code(s)	SPF255
Batch/Serial Number (s)	**232281101**

2. Customer Details	
Healthcare Organisation Name	
Organisation Address	
Contact Name	
Title or Function	
Telephone number	
Email	

3. Customer action undertaken on behalf of Healthcare Organization	
☐	I confirm the receipt, the reading and understanding of the Field Safety Notice
☐	I put in Quarantine all affected devices.
☐	The information and required actions have been brought to the attention of all relevant users and executed.
☐	I have identified affected devices - enter number of devices to be returned. **Quantity (number of boxes to be returned): _____**
☐	No affected devices are available for return.
☐	I performed all actions requested by the FSN.
Date : Name : Signature :	

4. Return acknowledgement to sender - (Case where sender is Distributor /Pharmacy)	
Email	Pre-filled by sender/requester
Distributor Helpline	Pre-filled by sender/requester
Postal Address	Pre-filled by sender/requester
Deadline for returning the customer reply form	Pre-filled by sender/requester

4.Return acknowledgement to sender – (Case where Sender is Vivacy France)	
Email	**vigilance@vivacy.fr**
Laboratoires VIVACY helpline	**+33 (0)4 84 79 05 03**
Postal Address	**Laboratoires VIVACY** **252 rue Douglas Engelbart** **ArchParc, 74160 Archamps, France**
Deadline for returning the customer reply form	**22 March 2024**

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.

Appendix 2 : DISTRIBUTOR / PHARMACY Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number	FSN24-001
FSN Date	8 March 2024
Product/ Device name	STYLAGE M LIDOCAINE
Product Code(s)	SPF255
Batch/Serial Number (s)	232281101

2.Distributor/Importer Details	
Company Name	
Address	
Contact Name	
Title or Function	
Telephone number	
Email	

3. DISTRIBUTORS / PHARMACY	
☐	I confirm the receipt, the reading and understanding of the Field Safety Notice
☐	I confirm I have received boxes from affected batch. **Number of boxes initially received: _____**
☐	I have checked my stock and put in quarantine all affected devices. **Number of boxes put in quarantine; _____**
☐	I have identified customers that received or may have received this device. **Number of boxes sold: _____**
☐	I have informed the identified customers of this FSN. Date of communication: _____ Number of customers informed: _____
☐	I have received confirmation of reply from all identified customers.

☐	I have collected and isolated **all** affected devices, ready to be returned. **Quantity to be returned (number of boxes):_____**
☐	Neither I nor any of my customers has any affected devices in inventory
Name :	
Signature :	
Date :	

4. Return acknowledgement to Sender	
Email	**vigilance@vivacy.fr**
VIVACY Helpline	**+33 (0)4 84 79 05 03**
Postal Address	**Laboratoires VIVACY** **252 rue Douglas Engelbart** **ArchParc, 74160 Archamps, France**
Deadline for returning the Distributor/Importer reply form	**22 March 2024**

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.