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FSN Ref: DNB.444.489.2023 FSCA Ref: DNB.444.489.2023

Date: 02.06.2024

Urgent Field Safety Notice

Juvelook

For Attention of*: Identify either by name or role who needs to be aware of the hazard and/or take action. If this is multiple recipients then include full list.

Contact details of local representative (name, e-mail, telephone, address etc.)*
Beautyeurope.eu Sp.z o.o.
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Urgent Field Safety Notice (FSN)
Juvelook
Risk addressed by FSN

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	Soft Tissue injectable Implant / Class III
1.	2. Commercial name(s)
	Juvelook
1.	3. Unique Device Identifier(s) (UDI-DI)
	(01)08800051300102
1.	4. Primary clinical purpose of device(s)*
	Device is intended to be used for intradermal and subcutaneous implantation to fill skindepressions as to restore and enhance soft tissue volume.
1.	5. Device Model/Catalogue/part number(s)*
	Juvelook
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range
	VJ220511
1.	8. Associated devices
	N/A

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	The adverse reaction occurred after administration of Juvelook (Lot no. VJ220511) on 3rd July 2023. Juvelook was applied to the eye area. After administration of the preparation, large thickenings (deposits, lumps) occurred. According to Polish CA opinion, in Juvelook IFU there is no clear description of area where medical device should be injected or clear delimitation of safe and non-safe areas. And, incident was caused by lack of clear relevant information on device's IFU about restrictions for application of Juvelook into eyelids.
2.	2. Hazard giving rise to the FSCA*
	The product must be handled and used by a plastic surgeon, dermatologist or a trained doctor with special knowledge and skills after fully understanding the product itself and its directions for use.
2.	3. Probability of problem arising
	None.
2.	4. Predicted risk to patient/users
	None.
2.	5. Further information to help characterise the problem
	Juvelook should not be used in periorbital area (eyebrow, eye spacing, eyelashes, upper eyelid, and lacrimal punctum)

	【Warnings】 Serious side effects such as loss of vision may occur when injected into blood vessels. Therefore, it should not be used in periorbital area (eyebrow, eye spacing, eyelashes, upper eyelid, lacrimal punctum). Do not inject products into shallow skin layers in periorbital area (eyebrow, eye spacing, eyelashes, upper eyelid, lacrimal punctum) to prevent papules or nodules. Papules or nodules can be caused by inappropriate procedures (injection into skin surface, an excessive amount of injection). Massaging the injection site to distribute the product evenly can minimize the incidence of papules and nodules. 【General Precautions】 Care should be taken not to inject thinner skin areas, such as periorbital area, because of the high risk of papules or nodules.
2.	6. Background on Issue
	We've only contracted with Beautyeurope.eu Sp.z o.o., our sole official representative and exclusive distributor, of Lensina and Juvelook products in Poland. The patient purchased the Juvelook through Lipstore which is not our distribution channel in Poland and was not injected by well-trained surgeon, dermatologist or a trained doctor for our product.
2.	7. Other information relevant to FSCA
	Product purchases must be made through established distribution channels.

	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	
3.	2. By when should the action be completed?	1Q, 2025 Specify where critical to patient/end user safety
3.	3. Particular considerations for: Choose an item. Is follow-up of patients or review of patients' previous results recommended? Choose an item. Provide further details of patient-level follow-up if required or a justification why none is required	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	No

3.	**5. Action Being Taken by the Manufacturer** ☐ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☒ IFU or labelling change ☐ Other ☐ None Provide further details of the action(s) identified. In the amended IFU, there will be clear direction that periorbital area includes eyebrow, eye spacing, eyelashes, upper eyelid, and lacrimal punctum and Juvelook shouldn't be injected in periorbital area in【Warnings】and【General Precautions】of Juvelook IFU.	
3	6. By when should the action be completed?	1Q, 2025 *Before the implementation of new Juvelook IFU, we will provide users with safety notes stating corrected warnings and general precautions.
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?	
	Choose an item. Choose an item.	

	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	Provide reference and date of previous FSN if relevant
4.	3. For Updated FSN, key new information as follows:	
	Summarise any key difference in devices affected and/or action to be taken.	
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:	
	Eg patient management, device modifications etc	
4	6. Anticipated timescale for follow-up FSN	For provision of updated advice.
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Only necessary if not evident on letter-head.
	b. Address	Only necessary if not evident on letter-head.
	c. Website address	Only necessary if not evident on letter-head.
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * Yes	
4.	9. List of attachments/appendices:	N/A
4.	10. Name/Signature	**Seungwook Lee** **Head of Regulatory Affairs**

	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.