croma

FSN Ref: DOC-0036

FSCA Ref: AUD-000210

Date: 12.09.2024

Urgent Field Safety Notice
NuVisc™ Pro

For Attention of:

Clinics where NuVisc Pro is used during cataract surgery, especially ophthalmic surgeons who are using NuVisc Pro and members of the medical team within the operating theatre.

Contact details of BVI representative:
BVI UK **Agnieszka Drzewiecka** Phone: +44 1789 490747 vigilance@bvimedical.com | bvimedical.com 8A Waterloo Industrial Estate Waterloo Road, Alcester B50 4JH, UK

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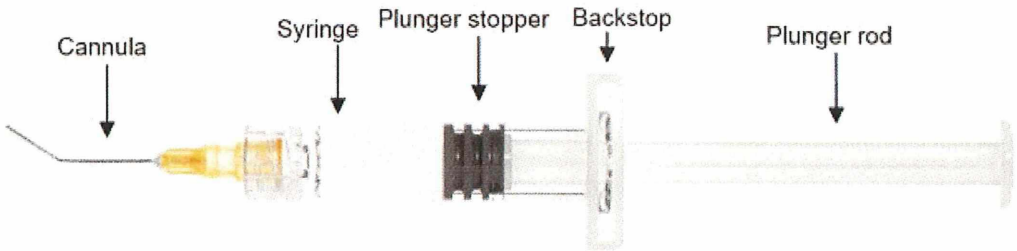
NuVisc™ Pro
- to prevent from eye injuries to patients -

	1. Information on Affected Devices*
1.	1. Device Type(s)*
	NuVisc Pro is a hyaluronic ophthalmic visco-surgical device intended to be used in ophthalmic anterior segment cataract surgery. The product consists of a highly viscous, cohesive, sterile, viscoelastic, clear, isotonic solution for intraocular use, supplied in a ready-to-use glass syringe with one sterile .5 x 22 mm (25G 7/8 in) cannula with a 45° angle. It is cohesive and easy to remove from the anterior chamber. One ready-to-use syringe contains 1 ml of the hyaluronic solution with a pH of 6.8–7.6. The device is provided sterile and is intended for single use only. Figure 1: Picture and description of the respective parts of NuVisc Pro 
1.	2. Commercial name
	NuVisc™ Pro
1.	3. Unique Device Identifier(s) (UDI-DI)
	GTIN: 9003502004645
1.	4. Primary clinical purpose of device(s)*
	NuVisc Pro is intended to be used in ophthalmic anterior segment cataract surgery in order to create and maintain space and protect intraocular tissues.
1.	5. Device Model/Catalogue/part number(s)*
	Catalogue numbers 37284 and 37758
1.	6. Software version
	n.a.
1.	7. Affected serial or lot number range
	n.a.
1.	8. Associated devices
	Viscoflow Cannula, sterile .5 x 22 mm (25G 7/8 in) cannula with a 45° angle

	2. Reason for Field Safety Corrective Action (FSCA)*
2.	1. Description of the product problem*
	Since May 2024, Croma has received 4 complaints, involving 5 incidents of NuVisc Pro, alleging the same medical device problem - "backstop detached" during surgery/injection or while preparing for surgery. Croma is thoroughly investigating these complaints. A connection with the quality of an individual product or with a certain product batch could not be established so far.
2.	2. Hazard giving rise to the FSCA*
	Not following the Instruction for Use could lead to a backstop being detached from the syringe during injection, associated with the risk of a serious eye injury of the patient.
2.	3. Probability of problem arising
	The probability of the problem to arise is very low, occurrence rate < 1:25,000.

2.	4. Predicted risk to patient/users
	See above
2.	5. Further information to help characterise the problem
	See above
2.	6. Background on Issue
	See above
2.	7. Other information relevant to FSCA
	n.a.

	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 Even though the probability of the problem to arise is very low, Croma has decided to amend the Warnings and Precautions section of the Instructions for Use (IFU) of NuVisc Pro by adding the following lines: - *Do not manipulate the backstop as this may cause instability in device handling during the surgical procedure.* - *Do not use the device if the backstop is loose or missing.* - *If the device is not used as described in these instructions for use, this may result in eye injuries to patients.*		
3.	2. By when should the action be completed?	n.a.	
3.	3. Particular considerations:	n.a.	
3.	4. Is customer Reply Required?		No

3.	**5. Action Being Taken by the Manufacturer**		
	☐ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☒ IFU or labelling change ☐ Other ☐ None		
3	6. By when should the action be completed?	New IFU with first delivery 2025.	
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?		
	n.a.		

	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	n.a.
4.	**3.** For Updated FSN, key new information as follows:	
	n.a.	
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:	
	n.a.	
4	6. Anticipated timescale for follow-up FSN	n.a.
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Croma-Pharma GmbH
	b. Address	Industriezeile 6, 2100 Leobendorf
	c. Website address	Home » Croma Pharma (https://www.cromapharma.com/)
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	n.a.
4.	10. Name/Signature	Johannes Wiesmann Global Director Quality Unit Croma-Pharma GmbH 12.09.2024

	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.