Rev 1: September 2018

FSN Ref: 2026/02 FSCA Ref: FA-0000155

Date: 30 JUL 2026

Urgent Field Safety Notice

HEALON EndoCoat™ PRO, HEALON DUET™ PRO II

For Attention of*::name of the Customer

Contact details of local representative (name, e-mail, telephone, address etc.)*
To be determined

Rev 1: September 2018

FSN Ref: 2026/02 FSCA Ref: FA-0000155

Urgent Field Safety Notice (FSN)

HEALON EndoCoat™ PRO, HEALON DUET™ PRO II

Device Insertion Technique Clarification

1. Information on Affected Devices	
1.	1. Device Type(s)
	The HEALON EndoCoat™ PRO Ophthalmic Viscosurgical Device (OVD) is a sterile, non-pyrogenic, transparent viscoelastic preparation of a highly purified, noninflammatory fraction of sodium hyaluronate from fermented bacteria with dispersive rheological properties. The HEALON EndoCoat PRO OVD contains30 mg/ ml (3 %) sodium hyaluronate, dissolved in a physiological sodium chloride phosphate buffer (pH 6.8-7.6). It has an average molecular weight of approximately 1,000,000 Daltons. This polymer consists of repeating disaccharide units of N acetylglucosamine and sodium glucuronate linked by glycosidic bonds. The HA in HEALON EndoCoat PRO OVD is produced by bacterial fermentation and does not contain any proteins, cells or tissue of human or animal origin.
1.	2. Commercial name(s)
	Healon EndoCoat PRO, Healon Duet PRO II
1.	3. Unique Device Identifier(s) (UDI-DI)
	5050474a000669W, 5050474a000679Y
1.	4. Primary clinical purpose of device(s)
	The HEALON EndoCoat PRO OVD is an opthalmic viscoelastic solution containing 3% sodium hyaluronate indicated for use as a surgical aid in ophthalmic anterior segment surgical procedures including: cataract surgery with an intraocular lens, cataract surgery without an intraocular lens, secondary intraocular lens implantation. The HEALON EndoCoat PRO OVD maintains a deep chamber during anterior segment surgery, aids in tissue manipulation during surgery, enhances visualization during the surgical procedure and protects the corneal endothelium and other ocular tissue. The viscoelasticity of the solution maintains the normal position of the vitreous face and prevents formation of a flat chamber during surgery. It may also be used to coat intraocular lenses and insertion instruments prior to intraocular lens implantation.
1.	5. Device Model/Catalogue/part number(s)
	10301012, 10301016
1.	6. Affected serial or lot number range
	UB33014, UB33041, UB33057, UB33060, UB33100, UB33190, UB33084, UB33194

2 Reason for Field Safety Corrective Action (FSCA)	
2.	1. Description of the product problem*
	HEALON EndoCoat™ PRO is supplied with an ultra-thin walled 25G orange cannula compared to the thin-walled 25G blue cannula supplied with HEALON EndoCoat. The cannula is designed to pass smoothly through the paracentesis (side-port) incision. Users have reported challenges related to insertion during procedure with the HEALON EndoCoat™ PRO OVD

Rev 1: September 2018

FSN Ref: 2026/02 FSCA Ref: FA-0000155

2.	2. Hazard giving rise to the FSCA
	Unintended tissue injury, including, but not limited to corneal abrasion, iris trauma or Descemet's Membrane Detachment, which may require medical or surgical intervention to preclude serious injury.
2.	3. Probability of problem arising
	The product problem has resulted in the identified harm, but only occasionally and/or under unusual circumstances.
2.	4. Predicted risk to patient/users
	The harms identified from complaints include: Corneal Abrasion and Iris damage which is reversible without medical intervention. This condition will resolve itself without treatment or long-term consequences. Descemet's Membrane Detachment which will require medical or surgical intervention to preclude a serious injury. This condition will result in permanent impairment if not treated. This does not impact the overall benefit-risk ratio of the affected products for HEALON EndoCoat™ PRO OVD. No patient at greatest risk was identified.
2.	5. Further information to help characterise the problem
	This instruction will help prevent potential hazards which may occur during the surgical procedure and use of this device. Please ensure that you read and consider this information.

	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) – see below
	☐ Other ☐ None
	This is a device technique clarification. We are not removing or recalling these products.
	This instruction will help prevent potential hazards which may occur during the surgical procedure and use of this device. Please ensure that you read and consider this information. This investigation is currently ongoing, and we will notify users if any additional information comes to light.
	The cannula is designed to pass smoothly through the paracentesis (side-port) incision. If resistance is encountered during insertion, withdraw the cannula and reassess the insertion conditions (i.e. insertion angle, incision size, etc.) before proceeding. Do <u>not</u> force the cannula through the incision, as this may increase the risk of unintended tissue injury, including, but not limited to corneal abrasion, iris trauma or Descemet's Membrane Detachment, which may require medical or surgical intervention to preclude serious injury.

Johnson&Johnson

Rev 1: September 2018

FSN Ref: 2026/02 FSCA Ref: FA-0000155

	Actions to be taken: ➢ Forward this notice to all surgeons using this device in your facility. ➢ If any of the subject product has been transported to another facility/surgeon, contact that facility/surgeon and provide/forward this notice to them. ➢ Keep a copy of this notice with the subject product. ➢ Please complete, sign, and return ***Attachment 1: Customer Reply Form*** within 5 business days by email per instruction below. If you have questions or concerns with regard to this notification, please contact Global Post Market Safety Team at <Insert Local Info here>. As with any medical device, adverse reactions or quality problems experienced with the use of this product should be reported to your national Competent Authority.	
3.	2. By when should the action be completed?	Immediately
3.	3. Is customer Reply Required? (If yes, form attached specifying deadline for return)	Yes
3.	**4. Action Being Taken by the Manufacturer** ☐ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☒ Other ☐ None This investigation is currently ongoing, and we will notify users if any additional information comes to light	
3	5. By when should the action be completed?	To be determined
3.	6. Is the FSN required to be communicated to the patient /lay user?	No
3	7. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?	
	No Not appended to this FSN	

	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

Rev 1: September 2018

FSN Ref: 2026/02 FSCA Ref: FA-0000155

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	AMO Uppsala AB
	b. Address	RAPSGATAN 7, SE75136, Uppsala, Sweden
	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.	
4.	9. List of attachments/appendices:	HEALON EndoCoat™ PRO, HEALON DUET™ PRO II FSN Customer Reply Form
4.	10. Name/Signature	

	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.

Rev 1: September 2018

FSN Ref: 2026/02 FSCA Ref: FA-0000155

ATTACHMENT 1: CUSTOMER REPLY FORM

HEALON EndoCoat™ PRO, HEALON DUET™ PRO II

Product Number	Product Name
10301012	HEALON EndoCoat™ PRO
10301016	HEALON DUET™ PRO II

PLEASE COMPLETE THIS FORM AND RETURN IT TO:
EMAIL: <Insert Local Info here>

Please complete this Customer Acknowledgement Form **within 5 business days upon receipt of the notification** and return to the e-mail address above.

JJV Account Number:	
Account Name:	
Address:	
Country:	
Telephone Number:	
E-Mail	

Person completing this form acknowledges receipt and understanding of the actions, as stated in the Product Notification letter:

Name: (print)	
Title/Position:	
Signature:	
Date:	