FAN ID: 15-12-2021 Language: English
Type: Advice from manufacturer regarding use by customer

EFTIAR Octane, syringes and vial, 5 ml and 7 ml (product codes EFT-05-OCT, EFT-07-OCT, EFT-OCT5-S, EFT-OCT7-S)

FAN Identifier: 15-12-2021

Att: [name customer]
[address customer]
[postal code, city]
[country]

Dear Customer,

The purpose of this letter is to inform you about the upcoming addition of a new warning and a new precaution in the Instructions of Use of the Eftiar Octane product line.

This letter concerns EFTIAR Octane vials and syringes (5ml and 7ml - product codes EFT-05-OCT, EFT-07-OCT, EFT-OCT5-S, EFT-OCT7-S). According to our information, in the last three years, you have ordered EFTIAR Octane, which is the reason why you receive this letter.

The new warning and precaution addresses a newly identified risk linked to the use of Per-Fluor-Carbon-Octane liquids in ophthalmic surgery. This risk was identified during the investigation of a serious adverse event. For this event it could not be excluded that ingress of EFTIAR Octane into the vascular system could have caused a fatal air embolism after uneventful choroidal melanoma endoresection without air infusion. The benefits of the use of EFTIAR Octane continue to outweigh the risk, providing that users take into account the additional warning and precaution.

Please review this information with relevant members of your staff and pass it on to all those who need to be aware of it (including other organizations who might have received this product from you).

If you need any further information or support concerning this letter, please contact our Customer Technical Service Center on +31 181 45 80 80 or at TSC@dorcglobal.com.

D.O.R.C. Dutch Ophthalmic Research Center (International) B.V. is committed to ensure patient safety and therefore decided to share this important information with you prior to implementation in the Instructions for Use. The appropriate Regulatory Agencies have been informed about this notification.

Kind regards,

…,

15 December 2021

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Field Safety Notice

Type: **Advice from manufacturer regarding use by customer**

Affected product, commercial name	EFTIAR Octane, vials and syringes, 5 ml and 7 ml
Affected product article number	EFT-05-OCT, EFT-07-OCT, EFT-OCT5-S, EFT-OCT7-S
How to identify affected products	The Field Safety Notice applies to the use of Per-Fluor-Carbon-Octane liquids in general, including DORC EFTIAR Octane
Reason for FCA	A new risk was identified during the investigation of a serious adverse event. For this event it could not be excluded that ingress of EFTIAR Octane into the vascular system could have caused a fatal air embolism after uneventful choroidal melanoma endoresection without air infusion. In addition a recent publication (Rojanaporn et al, Ocul Oncol Pathol 2021;7:321–325) cited two cases unrelated to the use of Eftiar Octane, where air embolism occurred after choroidal melanoma endoresection, despite avoiding air infusion during the surgery.
Risk of continued use	The benefits of the use of EFTIAR Octane continue to outweigh the risk, providing that users take into account the following additional warning and precaution: <u>Warning</u> Eftiar Octane should not be injected directly into the vortex vein. In addition, inadvertent leakage of intraocular perfluoro-octane into the vortex vein should be avoided. <u>Precaution</u> Special precautions are indicated when Eftiar Octane may enter the vascular circulation (e.g. during endoresection of intraocular tumors and ocular trauma). Rare cases of air embolisms potentially related to the PFCL ingress have been reported
Risks of previous use	None
Customer actions	We request that you take the following actions: • Please pass the information provided in this Field Safety Notice on to all those who need to be aware of it (including other organizations who might have received this product from you). • Complete the attached Field Safety Notice Acknowledgement Form, sign it and return a scan or photo of the signed form by email to at TSC@dorcglobal.com.
Manufacturer actions	• Informing you about the newly identified risk and resulting warning and precaution through this Field Safety Notice. • To add the additional warning and precaution to the IFU.

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Field Safety Notice Acknowledgement Form

By completing and signing the section below I confirm that I have read and understood the Field Safety Notice identified by FAN ID: 15-12-2021 and that this information was provided to all those who need to be aware of it.

Responder information
Organization name:
Full name of responder:
Title:
Contact phone:
Contact address:
Date of completion:
Signature of responder:

Please send a scanned copy or photo of this completed form per email as soon as possible to: TSC@dorcglobal.com