FLUORON® GmbH • Magirus-Deutz-Str. 10 • 89077 Ulm • GERMANY

Sender:
Fluoron GmbH
Phone: + 49 731 2055997 0
Fax: + 49 731 2055997 28
Email: complaints@fluoron.de

Ulm, 21 May 2019

Safety notice
VOLUNTARY BATCH RECALL

Affected product:	**Brilliant Peel**
Material number:	**G-81010**
Version:	**Syringe**
Lot number:	**BP 0.5S 300718**
Manufacturer:	**Fluoron GmbH, Magirus-Deutz-Str. 10, 89077 Ulm (DE)**

Dear Sir or Madam,

Feedback from the market and subsequent internal investigations have drawn our attention to an irregularity in a production batch of the above product. In a part of the batch concerned (BP 0.5S 300718), the application of the product in the pre-filled syringe may result in a noticeable resistance (sticky/halting) of the plunger. Due to increased pressure, there is a risk of a jet stream of fluid to enter the eye and potentially damage the retina. Application of the product in the central vitreous cavity can counteract or attenuate potential penetration of the retina by a jet stream. Corrective actions with increased quality assurance measures to measure and eliminate the irregularities have been implemented and are strictly monitored. The dosage form "Vial" as well as all other batches of the dosage form "Syringe" except the above-mentioned lot are not affected by this report.

Always, when using the product, strict adherence to the instructions for use must be observed, in particular the section >Warnings and precautions<
"Check to ensure that the syringe stopper moves smoothly prior to use" as well as
"The stopper must be retracted prior to the injection".

As a precaution, Fluoron GmbH is now voluntarily recalling the affected batch of the product.

Further use and distribution of the listed production batch must be discontinued immediately.

Measures to be taken immediately by the customer:
According to our documentation, you have received products from the batch mentioned by us. We kindly ask you to track, separate and quarantine these products.

FLUORON® GmbH
Gesellschaft für hochreine Biomaterialien
Sitz der Gesellschaft:
89077 ULM, GERMANY
Geschäftsführer: Volker Geuder
Amtsgericht Ulm HRB 723852
USt-IdNr.: DE812135435

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info@fluoron.de
www.fluoron.de

Commerzbank AG, Ulm
Konto-Nr.: 08 011 588 00
BLZ: 630 800 15
SWIFT-BIC: DRES DE FF630
IBAN: DE56630800 150801158800

Zertifiziert nach DIN EN 13485

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Please confirm with your signature on the enclosed feedback form that you have received this notice and that you have read and understood the necessary measures. We then kindly ask you to return the affected batch to us.

For products that are returned, a replacement or credit note will be provided. Contact your sales representative of the GEUDER AG to arrange the return of stock and suitable exchange.

Forwarding this notification:

Please ensure in your organisation that all users of the above-mentioned batch and other persons to be informed are aware of this notice. If you have delivered the products to third parties, please forward a copy of this information to all affected users and distributors.

Reshipment:

Please address the reshipment to:
GEUDER AG
Hertzstr. 4
69126 Heidelberg
Germany
phone: +49 6221 3066
Complaint Geuder AG <complaint@geuder.de>

For further information or support please contact Fluoron GmbH via
Email: complaints@fluoron.de, or phone: +49 731 20 55 997 0, or FAX: + 49 731 20 55 997 28.

Please keep this information at least until the action has been completed. We recommend that you keep a copy of this notification and a signed copy of the confirmation form in your files.

This notice has been sent to the relevant regulatory authorities.

We apologize for any inconvenience you, your staff and your patients may experience in this regard. However, Fluoron believes that this is the right step to take. The decision to perform this voluntary recall reflects Fluoron's commitment to high quality standards and an uncompromising commitment to patient safety.

Yours sincerely,

Dr. Wilfried Kugler
- Safety Officer for Medical Devices –

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Annex I / Customer feedback

Safety notice
VOLUNTARY BATCH RECALL

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Dear Sir or Madam,

We hereby confirm that we have read and understood your voluntary product recall dated 21 May 2019 and that we have informed all affected persons in our facility. We have discontinued the further use and distribution of the existing batch with immediate effect.

Yours sincerely,

Customer's / dealer's name:
Address:
ZIP / City:
Country:
Document completed by:
Phone:
E-Mail:

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Annex II / Stock confirmation

Safety notice
VOLUNTARY BATCH RECALL

Affected product:	**Brilliant Peel**
Material number:	**G-81010**
Version:	**Syringe**
Lot number:	**BP 0.5S 300718**
Manufacturer:	**Fluoron GmbH, Magirus-Deutz-Str. 10, 89077 Ulm (DE)**

Dear Sir or Madam,

Products still in stock or returned to us will be immediately returned to Geuder AG. For the return delivery we request a

☐ credit note

or

☐replacement

Please confirm the stocks of the affected product at your location.

Product	Quantity received	Quantity used	Quantity in stock	Quantity returned
Brilliant Peel Lot: BP 0.5S 300718				

Yours sincerely,

Customer's / dealer's name:
Address:
ZIP / City:
Country:
Document completed by:
Phone:
E-Mail:

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