

MEDICAL DEVICE RECALL

___ January 2016

Name
Address line 1
Address line 2

Ladies and Gentlemen,

We would like to inform you that Ivoclar Vivadent AG is removing Helioclear from circulation as a precautionary measure. It cannot be warranted that the material of the affected lot can be sufficiently cured with all polymerization lights.

We believe that there is no increased health hazard for patients, users or the environment.

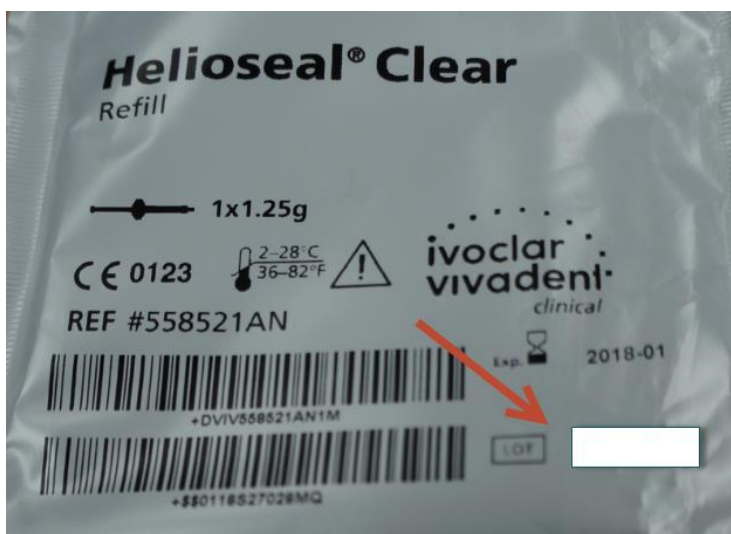
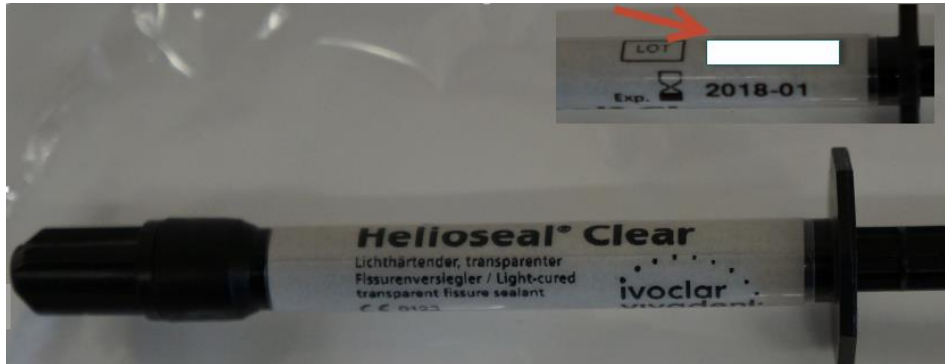
Please take the following measures:

- Check your inventory and block any products of the affected lot.
- Contact the author of this notification via email and inform her or him about the affected and blocked products in your inventory.
- Please find below the number of products from the affected Helioclear lot delivered to you:

Art. no.	Description	Lot no.	Delivery quantity	Delivery date:

You will find the lot code on the product and/or product packaging.





Required measures:

- Discontinue delivery of the affected lot/products.
- Assess how many products of the affected lot you hold in stock.
Inform us about the individual quantities of the affected lot/products you hold in stock. Your contact: Sandra Schwarzenberger
[**\(Sandra.Schwarzenberger@ivoclarvivadent.com\)**](mailto:Sandra.Schwarzenberger@ivoclarvivadent.com)
- Please return all affected products in your inventory to:

Ivoclar Vivadent AG
Sandra Schwarzenberger
Bendererstr. 2
FL-9494 Schaan
Liechtenstein

Returned products will be refunded by credit note or replacement delivery without delay.

Measures taken by the company:

We have introduced additional quality checks to prevent this problem from occurring again.

Additional information:

The manufacturer of the product, Ivoclar Vivadent AG in Liechtenstein, is responsible for this recall and we can assure you that the authorities have been informed of this incidence. If you have any questions, please contact your local Ivoclar Vivadent customer support centre. We would like to thank you in advance for your understanding and collaboration and would like to apologize for any inconvenience that this incidence may have caused to you.

Yours sincerely

IVOCLAR VIVADENT AG

Patrik Oehri
CQM - Corporate Quality Management
Safety officer