

RECALL OF A MEDICAL DEVICE

Ladies and Gentlemen

We would like to inform you that Ivoclar Vivadent AG recalls the product **Triplex Hot pink and Triplex Cold pink-V** as a precautionary measure.

Reason: The denture base materials Triplex Cold and Triplex Hot have been interchanged.

Risk assessment:

The risk for patients, users and third parties is considered acceptable. As the materials do not work properly (shade, polymerisation) it is detected by the technicians.

- Please check your storage facility and block the stock of the respective products / batches.
- Please inform all your laboratory and clinic partners that received the corresponding material.
- Please contact the author of this letter by e-mail and inform him/her about the quantity of the product blocked in your storage facility.
- Below, we will inform you about the quantities of the products in question delivered to you:

Art. No.	Description	Batch No.	Delivery quantity	Delivery date
541440	SR Triplex Cold Polymer 2x500g pink-V	XT1373		
541417	SR Triplex Hot Polymer 20x500g pink	XT1372		

The batch number (lot number) can be found on the product and/or the respective packaging.

Please take the following measures:

- Stop deliveries of the batches/products in question
- Recall all products delivered to your customers.
- Inventory of the batches/products in question
Please let us know by e-mail, the individual quantities of the batches/products in question.
Contact person: Claudia Stückler / claudia.stueckler@ivoclarvivadent.com
- Please return all your stocks of the batches/products in question to:

Ivoclar Vivadent AG
Attn. Claudia Stückler
Bendererstrasse 2
FL – 9494 Principality of Liechtenstein

You will receive a corresponding credit note and/or replacement delivery immediately.

Measures on the part of the company:

- The affected batches/products are to be destroyed in the headquarters.

Additional information:

The manufacturer Ivoclar Vivadent AG in Liechtenstein is responsible for this recall. Should you have any further question, please contact the Ivoclar Vivadent Customer Services in your country. Thank you very much for your cooperation and your understanding in this matter. We apologize for any inconvenience caused.

Sincerely,

Claudia Stückler

Ivoclar Vivadent AG
Coordinator Quality Complaint Management
Responsible for Technical Materials

On behalf of Patrik Oehri
Director CQM

ANNEX – 02-2019-003-R / Triplex Hot & Cold

Please return this completed form to the following address immediately:

Ivoclar Vivadent AG
 Attn. Claudia Stückler
 Bendererstrasse 2
 FL – 9494 Principality of Liechtenstein
Claudia.stueckler@ivoclarvivadent.com

Customer	
Name:	
Contact person:	
Customer number:	Phone number:

Material tally			
Batch No.	Units received	Units blocked	Units delivered

Traceability			
Batch No.	Customer No. / Name	Delivered quantity	Date

Date:	
Name:	
Signature:	

Company stamp:	
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Document history / change history

Reason for the preparation / revision: Revision

Replaces the following documents: TEFO-01678-EN V.1

DRAFT