

FIELD SAFETY CORRECTIVE ACTION OF A MEDICAL DEVICE

2021-10-25

Name
Address

Dear Ladies and Gentlemen,

We would like to inform you that Ivoclar Vivadent AG recalls the denture base material Probase Cold Monomer of the batches listed below as a precautionary measure.

Reason: Probase® Cold is designed as a self-curing denture base material. Due to a failure in composition of the affected batches the denture base material will not cure completely and stays rubbery.

Risk assessment: Insufficient curing of the self-curing denture base material is determined by the dental technician in every case. Therefore, there is no risk for the patient. **The insufficiently cured dental workpiece has a high residual monomer content of MMA and must be disposed of in accordance with the information in the safety data sheet (see attachment).**

Measures to be taken:

- Please check your storage facility and block the stock of the respective products / batches.
- 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. / Serial No.	Basic UDI-DI	SRN	Delivered quantity	Delivery date
531505	ProBase Cold Monomer 500 mL	Z02DS2; Z02DS1; Z02DRH; Z02FF2; Z02DRG; Z02DRZ	Not in scope of a EC MDR certificate yet	LI-MF-000000522		
531506	ProBase Cold Monomer 1000 mL	Z02DRT; Z02DRS; Z02DRR; Z02DRP; Z02DRN	Not in scope of a EC MDR certificate yet	LI-MF-000000522		
531542	ProBase Cold Monomer 4×1000 mL	Z02DRJ	Not in scope of a EC MDR certificate yet	LI-MF-000000522		

The batch 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
- 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: **Insert contact person / insert e-mail address**
- Please return all your stocks of the batches/products in question to:

Ivoclar Vivadent AG
Head of Department Valuestream
Mr. Marc Oelmann
Bendererstrasse 2
9494 Schaan
Liechtenstein

Please consider the section 14: Transport information of the attached material safety data sheet

- **Or** dispose the material according to material safety data sheet and document the disposal by using TEFO-04172-EN - FSCA Scrapping Log and return the filled in Scrapping Log.
Contact person: **Insert contact person / insert e-mail address**

Please consider the section 13: Disposal information of the attached material safety data sheet

You will receive a corresponding credit note or replacement delivery as you desire after receiving the returned material in Schaan or after receiving the Scrapping Log for the indicated amount. All other material will be replaced via Complaint Management.

Measures taken by the company:

1. Immediate termination of product delivery for the affected batches.
2. Separation and Blocking of the affected batches within all Ivoclar Vivadent warehouses world-wide.
3. Further corrective actions will be defined based on the findings of the Root Cause Analysis.

Additional information:

The manufacturer Ivoclar Vivadent AG in Liechtenstein is responsible for this FSCA 10-2021-002-R and we confirm that the authorities have been informed accordingly. Should you have any further question, please contact the Ivoclar Vivadent Customer Services in your country. We would like to thank you in advance for your cooperation and understanding. We apologize for any inconvenience that may arise or may have arisen as a result of this matter.

Sincerely,

Ivoclar Vivadent

Insert first name, last name
and position

Attachment