ivoclar vivadent
passion vision innovation

MEDICAL DEVICE RECALL

June 2016

Dear Sir, dear Madam,

we hereby inform you, that as a precautionary measure, Ivoclar Vivadent AG is recalling the product listed below.
The affected polisher may suffer increased wear during use. In this case there is no increased health risk to patients, users or the environment. Further measures, e.g. for patients who have already been treated, are not necessary.

We ask you to carry out the following measures:

- Please check your stock and secure the affected products and batch.
- Contact the author of this letter by email and inform them of the amount of stock secured in your warehouse.
- Please return all items of concern in your possession to:

  Ivoclar Vivadent AG
  Ms Sandra Schwarzenberger
  Bendererstrasse 2
  FL-9494 Schaan

You will receive a credit note immediately.

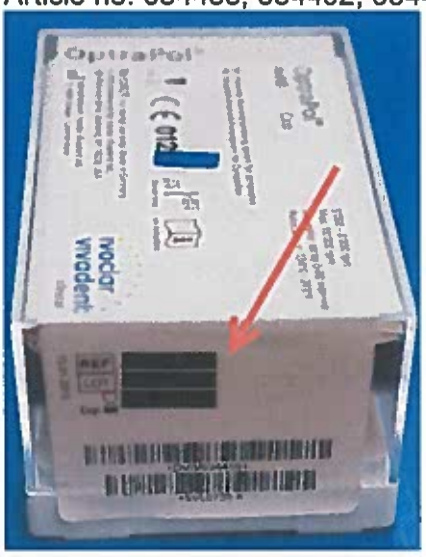
Below you can find information about the amount of affected product which was delivered to you:

Art. no.:	Description	Batch no.	Delivered quantity	Delivery date
634458	OptraPol Small Flame	VL0704		
634462	OptraPol PromoPack	VL0715		
634463	OptraPol TestPack	UL0838		
634464	OptraPol Assortment	VL0705		
634459	OptraPol Cup Refill	VL0733		
634459	OptraPol Cup Refill	UL0843		
680184AN	Tetric N-Ceram System Kit A2/N Univ. 6g	V17591		
680184AN	Tetric N-Ceram System Kit A2/N Univ. 6g	V19571		
680184AN	Tetric N-Ceram System Kit A2/N Univ. 6g	V19572		
680184AN	Tetric N-Ceram System Kit A2/N Univ. 6g	V19573		
680184AN	Tetric N-Ceram System Kit A2/N Univ. 6g	V20677		

628244AN	Telio CS C&B Starter Kit A2	V19582		
664756	Direct Restoratives Workshop Kit	V19868		
664703	Composite Workshop Kit (Emp. Bulk Fill)	V20567		

The batch no. (Lot) is on the product packaging:

Article no. 634458, 634462, 634464, 634459



Article no.6344663

Article no. 680184AN

Article no. 664756

Article no. 664703

Article no. 628244AN

Measures undertaken by the company:
Additional quality controls were introduced to prevent a recurrence of this error.

Further information:
This voluntary recall is the responsibility of the manufacturer Ivoclar Vivadent AG, Liechtenstein. We confirm that this matter has been reported to the appropriate authorities.

We would like to thank you in advance for your cooperation and for your understanding. We apologize for any inconvenience caused to you by this matter.

Best regards

IVOCLAR VIVADENT AG

Patrik Oehri
Director – Corporate Quality Management
Safety Officer