

Various Dental Polishers / Ivoclar Vivadent AG Recall (8/16)

Reason/Information:

Ivoclar Vivadent AG issued a Medical Device Recall on the following materiel (See Image on Message under Additional Documentation/Attachment). **Reason:** After a few seconds of polishing with moderate force, parts of the OptraPol cup are breaking away. OptraPol Small Flame is also affected. Two complaints were filed referring to OptraPol, claiming that the abrasive polishers wear faster than expected.

Disposition/Instructions:

Actions to be taken:

--Check stock and secure the affected materiel and batch.

--Contact Ivoclar Vivadent by email and inform them of the amount of stock secured in customer's warehouse.

--Return all items of concern in customer's possession to:

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

--Customers will receive a credit note immediately.

If customers have any questions regarding this notification contact Ivoclar Vivadent AG at 716-691-2260 or 800-533-6825.

Item Information:

NSN (FSC-NIIN): 6520 - NS1

PartNo: 634464

Nomenclature: OPTRAPOL NG ASSORTMENT #634464

UI: EA

Manufacturer: IVOCLAR VIVADENT

Distributor:

LOT / SN:

VL0705

NOTE 1:

FDA Recall #Z-2373-2016

NSN (FSC-NIIN): 6520 - NS2
PartNo: 634459
Nomenclature: OPTRAPOL NG CUP REFILL #634459
UI: EA
Manufacturer: IVOCLAR VIVADENT
Distributor:

LOT / SN:

UL0843 VL0733

NOTE 1:

FDA Recall #Z-2373-2016

NSN (FSC-NIIN): 6520 - NS3
PartNo: 634458
Nomenclature: OPTRAPOL NG SMALL FLAME REFILL *10#634458
UI: EA
Manufacturer: IVOCLAR VIVADENT
Distributor:

LOT / SN:

VL0704

NOTE 1:

FDA Recall #Z-2373-2016

NSN (FSC-NIIN): 6520 - NS4
PartNo: 634462
Nomenclature: OOTRAPOL PROMOPACK
UI: EA
Manufacturer: IVOCLAR VIVADENT
Distributor:

LOT / SN:

VL0715

NSN (FSC-NIIN): 6520 - NS5

PartNo: 680184AN

Nomenclature: TETRIC N-CERAM SYSTEM KIT A2/N UNIV. 6G

UI: EA

Manufacturer: IVOCLAR VIVADENT

Distributor:

LOT / SN:

V17591 V19571 V19572

V19573 V20677

NSN (FSC-NIIN): 6520 - NS6

PartNo: 628244AN

Nomenclature: TELIO CS C&B STARTER KIT A2

UI: EA

Manufacturer: IVOCLAR VIVADENT

Distributor:

LOT / SN:

V19582

NSN (FSC-NIIN): 6520 - NS7

PartNo: 664756

Nomenclature: DIRECT RESTORATIVES WORKSHOP KIT

UI: EA

Manufacturer: IVOCLAR VIVADENT

Distributor:

LOT / SN:

V19868

NSN (FSC-NIIN): 6520 - NS8

PartNo: 664703

Nomenclature: COMPOSITE WORKSHOP KIT (EMP. BULK FILL)

UI: EA

Manufacturer: IVOCCLAR VIVADENT

Distributor:

LOT / SN:

V20567

Additional information and documentation can be found by clicking [here](#).