



March 2, 2016

«PARTY_NAME»
«ADDRESS1»
«ADDRESS2»
«CITY», «STATE», «POSTAL_CODE»
«COUNTRY»

URGENT: MEDICAL DEVICE RECALL

Dear Valued Customer:

Kerr Corporation is voluntarily recalling certain lots of **Herculite Ultra, Herculite XRV, Point 4, and Premise**. The affected product may have been shipped to your facility from July 2015 to February 2016.

It has recently come to our attention that an issue with the production process used to package the affected lots of **Herculite Ultra, Herculite XRV, Point 4, and Premise** may lead to the presence of plastic particulates in the dental composite material. The particulate is visible to Doctors and should be easy to remove prior to or even after curing. Furthermore, the particulate is unlikely to cause any adverse health consequences. There is no need to replace any restorations placed with this material.

**Please refer to the enclosed Lot Number Tables
to determine if you have any of the affected product in your inventory.**

If you have any of the affected product listed above **please contact Kerr Customer Care at 1-800-537-7123 to receive an RMA number**. The RMA will allow for a quick return and replacement.

KERR CORPORATION KINDLY REQUESTS YOUR COOPERATION IN COMPLETING AND EMAILING BACK THE ENCLOSED ACKNOWLEDGEMENT FORM IN ORDER TO CONFIRM YOUR RECEIPT OF THIS FIELD CORRECTION LETTER, REGARDLESS OF WHETHER YOU HAVE ANY PRODUCT IN YOUR INVENTORY.

If you are an authorized Kerr Corporation distributor, we request that you identify those customers that may have been shipped the affected product and contact these customers to inform them of the issue.

Kerr Corporation sincerely apologizes for the inconvenience this situation causes you and your customers.

Thank you for your patience and support.

Sincerely Yours,



Mark Dzendzel
Senior Quality Systems and Compliance Manager



«PARTY_NAME»
«ADDRESS1»
«ADDRESS2»
«CITY», «STATE», «POSTAL_CODE»
«COUNTRY»

Unidose Acknowledgement and Recall Return Form

**Please refer to the enclosed Lot Number Tables
to determine if you have any of the affected product in your inventory.**

- ☐ *We acknowledge receipt of the Herculite Ultra, Herculite XRV, Point 4, and Premise Recall Notification. We have checked our inventory and were able to locate one or more units of the above-mentioned product. We will be returning the following quantity to Kerr Corporation. Additionally, we acknowledge that we will identify those customers that may have been shipped the affected product lot and contact these customers in order to recover their affected product.*

Product Name	Part Number	Lot Number	Quantity Returned

- ☐ *We acknowledge receipt of the Herculite Ultra, Herculite XRV, Point 4, and Premise Recall Notification. We have checked our inventory and were unable to locate any of the above-mentioned product. Additionally, we acknowledge that we will identify those customers that may have been shipped the affected product and will contact these customers in order to recover it.*

Contact Person (Please Print)

Facility

Signature/ Date:

Phone Number

**WE ALSO KINDLY REQUEST YOUR COOPERATION IN EMAILING THIS
ACKNOWLEDGEMENT FORM TO THE FOLLOWING ADDRESS TO CONFIRM
YOUR RECEIPT OF THIS NOTIFICATION WHETHER OR NOT YOU HAVE ANY
AFFECTED PRODUCT.**

unidose.response@kerrdental.com



TABLE 1: HERCULITE ULTRA LOT NUMBER TABLE

Brand	Shade	Item Number	Starting Lot Number	Ending Lot Number
HERCULITE ULTRA	XL	34346	5634445	5743402
HERCULITE ULTRA	A1	34347	5635804	5831960
HERCULITE ULTRA	A2	34348	5638138	5824459
HERCULITE ULTRA	A3	34349	5644674	5831957
HERCULITE ULTRA	B1	34350	5644694	5811172
HERCULITE ULTRA	C1	34351	5642342	5815630
HERCULITE ULTRA	A2	34352	5665960	5821234
HERCULITE ULTRA	A3	34353	5629018	5794251
HERCULITE ULTRA	LI	34354	5704433	5746354
HERCULITE ULTRA	A3.5	34448	5633741	5809373
HERCULITE ULTRA	A4	34776	5666021	5844811
HERCULITE ULTRA	B2	34777	5660063	5815628
HERCULITE ULTRA	C2	34778	5665948	5834779
HERCULITE ULTRA	C3	34779	5634444	5822619
HERCULITE ULTRA	D2	34780	5634249	5833228
HERCULITE ULTRA	B3	35159	5638513	5730861
HERCULITE ULTRA	B4	35160	5686298	5686298
HERCULITE ULTRA	D3	35161	5633740	5816861
HERCULITE ULTRA	D4	35162	5633739	5759330
HERCULITE ULTRA	B1	35163	5696921	5794316
HERCULITE ULTRA	C4	35166	5633736	5829146



TABLE 2: HERCULITE XRV LOT NUMBER TABLE

Brand	Shade	Item Number	Starting Lot Number	Ending Lot Number
HERCULITE XRV	A1	29835	5578094	5661436
HERCULITE XRV	A1	29835	5757948	5757948
HERCULITE XRV	A1	29835	5786128	5786128
HERCULITE XRV	A2	29836	5560979	5661617
HERCULITE XRV	A2	29836	5706090	5706090
HERCULITE XRV	A2	29836	5743307	5743307
HERCULITE XRV	A2	29836	5762801	5768139
HERCULITE XRV	A2	29836	5780662	5791379
HERCULITE XRV	A2	29836	5803348	5803348
HERCULITE XRV	A2	29836	5816037	5816037
HERCULITE XRV	A3	29837	5578099	5644670
HERCULITE XRV	A3	29837	5671945	5671945
HERCULITE XRV	A3	29837	5675655	5675655
HERCULITE XRV	A3	29837	5698321	5702365
HERCULITE XRV	A3.5	29838	5602184	5635456
HERCULITE XRV	A3.5	29838	5667818	5667818
HERCULITE XRV	A4	29839	5568988	5677791
HERCULITE XRV	A4	29839	5749776	5825986
HERCULITE XRV	B1	29840	5567550	5682219
HERCULITE XRV	B1	29840	5698258	5702362
HERCULITE XRV	B1	29840	5751198	5794276
HERCULITE XRV	B2	29841	5610478	5660067
HERCULITE XRV	B2	29841	5690773	5815632
HERCULITE XRV	B3	29842	5561045	5687452
HERCULITE XRV	B4	29843	5629015	5716343
HERCULITE XRV	C1	29844	5613689	5686347
HERCULITE XRV	C2	29845	5605334	5689927
HERCULITE XRV	C2	29845	5745185	5824460
HERCULITE XRV	C3	29846	5575685	5808193
HERCULITE XRV	C4	29847	5561043	5675681
HERCULITE XRV	C4	29847	5704501	5815505
HERCULITE XRV	D2	29848	5602170	5808191
HERCULITE XRV	D3	29849	5563692	5654406
HERCULITE XRV	D3	29849	5693249	5713474
HERCULITE XRV	D4	29850	5563689	5682623
HERCULITE XRV	A2	29851	5575686	5791388
HERCULITE XRV	A3	29852	5563691	5746358
HERCULITE XRV	A3.5	29853	5654699	5718890
HERCULITE XRV	B1	29854	5568986	5746231
HERCULITE XRV	B2	29855	5561013	5714471
HERCULITE XRV	C2	29856	5637520	5637520
HERCULITE XRV	D2	29857	5703013	5703013
HERCULITE XRV	LI	29858	5575687	5740262
HERCULITE XRV	MI	29859	5727665	5727665

**TABLE 3: POINT 4 LOT NUMBER TABLE**

Brand	Shade	Item Number	Starting Lot Number	Ending Lot Number
POINT 4	A1	29898	5641127	5641127
POINT 4	A1	29898	5686722	5700351
POINT 4	A2	29899	5621261	5640371
POINT 4	A2	29899	5677634	5713562
POINT 4	A2	29899	5745021	5780664
POINT 4	A2	29899	5808173	5808173
POINT 4	A3	29900	5677632	5677632
POINT 4	A3	29900	5789524	5797396
POINT 4	A3.5	29901	5641130	5810827
POINT 4	A4	29902	5641137	5798479
POINT 4	B1	29903	5689929	5806886
POINT 4	B2	29904	5633256	5798460
POINT 4	B3	29905	5666034	5792943
POINT 4	B4	29906	5664743	5664743
POINT 4	B4	29906	5738115	5738115
POINT 4	C1	29907	5638137	5796247
POINT 4	C2	29908	5660059	5784324
POINT 4	C3	29909	5635773	5706921
POINT 4	C4	29910	5705896	5716157
POINT 4	D2	29911	5677627	5821240
POINT 4	D3	29912	5679207	5679207
POINT 4	D4	29913	5641138	5738123
POINT 4	XL1	29914	5637633	5654787
POINT 4	XL2	29915	5727679	5727679
POINT 4	XL3	29916	5743918	5743918
POINT 4	T1	29917	5641311	5750051
POINT 4	T2	29918	5684074	5684074
POINT 4	T3	29919	5814075	5814075
POINT 4	A2	31368	5720005	5727670
POINT 4	A3	31369	5727671	5727671
POINT 4	A3.5	31370	5673892	5673892
POINT 4	B1	31372	5665999	5720367

**TABLE 4: PREMISE LOT NUMBER TABLE**

Brand	Shade	Item Number	Starting Lot Number	Ending Lot Number
PREMISE	A1	32650	5671940	5678804
PREMISE	A1	32650	5690778	5702809
PREMISE	A1	32650	5733890	5733890
PREMISE	A1	32650	5775595	5777283
PREMISE	A1	32650	5796224	5808278
PREMISE	A2	32651	5773245	5773245
PREMISE	A2	32651	5780663	5788293
PREMISE	A2	32651	5815615	5815615
PREMISE	A3	32652	5621258	5640373
PREMISE	A3	32652	5679190	5679190
PREMISE	A3	32652	5745032	5784489
PREMISE	A3	32652	5794679	5797741
PREMISE	A3.5	32653	5738136	5738136
PREMISE	A3.5	32653	5777219	5811267
PREMISE	A3.5	32653	5825965	5825965
PREMISE	A4	32654	5684736	5825969
PREMISE	B1	32655	5666015	5666015
PREMISE	B1	32655	5748480	5769524
PREMISE	B2	32656	5658521	5740136
PREMISE	B2	32656	5791382	5791382
PREMISE	B3	32657	5686115	5798635
PREMISE	B4	32658	5644521	5740966
PREMISE	C1	32659	5666029	5794689
PREMISE	C2	32660	5654951	5793320
PREMISE	C3	32661	5713471	5716181
PREMISE	C4	32662	5656232	5799613
PREMISE	D2	32663	5684430	5816980
PREMISE	D3	32664	5684737	5748486
PREMISE	D4	32665	5676111	5740973
PREMISE	XL1	32666	5667006	5805452
PREMISE	XL2	32667	5676105	5754526
PREMISE	A2	32668	5658338	5719950
PREMISE	A3	32669	5676087	5723552
PREMISE	A3.5	32670	5671861	5671861
PREMISE	A4	32671	5713473	5727686
PREMISE	B1	32672	5673633	5673633
PREMISE	B2	32673	5743325	5743325
PREMISE	C2	32674	5723554	5723554
PREMISE	D2	32675	5726406	5726406
PREMISE	TA	32676	5665994	5665994
PREMISE	TG	32677	5738513	5738513
PREMISE	TC	32678	5675946	5714515
PREMISE	TSC	32679	5727654	5727654