Recall Report November 21, 2013

Product	**IMPRINT™ II REGULAR BODY VPS REFILL 4-PACK PARADIGM™ REGULAR BODY VPS REFILL 2-PACK**
Report Number	**1**
Recall Number	**# 300517437011222013005-R**

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Date of Report	Date: November 22, 2013
Device Manufacturer (Owner/Operator)	3M ESPE Dental Products 2510 Conway Ave St. Paul, MN 55144-1000 FDA Establishment No: 2110898
Device Manufacturer's Representative Responsible for Conducting the Device Removal	Will Donovan Vice President, Quality, Regulatory & EHS Manager 3M ESPE Dental Products 2510 Conway Ave (651) 733-7767
Most Responsible Person	Joaquin Delgado Executive Vice President 3M Health Care Business 3M Center Bldg, 220-14E-14 St. Paul, MN 55144-1000
Address if Manufacturing Site	
Device Brand Name	IMPRINT™ II Regular Body VPS Impression Material PARADIGM™ Regular Body VPS Impression Material
Device Common Name	Impression Material
Device Classification Name	Class II
Intended Use of the Device	• Crown and bridge impressions • Inlay and onlay impressions • Functional impressions • Implant impressions • Denture and partial denture impressions
Marketing Status of the Device	Class II Medical Device per CFR Section 872.3660 510(k) #: K000591 Device Listing #: D021388
Product, Catalog/Model Number, and Lot Involved Subject to Recall	IMPRINT™ II Regular Body VPS Impression Material Refill 4-PACK Catalog Number 9379 • Lot Codes N510884 and N510889 PARADIGM™ Regular Body VPS Impression Material Refill 2-PACK Catalog Number 5315 • Lot Code N511952
Reason for Removal and Date and Circumstances under which the Product Deficiency was Discovered	3M ESPE Product Engineer received a single complaint sample for Imprint II Regular Body VPS Impression Material. After investigation, analysis, and a detailed mass balance calculation it was determined that the ingredient that gives hydrophilic properties to this impression material was left out of the formulation. The two different trade names and corresponding lot numbers are listed above. Proposed FDA Recall Classification: Class III

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Root Cause	Operator error
Corrective Actions, including Recall Strategy • Depth of Recall • Method of Notification • Class of Recall • Effectiveness Checks	All 3M Distributors and individual customers to whom affected product was shipped will be notified via e-mail and/or phone call, using customer sales records/data. Notification is anticipated starting November 22, 2013. 3M Distributors will be asked to notify all customers to whom the affected lots were shipped. Proposed FDA Recall Classification: III **Accounting of Affected Product:** **IMPRINT™ II REGULAR BODY VPS Impression Material REFILL 4-PACK** Lot Code: N510884 Kit quantity: 350 kits (Cartridge quantity: 1400 cartridges) 1. Japan received 350 kits in 5 separate shipments 2. No other country received product from LOT # N510884 **IMPRINT™ II REGULAR BODY VPS REFILL 4-PACK** Lot Code N510889 Kit quantity: 1696 kits (Cartridge quantity: 6784 cartridges) 1. Distributors in the USA received 565 Kits (2260 cartridges) 2. Korea received 600 kits (2400 cartridges) 3. EU Received 100 Kits (400 cartridges) 4. Canada received 60 kits (240 cartridges) 5. Mexico Received 110 Kits (440 cartridges) 6. Hong Kong received 22 Kits (44 cartridges) 7. Taiwan received 30 Kits (120 cartridges) 8. United Arab Emirates received 10 Kits (40 cartridges) 9. Irvine has placed 199 kits (796 cartridges) - Quarantine Status **PARADIGM™ REGULAR BODY VPS REFILL 2-PACK** Lot Code N511952 Kit quantity: 130 kits (Cartridge quantity: 260 cartridges) 1. All 130 kits (260 cartridges) were received by one distributor in USA Letters explaining the reason and scope of the recall will be sent to Distributors and Customers who received this product. Customers will receive replacement product upon request.
Preventive Action to Prevent Recurrence	Corrective action will be documented in CAPA-00482
Injuries Associated with the Use of the Device	None
Number and Summary of Product Quality Complaints	As of November 22, 2013 a single complaint has been received. Customer noticed the paste viscosity was thinner than he is accustomed using.

Date of Manufacture and Total Amount of Products Produced	• Paste manufacturing was completed on 08/19/13. • 7044 cartridges were produced using this paste batch
Amount of product on hand when recall began and disposition	IMPRINT™ II Regular Body VPS REFILL 4-PACK Catalog #9379, Lot Code N510889: 199 kits in 3M Irvine manufacturing facility Product was placed on Quarantine status and will be destroyed.
Number of Consignees Notified of the Recall and Date and Method of Communication	Distributors will be contacted. Individual customers will be notified by distributors.
Number of Consignees responding to the recall communication and amount of product on hand at the consignees at the time communication was received	TBD
Number of Consignees that have not responded	TBD
The amount of product returned or destroyed by the consignees contacted, and the quantity of product accounted for.	TBD
The number and results of effectiveness checks that were made	TBD
Date Recall Initiated (Date letters are sent to distributors, doctors, etc)	Communications to be sent to Distributors and Customers on November 21, 2013.
The estimated time frame for completion of this recall.	March 1, 2013
Date Recall Completed	TBD
For Drug Product, list the following: • NDA Number and NDC Number • Prescription or OTC Drug • Strength • Route of Administration	NA- Not a drug product