Recall Submission: InterGuard 5.5mm, Lots BC2GN, BC4L7

This document has been put together following the FDA guidance document, "Guidance for Industry: Product Recalls, Including Removals and Corrections," issued 3 November 2003, and 21 CFR Part 7. This is a voluntary recall, and we believe this recall represents a low risk to health. The local district recall coordinator, Caroline Li, was notified via email on December 10, 2015 of our intent to recall the two lots of the affected product. This document represents the recall submission outlined in the aforementioned guidance document.

1. PRODUCT INFORMATION:

Product Name	InterGuard 5.5mm
Description & Indications	Description: InterGuard is made of stainless steel and has a curl at each end. InterGuard fits snugly in both large and small interproximal spaces. It comes in two sizes, 4.0mm for short anatomical crowns and 5.5mm for tall anatomical crowns. Indications: InterGuard is a preventive aid for operative dentistry. It is used to protect adjacent teeth from iatrogenic preparation damage. This includes cavity and tunnel preparations as well as air abrasion.
Part Number	4012
Packaging	The Econo Refill kit contains 1 plastic, stackable container that contains 50 InterGuards. An Instruction for Use is placed in each container.
FDA Code	DZN
Regulation No.	872.4565 - Instrument, Dental Hand
510(k) No.	N/A Product is a Class I device
Shelf Life	N/A

List of attached labels (Appendix A):

Part Number	Description
20274	Die InterGuard 50pk
65432	InterGuard Instructions For Use

2. CODES (Production Identification Numbers):

Affected lot and part numbers:

Part No.	Description	Lot No.	Expiration Date
4012	InterGuard 5.5mm Econo Refill	BC2GN	N/A
4012	InterGuard 5.5mm Econo Refill	BC4L7	N/A

3. RECALLING FIRM:

Ultradent Products, Inc.
505 West 10200 South
South Jordan, UT 84095
Establishment Registration Number: 1718912
Firm type: Manufacturer, distributor, initial importer, repackager/relabeler
Types of products: Medical devices, OTC drugs, Cosmetics

Function	Name	Title	TEL	FAX	Email
Recall Contact	Karen Kakunes / Corey Jaseph	Sr. Regulatory Affairs Associate/ Regulatory Manager	801-553-4366 / 801-553-4420, 801-400-4940	801-553-4609	Karen.kakunes@ultradent.com Corey.jaseph@ultradent.com
Owner	Dr. Dan Fischer	President/ CEO	801-553-4193, 801-553-2198	801-572-0600	Dan.fischer@ultradent.com
Management Representative	Amber Schofield	Quality Assurance	801-553-4319	801-553-4601	Amber.schofield@ultradent.com

4. MANUFACTURER:

Ultradent Products, Inc.
505 West 10200 South
South Jordan, UT 84095

5. IDENTIFY FIRM RESPONSIBLE FOR THE VIOLATION/PROBLEM:

Ultradent Products, Inc.
505 West 10200 South
South Jordan, UT 84095

6. REASON FOR THE RECALL:

InterGuard is a purchased part which is then de-burred, kitted, and marketed by Ultradent Products, Inc. During internal QC Inspection, it was found that the floss tether hole was not punched through completely and that the blank is still attached in the punch hole area. No complaints have been received to date.

Investigation: A CAPA (CA-00362) has been opened with the supplier, Spring Works Utah, 2261 South 1560 West, Woods Cross, UT 84087, to address and correct the manufacturing issue of the tether hole not being completely punched through. The manufacturer identified that there was a lack of control on the overall punch usage. The punch, which is supplied by Ultradent Products, Inc., was being used for too many parts without being replaced. Based on the investigation, this appears to be an isolated error to the manufacturer production run (Job 45383).

During the investigation of the supplier corrective action, it was also discovered that there was not sufficient internal inspections being performed by Ultradent Products, Inc. In addition to the insufficient inspections, labeling errors were also in the Instruction for Use (IFU). A second CAPA, CA-00365, was opened to address these issues.

Summary and conclusion: The missing punch hole error was isolated to the identified manufacturer job (45383) and Ultradent Products, Inc. lot(s) BC2GN and BC4L7. The supplier has put a corrective actions into place which will include punches to only be used for 120,000 pieces (maximum) at which point a new punch will replace the old and running smaller batch sizes before visually inspecting parts and punch.
Internal inspections will be strengthened to coincide with the corrections made at vendor. The IFU will be updated to include the option of tethering floss through the curled end of the product as a means of reducing the risk of aspiration and swallowing during procedure.
Through inspection post quarantine, it was determined that approximately 7% of the finished goods would have the defective punch hole issue. The issue, while it could contribute to a safety concern, has not resulted in a customer/patient complaint.

7. HEALTH HAZARD ASSESSMENT:

Summary: Without the floss tether hole being properly stamped open, it eliminates one route of tethering floss. The floss can still be tethered through one of the curled ends of the InterGuard. Tethering via the designed hole or around the curled end is a training element of dentistry. Per in-house clinician, many dentists choose not to tether despite training. However, it is at our instruction that the floss be tethered through the hole. Given each of these elements, we have deemed this to be an issue that will not likely, through use as it is, cause any adverse events. This determination

has been made knowing that the dentist is trained in operative dentistry and knows how to properly use this common device.

The complete health hazard assessment may be found in Appendix B.

8. VOLUME OF RECALLED PRODUCT:

Lot BC2GN	
Total quantity produced	150*
Date produced	September 14, 2015
Quantity distributed	157*
Dates distributed	Sep 18, 2015 – Oct 21, 2015
Quantity quarantined	0
How quarantined	N/A – no remaining stock in inventory
Est. amt. rem. in mkt	Unknown
-Distribution	85 - Sold internationally to dental distribution centers
-Retail	N/A – not sold retail
-User (dentist)	72 – sold domestically directly to dentists
Status of product remaining in market	Used on dental patients or in stock at dental offices or international dental distribution offices

*Shipping discrepancy. CA-00365 will address this issue.

Lot BC4L7	
Total quantity produced	200
Date produced	October 19, 2015
Quantity distributed	30
Dates distributed	Oct 20, 2015 – Nov 13, 2015
Quantity quarantined	170
How quarantined	Moved to MRB and sent back to vendor for replacement
Est. amt. rem. in mkt	Unknown
-Distribution	17- Sold internationally to dental distribution centers
-Retail	N/A – not sold retail

Lot BC4L7	
-User (dentist)	13 – sold domestically directly to dentists
Status of product remaining in market	Used on dental patients or in stock at domestic dental offices or international distribution offices

9. DISTRIBUTION PATTERN:

26 of the 38 customers who purchased this item and identified lot numbers are either dental offices or schools located in the United States. One of these customers is further identified as either Ultradent Territory Account Managers or Ultradent Corporate. The remaining 12 customers are international distributors located in Austria, Canada, Colombia, Denmark, France, Germany, Great Britain, Iceland, and Portugal. The consignee list is attached in Appendix C.

10. RECALL STRATEGY:

- We are sending a letter to each customer who received the affected lot numbers. This letter will explain the recall, which part # and lot#s are affected, and how they should proceed. The letter will all be sent via FedEx on December 22, 2015 with a 2 day delivery and tracking number so we can verify receipt. The customer communications are included as Appendix D.
- All inquiries regarding the FDA recall will be sent to either Karen Kakunes or Corey Jaseph in Regulatory Affairs.
- Replacement product will be sent to each of the identified customers upon completion.