



## International Contact Template

To:

From: Heather Ivy-Wagstaff

Date:

Memorandum

1900 Aston Avenue  
Carlsbad, CA 92008

### **FIELD ACTION NOTIFICATION** **IMMEDIATE RESPONSE REQUIRED**

ATTENTION: Zimmer Dental Distributor/Zimmer Dental Subsidiary

Zimmer Dental is conducting a voluntary recall of the below products. Our records indicate that your office previously received a shipment of the affected lot(s).

Through investigation, Zimmer Dental determined that certain lots of the GemLock® Long Hex Driver, Catalog RHL2.5, (the "Affected Product") may not fit into the Fixture Mount Transfer (FMT) or the internal hex of the implant. The Affected Product was also distributed within the Tapered SwissPlus & SwissPlus Implant Systems Kit, Surgical, Complete, Catalog OPCST as well as the Tapered Screw-Vent Implant System Surgical Kit, Complete, Catalog TSVKIT, so please search all of your kits. The Affected Product is easily identifiable regardless of the lot number on the label, as the Affected Product is etched with one of the following supplier lot numbers: **62699693 & 62735177**. Nevertheless, please reference the above table for a listing of all lot numbers.

Catalog Number	Lot Number on Label	Etched Lot Number of RHL2.5	Quantity	Sales Order Number	Ship Date
RHL25	62712431	62699693			
RHL25	62743168	62735177			
OPCST	62766610	62735177			
TSVKIT	62702589	62699693			
TSVKIT	62710484	62699693			
TSVKIT	62712437	62699693			
TSVKIT	62743075	62735177			
TSVKIT	62750487	62735177			
TSVKIT	62753787	62735177			
TSVKIT	62756920	62735177			
TSVKIT	62759862	62735177			
TSVKIT	62760388	62735177			
TSVKIT	62768456	62735177			
TSVKIT	62773158	62735177			

Our records indicate that the above product was shipped to you. Please check your inventory and/or distribution records **immediately** for this particular product. If you have this product, **immediately quarantine and remove products from service and** secure it from possible use.

**Risks:**

- If the clinician attempts to use *GemLock* Long Hex Driver and the driver does not fit into the internal hex of the FMT, this could delay treatment while the surgeon obtains the *GemLock* Hex Short Driver (RH2.5) or *GemLock* Hex Drill Driver (RHD2.5) from the Instrument Kit to continue placement.
- If the clinician attempts to use the *GemLock* Long Hex Driver and the driver engages into the FMT but not the implant, this could delay treatment while the surgeon obtains the *GemLock* Hex Short Driver (RH2.5) or *GemLock* Hex Drill Driver (RHD2.5) from the Instrument Kit to continue placement.

Please complete the following:

1. **Please complete and return the questionnaire on the following page and return it to Heather Ivy-Wagstaff via fax (760) 929-4358 or e-mail [heather.ivy@zimmer.com](mailto:heather.ivy@zimmer.com) within seven days.** A return number will be provided to you.
2. Write the return number on the shipping box and return the product to the following address:  
Zimmer Dental Returns  
1900 Aston Avenue  
Carlsbad, CA 92008

**Do not return field action product with other returns.**

3. Your account will be credited upon return of product. If you need replacement parts, please contact Heather Ivy-Wagstaff via fax **(760) 929-4358** or e-mail [heather.ivy@zimmer.com](mailto:heather.ivy@zimmer.com).

If you have sold the product, or you are otherwise no longer in control of it, explain this in the questionnaire on page two of this letter and return it within **seven days** to the below named individual via Fax (760) 929-4358 or e-mail at [heather.ivy@zimmer.com](mailto:heather.ivy@zimmer.com).

If you have any questions, please call us at 800-854-7019.

Heather Ivy

Associate Manager, International Marketing

**DISTRIBUTOR/SUBSIDIARY QUESTIONNAIRE**  
**IMMEDIATE RESPONSE REQUIRED**

**PLEASE COMPLETE THE FOLLOWING AND RETURN TO ZIMMER DENTAL:**

Catalog Number	Lot Number	Quantity Received	Quantity Distributed	Quantity Returning

**Return Product To:**  
**Zimmer Dental Returns**  
**1900 Aston Avenue**  
**Carlsbad, CA 92008**

**DO NOT RETURN REMOVAL PRODUCT WITH OTHER RETURNS.**

**ALL PRODUCT MUST BE ACCOUNTED FOR. If you cannot account for product shipped to your account, please explain:**

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**Completion of this questionnaire confirms that my inventory and all my customer accounts have been checked for this product and all affected product will be returned to Zimmer Dental.**

**NAME OF DISTRIBUTOR/SALES ASSOCIATE COMPLETING THIS FORM:**

Printed Name: \_\_\_\_\_ Signature: \_\_\_\_\_

Title: \_\_\_\_\_ Telephone: (    ) \_\_\_\_ - \_\_\_\_ Date: \_\_/\_\_/\_\_

**NOTE: This form and affected product must be returned to Zimmer before this activity can be considered closed for your account.**