URGENT: DEVICE RECALL

RECALL OF *TRANSFX DRILL BIT*
DISTRIBUTED BY ZIMMER, INC.

May 1, 2009

INTENDED AUDIENCE	**Zimmer, Inc. Sales Force & Distributors (and User Facilities who received product from these entities)**	
PRODUCT	**Name of Product**	**Part Number and Lot Numbers**
	TRANSFX DRILL BIT	00-4450-054-00 00-4450-063-00 00-4450-056-00 00-4450-065-00 00-4450-058-00 00-4450-067-00 00-4450-061-00 See attached listing of affected lot numbers (page 4 of this notice).

REASON FOR RECALL

Zimmer, Inc. is initiating a voluntary recall of the *TransFx Drill Bit* item numbers 00-4450-054-00, 00-4450-063-00, 00-4450-056-00, 00-4450-065-00, 00-4450-058-00, 00-4450-067-00, and 00-4450-061-00.

These items possess non-conforming tip geometry, reducing the efficiency of drilling action, requiring more force and potentially heating the bone surface during operation.

TransFx drill bits can be found in the following kits:

Name	Part Number
TransFx Intermediate External Fixation System	00-4450-005-10
TransFx Large External Fixation System	00-4450-010-10
TransFx Small External Fixation System	00-4450-005-15

Note that only drill bits etched with the Immedica logo are affected by this recall. See page 5 for a visual aid. If the logo is not present, the part is not within the recall scope.

CLINICAL IMPLICATIONS (Risks to Health)

The geometry of the drill bit will not provide optimal cutting when engaged with bone. Friction between the poorly cutting drill and bone could result in heat generation. In most cases, the surgeon would likely conclude that a new drill bit is needed prior to the generation of heat capable of causing necrosis.

If the surgeon applies additional pressure to engage the drill bit, there is an increased risk of injury caused by drill slippage, skiving (off angle drilling), or fracture.

The surgery could be delayed while alternative equipment is obtained.

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ACTION	1. **Stop using the devices and quarantine all units immediately.** 2. **Destroy product at your location and discard** 3. Please provide a physical count of all affected product destroyed from your region and record this data on the Inventory Return Certification Form included with this letter. 4. **Fax a copy of the completed Inventory Return Certification form to:** Zimmer, Inc. at (574) 371-8603 *Important: If you have distributed these affected lots further, please provide a copy of this letter to these customers when you implement these recall instructions.*
OTHER INFORMATION	Notifications of this recall are being sent to all affected direct accounts of Zimmer, Inc. For shipping assistance, questions or assistance in notifying your accounts about the recall please contact Zimmer, Inc. at 1-800-613-6131. Zimmer, Inc. is committed to providing our customers with the highest level of service and product quality. We appreciate your cooperation, and we regret any inconvenience this action may cause your hospital and your staff. ***This voluntary recall will be reported to the U.S. Food and Drug Administration. The FDA will also receive from Zimmer progress reports on the implementation of this recall. Your urgent cooperation is requested.***
MEDWATCH REPORTING	Any adverse reactions experienced with the use of these products, and/or quality problems may also be reported to the FDA's MedWatch Program by phone at 1-800-FDA-1088, by Fax at 1-800-FDA-0178, by mail at MedWatch, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787, or on the MedWatch website at www.fda.gov/medwatch. Under 21 CFR Part 803, manufacturers are also required to report any serious injuries where a device has contributed to or may have contributed to the event. Please keep Zimmer informed of any adverse events associated with this device or any other Zimmer product.

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Recall Inventory Return Certification Form

Fax back to: Zimmer, Inc. at (574) 371-8603

Use the table below to record quantities of the affected product at your territory or hospital.

Part Number	Lot Number	Quantity Destroyed	Quantity Consumed/Used

Credit will be issued once we receive confirmation that the product was destroyed.

DO NOT RETURN RECALL PRODUCT WITH OTHER RETURNS.

Acknowledgement of Responsibility:
By signing below, I acknowledge that quantities of all **TransFx Drill Bits from the lot(s) detailed in this notification** in our territory are listed above and have been returned to Zimmer, Inc. in accordance with the Recall notice.

Printed Name:_____ Signature:_____

Title _____ Telephone: ( ) _____-_____ Date:____/____/____

Country: _____Account Number: _____