



URGENT: DEVICE RECALL

RECALL OF *MOST® HINGED TIBIA BASEPLATE SPACER*
DISTRIBUTED BY ZIMMER, INC.

February 11, 2009

INTENDED AUDIENCE	Zimmer Germany Sales Force & Distributors (and User Facilities who received product from these entities)	
PRODUCT	Name of Product	Part Number and Lot Numbers
	MOST® Hinged Tibia Baseplate Spacer	Part Number 5020-06-001 Lot Number 1635572
REASON FOR RECALL	<p>Zimmer, Inc. is initiating a voluntary recall of the MOST® Hinged Tibia Baseplate Spacer due to the package containing 11mm screws intended for the thicker spacers rather than the intended 6mm screws.</p> <div data-bbox="619 931 1145 1263" style="text-align: center;"> </div>	
CLINICAL IMPLICATIONS	<p>Condition has a high probability of discovery, but would not be discovered until the point of use in the operating room. If discovered a user can typically retrieve 6mm screws from another implant in the series.</p> <p>If the discovery is not made then, the following hazard could occur.</p> <ul style="list-style-type: none"> ▪ If the surgeon implanted the device as packaged, the result could have been a loose spacer, leading to the surgeon having to remove the spacer and try another one. If the loose spacer was not noticed there is a remote possibility that it could result in patient pain and an eventual revision. 	

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ACTION	<ol style="list-style-type: none">1. Stop using the provisional and quarantine it immediately.2. Please carry out a physical count of all affected product in your country and record this data on the Inventory Return Certification Form included with this letter.3. Fax a copy of the completed Inventory Return Certification form to: Zimmer, Inc. at (574) 371-86034. Request an IRA [REDACTED]5. Return the recalled product along with the completed Inventory Return Certification Form and IRA to: Zimmer Distribution Center Attn: Product Service 1777 West Center Street Warsaw, IN 465806. Credit will be issued upon receipt of the returned product.
OTHER INFORMATION	<p>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.</p> <p>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.</p> <p>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.</p> <p><i>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.</i></p>

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Inventory Return Certification Form

Fax back to: Zimmer, Inc. at (574) 372-4265

Use the table below to record quantities of the affected product in your country.

Part Number	Lot Number	Quantity Returned
5020-06-001	1635572	

Return Product To:
Zimmer Product Service Department
1777 West Center Street
Warsaw, IN 46580

DO NOT RETURN RECALL PRODUCT WITH OTHER RETURNS.

Acknowledgement of Responsibility:

By signing below, I acknowledge that quantities of **All MOST® Hinged Tibia Baseplate Spacer from the lot detailed in this notification** in our country 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: _____