

# FIELD NOTICE: PRODUCT REMOVAL

## Immediate Response Required



Wallaby III revision tibial insert D-14, constrained, REF 43.26.78-14, LOT 2367837  
**DISTRIBUTED BY ZIMMER WINTERTHUR**

04. September 2009

<b>PRODUCT</b>	<b>Name of Product</b>	<b>Part Number/Lot Number</b>
	<b>WALLABY III REVISION TIBIAL INSERT D-14, CONSTRAINED</b>	<b>Part Number 43.26.78-14  Lot Number 2367837</b>
	<b>Firm Conducting Removal:</b>	
		Zimmer GmbH Sulzerallee 8 / P.O. Box CH-8404 Winterthur
<b>REASON</b>	Zimmer GmbH is initiating a recall of the Wallaby III revision tibial insert D-14, constrained, REF 43.26.78-14, LOT 2367837  A packaging was found which actually contained a hip acetabular liner.	
<b>HEALTH RISK SUMMARY</b>	Potential for surgical delay while a suitable replacement is acquired. The potential also exists that a surgeon might have to select a different implant to complete the procedure.  The Lot of the hip acetabular liner was fully contained at our central warehouse.	
<b>COUNTRIES AFFECTED</b>	5 Germany, 2 France	
<b>REGULATORY IMPACT</b>	FSCA to European competent authorities – risk to health possible. Device not sold in U.S.	
<b>ACTION</b>	<ol style="list-style-type: none"> <li>1. Our records indicate the above mentioned product was shipped to your account. Please check your inventory for this product and at all your customer accounts of unused units. Stop using these devices and quarantine them immediately.</li> <li>2. Please carry out a physical count of all affected products in your account and record this data on the Inventory Return Certification Form included with this letter.</li> <li>3. Mail a copy of the completed Inventory Return Certification form to:  <a href="mailto:christof.mueller@zimmer.com">christof.mueller@zimmer.com</a> </li> </ol>	

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	<p>4. Return the product along with the completed Inventory Return Certification Form by 20<sup>th</sup> September 2009. Return under separate cover and labeled with "REC-010859" QUARANTINE, DO NOT USE" to:</p> <p><b>Zimmer International Logistics GmbH</b> Attn: [REDACTED] Max-Immelmann-Allee 12 79427 Eschbach Germany</p> <p style="text-align: right;"><b>Return #: REC-010859</b></p> <p><b>NOTE: DO NOT RETURN PRODUCT REMOVAL PRODUCTS WITH OTHER RETURNS.</b></p>
<p><b>OTHER INFORMATION</b></p>	<p>Notifications of this removal are being sent to all affected direct accounts of Zimmer GmbH. For shipping assistance, questions or assistance in notifying your accounts about the removal please contact via email <a href="mailto:christof.mueller@zimmer.com">christof.mueller@zimmer.com</a>.</p> <p>Zimmer 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. Your urgent collaboration is requested.</p>