



**Medical Devices Bureau, Ministry of Health Malaysia**  
**Level 4&5, Block E6, Parcel E, Precint 1,**  
**Federal Government Administration Centre,**  
**62590 Putrajaya**  
**Tel: 03-8883 2248/2249/2264**  
**Fax: 03-8888 6184**

**Medical Device / Equipment RECALL**

**Date Issued : 5 May 2008**

**Ref:MDB/R/2008/006**

<b>IMMEDIATE ACTION</b>	√
<b>ACTION</b>	
<b>UPDATE</b>	
<b>INFORMATION REQUEST</b>	

<b>PRODUCT</b>	<b>Surgical Blades manufactured by ConMed Linvatec Hall.</b>
<b>CLASS</b>	n/a
<b>USE</b>	Surgical blades in blister packaging – single-use device.
<b>SOURCE OF MEDICAL DEVICE RECALL / ALERT</b>	Medicines and Healthcare products Regulatory Agency, United Kingdom’s website, date issued: 29 <sup>th</sup> April 2008
<b>ALERTING / RECALLING FIRM</b>	ConMed Linvatec United Kingdom 73/74 Shrivenham Hundred Business Park Swindon Wiltshire SN6 8TY Tel: 01793 787 918 Fax: 01793 784 568 E-mail: CMurray@linvatec.com
<b>REASON</b>	<b>Sterility Concern.</b>  Holes have been discovered in the corners of the blister packaging for these devices.  This may compromise the sterility of the device and lead to the possibility of infection. The manufacturer is recalling products with codes and lot numbers listed in the Appendix 1.

<b>SCENARIO IN MALAYSIA</b>	<b>No details available at this moment.</b> Please check whether the device is available and contact the distributor.
<b>ACTION</b>	<p><i>Action or Recommendations For Healthcare Professionals</i></p> <ul style="list-style-type: none"> <li>• Ensure that all relevant staff in your institution are informed of this recall</li> <li>• Determine if you have the above products as mentioned in the Appendix 1.</li> <li>• Locate and cease using product from the mentioned lot numbers.</li> <li>• Determine how much of this product has been used</li> <li>• Follow the distributor / manufacturers recommendations for quarantine and disposal of affected products.</li> </ul>
<b>RECOMMENDATION</b>	<p>Users of the abovementioned device should contact the distributors/supplier of this device (if available) and <b>inform the Medical Devices Bureau, Ministry of Health</b> providing the following information:-</p> <ol style="list-style-type: none"> <li>a. Name of healthcare centre/hospital/clinic</li> <li>b. Contact person and contact number</li> <li>c. Numbers of units available</li> </ol>
<b>CONTACT/ENQUIRIES IN MALAYSIA</b>	<b>Currently No Information Available</b>
<b>REFERENCES</b>	<a href="http://www.mhra.gov.uk/Publications/Safetywarnings/MedicalDeviceAlerts/CON014973">http://www.mhra.gov.uk/Publications/Safetywarnings/MedicalDeviceAlerts/CON014973</a>

73/74 Shrivenham Hundred Business Park  
Swindon  
Wiltshire  
SN6 8TY

Phone: 01793 787910

Fax: 01793 784568



## URGENT MEMO

31 March 2008

Dear Sir/Madam

Please find attached our Medical Device Recall Notification. I would appreciate it if you could read through this documentation and reply accordingly.

If you do have some of the affected items, can you please ring me on 01793 787918 and I will arrange collection and replacements for you. Please also sign and complete the attached form and fax back to me for my records.

Please advise on the Reply Form if you wish me to send you replacements, or credit.

Can you please sign the Reply Form and fax it back to me on 01793 784568, if you do not have any of the affected items.

Kind Regards

Cal Murray  
Customer Services Department



**URGENT  
MEDICAL DEVICE RECALL**

**To:**

**Date:** March 19, 2008

International Customer -UK

**Attention: Risk Manager or Materials Manager**

**Product Description:** ConMed Linvatec Hall<sup>®</sup> Surgical Blades, Sterile, Single-use, packaged in Blisters (tray with Tyvek lid, sold as singles and boxes of 5)

**Catalog and Lot Number(s):** See Attached Listing of Affected Catalog and Lot Numbers

**Recall Reason:** ConMed Linvatec has determined there is a possibility that certain catalog numbers and lots of ConMed Linvatec Hall<sup>®</sup> Surgical Blades, may have a hole(s) in the corner(s) of the blister package (tray), thereby potentially compromising the sterility of the devices. This recall is being conducted to the distributor and user level. Please do not use the products.



**Package Example:**

**Area of Hole(s) in Blister**

**Health Risk:** Sterility of the devices may be compromised. However, to date, ConMed Linvatec has had no reports of infections associated with the use of the affected recalled products.

**Action to be taken:**

- ▶ Please check your facility's inventory **immediately** for the catalog and lot numbers in the attached list.
- ▶ To return the products to ConMed Linvatec for a credit, return the products and **REPLY FORM** to your ConMed Linvatec UK Distributor. Use ConMed Linvatec's return goods number **RG08** for your return. Your ConMed Linvatec UK Distributor will collect any affected products and the **Reply Form**, and will return them to ConMed Linvatec, Largo, FL.
- ▶ If your facility does not have any of the affected catalog and lot numbers in the attached list in inventory, please complete the **REPLY FORM** and mail or fax it to your ConMed Linvatec UK Distributor.

Please accept our sincere apology for any inconvenience this action may have caused. Should you have any additional questions, please contact Cal Murray, ConMed Linvatec UK Customer Services Supervisor, at 01793 797918 or fax at 01793 784568, email [cmurray@linvatec.com](mailto:cmurray@linvatec.com)

Sincerely,

Deborah Mahoney  
Recall Coordinator  
ConMed Linvatec USA  
(International Customer Notification-UK)

**APPENDIX 1 – AFFECTED LOT NUMBERS**

**CATALOG/PART  
NUMBER LOT**

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**CATALOG/PART  
NUMBER LOT**

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**CATALOG/PART  
NUMBER LOT**

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**CATALOG/PART  
NUMBER LOT**

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**00507116700** BBD22418 00507118100 BBD22416 00507119600 BBD34292  
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**00507130300** 00985291 00507155100 BBD27531 00507155600 BBD26022  
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**00507131400** 00985303 00507155200 BBD22163 00507155600 BBD35908  
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<b>00507134500</b> 00985322 00507155300	BBD26018 00507157200 BBD24161
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00507159000 BBD27087 <b>C8802</b>	BBD22165 K144 BBD23822

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00507159000 BBD38292 C8802 BBD37688	<b>K146</b> BBD27542
<b>00507210000</b> BBD26843 <b>C8804</b> BBD22409	<b>K147</b> BBD23025
<b>00507210100</b> BBD23982 C8804 BBD23262	K147 BBD24733
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00507210100 BBD27960 C8804 BBD31975	<b>K148</b> BBD22793
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00507210100 BBD29955 <b>C8806</b> 00101036	<b>K151</b> BBD22485
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00507210100 BBD34560 <b>C8902</b> BBD28003	K151 BBD29429
<b>00507210200</b> BBD27999 C8902 BBD29409	K151 BBD29465
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<b>00507210500</b> BBD22168 C8904	BBD29451 <b>K153</b> BBD23744
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00507210900 BBD26617 K121	BBD22487 <b>K155</b> BBD21410
00507210900 BBD30788 K121	BBD24496 <b>K156</b> BBD24422
00507210900 BBD40111 <b>K124</b>	BBD22492 <b>L121</b> BBD21756
<b>00507211100</b> BBD26284 <b>K132</b>	BBD24468 L121 BBD27692
<b>00507214000</b> BBD22176 <b>K133</b>	BBD22788 L122 BBD21757
00507214000 BBD33234 <b>K134</b>	BBD22627 L122 BBD22623
<b>00507215000</b> BBD31986 K134	BBD22786 <b>L124</b> BBD22400
00507215000 BBD35913 K134	BBD27300 L124 BBD23820
<b>00507215100</b> BBD21603 K134	BBD24759 L124 BBD26030
00507215100 BBD23268 K134	BBD27676 <b>L129</b> BBD34688

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<b>L130</b> BBD23467	L146 BBD34685	U551 BBD26292
<b>L135</b> BBD22872	<b>L192</b> BBD22178	U551 BBD29777
L135 BBD27346	<b>L197</b> BBD24649	U551 BBD31415
<b>L145</b> BBD26731	<b>P513</b> BBD23817	<b>U554</b> BBD22981
L145 BBD31737	<b>U332</b> BBD22177	<b>U655</b> BBD23126
L145 BBD31738	U332 BBD22938	<b>U773</b> BBD22983
L145 BBD31739	<b>U335</b> BBD22611	U773 BBD26291
<b>L146</b> BBD21976	<b>U438</b> BBD27677	U773 BBD29416
L146 BBD27690	U438 BBD35728	
L146 BBD31996	<b>U551</b> BBD22966	