URGENT: FIELD SAFETY NOTICE

ConMed Corporation Electrosurgery Active Electrodes and Accessories

7 January 2013

ConMed Corporation is sending this communication to provide you with important information concerning a packaging issue with certain ConMed Electrosurgery Disposable Active Electrodes and Accessories. All suspect product catalog numbers and lot codes are listed in Attachment I.

These devices were manufactured by ConMed Corporation. ConMed has received complaints of some devices which had broken through the seal of the sterile pouch. ConMed has confirmed instances where the pouch seal was compromised on the affected products. In no instance has it been reported to ConMed Corporation that a compromise in the sterile barrier has resulted in illness or injury. ConMed Corporation has decided to recall the devices listed on Attachment I to the user level. **Therefore, please stop the use of these devices immediately.**

Please review your inventory for any of the devices listed on Attachment I.

We ask that you contact all of those organizations within your facility and any other facilities that you may have supplied or given these affected products to. It is imperative that all end users of these devices receive this notice and respond immediately. **If you have questions, please contact Patricia Cotter, ConMed Recall Coordinator +1 315-624-3237 or fax to +1 315-624-3225 or email ultrablade@conmed.com.** You may also contact our Authorized Representative MDSS GmbH situated in Germany via email at info@mdss.com or via phone at +49 511 6262 8630.

If you have any devices listed on Attachment I, please complete Attachment II and return it with the devices to:
ConMed Corporation,
525 French Road, Utica, NY 13502
United States of America
Attn. [redacted]
Return via: FedEx Account # 487553646

Please process a commercial invoice for the return to the United States referencing your purchase price as a value for Custom's purposes and note on the commercial invoice that the return is for evaluation purposes only. Please include the following information on the invoice, with the returned product:
ConMed FDA Reg. # 1317214
MDL#: Please r*eference the table on page 2 for the correct MDL# for your returns*
510K #: Please r*eference the table on page 2 for the correct 510K# for your returns*
Please do not return used devices.

If you do not have any devices to return, please complete Attachment II, indicating you have no devices and fax it to +1 315-624-3225, Attn: Patricia Cotter.

We apologize for any inconvenience this will cause you or your staff.
The US Food and Drug Administration have been notified of this action. In addition, the appropriate foreign competent authorities have also been notified.

Sincerely,

[redacted]
Patricia Cotter
Recall Coordinator

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ConMed Corporation Electrosurgery Active Electrodes and Accessories

Table of MDL# and 510K# per Affected Catalog Numbers for Entry on Commercial Invoice for Returned Products

Catalog Number	Device Name	510(K)	MDL
7-100-8CS	Electrolase® Sterile Disposable Electrodes, Sharp Tips	K800617	D092250
7-101-8CS	Electrolase® Sterile Disposable Electrodes, Blunt Tips	K800617	D092250
60-7521-001	1” Goldvac™ UltraClean® Blade with Extended Insulation, Sterile	K991855	D085930
60-7523-001	6” Goldvac™ UltraClean® Blade with Extended Insulation, Sterile	K991855	D085930
60-7524-001	4” Goldvac™ UltraClean® Blade, Sterile	K991855	D085930
60-7526-001	6” Goldvac™ UltraClean® Blade, Sterile	K991855	D085930
130343	Single Use ABC® Nozzle, Sterile (For use with 130500 Reusable ABC® Handpiece)	K871435	E323246
135171	Disposable TUR Cable, 10’ (3.05mm), Sterile	K810273	D092258
137668	Disposable Safety Holster, Sterile	K790770	D092249
138025	6” ENT Needle Electrode with Extended Insulation, Single, Sterile	K810273	D092258
138029	Tip Cleaner, Single Use, Sterile	K874775	D092281
139100	1” UltraClean® Blade, Single Use, Sterile	K991855	D085930
139102	1” UltraClean® Needle, Single Use, Sterile	K991855	D085930
139104EXT	1” UltraClean® Blade with Extended Insulation, Single Use, Sterile	K991855	D085930
139105EXT	1” UltraClean® Needle with Extended Insulation, Single Use, Sterile	K991855	D085930
139107	6” UltraClean® Blade, Single Use, Sterile	K991855	D085930
139108	6” UltraClean® Needle, Single Use, Sterile	K991855	D085930
139110EXT	6” UltraClean® Blade with Extended Insulation, Single Use, Sterile	K991855	D085930
139112	4” UltraClean® Blade, Single Use, Sterile	K991855	D085930
139112EXT	4” UltraClean® Blade with Extended Insulation, Single Use, Sterile	K991855	D085930

ATTACHMENT I
PRODUCT CODES

FIELD SAFETY NOTICE

Identification of Affected Devices:

Catalog Number	Device Name
7-100-8CS	Electrolase® Sterile Disposable Electrodes, Sharp Tips
7-101-8CS	Electrolase® Sterile Disposable Electrodes, Blunt Tips
60-7521-001	1” Goldvac™ UltraClean® Blade with Extended Insulation, Sterile
60-7523-001	6” Goldvac™ UltraClean® Blade with Extended Insulation, Sterile
60-7524-001	4” Goldvac™ UltraClean® Blade, Sterile
60-7526-001	6” Goldvac™ UltraClean® Blade, Sterile
130343	Single Use ABC® Nozzle, Sterile (For use with 130500 Reusable ABC® Handpiece)
135171	Disposable TUR Cable, 10’ (3.05mm), Sterile
137668	Disposable Safety Holster, Sterile
138025	6” ENT Needle Electrode with Extended Insulation, Single Use, Sterile
138029	Tip Cleaner, Single Use, Sterile
139100	1” UltraClean® Blade, Single Use, Sterile
139102	1” UltraClean® Needle, Single Use, Sterile
139104EXT	1” UltraClean® Blade with Extended Insulation, Single Use, Sterile
139105EXT	1” UltraClean® Needle with Extended Insulation, Single Use, Sterile
139107	6” UltraClean® Blade, Single Use, Sterile
139108	6” UltraClean® Needle, Single Use, Sterile
139110EXT	6” UltraClean® Blade with Extended Insulation, Single Use, Sterile
139112	4” UltraClean® Blade, Single Use, Sterile
139112EXT	4” UltraClean® Blade with Extended Insulation, Single Use, Sterile

Affected lot codes for ALL catalog numbers listed above EXCEPT for Cat. No. 138029:

Lot codes for product manufactured to and including the dates listed below:

Beginning Manufacture Date	Beginning Lot Code	Ending Manufacture Date	Ending Lot Code
June 28, 2012	120628X	September 17, 2012	120917X

Affected lot codes for ONLY Cat. No. 138029:

Lot codes for product manufactured to and including the dates listed below:

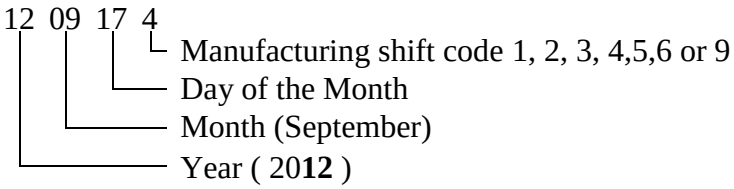
Beginning Manufacture Date	Beginning Lot Code	Ending Manufacture Date	Ending Lot Code
June 28, 2012	120628X	July 25, 2012	120725X

ATTACHMENT I
PRODUCT CODES

FIELD SAFETY NOTICE

Lot codes on boxes and packaging contain a lot code in the following form:

12 09 17 X



ATTACHMENT II
EFFECTIVENESS CHECK

FIELD SAFETY NOTICE

BUSINESS REPLY FORM

Please check all that apply:

- □ **We DO NOT have any stock of the suspect lots.**
- □ **We have notified our accounts to return their stocks of the product to us.**
- □ **We are returning: (Complete table below)**

Catalog # being returned	Quantity per Box	Quantity of Boxes
7-100-8CS	50/Box (12 bx/cs)	
7-101-8CS	50/Box (12 bx/cs)	
60-7521-001	25/Box	
60-7523-001	25/Box	
60-7524-001	25/Box	
60-7526-001	25/Box	
130343	20/Box	
135171	40/Box	
137668	40/Box	
138025	40/Box	
138029	40/Box	
139100	50/Box	
139102	50/Box	
139104EXT	50/Box	
139105EXT	50/Box	
139107	50/Box	
139108	50/Box	
139110EXT	50/Box	
139112	50/Box	
139112EXT	50/Box	

Have you received any reports of illness or injury related to this product? Yes_____ No___
If yes-please document specific information. Include it when this form is returned to Patricia Cotter.
Return this completed form by fax to: Patricia Cotter at +1 315-624-3225.
If you are returning product, include a copy of this completed form with the devices.
Charge shipping to: FedEx Acct # 487553646

Return devices to: **ConMed Corporation**
525 French Road
Utica, NY 13502 USA
Attn: [redacted]

Your Name:_____ Account #_____
(Please Print)
Signature:_____ Please complete at least one:
Distributor/Hospital :_____ Phone:_____
Address:_____ Fax:_____
_____ Email:_____

Credit will be issued for recall goods being returned