

February 26, 2013

RECALL NOTIFICATION

TO: Milex™ Pessary Customer

RE: **CooperSurgical Milex Pessary – Incontinence Ring, Incontinence Dish, Incontinence Dish with Support, Gellhorn and Cube**

Dear Valued Milex Pessary Customer:

CooperSurgical manufactures the Milex Pessary – Incontinence Ring, Incontinence Dish, Incontinence Dish with Support, Gellhorn and Cube. Recently, our ongoing quality surveillance discovered a packaging error in the Milex Pessary product line. The labels applied to some lots of packaging may not accurately reflect the size of the product contained in the package. The correct sizing of each pessary is molded into the device but the size on the outside packaging may not match. Our records show that the size on the label could be off no more than 5mm. The following pessary types and their respective lots are affected:

Description	Part Number	Lot #	Manufactured Date
Incontinence Ring	MXPCON04	117301	7/5/2012
Incontinence Dish with Support	MXPCONDS05	117443	11/8/2012
Incontinence Dish with Support	MXKPCONDS00	111732	6/25/2012
Incontinence Dish	MXKPCOND00	114288	6/25/2012
Incontinence Dish	MXPCOND00	114287	6/21/2012
Gellhorn	MXPGE2-3/4	117560	8/24/2012
Gellhorn	MXPGE3-	117568	8/28/2012
Cube	MXKPEC04	117376	9/6/2012
Cube w/Holes	MXKPECH00	121784	5/9/2012

CooperSurgical has thoroughly investigated this error and has implemented appropriate corrective actions.

Our records indicate you have been shipped some of the following specific lot numbers, which are being recalled. If you have any one of these affected lot numbers in your current inventory, please contact our Customer Service Department at 800-243-2974, or simply complete the attached form and fax to: 800-262-0105. Arrangements will be made to replace product in your possession at CooperSurgical's shipping expense.

Please note, if the physician followed the Milex Pessary Directions for Use which comes with each device and feels confident in fitting the pessary, there should be no patient impact. It is the evaluation of the individual fit of the placed pessary that is vital to ensure a correct size for the individual patient.

CooperSurgical deeply regrets the inconvenience that this problem has caused. Subsequent shipments of Milex Pessaries have been thoroughly inspected, meet product release specifications and will provide you with the product performance you have come to expect.

Sincerely,





**Request for Replacement of Recalled Product Numbers:
MILEX™ Pessary Gellhorn and/or Incontinence Dish.**

Facility Name: _____ or Account #: _____
Billing Address: _____
City: _____ State: _____ Zip: _____
Contact Name: _____ Phone: _____
Fax Number: _____ (Fax number is need so we can fax UPS return labels to you)

Please supply the quantity of product you are returning for replacement.

Description	Part Number	Lot #	Manufactured Date	Quantity you are returning
Incontinence Ring	MXPCON04	117301	7/5/2012	
Incontinence Dish with Support	MXPCONDS05	117443	11/8/2012	
Incontinence Dish with Support	MXKPCONDS00	111732	6/25/2012	
Incontinence Dish	MXKPCOND00	114288	6/25/2012	
Incontinence Dish	MXPCOND00	114287	6/21/2012	
Gellhorn	MXPGE2-3/4	117560	8/24/2012	
Gellhorn	MXPGE3-	117568	8/28/2012	
Cube	MXKPEC04	117376	9/6/2012	
Cube w/Holes	MXKPECH00	121784	5/9/2012	

Product may be picked up at CooperSurgical's expense at:

Address: _____ City: _____ St: _____ Zip: _____

Please send Replacement Product to: (Same location as above.)

Address: _____ City: _____ St: _____ Zip: _____

Fax to CooperSurgical, Inc., Attention Customer Service at 1-800-262-0105.

A Customer Service representative will be in contact with you shortly to provide you with a Return Merchandise Authorization Number (RMA) and an expected shipment date of replacement product.

February 26, 2013

RECALL NOTIFICATION

TO: Milex™ Pessary Distributor

RE: **CooperSurgical Milex Pessary – Incontinence Ring, Incontinence Dish, Incontinence Dish with Support, Gellhorn and Cube**

Dear Milex Pessary Distributor:

Recently, our ongoing quality surveillance discovered a packaging error in the Milex Pessary product line. The labels applied to some lots of packaging may not accurately reflect the size of the product contained in the package. The correct sizing of each pessary is molded into the device but the size on the outside packaging may not match. Our records show that the size on the label could be off no more than 5mm. The following pessary types and their respective lots are affected:

Description	Part Number	Lot #	Manufactured Date
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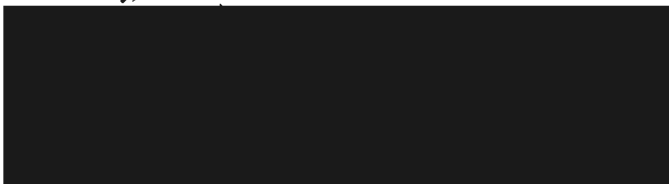
Effective immediately, you will need to forward the Recall Notification letter attached to the Milex Pessary Customers who received the lots in question and track the delivery of this letter for proof of receipt. The Recall Notification letter should be sent no later than March 31, 2013. Please send a copy of proof of delivery to:

CooperSurgical Inc.
 Business Assurance
 Attn: Regulatory Affairs Department
 95 Corporate Drive
 Trumbull, CT 06611

Please note, if the physician followed the Milex Pessary Directions for Use that comes with each device and instructs the physicians on how to properly fit a pessary, there should be no patient impact. It is the evaluation of the individual fit of the placed pessary that is vital to ensure a correct size for the individual patient.

We deeply regret the inconvenience that this problem has caused. Subsequent shipments of Milex Pessaries have been thoroughly inspected, meet product release specifications and will provide your customers with the product performance they have come to expect.

Sincerely,



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RE: **CooperSurgical Milex Pessary – Incontinence Ring, Incontinence Dish, Incontinence Dish with Support, Gellhorn and Cube**

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Cube	MXKPEC04	117376	9/6/2012
Cube w/Holes	MXKPECH00	121784	5/9/2012

CooperSurgical has thoroughly investigated this error and has implemented appropriate corrective actions.

If you have any one of these affected lot numbers in your current inventory, please contact your local CooperSurgical Distributor for product replacement.

Please note, if the physician followed the Milex Pessary Directions for Use that comes with each device and instructs the physicians on how to properly fit a pessary, there should be no patient impact. It is the evaluation of the individual fit of the placed pessary that is vital to ensure a correct size for the individual patient.

CooperSurgical deeply regrets the inconvenience that this problem has caused. Subsequent shipments of Milex Pessaries have been thoroughly inspected, meet product release specifications and will provide you with the product performance you have come to expect.

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