

URGENT MEDICAL DEVICE RECALL SECOND NOTIFICATION

**TELEFLEX MEDICAL HUDSON RCI® HUMIDIFIER ADAPTOR  
for use with AQUAPAK®**

[Date]

To: Risk Manager / Director of Purchasing

Teleflex Medical has issued a voluntary recall of Hudson RCI Humidifier Adaptor for use with AQUAPAK with the following catalog and lot numbers:

Teleflex Medical Catalog Number	Lot Number
003-40	738107
	741107
	762107
	764107
	766107
003-40F	733107
003-40J	740107
000-40	YK24
	YK24
	YL11
006-40	137106
006-40F	122106
	123106
006-40J	135106
	136106
400340	730107
	731107
	732107
	734107
	735107

The products listed above are being recalled because the packaging may not have been properly sealed, and therefore the sterility of the product cannot be guaranteed. If non-sterile products are used, there is a possible risk of infection.

Our records indicate that you have products that are subject to the recall. We are now notifying our customers to take the following actions:

1. Immediately discontinue use and quarantine any products with the catalog numbers and lot numbers listed above.
2. If you have affected stock, please complete the enclosed Recall Acknowledgement Form and fax to **[distributor fax number]**.
3. Once the fax is received, we will provide instructions on how to return any affected product directly to **[distributor name]**.

The U.S. Food and Drug Administration has been notified of this action.

We apologize for any inconvenience this notification may cause and remain committed to providing high quality, safe and effective products.

Sincerely,

**[Distributor Representative]**

Enclosure

## Recall Acknowledgment Form Immediate Attention Requested

**Check the appropriate box and fax this Form to [distributor fax number].**

- We have no inventory within the scope of this recall.
- We have the following affected product at our facility and have discontinued use and distribution. We have quarantined the affected product, and will return the following quantities. When the product is received by Teleflex Medical, please (select one):
- Send replacements
  - Credit our account

Quantity	Catalog Number	Lot Number(s)
	003-40	
	003-40F	
	003-40J	
	000-40	
	006-40	
	006-40F	
	006-40J	
	400340	

**Please print legibly.**

(Print Name)	(Date)
(Signature)	(Telephone Number)
(Institution Name)	(Email Address)
(Institution Street Address)	<b><u>Alternate Mailing Address</u></b>
(Institution City, State, Zip)	(Street Address)
(Country)	(City, State, Zip)