Teleflex
MEDICAL

September 27, 2006

Dear Valued Teleflex Medical Customer:

Urgent Medical Device Recall

Catalog Number (REF)	Description	Lot Numbers
5-16037	Sher-i-bronch® Endobronchial Tube, Left-Sided 37Fr	1188199
5-22006	Sheridan® Preformed Uncuffed Oral Endotracheal Tube, 3.0 mm	1189038
5-22210	Sheridan® Preformed Cuffed Oral Endotracheal Tube, 5.0 mm	1189023
5-22315	Sheridan® Preformed Cuffed Nasal Endotracheal Tube, 7.5 mm	1189026
5-24006	Sheridan Tracheal Tube Exchanger, 7.5mm-10.0mm	1189037

Teleflex Medical, Hudson, RCI has issued a voluntary recall for the above identified catalog numbers and lot numbers. Teleflex Medical has identified that the product did not pass validated sterility test requirements. The Food and Drug Administration has been notified of this action.

Our records indicate you have received the product included in the scope of this recall. In order to provide the highest level of quality product to our customers, we are notifying our customers to take the following actions:

1. **Cease use and Remove and quarantine all affected product immediately.**

   Check your stock for the product included within the scope of the recall (Lot Number listed above). Cease distribution and quarantine all affected product.

2. **<u>If you are a distributor,</u> communicate the recall notice to your customers who received affected product by providing a copy of this recall notification to your customers.**

   Have customers return all affected product in their possession to you along with the customer Acknowledgment & Stock Status Form so that you can reconcile the units with your distribution records. You may consolidate the product and return it to the address below, or forward it as it is received.

3. **Complete the enclosed Acknowledgment & Stock Status Form, which includes an option to obtain replacement product. Immediately fax back to Teleflex Medical GmbH**

   Product replacements will be shipped to the address noted on the Acknowledgment and Stock Status Form, unless an alternate address is provided.
   Fax number: 0049 / 7151 - 406 [redacted]

4. **Return any affected product along with Acknowledgment & Stock Status Form to the following:**

   Attn:
   [redacted]
   Teleflex Medical GmbH
   Reklamationsabteilung
   Willy-Rüsch-Strasse 4-10
   71394 KERNEN
   Germany

We apologize for any inconvenience this may have caused. If you require additional information or clarification regarding this matter, please contact 0049 / 7151 - 406 [redacted]

Sincerely,

[redacted]
Teleflex Medical

Acknowledgment & Stock Status Form

Hudson RCI, Catalog #5-16037, 5-22006, 5-22210, 5-22315, 5-24006

Immediate Attention Requested

Please check the appropriate box and return this form by fax to 0049 / 7151 - 406 566 ([redacted] Teleflex Medical GmbH, Kernen) immediately:

☐ We have no inventory within the scope of this recall.

☐ We have the following affected products at our facility. We have discontinued use, quarantined, and will return the product to Teleflex Medical.

Catalog	Lot Number	Quantity on Hand (eaches)	Quantity being returned
5-16037	1188199		
5-22006	1189038		
5-22210	1189023		
5-22315	1189026		
5-24006	1189037		

☐ We are requesting replacement product.

Print Name _____ Date _____

Signature _____ Telephone Number _____

Alternate Mailing Address (For Replacement Product)	
Street	
City, State, Zip	

Please pay attention!
Return affected product, along with a hardcopy of this form, to the following address:

Teleflex Medical GmbH
Complain Handling Dept.
[redacted]
Willy-Rüsch-GmbH
71394 Kernen
Germany

Please do not forget to mark the outer shipping carton (which contains products within the scope of the recall) with the wording: "Recalled Products"