**02.01.14**

**URGENT FIELD SAFETY NOTICE-Catheter CVC 4 Lumen- recall notification**

Dear Customer,

**Biometrix Catheter CVC 4 Lumen Product alert RE:**

Biometrix is requesting that you cease use of the products referenced above and detailed in the Appendix below. These products are the subject of a Field Safety Corrective Action/Recall and must be quarantined until further notice from Biometrix. Please read the remaining information for an explanation of this request.

|  |  |  |  |
| --- | --- | --- | --- |
| Ref no. | Description | Lot | Qty. |
| HH-8521 | 8.5fr X 20cm Quadro Lumen CVC Set with Nitinol G |  |  |

A leakage has been observed from the catheter’s hub right after the product’s insertion. When investigating this event we have discovered a failure in the manufacturing process of the catheter’s hub that can lead to a leakage from this area. (see picture in the appendix below). A leakage from the catheter’s hub can lead to complications of the patient’s state of health.

Root cause:

1. A problem occurs during the manufacturing process of the hub that can go undetected in some percentage of products.

Corrective Actions:

1. A different designed catheter will be offered to the customers as an alternative product.

**What you need to do**

Please locate and quarantine the product/products listed in the appendix below. The products can be identified by the reference number and lot number printed on the product/box labels.

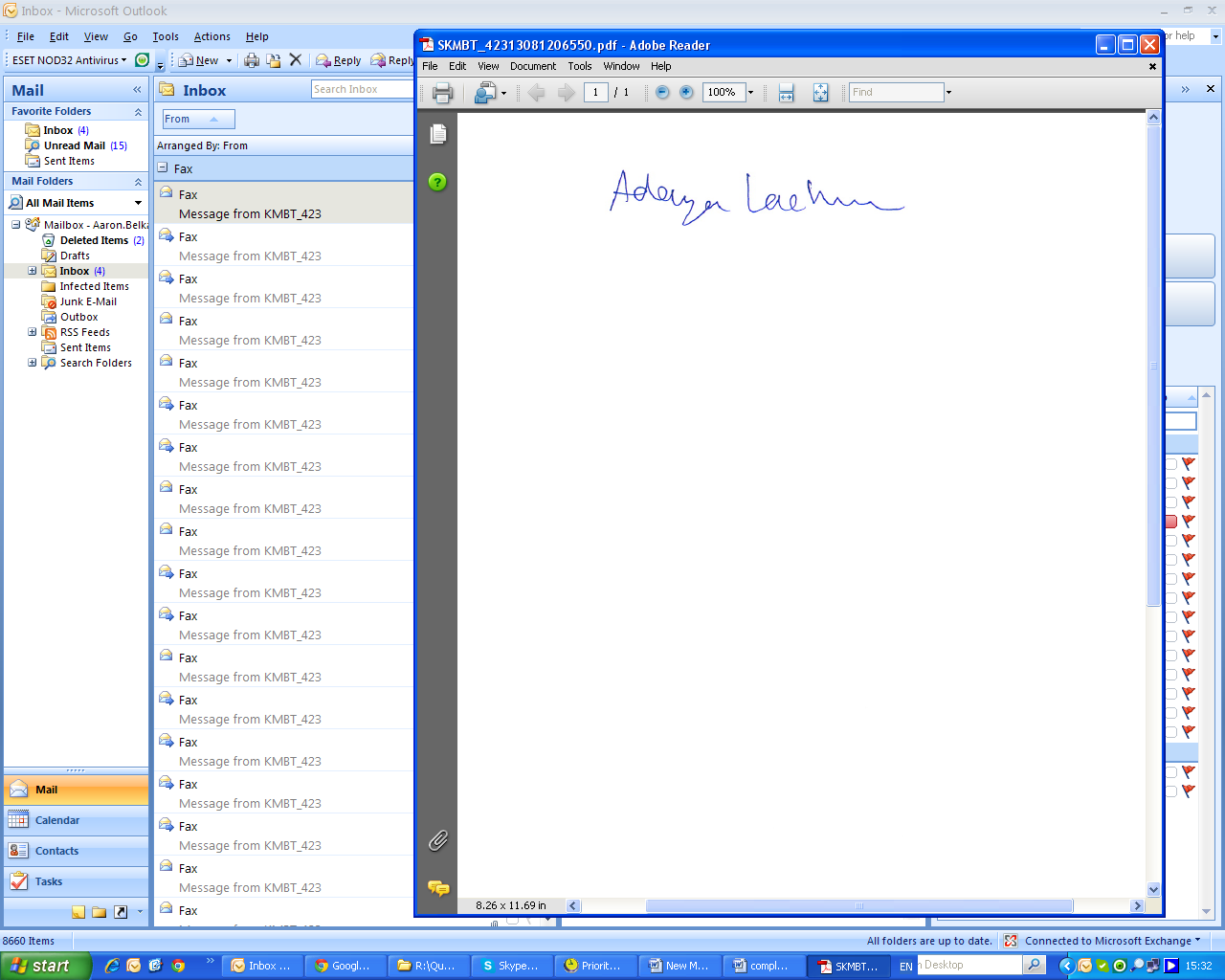
Please complete and return the attached Recall Response Card to Biometrix. Upon receipt of the Recall Response Card we will quickly contact you to make the necessary arrangements for the replacement of products.

**Note**: please complete the Recall Response Card even if you do not carry stock of the affected lots.

Please forward this information immediately to all your customers /departments within your organization who may be using, or ordering these products. Additionally, please ensure that a copy of this letter is provided to any other organizations to which the affected devices have been transferred.

Please accept our apologies for the inconvenience caused by this action.

If you have any questions regarding this please contact the following telephone number: +972-2-5861241.



Adaya Lachman Eliahou

QA Manager