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July 13, 2018

Important Field Safety Corrective Action- Product Recall

Dear Customer,

Our records indicate that you have received some of the identified products in short term hemodialysis product line. Please see the attached document for a full list of product codes and lot numbers. A product recall has been initiated for these products due to the potential for the suture wings to crack or break. **No patient injury has been reported**. Implanted catheters with intact suture wings do not need to be removed. However, an alternative method of catheter securement should be initiated for all implanted catheters, due to the potential for the suture wings to crack or break. Potential patient injury includes catheter dislocation, bleeding and air emboli.

The affected product was shipped between February 2016 and February 2018.

Medcomp is requesting the return of all un-used affected product. Immediately examine your inventory and quarantine product subject to recall. For any product that was further distributed, please identify the recipients and notify them at once of this product recall. Your notification may be enhanced by including a copy of this recall notification letter.

Please note: no other product from Medcomp Brand is affected by this recall.

Contact your customer service representative for a Returned Goods Authorization (RGA) number if necessary.

If you have any questions about this communication, please contact your distributor.

(Distributor information here)

We appreciate your assistance in this matter and apologize for any inconvenience. If you have any questions or concerns, please feel free to contact me directly.

Best regards,

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Cc: Compliance File; Customer Service; Product Management