



Field Safety Notice (FSN)

Cefndy Healthcare X220 & X221 (including X312 & X313) Bariatric Commodes

Date: 04th November 2011

Reference: CH/FSN/01/11

This notice is an update to the previous notice CH/FSN/01/10

The following safety notice applies to the X220, X221, X312, & X313 commodes supplied before the 16th August 2010. Batch Label formats are date followed by product code, ie. 210410X220 this example will be manufacture date 21st April 2010 product X220.

Any products X220, X221, X312, & X313 which have a batch label date prior to 16 08 10 are covered by this FSN



This notice is not applicable to the X222 & X314 versions (detachable arms)

Safety Information:

In the interests of the safety of customers the following advice is being issued around concerns over possible defects occurring over time around areas where the arms connect to the seat frame. Cefndy Healthcare was made aware of incidents in which the weld at the points mentioned failed, some of these incidents of failure caused injuries. Should this type of failure occur it could lead to the user falling from the chair.

The Chair structure has now been redesigned to eliminate the area of potential weakening.

For the chairs which are affected by this notice a modification kit has been produced by the Manufacturer and will be sent out to customers who still have these devices out in the field

Advice on Action to be taken for Commodes supplied before 16th August 2010:

- Contact the manufacturer and confirm the number of products that they have and request the amount of modification kits required.
- Fit the kit as per instruction leaflet enclosed with the kit.

Distribution and Further advice:

- All Relevant Competent Authorities have been informed of this notice.
- Attached with this notice is a feedback form please ensure that this is returned to Cefndy within 14 days of receiving this notice detailing your understanding of the notice and the corrective action required.
- Please ensure that all relevant Personnel and departments within your organisation are made aware of the FSN and that your customer base in receipt of these products is informed.

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