

Establishment
Address
Postcode City

ROCHECORBON,
The XXXXXXX

To: Heads of establishment, corresponding medical device vigilance system, technical services, purchasers

Subject: Information concerning the priority side rails replacement which are not conform to standards and equipping adult medical beds

Dear Sir or Madam,

Standards NF EN 60601-2-38, Amendment 1 and NF EN 1970 defines the minimum size and / or maximum areas with risk of trapping in an adult bed for medical use: between the bars, between the mattress and the bottom of the side rail between the mattress and side rail between the panel head or footboard and the end of the side rail. These dimensional requirements have been established in order to avoid trapping of the head, neck and thorax of adult patients. Trapping in these areas with risk can have serious consequences and sometimes cause death.

Four deaths of patients by trapping caused by side rails beds manufactured by our company have been reported between 2000 and 2006 in France. Most of these incidents occurred in the space between the bars of the bed rail sold before the publication of standards.

We send you the list of side rails involved in a pre-production standards and identified as not conforming to the dimensional requirements:

- 1025 range
- 1031 range
- SP 1027 range

In agreement with the AFSSAPS, CORONA MEDICAL, recommend the replacement priority side rails which are not compliant with above.

These side rails are very old, traceability is not complete. We invite you to contact CORONA MEDICAL at 33. (0) .247 885 844 as soon as possible, to consider an audit of your park and the alternatives considered.

We wish to inform you that several reports in recent years reported on side rails bed compliant with the applicable standards are caused by a bad positioning of the vices. The setting up of side rails is detailed in the document accompanying the product. It is particularly important to ensure compliance with this recommendation in order to prevent the creation of new areas of trapping.

Finally, we remind you that the AFSSAPS prepared a document concerning the "proper use of side rails bed in January 2006" available on the Agency's website on the internet:
<http://www.afssaps.fr/content/download/1531/14890/version/3/file/lits06.pdf>

Remaining at your disposal for further information, please accept, Sir or Madam, the assurance of my highest consideration.

Juliette DURAND
Medical Device Vigilance System Correspondent