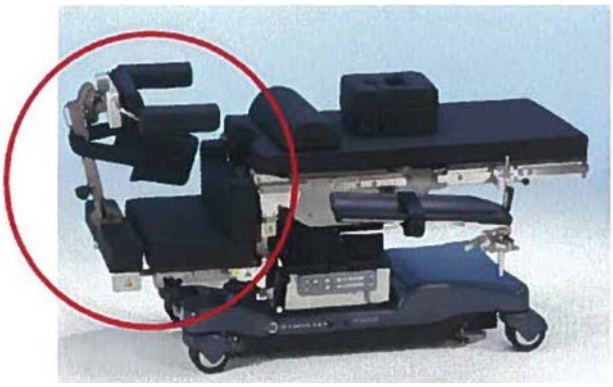
MERIVAARA

FIELD SAFETY NOTICE

28.8.2017

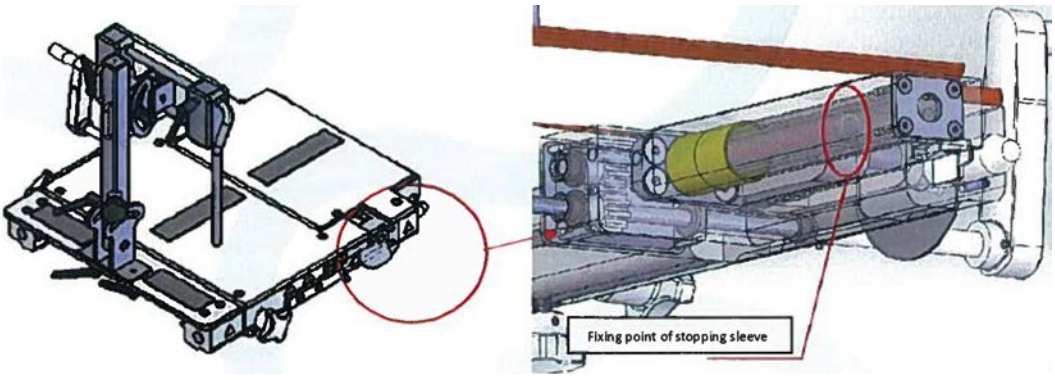
Knee-Chest Device, product code 100060060



Dear Customer,

As a manufacturer of high quality medica! products, Merivaara Corp. is committed to strict quality control and continous product monitoring.
During the course of our product monitoring, we have learned an safety-related issue in the fixation of foot and leg section of the Knee-Chest device.

Descrlptlon of the problem includlng cause determined:
Length of the leg section is adjusted with manual crank handle. Crank mechanism is moving two motion screws (pies. 2-4). At the end of screws are stopping sleeves, which are secured with fixing screws. Stopping sleeve works at the same time as bearing sleeve.



Pic 2. **Pic 3.**

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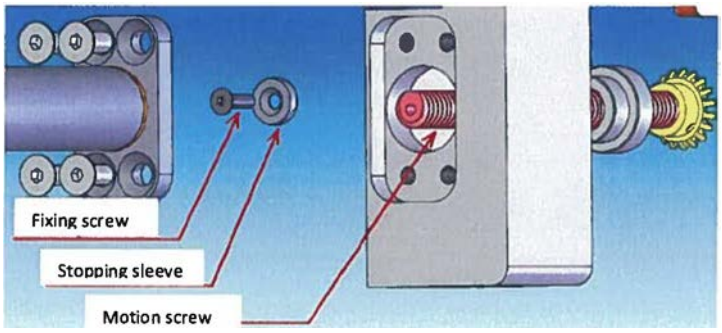
SWIFT code HANDFIHH

EUR 313130-01244516
USO 313130-5889019
SEK 313130-5889001
NOK 313130-5888995

IBAN Fl7231313001244516
IBAN Fl9131313005889019
!BAN Fl9231313005889001
IBAN Fl6031313005888995



Pic4.

It carne to our knowledge, that during service actions of one device, fixing of stopping sleeve loosened while device was held up. As a cause for this, foot section separated from the leg section. Further analysis determined that locking compound was not properly placed.

Knee Chest device consists of two same kind of fixing points in both sides of the leg section. Loosening is possible only if both fixings would get loose at the same time. Weight of the device keeps the sections together while it's not moved/lifted, even that fixing would be loosened. According to our experience, loosening is only possible if the device is lifted or moved. No realized cases have come to our knowledge, where any danger to a patient or personnel has occurred due to loosening of sections.

This situation is possible in Knee Chest-devices delivered before January 2016. According to our delivery information, you have received a device from us during mentioned time perioid. Enclosed is the list of serial numbers of products delivered for identification (attachment 1).

As a responsible manufacturer, Merivaara wants to ensure safe use of the product. We therefore request that you have the device inspected and locking compound secured by a hospita! technician according to the instructions in accordance with Attachment 2 in the short term.

We kindly ask you to ensure that all potentie! users are informed about this safety information.

We apologize for the inconvenience which may result from this action. We consider this preventive measure to be in the interest of user and patient safety, and thank you for your cooperation.

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EUR 313130-01244516 IBAN FI7231313001244516
USO 313130-5889019 IBAN F19131313005889019
SEK 313130-5889001 IBAN FI9231313005889001
NOK 313130-5888995 IBAN F16031313005888995

MERIVAARA

If you have any questions, please contact our Service:

Merivaara Corp. / Service
Teemu Rytkönen
Phone: +358 50 3535 766
E-mail: teemu.rytkonen@merivaara.com

Additionally, we kindly request you to return the confirmation of receipt (Attachment 3) to (service@merivaara.com).

Best regards,
Merivaara Corp.

Annexes:
1: List of devices (serial numbers)
2: Service instruction
3: Confirmation of receipt / service action done

MERIVAARA

FIELD SAFETY NOTICE, ATTACHMENT 3

Knee Chest Device

Confirmation of receipt

We kindly ask you to return filled form to service@merivaara.com:

Name of the hospita! / clinic:
Name of the contact persen:
Title:
Phone:
E-mail:
Address:

1 confirm the receipt of Field Safety Notice

1 confirm the actions done according to attachment 2 for the devices listed in attacment 1.

_____
Date

_____
Name and signature

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