Helsingborg 2025-07-04

SIKKERHEDSMEDDELELSE vedrørende
– CROSS Hemi Shoulder (28717)

Kære kunde,
Vi er blevet opmærksomme på, at den type magnetspænde, der anvendes i CROSS Hemi Shoulder, art.nr. 28717, ikke bør anvendes af personer med pacemaker/defibrillator.

PRODUKTTYPE: Skulderortose
PRODUKTNAVN: CROSS Hemi Shoulder
PRIMÆRT KLINISK FORMÅL: At give kontrolleret korrektion af armens og skulderens position gennem udadrotation og elevation.

ARTIKELNUMRE:

287171010	287172010
287171011	287172011
287171012	287172012
287171013	287172013
287171014	287172014

BERØRTE LOT-NUMRE: 52285 & 52686
Da CROSS Hemi Shoulder er blevet leveret til din organisation, vil vi hermed informere om, at kontraindikationerne i produktets IFU opdateres.
Dette er en forebyggende sikkerhedsforanstaltning, som ikke er foranlediget af nogen indberettet hændelse.

Camp Scandinavia AB
Karbingatan 38 SE-254 67 Helsingborg, Sverige | 042 25 27 00 | info@camp.se | camp.se

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DESCRIPTION OF THE ISSUE
The magnet in the magnetic buckle may affect pacemakers/defibrillators. While these devices commonly include built-in protection against unintended magnetic fields, we strongly advise against the use of CROSS Hemi Shoulder by individuals with pacemakers/defibrillators.

RISK MITIGATION MEASURE
- Please note the addition to the IFU, attached in the PDF.
- Kindly complete the attached form and return it to us by email as per the instructions on the form as soon as possible.

All CROSS Hemi Shoulder units shipped from July 3, 2025, onward will include the revised IFU.

The Swedish Medical Products Agency has been informed of this customer communication.

Contact Information:
Camp Scandinavia AB
Karbingatan 38
254 67 Helsingborg
Phone: +46 42 25 27 00
Email: regulatory@camp.se

Thank you in advance.

Carolina Nöbbelin
Regulatory Affairs Manager, Camp Scandinavia AB