

IMPORTANT SAFETY MESSAGE

(FIELD SAFETY NOTICE, FSN)

DATE: 2012-09-21

Recipient:

Information – actual product

Product: Hansson Outer Introd. L3-1462
Batch: 108581

Fault description

The 'heels' on the equipment, which orientates the hook on Hansson Pin (corresponding product), was incorrectly placed 180°. The error has occurred from a faulty production method.

Risk

The error, which is described under 'Fault description' above, could lead to that the hook in Hansson Pin is prompt through the joint cartilage. The expectation for this to occur is very low.

Identification of concerned products

The error only affects batch number 108581. It was possible to locate concerned products on the market by the batch number of the products of complaint and together with the distributor (Swemac).

Action customer/user

Incorrect products will be returned to Swemac, which is distributing them further to Elos Medtech Timmersdala AB who will destroy them. All products have been located and concerned customers have been contacted.

Actions Elos Medtech Timmerdala AB

The incorrect production method has been adjusted so the heels come into right position. More frequently controls have been made as preventive action.

Further information

Manufacture:

Elos Medtech Timmersdala AB
Bäckedalsvägen 5
S-540 16 Timmersdala
Sweden
Phone: 0511-44 06 00
E-mail: info@elosmedtech.com

Distributor:

Swemac Orthopaedics AB
Industrigatan 11
S-582 31 Linköping
Sweden
Telefon: +46 13 12 93 90

I confirm that 'Läkemedelverket' has got the information of the corrected safety action on the market (FSCA).

Emeli Söderberg
Quality Manager, Elos Medtech Timmerdala AB.

