2012-02-16

V.05/07

Report Form
Field Safety Corrective Action

Medical Devices Vigilance System
(MEDDEV 2.12/1 rev 5)

1. Administrative information Destination
Name of national competent authority (NCA) The Danish Medicines Agency
Address of national competent authority Axel Heides Gade 1 2300 Köbenhamn S Danmark
Date of this report 2012-04-15
Reference number assigned by the manufacturer ID CSFNSE1
Incidence reference number and name of the co-ordinating national competent authority (if applicable) 441:2011/77773 Läkemedelsverket Sweden
Identify to what other national competent authorities this report was also sent MPA in SE, NL,NO and Canada

2 Information on submitter of the report
Status of submitter
☒ Manufacturer
☐ Authorised representative within EEA
☐ Others (identify the role):

3 Manufacturer information	
Manufacturer name *Caresia AB*	
Manufacturer's contact person Detlev Scholz	
Address Sollidenvägen 8	
Postal code 236 42	City Höllviken
Phone +46 40459356	Fax +46 40459357
E-mail detlev@caresia.se	Country Sweden

4 Authorised representative information	
Name of the authorised representative	
The authorised representative's contact person	
Address	
Postal code	City
Phone	Fax
E-mail	Country

5 National contact point information	
National contact point name Meyra Ortopedia Danmark KS	
Name of the contact person	
Address Stöberivei 1	
Postal code 3660	City Stenlöse
Phone 47107755	Fax 47107753
E-mail	Country Denmark

6 Medical device information	
Class	
☐ AIMD Active implants	
☐ MDD Class III	☐ IVD Annex II List A
☐ MDD Class IIb	☐ IVD Annex II List B
☐ MDD Class IIa	☐ IVD Devices for self-testing
☒ MDD Class I	☐ IVD General
Nomenclature system (preferable GMDN)	
Nomenclature code	
Nomenclature text	
Commercial name/brand name/make Purelift	
Model number 62242-00	
Serial number(s) and/or lot/batch number(s) all	
Software version number (if applicable)	
Manufacturing date/expiry date (if applicable)	
Accessories/associated device (if applicable)	
Notified body (NB) ID- number	

7 Description of FSCA
Background information and reason for the FSCA It has come to Caresia attention that a patient at one time (1) has pressed his thigh into the intimate recess during toileting. The patient's thigh was caught in the intimate recess and the patients had to be helped by the staff to get his thigh free again.
Description and justification of the action (corrective/preventive) If the patient is short, slim or moving around restless on the seat, a smaller seat can be used. The smaller seat has a 3 cm smaller intimate recess and toilet hole. The seat can be ordered from Caresia The seat can be mounted reversed letting the intimate recess pointing backwards towards the back rest. The intended function of the intimate recess enabling easier access and better cleaning while assisting toileting is deleted and also the risk getting the thigh caught in the recess. Mounting instructions can be ordered from Caresia.

The operating manual has been updated and can be ordered free of charge from Caresia.

Advice on actions to be taken by the distributor and the user

If your patient is short, slim or moving around restless on the seat one should consider to use the smaller seat or mount the the seat reverse.

Attached please find

☒ Field Safety Notice (FSN) in English

☐ FSN in national language

☐ Others (please specify):

Time schedule for the implementation of the different actions

These countries within the EEA and Switzerland are affected by this FSCA

Within EEA and Switzerland:

☐ AT	☐ BE	☐ BG	☐ CH	☐ CY	☐ CZ	☐ DE	☒ DK	☐ EE	☐ ES
☐ FI	☐ FR	☐ GB	☐ GR	☐ HU	☐ IE	☐ IS	☐ IT	☐ LI	☐ LT
☐ LU	☐ LV	☐ MT	☒ NL	☒ NO	☐ PL	☐ PT	☐ RO	☒ SE	☐ SI
☐ SK									

Candidate Countries:

☐ CR ☐ TR

☐ All EEA, Candidate Countries and Switzerland

Others:

These countries outside the EEA and Switzerland are affected by this FSCA

Canada

8 Comments

I affirm that the information given above is correct to the best of my knowledge.

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Signature

Detlev Scholz	Höllviken	2012-04-15
Name	City	Date

Submission of this report does not, in itself, represent a conclusion by the manufacturer and/or authorized representative or the national competent authority that the content of this report is complete or accurate, that the medical device(s) listed failed in any manner and/or that the medical device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person.

ID CSFNSE1

Field safety notice

Product
Purelift Art nr 62242-00

Patient's thigh caught in intimate recess

Background of incident

The shower- and toilet chair Purelift has a seat with an intimate recess and a toilet hole. The toilet hole can be covered with a lid. Is the product used for toileting the lid is removed. The function of the intimate recess is to enable easier access and better cleaning while assisting toileting.

It has come to Caresia attention that a patient at one time (1) has pressed his thigh into the intimate recess during toileting. The patient's thigh was caught in the intimate recess and the patients had to be helped by the staff to get his thigh free again.

Recommendations of action

If the patient is short, slim or moving around restless on the seat, a smaller seat can be used. The smaller seat has a 3 cm smaller intimate recess and toilet hole. The seat can be ordered from Caresia

The seat can be mounted reversed letting the intimate recess pointing backwards towards the back rest. The intended function of the intimate recess enabling easier access and better cleaning while assisting toileting is deleted and also the risk getting the thigh caught in the recess.

Mounting instructions can be ordered from Caresia.

The operating manual has been updated and can be ordered free of charge from Caresia.

Do not leave your patient unattended during use of the product

Communicate this safety notice

This safety notice is sent to the invoice receiver of the product. As the user can be someone different we call on you to communicate the safety notice within your organization and to your customers who have bought or lent the product.

The undersigned confirms this safety notice has been reported to the relevant regulatory authorities. Questions are answered by the undersigned. For contact details see below.

2012-04-10
Caresia AB

Detlev Scholz, MD

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