Report Form
Field Safety Corrective Action
Medical Devices Vigilance System
(MEDDEV 2.12/1 rev 7)

new case, keep base data

Version 2.7en
2012-12-03

1 Administrative information
To which NCA(s) is this report being sent? Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) Kurt-Georg-Kiesinger Allee 3, D-53175 Bonn
Type of report (•) Initial report ( ) Follow-up report ( ) Final report
Date of this report 2015-03-02
Reference number assigned by the manufacturer SO-2015-084
FSCA reference number assigned by NCA
Incidence reference number assigned by NCA
Name of the co-ordinating NCACompetent Authority (if applicable)

2 Information on submitter of the report
Status of submitter (•) Manufacturer ( ) Authorised Representative within EEA and Switzerland ( ) Others: (identify the role)

3 Manufacturer information	new

Name Fresenius Medical Care AG & Co. KGaA	
Contact Name Marco Zimmer	
Address Else- Kröner- Str.1	
Postcode 61346	**City** Bad Homburg
Phone +49 6172-609 5461	**Fax** +49 6172-609 2512
E-mail medical-device-safety@fmc-ag.com	**Country** DE - Germany

4 Authorised Representative Information

new

Name	
Contact Name	
Address	
Postcode	**City**
Phone	**Fax**
E-mail	**Country** DE - Germany

5 National contact point information

new

National contact point name Fresenius Medical Care AG & Co. KGaA	
Name of the contact person Marco Zimmer	
Address Else- Kröner- Str.1	
Postcode 61346	**City** Bad Homburg
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6 Medical device information

new

Class

- ◯ AIMD Active implants
- ◯ MDD Class III
- ◉ MDD Class IIb
- ◯ MDD Class IIa
- ◯ MDD Class I
- ◯ IVD Annex II List A
- ◯ IVD Annex II List B
- ◯ IVD Devices for self-testing
- ◯ IVD General

Nomenclature system (preferable GMDN)	**Nomenclature code**
GMDN	47072

Nomenclature text

Commercial name/ brand name / make

FX CorDiax 40, 50, ... 120 and FX CorDiax HDF600,

Model number	**Catalogue number**
F00001588, F00001589, F00001590, F00001591, F00001592,	
Serial number(s)	**Lot/batch number(s)**
Device Mfr Date	**Expiry date**

Notified Body (NB) ID-number

0123

Accessories / associated devices (if applicable)

Software version number (if applicable)

7 Description of the FSCA

Background information and reason for the FSCA

During the continuous post market surveillance of our FX CorDiax dialysers, we have observed an increased number of cases of hypersensitivity and hypersensitivity-like reactions with the application of the FX CorDiax dialysers, including life threatening events.
We also identified that the description of side effects in the IFU does not adequately reflect the probability and nature of hypersensitivity and hypersensitivity-like reactions.

Description and justification of the action (corrective / preventive)

1. Immediate information of our customers about an increased rate of possible side effects and the precautions to take.
2. Corrective action: In order to better address possible hypersensitivity and hypersensitivity-like reactions in individual patients, we will adapt the IFU in the following points. The section side-effects will be expanded with a description of symptoms of the already labelled hypersensitivity reactions.
A more detailed advice regarding the use of the dialyser, the treatment modality (e.g. general advice for gradual adaptation to high performance HD) and the handling of hypersensitivity and hypersensitivity-like reactions will be provided.
We will also include at the contraindications section, that patients with known hypersensitivity to any of the dialyser's material must not be treated with the dialyser.
3. A product specific cause or mechanism is not known yet. We are not aware of any product/production deviation and therefore we are not able to implement further CAPA. Although the rate of possible events has increased, the positive risk benefit ratio of these products is confirmed.

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

User should carefully monitor patients who have not previously been treated with FX CorDiax dialyser, or who have shown possible hypersensitivity symptoms during previous treatments, or who have a history of allergy including asthma. Patients with known hypersensitivity to any of the dialyser's material must not be treated with these dialysers.
In patients not treated with these dialysers before and incident patients starting HD or HDF therapy, the treatment intensity shall be gradually increased to permit adequate adaptation.
If severe hypersensitivity or hypersensitivity-like reactions occur, the dialysis must be discontinued and the blood from the extracorporeal system must not be returned to the patient and appropriate emergency medical treatment must be initiated

Progress of FSCA , together with reconciliation data (Mandatory for a Final FSCA)

Time schedule for the implementation of the different actions

The FSN will be distributed as soon as possible to affected customers

Attached please find

- ☒ Field Safety Notice (FSN) in English
- ☐ FSN in national language
- ☐ Others (please specify)

FSN Status

- ○ Draft FSN
- ◉ Final FSN

The medical device has been distributed to the following countries:

within the 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	☐ TR

Candidate Countries

☐ HR

☒ All EEA, candidate countries and Switzerland

Others:

Please refer to the list of affected countries

8 Comments

Submission of this report does not, in itself, represent a conclusion by the manufacturer and/or authorised 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.

Signature

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

print | check | send XML-data by E-Mail