



Urgent Field Safety Notice

Hypersensitivity and hypersensitivity-like reactions with FX CorDiax dialysers

Date: March, 02nd 2015

Affected products: **FX CorDiax High-Flux dialysers and
FX CorDiax Haemodiafilters**

Reference No.: F00001588, F00001589, F00001590, F00001591,
F00001592, F00002384, F00005649, F00005650,
F00005651, F00005652, F00005653, F00005654,
F00001593, F00001594, F00001595, F00005655,
F00005656, F00005657

Dear customer,

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.

These reactions occurred mainly both in the first treatment hour and within the first weeks of treatment with the FX CorDiax dialysers. The symptomatology varies and includes: dyspnoea, chest congestion, bronchospasm, respiratory arrest, hypotension, tachycardia, urticaria, erythema, flushing, angioedema, ocular hyperaemia, pruritus, abdominal pain, nausea, convulsions and unconsciousness.

A product specific cause or mechanism is not known yet. Therefore, please 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.

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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. Initiate appropriate emergency medical treatment.

Please provide this Safety Notice to all those who need to be aware of it within your organization.

We sincerely apologize for the inconvenience. In case of any further questions do not hesitate to contact:

Name: Dr. Konstanze Schröck
Telephone: +49 6172 609 6985
e-mail: Konstanze.Schroeck@fmc-ag.com

Sincerely yours,

i.V. Marco Zimmer
Corporate Safety Officer
(Medical Devices) QREM

ppa. Dr. Annika S. Bien
Vice President
Law Department