FRESENIUS MEDICAL CARE

02nd June 2015

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Dear Healthcare Professionals,

In March 2015 you received a Field Safety Notice (FSN) informing you of the safety concerns (hypersensitivity or hypersensitivity like reactions) in relation to the use of FX CorDiax dialysers. Reference No: F00001588, F00001589, F00001590, F00001591, F00001592, F00001593, F00001594, F00001595 (please note that the following product code F00002384 did not appear on the initial FSN letter sent in March, due to an oversight on our part).

As follow up to this information, we are now providing you with updated Instructions for Use (IFUs) to ensure safe and effective use of FX CorDiax dialysers in relation to managing hypersensitivity reactions. The following sections in the IFUs for the FX CorDiax High-Flux dialysers and FX CorDiax Haemodiafilters have been updated, however, for more information please refer to the enclosed IFUs.

“Contraindications: Special contraindications are unknown. Generally, contraindications for dialysis are applicable. Patients with known hypersensitivity to any of the dialyser’s material must not be treated with the dialyser.

Side-effects: Certain side effects may occur during dialysis and may result from factors specific to the patient, operating parameters, equipment, priming procedure, dialysis solution, dialyser, anticoagulation, medication etc. Therefore the selection of a dialyser and the selection and monitoring of treatment parameters based on individual patient characteristics, therapy tolerance and clinical requirements as well as compliance with the water and dialysis fluid standards are essential to minimise side effects. The FX CorDiax dialyser/ FX CorDiax HDF haemodiafilter is designed for high performance dialysis. In patients not treated with this dialyser before and incident patients starting HD or HDF therapy, treatment intensity shall be gradually increased to permit adequate adaptation. Hypersensitivity or hypersensitivity-like reactions have been observed during dialysis mainly in the first weeks of treatment with the dialyser. Symptomatology can vary and may include: dyspnoea, chest congestion, bronchospasm, respiratory arrest, hypotension, tachycardia, urticaria, erythema, flushing, angioedema, ocular hyperaemia, pruritus, abdominal pain, nausea, convulsions and unconsciousness. Carefully monitor patients who have not previously been treated with the dialyser, or who have shown possible hypersensitivity symptoms during previous treatments, or who have a history of allergy including asthma. 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.

Anticoagulation: It is recommended to introduce an anticoagulant to the extracorporeal circuit. Anticoagulant requirements may vary with the patient’s condition, application site, dialyser characteristics and treatment modality. Nature, amount and method of application of an anticoagulant must be prescribed by the responsible physician.”

Should you require additional copy of the leaflet, they may be obtained from:

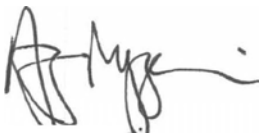
www.freseniusmedicalcare.co.uk

Call for reporting

Medical Device incidents should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Medical Device incidents should also be reported to Fresenius Medical Care on 01623 445 215 or vigilanceuk@fmc-ag.com.

Should you require any further information, please do not hesitate to contact us.

Yours sincerely,



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IFU UPDATE - related to Field Safety Notice from March 2015: Hypersensitivity and hypersensitivity-like reactions with FX CorDiax dialysers

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

Hospital Name: _____

I confirm receipt of the updated IFU related to the above mentioned Field Safety Notice and that the information has been provided to all those who need to be aware of it.

Name: _____

Job Title: _____

Signed: _____

Date: _____