

«Hospital»
«Specifics»
«Street» «space1»
«ZIP» «space» «city»

«customer no»

December 10th 2007

**Urgent Safety Notice: multiFiltrate acute dialysis system
Risk of potential ruptures of bloodline pump segments**

To whom it may concern,

During the continuous observation of our products in the market, it has come to our attention that in a few instances the bloodlines for acute dialysis with the multiFiltrate dialysis system have not reached the operation time of 72h, respectively the treated blood volume of 1250 L. In single cases, ruptures of the pump segment occurred including the loss of blood.

Therefore we would like to request you to currently monitor acute treatments with the multiFiltrate dialysis system closely, until we can confirm the operation time of the bloodlines again as stated in the Instruction for Use.

We are currently addressing this issue which clearly does not meet our quality standards and we are intensively working to eliminate the cause of this quality deficiency as soon as possible. We will inform you about it immediately.

Please provide this Safety Notice to all those who need to be aware of it within your organization or to any organization where the multiFiltrate dialysis system has been transferred.

For further information please contact
Mr./Ms. XXX (tel.: YYY)

We kindly request you to apologize for any inconvenience associated with these safety measures.

Sincerely yours,

Fresenius Medical Care ZZZ

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