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Date

August 14, 2006

Exchange of H.E.L.P. Heparin Adsorbers 500 (Lot 4291A111)

Dear Sirs,

recently on July 31st, 2006, we exchanged your H.E.L.P. Heparin Adsorbers (art. no. 706122A, lot 4291A111) by new ones from a different lot. The reason for this measure was the occurrence of bleeding events after H.E.L.P. therapies in two cases of patients being treated with H.E.L.P. Heparin Adsorbers of this lot. Ongoing investigations shall clarify the cause for these adverse events.

We would like to emphasize that we performed the recall of the H.E.L.P. Heparin Adsorbers only as a preventive measure in order to avoid any risk for your patients.

In this context, please allow us to call attention to our recommendation to control anticoagulation with coagulation checks at around every 30 minutes during therapy. Samples can be taken from the port of the arterial line.

We kindly ask you to provide this information to all colleagues and members of your staff performing the H.E.L.P. therapy.

Thank you very much for your kind cooperation and sympathy during the exchange measure. Please apologize any inconvenience that might have been caused.

If you have any further questions, please do not hesitate to contact us.

Yours sincerely,

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