

Important Customer Information!**Art. No. 7061226 H.E.L.P. LDL Apheresis Heparin Adsorber****Batch Recall for Batches 8072A111, 8073A111, 8074A111, 8093A111, 8094A111, 8113A111, and 8123A111**

Dear customer,

With our letter of *[date]*, we recalled four batches of H.E.L.P. LDL Apheresis Heparin Adsorbers (Art. No. 7061226) since a few cases of chills occurred toward the end of or immediately after H.E.L.P. Apheresis sessions.

According to the availability of new findings, we are extending the recall, as a safety precaution, to the above mentioned batches.

On *[date]*, *[xxx]* pieces of the Heparin Adsorbers from the affected batch *[number of the batch]* have also been shipped to you. We would ask you to review your stocks and use the attached form to let us know how many units you need to return. Once we have your fax, we will promptly dispatch replacements. *[Alternatively: The returned adsorbers will be credited to you after receipt.]*

As replacement we will offer our new H.E.L.P. Heparin Adsorber (Art. No. 7210688) to you. Additionally, in order to allow proper application of this new heparin adsorber, we would like to use the opportunity to introduce and implement the successor of the Plasmatec.Secura, the Plasmatec Futura system, at your site. Training of the application of the new devices will be agreed upon with you.

If you have any questions, our local sales manager *[please fill in your local contact]* is at your disposal.

Kindly acknowledge receipt of this letter by signing the attached form and returning it by fax to us at your earliest convenience.

We regret this inconvenience, and thank you for your support.

Sincerely,

Enc

Kurzzeichen:

Datum:

2008-05-07

Please return by fax to: *[please fill in your local fax number]*

We acknowledge receipt and confirm review of the Art. No. 7061226 H.E.L.P. LDL Apheresis Heparin Adsorber batch recall letter dated *[date of letter]*, and inform you as follows:

Art. No. 7061226 H.E.L.P. LDL Apheresis Heparin Adsorber

We have reviewed our stocks and report as follows:

Batch	Number Received	Number Used	Number to Return
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8093A111			
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Title, Name: _____

Telephone No.: _____

Date, Signature: _____

Stamp

Kurzzeichen:

Datum:

2008-05-07

Important Customer Information!

Art. No. 7061226 H.E.L.P. LDL Apheresis Heparin Adsorber
Batch Recall for Batches 8072A111, 8073A111, 8074A111, 8093A111, 8094A111,
8113A111, and 8123A111

Dear customer,

Over the past few weeks, a few cases of chills occurred toward the end of or immediately after H.E.L.P. Apheresis sessions.

As we cannot rule out at the present time that these cases might have been associated with H.E.L.P. LDL Apheresis Heparin Adsorber (Art. No. 7061226) used during those treatments, we are recalling all batches used in those cases, as a safety precaution. Additionally, we are recalling all batches produced from the same raw material batch group as well.

On *[date]*, *[xxx]* pieces of the Heparin Adsorbers from the affected batch *[number of the batch]* have also been shipped to you. We would ask you to review your stocks and use the attached form to let us know how many units you need to return. Once we have your fax, we will promptly dispatch replacements. *[Alternatively: The returned adsorbers will be credited to you after receipt.]*

As replacement we will offer our new H.E.L.P. Heparin Adsorber (Art. No. 7210688) to you. Additionally, in order to allow proper application of this new heparin adsorber, we would like to use the opportunity to implement a software update to the Plasmatec Futura machine. Training of the use of the new software will be agreed upon with you.

If you have any questions, our local sales manager *[please fill in your local contact]* is at your disposal.

Kindly acknowledge receipt of this letter by signing the attached form and returning it by fax to us at your earliest convenience.

We regret this inconvenience, and thank you for your support.

Sincerely,

Enc

Kurzzeichen:

Datum:

2008-05-07

Please return by fax to: *[please fill in your local fax number]*

- We acknowledge receipt and confirm review of the Art. No. 7061226 H.E.L.P. LDL Apheresis Heparin Adsorber batch recall letter dated *[date of letter]*, and inform you as follows:

Art. No. 7061226 H.E.L.P. LDL Apheresis Heparin Adsorber

We have reviewed our stocks and report as follows:

Batch	Number Received	Number Used	Number to Return
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8123A111			
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Title, Name: _____

Telephone No.: _____

Date, Signature: _____

Stamp

Kurzzeichen:

Datum:

2008-05-07