

Stapleline Universitätsstraße 90 · 44789 Bochum

Adresse

Stapleline GmbH
Universitätsstraße 90
44789 Bochum

Fon: +49 (0) 234. 417 43 80
Fax: +49 (0) 234. 417 43 82

info@stapleline.com
www.stapleline.com

Bochum, June 27th, 2007

Sample Letter !

With regard to: Recall of stapling products

Dear customer,

for reasons of precaution, the manufacturer Changzhou Zhiye Medical Devices Institute of the stapling products imported by us performs a voluntary recall of circular stapler and hemorrhoidal stapler.

As they told us, they found a material problem in the scalpel's steel which has to be taken seriously.

The instruments which will be listed with their corresponding lot numbers below should not be used anymore as in 1-2 % of the cases there might be a slight possibility of incomplete cutting edges of the tissue. This could lead to a necessity of a corrective resection.

As we also delivered some instruments of these lot numbers to you, we would like to ask you to check your inventory as soon as possible. Please inform us about the amount of products affected which is still available to you, i.e. about your inventory and consumption. For this, please fill out the attached fax reply and send it back to us.

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The instruments sorted out by you will be picked up by our sales force. Of course, you will get a free compensation at short notice.

In case you have any questions please do not hesitate to contact us:

Stapleline Medizintechnik GmbH
Universitätsstr. 90
44789 Bochum


Tel.-Nr.: 0234 / 417 438-0
Fax-Nr.: 0234 / 417 438-2

Products affected by this recall:

Stapleline Circular Stapler

Kat.Nr. WH-Y-29 LOT Nr.: 070420W6Y

Kat.Nr. WH-Y-32 LOT Nr.: 070420W7Y

Stapleline Hemorrhoidal Stapler

Kat.Nr. GH-Y-32 LOT Nr.: 070419GH7Y ; 070423GH7Y

Kat.Nr. GH-Y-34 LOT Nr.: 070417GH8Y ; 070422GH8Y ; 070418GH8Y

Kat.Nr. GH-Y-36 LOT Nr.: 070420GH9Y

Thanks a lot for your kind cooperation.

Best regards,


Regulatory Affairs
Stapleline Medizintechnik GmbH