

«Kundenname__Custer_name»
«Kundenname__Custer_name2»
«Adresse__Adress»
«PLZ» «Ort__Town»
«Land_Country»

Gebrüder Martin GmbH & Co. KG

Product management
Surgical instruments
Container systems

August 2014
Massimo Fiamma

Tel.: +49 (07461) 706-347
Fax: +49 (07461) 706-312
massimo.fiamma@klsmartin.com

Important safety notice

Recall of Scherbak weights:

Scherbak weight, 400 gr., on its own (Art. No. 32-302-10-01)

Scherbak weight, 800 gr., on its own (Art. No. 32-302-12-01)

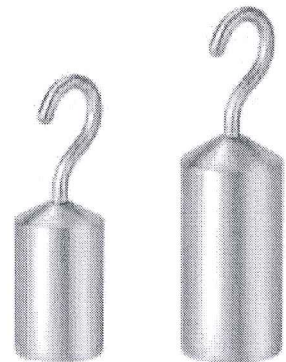
Our ref.: Report-MP010 | CPL 0451

Dear customer and user:

Due to an incident in the market we have discovered that at the weights we placed on the market, 400 gr. (Art. No. 32-302-10-01) and 800 gr. (Art. No. 32-302-12-01), for the Scherbak vaginal speculum fractures can occur in the laser welded seam between the holding hook and the weight involved.

It is our obligation to inform you of the risks to the user and patient that can arise when handling the relevant product from Gebrüder Martin GmbH & Co. KG due to detachment of the holding hook from the weights involved (Art. Nos. 32-302-10-01 and 32-302-12-01).

Please note that one of the affected Scherbak weights, 400 gr. (Art. No. 32-302-10-01), was also placed on the market in the full set we made available (Art. No. 32-302-00-01).



Scherbak
32-302-10

Scherbak
32-302-12

Gebrüder Martin GmbH & Co. KG
KLS Martin Platz 1 · 78532 Tuttlingen/Germany
Postfach 60 · 78501 Tuttlingen/Germany
Tel. +49 7461 706-0 · Fax +49 7461 706-193
info@klsmartin.com · www.klsmartin.com

Registergericht: Stuttgart
Handelsregister: HRA 450196
USt.-Id.-Nr.: DE 142930777

Gesellschafter:
Karl Leibinger Medizintechnik,
Stuckenbrock Medizintechnik

Persönlich haftende Gesellschafterin:
Martin Verwaltungsgesellschaft mbH
Registergericht: Stuttgart
Handelsregister: HRB 450711
WEEE-Reg.-Nr. 40473755

Geschäftsführer:

Karl Leibinger, Christian Leibinger, Donat Stucken

Deutsche Bank Tuttlingen: BLZ 653 700 75 · Kto. 2 184 000
IBAN DE 25 6537 0075 0218 4000 00 · BIC DEUT DE SS 653
Kreissparkasse Tuttlingen: BLZ 643 500 70 · Kto. 10234
IBAN DE 15 6435 0070 0000 0102 34 · BIC SOLADE S1 TUT
Commerzbank AG, Filiale Tuttlingen: BLZ 694 400 07 · Kto. 0 241 215 300
IBAN DE88 6944 0007 0241 2153 00 · BIC COBADEFF694

Advice on safety and conduct, and corrective action:

To eliminate unnecessary risks, Gebrüder Martin GmbH & Co. KG must request you to return all the weights that were delivered to you. This can involve the following article numbers:

32-302-10-01	Weight on its own, 400 gr., for 32-302-00-01
32-302-12-01	Weight on its own, 800 gr., for 32-302-00-01

Note: Please note that one of the affected Scherbak weights, 400 gr. (Art. No. 32-302-10-01), was also placed on the market in the full set we made available (Art. No. 32-302-00-01).

In **Attachment 1** you will find an overview of the products delivered to you and potentially affected.

We will also be pleased to contact you if you wish. If so, please place an appropriate cross on the attached reply fax, indicating the telephone number and contact person, and return it by fax to +49 7461 706 312.

Please ensure that your customers and the user, as well as the members of staff responsible in this matter, are notified of this safety notice and the instructions it contains.

We offer you replacement of the affected weights free of charge.

We would like to apologize for any inconvenience that this may cause you. If you should have any queries, please contact Product Management, Ms. Janett Barth, Tel. +49 7461 706 234, or send her an email at janett.barth@klsmartin.com.

Please keep this notice at least until the measure has been completed.

Kind regards

Gebrüder Martin GmbH & Co. KG
A KLS Martin Group company



p.p.



p.p.

Reinhold Bücher
Head of Quality Management
Safety Officer pursuant to the German
Medical Devices Act

Massimo Fiamma
Head of Product Management
Surgical Instruments
Container Systems

Attachments

Attachment 1, overview list

Reply fax

**FAX reply to +49 7461 706-312
for Gebrüder Martin GmbH & Co. KG**

Customer: «Kundenname__Custer_name», «Ort__Town»,
«Land_Country»
Customer No.: «Kunden_Nr__customer_No_»
Customer ID: «ID_Nr_»

Important safety notice | Risk to patients | Report-MP010
Scherbak weight, 400 gr., on its own (Art. No. 32-302-10-01)
Scherbak weight, 800 gr., on its own (Art. No. 32-302-12-01)

We hereby confirm:

Receipt of the letter "Important safety notice" from Gebrüder Martin GmbH & Co. KG dated August 2014 with Attachment 1.

That the content of the letter "Important safety notice" with Attachment 1 will be forwarded promptly to our customers to facilitate return of the delivered Scherbak weights, 400 gr. (Art. No. 32-302-10-01) and 800 gr. (Art. No. 32-302-12-01), as referred to in Attachment 1.

There are still (quantity) of the following articles on our premises:

- 32-302-10-01 Weight on its own, 400 gr., for 32-302-00-01
- 32-302-12-01 Weight on its own, 800 gr., for 32-302-00-01

Please note that one of the affected Scherbak weights, 400 gr. (Art. No. 32-302-10-01), was also placed on the market in the full set we made available (Art. No. 32-302-00-01).

We would like to be contacted by Gebrüder Martin GmbH & Co. KG.

Name:..... Tel:

Email:.....

Place, date

Name / position of the signatory

Company / stamp and signature

Gebrüder Martin GmbH & Co. KG
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IBAN DE 15 6435 0070 0000 0102 34 · BIC SOLADE S1 TUT
Commerzbank AG, Filiale Tuttlingen: BLZ 694 400 07 · Kto. 0 241 215 300
IBAN DE88 6944 0007 0241 2153 00 · BIC COBADEFF694