

Hospital
Specific client
Address
Post code Town

Country

Gebrüder MARTIN GmbH & Co. KG
Product Management
Hand & Trauma

November 2009

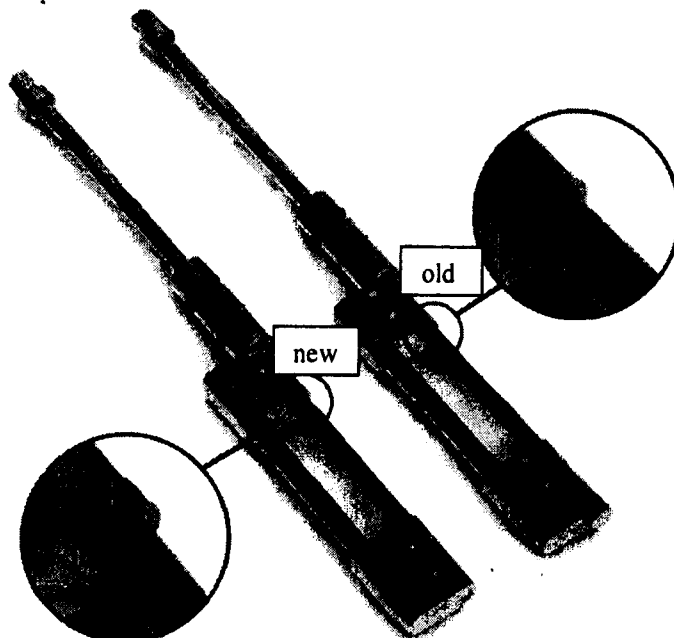
[REDACTED]
Product Manager
Tel.: 07461 / 706 428

Important Safety Notice

**Technical modification of spindle fixture on GENOS MC/MT MINI internal distractors
Distractors shipped between 1 June 2008 and 7 October 2009**

Dear Customer/User,

Regarding the above-mentioned GENOS MT/MC MINI internal distractors, we have received two reports from users indicating that the spindle fixture broke loose from the plate. This connection is subject to heavy loads as it must also take up tensile forces that may be caused by temporary overload during distraction. As an immediate measure, we have already implemented a technical change (see photo) in all hand & foot internal distractors still available at the manufacturers.



Distractors affected: 26-706-18 GENOS MC/MT MINI, 18 mm, right
 26-706-19 GENOS MC/MT MINI, 18 mm, left
 26-706-23 GENOS MC/MT MINI, 23 mm, right
 26-706-24 GENOS MC/MT MINI, 23 mm, left

Delivery period affected: 1 June 2008 - 7 October 2009

No other distractors are affected.

No incident had ever occurred with the GENOS MC/MT MINI distractors before. Nonetheless, the GENOS MINI internal distractors have now been improved as a preventive measure in order to minimize potential residual risks.

Safety instructions and handling recommendations to be followed until corrective measures have been implemented:

Judging from what we know to date, it must be assumed that distractor failure can occur, especially when the device is subject to unusually high loads during the distraction phase. Therefore, to minimize risks, we urgently recommend you to check all patients fitted with one of the above-mentioned GENOS MC/MT MINI internal distractors on a regular basis during the distraction phase so potential distractor failure can be detected at an early stage and corrective measures can be taken.

To prevent risks, Gebrüder MARTIN must ask you to check all of your above-mentioned GENOS MC/MT MINI internal distractors as soon as possible. The following list is intended to give you an overview of the distractors shipped to you during the affected delivery period (1 June 2008 to 7 October 2009):

List of specific distractors with lotnumber

Please ensure that all of your customers (if you are a specialized dealer) or your users and any other staff involved in the matter know about this Safety Notice and the instructions contained herein.

Moreover, we kindly ask you to return to us any affected distractors that have not been implanted yet so they can be adapted. You will then be credited with the corresponding amounts. As regards replacements for returned distractors, we'd like to ask you to reorder them at your convenience.

Please confirm receipt of this Safety Notice by completing the Return Fax form attached and faxing it to the following number: +49 7461 706 350.

Should you have any queries, please do not hesitate to contact our Hand & Trauma product management department at +49 7461 706 109.

We'd like to apologize for the inconvenience we are causing you. However, the requested actions are preventive measures designed to ensure the safety of patients and users alike.

Sincerely yours,

Gebrüder Martin GmbH & Co. KG,
a company of the KLS Martin Group



Product Manager
Hand & Trauma



Dr. 

Head of QA / Laboratory

Return Fax

Return FAX – send to: +49 7461 706-350

Gebrüder MARTIN GmbH & Co. KG

Customer: Hospital, Specific client, Town
Customer ID: Client number

Technical modification of spindle fixture on GENOS MC/MT MINI internal distractors

Distractors

26-706-18	GENOS MC/MT MINI, 18 mm, right
26-706-19	GENOS MC/MT MINI, 18 mm, left
26-706-23	GENOS MC/MT MINI, 23 mm, right
26-706-24	GENOS MC/MT MINI, 23 mm, left

placed on the market between 1 June 2008 and 7 October 2009.

We hereby confirm:

1) That we have received Gebrüder MARTIN's letter "Important Safety Notice" dated November 2009 including attachment 1 (Return Fax).

2a) As a specialized dealer:

That we will pass on the contents of Gebrüder MARTIN's "Important Safety Notice" complete with attachment 1 to our customers as soon as possible so the delivered and affected GENOS MINI internal distractors can be properly checked.

2b) As a user:

That we will check the delivered and affected GENOS MINI internal distractors as soon as possible.

City, date

Name/position of signatory:

Company name / stamp & signature
