

Customer address

Gebrüder Martin GmbH & Co. KG
Product Management Implant Systems

23.04.2020 TH
Tobias Held

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Safety notice - Additional product information about the screwdriver T6 Linos REF 26-975-39-07

Dear Sirs,

The purpose of this safety notice is to inform you about an additional product information initiated by Gebrüder Martin GmbH & Co.KG when using the T6 Linos screwdriver.

Description of circumstance

In the application, excessive mechanical torsional stress can cause the screwdriver to break at the working end.

Below you will find a corresponding illustration of such a breakage at the working end.



Possible risks of breakage

The breakage and the fragment stuck in the screw head could lead to permanent damage of the tissue. It may not be possible to explant the plate.

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

Registergericht: Stuttgart
Handelsregister: HRA 450196
Ust.-IdNr.: 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 Stuckenbrock

Deutsche Bank Tuttlingen: BLZ 653 700 75 · Kto. 2 184 000
IBAN DE 25 6537 0075 0218 4000 00 · BIC DEUT DE 33 653
Kreissparkasse Tuttlingen: BLZ 643 500 70 · Kto. 10234
IBAN DE 15 6435 0070 0000 0102 34 · BIC SOLADE 33 TUT
Commerzbank AG, Filiale Tuttlingen: BLZ 694 400 70 · Kto. 0 241 215 300
IBAN DE 88 6944 0007 0241 2153 00 · BIC COBADE33 694

NOTE for correct application of the T6 Linos screwdriver REF 26-975-39-07

If you cannot use an alternative product to the one mentioned above, we recommend performing the insertion of the multidirectional smartDrive® locking screws only until you feel a noticeable locking effect. It is not necessary to continue the rotation movement after this resistance; in worst case, this could result in damage of the screwdriver. The rotary motion itself should only come from the hand, rotation from the upper arm should be strictly avoided.

In addition to the product listed here, the Safety Notice must be considered for the following additional articles:

Material	Description German	Description English
26-975-33-07	smartDrive Schraubendreher kurz T5 drehb	smartDrive Screwdriver T5 rotating short
26-975-36-07	smartDrive Schraubendreher kurz T6 drehb	smartDrive Screwdriver T6 rotating short
26-975-37-07	smartdrive Schraubendreher T6	smartDrive Screwdriver T6
26-975-38-07	smartDrive Schraubendreher kurz T5	smartDrive Screwdriver T5 short
26-975-39-07	smartDrive Schraubendreher kurz T6	smartDrive Screwdriver T6 short
26-975-40-07	Schraubendreherklinge smartDrive T6, L	Screwdriver blade smartDrive T6, L

Transmission of safety notice "Additional product information"

Please ensure that all users of the product mentioned and other affected people in your organisation who need to be informed are aware of this safety notice for additional product information. If you have submitted the products to third parties, please forward a copy of this safety notice "Additional product information" or inform the contact persons below. Please keep this information at least until you have informed all the people in your company who has to be informed.

Gebrüder Martin GmbH & Co.KG

Your responsible health authority for medical devices has received a copy of this safety notice "Additional product information about the screwdriver T6 Linos REF 26-975-39-07".

Please do not hesitate to contact us in case of any further questions.

Kind regards,

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

i.V.



Reinhold Bücher

Head of Quality Management
Field Safety Officer / MPG

i.A.



Tobias Held

Senior Product Manager
Operational Product Management
Implant Systems

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Annex

**Reply-Fax to +49 7461 706-350
to Gebrüder Martin GmbH & Co.KG**

Customer _____

Customer-No. _____

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26-975-39-07	smartDrive Schraubendreher kurz T6	smartDrive Screwdriver T6 short
26-975-40-07	Schraubendreherklinge smartDrive T6, L	Screwdriver blade smartDrive T6, L

We herewith confirm:

Receipt of the letter safety note "Additional product information about the screwdriver T6 Linos REF 26-975-39-07" from Gebrüder Martin GmbH & Co.KG from April 2020.

Place, Date

Name / Position of signatory

Organisation / Stamp / Signature of signatory

Gebrüder Martin GmbH & Co. KG
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IBAN DE 88 6944 0007 0241 2153 00 · BIC COBADEF694