

MEDE TECHNIK • Rudolf-Diesel-Str. 13 • 78576 Emmingen • Germany

Chirurgie & Dental Instrumente
Surgical & dental instruments



Reparatur-Service | Hersteller | Händler
Repair-Service | Manufacturer | Dealer

08.Nov.2021

Urgent Safety Information

Relevant Product / Product Description

Product:	K-WIRES 15cm Ø1,4mm TR/RD
Article Number:	33.0214.150
Batch No.:	14T656

Dear Customer,

With this letter we would like to inform you that we are carrying out a recall of the above-mentioned product.

Reason for the safety information:

In the above mentioned batch K-Wires with Ø 1.6 mm have been discovered

Clinical Impact:

There is no risk for patients and users. There may be a short-term delay in operating time (< 30 min.) because a another K-Wire has to be used.

The version of the Ø 1.6 mm K-Wires is the same as that of the Ø 1.4 mm K-Wires. The material composition and strength of both versions are within the specifications of the standard. Both K-Wires only differ in diameter (0,2 mm).

There are no risks when implanting the thicker K-Wires - when using guide sleeves there may be problems because the wire does not pass through.

Page 1 of 2

Telefon: ++49 (0)7465 893
++49 (0)7465 2282
Fax: ++49 (0)7465 928119

eMail: info@mede.de
Internet: www.mede.de

USt-IdNr.: DE142945943
Inhaber: Lucia Weggler

Register Nr.: HRA450756
Reg. Gericht: Stuttgart

Postbank Stuttgart
BLZ 600 100 70
KTO 18 88 11 701
IBAN DE21 6001 0070 0188 6117 01
S.W.I.F.T. PBNKDEFF

Kreissparkasse Tuttlingen
BLZ 643 500 70
KTO 93 00
IBAN DE13 6435 0070 0000 0093 00
S.W.I.F.T. SOLA DES1TUT

Sparkasse Engen-
Gottmadingen
BLZ 692 514 45
KTO 52 23 672



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Necessary Measures:

Please check your stocks for the relevant item number / batch. We would like to ask you to stop using the K-Wires from this batch. If possible, check the wires from this batch for their diameter or return the affected batch to us for examination.

Please complete the enclosed response form and confirm that you have checked your stocks or have returned / will return the affected K-Wires and that you have informed your customers.

If you have any questions about this safety information, please contact our Quality Manager,

Mr. Florian Weggler

(Tel: +49 7465 893 / E-Mail: info@mede.de).

We would like to apologise for the inconvenience this has caused your house and assure you that we will take appropriate corrective and preventive measures to avoid such incidents in the future.

With best regards

MEDE TECHNIK GmbH


F. Weggler
(General Manager / Quality Manager)



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Customer Response Form

Please send this form by fax or e-mail to MEDE Technik GmbH, Attn: Mr Weggler.
Fax: +49 7465 2262 / E-Mail: info@mede.de

According to our traceability records, you have received K-Wires from the concerned batch. Please inform your customer(s) who have received the concerned item(s) and check your stock if necessary.

Article Number MEDE	Article Number Customer	Batch	Delivery Note No. / Pos. Invoice No.	Delivery Note Date
33.0214.150	-	14T656	1198768 / 160 97047	07.Oct.2021
K-Wires 15cm Ø1,4mm Trocar/ Round		60 pcs.		

Stock	Examination	Customer(s) informed
<input type="radio"/> yes <input type="radio"/> no	<input type="radio"/> yes <input type="radio"/> no Return to MEDE Technik <input type="radio"/> N/A	<input type="radio"/> yes <input type="radio"/> N/A

Please fill in the table above and sign below.

We hereby confirm that we have checked our stock (if applicable) and informed the concerned customer(s), if necessary. There are no further items of the concerned batch in our stock.

Name: _____

Position: _____

Signature: _____

Date: _____

Stamp:

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UST-IdNr.: DE142945943
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Reg. Gericht: Stuttgart

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BLZ 643 500 70
KTO 93 00
IBAN DE13 6435 0070 0000 0093 00
S.W.I.F.T. SOLA DES1TUT

Sparkasse Engen-
Geltmadingen
BLZ 692 514 45
KTO 52 23 672