

Field Safety Notice

27 April 2021

Product Recall

Lasse size 3, Lasse size 4, Da Vinci size 1, Da Vinci size 2

Identification of the affected medical devices:

Only the following products are affected by this product recall:

- Lasse size 3, size 4 (article number 164, 167) with serial number L10006348 and DEWERT MEGAMAT MCZ drive Serial-No:
H402930 0001 to H402930 0100 and R771107 0001 to R771107 0100
- Da Vinci size 1, size 2 (article number 168, 169) with serial number D1000875 and DEWERT MEGAMAT MCZ drive Serial-No:
H402930 0001 to H402930 0100 and R771107 0001 to R771107 0100

Description of the problem and cause:

Spindle nut detaches from the lifting tube, connection between spindle nut and lifting tube not perfect. Fault cause analysis of the drives was carried out by the quality assurance department of the production plant. Contrary to the spindle nut entered in the parts list, a loose spindle nut was installed.

There is no risk for the patient with the affected products as long as all safety instructions in the instructions for use are observed.

We assess the risk as low, since safety instructions and other provisions of the instructions for use must always be observed by the user as well as by the accompanying / supervising person.

Necessary measures:

- Contact your customers, there is an application stop
- Withdraw units with the affected drives from use. (DEWERT MEGAMAT MCZ drive Serial-No.: **H402930 0001 to H402930 0100 and R771107 0001 to R771107 0100**)
- Complete the attached customer response form and send it by email to sicherheit@rehatec.com
- Planned retrofitting of the affected units as of week 18

Disclosure of the information described herein:

Please ensure in your organisation that all users of the above-mentioned products and other persons to be informed are made aware of this "Urgent Safety Information". If you have given the products to third parties, please forward a copy of this information. Please keep this information at least until the measure has been completed.

The Federal Institute for Drugs and Medical Devices has received a copy of this "Urgent Safety Information".

Contact person:

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*Head of Sales*phone: +49 6228 91 36 91fax: +49 6228 91 36 99email: sicherheit@rehatec.com

Customer Reply Form

Recall: 01_04/2021

Company: _____

Street: _____

ZIP, town: _____

Your Name: _____

Date: _____

According to our records, you have received one or more Lasse size 3, size 4 and/or Da Vinci size 1, size 2 we supplied to you from 07/07/2020 to 29/03/2021.

Are you still the operator of the above products?

YES NO

If YES, which serial numbers (Serial-No.) have the DEWERT MEGAMAT MCZ drives:

Date	Order number	Receipt number	Commission	Product	Serial number	Serial-No. of DEWERT MEGAMAT MCZ drive
17/02/21	147480	37010810/ 1426781	37010810/ 1426781	Lasse size 4	L10006762	
03/02/21	146993	37010810/ 1417301	37010810/ 1417301	Lasse size 4	L10006731	
18/01/21	146520	37010810/ 1412841	37010810/ 1412841	Lasse size 4	L10006697	
14/12/20	145837	37010810/ 1405263	37010810/ 1405263	Lasse size 4	L10006654	
23/11/20	145219	37010810/ 1390635	37010810/ 1390635	Lasse size 4	L10006595	
05/11/20	144704	37010810/ 1387437	37010810/ 1387437	Lasse size 4	L10006560	

Date	Order number	Receipt number	Commission	Product	Serial number	Serial-No. of DEWERT MEGAMAT MCZ drive
02/11/20	144569	37010810/ 1382073	37010810/ 1382073	Lasse size 4	L10006548	
30/10/20	144537	37010810/ 1382073	37010810/ 1382073	Lasse size 4	L10006542	
01/10/20	143789	37010810/ 1366587	37010810/ 1366587	Lasse size 4	L10006499	
16/03/20	148271	37010810/ 1439171	37010810/ 1439171	Lasse size 4	L10006846	
16/03/21	148268	37010810/ 1431759	37010810/ 1431759	Lasse size 3	L10006843	
17/02/21	147479	37010810/ 1427574	37010810/ 1427574	Lasse size 3	L10006763	
16/02/21	147432	37010810/ 1425641	37010810/ 1425641	Lasse size 3	L10006759	
26/01/21	146756	37010810/ 1416044	37010810/ 1416044	Lasse size 3	L10006712	
18/01/21	146515	37010810/ 1412052	37010810/ 1412052	Lasse size 3	L10006694	
03/12/20	145517	37010810/ 1394456	37010810/ 1394456	Lasse size 3	L10006626	
05/11/20	144705	37010810/ 1388240	37010810/ 1388240	Lasse size 3	L10006561	
05/11/20	144707	37010810/ 1382679	37010810/ 1382679	Lasse size 3	L10006563	
29/10/20	144510	37010810/ 1379318	37010810/ 1379318	Lasse size 3	L10006539	
22/10/20	144286	37010810/ 1374013	37010810/ 1374013	Lasse size 3	L10006519	
23/09/20	143551	37010810/ 1363093	37010810/ 1363093	Lasse size 3	L10006480	
03/09/20	143102	37010810/ 1354175	37010810/ 1354175	Lasse size 3	L10006453	
06/08/20	142460	37010810/ 1328435	37010810/ 1328435	Lasse size 3	L10006396	

O If YES, please tick this box to confirm that you have taken the necessary action and that the customer has been informed. You hereby confirm that the unit will no longer be used as long as the corrective measures on the unit itself have not been completed.

O If NO, where are the affected units now (with serial number if applicable):

Serial number: _____ Serial number: _____

Company: _____ Company: _____

Street: _____ Street: _____

ZIP: _____ ZIP: _____

Town: _____ Town: _____

Phone: _____ Phone: _____

Serial number: _____ Serial number: _____

Company: _____ Company: _____

Street: _____ Street: _____

ZIP: _____ ZIP: _____

Town: _____ Town: _____

Phone: _____ Phone: _____

Signature: _____

Please send this form by email to sicherheit@rehatec.com.