Ideen bewegen mehr

Sanitätshaus XYZ
Mustermannstr.
XXXX Musterhausen
Musterland

Urgent safety information

Recall
affecting
V-MAX² P1605

Albstadt, 9. August 2022

Sender:

AAT Alber Antriebstechnik GmbH, Ehestetter Weg 11, D 72458 Albstadt - Ebingen

Addressee:

See address header above

Identifikation der betroffenen Medizinprodukte:

Handelsname:	V-MAX²
Modell-Name und/oder -Nummer:	P1605
Seriennummer:	See supplementary sheet

Description of the problems including the detected cause:

From May 2021 to July 2022, motor brake units were installed in individual V-MAX² push and brake aids, some of which were not properly installed and provided to us by a supplier.
Under unfavorable conditions, the affected devices can lead to a hazardous situation in that they can start rolling again after stopping on a downhill slope.

Potential risk:

➔ Loss of the additional holding force of the wheelchair on inclines / declines

In this case the product remains basically functional, because the function as pushing and braking aid is not affected and the device always brakes to a standstill, but the affected pushing and braking aid no longer supports stopping on uphill and downhill slopes, because the "safety collapse brake" of the motor-brake-unit no longer engages and the wheelchair can therefore roll away, unless (as prescribed in the operating instructions) the wheelchair's own mechanical parking brakes are activated for driving breaks to prevent from rolling away.

Acc. to safety reasons the affected V-MAX² shall not be used anymore, until the corrective measure has been carried out either by you on site or by us in the factory.

Which measures should the addressees take?

- Acc. to safety reasons the affected V-MAX² shall not be used anymore, until the corrective measure has been carried out either by you on site or by us in the factory.
- As a trained medical supply store, you can perform the corrective measure directly at your customer's site according to the instructions we sent. You can plan a time of approx. 30 minutes for the corrective measurement. It is important here that you have the required threadlocker "Loctite 648 or alternatively WEICON AN 306-48" on site, others are not approved for this case. We will provide you with the matching grub screws "DIN 916 M3x3".
- Unfortunately, devices that we notified you of during the recall campaign in June 2022 may also be affected. These devices must also be checked again.
- AAT Alber Antriebstechnik GmbH will carry out the corrective measure as soon as possible.

Distribution of the here described safety information

Please ensure without delay 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 passed the products on to third parties, please forward a copy of this information or inform the contact person stated below.
Please keep this information at least until the measurement has been completed.
The Federal Institute for Drugs and Medical Devices has received a copy of this "Urgent Safety Information".

Contactperson:	*for collecting, reshipment, repair and/or exchange of affected medical devices*	*Persons responsible for regulatory compliance (according to Art. 15, EU Medical Device Regulation 2017/745):*	
	Service - Center	*Daniel Mohr PRRC*	*Kordt Griepenkerl Deputy PRRC*
Tel.:	*+ 49 7431 12 95 550*	*+ 49 7431 12 95 502*	*+ 49 7431 12 95 0*
Fax:	*+ 49 7431 12 95 540*	*+49 74 31 12 95 37*	*+49.74 31.12 95 35*
e-mail:	servicecenter@aat-online.de	sicherheitsbeauftragter-mp@aat-online.de	

We regret the inconvenience this has caused you and thank you in advance for your cooperation.

Best regards,

...

Person responsible for regulatory compliance acc. to Art. 15, EU Medical Device Regulation 2017/745

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