NOTIFICATION LETTER

Safety corrective action for the Poweo patient lift with electric tilting suspension

QUALITY NOTICE ☐ SAFETY NOTICE ■

Reference	MT25-004-FSN-20250710-EN-RO
Action	Quarantine and inspection of POWEO patient lifts with electric tilting suspension
Date	July 10, 2025
Recipients	To the attention of competent authorities, distributors, service providers, healthcare professionals, and private users
Products Concerned	Electric tilting suspension of POWEO product range patient lifts

Subject : Safety corrective action on Patient Lifts Manufactured by SCALEO Medical Equipped with Electric Tilting Suspension

Dear Sir/Madam, Valued Customer,

We would like to inform you that SCALEO Medical is implementing a corrective action concerning the electric tilting suspension of POWEO product range patient lifts

We have been informed of a number of serious incidents occurring during use of the POWEO 200 lift equipped with electric tilting suspension. The entire suspension may detach during use, causing the patient to fall. To date, no patient has died or suffered serious injury.

An investigation conducted by SCALEO Medical on the affected POWEO 200 units indicates that two main load-bearing parts show significant deterioration after 2 to 3 years of use. The findings show that this wear is progressive, all POWEO lifts with electric suspension manufactured before June 2023 are affected, and that the daily transfer frequency, patient weight, and speed/duration of transport influence the deterioration rate.

As a precaution, all affected devices marketed before June 2023 — listed in the appendix — must be quarantined until the critical components are inspected. Devices manufactured from July 2023 will be subject to corrective action, by replacement of the defective parts, from mid-August.

We therefore provide you with all necessary information to inspect the devices and outline the corrective measures required to ensure safety.

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Potential Risk :

Risk of suspension detachment from the POWEO lift during transfer, potentially causing the patient to fall.

Problem Detection :

Visual inspection focuses on the condition of the concerned parts after disassembly of the suspension:
- Compliant BPPA Shaft and Shoulder: Parts are removable and show no signs of wear or deterioration.
- Non-compliant BPPA Shaft and Shoulder: Parts are not removable and/or show signs of wear or deterioration.

	Compliant BPPA axis and Shoulder: Parts are removable and show no signs of wear or deterioration.	**Non-compliant BPPA Shaft and Shoulder: Parts are not removable and/or show signs of wear or deterioration.**
AXIS BPPA – S19 10 122		

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	Compliant BPPA axis and Shoulder: Parts are removable and show no signs of wear or deterioration.	Non-compliant BPPA Shaft and Shoulder: Parts are not removable and/or show signs of wear or deterioration.
SHOULDER BPPA – S19 10 046		

Non-conforming suspension: The BPPA axis and BPPA shoulder cannot be removed from the suspension.

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Curative Measure :

1. Quarantine the lift until inspection is complete.

2. Inspect the lift by disassembling the suspension and verifying the specified parts:
- If the BPPA Shaft and Shoulder are compliant, the suspension can be reassembled and used until the replacement parts (S19 10 122 & S19 10 046) are received.
- If disassembly is not possible and/or any part is non-compliant, the product must remain quarantined until replacement.

Corrective Measure :

SCALEO Medical has developed and validated a new solution involving increased dimensions and a material change to improve the tensile strength and durability of the affected parts.

New parts will be available starting mid-August. A new safety notice will be sent with a working instruction.

Required actions :

Please complete and return the attached form confirming that you have:
- Read this safety notice.
- Inspected or will arrange for the inspection of affected devices.
- Will inform SCALEO Medical of the inspection results.

For support:
+33 (0)4 99 77 23 38 or info@scaleomedical.com

We apologize for any inconvenience and thank you for your understanding and cooperation.

Sincerely,
Quality Manager & materiovigilance Correspondent

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Annex – list of lifters serial number concerned by that notification:

PMG1512029
PML1906097
PML2101015
PML2101013
PML2101016
PML2101021
PML2101022
PML2101025
PML2112090
S16030ZZPML22J00053
S16030ZZPML22J00057
S16030ZZPML22J00058
S16030ZZPML22J00059
S16030ZZPML22J00060
S16030ZZPML22J00061
S16030ZZPML22J00062
S16030ZZPML22J00063
S16030ZZPML22J00064
S16030ZZPML22J00065
S16035ZZPML22L00068
S16035ZZPML22L00069
S16030ZZPML22L00077

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Response form

Name and address of the healthcare professional or distributor:

……..

Corrective safety action for the Poweo patient lift with electric tilting suspension

We kindly ask you to complete this reply form and return it as soon as possible to the following address

SCALEO Medical, 107 rue Dassin, PARC 2000, 34080 Montpellier France
Or by email : info@scaleomedical.com

I certify:

- **I have received the notification reference:** MT25-004-FSN-20250710-EN-RO
- **I have carried out or had carried out the inspection required by this notification**
- **I have noted that if non-compliance is detected, the product must be in quarantine**

The control results are :

Place	Serial number	Inspected by	Date of inspection	Results (Compliance / Non-compliance)

Name :
Function :
Address and City :
Date et signature :

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