

Letter to healthcare professionals

R1901643

Patient safety data

Date January 15th 2019

SAMSOFT 175 - MINI SAMSOFT 150 - SAMSOFT+ - MINI SAMSOFT+

Reminder of use and preventive maintenance requirements.

Information for health providers providing patient lifts or responsible for their maintenance

Dear Sirs,

Drive Devilbiss Healthcare France has received reports about the equipment crossbar axle breaking. Although those incidents are limited in relation to the number of marketed equipment, they may lead to a dangerous situation for the patients if the axle were to break when transferring.

The patient lifts comply with ISO 10535 standard and are reliable to use. This security data is issued to remind the instructions for use and preventive maintenance in order to prevent those incidents. The user guides were updated to strengthen those requirements. They are available on our Website (<http://www.drivedevilbiss.fr>).

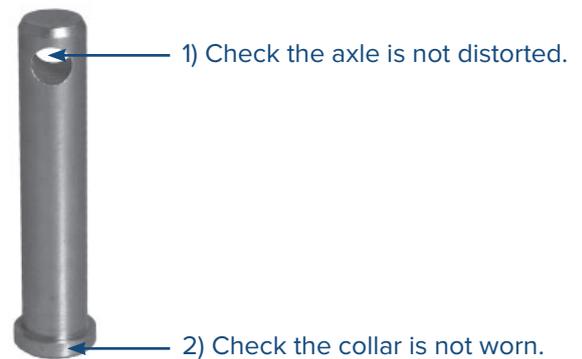
Reminder of preventive maintenance instructions:

Preventive maintenance should be performed once a year or as needed.

The crossbar axle, and its assembly as a critical part, should be fully and rigorously inspected. You should particularly check the axle and the assembly are not distorted 1) or worn 2).

It should be mandatorily **disassembled and lubricated**. In case of wear and tear sign, the axle and its assembly should be **NECESSARILY** replaced. Replacement kits are available, please contact us.

Note: for SAMSOFT+ - MINI SAMSOFT+, when disassembling the axle, self-locking nut M10 should be mandatorily replaced.



Reminder of use instructions:

We recall it is not recommended to move the patient when installed in the patient lift, and you should mandatorily move the patient lift with the handles located on the back of it. In no case shall the patient lift be moved with the crossbar or straps. Those instructions should be clearly indicated when the users are trained.

Notification of this safety notice:

The ANSM (French National Agency for Medicines and Health Products Safety) was informed.

Drive DeVilbiss Healthcare France thanks you for disseminating this safety notice to whom it may concern.

In case of questions related to this safety notice, please contact the Director, Regulatory Affairs and Quality Drive DeVilbiss Healthcare France: materiovigilance@drivedevilbiss.fr

Céline Lessard

Director, Regulatory Affairs and Quality

Reception notice of FSN R1901643

Receipt notice to be completed and return to Drive DeVilbiss Healthcare France :
 materiovigilance@drivedevilbiss.fr

Compagny	
Adress	
Contact (Name, position and e-mail adress)	

I confirm we:

- Identified the stock of SAMSOFT 175 - MINI SAMSOFT 150 - SAMSOFT+ - MINI SAMSOFT+ patient lifts
- Took note of the reminder of use and maintenance instructions above mentioned
- Informed our clients about those instructions
- Applied those instructions where appropriate.

Signed at on/...../..... (date)

Signature