



Hillrom™

Hillrom Luleå Nedre Vägen 100, 975 92
Luleå, Sweden

Field Safety Notice

FA 2021-05-002-LUL-003

Field Action Identifier: FA 2021-05-002-LUL-003

Date:

Customer name:

Commercial name of affected product:

OctoStretch™ with Stretch Leveler, FlexoStretch™, Stretch Leveler, LikoStretch™ 1900, LikoStretch™ Mod 600 IC.

Affected Devices:

OctoStretch with Stretch Leveler, FlexoStretch, Stretch Leveler, LikoStretch 1900, Liko Stretch Mod 600 IC. Models: 156056, 3156057, 3156200, 3156051, 3156065, 3156065B

Type of action: Field Safety Notice

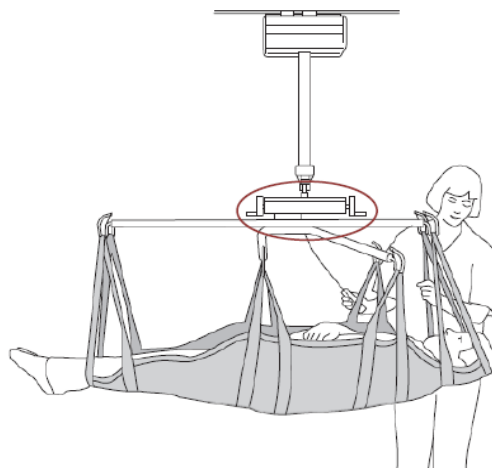
To: Facility Risk Manager/Facility Administrator, Chief Executive
Facility Administrator, Facility Engineer, Vigilance Manager, Biomedical Engineering, Medical Device Liaison Officer

Description of the problem:

Hillrom has become aware of a user report of Leveler breakage used with the Octo Stretch.

As a result of the breakage the Stretch Leveler has the potential to lose the function of maintaining a patient in the horizontal position when lifting and in motion. When this function is lost the patient can slide backwards and potentially may fall out of the Oct lift sheet back onto the surface it is being lifted from. See Figure 1: OctoStretch with Leveler in use, Stretch Leveler circled.

Figure 1





Hillrom™

Hillrom Luleå Nedre Vägen 100, 975 92
Luleå, Sweden

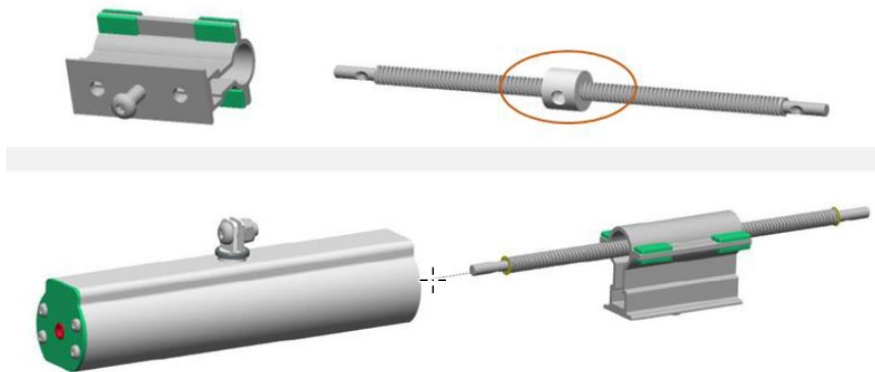
Field Safety Notice

FA 2021-05-002-LUL-003

Background:

The function of the Stretch Leveler connected to the OctoStretch is to allow for adjustment of the center of gravity during lift. The Stretch Leveler is composed of a trapezoidal nut attached to an attachment profile on a threaded rod. If the trapezoidal nut breaks the leveler can shift center of gravity without the user activating the function, causing the stretcher to tilt unexpectedly. See Figure 2: Main components and assembly of Stretch Leveler. Trapezoidal nut circled.

Figure 2



Potential Risk:

Hillrom risk assessment determined that the probability of harm has an improbable likelihood for the patient to sustain catastrophic injury. Based on the potential intended use of this device with particularly fragile patients and the improbably likelihood of harm, Hillrom is initiating this field correction notice to all customers and will be correcting devices with an updated to the leveler.

Actions being taken by Customer:

Please share this Field Safety Notice with all potential users in your organization. Please ensure inspection of the device prior to use as stated in the device Instruction for Use (IFU). Complete the attached response form, acknowledging receipt, indicate the number of devices and return to hillromLUL003OUS@stericycle.com within one month.

Action to be taken by the Distributor:

Please share this Field Safety Notice with your end users and complete the attached response form and return to hillromLUL003OUS@stericycle.com within one month. Contact hillromLUL003OUS@stericycle.com to receive an electronic copy of this notification and response form for onward distribution.

Action to be taken by the Hillrom:

Hillrom is replacing the stretch leveler to mitigate this risk of breakage. Upon completion of the enhancement(s), Hillrom will contact customers to coordinate update of the leveler device.



Hillrom™

 Hillrom™ Hillrom Luleå Nedre Vägen 100, 975 92 Luleå, Sweden	Field Safety Notice	FA 2021-05-002-LUL-003
---	----------------------------	-------------------------------

Contact Reference Person:

Should you have any questions regarding this Field Safety Notice and field corrective action, please contact Hillrom Technical Support, using email or number below.

Market /Region/ Country	Phone Number	Technical Support Email
Austria	(+ 43) 2 243 285 50	service.dach@hillrom.com
Germany	(+ 49) 2 0149869500	service.dach@hillrom.com
Switzerland	(+ 41) 8 48 81 1530	service.dach@hillrom.com
Netherlands	(+ 31) 347 323 532	service.nl@hillrom.com
Spain	(+ 34) 9 36856000	asistencia@hillrom.com
Italy	(+ 39) 02 950541	assistenza.tecnica@hillrom.com
France	(+ 33) 0 820 012345	sav@hillrom.com
Sweden	(+ 46) 20-781030	ordernordic@hillrom.com
UK/Ireland	(+ 44) 1530 562176	UKTechSupport@hillrom.com
Eastern Europe Countries	Contact your Local Hillrom Distributor	
Middle East & Africa	Contact your Local Hillrom Distributor	
India Sub-Continent	Contact your Local Hillrom Distributor	


Transmission of this Field Safety Notice:

Please ensure this notice is circulated to all appropriate personnel. This may include, but is not limited to:

A&E departments	In-house maintenance staff
Adult intensive care units	IV nurse specialists
All wards & Clinics	Medical directors
Biomedical engineering staff	Nursing executive directors
Clinical governance leads	Oncology units
Day case theatres	Pediatric intensive care units
EBME departments	Risk managers
Equipment stores & Libraries	Supplies managers
Health and safety managers	Theatres

Sincerely,

Andreas Persson
Director, Quality Assurance

 <p>Hillrom™ Hillrom Luleå Nedre Vägen 100, 975 92 Luleå, Sweden</p>	<p>Field Safety Notice</p>	<p>FA 2021-05-002-LUL-003</p>
---	-----------------------------------	--------------------------------------

Response Form / Receipt

**Subject: OctoStretch with Stretch Leveler, FlexoStretch, Stretch Leveler, LikoStretch 1900, LikoStretch Mod 600 IC- LEVELER REPLACEMENT.
(FA 2021-05-002-LUL-003)**

It is important that you return this form as acknowledgement of your receipt and provide us with the necessary information.

Please complete the following with the correct information and **return this Response Form** within **one month**. Thank you!

Hillrom account number (if known): _____

Name of the facility: _____

Address of the facility: _____

City: _____ Zip: _____ Country: _____

Facility Contact Person Name: (print) _____

Signature: _____ Date: ___/___/___

Title: _____ Phone: _____

Email: _____

Check actions taken:

Indicate number of leveler devices requiring update: _____

We have reviewed and understand the attached Field Safety Notice.

Yes No

Distributors Only: We have distributed the product further and notified our consumers of the attached Field Corrective Action per the instructions noted above.

Yes No

Response form shall be returned to hillromLUL003OUS@stericycle.com within one month.