Date
Customer Name

FSCA-identifier: FA-2021-12-005-LUL-007

Subject: Short center bolt on Universal Twinbar 670 QRH™

Commercial name of the impacted product:
UNIVERSAL TWINBAR 670 QRH™ (Quick Release Hook)

Potentially Impacted devices:
Model 3156087 & P3156087

Any UNIVERSAL TWINBAR 670 QRH™ manufactured before 28OCT2021 and distributed from Hillrom warehouses before 12JAN2022 may potentially be affected.

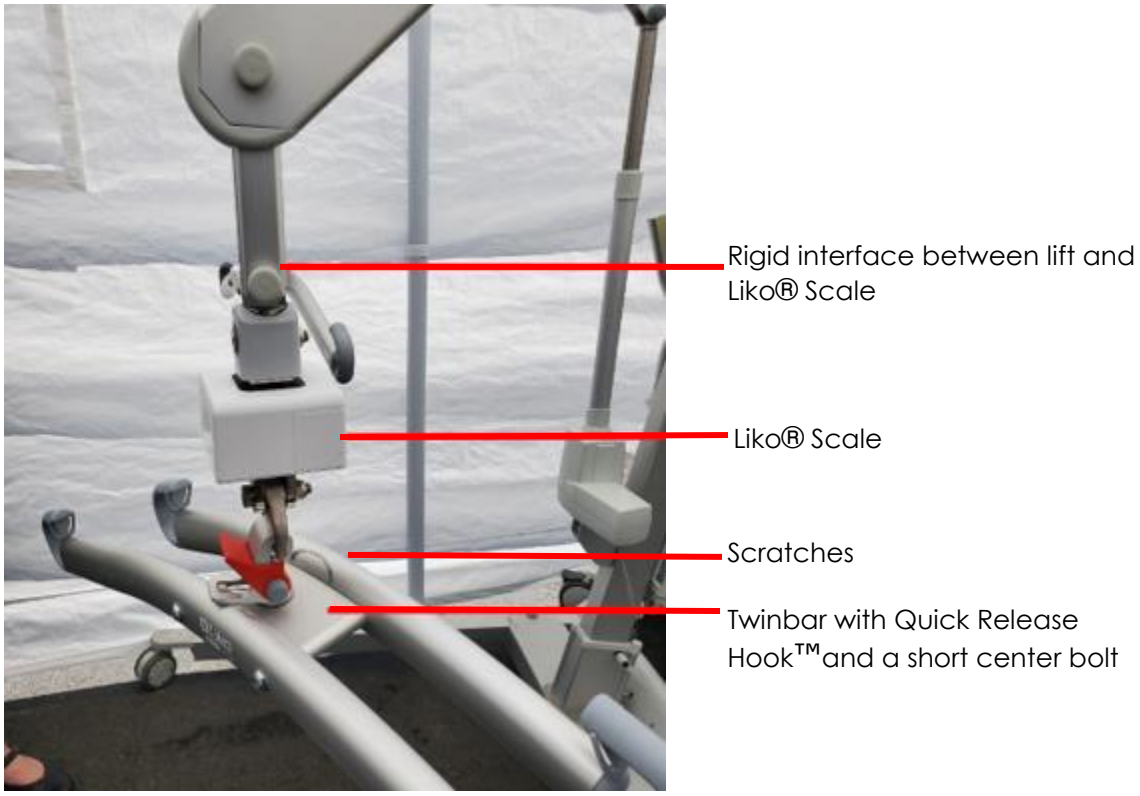
Type of action: Field Safety Notice

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 determined that there is a potential for patient fall with the Universal Twinbar 670 QRH™, which may have been manufactured with an incorrect, shorter center bolt. The potentially hazardous situation can occur when the Twinbar with the shorter center bolt, is used in combination with a Liko® Scale and a rigid (non-rotating) interface.

See figure 1 below

Figure 1

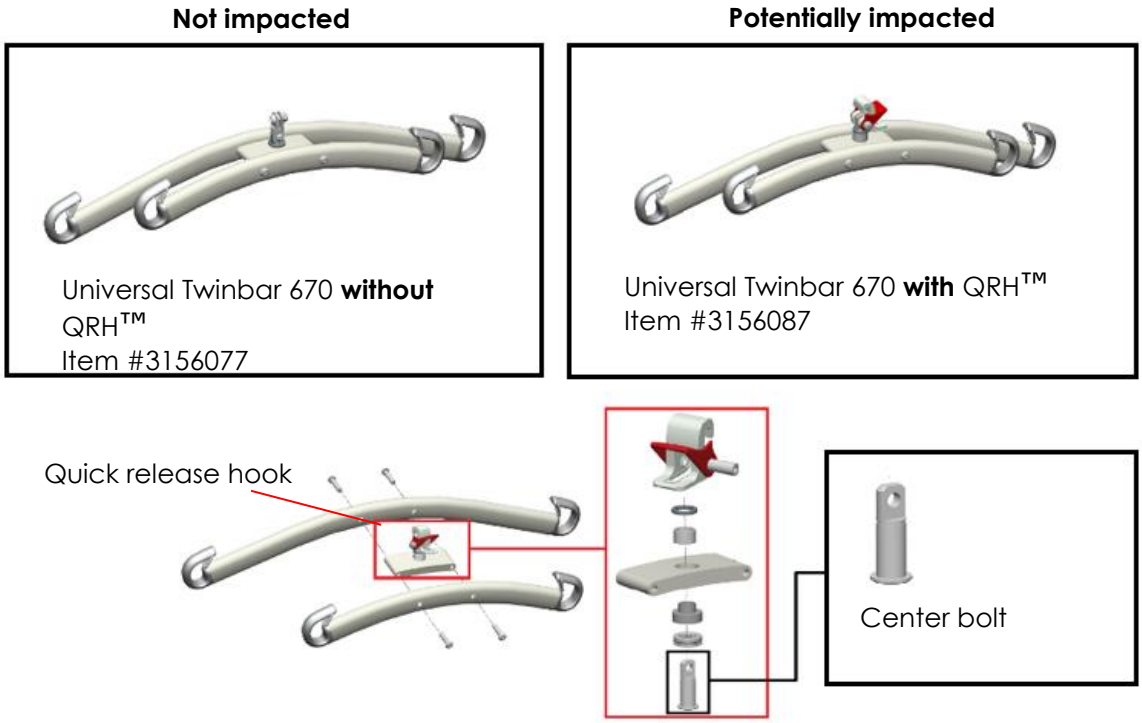


Background:
Hillrom received a report of a patient fall during the use of a Universal Twinbar 670 QRH™. The investigation determined the failure to be due to the inability of the quick release hook (QRH) to rotate freely due to contact between QRH and Twinbar (See figure 1 above). The center bolt prevented the Universal Twinbar 670 from swiveling when used in combination with Liko® Scale.

This was determined to be caused by a center bolt of incorrect length (too short) being installed as part of the manufacturing process.

See figure 2 below

Figure 2



Potential Risk:
Use of the Twinbar with the short center bolt in combination with the Liko® Scale (see figure 1 above), can result in the inability of free rotation in the Twinbar, which can potentially cause breakage between the Twinbar and the scale. This can potentially result in a patient fall.
Use of the Twinbar, independent of the scale, does not pose any risk.
Hillrom has received no reports of patient injury to date.

Actions to be taken by Customer:
Please identify if you have the potentially impacted product, as detailed on page 1, in your facility and return the response form below within two weeks. Manufacturing date can be found on the label of the Twinbar.

Upon receipt of the response form, Hillrom will contact you to arrange to inspect your Twinbar. Should the short bolts be present, your Twinbar will be corrected per intended specification.

Do not use your Universal Twinbar 670 with QRH™ together with a Liko® Scale until an inspection has been completed.

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 hillromLUL007OUS@sedgwick.com within two weeks. Hillrom will provide replacements for distributors to facilitate exchange among end users.

Action to be taken by Hillrom:

Hillrom will arrange to inspect the potentially affected units. If short bolts are identified, your Twinbar will be corrected per intended specification.

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 811530	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	UKCustomerCare@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

The undersign confirms that this notice has been communicated with the appropriate Regulatory Agency.

Sincerely

[redacted]

Response Form / Receipt

Subject: Short center bolt on Universal Twinbar 670 QRH
(FA 2021-12-005-LUL-007)

It is important that you return this form/receipt 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 two weeks.
Upon receipt of this Response Form, Hillrom will arrange to inspect the potentially affected units.
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:
We have reviewed and understand the attached Field Safety Notice. ☐ Yes ☐ No

Results from the inspection of our product inventory show we have:
☐ We do not have any potentially affected products.
☐ We have potentially affected products. Quantity _____

Distributors only:
☐ We have distributed the product further and notified our consumers of the attached Field Safety Notice per the instructions noted above.

☐ We will support our end users in inspecting, and correcting, where any non-conforming short bolts installed

☐ We require replacements for _____ devices (provide quantity needed)

Response form shall be returned to hillromLUL007OUS@Sedgwick.com within two weeks.