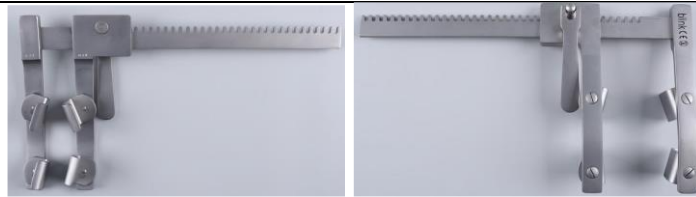


## Medical Devices Safety Notice

The National Health Regulatory Authority would like to alert all governmental and private healthcare facilities, local agents and distributors that the below medical device:

Device Details	
Device Name	Emergency Chest Re-opening Pack
Device Model	97113986-01
Batch No.	21410377
Manufacturer	Mölnlycke Health Care AB
Country of Origin	CZ
Reference	<a href="https://apps.tga.gov.au/Prod/sara/arn-detail.aspx?k=RC-2022-RN-00723-1">https://apps.tga.gov.au/Prod/sara/arn-detail.aspx?k=RC-2022-RN-00723-1</a>
Device picture	
Reason of Recall	NHRA initiates this FSN due to malfunction of Sternal retractor devices rendering the retractor unable to fulfil its intended purpose. There is a potential increased risk that the performance of the mechanical opening/closing of the retractor could malfunction with the mechanism becoming stuck/jammed and rendering the retractor unable to fulfil its intended purpose. This may result in a delay in patient treatment.
Action should be taken	Please stop using the above mentioned medical device and contact the authorized representative <b>YMH</b> at <a href="mailto:me.regulatory@ymh.com.bh">me.regulatory@ymh.com.bh</a> to take the necessary action for recall.

Your cooperation is highly appreciated in improving health services in the Kingdom of Bahrain.

For more information please contact [Medical\\_Devices@nhra.bh](mailto:Medical_Devices@nhra.bh)

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Recall 2022 0022