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	**The LimiTorr Volume Limiting CSF Drainage System and the MoniTorr ICP External CSF Drainage and Monitoring System**	
Device Model	**Catalogue No**	**Description**
	10-100 CSF Drainage System w/Patient Line One Way Valve	10-100 CSF Drainage System w/Patient Line One Way Valve
	10-102 CSF Drainage System w/Patient Line One Way Valve w	10-102 CSF Drainage System w/Patient Line One Way Valve w
	10-1010 CSF Drainage System used with Pole Mount System	10-1010 CSF Drainage System used with Pole Mount System
	10-140 CSF Drainage System w/Vinyl Measuring Strip	10-140 CSF Drainage System w/Vinyl Measuring Strip
	10-150 CSF Drainage System Simple Bag and Line	10-150 CSF Drainage System Simple Bag and Line
	10-150 CSF Drainage System w/o Manifold Stopcock	10-150 CSF Drainage System w/o Manifold Stopcock
	INS-1100 CSF Drainage System used with Pole Mount System	INS-1100 CSF Drainage System used with Pole Mount System

For more information please contact Medical_Devices@nhra.bh

	INS-9020 LIMITORR VOLUME LIMITING EVD 20 ML	INS-9020 LIMITORR VOLUME LIMITING EVD 20 ML
	INS- 9020SP1 LIMITORR VOLUME EVD 20ML	INS- 9020SP1 LIMITORR VOLUME EVD 20ML
	INS- 9020SP1 LIMITORR VOLUME LIMITING EVD 30 ML	INS- 9020SP1 LIMITORR VOLUME LIMITING EVD 30 ML
	INS- 9030SP1 LIMITORR VOLUME LIMITING EVD 30 ML	INS- 9030SP1 LIMITORR VOLUME LIMITING EVD 30 ML
	SP0017 Special EVD 10-110 w/o Y Site Latex Free Sites	SP0017 Special EVD 10-110 w/o Y Site Latex Free Sites
	SP0042 Special EVD 10-100 w/o Y Site	SP0042 Special EVD 10-100 w/o Y Site
	SP0090 Special EVD 10-110 w/o Y Site	SP0090 Special EVD 10-110 w/o Y Site
	SP0164 Special EVD 10-140 w/Y Site & Stopcock Reverse	SP0164 Special EVD 10-140 w/Y Site & Stopcock Reverse
	10-100 CSF Drainage System w/Patient Line One Way Valve	10-100 CSF Drainage System w/Patient Line One Way Valve
Manufacturer	**Integra LifeSciences**	
Country of Origin	**USA**	
Reference	https://www.fda.gov/medical-devices/medical-device-recalls/Integra-lifesciences-recalls-limitorr-volume-limiting-csf-drainage-system-and-monitorr-icp-external	
Reason of Recall	NHRA initiated this safety notice due to possible breakage of the LimiTorr Transducer and MoniTorr Panel Mount Stopcock. This breakage occurs when there is over-bending of the stopcock most often related to the use of LimiTorr or MoniTorr in combination with a Fluid Filled Transducer.	

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	The device failure could result in infection (meningitis or ventriculitis), fever, headache, over drainage leading to subdural hematoma, over-drainage leading to the shifting of brain tissue (herniation), backflow of air leading to a condition in which air or gas is trapped within the intracranial cavity (pneumocephalus), or death.
Action required	It is strictly prohibited to import, distribute and use the affected devices mentioned above and in case of having one of the affected models, please Stop using it and contact the manufacturer at custsvcnj@integralife.com to take the necessary action.

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