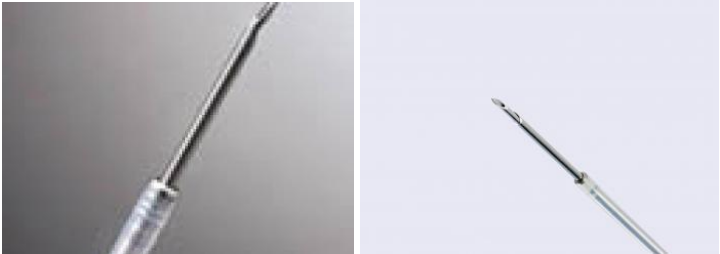


Medical Devices Safety Notice

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	Olympus TBNA Needle
Device Model	N2369930 / N188093
Lot No.	04K / 05K / 98K
Manufacturer	Olympus
Country of Origin	Japan
Reference	http://www.salute.gov.it/imgs/C_17_AvvisiSicurezza_9913_azione_itemAzione0_files_itemFiles0_fileAzione.pdf
Device picture	
Reason of Recall	NHRA initiates this FSN due to an anomaly in the packaging process of the devices and associated Lot Numbers listed above, it is possible that the sterility of these products is compromised due to a defective seal, which may allow a breach of the package's sterile barrier. This breach may be difficult to detect with the naked eye. The manufacturing dates for all of these devices were on or before 15 November, 2020
Action should be taken	Please stop using the defected medical device and contact the authorized representative Gulf Pharmacy at regulatoty@gctbh.com to take the necessary action for recall.

For more information please contact Medical_Devices@nhra.bh

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

For more information please contact Medical_Devices@nhra.bh

Recall 2021 0008