

## 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	22F Economy Anesthetic Face Masks	
Lot No.	Medical Device	Lot No.
	22F Size 3 Small Adult Economy Anesthetic Face Masks	381968, 381979, 382683, 383078, 383689,390392
	22F Elbow and Heat and Moisture Exchange Filter (HMEF) Size 3 Sma	31950385, 31955171, 31956664
	22F Size 4 Medium Adult Economy Anesthetic Face Masks	381956, 381969, 381980, 382687, 382690, 385070, 386256, 386267, 386280, 390393, 390398
	22F Elbow and Filter Size 4 Large Adult Economy Anesthetic Face Masks	1184725, 1184814, 1190009, 1190211,1190503, 1190808, 1191104, 1191610,1192668, 1191313, 1191856, 1192145,1192655, 1192668, 1192731
	22F Elbow and Filter Size 4 Medium Adult Economy Anesthetic Face Masks	31861245, 31951260, 31952066, 31952913, 31953188, 31953302, 31955172, 31956356,31956665, 31956954
	22F Size 5 Large Adult Economy Anesthetic Face Masks	382686, 382688, 383074, 383075, 383076,383077, 390394
	22F Elbow and Filter Size 5 Large Adult Economy Anesthetic Face Masks	1190502, 1191110, 1191314, 1191857,1192146, 1192732 ,31951987,

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

		31952496,31955174, 31956667
	22F Size 6 Extra Large Adult Economy Anesthetic Face Masks	381957, 382684, 385036, 385056, 385071
<b>Manufacturer</b>	Intersurgical Limited	
<b>Country of Origin</b>	UK	
<b>Reference</b>	<a href="https://www.gov.uk/drug-device-alerts/anaesthetic-face-masks-specific-intersurgical-economy-22f-taper-connection-may-be-oversized-and-leak-or-disconnect-from-the-breathing-circuit-mda-2019-033#technical-aspects">https://www.gov.uk/drug-device-alerts/anaesthetic-face-masks-specific-intersurgical-economy-22f-taper-connection-may-be-oversized-and-leak-or-disconnect-from-the-breathing-circuit-mda-2019-033#technical-aspects</a>	
<b>Reason of Recall</b>	NHRA initiates this FSN due to some masks may be larger than standard limits. This may create a loose or insecure connection with the mating device, which will result in possible disconnection from the mask taper.	
<b>Action should be taken</b>	<ol style="list-style-type: none"> <li>1. Before use, check the connection between the 22F Mask taper and mating device is secure using a push and twist action.</li> <li>2. If any problems are identified with any of these masks, please contact the local agent to arrange the return and replacement of the affected masks.</li> </ol>	

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

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