

# Hospital Authority dovetails to Field Safety Corrective Action notice of insufflation device

The following is issued on behalf of the Hospital Authority:

The spokesman for the Hospital Authority (HA) made the following announcement today (November 5) regarding the service arrangement of some elective surgeries due to the Field Safety Corrective Action notice against an insufflator device issued by the supplier:

The HA received notification from the Department of Health (DH) that the Field Safety Corrective Action notice was issued by the supplier against an insufflation device (Olympus High Flow Insufflation Unit, Model UHI-4), which is mainly used for laparoscopic or endoscopic surgeries, due to its risk of causing patients' arrhythmias and cardiac arrest during operations. After the assessment, as a precautionary measure, the HA decided to suspend the use of 142 insufflation devices of the model concerned immediately in public hospitals to dovetail with the concerned notice.

The HA is very concerned about the incident and, upon receiving notification from the DH, immediately worked with different hospital operation theatres to assess the situation. The HA has implemented a series of contingency measures, including using alternative devices of other brands or models, and deploying alternative devices among hospitals to maintain emergency surgeries. In addition, the HA has requested other suppliers to support the services by providing alternative devices in stock urgently. It is expected that the first batch of alternative devices will be distributed to public hospitals within the coming week.

In order to mobilise resources to maintain emergency surgeries, it is estimated that around 30 elective surgeries, mainly laparoscopic minimally invasive surgeries, scheduled at Tuen Mun Hospital, Pok Oi Hospital and Caritas Medical Centre are required to reschedule in the coming week. Healthcare staff are notifying patients affected and will reschedule their operations as soon as possible. Emergency surgeries in public hospitals are not affected.

The HA has contacted the supplier to express concerns regarding the safety corrective action of the devices and requested it to resolve the problems, together with taking remedial measures to minimise the impact on patient services as soon as practicable.

The HA will continue to closely liaise with the DH and the supplier to follow up on the incident.