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# Urgent Field Safety Notice

**Device:** 22mm Flextube Transport Breathing Systems with non-rebreathing valve

**REF numbers:** 2070000, 2070001, 2073000, 2074000, 2075000, 5020002

**LOT numbers:** from 31258704 to 31755743

**Manufacturer:** Intersurgical Ltd.

**FSCA-identifier**: 175137 **Date:** 16th August 2017

**Attention**: Chief Executive, Governance Lead, All clinical staff, managers and users of the above products, including Theatres, ICU/ITU, Accident & Emergency, and Purchasing/Procurement.

**Type of action:** Quarantine and destroy the above products and lot numbers.

**Description of the problem:** Intersurgical has voluntarily initiated a global recall of specific product codes and associated Lots above of the 22mm Flextube Transport Breathing Systems with non-rebreathing valve.

A fault has been identified in a non-rebreathing valve component in the above products, and could result in an occlusion due to the valve sticking. If a ventilator with no self test facility is being used the fault may not be identified. The outcome for the patient will depend on a number of variables, including the degree of occlusion and how quickly the source of the problem is identified allowing remedial action to be taken.

An internal assessment of product performance has confirmed that these devices can potentially raise serious risk to the patient. For this reason and to address any potential risk of harm, the affected products should not be used and should be destroyed.

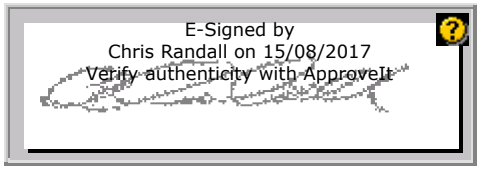
**Transmission of this Field Safety Notice:** This notice should be transmitted to all those who need to be aware within your organisation, or to any organisation where these potentially affected devices have been transferred.

Intersurgical apologises for any inconvenience this may cause. We are working to resolve this situation as quickly as possible, in the meantime we do have an alternative replacement for the systems that do not have an adjustable PEEP valve or monitoring line (alternative Product code 2080004). If you have any questions or would like the alternative product, please contact your distributor or local Intersurgical representative.

The relevant National Authorities have been advised of this Field Safety Corrective Action (FSCA). Please maintain awareness of this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

**Action to be taken by the user:** Stop the use of all affected devices immediately and ensure they are quarantined. Complete the section below with full details of lot numbers and quantities for each lot and return it to the contact above. Please complete and return the form even if you have none of the affected products in your stock. All affected products must be destroyed, and a credit will be arranged. Please continue to report any adverse events involving this product to Intersurgical.

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency.




Chris Randall, Wokingham Site Quality Manager, Intersurgical

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# Urgent Field Safety Notice
# Response Form

**Device:** 22mm Flextube Transport Breathing Systems with non-rebreathing valve
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**FSCA-identifier**: 175137 **Date:** 16th August 2017

**Hospital/Customer Name:** _____

**Hospital/Customer Address:** _____

**Please complete the section below, and send it back to the Intersurgical contact above even if no affected products remain in stock, so that we can reconcile the affected products supplied to customers.**

**I confirm that I have quarantined and destroyed the following products and lot numbers.**

| REF No. | LOT | Quantity | REF. No | LOT | Quantity |
|---|---|---|---|---|---|
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| | | | | | |

**Name:**
**Position:**
**Phone:**
**E-mail:**
**Date:**