

**Relevant Country Contact Name****Tel.:** Relevant country telephone**Fax:** Relevant country fax**Email:** Relevant country email

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## Field Safety Notice

**Device:**

REF	DESCRIPTION
7152012	BVM RESUSCITATOR ADULT 1.5L BAG SIZE 3 & 5 MASK

**LOT numbers:**

7152012	31859958, 31954342, 31950173, 31955117
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**Manufacturer:** Intersurgical Ltd**FSCA-identifier:** 238796**Date:** 19/08/2019**Attention:** Medical Device Safety Officers (MDSO)**Distribution:** All Emergency staff, managers and users of the above products**Type of action:** The removal of all lot numbers listed above to prevent their possible use.

**Description of the problem:** As a result of reports from the market we have identified a possible variation in the size of the 22F mask taper of Economy, Anaesthetic Face Masks, where some masks may be larger than standard limits. This may create a loose or insecure connection with the mating device, and in some circumstances this could result in possible disconnection from the mask taper.

The resuscitator catalogue number 7152012 includes Economy, Anaesthetic Face Mask, size 4. In an emergency situation when using resuscitator there may be no possibility to have a spare mask and this could result in inability to perform cardio pulmonary resuscitation effectively.

**Action to be taken by the user:**

Immediately quarantine all affected lot numbers listed above and do not use these devices. Please contact Intersurgical using the Response Form to confirm these have been disposed off locally or arrange collection of the devices and credit. If you have no affected devices in stock, please confirm this using the Response Form.

**Corrective Action being taken by manufacturer Intersurgical:**

Corrective actions to prevent reoccurrence are already implemented.

**Transmission of this Recall Notice:**

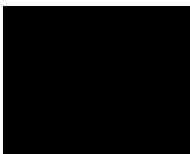
This notice should be transmitted to all those who need to be aware within your organisation, or to any organisation where these potentially affected devices have been transferred.

Intersurgical apologises for any inconvenience this may cause. If you have any questions, please contact your distributor or local Intersurgical representative.

The relevant National Authority has been advised about this Field Safety Corrective Action.

Please maintain awareness of this Recall Notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

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

**Intersurgical**

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## **Field Safety Notice Response Form**

**Device:**

REF	DESCRIPTION
7152012	BVM RESUSCITATOR ADULT 1.5L BAG SIZE 3 & 5 MASK

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**Manufacturer:** Intersurgical Ltd**FSCA-identifier:** 238796**Date:** 19/08/2019**Hospital Name:** \_\_\_\_\_**Hospital Address:** \_\_\_\_\_

Please tick one of the following options:

- ☐ We do not have any remaining stock of the affected products.
- ☐ We have quarantined our remaining stock of the following affected products and have disposed of these locally or wish to return them. Please arrange credit.

(Please complete the section below, and send it back to the contact above).

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

REF	LOT	Quantity of products per LOT number
[add more rows as required]		

**Form Completed and Returned by:****Name:** .....**Phone No:** .....**Position:** .....**E-mail:** .....**Date:** .....