INTERSURGICAL
COMPLETE RESPIRATORY SYSTEMS
Quality, innovation and choice

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Urgent Field Safety Notice

Devices: BVM (Bag-Valve-Mask) Manual Resuscitation Systems

REF numbers:
7150000, 7151000, 7152000, 7152005, 7152006, 7152007, 7152012, 7153000, 7153008, 7154000

LOT numbers:
7150000 – 363791, 370252, 370751, 371638, 372887, 372894, 375508
7151000 – 364909, 370253, 371091, 371639, 372886, 372890, 375711
7152000 – 363792, 364270, 364923, 365216, 370266, 370752, 371640, 371656, 372888, 372889, 372893, 373638, 373639, 375411
7152005 – 31753284, 31756956, 31757575
7152006 – 31660106, 31753127, 31756716, 31757576, 31758289
7152007 – 371092
7152012 – 31753733, 31756957
7153000 – 363793, 370738, 371907, 372892, 375509
7153008 – 31753734
7154000 – 370753, 372367

Manufacturer: Intersurgical Ltd

FSCA-identifier: 187200 **Date:** 22 December 2017

Attention: Medical Device Safety Officers (MDSO)

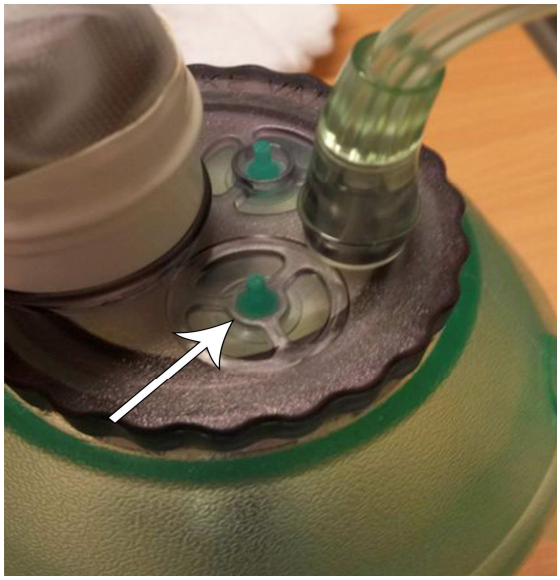
Distribution: All clinical staff, managers and users of the above products

Type of action: Users of the products and lot numbers listed above must quarantine all existing stock and then follow the instructions below. **Please note this does not supersede any previous FSNs regarding these products.**

Description of the problem:
A manufacturing fault has been identified with the Intersurgical BVM Manual Resuscitation System, which could result in the directional valves positioned on the ‘back plate’ of the self-inflating bag being orientated incorrectly. The images show the incorrect and correct orientation of the directional valves.

The incorrect orientation of the directional valves could result in the BVM Manual System becoming over pressurised, which could result in patient Barotrauma.

Incorrect orientation of directional valve



Correct orientation of directional valves

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.

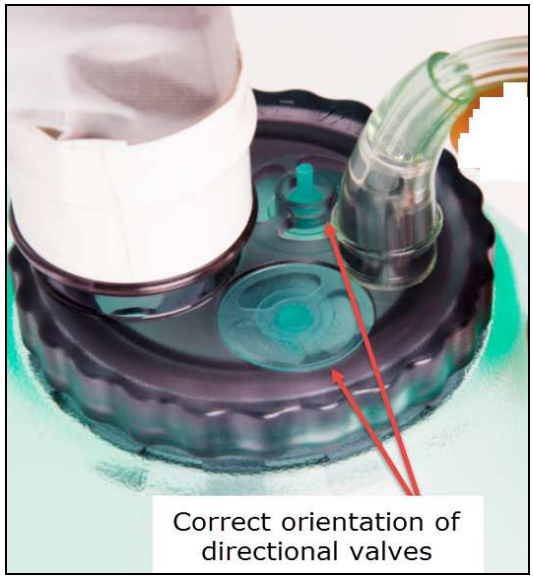
Intersurgical apologises for any inconvenience this may cause. If you have any questions, please contact your distributor or local Intersurgical representative.

The relevant National Authorities have been advised about this Field Safety Corrective Action.

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

Action to be taken by the user:
Quarantine all products identified in this document; stop the use of all affected devices, complete the enclosed Response Form and return it to the contact at the top of the Response Form to make necessary arrangements for credit, and return the products.

If no suitable replacement is available, users should check the orientation of the valves on the back plate of the self-inflating bag and ensure they are orientated correctly as shown in the photograph below. Continue to report any adverse events involving these products to Intersurgical at the contact in the header.



BVM Manual Resuscitation Systems with alternative directional valves configuration positioned on the 'back plate' are not affected by this FSN and are safe to use. This valves design is shown in the photograph below.

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

E-Signed by Ivan Seniut
VERIFY authenticity with ApproveIt

Ivan Seniut, Regulatory Affairs Director, Intersurgical

Contact details: *[letterhead with regional contacts header]*

Urgent Field Safety Notice
Response Form

Devices: BVM (Bag-Valve-Mask) Manual Resuscitation Systems

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Hospital Name: _____

Hospital Address: _____

Please complete the section below, and send it back to the contact above even if no affected products remain in stock, so that we can reconcile affected products supplied to our customers. If you have purchased from a distributor please also contact them in order to arrange any credit.

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

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

Form Completed and Returned From:

Name: **Position:**

Phone No / e-mail: **Date (yyyy-mm-dd):**