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Urgent Field Safety Notice

Device:

BVM (Bag-Valve-Mask) Manual Resuscitation Systems

REF numbers:

1. 7150000, 7151000, 7151001, 7152000, 7152007, 7152060, 7153000, 7154000, 7155000, 7156000
2. 7152003
3. 7150006, 7151006, 7152004, 7152005, 7152006, 7152009, 7152012, 7152014, 7152061, 7153006, 7153008
4. 7150170, 7151170, 7152170, 7152172, 7153170

LOT numbers:

1. All lot numbers up to and including lot 370253
2. All lot numbers up to and including lot 1170673
3. All lot numbers up to and including lot 31753734
4. All lot numbers up to and including lot 170504

Manufacturer: Intersurgical Ltd

FSCA-identifier: 170124

Date: 05 June 2017

Attention: Chief Executive, Governance Lead

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

Type of action: Users of the products and lot numbers listed above must check the function of the product before use.

Description of the problem: There is a possibility the valve of the BVM Manual Resuscitation System may become stuck during storage. This could result in the intended tidal volume not being delivered through the valve, which may cause a delay in treatment.

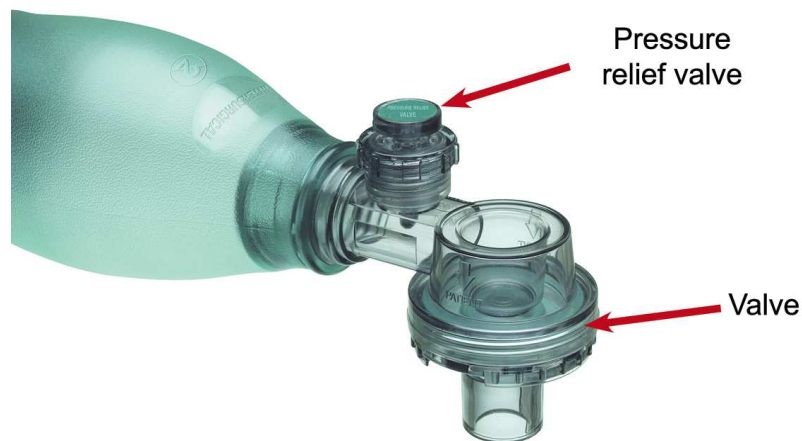
The instructions for use provided with these products include the requirement to ensure the bag, valve and oxygen delivery is functioning correctly prior to use. This Field Safety Notice gives additional information relating to this specific problem and the additional actions required.

Action to be taken:

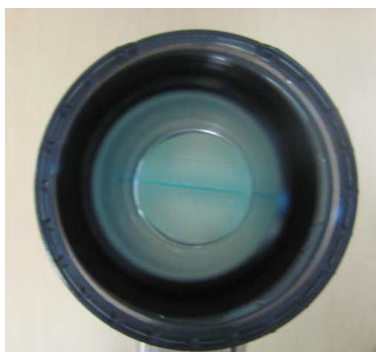
Inform all users of the above listed BVM Manual Resuscitation Systems in your hospital of the actions required and complete and return the attached response form as soon as possible:

Two configurations of these systems are available; one without a pressure relief valve and one with.

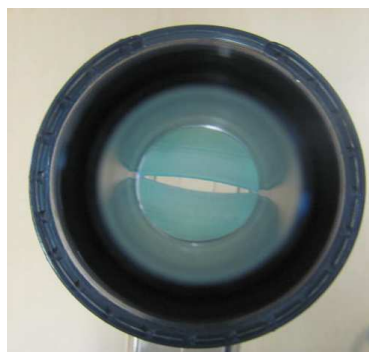
1. Ensure the valve opens prior to use when squeezing the resuscitation bag (Picture 1).
2. If the valve is stuck (Picture 2), squeeze the bag fast and firmly to open the valve (Picture 3).
3. If the BVM Manual Resuscitation System contains a pressure relief valve (Picture 1) manually hold this closed to prevent it from opening when squeezing the bag. Repeat action 2 whilst the pressure relief valve function is overridden.
4. Make sure the valve is now open and fully functional prior to use.



Picture 1: Position of valve and pressure relief valve if included in the system



Picture 2: Stuck valve

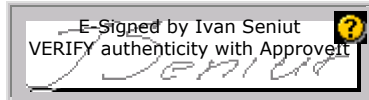


Picture 3: Open valve

Transmission of this Field Safety Notice: This notice must 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 of this Field Safety Corrective Action. Please maintain awareness of this notice and the required actions for the lifetime of the listed products and lot numbers to ensure the effectiveness of the corrective action.

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



E-Signed by Ivan Seniut
VERIFY authenticity with ApproveIt

The image shows a rectangular box containing an e-signature. The signature is written in cursive and appears to read 'Ivan Seniut'. Above the signature, the text 'E-Signed by Ivan Seniut' is displayed. Below the signature, the text 'VERIFY authenticity with ApproveIt' is visible. A small yellow question mark icon is located in the top right corner of the box.

Ivan Seniut
Group Quality and Regulatory Affairs Director

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Urgent Field Safety Notice Response Form

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FSCA-identifier: 170124

Date: 05 June 2017

Hospital Name:

Hospital Address:

Please confirm this Urgent Field Safety Notice has been received and distributed within your organisation by completing the section below and returning to the contact above.

I confirm that the relevant staff in the hospital have been informed of this FSN and the need to check the valve in the BVM Manual Resuscitation Systems using the technique described to ensure they are open prior to use.

Form Completed and Returned From:

Name:

Position:

Phone No / e-mail:

Date: