**FSCA Ref: 484380-A**

**FSCA Date: 11/06/2026**

# Urgent Field Safety Notice

## VARIOUS BVM RESUSCITATORS

**PLEASE NOTE: THIS URGENT FIELD SAFETY NOTICE SUPERCEDES THE PREVIOUS FIELD SAFETY NOTICE 484380 ISSUED ON 06/06/2025**

For Attention of*: MDSO's, All clinical staff, Managers and users of the above products

| Contact details of local representative (name, e-mail, telephone, address etc.)* |
|---|
| **Chris Randall**<br>**Wokingham Site Quality Manager**<br>**Intersurgical Ltd.**<br>**Crane house**<br>**Molly Millars Lane**<br>**Wokingham**<br>**Berkshire**<br>**RG41 2RZ**<br><br>**Email: priority@intersurgical.co.uk**<br>**Tel. No: 0118 9656 300** |

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## Urgent Field Safety Notice (FSN)

## VARIOUS BVM RESUSCITATORS

## Risk addressed by FSN

| | |
|---|---|
| | **1. Information on Affected Devices*** |
| 1. | 1. Device Type(s)* |
| | **Various BVM Resuscitators** |
| 1. | 2. Commercial name(s) |
| | • 7150000 - BVM RESUS INFANT 280ML BAG, PRV 40cmH20, SIZE 1 MASK<br>• 7151000 - RESUSCITATOR PAED 550ML BAG PRV 40cm H20, SIZE 3 MASK<br>• 7151001 - BVM RESUSCITATOR PAED 550ML BAG PRV 40CM H2O SIZE 3 MASK<br>• 7152000 - BVM RESUSCITATOR, ADULT, 1.5LTR BAG, SIZE 5 MASK<br>• 7152003 - BVM MAN RESUS B/SYS SM ADULT/PAED 1L BAG SIZE 3 & 5 MASK<br>• 7152060 - BVM RESUSCITATOR ADULT 1.5L BAG PRV 60cmH2O SIZE 5 MASK<br>• 7153000 - BVM RESUS SMALL ADULT/PAED 1LTR BAG PRV 40cmH20 SIZE 4 MASK<br>• 7154000 – BVM RESUSCITATOR, PAEDIATRIC, 550ML BAG PRV 40cmH20 SZ 1 MSK<br>• 7155000 - BVM RESUSCITATOR INFANT 280ML BAG PRV 40CM H20 SIZE 1 MASK<br>• 7156000 - BVM RESUSCITATOR PAED 550ML BAG PRV 40cm H20 SIZE 1 MASK |
| 1. | 3. Unique Device Identifier(s) (UDI-DI) |
| | • 7150000 - 5030267073238<br>• 7151000 – 5030267073245<br>• 7151001 – 5030267111657<br>• 7152000 – 5030267073252<br>• 7152003 – 5030267080915<br>• 7152060 – 5030267110322<br>• 7153000 – 5030267073276<br>• 7154000 – 5030267073283<br>• 7155000 - 5030267073290<br>• 7156000 – 5030267073306 |
| | 4. Primary clinical purpose of device(s)* |
| | The manual resuscitation breathing system is intended for manual ventilatory support and pulmonary resuscitation. |
| 1. | 5. Device Model/Catalogue/part number(s)* |
| | • 7150000<br>• 7151000<br>• 7151001<br>• 7152000<br>• 7152003<br>• 7152060<br>• 7153000 |

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| | • 7154000<br>• 7155000<br>• 7156000 |
| 1. | 6. Software version |
| | N/A |
| 1. | 7. Affected lot number range<br><br>All lot numbers with an expiry date in the range **2026-06 to 2030-02**, as indicated on the product label as shown as an example in the photo below.<br><br> |
| 1. | 8. Associated devices |
| | N/A. |

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| | **2. Reason for Field Safety Corrective Action (FSCA)*** |
| 2. | 1. Description of the product problem* |

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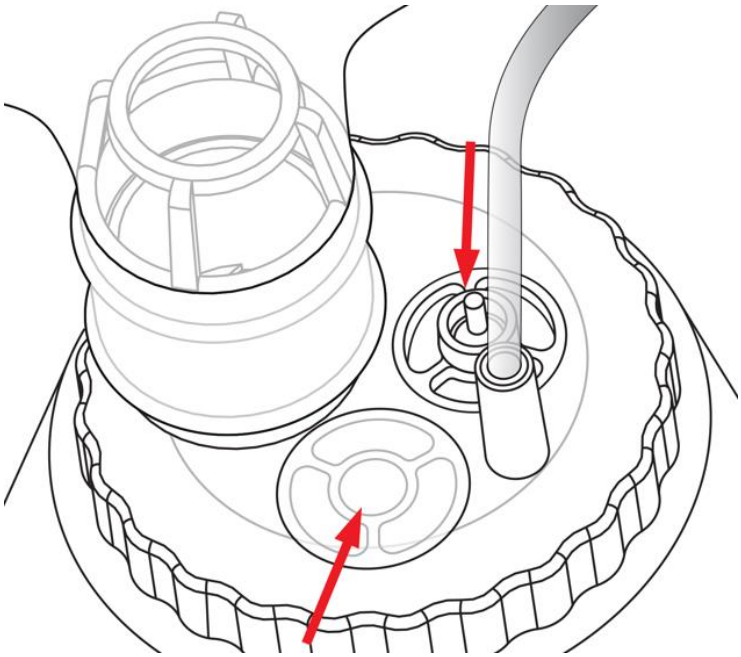
| | Some devices have been identified during pre-use checks as missing one of the valves at the rear of the BVM Resuscitator, position as shown below.<br>  <br>Since issuing the original FSN 484380 in June 2025, we have received further reports of the problem in later lot numbers. We are therefore re-distributing the FSN to include a wider range of potentially affected products. |
| 2. | 2. Hazard giving rise to the FSCA* |
| | If the BVM has been supplied without the one valve that controls entrainment of atmospheric air, which would result in dilution of Oxygen concentration and reduction of delivered FiO2.<br>This does not have an impact upon the ability to provide adequate ventilation but does have an impact upon the ability to deliver the higher Oxygen concentrations as detailed in the product instructions for use. This may result in negative impact upon clinical outcome during CPR. |
| 2. | 3. Probability of problem arising |
| | Whilst there is a possibility of 100% of the devices listed in the FSN to be affected, our investigation and evaluation of all available information has estimated the probability of failure rate to be 0.01% to 0.01% to 0.001% (1 in 10,000 to 1 in 100,000 products). |
| 2. | 4. Predicted risk to patient/users |
| | The risks associated with the identified fault have been reviewed, and whilst the probability of occurrence is low, we believe it is essential to address the issue promptly to further reduce the risk of any potential patient harm. |
| 2. | 5. Further information to help characterise the problem |
| | N/A |
| 2. | 6. Background on Issue |

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| | Following customer reports from the market and subsequent thorough inspection and analysis of internal stock, we have identified that some products have been manufactured without one of the valves at the rear of the BVM Resuscitator. | |
| 2. | 7. Other information relevant to FSCA<br><br>N/A | |
| | **3. Type of Action to mitigate the risk*** | |
| **3.** | **1. Action To Be Taken by the User***<br><br>☒ Identify Device ☒ Quarantine Device ☐ Return Device ☐ Destroy Device<br><br>☐ On-site device modification/inspection<br><br>☐ Follow patient management recommendations<br><br>☒ Take note of amendment/reinforcement of Instructions For Use (IFU)<br><br>☒ Other ☐ None<br><br>Please distribute this Field Safety Notice to all potential users of the BVM Resuscitators listed above, within your facility. This is for their awareness of the potential problem and to carry out the following actions.<br><br>To ensure the safety of patients we recommend the following actions.<br><br>1. Identify any potentially affected products from the affected codes and lot numbers listed above.<br>2. All users must perform a thorough visual inspection before use of the products and lot numbers listed above, to confirm both one-way valves are present.<br>3. Retain any affected sample(s) identified, and please report to us immediately.<br><br>**Please note**: This is not a product removal.<br><br>Please complete and return the Reply Form provided to priority@intersurgical.co.uk, to confirm receipt of this notice and that the necessary actions are being taken.<br><br>Please continue to report to Intersurgical any adverse events involving this product. | |
| 3. | 2. By when should the action be completed? | Immediately on receipt of this FSN, and awareness of this FSN should be ongoing until all potentially affected stock listed in this FSN has been used up. |
| 3. | 3. Particular considerations for: N/A<br><br>Is follow-up of patients or review of patients' previous results recommended?<br><br>Not applicable. | |
| 3. | 4. Is customer Reply Required? *<br>(If yes, form attached specifying deadline for return) | Yes |

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| **3.** | **5. Action Being Taken by the Manufacturer**<br><br>☐ Product Removal ☐ On-site device modification/inspection<br>☐ Software upgrade ☐ IFU or labelling change<br>☒ Other ☐ None<br><br>Corrective actions have been implemented in the manufacturing process to eliminate this problem for ongoing supply. | |
| 3 | 6. By when should the action be completed? | One month from receipt of the FSN |
| 3. | 7. Is the FSN required to be communicated to the patient /lay user? | No |
| 3 | 8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet? | |
| | N/A | |

| | | |
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| | **4. General Information*** | |
| 4. | 1. FSN Type* | New – Advisory Notice |
| 4. | 2. For updated FSN, reference number and date of previous FSN | N/A |
| 4. | 3. For Updated FSN, key new information as follows: | |
| | N/A | |
| 4. | 4. Further advice or information already expected in follow-up FSN? * | No |
| 4 | 5. If follow-up FSN expected, what is the further advice expected to relate to: | |
| | N/A | |
| 4 | 6. Anticipated timescale for follow-up FSN | N/A |
| 4. | 7. Manufacturer information<br>(For contact details of local representative refer to page 1 of this FSN) | |
| | a. Company Name | **Intersurgical Ltd.** |
| | b. Address | **Crane House, Molly Millars Lane, Wokingham, Berkshire, RG41 2RZ** |
| | c. Website address | **https://www.intersurgical.com/** |
| 4. | 8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * | |
| 4. | 9. List of attachments/appendices: | **Customer Reply Form** |
| 4. | 10. Name/Signature | **Ivan Seniut, Group Quality and Regulatory Affairs Director, Intersurgical** |

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| | | E-Signed by Ivan Seniut<br>VERIFY authenticity with ApproveIt |

| | Transmission of this Field Safety Notice |
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| | This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate)<br><br>Please transfer this notice to other organisations on which this action has an impact. (As appropriate)<br><br>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.<br><br>Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback. |

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.

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# Field Safety Notice Customer Reply Form

| **1. Field Safety Notice (FSN) information** | |
|---|---|
| FSN Reference number* | 484380-A |
| FSN Date* | 11/06/2026 |
| Product/ Device name* | • 7150000 - BVM RESUS INFANT 280ML BAG, PRV 40cmH20, SIZE 1 MASK<br>• 7151000 - RESUSCITATOR PAED 550ML BAG PRV 40cm H20, SIZE 3 MASK<br>• 7151001 - BVM RESUSCITATOR PAED 550ML BAG PRV 40CM H2O SIZE 3 MASK<br>• 7152000 - BVM RESUSCITATOR, ADULT, 1.5LTR BAG, SIZE 5 MASK<br>• 7152003 - BVM MAN RESUS B/SYS SM ADULT/PAED 1L BAG SIZE 3 & 5 MASK<br>• 7152060 - BVM RESUSCITATOR ADULT 1.5L BAG PRV 60cmH2O SIZE 5 MASK<br>• 7153000 - BVM RESUS SMALL ADULT/PAED 1LTR BAG PRV 40cmH20 SIZE 4 MASK<br>• 7154000 – BVM RESUSCITATOR, PAEDIATRIC, 550ML BAG PRV 40cmH20 SZ 1 MSK<br>• 7155000 - BVM RESUSCITATOR INFANT 280ML BAG PRV 40CM H20 SIZE 1 MASK<br>• 7156000 - BVM RESUSCITATOR PAED 550ML BAG PRV 40cm H20 SIZE 1 MASK |
| Product Code(s) | • 7150000<br>• 7151000<br>• 7151001<br>• 7152000<br>• 7152003<br>• 7152060<br>• 7153000<br>• 7154000<br>• 7155000<br>• 7156000 |
| Batch/Serial Number (s) | All lot numbers with an expiry date in the range **2026-06 to 2030-02**, as indicated on the product label as shown as an example in the photo in Sec. 1.7. above. |

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| 2. Customer Details | |
|---|---|
| Account Number | |
| Healthcare Organisation Name* | |
| Organisation Address* | |
| Department/Unit | |
| Contact Name* | |
| Title or Function | |
| Telephone number* | |
| Email* | |

| 3. Customer action undertaken on behalf of Healthcare Organisation | | | | | |
|---|---|---|---|---|---|
| ☐ | I confirm receipt of the Field Safety Notice and that I read and understood its content. | Customer to complete or enter N/A | | | |
| ☐ | The information and required actions have been brought to the attention of all relevant users and executed. | Customer to complete or enter N/A | | | |
| ☐ | I do not have any affected devices. | Customer to complete or enter N/A | | | |
| ☐ | We have the following potentially affected stock we wish to return for credit/replacement. (Please enter the quantity for each Code and Lot number). | **Code:** | **Lot:** | **Qty:** | |
| | | **Code:** | **Lot:** | **Qty:** | |
| | | **Code:** | **Lot:** | **Qty:** | |
| | | **Code:** | **Lot:** | **Qty:** | |
| | | **Code:** | **Lot:** | **Qty:** | |
| ☐ | Any Other comments: | | | | |
| Print Name* | | Customer print name here | | | |
| Signature* | | Customer sign here | | | |
| Date* | | | | | |

| 4. Return acknowledgement to sender | |
|---|---|
| Email | priority@intersurgical.co.uk |
| Customer Helpline | N/A |
| Postal Address | Intersurgical Ltd., Crane House, Molly Millars Lane, Wokingham, Berkshire, RG41 2RZ |
| Web Portal | N/A |
| Deadline for returning the customer reply form* | 10/07/2026 |

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Mandatory fields are marked with *

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.
Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.