Rev 1: September 2018
FSN Ref: 484380 - A FSCA Ref: 484380 - A

Date: 04/03/2026

Urgent Field Safety Notice

VARIOUS BVM RESUSCITATORS

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.)*
or **This could be a distributor or local branch of the manufacturer. To be added at the appropriate stage in the different local languages**

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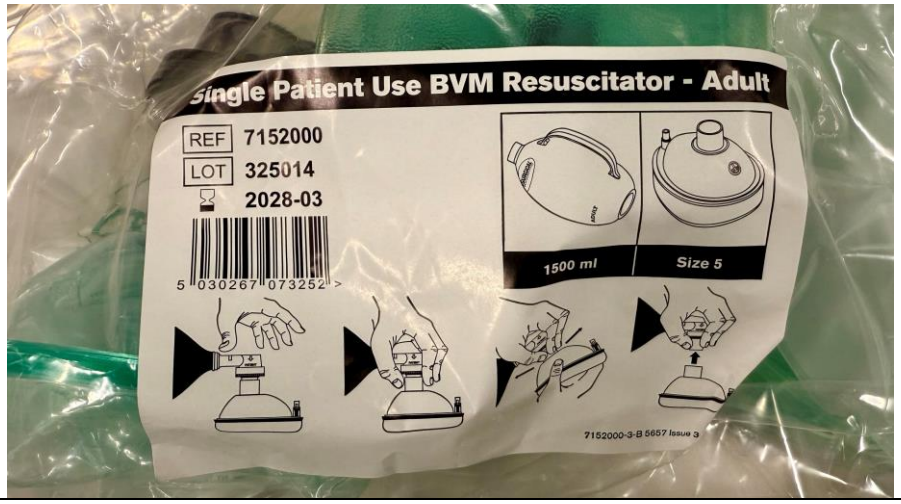
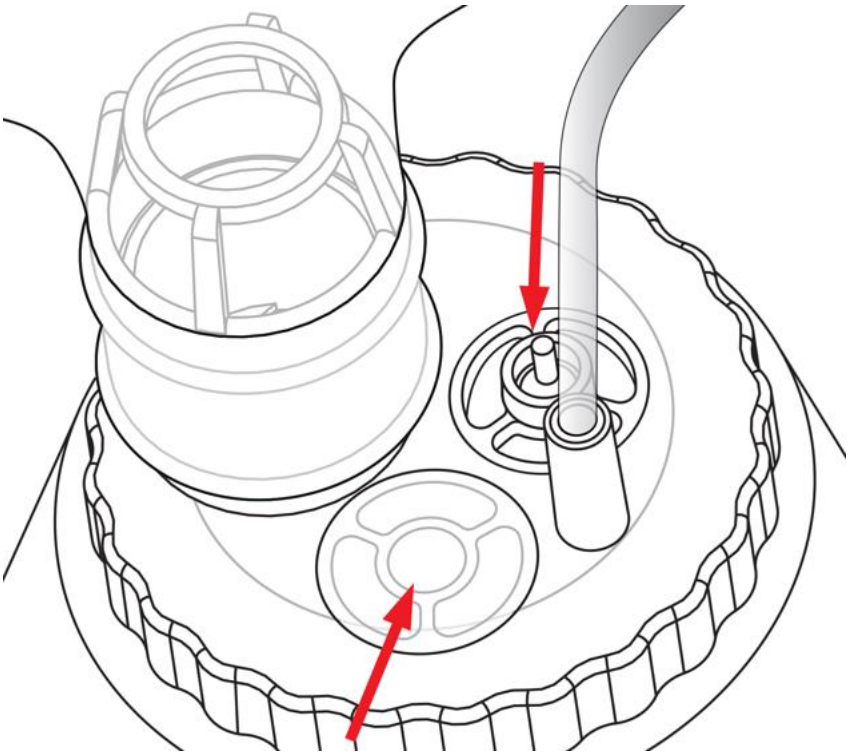
Risk addressed by FSN

	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 • 7151000 - RESUSCITATOR PAED 550ML BAG PRV 40cm H20, SIZE 3 MASK • 7151001 - BVM RESUSCITATOR PAED 550ML BAG PRV 40CM H2O SIZE 3 MASK • 7151006 - BVM RESUSCITATOR PAED 550ML PRV 40CM H20 ADJ PEEP SIZE 3 MSK • 7152000 - BVM RESUSCITATOR, ADULT, 1.5LTR BAG, SIZE 5 MASK • 7152003 - BVM MAN RESUS B/SYS SM ADULT/PAED 1L BAG SIZE 3 & 5 MASK • 7152005 - BVM RESUSCITATOR ADULT 1.5L BAG ADJ. PEEP VALVE SIZE 5 MASK • 7152060 - BVM RESUSCITATOR ADULT 1.5L BAG PRV 60cmH2O SIZE 5 MASK • 7152507 - MANUAL RESUS SYSTEM ADULT (1.5L BAG) WITH DETACHABLE BAG • 7153000 - BVM RESUS SMALL ADULT/PAED 1LTR BAG PRV 40cmH20 SIZE 4 MASK • 7153006 - BVM RESUSCITATOR SM ADULT/PAED 1L BAG PRV 40CM H20 ADJ PEEP • 7153502 - 2BVM RESUSCITATOR SM ADULT/PAED 1L BAG PRV 40cm (used in 7152003) • 7153506 - MANUAL RESUS SYS SMALL ADULT(1L BAG) WITH DETACHABLE O2 BAG • 7154000 – BVM RESUSCITATOR, PAEDIATRIC, 550ML BAG PRV 40cmH20 SZ 1 MSK • 7155000 - BVM RESUSCITATOR INFANT 280ML BAG PRV 40CM H20 SIZE 1 MASK • 7156000 - BVM RESUSCITATOR PAED 550ML BAG PRV 40cm H20 SIZE 1 MASK
1.	3. Unique Device Identifier(s) (UDI-DI)
	• 7150000 - 5030267073238 • 7151000 – 5030267073245 • 7151001 – 5030267111657 • 7151006 (used component ref 7156500) - 5030267104468 • 7152000 – 5030267073252 • 7152003 (used component ref 7153502) – 5030267080915 • 7152005 (used component ref 7152504) - 5030267102259 • 7152060 – 5030267110322 • 7152507 - 5030267153329 • 7153000 – 5030267073276 • 7153006 – 5030267104482 • 7153506 – 5030267153343 • 7154000 – 5030267073283 • 7155000 - 5030267073290 • 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 7151000 7151001 7151006 7152000 7152003 7152005 7152060 7152507 7153000 7153006 7153502 7153506 7154000 7155000 7156000
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range: All lot numbers with an expiry date in the range 2026-02 to 2030-02, as indicated on the product label as shown in the photo below. 
1.	8. Associated devices
	N/A.

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

	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.  Since issuing the original FSN 484380 in April 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. 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 0.001% (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

	Following a customer report 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 N/A
	3. Type of Action to mitigate the risk*
3.	**1. Action To Be Taken by the User*** ☒ Identify Device ☒ Quarantine Device ☐ Return Device ☐ Destroy Device ☐ On-site device modification/inspection ☐ Follow patient management recommendations ☒ Take note of amendment/reinforcement of Instructions For Use (IFU) ☒ Other ☐ None 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. To ensure the safety of patients we recommend the following actions. 1. Identify any potentially affected products from the affected codes and lot numbers listed above. 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. 3. Retain and destroy or return any affected sample(s) identified, to the distributor immediately. **Please note**: This is not a product removal. Please complete and return the Reply Form provided to giedriusb@intersurgical.lt or local contact e-mail address, to confirm receipt of this notice and that the necessary actions are being taken. 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. Considerations for: N/A Is follow-up of patients or review of patients' previous results recommended? Not applicable.	

3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes
3.	**5. Action Being Taken by the Manufacturer** ☐ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☒ Other ☐ None Corrective actions have been implemented in the manufacturing process to eliminate this problem for future supply.	
3	6. By when should the action be completed?	As soon as possible 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	

	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 (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	
	b. Address	
	c. Website address	
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	

	Transmission of this Field Safety Notice
	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) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. 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.