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

Date: 17/04/2025

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.)*
Giedrius Budrys **Customer Resolution and Relationship Manager** **Intersurgical UAB** **Arnioniu str 60, LT-18170 Pabrade Lithuania** **Email: giedriusb@intersurgical.lt** **Tel. +370 387 66611** **Fax: +370 387 66622** **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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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)
	• BVM resuscitator, paediatric 550ml bag with pressure relief valve (40cm H_20), size 3 mask • BVM resuscitator, adult, 1.5L bag, size 5 mask • BVM resuscitator, small adult/paediatric, 1L bag with pressure relief valve (40cm H20), size 4 mask • BVM resuscitator, paediatric 550ml bag detachable O_2 reservoir bag with pressure relief valve (40cm H_20), size 1 mask • BVM resuscitator, adult, 1.5L bag, with pressure relief valve (60cm H_20), size 5 mask • BVM resuscitator, small adult/paediatric, 1L bag, with pressure relief valve (40cm H20) size 3 & 5 • BVM resuscitator, small adult/paediatric, 1L bag, detachable O2 reservoir bag with pressure relief valve (40cm H20) size 4 mask
1.	3. Unique Device Identifier(s) (UDI-DI)
	• 7151000 - 5030267073245 • 7152000 – 5030267073252 • 7152003 - 5030267080915 • 7152060 - 5030267110322 • 7153000 – 5030267073276 • 7153006 - 5030267104482 • 7153502 – • 7153506 - • 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)* • 7151000 • 7152000 • 7152003 • 7152060 • 7153000 • 7153006 • 7153502 • 7153506 • 7156000
	6. Software version

1.	N/A
1.	7. Affected serial or lot number range:

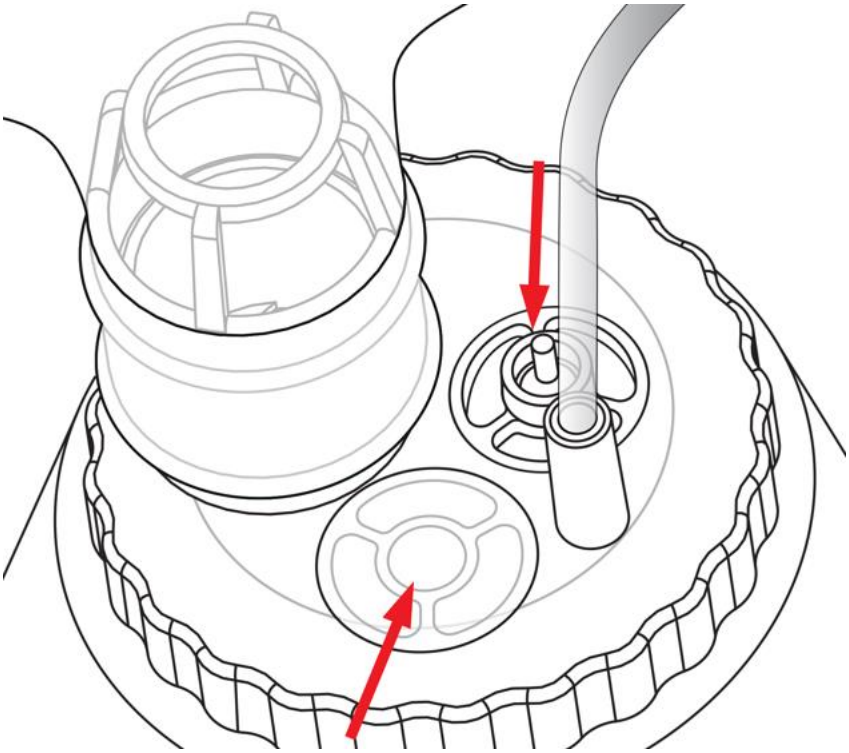
7151000	334337
7152000	333717
7152003	1250514
7152060	333720
7153000	333718; 334338; 334375
7153006	32413929
7153502	340232
7153506	340231; 340361
7156000	334340

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.



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	**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**
		

	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.

Field Safety Notice Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	484380
FSN Date*	17/04/2025
Product/ Device name*	• BVM resuscitator, paediatric 550ml bag with pressure relief valve (40cm H_20), size 3 mask • BVM resuscitator, adult, 1.5L bag, size 5 mask • BVM resuscitator, small adult/paediatric, 1L bag with pressure relief valve (40cm H20), size 4 mask • BVM resuscitator, paediatric 550ml bag detachable O_2 reservoir bag with pressure relief valve (40cm H_20), size 1 mask • BVM resuscitator, adult, 1.5L bag, with pressure relief valve (60cm H_20), size 5 mask • BVM resuscitator, small adult/paediatric, 1L bag, with pressure relief valve (40cm H20) size 3 & 5 • BVM resuscitator, small adult/paediatric, 1L bag, detachable O2 reservoir bag with pressure relief valve (40cm H20) size 4 mask
Product Code(s)	• 7151000 • 7152000 • 7153000 • 7156000 • 7152060 • 7152003 • 7153006
Batch/Serial Number (s)	• 7151000 – Lot 334337 • 7152000 – Lot 333717 • 7153000 – Lot 333718; 334338; 334375 • 7156000 – Lot 334340 • 7152060 – Lot 333720 • 7152003 – Lot 1250514 • 7153006 – Lot 32413929

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	Subs/Distributors contact details
Customer Helpline	N/A
Postal Address	Subs/Distributors contact details
Web Portal	N/A
Deadline for returning the customer reply form*	17/05/2025

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.