



THREE LIONS LIMITED

No. 21 Qunyi Private Zone, Hengshan Road, Kunshan, Jiangsu P.R. China, 215300

Tel: +86 512 5700 0981 Fax: +86 512 5700 8935 E-mail: three_lions@163.com

Field Safety Notice

Field Safety Notice No: 20210112

Document Date: January 29, 2021

URGENT MEDICAL DEVICE FIELD SAFETY NOTICE

Dear Customer,

The purpose of this Field Safety Notice (FSN) is to advise you that Three Lions Limited has initiated a voluntary Field Safety Corrective Action (FSCA) for due to the warping of the Flapper Valve on 7 specific Lots of 7 models of the Timesco Single Use Resuscitator (PVC) as listed below.

Affected Devices: Manual Resuscitator

Commercial name(s) Timesco Single Use Resuscitator (PVC)

Type of Action: Identify Devices, Quarantine Devices, Replace Devices

Date: January 27, 2021

Attention: Clinical medical staff, ambulance staff, and distributors who use Timesco Single Use Resuscitator (PVC).

Affected Devices: The following Model Number and Lot Number are potentially affected by this issue:

Product Code	Product Name	Lot No.
TDM-BVM-1600	Timesco Single Use Resuscitator (PVC) - Adult 1600ml with No.5 Mask	2007013
TDM-BVM-1600W	Timesco Single Use Resuscitator (PVC) - Adult 1600ml with No.5 Mask with 60 cm H2O Pressure Relief Valve	2007014
TDM-BVM-1400	Timesco Single Use Resuscitator (PVC) - Adult 1400ml with No.5 Mask	2007012
TDM-BVM-1000	Timesco Single Use Resuscitator (PVC) - Adult 1000ml with No.5 Mask	2007011
TDM-BVM-0550	Timesco Single Use Resuscitator (PVC) - Child 550ml with No.1 & 2 Mask	2007009
TDM-BVM-0551	Timesco Single Use Resuscitator (PVC) - Child 550ml with No. 0 & 1 & 2 Detached Mask	2007010
TDM-BVM-0300	Timesco Single Use Resuscitator (PVC) - Infant 350ml with No. 0 PVC Mask	2007008

REASON FOR Field Safety Corrective Action (FSCA) :

Faulty Air-Inlet one-way valve. Warping of the Flapper Valve.

RISK TO HEALTH:

The Flapper Valve is severely warped. This may reduce the volumetric flow of air from the bag into the patient during use. To date, Three Lions Limited has received 1 report of injuries related to this issue.



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Action Required:

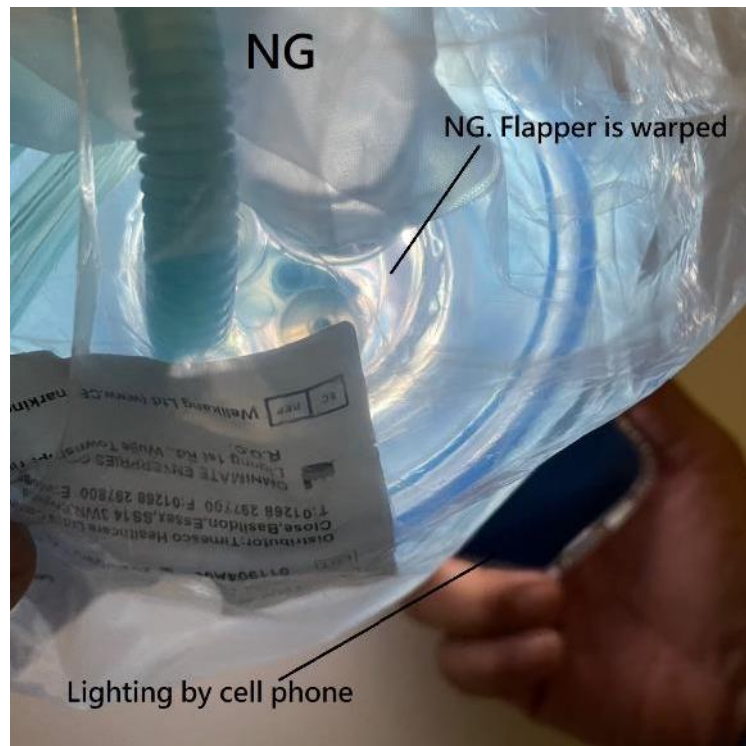
1. If you use / store / hold the Timesco Single Use Resuscitator (PVC), please check whether the model and Lot number indicated on the label are within the scope of affected devices listed above. If it is not within the scope of the affected devices, please continue to use it.

2. We remind you that you must check the devices you have in accordance with the Pre-Use Checks as outlined in the Instructions For Use.

3. If the device you hold is in the affected product range, please inspect the device in accordance to with the following instructions:

-) The inspection can be carried out without removing the device from the plastic bag.
-) Using a light, illuminate the bag from patient valve and visually inspect the flapper valve.

NG Items- To be Quarantined



If you find that the light shines through the air vent holes and the product appears to have a warped Flapper Valve as in the NG images above, please isolate it immediately and do not use it. Please contact us for return and exchange. If you have any doubts about identification, please quarantine the device and contact us for confirmation.



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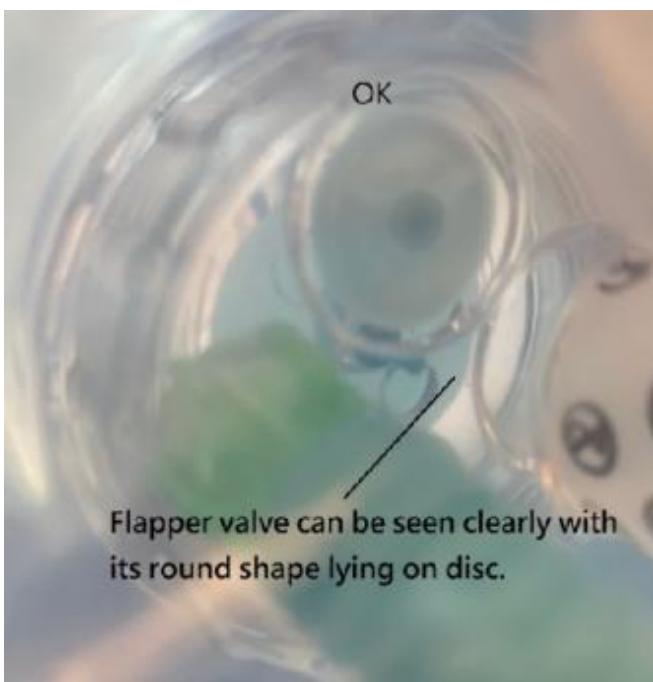
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OK Items- Continue to use

If you find that the light does not shine through the air vent holes and the Flapper Valve covers the air vent holes, please continue to use the device. Again, we remind you that you must check the devices you have in accordance with the Pre-Use Checks as outlined in the Instructions For Use. If you have any doubts about identification, please quarantine the device and contact us for confirmation.





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4. Complete the attached Urgent Field Safety Notice Response Form within 7 days of receipt, returning it via email to service_3l@163.com. The form must be returned even if you do not have any affected product in your possession. Product credit will be processed once the Urgent Field Safety Notice Response Form is received.

5. If you have distributed potentially affected devices to your customers, please immediately notify them of this Field Safety Notice along with the accompanying Response Form. For credit and replacement please contact our distributor, Timesco Healthcare Ltd via email at info@timesco.com.

Three Lions Ltd. is committed to providing quality products and service to its customers. We apologize for any inconvenience this situation may cause.

If you have any questions regarding this notification, please contact via email at service_3l@163.com.

Contact information:

Manufacturer contact:

Three Lions Ltd. via email at **service_3l@163.com**

Distributor contact:

Timesco Healthcare Ltd. via email at **info@timesco.com**

Sincerely,

Three Lions Ltd.

Management representative: Vincent Chou

Date: 2021.01.29

Please bring this notice to the attention of all personnel you deem need to be made aware of this safety issue. If you have forwarded the affected product(s) listed above, please provide a copy of this field safety notice to them.