

Customer Name

Address

URGENT FIELD SAFETY NOTICE

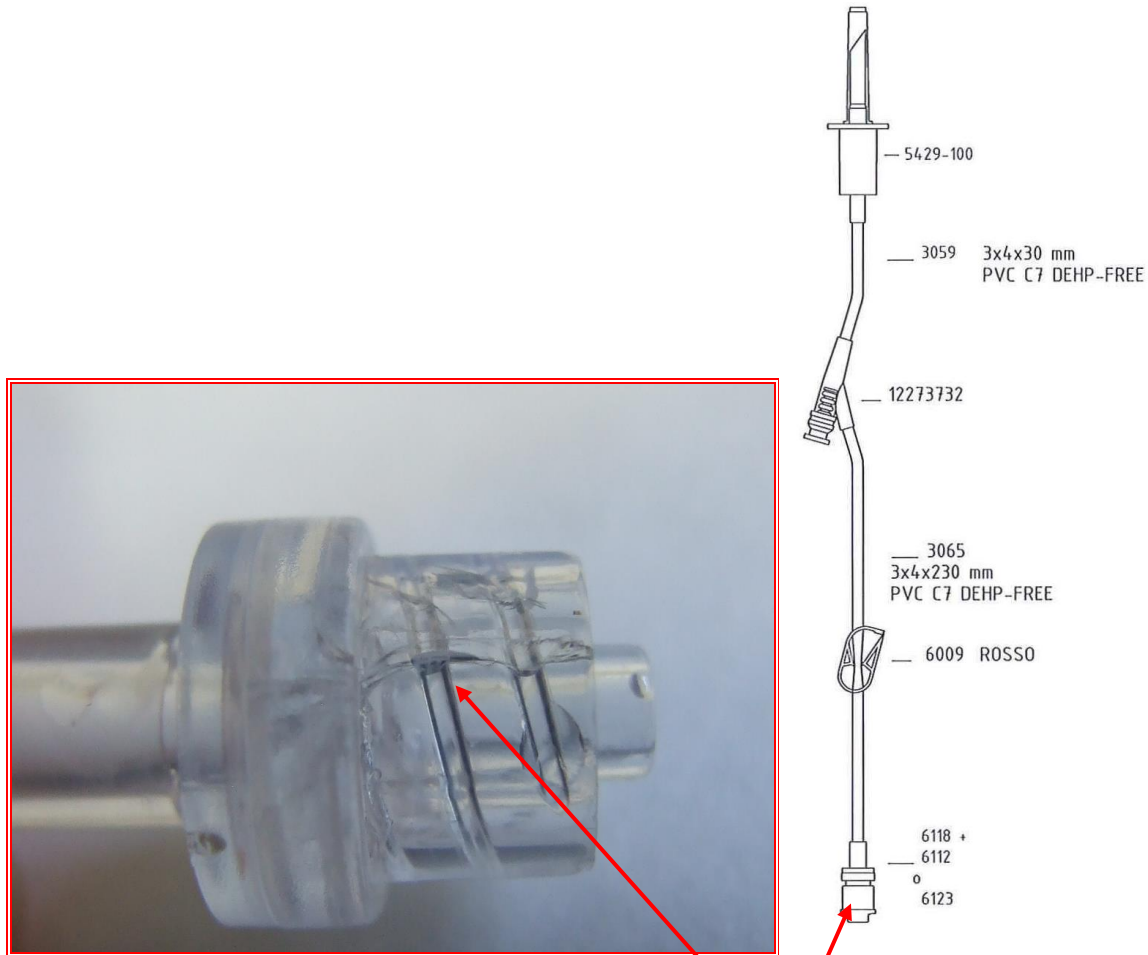
Product Name: **Secondary Sets containing Back Check Valve**
Product codes: **72951NE, 72947NE, 72948NE, 72949NE, 72987NE**
FSCA Identifier: **RA-2016-12-02**
Date: **February 2017**
Type of Action: **Removal & Destruction of Affected Products**

ATTENTION: Clinical Personnel, Risk Managers, Biomedical Personnel**Description of the Problem**

CareFusion has identified an issue with Back Check Valves Part Number 6122 & 6123 which are components in the following secondary sets:

72951NE - SECONDARY SET ONCOLOGY
72947NE - AMBER SECONDARY SET BCV
72948NE - Secondary set BCV, 0.2 micron filter
72949NE - SECONDARY SET WITH INTEGRATED SMART-SITE
72987NE - AMBER SECONDARY SET, VENTED, BCV

CareFusion has received reports of cracking of the secondary set back check valve male luer resulting in leakage of the infusion fluid. These secondary sets may be attached to a needle-free device that has been cleaned with a sanitising product containing IPA (Isopropyl Alcohol/PW 70%-30%) which appears to be contributing to the cracking of the plastic in this component.



Cracking at male luer lock

Potential Risk

Leakage at the back check valve connection could lead to the following effects:

- Unintentional Delays in start of infusion
- Exposure to chemicals
- Under infusion, without an alarm
- Infusion interruption.

Root Cause

Test performed on Part Number 6123 back check valves (6122 back check valves have the same core component as the 6123, but different caps) demonstrated that the IPA 70% can affect the Back Check Valve integrity which can lead to cracking resulting in leakage.

Failure investigation was completed and during the investigation, it was possible to reproduce the failure within the first 5-10 seconds of reaction time, the investigation concluded that the material of the BCV 6123 (& 6122) component has low resistance to the IPA 70%, this finding was also confirmed by the supplier who also indicated that the material has limited alcohol resistance.

Products Potentially Affected

CareFusion has identified an issue with Back Check Valves Part Number 6122 & 6123 which are components in the following secondary sets:

72951NE - SECONDARY SET ONCOLOGY

Affected LOT numbers: 1000089, 1000129, 1000208, 1000468, 1000469, 1000687 & 1000713.

72947NE - AMBER SECONDARY SET BCV

Affected LOT numbers: 1000056, 1000118, 1000161, 1000470, 1000471, 1000784 & 1000858.

72948NE - Secondary set BCV, 0.2 micron filter

Affected LOT numbers: 1000078.

72949NE - SECONDARY SET WITH INTEGRATED SMART-SITE

Affected LOT numbers: 516641 & 517036.

72987NE - AMBER SECONDARY SET, VENTED, BCV

Affected LOT numbers: 520847.

Recommended Action Required

In order that the potentially affected products are removed from use and destroyed please follow instructions below:

Step	Action				
1	Inspect inventory for product affected lot numbers of 72951NE - SECONDARY SET ONCOLOGY, 72947NE - AMBER SECONDARY SET BCV, 72948NE - Secondary set BCV, 0.2 micron filter, 72949NE - SECONDARY SET WITH INTEGRATED SMART-SITE, 72987NE - AMBER SECONDARY SET, VENTED, BCV (listed above)				
	<table border="1"> <thead> <tr> <th data-bbox="293 1753 708 1803">If...</th> <th data-bbox="708 1753 1481 1803">Then...</th> </tr> </thead> <tbody> <tr> <td data-bbox="293 1803 708 1890">No affected lot numbers are found</td> <td data-bbox="708 1803 1481 1890"> <ul style="list-style-type: none"> Complete sections A & B of Appendix 1 </td> </tr> </tbody> </table>	If...	Then...	No affected lot numbers are found	<ul style="list-style-type: none"> Complete sections A & B of Appendix 1
If...	Then...				
No affected lot numbers are found	<ul style="list-style-type: none"> Complete sections A & B of Appendix 1 				

	Affected lot numbers are found	<ul style="list-style-type: none">• Complete sections A & C of Appendix 1• Destroy affected product according to hospital protocol
2	Return completed verification form (Appendix 1) to your CareFusion representative no later than 22 June 2017	
3	Please contact your local CareFusion representative to order alternative products.	

On receipt of the completed verification form Appendix 1, CareFusion will credit you for any product destroyed.

We sincerely apologise for any inconvenience this action may have caused you or your staff.

Should you have any questions or require assistance relating to this Field Safety Corrective Action, please contact your Local CareFusion representative.

Transmission of this Field Safety Notice

Please distribute this notice to all those who need to be aware of this action within your organisation.

Sincerely,

CareFusion Representative



Appendix 1 – To be completed and returned by End User

URGENT FIELD SAFETY NOTICE – Acknowledgement Form

Product Name: **Secondary Sets containing Back Check Valve**
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Section A

Name of Hospital / Facility	
Hospital / Facility Address	
Telephone Number	
Name	
Signature	
Date	

Section B

I have read and understood the contents of this Field Action and confirm that our inventory has been checked and we have no inventory of the listed products.

Section C

I have read and understood the contents of this Field Action and confirm that our inventory has been checked and the following products have been destroyed:

Batch Number	Quantity Destroyed	Batch Number	Quantity Destroyed	Batch Number	Quantity Destroyed
1000056		1000208		1000713	
1000078		1000468		1000784	
1000089		1000469		1000858	
1000118		1000470		516641	
1000129		1000471		517036	
1000161		1000687		520847	

Please return no later than **22 June 2017** to:

Local CareFusion Representative

Address:

Via Fax:

Via Email: