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## FIELD SAFETY UPDATE

<b>Product Name:</b>	<b>Microbore Administration sets:</b> <b>AP403</b>	<b>AP424</b>
<b>Product Reference:</b>	<b>12003-000-0005</b>	<b>12003-000-0015</b>
<b>Batch Numbers:</b>	<ul style="list-style-type: none"><li>• 0112001614</li><li>• 0112001714</li><li>• 0112001814</li><li>• 0112001914</li><li>• 0112002014</li></ul>	<ul style="list-style-type: none"><li>• 0083000514</li><li>• 0167000814</li><li>• 0167001314</li><li>• 0167001414</li><li>• 0167001514</li><li>• 0167001914</li><li>• 0167002414</li><li>• 0167002514</li><li>• 0167002614</li><li>• 0167003314</li></ul>
<b>FSCA Identifier:</b>	<b>FSCA01-2014</b>	
<b>Date:</b>	<b>January, 2015</b>	
<b>Type of Action:</b>	<b>Removal &amp; Destruction of Remaining Affected Products</b>	

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### Dear Clinical Personnel, Risk Managers, Biomedical Personnel

Further to the Field Safety notification letter dated October 16<sup>th</sup> 2014 with regard to the potential for leakage in the above-specified batches of AP403 (12003-000-0005) and AP424 (12003-000-0015) Microbore Administration sets, Q Core would like to inform you that the problem has been resolved and new batches of these Administration Sets are now available from your local distributor.

### Action Required

So that any remaining potentially affected products are removed from use and destroyed please follow the instructions below:

Step	Action				
1	Inspect inventory for the following products: AP403 12003-000-0005 AP424 12003-000-0015				
	<table border="1"><thead><tr><th>If</th><th>Then</th></tr></thead><tbody><tr><td>Affected Batch Numbers are</td><td>• Destroy affected product according to hospital</td></tr></tbody></table>	If	Then	Affected Batch Numbers are	• Destroy affected product according to hospital
	If	Then			
Affected Batch Numbers are	• Destroy affected product according to hospital				



Step	Action	
	found	protocol • Complete sections A & C of Appendix 1
	No affected Batch Numbers are found	Complete sections A & B of Appendix 1
2	Return completed verification form (Appendix 1) to your [Hospira] representative no later than January 29 <sup>th</sup> , 2015	
3	Please contact your local [Hospira] representative to order alternative products.	

On receipt of the completed verification form Appendix 1, Q Core Medical Ltd, via its distributor [Hospira], will credit you for any product destroyed.

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

Should you have any further questions or require assistance, please contact Mr. Avi Hirshnzon, VP of Quality & Regulatory Tel. +972-73-2388825, e-mail: [Avi.Hirshnzon@qcore.com](mailto:Avi.Hirshnzon@qcore.com).

### **Transmission of this Field Safety Update Notice**

Please distribute this notice to all those who need to be aware of this update within your organization.

Please forward a copy of this information to all your third party customers and to their customers as well, where applicable.

The verification form Appendix 1 attached to this notice should be completed by all users of the products, including said third party customers, and sent back to the email or fax noted on the form.

Sincerely,

[Signature]

Tally Eitan  
President



## Appendix 1

### FIELD SAFETY UPDATE – Verification Form

<b>Product Name:</b>	<b>Microbore Administration sets:</b> <b>AP403</b>	<b>AP424</b>
<b>Product Reference:</b>	<b>12003-000-0005</b>	<b>12003-000-0015</b>
<b>Batch Numbers:</b>	<ul style="list-style-type: none"><li>• 0112001614</li><li>• 0112001714</li><li>• 0112001814</li><li>• 0112001914</li><li>• 0112002014</li></ul>	<ul style="list-style-type: none"><li>• 0083000514</li><li>• 0167000814</li><li>• 0167001314</li><li>• 0167001414</li><li>• 0167001514</li><li>• 0167001914</li><li>• 0167002414</li><li>• 0167002514</li><li>• 0167002614</li><li>• 0167003314</li></ul>
<b>FSCA Identifier:</b>	<b>FSCA01-2014</b>	
<b>Date:</b>	<b>January, 2015</b>	
<b>Type of Action:</b>	<b>Removal &amp; Destruction of Remaining Affected Products</b>	

IMPORTANT: Please complete this form and fax or email back to the following address by January 29<sup>th</sup>, 2015 to [Hospira email] or to fax [Hospira fax].

### Section A

<b>Customer name</b>	
<b>Company / Hospital</b>	
<b>Country</b>	
<b>Telephone Number</b>	
<b>Name</b>	
<b>Signature</b>	
<b>Date</b>	

This is to confirm that:

- The Urgent Field Safety Notice has been circulated among all relevant users in the organization and forwarded to any relevant third party users.



**Section B** (to be completed if affected Batch Numbers are not found)

This is to confirm that:

- I have read and understood the contents of this update and confirm that the listed products are not within our possession.

**Section C** (to be completed if affected Batch Numbers are found)

- I have read and understood the contents of this update and confirm that the following products have been destroyed:

Batch Number	Quantity Destroyed	Batch Number	Quantity Destroyed

Name: \_\_\_\_\_ Position: \_\_\_\_\_  
Signature: \_\_\_\_\_