

«Hospital_Name»

«Users_Name»- «Department»

«Customer_Address»

«Zip_Code» «City» -«Country_name»

Reference: 92115538-FA

16 June 2017

Field Safety Notice - Immediate Action Required Encore™ 26 Inflation Device Single Pack

Dear «Users_Name»,

Boston Scientific is implementing a field action on specific lots of Encore 26 Inflation Device **single packs**, which are listed in Attachment 1. The device trays from these lots have the potential to crack under certain handling conditions, such as impact during shipment. This issue has been attributed to a change in the material used in the packaging process. The complaints received for this issue have shown that this cracking, which is observed at a low rate (approximately 0.026%), only occurs on one section of the device tray, shown in images 1 and 2 below, potentially causing a sterile barrier breach.

This field action only affects the single pack Encore 26 Inflation Device. It does not affect Encore Advantage Kits, Encore five (5) packs or other kits containing the Encore device.

While the risk is remote, use of an Encore device with a cracked device tray during a procedure could result in patient infection if used within the sterile field. No reports of patient harm have been received from any associated complaints to date.

Images 1 & 2 – Location of observed cracking in analyzed complaint units



INSTRUCTIONS:

Please read carefully through the instructions included in this notification, and follow the product Directions for Use which states “Do not use if sterile barrier is damaged.”:

1- Immediately check your inventory and identify whether there are products with UPNs and lot numbers **listed in Attachment 1**.

2- Inspect the device tray in the area highlighted above. If you identify any units with a cracked tray in your supply, immediately discontinue use and segregate affected units in a secure location.

3- Arrange for the damaged units to be returned to Boston Scientific by completing the attached Verification Form.

4- **If no damage is identified, the device may be used as normal**

5- **Please complete the attached Verification Form even if you do not have any product to return. When completed, please return the Verification Form to your local Boston Scientific office** for the attention of Cas Sherrard - Fax: 01442 411816 - Email: UK-Quality@bsci.com; on or before **01 July 2017**.

6- Please pass this notice to any healthcare professional from your organization that needs to be aware and to any organization where the potentially affected devices have been transferred (If appropriate). Please provide Boston Scientific with details of any affected devices that have been transferred to other organizations (if appropriate).

Your Competent Authority is being notified of this Field Safety Notice.

We regret any inconvenience that this action may cause, and we appreciate your understanding as we act to ensure patient safety and customer satisfaction.

If you have any questions or would like assistance with this Field Safety Notice, please contact your local Sales Representative.

Yours sincerely,



Marie Pierre Barlanga
Quality Department
Boston Scientific International S.A.

Attachment: - Verification Form

Attachment 1 : Affected Product Listing

Encore™ 26 Inflation Device Single Pack

Our records indicate that your facility received some of the concerned product. The **table below provides a complete list of all affected products**, including Product Description, Material Number (UPN) and Lot numbers. Please note that **only the devices listed below are affected. No other Boston Scientific product is involved in this Field Safety Notice.**

Product Name	UPN	Lot Number			
Encore™ 26 Inflation Device Single Pack	H74904526011	19563006	20054530	20242335	20423645
		19587644	20077271	20285571	20456071
		19623142	20083051	20309573	20481170
		19650458	20127928	20309574	20534557
		19704550	20159518	20336380	
		19725489	20202728	20394218	
		19769215	20206930	20423644	

Product Name	UPN	Lot Number			
Encore™ 26 Inflation Device Single Pack	M001151050	19640750	20030825	20233700	20364929
		19667072	20060033	20256035	20364930
		19704551	20087896	20279769	20423650
		19755302	20117909	20303751	20472532
		19755307	20159601	20336385	20493563
		19785021	20171449	20336386	20507373
		19808183	20206929	20364928	20534581

Product Name	UPN	Lot Number			
Encore™ 26 Inflation Device Single Pack	M00566670	20157078	19755304	20146417	20456079
		19623019	20056496	20264032	

Product Name	UPN	Lot Number			
Encore™ 26 Inflation Device Single Pack	M0067101140	19594194	19808180	20223176	20394350
		19717352	20121252	20336387	20534582