Boston Scientific

Urgent Medical Device Information - Immediate Action Required

Encore™ 26 Inflation Device Single Pack

DATE

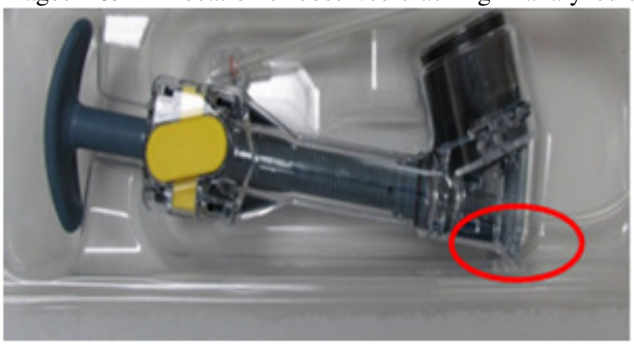
Dear Materials Manager / Field Action Contact:

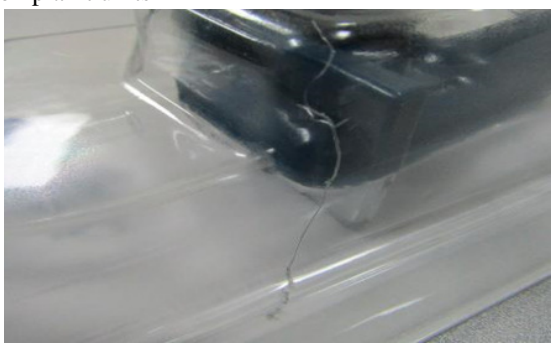
Boston Scientific is implementing a field action on specific lots of Encore 26 Inflation Device **single packs**, which are listed in Attachment 1. The device trays from these lots have the potential to crack under certain handling conditions, such as impact during shipment. This issue has been attributed 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 Reply Verification Tracking Form.

4. **If no damage is identified, the device may be used as normal.** Please complete and return the attached Reply Verification Tracking Form.

This action affects only damaged units from the UPNs and lots listed in Attachment 1. Customers will receive a credit for all affected product returned to Boston Scientific.

Your local Sales Representative can answer any questions that you may have.

If you are a distributor, please note that this removal is to the customer level. Please notify any customer who has received the product listed in Attachment 1.

Boston Scientific is notifying the appropriate worldwide regulatory authorities of this removal as required.

We regret any inconvenience that this action may cause, and we appreciate your understanding as we work to ensure patient safety and customer satisfaction. We are committed to continuing to offer products that meet the highest quality standards that you expect from Boston Scientific.

Sincerely,

Encl: Removal Instructions
Reply Verification Tracking Form

Urgent Medical Device Information - Instructions

The Reply Verification Tracking Form enclosed with this Notice must be completed and returned **even if you do not have any affected units**.

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.
3. If you identify any units with a cracked tray in your supply, immediately discontinue use and segregate affected units in a secure location.
4. Arrange for the damaged units to be returned to Boston Scientific by completing the included Reply Verification Tracking Form (see below).
5. If no damage is identified the device may be used as normal but you still need to complete and return the included Reply Verification Tracking Form.
6. If you are a distributor, please note that the removal depth is to the hospital level and the removal notification should be forwarded to your customers.

1. **Complete and return the Reply Verification Tracking Form.**
   - Complete the enclosed Reply Verification Tracking Form even if you do not have any product to return, following the directions on this page and on the Reply Form.
   - Indicate on your Reply Verification Tracking Form the quantity of units from each lot that you will be returning.
   - Return the Reply Verification Tracking Form as described below:

     Email:

     or

     Fax to:

   Please email or fax your Reply Verification Tracking Form(s) immediately. You will be contacted by Boston Scientific and provided a Returned Goods Authorization (RGA) Number after your RVTF is received. When returning the product, place the original form with returned products.

2. **Package/Ship the Removed Product.**
   - Package any product that is being returned in an appropriate shipping box.
   - Affix a shipping label to the outside of the shipping box.
   - Write the **RGA number** in large print on the outside of the box, either on or near the shipping label.
   - Seal the box, and return it to:

Attachment 1 – Affected Product Listing
Encore™ 26 Inflation Device Single Pack

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