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stryker
Medical

URGENT MEDICAL DEVICE RECALL

Re: Stryker and Gaymar Blood/Fluid Warmer Cassettes

Stryker Reference: RA 2014-081

August 13, 2014

Dear Customer

The purpose of this letter is to advise you that Stryker Medical is voluntarily recalling Stryker and Gaymar brand Blood/Fluid Warmer Cassettes.

Manufacturer Model Numbers	Product Description	Lot Numbers
D25310NL D25310CE D25315CE D25340CE	Blood/Fluid Warmer Cassettes	See Appendix

Product Description

The blood and fluid warmer sets are sterile, single use disposable devices designed to be used in conjunction with the blood and fluid warming device (FW300/FW400/FW600) to warm the patient transfused fluid. These products include latex-free cassettes that allow fluid to circulate through the cassette inside the warming device. There are several different cassette models available in a range of configurations with varying lengths of patient extensions, needle and needless injection ports, and manual bubble traps. (Only the D25310NL, the D25310CE, the D25315CE and the D25340CE are included in the scope of this notification.) The fluid warmer cassette is packed individually inside a chevron pouch, with ten (10) pouches placed in a box, and then five (5) boxes placed in the shipper box and submitted for Gamma sterilization. All D25000 Series Blood/Fluid Warming Sets have a three (3) year shelf life (i.e., expiration).

Product Issue

Stryker Medical has received customer complaints in regards to malformed threads on the female luer fitting of specific models of blood/fluid warmer cassettes. Our investigation has found that malformed threads are caused during the bonding operation between the luer fitting and the tubing. The bonding process involves expanding the end of the tubing in a spreader, dipping the luer fitting in a solvent (cyclohexanone), and then inserting the end of the fitting (with applied solvent) inside the flexible tubing to create a bond. There are several bonded joints on the assembly, but investigation has shown that the only joint capable of producing malformed threads on the adjacent fitting is at this female luer fitting on the inlet. Note that this issue is limited in scope to specific model numbers and product lots listed in this notice and does not impact all Stryker and Gaymar cassettes.

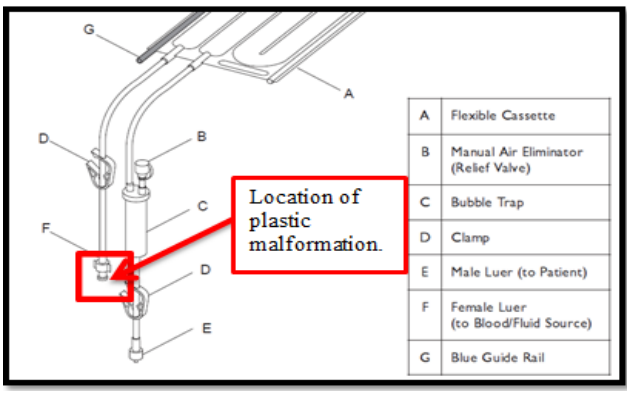

Figure 1 – Location of the plastic malformation

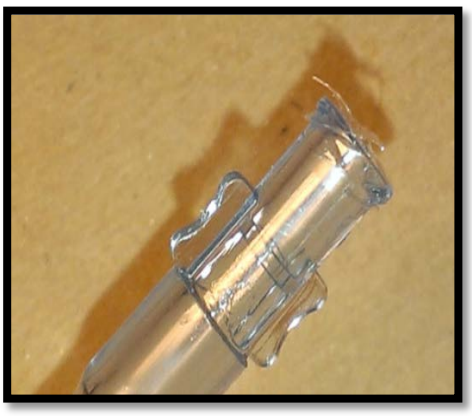

Figure 2 - Picture of reported issue

Potential Hazard

Stryker conducted a medical risk assessment to establish the probability and severity of any potential harm(s) related to the malformed threads on the luer fitting. This risk assessment determined that there is a remote probability of harm requiring medical intervention should any particle separate from the malformed thread. Testing concluded that it is highly unlikely for any malformed threads to break off the luer fitting. Additionally, Stryker has not received any reports of injury related to this discrepancy during the product's life.

Actions Needed

1. Immediately locate and quarantine subject devices.

2. Ensure that all users of the devices are informed of this action.

3. Circulate this Field Safety Notice internally to all interested / affected parties.

4. Maintain awareness of this notice internally until all required actions have been completed within your facility.

5. Complete and sign the enclosed Customer Response Form and return to xxx by fax (xxx) or by e-mail (xxx@stryker.com).
   - Please complete this form even if you no longer have any devices. This will allow us to update our records and negate the need to send any reminder notices.
   - Upon receipt of a completed customer response form, a Stryker representative will be in contact to arrange collection and replacement of any affected product.

6. Inform Stryker of any issues / adverse events concerning this action.
   - Please comply with any local laws or regulations concerning the notification of adverse events to your National Competent Authority.

7. If you have loaned or sold any of the devices listed in this letter please forward a copy of this notice to the new users and inform us of their location.

Stryker maintains its commitment to developing, manufacturing and marketing the highest quality products for surgeons and patients. We apologise for any inconvenience this Field Safety Corrective Action may create and appreciate your cooperation with our request.

If you have any further enquiries, please do not hesitate to contact the undersigned.

Yours sincerely

APPENDIX - AFFECTED LOT CODES

D25310CE			D25315CE	D25340CE	D25310NL
M0112	M1313	M2713	M0112	M0312	M0312
M0113	M1412	M2811	M0213	M1112	M0412
M0114	M1413	M2812	M0413	M1511	M0414
M0212	M1512	M2911	M0414	M1712	M0713
M0213	M1513	M2912	M0512	M1811	M0812
M0214	M1611	M2913	M0612	M2311	M0913
M0314	M1612	M3011	M0713	M2312	M1012
M0412	M1613	M3012	M1014	M2411	M1314
M0413	M1711	M3013	M1114	M2513	M1511
M0414	M1712	M3111	M1511	M2712	M1811
M0512	M1713	M3112	M1611	M3011	M1812
M0514	M1812	M3113	M1813	M3213	M2011
M0612	M1813	M3211	M1912	M3311	M2013
M0614	M1911	M3312	M1913	M3611	M2211
M0712	M1912	M3313	M2212	M3711	M2212
M0713	M2011	M3412	M2411		M2411
M0714	M2012	M3511	M2413		M2412
M0812	M2111	M3612	M2513		M2413
M0814	M2113	M3613	M2611		M2512
M0914	M2211	M3712	M2613		M2513
M1012	M2213	M3713	M2913		M2711
M1014	M2311	M3811	M3111		M2811
M1112	M2312	M3911	M3113		M3011
M1113	M2313	M4011	M3211		M3012
M1114	M2412	M4012	M3213		M3111
M1213	M2413	M4112	M3413		M3311
M1214	M2612	M4211	M3511		M3413
			M3513		M3512
			M3611		M3711
			M3612		M3812
			M3713		M4011
			M3812		
			M3813		
			M4011		
			M4012		
			M4111		
			M4212		

RA 2014-081: PFA ACKNOWLEDGMENT FORM

Description: Blood/Fluid Warmer Cassettes

Catalogue No: D25310NL - D25310CE - D25315CE - D25340CE

Lot No: Various – please refer to the attached FSN

I acknowledge receipt of the Field Safety Notice for RA 2014-081 and can confirm that:

We have not located any of these devices in our inventory: ***(please delete if not applicable)***			
We have located the following devices:			
Product description	**Product Reference**	**Lot Number**	**Qty**
We have further distributed subject devices to the following organisations:			
Facility Name			
Facility Address			
Form completed by:			

Please sign and return this form to acknowledge receipt of product notice.			
Name of Hospital/ Organisation		Address	
Contact Name			
Contact Title			
Contact Signature			
Contact Phone No.		Date	

PLEASE COMPLETE AND FAX THIS FORM TO xxxx
OR EMAIL TO xxx@STRYKER.COM.