

Smiths Medical International Ltd.
1500 Eureka Park, Lower Pemberton
Ashford, Kent, TN25 4BF
UK

URGENT FIELD SAFETY NOTICE

For Medex™ Cardiothoracic Custom sets

Affected Devices:	Attachment 1
Type of Action:	Field Safety Corrective Action - Recall
Date:	07 April 2016
Attention:	Risk/ Safety Managers, Clinicians, Nurses and other users of the device
Details on affected devices:	Product Reorder Codes: See Attachment 1
Lot Number:	See Attachment 1: All lots within their expiration date

Dear Valued Customer:

Smiths Medical is providing this Urgent Field Safety Notice to advise its customers of a Field Safety Corrective Action for Cardiothoracic Custom sets. Smiths Medical is voluntarily initiating this Field Safety Corrective Action with the knowledge of the relevant Regulatory Agencies.

Smiths Medical has become aware of the potential for a small number of Cardiothoracic Custom sets to have punctures in the sterile breather bag packaging. This was discovered during performance of simulated distribution testing. Since these breather bags are used as a sterile barrier to maintain the device sterility, the potential risk is device sterility may be compromised.

Punctures in the blister packaging were identified during internal simulated distribution testing under extreme transportation conditions. Pin holes of around 0.2 mm were detected in the external packaging of products enclosed in protective wrapping. This wrapping material presents an additional sterility barrier therefore the likelihood that sterility may be compromised is very low. As a precautionary measure, Smiths Medical is advising its customers to return any unused affected products for credit or replacement.

Please also note the following: Smiths Medical has received no complaints or reports of patient injury related to this issue. Also, Smiths Medical's Instructions For Use states: "do not use if package is opened or damaged".

As a precautionary measure all unexpired Lots of Product Reorder Codes listed in Attachment 1 are impacted by this Field Safety Corrective Action.

Advice on Action to be taken by the User:

- 1) Inspect your inventory for products on the attached list and contact Smiths Medical to discuss your options for replacement or credit at 0845 850 0445 ext. 2116 or email at ukcs@smiths-medical.com. Unfortunately, at this time, Smiths Medical anticipates supply constraints that may impact our ability to provide timely replacements.
- 2) Complete and return the Confirmation Form (Attachment 2), either by fax at +44 (0) 1233 722153 or by e-mail to WS25@smiths-medical.com within five (5) days of receipt of this notice.

Transmission of this Urgent Field Safety Notice

This notice shall be passed on to all personnel who need to be aware within your organization, including points of use or to any organization where the potentially affected devices have been transferred. If you, or your facility, has distributed these affected products to other persons or facilities, please promptly forward the recipients a copy of this Urgent Field Safety Notice.

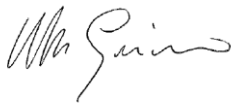
Please maintain awareness of this Notice and resulting action for an appropriate period to ensure effectiveness of this Urgent Field Safety Corrective Action.

Customers should report any issues with these products to Smiths Medical's Global Complaint Department at 00 800 76 48 47 00 or globalcomplaints@smiths-medical.com.

If you should have any questions regarding this information, please contact Smiths Medical's Customer Service Department at 0845 850 0445 ext. 2116 or by email to WS25@smiths-medical.com

Smiths Medical is committed to providing quality products and service to its customers. We apologize for any inconvenience this situation may have caused.

Sincerely,



Marco Savino
Regional Director, Quality Systems
Smiths Medical

Enclosures:

- Attachment 1 – Product Reorder Codes and Lot Numbers
- Attachment 2 – Field Safety Notice Confirmation Form

Attachment 1- Affected Product Reorder Codes and Associated Lot Numbers

Product Reorder Number	Lot Number
MX1680-61	2445264 2511291 2585333
SXP530850	2483712 2597624
SXP530852	2458362 2483838 2509962 2545189
SXP550271	2379590 2384326 2429255 2429694 2469860 2472195 2479723 2500036 2553899 2593962 2602000 2628537 2645680 2682518 2721239 2729173 2746669 2765179 2768797 2772037 2804580 2832880 2878151 2906704 2945598 2953924 2988621 2998522 3003950 3014307 3028218 3044504 3048870 3105079
SXP550280	2409964 2411976 2413656 2449740 2466733

SXP550289	2379591 2392782 2425032 2438872 2479518 2488460 2505345 2540649 2558546
SXP550308	2388401 2397821 2411960 2415964 2462690 2513825 2523985 2553876 2553895 2589031 2611855 2632181 2655224 2663066 2692177 2702322 2726521 2735096 2746670 2770604 2802006 2821715 2850588 2878149 2878150 2899752 2906706 2940270 2962709 2973162 2986212 3001615 3031056 3105080

SXP550311	2416897 2420739 2454374 2467045 2479724 2496736 2509963 2523986 2532822 2549564 2563083 2581013 2607595 2615627 2628535 2632182 2650404 2672095 2686766 2697143 2712255 2713876 2726450 2735094 2751591 2765184 2768798 2778321 2798391 2804579 2844561 2878147 2886345 2895586 2913330 2936126 2949458 2960307 2966826 2979843 2988589 3001616 3005914 3028217 3031058 3040369 3048873
SXP550324	2379592 2409961 2458043 2483840 2509918 2536650

SXP550384	2411961 2425031 2458027 2469862 2488461 2520470 2536584 2558439 2628534 2650403 2678147 2729522 2735093 2790987 2798390 2850590 2913331 2969738 3031059
SXP570799	2368687 2411968 2524014 2640564 2674044 2731426 2735091
SXP580603	2416899 2462688
SXP580637	2384327 2411967
SXP590230A	2388330 2425308 2454375 2483830 2500048 2505343 2513823 2540650 2558547 2576570 2585332 2597662 2620862 2628542 2640970 2655226 2682515 2716799 2726456 2742190 2751595 2794238 2804475 2804578 2844560 2852377 2879385 2902108 2911080 2924564

	2926921 2949480 2963482 2977157 3001617 3003951
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SXP650203	2438875 2462689 2520474 2537704 2572814 2620870 2672643 2844559 2995776

SXP650246	2388397 2416900 2449744 2475411 2479732 2524058 2584867 2589037 2642819 2649996 2654638 2659161 2678148 2692167 2716801 2731427 2746672 2776221 2791099 2913333 2931517 2947856 2960308 3001618 3001619 3035391
SXP700420	2374672 2466729 2509970 2536577 2558548 2597623 2628540 2696666 2804476 2896011 2913335 3109316

SXP700421	2374691 2388400 2397762 2411974 2415966 2459913 2471579 2471580 2471581 2483831 2488462 2500037 2509959 2513826 2536586 2545205 2549561 2563107 2584874 2589039 2611856 2611857 2615628 2631960 2654706 2659539 2692170 2702321 2969737 3003954
SXP700427	2343852 2374682 2397817 2415967 2458038
SXP720114	2369149 2379595 2388396 2392784 2397818 2443910 2453955 2454027 2459906 2475733 2479726 2488463 2500038 2505346

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SXP720369	2392786 2394161 2397819 2411972 2415960 2420740 2425030 2429252 2434110 2438867 2443908 2466734 2469857 2479523 2479524 2479728 2479729 2482885 2483832 2488464 2496735 2500040 2505347 2509964 2513881 2519334 2523993 2523994 2523995 2524065 2532828 2536579 2537708 2540645 2545210 2553897 2561570 2567137 2567138 2567139 2572816 2581011 2585325 2585326 2589038 2589058 2597663 2602744 2607087 2611670 2612346 2612347 2620865 2620866 2624022 2624463 2631954 2632091 2645681 2645682
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SXP720471	2384332 2388325 2388326 2388327 2392779 2425033 2425317 2450421 2457999 2466735 2469864 2479525
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SXP720629	2392787 2457995 2514011 2563489 2564510 2576578 2649999 2721111 2742197

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SXP720728	2411973 2425035 2448867 2457996 2483835 2524068 2540651 2567134 2615388 2655227 2707828 2721240 2751252 2790990 2832721 2871262 2895592 2929010 2995781 3044512

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SXP721442	2466732 2488459 2519336 2519337
SXP721461	2624459 2706550 2712895 2726516 2728837 2737566 2740187 2787144 2819132 2822095 2873427 2949469 2988624 3011822 3037866 3101355 2501322

SXP721494	2501326 2505327 2509965 2513884 2524000 2524071 2536582 2553896 2553898 2567132 2576576
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Attachment 2- FSN Confirmation

FIELD SAFETY NOTICE- CONFIRMATION FORM Medex™ Cardiothoracic Custom sets

07 April 2016

Customer Account No. _____

Please complete and return this Form via fax at +44 (0) 1233 722153 or by e-mail to: WS25@smiths-medical.com.

<input type="checkbox"/> Yes, I acknowledge the receipt of the FSN and understood its content. I have Medex™ Cardiothoracic Custom sets and would like Smiths Medical to contact me regarding replacements or credit for all of them.	Number of total products I have: Product codes: _____ Lot numbers: _____
<input type="checkbox"/> Yes, I acknowledge the receipt of the FSN and understood its content. We have NO Medex™ Cardiothoracic Custom sets	

Facility Name:	Facility Address:
Signature:	Facility Shipping Address:
Print Name:	Date:
Department:	
Email:	Phone Number: ()