

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

**URGENT FIELD SAFETY NOTICE**

**For Medex™ Cardiothoracic Custom sets**

<b>Affected Devices:</b>	Attachment 1
<b>Type of Action:</b>	<b>Field Safety Corrective Action - Recall</b>
<b>Date:</b>	07 April 2016
<b>Attention:</b>	Risk/ Safety Managers, Clinicians, Nurses and other users of the device
<b>Details on affected devices:</b>	<b>Product Reorder Codes:</b> See Attachment 1
<b>Lot Number:</b>	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](mailto: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](mailto: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](mailto: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](mailto: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**

<b>Product Reorder Number</b>	<b>Lot Number</b>
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
SXP630261	2388329 2443906 2459910 2479725 2505344 2516127 2520473 2537703 2558542 2567135 2572815 2597626 2607599 2659164 2686904 2702320 2724223 2740169 2764826 2776219 2802007 2821717 2852378 2889377 2895587 2906742 2936128 2971755 2991537 2993963 3005915 3014309 3031060 3044507
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

SXP720188	2413746 2425034 2434789 2458045 2469855 2481146 2488458 2492444 2497806 2506232 2520476 2537707 2563487 2563488 2572813 2581012 2586167 2589033 2602743 2611861 2624460 2640969 2655222 2663411 2672642 2678152 2702318 2716798 2726451 2726517 2744171 2746768 2748685 2765185 2768129 2776222 2780741 2790988 2798389 2852380 2889378 2899753 2908811 2926942 2953950 2969734 2979844 2982001 3001620 3018630 3022261 3028215 3047888 3048875
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SXP720323	2392785
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	2429262
	2457998
	2479213
	2506233
	2536578
	2576575
	2589054
	2667944
	2711896
	2733482
	2765186
	2784639

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

2645686
2650401
2655228
2679309
2684628
2689613
2697138
2697139
2704453
2707830
2711918
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2716800
2726518
2726519
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2735090
2740170
2744172
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2751596
2765187
2770605
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2777161
2778322
2778323
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2791101
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2794240
2804575
2804577
2819133
2821718
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2844558
2850591
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2871261
2879384
2883670
2886347
2889621
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2902110
2906743
2911081
2913336

	2926102 2926943 2931525 2934886 2938212 2943139 2947857 2953953 2956083 2956084 2962716 2965766 2977156 2979845 2979846 2979847 2988576 2988591 2988623 2993965 3001621 3001622 3005916 3005917 3009837 3014310 3018631 3023580 3028214 3035392 3035393 3044508 3044509 3044510 3044511 3048876 3053025 3053026
SXP720471	2384332 2388325 2388326 2388327 2392779 2425033 2425317 2450421 2457999 2466735 2469864 2479525
SXP720584	2388834
SXP720629	2392787 2457995 2514011 2563489 2564510 2576578 2649999 2721111 2742197

	2797776
SXP720682	2413141 2415974 2466736 2516133 2589086 2620327 2701537 2726520 2821337 2883659 3009839
SXP720714	2374685 2384333 2388399 2397824 2415975 2458000 2466730 2479731 2483834
SXP720728	2411973 2425035 2448867 2457996 2483835 2524068 2540651 2567134 2615388 2655227 2707828 2721240 2751252 2790990 2832721 2871262 2895592 2929010 2995781 3044512

SXP720896	2392777 2411966 2425036 2459914 2765190 2780761 2844360 2879383 2881586 2885061 2895623 2524070 2664509 2712257 2733483 2852379 3009842
SXP721355	2476088 2488465 2540648 2558549 2667495 2692174 2746767 2751258 2765829 2772057 2871263 2938214 2995782 3031061 3083158
SXP721438	2466731 2470867 2483837 2540646 2558444
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](mailto:WS25@smiths-medical.com).

<input type="checkbox"/> <b>Yes,</b> I acknowledge the receipt of the FSN and understood its content. <b>I have Medex™ Cardiothoracic Custom sets</b> 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"/> <b>Yes,</b> I acknowledge the receipt of the FSN and understood its content. <b>We have NO Medex™ Cardiothoracic Custom sets</b>	

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