



رقم المحفوظات: ٣٨/٢٥
رقم الصادر: ٣/١/٢٥٤١٧
بيروت، في: ٣٠ تموز ٢٠١٢

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي
Gowns, Medical, Hytrel Toga

الجهاز المعنى بالمتابعة:

- Gowns, Medical, Hytrel Toga
- Trade Mark: Stryker Instruments
- Local Representative:

بناء على التقرير الصادر عن وكالة ال FDA
والتوصية الصادرة عن الشركة المصنعة والتي تشير الى وجود خلل في فعالية التعقيم، نرجو
منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ربطا:

- التقرير الصادر عن وكالة ال FDA

يبلغ:

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

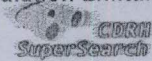
مدير عام الصحة

د. وليد عمار



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Medical & Radiation Emitting Device Recalls

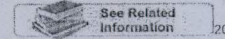


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Class 2 Recall
Hytre! Toga



Date Posted	June 06, 2013
Recall Number	Z-1489-2013
Product	Stryker Instruments 0400-710-000 T4 Pullover Toga (S/M) Sterile, EO; single use; Product Usage: Protection System and are intended to protect the patient, healthcare personnel and operating room personnel against contamination, exposure of infectious bodily fluids, and the transfer of microorganisms and particulate material.
Code Information	1006134, 1101020, 1106424
Recalling Firm/Manufacturer	Stryker Instruments Div. of Stryker Corporation 4100 E Milham Ave Portage, Michigan 49002-9704
Reason for Recall	Based on an accelerated aging test for this product packaging, there is an indicator of potential for a breach in the sterile barrier in the header bag and potentially the blue sterilization wrap for togas within the second and third year of shelf life. The test method used involved high heat to accelerate the aging of the packaging. Stryker is conducting additional testing and assessing this pr
Action	Stryker sent an Urgent Recall notifications letter dated May 7, 2013 via certified US mail and E-mail to all affected customers, distributors and direct accounts. The letter identified the affected products, problem, risk to health, and actions to be taken. Customers were instructed to check inventory, immediately quarantine any affected product, and open each package before discarding to prevent use. Customers were directed to fill out and return a Business Reply Form to Stericycle, Phone: 888-943-2396 Fax: 888-943-4192, Email: stryker5893@stericycle.com verifying directions and confirming recalled product was destroyed. For questions call 269-389-4354 or 269-389-4518.
Quantity in Commerce	2,980 units (298 boxes)
Distribution	USA Nationwide Distribution

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20. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/relateditems.cfm?page_title=medical%20device%20recalls&item1_text=%3Ch3%3Erelated%20recalls%20for%20Hytre!%20Toga%3C%2Fh3%3E&item1_url=www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?start_search=1&event_id=65321&item2_text=medical%20device%20recalls%20&item2_url=www.fda.gov/medicaldevices/safety/recalls/corrections/removals/listofrecalls/default.htm&item3_text=fda%20enforcement%20report%20index&item3_url=www.fda.gov/safety/recalls/enforcementreports/default.htm

RA2013-019: List of Affected Catalogue Numbers

Stryker Part #	Stryker Lot #	Description	Dates of Distribution
0400-710-000	See attached list	T4 Pullover Toga (S/M)	13-Jul-2010 thru 05-May-2012
0400-720-000	See attached list	T4 Pullover Toga (L/XL)	08-Aug-2010 thru 05-Jan-2012
0400-720-00055	See attached list	T5 Pullover Toga w/Peel Away	12-Aug-2010 thru 21-May-2012
0400-750-000	See attached list	T4 Toga, Pullover, Regular	15-Jun-2010 thru 25-May-2012
0400-760-000	See attached list	T4 Toga, Pullover, Large	09-Jun-2010 thru 21-Dec-2011
0400-770-000	See attached list	T4 Toga, Pullover, Extra Large	07-Jun-2010 thru 12-Dec-2011
0400-810-000	See attached list	T4 Zipper Toga (S/M)	02-Jul-2010 thru 03-Feb-2012
0400-820-000	See attached list	T4 Zipper Toga (L/XL)	07-Jul-2010 thru 22-Feb-2012
0400-820-00053	See attached list	T4 Toga w/Inside Shoulder Ties	01-Oct-2010 thru 16-May-2012
0400-820-00057	See attached list	T4 XXL Toga w/T3 Cut	26-May-2010 thru 05-Mar-2012
0400-820-100	See attached list	T5 Zipper Toga with Peel Away	15-Jul-2010 thru 16-Dec-2011
0400-830-000	See attached list	T4 Toga, Zipper, Regular	20-Jul-2010 thru 20-Dec-2011
0400-840-000	See attached list	T4 Toga, Zipper, Large	29-Jun-2010 thru 21-Dec-2011
0400-850-000	See attached list	T4 Toga, Zipper, (XL-Tall)	21-Jul-2010 thru 09-Dec-2011
0400-850-00052	See attached list	T4 Toga, XL, w/Inside Ties	11-Feb-2011 thru 08-Jun-2012
0400-850-100	See attached list	T5 zipper Toga with Peel Away	25-Aug-2010 thru 04-Jan-2012

Affected Part/ Lot Number List

0400-710-000	1006134
T4 Pullover Toga (S/M)	1101020
	1106424

0400-720-000	1005105	1010244	1101004	1104289	1107568
T4 Pullover Toga (L/XL)	1005119	1010261	1101030	1104324	1108625
	1006129	1011276	1101047	1105390	1108672
	1006140	1011296	1102073	1105355	1109730

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	1007151	1012314	1102127	1106431	1109782
	1007163	1012337	1102131	1106467	1109858
	1009213	1012346	1104253	1107515	

0400-720-00055	1007157
T5 Pullover Toga w/Peel Away	1103202

0400-750-000 T4 Toga, Pullover, Regular	1005111
	1011282
	1107491
	1107492

0400-760-000 T4 Toga, Pullover, Large	1006134	1012304	1104308
	1007152	1101020	1105365
	1007170	1102080	1106421
	1008188	1102147	1106469
	1009205	1103193	1108628
	1010229	1103198	1108697
	1010253	1102149	1109789
	1011277	1104248	

0400-770-000 T4 Toga, Pullover, Extra Large	1005105	1009214	1104308
	1006130	1010260	1104312
	1007152	1012346	1105378
	1007163	1012303	1106460
	1007164	1101062	1107542
	1008189	1101063	1108660
	1008188	1102149	1109760

RA2013-019 Stryker T4/T5 Hytrel Toga

	1009213	1103219	
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0400-810-000 T4 Zipper Toga (S/M)	1006129	1103201
	1009197	1105391
	1009198	1107548
	1012302	1109788
	1102127	

0400-820-000 T4 Zipper Toga (L/XL)	1005097	1009205	1011294	1102105	1104268	1106463	1108633	1109857
	1005098	1009219	1012313	1102109	1104305	1106465	1108648	1109812
	1005104	1008192	1011281	1102119	1104307	1106470	1108654	1109860
	1005105	1009213	1012325	1102123	1104308	1107493	1108659	1109817
	1005110	1009197	1012327	1102141	1104320	1107488	1108666	
	1005111	1009204	1012335	1102147	1104327	1107497	1108667	
	1005118	1010227	1012345	1102150	1105370	1106474	1108671	
	1006123	1010234	1101014	1103170	1105342	1107511	1108675	
	1007155	1010235	1012344	1103171	1105356	1107512	1108701	
	1006127	1010251	1101003	1103223	1105110	1107516	1108704	
	1006133	1010258	1101017	1103189	1105379	1107537	1109778	
	1006140	1010243	1101002	1103194	1105390	1107546	1107520	
	1008181	1012314	1101029	1103184	1105401	1107595	1108710	
	1007163	1010259	1101046	1103227	1106418	1107604	1108713	
	1007145	1010252	1101053	1104280	1106432	1107561	1109740	
	1007156	1011266	1102073	1104248	1106453	1108624	1109750	
	1007169	1011267	1102092	1104259	1106444	1107599	1109729	
	1007151	1011275	1101055	1104264	1106451	1107567	1109735	
	1008176	1011280	1102085	1104290	1106437	1107578	1109755	
	1008178	1011295	1102099	1104278	1106455	1107570	1109781	
1008188	1011276	1102080	1104283	1106460	1108619	1109809		

RA2013-019 Stryker T4/T5 Hytrel Toga

0400-820-000S3	1007145
T4 Toga w/Inside Shoulder Ties	1101004
	1107487

0400-820-000S7	1005098
T4 XXI Toga w/T3 Cut	1010228
	1012337
	1105367

0400-820-100 T5 Zipper Toga with Peel Away	1006130	1101034
	1006134	1102133
	1007151	1103208
	1007170	1104297
	1009205	1105360
	1010228	1106476
	1010260	1107569
	1011296	1108676
1012336	1109786	

0400-830-000	1006141
T4 Toga, Zipper, Regular	1012303
	1102110
	1104324
	1108664

0400-840-000	1105390
T4 Toga, Zipper, Large	1107543

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0400-850-000 T4 Toga, Zipper, (XL-Tall)	1005097	1008188	1011281	1103194	1106465	1107519
	1005105	1008192	1011296	1103201	1107501	1109763
	1005111	1009198	1012303	1103223	1107550	1109777
	1005118	1009213	1012314	1104282	1107560	1109822
	1006129	1009219	1012325	1104290	1107605	1109850
	1008181	1009220	1012335	1104320	1107606	
	1006135	1010228	1012344	1104312	1108618	
	1007145	1010236	1101003	1105346	1108663	
	1007151	1010235	1101030	1105355	1108677	
	1007156	1010243	1101055	1105378	1108709	
	1007163	1010252	1102109	1106411	1108714	
	1007169	1010260	1102123	1105405	1109728	
	1008183	1011276	1102141	1106430	1104275	

0400-850-00052	1010236
T4 Toga, XL, w/Inside Ties	1108682

0400-850-100 T5 zipper Toga with Peel Away	1006124
	1007164
	1010236
	1011296
	1103168
	1105341
	1108634

RA2015-019 Stryker T4/T5 Hytel Toga