

Safety Communication

رسالة سلامة

LOR Syringes May Fail, Potentially Resulting in Dural Puncture

Device/ Product Description:	Epidural Catheterization Kits and Sets						
Brand:	Multiple						
Affected product:	Product Code	Lot Numbers					
	AA-05400-B	71F19E2457	71F19G0988	71F19H1281	71F19K2009		
		71F19F1658	71F19G2371	71F19J1079			
	AA-05400-E	71F19B2081	71F19C1655	71F19E2128	71F19G2444		
		71F19B2586	71F19E1245	71F19F1432	71F19J1685		
	AK-05500	13F19G0085	13F19H0381				
	AK-05501	23F19A0301	23F19F0108	23F19F0481	23F19H0079	23F19J0305	23F19L0094
		23F19C0303	23F19F0297	23F19G0039	23F19H0145	23F19J0484	23F19L0209
		23F19D0266	23F19F0388	23F19G0263	23F19H0386	23F19K0171	23F19M0112
	ALZANO-05400-B	71F19B0681	71F19C0035	71F19D2827	71F19F2028	71F19H1633	71F19K1574
	ASK-02220-SRH	13F19F0303	13F19G0072	13F19L0140			
	ASK-05001-SLR1	23F18M0499	23F19F0164	23F19H0109	23F19L0471		
		23F19C0409	23F19G0535	23F19K0082			
	ASK-05400-CA1	13F19B0343	13F19B0501	13F19E0698	13F19H0470		
	ASK-05500-BID	23F19E0337	23F19J0065	23F19K0100	23F19L0218		
		23F19H0048	23F19J0314	23F19K0303	23F19M0007		
	ASK-05500-TM	23F19E0116	23F19G0501	23F19K0188			
	ASK-05501-SH	23F19A0240	23F19G0305	23F19J0292	23F19L0414		
23F19E0112		23F19G0496	23F19K0152				
	23F19C0385	23F19G0310	23F19H0234	23F19K0248			

	ASK-05502-NY	23F19F0167	23F19G0434	23F19J0063			
	ASK-05503-BID	23F19G0306	23F19H0035	23F19K0149	23F19L0411		
	ASK-05560-TG1	23F19A0154	23F19C0273	23F19F0029	23F19G0360	23F19M0226	
	ASK-05560-WH	13F18L0892	13F19C0478	13F19E0433	13F19K0051		
		13F19B0588	13F19D0327	13F19H0209	13F19L0079		
	ASK-17019-MSC	13F18K0094	13F19B0335	13F19C0594	13F19G0068	13F19G0591	13F19J0119
	AT-05501-LEO	71F19B0740	71F19C1369	71F19G1023	71F19J1434		
		71F19C0033	71F19E1660	71F19H1350			
	AT-05501-LIN	71F19C1431	71F19H1811	71F19K1515			
	BE-05400B-ETTEL	71F19C0509	71F19G0116	71F19H1409	71F19J1840		
		71F19D2945	71F19G2238	71F19J0078			
	BE-05400-DCHH	71F19D0610	71F19G2151				
	BE-05400-DCSHO	71F19C0983	71F19D0315	71F19E1828	71F19H1445	71F19J1822	71F19K1828
	BE-080180-BXL	71F19B0729	71F19E2327	71F19G1496	71F19J1005		
		71F19C1089	71F19F0733	71F19H0793			
	BE-080180-CHH	71F19D0608	71F19F1570	71F19H2423	71F19K1108		
		71F19E2537	71F19G2485	71F19J1513			
	BJC-05400-BEN	71F19A1610	71F19C1989	71F19F0568	71F19G2407	71F19K2654	
		71F19B0253	71F19E1613	71F19G0263	71F19H1828		
	CA-02220	13F18J0481	13F19D0441	13F19E0237	13F19K0136	13F19L0363	
		13F19A0671	13F19D0671	13F19G0613	13F19K0544		
	CZ-05400-EPI	71F19B0663	71F19E2004	71F19G2408	71F19K2838		
		71F19C0095	71F19G0885	71F19H1697			
	DE-05400D-BO	71F19D2769	71F19H0716	71F19K1690			
	EC-05520-P	71F19B2227	71F19E1297	71F19G1231	71F19G2158	71F19H2674	71F19J0430
	FR-05501-04	71F19B0678	71F19C1428	71F19E1149	71F19G0313	71F19J0072	71F19L0492
		71F19B2751	71F19D0558	71F19E1781	71F19G2388	71F19J1370	71F19L0493
		71F19C0778	71F19D2449	71F19F0737	71F19H1817	71F19K2849	
	FR-05501-10	71F19B1457	71F19D1662	71F19G0145	71F19H2708	71F19K2670	
		71F19C1527	71F19E1145	71F19G2429	71F19J1367		
		71F19C2577	71F19E2862	71F19H1833	71F19K0948		
	FR-05501-12	71F19A0623	71F19C1042	71F19E1144	71F19G2853	71F19K0248	
		71F19A2996	71F19C2596	71F19E2950	71F19H2549	71F19K2117	
		71F19B1149	71F19D2545	71F19G1138	71F19J1815	71F19L0436	
	IT-05400-DC	71F19B2176	71F19C0468	71F19G1135	71F19L1545		
	JC-05400-B	71F19A0552	71F19C0531	71F19D1772	71F19F0481	71F19G2970	71F19K1979
		71F19A1876	71F19C1329	71F19D2237	71F19F0794	71F19H1056	71F19K2381
		71F19A2686	71F19C2027	71F19D2580	71F19F1426	71F19H1236	71F19K2382
		71F19A2926	71F19C2239	71F19E0587	71F19F2006	71F19H1300	71F19L0281
		71F19B0499	71F19C2723	71F19E0689	71F19G0494	71F19H2034	71F19L0502

		71F19B1222	71F19C2866	71F19E1636	71F19G1028	71F19J0768	71F19L0653
		71F19B2079	71F19D0056	71F19E2838	71F19G1720	71F19J1251	
		71F19B2664	71F19D0839	71F19E3183	71F19G2237	71F19J2203	
		71F19B2849	71F19D1511	71F19F0256	71F19G2837	71F19J2204	
JC-05400-DCS		71F19B0226	71F19B2848	71F19D0451	71F19E0081	71F19F0245	71F19J1235
		71F19B0707	71F19C0406	71F19D0826	71F19E0998	71F19F0482	71F19J2164
		71F19B0935	71F19C2047	71F19D1267	71F19E1253	71F19G1938	71F19K2878
		71F19B1484	71F19C2433	71F19D2474	71F19E1315	71F19G2556	
		71F19B1832	71F19D0055	71F19D2761	71F19E2505	71F19H2404	
JC-05400-E		71F19A1623	71F19B0507	14F19D0467	71F19G0728	71F19J1893	71F19K2112
		71F19A2295	14F19B0224	71F19E1270	71F19G0974	14F19K0467	14F19L0127
		71F19A2972	14F19D0011	71F19E1868	71F19J0168	71F19K0694	
		71F19B0343	71F19D2947	71F19F0330	14F19J0132	71F19K0899	
JC-05400-LB		71F19B2180	71F19E1142	71F19F1082	71F19H2578		
		71F19E0149	71F19F1081	71F19G2551	71F19K1691		
LR-05501		13F18J0916	13F19C0321	13F19G0070	13F19H0274	13F19J0039	13F19L0252
		13F18K0675	13F19D0335	13F19G0071	13F19H0275	13F19J0040	
		13F18L0737	13F19E0141	13F19G0458	13F19H0634	13F19J0596	
		13F18M0178	13F19E0212	13F19H0085	13F19J0038	13F19K0097	
MP-17019-TIP		13F19A0544	13F19B0451	13F19E0017	13F19K0394		
		13F19A0796	13F19D0481	13F19G0086	13F19L0070		
MP-17019-TKP		23F19C0216	23F19F0037	23F19G0368	23F19J0089	23F19K0199	23F19M0018
		23F19E0350	23F19F0269	23F19H0131	23F19J0208	23F19L0230	
MTO-05500-SU		71F19D0624	71F19E0717	71F19F1173	71F19F1768	71F19L0352	
MTO-05500-TK		71F19A2894	71F19B1150	71F19F0028	71F19G1441	71F19H1499	
MTO-09903-KU		71F19B1406	71F19E2026	71F19G1921			
NYU-05500-1		23F19A0245	23F19G0253				
TI-05501-ME		71F19A1324	71F19C2255	71F19E3165	71F19H1740	71F19K0132	
		71F19B0614	71F19C2567	71F19G0092	71F19H1742	71F19K0134	
		71F19C2254	71F19E0766	71F19G1018	71F19H2570	71F19L0033	
TI-05520-EPI		71F19E2613	71F19F1493				
UR-05501		71F19C0040	71F19E1143	71F19G1454	71F19H2552		
		71F19C1116	71F19E2861	71F19H0787	71F19J0868		
UR-05501-EXP		71F19B0254	71F19B2777	71F19D0314	71F19H1729	71F19J0073	
		71F19B1059	71F19C1077	71F19E2614	71F19H1730	71F19J1838	
		71F19B1882	71F19C2279	71F19G0087	71F19H1731	71F19K2852	
UR-05501-FR1		71F19B0757	71F19D1493	71F19E2344	71F19G2640	71F19J0575	
		71F19C0748	71F19E0193	71F19G1146	71F19H2120	71F19K1689	
YC-02220		13F19B0340	13F19E0025	13F19G0069	13F19H0066	13F19K0137	13F19K0582
Manufacturer:	Teleflex Medical.						

<p>Problem:</p>	<p>Various failures with the LOR (loss of resistance) syringes included in the kits resulting in dural puncture with some also requiring a blood patch. An inadvertent dural puncture may lead to headache, tinnitus and rarely intra-cranial hemorrhage. Failures may present as follows:</p> <ul style="list-style-type: none"> • The syringe may be blocked/sticking which may lead to a false negative result, as it would be possible to enter the epidural space with the epidural needle and be unaware of having done so because there would be no loss of resistance. There is a risk of inadvertently administering an inappropriate dose of local anesthetic to the subarachnoid space, leading to risk of significant harm to the patient or risking injury to nerves, resulting in a permanent spinal cord injury. • The syringe may leak which could lead to a false positive result, i.e. the clinician will think they have reached the epidural space before they do reach it, potentially resulting in catheter misplacement, repeated procedure attempts and a delay in therapy.
<p>Recommendation/ Actions:</p>	<ol style="list-style-type: none"> 1. Review this notice and ensure that affected personnel are aware of the contents. 2. Immediately stop using and quarantine the affected devices 3. Contact the authorized representative for required correction. <p>For more information, Please click here.</p> <p>If you think you had a problem with your device or a device your patient uses, please do not hesitate to report the problem to SFDA through: NCMDR Vigilance system 19999 unified call center</p>

Devices/Products photo:



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