Teleflex Medical
IDA Business & Technology Park
Dublin Road, Athlone
Westmeath, Ireland

30th Jan 2020

URGENT – FIELD SAFETY NOTICE

Type of Action				Recall
Teleflex Reference				EIF-000395
Commercial Name				Arrow® EPIDURAL CATHETERIZATION Kits and Sets
Product Code				Lot Number
AA-05400-B	ASK-05560-TG1	CZ-05400-EPI	MP-17019-TIP	Refer to Appendix 2
AA-05400-E	ASK-05560-WH	DE-05400D-BO	MP-17019-TKP	
AK-05500	ASK-17019-MSC	EC-05520-P	MTO-05500-SU	
AK-05501	AT-05501-LEO	FR-05501-04	MTO-05500-TK	
ALZANO-05400-B	AT-05501-LIN	FR-05501-10	MTO-09903-KU	
ASK-02220-SRH	BE-05400B-ETTEL	FR-05501-12	NYU-05500-1	
ASK-05001-SLR1	BE-05400-DCHH	IT-05400-DC	TI-05501-ME	
ASK-05400-CA1	BE-05400-DCSHO	JC-05400-B	TI-05520-EPI	
ASK-05500-BID	BE-080180-BXL	JC-05400-DCS	UR-05501	
ASK-05500-TM	BE-080180-CHH	JC-05400-E	UR-05501-EXP	
ASK-05501-SH	BJC-05400-BEN	JC-05400-LB	UR-05501-FR1	
ASK-05502-NY	CA-02220	LR-05501	YC-02220	
ASK-05503-BID				

Dear Customer,

Teleflex has initiated a voluntary Field Safety Corrective Action for the above listed product codes.

Description of the problem & immediate actions required

Arrow International, a subsidiary of Teleflex, is recalling the above product codes and lots due to receipt of complaints reporting 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 haemorrhage. Failures may present as follows:

- 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.
- 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.

In the first setting, it would be possible to enter the subarachnoid space unknowingly. There is a risk of inadvertently administering an inappropriate dose of local anaesthetic 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. This potential harm is also highly dependent on the level at which the procedure is performed. When performed for the purpose of providing epidural analgesia following thoracic surgery for example, there is the risk of spinal cord injury. Whereas, when performed for the relief of pain during labour and delivery, the procedure is ordinarily performed below the level of termination of the spinal cord.

Our records indicate that you have received products that are subject to this recall.

Depending on your device location please adhere to the following Action list:

Device location	Action List Number
Medical facilities	**1**
Distributors	**2**

Action list number 1 – Medical facilities

1. We request that you check your inventory for product within the scope of this FSCA. Users should cease use and distribution of impacted product and quarantine immediately.
2. If you do have stock in scope of this FSCA, mark the according checkbox on the Acknowledgement Form (Appendix 1) and contact customer service by calling the phone number mentioned below. Customer service will issue you with a return number. Write the return number into the respective field in the Acknowledgement Form and return this form immediately to Customer Service.
3. If you do not have stock in scope of this FSCA mark the according checkbox on the Acknowledgement Form (Appendix 1) and return the form to the fax number or e-Mail address mentioned below.
4. Teleflex (or your local dealer) will issue a credit note upon receipt of the returned affected product.

Action list number 2 – Distributors

1. Provide this field safety notice to all customers who have received product in scope of this FSCA. Your customer is then required to complete the acknowledgement form and return to you.
2. We request that you check your inventory for product within the scope of this FSCA. Cease use and distribution of impacted product and quarantine immediately. You may then return all product in scope to Teleflex.
3. As a distributor, you are then required to confirm to Teleflex that you have completed the field activity outlined above. Upon completion of your actions, please forward the completed Acknowledgement Form to Customer Service.
4. Please be aware that all European Economic Area/Switzerland (EEA/CH) and Turkey Member State Competent Authorities in which Teleflex distribute directly will be notified by Teleflex.
5. If you have further distributed product outside of your country, please notify Teleflex by return email to the e-Mail address below.
6. If you are a distributor and/or have a reporting responsibility within or outside the EEA/CH/TR region, please notify your local Competent Authority of this action. Please forward the notification and all communication with your local competent authority to Teleflex.

Teleflex

Teleflex informs all customers, employees of Teleflex and distributors of this Field Safety Corrective Action.

Transmission of this Field Safety Notice

This notice should be passed on to all persons who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. Please consider end users, clinicians, risk managers, supply chain/distribution centres etc. in the circulation of this notice. Maintain awareness of this notice until all required actions have been completed in your organisation.

Contact reference person
Should you require any further information or support concerning this issue, please contact:

Customer Service:
Contact: Nicole Morawiec
Telephone: +41 (0) 31 818 40 90
FAX: +41 (0) 31 818 40 93
Email: info.ch@teleflex.com

Please be advised that all Economic Area/Switzerland (EEA/CH) and Turkey Member State Competent Authorities to which Teleflex distribute directly will be notified by Teleflex. Teleflex is committed to providing high quality, safe and effective products. We sincerely apologise for any inconvenience this action may cause your operations. If you have any other questions, feel free to contact your local sales representative or Customer Service.

For and on behalf of Teleflex,

Padraig Hegarty

Padraig Hegarty VP, QA (Manufacturing)

Teleflex MEDICAL

Appendix 1

Customer No _____

FIELD SAFETY CORRECTIVE ACTION
ACKNOWLEDGEMENT FORM

PRODUCT FIELD ACTION BY TELEFLEX – IMMEDIATE ATTENTION REQUIRED

Ref. EIF-000395

RETURN COMPLETED FORM IMMEDIATELY TO:

FAX: +41 (0) 31 818 40 93 Email: info.ch@teleflex.com

☐ We confirm receipt of this FSN and have completed the required actions contained therein. We confirm that our inventory does **NOT** include products affected by this Field Action.	☐ We confirm receipt of this FSN and have completed the required actions contained therein. We confirm our inventory **DOES** include products affected by this Field Action. The use and further distribution of the affected products is stopped. All products are put on hold and the amount below will be returned. **Return Authorisation No:** _____

PLEASE PRINT PRODUCT QUANTITY NUMBERS CLEARLY

PRODUCT NUMBER	LOT NUMBER	QUANTITY (Returning)

- Include a copy of the **completed Acknowledgement Form** in the returns package with the returned units
- Ensure the **RAN number is clearly visible** on the returns package
- Please label returns as **"Field Safety Returns"**

Complete this Acknowledgement form and return immediately by using fax number or e-Mail address above.

INSTITUTION NAME (EG NAME OF HOSPITAL, HEALTH CARE ORGANISATION)	
INSITIUTION ADDRESS	**Phone/FAX**
FORM COMPLETED BY:	**Stamp**
PRINT NAME: _____ **SIGNATURE:** _____	
DATE	

Product Code	Commercial Name
AA-05400-B	FlexTip Plus(R) Combined Spinal Epidural Catheterization Set
AA-05400-E	FlexTip Plus(R) Epidural Catheterization Set
AK-05500	FlexTip Plus(R) Epidural Catheterization Kit
AK-05501	FlexTip Plus(R) Epidural Catheterization Kit
ALZANO-05400-B	Epidural Catheterization Kit
ASK-02220-SRH	FlexTip Plus(R) Epidural Catheterization Kit.
ASK-05001-SLR1	TheraCath(R) Epidural Catheterization Kit
ASK-05400-CA1	FlexTip Plus(R) Epidural Catheterization Kit
ASK-05500-BID	FlexTip Plus(R) Combined Spinal Epidural Catheterization Kit
ASK-05500-TM	FlexTip Plus(R) Epidural Catheterization Kit
ASK-05501-SH	FlexTip Plus(R) Epidural Catheterization Kit
ASK-05502-NY	Epidural Catheterization Kit with FlexTip Plus(R), Open Tip, Single-Port Catheter
ASK-05503-BID	FlexTip Plus(R) Epidural Catheterization Kit
ASK-05560-TG1	FlexTip Plus(R) Combined Spinal Epidural Catheterization Kit
ASK-05560-WH	FlexTip Plus(R) Combined Spinal Epidural Catheterization Kit
ASK-17019-MSC	FlexTip Plus(R) Epidural Catheterization Kit
AT-05501-LEO	Cutlery for Epidural Catheterization with FlexTip Plus catheter
AT-05501-LIN	FlexTip Plus(R) Epidural Catheterization Kit
BE-05400B-ETTEL	Epidural Catheterization Kit
BE-05400-DCHH	Epidural Catheterization Kit with FlexTip Plus(R), Closed Tip Multi-Port Catheter
BE-05400-DCSHO	Epidural Catheterization Kit
BE-080180-BXL	Single Injection Epidural Product
BE-080180-CHH	Single Injection Epidural Product
BJC-05400-BEN	Epidural Catheterization Set
CA-02220	FlexTip Plus(R) Epidural Catheterization Kit
CZ-05400-EPI	FlexTip Plus(R) Epidural Catheterization Kit
DE-05400D-BO	EPIDURAL CATHETER KIT WITH FLEX TIP PLUS, multi-port catheter with closed tip
EC-05520-P	FlexTip Plus(R) Epidural Catheterization Set for Pediatric Lumbar Placement
FR-05501-04	Epidural Catheterization Kit
FR-05501-10	Epidural Catheterization Kit
FR-05501-12	Epidural Catheterization Kit
IT-05400-DC	Epidural Catheterization Kit with FlexTip Plus(R), Closed Tip Multi-Port Catheter
JC-05400-B	FlexTip Plus(R) Epidural Catheterization Set
JC-05400-DCS	FlexTip Plus(R) Epidural Catheterization Set
JC-05400-E	FlexTip Plus(R) Epidural Catheterization Set
JC-05400-LB	Epidural Catheterization Kit
LR-05501	10 mL Luer-Slip Loss of Resistance Syringe
MP-17019-TIP	FlexTip Plus(R) Epidural Catheterization Set
MP-17019-TKP	FlexTip Plus(R) Epidural Catheterization Kit
MTO-05500-SU	FlexTip Plus(R) Epidural Catheterization Kit
MTO-05500-TK	FlexTip Plus(R) Epidural Catheterization Kit
MTO-09903-KU	Percutaneous Sheath Introducer Kit
NYU-05500-1	FlexTip Plus(R) Epidural Catheterization Kit
TI-05501-ME	FlexTip Plus(R) Epidural Catheterization Kit
TI-05520-EPI	Epidural Catheterization Kit with FlexTip Plus(R) Catheter
UR-05501	FlexTip Plus(R) Epidural Catheterization Kit
UR-05501-EXP	Epidural Catheterization Set
UR-05501-FR1	Epidural Catheterization Kit
YC-02220	FlexTip Plus(R) Epidural Catheterization Kit

Appendix 2 - Scope of Product (EIF-000395)

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			
ASK-05502-NY	23F19C0385	23F19G0310	23F19H0234	23F19K0248		
	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

Appendix 2 - Scope of Product (EIF-000395)

Product Code	Lot Numbers					
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	

Appendix 2 - Scope of Product (EIF-000395)

Product Code	Lot Numbers					
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