

附件 1

医疗器械召回事件报告表

提交：■企业所在地省级食品药品监督管理部门

■器械注册/备案部门

产品名称	动脉穿刺导管组 Arterial Catheter Kits and Sets	注册证或备案 凭证编码	国械注进 20163032161
生产企业名称	Arrow International LLC 箭牌国际公司		
代理人名称	泰利福医疗器械商贸（上海）有限公司		
召回单位负责人和联系方式，经办人和联系方式	负责人：陆仙娟 021-60606980;15921579712 经办人：尹玲 021-60606981;13818569759		
产品的适用范围	该产品用于在外周动脉提供介入通路。		
涉及地区和国家	澳大利亚;中国;马来西亚;新西兰;菲律宾;新加坡;泰国	召回级别	一级召回
涉及产品生产（或进口中国）批次、数量	见附件、267,600 个	涉及产品型号、规格	见附件
识别信息（如批号）	见附件	涉及产品在中国的销售数量	254,850
召回原因简述	收到的投诉涉及导丝手柄/管腔在使用过程中存在阻力。该组件问题可能对健康造成的短期后果是因反复多次动脉穿刺造成动脉血管痉挛和血管损伤。任何长期后果将取决于短期后果的严重程度。如果在使用前按照使用说明书和临床试验质量管理规范进行测试，使用者可以在使用前发现该组件问题。		
纠正行动简述（包括召回要求和处理方式等）	1.泰利福向所有受影响的一级经销商发送医疗器械主动召回通知函，再由一级经销商逐级通知受影响的下级经销商和/或医院，并要求返回召回确认表。 2.要求客户停止经营或使用受影响的特定批次产品，并退回未使用的产品。受影响的产品退回后将会被统一隔离在仓库，根据最终处置决定就地销毁或者退回原厂。 3.已经使用的产品，无需采取进一步措施。		

报告单位：  
报告人：



负责人：  
报告日期：

陆仙娟  
2024年3月25日

附录 2: EIF-000556 召回在中国受影响的产品清单

产品型号	批号	医疗器械唯一标识
RA-04220	14F23B0041	(01)20801902180678(17)280131(10)14F23B0041
RA-04220	14F21L0189	(01)30801902193309(17)261031(10)14F21L0189
RA-04220	14F21L0190	(01)30801902193309(17)261031(10)14F21L0190
RA-04220	14F21L0250	(01)30801902193309(17)261130(10)14F21L0250
RA-04220	14F21L0251	(01)30801902193309(17)261130(10)14F21L0251
RA-04220	14F21L0252	(01)30801902193309(17)261130(10)14F21L0252
RA-04220	14F21L0253	(01)30801902193309(17)261130(10)14F21L0253
RA-04220	14F21M0130	(01)30801902193309(17)261231(10)14F21M0130
RA-04220	14F21M0131	(01)30801902193309(17)261231(10)14F21M0131
RA-04220	14F21M0205	(01)30801902193309(17)261231(10)14F21M0205
RA-04220	14F21M0206	(01)30801902193309(17)261231(10)14F21M0206
RA-04220	14F22A0044	(01)30801902193309(17)261231(10)14F22A0044
RA-04220	14F22A0123	(01)30801902193309(17)261231(10)14F22A0123
RA-04220	14F22A0124	(01)30801902193309(17)261231(10)14F22A0124
RA-04220	14F22A0143	(01)30801902193309(17)261231(10)14F22A0143
RA-04220	14F22A0144	(01)30801902193309(17)270131(10)14F22A0144
RA-04220	14F22B0163	(01)30801902193309(17)270131(10)14F22B0163
RA-04220	14F22B0164	(01)30801902193309(17)270131(10)14F22B0164
RA-04220	14F22B0175	(01)30801902193309(17)270228(10)14F22B0175
RA-04220	14F22C0017	(01)30801902193309(17)270228(10)14F22C0017
RA-04220	14F22C0018	(01)30801902193309(17)270228(10)14F22C0018
RA-04220	14F22C0019	(01)30801902193309(17)270228(10)14F22C0019
RA-04220	14F22C0020	(01)30801902193309(17)270228(10)14F22C0020
RA-04220	14F22C0021	(01)30801902193309(17)270228(10)14F22C0021
RA-04220	14F22C0022	(01)30801902193309(17)270228(10)14F22C0022
RA-04220	14F22C0216	(01)30801902193309(17)270228(10)14F22C0216
RA-04220	14F22C0284	(01)30801902193309(17)270228(10)14F22C0284
RA-04220	14F22C0346	(01)30801902193309(17)270331(10)14F22C0346
RA-04220	14F22C0347	(01)30801902193309(17)270331(10)14F22C0347
RA-04220	14F22D0023	(01)30801902193309(17)270331(10)14F22D0023
RA-04220	14F22D0024	(01)30801902193309(17)270331(10)14F22D0024
RA-04220	14F22D0110	(01)30801902193309(17)270331(10)14F22D0110
RA-04220	14F22D0217	(01)30801902193309(17)270430(10)14F22D0217
RA-04220	14F22D0291	(01)30801902193309(17)270430(10)14F22D0291
RA-04220	14S22D0218	(01)30801902193309(17)270430(10)14S22D0218
RA-04220	14F22E0016	(01)30801902193309(17)270531(10)14F22E0016
RA-04220	14F22E0173	(01)30801902193309(17)270531(10)14F22E0173
RA-04220	14F22E0215	(01)30801902193309(17)270531(10)14F22E0215
RA-04220	14F22F0003	(01)30801902193309(17)270531(10)14F22F0003
RA-04220	14F22F0062	(01)30801902193309(17)270531(10)14F22F0062
RA-04220	14F22F0208	(01)30801902193309(17)270531(10)14F22F0208
RA-04220	14F22F0209	(01)30801902193309(17)270531(10)14F22F0209



## 附录 2: EIF-000556 召回在中国受影响的产品清单

产品型号	批号	医疗器械唯一标识
RA-04220	14F22F0210	(01)30801902193309(17)270630(10)14F22F0210
RA-04220	14F22F0212	(01)30801902193309(17)270630(10)14F22F0212
RA-04220	14F22F0335	(01)30801902193309(17)270630(10)14F22F0335
RA-04220	14F22F0336	(01)30801902193309(17)270630(10)14F22F0336
RA-04220	14F22G0297	(01)30801902193309(17)270731(10)14F22G0297
RA-04220	14F22G0298	(01)30801902193309(17)270731(10)14F22G0298
RA-04220	14F22G0325	(01)30801902193309(17)270731(10)14F22G0325
RA-04220	14F22G0326	(01)30801902193309(17)270731(10)14F22G0326
RA-04220	14F22H0078	(01)30801902193309(17)270731(10)14F22H0078
RA-04220	14F22H0079	(01)30801902193309(17)270731(10)14F22H0079
RA-04220	14F22H0250	(01)30801902193309(17)270731(10)14F22H0250
RA-04220	14F22J0078	(01)30801902193309(17)270831(10)14F22J0078
RA-04220	14F22J0079	(01)30801902193309(17)270831(10)14F22J0079
RA-04220	14F22J0080	(01)30801902193309(17)270831(10)14F22J0080
RA-04220	14F22J0081	(01)30801902193309(17)270831(10)14F22J0081
RA-04220	14F22J0082	(01)30801902193309(17)270831(10)14F22J0082
RA-04220	14F22J0083	(01)30801902193309(17)270831(10)14F22J0083
RA-04220	14F22J0257	(01)30801902193309(17)270930(10)14F22J0257
RA-04220	14F22K0182	(01)30801902210631(17)270930(10)14F22K0182
RA-04220	14F22K0183	(01)30801902210631(17)270930(10)14F22K0183
RA-04220	14F22K0184	(01)30801902210631(17)270930(10)14F22K0184
RA-04220	14F22K0185	(01)30801902210631(17)270930(10)14F22K0185
RA-04220	14F22K0223	(01)30801902210631(17)271031(10)14F22K0223
RA-04220	14F22M0032	(01)30801902210631(17)271130(10)14F22M0032
RA-04220	14F22M0033	(01)30801902210631(17)271130(10)14F22M0033
RA-04220	14F22M0034	(01)30801902210631(17)271130(10)14F22M0034
RA-04220	14F22M0035	(01)30801902210631(17)271130(10)14F22M0035
RA-04220	14F22M0036	(01)30801902210631(17)271130(10)14F22M0036
RA-04220	14F22M0132	(01)30801902210631(17)271231(10)14F22M0132
RA-04220	14F23B0042	(01)30801902210631(17)280131(10)14F23B0042
RA-04220	14F23B0142	(01)30801902210631(17)280131(10)14F23B0142
RA-04220	14F23B0143	(01)30801902210631(17)280131(10)14F23B0143
RA-04220	14F23B0144	(01)30801902210631(17)280131(10)14F23B0144
RA-04220	14F23B0154	(01)30801902210631(17)280131(10)14F23B0154
RA-04220	14F23D0203	(01)30801902210631(17)280430(10)14F23D0203
RA-04220	14F23D0204	(01)30801902210631(17)280430(10)14F23D0204
RA-04220	14F23D0205	(01)30801902210631(17)280430(10)14F23D0205
RA-04220	14F23D0206	(01)30801902210631(17)280430(10)14F23D0206
RA-04220	14F23D0207	(01)30801902210631(17)280430(10)14F23D0207
RA-04220	14F23E0093	(01)30801902210631(17)280430(10)14F23E0093
RA-04220	14F23E0094	(01)30801902210631(17)280430(10)14F23E0094
RA-04220	14F23E0210	(01)30801902210631(17)280430(10)14F23E0210
RA-04220	14F23E0211	(01)30801902210631(17)280430(10)14F23E0211
RA-04220	14F23F0036	(01)30801902210631(17)280531(10)14F23F0036

## 附录 2: EIF-000556 召回在中国受影响的产品清单

产品型号	批号	医疗器械唯一标识
RA-04220	14F23F0037	(01)30801902210631(17)280531(10)14F23F0037
RA-04220	14F23F0038	(01)30801902210631(17)280531(10)14F23F0038
RA-04220	14F23F0252	(01)30801902210631(17)280531(10)14F23F0252
RA-04220	14F23F0253	(01)30801902210631(17)280531(10)14F23F0253
RA-04220	14F23F0377	(01)30801902210631(17)280630(10)14F23F0377
RA-04220	14F23F0378	(01)30801902210631(17)280630(10)14F23F0378
RA-04220	14F23F0379	(01)30801902210631(17)280630(10)14F23F0379
RA-04220	14F23G0147	(01)30801902210631(17)280630(10)14F23G0147
RA-04220	14F23G0148	(01)30801902210631(17)280630(10)14F23G0148
RA-04220	14F23G0149	(01)30801902210631(17)280630(10)14F23G0149
RA-04220	14F23G0150	(01)30801902210631(17)280630(10)14F23G0150
RA-04220	14F23G0151	(01)30801902210631(17)280630(10)14F23G0151
RA-04220	14F23G0252	(01)30801902210631(17)280630(10)14F23G0252
RA-04220	14F23H0087	(01)30801902210631(17)280731(10)14F23H0087
RA-04220	14F23H0088	(01)30801902210631(17)280731(10)14F23H0088
RA-04220	14F23H0089	(01)30801902210631(17)280731(10)14F23H0089
RA-04220	14F23H0090	(01)30801902210631(17)280731(10)14F23H0090
RA-04220	14F23H0163	(01)30801902210631(17)280731(10)14F23H0163
RA-04220	14F23H0253	(01)30801902210631(17)280731(10)14F23H0253
RA-04220	14F23H0254	(01)30801902210631(17)280731(10)14F23H0254
RA-04220	14F23H0255	(01)30801902210631(17)280731(10)14F23H0255
RA-04220	14F23J0031	(01)30801902210631(17)280831(10)14F23J0031
RA-04220	14F23J0032	(01)30801902210631(17)280831(10)14F23J0032
RA-04220	14F23J0137	(01)30801902210631(17)280831(10)14F23J0137
RA-04220	14F23J0138	(01)30801902210631(17)280831(10)14F23J0138
RA-04220	14F23J0276	(01)30801902210631(17)280930(10)14F23J0276
RA-04220	14F23J0277	(01)30801902210631(17)280930(10)14F23J0277

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