

Arrow International LLC
 3015 Carrington Mill Blvd.
 Morrisville, NC 27560

May-2023

URGENT MEDICAL DEVICE RECALL

Type of Action	Recall Notice		
Teleflex Reference	EIF-000538		
Product Code & Batch/Lot Number	Refer to Appendix 2		
Commercial Name	Product Codes		
Arrow Endurance™ Extended Dwell Peripheral Catheter System	ASK-00620-MSH	ASK-00620-TMC	ASK-00622-MSH
	ASK-00818-IVA	ASK-00820-FLH	ASK-00820-TMC
	EDC-00620	EDC-00620-B	EDC-00622
	EDC-00622-B	EDC-00818	EDC-00818-B
	EDC-00820	EDC-00820-B	EDC-00822
	EDC-00822-B		

Dear Customer,

Details of affected devices

Arrow International LLC, a subsidiary of Teleflex Incorporated, has initiated a voluntary recall for the above listed products; refer to Appendix 2 for Unique Device Identifier (“UDI”) and lot number information.

Description of the problem & immediate actions required

This voluntary recall has been initiated due to reports of catheter separation or leakage. If the catheter separates while in venous or arterial use, the catheter fragments could be left inside the patient’s bloodstream, where they may migrate. This could possibly lead to serious adverse health consequences such as blockage of blood vessels, ischemia, injury to blood vessel walls, development of blood clots, pulmonary embolism, heart attack or death. Some situations may require medical or surgical intervention.

Between May 2018 and May 2023, Teleflex received 83 complaints reporting separations and leakage. No deaths or long-term patient injuries have been reported at this time.

For current indwelling devices, Teleflex recommends that clinical staff weigh the benefits versus risks of removing and replacing the device.

Our records indicate 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 (hospitals, medical staff, etc.)	1
Distributors	2

Action list number 1 – Medical facilities

1. We request that you immediately check your inventory for product within the scope of this recall. **Users should immediately cease use and distribution of affected product and immediately quarantine the affected product.**
2. If you have affected product, mark the applicable checkbox on the Acknowledgement Form (Appendix 1) and fax it to 1-855-419-8507, including “Attn: Customer Service”, or e-mail it to recalls@teleflex.com. This will allow us to document the amount of affected product you have on hand for return. A customer service representative will contact you with a Return Goods Authorization (RGA) number and will provide instructions for the return of affected products to Teleflex.
3. If you do not have affected product, mark the applicable checkbox on the Acknowledgement Form (Appendix 1) and return the form to Teleflex at the contact details provided.
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 a copy of this recall notice to all customers who have received impacted product. Each of your customers is then required to complete the Acknowledgement Form and return it to you.
2. We request that you immediately check your inventory for affected product. **Immediately cease use and distribution of, and immediately quarantine, the affected product.** You may then return all product in scope.
3. As a distributor, you are then required to confirm to Teleflex that you have completed the field activity outlined in actions 1 and 2 of this Action List Number 2. Upon completion of your actions, please forward the completed Acknowledgement Form to the e-mail address below. **Important** - Please ensure you only list batch numbers in scope of this recall notice when completing this form.
4. If you have further distributed product outside of your country, please notify Teleflex Customer Service by return e-mail to the e-mail address below.

Adverse reactions or quality problems experienced with the use of this product should be reported to Teleflex Customer Service using the contact information below or may also be reported to the FDA’s MedWatch Adverse Event Reporting program either by phone at [1-888-INFO-FDA \(1-888-463-6332\)](tel:1-888-INFO-FDA) or online at <https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program>.

Transmission of this Field Safety Notice

This notice should be passed on to all persons who need to be aware within your organization or to any organization 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. Please maintain awareness of this notice until all required actions have been completed in your organization.

Contact reference person

Should you require further information or support concerning this issue, please contact Customer Service via email, phone, or FAX using the details provided below. Customer Service hours of operation are 8am–7pm EST.

Customer Service:

Contact: Customer Service

FAX: 1-855-419-8507

Telephone: 1-866-396-2111

Email: Recalls@teleflex.com

Teleflex is committed to providing high quality, safe and effective products. We regret any inconvenience this action may cause your operations. If you have any other questions, please contact your local Teleflex sales representative or Teleflex Customer Service.

For and on behalf of Teleflex,

Padraig Hegarty

Padraig Hegarty VP, Global QA (Manufacturing)

Appendix 1

Consignee No

RECALL
ACKNOWLEDGEMENT FORM

MEDICAL DEVICE RECALL BY TELEFLEX – IMMEDIATE ATTENTION REQUIRED
Ref. EIF-000538

RETURN COMPLETED FORM IMMEDIATELY TO:

E-mail: Recalls@teleflex.com

<input type="checkbox"/> We confirm receipt of this recall notice and completion of the required actions contained therein. We further confirm that our inventory does NOT include products impacted by this recall.	<input type="checkbox"/> We confirm receipt of this recall notice and completion of the required actions contained therein. We further confirm our inventory DOES include products impacted by this recall. The use and further distribution of the affected products is stopped. All products are put on hold and the amount below will be returned.
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Complete this Acknowledgement Form and return the completed form immediately using the contact information above.

Product code	Lot/batch number	Quantity returning
Important - Please ensure you only list batch numbers in scope of this Field Safety Notice when completing this form.		
<ul style="list-style-type: none"> •Include a copy of the completed Acknowledgement Form in the returns package with the returned units •Please label returns as "Field Safety Returns" 		

INSTITUTION NAME (E.G., NAME OF HOSPITAL, HEALTH CARE ORGANIZATION)	
INSTITUTION ADDRESS	PHONE/FAX
FORM COMPLETED BY	E-MAIL
PRINT NAME: _____	
SIGNATURE: _____	
DATE	

Appendix 2: Product in scope of EIF-000538

Product Code	Batch	Unique Device Identifier (UDI)
ASK-00620-MSH	13F22H0910	(01)10801902212105 (17)240630 (11)220914 (10)13F22H0910
ASK-00620-MSH	13F22L0492	(01)10801902212105 (17)240630 (11)221118 (10)13F22L0492
ASK-00620-TMC	13F21J0257	(01)10801902193022 (17)230531 (10)13F21J0257
ASK-00620-TMC	13F22E0014	(01)10801902193022 (17)230731 (11)220511 (10)13F22E0014
ASK-00620-TMC	13F22E0263	(01)10801902193022 (17)230731 (11)220527 (10)13F22E0263
ASK-00620-TMC	13F22G0191	(01)10801902193022 (17)240229 (11)220729 (10)13F22G0191
ASK-00620-TMC	13F22K0352	(01)10801902193022 (17)240430 (11)221012 (10)13F22K0352
ASK-00620-TMC	13F23A0220	(01)10801902193022 (17)240430 (11)230113 (10)13F23A0220
ASK-00620-TMC	33F23B1020	(01)10801902193022 (17)240731 (11)230309 (10)33F23B1020
ASK-00622-MSH	13F22H0912	(01)10801902212112 (17)240630 (11)220909 (10)13F22H0912
ASK-00622-MSH	13F22L0361	(01)10801902212112 (17)240630 (11)221114 (10)13F22L0361
ASK-00818-IVA	13F21L0242	(01)10801902144499 (17)231031 (10)13F21L0242
ASK-00818-IVA	13F22C0480	(01)10801902144499 (17)240229 (11)220324 (10)13F22C0480
ASK-00820-FLH	13F22A0808	(01)10801902146318 (17)230630 (11)220124 (10)13F22A0808
ASK-00820-FLH	13F22E0250	(01)10801902146318 (17)230930 (11)220530 (10)13F22E0250
ASK-00820-FLH	13F22F0034	(01)10801902146318 (17)231231 (11)220606 (10)13F22F0034
ASK-00820-FLH	13F22K1112	(01)10801902146318 (17)240331 (11)221107 (10)13F22K1112
ASK-00820-FLH	13F22L0530	(01)10801902146318 (17)240331 (11)221122 (10)13F22L0530
ASK-00820-FLH	33F23B1019	(01)10801902146318 (17)240831 (11)230309 (10)33F23B1019
ASK-00820-TMC	13F22B0679	(01)10801902192988 (17)230731 (11)220309 (10)13F22B0679
ASK-00820-TMC	13F22C0817	(01)10801902192988 (17)230731 (11)220412 (10)13F22C0817
ASK-00820-TMC	13F22E0442	(01)10801902192988 (17)230731 (11)220527 (10)13F22E0442
ASK-00820-TMC	13F22F0601	(01)10801902192988 (17)230731 (11)220715 (10)13F22F0601
ASK-00820-TMC	13F22J0341	(01)10801902192988 (17)240229 (11)220924 (10)13F22J0341
ASK-00820-TMC	13F22K1113	(01)10801902192988 (17)240430 (11)221107 (10)13F22K1113
ASK-00820-TMC	13F22L0266	(01)10801902192988 (17)240430 (11)221114 (10)13F22L0266
ASK-00820-TMC	13F22L0910	(01)10801902192988 (17)240430 (11)221206 (10)13F22L0910
ASK-00820-TMC	33F23B1025	(01)10801902192988 (17)240731 (11)230309 (10)33F23B1025
EDC-00620	14F18H0260	(01)10801902132908 (17)230831 (10)14F18H0260
EDC-00620	14F18H0451	(01)10801902132908 (17)230831 (10)14F18H0451
EDC-00620	14F18K0137	(01)10801902132908 (17)200930 (10)14F18K0137
EDC-00620	14F18L0078	(01)10801902132908 (17)231031 (10)14F18L0078
EDC-00620	14F18M0028	(01)10801902132908 (17)201130 (10)14F18M0028
EDC-00620	14F21E0292	(01)10801902132908 (17)230531 (10)14F21E0292
EDC-00620	14F21F0075	(01)10801902132908 (17)230531 (10)14F21F0075
EDC-00620	14F21F0129	(01)10801902132908 (17)230531 (10)14F21F0129
EDC-00620	14F21F0250	(01)10801902132908 (17)230731 (10)14F21F0250
EDC-00620	14F21G0240	(01)10801902132908 (17)230731 (10)14F21G0240
EDC-00620	14F21H0189	(01)10801902132908 (17)230731 (10)14F21H0189
EDC-00620	14F21H0220	(01)10801902132908 (17)230831 (10)14F21H0220
EDC-00620	14F21J0112	(01)10801902132908 (17)230831 (10)14F21J0112
EDC-00620	14F21J0169	(01)10801902132908 (17)230930 (10)14F21J0169
EDC-00620	14F21K0030	(01)10801902132908 (17)230930 (10)14F21K0030

Appendix 2: Product in scope of EIF-000538

Product Code	Batch	Unique Device Identifier (UDI)
EDC-00620	14F21K0053	(01)10801902132908 (17)230930 (10)14F21K0053
EDC-00620	14F21L0209	(01)10801902132908 (17)231031 (10)14F21L0209
EDC-00620	14F21L0210	(01)10801902132908 (17)231031 (10)14F21L0210
EDC-00620	14F21L0211	(01)10801902132908 (17)231031 (10)14F21L0211
EDC-00620	14F21M0098	(01)10801902196368 (17)231231 (10)14F21M0098
EDC-00620	14F21M0099	(01)10801902196368 (17)231231 (10)14F21M0099
EDC-00620	14F22A0008	(01)10801902196368 (17)231231 (10)14F22A0008
EDC-00620	14F22C0097	(01)10801902196368 (17)240229 (10)14F22C0097
EDC-00620	14F22C0098	(01)10801902196368 (17)240229 (10)14F22C0098
EDC-00620	14F22C0099	(01)10801902196368 (17)240229 (10)14F22C0099
EDC-00620	14F22C0100	(01)10801902196368 (17)240229 (10)14F22C0100
EDC-00620	14F22C0270	(01)10801902196368 (17)240229 (10)14F22C0270
EDC-00620	14F22C0271	(01)10801902196368 (17)240331 (10)14F22C0271
EDC-00620	14F22C0272	(01)10801902196368 (17)240331 (10)14F22C0272
EDC-00620	14F22D0083	(01)10801902196368 (17)240331 (10)14F22D0083
EDC-00620	14F22D0084	(01)10801902196368 (17)240331 (10)14F22D0084
EDC-00620	14F22E0009	(01)10801902196368 (17)240430 (10)14F22E0009
EDC-00620	14F22E0068	(01)10801902196368 (17)240430 (10)14F22E0068
EDC-00620	14F22E0125	(01)10801902132908 (17)240430 (10)14F22E0125
EDC-00620	14F22F0071	(01)10801902196368 (17)240531 (10)14F22F0071
EDC-00620	14F22F0333	(01)10801902196368 (17)240630 (10)14F22F0333
EDC-00620	14F22G0051	(01)10801902196368 (17)240630 (10)14F22G0051
EDC-00620	14F22G0052	(01)10801902196368 (17)240630 (10)14F22G0052
EDC-00620	14F22G0217	(01)10801902196368 (17)240731 (10)14F22G0217
EDC-00620	14F22G0218	(01)10801902196368 (17)240731 (10)14F22G0218
EDC-00620	14F22H0342	(01)10801902196368 (17)240831 (10)14F22H0342
EDC-00620	14F22J0279	(01)10801902196368 (17)240930 (10)14F22J0279
EDC-00620	14F22K0061	(01)10801902196368 (17)240930 (10)14F22K0061
EDC-00620	14F22K0210	(01)10801902196368 (17)241031 (10)14F22K0210
EDC-00620	14F22L0027	(01)10801902196368 (17)241031 (10)14F22L0027
EDC-00620	14F22L0028	(01)10801902196368 (17)241031 (10)14F22L0028
EDC-00620	14F22L0070	(01)10801902196368 (17)241031 (10)14F22L0070
EDC-00620	14F22L0071	(01)10801902196368 (17)241031 (10)14F22L0071
EDC-00620	14F22L0161	(01)10801902196368 (17)241130 (10)14F22L0161
EDC-00620	14F23A0058	(01)10801902196368 (17)241231 (10)14F23A0058
EDC-00620	14F23A0174	(01)10801902196368 (17)241231 (10)14F23A0174
EDC-00620	14F23A0175	(01)10801902196368 (17)241231 (10)14F23A0175
EDC-00620	14F23A0176	(01)10801902196368 (17)241231 (10)14F23A0176
EDC-00620	14F23A0177	(01)10801902196368 (17)241231 (10)14F23A0177
EDC-00620	14F23A0308	(01)10801902196368 (17)241231 (10)14F23A0308
EDC-00620	14F23B0201	(01)10801902196368 (17)250131 (10)14F23B0201
EDC-00620-B	13F21E0852	(01)10801902133004 (17)230531 (10)13F21E0852
EDC-00620-B	13F21F0212	(01)10801902133004 (17)230531 (10)13F21F0212

Appendix 2: Product in scope of EIF-000538

Product Code	Batch	Unique Device Identifier (UDI)
EDC-00620-B	13F21F0523	(01)10801902133004 (17)230531 (10)13F21F0523
EDC-00620-B	13F21G1197	(01)10801902133004 (17)230630 (10)13F21G1197
EDC-00620-B	13F21H1179	(01)10801902133004 (17)230831 (10)13F21H1179
EDC-00620-B	13F21J0282	(01)10801902133004 (17)230831 (10)13F21J0282
EDC-00620-B	13F21K0896	(01)10801902133004 (17)230930 (10)13F21K0896
EDC-00620-B	13F21M0122	(01)10801902133004 (17)231130 (10)13F21M0122
EDC-00620-B	13F22A0152	(01)10801902133004 (17)231231 (10)13F22A0152
EDC-00620-B	13F22B0677	(01)10801902133004 (17)240229 (10)13F22B0677
EDC-00620-B	13F22E0261	(01)10801902133004 (17)240430 (10)13F22E0261
EDC-00620-B	13F22G0196	(01)10801902133004 (17)240630 (10)13F22G0196
EDC-00620-B	13F22K0354	(01)10801902133004 (17)240930 (10)13F22K0354
EDC-00620-B	13F22K0563	(01)10801902133004 (17)240930 (10)13F22K0563
EDC-00620-B	13F22M0126	(01)10801902133004 (17)241130 (11)221214 (10)13F22M0126
EDC-00620-B	13F22M0468	(01)10801902133004 (17)241231 (11)230105 (10)13F22M0468
EDC-00620-B	33F23B1021	(01)10801902133004 (17)250228 (11)230310 (10)33F23B1021
EDC-00622	14F21D0276	(01)10801902132922 (17)230531 (10)14F21D0276
EDC-00622	14F21F0151	(01)10801902132922 (17)230531 (10)14F21F0151
EDC-00622	14F21G0117	(01)10801902132922 (17)230630 (10)14F21G0117
EDC-00622	14F21G0286	(01)10801902132922 (17)230731 (10)14F21G0286
EDC-00622	14F21H0218	(01)10801902132922 (17)230831 (10)14F21H0218
EDC-00622	14F21J0111	(01)10801902132922 (17)230831 (10)14F21J0111
EDC-00622	14F21K0051	(01)10801902132922 (17)230930 (10)14F21K0051
EDC-00622	14F21L0212	(01)10801902132922 (17)231130 (10)14F21L0212
EDC-00622	14F21L0218	(01)10801902132922 (17)231130 (10)14F21L0218
EDC-00622	14F21M0101	(01)10801902196375 (17)231231 (10)14F21M0101
EDC-00622	14F22A0055	(01)10801902196375 (17)231231 (10)14F22A0055
EDC-00622	14F22C0101	(01)10801902196375 (17)240229 (10)14F22C0101
EDC-00622	14F22E0008	(01)10801902196375 (17)240430 (10)14F22E0008
EDC-00622	14F22F0152	(01)10801902196375 (17)240531 (10)14F22F0152
EDC-00622	14F22G0219	(01)10801902196375 (17)240731 (10)14F22G0219
EDC-00622	14F22G0243	(01)10801902196375 (17)240731 (10)14F22G0243
EDC-00622	14F22J0148	(01)10801902196375 (17)240831 (10)14F22J0148
EDC-00622	14F22K0211	(01)10801902196375 (17)241031 (10)14F22K0211
EDC-00622	14F22M0119	(01)10801902196375 (17)241130 (10)14F22M0119
EDC-00622	14F23A0072	(01)10801902196375 (17)241231 (10)14F23A0072
EDC-00622-B	13F21J0635	(01)10801902133028 (17)230831 (10)13F21J0635
EDC-00622-B	13F22E0264	(01)10801902133028 (17)240430 (10)13F22E0264
EDC-00622-B	13F22J0565	(01)10801902133028 (17)240831 (11)220928 (10)13F22J0565
EDC-00622-B	13F22K1119	(01)10801902133028 (17)241031 (11)221103 (10)13F22K1119
EDC-00622-B	13F22M0124	(01)10801902133028 (17)241130 (11)221214 (10)13F22M0124
EDC-00622-B	13F22M0459	(01)10801902133028 (17)241130 (11)230102 (10)13F22M0459
EDC-00818	14F21F0077	(01)10801902132946 (17)230531 (10)14F21F0077
EDC-00818	14F21G0241	(01)10801902132946 (17)230731 (10)14F21G0241

Appendix 2: Product in scope of EIF-000538

Product Code	Batch	Unique Device Identifier (UDI)
EDC-00818	14F21H0187	(01)10801902132946 (17)230731 (10)14F21H0187
EDC-00818	14F21H0219	(01)10801902132946 (17)230831 (10)14F21H0219
EDC-00818	14F21J0110	(01)10801902132946 (17)230831 (10)14F21J0110
EDC-00818	14F21J0170	(01)10801902132946 (17)231031 (10)14F21J0170
EDC-00818	14F21K0054	(01)10801902132946 (17)230930 (10)14F21K0054
EDC-00818	14F21L0213	(01)10801902132946 (17)231130 (10)14F21L0213
EDC-00818	14F21L0214	(01)10801902132946 (17)231130 (10)14F21L0214
EDC-00818	14F21L0219	(01)10801902132946 (17)231130 (10)14F21L0219
EDC-00818	14F22A0189	(01)10801902196382 (17)231231 (10)14F22A0189
EDC-00818	14F22A0190	(01)10801902196382 (17)231231 (10)14F22A0190
EDC-00818	14F22C0102	(01)10801902196382 (17)240229 (10)14F22C0102
EDC-00818	14F22C0103	(01)10801902196382 (17)240229 (10)14F22C0103
EDC-00818	14F22C0104	(01)10801902196382 (17)240229 (10)14F22C0104
EDC-00818	14F22D0101	(01)10801902196382 (17)240331 (10)14F22D0101
EDC-00818	14F22E0010	(01)10801902196382 (17)240430 (10)14F22E0010
EDC-00818	14F22F0005	(01)10801902132946 (17)240531 (10)14F22F0005
EDC-00818	14F22F0006	(01)10801902196382 (17)240531 (10)14F22F0006
EDC-00818	14F22F0089	(01)10801902196382 (17)240531 (10)14F22F0089
EDC-00818	14F22G0123	(01)10801902196382 (17)240630 (10)14F22G0123
EDC-00818	14F22H0344	(01)10801902196382 (17)240831 (10)14F22H0344
EDC-00818	14F22J0208	(01)10801902196382 (17)240831 (10)14F22J0208
EDC-00818	14F22K0128	(01)10801902196382 (17)240930 (10)14F22K0128
EDC-00818	14F22K0129	(01)10801902196382 (17)240930 (10)14F22K0129
EDC-00818	14F22K0212	(01)10801902196382 (17)241031 (10)14F22K0212
EDC-00818	14F22K0213	(01)10801902196382 (17)241031 (10)14F22K0213
EDC-00818	14F23A0180	(01)10801902196382 (17)241231 (10)14F23A0180
EDC-00818	14F23A0309	(01)10801902196382 (17)241231 (10)14F23A0309
EDC-00818	14F23B0330	(01)10801902196382 (17)250228 (10)14F23B0330
EDC-00818-B	13F21F1022	(01)10801902133042 (17)230531 (10)13F21F1022
EDC-00818-B	13F21J0283	(01)10801902133042 (17)230831 (10)13F21J0283
EDC-00818-B	13F21K0047	(01)10801902133042 (17)230930 (10)13F21K0047
EDC-00818-B	13F21L0653	(01)10801902133042 (17)231031 (10)13F21L0653
EDC-00818-B	13F21M0598	(01)10801902133042 (17)231231 (10)13F21M0598
EDC-00818-B	13F22C0492	(01)10801902133042 (17)240229 (10)13F22C0492
EDC-00818-B	13F22E0440	(01)10801902133042 (17)240430 (10)13F22E0440
EDC-00818-B	13F22J0572	(01)10801902133042 (17)240831 (11)220923 (10)13F22J0572
EDC-00818-B	13F22K0681	(01)10801902133042 (17)240930 (11)221021 (10)13F22K0681
EDC-00818-B	13F22L0279	(01)10801902133042 (17)241031 (11)221114 (10)13F22L0279
EDC-00818-B	13F22M0125	(01)10801902133042 (17)241130 (11)221213 (10)13F22M0125
EDC-00818-B	33F23B1023	(01)10801902133042 (17)250228 (11)230309 (10)33F23B1023
EDC-00820	14F18H0447	(01)10801902132960 (17)230831 (10)14F18H0447
EDC-00820	14F21E0293	(01)10801902132960 (17)230531 (10)14F21E0293
EDC-00820	14F21F0076	(01)10801902132960 (17)230531 (10)14F21F0076

Appendix 2: Product in scope of EIF-000538

Product Code	Batch	Unique Device Identifier (UDI)
EDC-00820	14F21F0253	(01)10801902132960 (17)230731 (10)14F21F0253
EDC-00820	14F21G0239	(01)10801902132960 (17)230731 (10)14F21G0239
EDC-00820	14F21J0114	(01)10801902132960 (17)231031 (10)14F21J0114
EDC-00820	14F21J0372	(01)10801902132960 (17)230930 (10)14F21J0372
EDC-00820	14F21K0052	(01)10801902132960 (17)230930 (10)14F21K0052
EDC-00820	14F21L0138	(01)10801902132960 (17)231031 (10)14F21L0138
EDC-00820	14F21L0139	(01)10801902132960 (17)231031 (10)14F21L0139
EDC-00820	14F21L0215	(01)10801902132960 (17)231130 (10)14F21L0215
EDC-00820	14F21L0216	(01)10801902132960 (17)231130 (10)14F21L0216
EDC-00820	14F21L0220	(01)10801902132960 (17)231130 (10)14F21L0220
EDC-00820	14F21M0014	(01)10801902132960 (17)231130 (10)14F21M0014
EDC-00820	14F22C0105	(01)10801902196399 (17)240229 (10)14F22C0105
EDC-00820	14F22C0106	(01)10801902196399 (17)240229 (10)14F22C0106
EDC-00820	14F22C0107	(01)10801902196399 (17)240229 (10)14F22C0107
EDC-00820	14F22C0108	(01)10801902196399 (17)240229 (10)14F22C0108
EDC-00820	14F22C0109	(01)10801902196399 (17)240229 (10)14F22C0109
EDC-00820	14F22C0110	(01)10801902196399 (17)240229 (10)14F22C0110
EDC-00820	14F22D0085	(01)10801902196399 (17)240331 (10)14F22D0085
EDC-00820	14F22D0086	(01)10801902196399 (17)240331 (10)14F22D0086
EDC-00820	14F22D0087	(01)10801902196399 (17)240331 (10)14F22D0087
EDC-00820	14F22E0114	(01)10801902196399 (17)240430 (10)14F22E0114
EDC-00820	14F22E0117	(01)10801902196399 (17)240430 (10)14F22E0117
EDC-00820	14F22F0008	(01)10801902132960 (17)240531 (10)14F22F0008
EDC-00820	14F22F0090	(01)10801902196399 (17)240531 (10)14F22F0090
EDC-00820	14F22G0124	(01)10801902196399 (17)240630 (10)14F22G0124
EDC-00820	14F22G0125	(01)10801902196399 (17)240630 (10)14F22G0125
EDC-00820	14F22H0345	(01)10801902196399 (17)240831 (10)14F22H0345
EDC-00820	14F22K0030	(01)10801902196399 (17)240930 (10)14F22K0030
EDC-00820	14F22K0159	(01)10801902196399 (17)240930 (10)14F22K0159
EDC-00820	14F22K0222	(01)10801902196399 (17)241031 (10)14F22K0222
EDC-00820	14F22L0072	(01)10801902196399 (17)241031 (10)14F22L0072
EDC-00820	14F22M0039	(01)10801902196399 (17)241130 (10)14F22M0039
EDC-00820	14F22M0040	(01)10801902196399 (17)241130 (10)14F22M0040
EDC-00820	14F22M0117	(01)10801902196399 (17)241130 (10)14F22M0117
EDC-00820	14F22M0118	(01)10801902196399 (17)241130 (10)14F22M0118
EDC-00820	14F23A0178	(01)10801902196399 (17)241231 (10)14F23A0178
EDC-00820	14F23A0310	(01)10801902196399 (17)241231 (10)14F23A0310
EDC-00820	14F23A0311	(01)10801902196399 (17)241231 (10)14F23A0311
EDC-00820	14F23B0326	(01)10801902196399 (17)250228 (10)14F23B0326
EDC-00820	14F23B0327	(01)10801902196399 (17)250228 (10)14F23B0327
EDC-00820-B	13F21E0851	(01)10801902133066 (17)230531 (10)13F21E0851
EDC-00820-B	13F21F0214	(01)10801902133066 (17)230531 (10)13F21F0214
EDC-00820-B	13F21F0524	(01)10801902133066 (17)230531 (10)13F21F0524

Appendix 2: Product in scope of EIF-000538

Product Code	Batch	Unique Device Identifier (UDI)
EDC-00820-B	13F21F1021	(01)10801902133066 (17)230531 (10)13F21F1021
EDC-00820-B	13F21G1201	(01)10801902133066 (17)230630 (10)13F21G1201
EDC-00820-B	13F21H0533	(01)10801902133066 (17)230731 (10)13F21H0533
EDC-00820-B	13F21H0824	(01)10801902133066 (17)230731 (10)13F21H0824
EDC-00820-B	13F21J0067	(01)10801902133066 (17)230831 (10)13F21J0067
EDC-00820-B	13F21J0597	(01)10801902133066 (17)230831 (10)13F21J0597
EDC-00820-B	13F21K0048	(01)10801902133066 (17)230930 (10)13F21K0048
EDC-00820-B	13F21L0427	(01)10801902133066 (17)231031 (10)13F21L0427
EDC-00820-B	13F21M0283	(01)10801902133066 (17)231130 (10)13F21M0283
EDC-00820-B	13F22A1064	(01)10801902133066 (17)240131 (10)13F22A1064
EDC-00820-B	13F22E0183	(01)10801902133066 (17)240430 (10)13F22E0183
EDC-00820-B	13F22G0461	(01)10801902133066 (17)240630 (11)220718 (10)13F22G0461
EDC-00820-B	13F22J0599	(01)10801902133028 (17)241130 (11)230102 (10)13F22M0459
EDC-00820-B	13F22K1046	(01)10801902133066 (17)240930 (11)221028 (10)13F22K1046
EDC-00820-B	13R22J0599	(01)10801902133066 (17)241031 (11)221115 (10)13R22J0599
EDC-00820-B	33F23B1066	(01)10801902133066 (17)250228 (11)230308 (10)33F23B1066
EDC-00820-B	33F23C0237	(01)10801902133066 (17)250228 (11)230328 (10)33F23C0237
EDC-00820-B	33F23C0974	(01)10801902133066 (17)250331 (11)230404 (10)33F23C0974
EDC-00822	14F21G0118	(01)10801902132984 (17)230731 (10)14F21G0118
EDC-00822	14F21H0188	(01)10801902132984 (17)230731 (10)14F21H0188
EDC-00822	14F21L0217	(01)10801902132984 (17)231130 (10)14F21L0217
EDC-00822	14F22D0102	(01)10801902196405 (17)240331 (10)14F22D0102
EDC-00822	14F23A0063	(01)10801902196405 (17)241231 (10)14F23A0063
EDC-00822	14F23B0128	(01)10801902196405 (17)250131 (10)14F23B0128
EDC-00822-B	13F21K0049	(01)10801902133080 (17)230930 (10)13F21K0049
EDC-00822-B	13F21L0020	(01)10801902133080 (17)231031 (10)13F21L0020
EDC-00822-B	13F22E0443	(01)10801902133080 (17)240430 (10)13F22E0443
EDC-00822-B	13F22J0463	(01)10801902133080 (17)240831 (11)220924 (10)13F22J0463
EDC-00822-B	13F22K0572	(01)10801902133080 (17)240930 (11)221021 (10)13F22K0572
EDC-00822-B	13F22L0388	(01)10801902133080 (17)241031 (11)221115 (10)13F22L0388
EDC-00822-B	13R22H0448	(01)10801902133080 (17)240831 (11)220922 (10)13R22H0448

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