

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

April-2026

**URGENT – FIELD SAFETY NOTICE**

<b>Type of Action</b>	<b>Recall – Removal</b>	
<b>Teleflex Reference</b>	EIF-000605	
<b>Product Name</b>	Arrow Edge® Hemodialysis Catheterization Product	
	Arrow-Clark™ VectorFlow™ Antegrade Chronic Hemodialysis Catheter	
	Arrow-Clark™ VectorFlow™ Retrograde Chronic Hemodialysis Catheter	
	Cannon® II Plus Chronic Hemodialysis Catheter	
	NextStep® Antegrade Chronic Hemodialysis Catheter	
	NextStep® Retrograde Chronic Hemodialysis Catheter	
<b>Product Code, Batch/Lot Number and Unique Device Identifier (UDI)</b>		Refer to Appendix 2
<b>A copy of this FSN &amp; an option to submit the Acknowledgement electronically can be found using the below link.</b>		
<b>FSN Portal Link</b>	Ireland-English: <a href="https://fca.myteleflex.com/en_GB/recall/000605">https://fca.myteleflex.com/en_GB/recall/000605</a>	

Dear Customer,

**Details of affected devices**

Arrow International LLC, a subsidiary of Teleflex Incorporated, received the attached Field Safety Notice (FSN) from Merit Medical Systems, Inc. (Merit), announcing a recall of the Merit 16F Dual-Valved Splittable Sheath Introducer. (refer to **Appendix 3**). As such Arrow International LLC is initiating a voluntary Field Safety Corrective Action (“FSCA”) for specific production lots of the above listed products, which contain affected sheath introducer components.

Refer to **Appendix 2** for Product Code, Lot Number and Unique Device Identifier (UDI) information.

**Description of the issue & immediate actions required**

Arrow International LLC is voluntarily recalling the product referenced above due to a supplier-initiated recall of the Merit 16F Dual-Valved Splittable Sheath Introducer component, which is included in impacted Arrow Hemodialysis Kits & Sets. According to the Merit FSN, in some cases the sheath introducer may not split as intended due to a design related issue.

Use of a sheath introducer that does not split as intended during removal may result in immediate procedural complications, such as resistance during withdrawal, prolonged procedure time, localised pain, minor bleeding, hematoma, or superficial tissue injury. Application of excessive force during removal may lead to vessel wall injury or significant bleeding requiring medical or surgical intervention. Long-term health consequences are not anticipated, as the malfunction occurs during removal of the sheath introducer and would be promptly recognised and managed by trained healthcare professionals.

As of 24-Feb-2026, Teleflex has received a total of 33 complaints, for products in scope of this Field Safety Notice, in which users reported difficulty peeling away the sheath or that the sheath did not tear as intended. Of these 33 complaints, no complaints reported patient injury.

Our records indicate you have received products that are in scope of this Field Safety Notification.

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

Device location	Action List Number
Medical facilities (hospitals, medical staff, etc.)	<b>1</b>
Distributors	<b>2</b>

**Action list number 1 – Medical facilities**

1. We request that you immediately check your inventory for product within the scope of this FSCA. **Users should 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 contact Teleflex Customer Service utilising **one** of the following methods:
  - a. Call or email customer service using the point of contact details outlined on Page 3 with a copy of Appendix 1  
**OR**
  - b. Using the online FSN Portal, complete the acknowledgement form virtually using the following link: [https://fca.myteleflex.com/en\\_GB/recall/000605](https://fca.myteleflex.com/en_GB/recall/000605)  
**Note: Option B is solely applicable to customers who received product direct from 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 field safety 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 as their distributor.
2. We request that you immediately check your inventory for affected product. **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 field safety notice when completing this form.
4. If you have further distributed product outside of your country, please notify Teleflex Customer Service by return email to the email address provided below.
5. If you are a distributor and/or have a reporting responsibility within or outside the EEA/CH/UK/TR area, please notify your local Competent Authority of this action. Please forward the notification confirmation and all communication with your local competent authority to Teleflex.

**Note: Should a Teleflex distributor wish to submit their acknowledgement form virtually this can be done so using the following link: [https://fca.myteleflex.com/en\\_GB/recall/000605](https://fca.myteleflex.com/en_GB/recall/000605)**

Adverse reactions or quality problems experienced with the use of this product should be reported to Teleflex Customer Service at the contact information below.

**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:

**Teleflex Point of Contact:**

**Contact:** Clíodhna Coffey

**Telephone:** + 44 1494 532 761

**Email:** [recalls.uk@teleflex.com](mailto:recalls.uk@teleflex.com)

**FSN Portal Link: Ireland, English:** [https://fca.myteleflex.com/en\\_GB/recall/000605](https://fca.myteleflex.com/en_GB/recall/000605)

Teleflex is committed to providing high quality, safe and effective products. We sincerely regret 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.

The undersign confirms this notice has been notified to the appropriate Regulatory Authority.

*For and on behalf of Teleflex,*

*Padraig Hegarty*

*Padraig Hegarty, VP Global Product Quality Assurance & Strategic Projects*

**Appendix 1**

**FIELD SAFETY CORRECTIVE ACTION  
ACKNOWLEDGEMENT FORM**

**Customer No**  
\_\_\_\_\_

**PRODUCT FIELD ACTION BY TELEFLEX – IMMEDIATE ATTENTION REQUIRED**

Ref. EIF-000605

**RETURN COMPLETED FORM IMMEDIATELY TO:**

**E-mail:** [recalls.UK@teleflex.com](mailto:recalls.UK@teleflex.com)

<input type="checkbox"/> We confirm receipt of this recall notice and completion of the required actions contained therein. We confirm that our inventory does <b>NOT</b> 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 confirm our inventory <b>DOES</b> include products impacted by this recall. The use and further distribution of the affected products is stopped. All products are on hold and the amount below will be returned.
---	--

**Complete this Acknowledgement form and return immediately by using the contact information above.**

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

<b>INSTITUTION NAME (E.G., NAME OF HOSPITAL, HEALTH CARE ORGANISATION)</b>	
<b>INSTITUTION ADDRESS</b>	<b>PHONE/FAX</b>
<b>FORM COMPLETED BY</b>	<b>STAMP</b>
<b>PRINT NAME:</b> _____  <b>SIGNATURE:</b> _____	
<b>DATE:</b> _____	

**Appendix 2: EIF-000605 – Product code, Lot Number, Unique Device Identifier (UDI) Information**

Product Code	Batch	UDI#
AC-15192-SFX	33F24G0631	(01)30801902197758(10)33F24G0631(11)240918(17)270831
AC-15192-X	33F23F0744	(01)00801902095879(10)33F23F0744(11)230707(17)260630
AC-15192-X	33F24E0784	(01)00801902095879(10)33F24E0784(11)240725(17)270630
AC-15192-X	33F25D0685	(01)00801902095879(10)33F25D0685(11)250507(17)280430
AC-15232-SFX	33F23H1018	(01)00801902095909(10)33F23H1018(11)230928(17)260831
AC-15232-X	33F23H1013	(01)00801902095916(10)33F23H1013(11)231018(17)260930
AC-15232-X	33F24J0068	(01)00801902095916(10)33F24J0068(11)241206(17)271130
AC-15232-X	33F25C0675	(01)00801902095916(10)33F25C0675(11)250417(17)280225
AC-15232-X	33F25J0589	(01)00801902095916(10)33F25J0589(11)251107(17)280608
AC-15272-X	33F23H1023	(01)00801902095954(10)33F23H1023(11)231119(17)261031
ACS-15192-VF	33F24G0637	(01)10801902126693(10)33F24G0637(11)241204(17)271130
ACS-15192-VFI	33F23G0040	(01)10801902126709(10)33F23G0040(11)230721(17)260630
ACS-15192-VFI	33F25C0689	(01)10801902126709(10)33F25C0689(11)250408(17)280331
ACS-15232-VF	33F23H1016	(01)10801902126716(10)33F23H1016(11)231012(17)260930
ACS-15232-VFI	33F23G0045	(01)10801902126723(10)33F23G0045(11)230719(17)260630
ACS-15232-VFI	33F25C0678	(01)10801902126723(10)33F25C0678(11)250414(17)280315
ACS-15272-VF	33F23H1024	(01)10801902126730(10)33F23H1024(11)231003(17)260930
ACS-15272-VFI	33F24G0638	(01)10801902126747(10)33F24G0638(11)240917(17)270831
ACS-15552-VF	33F23H1021	(01)10801902126792(10)33F23H1021(11)231003(17)260930
CS-15192-SFX	33F23E0575	(01)30801902195297(10)33F23E0575(11)230721(17)260630
CS-15192-SFX	33F23G0530	(01)30801902195297(10)33F23G0530(11)230830(17)260731
CS-15192-SFX	33F23K0187	(01)30801902195297(10)33F23K0187(11)231102(17)261031
CS-15192-SFX	33F23K1104	(01)30801902195297(10)33F23K1104(11)231115(17)261031
CS-15192-SFX	33F23L0929	(01)30801902195297(10)33F23L0929(11)240110(17)261231
CS-15192-SFX	33F24A0275	(01)30801902195297(10)33F24A0275(11)240217(17)270131
CS-15192-SFX	33F24C0068	(01)30801902195297(10)33F24C0068(11)240424(17)270331
CS-15192-SFX	33F24D1012	(01)30801902195297(10)33F24D1012(11)240503(17)270430
CS-15192-SFX	33F25C0020	(01)30801902195297(10)33F25C0020(11)250311(17)280229
CS-15192-SFX	33F25E1083	(01)30801902195297(10)33F25E1083(11)250717(17)280630
CS-15192-SFX	33F25G0636	(01)30801902195297(10)33F25G0636(11)250818(17)280731
CS-15192-SFX	33F25H0292	(01)30801902195297(10)33F25H0292(11)250901(17)280831
CS-15192-SFX	33F25H0790	(01)30801902195297(10)33F25H0790(11)251016(17)280524
CS-15192-SFX	33F25L0038	(01)30801902195297(10)33F25L0038(11)251127(17)280608
CS-15192-SFXM	33F25C0015	(01)10801902127157(10)33F25C0015(11)250310(17)271218
CS-15192-SFXM	33F25E1084	(01)10801902127157(10)33F25E1084(11)250620(17)280121
CS-15192-VF	33F23K0186	(01)20801902193593(10)33F23K0186(11)231107(17)261031
CS-15192-VF	33F23L0931	(01)20801902193593(10)33F23L0931(11)240129(17)261231
CS-15192-VF	33F24C0082	(01)20801902193593(10)33F24C0082(11)240425(17)270331
CS-15192-VF	33F24E0788	(01)20801902193593(10)33F24E0788(11)240610(17)270531
CS-15192-VF	33F24J0054	(01)20801902193593(10)33F24J0054(11)241107(17)271031
CS-15192-VF	33F24M0162	(01)20801902193593(10)33F24M0162(11)241213(17)271130
CS-15192-VF	33F24M0230	(01)20801902193593(10)33F24M0230(11)250222(17)280131
CS-15192-VF	33F25D0271	(01)20801902193593(10)33F25D0271(11)250807(17)280731
CS-15192-VFE	33F23E0776	(01)10801902195460(10)33F23E0776(11)230628(17)260531
CS-15192-VFE	33F23F0728	(01)10801902195460(10)33F23F0728(11)230706(17)260630
CS-15192-VFE	33F23G0531	(01)10801902195460(10)33F23G0531(11)230919(17)260831
CS-15192-VFE	33F24A0917	(01)10801902195460(10)33F24A0917(11)240506(17)270430
CS-15192-VFE	33F24C0063	(01)10801902195460(10)33F24C0063(11)240429(17)270331
CS-15192-VFE	33F24D1003	(01)10801902195460(10)33F24D1003(11)240528(17)270430
CS-15192-VFE	33F24E0789	(01)10801902195460(10)33F24E0789(11)240611(17)270531
CS-15192-VFE	33F24J0039	(01)10801902195460(10)33F24J0039(11)241106(17)271031
CS-15192-VFE	33F24L0069	(01)10801902195460(10)33F24L0069(11)241119(17)271031

**Appendix 2: EIF-000605 – Product code, Lot Number, Unique Device Identifier (UDI) Information**

Product Code	Batch	UDI#
CS-15192-VFE	33F24M0156	(01)10801902195460(10)33F24M0156(11)250122(17)271231
CS-15192-VFE	33F24M0159	(01)10801902195460(10)33F24M0159(11)241213(17)271130
CS-15192-VFE	33F25C0683	(01)10801902195460(10)33F25C0683(11)250408(17)280331
CS-15192-VFE	33F25D0107	(01)10801902195460(10)33F25D0107(11)250609(17)280531
CS-15192-VFE	33F25D0220	(01)10801902195460(10)33F25D0220(11)250424(17)280331
CS-15192-VFE	33F25E0343	(01)10801902195460(10)33F25E0343(11)250620(17)280531
CS-15192-VFE	33F25F0273	(01)10801902195460(10)33F25F0273(11)250828(17)280731
CS-15192-VFE	33F25F0462	(01)10801902195460(10)33F25F0462(11)250708(17)280510
CS-15192-VFE	33F25G0444	(01)10801902195460(10)33F25G0444(11)250929(17)280517
CS-15192-VFE	33F25H0820	(01)10801902195460(10)33F25H0820(11)251030(17)280524
CS-15192-VFE	33F25K0384	(01)10801902195460(10)33F25K0384(11)251127(17)280608
CS-15192-VFI	33F23E0579	(01)10801902127188(10)33F23E0579(11)230608(17)260531
CS-15192-VFI	33F23G0042	(01)10801902193572(10)33F23G0042(11)230721(17)260630
CS-15192-VFI	33F23K0170	(01)10801902193572(10)33F23K0170(11)231013(17)260930
CS-15192-VFI	33F23L0933	(01)10801902193572(10)33F23L0933(11)240417(17)270331
CS-15192-VFI	33F24E0271	(01)10801902193572(10)33F24E0271(11)240610(17)270531
CS-15192-VFI	33F24G0166	(01)10801902193572(10)33F24G0166(11)240904(17)270831
CS-15192-VFI	33F24J0086	(01)10801902193572(10)33F24J0086(11)240918(17)270831
CS-15192-VFI	33F24L0064	(01)10801902193572(10)33F24L0064(11)241209(17)271130
CS-15192-VFI	33F24M0224	(01)10801902193572(10)33F24M0224(11)250214(17)271125
CS-15192-VFI	33F25C0652	(01)10801902193572(10)33F25C0652(11)250409(17)280315
CS-15192-VFI	33F25D0052	(01)10801902193572(10)33F25D0052(11)250508(17)280430
CS-15192-VFI	33F25D0700	(01)10801902193572(10)33F25D0700(11)250521(17)271125
CS-15192-VFI	33F25E1081	(01)10801902193572(10)33F25E1081(11)250602(17)280430
CS-15192-VFI	33F25F0015	(01)10801902193572(10)33F25F0015(11)250606(17)280531
CS-15192-VFI	33F25F0388	(01)10801902193572(10)33F25F0388(11)250716(17)280630
CS-15192-VFI	33F25G0702	(01)10801902193572(10)33F25G0702(11)250901(17)280831
CS-15192-VFI	33F25H0785	(01)10801902193572(10)33F25H0785(11)251105(17)280608
CS-15192-VFIE	33F23D0853	(01)10801902199659(10)33F23D0853(11)230529(17)260430
CS-15192-VFIE	33F23E0773	(01)10801902199659(10)33F23E0773(11)230703(17)260630
CS-15192-VFIE	33F23G0044	(01)10801902199659(10)33F23G0044(11)230720(17)260630
CS-15192-VFIE	33F23G0532	(01)10801902199659(10)33F23G0532(11)230823(17)260731
CS-15192-VFIE	33F23H0611	(01)10801902199659(10)33F23H0611(11)230919(17)260831
CS-15192-VFIE	33F23K0169	(01)10801902199659(10)33F23K0169(11)231012(17)260930
CS-15192-VFIE	33F23K1105	(01)10801902199659(10)33F23K1105(11)231213(17)261130
CS-15192-VFIE	33F23L0934	(01)10801902199659(10)33F23L0934(11)240126(17)261231
CS-15192-VFIE	33F24A0912	(01)10801902199659(10)33F24A0912(11)240312(17)270228
CS-15192-VFIE	33F24A0913	(01)10801902199659(10)33F24A0913(11)240226(17)270131
CS-15192-VFIE	33F24C0058	(01)10801902199659(10)33F24C0058(11)240419(17)270331
CS-15192-VFIE	33F24D1001	(01)10801902199659(10)33F24D1001(11)240507(17)270430
CS-15192-VFIE	33F24G0167	(01)10801902199659(10)33F24G0167(11)240902(17)270831
CS-15192-VFIE	33F24G0187	(01)10801902199659(10)33F24G0187(11)241002(17)270930
CS-15192-VFIE	33F24J0030	(01)10801902199659(10)33F24J0030(11)240929(17)270831
CS-15192-VFIE	33F24J0032	(01)10801902199659(10)33F24J0032(11)241013(17)270930
CS-15192-VFIE	33F24J0339	(01)10801902199659(10)33F24J0339(11)240917(17)270831
CS-15192-VFIE	33F24J0381	(01)10801902199659(10)33F24J0381(11)240920(17)270831
CS-15192-VFIE	33F24K0659	(01)10801902199659(10)33F24K0659(11)241128(17)271031
CS-15192-VFIE	33F24L0058	(01)10801902199659(10)33F24L0058(11)241111(17)271031
CS-15192-VFIE	33F24L0511	(01)10801902199659(10)33F24L0511(11)241209(17)271130
CS-15192-VFIE	33F24M0155	(01)10801902199659(10)33F24M0155(11)241216(17)271130
CS-15192-VFIE	33F24M0215	(01)10801902199659(10)33F24M0215(11)250131(17)271125
CS-15192-VFIE	33F24M0265	(01)10801902199659(10)33F24M0265(11)250122(17)271231

**Appendix 2: EIF-000605 – Product code, Lot Number, Unique Device Identifier (UDI) Information**

Product Code	Batch	UDI#
CS-15192-VFIE	33F25A0143	(01)10801902199659(10)33F25A0143(11)250214(17)280131
CS-15192-VFIE	33F25A0407	(01)10801902199659(10)33F25A0407(11)250205(17)271125
CS-15192-VFIE	33F25B0259	(01)10801902199659(10)33F25B0259(11)250228(17)280131
CS-15192-VFIE	33F25C0037	(01)10801902199659(10)33F25C0037(11)250319(17)271215
CS-15192-VFIE	33F25D0285	(01)10801902199659(10)33F25D0285(11)250701(17)280420
CS-15192-VFIE	33F25D0738	(01)10801902199659(10)33F25D0738(11)250716(17)280630
CS-15192-VFIE	33F25F0060	(01)10801902199659(10)33F25F0060(11)250620(17)280531
CS-15192-VFIE	33F25G0635	(01)10801902199659(10)33F25G0635(11)250926(17)280831
CS-15192-VFIM	33F24E0792	(01)10801902193589(10)33F24E0792(11)240904(17)270831
CS-15192-VFIM	33F25C0676	(01)10801902193589(10)33F25C0676(11)250429(17)280118
CS-15192-VFIM	33F25L0035	(01)10801902193589(10)33F25L0035(11)251127(17)280227
CS-15192-VFM	33F23K0189	(01)10801902193602(10)33F23K0189(11)231107(17)260930
CS-15192-VFM	33F24C0078	(01)10801902193602(10)33F24C0078(11)240425(17)270331
CS-15192-VFM	33F24J0049	(01)10801902193602(10)33F24J0049(11)241113(17)270630
CS-15192-VFM	33F24M0243	(01)10801902193602(10)33F24M0243(11)250221(17)280108
CS-15192-VFM	33F25C0672	(01)10801902193602(10)33F25C0672(11)250430(17)280118
CS-15192-VFM	33F25E1077	(01)10801902193602(10)33F25E1077(11)250718(17)280121
CS-15192-VFM	33F25F0418	(01)10801902193602(10)33F25F0418(11)251022(17)280108
CS-15192-X	33F23C0886	(01)30801902195303(10)33F23C0886(11)230411(17)260331
CS-15192-X	33F23E0564	(01)30801902195303(10)33F23E0564(11)230601(17)260430
CS-15192-X	33F23G0263	(01)30801902195303(10)33F23G0263(11)230727(17)260630
CS-15192-X	33F23G0533	(01)30801902195303(10)33F23G0533(11)231025(17)260930
CS-15192-X	33F23K0712	(01)30801902195303(10)33F23K0712(11)231109(17)261031
CS-15192-X	33F23L0935	(01)30801902195303(10)33F23L0935(11)240227(17)270131
CS-15192-X	33F24E0187	(01)30801902195303(10)33F24E0187(11)240726(17)270630
CS-15192-X	33F24E0793	(01)30801902195303(10)33F24E0793(11)240714(17)270630
CS-15192-X	33F24G0171	(01)30801902195303(10)33F24G0171(11)240823(17)260831
CS-15192-X	33F24J0017	(01)30801902195303(10)33F24J0017(11)241107(17)271031
CS-15192-X	33F24J0041	(01)30801902195303(10)33F24J0041(11)241122(17)271031
CS-15192-X	33F25D0701	(01)30801902195303(10)33F25D0701(11)250516(17)280430
CS-15192-X	33F25E0476	(01)30801902195303(10)33F25E0476(11)250717(17)280630
CS-15192-X	33F25F0486	(01)30801902195303(10)33F25F0486(11)250826(17)280731
CS-15192-X	33F25H0783	(01)30801902195303(10)33F25H0783(11)251030(17)280524
CS-15192-X	33F25H0857	(01)30801902195303(10)33F25H0857(11)251111(17)280608
CS-15192-XM	33F25D0711	(01)10801902127225(10)33F25D0711(11)250507(17)280108
CS-15232-SFX	33F23E0576	(01)30801902195549(10)33F23E0576(11)230707(17)260630
CS-15232-SFX	33F23G0534	(01)30801902195549(10)33F23G0534(11)231026(17)260930
CS-15232-SFX	33F23L0936	(01)30801902195549(10)33F23L0936(11)240110(17)261231
CS-15232-SFX	33F24A0279	(01)30801902195549(10)33F24A0279(11)240215(17)270131
CS-15232-SFX	33F24C0067	(01)30801902195549(10)33F24C0067(11)240418(17)270331
CS-15232-SFX	33F24D1006	(01)30801902195549(10)33F24D1006(11)240502(17)270430
CS-15232-SFX	33F24E0684	(01)30801902195549(10)33F24E0684(11)240531(17)270430
CS-15232-SFX	33F24H0258	(01)30801902195549(10)33F24H0258(11)240824(17)270731
CS-15232-SFX	33F24J0033	(01)30801902195549(10)33F24J0033(11)241122(17)271031
CS-15232-SFX	33F24J0085	(01)30801902195549(10)33F24J0085(11)241031(17)270930
CS-15232-SFX	33F24J0342	(01)30801902195549(10)33F24J0342(11)240920(17)270831
CS-15232-SFX	33F24L0056	(01)30801902195549(10)33F24L0056(11)241107(17)271031
CS-15232-SFX	33F24M0231	(01)30801902195549(10)33F24M0231(11)250124(17)271031
CS-15232-SFX	33F25A0405	(01)30801902195549(10)33F25A0405(11)250226(17)280131
CS-15232-SFX	33F25C0036	(01)30801902195549(10)33F25C0036(11)250311(17)271215
CS-15232-SFX	33F25C0664	(01)30801902195549(10)33F25C0664(11)250417(17)280225
CS-15232-SFX	33F25D0739	(01)30801902195549(10)33F25D0739(11)250729(17)280630

**Appendix 2: EIF-000605 – Product code, Lot Number, Unique Device Identifier (UDI) Information**

Product Code	Batch	UDI#
CS-15232-SFX	33F25E0433	(01)30801902195549(10)33F25E0433(11)250519(17)280430
CS-15232-SFX	33F25G0716	(01)30801902195549(10)33F25G0716(11)250901(17)280831
CS-15232-SFX	33F25H0248	(01)30801902195549(10)33F25H0248(11)251031(17)280928
CS-15232-SFXM	33F25C0671	(01)10801902127232(10)33F25C0671(11)250404(17)280118
CS-15232-VF	33F23C0873	(01)10801902193626(10)33F23C0873(11)230428(17)260331
CS-15232-VF	33F23J0546	(01)10801902193626(10)33F23J0546(11)231011(17)260930
CS-15232-VF	33F24A0294	(01)10801902193626(10)33F24A0294(11)240114(17)261231
CS-15232-VF	33F24C0071	(01)10801902193626(10)33F24C0071(11)240605(17)270531
CS-15232-VF	33R24G0168	(01)10801902193626(10)33R24G0168(11)241023(17)270831
CS-15232-VF	33F24J0044	(01)10801902193626(10)33F24J0044(11)241031(17)270930
CS-15232-VF	33F25D0089	(01)10801902193626(10)33F25D0089(11)250422(17)280225
CS-15232-VF	33F25E0333	(01)10801902193626(10)33F25E0333(11)250718(17)280420
CS-15232-VF	33F25E0427	(01)10801902193626(10)33F25E0427(11)250520(17)280430
CS-15232-VF	33F25E1095	(01)10801902193626(10)33F25E1095(11)250910(17)280831
CS-15232-VF	33F25F0404	(01)10801902193626(10)33F25F0404(11)250805(17)280510
CS-15232-VF	33F25H0294	(01)10801902193626(10)33F25H0294(11)250930(17)280831
CS-15232-VF	33F25J1009	(01)10801902193626(10)33F25J1009(11)251205(17)270427
CS-15232-VFE	33F23E0775	(01)10801902195132(10)33F23E0775(11)230628(17)260531
CS-15232-VFE	33F23F0720	(01)10801902195132(10)33F23F0720(11)230629(17)260531
CS-15232-VFE	33F23K0176	(01)10801902195132(10)33F23K0176(11)231101(17)261031
CS-15232-VFE	33F23K0194	(01)10801902195132(10)33F23K0194(11)231130(17)261130
CS-15232-VFE	33F23L0937	(01)10801902195132(10)33F23L0937(11)231206(17)261130
CS-15232-VFE	33F24A0927	(01)10801902195132(10)33F24A0927(11)240213(17)270131
CS-15232-VFE	33F24C0059	(01)10801902195132(10)33F24C0059(11)240528(17)270430
CS-15232-VFE	33F24D1010	(01)10801902195132(10)33F24D1010(11)240506(17)270430
CS-15232-VFE	33F24E0270	(01)10801902195132(10)33F24E0270(11)240605(17)270531
CS-15232-VFE	33F24E0796	(01)10801902195132(10)33F24E0796(11)240904(17)270831
CS-15232-VFE	33F24G0045	(01)10801902195132(10)33F24G0045(11)240714(17)270630
CS-15232-VFE	33F24J0035	(01)10801902195132(10)33F24J0035(11)241203(17)271130
CS-15232-VFE	33F24J0083	(01)10801902195132(10)33F24J0083(11)240909(17)270831
CS-15232-VFE	33F24L0171	(01)10801902195132(10)33F24L0171(11)241122(17)271031
CS-15232-VFE	33F24M0216	(01)10801902195132(10)33F24M0216(11)250109(17)271231
CS-15232-VFE	33F25A0004	(01)10801902195132(10)33F25A0004(11)250214(17)280131
CS-15232-VFE	33F25A0083	(01)10801902195132(10)33F25A0083(11)250122(17)271231
CS-15232-VFE	33F25C0023	(01)10801902195132(10)33F25C0023(11)250325(17)280229
CS-15232-VFE	33F25C0659	(01)10801902195132(10)33F25C0659(11)250409(17)280331
CS-15232-VFE	33F25D0106	(01)10801902195132(10)33F25D0106(11)250502(17)280131
CS-15232-VFE	33F25D0219	(01)10801902195132(10)33F25D0219(11)250422(17)280131
CS-15232-VFE	33F25D0726	(01)10801902195132(10)33F25D0726(11)250626(17)271125
CS-15232-VFE	33F25E0478	(01)10801902195132(10)33F25E0478(11)250523(17)280430
CS-15232-VFE	33F25E1105	(01)10801902195132(10)33F25E1105(11)250725(17)280420
CS-15232-VFE	33F25F0298	(01)10801902195132(10)33F25F0298(11)250829(17)280731
CS-15232-VFE	33F25J1056	(01)10801902195132(10)33F25J1056(11)251023(17)280524
CS-15232-VFE	33F25K0335	(01)10801902195132(10)33F25K0335(11)251106(17)280608
CS-15232-VFE	33F25L0011	(01)10801902195132(10)33F25L0011(11)251205(17)280608
CS-15232-VFI	33F23C0864	(01)10801902194463(10)33F23C0864(11)230404(17)260331
CS-15232-VFI	33F23E0578	(01)10801902127263(10)33F23E0578(11)230608(17)260531
CS-15232-VFI	33F23E0832	(01)10801902194463(10)33F23E0832(11)230708(17)260630
CS-15232-VFI	33F23G0535	(01)10801902194463(10)33F23G0535(11)230802(17)260630
CS-15232-VFI	33F23G0840	(01)10801902194463(10)33F23G0840(11)230816(17)260731
CS-15232-VFI	33F23H0612	(01)10801902194463(10)33F23H0612(11)230919(17)260831
CS-15232-VFI	33F23K0144	(01)10801902194463(10)33F23K0144(11)231012(17)260930

**Appendix 2: EIF-000605 – Product code, Lot Number, Unique Device Identifier (UDI) Information**

Product Code	Batch	UDI#
CS-15232-VFI	33F24A0914	(01)10801902194463(10)33F24A0914(11)240306(17)270228
CS-15232-VFI	33F24C0079	(01)10801902194463(10)33F24C0079(11)240509(17)270430
CS-15232-VFI	33F24E0269	(01)10801902194463(10)33F24E0269(11)240903(17)270831
CS-15232-VFI	33F24J0042	(01)10801902194463(10)33F24J0042(11)241011(17)270930
CS-15232-VFI	33F25B0256	(01)10801902194463(10)33F25B0256(11)250219(17)280131
CS-15232-VFI	33F25C0014	(01)10801902194463(10)33F25C0014(11)250325(17)280229
CS-15232-VFI	33F25C0709	(01)10801902194463(10)33F25C0709(11)250401(17)280331
CS-15232-VFI	33F25C0650	(01)10801902194463(10)33F25C0650(11)250409(17)280225
CS-15232-VFI	33F25E1085	(01)10801902194463(10)33F25E1085(11)250603(17)280427
CS-15232-VFI	33F25E1130	(01)10801902194463(10)33F25E1130(11)250716(17)280630
CS-15232-VFI	33F25F0009	(01)10801902194463(10)33F25F0009(11)250610(17)280531
CS-15232-VFI	33F25G0023	(01)10801902194463(10)33F25G0023(11)250818(17)280731
CS-15232-VFI	33F25G0450	(01)10801902194463(10)33F25G0450(11)250910(17)280831
CS-15232-VFI	33F25H0341	(01)10801902194463(10)33F25H0341(11)251016(17)280930
CS-15232-VFI	33F25J1014	(01)10801902194463(10)33F25J1014(11)251212(17)280629
CS-15232-VFIE	33F23D0855	(01)10801902195149(10)33F23D0855(11)230529(17)260430
CS-15232-VFIE	33F23E0774	(01)10801902195149(10)33F23E0774(11)230706(17)260630
CS-15232-VFIE	33F23G0047	(01)10801902195149(10)33F23G0047(11)230721(17)260630
CS-15232-VFIE	33F23G0048	(01)10801902195149(10)33F23G0048(11)230727(17)260630
CS-15232-VFIE	33F23G0049	(01)10801902195149(10)33F23G0049(11)230810(17)260731
CS-15232-VFIE	33F23K0145	(01)10801902195149(10)33F23K0145(11)231019(17)260930
CS-15232-VFIE	33F23K0175	(01)10801902195149(10)33F23K0175(11)231025(17)260930
CS-15232-VFIE	33F23L0938	(01)10801902195149(10)33F23L0938(11)231208(17)261130
CS-15232-VFIE	33F24A0915	(01)10801902195149(10)33F24A0915(11)240306(17)270228
CS-15232-VFIE	33F24C0069	(01)10801902195149(10)33F24C0069(11)240417(17)270331
CS-15232-VFIE	33F24G0169	(01)10801902195149(10)33F24G0169(11)240905(17)270831
CS-15232-VFIE	33F24J0026	(01)10801902195149(10)33F24J0026(11)241011(17)270930
CS-15232-VFIE	33F24J0027	(01)10801902195149(10)33F24J0027(11)241011(17)270930
CS-15232-VFIE	33F24J0028	(01)10801902195149(10)33F24J0028(11)241029(17)270930
CS-15232-VFIE	33F24J0084	(01)10801902195149(10)33F24J0084(11)241111(17)271031
CS-15232-VFIE	33F24K0700	(01)10801902195149(10)33F24K0700(11)241205(17)271130
CS-15232-VFIE	33F24L0178	(01)10801902195149(10)33F24L0178(11)241125(17)270811
CS-15232-VFIE	33F24M0005	(01)10801902195149(10)33F24M0005(11)250122(17)271231
CS-15232-VFIE	33F24M0214	(01)10801902195149(10)33F24M0214(11)250108(17)271231
CS-15232-VFIE	33F24M0219	(01)10801902195149(10)33F24M0219(11)250214(17)280131
CS-15232-VFIE	33F25C0646	(01)10801902195149(10)33F25C0646(11)250402(17)280331
CS-15232-VFIE	33F25C0665	(01)10801902195149(10)33F25C0665(11)250424(17)280331
CS-15232-VFIE	33F25D0097	(01)10801902195149(10)33F25D0097(11)250508(17)280430
CS-15232-VFIE	33F25E0358	(01)10801902195149(10)33F25E0358(11)250530(17)280430
CS-15232-VFIE	33F25E0434	(01)10801902195149(10)33F25E0434(11)250520(17)280430
CS-15232-VFIE	33F25F0012	(01)10801902195149(10)33F25F0012(11)250618(17)280531
CS-15232-VFIE	33F25F0275	(01)10801902195149(10)33F25F0275(11)250805(17)280731
CS-15232-VFIE	33F25F0328	(01)10801902195149(10)33F25F0328(11)250618(17)280531
CS-15232-VFIE	33F25G0069	(01)10801902195149(10)33F25G0069(11)250821(17)280731
CS-15232-VFIE	33F25H0293	(01)10801902195149(10)33F25H0293(11)250929(17)280517
CS-15232-VFIE	33F25H0822	(01)10801902195149(10)33F25H0822(11)251022(17)280524
CS-15232-VFIE	33F25K0235	(01)10801902195149(10)33F25K0235(11)251207(17)280629
CS-15232-VFIM	33F23C0879	(01)10801902193619(10)33F23C0879(11)230429(17)260331
CS-15232-VFIM	33F23L0939	(01)10801902193619(10)33F23L0939(11)231207(17)260930
CS-15232-VFIM	33F24A0304	(01)10801902193619(10)33F24A0304(11)240115(17)261231
CS-15232-VFIM	33F24E0798	(01)10801902193619(10)33F24E0798(11)240903(17)270831
CS-15232-VFIM	33F24J0047	(01)10801902193619(10)33F24J0047(11)241212(17)271130

**Appendix 2: EIF-000605 – Product code, Lot Number, Unique Device Identifier (UDI) Information**

Product Code	Batch	UDI#
CS-15232-VFM	33F23J0547	(01)10801902193633(10)33F23J0547(11)230927(17)260930
CS-15232-VFM	33F24A0289	(01)10801902193633(10)33F24A0289(11)240115(17)261231
CS-15232-VFM	33F24C0077	(01)10801902193633(10)33F24C0077(11)240508(17)270430
CS-15232-VFM	33F24E0799	(01)10801902193633(10)33F24E0799(11)240712(17)270531
CS-15232-VFM	33F24J0045	(01)10801902193633(10)33F24J0045(11)241014(17)270930
CS-15232-VFM	33F24J0093	(01)10801902193633(10)33F24J0093(11)240915(17)270831
CS-15232-VFM	33F25A0026	(01)10801902193633(10)33F25A0026(11)250217(17)280108
CS-15232-VFM	33F25C0050	(01)10801902193633(10)33F25C0050(11)250325(17)280108
CS-15232-VFM	33F25E0348	(01)10801902193633(10)33F25E0348(11)250618(17)280121
CS-15232-VFM	33F25K0348	(01)10801902193633(10)33F25K0348(11)251104(17)280227
CS-15232-X	33F23C0862	(01)30801902195556(10)33F23C0862(11)230405(17)260331
CS-15232-X	33F23E0566	(01)30801902195556(10)33F23E0566(11)230605(17)260531
CS-15232-X	33F23F0722	(01)30801902195556(10)33F23F0722(11)230706(17)260630
CS-15232-X	33F23K0171	(01)30801902195556(10)33F23K0171(11)231018(17)260930
CS-15232-X	33F23L0940	(01)30801902195556(10)33F23L0940(11)240220(17)270131
CS-15232-X	33F24A0916	(01)30801902195556(10)33F24A0916(11)240305(17)270228
CS-15232-X	33F24C0061	(01)30801902195556(10)33F24C0061(11)240509(17)270430
CS-15232-X	33F24D1037	(01)30801902195556(10)33F24D1037(11)240531(17)270531
CS-15232-X	33F24E0800	(01)30801902195556(10)33F24E0800(11)240610(17)270531
CS-15232-X	33F24J0043	(01)30801902195556(10)33F24J0043(11)241107(17)271031
CS-15232-X	33F24L0176	(01)30801902195556(10)33F24L0176(11)241119(17)271031
CS-15232-X	33F25A0028	(01)30801902195556(10)33F25A0028(11)250221(17)280131
CS-15232-X	33F25C0029	(01)30801902195556(10)33F25C0029(11)250311(17)271215
CS-15232-X	33F25C0644	(01)30801902195556(10)33F25C0644(11)250402(17)280331
CS-15232-X	33F25D0096	(01)30801902195556(10)33F25D0096(11)250516(17)280430
CS-15232-X	33F25E0352	(01)30801902195556(10)33F25E0352(11)250610(17)280531
CS-15232-X	33F25F0300	(01)30801902195556(10)33F25F0300(11)250804(17)280420
CS-15232-X	33F25F0513	(01)30801902195556(10)33F25F0513(11)250909(17)280831
CS-15232-X	33F25E0477	(01)30801902195556(10)33F25E0477(11)250723(17)280630
CS-15232-X	33F25J0745	(01)30801902195556(10)33F25J0745(11)251016(17)280517
CS-15232-XM	33F25E0435	(01)10801902127300(10)33F25E0435(11)250519(17)280118
CS-15242-I	33F23G0536	(01)30801902195280(10)33F23G0536(11)230905(17)260831
CS-15242-SPM	33F23D0867	(01)10801902193527(10)33F23D0867(11)230529(17)260430
CS-15242-SPM	33F23K0192	(01)10801902193527(10)33F23K0192(11)240305(17)260930
CS-15242-SPM	33F24A0288	(01)10801902193527(10)33F24A0288(11)240419(17)260930
CS-15242-SPM	33F24E0802	(01)10801902193527(10)33F24E0802(11)240725(17)270630
CS-15242-SPM	33F24M0244	(01)10801902193527(10)33F24M0244(11)250227(17)280108
CS-15242-SPM	33F25C0669	(01)10801902193527(10)33F25C0669(11)250502(17)280118
CS-15242-SPM	33F25E0338	(01)10801902193527(10)33F25E0338(11)250627(17)280108
CS-15242-SPM	33F25G0586	(01)10801902193527(10)33F25G0586(11)250822(17)280121
CS-15242-VSP	33F23C0870	(01)30801902195273(10)33F23C0870(11)230411(17)260331
CS-15242-VSP	33F23D0857	(01)30801902195273(10)33F23D0857(11)230525(17)260430
CS-15242-VSP	33F23F0719	(01)30801902195273(10)33F23F0719(11)230629(17)260531
CS-15242-VSP	33F23K0182	(01)30801902195273(10)33F23K0182(11)231206(17)261130
CS-15242-VSP	33F24A0265	(01)30801902195273(10)33F24A0265(11)240211(17)270131
CS-15242-VSP	33F24C0062	(01)30801902195273(10)33F24C0062(11)240424(17)270331
CS-15242-VSP	33F24D1000	(01)30801902195273(10)33F24D1000(11)240506(17)270430
CS-15242-VSP	33F24D1039	(01)30801902195273(10)33F24D1039(11)240530(17)270430
CS-15242-VSP	33F24E0803	(01)30801902195273(10)33F24E0803(11)241115(17)271031
CS-15242-VSP	33F24H0038	(01)30801902195273(10)33F24H0038(11)240808(17)270731
CS-15242-VSP	33F24H0261	(01)30801902195273(10)33F24H0261(11)240827(17)270731
CS-15242-VSP	33F24K0505	(01)30801902195273(10)33F24K0505(11)241128(17)271031

**Appendix 2: EIF-000605 – Product code, Lot Number, Unique Device Identifier (UDI) Information**

Product Code	Batch	UDI#
CS-15242-VSP	33F24M0039	(01)30801902195273(10)33F24M0039(11)241220(17)271130
CS-15242-VSP	33F24M0218	(01)30801902195273(10)33F24M0218(11)250122(17)271231
CS-15242-VSP	33F25A0141	(01)30801902195273(10)33F25A0141(11)250222(17)280131
CS-15242-VSP	33F25C0657	(01)30801902195273(10)33F25C0657(11)250401(17)280331
CS-15242-VSP	33F25D0125	(01)30801902195273(10)33F25D0125(11)250414(17)280225
CS-15242-VSP	33F25E0305	(01)30801902195273(10)33F25E0305(11)250520(17)280430
CS-15242-VSP	33F25E0429	(01)30801902195273(10)33F25E0429(11)250602(17)280531
CS-15242-VSP	33F25E0430	(01)30801902195273(10)33F25E0430(11)250619(17)280531
CS-15242-VSP	33F25E1131	(01)30801902195273(10)33F25E1131(11)250715(17)280510
CS-15242-VSP	33F25F0042	(01)30801902195273(10)33F25F0042(11)250808(17)280731
CS-15242-VSP	33F25G0070	(01)30801902195273(10)33F25G0070(11)250818(17)280731
CS-15242-VSP	33F25H0295	(01)30801902195273(10)33F25H0295(11)250910(17)280831
CS-15242-VSP	33F25H0366	(01)30801902195273(10)33F25H0366(11)251006(17)280524
CS-15242-VSP	33F25H0674	(01)30801902195273(10)33F25H0674(11)250901(17)280731
CS-15242-VSP	33F25J1015	(01)30801902195273(10)33F25J1015(11)251105(17)280524
CS-15272-SFX	33F23B0321	(01)10801902195217(10)33F23B0321(11)230217(17)260630
CS-15272-SFX	33F23D0859	(01)10801902195217(10)33F23D0859(11)230706(17)260630
CS-15272-SFX	33F23H0500	(01)10801902195217(10)33F23H0500(11)230829(17)260731
CS-15272-SFX	33F23K0177	(01)10801902195217(10)33F23K0177(11)231107(17)261031
CS-15272-SFX	33F23L0943	(01)10801902195217(10)33F23L0943(11)240110(17)261231
CS-15272-SFX	33F24A0280	(01)10801902195217(10)33F24A0280(11)240213(17)270131
CS-15272-SFX	33F24C0083	(01)10801902195217(10)33F24C0083(11)240425(17)270331
CS-15272-SFX	33F24H0042	(01)10801902195217(10)33F24H0042(11)240809(17)270731
CS-15272-SFX	33F24H0260	(01)10801902195217(10)33F24H0260(11)240823(17)270731
CS-15272-SFX	33F24J0022	(01)10801902195217(10)33F24J0022(11)240909(17)270831
CS-15272-SFX	33F24J0038	(01)10801902195217(10)33F24J0038(11)241209(17)271130
CS-15272-SFX	33F24J0088	(01)10801902195217(10)33F24J0088(11)241025(17)270930
CS-15272-SFX	33F24L0177	(01)10801902195217(10)33F24L0177(11)241121(17)271031
CS-15272-SFX	33F25C0028	(01)10801902195217(10)33F25C0028(11)250311(17)271215
CS-15272-SFX	33F25E1090	(01)10801902195217(10)33F25E1090(11)250723(17)280630
CS-15272-SFX	33F25F0301	(01)10801902195217(10)33F25F0301(11)250805(17)280420
CS-15272-SFX	33F25F0514	(01)10801902195217(10)33F25F0514(11)250905(17)280831
CS-15272-VF	33F23C0880	(01)10801902193657(10)33F23C0880(11)230430(17)260331
CS-15272-VF	33F23F0740	(01)10801902193657(10)33F23F0740(11)230706(17)260630
CS-15272-VF	33F23L0944	(01)10801902193657(10)33F23L0944(11)231210(17)261130
CS-15272-VF	33F24C0081	(01)10801902193657(10)33F24C0081(11)240422(17)270331
CS-15272-VF	33F24E0804	(01)10801902193657(10)33F24E0804(11)240611(17)270531
CS-15272-VF	33F24J0051	(01)10801902193657(10)33F24J0051(11)240917(17)270831
CS-15272-VF	33F24J0686	(01)10801902193657(10)33F24J0686(11)241203(17)271031
CS-15272-VF	33F24M0228	(01)10801902193657(10)33F24M0228(11)250214(17)280131
CS-15272-VF	33F25C0668	(01)10801902193657(10)33F25C0668(11)250408(17)280331
CS-15272-VF	33F25E0337	(01)10801902193657(10)33F25E0337(11)250627(17)280420
CS-15272-VF	33F25F0403	(01)10801902193657(10)33F25F0403(11)250719(17)280630
CS-15272-VF	33F25J0590	(01)10801902193657(10)33F25J0590(11)251030(17)280524
CS-15272-VFE	33F23E0777	(01)10801902195248(10)33F23E0777(11)230629(17)260531
CS-15272-VFE	33F23F0732	(01)10801902195248(10)33F23F0732(11)230706(17)260531
CS-15272-VFE	33F23H0980	(01)10801902195248(10)33F23H0980(11)230914(17)260831
CS-15272-VFE	33F23K0172	(01)10801902195248(10)33F23K0172(11)231017(17)260930
CS-15272-VFE	33F23L0945	(01)10801902195248(10)33F23L0945(11)231206(17)261130
CS-15272-VFE	33F24A0918	(01)10801902195248(10)33F24A0918(11)240212(17)270131
CS-15272-VFE	33F24C0064	(01)10801902195248(10)33F24C0064(11)240603(17)270531
CS-15272-VFE	33F24H0044	(01)10801902195248(10)33F24H0044(11)240812(17)270731

**Appendix 2: EIF-000605 – Product code, Lot Number, Unique Device Identifier (UDI) Information**

Product Code	Batch	UDI#
CS-15272-VFE	33F24H0255	(01)10801902195248(10)33F24H0255(11)240826(17)270731
CS-15272-VFE	33F24M0237	(01)10801902195248(10)33F24M0237(11)250222(17)280131
CS-15272-VFE	33F25C0049	(01)10801902195248(10)33F25C0049(11)250325(17)280229
CS-15272-VFE	33F25E0349	(01)10801902195248(10)33F25E0349(11)250627(17)280420
CS-15272-VFE	33F25E1132	(01)10801902195248(10)33F25E1132(11)250721(17)280420
CS-15272-VFE	33F25G0637	(01)10801902195248(10)33F25G0637(11)251031(17)280928
CS-15272-VFI	33F23E0871	(01)10801902193640(10)33F23E0871(11)230606(17)260531
CS-15272-VFI	33F23F0742	(01)10801902127362(10)33F23F0742(11)230710(17)260630
CS-15272-VFI	33F23H0981	(01)10801902193640(10)33F23H0981(11)230912(17)260831
CS-15272-VFI	33F23K0181	(01)10801902193640(10)33F23K0181(11)231025(17)260930
CS-15272-VFI	33F24A0306	(01)10801902193640(10)33F24A0306(11)240115(17)261231
CS-15272-VFI	33F24C0084	(01)10801902193640(10)33F24C0084(11)240501(17)270331
CS-15272-VFI	33F24J0062	(01)10801902193640(10)33F24J0062(11)241003(17)270930
CS-15272-VFI	33F25D0098	(01)10801902193640(10)33F25D0098(11)250508(17)280430
CS-15272-VFI	33F25E0307	(01)10801902193640(10)33F25E0307(11)250512(17)280225
CS-15272-VFI	33F25E0332	(01)10801902193640(10)33F25E0332(11)250530(17)280430
CS-15272-VFI	33F25E0354	(01)10801902193640(10)33F25E0354(11)250519(17)280430
CS-15272-VFI	33F25F0058	(01)10801902193640(10)33F25F0058(11)250610(17)280531
CS-15272-VFI	33F25F0245	(01)10801902193640(10)33F25F0245(11)250710(17)280420
CS-15272-VFI	33F25J0659	(01)10801902193640(10)33F25J0659(11)251106(17)280608
CS-15272-VFIE	33F23E0886	(01)10801902195255(10)33F23E0886(11)230606(17)260531
CS-15272-VFIE	33F23G0537	(01)10801902195255(10)33F23G0537(11)230802(17)260630
CS-15272-VFIE	33F23H0982	(01)10801902195255(10)33F23H0982(11)230913(17)260831
CS-15272-VFIE	33F23K0180	(01)10801902195255(10)33F23K0180(11)231026(17)260930
CS-15272-VFIE	33F23L0946	(01)10801902195255(10)33F23L0946(11)231206(17)261130
CS-15272-VFIE	33F24A0922	(01)10801902195255(10)33F24A0922(11)240212(17)270131
CS-15272-VFIE	33F24C0065	(01)10801902195255(10)33F24C0065(11)240415(17)270331
CS-15272-VFIE	33F24D1011	(01)10801902195255(10)33F24D1011(11)240509(17)270430
CS-15272-VFIE	33F24E0686	(01)10801902195255(10)33F24E0686(11)240531(17)270430
CS-15272-VFIE	33F24E0805	(01)10801902195255(10)33F24E0805(11)240610(17)270531
CS-15272-VFIE	33F24K0508	(01)10801902195255(10)33F24K0508(11)241205(17)271130
CS-15272-VFIE	33F24M0223	(01)10801902195255(10)33F24M0223(11)250219(17)300731
CS-15272-VFIE	33F25A0410	(01)10801902195255(10)33F25A0410(11)250224(17)280131
CS-15272-VFIE	33F25C0009	(01)10801902195255(10)33F25C0009(11)250325(17)280229
CS-15272-VFIE	33F25G0717	(01)10801902195255(10)33F25G0717(11)250905(17)300731
CS-15272-VFIM	33F23H1027	(01)10801902197761(10)33F23H1027(11)230930(17)260831
CS-15272-VFM	33F25C0687	(01)10801902127393(10)33F25C0687(11)250414(17)280118
CS-15272-X	33F23C0887	(01)10801902195224(10)33F23C0887(11)230411(17)260331
CS-15272-X	33F23F0731	(01)10801902195224(10)33F23F0731(11)230706(17)260630
CS-15272-X	33F23H0983	(01)10801902195224(10)33F23H0983(11)230927(17)260831
CS-15272-X	33F23K0190	(01)10801902195224(10)33F23K0190(11)231107(17)261031
CS-15272-X	33F23L0947	(01)10801902195224(10)33F23L0947(11)240226(17)270131
CS-15272-X	33F24E0807	(01)10801902195224(10)33F24E0807(11)240730(17)270630
CS-15272-X	33F24F0124	(01)10801902195224(10)33F24F0124(11)240612(17)270531
CS-15272-X	33F24J0018	(01)10801902195224(10)33F24J0018(11)240909(17)270831
CS-15272-X	33F24J0050	(01)10801902195224(10)33F24J0050(11)221125(17)270930
CS-15272-X	33F24L0054	(01)10801902195224(10)33F24L0054(11)241108(17)271031
CS-15272-X	33F24L0063	(01)10801902195224(10)33F24L0063(11)241209(17)271130
CS-15272-X	33F24M0006	(01)10801902195224(10)33F24M0006(11)250124(17)271125
CS-15272-X	33F25C0684	(01)10801902195224(10)33F25C0684(11)250522(17)280430
CS-15272-X	33F25E0342	(01)10801902195224(10)33F25E0342(11)250722(17)280630
CS-15272-X	33F25F0276	(01)10801902195224(10)33F25F0276(11)250801(17)280420

**Appendix 2: EIF-000605 – Product code, Lot Number, Unique Device Identifier (UDI) Information**

Product Code	Batch	UDI#
CS-15272-X	33F25J0641	(01)10801902195224(10)33F25J0641(11)251105(17)280608
CS-15272-XM	33F25C0680	(01)10801902127409(10)33F25C0680(11)250430(17)280118
CS-15272-XM	33F25K0272	(01)10801902127409(10)33F25K0272(11)251205(17)270427
CS-15282-I	33F23C0877	(01)30801902195532(10)33F23C0877(11)230503(17)260430
CS-15282-I	33F24A0281	(01)30801902195532(10)33F24A0281(11)240116(17)261231
CS-15282-I	33F24H0041	(01)30801902195532(10)33F24H0041(11)240809(17)270731
CS-15282-SPM	33F23C0872	(01)10801902193688(10)33F23C0872(11)230408(17)260331
CS-15282-SPM	33F23D0864	(01)10801902193688(10)33F23D0864(11)230506(17)260430
CS-15282-SPM	33F23G0539	(01)10801902193688(10)33F23G0539(11)231005(17)260930
CS-15282-SPM	33F23L0949	(01)10801902193688(10)33F23L0949(11)231206(17)260930
CS-15282-SPM	33F24A0278	(01)10801902193688(10)33F24A0278(11)240123(17)261231
CS-15282-SPM	33F24C0075	(01)10801902193688(10)33F24C0075(11)240419(17)270331
CS-15282-SPM	33F24E0808	(01)10801902193688(10)33F24E0808(11)240712(17)270630
CS-15282-SPM	33F24H0254	(01)10801902193688(10)33F24H0254(11)240823(17)270731
CS-15282-SPM	33F24J0036	(01)10801902193688(10)33F24J0036(11)241108(17)271031
CS-15282-SPM	33F24L1166	(01)10801902193688(10)33F24L1166(11)241128(17)271031
CS-15282-SPM	33F24M0233	(01)10801902193688(10)33F24M0233(11)250124(17)271125
CS-15282-SPM	33F25A0413	(01)10801902193688(10)33F25A0413(11)250204(17)271125
CS-15282-SPM	33F25C0666	(01)10801902193688(10)33F25C0666(11)250331(17)271218
CS-15282-SPM	33F25H0824	(01)10801902193688(10)33F25H0824(11)251001(17)280108
CS-15282-VSP	33F23C0866	(01)30801902195518(10)33F23C0866(11)230406(17)260331
CS-15282-VSP	33F23D0854	(01)30801902195518(10)33F23D0854(11)230503(17)260430
CS-15282-VSP	33F23E0572	(01)30801902195518(10)33F23E0572(11)230525(17)260430
CS-15282-VSP	33F23F0594	(01)30801902195518(10)33F23F0594(11)230630(17)260531
CS-15282-VSP	33F23G0540	(01)30801902195518(10)33F23G0540(11)231006(17)260930
CS-15282-VSP	33F23J0544	(01)30801902195518(10)33F23J0544(11)231020(17)260930
CS-15282-VSP	33F23K0174	(01)30801902195518(10)33F23K0174(11)231130(17)261130
CS-15282-VSP	33F23L0950	(01)30801902195518(10)33F23L0950(11)240108(17)261231
CS-15282-VSP	33F24B0010	(01)30801902195518(10)33F24B0010(11)240301(17)270228
CS-15282-VSP	33F24C0060	(01)30801902195518(10)33F24C0060(11)240416(17)270331
CS-15282-VSP	33F24D0993	(01)30801902195518(10)33F24D0993(11)240508(17)270430
CS-15282-VSP	33F24D1040	(01)30801902195518(10)33F24D1040(11)240527(17)270430
CS-15282-VSP	33F24E0268	(01)30801902195518(10)33F24E0268(11)240603(17)270531
CS-15282-VSP	33F24E0809	(01)30801902195518(10)33F24E0809(11)240619(17)270531
CS-15282-VSP	33F24F0155	(01)30801902195518(10)33F24F0155(11)220825(17)270630
CS-15282-VSP	33F24J0037	(01)30801902195518(10)33F24J0037(11)230125(17)271130
CS-15282-VSP	33F24M0007	(01)30801902195518(10)33F24M0007(11)230225(17)271231
CS-15282-VSP	33F24M0040	(01)30801902195518(10)33F24M0040(11)230125(17)271130
CS-15282-VSP	33F24M0165	(01)30801902195518(10)33F24M0165(11)241220(17)271130
CS-15282-VSP	33F24M0217	(01)30801902195518(10)33F24M0217(11)250121(17)271222
CS-15282-VSP	33F25A0406	(01)30801902195518(10)33F25A0406(11)250218(17)280131
CS-15282-VSP	33F25B0269	(01)30801902195518(10)33F25B0269(11)250226(17)280131
CS-15282-VSP	33F25C0021	(01)30801902195518(10)33F25C0021(11)250311(17)280105
CS-15282-VSP	33F25C0045	(01)30801902195518(10)33F25C0045(11)250325(17)280229
CS-15282-VSP	33F25C0642	(01)30801902195518(10)33F25C0642(11)250402(17)280331
CS-15282-VSP	33F25D0013	(01)30801902195518(10)33F25D0013(11)250506(17)280406
CS-15282-VSP	33F25D0713	(01)30801902195518(10)33F25D0713(11)250628(17)280510
CS-15282-VSP	33F25F0249	(01)30801902195518(10)33F25F0249(11)251006(17)280524
CS-15282-VSP	33F25H0296	(01)30801902195518(10)33F25H0296(11)251105(17)280608
CS-15282-VSP	33F25J0051	(01)30801902195518(10)33F25J0051(11)251208(17)280524
CS-15312-SFX	33F23G0541	(01)30801902197529(10)33F23G0541(11)230822(17)260731
CS-15312-SFX	33F23H0984	(01)30801902197529(10)33F23H0984(11)230906(17)260831

**Appendix 2: EIF-000605 – Product code, Lot Number, Unique Device Identifier (UDI) Information**

Product Code	Batch	UDI#
CS-15312-SFX	33F23L0951	(01)30801902197529(10)33F23L0951(11)240112(17)261231
CS-15312-SFX	33F24A0283	(01)30801902197529(10)33F24A0283(11)240213(17)270131
CS-15312-VF	33F24G0060	(01)10801902127447(10)33F24G0060(11)241106(17)271031
CS-15312-VF	33F25D0216	(01)10801902127447(10)33F25D0216(11)250422(17)280131
CS-15312-VFE	33F23F0734	(01)10801902195484(10)33F23F0734(11)230706(17)260630
CS-15312-VFE	33F23G0542	(01)10801902195484(10)33F23G0542(11)231107(17)261031
CS-15312-VFE	33F23L0952	(01)10801902195484(10)33F23L0952(11)231211(17)261130
CS-15312-VFE	33F24A0925	(01)10801902195484(10)33F24A0925(11)240212(17)270131
CS-15312-VFE	33F24C0076	(01)10801902195484(10)33F24C0076(11)240419(17)270331
CS-15312-VFE	33F24J0053	(01)10801902195484(10)33F24J0053(11)241126(17)271031
CS-15312-VFE	33F24M0225	(01)10801902195484(10)33F24M0225(11)250121(17)271222
CS-15312-VFE	33F25A0033	(01)10801902195484(10)33F25A0033(11)250220(17)280131
CS-15312-VFE	33F25C0667	(01)10801902195484(10)33F25C0667(11)250402(17)280331
CS-15312-VFE	33F25E0320	(01)10801902195484(10)33F25E0320(11)250516(17)280430
CS-15312-VFE	33F25E0469	(01)10801902195484(10)33F25E0469(11)250704(17)280630
CS-15312-VFE	33F25G0603	(01)10801902195484(10)33F25G0603(11)251113(17)280524
CS-15312-VFI	33F23G0543	(01)10801902197778(10)33F23G0543(11)230802(17)260731
CS-15312-VFI	33F23L0953	(01)10801902197778(10)33F23L0953(11)231206(17)261130
CS-15312-VFI	33F24D1007	(01)10801902197778(10)33F24D1007(11)240509(17)270430
CS-15312-VFI	33F24E0810	(01)10801902197778(10)33F24E0810(11)240804(17)270731
CS-15312-VFI	33F24J0048	(01)10801902197778(10)33F24J0048(11)241014(17)270930
CS-15312-VFI	33F25C0039	(01)10801902197778(10)33F25C0039(11)250318(17)280225
CS-15312-VFI	33F25D0218	(01)10801902197778(10)33F25D0218(11)250417(17)280225
CS-15312-VFI	33F25E0470	(01)10801902197778(10)33F25E0470(11)250716(17)280630
CS-15312-VFI	33F25J0021	(01)10801902197778(10)33F25J0021(11)251016(17)280930
CS-15312-VFIE	33F23K0183	(01)10801902195491(10)33F23K0183(11)231102(17)261031
CS-15312-VFIE	33F23L0954	(01)10801902195491(10)33F23L0954(11)231206(17)261130
CS-15312-VFIE	33F24A0923	(01)10801902195491(10)33F24A0923(11)240212(17)270131
CS-15312-VFIE	33F24D1013	(01)10801902195491(10)33F24D1013(11)240508(17)270430
CS-15312-VFIE	33F25A0403	(01)10801902195491(10)33F25A0403(11)250222(17)280131
CS-15312-VFIE	33F25F0534	(01)10801902195491(10)33F25F0534(11)250707(17)280112
CS-15312-VFIE	33F25G0722	(01)10801902195491(10)33F25G0722(11)250825(17)280731
CS-15312-X	33F23C0863	(01)30801902195310(10)33F23C0863(11)230405(17)260331
CS-15312-X	33F23D0858	(01)30801902195310(10)33F23D0858(11)230530(17)260430
CS-15312-X	33F23G0544	(01)30801902195310(10)33F23G0544(11)231014(17)260930
CS-15312-XM	33F25E0442	(01)10801902127508(10)33F25E0442(11)250523(17)280108
CS-15322-I	33F23G0545	(01)30801902197451(10)33F23G0545(11)230904(17)260831
CS-15322-SPM	33F23D0865	(01)30801902193538(10)33F23D0865(11)230507(17)260430
CS-15322-SPM	33F23H1010	(01)30801902193538(10)33F23H1010(11)231005(17)260930
CS-15322-SPM	33F23L0955	(01)30801902193538(10)33F23L0955(11)231214(17)260930
CS-15322-SPM	33F24E0812	(01)30801902193538(10)33F24E0812(11)240715(17)270630
CS-15322-SPM	33F25C0682	(01)30801902193538(10)33F25C0682(11)250430(17)280118
CS-15322-SPM	33F25E0335	(01)30801902193538(10)33F25E0335(11)250716(17)280121
CS-15322-VSP	33F23C0869	(01)20801902195184(10)33F23C0869(11)210526(17)260331
CS-15322-VSP	33F23D0862	(01)20801902195184(10)33F23D0862(11)210625(17)260430
CS-15322-VSP	33F23F0723	(01)20801902195184(10)33F23F0723(11)210825(17)260630
CS-15322-VSP	33F23H0985	(01)20801902195184(10)33F23H0985(11)240104(17)261231
CS-15322-VSP	33F24A0272	(01)20801902195184(10)33F24A0272(11)240212(17)270131
CS-15322-VSP	33F24C0066	(01)20801902195184(10)33F24C0066(11)240618(17)270531
CS-15322-VSP	33F24E0813	(01)20801902195184(10)33F24E0813(11)240722(17)270630
CS-15322-VSP	33F24G0170	(01)20801902195184(10)33F24G0170(11)240802(17)270731
CS-15322-VSP	33F24G0185	(01)20801902195184(10)33F24G0185(11)240802(17)270731

**Appendix 2: EIF-000605 – Product code, Lot Number, Unique Device Identifier (UDI) Information**

Product Code	Batch	UDI#
CS-15322-VSP	33F24H0256	(01)20801902195184(10)33F24H0256(11)240829(17)270731
CS-15322-VSP	33F24J0040	(01)20801902195184(10)33F24J0040(11)250122(17)271231
CS-15322-VSP	33F24L0183	(01)20801902195184(10)33F24L0183(11)241126(17)271031
CS-15322-VSP	33F24M0222	(01)20801902195184(10)33F24M0222(11)250204(17)280131
CS-15322-VSP	33F25A0426	(01)20801902195184(10)33F25A0426(11)250224(17)280131
CS-15322-VSP	33F25C0022	(01)20801902195184(10)33F25C0022(11)250311(17)271215
CS-15322-VSP	33F25C0593	(01)20801902195184(10)33F25C0593(11)250325(17)280229
CS-15322-VSP	33F25E1082	(01)20801902195184(10)33F25E1082(11)250721(17)280630
CS-15322-VSP	33F25G0024	(01)20801902195184(10)33F25G0024(11)250930(17)280524
CS-15322-VSP	33F25H0297	(01)20801902195184(10)33F25H0297(11)251105(17)280608
CS-15362-SPM	33F24G0062	(01)20801902193548(10)33F24G0062(11)241128(17)271031
CS-15362-VSP	33F23C0875	(01)30801902195525(10)33F23C0875(11)230504(17)260430
CS-15362-VSP	33F23G0546	(01)30801902195525(10)33F23G0546(11)230915(17)260831
CS-15362-VSP	33F23K0195	(01)30801902195525(10)33F23K0195(11)240213(17)270131
CS-15362-VSP	33F24E0186	(01)30801902195525(10)33F24E0186(11)240620(17)270531
CS-15362-VSP	33F24H0039	(01)30801902195525(10)33F24H0039(11)240823(17)270731
CS-15362-VSP	33F24L0201	(01)30801902195525(10)33F24L0201(11)241122(17)271031
CS-15362-VSP	33F24M0235	(01)30801902195525(10)33F24M0235(11)250129(17)271125
CS-15362-VSP	33F25C0647	(01)30801902195525(10)33F25C0647(11)250408(17)280331
CS-15362-VSP	33F25E0326	(01)30801902195525(10)33F25E0326(11)250526(17)280430
CS-15362-VSP	33F25G0058	(01)30801902195525(10)33F25G0058(11)250919(17)280831
CS-15362-VSP	33F25J0043	(01)30801902195525(10)33F25J0043(11)251107(17)280608
CS-15422-SFX	33F23K0179	(01)30801902195327(10)33F23K0179(11)231027(17)260930
CS-15422-SFX	33F23L0956	(01)30801902195327(10)33F23L0956(11)240111(17)261231
CS-15422-SFX	33F24A0290	(01)30801902195327(10)33F24A0290(11)240501(17)270331
CS-15422-SFX	33F24E0814	(01)30801902195327(10)33F24E0814(11)240612(17)270531
CS-15422-VF	33F23H1020	(01)10801902128666(10)33F23H1020(11)230929(17)260831
CS-15422-VF	33F25G0734	(01)10801902128666(10)33F25G0734(11)250825(17)280731
CS-15422-VFE	33F23G0548	(01)10801902197341(10)33F23G0548(11)230802(17)260531
CS-15422-VFE	33F23H0986	(01)10801902197341(10)33F23H0986(11)230905(17)260831
CS-15422-VFE	33F23L0957	(01)10801902197341(10)33F23L0957(11)231206(17)261130
CS-15422-VFE	33F24A0929	(01)10801902197341(10)33F24A0929(11)240201(17)270131
CS-15422-VFE	33F24J0483	(01)10801902197341(10)33F24J0483(11)241205(17)271130
CS-15422-VFE	33F24M0229	(01)10801902197341(10)33F24M0229(11)250120(17)271231
CS-15422-VFE	33F25C0681	(01)10801902197341(10)33F25C0681(11)250417(17)280225
CS-15422-VFE	33F25E0440	(01)10801902197341(10)33F25E0440(11)250523(17)280430
CS-15422-VFE	33F25F0250	(01)10801902197341(10)33F25F0250(11)250709(17)270731
CS-15422-VFE	33F25G0484	(01)10801902197341(10)33F25G0484(11)250825(17)280731
CS-15422-VFI	33F23G0549	(01)10801902193664(10)33F23G0549(11)230802(17)260731
CS-15422-VFI	33F24E0815	(01)10801902193664(10)33F24E0815(11)240621(17)270531
CS-15422-VFI	33F25E1074	(01)10801902193664(10)33F25E1074(11)250825(17)280420
CS-15422-VFIE	33F23G0550	(01)10801902197440(10)33F23G0550(11)230905(17)260831
CS-15422-VFIE	33F23K0178	(01)10801902197440(10)33F23K0178(11)231108(17)261031
CS-15422-VFIE	33F23L0958	(01)10801902197440(10)33F23L0958(11)231209(17)261130
CS-15422-VFIE	33F24A0919	(01)10801902197440(10)33F24A0919(11)240207(17)270131
CS-15422-VFIE	33F24C0073	(01)10801902197440(10)33F24C0073(11)240501(17)270430
CS-15422-VFIE	33F24E0816	(01)10801902197440(10)33F24E0816(11)241003(17)270930
CS-15422-VFIE	33F25F0303	(01)10801902197440(10)33F25F0303(11)250825(17)280731
CS-15502-SFX	33F23L0959	(01)30801902195563(10)33F23L0959(11)240110(17)261231
CS-15502-SFX	33F24A0286	(01)30801902195563(10)33F24A0286(11)240502(17)270430
CS-15502-SFX	33F24J0060	(01)30801902195563(10)33F24J0060(11)241011(17)270930
CS-15552-VF	33F23H1012	(01)10801902128703(10)33F23H1012(11)230928(17)260831

**Appendix 2: EIF-000605 – Product code, Lot Number, Unique Device Identifier (UDI) Information**

Product Code	Batch	UDI#
CS-15552-VF	33F25C0674	(01)10801902128703(10)33F25C0674(11)250404(17)280331
CS-15552-VF	33F25J0588	(01)10801902128703(10)33F25J0588(11)251029(17)280930
CS-15552-VFE	33F23D0868	(01)10801902195156(10)33F23D0868(11)230529(17)260430
CS-15552-VFE	33F23G0261	(01)10801902195156(10)33F23G0261(11)230719(17)260630
CS-15552-VFE	33F23G0551	(01)10801902195156(10)33F23G0551(11)230905(17)260831
CS-15552-VFE	33F23K0173	(01)10801902195156(10)33F23K0173(11)231018(17)260930
CS-15552-VFE	33F24A0928	(01)10801902195156(10)33F24A0928(11)240129(17)261231
CS-15552-VFE	33F24D1014	(01)10801902195156(10)33F24D1014(11)240607(17)270531
CS-15552-VFE	33F24E0818	(01)10801902195156(10)33F24E0818(11)240611(17)270531
CS-15552-VFE	33F24J0059	(01)10801902195156(10)33F24J0059(11)241004(17)270930
CS-15552-VFE	33F24K0511	(01)10801902195156(10)33F24K0511(11)241129(17)271031
CS-15552-VFE	33F25C0670	(01)10801902195156(10)33F25C0670(11)250401(17)280331
CS-15552-VFE	33F25E0471	(01)10801902195156(10)33F25E0471(11)250620(17)280531
CS-15552-VFE	33F25F0455	(01)10801902195156(10)33F25F0455(11)250707(17)280510
CS-15552-VFE	33F25G0447	(01)10801902195156(10)33F25G0447(11)250825(17)280731
CS-15552-VFI	33F23K0184	(01)10801902193671(10)33F23K0184(11)231109(17)261031
CS-15552-VFI	33F24J0076	(01)10801902193671(10)33F24J0076(11)241205(17)271130
CS-15552-VFI	33F25E1075	(01)10801902193671(10)33F25E1075(11)250704(17)280630
CS-15552-VFIE	33F23E0865	(01)10801902195163(10)33F23E0865(11)230606(17)260531
CS-15552-VFIE	33F23F0743	(01)10801902195163(10)33F23F0743(11)230710(17)260630
CS-15552-VFIE	33F24D0972	(01)10801902195163(10)33F24D0972(11)240501(17)270430
CS-15552-VFIE	33F24E0819	(01)10801902195163(10)33F24E0819(11)240718(17)270630
CS-15552-VFIE	33F24G0098	(01)10801902195163(10)33F24G0098(11)241025(17)270902
CS-15552-VFIE	33F24K0656	(01)10801902195163(10)33F24K0656(11)241206(17)271130
CS-15552-VFIE	33F25A0032	(01)10801902195163(10)33F25A0032(11)250228(17)280131
CS-15552-VSP	33F23G0552	(01)30801902195198(10)33F23G0552(11)230802(17)260731
CS-15552-VSP	33F23H0987	(01)30801902195198(10)33F23H0987(11)230906(17)260831
CS-15552-VSP	33F23L0961	(01)30801902195198(10)33F23L0961(11)240103(17)261130
CS-15552-VSP	33F24C0070	(01)30801902195198(10)33F24C0070(11)220625(17)270430
CS-15552-VSP	33F24E0820	(01)30801902195198(10)33F24E0820(11)240801(17)270731
CS-15552-VSP	33F24H0257	(01)30801902195198(10)33F24H0257(11)240824(17)270731
CS-15552-VSP	33F24L0068	(01)30801902195198(10)33F24L0068(11)250220(17)280131
CS-15552-VSP	33F24M0227	(01)30801902195198(10)33F24M0227(11)250124(17)271125
CS-15552-VSP	33F25C0654	(01)30801902195198(10)33F25C0654(11)250422(17)280225
CS-15552-VSP	33F25E0432	(01)30801902195198(10)33F25E0432(11)250519(17)280430
CSD-15242-SP	33F24A0303	(01)20801902096610(10)33F24A0303(11)240411(17)270331
CSD-15242-SP	33F25C0688	(01)20801902096610(10)33F25C0688(11)250423(17)280225
CSD-15282-SP	33F23K1087	(01)20801902096634(10)33F23K1087(11)240114(17)261231
CSD-15282-SP	33F24A0297	(01)20801902096634(10)33F24A0297(11)240116(17)261231

## URGENT MEDICAL DEVICE RECALL NOTICE

**Name of Affected Products:** 16F Dual-Valved Splittable Sheath Introducer

**Action Required:** Destroy at the point of use

---

Merit Medical Systems, Inc. (Merit) is conducting a voluntary recall of the Merit 16F Dual-Valved Splittable Sheath Introducer due to a design defect. Specifically, the sheath introducer may not split as intended. This sheath introducer is used in several Merit finished devices, a complete list of affected products and lots can be found in the table attached or can be accessed at "<https://www.merit.com/products/documents/product-notices/16FDualValvedSheath-recall/>".

Merit has received customer complaints regarding this issue, some of which involve patient injury. Failure of the sheath introducer to split as intended may result in hemorrhage, foreign bodies, and procedure delay.

Merit is requesting you to immediately discontinue the use of the 16F Dual-Valved Splittable Sheath Introducer and destroy the sheath introducer at point of use. The other products included with the sheath introducer may continue to be used.

### Actions required of you:

1. Please immediately determine if any of the devices identified in the attached Customer Response Form (CRF) are within your facility.
2. A picture of the 16F Dual-Valved Splittable Sheath Introducer is attached to help you identify the product. Please place this notice and the picture on or near the affected Merit product in your inventory (if applicable).



3. Please immediately discontinue the use of the 16F Dual-Valved Splittable Sheath Introducer and destroy the sheath introducer at the point of use.
4. Ensure that applicable personnel within your organization are made aware of this field action.
5. If the product has been further distributed to other facilities, institutions, or manufacturers, please ensure this notice is immediately shared with them and note the quantity distributed on the CRF. Additional distribution details may be required by health authorities.
6. Please fill out, scan and email the completed Customer Response Form to Customer Service at [REDACTED] within 10 business days. All affected product shipped to you must be accounted for on the CRF.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, or by fax.

[REDACTED]

Merit Medical is committed to providing high quality products to you and apologizes for any inconvenience this field action may cause.

Enclosure(s)

**Affected Lots Table**  
(16F Dual-Valved Splittable Sheath Introducer)

Catalog Code	Lot Number
CENFP15K/A	H3357122
CENFP15K/B	H2797565
CENFP17K/A	H2643728
	H2644554
	H2755843
	H2777866
	H3357123
CENFP19K/A	H2415318
	H2466455
	H2466456
	H2608337
	H2632772
	H2632921
	H2643525
	H2643729
	H2658246
	H2658395
	H2663614
	H2708827
	H2777850
	H2817064
	H2817066
	H2834183
	H2834184
	H2835774
	H2875195
	H2892153
	H2900496
	H2900649
	H2918430
	H2938756
	H2982068
	H2998532
	H3019164
	H3028009
	H3089474
	H3096774
	H3101839
	H3110067
	H3123035
H3131873	
H3139507	
H3143969	
H3152236	
H3328470	
H3332131	
H3332133	
H3357124	
H3383280	
H3398546	
CENFP23K/A	H2368055
	H2460265
	H2543292
	H2612929

Catalog Code	Lot Number
DC21453227/C	H2630602
DC21454035/C	H2628887
DC21455550/C	H2630553
	H2659229
FCL-174-00/B	I2362705
	I2370091
	I2370711
	I2370712
	I2377840
	I2377841
	I2391548
	I2397290
	I2415120
	I2417400
	I2417401
	I2417402
	I2428656
	I2428657
	I2428658
	I2428659
	I2469204
	I2469205
	I2469206
	I2469207
	I2473119
	I2485668
	I2485669
	I2485670
	I2485671
	I2485672
	I2485673
	I2485674
	I2485675
	I2496785
	I2496787
	I2496790
	I2516610
I2516611	
I2516612	
I2516613	
I2516614	
I2516615	
I2539710	
I2539711	
I2539713	
I2539714	
I2539715	
I2539717	
I2561078	
I2561079	
I2561081	
I2561082	
I2573969	
I2606642	

Catalog Code	Lot Number
H965103028031/A	I3120008
	I3156395
	I3161825
	I3178917
	I3202927
	I3236144
	I3236147
	I3236157
	I3236162
	I3236164
I3368281	
H965103028031/EU	I3219447
	I3270828
H965103028041/A	I3288591
	I2838431
	I2910263
	I2910264
	I2910265
	I2973186
	I2975804
	I2975805
	I2979959
	I2979960
	I3015758
	I3064923
	I3064925
	I3072563
	I3108163
	I3120003
	I3120006
	I3156399
	I3165147
	I3175748
	I3178899
I3208677	
I3236145	
I3236148	
I3236158	
I3236163	
I3236165	
I3312321	
I3315961	
I3323271	
I3347039	
H965103028041/EU	I3217180
	I3270829
H965103028051/A	I3302439
	I2929337
H965103028051/EU	I2997999
	I3311219
H965103028061/A	I3219448
	I3270832
	I3302440
	I2920321

Affected Lots Table  
(16F Dual-Valved Splittable Sheath Introducer)

Catalog Code	Lot Number
CENFP23K/A	H2622368
	H2623456
	H2631340
	H2640771
	H2663612
	H2663613
	H2719753
	H2812164
	H2817069
	H2834179
	H2834181
	H2847016
	H2868174
	H2880283
	H2897527
	H2900497
	H2900550
	H2907334
	H2911460
	H2938761
	H2978595
	H2990699
	H3004608
	H3019163
	H3049760
	H3049761
	H3052479
	H3071291
	H3075039
	H3089475
	H3092914
	H3096777
	H3104588
	H3107507
	H3120779
	H3131874
	H3143970
	H3145117
	H3191613
	H3211721
H3316467	
H3328494	
H3332218	
H3332219	
H3332220	
H3351695	
CENFP27K/A	H2286892
	H2480924
	H2623453
	H2643731
	H2643732
	H2653626
	H2663616
	H2777861

Catalog Code	Lot Number
FCL-174-00/B	I2606643
	I2606644
	I2606645
	I2619459
	I2621646
	I2621647
	I2621648
	I2621649
	I2621650
	I2621651
	I2621652
	I2621653
	I2642738
	I2642739
	I2642740
	I2644031
	I2644032
	I2644033
	I2644034
	I2644036
	I2661872
	I2661873
	I2661874
	I2661875
	I2661876
	I2661877
	I2708121
	I2708122
	I2708123
	I2708124
	I2720071
	I2720074
	I2720075
	I2720076
	I2720077
	I2720078
	I2720079
	I2729938
	I2729939
	I2729940
I2729941	
I2729942	
I2729943	
I2729944	
I2729945	
I2759253	
I2759254	
I2759255	
I2759256	
I2759257	
I2759258	
I2759260	
I2759261	
I2759268	

Catalog Code	Lot Number
H965103028061/A	I2980492
	I3154945
H965103028061/EU	I3254911
	I3196140
H965103028070/A	I3270833
	I3312332
	I3015819
H965103028070/EU	I3113237
	I3170179
	I3247943
H965103028080/A	I3288616
	I3255305
	I3307483
H965103028080/EU	I3002021
	I3064921
	I3178919
H965103028090/A	I3302450
	I3343031
	I3196137
H965103028090/EU	I3302445
	I3334625
	I2920165
H965103028090/A	I3103138
	I3178922
	I3290565
H965103028090/EU	I3196135
	I3302441
	I3352493
H965103028161/A	I2914680
	I2980457
	I3098578
H965103028181/A	I2890978
	I2902665
	I2909617
	I2909618
	I2929338
	I3076856
	I3085067
	I3098579
	I3178915
	I3254917
I3255301	
H965103028191/A	I3283028
	H2936911
	I2870746
	I2908636
	I2909637
	I2910257
	I2920337
	I2927199
	I3144031
	I3164176
I3219662	
I3236146	

Affected Lots Table  
(16F Dual-Valved Splittable Sheath Introducer)

Catalog Code	Lot Number
	H2798003
<b>CENFP27K/A</b>	H2833668
	H2834185
	H2880284
	H2900619
	H2907339
	H2910719
	H2911565
	H2978601
	H2986646
	H2998508
	H3004606
	H3013812
	H3019148
	H3096779
	H3110068
	H3131879
	H3143988
	H3145119
	H3156431
	H3357125
H3383281	
<b>CENFP31K/A</b>	H2623455
	H2643737
	H2663617
	H3052480
	H3071293
	H3071294
	H3110069
	H3113265
	H3143998
	H3196708
	H3328496
	H3332421
	<b>CENFT15K</b>
H2907340	
H2911505	
H2978606	
H3004602	
<b>CENFT15K/D</b>	H3071303
	H3075046
	H3116838
<b>CENFT17K</b>	H2750962
	H2755782
	H2777600
	H3034899
	H3059017
	H3059018
H3062346	
<b>CENFT17K/A</b>	H2911456
<b>CENFT17K/D</b>	H3139508
<b>CENFT19K</b>	H2632775
	H2658397
	H2709212

Catalog Code	Lot Number
	I2759269
<b>FCL-174-00/B</b>	I2781492
	I2781493
	I2781494
	I2781495
	I2781496
	I2781497
	I2781498
	I2781499
	I2788883
	I2788884
	I2788885
	I2788886
	I2788887
	I2788888
	I2788889
	I2788890
	I2788891
	I2788892
	I2810292
	I2810293
	I2810294
	I2810296
	I2810297
	I2841474
	I2841475
	I2849305
	I2849306
	I2854355
	I2854356
	I2854357
	I2860217
	I2860218
I2861568	
I2861569	
I2871785	
I2871786	
I2871787	
I2883689	
I2883691	
I2890983	
I2904247	
I2904250	
I2927630	
I2927631	
I2942563	
I2942564	
I2942565	
I2942566	
I2942567	
I2942568	
I2942569	
I2942570	
I2942571	

Catalog Code	Lot Number
	I3288655
<b>H965103028191/A</b>	I3368110
<b>H965103028191/EU</b>	I3309111
<b>H965103028201/A</b>	I2973187
	I3173621
	I3178898
	I3236149
	I3288573
<b>H965103028211/A</b>	I2909764
	I3144033
	I3302435
	I3343037
<b>H965103028220/A</b>	I2909788
	I3394016
<b>H965103028230/A</b>	I2982337
	I3044847
	I3191920
	I3288574
	I3334623
<b>H965103028240/A</b>	I2929339
	I3002035
	I3049565
	I3108165
	I3254923
	I3302451
<b>H965103038181/A</b>	I2890952
	I2902661
	I2902662
<b>K12-03886DP</b>	H3138928
<b>H787103028235/A</b>	I3178905
<b>H965103028011/A</b>	I3105589
	I3115469
	I3314948
	I3343030
<b>H965103028021/A</b>	I2985084
	I3235297
	I3302100
	I3343023
<b>H965103028021/EU</b>	I3254932
<b>H965103028031/A</b>	I2890967
	I2909607
	I2909610
	I2909613
	I2922255
	I2928443
	I2928445
	I2973185
	I2975817
	I2979931
	I2979932
	I3010126
	I3015730
I3015731	
I3072562	

Affected Lots Table  
(16F Dual-Valved Splittable Sheath Introducer)

Catalog Code	Lot Number	
CENFT19K	H2817067	
	H2821275	
	H2835372	
	H2856854	
	H2864393S1	
	H2884659	
	H2900500	
	H2907322	
	H2907349	
	H2918517	
	H2933863	
	H2937909	
	H2937910	
	H2978622	
	H2999167	
	H3019145	
	H3034898	
H3049764		
CENFT19K/A	H2907422	
CENFT19K/B	H2801414	
CENFT19K/D	H3049766	
	H3049767	
	H3071304	
	H3075050	
	H3089478	
	H3126999	
	H3144001	
	H3152238	
	H3156433	
	H3162590	
	H3179819	
	H3196714	
	H3221338	
	H3233980	
	H3239914	
	H3253651	
	H3261220	
	H3283451	
	H3306069	
	H3350849	
	H3357127	
	H3357128	
	H3365884	
	H3372112	
	H3398547	
	CENFT23K	H2368107
		H2657097
H2709213		
H2719652		
H2783586		
H2812165		
H2834187		
H2834188		
H2864382S1		

Catalog Code	Lot Number
FCL-174-00/B	I2942667
	I2942669
	I2988895
	I2988896
	I2988897
	I3013245
	I3013246
	I3075993
	I3075994
	I3075995
	I3075996
	I3075997
	I3083308
	I3083309
	I3083310
	I3083312
	I3083314
	I3083317
	I3098214
	I3098256
	I3127468
	I3138237
	I3138238
	I3138239
	I3138240
	I3138241
	I3138242
	I3159773
	I3159774
	I3159776
I3159777	
I3186218	
I3257331	
H787103028015/A	I3049562
H787103028025/A	I3309371
H787103028031/A	I2929299
	I3072553
	I3154760
	I3175731
I3178921	
I3315957	
H787103028035/A	I2910259
	I2910261
	I2910262
	I2980545
	I2995795
	I3021388
	I3076851
	I3085062
	I3219446
	I3219454
I3255314	
I3288649	
I3334618	

Catalog Code	Lot Number
	I3108161
	I3115487

**Affected Lots Table**  
(16F Dual-Valved Splittable Sheath Introducer)

Catalog Code	Lot Number
	H2870049
	H2892155
	H2898665
<b>CENFT23K</b>	H2900501
	H2907365
	H2911451
	H2911452
	H2934395
	H2971862
	H2986161
	H2986162
	H2998549
	H3007025
	H3019139
	H3028000
	<b>CENFT23K/A</b>
H2817068	
H2911454	
H2990794	
H3013830	
H3019136	
H3034895	
<b>CENFT23K/B</b>	H2801413
<b>CENFT23K/D</b>	H3049771
	H3049772
	H3071305
	H3071306
	H3145122
	H3152240
	H3170518
	H3196713
	H3201956
	H3211729
	H3221345
	H3233987
	H3239915
	H3249275
	H3275167
	H3301761
	H3306072
	H3323733
	H3332225
	H3342600
<b>CENFT27K</b>	H2618709
	H2642807
	H2783590
	H2817065
	H2835374
	H2884649
	H2892156
	H2900227
	H2910433
	H2937927
	H2949972

Catalog Code	Lot Number
<b>H787103028041/A</b>	I2909647
	I3115465
	I3178909
	I3236154
<b>H787103028045/A</b>	I3004072
	I3015761
	I3044845
	I3072554
	I3108153
	I3176646
	I3178918
	I3213147
	I3219456
	I3281054
	I3334627
<b>H787103028051/A</b>	I2995730
	I3072556
	I3213145
	I3219455
	I3288560
<b>H787103028055/A</b>	I3178903
<b>H787103028061/A</b>	I2929300
	I2995814
	I3072557
	I3165105
	I3207168
	I3236155
	I3334619
<b>H787103028075/A</b>	I2995817
	I3209313
	I3270826
<b>H787103028085/A</b>	I2890956
	I3072561
	I3108155
	I3288562
	I3302444
<b>H787103028095/A</b>	I2909667
	I2929315
	I3021151
	I3098576
	I3219463
	I3288581
<b>H787103028165/A</b>	I3049563
<b>H787103028181/A</b>	I2929317
	I3178900
	I3208675
<b>H787103028185/A</b>	I2927170
	I2929318
	I2929319
	I3002050
	I3015762
	I3021450
	I3049572

Catalog Code	Lot Number
--------------	------------

**Affected Lots Table**  
(16F Dual-Valved Splittable Sheath Introducer)

Catalog Code	Lot Number
	H2971939
	H3019133
	H3027993
	H3059051
<b>CENFT27K</b>	H3062349
	H3071308
<b>CENFT27K/A</b>	H2831335
	H2847031
	H2911463
	H3019129
<b>CENFT27K/B</b>	H2801412
<b>CENFT27K/D</b>	H3049776
	H3049777
	H3080509
	H3152241
	H3179811
	H3186110
	H3191615
	H3201954
	H3206164
	H3301764
	H3323734
	H3342755
	H3372113
	H3385315
<b>CENFT31K</b>	H2821396
	H2884650
	H2900615
	H2911536
	H2933865
	H2971861
	H3003224
	H3059059
	H3059060
	H3089477
	H3101838
<b>CENFT31K/A</b>	H2938653
	H3013843
<b>CENFT31K/B</b>	H2811536
<b>CENFT31K/D</b>	H3071085
	H3071309
	H3082414
	H3144317
	H3163092
	H3179823
	H3191620
	H3206153
	H3239916
	H3249277
	H3275168
	H3283445
	H3306075
	H3323741
<b>DC0145550/C</b>	H2600169

Catalog Code	Lot Number
	I3085060
	I3173615
	I3178896
	I3195157
<b>H787103028185/A</b>	I3288651
	I3334629
<b>H787103028191/A</b>	I2909758
<b>H787103028195/A</b>	I2890957
	I2929321
	I3021395
	I3049573
	I3076853
	I3124837
	I3169030
	I3213148
	I3236141
	I3236161
	I3302447
	I3343042
<b>H787103028205/A</b>	I2927146
	I2995766
	I3015801
	I3044846
	I3144026
	I3219464
	I3288564
	I3302448
<b>H787103028215/A</b>	I3178904
<b>H787103028225/A</b>	I3044836
	I3108157
	I3236142
	I3315958
<b>DC21452419/C</b>	H2659228
<b>DC21452419-NE5/C</b>	H3249278
<b>DC21452823/C</b>	H2600164
	H2628890
<b>DC21452823-NE5/C</b>	H2990807

Catalog Code	Lot Number
--------------	------------

--