

Arrow International LLC  
 c/o Teleflex Medical  
 IDA Business & Technology Park  
 Dublin Road, Athlone  
 Westmeath, Ireland

January 2022

**URGENT – FIELD SAFETY NOTICE**

Type of Action	Recall					
Teleflex Reference	EIF-000499					
Commercial Name	Arrow-Trerotola™ Over-The-Wire PTD Kit® Percutaneous Thrombolytic Device Arrow-Trerotola™ PTD Set® Percutaneous Thrombolytic Device Arrow-Trerotola™ Kit® Percutaneous Thrombolytic Device					
Product Code	Lot Number					
PT-12709-WC	13F20C0094	13F20G0284	13F20L0282	13F21A0497	13F21A0718	13X21E0008
	13F21F1187					
PT-65709-HFWC	13F20A0323	13F20B0139	13F20C0594	13F20F0083	13F20F0230	13F20F0577
	13F20H0756	13F20K0849	13F20L0283	13F20M0182	13F21A0498	13F21B0158
	13F21C0747	13F21E0555				
PT-65709-W	13F19M0129	13F20B0053	13F20C0595	13F20F0231	13F20G0361	13F20K0632
	13F21A0353	13F21C0748	13F21D0721	13F21E0823	13F21F1189	
PT-65709-WC	13F20C0596	13F20F0081	13F20F0229	13F20F0509	13F20F0578	13F20G0177
	13F20G0566	13F20H0531	13F20J0379	13F20L0514	13F21A0354	13F21C0081
	13F21C0749	13F21D0870	13F21E0415	13F21F1188		
PT-45509	13F20A0209	13F20B0054	13F20B0527	13F20C0427	13F20D0127	13F20D0402
	13F20F0390	13F20G0285	13F20J0545	13F20J0933	13F20K0851	13F20M0174
	13F21A0662	13F21C0079	13F21C0751	13X21D0027	13F21F0399	13F21G0226
	13F21G1343	13F21H0639	13F21H1272	13F21L0900		
PT-65509-HFC	13F20A0359	13F20A0519	13F20B0140	13F20B0423	13F20C0223	13F20C0593
	13F20D0128	13F20D0386	13F20F0576	13F20G0176	13F20J0139	13F20J0547
	13F20K0212	13F20L0160	13F20M0183	13F21B0224	13F21C0080	13F21C0366
	13F21D0106	13X21D0026	13F21E0078	13F21E0557	13F21G1344	13F21H0213
	13F21H0659	13F21J0455	13F21K0897	13F21L0901		
PT-65509	13F20A0286	13F20A0426	13F20A0640	13F20B0141	13F20B0276	13F20B0353
	13F20B0424	13F20C0352	13F20C0425	13F20C0426	13F20D0122	13F20D0123
	13F20D0124	13F20D0403	13F20E0204	13F20F0232	13F20F0389	13F20G0353
	13F20H0729	13F20J0378	13F20J0546	13F20J0771	13F20K0503	13F20K0504
	13F20K0630	13F20K0631	13F20M0175	13F20M0176	13F20M0177	13F20M0178
	13F20M0181	13F21A0352	13F21B0159	13F21B0222	13F21B0519	13F21C0364
	13F21C0365	13F21D0462	13F21E0079	13F21E0259	13F21E0260	13F21E0556
	13F21F0641	13F21G0227	13F21G0401	13F21G0772	13F21H0447	13F21K0827
13F21K0898	13F21L0227	13F21L0507	13F21L0898			

Note: Refer to **Appendix 3** for Unique Device Identifier (UDI) Information

Dear Customer,

**Details of affected devices**

Arrow International LLC, a subsidiary of Teleflex Incorporated, has initiated a voluntary Field Safety Corrective Action (FSCA) for 5FR and 7FR Percutaneous Thrombolytic Device (PTD®) Sets and Kits; refer to appendix 2 for a list of product codes and lots impacted.

**IMPORTANT NOTE REGARDING SCOPE** – The scope of this action includes all 5FR and 7FR devices within shelf life. 7FR devices are also in scope of a previous Field Safety Corrective Action. For safety reasons, Teleflex is including all information in this new action.

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

Teleflex is initiating a voluntary Field Safety Corrective Action due to reports received indicating PTD® tip separation during use. If the tip separates during use, clinicians may exercise their medical judgment to either retrieve endovascularly with a snare device or with a minor surgical procedure or elect not to retrieve the tip given the recognition that embolism of a small and inert tip may be less likely to be harmful than extraordinary attempts to retrieve said tip. Partial or full embolization of foreign material into the arterial or venous circulation is possible, potentially leading to vascular complications, including but not limited to mechanical obstruction of an artery or vein, arterial or venous thrombosis, ischemia, or infarction in the territory subtended by an obstructed or thrombosed artery (including pulmonary embolism and infarction), and remotely, endovascular infection. The consequences of embolizing foreign material into the peripheral or pulmonary circulation or components thereof are substantially determined by the size of the embolus. Clinicians may also elect to exclude the embolus from the circulation by trapping the embolus outside a newly deployed stent.

As of December 2021, a total of 35 complaints reporting tip separation have been received for 5FR and 7FR products in scope combined. Of these 35 complaints (30 for 5FR; 4 for 7FR; 1 for unknown), 9 complaints (9 for 5FR) involved use of a stent to manage the embolism. No deaths or long-term patient injuries have been reported at this time.

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

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

**Action list number 2 – Distributors**

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

**Teleflex**

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

**Transmission of this Field Safety Notice**

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

**Contact reference person**

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

**Contact:** Sales Assistants

**Telephone:** +31 (0) 88 00 215 00

**FAX:** +31 (0) 88 00 215 10

**Email:** [productcomplaints.netherlands@teleflex.com](mailto:productcomplaints.netherlands@teleflex.com)

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

*For and on behalf of Teleflex,*

**xxx**

**Appendix 1**

**Customer No**  
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**FIELD SAFETY CORRECTIVE ACTION**  
**ACKNOWLEDGEMENT FORM**

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

Ref. EIF-000499

**RETURN COMPLETED FORM IMMEDIATELY TO:**

**FAX:** +31 (0) 88 00 215 10

**Email:** [productcomplaints.netherlands@teleflex.com](mailto:productcomplaints.netherlands@teleflex.com)

<input type="checkbox"/> We confirm receipt of this FSN and completed the required actions contained therein. We confirm that our inventory does <b>NOT</b> include products affected by this Field Action.	<input type="checkbox"/> We confirm receipt of this FSN and completed the required actions contained therein. We confirm our inventory <b>DOES</b> include products affected by this Field Action. The use and further distribution of the affected products is stopped. All products are put on hold and the amount below will be returned. <b>Return Authorisation No</b> _____
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**PLEASE PRINT PRODUCT QUANTITY NUMBERS CLEARLY**

PRODUCT NUMBER	LOT NUMBER	QUANTITY (Returning)
<b>Important</b> - Please ensure you only list batch numbers in scope of this Field Safety 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>RAN number is clearly visible</b> on the returns package</li> <li>• Please label returns as <b>"Field Safety Returns"</b></li> </ul> <p><b>Note:</b> Non FSCA product returns should be processed per standard product return processes</p>		

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

<b>INSTITUTION NAME (EG 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

### Kit configuration

- Components are packed in a box and the boxes are labelled with an overarching product code and lot number.
- Within each box there is a predefined number of components, each component has its own semi-finished code and lot number on the label (refer to appendices 2A-2F).

Due to the nature of these kits, Teleflex is providing all finished product codes and lot numbers and semi-finished codes and lot numbers and UDI information (refer to **Appendix 3**) to ensure ease of product identification depending on the storage method at each location.

### Appendix 2(A)

Overarching Product		Component Product									
Product Code	Lot Number	Code	Lot number	Code	Lot number	Code	Lot number	Code	Lot number	Code	Lot number
PT-12709-WC (3 components)	13F20C0094	PT-12709-C	13C20C0498	PT-65709-HS	14C19K1035	PT-03009	13C19L0622	PT-03009	13C19M0278	PT-03009	13C19J1873
	13F20G0284	PT-12709-C	13C20G0230	PT-65709-HS	14C20D1061	PT-03009	13C20G0238	PT-03009	13C20F2585		
	13F20L0282	PT-12709-C	13C20J0307	PT-65709-HS	14C20H0384	PT-03009	13C20L0872				
	13F21A0497	PT-12709-C	13C20J0307	PT-65709-HS	14C20J1453	PT-03009	13C20M0144				
	13F21A0718	PT-12709-C	13C21A1963	PT-65709-HS	14C20J1453	PT-03009	13C21A0855	PT-03009	13C20M0144		
	13F21F1187	PT-12709-C	13C21C1690	PT-65709-HS	14C21D0635	PT-65709-HS	14C21C0476	PT-03009	13C21C2413		
	13X21E0008	PT-12709-C	13X21E0009	PT-65709-HS	14X21D0002	PT-03009	13X21E0007				

**Appendix 2(B)**

Overarching Product		Component Product									
Product Code	Lot Number	Code	Lot number	Code	Lot number	Code	Lot number	Code	Lot number	Code	Lot number
PT-65709-HFWC (3 Components)	13F20A0323	PT-65709-C	13C19M0499	PT-65709-HFS	14C19J0342	PT-03009	13C19J1873	PT-03009	13C19L0622	PT-03009	13C19J0572
		PT-03009	13C19K0832								
	13F20B0139	PT-65709-C	13C20A0970	PT-65709-HFS	14C20A0611	PT-65709-HFS	14C19G0671	PT-03009	13C19L0622		
	13F20C0594	PT-65709-C	13C20C2082	PT-65709-HFS	14C20A0611	PT-65709-HFS	14C19J0342	PT-03009	13C20B1435		
	13F20F0083	PT-65709-C	13C20F0572	PT-65709-HFS	14C20D1060	PT-65709-HFS	14C20A0611	PT-03009	13C20C1558	PT-03009	13C20B1435
	13F20F0230	PT-65709-C	13C20F1139	PT-65709-HFS	14C20F0586	PT-65709-HFS	14C20D1060	PT-03009	13C20F0570		
	13F20F0577	PT-65709-C	13C20F2175	PT-65709-HFS	14C20F0586	PT-03009	13C20F1138	PT-03009	13C20F0570		
	13F20H0756	PT-65709-C	13C20G1976	PT-65709-HFS	14C20F0274	PT-65709-HFS	14C20F0586	PT-03009	13C20H0604	PT-03009	13C20G1198
	13F20K0849	PT-65709-C	13C20H1675	PT-65709-C	13C20G1976	PT-65709-HFS	14C20F0586	PT-65709-HFS	14C20F0274	PT-03009	13C20H0604
	13F20L0283	PT-65709-C	13C20H1675	PT-65709-C	13C20J2689	PT-65709-HFS	14C20J1446	PT-65709-HFS	14C20F0586	PT-03009	13C20L0872
	13F20M0182	PT-65709-C	13C20J2689	PT-65709-C	13C20H1675	PT-65709-HFS	14C20L0665	PT-65709-HFS	14C20J1446	PT-03009	13C20L0871
	13F21A0498	PT-65709-C	13C20M0639	PT-65709-HFS	14C20J1446	PT-03009	13C21A0855				
	13F21B0158	PT-65709-C	13C21A1348	PT-65709-HFS	14C20M0932	PT-65709-HFS	14C20L0665	PT-65709-HFS	14C20J1446	PT-03009	13C21A0855
	13F21C0747	PT-65709-C	13C21C0326	PT-65709-C	13C21A1348	PT-65709-HFS	14C20L0665	PT-65709-HFS	14C20M0932	PT-03009	13C21B1533
13F21E0555	PT-65709-C	13C21E0328	PT-65709-C	13C21D0717	PT-65709-C	13C21C2412	PT-65709-HFS	14C21C0895	PT-65709-HFS	14C20M0932	
	PT-03009	13C21C2413	PT-03009	13C21C2397							

**Appendix 2(C)**

Overarching Product		Component Product					
Product Code	Lot Number	Code	Lot number	Code	Lot number	Code	Lot number
PT-65709-W (1 Component)	13F19M0129	PT-65709-C	13C19M0499				
	13F20B0053	PT-65709-C	13C20A0970				
	13F20C0595	PT-65709-C	13C20C2089	PT-65709-C	13C20C2082		
	13F20F0231	PT-65709-C	13C20F1139				
	13F20G0361	PT-65709-C	13C20G1199	PT-65709-C	13C20G0228		
	13F20K0632	PT-65709-C	13C20H1675				
	13F21A0353	PT-65709-C	13C20M0639	PT-65709-C	13C20J2689		
	13F21C0748	PT-65709-C	13C21C1696				
	13F21D0721	PT-65709-C	13C21C1696	PT-65709-C	13C21C2412	PT-65709-C	13C21C0326
	13F21E0823	PT-65709-C	13C21E0328				
	13F21F1189	PT-65709-C	13C21E1991	PT-65709-C	13C21E0328		

Appendix 2(D)

Overarching Product		Component Product									
Product Code	Lot Number	Code	Lot number	Code	Lot number	Code	Lot number	Code	Lot number	Code	Lot number
PT-65709-WC (3 Components)	13F20C0596	PT-65709-C	13C20C2082	PT-65709-HS	14C20C1417	PT-03009	13C20B1435	PT-03009	13C19M0278	PT-03009	13C19L0622
		PT-03009	13C20C1558								
	13F20F0081	PT-65709-C	13C20F0572	PT-65709-C	13C20C2082	PT-65709-HS	14C20C0866	PT-65709-HS	14C19K1035	PT-03009	13C20C1558
	13F20F0229	PT-65709-C	13C20F0572	PT-65709-HS	14C20C0866	PT-03009	13C20F0570	PT-03009	13C20C1558		
	13F20F0509	PT-65709-C	13C20F1139	PT-65709-HS	14C20C0866	PT-65709-HS	14C20C1417	PT-03009	13C20F0570		
	13F20F0578	PT-65709-C	13C20F2175	PT-65709-HS	14C20D1061	PT-65709-HS	14C20C0866	PT-03009	13C20F2585	PT-03009	13C20F1138
	13F20G0177	PT-65709-C	13C20G0228	PT-65709-HS	14C20D1061	PT-03009	13C20F2585	PT-03009	13C20G0238		
	13F20G0566	PT-65709-C	13C20G1199	PT-65709-HS	14C20D1061	PT-03009	13C20G0864	PT-03009	13C20G0238	PT-03009	13C20F2585
	13F20H0531	PT-65709-C	13C20G1976	PT-65709-C	13C20G1199	PT-65709-HS	14C20G0395	PT-03009	13C20G1198	PT-03009	13C20G0864
	13F20J0379	PT-65709-C	13C20G1976	PT-65709-C	13C20G1199	PT-65709-HS	14C20H0384	PT-03009	13C20H0604		
	13F20L0514	PT-65709-C	13C20J2689	PT-65709-HS	14C20H0384	PT-65709-HS	14C20J1453	PT-03009	13C20L0871	PT-03009	13C20L0872
	13F21A0354	PT-65709-C	13C20M0639	PT-65709-HS	14C20J1453	PT-03009	13C20M0144				
	13F21C0081	PT-65709-C	13C21A1348	PT-65709-HS	14C20J1453	PT-03009	13C21B1533	PT-03009	13C21A0855		
	13F21C0749	PT-65709-C	13C21C1696	PT-65709-HS	14C21B0690	PT-65709-HS	13C21C1696	PT-03009	13C21C0327	PT-03009	13C21B1533
	13F21D0870	PT-65709-C	13C21D0717	PT-65709-C	13C21C1696	PT-65709-HS	14C21B0690	PT-65709-HS	14C20J1453	PT-03009	13C21C0327
	13F21E0415	PT-65709-C	13C21C2412	PT-65709-C	13C21D0717	PT-65709-C	13C21C1696	PT-65709-HS	14C21C0476	PT-65709-HS	14C21B0690
		PT-03009	13C21C2397	PT-03009	13C21C2413	PT-03009	13C21C0327	PT-03009	13C21B1533		
	13F21F1188	PT-65709-C	13C21E0328	PT-65709-C	13C21E1991	PT-65709-HS	14C21D0635	PT-65709-HS	14C21C0476	PT-03009	13C21C2413
PT-03009		13C21E0722									



Appendix 2(E)

Overarching Product		Component Product									
Product Code	Lot Number	Code	Lot number	Code	Lot number	Code	Lot number	Code	Lot number	Code	Lot number
PT-45509 (2 Components)	13F20A0209	PT-45509-S6	14C19F1336	PT-45509-S6	14C19J0340	PT-45509-T	13C19L1173	PT-45509-T	13C19M0193		
	13F20B0054	PT-45509-S6	14C19F1336	PT-45509-S6	14C19J0340	PT-45509-S6	14C20A0602	PT-45509-T	13C19L1173	PT-45509-T	13C20A1583
		PT-45509-T	13C19M0193								
	13F20B0527	PT-45509-T	13C20A2409	PT-45509-S6	14C20A0602						
	13F20C0427	PT-45509-S6	14C20A0602	PT-45509-T	13C20A2409	PT-45509-T	13C20A2409	PT-45509-T	13C20C0842		
	13F20D0127	PT-45509-S6	14C20A0602	PT-45509-S6	14C20C1054	PT-45509-T	13C20D0847				
	13F20D0402	PT-45509-S6	14C20C1054	PT-45509-S6	14C20D0569	PT-45509-T	13C20D2088				
	13F20F0390	PT-45509-S6	14C20C1054	PT-45509-S6	14C20D0569	PT-45509-T	13C20E0902				
	13F20G0285	PT-45509-S6	14C20G0393	PT-45509-S6	PT-45509-T	13C20G0868					
	13F20J0545	PT-45509-S6	14C20G0393	PT-45509-T	13C20G1979						
	13F20J0933	PT-45509-S6	14C20J1445	PT-45509-T	13C20G1979	PT-45509-T	13C20J1577				
	13F20K0851	PT-45509-S6	14C20G0393	PT-45509-S6	14C20J1445	PT-45509-T	13C20G1979	PT-45509-T	13C20J1577		
	13F20M0174	PT-45509-S6	14C20K1177	PT-45509-S6	14C20G0393	PT-45509-T	13C20K1686	PT-45509-T	13C20L1807		
	13F21A0662	PT-45509-S6	14C20G0393	PT-45509-S6	14C21A0480	PT-45509-T	13C20K1686	PT-45509-T	13C20L1807		
	13F21C0079	PT-45509-S6	14C21A0480	PT-45509-T	13C20J0354						
	13F21C0751	PT-45509-S6	14C21A0480	PT-45509-S6	14C21B0676	PT-45509-S6	14C21C0477	PT-45509-T	13C21C1697	PT-45509-T	13C21B0771
	13X21D0027	PT-45509-S6	14X21D0003	PT-45509-S6	14C21B0676	PT-45509-T	13X21D0009				
	13F21F0399	PT-45509-S6	14C21C0477	PT-45509-S6	14C21D0675	PT-45509-T	13C21E0717				
	13F21G0226	PT-45509-S6	14C21C0477	PT-45509-S6	14C21E0925	PT-45509-T	13C21F2205				
	13F21G1343	PT-45509-S6	14C21E0925	PT-45509-T	13C21F2205						
13F21H0639	PT-45509-S6	14C21E0925	PT-45509-S6	14C21G1307	PT-45509-T	13C21H0942					
13F21H1272	PT-45509-T2	13C21H2037	PT-45509-S7	14C21H0978							
13F21L0900	PT-45509-T2	13C21L1103	PT-45509-S7	14C21H1310							

Appendix 2(F)

Overarching Product		Component Product									
Product Code	Lot Number	Code	Lot number	Code	Lot number	Code	Lot number	Code	Lot number	Code	Lot number
PT-65509-HFC (3 Components)	13F20A0359	PT-65509-S	14C19H0644	PT-65509-S	14C19L1402	PT-03000	13C19J0203	PT-01000-D	13C19L2034		
	13F20A0519	PT-65509-S	14C19L1402	PT-03000	13C19J0203	PT-03000	13C19M0279	PT-01000-D	13C20A0986		
	13F20B0140	PT-65509-S	14C19L1402	PT-03000	13C19M0279	PT-03000	13C19M0954	PT-01000-D	13C20A2408		
	13F20B0423	PT-65509-S	14C19L1402	PT-03000	13C19M0954	PT-03000	13C20A0627	PT-01000-D	13C20B1758		
	13F20C0223	PT-65509-S	14C19L1402	PT-03000	13C19M0954	PT-03000	13C20A0627	PT-01000-D	13C20B2334		
	13F20C0593	PT-65509-S	14C19L1402	PT-65509-S	14C20C0858	PT-03000	13C20A0627	PT-01000-D	13C20B2334	PT-01000-D	13C20C1557
	13F20D0128	PT-65509-S	14C20C0858	PT-65509-S	14C20D0475	PT-03000	13C20B0812	PT-01000-D	13C20C1557	PT-01000-D	13C20D1155
	13F20D0386	PT-65509-S	14C20D0475	PT-03000	13C20C2655	PT-01000-D	13C20D1155	PT-01000-D	13C20D0848		
	13F20F0576	PT-65509-S	14C20D0475	PT-65509-S	14C20E0949	PT-03000	13C20D1154	PT-01000-D	13C20E0897		
	13F20G0176	PT-65509-S	14C20E0949	PT-03000	13C20G0231	PT-01000-D	13C20E0897	PT-01000-D	13C20G0235		
	13F20J0139	PT-65509-S	14C20G0394	PT-65509-S	14C20E0949	PT-01000-D	13C20E0897	PT-01000-D	13C20E0897	PT-01000-D	13C20E0897
		PT-01000-D	13C20G035	PT-01000-D	13C20G1571						
	13F20J0547	PT-65509-S	14C20G0394	PT-03000	13C20G1570	PT-03000	13C20J0904	PT-01000-D	13C20E0897	PT-01000-D	13C20H2329
		PT-01000-D	13C20G1571								
	13F20K0212	PT-65509-S	14C20G0394	PT-03000	13C20J0904	PT-01000-D	13C20H2329	PT-01000-D	13C20E0897		
	13F20L0160	PT-65509-S	14C20G0394	PT-03000	13C20J2204	PT-01000-D	13C20K0550	PT-01000-D	13C20H2329		
	13F20M0183	PT-65509-S	14C20G0394	PT-65509-S	14C20K1044	PT-03000	13C20J09904	PT-03000	13C20J2204	PT-03000	13C20K2183
		PT-03000	13C20L1808	PT-01000-D	13C20K0550	PT-01000-D	13C20H2329	PT-01000-D	13C20M0603		
	13F21B0224	PT-65509-S	14C20K1044	PT-65509-S	14C20M0931	PT-03000	13C20J0904	PT-03000	13C20M0145	PT-03000	13C21A0856
		PT-03000	13C20L1808	PT-01000-D	13C20M0603	PT-01000-D	13C20M0603	PT-01000-D	13C20H2329		
	13F21C0080	PT-65509-S	14C20M0931	PT-65509-S	14C21B0685	PT-03000	13C20M0145	PT-03000	13C21A0856	PT-03000	13C21B0561
		PT-01000-D	13C21B0563	PT-01000-D	13C20H2329						
	13F21C0366	PT-65509-S	14C20M0931	PT-65509-S	14C21B0685	PT-03000	13C21A0856	PT-01000-D	13C21B0563	PT-01000-D	13C20H2329
	13F21D0106	PT-65509-S	14C21B0685	PT-03000	13C21A0856	PT-03000	13C21B0561	PT-03000	13C21C2403	PT-01000-D	13C21C1154
		PT-01000-D	13C21B0563	PT-01000-D	13C20H2329						
	13X21D0026	PT-65509-S	14C21B0685	PT-65509-S	14X21D0004	PT-03000	13X21D0011	PT-01000-D	13C21C1154	PT-01000-D	13X21D0010
	13F21E0078	PT-65509-S	14C21B0685	PT-65509-S	14C21D0123	PT-03000	13C21D1120	PT-01000-D	13C21C1154	PT-01000-D	13C21C1693
	13F21E0557	PT-65509-S	14C21D0123	PT-65509-S	14C21E0930	PT-65509-S	14C21D1205	PT-65509-S	14C21F1318	PT-03000	13C21E1975
		PT-03000	13C21D1120	PT-03000	13C21E1463	PT-01000-D	13C21C1154	PT-01000-D	13C21E0333		
	13F21G1344	PT-65509-S	14C21F1318	PT-65509-S	14R21D0123	PT-65509-S	14R21D1205	PT-03000	13C21E1463	PT-03000	13C21E1975
		PT-01000-D	13C21E0333	PT-01000-D	13C21E1985						
	13F21H0213	PT-65509-S	14R21D1205	PT-65509-S	14R21D1205	PT-65509-S	14R21E0930	PT-03000	13C21G0966	PT-03000	13C21E1975
PT-01000-D		13C21G0965	PT-01000-D	13C21E1985							
13F21H0659	PT-65509-S2	14C21H0977	PT-03000-S	13C21H1235	PT-01000-D2	13C21H1234					
13F21J0455	PT-65509-S2	14C21H0977	PT-03000-S	13C21H1235	PT-03000-S	13C21J0983	PT-01000-D2	13C21H1234	PT-01000-D2	13C21J0982	

**Appendix 2(F)**

Overarching Product		Component Product									
Product Code	Lot Number	Code	Lot number	Code	Lot number	Code	Lot number	Code	Lot number	Code	Lot number
PT-65509-HFC (3 Component)	13F21K0897	PT-65509-S2	14C21H1311	PT-65509-S2	14C21H0977	PT-03000-S	13C21J0983	PT-01000-D2	13C21J0982	PT-01000-D2	13C21K1835
	13F21L0901	PT-65509-S2	14C21H1311	PT-65509-S2	14C21K0161	PT-03000-S	13C21J0983	PT-03000-S	13C21K2035	PT-03000-S	13C21L1102
		PT-01000-D2	13C21L1104								

**Appendix 3 – Unique Device Identifier (UDI)**

Product Code	Lot Number	UDI
PT-12709-WC	13F20C0094	(01)10801902121254 (17)220228 (10)13F20C0094
	13F20G0284	(01)10801902121254 (17)220630 (10)13F20G0284
	13F20L0282	(01)10801902121254 (17)221031 (10)13F20L0282
	13F21A0497	(01)10801902121254 (17)221231 (10)13F21A0497
	13F21A0718	(01)10801902121254 (17)230131 (10)13F21A0718
	13X21E0008	(01)10801902121254 (17)230630 (10)13F21F1187
	13F21F1187	(01)10801902121254 (17)230531 (10)13X21E0008
PT-65709-HFWC	13F20A0323	(01)108019022121292 (17)211231 (10)13F20A0323
	13F20B0139	(01)10801902121292 (17)220131 (10)13F20B0139
	13F20C0594	(01)10801902121292 (17)220331 (10)13F20C0594
	13F20F0083	(01)10801902121292 (17)220531 (10)13F20F0083
	13F20F0230	(01)10801902121292 (17)220531 (10)13F20F0230
	13F20F0577	(01)10801902121292 (17)220630 (10)13F20F0577
	13F20H0756	(01)10801902121292 (17)220831 (10)13F20H0756
	13F20K0849	(01)10801902121292 (17)221031 (10)13F20K0849
	13F20L0283	(01)10801902121292 (17)221031 (10)13F20L0283
	13F20M0182	(01)10801902121292 (17)221231 (10)13F20M0182
	13F21A0498	(01)10801902121292 (17)221231 (10)13F21A0498
	13F21B0158	(01)10801902121292 (17)230131 (10)13F21B0158
	13F21C0747	(01)10801902121292 (17)230331 (10)13F21C0747
	13F21E0555	(01)10801902121292 (17)230430 (10)13F21E0555
PT-65709-W	13F19M0129	(01)10801902121315 (17)211130 (10)13F19M0129
	13F20B0053	(01)108019022121315 (17)220131 (10)13F20B0053
	13F20C0595	(01)10801902121315 (17)220331 (10)13F20C0595
	13F20F0231	(01)10801902121315 (17)220531 (10)13F20F0231
	13F20G0361	(01)10801902121315 (17)220731 (10)13F20G0361
	13F20K0632	(01)10801902121315 (17)221031 (10)13F20K0632
	13F21A0353	(01)10801902121315 (17)221231 (10)13F21A0353
	13F21C0748	(01)10801902121315 (17)230331 (10)13F21C0748
	13F21D0721	(01)10801902121315 (17)230430 (10)13F21D0721
	13F21E0823	(01)10801902121315 (17)230531 (10)13F21E0823
13F21F1189	(01)10801902121315 (17)230630 (01)13F21F1189	
PT-65709-WC	13F20C0596	(01)10801902121308 (17)220331 (10)13F20C0596
	13F20F0081	(01)10801902121308 (17)220531 (10)13F20F0081
	13F20F0229	(01)10801902121308 (17)220531 (10)13F20F0229
	13F20F0509	(01)10801902121308 (17)220531 (10)13F20F0509
	13F20F0578	(01)10801902121308 (17)220630 (10)13F20F0578
	13F20G0177	(01)10801902121308 (17)220630 (10)13F20G0177
	13F20G0566	(01)10801902121308 (17)220630 (10)13F20G0566
	13F20H0531	(01)10801902121308 (17)220831 (10)13F20H0531
	13F20J0379	(01)10801902121308 (17)220831 (10)13F20J0379
	13F20L0514	(01)10801902121308 (17)221031 (10)13F20L0514
	13F21A0354	(01)10801902121308 (17)221231 (10)13F21A0354
	13F21C0081	(01)10801902121308 (17)230228 (10)13F21C0081
	13F21C0749	(01)10801902121308 (17)230331 (10)13F21C0749
	13F21D0870	(01)10801902121308 (17)230430 (10)13F21D0870
	13F21E0415	(01)10801902121308 (17)230430 (10)13F21E0415
13F21F1188	(01)10801902121308 (17)230630 (10)13F21F1188	
PT-45509	13F20A0209	(01)10801902121261(17)211231(10)13F20A0209
	13F20B0054	(01)10801902121261(17)220131(10)13F20B0054
	13F20B0527	(01)10801902121261(17)220228(10)13F20B0527
	13F20C0427	(01)10801902121261(17)220228(10)13F20C0427

**Appendix 3 – Unique Device Identifier (UDI)**

Product Code	Lot Number	UDI	
PT-45509	13F20D0127	(01)10801902121261(17)220331(10)13F20D0127	
	13F20D0402	(01)10801902121261(17)220430(10)13F20D0402	
	13F20F0390	(01)10801902121261(17)220531(10)13F20F0390	
	13F20G0285	(01)10801902121261(17)220630(10)13F20G0285	
	13F20J0545	(01)10801902121261(17)220831(10)13F20J0545	
	13F20J0933	(01)10801902121261(17)220930(10)13F20J0933	
	13F20K0851	(01)10801902121261(17)221031(10)13F20K0851	
	13F20M0174	(01)10801902121261(17)221120(10)13F20M0174	
	13F21A0662	(01)10801902121261(17)230131(10)13F21A0662	
	13F21C0079	(01)10801902121261(17)230228(10)13F21C0079	
	13F21C0751	(01)10801902121261(17)230331(10)13F21C0751	
	13X21D0027	(01)10801902121261(17)230430(10)13X21D0027	
	13F21F0399	(01)10801902121261(17)230531(10)13F21F0399	
	13F21G0226	(01)10801902121261(17)230630(10)13F21G0226	
	13F21G1343	(01)10801902121261(17)230731(10)13F21G1343	
	13F21H0639	(01)10801902121261(17)230731(10)13F21H0639	
	13F21H1272	(01)10801902194067(17)230831(10)13F21H1272	
	13F21L0900	(01)10801902194067(17)231130(10)13F21L0900	
	PT-65509-HFC	13F20A0359	(01)10801902121285(17)211231(10)13F20A0359
13F20A0519		(01)10801902121285(17)211131(10)13F20A0519	
13F20B0140		(01)10801902121285(17)220131(10)13F20B0140	
13F20B0423		(01)10801902121285(17)220228(10)13F20B0423	
13F20C0223		(01)10801902121285(17)220228(10)13F20C0223	
13F20C0593		(01)10801902121285(17)220331(10)13F20C0593	
13F20D0128		(01)10801902121285(17)220331(10)13F20D0128	
13F20D0386		(01)10801902121285(17)220331(10)13F20D0386	
13F20F0576		(01)10801902121285(17)220630(10)13F20F0576	
13F20G0176		(01)10801902121285(17)220630(10)13F20G0176	
13F20J0139		(01)10801902121285(17)220831(10)13F20J0139	
13F20J0547		(01)10801902121285(17)220831(10)13F20J0547	
13F20K0212		(01)10801902121285(17)220930(10)13F20K0212	
13F20L0160		(01)10801902121285(17)221031(10)13F20L0160	
13F20M0183		(01)10801902121285(17)22123(10)13F20M0183	
13F21B0224		(01)10801902121285(17)230131(10)13F21B0224	
13F21C0080		(01)10801902121285(17)230228(10)13F21C0080	
13F21C0366		(01)10801902121285(17)230228(10)13F21C0366	
13F21D0106		(01)10801902121285(17)230331(10)13F21D0106	
13X21D0026		(01)10801902121285(17)230430(10)13X21D0026	
13F21E0078		(01)10801902121285(17)230430(10)13F21E0078	
13F21E0557		(01)10801902121285(17)230630(10)13F21E0557	
13F21G1344		(01)10801902121285(17)230731(10)13F21G1344	
13F21H0213		(01)10801902121285(17)230731(10)13F21H0213	
13F21H0659		(01)10801902194081(17)230831(10)13F21H0659	
13F21J0455		(01)10801902194081(17)230930(10)13F21J0455	
13F21K0897		(01)10801902194081(17)231031(10)13F21K0897	
13F21L0901		(01)10801902194081(17)231130(10)13F21L0901	
PT-65509		13F20A0286	(01)00801902013156(17)211231(10)13F20A0286
		13F20A0426	(01)00801902013156(17)211231(10)13F20A0426
	13F20A0640	(01)00801902013156(17)220131(10)13F20A0640	
	13F20B0141	(01)00801902013156(17)220131(10)13F20B0141	
	13F20B0276	(01)00801902013156(17)220228(10)13F20B0276	
13F20B0353	(01)00801902013156(17)220228(10)13F20B0353		

**Appendix 3 – Unique Device Identifier (UDI)**

Product Code	Lot Number	UDI
PT-65509	13F20B0424	(01)00801902013156(17)220228(10)13F20B0424
	13F20C0352	(01)00801902013156(17)220228(10)13F20C0352
	13F20C0425	(01)00801902013156(17)220331(10)13F20C0425
	13F20C0426	(01)00801902013156(17)220331(10)13F20C0426
	13F20D0122	(01)00801902013156(17)220331(10)13F20D0122
	13F20D0123	(01)00801902013156(17)220430(10)13F20D0123
	13F20D0124	(01)00801902013156(17)220331(10)13F20D0124
	13F20D0403	(01)00801902013156(17)220430(10)13F20D0403
	13F20E0204	(01)00801902013156(17)220430(10)13F20E0204
	13F20F0232	(01)00801902013156(17)220531(10)13F20F0232
	13F20F0389	(01)00801902013156(17)220630(10)13F20F0389
	13F20G0353	(01)00801902013156(17)220630(10)13F20G0353
	13F20H0729	(01)00801902013156(17)220831(10)13F20H0729
	13F20J0378	(01)00801902013156(17)220831(10)13F20J0378
	13F20J0546	(01)00801902013156(17)220831(10)13F20J0546
	13F20J0771	(01)00801902013156(17)220831(10)13F20J0771
	13F20K0503	(01)00801902013156(17)220930(10)13F20K0503
	13F20K0504	(01)00801902013156(17)220930(10)13F20K0504
	13F20K0630	(01)00801902013156(17)220930(10)13F20K0630
	13F20K0631	(01)00801902013156(17)220930(10)13F20K0631
	13F20M0175	(01)00801902013156(17)221130(10)13F20M0175
	13F20M0176	(01)00801902013156(17)221130(10)13F20M0176
	13F20M0177	(01)00801902013156(17)221130(10)13F20M0177
	13F20M0178	(01)10801902013153(17)221130(10)13F20M0178
	13F20M0181	(01)00801902013156(17)221231(10)13F20M0181
	13F21A0352	(01)00801902013156(17)221231(10)13F21A0352
	13F21B0159	(01)00801902013156(17)230131(10)13F21B0159
	13F21B0222	(01)00801902013156(17)230131(10)13F21B0222
	13F21B0519	(01)10801902013153(17)230228(10)13F21B0519
	13F21C0364	(01)00801902013156(17)230228(10)13F21C0364
	13F21C0365	(01)00801902013156(17)230228(10)13F21C0365
	13F21D0462	(01)00801902013156(17)230331(10)13F21D0462
	13F21E0079	(01)00801902013156(17)230430(10)13F21E0079
	13F21E0259	(01)00801902013156(17)230430(10)13F21E0259
	13F21E0260	(01)00801902013156(17)230430(10)13F21E0260
	13F21E0556	(01)00801902013156(17)230430(10)13F21E0556
	13F21F0641	(01)00801902013156(17)230531(10)13F21F0641
	13F21G0227	(01)00801902013156(17)230630(10)13F21G0227
	13F21G0401	(01)00801902013156(17)230630(10)13F21G0401
	13F21G0772	(01)00801902013156(17)230630(10)13F21G0772
	13F21H0447	(01)10801902194074(17)230731(10)13F21H0447
	13F21K0827	(01)10801902194074(17)231031(10)13F21K0827
	13F21K0898	(01)10801902194074(17)231031(10)13F21K0898
	13F21L0227	(01)20801902194071(17)231031(10)13F21L0227
	13F21L0507	(01)10801902194074(17)231031(10)13F21L0507
	13F21L0898	(01)10801902194074(17)231031(10)13F21L0898

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