

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

06th August 2019

URGENT – FIELD SAFETY NOTICE

Type of Action	Recall
Teleflex Reference	EIF-000361-01
Commercial Name	Select Hudson RCI Sheridan[®] branded Endotracheal Tubes and Connectors
Product Code/Lot Number	See Appendix 2 for a list of product codes and lots in scope

Dear Customer,

Teleflex Medical has voluntarily issued a recall for the product codes and lot numbers listed in Appendix 2.

This recall is an amendment to a recent recall reference EIF-000361. The expansion is necessary to include additional product codes and lots based on the outcome of the root cause investigation carried out and out of an abundance of caution. If you did not receive a copy of the original recall letter, it is because we have identified that you had only received products from the expanded scope of products involved, and did not receive any affected lots of the Hudson RCI Sheridan[®] Endotracheal Tubes and Connectors that were included in the original recall scope. Regardless, if you had originally responded to the initial notification, or are just receiving notification for the first time, it is required that you complete and sign the attached response form confirming that you had been notified of this action and took the required action.

Description of the problem & immediate actions required

This voluntary recall is due to reported complaints indicating that there is an increased incidence of specific lots (see appendix 2) of the 15 mm Sheridan connector becoming disconnected from the endotracheal tube (ETT). The immediate consequence to patients is disconnection from the breathing circuit, which may result in insufficient oxygenation, requiring medical intervention.

In total, (involving all lots affected by the original and extended recall) Teleflex has received four reports of death, and additional reports of serious injury where ETT disconnection may have been a contributing factor. In most reported cases, detachment of the connector was identified by clinical personnel or via eventual decrease in ventilator circuit pressure that triggered ventilator alarms.

For product in situ, Teleflex advises clinical staff to ensure that the 15 mm connector is seated firmly in the Endotracheal tube to prevent disconnection during use per the instructions in the IFU. Should disconnection occur, reconnect the two components promptly and securely in the manner described in the IFU or clinical staff may consider replacing the endotracheal tube, making sure to evaluate the risks associated with reintubation.

Update to the above problem statement:

The expansion to include additional product codes and lots to this recall is based on the root cause investigation carried out.

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

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

Device location	Action List Number
Medical facilities	1
Distributors	2

Action list number 1 – Medical facilities

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

Action list number 2 – Distributors

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

Teleflex

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

Transmission of this Field Safety Notice

This notice should be passed on to all persons who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. Please consider end



users, clinicians, risk managers, supply chain/distribution centres etc. in the circulation of this notice. Maintain awareness of this notice until all required actions have been completed in your organisation.

Contact reference person

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

Customer Service:

Contact: Nicole Morawiec

Telephone: +41 (0) 31 818 40 90

FAX: +41 (0) 31 818 40 93

Email: info.ch@teleflex.com

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

For and on behalf of Teleflex,

Padraig Hegarty

Padraig Hegarty VP, QA (Manufacturing)

Appendix 1

Customer No

FIELD SAFETY CORRECTIVE ACTION
ACKNOWLEDGEMENT FORM

PRODUCT FIELD ACTION BY TELEFLEX – IMMEDIATE ATTENTION REQUIRED

Ref. EIF-000361-01

RETURN COMPLETED FORM IMMEDIATELY TO:

FAX: +41 (0) 31 818 40 93

Email: info.ch@teleflex.com

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

PLEASE PRINT PRODUCT QUANTITY NUMBERS CLEARLY

PRODUCT NUMBER	LOT NUMBER	QUANTITY (Returning)
<ul style="list-style-type: none"> Include a copy of the completed Acknowledgement Form in the returns package with the returned units Ensure the RAN number is clearly visible on the returns package Please label returns as "Field Safety Returns" 		

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

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

**Appendix 2- Product Codes and
Lots in Scope**

Original Scope

Product Name	Product Code
Hudson RCI® Sheridan LTS®	5-11112
Hudson RCI® Sheridan/CF® 6.0 mm	5-10112
	5-10212
Hudson RCI® Sheridan/CF® 6.5 mm	5-10113
	5-10213
Hudson RCI® Sheridan/CF® 7.0 mm	5-10114
	5-10214
Hudson RCI® Sheridan/CF® 7.5 mm	V5-10115
	5-10115
	5-10215
Hudson RCI® Sheridan/CF® 8.0 mm	5-10116
	5-10216
	V5-10116
Hudson RCI® Sheridan/CF® 8.5 mm	5-10117
	5-10217
Hudson RCI® Sheridan® EZ-ENDO 7.0 mm	5-22514
Hudson RCI® Sheridan® EZ-ENDO 7.5 mm	5-22515
Hudson RCI® Sheridan® EZ-ENDO 8.0 mm	5-22516
Hudson RCI® Sheridan® EZ-ENDO 8.5 mm	5-22517
Hudson RCI® Sheridan® Preformed 6.0 mm	5-22212
	5-22312
	5-22112
	5-22012
Hudson RCI® Sheridan® Preformed 6.5 mm	5-22313
	5-22213
	5-22013
	5-22113
Hudson RCI® Sheridan® Preformed 7.0 mm	5-22214
	5-22314
	5-22014
	5-22114
Hudson RCI® Sheridan® Preformed 7.5 mm	5-22215
	5-22315
Hudson RCI® Sheridan® Preformed 8.0 mm	5-22216
	5-22316
Hudson RCI® Sheridan® Preformed 8.5 mm	5-22217
Hudson RCI® Sheridan® Uncuffed 6.0 mm	5-10412
Hudson RCI® Sheridan® Uncuffed 6.5 mm	5-10413
Hudson RCI® Sheridan® Uncuffed 7.0 mm	5-10414
Hudson RCI® Sheridan®/EZ-ENDO 6.0 mm	5-22512
Hudson RCI® Sheridan®/EZ-ENDO 6.5 mm	5-22513
Hudson RCI® Sheridan®/HVT® 6.0 mm	5-10312
Hudson RCI® Sheridan®/HVT® 6.5 mm	5-10313
Hudson RCI® Sheridan®/HVT® 7.0 mm	5-10314
Hudson RCI® Sheridan®/HVT® 7.5 mm	5-10315
Hudson RCI® Sheridan®/HVT® 8.0 mm	5-10316
Hudson RCI® Sheridan®/HVT® 8.5 mm	5-10317
Sheridan/CF Novaplus® 7.0 mm	V5-10114
Sheridan/HVT® Novaplus® 7.0 mm	V5-10314
Sheridan/HVT® Novaplus® 7.5 mm	V5-10315
Sheridan/HVT® Novaplus® 8.0 mm	V5-10316
Sheridan/HVT® Novaplus® 8.5 mm	V5-10317

Appendix 2- Product Codes and Lots in Scope

Original Scope

Product Code	Lot Number	Product Code	Lot Number	Product Code	Lot Number	
5-10112	73A1700085	5-10313 (cont.)	73D1800306	5-22215 (cont.)	73D1700645	
	73A1700246		73D1800457		73D1800473	
	73A1700717		73E1700094		73E1700494	
	73A1800042		73E1700222		73E1800396	
	73A1800281		73E1700461		73F1700729	
	73A1800662		73E1800073		73F1800185	
	73B1700288		73E1800227		73F1800560	
	73B1700395		73E1800548		73G1700610	
	73B1700615		73F1700014		73H1700617	
	73B1800114		73F1700375		73J1600380	
	73B1800474		73F1700539		73J1700138	
	73B1800700		73F1700704		73J1700483	
	73C1700223		73F1800328		73J1800527	
	73C1700397		73F1800708		73K1600150	
	73C1700541		73G1700412		73K1700432	
	73C1800183		73G1800119		73K1700742	
	73C1800469		73G1800219		73L1700513	
	73D1700236		73G1800800		73M1700146	
	73D1700610		73H1700319		5-22216	
	73D1800300		73H1700474			73A1700115
	73D1800624		73H1700594			73A1700736
	73E1700217		73J1600356	73A1800454		
	73E1700454		73J1600357	73B1700422		
	73E1700698		73J1600565	73B1800139		
	73E1800061		73J1600752	73B1800499		
	73E1800225		73J1700283	73C1700258		
	73E1800779		73J1700461	73C1700696		
	73F1700532		73J1700595	73D1700646		
	73F1800157		73K1600138	73D1800152		
	73F1800529		73K1600572	73E1700495		
	73F1800697		73K1600573	73E1800573		
	73G1700137		73K1700058	73F1700172		
	73G1700214		73K1700410	73F1700554		
	73G1700585		73K1700588	73F1800348		
	73G1800115		73K1700726	73G1700611		
	73G1800212		73L1600139	73G1800137		
	73G1800562		73L1600339	73H1700618		
	73G1800791		73L1600489	73H1800682		
	73H1700033		73L1600651	73J1600381		
	73H1700466		73L1700311	73J1700139		
	73H1800178		73L1700499	73J1800107		
	73H1800652		73L1700662	73J1800528		
73J1600560	73M1600134	73K1600383				
73J1600743	73M1700241	73K1700743				
73J1700125	73M1700425	73L1600162				
73J1700277	73M1700451	73L1600511				
		73L1700514				

Appendix 2- Product Codes and Lots in Scope

Original Scope

Product Code	Lot Number	Product Code	Lot Number	Product Code	Lot Number	
5-10112	73J1700588	5-10314	73A1700093	5-22216	73M1700147	
	73J1800082		73A1700094		73M1700460	
	73J1800317		73A1700095	5-22217	73A1800025	
	73J1800496		73A1800293		73A1800303	
	73J1800656		73A1800294		73B1800366	
	73K1600130		73A1800295		73B1800724	
	73K1600565		73A1800429		73C1700796	
	73K1700053		73A1800798		73E1800397	
	73K1700249		73A1800799		73F1700555	
	73K1700394		73B1700138		73F1800349	
	73K1700582		73B1700139		73H1700343	
	73K1800359		73B1700297		73J1700140	
	73L1600008		73B1700404		73J1800529	
	73L1600325		73B1700405		73L1600163	
	73L1600642		73B1700406		73L1600363	
	73L1600830		73B1700407		73L1700515	
	73L1700166		73B1800343		73L1800828	
	73L1700306		73B1800344		73M1700148	
	73L1700521		73B1800345		5-22312	73A1700737
	73L1700659		73C1700403			73A1800023
73L1800193	73C1700404		73B1700423			
73M1600126	73C1700551		73B1800140			
73M1700133	73C1700552		73B1800500			
73M1700445	73C1700680		73C1700697			
5-10113	73A1700086		73C1700681	73C1800328		
	73A1700247		73C1700681	73D1700426		
	73A1700400		73C1800344	73D1800474		
	73A1700640		73C1800345	73E1700561		
	73A1700718		73C1800346	73E1700721		
	73A1800038		73C1800477	73E1800398		
	73A1800663		73C1800565	73F1700173		
	73B1700289		73C1800566	73F1700730		
	73B1700396		73C1800567	73F1800561		
	73B1700616		73D1700616	73G1700612		
	73B1800115		73D1800630	73G1800139		
	73B1800475		73D1800631	73H1700620		
	73B1800701		73D1800632	73H1800683		
	73C1700542		73E1700095	73J1700141		
	73C1700672		73E1700096	73J1700484		
	73C1800184		73E1700242	73J1800109		
	73C1800336	73E1700462	73K1600151			
	73C1800559	73E1700463	73K1700078			
	73D1700122	73E1700703	73K1700433			
	73D1700237	73E1700705	73K1700744			
73D1700405	73E1700706	73K1800188				
73D1800060	73E1800074	73L1600512				
	73E1800075					

Appendix 2- Product Codes and Lots in Scope

Original Scope

Product Code	Lot Number	Product Code	Lot Number	Product Code	Lot Number	
5-10113	73D1800301	5-10314	73E1800382	5-22312	73L1700516	
	73D1800625		73E1800383		73M1600159	
	73E1700455		73E1800549	5-22313	73A1700116	
	73E1700699		73E1800550		73A1700738	
	73E1800069		73E1800786		73A1800304	
	73E1800226		73E1800787		73B1800367	
	73E1800376		73F1700015		73C1700698	
	73E1800780		73F1700016		73C1800368	
	73F1700533		73F1700146		73D1700647	
	73F1700697		73F1700147		73D1800292	
	73F1800158		73F1700148		73E1700760	
	73F1800324		73F1700149		73E1800399	
	73F1800530		73F1700540		73F1700401	
	73F1800698		73F1700541		73F1800351	
	73G1700215		73F1700542		73G1700613	
	73G1700403		73F1700543		73G1800140	
	73G1800213		73F1700705		73G1800821	
	73H1700312		73F1800709		73H1700621	
	73H1700589		73F1800710		73J1600382	
	73H1700775		73F1800711		73J1700485	
	73H1800179		73G1700125		73K1600384	
	73J1600561		73G1700143		73K1600732	
	73J1600744		73G1700219		73K1700079	
	73J1700126		73G1700220		73K1700434	
	73J1700278		73G1700221		73K1700745	
	73J1700450		73G1700222		73L1600668	
	73J1700589		73G1700592		73M1600160	
	73J1800318		73G1800120		73M1700270	
	73K1600131		73G1800121		5-22314	73A1700117
	73K1600352		73G1800149			73A1700739
	73K1600566		73G1800220			73A1800455
	73K1600567		73G1800487			73B1800141
	73K1700250		73G1800636			73B1800456
	73K1700402		73G1800637			73C1700566
	73K1700583		73G1800638			73D1700648
	73K1800360		73G1800913			73D1800153
	73L1600132		73G1800914			73D1800475
	73L1600326		73G1800915			73E1800574
	73L1600482		73H1700024			73F1700065
	73L1600831		73H1700025			73F1700731
	73L1700167		73H1700475	73F1800352		
	73L1700307		73H1700476	73G1700431		
73L1700522	73H1700595	73G1800141				
73L1700660	73H1700596	73G1800822				
73M1600127	73H1800422	73H1700622				
73M1700134	73H1800726	73J1600383				

Appendix 2- Product Codes and Lots in Scope

Original Scope

Product Code	Lot Number	Product Code	Lot Number	Product Code	Lot Number
5-10113	73M1700446		73J1600358		73J1700142
	73A1700087		73J1600359		73J1800111
	73A1700088		73J1600360		73K1700080
	73A1800439		73J1600753	5-22314	73K1700746
	73A1800440		73J1600754		73K1800190
	73A1800441		73J1700148		73L1600164
	73B1700290		73J1700284		73L1600868
	73B1700291		73J1700285		73M1600161
	73B1700292		73J1700596		73M1700461
	73B1700293		73J1800088		73A1800022
	73B1700397		73J1800089		73A1800456
	73B1800219		73J1800354		73B1800142
	73B1800220		73J1800508		73C1700417
	73B1800221		73J1800509		73C1800369
	73B1800222		73J1800510		73D1700134
	73B1800335		73J1800651		73D1700649
	73B1800336		73J1800665		73D1800476
	73C1700398		73K1600139		73E1800400
	73C1700399		73K1600140		73F1700174
	73C1700400		73K1600141		73F1700732
	73C1700543		73K1600142		73G1800142
	73C1700544		73K1600359	5-22315	73G1800823
	73C1700545		73K1600360		73H1700344
5-10114	73C1700546	5-10314	73K1600574		73H1700789
	73C1800337		73K1600575		73H1800685
	73C1800338		73K1600576		73J1600384
	73C1800339		73K1600723		73J1700486
	73C1800470		73K1700059		73J1800112
	73C1800471		73K1700256		73J1800690
	73C1800472		73K1700257		73K1700278
	73C1800473		73K1700258		73K1800191
	73D1700611		73K1700589		73L1600869
	73D1800448		73K1700727		73M1600162
	73D1800449		73L1600340		73M1700271
	73D1800450		73L1600490		73B1800501
	73D1800626		73L1600491		73C1700260
	73D1800627		73L1600839		73C1700795
	73E1700088		73L1600840		73D1800477
	73E1700089		73L1700223		73F1700402
	73E1700090		73M1600135	5-22316	73F1800353
	73E1700700		73M1700205		73G1800824
	73E1800544		73M1700242		73H1700345
	73E1800545		73M1700243		73H1700790
	73E1800781		73M1700244		73H1800755
	73F1700138		73M1700426		73K1800192
	73F1700143		73M1700437		73L1700517

Appendix 2- Product Codes and Lots in Scope

Original Scope

Product Code	Lot Number	Product Code	Lot Number	Product Code	Lot Number	
5-10114	73F1700534	5-10314	73M1700438	5-22512	73A1700280	
	73F1700535		73A1700257		73C1700567	
	73F1700698		73A1700258		73E1700496	
	73F1800112		73A1700405		73E1800401	
	73F1800531		73A1700724		73E1800575	
	73F1800532		73A1800431		73F1700403	
	73F1800699		73A1800667		73F1800354	
	73F1800700		73A1800668		73H1700347	
	73F1800701		73A1800669		73K1600152	
	73G1700144		73A1800670		73M1600163	
	73G1700145		73A1800794		73M1700272	
	73G1700216		73B1700140		5-22513	73B1700155
	73G1700586		73B1700631			73C1700568
	73G1700587		73B1700632			73E1800576
	73G1800116		73B1800481			73F1700404
	73G1800117		73B1800714			73F1800355
	73G1800214		73C1700229			73G1700432
	73H1700034		73C1700230			73H1700348
	73H1700467	73C1700231	73J1600766			
	73H1700590	73C1700682	5-22514	73A1700118		
	73H1800180	73C1700707		73C1700569		
	73H1800715	73C1800568		73D1800653		
	73J1600745	73D1700140		73E1700722		
	73J1600746	73D1700244		73F1700175		
	73J1600747	73D1700245		73F1700405		
	73J1700149	73D1700268		73F1800562		
	73J1700150	73D1800135		73F1800720		
	73J1700279	73D1800136		73G1700433		
	73J1700590	73D1800285		73H1700349		
	73J1800084	73D1800307		73H1700494		
	73J1800498	73E1700223		73H1700711		
	73J1800499	73E1700224		73H1800450		
	73J1800657	73E1700225		73J1700143		
	73K1600132	73E1700464		73J1800531		
	73K1600720	73E1700465		73K1700081		
	73K1700054	73E1700466		73K1700610		
	73K1700055	73E1800076		73K1800328		
	73K1700056	73E1800228	73K1800786			
	73K1700251	73E1800384	73L1700181			
	73K1700584	73E1800385	73M1700273			
	73K1700720	73F1700279	5-22515	73A1800068		
	73K1800714	73F1700376		73A1800683		
73K1800715	73F1700377	73B1700316				
73L1600327	73F1700378	73B1800502				
73L1600328	73F1700379	73C1700262				
73L1600832	73F1800164	73C1700418				
		5-10315				

Appendix 2- Product Codes and Lots in Scope

Original Scope

Product Code	Lot Number	Product Code	Lot Number	Product Code	Lot Number	
5-10114	73L1600833	5-10315	73F1800329	5-22515	73C1800201	
	73L1800511		73F1800330		73D1800154	
	73M1600272		73F1800537		73E1700104	
	73M1700236		73F1800538		73E1700723	
	73M1700237		73F1800539		73E1800402	
	73M1700427		73F1800540		73F1700176	
	73M1700428		73G1700203		73F1700406	
5-10115	73A1700248		73G1700223		5-22516	73F1800565
	73A1700719		73G1700413			73G1700434
	73A1700720		73G1700414			73G1800591
	73A1800656		73G1800570			73H1700350
	73A1800796		73G1800802			73H1800451
	73A1800797		73G1800803			73H1800686
	73B1700131		73G1800917			73J1700302
	73B1700132		73G1800918			73J1700497
	73B1700626		73G1800919			73J1800113
	73B1700627		73H1700303			73K1700747
	73B1800476		73H1700320			73K1800736
	73B1800477		73H1700597			73M1700274
	73B1800478		73H1700780			73A1700282
	73C1700224		73H1800072			73A1800684
	73C1700225	73H1800073	73B1700158			
	73C1700226	73H1800186	73B1700317			
	73C1700673	73H1800659	73B1800503			
	73C1700674	73H1800660	73C1700570			
	73C1800561	73H1800727	73C1800371			
	73D1700123	73J1600361	73E1800577			
	73D1700124	73J1600362	73F1700036			
	73D1700238	73J1600566	73F1700177			
	73D1800126	73J1600567	73F1700407			
	73D1800127	73J1700462	73G1700614			
	73D1800128	73J1700463	73G1800232			
	73D1800287	73J1800090	73H1700495			
	73E1700218	73J1800325	73J1700487			
	73E1700219	73J1800326	73J1800532			
	73E1700220	73K1700259	73K1600594			
	73E1700456	73K1700411	73K1700082			
	73E1800063	73K1700412	73K1800327			
	73E1800070	73K1700729	5-22517	73C1800202		
	73E1800222	73K1800164		73J1600767		
73E1800366	73K1800321	V5-10114	73A1700120			
73E1800367	73K1800351		73B1700321			
73F1700369	73K1800352		73B1800223			
73F1700370	73L1600492		73B1800371			
73F1700371	73L1600652		73C1700425			
73F1800159	73L1600653		73C1800372			

Appendix 2- Product Codes and Lots in Scope

Original Scope

Product Code	Lot Number	Product Code	Lot Number	Product Code	Lot Number
5-10115	73F1800160	5-10315	73L1600686	V5-10114	73D1700630
	73F1800302		73L1700312		73D1800655
	73F1800325		73L1700313		73E1700504
	73F1800326		73L1700314		73E1800579
	73F1800533		73L1700315		73G1700146
	73F1800534		73M1600136		73G1800627
	73G1700217		73M1600137		73H1700053
	73G1700404		73M1600267		73H1800203
	73G1800563		73M1700430		73H1800429
	73G1800794		73A1700413		73H1800758
	73G1800795		73A1700414		73J1700307
	73G1800796		73A1700654		73J1800118
	73H1700035		73A1800053		73J1800696
	73H1700313		73A1800054		73K1600156
	73H1700591		73B1700408		73K1600735
	73H1700776		73B1700619		73K1700085
	73H1800074		73B1700620		73L1600501
	73H1800181		73B1800693		73B1700164
	73H1800653	73C1800189	73B1800511		
	73H1800716	73C1800190	73C1700701		
	73J1600562	73C1800191	73D1700264		
	73J1700280	73D1700246	73D1800157		
	73J1700451	73D1700416	73E1700505		
	73J1800085	73D1700417	73E1800097		
	73J1800328	73D1700418	73E1800234		
	73J1800500	73D1700617	73F1800361		
	73K1600133	73D1700618	73G1700435		
	73K1600134	73D1800290	73G1800594		
	73K1700252	73D1800458	73H1700054		
	73K1700253	73D1800459	73H1700795		
	73K1700403	73E1700707	73H1800204		
	73K1700404	73E1700708	73H1800687		
	73K1700721	73E1800788	73J1600386		
	73K1800324	73E1800789	73J1800119		
	73K1800361	73F1700018	73K1700280		
	73K1800362	73F1700563	73K1700752		
	73K1800535	73F1700706	73K1800323		
	73K1800536	73F1700707	73L1600171		
	73L1600133	73F1700708	73L1600517		
	73L1600483	73F1800071	73M1600276		
	73L1600645	73G1700415	73A1800248		
	73L1700191	73G1700416	73B1700427		
73L1700308	73G1700593	73B1800692			
73L1700309	73G1700594	73C1800204			
73L1800263	73G1800221	73D1700265			
73M1600128	73G1800222	73D1800482			
			V5-10115		
				V5-10116	

Appendix 2- Product Codes and Lots in Scope

Original Scope

Product Code	Lot Number	Product Code	Lot Number	Product Code	Lot Number
5-10115	73M1700447		73G1800571	V5-10116	73F1700037
	73M1700448		73G1800572		73F1700733
5-10116	73A1700650		73G1800639		73F1800020
	73A1800048		73H1700321		73G1700436
	73A1800049		73H1700477		73G1800233
	73A1800050		73H1700781		73H1700351
	73A1800387		73H1800435		73H1800455
	73B1700398		73H1800436		73H1800689
	73B1700628		73H1800661		73J1600771
	73B1800709		73H1800662		73J1700146
	73B1800710		73J1600568		73J1700608
	73C1800185		73J1600755		73J1800330
	73D1700239		73J1700444		73K1700088
	73D1700412		73J1700464		73K1800194
	73D1700413		73J1700598		73L1600172
	73D1700414		73J1800332		73L1600671
	73D1700612		73J1800333		73M1700027
	73D1800289		73J1800666		
	73D1800451		73K1600577		73A1700121
	73E1800782		73K1700413		73A1700122
	73F1700009	73K1700590	73A1800296		
	73F1700010	73K1700591	73A1800430		
	73F1700699	73K1800124	73B1700322		
	73F1700700	73K1800165	73B1700428		
	73F1800018	73K1800166	73B1800218		
	73F1800019	73K1800167	73B1800372		
	73G1700405	73K1800227	73B1800373		
	73G1700588	73L1600143	73B1800374		
	73G1800215	73L1600341	73B1800512		
	73G1800564	73L1600342	73B1800513		
	73G1800565	73L1600343	73C1700426		
	73H1700314	73L1600555	73C1700576		
	73H1700468	73L1600654	73C1700577		
	73H1800432	73L1600841	73C1700702		
	73H1800433	73L1600842	73C1700703		
	73H1800692	73L1800480	73C1800373		
	73J1600563	73M1700122	73C1800574		
	73J1600678	73M1700123	73C1800575		
	73J1600748	73M1700124	73D1800656		
	73J1700145	73A1800299	73D1800657		
	73J1700452	73B1800716	73E1700106		
	73J1700591	73C1700683	73E1700107		
73J1800329	73C1800569	73E1700108			
73J1800501	73D1700619	73E1700239			
73J1800650	73F1700544	73E1800580			
73K1600569	73F1800165	73E1800581			
		73E1800809			

Appendix 2- Product Codes and Lots in Scope

Original Scope

Product Code	Lot Number	Product Code	Lot Number	Product Code	Lot Number		
5-10116	73K1700395	5-10317	73G1700417	V5-10314	73F1700560		
	73K1700585		73G1800920		73F1800723		
	73K1800158		73H1700322		73G1700147		
	73K1800159		73J1700286		73G1700148		
	73K1800228		73J1800511		73G1700302		
	73L1600134		73K1600364		73G1700303		
	73L1600329		73K1800546		73G1700623		
	73L1600330		73L1600344		73G1700624		
	73L1600404		73L1600655		73G1800107		
	73L1600646		73M1700024		73H1700055		
	73L1600834		73A1700264		73H1700497		
	73M1600129		73A1800060		73H1700568		
	73M1700026		73B1700300		73H1700628		
	73M1700135		73B1800348		73H1800205		
	73M1700136		73B1800487		73H1800456		
5-10117	73B1800711	5-10412	73C1700688	V5-10314	73H1800457		
	73C1700675		73C1800349		73H1800759		
	73C1800562		73C1800482		73H1800760		
	73D1700613		73D1800464		73J1600387		
	73F1700528		73E1700098		73J1600388		
	73F1800161		73E1700712		73J1700309		
	73G1700406		73E1800389		73J1800120		
	73G1800910		73F1800171		73J1800534		
	73H1700315		73G1700132		73J1800697		
	73J1700281		73G1800923		73K1600157		
	73J1800008		73H1700327		73K1600603		
	73J1800502		73J1600363		73K1600604		
	73K1800537		73J1700290		73K1600736		
	73L1600331		73K1600581		73K1700086		
	73L1600647		73K1700065		73K1700087		
5-10212	73J1600749	5-10413	73K1700415	V5-10315	73K1700616		
	73J1800345		73L1600347		73L1600367		
	73K1800367		73L1600552		73L1600368		
5-10213	73A1700252		73L1600850		73L1600502		
	73B1800339		73L1700169		73L1600870		
	73D1700241		73L1700320		73M1600165		
	73J1700458		73M1600138		73M1600270		
5-10214	73A1800297		5-10413		73M1700250	V5-10315	73A1700289
	73B1800340				73A1800061		73A1700290
	73C1700401				73B1700301		73A1700741
	73C1800343				73B1800349		73A1800687
	73D1700614				73B1800488		73A1800795
	73D1800628				73D1800634		73B1700165
	73E1800547				73E1700472		73B1700638
	73F1700144				73F1800544		73B1800514
	73F1800705	73G1700127		73C1700265			

Appendix 2- Product Codes and Lots in Scope

Original Scope

Product Code	Lot Number	Product Code	Lot Number	Product Code	Lot Number	
5-10214	73G1700124	5-10413	73G1800924	V5-10315	73D1700137	
	73H1700036		73K1700416		73D1700138	
	73H1800720		73M1600139		73D1700266	
	73J1800086	5-10414	73A1700100		73D1700267	
	73J1800660		73F1700064		73D1800158	
	73K1600136		73L1800406		73D1800286	
	73K1600722	5-11112	73A1700646		73E1700240	
	73L1600334		73A1800671		73E1800098	
	73L1600405		73B1800350		73E1800309	
	73M1600269		73C1700238		73E1800312	
	73M1700204		73D1700625		73E1800407	
	73M1700429		73D1800138		73E1800408	
	5-10215		73B1800452		73E1700475	73F1700281
			73E1800368		73F1700387	73F1700365
73F1800327			73F1800174		73F1700414	
73G1800555			73G1800126		73F1800191	
73H1700316			73G1800806		73F1800192	
73H1800182			73H1700041		73F1800362	
73H1800721			73H1700483		73F1800363	
73J1800087		73J1700292	73G1700237			
73K1800368		73J1800308	73G1700437			
73L1700310		73K1600369	73G1800595			
73M1600131		73K1800172	73G1800831			
73M1700436	73K1800173	73H1700056				
5-10216	73A1800052	73L1600011	73H1700352			
	73B1700401	73L1700503	73H1700629			
	73B1800712	73L1800225	73H1700796			
	73D1700242	73M1700453	73H1800078			
	73F1700012	5-22012	73D1800651		73H1800688	
	73F1700701		73E1700491		73H1800761	
	73G1700409		73J1800335	73J1600389		
	73G1800217		73L1600863	73J1600580		
	73H1700317	73L1700332	73J1600581			
	73J1600750	5-22013	73A1700274	73J1700443		
	73J1700147		73H1700612	73J1800327		
	73J1700592	5-22014	73J1700474	73K1600158		
	73J1800331		73F1700027	73K1700435		
	73J1800661		73F1800342	73K1700436		
	73K1800162		73K1700427	73K1700754		
	73L1600335		73K1800182	73K1800322		
73L1600648	73K1800730	73L1600260				
5-10217	73B1800713	5-22112	73A1700278	73L1600518		
	73F1800162		73B1800492	73L1600672		
	73J1800506		73C1700415	73L1700672		
	73K1800538		73F1700168	73L1700673		
5-10312	73A1700091		73G1700426	73M1600268		

Appendix 2- Product Codes and Lots in Scope

Original Scope

Product Code	Lot Number	Product Code	Lot Number	Product Code	Lot Number	
5-10312	73A1700254	5-22112	73H1700615	V5-10316	73A1700428	
	73A1700721		73H1800678		73A1700661	
	73A1800284		73K1800326		73A1800070	
	73A1800442		73K1800374		73B1700625	
	73A1800665		73L1600359		73B1800728	
	73A1800810		73L1700650		73B1800729	
	73B1700136		73M1600155		73C1800205	
	73B1700296		5-22113		73E1800394	73C1800207
	73B1700402				73G1700427	73D1700430
	73B1700617		5-22114		73F1700399	73D1700431
	73B1800342	73K1800734			73D1700432	
	73B1800702	5-22212	73A1800302		73D1700631	
	73C1700402		73A1800450		73D1800291	
	73C1700678		73B1700049		73D1800483	
	73C1800188		73B1700313		73D1800484	
	73C1800564		73B1800138		73E1800810	
	73D1700127		73C1700416		73F1700038	
	73D1800059		73C1800551		73F1700039	
	73D1800133		73D1700643		73F1700734	
	73D1800305		73D1800150		73G1700438	
	73D1800456		73E1800570		73G1700625	
	73D1800629		73F1700034		73G1800234	
	73E1700093		73F1700171		73G1800596	
	73E1700460		73F1700728		73H1700353	
	73E1800072		73F1800345		73H1700499	
	73E1800381		73G1700609		73H1700797	
	73E1800785		73H1700341		73H1800458	
	73F1700137		73H1800196		73J1600582	
	73F1700538		73J1600378		73J1600772	
	73F1700703		73J1700481		73J1700144	
	73F1800163		73J1700681		73J1700493	
	73F1800707		73J1800290		73J1700610	
	73G1700218		73K1600730		73J1800334	
	73G1700591		73K1700431		73J1800698	
	73G1800118		73K1800186		73K1600605	
	73G1800218		73L1600665		73K1700617	
	73G1800568		73L1700179		73K1800195	
	73G1800799		73L1700511		73L1600174	
	73G1800911		73M1600158		73L1600369	
	73H1700318		73M1700267		73L1600370	
	73H1700473		5-22213		73A1700114	73L1600673
	73H1700778				73A1800451	73L1600871
73H1800184	73B1700314			73M1700150		
73H1800420	73B1800496			73B1700639		
73H1800724	73C1700694			73B1800730		
73J1600355	5-22213			73D1700644	73C1700704	
				V5-10317		

Appendix 2- Product Codes and Lots in Scope

Original Scope

Product Code	Lot Number	Product Code	Lot Number	Product Code	Lot Number
5-10312	73J1600564	5-22213	73D1800151	V5-10317	73D1700632
	73J1600751		73E1800571		73F1700561
	73J1700127		73F1700400		73F1800193
	73J1700460		73F1800346		73G1700439
	73J1700594		73G1700428		73G1800019
	73J1800072		73H1700342		73H1700354
	73J1800663		73H1700788		73H1800093
	73K1600137		73J1700482		73K1800574
	73K1600571		73K1600149		73L1600674
	73K1700057		73K1700277		73M1700025
	73K1700409		73L1600666		
	73K1700587		73L1700180		
	73K1700725		73L1700512		
	73K1800163		73M1700268		
	73K1800369		73A1800452		
	73K1800456		73B1700315		
	73L1600138		73B1800364		
	73L1600338		73B1800497		
	73L1600488		73C1700695		
	73L1600650		73C1800366		
	73L1600838		73D1700425		
	73L1700498		73D1800472		
	73L1800799		73E1700493		
	73M1600133		73E1800572		
	73M1700240		73F1800347		
	73M1700450		73G1700429		
5-10313	73A1700092	5-22214	73G1800935		
	73A1700255		73H1700493		
	73A1700404		73H1800447		
	73A1700643		73H1800681		
	73A1700722		73J1600379		
	73A1800043		73J1700137		
	73A1800285		73J1800106		
	73A1800666		73K1600593		
	73B1700137		73K1700076		
	73B1700403		73K1700608		
	73B1700618		73L1600667		
	73B1800117		73L1700335		
	73B1800480		73M1700269		
	73B1800703	73M1700459			
	73C1700228	5-22215	73A1800453		
	73C1700550		73B1800365		
	73C1700679		73B1800498		
	73C1800476		73C1700257		
	73D1700615		73C1700565		
	73D1800134		73C1800367		

**Appendix 2 - Product Codes
and Lots in Scope**

Expanded Scope

Product Name	Product Code
Hudson RCI® Sheridan LTS® 4.0 mm	5-11108
Hudson RCI® Sheridan LTS® 5.0 mm	5-11110
Hudson RCI® Sheridan/CF® 3.0 mm	5-10106 5-10206
Hudson RCI® Sheridan/CF® 3.5 mm	5-10107
Hudson RCI® Sheridan/CF® 4.0 mm	5-10108 5-10208
Hudson RCI® Sheridan/CF® 4.5 mm	5-10109
Hudson RCI® Sheridan/CF® 5.0 mm	5-10110 5-10210
Hudson RCI® Sheridan/CF® 5.5 mm	5-10111
Hudson RCI® Sheridan/CF® 9.0 mm	5-10118 5-10218
Hudson RCI® Sheridan/CF® 9.5 mm	5-10119
Hudson RCI® Sheridan/CF® 10.0 mm	5-10120 5-10220
Hudson RCI® Sheridan® EZ-ENDO 5.0 mm	5-22510
Hudson RCI® Sheridan® EZ-ENDO 5.5 mm	5-22511
Hudson RCI® Sheridan® EZ-ENDO 9.0 mm	5-22518
Hudson RCI® Sheridan® Preformed 3.0 mm	5-22006 5-22106
Hudson RCI® Sheridan® Preformed 3.5 mm	5-22007 5-22107
Hudson RCI® Sheridan® Preformed 4.0 mm	5-22008 5-22108 5-22208
Hudson RCI® Sheridan® Preformed 4.5 mm	5-22009 5-22109 5-22209
Hudson RCI® Sheridan® Preformed 5.0 mm	5-22010 5-22110 5-22210
Hudson RCI® Sheridan® Preformed 5.5 mm	5-22011 5-22111 5-22211
Hudson RCI® Sheridan® Preformed 9.0 mm	5-22218
Hudson RCI® Sheridan® Uncuffed 2.0 mm	5-10404
Hudson RCI® Sheridan® Uncuffed 2.5 mm	5-10405
Hudson RCI® Sheridan® Uncuffed 3.0 mm	5-10406
Hudson RCI® Sheridan® Uncuffed 3.5 mm	5-10407
Hudson RCI® Sheridan® Uncuffed 4.0 mm	5-10408
Hudson RCI® Sheridan® Uncuffed 4.5 mm	5-10409
Hudson RCI® Sheridan® Uncuffed 5.0 mm	5-10410
Hudson RCI® Sheridan® Uncuffed 5.5 mm	5-10411
Hudson RCI® Sheridan®/HVT® 5.0 mm	5-10310
Hudson RCI® Sheridan®/HVT® 5.5 mm	5-10311
Hudson RCI® Sheridan®/HVT® 9.0 mm	5-10318
Hudson RCI® Sheridan®/HVT® 10.0 mm	5-10320

**Appendix 2 - Product Codes
and Lots in Scope**

Expanded Scope

Product Code	Lot Number	Product Code	Lot Number	Product Code	Lot Number
5-10106	73L1600638	5-10118 (Cont.)	73J1800658	5-11110 (cont.)	73E1700474
	73L1600825		73K1800363		73F1700386
	73M1600121		73K1800755		73H1700040
	73A1700079		73L1800217		73H1700482
	73C1700394		73L1800596		73H1700599
	73D1700234		73L1600484		73J1700291
	73D1700235	73L1600835	73K1700067		
	73D1700436	73A1700090	73L1700502		
	73E1700214	73A1700250	73M1700452		
	73E1700450	73D1700407	73B1800124		
	73F1700366	73F1700372	73D1800313		
	73G1700211	73F1700537	73F1800173		
	73G1700579	73G1700408	73G1800125		
	73H1700309	73H1700469	73K1800170		
	73H1700461	73J1700453	73L1800224		
	73H1700583	73M1700449	5-22006		73E1700489
	73H1700768	73A1800040			73G1700128
	73J1700119	73B1800116			73K1700075
	73J1700585	73B1800601		73L1700176	
	73K1700245	73C1800341		73C1800361	
	73K1700718	73D1800121		73E1800241	
	73L1700302	73D1800452		73F1800556	
	73L1700654	73E1800546		73G1800589	
	73M1700232	73F1800702		73G1800932	
	73A1800276	73H1800717		73L1800417	
	73A1800428	73K1800160		73L1800418	
	73B1800112	73B1700294		73M1800194	
	73B1800472	73D1700125	73M1800195		
	73B1800614	73D1700240	5-22007	73L1600002	
	73C1800332	73G1700589		73K1700426	
	73D1800120	73H1700506		73A1800460	
	73D1800446	73H1700593		73D1800648	
	73E1800373	73M1700238		73E1800565	
	73E1800775	73A1800051		5-22008	73C1700413
	73G1800111	73B1800479	73F1700164		
	73H1800174	73C1800342	73G1700129		
	73H1800711	73D1800131	73J1700300		
	73J1800313	73D1800453	73A1800461		
	73J1800492	73E1800377	73B1800362		
	73K1800151	73F1800703	73F1800183		
	73K1800320	73G1800566	5-22009	73L1600003	
	73K1800356	73H1800655		73C1700414	
73K1800708	73J1800348	73D1700640			
73L1800210	73K1800161	73F1700026			
73L1800386	73H1700470	73G1700130			
73M1800158	73J1700455	73H1700610			
		5-10119			
		5-10120			
		5-10206			

**Appendix 2 - Product Codes
and Lots in Scope**

Expanded Scope

Product Code	Lot Number	Product Code	Lot Number	Product Code	Lot Number
5-10107	73K1600124	5-10206	73L1700647	5-22009	73K1700274
	73K1600348		73B1800338		73A1800066
	73K1600560		73F1800704		73C1800464
	73K1600718		73K1800012		73D1800649
	73L1600480		73K1800364		73E1800566
	73L1600639		5-10208		73L1600485
	73L1600826	73J1700456		73L1800633	
	73A1700080	73K1700408		73L1800822	
	73A1700241	73C1800474		5-22010	73A1700109
	73C1700395	73H1800656			73B1700414
	73C1700538	73K1800365			73D1700627
	73C1700670	73J1700457	73H1700611		
	73D1700404	73L1700648	73A1800044		
	73E1700215	73K1800366	73C1800550		
	73E1700451	5-10218	73C1700549	73E1800393	
	73F1700139		73J1800347	73G1800590	
	73F1700367	5-10220	73J1800715	5-22011	73K1600589
	73F1700695		73C1800475		73L1600862
	73G1700212	73J1800507	73B1700309		
	73G1700400	5-10310	73K1600356		73D1700628
	73G1700580		73L1600336		73F1700165
	73H1700029		73L1600486		73L1700331
	73H1700462		73L1600836	73A1800020	
	73H1700584		73M1600132	73D1800650	
	73H1700769		73B1700134	73F1800341	
	73J1700120		73C1700227	5-22106	73E1700719
	73J1700273		73C1700676		73M1700260
	73J1700586		73D1700243		73E1800567
	73K1700246		73E1700091	5-22107	73J1800524
	73K1700399		73F1700013		73K1800731
	73K1700706		73F1700145		5-22108
	73K1700719		73F1700702	73F1700166	
	73L1700303		73G1700410	73E1800088	
	73L1700497		73H1700471	5-22109	73K1800772
	73L1700655		73H1700777		73K1600590
	73M1700233		73J1700593		73M1600152
	73M1700417		73K1700254		73A1700110
	73A1800277	73K1700723	73D1700629		
	73A1800436	73L1700661	73F1700028		
	73A1800804	73A1800282	73B1800133		
	73B1800473	73A1800664	73E1800089		
	73B1800696	73B1800341	73G1800933		
73C1800333	73C1800186	73J1800100			
73C1800449	73C1800563	5-22109	73L1600160		
73C1800465	73D1800303		73L1600865		
73D1800122	73D1800454		73M1600153		

**Appendix 2 - Product Codes
and Lots in Scope**

Expanded Scope

Product Code	Lot Number	Product Code	Lot Number	Product Code	Lot Number		
5-10107	73D1800447	5-10310	73E1800071	5-22109	73A1700275		
	73D1800619		73E1800378		73B1700310		
	73D1800679		73F1800706		73C1700563		
	73E1800542		73G1800567		73D1700423		
	73E1800543		73K1800540		73F1700029		
	73F1800154		73K1800541		73H1700613		
	73F1800525		73K1600357		73J1700475		
	73F1800694		73L1600337		73K1700428		
	73G1800208	73L1600487	73M1700261				
	73G1800559	73L1600837	73B1800363				
	73K1800532	73A1700253	73C1800362				
	73K1800743	73C1700677	73D1800652				
	73L1800211	73D1700126	73E1800568				
	73L1800512	73E1700092	73G1800819				
	5-10108	73K1600719	5-10311		73E1700459	5-22110	73H1800444
		73L1600128			73E1700221		73J1800525
		73L1600321			73F1700374		73K1800762
73L1600481		73G1700411		73L1800823			
73L1600827		73G1700590		73K1600591			
73A1700081		73H1700472		73L1600161			
73A1700242		73J1700459		73L1600866			
73B1700285		73K1700255		73A1700111			
73B1700612		73K1700724		73A1700276			
73C1700221		73M1700239		73B1700416			
73C1700539		73A1800283		73C1700251			
73D1700119		73A1800809		73C1700693			
73D1700606		73C1800187		73F1700030			
73E1700216		73D1800132		73G1700425			
73E1700452		73D1800304		73J1700476			
73E1700694		73D1800455		73L1700333			
73F1700006		73E1800379		73M1700262			
73F1700140		73E1800784	73B1800453				
73F1700368		73F1800536	73C1800363				
73F1700529		73H1800183	73E1800090				
73G1700133		5-10318	73L1600144	5-22111	73F1800343		
73G1700401			73L1600493		73G1800820		
73G1700581			73L1600701		73H1800445		
73H1700030			73L1600843		73K1800733		
73H1700310			73A1700259		73J1600377		
73H1700463			73C1700232		73K1600592		
73H1700585			73C1700684		73L1600358		
73H1700770			73D1700247		73L1600867		
73J1700121			73E1700097		73M1600154		
73J1700274			73E1700468		73A1700277		
73J1700587			73F1700150		73B1700417		
73K1700049		73F1700380	73C1700564				

**Appendix 2 - Product Codes
and Lots in Scope**

Expanded Scope

Product Code	Lot Number	Product Code	Lot Number	Product Code	Lot Number
5-10108	73K1700247	5-10318	73F1700709	5-22111	73F1700398
	73K1700400		73G1700595		73H1700614
	73L1700161		73H1700170		73J1700477
	73L1700519		73H1700598		73A1800067
	73M1700129		73K1700060		73B1800134
	73M1700234		73K1700260		73C1800364
	73M1700418		73K1700593		73F1800344
	73M1700443		73L1700316		5-22208
	73A1800278		73L1700663	73A1700112	
	73A1800654		73M1700245	73D1700258	
	73B1800113		73A1800286	73F1700032	
	73B1800697		73A1800443	73F1700725	
	73C1800176		73B1800119	73G1700605	
	73C1800466		73B1800482	73H1700786	
	73D1800123		73C1800347	73J1700478	
	73D1800296		73D1800308	73K1700275	
	73D1800620		73D1800460	73K1700740	
	73D1800621		73E1800551	73L1700508	
	73E1800067		73F1800166	73M1700263	
	73E1800374		73F1800712	73A1800316	
	73E1800700		73G1800123	73A1800816	
	73F1800155		73G1800573	73B1800493	
	73F1800321		73H1800187	73C1800365	
	73F1800526		73H1800663	73D1800147	
	73G1800112		73H1800728	73E1800091	
	73G1800209		73J1800322	73E1800569	
	73G1800789		73J1800667	73F1800557	
	73H1800175		73K1800547	73H1800679	
5-10109	73L1600129	5-10320	73L1700500	5-22209	73L1600127
	73L1600130		73J1800512		73L1600509
	73L1600322		73K1800168		73M1600156
	73L1600644	5-10404	73L1600844		73A1700279
	73M1600123		73A1700096		73B1700311
	73A1700082		73A1700260		73D1700132
	73A1700243		73B1700298		73D1700424
	73B1700286		73C1700405		73E1700720
	73C1700222		73F1700381		73F1700169
	73C1700540		73F1700710		73G1700606
	73C1700671		73H1700323		73H1700338
	73D1700607		73H1700478		73J1700479
	73E1700087		73M1700246		73K1700276
	73E1700453		73A1800055		73K1700429
	73E1700695		73B1800120		73L1700177
	73F1700007		73E1800552		73L1700509
	73F1700141		73J1800091		73M1700264
	73F1700530		73L1800610		73A1800024

**Appendix 2- Product Codes
and Lots in Scope**

Expanded Scope

Product Code	Lot Number	Product Code	Lot Number	Product Code	Lot Number	
5-10109	73F1700696	5-10405	73L1600845	5-22209	73A1800300	
	73G1700134		73A1700097		73B1800135	
	73G1700402		73A1700725		73B1800454	
	73G1700582		73B1700299		73C1800491	
	73H1700031		73F1700712		73D1800148	
	73H1700311		73G1700418		73E1800092	
	73H1700586		73H1700038		73E1800395	
	73H1700771		73H1700479		73F1800719	
	73J1700122		73J1700287		73H1800194	
	73J1700275		73A1800056		73J1800103	
	73K1700050		73A1800462		5-22210	73K1600379
	73K1700579		73B1800121			73L1600361
	73L1700293		73E1800553			73L1600663
	73L1700520		73F1800713			73M1600157
	73L1700656		73H1800423			73B1700312
	73M1700130		73H1800664			73C1700254
	73M1700235		73K1800376			73D1700641
	73M1700419		73L1600495			73F1700170
	73A1800041	73B1700621	73F1700726			
	73A1800655	73D1700622	73G1700607			
	73A1800805	73E1700710	73H1700339			
	73B1800332	73F1700152	73H1700616			
	73C1800180	73G1700131	73J1700135			
	73C1800557	73H1700480	73J1700447			
	73D1800297	73J1700128	73K1700607			
	73E1800068	73J1700599	73L1700178			
	73E1800224	73K1700594	73L1700334			
	73E1800776	73L1700318	73M1700265			
	73F1800322	73M1700139	73A1800448			
	73F1800695	73M1700415	73B1800136			
	73G1800790	73A1800057	73B1800494			
	73G1800906	73A1800463	73C1800498			
	73H1800415	73A1800811	73E1800093			
	73J1800314	73B1800484	73F1800558			
	73J1800494	73C1800192	5-22211	73K1600380		
	73J1800655	73D1800310		73K1600729		
73K1800753	73D1800462	73L1600664				
73L1800591	73E1800386	73B1700420				
5-10110	73J1600742	73E1800790		73C1700255		
	73K1600128	73F1800541		73D1700133		
	73K1600351	73G1800576		73D1700642		
	73K1600563	73H1800189		73F1700033		
	73L1600006	73H1800665	73F1700727			
	73L1600131	73J1800092	73G1700608			
	73L1600323	73L1800209	73H1700340			
73L1600640	73L1800404	73H1700787				

**Appendix 2 - Product Codes
and Lots in Scope**

Expanded Scope

Product Code	Lot Number	Product Code	Lot Number	Product Code	Lot Number	
5-10110	73L1600828	5-10406	73L1800513	5-22211	73J1700136	
	73A1700244		73L1800611		73J1700480	
	73B1700287		73L1800727		73K1700430	
	73B1700393		73M1800178		73K1700741	
	73B1700613		73M1800342		73L1700510	
	73D1700120		5-10407		73K1600366	73M1700266
	73D1700608	73L1600643			73A1800301	
	73E1700241	73A1700261			73A1800449	
	73E1700696	73D1700408			73B1800137	
	73F1700142	73G1700419			73B1800495	
	73F1700531	73H1700039			73C1800177	
	73G1700135	73K1700261			73D1800149	
	73G1700583	73K1700595			73E1800094	
	73H1700032	73M1700416			73F1800184	
	73H1700464	73A1800812			73F1800559	
	73H1700587	73C1800175			73L1800437	
	73H1700772	73E1800229			5-22218	73F1700556
	73J1700123	73F1800542				73G1700430
	73J1700276	73G1800921		73H1700619		
	73J1700448	73K1800549		73J1700301		
	73J1700614	5-10408		73K1600725		73F1800350
	73K1700051			73L1600656		73G1800138
	73K1700248			73B1700143	73J1800108	
	73K1700401		73C1700554	73J1800530		
	73K1700580		73D1700409	5-22510	73B1700556	
	73L1700164		73E1700226		73D1700650	
	73L1700304		73E1700711		73H1700346	
	73L1700657		73F1700383	5-22511	73H1800449	
	73M1700131		73F1700714		73C1700261	
	73M1700420		73H1700481		73K1700609	
	73A1800279		73J1700288	5-22518	73C1800370	
	73A1800437		73J1700600		73K1600595	
	73A1800661		73M1700248		73E1800459	
	73A1800806		73B1800122	73M1800288		
	73B1800333		73B1800485			
	73B1800698		73B1800705			
	73C1800181		73D1800311			
	73C1800334		73D1800463			
	73C1800467	73E1800387				
	73C1800558	73F1800331				
	73D1800124	73G1800805				
	73D1800298	73H1800667				
73D1800622	73J1800324					
73E1800245	5-10409	73K1600726				
73E1800375		73L1600847				
73E1800777		73A1700098				

**Appendix 2 - Product Codes
and Lots in Scope**

Expanded Scope

Product Code	Lot Number	Product Code	Lot Number
5-10110	73F1800527	5-10409	73A1700262
	73F1800696		73C1700233
	73G1800113		73C1700685
	73G1800560		73D1700410
	73G1800907		73E1700227
	73H1800176		73F1700154
	73H1800210		73F1700715
	73K1800358		73H1700324
	73K1800534		73J1700129
	73K1800710		73J1700289
73L1800514	73K1700062		
5-10111	73J1600351		73K1700730
	73J1600720		73M1700140
	73K1600129		73A1800058
	73K1600564		73B1800329
	73L1600007		73B1800486
	73L1600324		73B1800706
	73L1600641		73C1800480
	73L1600829		73D1800312
	73M1600125		73E1800059
	73A1700084	73E1800554	
	73A1700245	73F1800169	
	73B1700614	5-10410	73K1600579
	73C1700396		73L1600146
	73D1700121		73L1600848
	73D1700609		73A1700099
	73E1700697		73B1700145
	73G1700136		73B1700389
	73G1700213		73C1700234
	73G1700584		73C1700686
	73H1700465		73D1700411
	73H1700588		73E1700470
	73H1700773		73F1700155
	73J1700124		73F1700384
	73J1700449		73F1700716
	73K1700052		73H1700325
	73K1700172		73J1700130
	73K1700581		73K1700063
	73L1700165		73K1700731
	73L1700305		73M1700141
	73L1700658		73B1800346
	73M1700132		73B1800707
	73M1700335	73C1800481	
73M1700444	73E1800230		
73A1800280	73E1800791		
73A1800438	73F1800543		

**Appendix 2 - Product Codes
and Lots in Scope**

Expanded Scope

Product Code	Lot Number	Product Code	Lot Number
5-10111	73A1800807	5-10411	73J1600685
	73B1800334		73K1600580
	73B1800699		73L1600849
	73C1800182		73A1700263
	73C1800335		73C1700235
	73C1800468		73C1700687
	73D1800125		73D1700623
	73D1800299		73E1700471
	73D1800623		73F1700156
	73E1800778		73F1700717
	73F1800156		73G1700420
	73F1800323		73H1700326
	73F1800528		73J1700131
	73G1800114		73K1700064
	73G1800211		73K1700732
	73G1800561		73L1700319
	73H1800177		73M1700249
73K1800379	73A1800059		
73L1800537	73B1800347		
5-10118	73L1600009	5-11108	73B1800708
	73L1600332		73D1800633
	73M1600130		73E1800388
	73A1700089		73F1800170
	73A1700249		73G1800223
	73B1700399		73G1800922
	73C1700547		73H1800730
	73D1700406		73L1600010
	73E1700701		73A1700644
	73F1700536		73C1700236
	73G1700407	73D1700438	
	73H1700592	73E1700473	
	73J1700282	73F1700385	
	73K1700405	73K1700066	
	73M1700137	73L1700501	
	73A1800039	73B1800123	
	73A1800808	73D1800137	
	73B1800337	73F1800172	
	73C1800340	73G1800124	
	73D1800130	73G1800925	
	73D1800302	73H1800731	
	73E1800783	5-11110	73K1600368
	73F1800535		73K1600727
	73G1800798		73A1700645
	73H1800654		73B1700410
	73J1800319		73C1700237
73J1800503	73D1700624		