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

06. avgust 2019

NUJNO – OBVESTILO O VARNOSTNEM POPRAVLJALNEM UKREPU

Vrsta ukrepa	Odpoklic
Referenčna oznaka Teleflex	EIF-000361-01
Trgovsko ime	**Endotrahelani tubusi in priključki znamke Select Hudson RCI Sheridan ®**
Koda izdelka/številka serije	**Za seznam kod izdelkov in številk serij, ki jih zajema ta ukrep, glejte Dodatek 2**

Spoštovana stranka,

Podjetje Teleflex Medical je prostovoljno izdalo odpoklic za kode in številke serij izdelkov, navedenih v Dodatku 2.

Ta odpoklic je dopolnilo nedavnega odpoklica z referenčno oznako EIF-000361. Razširitev je bila potrebna zaradi vključitve dodatnih kod in serij izdelkov na osnovi izida preiskave temeljnega vzroka in upoštevanja načela previdnosti. Če niste prejeli pisma o izvirnem odpoklicu, je to zato, ker ste prejeli samo izdelke iz razširjenega odpoklica in ker niste prejeli prizadetih serij endotrahelanih tubusov in priključkov Hudson RCI Sheridan®, ki so bili zajeti v izvirnem odpoklicu. Ne glede na to, ali ste se odzvali na izvirno obvestilo ali ste prejeli obvestilo prvič, morate izpolniti in podpisati priloženi obrazec za odgovor, s katerim boste potrdili, da ste bili obveščeni o tem ukrepu in da ste sprejeli ustrezne ukrepe.

Opis težave in ukrepov, ki zahtevajo takojšno pozornost
Ta prostovoljni odpoklic je bil sprejet zaradi sporočenih pritožb, ki kažejo na povečano verjetnost, da se bo pri določenih serijah izdelkov (glejte dodatek 2) 15 mm priključek odklopil z endotrahealnega tubusa (ETT). Takojšna posledica za paciente je odklop z dihalne cevi, kar lahko privede do nezadostne oksigenacije, ki zahteva zdravniški poseg.

Teleflex je skupaj prejel poročila o štirih smrtnih primerih (v katerih so bile vpletene serije iz izvirnega in razširjenega odpoklica) in dodatna poročila o hudih poškodbah, kjer bi bil lahko odklop endotrahelanega tubusa (ETT) prispevajoči dejavnik. V večini sporočenih primerov je klinično osebje zaznalo odklop priključka takoj ali pozneje zaradi sproženih alarmov na ventilatorju, ki jih je sprožil padec tlaka v ceveh ventilatorja.

Za izdelke in situ Teleflex svetuje, da klinično osebje preveri, ali je 15 mm priključek nameščen trdno v endotrahealni tubus v skladu z navodili za uporabo, da se prepreči njegov odklop med uporabo. Če pride do odklopa, takoj trdno priklopite oba sestavna dela ponovno, kot je opisano v navodilih za uporabo, oziroma klinično osebje lahko tudi presodi, da je treba opraviti zamenjavo endotrahealnega tubusa, če pred tem upošteva tveganja, ki so povezana z reintubacijo.

Posodobitev zgornje izjave o težavi:
Razširitev odpoklica vključuje dodatne kode in serije izdelkov na osnovi izida preiskave temeljnega vzroka.

Naša dokumentacija navaja, da ste prejeli izdelke, ki so predmet tega razširjenega odpoklica.

Upoštevajte spodaj navedene ukrepe samo za navedeno lokacijo naprave:

Lokacija naprave	Številka seznama ukrepov
Zdravstvene ustanove	**1**
Distributerji	**2**

Številka seznama ukrepov 1 – Zdravstvene ustanove

1. Prosimo, da preverite zalogo izdelkov, ki jih zajema ta varnostni popravljalni ukrep. Uporabniki morajo prenehati z uporabo in distribucijo prizadetih izdelkov ter takoj izolirati vse prizadete izdelke.
2. Če imate prizadete izdelke, ki so navedeni v tem varnostnem popravljalnem ukrepu, potem odkljukajte ustrezno polje na potrditvenem obrazcu (glejte Dodatek 1) in se obrnite na službo za pomoč strankam, tako da pokličete na telefonsko številko, navedeno v nadaljevanju, in posredovali vam bomo povratno številko. To številko vpišite v ustrezno polje na potrditvenem obrazcu in ga takoj vrnite službi za pomoč strankam.
3. Če na zalogi nimate izdelkov, ki so navedeni v tem varnostnem popravljalnem ukrepu, potem odkljukajte ustrezno polje na potrditvenem obrazcu (Dodatek 1) in obrazec vrnite po faksu ali e-pošti na spodaj naveden e-poštni naslov.
4. Podjetje Teleflex (ali lokalni zastopnik) bo po prejemu vrnjenega prizadetega izdelka izdalo dobropis.

Številka seznama ukrepov 2 – Distributerji

1. Posredujte to obvestilo o varnostnem popravljalnem ukrepu vsem strankam, ki so prejele izdelke, zajete v ta varnostni popravljalni ukrep. Stranke morajo nato izpolniti potrditveni obrazec in vam ga vrniti.
2. Preverite zalogo izdelkov, ki jih zajema ta varnostni popravljalni ukrep. Prenehajte z uporabo in distribucijo prizadetih izdelkov ter takoj izolirajte vse prizadete izdelke. Nato lahko podjetju Teleflex vrnete vse izdelke, ki jih zajema ta ukrep.
3. Kot distributer morate podjetju Teleflex potrditi, da ste izvedli vse potrebne ukrepe odpoklica, ki so navedeni zgoraj. Po izvedbi vseh ukrepov pošljite izpolnjeni potrditveni obrazec službi za pomoč strankam.
4. Vse pristojne organe v državah članicah Evropskega gospodarskega prostora/Švici (EGP/CH) in Turčiji, kjer podjetje Teleflex opravlja neposredno distribucijo izdelka, bo obvestilo podjetje Teleflex.
5. Če ste izdelek distribuirali tudi izven svoje države, o tem obvestite Teleflex s povratno elektronsko pošto na spodaj navedeni e-poštni naslov.
6. Če ste distributer in/ali ste odgovorni za poročanje v ali izven območja EGP/CH/TR, vas prosimo, da o tem ukrepu obvestite lokalni pristojni organ. Obvestilo in vso komunikacijo med vami in lokalnim pristojnim organom posredujte podjetju Teleflex.

Teleflex

Podjetje Teleflex bo o tem varnostnem popravljalnem ukrepu obvestilo vse stranke, zaposlene v podjetju Teleflex in distributerje.

Posredovanje obvestila o varnostnem popravljalnem ukrepu

To obvestilo je treba posredovati vsem znotraj organizacije, ki jih zadeva, ali vsem organizacijam, ki so prejele potencialno prizadete izdelke. Poskrbite, da bodo s tem obvestilom seznanjeni končni uporabniki, klinični zdravniki, odgovorno osebje za obvladovanje tveganja, oskrbovalna veriga/distribucijski centri itd. Ohranite ozaveščenost o tem obvestilu, dokler v vaši organizaciji ne bodo opravljeni vsi potrebni ukrepi.

Oseba za stik

Za dodatne informacije ali pomoč glede te težave se obrnite na:

Služba za pomoč strankam:

Stik: Shane Kenny **Telefon:** +353 0 90 64608769

FAKS: +353 0 14370773 **E-pošta**: recalls.intl@teleflex.com

Vse pristojne organe v državah članicah Evropskega gospodarskega prostora/Švici (EGP/CH) in Turčiji, kjer podjetje Teleflex opravlja neposredno distribucijo izdelka, bo obvestilo podjetje Teleflex. Pri podjetju Teleflex težimo h kakovosti, varnosti in učinkovitosti naših izdelkov. Iskreno se opravičujemo za vse morebitne nevšečnosti, ki smo vam jih povzročili s tem ukrepom. Za vsa dodatna vprašanja se obrnite na lokalnega prodajnega zastopnika ali službo za pomoč strankam.

Za in v imenu podjetja Teleflex,

Padraig Hegarty

Padraig Hegarty, podpredsednik za zagotavljanje kakovosti (v proizvodnji)

Teleflex MEDICAL

Dodatek 1

Št. stranke
_____

VARNOSTNI POPRAVLJALNI UKREP
POTRDITVENI OBRAZEC

UKREP PODJETJA TELEFLEX ZA IZDELEK – PROSIMO ZA TAKOJŠNJO POZORNOST

Referenčna oznaka EIF-000361-01

IZPOLNJEN OBRAZEC TAKOJ VRNITE NA:

FAKS: +353 0 14370773 **E-pošta**: recalls.intl@teleflex.com

☐ Potrjujemo prejem tega varnostnega obvestila in da smo izpolnili navedene potrebne ukrepe. Potrjujemo, da naš inventar **NE** vsebuje izdelkov, za katere velja ta ukrep.	☐ Potrjujemo, da smo prejeli to varnostno obvestilo in izvedli vse potrebne ukrepe, ki jih obvestilo vsebuje. Potrjujemo, da naš inventar **VKLJUČUJE** izdelke, za katere velja ta ukrep. Uporaba in nadaljnja distribucija prizadetih izdelkov sta ustavljeni. Vsi izdelki so vzeti iz uporabe in spodaj navedena količina bo vrnjena. **Št. dovoljenja za vračilo: _____**

ŠTEVILKE ZA KOLIČINO IZDELKOV NAJ BODO NAPISANE ČITLJIVO

ŠTEVILKA IZDELKA	ŠTEVILKA SERIJE	KOLIČINA (za vračilo)

- V vračilni paket z vrnjenimi enotami priložite kopijo **izpolnjenega potrditvenega obrazca**
- Poskrbite, da bo **številka RAN jasno vidna** na vračilnem paketu
- Vrnjene izdelke označite kot **»Vrnjeno v skladu z ukrepom«**

Izpolnite ta potrditveni obrazec in ga takoj pošljite po faksu ali e-pošti na zgoraj navedeno številko ali naslov.

IME USTANOVE (NPR. IME BOLNIŠNICE, ZDRAVSTVENE ORGANIZACIJE)	
NASLOV USTANOVE	**Telefon/FAKS**
OBRAZEC JE IZPOLNIL:	**Žig**
IME S TISKANIMI ČRKAMI: _____ **PODPIS: _____**	
DATUM	

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
5-10112	73A1700085
	73A1700246
	73A1700717
	73A1800042
	73A1800281
	73A1800662
	73B1700288
	73B1700395
	73B1700615
	73B1800114
	73B1800474
	73B1800700
	73C1700223
	73C1700397
	73C1700541
	73C1800183
	73C1800469
	73D1700236
	73D1700610
	73D1800300
	73D1800624
	73E1700217
	73E1700454
	73E1700698
	73E1800061
	73E1800225
	73E1800779
	73F1700532
	73F1800157
	73F1800529
	73F1800697
	73G1700137
	73G1700214
	73G1700585
	73G1800115
	73G1800212
	73G1800562
	73G1800791
	73H1700033
	73H1700466
	73H1800178
	73H1800652
	73J1600560
	73J1600743
	73J1700125
	73J1700277

Product Code	Lot Number
5-10313 (cont.)	73D1800306
	73D1800457
	73E1700094
	73E1700222
	73E1700461
	73E1800073
	73E1800227
	73E1800548
	73F1700014
	73F1700375
	73F1700539
	73F1700704
	73F1800328
	73F1800708
	73G1700412
	73G1800119
	73G1800219
	73G1800800
	73H1700319
	73H1700474
	73H1700594
	73J1600356
	73J1600357
	73J1600565
	73J1600752
	73J1700283
	73J1700461
	73J1700595
	73K1600138
	73K1600572
	73K1600573
	73K1700058
	73K1700410
	73K1700588
	73K1700726
	73L1600139
	73L1600339
	73L1600489
	73L1600651
	73L1700311
	73L1700499
	73L1700662
	73M1600134
	73M1700241
	73M1700425
	73M1700451

Product Code	Lot Number
5-22215 (cont.)	73D1700645
	73D1800473
	73E1700494
	73E1800396
	73F1700729
	73F1800185
	73F1800560
	73G1700610
	73H1700617
	73J1600380
	73J1700138
	73J1700483
	73J1800527
	73K1600150
	73K1700432
	73K1700742
	73L1700513
	73M1700146
5-22216	73A1700115
	73A1700736
	73A1800454
	73B1700422
	73B1800139
	73B1800499
	73C1700258
	73C1700696
	73D1700646
	73D1800152
	73E1700495
	73E1800573
	73F1700172
	73F1700554
	73F1800348
	73G1700611
	73G1800137
	73H1700618
	73H1800682
	73J1600381
	73J1700139
	73J1800107
	73J1800528
	73K1600383
	73K1700743
	73L1600162
	73L1600511
	73L1700514

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

Product Code	Lot Number
5-10112	73J1700588
	73J1800082
	73J1800317
	73J1800496
	73J1800656
	73K1600130
	73K1600565
	73K1700053
	73K1700249
	73K1700394
	73K1700582
	73K1800359
	73L1600008
	73L1600325
	73L1600642
	73L1600830
	73L1700166
	73L1700306
	73L1700521
	73L1700659
	73L1800193
	73M1600126
	73M1700133
	73M1700445
5-10113	73A1700086
	73A1700247
	73A1700400
	73A1700640
	73A1700718
	73A1800038
	73A1800663
	73B1700289
	73B1700396
	73B1700616
	73B1800115
	73B1800475
	73B1800701
	73C1700542
	73C1700672
	73C1800184
	73C1800336
	73C1800559
	73D1700122
	73D1700237
	73D1700405
	73D1800060

Product Code	Lot Number
5-10314	73A1700093
	73A1700094
	73A1700095
	73A1800293
	73A1800294
	73A1800295
	73A1800429
	73A1800798
	73A1800799
	73B1700138
	73B1700139
	73B1700297
	73B1700404
	73B1700405
	73B1700406
	73B1700407
	73B1800343
	73B1800344
	73B1800345
	73C1700403
	73C1700404
	73C1700551
	73C1700552
	73C1700680
	73C1700681
	73C1800344
	73C1800345
	73C1800346
	73C1800477
	73C1800565
	73C1800566
	73C1800567
	73D1700616
	73D1800630
	73D1800631
	73D1800632
	73E1700095
	73E1700096
	73E1700242
	73E1700462
	73E1700463
	73E1700703
	73E1700705
	73E1700706
	73E1800074
	73E1800075

Product Code	Lot Number
5-22216	73M1700147
	73M1700460
5-22217	73A1800025
	73A1800303
	73B1800366
	73B1800724
	73C1700796
	73E1800397
	73F1700555
	73F1800349
	73H1700343
	73J1700140
	73J1800529
	73L1600163
	73L1600363
	73L1700515
	73L1800828
	73M1700148
5-22312	73A1700737
	73A1800023
	73B1700423
	73B1800140
	73B1800500
	73C1700697
	73C1800328
	73D1700426
	73D1800474
	73E1700561
	73E1700721
	73E1800398
	73F1700173
	73F1700730
	73F1800561
	73G1700612
	73G1800139
	73H1700620
	73H1800683
	73J1700141
	73J1700484
	73J1800109
	73K1600151
	73K1700078
	73K1700433
	73K1700744
	73K1800188
	73L1600512

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
5-10113	73M1700446
5-10114	73A1700087
	73A1700088
	73A1800439
	73A1800440
	73A1800441
	73B1700290
	73B1700291
	73B1700292
	73B1700293
	73B1700397
	73B1800219
	73B1800220
	73B1800221
	73B1800222
	73B1800335
	73B1800336
	73C1700398
	73C1700399
	73C1700400
	73C1700543
	73C1700544
	73C1700545
	73C1700546
	73C1800337
	73C1800338
	73C1800339
	73C1800470
	73C1800471
	73C1800472
	73C1800473
	73D1700611
	73D1800448
	73D1800449
	73D1800450
	73D1800626
	73D1800627
	73E1700088
	73E1700089
	73E1700090
	73E1700700
	73E1800544
	73E1800545
	73E1800781
	73F1700138
	73F1700143

Product Code	Lot Number
5-10314	73J1600358
	73J1600359
	73J1600360
	73J1600753
	73J1600754
	73J1700148
	73J1700284
	73J1700285
	73J1700596
	73J1800088
	73J1800089
	73J1800354
	73J1800508
	73J1800509
	73J1800510
	73J1800651
	73J1800665
	73K1600139
	73K1600140
	73K1600141
	73K1600142
	73K1600359
	73K1600360
	73K1600574
	73K1600575
	73K1600576
	73K1600723
	73K1700059
	73K1700256
	73K1700257
	73K1700258
	73K1700589
	73K1700727
	73L1600340
	73L1600490
	73L1600491
	73L1600839
	73L1600840
	73L1700223
	73M1600135
	73M1700205
	73M1700242
	73M1700243
	73M1700244
	73M1700426
	73M1700437

Product Code	Lot Number
5-22314	73J1700142
	73J1800111
	73K1700080
	73K1700746
	73K1800190
	73L1600164
	73L1600868
	73M1600161
	73M1700461
5-22315	73A1800022
	73A1800456
	73B1800142
	73C1700417
	73C1800369
	73D1700134
	73D1700649
	73D1800476
	73E1800400
	73F1700174
	73F1700732
	73G1800142
	73G1800823
	73H1700344
	73H1700789
	73H1800685
	73J1600384
	73J1700486
	73J1800112
	73J1800690
	73K1700278
	73K1800191
	73L1600869
	73M1600162
	73M1700271
5-22316	73B1800501
	73C1700260
	73C1700795
	73D1800477
	73F1700402
	73F1800353
	73G1800824
	73H1700345
	73H1700790
	73H1800755
	73K1800192
	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	5-10315	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

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

Product Code	Lot Number
5-10114	73L1600833
	73L1800511
	73M1600272
	73M1700236
	73M1700237
	73M1700427
	73M1700428
5-10115	73A1700248
	73A1700719
	73A1700720
	73A1800656
	73A1800796
	73A1800797
	73B1700131
	73B1700132
	73B1700626
	73B1700627
	73B1800476
	73B1800477
	73B1800478
	73C1700224
	73C1700225
	73C1700226
	73C1700673
	73C1700674
	73C1800561
	73D1700123
	73D1700124
	73D1700238
	73D1800126
	73D1800127
	73D1800128
	73D1800287
	73E1700218
	73E1700219
	73E1700220
	73E1700456
	73E1800063
	73E1800070
	73E1800222
	73E1800366
	73E1800367
	73F1700369
	73F1700370
	73F1700371
	73F1800159

Product Code	Lot Number
5-10315	73F1800329
	73F1800330
	73F1800537
	73F1800538
	73F1800539
	73F1800540
	73G1700203
	73G1700223
	73G1700413
	73G1700414
	73G1800570
	73G1800802
	73G1800803
	73G1800917
	73G1800918
	73G1800919
	73H1700303
	73H1700320
	73H1700597
	73H1700780
	73H1800072
	73H1800073
	73H1800186
	73H1800659
	73H1800660
	73H1800727
	73J1600361
	73J1600362
	73J1600566
	73J1600567
	73J1700462
	73J1700463
	73J1800090
	73J1800325
	73J1800326
	73K1700259
	73K1700411
	73K1700412
	73K1700729
	73K1800164
	73K1800321
	73K1800351
	73K1800352
	73L1600492
	73L1600652
	73L1600653

Product Code	Lot Number
5-22515	73C1800201
	73D1800154
	73E1700104
	73E1700723
	73E1800402
	73F1700176
	73F1700406
	73F1800565
	73G1700434
	73G1800591
	73H1700350
	73H1800451
	73H1800686
	73J1700302
	73J1700497
	73J1800113
	73K1700747
	73K1800736
	73M1700274
5-22516	73A1700282
	73A1800684
	73B1700158
	73B1700317
	73B1800503
	73C1700570
	73C1800371
	73E1800577
	73F1700036
	73F1700177
	73F1700407
	73G1700614
	73G1800232
	73H1700495
	73J1700487
	73J1800532
	73K1600594
	73K1700082
	73K1800327
5-22517	73C1800202
	73J1600767
V5-10114	73A1700120
	73B1700321
	73B1800223
	73B1800371
	73C1700425
	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	5-10316	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	V5-10115	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	V5-10116	73A1800248
	73L1700191		73G1700416		73B1700427
	73L1700308		73G1700593		73B1800692
	73L1700309		73G1700594		73C1800204
	73L1800263		73G1800221		73D1700265
	73M1600128		73G1800222		73D1800482

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

Product Code	Lot Number
5-10115	73M1700447
	73M1700448
5-10116	73A1700650
	73A1800048
	73A1800049
	73A1800050
	73A1800387
	73B1700398
	73B1700628
	73B1800709
	73B1800710
	73C1800185
	73D1700239
	73D1700412
	73D1700413
	73D1700414
	73D1700612
	73D1800289
	73D1800451
	73E1800782
	73F1700009
	73F1700010
	73F1700699
	73F1700700
	73F1800018
	73F1800019
	73G1700405
	73G1700588
	73G1800215
	73G1800564
	73G1800565
	73H1700314
	73H1700468
	73H1800432
	73H1800433
	73H1800692
	73J1600563
	73J1600678
	73J1600748
	73J1700145
	73J1700452
	73J1700591
	73J1800329
	73J1800501
	73J1800650
	73K1600569

Product Code	Lot Number
5-10316	73G1800571
	73G1800572
	73G1800639
	73H1700321
	73H1700477
	73H1700781
	73H1800435
	73H1800436
	73H1800661
	73H1800662
	73J1600568
	73J1600755
	73J1700444
	73J1700464
	73J1700598
	73J1800332
	73J1800333
	73J1800666
	73K1600577
	73K1700413
	73K1700590
	73K1700591
	73K1800124
	73K1800165
	73K1800166
	73K1800167
	73K1800227
	73L1600143
	73L1600341
	73L1600342
	73L1600343
	73L1600555
	73L1600654
	73L1600841
	73L1600842
	73L1800480
	73M1700122
	73M1700123
	73M1700124
5-10317	73A1800299
	73B1800716
	73C1700683
	73C1800569
	73D1700619
	73F1700544
	73F1800165

Product Code	Lot Number
V5-10116	73F1700037
	73F1700733
	73F1800020
	73G1700436
	73G1800233
	73H1700351
	73H1800455
	73H1800689
	73J1600771
	73J1700146
	73J1700608
	73J1800330
	73K1700088
	73K1800194
	73L1600172
	73L1600671
	73M1700027
V5-10314	73A1700121
	73A1700122
	73A1800296
	73A1800430
	73B1700322
	73B1700428
	73B1800218
	73B1800372
	73B1800373
	73B1800374
	73B1800512
	73B1800513
	73C1700426
	73C1700576
	73C1700577
	73C1700702
	73C1700703
	73C1800373
	73C1800574
	73C1800575
	73D1800656
	73D1800657
	73E1700106
	73E1700107
	73E1700108
	73E1700239
	73E1800580
	73E1800581
	73E1800809

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

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

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

Product Code	Lot Number
5-10214	73G1700124
	73H1700036
	73H1800720
	73J1800086
	73J1800660
	73K1600136
	73K1600722
	73L1600334
	73L1600405
	73M1600269
	73M1700204
	73M1700429
5-10215	73B1800452
	73E1800368
	73F1800327
	73G1800555
	73H1700316
	73H1800182
	73H1800721
	73J1800087
	73K1800368
	73L1700310
	73M1600131
	73M1700436
5-10216	73A1800052
	73B1700401
	73B1800712
	73D1700242
	73F1700012
	73F1700701
	73G1700409
	73G1800217
	73H1700317
	73J1600750
	73J1700147
	73J1700592
	73J1800331
	73J1800661
	73K1800162
	73L1600335
	73L1600648
5-10217	73B1800713
	73F1800162
	73J1800506
	73K1800538
5-10312	73A1700091
5-10413	73G1800924
	73K1700416
	73M1600139
5-10414	73A1700100
	73F1700064
	73L1800406
5-11112	73A1700646
	73A1800671
	73B1800350
	73C1700238
	73D1700625
	73D1800138
	73E1700475
	73F1700387
	73F1800174
	73G1800126
	73G1800806
	73H1700041
	73H1700483
	73J1700292
	73J1800308
	73K1600369
	73K1800172
	73K1800173
	73L1600011
	73L1700503
	73L1800225
	73M1700453
5-22012	73D1800651
	73E1700491
	73J1800335
	73L1600863
	73L1700332
5-22013	73A1700274
	73H1700612
	73J1700474
5-22014	73F1700027
	73F1800342
	73K1700427
	73K1800182
	73K1800730
5-22112	73A1700278
	73B1800492
	73C1700415
	73F1700168
	73G1700426
V5-10315	73D1700137
	73D1700138
	73D1700266
	73D1700267
	73D1800158
	73D1800286
	73E1700240
	73E1800098
	73E1800309
	73E1800312
	73E1800407
	73E1800408
	73F1700281
	73F1700365
	73F1700414
	73F1800191
	73F1800192
	73F1800362
	73F1800363
	73G1700237
	73G1700437
	73G1800595
	73G1800831
	73H1700056
	73H1700352
	73H1700629
	73H1700796
	73H1800078
	73H1800688
	73H1800761
	73J1600389
	73J1600580
	73J1600581
	73J1700443
	73J1800327
	73K1600158
	73K1700435
	73K1700436
	73K1700754
	73K1800322
	73L1600260
	73L1600518
	73L1600672
	73L1700672
	73L1700673
	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	V5-10317	73B1700639
	73H1800724		73C1700694		73B1800730
	73J1600355		73D1700644		73C1700704

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

Product Code	Lot Number
5-10312	73J1600564
	73J1600751
	73J1700127
	73J1700460
	73J1700594
	73J1800072
	73J1800663
	73K1600137
	73K1600571
	73K1700057
	73K1700409
	73K1700587
	73K1700725
	73K1800163
	73K1800369
	73K1800456
	73L1600138
	73L1600338
	73L1600488
	73L1600650
	73L1600838
	73L1700498
	73L1800799
	73M1600133
	73M1700240
	73M1700450
5-10313	73A1700092
	73A1700255
	73A1700404
	73A1700643
	73A1700722
	73A1800043
	73A1800285
	73A1800666
	73B1700137
	73B1700403
	73B1700618
	73B1800117
	73B1800480
	73B1800703
	73C1700228
	73C1700550
	73C1700679
	73C1800476
	73D1700615
	73D1800134

Product Code	Lot Number
5-22213	73D1800151
	73E1800571
	73F1700400
	73F1800346
	73G1700428
	73H1700342
	73H1700788
	73J1700482
	73K1600149
	73K1700277
	73L1600666
	73L1700180
	73L1700512
	73M1700268
5-22214	73A1800452
	73B1700315
	73B1800364
	73B1800497
	73C1700695
	73C1800366
	73D1700425
	73D1800472
	73E1700493
	73E1800572
	73F1800347
	73G1700429
	73G1800935
	73H1700493
	73H1800447
	73H1800681
	73J1600379
	73J1700137
	73J1800106
	73K1600593
	73K1700076
	73K1700608
	73L1600667
	73L1700335
	73M1700269
	73M1700459
5-22215	73A1800453
	73B1800365
	73B1800498
	73C1700257
	73C1700565
	73C1800367

Product Code	Lot Number
V5-10317	73D1700632
	73F1700561
	73F1800193
	73G1700439
	73G1800019
	73H1700354
	73H1800093
	73K1800574
	73L1600674
	73M1700025

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
5-10106	73L1600638
	73L1600825
	73M1600121
	73A1700079
	73C1700394
	73D1700234
	73D1700235
	73D1700436
	73E1700214
	73E1700450
	73F1700366
	73G1700211
	73G1700579
	73H1700309
	73H1700461
	73H1700583
	73H1700768
	73J1700119
	73J1700585
	73K1700245
	73K1700718
	73L1700302
	73L1700654
	73M1700232
	73A1800276
	73A1800428
	73B1800112
	73B1800472
	73B1800614
	73C1800332
	73D1800120
	73D1800446
	73E1800373
	73E1800775
	73G1800111
	73H1800174
	73H1800711
	73J1800313
	73J1800492
	73K1800151
	73K1800320
	73K1800356
	73K1800708
	73L1800210
	73L1800386
	73M1800158

Product Code	Lot Number
5-10118 (Cont.)	73J1800658
	73K1800363
	73K1800755
	73L1800217
	73L1800596
5-10119	73L1600484
	73L1600835
	73A1700090
	73A1700250
	73D1700407
	73F1700372
	73F1700537
	73G1700408
	73H1700469
	73J1700453
	73M1700449
	73A1800040
	73B1800116
	73B1800601
	73C1800341
	73D1800121
	73D1800452
	73E1800546
	73F1800702
	73H1800717
	73K1800160
5-10120	73B1700294
	73D1700125
	73D1700240
	73G1700589
	73H1700506
	73H1700593
	73M1700238
	73A1800051
	73B1800479
	73C1800342
	73D1800131
	73D1800453
	73E1800377
	73F1800703
	73G1800566
	73H1800655
	73J1800348
	73K1800161
5-10206	73H1700470
	73J1700455

Product Code	Lot Number
5-11110 (cont.)	73E1700474
	73F1700386
	73H1700040
	73H1700482
	73H1700599
	73J1700291
	73K1700067
	73L1700502
	73M1700452
	73B1800124
	73D1800313
	73F1800173
	73G1800125
	73K1800170
	73L1800224
5-22006	73E1700489
	73G1700128
	73K1700075
	73L1700176
	73C1800361
	73E1800241
	73F1800556
	73G1800589
	73G1800932
	73L1800417
	73L1800418
	73M1800194
	73M1800195
5-22007	73L1600002
	73K1700426
	73A1800460
	73D1800648
	73E1800565
5-22008	73C1700413
	73F1700164
	73G1700129
	73J1700300
	73A1800461
	73B1800362
	73F1800183
5-22009	73L1600003
	73C1700414
	73D1700640
	73F1700026
	73G1700130
	73H1700610

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

Product Code	Lot Number
5-10107	73K1600124
	73K1600348
	73K1600560
	73K1600718
	73L1600480
	73L1600639
	73L1600826
	73A1700080
	73A1700241
	73C1700395
	73C1700538
	73C1700670
	73D1700404
	73E1700215
	73E1700451
	73F1700139
	73F1700367
	73F1700695
	73G1700212
	73G1700400
	73G1700580
	73H1700029
	73H1700462
	73H1700584
	73H1700769
	73J1700120
	73J1700273
	73J1700586
	73K1700246
	73K1700399
	73K1700706
	73K1700719
	73L1700303
	73L1700497
	73L1700655
	73M1700233
	73M1700417
	73A1800277
	73A1800436
	73A1800804
	73B1800473
	73B1800696
	73C1800333
	73C1800449
	73C1800465
	73D1800122

Product Code	Lot Number
5-10206	73L1700647
	73B1800338
	73F1800704
	73K1800012
	73K1800364
5-10208	73L1600485
	73J1700456
	73K1700408
	73C1800474
	73H1800656
	73K1800365
5-10210	73J1700457
	73L1700648
	73K1800366
5-10218	73C1700549
	73J1800347
	73J1800715
5-10220	73C1800475
	73J1800507
5-10310	73K1600356
	73L1600336
	73L1600486
	73L1600836
	73M1600132
	73B1700134
	73C1700227
	73C1700676
	73D1700243
	73E1700091
	73F1700013
	73F1700145
	73F1700702
	73G1700410
	73H1700471
	73H1700777
	73J1700593
	73K1700254
	73K1700723
	73L1700661
	73A1800282
	73A1800664
	73B1800341
	73C1800186
	73C1800563
	73D1800303
	73D1800454

Product Code	Lot Number
5-22009	73K1700274
	73A1800066
	73C1800464
	73D1800649
	73E1800566
	73F1800340
	73L1800633
	73L1800822
5-22010	73A1700109
	73B1700414
	73D1700627
	73H1700611
	73A1800044
	73C1800550
	73E1800393
	73G1800590
5-22011	73K1600589
	73L1600862
	73B1700309
	73D1700628
	73F1700165
	73L1700331
	73A1800020
	73D1800650
	73F1800341
5-22106	73E1700719
	73M1700260
	73E1800567
	73J1800524
	73K1800731
5-22107	73L1600864
	73F1700166
	73E1800088
	73K1800772
5-22108	73K1600590
	73M1600152
	73A1700110
	73D1700629
	73F1700028
	73B1800133
	73E1800089
	73G1800933
	73J1800100
5-22109	73L1600160
	73L1600865
	73M1600153

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

Product Code	Lot Number
5-10107	73D1800447
	73D1800619
	73D1800679
	73E1800542
	73E1800543
	73F1800154
	73F1800525
	73F1800694
	73G1800208
	73G1800559
	73K1800532
	73K1800743
	73L1800211
	73L1800512
5-10108	73K1600719
	73L1600128
	73L1600321
	73L1600481
	73L1600827
	73A1700081
	73A1700242
	73B1700285
	73B1700612
	73C1700221
	73C1700539
	73D1700119
	73D1700606
	73E1700216
	73E1700452
	73E1700694
	73F1700006
	73F1700140
	73F1700368
	73F1700529
	73G1700133
	73G1700401
	73G1700581
	73H1700030
	73H1700310
	73H1700463
	73H1700585
	73H1700770
	73J1700121
	73J1700274
	73J1700587
	73K1700049

Product Code	Lot Number
5-10310	73E1800071
	73E1800378
	73F1800706
	73G1800567
	73K1800540
	73K1800541
5-10311	73K1600357
	73L1600337
	73L1600487
	73L1600837
	73A1700253
	73C1700677
	73D1700126
	73E1700092
	73E1700459
	73E1700221
	73F1700374
	73G1700411
	73G1700590
	73H1700472
	73J1700459
	73K1700255
	73K1700724
	73M1700239
	73A1800283
	73A1800809
	73C1800187
	73D1800132
	73D1800304
	73D1800455
	73E1800379
	73E1800784
	73F1800536
	73H1800183
5-10318	73L1600144
	73L1600493
	73L1600701
	73L1600843
	73A1700259
	73C1700232
	73C1700684
	73D1700247
	73E1700097
	73E1700468
	73F1700150
	73F1700380

Product Code	Lot Number
5-22109	73A1700275
	73B1700310
	73C1700563
	73D1700423
	73F1700029
	73H1700613
	73J1700475
	73K1700428
	73M1700261
	73B1800363
	73C1800362
	73D1800652
	73E1800568
	73G1800819
	73H1800444
	73J1800525
	73K1800762
	73L1800823
5-22110	73K1600591
	73L1600161
	73L1600866
	73A1700111
	73A1700276
	73B1700416
	73C1700251
	73C1700693
	73F1700030
	73G1700425
	73J1700476
	73L1700333
	73M1700262
	73B1800453
	73C1800363
	73E1800090
	73F1800343
	73G1800820
	73H1800445
	73K1800733
5-22111	73J1600377
	73K1600592
	73L1600358
	73L1600867
	73M1600154
	73A1700277
	73B1700417
	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	73L1600360
	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
5-10109	73F1700696
	73G1700134
	73G1700402
	73G1700582
	73H1700031
	73H1700311
	73H1700586
	73H1700771
	73J1700122
	73J1700275
	73K1700050
	73K1700579
	73L1700293
	73L1700520
	73L1700656
	73M1700130
	73M1700235
	73M1700419
	73A1800041
	73A1800655
	73A1800805
	73B1800332
	73C1800180
	73C1800557
	73D1800297
	73E1800068
	73E1800224
	73E1800776
	73F1800322
	73F1800695
	73G1800790
	73G1800906
	73H1800415
	73J1800314
	73J1800494
	73J1800655
	73K1800753
	73L1800591
5-10110	73J1600742
	73K1600128
	73K1600351
	73K1600563
	73L1600006
	73L1600131
	73L1600323
	73L1600640

Product Code	Lot Number
5-10405	73L1600845
	73A1700097
	73A1700725
	73B1700299
	73F1700712
	73G1700418
	73H1700038
	73H1700479
	73J1700287
	73A1800056
	73A1800462
	73B1800121
	73E1800553
	73F1800713
	73H1800423
	73H1800664
	73K1800376
5-10406	73L1600495
	73B1700621
	73D1700622
	73E1700710
	73F1700152
	73G1700131
	73H1700480
	73J1700128
	73J1700599
	73K1700594
	73L1700318
	73M1700139
	73M1700415
	73A1800057
	73A1800463
	73A1800811
	73B1800484
	73C1800192
	73D1800310
	73D1800462
	73E1800386
	73E1800790
	73F1800541
	73G1800576
	73H1800189
	73H1800665
	73J1800092
	73L1800209
	73L1800404

Product Code	Lot Number
5-22209	73A1800300
	73B1800135
	73B1800454
	73C1800491
	73D1800148
	73E1800092
	73E1800395
	73F1800719
	73H1800194
	73J1800103
5-22210	73K1600379
	73L1600361
	73L1600663
	73M1600157
	73B1700312
	73C1700254
	73D1700641
	73F1700170
	73F1700726
	73G1700607
	73H1700339
	73H1700616
	73J1700135
	73J1700447
	73K1700607
	73L1700178
	73L1700334
	73M1700265
	73A1800448
	73B1800136
	73B1800494
	73C1800498
	73E1800093
	73F1800558
5-22211	73K1600380
	73K1600729
	73L1600664
	73B1700420
	73C1700255
	73D1700133
	73D1700642
	73F1700033
	73F1700727
	73G1700608
	73H1700340
	73H1700787

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

Product Code	Lot Number
5-10110	73L1600828
	73A1700244
	73B1700287
	73B1700393
	73B1700613
	73D1700120
	73D1700608
	73E1700241
	73E1700696
	73F1700142
	73F1700531
	73G1700135
	73G1700583
	73H1700032
	73H1700464
	73H1700587
	73H1700772
	73J1700123
	73J1700276
	73J1700448
	73J1700614
	73K1700051
	73K1700248
	73K1700401
	73K1700580
	73L1700164
	73L1700304
	73L1700657
	73M1700131
	73M1700420
	73A1800279
	73A1800437
	73A1800661
	73A1800806
	73B1800333
	73B1800698
	73C1800181
	73C1800334
	73C1800467
	73C1800558
	73D1800124
	73D1800298
	73D1800622
	73E1800245
	73E1800375
	73E1800777

Product Code	Lot Number
5-10406	73L1800513
	73L1800611
	73L1800727
	73M1800178
	73M1800342
5-10407	73K1600366
	73L1600643
	73A1700261
	73D1700408
	73G1700419
	73H1700039
	73K1700261
	73K1700595
	73M1700416
	73A1800812
	73C1800175
	73E1800229
	73F1800542
	73G1800921
	73K1800549
5-10408	73K1600725
	73L1600656
	73B1700143
	73C1700554
	73D1700409
	73E1700226
	73E1700711
	73F1700383
	73F1700714
	73H1700481
	73J1700288
	73J1700600
	73M1700248
	73B1800122
	73B1800485
	73B1800705
	73D1800311
	73D1800463
	73E1800387
	73F1800331
	73G1800805
	73H1800667
	73J1800324
5-10409	73K1600726
	73L1600847
	73A1700098

Product Code	Lot Number
5-22211	73J1700136
	73J1700480
	73K1700430
	73K1700741
	73L1700510
	73M1700266
	73A1800301
	73A1800449
	73B1800137
	73B1800495
	73C1800177
	73D1800149
	73E1800094
	73F1800184
	73F1800559
	73L1800437
5-22218	73F1700556
	73G1700430
	73H1700619
	73J1700301
	73F1800350
	73G1800138
	73J1800108
	73J1800530
5-22510	73B1700556
	73D1700650
	73H1700346
	73H1800449
5-22511	73C1700261
	73K1700609
	73C1800370
5-22518	73K1600595
	73E1800459
	73M1800288

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

Product Code	Lot Number
5-10110	73F1800527
	73F1800696
	73G1800113
	73G1800560
	73G1800907
	73H1800176
	73H1800210
	73K1800358
	73K1800534
	73K1800710
	73L1800514
5-10111	73J1600351
	73J1600720
	73K1600129
	73K1600564
	73L1600007
	73L1600324
	73L1600641
	73L1600829
	73M1600125
	73A1700084
	73A1700245
	73B1700614
	73C1700396
	73D1700121
	73D1700609
	73E1700697
	73G1700136
	73G1700213
	73G1700584
	73H1700465
	73H1700588
	73H1700773
	73J1700124
	73J1700449
	73K1700052
	73K1700172
	73K1700581
	73L1700165
	73L1700305
	73L1700658
	73M1700132
	73M1700335
	73M1700444
	73A1800280
	73A1800438

Product Code	Lot Number
5-10409	73A1700262
	73C1700233
	73C1700685
	73D1700410
	73E1700227
	73F1700154
	73F1700715
	73H1700324
	73J1700129
	73J1700289
	73K1700062
	73K1700730
	73M1700140
	73A1800058
	73B1800329
	73B1800486
	73B1800706
	73C1800480
	73D1800312
	73E1800059
	73E1800554
	73F1800169
5-10410	73K1600579
	73L1600146
	73L1600848
	73A1700099
	73B1700145
	73B1700389
	73C1700234
	73C1700686
	73D1700411
	73E1700470
	73F1700155
	73F1700384
	73F1700716
	73H1700325
	73J1700130
	73K1700063
	73K1700731
	73M1700141
	73B1800346
	73B1800707
	73C1800481
	73E1800230
	73E1800791
	73F1800543

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

Product Code	Lot Number
5-10111	73A1800807
	73B1800334
	73B1800699
	73C1800182
	73C1800335
	73C1800468
	73D1800125
	73D1800299
	73D1800623
	73E1800778
	73F1800156
	73F1800323
	73F1800528
	73G1800114
	73G1800211
	73G1800561
	73H1800177
	73K1800379
	73L1800537
5-10118	73L1600009
	73L1600332
	73M1600130
	73A1700089
	73A1700249
	73B1700399
	73C1700547
	73D1700406
	73E1700701
	73F1700536
	73G1700407
	73H1700592
	73J1700282
	73K1700405
	73M1700137
	73A1800039
	73A1800808
	73B1800337
	73C1800340
	73D1800130
	73D1800302
	73E1800783
	73F1800535
	73G1800798
	73H1800654
	73J1800319
	73J1800503

Product Code	Lot Number
5-10411	73J1600685
	73K1600580
	73L1600849
	73A1700263
	73C1700235
	73C1700687
	73D1700623
	73E1700471
	73F1700156
	73F1700717
	73G1700420
	73H1700326
	73J1700131
	73K1700064
	73K1700732
	73L1700319
	73M1700249
	73A1800059
	73B1800347
	73B1800708
	73D1800633
	73E1800388
	73F1800170
	73G1800223
	73G1800922
	73H1800730
5-11108	73L1600010
	73A1700644
	73C1700236
	73D1700438
	73E1700473
	73F1700385
	73K1700066
	73L1700501
	73B1800123
	73D1800137
	73F1800172
	73G1800124
	73G1800925
	73H1800731
5-11110	73K1600368
	73K1600727
	73A1700645
	73B1700410
	73C1700237
	73D1700624